Dear Shareholder:

On May 20, 2021, Allarity Therapeutics, Inc. ("Allarity Delaware"), a Delaware corporation and a direct and wholly owned subsidiary of Allarity Therapeutics A/S. ("Allarity A/S"), on behalf of itself and Allarity Acquisition Subsidiary, Inc. ("Acquisition Sub"), a wholly owned subsidiary of Allarity Delaware, entered into a Plan of Reorganization and Asset Purchase Agreement, which was subsequently Amended and Restated on September 23, 2021 (as it may be amended from time to time, the "Reorganization Agreement") with Allarity A/S. If the Reorganization Agreement and the transactions contemplated thereby are approved by Allarity A/S's shareholders, Allarity Delaware will capitalize the Acquisition Sub with shares of Allarity Delaware common stock (the "Delaware Common Stock) in exchange for the common stock of the Acquisition Sub and Acquisition Sub will acquire substantially all of the assets and assume substantially all of the liabilities of Allarity A/S in exchange for the Delaware Common Stock issued pursuant to this information statement/prospectus and Allarity A/S will distribute the Delaware Common Stock received as the purchase price for Allarity A/S's assets and assumption of liabilities to the holders of Allarity A/S ordinary shares (as defined below) first by a share exchange "swap" program where Allarity A/S ordinary shares will be exchanged for Delaware Common Stock on the basis of the exchange ratio described below and then pro rata as an extraordinary dividend and/or liquidating distribution to shareholders who have not exchanged their Allarity A/S ordinary shares for Delaware Common Stock. After the distribution of the Delaware Common Stock issued pursuant to this information statement/prospectus, Allarity A/S will dissolve and liquidate in accordance with Part 14 of Danish Companies Act (the "DCA"). In this information statement/prospectus, when we refer to Allarity Delaware, we mean Allarity Therapeutics, Inc., a Delaware corporation that was formed as a direct wholly owned subsidiary of Allarity Therapeutics A/S for the purpose of consummating the reorganization and that will become the parent holding company of substantially all of the assets, liabilities and business operations of Allarity Therapeutics A/S after the reorganization, and when we refer to Allarity A/S we mean Allarity Therapeutics A/S, the existing parent of Allarity Delaware, whose assets, liabilities and business operations will become the assets, liabilities, and business operations of a direct, wholly owned subsidiary of Allarity Delaware with the shareholders of Allarity A/S owning substantially the same percentage ownership of Allarity Delaware that they owned of Allarity A/S subject to future dilution from 3i, LP, a Delaware limited partnership who will invest $20 million in Allarity Delaware convertible preferred stock upon the closing of the transaction and the listing of Allarity Delaware's common stock on the Nasdaq Stock Market (the "PIPE Investment"). An application for listing the shares of Allarity Delaware common stock has been filed with the Nasdaq Stock Market under the trading symbol ("ALLR"). We refer to the reorganization and the asset purchase and liability assumption in exchange for the Delaware Common Stock described in the Reorganization Agreement collectively as the "Recapitalization Share Exchange".

As part of the Recapitalization Share Exchange, each outstanding Allarity A/S ordinary share will be entitled to receive, either in the share exchange swap program or by extraordinary dividend, a number of shares of Allarity Delaware Common Stock equal to the exchange ratio. In each case, these share amounts will be rounded down to the nearest whole number on a holder-by-holder basis and any fractional interest will be settled in cash. The "exchange ratio" means the quotient of the number of Allarity A/S ordinary shares outstanding in Allarity A/S divided by fifty (50) or 0.02 shares of Delaware Common Stock for each Allarity A/S ordinary share issued and outstanding (as defined in the Reorganization Agreement), as of immediately prior to the effective time.

At the effective time, each warrant (option) conferring the right to subscribe for Allarity A/S ordinary shares held by the officers, directors, employees and consultants (each, a "Compensatory Warrant") that is outstanding immediately prior to the effective time, whether vested or unvested, will be assumed by Allarity Delaware and converted into an option (each, a "Converted Option") to purchase a number of shares of Delaware Common Stock equal to the product (rounded to the nearest whole number) of (a) the number of ordinary shares of Allarity A/S subject to such Compensatory Warrant immediately prior to the effective time multiplied by (b) the exchange ratio, at an exercise price per share (rounded up to the nearest whole cent) equal to (i) the exercise price per share of such Compensatory Warrant immediately prior to the effective time divided by (ii) the exchange ratio and then converted into U.S. dollars;

provided, however, that the exercise price and the number of shares of Delaware Common Stock purchasable pursuant to the Converted Options will be determined in a manner consistent with the requirements of Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"); provided, further, however, that in the case of any Converted Option to which Section 422 of the Code applies, the exercise price and the number of shares of Delaware Common Stock purchasable pursuant to such option will be determined in accordance with the foregoing, subject to such adjustments in a manner consistent with Treasury Regulation Section 1.424-1, such that the Converted Option will not constitute a modification of such Converted Option for purposes of Section 409A or Section 424 of the Code. Except as specifically provided above, following the effective time, each Converted Option will continue to be governed by the same terms and conditions (including vesting and exercisability terms) as were applicable to the corresponding former Compensatory Warrant immediately prior to the effective time.

Based on the exchange ratio as of the date of this information statement/prospectus of approximately 0.02 shares of Delaware Common Stock for each ordinary share of Allarity A/S outstanding immediately prior to the effective time, the total number of shares of Delaware Common Stock expected to be issued in connection with the Recapitalization Share Exchange (excluding shares that will be issuable upon exercise of Converted Options and shares to be issued in the PIPE Investment upon to the consummation of the Recapitalization Share Exchange) is approximately 8,075,824 shares and these shares of Delaware Common Stock are expected to represent 100% of the issued and outstanding shares of Allarity Delaware common stock at the closing of the Recapitalization Share Exchange, but will be subject to future dilution from the PIPE Investment (as defined below), on an "as converted" basis based upon the initial fixed conversion price of the Allarity Delaware Series A Preferred Stock to be issued in the PIPE Investment, as further described herein. Allarity A/S's ordinary shares are publicly traded on the Nasdaq First North Growth Market in Stockholm, Sweden ("Nasdaq First North Growth Market"). We have filed an application to list the Delaware Common Stock issued in the Recapitalization Share Exchange on the Nasdaq Capital Market division of the Nasdaq Stock Market in the United States effective upon the closing of the Recapitalization Share Exchange. Accordingly, we anticipate that there will be no ordinary shares of Allarity A/S listed for trading on the Nasdaq First North Growth Market following consummation of the Recapitalization Share Exchange.

Allarity A/S will hold an extraordinary general meeting of shareholders (the "Allarity A/S Extraordinary General Meeting") as required by the DCA to consider matters and transactions relating to the proposed Recapitalization Share Exchange. The Recapitalization Share Exchange cannot be consummated unless Allarity A/S shareholders approve all of the proposals submitted for approval at the Allarity A/S Extraordinary General Meeting in accordance with the DCA and the procedures set forth in the Reorganization Agreement and the transactions contemplated thereby, including the issuance of Delaware Common Stock to be issued as consideration for the transfer of substantially all of the assets, liabilities and business operations of Allarity A/S to Allarity Delaware's direct wholly owned subsidiary Acquisition Sub. Allarity A/S is sending you this information statement/prospectus to ask you to vote "**FOR**" all of these proposals and the other matters described in this information statement/prospectus.

Please note that you are advised not to attend the Allarity A/S Extraordinary General Meeting in person. In light of the ongoing COVID-19 pandemic and to protect the health of Allarity A/S shareholders, management, employees and the community, the Allarity A/S board of directors intends to conduct the Allarity A/S Extraordinary General Meeting in a reasonable manner and with the fewest possible participants. You are therefore encouraged to vote by proxy or to vote by mail instead of opting for physical attendance at the Allarity A/S Extraordinary General Meeting. You will be able to follow the meeting in a live webcast in English as described in the convening notice below.

YOUR VOTE IS VERY IMPORTANT, REGARDLESS OF THE NUMBER OF ORDINARY SHARES OF ALLARITY A/S YOU OWN. To ensure your representation at the Allarity A/S Extraordinary General Meeting, please refer to the notice convening the meeting as set out below.

After careful consideration, the Allarity A/S board of directors has unanimously approved the Recapitalization Share Exchange and the transactions contemplated thereby and recommends that Allarity A/S shareholders vote "**FOR**" the approval of The Recapitalization Share Exchange Proposals, "**FOR**" the approval of the Nasdaq Pipe Proposal, and "**FOR**" the approval of the 2021 Equity Incentive Plan and other matters to be considered at the Allarity A/S Extraordinary General Meeting.

This information statement/prospectus provides you with detailed information about the proposed Recapitalization Share Exchange. It also contains or references information about Allarity Delaware and Allarity A/S and certain related matters. You are encouraged to read this information statement/prospectus, including the financial statements and annexes and other documents referred to herein, carefully and in its entirety. **In particular, you should read the "Risk Factors" section beginning on page 26 herein for a discussion of the risks you should consider in evaluating the proposed Recapitalization Share Exchange and how they will affect you.**

If you have any questions regarding the accompanying information statement/prospectus, you may contact the Allarity Therapeutics investor relations team, at +45 88 74 24 15 or email investorrelations@allarity.com.

On behalf of the Allarity A/S board of directors, I would like to thank you for your support and look forward to the successful completion of the Recapitalization Share Exchange.

Sincerely,

/s/ Duncan Moore
Duncan Moore
Chairman of the Board

/s/ Steve R. Carchedi
Steve R. Carchedi
Chief Executive Officer

Neither the Securities and Exchange Commission (the "SEC"), any state securities commission nor the Danish Financial Supervisory Authority has approved or disapproved of the Recapitalization Share Exchange, the issuance of shares of Allarity Delaware common stock in connection with the Recapitalization Share Exchange or the other transactions described in this information statement/prospectus, or passed upon the adequacy or accuracy of the disclosure in this information statement/prospectus. Any representation to the contrary is a criminal offense.

This information statement/prospectus is dated November 5, 2021 and is first being distributed to shareholders of Allarity A/S on or about November 5, 2021.

Allarity Therapeutics A/S
Venlighedsvej 1
2970 Horsholm
Denmark

NOTICE OF THE EXTRAORDINARY GENERAL MEETING OF SHAREHOLDERS OF ALLARITY THERAPEUTICS A/S TO BE HELD ON NOVEMBER 22, 2021

THE BOARD OF DIRECTORS HEREBY CONVENES an extraordinary general meeting of the shareholders of Allarity Therapeutics A/S ("Allarity A/S") to be held on November 22, 2021 at 10:00 a.m. Central European Time at the offices of Mazanti-Andersen Advokatpartnerselskab, Amaliegade 10, DK-1256, Copenhagen K, Denmark (the "Allarity A/S Extraordinary General Meeting"). You will be able to follow the Allarity A/S Extraordinary General Meeting via live webcast in English by visiting *www.allarity.com/egm2021* as further explained below. Please note that shareholders wishing to follow the Allarity A/S Extraordinary General Meeting online and to vote on the proposals of the agenda must do so in advance as explained below.

AGENDA AND COMPLETE PROPOSALS:

1. *Election of Chairman of the Meeting* — The board of directors proposes that attorney-at-law Lars Lüthjohan Jensen be elected as chairman of the Allarity A/S Extraordinary General Meeting.

2. *The Recapitalization Share Exchange Proposals* — The board of directors proposes to vote upon a proposal to approve, for U.S. tax purposes and Danish legal purposes, the Amended and Restated Plan of Reorganization and Asset Purchase Agreement (the "Reorganization Agreement") and the transactions contemplated by the Reorganization Agreement (also referred to as the Recapitalization Share Exchange). A copy of the Reorganization Agreement is attached to the information statement/prospectus as Annex A (the "Recapitalization Share Exchange Proposal") accompanying this notice (Proposal No. 1)

   In order to implement Proposal No. 1, shareholders will consider and vote upon the following proposals related to Proposal No. 1:

   1.A. To consider and vote upon a resolution approving the sale of substantially all of the assets and the assumption of liabilities of Allarity A/S to Acquisition Sub in exchange for Allarity Delaware Common Stock.

   1.B. To consider and vote upon a resolution approving the initiation by the board of directors of a share swap program as further described in an Offer Document to be prepared by Allarity A/S's Danish legal counsel involving, inter alia, the exchange of 0.02 shares of Delaware Common Stock for each Allarity A/S ordinary share and in connection therewith adopting the following resolution:

   Proposal to decrease the Company's share capital from nominal DKK 20,189,560 to nominal DKK 400,000 against distributions to shareholders, payment of losses and/or transfers to a special reserve fund.

   1.C. To consider and vote upon a resolution approving that the board of directors pursuant to its current authorization in the articles of association declare and pay an extraordinary dividend of 0.02 shares of Delaware Common Stock for each Allarity A/S ordinary share that has not exchanged their shares in the share swap program.

   1.D To amend the authorization in article 6.12 of the articles of association to the effect that the board of directors is authorized to issue warrants conferring the right to subscribe for up to nominal DKK 2,750,000 with an exercise price that is not below SEK 0.945 per share of nominal DKK 0.05. The proposed amended wording of paragraph 1 of 6.12 will thus be as follows:

   The board of directors is authorized during the period until 30 August 2026 on one or more occasions to issue warrants to the board members, employees, advisors and consultants of the company or its subsidiaries entitling the holder to subscribe for shares for a total of up to nominal DKK 2,750,000 without pre-emptive rights for the company's shareholders. The exercise price for the warrants shall not be less than SEK 0.945. The board of directors shall determine the terms for the warrants and the distribution hereof.

In paragraph 2 of article 6.12, 2,049,006.75 is changed to 2,750,000.

Allarity A/S shareholders must approve Proposals 1A, 1B, 1.C and 1D in order to approve Proposal No. 1.

3. *The Nasdaq Pipe Proposal* — To consider and vote upon a proposal to approve, for purposes of complying with applicable listing rules of the Nasdaq Stock Market (the "Nasdaq") the issuance of shares of Series A Preferred Stock in Allarity Delaware that is convertible into share of Allarity Delaware common stock at an initial conversion price of $9.906, subject to adjustment, and the issuance of warrants to purchase 2,018,958 shares of common stock at an initial exercise price of $9.906, subject to adjustment, resulting in the potential issuance of twenty percent (20%) or more of Allarity Delaware common stock in exchange for an investment of $20 million (the "Nasdaq Pipe Proposal") (Proposal No. 2);

4. *The Incentive Plan Proposal* — To consider and vote upon a proposal to approve, for purposes of complying with applicable listing rules of the Nasdaq, and adopt the 2021 Equity Incentive Plan (the "2021 Plan") for Allarity Delaware, a copy of which is attached to this information statement/prospectus as Annex B, including the authorization of the initial share reserve under the 2021 Plan (the "Incentive Plan Proposal") (Proposal No. 3); and

5. *Other Matters* — To consider other matters that properly come before the meeting.

The Recapitalization Share Exchange Proposals, the Nasdaq Pipe Proposal, and the Incentive Plan Proposal are collectively referred to herein as the "proposals."

The record date for the Allarity A/S Extraordinary General Meeting is November 15, 2021 (the "Allarity A/S record date") set in accordance with the Allarity A/S articles of association. The right of a shareholder to attend the Allarity A/S Extraordinary General Meeting and to vote in respect of his/her shares is determined on the basis of the shares held by the shareholder at the Allarity A/S record date. The shareholdings and voting rights are calculated on the basis of entries in the Allarity A/S shareholders' register and any notice of ownership received by Allarity A/S for the purpose of registration in the shareholders' register. Shareholders wishing to exercise their voting rights at the Allarity A/S Extraordinary General Meeting are encouraged to contact their depository bank well in advance of the Allarity A/S record date to ensure correct and sufficient registration.

Shareholders can vote by proxy or by mail no later than the end of day on November 19, 2021. The proxy and the vote by mail can be submitted in writing by using the proxy and voting by mail form which can be downloaded by visiting *www.allarity.com/egm2021*. If the form is used, it must be completed, signed and forwarded to investorrelations@allarity.com before the deadline.

Shareholders who should choose to attend the Allarity A/S Extraordinary General Meeting in person must notify Allarity A/S of their attendance no later the end of day on November 19, 2021. Notification of attendance must be forwarded to investorrelations@allarity.com before the deadline.

Special voting rules apply for shareholders whose shares are registered in the name of a nominee. In order to exercise voting rights at the Allarity A/S Extraordinary General Meeting, such shareholders must instruct the nominee to exercise the voting rights attached to the nominee-registered shares on their behalf.

Under the Reorganization Agreement, the approval of each of the proposals is a condition to the consummation of the reorganization. Failure to receive approval of any of the proposals provides each of Allarity A/S and Allarity Delaware with a right to terminate the Reorganization Agreement. If our shareholders do not approve each of the proposals, the reorganization may not be consummated. Approval of (i) Proposal 1.A approving the sale of substantially all of Allarity A/S's assets, liabilities and business operations to its subsidiary Allarity Delaware in The Recapitalization Share Exchange Proposals, (ii) Proposal 1.D approving the amendment to the authorization in article 6.12 of the Allarity A/S articles of association and (iii) Proposal No. 3 on the Incentive Plan Proposal requires the affirmative vote of 66.67% of the votes cast and the share capital represented at the Allarity A/S Extraordinary General Meeting, and the proposal to elect the chairman of the meeting and the other proposals in the Recapitalization Share Exchange Proposals and the Nasdaq Pipe Proposal require the affirmative vote of a majority of the votes cast and the share capital represented at the Allarity A/S Extraordinary General Meeting. Because approval of each of the proposals only requires 66.67% of the votes cast and the share capital represented with respect to Proposals 1.A and 1.D of The Recapitalization Share Exchange Proposals and Proposal No. 3 of the Incentive Plan Proposal and a majority of the votes cast and the share capital represented for

each of the other proposals, and because the Danish Companies Act ("DCA") does not require a minimum number of votes and shares present in person or by proxy to establish a quorum at the Allarity A/S Extraordinary General Meeting, if you do not vote or do not instruct your bank, broker or other nominee how to vote, it will have no effect on each of these proposals because such action would not count as a vote cast at the Allarity A/S Extraordinary General Meeting. The Allarity A/S board of directors has already approved the proposals subject to shareholder approval.

If Allarity A/S shareholders fail to approve The Recapitalization Share Exchange Proposals, the reorganization will not be consummated. The information statement/prospectus accompanying this notice explains the Reorganization Agreement and the other transactions contemplated thereby, as well as the proposals to be considered at the Allarity A/S Extraordinary General Meeting. Please review the information statement/prospectus, including the financial statements and annexes and other documents referred to herein, carefully and in its entirety. In addition to the information statement/prospectus, the following documents will be made available on *www.allarity.com/egm2021*: the notice convening the Allarity A/S Extraordinary General Meeting and the proxy and voting by mail form.

After careful consideration, the Allarity A/S board of directors has unanimously approved the Reorganization Agreement and the transactions contemplated thereby and recommends that you vote "**FOR**" all of the proposals in the Recapitalization Share Exchange Proposals, "**FOR**" the Nasdaq Pipe Proposal, and "**FOR**" the Incentive Plan Proposal.

The existence of financial and personal interests of one or more of Allarity A/S's directors may result in a conflict of interest on the part of such director(s) between what he or they may believe is in the best interests of Allarity A/S and its shareholders and what he or they may believe is best for themselves in determining to recommend that shareholders vote for the proposals. See *"The Recapitalization Share Exchange — Interests of Certain Persons in the Recapitalization Share Exchange"* beginning on page 239 of this information statement/prospectus.

Your attention is directed to the information statement/prospectus accompanying this notice (including the financial statements and annexes attached thereto) for a more complete description of the proposed Recapitalization Share Exchange and related transactions and each of our proposals. We encourage you to read this information statement/prospectus carefully.

ON BEHALF OF THE BOARD OF DIRECTORS

/s/ Duncan Moore
Duncan Moore
Chairman of the Board of Directors

November 5, 2021

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ABOUT THIS INFORMATION STATEMENT/PROSPECTUS

This document, which forms part of a registration statement on Form S-4 filed with the SEC by Allarity Therapeutics, Inc. ("Allarity Delaware") (File No. 333-258968) (the "Registration Statement"), constitutes a prospectus of Allarity Delaware under Section 5 of the Securities Act of 1933, as amended, with respect to the shares of Allarity Delaware Common Stock to be issued in the reorganization if the Recapitalization Share Exchange described below is consummated. This document also includes a draft notice of an extraordinary general meeting of Allarity A/S pursuant to the Danish Companies Act ("DCA") and the applicable rules of the Nasdaq First North Growth Market in Stockholm with respect to the Allarity A/S Extraordinary General Meeting at which Allarity A/S shareholders will be asked to consider and vote upon a proposal to approve The Recapitalization Share Exchange Proposals, among other matters.

You can read this information statement/prospectus, over the Internet at the SEC's website at *http://www.sec.gov.*

If you would like additional copies of this information statement/prospectus or if you have questions about the Recapitalization Share Exchange, the Reorganization Agreement, or the other proposals to be presented at the Allarity A/S Extraordinary General Meeting, you should contact us by telephone or in writing:

Jens Knudsen
Chief Financial Officer
Allarity Therapeutics A/S
Venlighedsvej 1
2970 Horsholm, Denmark
Tel: +45 88 74 24 15
Email: investorrelations@allarity.com

If you are a shareholder of Allarity A/S and would like to request documents, please do so by November 15, 2021 to receive them before the Allarity A/S Extraordinary General Meeting. If you request any documents from us, we will mail them to you by first class mail, or another equally prompt means.

GLOSSARY

Reference to Allarity A/S refer to Allarity Therapeutics A/S and its subsidiaries and references to Allarity Delaware refers to Allarity Therapeutics, Inc., a Delaware corporation and a direct, wholly owned subsidiary of Allarity Therapeutics A/S formed for the purpose of consummating the Recapitalization Share Exchange. Unless otherwise stated or unless the context otherwise requires, the terms "we," "us" and "our" refer to both Allarity A/S and Allarity Delaware both before and after the Recapitalization Share Exchange.

Unless otherwise noted or the context otherwise requires, in this document:

- references to "2021 Plan" or "2021 Equity Plan" are to the Allarity Therapeutics, Inc. 2021 Equity Incentive Plan;
- references to "Compensatory Warrant" are to warrants to purchase the ordinary shares of Allarity A/S issued to its officers, directors, employees or consultants;
- references to "Converted Option" are to each Compensatory Warrant converted to an option to purchase Delaware Common Stock;
- references to "Delaware Common Stock" refer to the common stock of Allarity Therapeutics, Inc., a Delaware corporation, that are registered with the SEC for issuance in connection with the Recapitalization Share Exchange on the registration statement of which this information statement/prospectus is a part;
- references to "DWAC" are to the Depository Trust Company's Deposit Withdrawal at Custodian System;
- references to "effective time" are to the time at which the reorganization becomes effective;
- references to the Exchange Act are to the Securities Exchange Act of 1934, as amended;
- references to "reorganization" are to the proposed reorganization of Allarity A/S with Acquisition Sub acquiring substantially all of the assets and assuming substantially all of the liabilities of Allarity A/S in exchange for the Delaware Common Stock and the subsequent distribution of the Delaware Common Stock to the shareholders of Allarity A/S either by way of the share exchange swap program or by extraordinary dividend;
- references to "Acquisition Sub" are to Allarity Acquisition Subsidiary, Inc., a direct wholly owned subsidiary of Allarity Delaware to be organized under the laws of the State of Delaware;
- references to "Nasdaq" are to the Nasdaq Stock Market LLC;
- references to "Allarity A/S ordinary shares" are to the share capital of Allarity A/S (DKK 0.05) prior to the effective time;
- references to "Allarity A/S Extraordinary General Meeting" are to an extraordinary meeting of the shareholders of Allarity A/S;
- references to "common stock" are to the common stock, par value $0.0001, of Allarity Delaware
- references to "PIPE investment" are to the securities purchase agreement entered into between Allarity Delaware and Allarity A/S with 3i, LP, a Delaware limited partnership for a private placement of shares of Allarity Delaware preferred stock that is convertible into common stock and the issuance of common stock purchase warrants to close at the effective time;
- references to "preferred stock" are to shares of Allarity Delaware preferred stock, $0.0001 par value;
- references to "Securities Act" are to the Securities Act of 1933, as amended; and
- references to "SEC" are to the Securities and Exchange Commission.

Unless specified otherwise, amounts in this information statement/prospectus are presented in United States ("U.S.") dollars.

Defined terms in the financial statements contained in this information statement/prospectus have the meanings ascribed to them in the financial statements.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This information statement/prospectus includes forward-looking statements regarding, among other things, our plans, strategies and prospects, both business and financial. These statements are based on the beliefs and assumptions of our management. Although we believe that our plans, intentions and expectations reflected in or suggested by these forward-looking statements are reasonable, we cannot assure you that we will achieve or realize these plans, intentions or expectations. Forward-looking statements are inherently subject to risks, uncertainties and assumptions. Generally, statements that are not historical facts, including statements concerning possible or assumed future actions, business strategies, events or results of operations, are forward-looking statements. These statements may be preceded by, followed by or include the words "believes," "estimates," "expects," "projects," "forecasts," "may," "will," "should," "seeks," "plans," "scheduled," "anticipates," "intends" or similar expressions. Forward-looking statements contained in this information statement/prospectus include, but are not limited to, statements that may relate to:

- the benefits from the Recapitalization Share Exchange;
- our ability to consummate the Recapitalization Share Exchange;
- any satisfaction or waiver (if applicable) of the conditions to the Recapitalization Share Exchange, including, but not limited to: the satisfaction or waiver of certain customary closing conditions, the existence of no material adverse effect at Allarity Delaware or Allarity A/S and receipt of certain shareholder approvals contemplated by this information statement/prospectus;
- the occurrence of any other event, change or other circumstances that could give rise to the termination or delay of the Reorganization Agreement;
- our plans to develop and commercialize its drug candidates;
- the initiation, timing, progress and results of our current and future preclinical studies and clinical trials, as well as our research and development programs;
- our expectations regarding the impact of the ongoing COVID-19 pandemic on its business, industry and the economy;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing after the reorganization;
- our ability to successfully acquire or in-license additional product candidates on reasonable terms;
- our ability to maintain and establish collaborations or obtain additional funding;
- our ability to obtain regulatory approval of its current and future drug candidates;
- our expectations regarding the potential market size and the rate and degree of market acceptance of such drug candidates;
- our continued reliance on third parties to conduct clinical trials of its drug candidates, and for the manufacture of its drug candidates for preclinical studies and clinical trials;
- our ability to fund our working capital requirements and expectations regarding the sufficiency of its capital resources;
- the implementation of our business model and strategic plans for our business and product candidates following the Recapitalization Share Exchange;
- our intellectual property position and the duration of our patent rights;
- developments or disputes concerning our intellectual property or other proprietary rights;
- our expectations regarding government and third-party payor coverage and reimbursement;
- our ability to compete in the markets we intend to serve;

- the impact of government laws and regulations and liabilities thereunder;
- our need to hire additional personnel and our ability to attract and retain such personnel;
- our ability to consummate the PIPE investment or raise financing in the future;
- the use of proceeds from the PIPE investment;
- the anticipated cash available at the closing of the Recapitalization Share Exchange; and
- the anticipated use of our cash and cash equivalents.

These forward-looking statements are based on information available as of the date of this information statement/prospectus, and current expectations, forecasts and assumptions, and involve a number of risks and uncertainties. Accordingly, forward-looking statements should not be relied upon as representing our views as of any subsequent date, and we do not undertake any obligation to update forward-looking statements to reflect events or circumstances after the date they were made, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

In addition, statements that we "believe," and similar statements, reflect such our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this information statement/prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and these statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information.

Forward-looking statements are not guarantees of performance. You should not put undue reliance on these statements which speak only as of the date hereof. You should understand that the following important factors, in addition to those discussed under the heading "Risk Factors" and elsewhere in this information statement/prospectus, could affect our future results and could cause those results or other outcomes to differ materially from those expressed or implied in the forward-looking statements in this information statement/prospectus:

- the occurrence of any event, change or other circumstances that could give rise to the termination or delay of the Recapitalization Share Exchange;
- the outcome of any legal proceedings that may be instituted against Allarity A/S, or others following announcement of the Recapitalization Share Exchange and the transactions contemplated therein;
- the inability to complete the transactions contemplated by the Recapitalization Share Exchange due to the failure to obtain approval of the shareholders of Allarity A/S, failure to obtain regulatory approval, or other conditions to closing in the Reorganization Agreement;
- the risk that the proposed transaction disrupts current plans and operations as a result of the announcement and consummation of the Recapitalization Share Exchange;
- the ability to recognize the anticipated benefits of the Recapitalization Share Exchange, which may be affected by, among other things, our ability to grow and manage growth profitably, maintain relationships with customers, compete within its industry and retain its key employees;
- the costs related to the proposed Recapitalization Share Exchange;
- the possibility that we may be adversely impacted by other economic, business, and/or competitive factors;
- any future currency exchange and interest rates;
- the significant uncertainty created by the COVID-19 pandemic; and
- other risks and uncertainties indicated in this information statement/prospectus, including those under "Risk Factors" herein.

QUESTIONS AND ANSWERS FOR SHAREHOLDERS OF ALLARITY A/S

The following questions and answers highlight selected information from this information statement/prospectus and briefly address certain questions that you may have regarding the Recapitalization Share Exchange and the Allarity A/S Extraordinary General Meeting. We urge you to read carefully the remainder of this information statement/prospectus and the notice convening the Allarity A/S Extraordinary General Meeting because the information in this section may not provide all the information that might be important to you in determining how to vote. Additional important information is also contained in the financial statements and annexes attached hereto and other documents referred to herein.

Questions and Answers about the Recapitalization Share Exchange and Reorganization Agreement

Q: How do I attend and vote at the general meeting?

A: The Allarity A/S Extraordinary General Meeting will be held as a physical meeting with a live webcast in English. Shareholders wishing to attend the Allarity A/S Extraordinary General Meeting must notify Allarity A/S of their attendance prior to the meeting as set out in the convening notice. Shareholders may — instead of opting for physical attendance — vote by proxy or by mail prior to the meeting, and such shareholders can follow the general meeting online via live webcast in English with a link being made available on *www.allarity.com/egm2021*. Whether voting in person or by proxy or mail, the right to vote at the Allarity A/S Extraordinary General Meeting is determined on the basis of the shares held by the shareholder at the Allarity A/S record date. The shareholdings and voting rights are calculated on the basis of entries in the Allarity A/S shareholders' register and any notice of ownership received by Allarity A/S for the purpose of registration in the shareholders' register. Shareholders wishing to exercise their voting rights at the Allarity A/S Extraordinary General Meeting are encouraged to contact their depository bank well in advance of the Allarity A/S record date to ensure correct and sufficient registration.

Q: What is the Reorganization Agreement?

A: The Reorganization Agreement contains the official terms and conditions of the reorganization that is part of the Recapitalization Share Exchange wherein Allarity Delaware, a direct wholly owned subsidiary of Allarity A/S, through its direct wholly owned subsidiary Acquisition Sub, has agreed to acquire substantially all of the assets and assume substantially all of the liabilities of Allarity A/S in exchange for Delaware Common Stock and the shareholders of Allarity A/S will receive 0.02 shares of Delaware Common Stock for each Allarity A/S ordinary share either through a share exchange swap program or as an extraordinary dividend and thereafter Allarity A/S will be dissolved and liquidated. Allarity A/S will hold the Allarity A/S Extraordinary General Meeting to, among other things, obtain the approvals required for the Reorganization Agreement and the other transactions contemplated by the Recapitalization Share Exchange, and you are receiving this information statement/prospectus in connection with such meeting. In addition, a copy of the Reorganization Agreement is attached to this information statement/prospectus as Annex A. We urge you to read carefully this information statement/prospectus and the Reorganization Agreement in their entirety.

Q: Why am I receiving this document?

A: Allarity A/S is sending this information statement/prospectus to its shareholders to help them decide how to vote their Allarity A/S ordinary shares with respect to the matters to be considered at the Allarity A/S Extraordinary General Meeting.

The Reorganization Agreement and the Recapitalization Share Exchange contemplated therein cannot be completed unless Allarity A/S's shareholders approve The Recapitalization Share Exchange Proposals, the Nasdaq Pipe Proposal, and the Incentive Plan Proposal, collectively referred to herein as the "proposals," set forth in this information statement/prospectus for their approval. To approve The Recapitalization Share Exchange Proposals, shareholders must also approve (i) a resolution approving the sale of substantially all of the assets and the assumption of substantially all of the liabilities of Allarity A/S to the Acquisition Sub in exchange for the Delaware Common Stock; (ii) a resolution approving the share exchange swap program; (iii) a resolution approving the declaration and payment of the extraordinary dividend: and (iv) a resolution approving the amendment to the authorization in article 6.12 of the Allarity A/S articles of association. Information about

the Allarity A/S Extraordinary General Meeting, the Recapitalization Share Exchange and the other business to be considered by shareholders at the Allarity A/S Extraordinary General Meeting is contained in this information statement/prospectus.

This document constitutes an information statement of Allarity A/S and a prospectus of Allarity Delaware. It is an information statement because the board of directors of Allarity A/S is soliciting approval of its shareholder of the proposals using this information statement/prospectus. It is a prospectus because the Delaware Common Stock will be used by Acquisition Sub as the payment for the assets and liabilities of Allarity A/S that will be distributed to Allarity A/S shareholder as part of the share exchange swap program or extraordinary dividend pursuant to the Reorganization Agreement. See "*THE REORGANIZATION AGREEMENT — Allarity Delaware's Purchase of Allarity A/S Assets in Exchange for Delaware Common Stock*" beginning on page 241 of this information statement/prospectus.

Q: I am an Allarity A/S Compensatory Warrant holder. Why am I receiving this document?

A: At the effective time, each warrant (option) to subscribe for Allarity A/S ordinary shares held by the officers, directors, employees and consultants (each, a "Compensatory Warrant") that is outstanding immediately prior to the effective time, whether vested or unvested, will be assumed by Allarity Delaware and converted into an option (each, a "Converted Option") to purchase a number of shares of Delaware Common Stock equal to the product (rounded to the nearest whole number) of (a) the number of ordinary shares of Allarity A/S subject to such Compensatory Warrant immediately prior to the effective time multiplied by (b) the exchange ratio, at an exercise price per share (rounded up to the nearest whole cent) equal to (i) the exercise price per share of such Compensatory Warrant immediately prior to the effective time divided by (ii) the exchange ratio and converted into U.S. dollars; provided, however, that the exercise price and the number of shares of Delaware Common Stock purchasable pursuant to the Converted Options will be determined in a manner consistent with the requirements of Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"); provided, further, however, that in the case of any Converted Option to which Section 422 of the Code applies, the exercise price and the number of shares of Delaware Common Stock purchasable pursuant to such option will be determined in accordance with the foregoing, subject to such adjustments in a manner consistent with Treasury Regulation Section 1.424-1, such that the Converted Option will not constitute a modification of such Converted Option for purposes of Section 409A or Section 424 of the Code. Except as specifically provided above, following the effective time, each Converted Option will continue to be governed by the same terms and conditions (including vesting and exercisability terms) as were applicable to the corresponding former Compensatory Warrant immediately prior to the effective time. This information statement/prospectus includes important information about Allarity Delaware after the consummation of the Recapitalization Share Exchange. Allarity A/S urges you to read the information contained in this information statement/prospectus carefully.

Q: What will Allarity A/S shareholders receive in the Recapitalization Share Exchange?

A: At the effective time of the Recapitalization Share Exchange (the "effective time"), from the Delaware Common Stock exchanged for substantially all of the assets and the assumption of substantially all of the liabilities of Allarity A/S, each outstanding ordinary share of Allarity A/S will be entitled to receive, either as payment in the share exchange swap program or by way of extraordinary dividend (subject to applicable tax withholding requirements), a number of shares of Delaware Common Stock equal to the exchange ratio. In each case, these share amounts will be rounded down to the nearest whole number on a holder-by-holder basis and any fractional interest will be settled in cash. The "exchange ratio" means the quotient of the number of ordinary shares of Allarity A/S owned by each shareholder divided by fifty (50) or 0.02 shares of Delaware Common Stock for each ordinary share in Allarity A/S (as defined in the Reorganization Agreement), as of immediately prior to the effective time.

Q: What happens if I sell my Allarity A/S ordinary shares before the Allarity A/S Extraordinary General Meeting?

A: The record date for Allarity A/S Extraordinary General Meeting will be one week before the meeting is held. If you transfer your shares of Allarity A/S ordinary shares after the record date, but before the Allarity A/S Extraordinary General Meeting, unless the transferee obtains from you a proxy to vote those shares, you will retain your right to vote at the Allarity A/S Extraordinary General Meeting. However, you will not become an

Allarity Delaware shareholder following the effective time of the Recapitalization Share Exchange because only Allarity A/S's shareholders on the effective time will receive Delaware Common Stock and thus become Allarity Delaware shareholders.

Q: Will the PIPE investors have the right to vote at the Allarity A/S Extraordinary General Meeting in connection with the Recapitalization Share Exchange?

A: No. The PIPE investors are investing in the convertible preferred stock of Allarity Delaware that will be issued only upon the consummation of the Recapitalization Share Exchange pursuant to the Reorganization Agreement. Consequently, the PIPE investors will not have the right to vote or otherwise approve or disapprove of the Reorganization Agreement.

Q: When will the Recapitalization Share Exchange and the reorganization contemplated in the Reorganization Agreement be completed?

A: The parties currently expect that the Recapitalization Share Exchange and reorganization under the Reorganization Agreement will be completed during the fourth quarter of 2021. However, Allarity A/S cannot assure you of when, or if, the Recapitalization Share Exchange contemplated by the Reorganization Agreement will be completed, and it is possible that factors outside of the control of Allarity A/S could result in the Recapitalization Share Exchange and the transactions contemplated in the Reorganization Agreement being completed at a different time or not at all. Allarity A/S must first obtain the approval of its shareholders for each of the proposals set forth in this information statement/prospectus for their approval and satisfy other closing conditions. See "*THE REORGANIZATION AGREEMENT — Closing and Effective Time of the Recapitalization Share Exchange*" beginning on page 241 of this information statement/prospectus.

Questions and Answers About Allarity A/S's Extraordinary Meeting

Q: What am I being asked to vote on and why is this approval necessary?

A: Allarity A/S shareholders are being asked to vote on the following proposals:

1. The Recapitalization Share Exchange Proposals which includes votes on three separate resolutions consisting of (1.A) a resolution to approve the sale of substantially all of the assets, and the assumption of substantially all of the liabilities of Allarity A/S to Acquisition Sub in exchange for Delaware Common Stock; (1.B) a resolution to approve the share exchange swap program; (1.C) a resolution to approve the declaration and payment of an extraordinary dividend of the Delaware Common Stock to shareholders who have not participated in the share exchange swap program, and (1.D) a resolution to approve the amendment to the authorization in article 6.12 of the Articles of Association

2. the Nasdaq Pipe Proposal; and

3. the Incentive Plan Proposal.

The Recapitalization Share Exchange is conditioned upon the approval of each of the proposals. Failure to receive approval of any of the proposals provides each of Allarity A/S and Allarity Delaware with a right to terminate the Reorganization Agreement. If our shareholders do not approve each of the proposals, the reorganization may not be consummated. If The Recapitalization Share Exchange Proposals is not approved, each of the other proposals will not be presented to the shareholders for a vote.

Q: Why is Allarity A/S proposing the Recapitalization Share Exchange?

A: The board of directors of Allarity A/S considered a number of reasons pertaining to the Recapitalization Share Exchange as generally supporting its decision to enter into the Reorganization Agreement and the transactions contemplated thereby, including:

- ***Substantial Investment of $20 million.*** The PIPE Investment of $20 million from 3i, LP, a Delaware limited partnership, is conditioned upon the consummation of the Recapitalization Share Exchange and a listing of the Delaware Common Stock on the Nasdaq Stock Market and will represent the largest investment by an institutional investor in Allarity A/S ever made.

- ***Enhanced Shareholder Value through Access to Capital.*** The Recapitalization Share Exchange presents an opportunity to enhance long-term value for shareholders, through attracting deeper and growing pools of passive investment capital in the U.S., like 3i, LP, a Delaware limited partnership that primarily invest in U.S. listed companies.
- ***Redomiciling to the U.S.*** The Recapitalization Share Exchange will redomicile the company as a U.S.-based biopharmaceutical company, which we believe will level the playing field with our principal competitors, many of which are U.S.-based companies;
- ***Executive Management.*** We will continue to use our proprietary DRP® predictive biomarker platform to generate drug-specific companion diagnostics from our research facilities in Denmark while maintaining executive offices in the U.S. for our U.S. based senior executives.
- ***Comparable Peer Group.*** Following the Recapitalization Share Exchange, shares of our common stock will be listed on the Nasdaq Stock Market and we will report our consolidated financial results in U.S. dollars instead of SEK and in accordance with U.S. GAAP instead of IFRS, and will file reports with the SEC making it easier for the market to compare our business, pipeline of therapeutic candidates, and prospects with our peer group of U.S. listed comparable companies.
- ***Broadening Investor Base Enhancing Market Capitalization.*** We believe that our listing on the Nasdaq Stock Market and enhancing our comparability to our U.S. peers will enable a broader range of potential investors to invest in our shares and may result in a market capitalization closer to other U.S. listed biopharmaceutical companies with a comparable pipeline of therapeutic candidates.
- ***Delaware Incorporation.*** Redomiciling in Delaware will provide for greater comparability to other U.S. public companies, many of which are incorporated in Delaware.
- ***Shareholder Approval.*** The Recapitalization Share Exchange is subject to obtaining the approval of our shareholders.
- ***U.S. Listing on the Nasdaq Stock Market.*** The consummation of the Recapitalization Share Exchange is conditioned upon the listing of Delaware Common Stock of the Nasdaq Stock Market.

See "*THE RECAPITALIZATION SHARE EXCHANGE — Recommendation of the Allarity A/S Board of Directors and Reasons for the Recapitalization Share Exchange*" beginning on page 237 of this information statement/prospectus.

Q: Did the Allarity A/S board of directors obtain a third-party valuation or fairness opinion in determining whether or not to proceed with the Recapitalization Share Exchange?

A: No. Because the Recapitalization Share Exchange in substance is analogous to a "reverse stock split" coupled with a redomicile to the U.S. State of Delaware and a listing on the Nasdaq Stock Market, the Allarity A/S board of directors decided that a third-party valuation or fairness opinion would not add any meaningful information to the total mix of information considered by the Allarity A/S board of directors.

Q: Do I have redemption or appraisal rights?

A: No. Shareholders of Allarity A/S do not have redemption or appraisal rights as a result of the Recapitalization Share Exchange. After the shareholders of Allarity A/S approve all of the proposals at the Allarity A/S Extraordinary General Meeting, shareholders will be given the opportunity to exchange their ordinary shares for shares of Delaware Common Stock offered by this information statement/prospectus in a share swap program in proportion to the Exchange Ratio. Shareholders who do not participate in the share swap program will receive shares of Delaware Common Stock offered by this information statement/prospectus as a dividend, which may have more adverse tax consequences in Denmark than the share exchange in the share swap program.

Q: What happens if the Recapitalization Share Exchange is not consummated?

A: If the Recapitalization Share Exchange is not consummated for any reason, you will still own your ordinary shares in Allarity A/S that will continue to be listed on the Nasdaq First North Growth Market in Stockholm and the $20 million PIPE Investment by 3i, LP, a Delaware limited partnership, will not occur.

Q: How do the Directors and other insiders intend to vote on the proposals?

A: Members of the Allarity A/S board of directors that own Allarity A/S ordinary shares intend to vote "FOR" all of the proposals, including the Recapitalization Share Exchange Proposals.

Q: What constitutes a quorum at the Allarity A/S Extraordinary General Meeting?

A: Under the DCA, there is not a minimum number of ordinary shares that must be represented in person or by proxy to conduct business at the Allarity A/S Extraordinary General Meeting.

Q: Do I need to attend the Allarity A/S Extraordinary General Meeting to vote my shares?

A: You may vote your shares at the Allarity A/S Extraordinary General Meeting by way of proxy or voting by mail to be submitted in writing by using the proxy and voting by mail form which can be downloaded by visiting *www.allarity.com/egm2021*. If the form is used, it must be completed, signed and forwarded to Allarity A/S before the deadline set out in the convening notice.

Q: What vote is required to approve each proposal at the Allarity A/S Extraordinary General Meeting?

A: *The Recapitalization Share Exchange Proposals:* Approval of Proposals 1.A and 1.D of The Recapitalization Share Exchange Proposals requires the affirmative vote of 66.67% of the votes cast and the share capital represented at the Allarity A/S Extraordinary General Meeting while a majority of the votes cast and the share capital represented at the Allarity A/S Extraordinary General Meeting is required to approve Proposals 1.B and 1.C of The Recapitalization Share Exchange Proposals.

The Nasdaq Pipe Proposal: The affirmative vote of a majority of the votes cast and the share capital represented at the Allarity A/S Extraordinary General Meeting is required to approve the Nasdaq Pipe Proposal. Notwithstanding the approval of the Nasdaq Pipe Proposal, if the reorganization is not consummated for any reason, the actions contemplated by the Nasdaq Pipe Proposal will not be undertaken.

The Incentive Plan Proposal: The affirmative vote of 66.67% of the votes cast and the share capital represented at the Allarity A/S Extraordinary Meeting is required to approve the Incentive Plan Proposal. Notwithstanding the approval of the Incentive Plan Proposal, if the reorganization is not consummated for any reason, the actions contemplated by the Incentive Plan Proposal will not be undertaken.

Q: Do any of Allarity A/S's directors, officers or affiliates have interests in the Recapitalization Share Exchange that may differ from or be in addition to the interests of the Allarity A/S shareholders?

A: Allarity A/S's executive officers and certain non-employee directors may have interests in the Recapitalization Share Exchange that may be different from, or in addition to, the interests of Allarity A/S shareholders generally. The Allarity A/S board of directors was aware of and considered these interests to the extent such interests existed at the time, among other matters, in approving the Reorganization Agreement and in recommending that the Recapitalization Share Exchange and the transactions contemplated thereby be approved by the shareholders of Allarity A/S. See, "*THE RECAPITALIZATION SHARE EXCHANGE — Interests of Certain Persons in the Recapitalization Share Exchange*" beginning on page 239 of this information statement/prospectus.

Q: What do I need to do now?

A: After carefully reading and considering the information contained in this information statement/prospectus and the notice convening the Allarity A/S Extraordinary General Meeting, please exercise your voting rights as set forth in the convening notice so that your shares will be represented at the Allarity A/S Extraordinary General Meeting. Please follow the instructions set forth in the convening notice. Your attention is directed to the information statement/prospectus accompanying this Q&A (including the financial statements and annexes attached thereto) for a more complete description of the proposals. We encourage you to read this information statement/prospectus carefully. If you have any questions or need assistance with voting, please contact Allarity A/S's at +45 88 74 24 15 or email investorrelations@allarity.com.

Q: How do I vote?

A: If you are a shareholder as of the record date of November 15, 2021, the Allarity A/S record date, you may submit your vote or proxy as set forth in the notice convening the Allarity A/S Extraordinary General Meeting.

Q: When and where is the Allarity A/S Extraordinary General Meeting?

A: The Allarity A/S Extraordinary General Meeting will be held on November 22, 2021 at 10:00 a.m. Central European Time at the offices of Mazanti-Andersen Advokatpartnerselskab, Amaliegade 10, DK-1256, Copenhagen K, Denmark. The shareholders may make use of the possibility to give proxy or vote by mail and follow the Allarity A/S Extraordinary General Meeting via live stream instead of attending in person.

Q: If my shares are held in "street name" by a broker, bank or other nominee, will my broker, bank or other nominee vote my shares for me?

A: If your shares are held in "street name" in a stock brokerage account or by a broker, bank or other nominee, you must provide the holder of your shares with instructions on how to vote your shares. Please note that you may not vote shares held in "street name" by returning a completed proxy and voting by mail form directly to Allarity A/S unless you provide a "legal proxy", which you must obtain from your broker, bank or other nominee. If you are an Allarity A/S shareholder holding your shares in "street name" and you do not instruct your broker, bank or other nominee on how to vote your shares, your broker, bank or other nominee will not vote your shares on any of the proposals.

Q: What if I attend the Allarity A/S Extraordinary General Meeting and abstain or do not vote?

A: For purposes of the Allarity A/S Extraordinary General Meeting, an abstention occurs when a shareholder attends the meeting in person and does not vote or returns a proxy with an "abstain" vote. Approval of Proposals 1.A and 1.D of The Recapitalization Share Exchange Proposals and Proposal No. 3 on the Incentive Plan Proposal requires the affirmative vote of 66.67% of the votes cast and the share capital represented at the Allarity A/S Extraordinary General Meeting and the remaining proposals in the Recapitalization Share Exchange Proposals and the Nasdaq Pipe Proposal requires the affirmative vote of a majority of the votes cast and the share capital represented at the Allarity A/S Extraordinary General Meeting. Because approval of Proposals 1.A and 1.D of The Recapitalization Share Exchange Proposals and Proposal No. 3 on the Incentive Plan Proposal only requires a favorable vote of 66.67% of the votes cast and the share capital represented at the Allarity A/S Extraordinary General Meeting, or for all other proposals a majority of the votes cast and the share capital represented at the Allarity A/S Extraordinary General Meeting, if you do not vote or do not instruct your bank, broker or other nominee how to vote, it will have no effect on these proposals because such action would not count as a vote cast at the Allarity A/S Extraordinary General Meeting.

Q: What happens if I fail to take any action with respect to the Allarity A/S Extraordinary General Meeting?

A: If you fail to take any action with respect to the Allarity A/S Extraordinary General Meeting and The Recapitalization Share Exchange Proposals is approved by shareholders and consummated, you will receive Delaware Common Stock either as a participant in the share exchange swap program or by extraordinary dividend. If you fail to take any action with respect to the Allarity A/S Extraordinary General Meeting and The Recapitalization Share Exchange Proposals is not approved, you will continue to be a shareholder of Allarity A/S.

Q: What should I do if I receive more than one set of voting materials?

A: Shareholders may receive more than one set of voting materials, including multiple copies of this information statement/prospectus. For example, if you hold your shares in more than one brokerage account, you will receive a separate convening notice for each brokerage account in which you hold shares.

Q: Whom should I contact if I have any questions about the proxy materials or voting?

A: If you have any questions about the proxy materials, need assistance submitting your proxy or voting your shares or need additional copies of this information statement/prospectus or the enclosed proxy and voting by mail form, you should contact Allarity A/S, at +45 88 74 24 15 or via email at investorrelations@allarity.com.

Q: How will the Recapitalization Share Exchange transaction be taxed.

A: The parties to the Reorganization Agreement intend the Recapitalization Share Exchange to qualify as a tax free "reorganization" under Section 368(a) of the Code and we have obtained the opinion of our counsel, Lewis Brisbois Bisgaard & Smith LLP to that effect. *See, PROPOSAL NO. 1 — THE RECAPITALIZATION SHARE EXCHANGE PROPOSALS — United States Federal Income Tax Considerations.* However, for Allarity A/S and all holders of Allarity A/S ordinary shares that are citizens or tax residents of Denmark or other countries who are not "US Holders," we believe that the Recapitalization Share Exchange will be a taxable sale of Allarity A/S assets followed by a taxable sale of Allarity A/S ordinary shares for shareholders participating in the share exchange swap program or taxable as a dividend for shareholders who do not participate in the share exchange swap program. *See, PROPOSAL NO. 1 — THE RECAPITALIZATION SHARE EXCHANGE PROPOSALS — Income Tax Considerations for Non-U.S. Holders.* **You should consult your own tax advisor to determine whether you should participate in the share exchange swap program or wait to receive your shares of Delaware Common Stock as a fully taxable dividend subject to applicable withholding requirements.**

SUMMARY OF INFORMATION STATEMENT/PROSPECTUS

This summary highlights selected information from this information statement/prospectus and does not contain all of the information that may be important to you. We urge you to read carefully the entire information statement/prospectus, including its annexes and other documents referred to herein, before you decide how to vote. Each item in this summary includes a page reference directing you to a more complete description of that item.

Information About the Parties to the Reorganization

Allarity A/S

We are a clinical stage biopharmaceutical company targeting some of the greatest unmet needs in oncology by developing differentiated and novel therapeutic candidates together with our proprietary DRP® companion diagnostics in a precision medicine approach. Our business strategy includes a focus on leveraging our proprietary DRP® companion diagnostics platform to streamline the drug development process and to identify patients that will benefit from therapeutic candidates that other biotechnology or pharmaceutical companies have abandoned or shelved after initiating clinical trials under an IND application filed with the FDA, including candidates that have failed to achieve statistical significance on the original endpoints established in the clinical trials. We use our proprietary DRP® companion diagnostics platform to advance therapeutic candidates by targeting and evaluating patient sub-populations having gene signatures, determined by our DRP® companion diagnostics platform, that will potentially correlate with drug efficacy and patient response to treatment. While we have not yet successfully received regulatory or marketing approval for any of our therapeutic candidates or companion diagnostics, and while we believe that our approach has the potential to reduce the cost and time of drug development through the identification and selection of patient populations more likely to respond to therapy, our strategy involves risks and uncertainties that differ from other biotechnology companies that focus solely on new therapeutic candidates that do not have a history of failed clinical development. By utilizing our DRP® platform to generate a drug-specific companion diagnostic for each of our therapeutic candidates, if approved by the FDA, we believe our therapeutic candidates have the potential to advance the goal of personalized medicine by selecting the patients most likely to benefit from each of our therapeutic candidates and avoid the treatment of non-responder patients. All of our therapeutic candidates are clinical stage assets and the FDA has not yet approved any of our therapeutic candidates or any of our DRP® companion diagnostics. As used in this information statement/prospectus, statements regarding the use of our proprietary DRP® companion diagnostics or our proprietary DRP® platform or our observations that a therapeutic candidate may have anti-cancer or anti-tumor activity or is observed to be well tolerated in a patient population should not be construed to mean that we have resolved all issues of safety and/or efficacy for any of our therapeutic candidates or DRP® companion diagnostic. Issues of safety and efficacy for any therapeutic candidate companion diagnostic may only be determined by the U.S. FDA or other applicable regulatory authorities in jurisdictions outside the United States.

Our DRP® platform has been retrospectively validated by us using retrospective observational studies in 35 clinical trials that were conducted or sponsored by other companies. The FDA considers a retrospective observational study to be one in which the study identifies the population and determines the exposure/treatment from historical data (i.e. data generated prior to the initiation of the study) with the variables and outcomes of interest determined at the time the study is designed. See, *Framework for FDA's Real-World Evidence Program*, page 6 (December 2018), *https://www.fda.gov/media/120060/download*. The FDA has accepted our retrospective validation in support of two Investigational Device Exemption ("IDE") applications to conduct clinical trials, one with respect to LiPlaCis® and one with respect to stenoparib.

We anticipate submitting a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for our lead therapeutic candidate, dovitinib, a second-generation "pan"-tyrosine kinase inhibitor (TKI), before December 31, 2021, while continuing to expand patient enrollment in our ongoing Phase 2 clinical trials for our two other priority programs, stenoparib, a novel inhibitor of the key DNA damage repair enzyme poly-ADP-ribose polymerase (PARP), and IXEMPRA® (ixabepilone), a selective microtubule inhibitor. We may additionally conduct a near-term clinical trial for stenoparib to test the anti-viral activity of this therapeutic candidate as a potential treatment for SARS-CoV-2 (COVID-19) applications. We have not yet submitted an Investigational New Drug ("IND") application to the FDA to conduct such a trial and if we decide to do so, the FDA may not approve our IND application. We also intend to opportunistically acquire other promising oncology assets, which have undergone prior clinical trial data demonstrating that these candidates are well tolerated in the tested patient population coupled with promising signs of anti-tumor activity, for our pipeline over the next five years. We were founded in Denmark in 2004 by our chief scientific officer,

Steen Knudsen, Ph.D., and our Senior Vice President of Information Technologies, Thomas Jensen, both of whom were formerly academic researchers at the Technical University of Denmark working to advance novel bioinformatic and diagnostic approaches to improving cancer patient response to therapeutics.

Our clinical and commercial development team is advancing our pipeline of targeted oncology therapeutic candidates, all of which have previously succeeded at least though Phase 1 clinical demonstrating that the therapeutic candidate is well tolerated. Our three priority assets, dovitinib, stenoparib, and IXEMPRA® (ixabepilone) are all former drug candidates of large pharmaceutical companies. Our lead therapeutic candidate, dovitinib, is a selective inhibitor of several classes of tyrosine kinases, including FGFR and VEGFR, and was formerly developed by Novartis Pharmaceuticals through Phase 3 clinical trials in numerous indications. We anticipate submitting an NDA with the FDA before December 31, 2021, for the treatment of third line renal cell carcinoma (RCC or kidney cancer) in patients selected by our Dovitinib-DRP® companion diagnostic. Our anticipated NDA will be supported by a concomitant Pre-Market Approval (PMA) application to the FDA for approval of our dovitinib-specific DRP® companion diagnostic for use to select and treat patients likely to respond to dovitinib. Our second priority therapeutic candidate is stenoparib (formerly E7449), a novel inhibitor of the key DNA damage repair enzyme poly-ADP-ribose polymerase (PARP), which also has an observed inhibitory action against Tankyrases, another important group of DNA damage repair enzymes. Stenoparib was formerly developed by Eisai, Inc. (Eisai) through Phase 1 clinical trials, and we are currently advancing a Phase 2 clinical trial of this therapeutic candidate for the treatment of ovarian cancer at the Dana-Farber Cancer Institute (Boston, MA USA.) together with its stenoparib-specific DRP® companion diagnostic, for which the FDA has previously approved an Investigational Device Exemption (IDE) application.

Our third priority therapeutic candidate is IXEMPRA® (ixabepilone), a selective microtubule inhibitor, which has been shown to interfere with cancer cell division, leading to cell death. IXEMPRA® (ixabepilone) was formerly developed and brought to market by Bristol-Myers Squibb, is currently marketed and sold in the U.S. by R-PHARM US LLC, for the treatment of metastatic breast cancer treated with two or more prior chemotherapies. We are currently advancing IXEMPRA®, together with its drug-specific DRP® companion diagnostic, in a Phase 2 European clinical trial for the same indication, with the goal of eventually submitting an application for Marketing Authorization (MA) with the European Medicine Agency (EMA) to market IXEMPRA®, together with its drug-specific DRP® companion diagnostic, in the European market.

We have in-licensed the intellectual property rights to develop, use and market our two lead therapeutic candidates, dovitinib and stenoparib. Consequently, we must perform all of the obligations under these license agreements, including the payment of substantial development milestones payments and royalty payments on future sales in the event we receive marketing approval for dovitinib or stenoparib in the future. If we fail to perform our obligations under our license agreements, we may lose the intellectual property rights to these therapeutic candidates which will have a material adverse effect on our business.

Our focused approach to address major unmet needs in oncology leverages our management's significant expertise in discovery, medicinal chemistry, manufacturing, clinical development, and commercialization. As a result, we have created substantial intellectual property around the composition of matter for our new chemical entities. The foundations of our approach include:

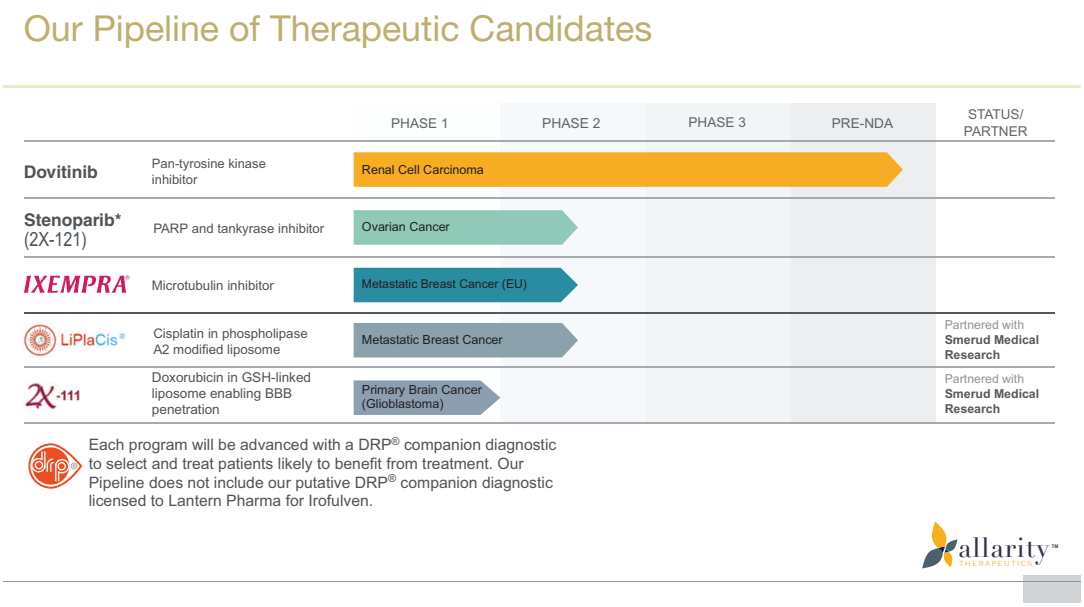
- ***The pursuit of clinical-stage assets:*** We strive to identify and pursue novel oncology therapeutic candidates that have advanced beyond Phase 1 clinical trials and are preferably Phase 2 to Phase 3 clinical stage assets. Accordingly, the assets we have acquired, and intend to acquire, have undergone prior clinical trials by other pharmaceutical companies with clinical data that helps us evaluate whether these candidates will be well tolerated in the tested patient population, and in some cases, have observed anti-cancer or anti-tumor activity that would support additional clinical trials using our DRP® platform. We often focus our acquisition efforts on therapeutic candidates that have been the subject of clinical trials conducted by large pharmaceutical companies. Further we intend to select therapeutic candidates for which we believe we can develop a drug-specific DRP® to advance together with the therapeutic candidate in further clinical trials as a companion diagnostic to select and treat the patients most likely to respond to the therapeutic candidate. We further consider whether the licensor or assignor can provide us substantial clinical grade active pharmaceutical ingredients (API) for the therapeutic candidate, at low-to-no cost, for our use in future clinical trials. The availability of API at low-to-no cost reduces both our future clinical trial costs and the lead time it takes us to start a new clinical trial for the therapeutic candidate. As an example, our lead therapeutic candidate, dovitinib, was developed by Novartis through Phase 2 clinical trials in

numerous indications and in Phase 3 clinical trials for RCC before we acquired the therapeutic candidate, and it came with a substantial API supply to support our continuing advancement towards submitting an NDA to the FDA.

- ***Our proprietary DRP® companion diagnostics:*** We believe our proprietary and patented Drug Response Predictor (DRP®) platform provides us with a substantial clinical and commercial competitive advantage for each of therapeutic candidates in our pipeline. DRP® is a proprietary, predictive biomarker technology that employs complex systems biology, bio-analytics with a proprietary clinical relevance filter to bridge the gap between *in vitro* cancer cell responsiveness to a given therapeutic candidate and in vivo likelihood of actual patient response to that therapeutic candidate. The DRP® platform has been retrospectively validated by us using retrospective observational studies in 35 clinical trials that were conducted or sponsored by other companies. We intend to develop and validate a drug-specific DRP® biomarker for each and every therapeutic candidate in our therapeutic candidate pipeline to serve as a companion diagnostic to select and treat patients most likely to respond to that therapeutic candidate. Our DRP® technology has also been peer-reviewed by numerous publications and we have patented DRP®s for more than 70 anti-cancer drugs.

- ***A precision oncology approach:*** Our focused strategy is to advance our pipeline of therapeutic candidates, together with DRP® companion diagnostics, to bring these therapeutic candidates, once approved, to market and to patients through a precision oncology approach. DRP® provides a gene expression fingerprint that we believe reveals whether a specific tumor in a specific patient is likely to respond to one of our therapeutic candidates and therefore can be used to identify those patients who are most likely to respond to a particular therapeutic treatment in order to guide therapy decisions and lead to better treatment outcomes. Our DRP® companion diagnostics may be used both to identify a susceptible patient population for inclusion in clinical trials during the drug development process (and to exclude the non-susceptible patient population), and further to select the optimal anti-cancer drug for individual patients in the treatment setting once an anti-cancer drug is approved and marketed. By including only patients that have tumors that we believe may respond to our therapeutic candidate in our clinical trials, we believe our proprietary DRP® companion diagnostics platform has the potential to improve the overall treatment response in our clinical trials and thereby improving our chances for regulatory approval to market our therapeutic candidate, while potentially reducing the time, cost, and risk of clinical development.

The following chart summarizes our therapeutic candidate pipeline:



We have out-licensed LiPlaCis® and 2X-111 to our longtime CRO partner Smerud Medical Research International.

Since our inception, we have incurred losses and have an accumulated deficit of $37.4 million as of December 31, 2020. Our net losses were $5,073,000 and $14,400,000 for the years ended December 31, 2020 and 2019, respectively. Our net losses were $7,658,000 and $2,937,000 for the six months ended June 30, 2021 and June 30, 2020, respectively, resulting in an increase of our accumulated deficit to $45 million. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. None of our current therapeutic candidates have been approved for marketing in the United States, or in any other jurisdiction, and may never receive such approval. It could be several years, if ever, before we have a commercialized drug that generates significant revenues. As a result, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain profitability.

Our recurring losses from operations since inception and required additional funding to finance our operations raise substantial doubt about our ability to continue as a going concern. Furthermore, our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements included in this information statement/prospectus. Our audited financial statements at December 31, 2020 and 2019 and for the years then ended were prepared assuming that we will continue as a going concern.

We believe that the net proceeds from the PIPE Investment, together with our existing cash and cash equivalents as of the date of this information statement/prospectus, and our anticipated expenditures and commitments for calendar year 2021 and 2022, will enable us to fund our operating expenses and capital expenditure requirements for at least 12 months from the date of this information statement/prospectus. Our estimate as to how long we expect the net proceeds from the PIPE Investment, together with our existing cash and cash equivalents, to be able to continue to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Further, changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

Allarity Delaware and Allarity Acquisition Sub

Allarity Delaware is a Delaware corporation and a directly wholly owned subsidiary of Allarity A/S, which was formed on April 6, 2021 for the purpose of effecting a reorganization with Allarity A/S that is described in this information statement/prospectus as a Recapitalization Share Exchange. Allarity Delaware does not own any material assets or operate any business. Allarity Acquisition Subsidiary, Inc. ("Acquisition Sub") is a Delaware corporation and a directly wholly owned subsidiary of Allarity Delaware formed on June 24, 2021, for the purpose of effecting the Recapitalization Share Exchange that is described in this information prospectus. Acquisition Sub does not own any material assets or operation any business. After the Recapitalization Share Exchange, substantially all of the assets and liabilities of Allarity A/S will be transferred to Acquisition Sub in exchange for the voting common stock of Allarity Delaware which will be distributed to the Shareholders of Allarity A/S either by an exchange offer or by extraordinary dividend and then Allarity A/S will liquidate and dissolve.

The Recapitalization Share Exchange and the Reorganization Agreement

The terms and conditions of the Recapitalization Share Exchange are contained in the Amended and Restated Plan of Reorganization and Asset Purchase Agreement, which is attached as Annex A to this information statement/prospectus (the "Reorganization Agreement"). We encourage you to read the Reorganization Agreement carefully, as it is the legal document that governs the Recapitalization Share Exchange.

If the Reorganization Agreement is approved and adopted and the Recapitalization Share Exchange is subsequently completed, Acquisition Sub will acquire substantially all of the assets and liabilities of Allarity A/S in exchange for Delaware Common Stock. The Delaware Common Stock issued in exchange for substantially all of the assets and liabilities of Allarity A/S will then be distributed to the shareholders of Allarity A/S either by a share exchange swap program or, for those shareholders who do not participate in the share exchange swap program, by extraordinary dividend subject to any withholding requirements. After the completion of the Recapitalization Share Exchange, Allarity Delaware will own, directly or indirectly, all of the business assets of Allarity A/S and Allarity A/S will liquidate and dissolve under the DCA.

Terms of the Recapitalization Share Exchange

The number of shares of Delaware Common Stock that will be issued in exchange for substantially all of the assets and liabilities of Allarity A/S and subsequently distributed to the shareholders of Allarity A/S is determined by an exchange ratio of 0.02 share of Delaware Common Stock for each ordinary share of Allarity A/S outstanding immediately prior to the effective time. As of the date of this information statement, prospectus, we anticipate issuing approximately 8,075,824 shares of Delaware Common Stock in the Recapitalization Share Exchange.

Shareholders of Allarity A/S will then be given the opportunity to exchange their ordinary shares of Allarity A/S for an amount of Delaware Common Stock equal to the Exchange Ratio rounded down to the nearest whole number during the share swap program and any fractional interest will be settled in cash. Any shares of Delaware Common Stock remaining after the share exchange swap program expires will be distributed to the remaining shareholders of Allarity A/S by an extraordinary dividend or liquidating distribution, subject to any required withholding for taxes. No fractional shares will be issued in the Share Exchange Recapitalization.

At the effective time, each warrant (option) conferring the right to subscribe for Allarity A/S ordinary shares held by the officers, directors, employees and consultants (each, a "Compensatory Warrant") that is outstanding immediately prior to the effective time, whether vested or unvested, will be assumed by Allarity Delaware and converted into an option (each, a "Converted Option") to purchase a number of shares of Delaware Common Stock equal to the product (rounded down to the nearest whole number) of (a) the number of ordinary shares of Allarity A/S subject to such Compensatory Warrant immediately prior to the effective time multiplied by (b) the exchange ratio, at an exercise price per share (rounded up to the nearest whole cent) equal to (i) the exercise price per share of such Compensatory Warrant immediately prior to the effective time divided by (ii) the exchange ratio and converted into U.S. dollars; provided, however, that the exercise price and the number of shares of Delaware Common Stock purchasable pursuant to the Converted Options will be determined in a manner consistent with the requirements of Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"); provided, further, however, that in the case of any Converted Option to which Section 422 of the Code applies, the exercise price and the number of shares of Delaware Common Stock purchasable pursuant to such option will be determined in accordance with the foregoing, subject to such adjustments in a manner consistent with Treasury Regulation Section 1.424-1, such that the Converted Option will not constitute a modification of such Converted Option for purposes of Section 409A or Section 424 of the Code. Except as specifically provided above, following the effective time, each Converted Option will continue to be governed by the same terms and conditions (including vesting and exercisability terms) as were applicable to the corresponding former Compensatory Warrant immediately prior to the effective time.

Recommendation of the Allarity A/S Board of Directors

The Allarity A/S board of directors has unanimously determined that the reorganization, on the terms and conditions set forth in the Reorganization Agreement, is advisable and in the best interests of Allarity A/S and its shareholders and has directed that the proposals set forth in this information statement/prospectus and the convening notice be submitted to its shareholders for approval at the Allarity A/S Extraordinary General Meeting on the date and at the time and place set forth in this information statement/prospectus and in the convening notice. The Allarity A/S board of directors unanimously recommends that Allarity A/S's shareholders vote "**FOR**" The Recapitalization Share Exchange Proposals, "**FOR**" the Nasdaq Pipe Proposal, and "**FOR**" the Incentive Plan Proposal. See "*THE RECAPITALIZATION SHARE EXCHANGE — Recommendation of the Allarity A/S Board of Directors and Reasons for the Recapitalization Share Exchange*" beginning on page 237 of this information statement/prospectus.

Allarity A/S Extraordinary General Meeting of Shareholders

The Allarity A/S Extraordinary General Meeting will be held as a physical meeting with live webcast in English. Shareholders wishing to attend the Allarity A/S Extraordinary General Meeting must notify Allarity A/S of their attendance prior to the meeting as set out in the convening notice. Shareholders may — instead of opting for physical attendance — vote by proxy or by mail prior to the meeting. Whether voting in person or by proxy or mail, the right to vote at the Allarity A/S Extraordinary General Meeting is determined on the basis of the shares held by the shareholder at the Allarity A/S record date. The shareholdings and voting rights are calculated on the basis of entries in the Allarity A/S shareholders' register and any notice of ownership received by Allarity A/S for the purpose of registration in the

shareholders' register. Shareholders wishing to exercise their voting rights at the Allarity A/S Extraordinary General Meeting are encouraged to contact their depository bank well in advance of the Allarity A/S record date to ensure correct and sufficient registration.

The Allarity A/S board of directors has fixed the close of business on November 15, 2021 as the Allarity A/S record date for determining the holders of Allarity A/S ordinary shares entitled to receive notice of and to vote at the Allarity A/S Extraordinary General Meeting. As of the Allarity A/S record date, there were 403,791,200 ordinary shares of Allarity A/S outstanding and entitled to vote at the Allarity A/S Extraordinary General Meeting. Each ordinary share of Allarity A/S entitles the holder to one vote at the Allarity A/S Extraordinary General Meeting on each proposal to be considered at the Allarity A/S Extraordinary General Meeting. As of the Allarity A/S record date, the Allarity A/S's directors and executive officers and their affiliates owned and were entitled to vote 9,123,430 ordinary shares of Allarity A/S, representing approximately 2.3% of the ordinary shares of Allarity A/S outstanding on that date. Allarity A/S currently expects that the Allarity A/S's directors and officers will vote their shares in favor of each of the proposals set forth in this information statement/prospectus and the convening notice.

Approval of (i) Proposal 1.A approving the sale of substantially all of Allarity A/S's assets, liabilities and business operations to its subsidiary Allarity Delaware in The Recapitalization Share Exchange Proposals, (ii) Proposal 1.D, a resolution to approve the amendment to the authorization in article 6.12 of the Articles of Association and (iii) Proposal No. 3 on the Incentive Plan Proposal requires the affirmative vote of 66.67% of the votes cast and the share capital represented at the Allarity A/S Extraordinary General Meeting. Approval of Proposal 1.B on approving the share swap program, Proposal 1.C on the authorization to declare and pay extraordinary dividends in the Recapitalization Share Exchange Proposals and the Nasdaq Pipe Proposal require the affirmative vote of a majority of the votes cast and the share capital represented at the Allarity A/S Extraordinary General Meeting. Because approval of each of the proposals only requires 66.67% of the votes cast and the share capital represented with respect to Proposals 1.A and 1.D of The Recapitalization Share Exchange Proposals and Proposal No. 3 of the Incentive Plan Proposal and a majority of the votes cast and the share capital represented for each of the other proposals, and because the DCA does not require a minimum number of votes and shares present in person or by proxy to establish a quorum at the Allarity A/S Extraordinary General Meeting, if you do not vote or do not instruct your bank, broker or other nominee how to vote, it will have no effect on each of these proposals because such action would not count as a vote cast at the Allarity A/S Extraordinary General Meeting. The Allarity A/S board of directors has already approved the proposals subject to shareholder approval.

The Recapitalization Share Exchange is conditioned upon the approval of each of the proposals. Failure to receive approval of any of the proposals provides each of Allarity A/S and Allarity Delaware with a right to terminate the Reorganization Agreement. If our shareholders do not approve each of the proposals, the Recapitalization Share Exchange may not be consummated. If The Recapitalization Share Exchange Proposals is not approved, each of the other proposals will not be presented to the shareholders for a vote.

Interests of Certain Persons in the Recapitalization Share Exchange

Certain of Allarity A/S's executive officers and directors may have interests in the Recapitalization Share Exchange that may be different from, or in addition to, the interests of Allarity A/S's shareholders. The members of the Allarity A/S board of directors were aware of and considered these interests, among other matters, when they approved the Reorganization Agreement and recommended that Allarity A/S shareholders approve the proposals required to effect the reorganization. See "*RECAPITALIZATION SHARE EXCHANGE — Interests of Certain Persons in the Recapitalization Share Exchange*" beginning on page 239 of this information statement/prospectus. In considering these interests, the Allarity A/S board of directors concluded that the reasons for entering into the Reorganization Agreement far outweighed the interests of Allarity A/S's executive officers and directors. See "*THE RECAPITALIZATION SHARE EXCHANGE — Recommendation of the Allarity A/S Board of Directors and Reasons for the Recapitalization Share Exchange*" beginning on page 237 of this information statement/prospectus.

Appraisal Rights

Appraisal rights are not available to holders of shares of Allarity A/S ordinary shares in connection with the Recapitalization Share Exchange.

Conditions to Closing

Consummation of the Recapitalization Share Exchange is conditioned upon the satisfaction or, to the extent permitted by applicable law, waiver by the party for whose benefit such condition exists, of each of the following conditions:

- no provisions of any applicable law, and no order by any governmental authority will restrain or prohibit or impose any condition on the consummation of the closing;
- there will not be any action brought by any governmental authority to enjoin or otherwise restrict or make illegal the consummation of the closing;
- this information statement/prospectus will have become effective under the Securities Act and no stop order suspending the effectiveness of this information statement/prospectus will have been issued and no proceedings for those purposes will have been initiated or threatened by the SEC and not withdrawn;
- the shares of Delaware Common Stock issuable as Asset Acquisition Consideration pursuant to the Reorganization Agreement shall have been approved for listing on the Nasdaq Stock Market, subject to official notice of issuance.
- Allarity A/S shareholder approval will have been obtained in accordance with the provisions of Allarity A/S's articles of association and the DCA; and
- Allarity Delaware shareholder approval will have been duly obtained in accordance with the DGCL and Allarity Delaware's organizational documents, as amended and in effect on the date of the Reorganization Agreement.

Any of conditions to the Recapitalization Share Exchange listed above may be waived by Allarity A/S, Allarity Delaware and Acquisition Sub.

Termination

The Reorganization Agreement may be terminated and/or abandoned at any time prior to the closing, whether before or after approval of the proposals being presented to Allarity A/S's shareholders:

- if the closing has not occurred on or prior to December 31, 2021 (the "End Date"); provided, however, that a party will not be permitted to terminate if the failure of the closing to occur prior to the End Date is attributable to the failure on the part of such party to perform in any material respect any covenant or obligation in the Reorganization Agreement required to be performed by such party;
- if there shall have been a breach of any representation, warranty, covenant, or agreement on the part of Allarity A/S or Allarity Delaware set forth in this Reorganization Agreement such that the conditions to the Closing of the Recapitalization Share Exchange would not be satisfied and, in either such case, such breach is incapable of being cured by the End Date; and
- by the mutual written agreement of the parties to the Reorganization Agreement.

Effect of Termination

In the event of termination by either Allarity A/S or Allarity Delaware, all further obligations of the parties will terminate.

PIPE Investment

In connection with the execution of the Reorganization Agreement, we have entered into a securities purchase agreement with 3i, LP, a Delaware limited partnership for a $20 million PIPE investment for a private placement of shares of Allarity Delaware preferred stock. The PIPE investment is conditioned upon the completion of the Recapitalization Share Exchange and an effective registration statement. See "The Reorganization Agreement — Related Agreements — PIPE Investment" beginning on page 247 of this information statement/prospectus.

Stock Exchange Listing

The completion of the Recapitalization Share Exchange and the PIPE Investment is conditioned upon the shares of Delaware Common Stock being approved for listing on the Nasdaq Stock Market, subject to official notice of issuance.

Comparison of Shareholders' Rights

Following the Recapitalization Share Exchange, the rights of Allarity A/S shareholders will no longer be governed by the existing articles of association of Allarity A/S and instead will be governed by the certificate of incorporation and bylaws of Allarity Delaware.

Risk Factors

You should consider all the information contained in this information statement/prospectus in deciding how to vote for the proposals presented in the information statement/prospectus. In particular, you should consider the factors described under "*Risk Factors*" beginning on page 26 of this information statement/prospectus, which include, among others, the following:

- We have incurred significant losses since inception and anticipate that we may continue to incur losses for the foreseeable future and may never achieve or maintain profitability.
- Our recurring losses from operations since inception and required additional funding to finance our operations raise substantial doubt about our ability to continue as a going concern. Furthermore, our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements included in this information statement/prospectus. Our audited financial statements at December 31, 2020 and 2019 and for the years then ended were prepared assuming that we will continue as a going concern. We have incurred significant losses and has an accumulated deficit of $45 million as of June 30, 2021. As of August 20, 2021, our cash which includes the proceeds of our rights offering in June 2021 is insufficient to fund our current operating plan and planned capital expenditures for at least the next 12 months. These conditions give rise to a substantial doubt over our ability to continue as a going concern.
- We will need substantial funding to pursue our business objectives. If we are unable to raise capital when needed or on favorable terms, we could be forced to delay, reduce or terminate our product development, other operations or commercialization efforts.
- If we do not obtain regulatory approval for and successfully commercialize our therapeutic candidates in one or more indications or we experience significant delays in doing so, we may never generate any revenue or become profitable.
- Our approach to the discovery and development of therapeutic candidates based on our DRP® platform is unproven, and we do not know whether we will be able to develop any therapeutic candidates of commercial value, or if competing technological approaches will limit the commercial value of our therapeutic candidates or render our DRP® platform obsolete.
- Our DRP® platform-based therapeutic candidates are based on a novel technology, which makes it difficult to predict the time and cost of therapeutic candidate development.
- If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- We face competition, which may result in others discovering, developing or commercializing cancer therapies before or more successfully than us.
- We rely on third parties to perform the chemistry work associated with our drug discovery, preclinical activities and to conduct our preclinical studies and clinical trials, and our business could be substantially harmed if these third parties cease performing services or perform in an unsatisfactory manner.

- We do not have our own manufacturing capabilities and will rely on third parties to produce clinical and commercial supplies of API for our therapeutic candidates.
- If we are unable to obtain, maintain, protect and enforce sufficient patent and other intellectual property rights for our therapeutic candidates and technology, or if the scope of patent and other intellectual property rights obtained is not sufficiently broad, we may not be able to compete effectively in our market.
- The patent protection we obtain for our therapeutic candidates and technology may be challenged or not sufficient enough to provide us with any competitive advantage.
- Our business, operations and clinical development plans and timelines and supply chain could be adversely affected by the effects of health epidemics, including the ongoing COVID-19 pandemic, on the manufacturing, clinical trial and other business activities performed by us or by third parties with whom we conduct business, including our contract manufacturing organizations ("CMOs"), contract research organizations ("CROs"), shippers and others.
- Our future success depends on our ability to retain our founder Dr. Steen Knudsen, our CEO Steve Carchedi and our other key employees, consultants and advisors and to attract, retain and motivate qualified personnel.
- The consummation of the Recapitalization Share Exchange is subject to a number of conditions and if those conditions are not satisfied or waived, the Reorganization Agreement may be terminated in accordance with its terms and the Recapitalization Share Exchange may not be completed.

Emerging Growth Company

We are an "emerging growth company," as defined in Section 2(a) of the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), and it may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the independent registered public accounting firm attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in its periodic reports and information statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. We have elected not to opt out of such extended transition period which means that when a standard is issued or revised and it has different application dates for public or private companies, we, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of our financial statements with another public company which is neither an emerging growth company nor an emerging growth company which has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

We will remain an emerging growth company until the earlier of: (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of the Recapitalization Share Exchange, (b) when we have total annual gross revenue of at least $1.07 billion or (c) when we are deemed to be a large accelerated filer, which means the market value of our common equity that is held by non-affiliates exceeds $700.0 million as of the end of the prior fiscal year's second fiscal quarter; and (2) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period. References herein to "emerging growth company" shall have the meaning associated with it in the JOBS Act.

Summary of the Transactions

Set forth below is a summary of transactions that are contemplated to occur in connection with the Recapitalization Share Exchange.

Asset Purchase in Exchange for Common Stock

In the Recapitalization Share Exchange, Allarity Delaware will purchase substantially all of the assets and assume substantially all of the liabilities of Allarity A/S in exchange for shares of Allarity Delaware voting common stock. The number of shares of Allarity Delaware voting common stock that will be issued in the transaction is determined by an exchange ratio of 0.02 share of Delaware Common Stock for each ordinary share of Allarity A/S (the "Exchange Ratio") outstanding at the closing. As of the date of this information statement, prospectus, we anticipate issuing approximately 8,075,824 shares of Delaware Common Stock in the Recapitalization Share Exchange.

Distribution of the Common Stock to the Shareholders of Allarity A/S

Shareholders of Allarity A/S will then be given the opportunity to exchange their ordinary shares of Allarity A/S for an amount of Delaware Common Stock equal to the Exchange Ratio rounded down to the nearest whole number during the share swap program and any fractional interest will be settled in cash. Any shares of Delaware Common Stock remaining after the share exchange swap program expires will be distributed to the remaining shareholders of Allarity A/S by an extraordinary dividend or liquidating distribution, subject to any required withholding for taxes. No fractional shares will be issued in the Share Exchange Recapitalization and any fractional interest will be settled in cash.

Conversion of Compensatory Warrants Held by Management

At the effective time, each warrant (option) conferring the right to subscribe for Allarity A/S ordinary shares held by the officers, directors, employees and consultants (each, a "Compensatory Warrant") that is outstanding immediately prior to the effective time, whether vested or unvested, will be converted into an option (each, a "Converted Option") to purchase a number of shares of Allarity Delaware Common Stock equal to the product (rounded down to the nearest whole number) of (a) the number of ordinary shares of Allarity A/S subject to such Compensatory Warrant immediately prior to the effective time multiplied by (b) the exchange ratio, at an exercise price per share (rounded up to the nearest whole cent) equal to (i) the exercise price per share of such Compensatory Warrant immediately prior to the effective time divided by (ii) the exchange ratio and converted into U.S. dollars; provided, however, that the exercise price and the number of shares of Delaware Common Stock purchasable pursuant to the Converted Options will be determined in a manner consistent with the requirements of Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"); provided, further, however, that in the case of any Converted Option to which Section 422 of the Code applies, the exercise price and the number of shares of Delaware Common Stock purchasable pursuant to such option will be determined in accordance with the foregoing, subject to such adjustments in a manner consistent with Treasury Regulation Section 1.424-1, such that the Converted Option will not constitute a modification of such Converted Option for purposes of Section 409A or Section 424 of the Code. Except as specifically provided above, following the effective time, each Converted Option will continue to be governed by the same terms and conditions (including vesting and exercisability terms) as were applicable to the corresponding former Compensatory Warrant immediately prior to the effective time.

We refer to these transactions, together with the reorganization and the other transactions contemplated by the Reorganization Agreement as the "Recapitalization Share Exchange".

PIPE Investment

At the effective time, 3i, LP, a Delaware limited partnership will purchase shares of Allarity Delaware preferred stock for a purchase price of $20 million conditioned upon the completion of the Recapitalization Share Exchange and an effective registration statement. See "*The Reorganization Agreement — Related Agreements — PIPE Investment*" beginning on page 247 of this information statement/prospectus.

Ownership of Allarity A/S

The outstanding share capital stock of Allarity A/S is 403,791,200 ordinary shares, nominal value DKK 0.05 per share, as of the date of this information statement/prospectus. In addition, as of the date of this information statement/prospectus, officers, directors and employees of Allarity A/S held rights to 46,287,002 compensatory warrants conferring the right to subscribe for Allarity A/S ordinary shares and shareholders of Allarity A/S held 3,996,684 investment warrants conferring the right to subscribe for Allarity A/S ordinary shares, with an exercise price of SEK 3.30 per share expiring on February 24, 2023, (the "Financial Consultant warrants"). Each compensatory warrant and

investment warrant entitles the holder thereof to purchase one ordinary share of Allarity A/S. Therefore, as of the date of this information statement/prospectus (without giving effect to the Recapitalization Share Exchange), assuming that each outstanding warrant is exercised and one ordinary share of Allarity A/S is issued as a result of such exercise, the Allarity A/S fully diluted share capital would be 454,074,886 ordinary shares. Other than the compensatory warrants held by officers, directors, and employees which will be converted into Converted Stock Options described elsewhere in this information statement/prospectus, holders of Financial Consultant warrants will be provided the opportunity to exercise their warrants prior to the effective date of the Recapitalization Share Exchange and if all such warrants are exercised, then we would issue up to 8,155,758 shares of Delaware Common Stock in the Recapitalization Share Exchange. However, we do not anticipate that the Financial Consultant warrants will be exercised due to a combination of factors, including the fact that their exercise prices of SEK 3.30 are higher than the anticipated market price prior to the effective date of the Recapitalization Share Exchange.

Ownership of Allarity Delaware Following the Recapitalization Share Exchange

- the holders of Allarity A/S ordinary shares will own shares of common stock in Allarity Delaware in proportion to the Exchange Ratio of 0.02 shares of Delaware Common Stock for each ordinary share of Allarity A/S outstanding at the closing and substantially all of the assets and liabilities of Allarity A/S will be owned, directly or indirectly, by Allarity Delaware;

- the holders of Allarity A/S Financial Consultant warrants who exercise their warrants before the effective time will own shares of common stock in Allarity Delaware in proportion to the Exchange Ratio of 0.02 shares of Delaware Common Stock for each ordinary share of Allarity A/S. If a holder of Financial Consultant warrants does not exercise their warrant prior to the effective time, or the time before the effective time designated by the board of directors of Allarity A/S, the Financial Consultant warrant will expire and will not be assumed by Allarity Delaware;

- the holders of Allarity A/S compensatory warrants will receive options (the "Converted Options") to purchase shares of Delaware Common Stock equal to the product (rounded down to the nearest whole number) of (a) the number of ordinary shares of Allarity A/S subject to such Compensatory Warrant immediately prior to the effective time multiplied by (b) the exchange ratio, at an exercise price per share (rounded up to the nearest whole cent) equal to (i) the exercise price per share of such Compensatory Warrant immediately prior to the effective time divided by (ii) the exchange ratio and converted into U.S. dollars; and

- 3i, LP, a Delaware limited partnership, will own all of Allarity Delaware's Series A Convertible Preferred Stock that initially has the right to convert into 2,018,958 share of Allarity Delaware's common stock, (initially 20% of the issued and outstanding shares of Allarity Delaware common stock) at a conversion price of $9.906, on an "as converted basis" and without giving effect to a 4.99% beneficial ownership limitation and without giving effect to any future conversion price adjustments, anti-dilution provisions, or a one-time special dividend upon certain events). 3i, LP will also own warrants to purchase an additional 2,018,958 shares of Allarity Delaware common stock, at an initial exercise price of $9.906 per share, the exercise of which is subject to a 4.99% beneficial ownership limitation.

SUMMARY HISTORICAL FINANCIAL INFORMATION

The following summary historical financial information of Allarity Therapeutics A/S set forth below should be read in conjunction with "*Allarity Therapeutics Management's Discussion and Analysis of Financial Condition and Results of Operations*" and Allarity Therapeutics A/S, historical financial statements and the related notes thereto contained elsewhere in this information statement/prospectus.

The summary consolidated statements of operation and comprehensive loss data for the year ended December 31, 2020 and 2019, and the summary consolidated balance sheet data as of December 31, 2020 and 2019 are each derived from Allarity Therapeutics A/S' audited consolidated financial statements appearing elsewhere in this information statement/prospectus. The summary consolidated statements of operation and comprehensive loss data for the six months ended June 30, 2021 and 2020, and the summary consolidated balance sheet data as of June 30, 2021, are derived from Allarity Therapeutics A/S' unaudited condensed consolidated financial statements appearing elsewhere in this information statement/prospectus. The Allarity Therapeutics A/S unaudited interim condensed consolidated financial statements were prepared on the same basis as its audited annual financial statements and include all adjustments, consisting only of normal recurring adjustments that are considered necessary for a fair statement of the financial information set forth in those statements. The historical results are not necessarily indicative of the results to be expected in the future.

	As of December 31, 2020	As of December 31, 2019	As of June 30, 2021
Consolidated Balance Sheet Data:			
Total assets	$ 33,403	$ 31,607	$ 38,780
Total liabilities	$ 6,552	$ 10,704	$ 9,960
Total stockholders' equity	$ 26,851	$ 20,903	$ 28,820

	Year Ended December 31, 2020	Year Ended December 31, 2019	Period from January 1 to June 30, 2021	Period from January 1 to June 30, 2020
Consolidated Statements of Operation and Comprehensive Loss Data				
Revenue	$ —	$ 120	$ —	—
Operating expenses				
Research and development	5,126	6,367	3,755	2,221
General and administrative	4,101	3,870	3,521	2,292
Impairment	—	7,494	—	—
Total operating expenses	9,227	17,731	7,276	4,513
Loss from operations	(9,227)	(17,611)	(7,276)	(4,513)
Other (income) expense				
Interest income	—	(7)	—	—
(Gain) loss on investment	(708)	—	180	(411)
Interest expense	227	3,312	509	336
Foreign exchange (gain) loss, net	(62)	(80)	80	(86)
Fair value adjustment on derivative liabilities	(2,131)	(1,859)	(30)	(1,061)
Change in fair value of convertible debt	681	—	298	475
Total other (income) expense	(1,993)	1,366	1,037	(747)
Loss before income taxes	(7,234)	(18,977)	(8,313)	(3,766)
Income tax benefit	2,161	4,577	655	829
Net loss	(5,073)	(14,400)	(7,658)	(2,937)
Net loss attributable to non-controlling interests	(15)	(87)	—	(15)
Net loss attributable to Allarity A/S., common stockholders	(5,058)	(14,313)	(7,658)	(2,922)

COMPARATIVE PER SHARE DATA

The following table sets forth:

- historical per share information of Allarity A/S ordinary shares for the period ending December 31, 2020;
- pro forma per share information for the year ended December 31, 2020 and the six months ended June 30, 2021 and 2020 after giving effect to the Recapitalization Share Exchange.

The pro forma per share information does not include the 145,161,083 Allarity A/S ordinary shares and investment warrants (the "TO3 warrants") to purchase an additional 145,161,083 Allarity A/S ordinary shares issued as part of a rights offering in June 2021.

The historical information should be read in conjunction with "*Selected Historical Financial Information*" and *Management's Discussion and Analysis of Financial Condition and Results of Operations*" contained elsewhere in this information statement/prospectus and the audited consolidated financial statements and the related notes of Allarity Therapeutics A/S contained elsewhere in this information statement/prospectus.

The pro forma per share information is derived from, and should be read in conjunction with, the audited and unaudited financial information and related notes included elsewhere in this information statement/prospectus. The pro forma combined net loss per share information below does not purport to represent what the actual results of operations of Allarity Delaware would have been had the Recapitalization Share Exchange been completed, or to project Allarity Delaware results of operations that may be achieved after the Recapitalization Share Exchange. The pro forma book value per share information below does not purport to represent what the book value of Allarity Delaware would have been had the Recapitalization Share Exchange been completed nor the book value per share for any future date or period.

	Historical	Pro Forma
As of and for the Six months Ended June 30, 2021		
Book value per share – basic[(1)]	$ 0.08	$ 3.95
Net loss per share – basic	$ (0.03)	$ (1.60)
As of and for the Six months Ended June 30, 2020		
Book value per share – basic[(1)]	$ 0.13	$ 6.72
Net loss per share – basic	$ (0.02)	$ (1.00)

	Historical	Pro Forma
As of and for the Year Ended December 31, 2020		
Net loss per share – basic[(2)]	$ (0.03)	$ (1.55)
As of and for the Year Ended December 31, 2019		
Net loss per share – basic[(1)]	$ (0.21)	$ (10.62)

(1) Book value per share is calculated as total equity divided by:

- Ordinary Shares of Allarity A/S outstanding at June 30, 2021;
- Shares of common stock outstanding at June 30, 2021, after the 50:1 share re-capitalization, for the pro forma information.

(2) Net loss per ordinary share are based on:

- Weighted average number of ordinary shares outstanding for the year ended December 31, 2020;
- Weighted average number of ordinary shares outstanding for the year ended December 31, 2020, after the 50:1 share re-capitalization, for the pro forma information.

MARKET PRICE AND DIVIDEND INFORMATION

Allarity A/S

Allarity A/S's ordinary shares are currently listed on the First North Market in Stockholm under the symbol "ALLR.ST".

The closing price of Allarity A/S ordinary shares on May 20, 2021, the last trading day before the public announcement of the Recapitalization Share Exchange, was SEK 0.83. As of November 5, 2021, the date of this information statement/prospectus, the most recent closing price for Allarity A/S ordinary shares was SEK 1.49.

Holders of Allarity A/S ordinary share should obtain current market quotations for their shares. The market price of Allarity A/S's ordinary shares could vary at any time before the Recapitalization.

Holders

As of the date of this information statement/prospectus, there were approximately 139 holders of record of Allarity A/S's ordinary shares. The number of holders of record does not include a substantially greater number of "street name" holders or beneficial holders whose ordinary shares are held of record by banks, brokers and other financial institutions.

Dividend Policy

Allarity A/S has not paid any cash dividends on its ordinary shares to date and does not intend to pay cash dividends prior to the completion of the Recapitalization Share Exchange. The payment of cash dividends in the future will be dependent upon Allarity Delaware's revenues and earnings, if any, capital requirements and general financial condition subsequent to completion of the Recapitalization Share Exchange. The payment of any cash dividends subsequent to the Recapitalization Share Exchange will be within the discretion of Allarity Delaware's board of directors at such time.

Allarity Delaware

Historical market price information for Allarity Delaware's capital stock is not provided because there is no public market for Allarity Delaware's capital stock.

RISK FACTORS

In addition to the other information contained in this information statement/prospectus, including the matters addressed under the heading "Cautionary Note Regarding Forward-Looking Statements; Market, Ranking and Other Industry Data," you should carefully consider the following risk factors in deciding how to vote on the proposals presented in this information statement/prospectus. References to "we," "our," "Company," or "Allarity Therapeutics" refer to Allarity Therapeutics A/S and its consolidated subsidiaries before the Recapitalization Share Exchange and Allarity Delaware and Acquisition Sub after the Recapitalization Share Exchange.

Risks Related to Financial Position and Need for Capital

We have a limited operating history and have never generated any revenues other than from research grants and a limited number of DRP® biomarker development agreements, which may make it difficult to evaluate the success of our business to date and to assess our future viability.

We were organized under the laws of Denmark on September 9, 2004, and to date have been largely focused on organizing and staffing our company, raising capital, developing our proprietary DRP® companion diagnostics platform and acquiring the rights to, and advancing the development of, our therapeutic candidates, including conducting clinical trials on our therapeutic candidates. We have not yet demonstrated an ability to successfully obtain marketing approvals, manufacture drugs on a commercial scale, or conduct sales and marketing activities necessary for successful commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing drugs.

We expect our financial condition and operating results to continue to fluctuate from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. We will need to eventually transition from a company with a research and development focus to a company capable of undertaking commercial activities. We may encounter unforeseen expenses, difficulties, complications and delays, and may not be successful in such a transition.

We have incurred significant operating losses since inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future and may never achieve or maintain profitability.

Since our inception, we have incurred losses and have an accumulated deficit of $37.4 million as of December 31, 2020. Our net losses were $5,073,000 and $14,400,000 for the years ended December 31, 2020 and 2019, respectively. Our net losses were $7,658,000 and $2,937,000 for the six months ended June 30, 2021 and June 30, 2020, respectively, resulting in an increase of our accumulated deficit to $45 million. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. None of our current therapeutic candidates have been approved for marketing in the United States, or in any other jurisdiction, and may never receive such approval. It could be several years, if ever, before we have a commercialized drug that generates significant revenues. As a result, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain profitability. The net losses we incur may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially as we:

- continue the development of our therapeutic candidates, including, but not limited to, the submission of an application for New Drug Approval ("NDA") for dovitinib, our most advanced therapeutic candidate, to the U.S. Food and Drug Administration ("FDA") and advancing our DRP®-guided Phase 2 clinical trial of stenoparib as a treatment for ovarian cancer, being conducted at the Dana-Farber Cancer Institute (Boston, MA USA.) and our DRP®-guided Phase 2 clinical trial of IXEMPRA® as a treatment for metastatic breast cancer, being conducted at numerous locations in Europe;
- initiate preclinical studies and clinical trials for any additional indications for our current therapeutic candidates and any future therapeutic candidates that we may pursue;
- continue to build our portfolio of therapeutic candidates through the acquisition or in-license of additional therapeutic candidates or technologies;
- continue to develop, maintain, expand and protect our intellectual property portfolio;
- continue to develop, maintain, and expand our proprietary DRP® companion diagnostics platform;

- pursue regulatory approvals for our current and future therapeutic candidates that successfully complete clinical trials;
- ultimately establish a sales, marketing, distribution and other commercial infrastructure to commercialize any therapeutic candidate for which we may obtain marketing approval, or partner with third parties to effect the same;
- hire additional clinical, regulatory, scientific and accounting personnel; and
- incur additional legal, accounting and other expenses in operating as a U.S. listed public company.

To become and remain profitable, we must develop and eventually commercialize one or more therapeutic candidates with significant market potential or license one or more of our therapeutic candidates to an industry partner. This will require us to be successful in a range of challenging activities, including completing clinical trials of our therapeutic candidates, publishing our data and findings on our therapeutic candidates with peer reviewed publications, developing commercial scale manufacturing processes, obtaining marketing approval, manufacturing, marketing and selling any current and future therapeutic candidates for which we may obtain marketing approval, and satisfying any post-marketing requirements. While we anticipate submitting an NDA to the U.S. FDA on our therapeutic candidate Dovitinib before December 31, 2021, we are only in the early stages of most of these activities and, in some cases, have not yet commenced certain of these activities. We may never succeed in any or all of these activities and, even if we do, we may never generate sufficient revenue to achieve profitability.

Because of the numerous risks and uncertainties associated with drug development, we are unable to accurately predict the timing or amount of expenses or when, or if, we will obtain marketing approval to commercialize any of our therapeutic candidates. If we are required by the FDA, or other regulatory authorities such as the European Medicines Agency, or EMA, to perform studies and trials in addition to those currently expected, or if there are any delays in the development, or in the completion of any planned or future preclinical studies or clinical trials of our current or future therapeutic candidates, our expenses could increase and profitability could be further delayed.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company also could cause you to lose all or part of your investment.

Our recurring losses from operations since inception and required additional funding to finance our operations raise substantial doubt about our ability to continue as a going concern. Furthermore, our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements included in this information statement/prospectus. Our audited financial statements at December 31, 2020 and 2019 and for the years then ended were prepared assuming that we will continue as a going concern.

Our report from our independent registered public accounting firm for the years ended December 31, 2020 and 2019 includes an explanatory paragraph stating that our recurring losses from operations since inception and required additional funding to finance our operations raise substantial doubt about our ability to continue as a going concern. Such an opinion could materially limit our ability to raise additional funds through the issuance of new debt or equity securities or otherwise. There is no assurance that sufficient financing will be available when needed to allow us to continue as a going concern. The perception that we may not be able to continue as a going concern may also make it more difficult to operate our business due to concerns about our ability to meet our contractual obligations. Our ability to continue as a going concern is contingent upon, among other factors, the sale of the shares of our preferred stock in the PIPE Investment discussed elsewhere in this information statement/prospectus or obtaining alternate financing. We cannot provide any assurance that we will be able to raise additional capital.

If we are unable to secure additional capital, we may be required to curtail our clinical and research and development initiatives and take additional measures to reduce costs in order to conserve our cash in amounts sufficient to sustain operations and meet our obligations. These measures could cause significant delays in our clinical and regulatory efforts, which is critical to the realization of our business plan. The accompanying financial statements do not include any adjustments that may be necessary should we be unable to continue as a going concern. It is not possible for us to predict at this time the potential success of our business. The revenue and income potential of our proposed business and operations are currently unknown. If we cannot continue as a viable entity, you may lose some or all of your investment.

Even if the Recapitalization Share Exchange is successful, we will need substantial additional funding, and if we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our drug development programs or commercialization efforts.

We anticipate that our expenses will increase substantially as we continue preparations for the submission of an NDA to the U.S. FDA for our therapeutic candidate dovitinib and as we advance our DRP®-guided Phase 2 clinical trial of stenoparib as a treatment for ovarian cancer, being conducted at the Dana-Farber Cancer Institute (Boston, MA USA.), our DRP®-guided Phase 2 clinical trial of IXEMPRA® as a treatment for metastatic breast cancer, being conducted at numerous locations in Europe, and advance development of our other therapeutic candidates; seek to identify and develop additional therapeutic candidates; acquire or in-license other therapeutic candidates or technologies; seek regulatory and marketing approvals for our therapeutic candidates that successfully complete clinical trials, if any; establish sales, marketing, distribution and other commercial infrastructure in the future to commercialize various drugs for which we may obtain marketing approval, if any; require the manufacture of larger quantities of therapeutic candidates for clinical development and, potentially, commercialization; maintain, expand and protect our intellectual property portfolio; develop, maintain, and expand our proprietary DRP® companion diagnostics platform; hire and retain additional personnel, such as clinical, quality control and scientific personnel; add operational, financial and management information systems and personnel, including personnel to support our drug development and help us comply with our obligations as a public company; and add equipment and physical infrastructure to support our research and development programs.

We plan to use the net proceeds of the PIPE Investment primarily to fund our ongoing clinical development efforts for our three priority pipeline projects. We will be required to expend significant funds in order to prepare and submit an NDA with the U.S. FDA for our therapeutic candidate dovitinib and to advance the development of stenoparib, IXEMPRA® and our other therapeutic candidates. In addition, while we may seek one or more collaborators for future development of our current therapeutic candidates or any future therapeutic candidates that we may develop for one or more indications, we may not be able to enter into a partnership or out-license for any of our therapeutic candidates for such indications on suitable terms, on a timely basis or at all. In any event, the net proceeds of the PIPE Investment and our existing cash and cash equivalents will not be sufficient to fund all of the efforts that we plan to undertake or to fund the completion of development of our therapeutic candidates or our other preclinical studies. Accordingly, we will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources. Other than the PIPE Investment, we do not have any committed external source of funds. Further financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy.

We believe that the net proceeds from the PIPE Investment, together with our existing cash and cash equivalents as of the date of this information statement/prospectus, and our anticipated expenditures and commitments for calendar year 2021, will enable us to fund our operating expenses and capital expenditure requirements for at least 12 months from the date of this information statement/prospectus. Our estimate as to how long we expect the net proceeds from the PIPE Investment, together with our existing cash and cash equivalents, to be able to continue to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Further, changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. Our future funding requirements, both short-term and long-term, will depend on many factors, including:

- the scope, progress, timing, costs and results of our DRP®-guided Phase 2 clinical trial of stenoparib as a treatment for ovarian cancer, being conducted at the Dana-Farber Cancer Institute (Boston, MA USA.), our DRP®-guided Phase 2 clinical trial of IXEMPRA® as a treatment for metastatic breast cancer, being conducted at numerous locations in Europe, and our preclinical studies and clinical trials of our other therapeutic candidates;
- the costs associated with maintaining, expanding and updating our proprietary DRP® companion diagnostics platform;
- the costs, timing and outcome of seeking regulatory approvals;
- the costs of our licensing or commercialization activities for any of our therapeutic candidates that receive marketing approval to the extent such costs are not the responsibility of any future collaborators, including the costs and timing of establishing drug sales, marketing, distribution and manufacturing capabilities;

- our headcount growth and associated costs as we expand our research and development activities as well as potentially establish a commercial infrastructure;
- our ability to enter into and the terms and timing of any collaborations, licensing agreements or other arrangements;
- revenue received from commercial sales, if any, of our current and future therapeutic candidates;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property related claims;
- the number of future therapeutic candidates that we pursue and their development requirements;
- changes in regulatory policies or laws that may affect our operations;
- changes in physician acceptance or medical society recommendations that may affect commercial efforts;
- the costs of acquiring potential new therapeutic candidates or technology;
- the costs associated with maintaining and expanding our cybersecurity systems; and
- the costs of operating as a public company.

We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weakness, or if we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business and stock price.

Prior to the date of this information statement/prospectus, we had limited accounting personnel and other resources with which to address our internal controls and procedures. Our independent registered public accounting firm has not conducted an audit of our internal control over financial reporting. However, in connection with the audit of our consolidated financial statements as of and for year ended December 31, 2020, we and our independent registered public accounting firm identified three material weaknesses in our internal control over financial reporting.

The material weaknesses identified were:

- a lack of accounting resources required to fulfill US GAAP and SEC reporting requirements;
- a lack of comprehensive US GAAP accounting policies and financial reporting procedures; and
- a lack of segregation of duties given the size of our finance and accounting team.

We have implemented and are continuing to implement various measures to address the material weaknesses identified; these measures include:

- the hiring of a chief financial officer that is a CPA in the U.S;
- The retention of an outside consultant who is a CPA, CA, CPA (Illinois) who is experienced with public company reporting and is conversant in IFRS, US GAAP and SEC accounting issues. Said consultant is being retained to assist us in our ongoing development of our comprehensive US GAAP accounting policies, financial reporting procedures and internal controls over financial reporting; and
- increasing the accounting resources in Denmark.

A significant deficiency is a control deficiency, or a combination of control deficiencies, that adversely affects our ability to initiate, authorize, record, process, or report external financial data reliably in accordance with US GAAP such that there is more than a remote likelihood that a misstatement of our annual or interim financial statements that is more than inconsequential will not be prevented or detected by our employees. A material weakness is a significant deficiency, or combination of significant deficiencies, that results in more than a remote likelihood that a material misstatement of our annual or interim financial statement will not be prevented or detected by our employees. In response, we have begun the process of evaluating our internal control over financial reporting, although we may not complete our review until after this offering is completed. We have also taken several remedial actions set forth above to address these material weaknesses.

Furthermore, it is possible that, had our independent registered public accounting firm conducted an audit of our internal control over financial reporting such firm might have identified additional material weaknesses and deficiencies. Upon the completion of this offering, we will become a public company in the United States subject to the Sarbanes-Oxley Act of 2002. Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, will require that we include a report of management on our internal control over financial reporting in our annual report on Form 10-K beginning with our annual report for the fiscal year ending December 31, 2022. In addition, once we cease to be an "emerging growth company" as such term is defined in the JOBS Act and a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K, our independent registered public accounting firm must attest to and report on the effectiveness of our internal control over financial reporting. Our management may conclude that our internal control over financial reporting is not effective. Moreover, even if our management concludes that our internal control over financial reporting is effective, our independent registered public accounting firm, after conducting its own independent testing, may issue a report that is qualified if it is not satisfied with our internal controls or the level at which our controls are documented, designed, operated or reviewed, or if it interprets the relevant requirements differently from us. In addition, after this Offering, our reporting obligations may place a significant strain on our management, operational and financial resources and systems for the foreseeable future. We may be unable to timely complete our evaluation, testing and any required remediation.

During the course of documenting and testing our internal control procedures in order to satisfy the requirements of Section 404, we may identify other weaknesses and deficiencies in our internal control over financial reporting. In addition, if we fail to maintain the adequacy of our internal control over financial reporting, as these standards are modified, supplemented or amended from time to time, we may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with Section 404. If we fail to achieve and maintain an effective internal control environment, we could experience material misstatements in our financial statements and fail to meet our reporting obligations, which would likely cause investors to lose confidence in our reported financial information. This could in turn limit our access to capital markets, harm our results of operations, and lead to a decline in the trading price of our ordinary shares. Additionally, ineffective internal control over financial reporting could expose us to increased risk of fraud or misuse of corporate assets and subject us to potential delisting from The Nasdaq Stock Market, regulatory investigations and civil or criminal sanctions. We may also be required to restate our financial statements for prior periods.

Risks Related to the Discovery and Development of Our Therapeutic Candidates

Clinical trials are very expensive, time-consuming and difficult to design and implement, and involve uncertain outcomes. Furthermore, results of earlier preclinical studies and clinical trials may not be predictive of results of future preclinical studies or clinical trials.

The risk of failure for most of our therapeutic candidates is substantial. It is impossible to predict when or if any of our therapeutic candidates will prove effective or safe or effective in humans or will receive regulatory approval. To obtain the requisite regulatory approvals to market and sell any of our therapeutic candidates, we must demonstrate through extensive preclinical studies and clinical trials that our therapeutic candidates are safe and effective in humans for use in each target indication. Preclinical investigation and clinical testing is expensive and can take many years to complete, and the outcome is inherently uncertain. Failure can occur at any time during the preclinical investigation or clinical trial process, or during the regulatory approval process.

In addition, the results of preclinical studies and earlier clinical trials may not be predictive of the results of later-stage preclinical studies or clinical trials. The results generated to date in preclinical studies and clinical trials for our therapeutic candidates do not ensure that later preclinical studies or clinical trials will demonstrate similar results. Therapeutic candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical and earlier stage clinical trials. In later-stage clinical trials, we will likely be subject to more rigorous statistical analyses than in completed earlier stage clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in later-stage clinical trials due to adverse safety profiles or lack of efficacy, notwithstanding promising results in earlier trials, and we cannot be certain that we will not face similar setbacks. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their therapeutic candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same therapeutic candidate due to numerous factors, including changes in clinical trial procedures set forth in protocols, differences in the size and type of the patient populations, adherence to the dosing regimen and other clinical trial protocols, and the rate of dropout among clinical trial participants. If we fail to produce positive results in our planned preclinical studies or clinical trials of any of our therapeutic candidates, the development timeline and regulatory approval and commercialization prospects for our therapeutic candidates, and, correspondingly, our business and financial prospects, would be materially and adversely affected.

We may encounter substantial delays in our preclinical studies or clinical trials or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.

Before obtaining marketing approval from regulatory authorities for the sale of our therapeutic candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the therapeutic candidate for its intended indications. Preclinical studies and clinical trials are expensive, time-consuming and uncertain as to outcome. We cannot guarantee that any preclinical studies or clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more preclinical studies or clinical trials can occur at any stage of testing. Events that may prevent successful or timely completion of preclinical or clinical development include:

- delays in conducting experiments or preclinical studies or unsatisfactory results from such experiments or studies;
- delays in reaching a consensus with regulatory authorities on trial design;
- delays in reaching agreement or failing to agree on acceptable terms with prospective CROs and clinical trial sites;
- delays in opening sites and recruiting suitable patients to participate in our clinical trials;
- delays in enrollment due to travel or quarantine policies, or other factors, related to COVID-19, other pandemics or other events outside our control;
- imposition of a clinical hold by regulatory authorities as a result of a serious adverse event, concerns with a class of therapeutic candidates or after an inspection of our clinical trial operations or trial sites;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- occurrence of serious adverse events associated with the therapeutic candidate that are viewed to outweigh its potential benefits; or
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

For instance, the ongoing COVID-19 pandemic and the measures taken by the governmental authorities could disrupt the supply chain and the manufacture or shipment of drug substances and finished drug products for our therapeutic candidates for use in our research and clinical trials, delay, limit or prevent our employees and CROs from continuing research and development activities, impede the ability of patients to enroll or continue in clinical trials, or impede testing, monitoring, data collection and analysis or other related activities, any of which could delay our clinical trials and increase our development costs, and have a material adverse effect on our business, financial condition and results of operations.

Any inability to timely and successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to achieve regulatory and commercialization milestones. In addition, if we make manufacturing or formulation changes to our therapeutic candidates, we may need to conduct additional testing to bridge our modified therapeutic candidate to earlier versions. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our therapeutic candidates, if approved, or allow our competitors to bring comparable drugs to market before we do, which could impair our ability to successfully commercialize our therapeutic candidates and may harm our business, financial condition, results of operations and prospects.

Additionally, if the results of our clinical trials are inconclusive or if there are safety concerns or serious adverse events associated with our therapeutic candidates, we may:

- be delayed in obtaining marketing approval, if at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw, or suspend, their approval of the drug or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy, or REMS;
- be subject to the addition of labeling statements, such as warnings or contraindications;
- be sued; or
- experience damage to our reputation.

Our drug development costs will also increase if we experience delays in testing or obtaining marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, need to be restructured or be completed on schedule, if at all.

Further, we, the FDA or an institutional review board ("IRB") may suspend our clinical trials at any time if it appears that we or our collaborators are failing to conduct a trial in accordance with regulatory requirements, including the FDA's current Good Clinical Practice, ("GCP"), regulations, that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our Investigational New Drug ("IND") Applications, or INDs, or the conduct of these trials. Therefore, we cannot predict with any certainty the schedule for commencement and completion of future clinical trials. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our therapeutic candidates could be negatively impacted, and our ability to generate revenues from our therapeutic candidates may be delayed or eliminated entirely.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including challenges resulting from the ongoing COVID-19 pandemic. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size and health of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the therapeutic candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents;
- sufficient number of patients willing to consent to a recent biopsy; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

In addition, our clinical trials will compete with other clinical trials for therapeutic candidates that are in the same therapeutic areas as our therapeutic candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial site. Moreover, because our therapeutic candidates represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies rather than enroll patients in any future clinical trial.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our current or planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our therapeutic candidates.

If we fail to comply with our obligations in the agreements under which we have licensed the intellectual property rights from third parties for our therapeutic candidates dovitinib and stenoparib or otherwise experience disruptions to our business relationships with our licensors, we could lose rights to advance the development of dovitinib and stenoparib which would have a material adverse effect on our business.

We have entered into intellectual property license agreements with third party licensors for our two lead therapeutic candidates, dovitinib and stenoparib that are important to our business. These license agreements impose various diligence, milestone payment, royalty and other obligations on us. If we fail to comply with any obligations under any of these agreements with our licensors, we may be subject to termination of the license agreements in whole or in part; increased financial obligations to our licensors or loss of exclusivity in a particular field or territory, in which case our ability to develop or commercialize the therapeutic candidate covered by the license agreement will be impaired.

In addition, disputes may arise regarding intellectual property rights subject to the license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our diligence obligations under the license agreement and what activities satisfy those obligations;
- if a third-party expresses interest in an area under a license that we are not pursuing, under the terms of certain of our license agreements, we may be required to sublicense rights in that area to a third party, and that sublicense could harm our business; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our future licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the therapeutic candidate covered by the license agreement which would have a material adverse effect on our business.

We may expend our limited resources to pursue a particular therapeutic candidate or indication and fail to capitalize on therapeutic candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs that we identify for specific indications using our proprietary DRP® companion diagnostics platform. As a result, we may forego or delay pursuit of opportunities with other therapeutic candidates or for other indications, even those that we have begun investigating and that may have shown promise, that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial therapies or profitable market opportunities. Our spending on current and future research and development programs and therapeutic candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular therapeutic candidate, we may relinquish valuable rights to that therapeutic candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such therapeutic candidate.

We have limited experience in drug discovery and drug development and may not receive regulatory approval to market our therapeutic candidates.

Prior to the acquisition of our therapeutic candidates, we were not involved in and had no control over their preclinical and clinical development. In addition, we rely upon the parties from whom we have acquired our therapeutic candidates from to have conducted such research and development in accordance with the applicable protocol, legal, regulatory and scientific standards, having accurately reported the results of all clinical trials conducted prior to our acquisition of the applicable therapeutic candidate, and having correctly collected the data from these studies and trials. To the extent any of these has not occurred, our expected development time and costs may be increased, which could adversely affect our prospects for marketing approval of, and receiving any future revenue from, these therapeutic candidates.

In the near term, we are dependent on our ability to advance the development of our therapeutic candidates. If we are unable to submit an NDA to the U.S. FDA for our therapeutic candidate dovitinib, or initiate or complete the clinical development of, obtain marketing approval for or successfully commercialize our other therapeutic candidates, either alone or with a collaborator, or if we experience significant delays in doing so, our business could be substantially harmed.

Although we anticipate submitting an NDA to the FDA for our therapeutic candidate dovitinib during 2021, we currently do not have any drugs that have received regulatory approval and may never be able to develop marketable therapeutic candidates. We are investing a significant portion of our efforts and financial resources in the advancement of dovitinib, stenoparib, IXEMPRA®, and our other therapeutic candidates and in the development of our proprietary DRP® companion diagnostics platform. Our prospects are substantially dependent on our ability, or those of any future collaborator, to develop, obtain marketing approval for and successfully commercialize therapeutic candidates in one or more disease indications.

The success of dovitinib, stenoparib, IXEMPRA®, and our other therapeutic candidates will depend on several factors, including the following:

- submission of an NDA for dovitinib to the FDA and receiving marketing approval for dovitinib for an indication of Renal Cell Carcinoma ("RCC") together with our DRP® companion diagnostic;
- advancing our DRP®-guided Phase 2 clinical trial of stenoparib as a treatment for ovarian cancer, being conducted at the Dana-Farber Cancer Institute (Boston, MA USA.) and our DRP®-guided Phase 2 clinical trial of IXEMPRA® as a treatment for metastatic breast cancer, being conducted at numerous locations in Europe;
- initiation, progress, timing, costs and results of clinical trials of our other therapeutic candidates and potential therapeutic candidates;
- establishment of a safety, tolerability and efficacy profile that is satisfactory to the FDA or any comparable foreign regulatory authority for marketing approval;
- obtaining and maintaining patent, trade secret protection and regulatory exclusivity, both in the United States and relevant global markets;
- the performance of our future collaborators, if any;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- establishment of supply arrangements with third-party raw materials suppliers and manufacturers;
- establishment of arrangements with third-party manufacturers to obtain finished drug product that is appropriately packaged for sale;
- protection of our rights in our intellectual property portfolio;
- successful launch of commercial sales following any marketing approval;
- a continued acceptable safety profile following any marketing approval;
- commercial acceptance by patients, the medical community and third-party payors; and
- our ability to compete with other therapies.

Many of these factors are beyond our control, including the results of clinical trials, the time required for the FDA or any comparable foreign regulatory authorities to review any regulatory submissions we may make, potential threats to our intellectual property rights and the manufacturing, marketing and sales efforts of any future collaborator. If we are unable to develop, receive marketing approval for and successfully commercialize dovitinib and our other therapeutic candidates, on our own or with any future collaborator or experience delays as a result of any of these factors or otherwise, our business could be substantially harmed. The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming, expensive and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our therapeutic candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but can take many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. The results of preclinical studies and early clinical trials of our therapeutic candidates may not be predictive of the results of later-stage clinical trials. Therapeutic candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. It is not uncommon for companies in the biotechnology and pharmaceutical industries to suffer significant setbacks in advanced clinical trials due to nonclinical findings made while clinical studies were underway and safety or efficacy observations made in clinical studies, including previously unreported adverse events. Our future clinical trial results may not be successful, and notwithstanding any potential promising results in earlier studies, we cannot be certain that we will not face similar setbacks. The historical failure rate for therapeutic candidates in our industry is high. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a therapeutic candidate's clinical development and may vary among jurisdictions. We have not obtained final regulatory approval for any therapeutic candidate and it is possible that none of our existing therapeutic candidates or any therapeutic candidates we may seek to develop in the future will ever obtain regulatory approval.

Our therapeutic candidates could fail to receive regulatory clearance or marketing approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials, including, but not limited to, the use of genomic or biomarker signatures to identify patients that may respond to drug efficacy;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a therapeutic candidate is safe and effective for its proposed indication;
- we may be unable to identify and recruit a sufficient number of patients with relevant genomic or biomarker signatures in order to conduct clinical trials on our therapeutic candidates or the FDA or comparable foreign regulatory authorities may not approve a DRP® companion diagnostic that is required to select patients responsive to one of our therapeutic candidates;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our therapeutic candidates may not be sufficient to support the submission of an NDA, or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

We have not previously completed all clinical trials for any of our therapeutic candidates and we are relying on the clinical trial results of others to advance dovitinib to the submission of an NDA with the FDA. Consequently, we may not have the necessary capabilities, including adequate staffing, to successfully manage the execution and completion of any clinical trials we initiate in a way that leads to our obtaining marketing approval for our therapeutic

candidates in a timely manner, or at all. This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our therapeutic candidates, which would significantly harm our business, results of operations and prospects.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our therapeutic candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our drugs, may grant approval contingent on the performance of costly post-marketing clinical trials, may approve a therapeutic candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that therapeutic candidate or may restrict its distribution. Any of the foregoing restrictions or requirements could materially harm the commercial prospects for our therapeutic candidates.

We have not previously submitted an NDA to the FDA or similar drug approval filings to comparable foreign authorities, for any therapeutic candidate, and we cannot be certain that any of our therapeutic candidates will be successful in clinical trials or receive regulatory approval. Further, our therapeutic candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our therapeutic candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more of our therapeutic candidates, our revenues will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for patients that we are targeting for our therapeutic candidates are not as significant as we estimate, or if the price we charge for our therapeutic candidate is too high, we may not generate significant revenues from sales of such drugs, if approved.

We plan to seek regulatory approval to commercialize our therapeutic candidates both in the United States and the European Union and in additional foreign countries. While the scope of regulatory approval is similar in other countries, to obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and possible limitations placed upon commercial sales, pricing and distribution of our therapeutic candidates, and we cannot predict success in these jurisdictions.

Our business strategy of using our proprietary DRP® companion diagnostics platform to advance therapeutic candidates that have previously failed therapeutic clinical trial endpoints in Phase 2 or later clinical trials conducted by others and that we believe may be successfully developed with a DRP® companion diagnostic may not be successful, and important issues relating to safety and efficacy remain to be resolved for most of our therapeutic candidates. Our strategy also involves risks and uncertainties that differ from other biotechnology companies that focus solely on new therapeutic candidates that do not have a history of failed clinical trials.

Our therapeutic candidate portfolio includes small molecules that others have tried, but failed, to develop into an approved commercialized drug. Our strategy to use our proprietary DRP® companion diagnostics platform to identify and subsequently clinically advance therapeutic candidates that have previously failed clinical trial endpoints but that we believe have potential to succeed with a DRP® companion diagnostic may not be successful.

Our business strategy includes a focus on leveraging our proprietary DRP® companion diagnostics platform to streamline the drug development process and to identify patients that will benefit from therapeutic candidates that other biotechnology or pharmaceutical companies have abandoned or shelved after initiating clinical trials under an IND application filed with the FDA, including candidates that have failed to achieve statistical significance on the original endpoints established in the clinical trials. We use our proprietary DRP® companion diagnostics platform to advance therapeutic candidates by targeting and evaluating patient sub-populations having gene signatures, determined by our DRP® companion diagnostics platform, that will potentially correlate with drug efficacy and patient response to treatment. While we have not yet successfully received regulatory or marketing approval for any of our therapeutic candidates or companion diagnostics, and while we believe that our approach has the potential to reduce the cost and time of drug development through the identification and selection of patient populations more likely to respond to therapy, our strategy involves risks and uncertainties that differ from other biotechnology companies that focus solely on new therapeutic candidates that do not have a history of failed clinical development. These risks and uncertainties include, but are not limited to, the following:

- The remaining term of the initial patents filed with respect to a therapeutic candidate may be significantly less than the patent term for a newly discovered therapeutic candidate;
- Potential out-licensees, alliance partners and collaborators may view a therapeutic candidate identified with our proprietary DRP® companion diagnostics platform with more skepticism because of its history

of failed clinical trials, thereby requiring a higher level of additional data and further explanations of mechanisms of action in order to overcome this skepticism and obtain commercially reasonable terms for future development or collaboration;

- key personnel and institutional knowledge relating to a therapeutic candidate that we couple with a DRP® companion diagnostic may no longer be available for us;
- The current standard of care in the targeted therapeutic indication for the DRP® companion diagnostic-selected patient population may be different than the standard of care that existed during the candidate's last clinical trial, which will require more time and resources from us to reassess and redesign the regulatory development path for the DRP® -coupled therapeutic candidate; and
- The DRP®-coupled therapeutic candidate may be perceived to be in an "older" therapeutic drug type or focus area of oncology, thereby generating less enthusiasm and support compared to therapeutic focus areas of oncology that may be perceived as more recent.

We are dependent on Smerud Medical Research International for the development of LiPlaCis® and 2X-111.

We have out-licensed both LiPlaCis® and 2X-111, to our longtime CRO partner Smerud Medical Research International, in our efforts to advance the clinical development of these assets. Smerud intends to conduct expanded enrollment of a DRP®-guided Phase 2 clinical trial in Europe for LiPlaCis® and 2X-111, with the intent of establishing sufficient clinical results to garner the interest of a larger pharmaceutical acquirer or partner to advance the programs through Phase 3 clinical trials and, if approved, to market. Although Smerud will be solely responsible for the clinical development of LiPlaCis® and 2X-111, we intend to support both of these clinical trials with our proprietary DRP® companion diagnostics and our clinical trial and regulatory expertise. Under the agreement, we are entitled to receive certain specified milestone payments from Smerud and we are also entitled to receive royalty payments based on incremental levels of annual sales of LiPlaCis® and 2X-111 by Smerud or any third-party program acquirer. As a result of the license agreement with Smerud, we are completely dependent on Smerud for the development of LiPlaCis® and 2X-111.

We may depend on enrollment of patients with specific genomic or biomarker signatures, identified through DRP® companion diagnostics, in our clinical trials in order for us to continue development of our therapeutic candidates. If we are unable to enroll patients with specific genomic or biomarker signatures in our clinical trials, our research, development and commercialization efforts could be adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients with genomic or biomarker signatures we have identified by our DRP® companion diagnostics platform, and who remain in the study until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. Patient enrollment is affected by many factors including the size and nature of the patient population with the specific genomic or biomarker signature we have identified, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, the size of the patient population required for analysis of the trial's primary endpoints, the proximity of patients to study sites, our ability to recruit clinical trial investigators with the appropriate competencies and experience, our ability to obtain and maintain patient consents, the risk that patients enrolled in clinical trials will drop out of the trials before completion, and competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. We will compete with other pharmaceutical companies for clinical sites, physicians and the limited number of patients who fulfill the stringent requirements for participation in oncology clinical trials. Also, due to the confidential nature of clinical trials, we do not know how many of the eligible patients may be enrolled in competing studies and who are consequently not available to us for our clinical trials. Our clinical trials may be delayed or terminated due to the inability to enroll enough patients. The delay or inability to meet planned patient enrollment may result in increased costs and delay or termination of our trials, which could have a harmful effect on our ability to develop drugs.

Delays in clinical testing could result in increased costs to us and delay our ability to generate revenue.

Although we intend to advance our ongoing DRP®-guided Phase 2 clinical trial of stenoparib as a treatment for ovarian cancer, being conducted at the Dana-Farber Cancer Institute (Boston, MA USA.) and our ongoing DRP®-guided Phase 2 clinical trial of IXEMPRA® as a treatment for metastatic breast cancer, being conducted at numerous locations

in Europe, we are planning for certain clinical trials relating to our other therapeutic candidates, or for other indications of all of our therapeutic candidates, there can be no assurance that the FDA will accept our proposed trial designs. We may experience delays in our clinical trials and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- obtaining regulatory clearance to commence a trial or obtaining regulatory approval to utilize a DRP® companion diagnostic in a trial to select and treat patients;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in our CRO's schedules relating to testing patients involved in our clinical trials;
- obtaining institutional review board, or IRB, approval at each site;
- recruiting suitable patients to participate in a trial;
- identifying clinical sites with adequate infrastructure (including data collection) to conduct the trial;
- clinical sites deviating from trial protocol or dropping out of a trial;
- addressing patient safety concerns that arise during the course of a trial;
- having patients complete a trial or return for post-treatment follow-up;
- adding a sufficient number of clinical trial sites; or
- manufacturing sufficient quantities and quality of a therapeutic candidate for use in clinical trials.

We may also experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our therapeutic candidates, including:

- we may receive feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- we may not have the ability to test patients for our clinical trials that require a specific genomic or biomarker signature in order to qualify for enrollment;
- clinical trials of our therapeutic candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs;
- the number of patients required for clinical trials of our therapeutic candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- the cost of clinical trials of our therapeutic candidates may be greater than we anticipate;
- the supply or quality of our therapeutic candidates or other materials necessary to conduct clinical trials of our therapeutic candidates may be insufficient or inadequate;
- regulators may revise the requirements for approving our therapeutic candidates, or such requirements may not be as we anticipate; and
- any future collaborators that conduct clinical trials may face any of the above issues, and may conduct clinical trials in ways they view as advantageous to themselves but that are suboptimal for us.

If we are required to conduct additional clinical trials or other testing of our therapeutic candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our therapeutic candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- incur unplanned costs;
- be delayed in obtaining marketing approval for our therapeutic candidates or not obtain marketing approval at all;
- obtain marketing approval in some countries and not in others;
- obtain marketing approval for indications or patient populations that are not as broad as intended or desired;
- obtain marketing approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements; or
- have the drug removed from the market after obtaining marketing approval.

Furthermore, we intend to rely on CROs, cancer research centers and clinical trial sites to ensure the proper and timely conduct of our clinical trials and we intend to have agreements governing their committed activities. They may not perform as required or we may face competition from other clinical trials being conducted by other pharmaceutical companies.

We could encounter delays if a clinical trial is suspended or terminated by us, by the Institutional Review Board or IRB of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Further, conducting clinical trials in foreign countries, as we may do for our current and future therapeutic candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

If we experience delays in the completion of, or termination of, any clinical trial of our therapeutic candidates, the commercial prospects of our therapeutic candidates will be harmed, and our ability to generate revenues from any of these therapeutic candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our therapeutic candidate development and approval process and jeopardize our ability to commence drug sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our therapeutic candidates.

Our therapeutic candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by our therapeutic candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. The clinical evaluation of some of our therapeutic candidates in patients is still in the early stages and it is possible that there may be side effects associated with their use. In such an event, we, the FDA, the IRBs at the institutions in which our studies are conducted, or the DSMB could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our therapeutic candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the clinical trial or result in potential

product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our therapeutic candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our therapeutic candidates. Inadequate training in recognizing or managing the potential side effects of our therapeutic candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, if one or more of our therapeutic candidates receives marketing approval, and we or others later identify undesirable side effects caused by such drugs, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such drugs;
- we may be required to recall a drug or change the way such a drug is administered to patients;
- additional restrictions may be imposed on the marketing or distribution of the particular drug or the manufacturing processes for the drug or any component thereof;
- regulatory authorities may require additional warnings on the label, such as a "black box" warning or contraindication;
- we may be required to implement Risk Evaluation and Mitigation Strategies, or REMS, or create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- our drug may become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular therapeutic candidate or for particular indications of a therapeutic candidate, if approved, and could significantly harm our business, results of operations and prospects.

We are leveraging our proprietary DRP® companion diagnostics platform in an attempt to create a pipeline of therapeutic candidates using biomarker identification and patient stratification for the development of oncology drugs in a personalized medicine approach. While we believe that applying our proprietary DRP® companion diagnostics platform to drugs that have failed, been abandoned or otherwise failed to meet clinical endpoints and then developing a precision oncology approach that identifies the mechanism of action, potential combination drug usage and potentially responsive patient population is a powerful strategy, our approach is both innovative and has not been approved by the FDA or any equivalent foreign regulatory authority. While we have retrospectively validated our proprietary DRP® companion diagnostics platform in 35 clinical trials conducted by other companies, we have not yet received approval from the FDA or other regulatory agency to market a companion diagnostic. Because our approach is both innovative and in the early stages of development, the cost and time needed to develop our therapeutic candidates is difficult to predict, and our efforts may not result in the successful discovery and development of commercially viable medicines. We may also be incorrect about the effects of our therapeutic candidates on the diseases of our defined patient populations, which may limit the utility of our approach or the perception of the utility of our approach. Furthermore, our estimates of our defined patient populations available for study and treatment may be lower than expected, which could adversely affect our ability to conduct clinical trials and may also adversely affect the size of any market for medicines we may successfully commercialize. Our approach may not result in time savings, higher success rates or reduced costs as we expect it to, and if not, we may not attract collaborators or develop new drugs as quickly or cost effectively as expected and therefore we may not be able to commercialize our approach as originally expected.

Our proprietary DRP® companion diagnostics platform may fail to help us select and treat likely responder patients for our therapeutic candidates or help us identify additional potential therapeutic candidates.

Any drug development that we are conducting using our proprietary DRP® companion diagnostics platform may not be successful or have commercial value or therapeutic utility. Our proprietary DRP® companion diagnostics platform may initially show promise in identifying potential therapeutic candidates, yet fail to yield viable therapeutic candidates for clinical development or commercialization for a number of reasons, including:

- research programs to identify new therapeutic candidates will require substantial technical, financial and human resources, and we may be unsuccessful in our efforts to identify new therapeutic candidates. If we are unable to identify suitable additional compounds for preclinical and clinical development, our ability to develop therapeutic candidates and obtain product revenues in future periods could be compromised, which could result in significant harm to our financial position and adversely impact our stock price;
- compounds identified through our proprietary DRP® companion diagnostics platform may not demonstrate efficacy, safety or tolerability at levels acceptable to regulatory authorities;
- our a DRP® companion diagnostics platform may fail to successfully identify likely responder patients and therefore not yield greater therapeutic benefit than observed in un-selected patients.
- potential therapeutic candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to receive marketing approval and achieve market acceptance;
- competitors may develop alternative therapies that render our potential therapeutic candidates non-competitive or less attractive; or
- a potential therapeutic candidate may not be capable of being produced at an acceptable cost.

Any failure by us to comply with existing regulations could harm our reputation and operating results.

We will be subject to extensive regulation by U.S. federal and state and foreign governments in each of the markets where we intend to sell our therapeutic candidates if and after they are approved. For example, we will have to adhere to all regulatory requirements including the FDA's current GCPs, Good Laboratory Practice, or GLP, and GMP requirements. If we fail to comply with applicable regulations, including FDA pre-or post- approval cGMP requirements, then the FDA or other foreign regulatory authorities could sanction us. Even if a drug is FDA-approved, regulatory authorities may impose significant restrictions on a drug's indicated uses or marketing or impose ongoing requirements for potentially costly post-marketing studies.

Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and damage our reputation. We will need to expend significant resources on compliance efforts and such expenses are unpredictable and might adversely affect our results.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our therapeutic candidates. For example, in December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and spur innovation, but its ultimate implementation is unclear. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

In addition, we cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

We may be subject to extensive regulations outside the United States and may not obtain marketing approvals for drugs in Europe and other jurisdictions.

In addition to regulations in the United States, should we or our collaborators pursue marketing approvals for our therapeutic candidates internationally, we and our collaborators will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our drugs. Whether or not we, or our collaborators, obtain applicable FDA regulatory clearance and marketing approval for a drug,

we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the drug in those countries. The requirements and process governing the conduct of clinical trials, drug licensing, pricing and reimbursement vary from country to country.

We expect to pursue marketing approvals for IXEMPRA® and our other therapeutic candidates in Europe and other jurisdictions outside the United States with collaborative partners. The time and process required to obtain regulatory approvals and reimbursement in Europe and other jurisdictions may be different from those in the United States regulatory and approval in one jurisdiction does not ensure approvals in any other jurisdiction; however, negative regulatory decisions in any jurisdiction may have a negative impact on the regulatory process in other jurisdictions.

Additionally, on June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union, commonly referred to as Brexit. On March 29, 2017, the country formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty triggering a two-year period for the United Kingdom to formally leave the European Union. Following a series of extensions to leave the European Union, on January 31, 2020, the United Kingdom officially left the European Union commencing a transition period in which the United Kingdom is required to continue to follow all European Union rules and trading relationships, but will no longer be represented in the European Parliament. During the transition period, the United Kingdom and the European Union will engage in negotiations for new trade agreements and, among other things, the regulation of their pharmaceutical industries. Since a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, the transition period could materially impact the regulatory regime with respect to the approval of our therapeutic candidates in the United Kingdom or the European Union. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our therapeutic candidates in the United Kingdom and/or the European Union and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or European Union for our therapeutic candidates, which could materially and adversely affect our business.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors and customers will be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, health information privacy and security laws and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Although we do not currently have any therapeutic products on the market, our current and future operations may be, directly or indirectly through our prescribers, customers and third-party payors, subject to various U.S. federal and state healthcare laws and regulations, including, without limitation, the U.S. federal Anti-Kickback Statute, the U.S. federal civil and criminal false claims laws and the Physician Payments Sunshine Act and regulations. Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. These laws may impact, among other things, our current business operations, including our clinical research activities, and proposed sales, marketing and education programs and constrain the business of financial arrangements and relationships with healthcare providers, physicians and other parties through which we may market, sell and distribute our therapeutic products for which we obtain marketing approval. In addition, we may be subject to patient data privacy and security regulation by both the U.S. federal government and the states in which we conduct our business. Finally, we may be subject to additional healthcare, statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. The laws that may affect our ability to operate include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal false claims, including the False Claims Act, which can be enforced through whistleblower actions, and civil monetary penalties laws, which, among other things, impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or

causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, and as amended again by the Modifications to the HIPAA Privacy, Security, Enforcement and Breach Notification Rules Under HITECH and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules, commonly referred to as the Final HIPAA Omnibus Rule, published in January 2013, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the Final HIPAA Omnibus Rule, i.e. health plans, healthcare clearinghouses and certain healthcare providers, as well as their business associates that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information;

- the U.S. Federal Food, Drug and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;

- the U.S. federal legislation commonly referred to as Physician Payments Sunshine Act, enacted as part of the Affordable Care Act, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the CMS information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;

- analogous state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and

- European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines,

exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the delay, reduction, termination or restructuring of our operations. Further, defending against any such actions can be costly and time-consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business is found to not be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations.

Our inability to obtain or retain sufficient clinical trial liability insurance at an acceptable cost to protect against potential liability claims could prevent or inhibit our ability to conduct clinical trials for therapeutic candidates we develop.

Although we currently have clinical trial liability insurance, in the future we may need to secure additional coverage before commencing patient enrollment for our clinical trials in the United States or other jurisdictions. Any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our existing insurance or that is in excess of the limits of our insurance coverage. We expect we will supplement our clinical trial coverage with product liability coverage in connection with the commercial launch of dovitinib or other therapeutic candidates we develop in the future; however, we may be unable to obtain such increased coverage on acceptable terms or at all. If we are found liable in a clinical trial lawsuit or a product liability lawsuit in the future, we will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If we are found to have improperly promoted off-label uses of our drugs or therapeutic candidates, if approved, we may become subject to significant liability. Such enforcement has become more common in the industry. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription drug products, such as our therapeutic candidates, if approved. In particular, a drug may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the drug's approved labeling. If we receive marketing approval for our therapeutic candidates for our proposed indications, physicians may nevertheless use our drugs for their patients in a manner that is inconsistent with the approved label, if the physicians personally believe in their professional medical judgment it could be used in such manner. However, if we are found to have promoted our drugs for any off-label uses, the federal government could levy civil, criminal and/or administrative penalties, and seek fines against us. The FDA or other regulatory authorities could also request that we enter into a consent decree or a corporate integrity agreement, or seek a permanent injunction against us under which specified promotional conduct is monitored, changed or curtailed. If we cannot successfully manage the promotion of our therapeutic candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Risks Related to the Approval and Commercialization of Our Therapeutic Candidates

Even if we are successful in completing all preclinical studies and clinical trials, we may not be successful in commercializing one or more of our therapeutic candidates.

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our therapeutic candidates. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize our therapeutic candidates, and our ability to generate revenue will be materially impaired.

Our therapeutic candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, export and import are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the EMA and similar regulatory authorities outside of the United States. Failure to obtain marketing approval for a therapeutic candidate will prevent us from commercializing the therapeutic candidate. We have not submitted an application for or received marketing approval for any of our therapeutic candidates in the United States or in any other jurisdiction.

We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party clinical research organizations or other third-party consultants or vendors to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the therapeutic candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our therapeutic candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. New cancer drugs frequently are indicated only for patient populations that have not responded to an existing therapy or have relapsed. If any of our therapeutic candidates receives marketing approval, the accompanying label may limit the approved use of our drug in this way, which could limit sales of the drug.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the therapeutic candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted drug application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical studies and clinical trials could delay, limit or prevent marketing approval of a therapeutic candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved drug not commercially viable.

If our drugs do not gain market acceptance, our business will suffer because we might not be able to fund future operations.

A number of factors may affect the market acceptance of our drugs or any other products we develop or acquire, including, among others:

- the price of our drugs relative to other products for the same or similar treatments;
- the perception by patients, physicians and other members of the health care community of the effectiveness and safety of our drugs for their indicated applications and treatments, or the value of our DRP® companion diagnostics in improving patient benefit;
- our ability to fund our sales and marketing efforts; and
- the effectiveness of our sales and marketing efforts.

If our drugs do not gain market acceptance, we may not be able to fund future operations, including developing, testing and obtaining regulatory approval for new therapeutic candidates and expanding our sales and marketing efforts for our approved drugs, which would cause our business to suffer.

We may in the future develop therapeutic candidates in combination with other therapies and that may expose us to additional risks.

We may develop future therapeutic candidates for use in combination with one or more currently approved cancer therapies. Even if any therapeutic candidate we develop was to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or similar foreign regulatory authorities could revoke approval of the therapy used in combination with our therapeutic candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. Combination therapies

are commonly used for the treatment of cancer, and we would be subject to similar risks if we develop any of our therapeutic candidates for use in combination with other drugs or for indications other than cancer. This could result in our own products being removed from the market or being less successful commercially.

We may also evaluate our therapeutic candidates in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA or similar foreign regulatory authorities. We will not be able to market and sell our therapeutic candidates we develop in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval.

If the FDA or similar foreign regulatory authorities do not approve or revoke the approval of these other drugs, or if safety, efficacy, manufacturing or supply issues arise with the drugs we choose to evaluate in combination with our therapeutic candidates, we may be unable to obtain approval of or market our therapeutic candidates.

We may rely on orphan drug status to commercialize some of our therapeutic candidates, and even if orphan drug status is approved, such approval may not confer marketing exclusivity or other commercial advantages or expected commercial benefits.

We may rely on orphan drug exclusivity for our therapeutic candidates. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a drug that has orphan drug designation subsequently receives the first FDA marketing approval for the disease for which it has such designation, the drug is entitled to orphan drug exclusivity. Orphan drug exclusivity in the United States provides that the FDA may not approve any other applications, including a full NDA, to market the same drug for the same indication for seven years, and except in limited circumstances the applicable exclusivity period is ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified.

Even if we, or any future collaborators, obtain orphan drug designation for a therapeutic candidate, we, or they, may not be able to obtain or maintain orphan drug exclusivity for that therapeutic candidate. We may not be the first to obtain marketing approval of any therapeutic candidate for which we have obtained orphan drug designation for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products, and it is possible that another company also holding orphan drug designation for the same therapeutic candidate will receive marketing approval for the same indication before we do. If that were to happen, our applications for that indication may not be approved until the competing company's period of exclusivity expires. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the drug to meet the needs of patients with the rare disease or condition. Further, even if we, or any future collaborators, obtain orphan drug exclusivity for a drug, that exclusivity may not effectively protect the drug from competition because different drugs with different active moieties may be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care or the manufacturer of the drug with orphan exclusivity is unable to maintain sufficient drug quantity. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process, nor does it prevent competitors from obtaining approval of the same therapeutic candidate as ours for indications other than those in which we have been granted orphan drug designation.

On August 3, 2017, the U.S. Congress passed the FDA Reauthorization Act of 2017, or FDARA. FDARA, among other things, codified the FDA's preexisting regulatory interpretation, to require that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. The new legislation reverses prior precedent holding that the Orphan Drug Act unambiguously requires that the FDA recognize the orphan exclusivity period regardless of a showing of clinical superiority. The FDA may further reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

A Breakthrough Therapy designation by the FDA for our therapeutic candidates may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our therapeutic candidates will receive marketing approval.

We may seek a breakthrough therapy designation for some of our therapeutic candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs and biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for accelerated approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our therapeutic candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. Even if we receive Breakthrough Therapy designation, the receipt of such designation for a therapeutic candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our therapeutic candidates qualify as breakthrough therapies, the FDA may later decide that the drugs no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

A Fast Track designation by the FDA may not lead to a faster development or regulatory review or approval process.

We may seek Fast Track designation for some of our therapeutic candidates. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA Fast Track designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular therapeutic candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program.

Failure to obtain marketing approval in foreign jurisdictions would prevent our therapeutic candidates from being marketed abroad.

In order to market and sell our drugs in the European Union and many other foreign jurisdictions, we or our potential third-party collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA marketing approval. The regulatory approval process outside of the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside of the United States, it is required that the drug be approved for reimbursement before the drug can be approved for sale in that country. We or our potential third-party collaborators may not obtain approvals from regulatory authorities outside of the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside of the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our drugs in any market.

If we are required by the FDA to obtain approval of a DRP® companion diagnostic in connection with approval of a therapeutic candidate, and we do not obtain or face delays in obtaining FDA approval of a DRP® diagnostic device, we will not be able to commercialize the therapeutic candidate and our ability to generate revenue will be materially impaired.

According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic drug or indication, the FDA generally will not approve the therapeutic drug or new therapeutic drug indication if the companion diagnostic is not also approved or cleared for that indication.

Under the Federal Food, Drug, and Cosmetic Act, or FDCA, companion diagnostics are regulated as medical devices, and the FDA has generally required companion diagnostics intended to select the patients who will respond to cancer treatment to obtain Premarket Approval, or a PMA, for the diagnostic. The PMA process, including the gathering of clinical and preclinical data and the submission to and review by the FDA, involves a rigorous premarket review during which the applicant must prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing and labeling. A PMA is not guaranteed and may take considerable time, and the FDA may ultimately respond to a PMA submission with a "not approvable" determination based on deficiencies in the application and require additional clinical trial or other data that may be expensive and time-consuming to generate and that can substantially delay approval. As a result, if we are required by the FDA to obtain approval of a companion diagnostic for a therapeutic candidate, and we do not obtain or there are delays in obtaining FDA approval of a diagnostic device, we may not be able to commercialize the therapeutic candidate on a timely basis or at all and our ability to generate revenue will be materially impaired.

Our business strategy involving drug development includes the development of a companion diagnostic using our proprietary DRP® companion diagnostics platform for each of our therapeutic candidates. On April 2, 2021, we filed a PMA with the FDA for a companion diagnostic for dovitinib, which is currently under review by the FDA, and we intend to file a PMA for each of our therapeutic candidates if, and when, we decide to pursue the submission of an NDA for each therapeutic candidate.

Any therapeutic candidate for which we obtain marketing approval could be subject to post-marketing restrictions or withdrawal from the market and we may be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our drugs, when and if any of them are approved.

Any therapeutic candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such drug, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a therapeutic candidate is granted, the approval may be subject to limitations on the indicated uses for which the drug may be marketed or to the conditions of approval, including the requirement to implement a REMS. New cancer drugs frequently are indicated only for patient populations that have not responded to an existing therapy or have relapsed. If any of our therapeutic candidates receives marketing approval, the accompanying label may limit the approved use of our drug in this way, which could limit sales of the drug.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the drug, including the adoption and implementation of REMS. The FDA and other agencies, including the Department of Justice, or the DOJ, closely regulate and monitor the post-approval marketing and promotion of drugs to ensure they are marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and DOJ impose stringent restrictions on manufacturers' communications regarding off-label use, and if we do not market our drugs for their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the FDCA and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations and enforcement actions alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our drugs, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may have various consequences, including:

- restrictions on such drugs, manufacturers or manufacturing processes;
- restrictions and warnings on the labeling or marketing of a drug;
- restrictions on drug distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;

- withdrawal of the drugs from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of drugs;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our drugs;
- drug seizure;
- injunctions or the imposition of civil or criminal penalties; or
- litigation involving patients using our drugs.

We operate in a highly competitive and rapidly changing industry.

Biotechnological and pharmaceutical drug development is highly competitive and subject to rapid and significant technological advancements. Our success is highly dependent upon our ability to in-license, acquire, develop and obtain regulatory approval for new and innovative drugs on a cost-effective basis and to market them successfully, as well as maintaining the competitive advantages of our DRP® companion diagnostics platform. In doing so, we face and will continue to face intense competition from a variety of businesses, including large, fully integrated, well-established pharmaceutical companies who already possess a large share of the market, specialty pharmaceutical and biopharmaceutical companies, academic institutions, government agencies and other private and public research institutions in the United States, the European Union and other jurisdictions.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a small number of our competitors.

Competition may further increase as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, drugs that are more effective or less costly than any therapeutic candidate that we may develop.

Established pharmaceutical and biotechnology companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our therapeutic candidates less competitive. Similarly, such companies may invest heavily to accelerate discovery and development of novel companion diagnostic approaches that make our DRP® companion diagnostics platform less competitive. In addition, any new drug that competes with an approved drug must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, discovering, developing, receiving FDA approval for or commercializing drugs before we do, which would have an adverse impact on our business and results of operations.

The availability of our competitors' drugs, or competitive companion diagnostics, could limit the demand and the price we are able to charge for any therapeutic candidate we commercialize, if any. The inability to compete with existing or subsequently introduced drugs would harm our business, financial condition and results of operations.

If we are unable to develop satisfactory sales and marketing capabilities, we may not succeed in commercializing our therapeutic candidate.

We have no experience in marketing and selling drug products. We have not yet entered into arrangements for the sale and marketing of dovitinib, stenoparib, IXEMPRA® or any other therapeutic candidate, although we are exploring a number of such arrangements. Typically, pharmaceutical companies would employ groups of sales representatives and associated sales and marketing staff numbering in the hundreds to thousands of individuals to call on this large number of physicians and hospitals. We may seek to collaborate with a third-party to market our drugs or may seek to market and sell our drugs by ourselves. If we seek to collaborate with a third-party, we cannot be sure that a collaborative agreement can be reached on terms acceptable to us. If we seek to market and sell our drugs directly, we will need to hire additional personnel skilled in marketing and sales. We cannot be sure that we will be able to acquire, or establish third-party relationships to provide, any or all of these marketing and sales capabilities. The establishment of a direct sales force or a contract sales force or a combination direct and contract sales force to market our drugs will be expensive and time-consuming and could delay any drug launch. Further, we can give no assurances that we may be able to maintain a direct and/or contract sales force for any period of time or that our sales efforts will be sufficient to generate or to grow our revenues or that our sales efforts will ever lead to profits.

Even if we obtain regulatory approvals to commercialize dovitinib, stenoparib, IXEMPRA® or our other therapeutic candidates, our therapeutic candidates may not be accepted by physicians or the medical community in general.

There can be no assurance that dovitinib, stenoparib, IXEMPRA® and our other therapeutic candidates or any other therapeutic candidate successfully developed by us, independently or with partners, will be accepted by physicians, hospitals and other health care facilities. Dovitinib, stenoparib, IXEMPRA® and our other and any future therapeutic candidates we develop will compete with a number of drugs manufactured and marketed by major pharmaceutical and biotech companies. The degree of market acceptance of any drugs we develop depends on a number of factors, including:

- our demonstration of the clinical efficacy and safety of dovitinib, stenoparib, IXEMPRA® and our other therapeutic candidates;
- timing of market approval and commercial launch of dovitinib, stenoparib, IXEMPRA® and our other therapeutic candidates;
- the clinical indication(s) for which dovitinib, stenoparib, IXEMPRA® and our other therapeutic candidates are approved;
- drug label and package insert requirements;
- advantages and disadvantages of our therapeutic candidates compared to existing therapies, particularly in combination with our DRP® companion diagnostics;
- continued interest in and growth of the market for anticancer tyrosine kinase inhibitory, PARP inhibitory, and microtubule inhibitory drugs;
- strength of sales, marketing, and distribution support;
- drug pricing in absolute terms and relative to alternative treatments;
- future changes in health care laws, regulations, and medical policies; and
- availability of reimbursement codes and coverage in select jurisdictions, and future changes to reimbursement policies of government and third-party payors.

Significant uncertainty exists as to the coverage and reimbursement status of any therapeutic candidate for which we obtain regulatory approval. In the United States and markets in other countries, sales of any drugs for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payors. Third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations.

Healthcare reform measures could hinder or prevent our therapeutic candidates' commercial success.

The U.S. government and other governments have shown significant interest in pursuing healthcare reform. Any government-adopted reform measures could adversely impact the pricing of healthcare drugs and services in the United States or internationally and the amount of reimbursement available from governmental agencies or other third-party payors. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payors of health care services to contain or reduce health care costs may adversely affect our ability to set prices for our drugs which we believe are fair, and our ability to generate revenues and achieve and maintain profitability.

New laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and decisions, that relate to healthcare availability, methods of delivery or payment for products and services, or sales, marketing or pricing, may limit our potential revenue, and we may need to revise our research and development programs. The pricing and reimbursement environment may change in the future and become more challenging due to several reasons, including policies advanced by the current executive administration in the United States, new healthcare legislation or fiscal challenges faced by government health administration authorities. Specifically, in both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our drugs profitably.

For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the PPACA has substantially changed the way healthcare is financed by both government health plans and private insurers, and significantly impacts the pharmaceutical industry. The PPACA contains a number of provisions that are expected to impact our business and operations in ways that may negatively affect our potential revenues in the future. For example, the PPACA imposes a non-deductible excise tax on pharmaceutical manufacturers or importers that sell branded prescription drugs to government programs which we believe will increase the cost of our drugs. In addition, as part of the PPACA's provisions closing a funding gap that currently exists in the Medicare Part D prescription drug program, we will be required to provide a discount on branded prescription drugs equal to 50% of the government-negotiated price, for drugs provided to certain beneficiaries who fall within the donut hole. Similarly, PPACA increases the level of Medicaid rebates payable by manufacturers of brand-name drugs from 15.1% to 23.1% and requires collection of rebates for drugs paid by Medicaid managed care organizations. The PPACA also includes significant changes to the 340B drug discount program including expansion of the list of eligible covered entities that may purchase drugs under the program. At the same time, the expansion in eligibility for health insurance benefits created under PPACA is expected to increase the number of patients with insurance coverage who may receive our drugs. While it is too early to predict all the specific effects the PPACA or any future healthcare reform legislation will have on our business, they could have a material adverse effect on our business and financial condition.

Congress periodically adopts legislation like the PPACA and the Medicare Prescription Drug, Improvement and Modernization Act of 2003, that modifies Medicare reimbursement and coverage policies pertaining to prescription drugs. Implementation of these laws is subject to ongoing revision through regulatory and sub regulatory policies. Congress also may consider additional changes to Medicare policies, potentially including Medicare prescription drug policies, as part of ongoing budget negotiations. While the scope of any such legislation is uncertain at this time, there can be no assurances that future legislation or regulations will not decrease the coverage and price that we may receive for our proposed drugs. Other third-party payors are increasingly challenging the prices charged for medical products and services. It will be time consuming and expensive for us to go through the process of seeking coverage and reimbursement from Medicare and private payors. Our proposed drugs may not be considered cost-effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our proposed drugs on a profitable basis. Further federal and state proposals and health care reforms are likely which could limit the prices that can be charged for the therapeutic candidates that we develop and may further limit our commercial opportunities. Our results of operations could be materially adversely affected by proposed healthcare reforms, by the Medicare prescription drug coverage legislation, by the possible effect of such current or future legislation on amounts that private insurers will pay and by other health care reforms that may be enacted or adopted in the future.

In September 2007, the Food and Drug Administration Amendments Act of 2007 was enacted, giving the FDA enhanced post-marketing authority, including the authority to require post-marketing studies and clinical trials, labeling changes based on new safety information, and compliance with risk evaluations and mitigation strategies approved by the FDA. The FDA's exercise of this authority could result in delays or increased costs during drug development, clinical trials and regulatory review, increased costs to assure compliance with post-approval regulatory requirements, and potential restrictions on the sale and/or distribution of approved drugs.

Governmental efforts to pursue regulatory reform may limit the FDA's ability to engage in oversight and implementation activities in the normal course, and that could negatively impact our business.

Prior presidential administrations have taken several executive actions, including the issuance of a number of executive orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. On January 30, 2017, President Trump issued an executive order, applicable to all executive agencies, including the FDA, requiring that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This executive order included a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the executive order required agencies to identify regulations to offset any incremental cost of a new regulation. While the current Biden administration has revoked this executive order, no assurances can be given that a future presidential administration will not issue a similar executive order. If a future presidential administration were to issue a similar executive order, it would be difficult to predict how those requirements would be implemented, and the extent to which they would impact the FDA's ability to exercise its regulatory authority. If future executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our therapeutic candidates and affect the prices we may charge for such therapeutic candidates.

The U.S. and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our therapeutic candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval.

The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "Affordable Care Act"), includes measures that have significantly changed the way healthcare is financed by both governmental and private insurers. There remain judicial, executive and congressional challenges to certain aspects of the Affordable Care Act. Since 2017, there have been executive orders and other directives designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. In addition, while Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the Affordable Care Act such as removing penalties, effective January 1, 2019, for not complying with the Affordable Care Act's individual mandate to carry health insurance. Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the Affordable Care Act-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. In 2018, a U.S. District Court ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was effectively repealed by Congress as part of the Tax Act. Additionally, in 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. The U.S. Supreme Court heard oral argument on the case on November 10, 2020 and issued its decision on June 17, 2021, holding that the state plaintiff's in the case challenging the constitutionality of minimum essential health care coverage provisions of the Affordable Care Act lacked standing to bring an action under Article III, Section 2 of the U.S. Constitution. On February 10, 2021, the Biden administration withdrew the federal government's support for overturning the Affordable Care Act. Although the U.S. Supreme Court had not yet ruled on the constitutionality of the Affordable Care Act, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace, which began on February 15, 2021 and will remain open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. Notwithstanding the Supreme Court recent ruling on standing to challenge the constitutionality of the Affordable Care Act, it is unclear how additional litigation and the healthcare reform measures of the Biden administration will impact the Affordable Care Act and our business. We continue to evaluate the effect that the Affordable Care Act and its possible repeal and replacement has on our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction, which triggered the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year through 2030 unless Congress takes additional action. However, COVID-19 relief legislation suspended the 2% Medicare sequester from May 1, 2020, through December 31, 2021. Recently, there has been increasing legislative and enforcement interest in the U.S. with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. congressional inquiries and legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. For example, at the federal level, the Trump administration's used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020, the administration announced several executive orders to lower drug prices that attempt to implement several of the administration's proposals. Additionally, the FDA recently released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the Department of Health and Human Services finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been until January 1, 2023. On November 20, 2020, the Centers for Medicare & Medicaid Services ("CMS") issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. It is possible that additional governmental action is taken in response to the COVID-19 pandemic, which may impact our business. We are unable to predict the future course of federal or state healthcare legislation in the U.S. directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. These and any further changes in the law or regulatory framework that reduce our revenue or increase our costs could also have a material and adverse effect on our business, financial condition and results of operations.

We expect that the healthcare reform measures that have been adopted and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved therapeutic product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our therapeutic candidates.

Governments outside of the United States tend to impose strict price controls, which may adversely affect our revenues, if any.

In some countries, particularly the countries of the European Union and Canada, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our therapeutic candidate to other available therapies. If reimbursement of our drugs is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

If we or any third-party manufacturers or contractors we engage now or in the future fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs or liabilities that could harm our business.

We and third-party manufacturers we engage now are, and any third-party manufacturers we may engage in the future will be, subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations, including work conducted through third-party manufacturers or contractors, involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Liability under certain environmental laws governing the release and cleanup of hazardous materials is joint and several and could be imposed without regard to fault. We also could incur significant costs associated with civil or criminal fines and penalties or become subject to injunctions limiting or prohibiting our activities for failure to comply with such laws and regulations.

Although we maintain general liability insurance as well as workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Further, with respect to the operations of our current and any future third-party contract manufacturers or other contractors, it is possible that if they fail to operate in compliance with applicable environmental, health and safety laws and regulations or properly dispose of wastes associated with our drugs, we could be held liable for any resulting damages, suffer reputational harm or experience a disruption in the manufacture and supply of our therapeutic candidates or drugs. In addition, our supply chain may be adversely impacted if any of our third-party contract manufacturers become subject to injunctions or other sanctions as a result of their non-compliance with environmental, health and safety laws and regulations.

We may experience challenges with the acquisition, development, enhancement or deployment of technology necessary for our proprietary DRP® companion diagnostics platform.

Our proprietary DRP® companion diagnostics platform and other aspects of our business strategy requires sophisticated computer systems and software for data collection, data processing, cloud-based platforms, analytics, statistical projections and forecasting, and other applications and technologies. We seek to address our technology risks by increasing reliance on the use of innovations by cross-industry technology leaders and adapt these innovations for their biopharmaceutical and diagnostic use in our proprietary DRP® companion diagnostics platform. Some of the technologies supporting these industries are changing rapidly and we must continue to adapt to these changes in a timely and effective manner at an acceptable cost. There can be no guarantee that we will be able to develop, acquire or integrate new technologies, that these new technologies will meet our needs or achieve our expected goals, or that we will be able to do so as quickly or cost-effectively as our competitors. Significant technological change could render our proprietary DRP® companion diagnostics platform obsolete. Our continued success will depend on our ability to adapt to changing technologies, manage and process ever-increasing amounts of data and information and improve the performance, features and reliability of our services in response to changing client and industry demands. We may experience difficulties that could delay or prevent the successful design, development, testing, and introduction of advanced versions of our proprietary DRP® companion diagnostics platform, limiting our ability to identify new therapeutic candidates. New services, or enhancements to existing services, using our proprietary DRP® companion diagnostics platform may not adequately meet our requirements. Any of these failures could have a material adverse effect on our operating results and financial condition.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully perform their contractual legal and regulatory duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our therapeutic candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third-party medical institutions, clinical investigators, contract laboratories and other third-party CROs to monitor and manage data for our ongoing preclinical and clinical programs. We have also out-licensed two of our therapeutic candidates, LiPlaCis® and 2X-111, to Smerud Medical Research International ("Smerud"), our long-time CRO partner in Europe. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with cGCPs, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, or EEA, and comparable foreign regulatory authorities for all of our drugs in clinical development.

Regulatory authorities enforce these cGCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, the EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with cGCP regulations. In addition, our clinical trials must be conducted with product produced under current good manufacturing practices, or cGMP, regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our on-going clinical, nonclinical and preclinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our therapeutic candidates. As a result, our results of operations and the commercial prospects for our therapeutic candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. If the third parties conducting our clinical trials do not perform their contractual duties or obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical trial protocols or to GCPs, or for any other reason, we may need to enter into new arrangements with alternative third parties. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We are substantially dependent on third parties for the manufacture of our clinical supplies of our therapeutic candidates and Clinical Laboratory Improvements Act ("CLIA") diagnostic laboratories to test patient biopsies in support of our clinical trials, and we intend to rely on third parties to produce commercial supplies of any approved therapeutic candidate. Therefore, our development of our drugs could be stopped or delayed, and our commercialization of any future drug could be stopped or delayed or made less profitable if third-party diagnostic laboratories lose their CLIA credentials or manufacturers fail to obtain approval of the FDA or comparable regulatory authorities or fail to provide us timely test results or with drug products in sufficient quantities or at acceptable prices.

The manufacture of pharmaceutical products is complex and requires significant expertise, capital investment, process controls and know-how. Common difficulties in pharmaceutical manufacturing may include: sourcing and producing raw materials, transferring technology from chemistry and development activities to production activities, validating initial production designs, scaling manufacturing techniques, improving costs and yields, establishing and maintaining quality controls and stability requirements, eliminating contaminations and operator errors, and maintaining compliance with regulatory requirements. We do not currently have nor do we plan to acquire the infrastructure or capability internally in accordance with cGMP prescribed by the FDA or to produce an adequate supply of compounds to meet future requirements for clinical trials and commercialization of our drugs. Drug manufacturing facilities are subject to inspection before the FDA will issue an approval to market a new drug product, and all of the manufacturers that we intend to use must adhere to the cGMP regulations prescribed by the FDA.

We expect therefore to rely on third-party manufacturers for clinical supplies of our therapeutic candidates that we may develop. These third-party manufacturers will be required to comply with current good manufacturing practices, or cGMPs, and other applicable laws and regulations. We will have no control over the ability of these third parties to comply with these requirements, or to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or any other applicable regulatory authorities do not approve the facilities of these third parties for the manufacture of our other therapeutic candidates or any drugs that we may successfully develop, or if it withdraws any such approval, or if our suppliers or contract manufacturers decide they no longer want to supply or manufacture for us, we may need to find alternative manufacturing facilities, in which case we might not be able to identify manufacturers for clinical or commercial supply on acceptable terms, or at all. Any of these factors would significantly impact our ability to develop, obtain regulatory approval for or market our therapeutic candidates and adversely affect our business.

We and/or our third-party manufacturers may be adversely affected by developments outside of our control, and these developments may delay or prevent further manufacturing of our drugs. Adverse developments may include labor disputes, resource constraints, shipment delays, inventory shortages, lot failures, unexpected sources of contamination, lawsuits related to our manufacturing techniques, equipment used during manufacturing, or composition of matter, unstable political environments, pandemics, acts of terrorism, war, natural disasters, and other natural and man-made disasters. If we or our third-party manufacturers were to encounter any of the above difficulties, or otherwise fail to comply with contractual obligations, our ability to provide any drug for clinical trial or commercial purposes would be jeopardized. This may increase the costs associated with completing our clinical trials and commercial production. Further, production disruptions may cause us to terminate ongoing clinical trials and/or commence new clinical trials at additional expense. We may also have to take inventory write-offs and incur other charges and expenses for drugs that fail to meet specifications or pass safety inspections. If production difficulties cannot be solved with acceptable costs, expenses, and timeframes, we may be forced to abandon our clinical development and commercialization plans, which could have a material adverse effect on our business, prospects, financial condition, and the value of our securities.

We also rely on third-party diagnostic laboratories certified under CLIA for testing of patient biopsies in our clinical trials. Under the CLIA, diagnostic laboratories are subject to inspection and certification by the Center for Medicare and Medicaid Services ("CMS") and if a diagnostic laboratory we use to test patient biopsies fail their CMS inspection or lose their CMS certification for the type of tests we need, our clinical trials could be delayed or the results from our clinical trials may not be acceptable to the FDA or an equivalent foreign regulatory authority.

We, or third-party manufacturers on whom we rely, may be unable to successfully scale-up manufacturing of our therapeutic candidates in sufficient quality and quantity, which would delay or prevent us from developing our therapeutic candidates and commercializing approved drugs, if any.

In order to conduct clinical trials of our therapeutic candidates and commercialize any approved therapeutic candidates, we, or our manufacturers, will need to manufacture them in large quantities. We, or our manufacturers, may be unable to successfully increase the manufacturing capacity for any of our therapeutic candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If we, or any of our manufacturers, are unable to successfully scale up the manufacture of our therapeutic candidates in sufficient quality and quantity, the development, testing, and clinical trials of that therapeutic candidate may be delayed or infeasible, and regulatory approval or commercial launch of any resulting drug may be delayed or not obtained, which could significantly harm our business. If we are unable to obtain or maintain third-party manufacturing for commercial supply of our therapeutic candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our therapeutic candidates successfully.

Our failure to find third-party collaborators to assist or share in the costs of drug development could materially harm our business, financial condition and results of operations.

Our strategy for the development and commercialization of our proprietary therapeutic candidates may include the formation of collaborative arrangements with third parties. Existing and future collaborators have significant discretion in determining the efforts and resources they apply and may not perform their obligations as expected. Potential third-party collaborators include biopharmaceutical, pharmaceutical and biotechnology companies, academic institutions and other entities. Third-party collaborators may assist us in:

- funding research, preclinical development, clinical trials and manufacturing;
- seeking and obtaining regulatory approvals; and
- successfully commercializing any future therapeutic candidates.

If we are not able to establish further collaboration agreements, we may be required to undertake drug development and commercialization at our own expense. Such an undertaking may limit the number of therapeutic candidates that we will be able to develop, significantly increase our capital requirements and place additional strain on our internal resources. Our failure to enter into additional collaborations could materially harm our business, financial condition and results of operations.

In addition, our dependence on licensing, collaboration and other agreements with third parties may subject us to a number of risks. These agreements may not be on terms that prove favorable to us and may require us to relinquish certain rights in our therapeutic candidates. To the extent we agree to work exclusively with one collaborator in a given area, our opportunities to collaborate with other entities could be curtailed. Lengthy negotiations with potential new collaborators may lead to delays in the research, development or commercialization of therapeutic candidates. The decision by our collaborators to pursue alternative technologies or the failure of our collaborators to develop or commercialize successfully any therapeutic candidate to which they have obtained rights from us could materially harm our business, financial condition and results of operations.

Risks Related to Our Business and Industry

Our business, operations and clinical development plans and timelines and supply chain could be adversely affected by the effects of health epidemics, including the ongoing COVID-19 pandemic, on the manufacturing, clinical trial and other business activities performed by us or by third parties with whom we conduct business, including our CMOs, CROs, shippers and others.

Our business could be adversely affected by health epidemics wherever we have clinical trial sites or other business operations. In addition, health epidemics could cause significant disruption in the operations of CMOs, CROs and other third parties upon whom we rely. For example, the COVID-19 pandemic has presented a substantial public health and economic challenge around the world and is affecting employees, patients, communities and business operations, as well as the U.S. economy and financial markets. Many geographic regions have imposed, or in the future may impose, "shelter-in-place" orders, quarantines or similar orders or restrictions to control the

spread of COVID-19. Our U.S. headquarters is located in the eastern portion of the U.S. and we have implemented work-from-home policies for all employees. The effects of the executive orders and our work-from-home policies may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

We are dependent on a worldwide supply chain for products to be used in our clinical trials and, if approved by the regulatory authorities, for commercialization. Quarantines, shelter-in-place and similar government orders, or the expectation that such orders, shutdowns or other restrictions could occur, whether related to COVID-19 or other infectious diseases, could impact personnel at third-party manufacturing facilities in the U.S. and other countries, or the availability or cost of materials or supplies, which could disrupt our supply chain or our ability to enroll patients in or perform testing for our clinical trials. In addition, closures of transportation carriers and modal hubs could materially impact our clinical development and any future commercialization timelines.

If our relationships with our suppliers or other vendors are terminated or scaled back as a result of the COVID-19 pandemic or other health epidemics, we may not be able to enter into arrangements with alternative suppliers or vendors or do so on commercially reasonable terms or in a timely manner. Switching or adding additional suppliers or vendors involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new supplier or vendor commences work. As a result, delays generally occur, which could adversely impact our ability to meet our desired clinical development and any future commercialization timelines. Although we carefully manage our relationships with our suppliers and vendors, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on our business, financial condition and prospects. See "Risk Factors — Risks Related to Our Dependence on Third Parties."

In addition, our ongoing clinical trials in the U.S. and Europe may be affected by the COVID-19 pandemic. In the future, clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic or concerns among patients about participating in clinical trials during a pandemic and public health measures imposed by the respective national governments of countries in which the clinical sites are located. Some patients may have difficulty following certain aspects of clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our inability to successfully recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 or experience additional restrictions by their institutions, city or state governments could adversely impact our clinical trial operations.

The spread of COVID-19 has also led to disruption and volatility in the global capital markets, which increases the cost of, and adversely impacts access to, capital and increases economic uncertainty. The trading prices for the common stock of other biopharmaceutical companies have, at times, been highly volatile as a result of COVID-19. To the extent the COVID-19 pandemic adversely affects our business, financial results and value of our common stock, it may also affect our ability to access capital, which could in the future negatively affect our liquidity.

The global pandemic of COVID-19 continues to evolve rapidly. The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. However, these effects could have a material impact on our operations, and we will continue to monitor the COVID-19 situation closely.

We will need to increase the size of our organization and the scope of our outside vendor relationships, and we may experience difficulties in managing growth.

As of the date of this information statement/prospectus, we employed a total of 13 full-time employees. Our current internal departments include research and development, finance and administration. We intend to expand our management team to include an operation ramp up of additional scientific development and technical staff required to achieve our business objectives. We will need to expand our managerial, operational, technical and scientific, financial

and other resources in order to manage our operations and clinical trials, establish independent manufacturing, continue our research and development activities, and commercialize our therapeutic candidates. Our management and scientific personnel, systems and facilities currently in place may not be adequate to support our future growth.

Our need to effectively manage our operations, growth and various projects requires that we:

- manage our ongoing and future clinical trials effectively;
- manage our internal development efforts effectively while carrying out our contractual obligations to licensors, contractors and other third parties;
- continue to improve our operational, financial and management controls and reporting systems and procedures; and
- attract and retain sufficient numbers of talented employees.

We may utilize the services of vendors and research partners or collaborators to perform tasks including preclinical studies and clinical trial management, statistics and analysis, regulatory affairs, medical advisory, market research, formulation development, chemistry, manufacturing and control activities, other drug development functions, legal, auditing, financial advisory, and investor relations. Our growth strategy may also entail expanding our group of contractors or consultants to implement these and other tasks going forward. Because we rely on numerous consultants to outsource many key functions of our business, we will need to be able to effectively manage these consultants to ensure that they successfully carry out their contractual obligations and meet expected deadlines. However, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for our therapeutic candidate or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may be unable to successfully implement the tasks necessary to further develop and commercialize our therapeutic candidate and, accordingly, may not achieve our research, development and commercialization goals.

We depend on our senior management team, and the loss of one or more of our executive officers or key employees or an inability to attract and retain highly skilled employees could adversely affect our business.

Our success depends largely upon the continued services of our founder and Chief Scientific Officer, Dr. Steen Knudsen, Ph.D., Steve Carchedi, our Chief Executive Officer, President and Director and James G. Cullem, our Senior Vice President of Corporate Development. We do not maintain "key person" insurance for Messrs. Knudsen, Carchedi, Cullem or any of our other key employees. We also rely on employees in the areas of research and development, regulatory compliance and approvals, and general and administrative functions. From time to time, there may be changes in our executive management and employees resulting from the hiring or departure of executives or other key employees which could disrupt our business. The replacement of one or more of our executive officers or other key employees would likely involve significant time and costs and may significantly delay or prevent the achievement of our business objectives.

To continue to execute our growth strategy, we also must attract and retain highly skilled personnel. We might not be successful in maintaining our unique culture and continuing to attract and retain qualified personnel. We have from time to time in the past experienced, and we expect to continue to experience in the future, difficulty in hiring and retaining highly skilled personnel with appropriate qualifications. The pool of qualified personnel with experience in bioinformatics, genomics, or experience working with the biopharma market is limited overall. In addition, many of the companies with which we compete for experienced personnel have greater resources than we have.

In addition, in making employment decisions, particularly in the biotechnology and pharmaceutical industries, job candidates often consider the value of the stock options or other equity instruments they are to receive in connection with their employment. Volatility in the price of our stock might, therefore, adversely affect our ability to attract or retain highly skilled personnel. Furthermore, the requirement to expense stock options and other equity instruments might discourage us from granting the size or type of stock option or equity awards that job candidates require to join our company. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business and future growth prospects could be severely harmed.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or unauthorized activities that violates (1) the laws and regulations of the FDA, the EMA, and other similar regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities, (2) manufacturing standards, (3) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the U.S. and abroad and (4) laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of individually identifiable information, including information obtained in the course of clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of therapeutic candidates, which could result in regulatory sanctions and serious harm to our reputation.

In connection with the Recapitalization Share Exchange, we will adopt a code of business conduct and ethics, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, including damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm and the delay, reduction, termination or restructuring of our operations.

International operations may expose us to business, regulatory, political, operational, financial, pricing and reimbursement risks associated with doing business outside of the U.S.

Our business will be subject to risks associated with conducting business internationally. Some of our suppliers, industry partners and clinical study centers are located outside of the U.S. Furthermore, our business strategy incorporates potential international expansion as we seek to obtain regulatory approval for, and commercialize, our therapeutic candidates in patient populations outside the U.S. If approved, we may hire sales representatives and conduct physician and patient association outreach activities outside of the U.S. Doing business internationally involves a number of risks, including but not limited to:

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries;
- rejection or qualification of foreign clinical trial data by the competent authorities of other countries;
- delays or interruptions in the supply of clinical trial materials resulting from any events affecting raw material supply or manufacturing capabilities abroad, including those that may result from the ongoing COVID-19 pandemic;
- additional potentially relevant third-party patent and other intellectual property rights;
- complexities and difficulties in obtaining, maintaining, protecting and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;

- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our therapeutic candidates and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, including COVID-19 and related shelter-in-place orders, travel, social distancing and quarantine policies, boycotts, curtailment of trade and other business restrictions;
- certain expenses including, among others, expenses for travel, translation and insurance; and
- regulatory and compliance risks that relate to anti-corruption compliance and record-keeping that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its accounting provisions or its anti-bribery provisions or provisions of anti-corruption or anti-bribery laws in other countries.

Any of these factors could harm our future international expansion and operations and, consequently, our results of operations.

Our failure to successfully acquire, develop and market additional therapeutic candidates could impair our ability to grow.

As part of our growth strategy, we may evaluate, acquire, license, develop and/or market additional therapeutic candidates and technologies. We anticipate these investments will constitute a material portion of our business. However, our internal research capabilities are limited and we may be dependent upon pharmaceutical and biopharmaceutical companies, academic scientists and other researchers to sell or license therapeutic candidates or technologies to us. The success of this strategy depends partly upon our ability to identify, select and acquire promising pharmaceutical therapeutic candidates for further development together with our proprietary DRP® companion diagnostics platform. The process of proposing, negotiating and implementing a license or acquisition of a therapeutic candidate is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of therapeutic candidates and technologies. We have limited resources to identify and execute the acquisition or in-licensing of potential therapeutic candidates and technologies and to integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. Furthermore, we may not be able to acquire the rights to additional therapeutic candidates on terms that we find acceptable, or at all.

In addition, future acquisitions of intellectual property rights may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's and technical personnel's time and attention to develop acquired therapeutic candidates or technologies;
- incurrence of substantial debt or dilutive issuances of securities to pay for acquisition costs;
- higher than expected acquisition costs; and
- increased amortization expenses.

Any therapeutic candidate that we acquire may require additional development efforts prior to commercial sale or out-licensing, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All therapeutic candidates are prone to risks of failure typical of pharmaceutical drug development, including the possibility that a therapeutic candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot provide assurance that any drugs that we may develop or approved drugs that we may acquire will be manufactured profitably or achieve market acceptance.

We have obtained statistical data, market data and other industry data and forecasts used throughout this Information statement/prospectus from market research, publicly available information and industry publications which we believe are reliable.

This information statement/prospectus contains estimates, projections and other information concerning our industry, our business and the markets for our therapeutic candidates, including data regarding the estimated size of such markets and the incidence of certain medical conditions. We obtained the industry, market and similar data set forth in this information statement/prospectus from our internal estimates and research and from academic and industry research, publications, surveys and studies conducted by third parties, including governmental agencies. In some cases, we do not expressly refer to the sources from which this data is derived. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information.

Risks Related to Our Intellectual Property

If we do not obtain patent term extension for any therapeutic candidates we may develop or obtain a patent on our DRP® companion diagnostic for a therapeutic candidate, our business may be materially harmed.

In the United States, depending upon the timing, duration, and specifics of any FDA marketing approval of a therapeutic candidate, the patent term of a patent that covers an FDA-approved drug may be eligible for limited patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of drug approval, and only one patent applicable to an approved drug may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in Europe and other non-United States jurisdictions to extend the term of a patent that covers an approved drug. While, in the future, if and when our therapeutic candidates receive FDA approval, we expect to apply for patent term extensions on patents directed to those therapeutic candidates, there is no guarantee that the applicable authorities will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions. We may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of the relevant patents, or otherwise failing to satisfy applicable requirements. If we are unable to obtain any patent term extension or the term of any such extension is less than we request, or if we are not able to obtain a patent on our DRP® companion diagnostic for our therapeutic candidate, our competitors may obtain approval of competing drugs following the expiration of our patent rights, or use a similar companion diagnostic, and our business, financial condition, results of operations, and prospects could be materially harmed.

Changes to patent laws in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our drugs.

Changes in either the patent laws or interpretation of patent laws in the United States, including patent reform legislation such as the Leahy-Smith America Invents Act, or the Leahy-Smith Act, could increase the uncertainties and costs surrounding the prosecution of our owned and in-licensed patent applications and the maintenance, enforcement or defense of our owned and in-licensed issued patents. The Leahy-Smith Act includes a number of significant changes to United States patent law. These changes include provisions that affect the way patent applications are prosecuted, redefine prior art, provide more efficient and cost-effective avenues for competitors to challenge the validity of patents, and enable third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent at USPTO-administered post-grant proceedings, including post-grant review, inter parties review, and derivation proceedings. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent.

After March 2013, under the Leahy-Smith Act, the United States transitioned to a first-to-file system in which, assuming that the other statutory requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third-party was the first to invent the claimed invention. As such, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future.

We or our licensors may become involved in lawsuits to protect or enforce our patent or other intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors and other third parties may infringe, misappropriate or otherwise violate our or our licensor's issued patents or other intellectual property. As a result, we or our licensors may need to file infringement, misappropriation or other intellectual property related claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke such parties to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their intellectual property. In addition, in a patent infringement proceeding, such parties could counterclaim that the patents we or our licensors have asserted are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may institute such claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter parties review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings).

An adverse result in any such proceeding could put one or more of our owned or in-licensed patents at risk of being invalidated or interpreted narrowly, and could put any of our owned or in-licensed patent applications at risk of not yielding an issued patent. A court may also refuse to stop the third-party from using the technology at issue in a proceeding on the grounds that our owned or in-licensed patents do not cover such technology. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information or trade secrets could be compromised by disclosure during this type of litigation. Any of the foregoing could allow such third parties to develop and commercialize competing technologies and products and have a material adverse impact on our business, financial condition, results of operations, and prospects.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability, and the ability of our collaborators, to develop, manufacture, market and sell our therapeutic candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. There is considerable patent and other intellectual property litigation in the pharmaceutical and biotechnology industries. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our technology and therapeutic candidates, including interference proceedings, post grant review, inter parties review, and derivation proceedings before the USPTO and similar proceedings in foreign jurisdictions such as oppositions before the European Patent Office.

The legal threshold for initiating litigation or contested proceedings is low, so that even lawsuits or proceedings with a low probability of success might be initiated and require significant resources to defend. Litigation and contested proceedings can also be expensive and time-consuming, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. The risks of being involved in such litigation and proceedings may increase if and as our therapeutic candidates near commercialization and as we gain the greater visibility associated with being a public company. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of merit. We may not be aware of all such intellectual property rights potentially relating to our technology and therapeutic candidates and their uses. Thus, we do not know with certainty that our technology and therapeutic candidates, or our development and commercialization thereof, do not and will not infringe, misappropriate or otherwise violate any third-party's intellectual property.

Even if we believe that third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of misappropriation, infringement, validity, enforceability, or priority. A court of competent jurisdiction could hold these third-party patents are valid, enforceable, and infringed, which could materially and adversely affect our ability to commercialize any technology or therapeutic candidate covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent.

If we are found to infringe, misappropriate or otherwise violate a third-party's intellectual property rights, we could be required to obtain a license from such third-party to continue developing, manufacturing and marketing our technology and therapeutic candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive; thereby giving our competitors and other third parties access to the same technologies licensed to us and could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or drug. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right and could be forced to indemnify our collaborators or others. A finding of infringement could prevent us from commercializing our therapeutic candidates or force us to cease some of our business operations, which could materially harm our business. In addition, we may be forced to redesign our therapeutic candidates, seek new regulatory approvals and indemnify third parties pursuant to contractual agreements. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations, and prospects.

Intellectual property litigation or other legal proceedings relating to intellectual property could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and may also have an advantage in such proceedings due to their more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of intellectual property litigation or other proceedings could compromise our ability to compete in the marketplace.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance, renewal and annuity fees and various other government fees on any issued patent and pending patent application must be paid to the USPTO and foreign patent agencies in several stages or annually over the lifetime of our owned and in-licensed patents and patent applications. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In certain circumstances, we rely on our licensing partners to pay these fees to, or comply with the procedural and documentary rules of, the relevant patent agency. With respect to our patents, we rely on an annuity service to remind us of the due dates and to make payment after we instruct them to do so. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, potential competitors might be able to enter the market with similar or identical products or technology. If we or our licensors fail to maintain the patents and patent applications directed to our therapeutic candidates, it would have a material adverse effect on our business, financial condition, results of operations, and prospects.

If we fail to comply with our obligations in our intellectual property licenses and funding arrangements with third parties, we could lose rights that are important to our business.

We are party to license and funding agreements that impose, and we may enter into additional licensing and funding arrangements with third parties that may impose, diligence, development and commercialization timelines, milestone payment, royalty, insurance and other obligations on us. Under our existing licensing and funding agreements, we are obligated to pay certain specified milestone payments and royalties on net drug sales of therapeutic candidates or related technologies to the extent they are covered by the agreements. If we fail to comply with such obligations under current or future license and funding agreements, our counterparties may have the right to terminate these agreements or require us to grant them certain rights. Such an occurrence could materially adversely affect the value of any therapeutic candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, which would have a material adverse effect on our business, financial condition, results of operations, and prospects.

Additionally, these and other license agreements may not provide exclusive rights to use the licensed intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and drugs in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products and technology in fields of use and territories not included in such agreements. In addition, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications directed to the technology that we license from third parties. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, and defended in a manner consistent with the best interests of our business. If our licensors fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our drugs that are the subject of such licensed rights could be adversely affected.

We may need to obtain additional licenses from others to advance our research or allow commercialization of our therapeutic candidates. It is possible that we may be unable to obtain additional licenses at a reasonable cost or on reasonable terms, if at all, or such licenses may be non-exclusive. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all.

If we are unable to obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may be required to expend significant time and resources to redesign our technology, therapeutic candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected technology and therapeutic candidates, which could harm our business, financial condition, results of operations, and prospects significantly.

Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected technology and therapeutic candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

Our licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents and patent applications we in-licensed. If other third parties have ownership rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

In spite of our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize therapeutic candidates and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying intellectual property fails to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products and technologies identical to ours. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

We may not be able to protect our intellectual property and proprietary rights throughout the world.

Filing, prosecuting, and defending patents on therapeutic candidates in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection or licenses but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to pharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

We may be subject to claims by third parties asserting that our employees, consultants, contractors or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees, consultants, contractors and advisors were previously employed, or may currently be employed, at universities or other pharmaceutical or biotechnology companies, including our competitors or potential competitors. Although we try to ensure that our employees, contractors and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims.

In addition, while it is our policy to require our employees, consultants, contractors and advisors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our intellectual property assignment agreements with them may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could have a material adverse effect on our competitive business position and prospects. Such intellectual property rights could be awarded to a third-party, and we could be required to obtain a license from such third-party to commercialize our technology or products, which license may not be available on commercially reasonable terms, or at all, or such license may be non-exclusive. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and employees.

In addition to seeking patents for some of our technology and therapeutic candidates, we also rely on trade secrets and confidentiality agreements relating to the development of our proprietary DRP® companion diagnostics platform to protect our unpatented know-how, technology and other proprietary information, in order to maintain our competitive position. We seek to protect our trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties. Although we may not have done so in the past, we intend to enter into confidentiality and invention or patent assignment agreements with our employees and consultants in the future. We cannot guarantee that we have entered into such agreements with each party that may have or has had access to our

trade secrets or proprietary technology. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Detecting the disclosure or misappropriation of a trade secret and enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside of the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third-party, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third-party, our competitive position would be materially and adversely harmed.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- we, or our license partners or current or future collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent applications that we license or may own in the future;
- we, or our license partners or current or future collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or in-licensed intellectual property rights;
- it is possible that our owned and in-licensed pending patent applications or those we may own or in-license in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third-party may subsequently file a patent covering such intellectual property, or may independently develop such trade secret and be free to exploit it.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Risks Related to the Recapitalization Share Exchange

Since the Allarity A/S directors and executive officers have interests that are different, or in addition to (and which may conflict with), the interests of our shareholders, a conflict of interest may have existed in determining whether the Recapitalization Share Exchange is appropriate and in the best interests of Allarity A/S and its shareholders.

When you consider the recommendation of Allarity A/S's board of directors in favor of the Recapitalization Share Exchange Proposals and the other proposals submitted for shareholder approval at the Allarity A/S Extraordinary General Meeting, you should keep in mind that the Allarity A/S directors and officers have interests in such proposal that are different from, or in addition to, those of our shareholders generally. These interests include those discussed in *"The Recapitalization Share Exchange — Interests of Certain Persons in the Recapitalization Share Exchange"* beginning on page 239 on this information statement/prospectus.

The existence of financial and personal interests of one or more of our directors may result in a conflict of interest on the part of such director(s) between what he, she or they may believe is in the best interests of Allarity A/S and its shareholders and what he, she or they may believe is best for himself or themselves in determining to recommend that shareholders vote for the proposals.

The consummation of the Recapitalization Share Exchange is subject to a number of conditions and if those conditions are not satisfied or waived, the Reorganization Agreement may be terminated in accordance with its terms and the Recapitalization Share Exchange may not be completed.

The Reorganization Agreement is subject to a number of conditions which must be fulfilled in order to complete the Recapitalization Share Exchange. Those conditions include: approval of the Recapitalization Share Exchange Proposals and other proposals submitted for shareholder approval at the Allarity A/S Extraordinary General Meeting, the acceptance for listing of the Delaware Common Stock to be issued in the Recapitalization Share Exchange on the Nasdaq Stock Market, absence of orders prohibiting completion of the Recapitalization Share Exchange, effectiveness of the registration statement of which this information statement/prospectus is a part, the accuracy of the representations and warranties by all parties (subject to the materiality standards set forth in the Reorganization Agreement) and the performance by all parties of their covenants and agreements. These conditions to the closing of the Recapitalization Share Exchange may not be fulfilled in a timely manner or at all, and, accordingly, the Recapitalization Share Exchange may not be completed. In addition, the parties can mutually decide to terminate the Reorganization Agreement at any time, before or after shareholder approval, or any party may elect to terminate the Reorganization Agreement if the Recapitalization Share Exchange is not consummated by December 31, 2021, and in certain other circumstances.

Termination of the Reorganization Agreement and the Recapitalization Share Exchange contemplated thereby could negatively impact our future business.

If the Recapitalization Share Exchange is not completed for any reason, including as a result of our shareholders declining to approve the proposals required to effect the Recapitalization Share Exchange, our ongoing business may be adversely impacted and, without realizing any of the anticipated benefits of completing the Recapitalization Share Exchange, would be subject to a number of risks, including the following:

- we may experience negative reactions from the financial markets, including negative impacts on our share price on the Nasdaq First North Growth Market (including to the extent that the current market price reflects a market assumption that the Recapitalization Share Exchange will be completed);
- we will have incurred substantial expenses and will be required to pay certain costs relating to the Recapitalization Share Exchange, whether or not the Recapitalization Share Exchange is completed; and
- we will not receive the net proceeds from the PIPE Investment, which may force us to curtail our business operations and liquidate our pipeline of therapeutic candidates at unfavorable prices or on unfavorable terms.

We will incur transaction costs in connection with the Recapitalization Share Exchange.

We have incurred and expects that we will further incur significant, non-recurring costs in connection with consummating the Recapitalization Share Exchange. We may also incur additional costs to retain key employees. We will also incur significant legal, financial advisor, and accounting fees, SEC filing fees, printing and mailing fees and other costs associated with the Recapitalization Share Exchange. Most of these costs are payable regardless of whether the Recapitalization Share Exchange is completed.

We may be at risk of litigation arising from the terms and conditions of the Recapitalization Share Exchange.

We may be at risk of litigation relating to the terms and conditions of the Recapitalization Share Exchange. For example, while we believe that the terms and conditions of the Recapitalization Share Exchange relating to treatment of holders of our warrants to purchase ordinary shares of Allarity A/S are in compliance with the existing terms and conditions of the warrants, no assurances can be given that warrant holders will agree, or that litigation may not ensue challenging the treatment of the warrants in the Recapitalization Share Exchange.

In evaluating Recapitalization Share Exchange, our management has relied on the availability of all of the funds from the PIPE Investment that is conditioned upon the consummation of the Recapitalization Share Exchange. If the PIPE Investment fails to close for any reason, we may lack sufficient funds to continue in business without curtailing our operations which would likely delay the clinical advancement of our pipeline of therapeutic candidates and force us to liquidate one or all of our therapeutic candidates at unfavorable prices or on unfavorable terms, or both.

In connection with Reorganization Agreement, we entered into a securities purchase agreement and registration rights agreement with 3i, LP, a Delaware limited partnership, for a $20 million investment in our Series A Convertible Preferred Stock and the issuance of a common stock purchase warrant for an additional $20 million if the common stock purchase warrant is exercised in the future (the "PIPE Investment"). The closing of the PIPE Investment is conditioned upon, among other things, the consummation of the Recapitalization Share Exchange. If the Recapitalization Share Exchange is consummated but the PIPE Investment fails to close for any reason, we may lack sufficient funds to continue to advance our therapeutic candidates and may be forced to curtail our business operations which will have an adverse effect on our business, financial condition, and results of operations and which may force us to liquidate our pipeline of therapeutic candidates at unfavorable prices on upon unfavorable terms, or both.

If the Recapitalization Share Exchange's benefits do not meet the expectations of investors or securities analysts or for other reasons, the market price of our ordinary shares traded on the Nasdaq First North Growth Market or, following the Recapitalization Share Exchange, our common stock traded on the Nasdaq Stock Market, may decline.

If the perceived benefits of the Recapitalization Share Exchange do not meet the expectations of investors or securities analysts, the market price of ordinary shares traded on the Nasdaq First North Growth Market in Stockholm prior to the Closing may decline. The market values of our ordinary shares at the time of the Recapitalization Share Exchange may vary significantly from their prices on the date the Reorganization Agreement was executed, the date of this information statement/prospectus, or the date on which our shareholders vote on the proposals submitted for their approval at the Allarity A/S Extraordinary General Meeting.

In addition, following the Recapitalization Share Exchange, fluctuations in the price of common stock could contribute to the loss of all or part of your investment. Prior to the Recapitalization Share Exchange, there has not been a public market for common stock in the U.S. Accordingly, the valuation ascribed to our ordinary shares on the Nasdaq First North Growth Market may not be indicative of the price that will prevail in the trading market for our common stock following the Recapitalization Share Exchange. If an active market for our common stock develops and continues, the trading price of our common stock following the Recapitalization Share Exchange could be volatile and subject to wide fluctuations in response to various factors, some of which are beyond our control. Any of the factors listed below could have a negative impact on your investment in our securities and our securities may trade at prices significantly below the price you paid for them. In such circumstances, the trading price of our securities may not recover and may experience a further decline.

Factors affecting the trading price of our securities may include:

- adverse regulatory decisions;
- any delay in our regulatory filings for our therapeutic candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- the impacts of the ongoing COVID-19 pandemic and related restrictions;
- the commencement, enrollment or results of any future clinical trials we may conduct, or changes in the development status of our therapeutic candidates;
- adverse results from, delays in or termination of clinical trials;
- unanticipated serious safety concerns related to the use of our therapeutic candidates;
- lower than expected market acceptance of our therapeutic candidates following approval for commercialization, if approved;

- changes in financial estimates by us or by any securities analysts who might cover our securities;
- conditions or trends in our industry;
- changes in the market valuations of similar companies;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- investors' general perception of our business prospects or management;
- recruitment or departure of key personnel;
- overall performance of the equity markets;
- trading volume of our common stock once listed on the Nasdaq Stock Market or before;
- disputes or other developments relating to intellectual property rights, including patents, litigation matters and our ability to obtain, maintain, defend, protect and enforce patent and other intellectual property rights for our technologies;
- significant lawsuits, including patent or shareholder litigation;
- proposed changes to healthcare laws in the U.S. or foreign jurisdictions, or speculation regarding such changes;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, in the past, stockholders have initiated class action lawsuits against biopharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business.

There can be no assurance that the Delaware Common Stock to be issued in the Recapitalization Share Exchange will be approved for listing on the Nasdaq Stock Market or that we will be able to comply with the continued listing standards of the Nasdaq Stock Market.

In connection with the completion of the Recapitalization Share Exchange, we intend to list the Delaware Common Stock to be issued in the Recapitalization Share Exchange on the Nasdaq Stock Market under the symbol "ALLR". Our continued eligibility for listing will depend on our compliance with the continued listing standards of the Nasdaq Stock Market and may depend on factors beyond our control. If, after the Recapitalization Share Exchange, the Nasdaq Stock Market delists our shares from trading on its exchange for failure to meet the listing standards, we and our stockholders could face significant negative consequences including:

- limited availability of market quotations for our securities;
- a determination that our common stock is a "penny stock" which will require brokers trading in common stock to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for shares of common stock;
- a limited amount of analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

Following the completion of the Recapitalization Share Exchange, we will incur significant increased expenses and administrative burdens as a U.S. public company, which could negatively impact our business, financial condition and results of operations.

Following the completion of the Recapitalization Share Exchange, we will face increased legal, accounting, administrative and other costs and expenses as a U.S. public company that we did not incur as a prior to the Recapitalization Share Exchange. The Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), including the requirements of Section 404, as well as rules and regulations subsequently implemented by the SEC, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 and the rules and regulations promulgated and to be promulgated thereunder, the PCAOB and the securities exchanges, impose additional reporting and other obligations on public companies. Compliance with public company requirements will increase costs and make certain activities more time-consuming. A number of those requirements will require us to carry out activities we have not done previously. For example, we will create new board committees and adopt new internal controls and disclosure controls and procedures. In addition, expenses associated with SEC reporting requirements will be incurred. Furthermore, if any issues in complying with those requirements are identified (for example, if the auditors identify a material weakness or significant deficiency in the internal control over financial reporting), we could incur additional costs rectifying those issues, and the existence of those issues could adversely affect our reputation or investor perceptions of it. It may also be more expensive to obtain director and officer liability insurance. Risks associated with our status as a public company may make it more difficult to attract and retain qualified persons to serve on our board of directors or as executive officers. The additional reporting and other obligations imposed by these rules and regulations will increase legal and financial compliance costs and the costs of related legal, accounting and administrative activities. These increased costs will require us to divert a significant amount of money that could otherwise be used to expand our business and achieve strategic objectives. Advocacy efforts by stockholders and third parties may also prompt additional changes in governance and reporting requirements, which could further increase costs.

Risks Related to Owning our Common Stock and this Offering

An active trading market for our common stock may not develop, and you may not be able to sell your common stock at or above the initial public offering price.

Prior to the consummation of this offering, there has been no public market for our Delaware Common Stock. An active trading market for shares of our Delaware Common Stock may never develop or be sustained following the Recapitalization Share Exchange. If an active trading market does not develop, you may have difficulty selling your shares of Delaware Common Stock at an attractive price, or at all. The implied price for our Delaware Common Stock derived by applying the exchange ratio in the Recapitalization Share Exchange to the trading price of Allarity A/S ordinary shares on the Nasdaq First North Growth Market in Stockholm may not be indicative of prices that will prevail in the Nasdaq Stock Market following the Recapitalization Share Exchange. Consequently, you may not be able to sell your common stock at or above the implied price derived from trading on the Nasdaq First North Growth Market in Stockholm or at any other price or at the time that you would like to sell. An inactive market may also impair our ability to raise capital by selling our common stock, and it may impair our ability to attract and motivate our employees through equity incentive awards and our ability to acquire other companies, drugs or technologies by using our common stock as consideration.

The price of our common stock may fluctuate substantially.

You should consider an investment in our common stock to be risky, and you should invest in our common stock only if you can withstand a significant loss and wide fluctuations in the market value of your investment. Some factors that may cause the market price of our common stock to fluctuate, in addition to the other risks mentioned in this "Risk Factors" section and elsewhere in this information statement/prospectus, are:

- sale of our common stock by our stockholders, executives, and directors;
- volatility and limitations in trading volumes of our shares of common stock;
- our ability to obtain financings to conduct and complete research and development activities including, but not limited to, our proposed clinical trials, and other business activities;

- possible delays in the expected recognition of revenue due to lengthy and sometimes unpredictable sales timelines;
- the timing and success of introductions of new drugs by our competitors or any other change in the competitive dynamics of our industry, including consolidation among competitors, customers or strategic partners;
- network outages or security breaches;
- the lack of market acceptance and sales growth for our therapeutic candidates, if any, that receive marketing approval;
- our ability to secure resources and the necessary personnel to conduct clinical trials on our desired schedule;
- commencement, enrollment or results of our clinical trials for our therapeutic candidates or any future clinical trials we may conduct;
- changes in the development status of our therapeutic candidates;
- any delays or adverse developments or perceived adverse developments with respect to the FDA's review of our planned NDA, PMA and clinical trials;
- any delay in our submission for studies or drug approvals or adverse regulatory decisions, including failure to receive regulatory approval for our therapeutic candidates;
- unanticipated safety concerns related to the use of our therapeutic candidates;
- failures to meet external expectations or management guidance;
- changes in our capital structure or dividend policy and future issuances of securities;
- sales of large blocks of common stock by our stockholders, including, but not limited to, sales by 3i, LP, a Delaware limited partnership as a result of the conversion of a Series A Convertible Preferred Stock into common stock and the liquidation of the PIPE Investment;
- our cash position;
- announcements and events surrounding financing efforts, including debt and equity securities;
- our inability to enter into new markets or develop new drugs;
- reputational issues;
- competition from existing technologies and drugs or new technologies and drugs that may emerge;
- announcements of acquisitions, partnerships, collaborations, joint ventures, new drugs, capital commitments, or other events by us or our competitors;
- changes in general economic, political and market conditions in or any of the regions in which we conduct our business;
- changes in industry conditions or perceptions;
- changes in valuations of similar companies or groups of companies;
- analyst research reports, recommendation and changes in recommendations, price targets, and withdrawals of coverage;
- departures and additions of key personnel;
- disputes and litigations related to intellectual properties, proprietary rights, and contractual obligations;

- changes in applicable laws, rules, regulations, or accounting practices and other dynamics; and
- other events or factors, many of which may be out of our control.

In addition, if the market for stocks in our industry or industries related to our industry, or the stock market in general, experiences a loss of investor confidence, the trading price of our common stock could decline for reasons unrelated to our business, financial condition and results of operations. If any of the foregoing occurs, it could cause our stock price to fall and may expose us to lawsuits that, even if unsuccessful, could be costly to defend and a distraction to management.

We have broad discretion in the use of the net proceeds from the PIPE Investment and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from the PIPE Investment. Because of the number and variability of factors that will determine our use of the net proceeds from the PIPE Investment, their ultimate use may vary substantially from their currently intended use. Our management may not apply our cash from the PIPE Investment in ways that ultimately increase the value of any investment in our securities or enhance stockholder value. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from the PIPE Investment in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest or apply our cash in ways that enhance stockholder value, we may fail to achieve expected financial results, which may result in a decline in the price of our shares of common stock, and, therefore, may negatively impact our ability to raise capital, invest in or expand our business, acquire additional therapeutic candidates or licenses, commercialize our therapeutic candidates, or continue our operations.

Because certain of our stockholders control a significant number of shares of our common stock, they may have effective control over actions requiring stockholder approval.

Following this offering, our directors, executive officers and principal stockholders, and their respective affiliates, in the aggregate will beneficially own approximately 3.8% of our outstanding shares of common stock. As a result, these stockholders, acting together, may have the ability to control, or influence the control, the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these stockholders, acting together, may have the ability to control the management and affairs of our company. Accordingly, this concentration of ownership might harm the market price of our common stock by:

- delaying, deferring or preventing a change in corporate control;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

Future sales, or the perception of future sales, by us or our stockholders in the public market following the Recapitalization Share Exchange could cause the market price for our common stock to decline.

The sale of shares of our common stock in the public market, or the perception that such sales could occur, could harm the prevailing market price of shares of our common stock. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that it deems appropriate.

Upon consummation of the Recapitalization Share Exchange, we anticipate having a total of approximately 8,075,824 shares of common stock outstanding and 20,000 shares of Series A Convertible Preferred Stock outstanding assuming the closing of the PIPE Investment has occurred convertible into 2,018,958 shares of common stock at an anticipated fixed conversion price of $9.906 per share, subject to adjustments. All shares of Delaware Common Stock issued in the Recapitalization Share Exchange and upon conversion of the Series A Convertible Preferred Stock, from time to time, will be freely tradable without registration under the Securities Act, and without restriction by persons other than our "affiliates" (as defined under Rule 144 of the Securities Act, "Rule 144"), including our directors, executive officers and other affiliates.

In addition, the shares of common stock reserved for Converted Options and future issuances under our 2021 Equity Incentive Plan will become eligible for sale in the public market once those shares are issued, subject to provisions relating to various vesting agreements, lock-up agreements and, in some cases, limitations on volume and manner of sale applicable to affiliates under Rule 144, as applicable. A total of approximately 15% of the issued and outstanding shares of our common stock immediately before the effective time of the Recapitalization Share Exchange is expected to be reserved for future issuance under our 2021 Equity Incentive Plan. We expect to file one or more registration statements on Form S-8 under the Securities Act to register shares of our common stock or securities convertible into or exchangeable for shares of our common stock issued pursuant to our 2021 Equity Incentive Plan. Any such Form S-8 registration statements will automatically become effective upon filing. Accordingly, shares registered under such registration statements will be available for sale in the open market.

In the future, we may also issue our securities in connection with investments or acquisitions. The amount of shares of our common stock issued in connection with an investment or acquisition could constitute a material portion of our then-outstanding shares of common stock. Any issuance of additional securities in connection with investments or acquisitions may result in additional dilution to our stockholders.

Because there are no current plans to pay cash dividends on shares of our common stock for the foreseeable future, you may not receive any return on investment unless you sell your shares of common stock for a price greater than that which you paid for it.

We intend to retain future earnings, if any, for future operations, expansion and debt repayment and have no current plans to pay any cash dividends for the foreseeable future. Any decision to declare and pay dividends as a public company in the future will be made at the discretion of our board of directors and will depend on, among other things, our results of operations, financial condition, cash requirements, contractual restrictions and other factors that our board of directors may deem relevant. In addition, our ability to pay dividends may be limited by covenants of any existing and future outstanding indebtedness we or our subsidiaries incur or from restrictions imposed by any preferred stock we may issue in the future. As a result, you may not receive any return on an investment in our common stock unless you sell your shares of common stock for a price greater than that which you paid for it.

There is no assurance that an active and liquid trading market in our common stock will develop.

Even though our shares may be listed on the Nasdaq Stock Market, there can be no assurance any broker will be interested in trading our common stock. Therefore, it may be difficult to sell any shares you purchase in this offering if you desire or need to sell them. The underwriters are not obligated to make a market in our common stock, and even after making a market, can discontinue market making at any time without notice. We cannot provide any assurance that an active and liquid trading market in our common stock will develop or, if developed, that the market will continue.

Our certificate of incorporation and our by-laws, and Delaware law may have anti-takeover effects that could discourage, delay or prevent a change in control, which may cause our stock price to decline.

Our certificate of incorporation, and our by-laws, and Delaware law could make it more difficult for a third-party to acquire us, even if closing such a transaction would be beneficial to our stockholders. We will be authorized to issue up to 5,000,000 shares of preferred stock upon the completion of the Recapitalization Share Exchange, 20,000 shares of which have been designated as Series A Preferred Stock that is being sold in the PIPE Investment. The remaining preferred stock may be issued in one or more series, the terms of which may be determined at the time of issuance by our board of directors without further action by stockholders. The terms of any series of preferred stock may include voting rights (including the right to vote as a series on particular matters), preferences as to dividend, liquidation, conversion and redemption rights and sinking fund provisions. None of our preferred stock will be outstanding at the closing of this offering. The issuance of any preferred stock could materially adversely affect the rights of the holders of our common stock, and therefore, reduce the value of our common stock. In particular, specific rights granted to future holders of preferred stock could be used to restrict our ability to merge with, or sell our assets to, a third-party and thereby preserve control by the present management.

Provisions of our certificate of incorporation, by-laws and Delaware law also could have the effect of discouraging potential acquisition proposals or making a tender offer or delaying or preventing a change in control, including changes a stockholder might consider favorable. Such provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. In particular, our certificate of incorporation and by-laws and Delaware law, as applicable, among other things:

- provide for a classified board of directors;
- provide the board of directors with the ability to alter the by-laws without stockholder approval;
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings; and
- provide that vacancies on the board of directors may be filled by a majority of directors in office, although less than a quorum.

Our Certificate of Incorporation designates the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware) as the exclusive forum for certain types of claims that the federal courts do not have exclusive jurisdiction, which may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable.

Article Fourteenth of our Certificate of Incorporation specifies that unless we consent in writing to the selection of an alternative forum, the court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware) shall, to the fullest extent permitted by law, be the sole and exclusive forum for: (a) any derivative action or proceeding brought on our behalf; any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers or other employees to us or to our stockholders; (b) any action asserting a claim against us arising pursuant to the Delaware General Corporation Law ("DGCL") or certificate of incorporation or our by-laws; or (c) or any action asserting a claim against us that is governed by the internal affairs doctrine. There is uncertainty as to whether a court would enforce this provision with respect to claims under the Securities Act where the state courts have concurrent jurisdiction and our stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder. The exclusive forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes against us and our directors, officers and other employees, which may discourage such lawsuits, or may require increased costs to bring a claim. The exclusive forum provision does not apply to actions brought to enforce a duty or liability created by the Exchange Act or any other claim for which federal courts have exclusive jurisdiction.

General Risk Factors

We are an "emerging growth company" and a "smaller reporting company" and will be able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies, which could make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In addition, Section 107 of the JOBS Act also provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We are not electing to delay such adoption of new or revised accounting standards, and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting

exemptions until we are no longer an "emerging growth company." We will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

Additionally, we are a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K. Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to continue to take advantage of many of the same exemptions from disclosure requirements, including presenting only the two most recent fiscal years of audited financial statements and reduced disclosure obligations regarding executive compensation in this information statement/prospectus and our periodic reports and proxy statements. We may continue to be a smaller reporting company after the Recapitalization Share Exchange is consummated if either (i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million. To the extent we take advantage of such reduced disclosure obligations, it may also make comparison of our financial statements with other public companies difficult or impossible.

We may be at risk of securities class action litigation.

We may be at risk of securities class action litigation. In the past, biotechnology and pharmaceutical companies have experienced significant stock price volatility, particularly when associated with binary events such as clinical trials and drug approvals. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business and results in a decline in the market price of our common stock.

Financial reporting obligations of being a public company in the United States require well defined disclosure and procedures and internal control over financial reporting that Allarity A/S did not have as a Danish company and that are expensive and time-consuming requiring our management to devote substantial time to compliance matters.

As a publicly traded company in the U.S., we will incur significant additional legal, accounting and other expenses that Allarity A/S did not incur as a Danish company. For example, as a Danish company with our ordinary shares listed on the Nasdaq First North Growth Market in Stockholm, we were not required to have, and did not have, well defined disclosure controls and procedures and internal controls over financial reporting that are generally required of U.S. publicly held companies. In connection with our review of our previously existing internal controls as part of our preparations for becoming a U.S. publicly traded company, we determined that our internal control over financial reporting for prior periods were ineffective and included material weaknesses that needed to be remedied. See, "— *We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weakness, or if we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business and stock price*". Although we have taken, and are continuing to take, additional steps to remedy these material weaknesses in order to assure compliance with our future financial reporting obligations, there can be no assurance that we will be able to do so in a timely manner or at all, or that additional material weaknesses may not exist.

These reporting obligations associated with being a public company in the United States require significant expenditures and will place significant demands on our management and other personnel, including costs resulting from our reporting obligations under the Securities Exchange Act of 1934, as amended, (the "Exchange Act"), and the rules and regulations regarding corporate governance practices, including those under the Sarbanes-Oxley Act of 2002, as amended, (the "Sarbanes-Oxley Act"), the Dodd-Frank Wall Street Reform and Consumer Protection Act, as amended, (the "Dodd-Frank Act"), and the listing requirements of the stock exchange on which our securities are to be listed. These rules require the establishment and maintenance of effective disclosure controls and procedures and internal controls over financial reporting and changes in corporate governance practices, among many other complex rules that are often difficult to implement, monitor and maintain compliance with. Moreover, despite recent reforms made possible by the JOBS Act, the reporting requirements, rules, and regulations will make some activities more time-consuming and costly, particularly after we are no longer an "emerging growth company." In addition, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability

insurance. Our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all of these requirements and to keep pace with new regulations, otherwise we may fall out of compliance and risk becoming subject to litigation or being delisted, among other potential problems.

If we fail to comply with the rules under the Sarbanes-Oxley Act related to our disclsoure controls and procedures or internal controls over our financial reporting in the future, or, if we discover additional material weaknesses and other deficiencies in our internal controls over financial reporting, our stock price could decline significantly and raising capital could be more difficult.

Section 404 of the Sarbanes-Oxley Act requires annual management assessments of the effectiveness of our internal controls over financial reporting after a transition period ending with our second annual report on Form 10-K filed under Section 13(a) of the Exchange Act. If we fail to comply with the rules under the Sarbanes-Oxley Act related to disclosure controls and procedures in the future, or, if in the future we discover additional material weaknesses and other deficiencies in our internal controls over financial reporting, our stock price could decline significantly and raising capital could be more difficult.

We may acquire other companies or technologies, which could divert our management's attention, result in dilution to our stockholders and otherwise disrupt our operations and adversely affect our operating results.

We may in the future seek to acquire or invest in businesses, applications and services or technologies that we believe could complement or expand our services, enhance our technical capabilities or otherwise offer growth opportunities. The pursuit of potential acquisitions may divert the attention of management and cause us to incur various expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated.

In addition, we do not have any experience in acquiring other businesses. If we acquire additional businesses, we may not be able to integrate the acquired personnel, operations and technologies successfully or effectively manage the combined business following the acquisition. We also may not achieve the anticipated benefits from the acquired business due to a number of factors, including:

- inability to integrate or benefit from acquired technologies or services in a profitable manner;
- unanticipated costs or liabilities associated with the acquisition;
- difficulty integrating the accounting systems, operations and personnel of the acquired business;
- difficulties and additional expenses associated with supporting legacy drugs and hosting infrastructure of the acquired business;
- difficulty converting the customers, if any, of the acquired business onto our platform and contract terms, including disparities in the revenue, licensing, support or professional services model of the acquired company;
- diversion of management's attention from other business concerns;
- adverse effects to our existing business relationships with business partners and customers as a result of the acquisition;
- the potential loss of key employees;
- use of resources that are needed in other parts of our business; and
- use of substantial portions of our available cash to consummate the acquisition.

In addition, a significant portion of the purchase price of companies we acquire may be allocated to acquired goodwill and other intangible assets, which must be assessed for impairment at least annually. In the future, if our acquisitions do not yield expected returns, we may be required to take charges to our operating results based on this impairment assessment process, which could adversely affect our results of operations.

Acquisitions could also result in dilutive issuances of equity securities or the incurrence of debt, which could adversely affect our operating results. In addition, if an acquired business fails to meet our expectations, our operating results, business and financial position may suffer.

Market and economic conditions may negatively impact our business, financial condition and share price.

Concerns over inflation, energy costs, geopolitical issues, the U.S. mortgage market and a declining real estate market, unstable global credit markets and financial conditions, and volatile oil prices have led to periods of significant economic instability, diminished liquidity and credit availability, declines in consumer confidence and discretionary spending, diminished expectations for the global economy and expectations of slower global economic growth going forward, increased unemployment rates, and increased credit defaults in recent years. Our general business strategy may be adversely affected by any such economic downturns, volatile business environments and continued unstable or unpredictable economic and market conditions. If these conditions continue to deteriorate or do not improve, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance, and share price and could require us to delay or abandon development or commercialization plans.

Business interruptions could adversely affect future operations, revenues, and financial conditions, and may increase our costs and expenses.

Our operations, and those of our directors, advisors, contractors, consultants, CROs, and collaborators, could be adversely affected by earthquakes, floods, hurricanes, typhoons, extreme weather conditions, fires, water shortages, power failures, business systems failures, medical epidemics and other natural and man-made disaster or business interruptions. Our phones, electronic devices and computer systems and those of our directors, advisors, contractors, consultants, CROs, and collaborators are vulnerable to damages, theft and accidental loss, negligence, unauthorized access, terrorism, war, electronic and telecommunications failures, and other natural and man-made disasters. Operating as an international company, our employees conduct business outside of our headquarters and leased or owned facilities. These locations may be subject to additional security and other risk factors due to the limited control of our employees. If such an event as described above were to occur in the future, it may cause interruptions in our operations, delay research and development programs, clinical trials, regulatory activities, manufacturing and quality assurance activities, sales and marketing activities, hiring, training of employees and persons within associated third parties, and other business activities. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

Likewise, we will rely on third parties to manufacture our therapeutic candidates and conduct clinical trials, and similar events as those described in the prior paragraph relating to their business systems, equipment and facilities could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our therapeutic candidate could be delayed or altogether terminated.

Failure to comply with current or future federal, state and foreign laws and regulations and industry standards relating to privacy and data protection laws could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.

We and our collaborators and third-party providers may be subject to federal, state and foreign data privacy and security laws and regulations. In the U.S., numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws, such as Section 5 of the Federal Trade Commission Act, that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators and third-party providers.

In many jurisdictions, enforcement actions and consequences for noncompliance are rising. In the U.S., these include enforcement actions in response to rules and regulations promulgated under the authority of federal agencies and state attorneys general and legislatures and consumer protection agencies. In addition, privacy advocates and industry groups have regularly proposed, and may propose in the future, self-regulatory standards that may legally or contractually apply to us. If we fail to follow these security standards, even if no customer information is compromised, we may incur significant fines or experience a significant increase in costs. Many state legislatures have adopted

legislation that regulates how businesses operate online, including measures relating to privacy, data security and data breaches. Laws in all 50 states require businesses to provide notice to customers whose personally identifiable information has been disclosed as a result of a data breach. The laws are not consistent, and compliance in the event of a widespread data breach is costly. States are also constantly amending existing laws, requiring attention to frequently changing regulatory requirements. Furthermore, California recently enacted the California Consumer Privacy Act (the "CCPA"), which became effective in January 2020. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. At this time, we do not collect personal data on residents of California but should we begin to do so, the CCPA will impose new and burdensome privacy compliance obligations on our business and will raise new risks for potential fines and class actions.

Foreign data protection laws, including EU General Data Protection Regulation (the "GDPR"), may also apply to health-related and other personal information obtained outside of the U.S. The GDPR, which came into effect in 2018, introduced new data protection requirements in the European Union, as well as potential fines for noncompliant companies of up to the greater of €20.0 million or 4% of annual global revenue. The regulation imposes numerous new requirements for the collection, use and disclosure of personal information, including more stringent requirements relating to consent and the information that must be shared with data subjects about how their personal information is used, the obligation to notify regulators and affected individuals of personal data breaches, extensive new internal privacy governance obligations and obligations to honor expanded rights of individuals in relation to their personal information (e.g., the right to access, correct and delete their data). Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the U.S., and the efficacy and longevity of current transfer mechanisms between the EU and the U.S. remains uncertain. For example, in 2016, the EU and U.S. agreed to a transfer framework for data transferred from the EU to the U.S., called the Privacy Shield, but the Privacy Shield was invalidated in July 2020 by the Court of Justice of the European Union. Because we undertake clinical trials in Europe, we are subject to the GDPR and as a result will increase our responsibility and potential liability in relation to personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance with the new EU data protection rules.

Compliance with U.S. and foreign data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure by us or our collaborators and third-party providers to comply with U.S. and foreign data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend, could result in adverse publicity and could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our internal computer systems, or those used by our CROs or other contractors or consultants, may fail or experience security breaches or other unauthorized or improper access.

Despite the implementation of security measures, our internal computer systems, and those of our CROs and other third parties on which we rely, are vulnerable to privacy and information security incidents, such as data breaches, damage from computer viruses and unauthorized access, malware, natural disasters, fire, terrorism, war and telecommunication, electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. While we have not experienced any such material system failure or security breach to our knowledge to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in our

regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our therapeutic candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business.

Unauthorized disclosure of sensitive or confidential data, including personally identifiable information, whether through a breach of computer systems, systems failure, employee negligence, fraud or misappropriation, or otherwise, or unauthorized access to or through our information systems and networks, whether by our employees or third parties, could result in negative publicity, legal liability and damage to our reputation. Unauthorized disclosure of personally identifiable information could also expose us to sanctions for violations of data privacy laws and regulations around the world. To the extent that any disruption or security breach resulted in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our therapeutic candidates could be delayed.

As we become more dependent on information technologies to conduct our operations, cyber incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, may increase in frequency and sophistication. These threats pose a risk to the security of our systems and networks, the confidentiality and the availability and integrity of our data and these risks apply both to us, and to third parties on whose systems we rely for the conduct of our business. Because the techniques used to obtain unauthorized access, disable or degrade service or sabotage systems change frequently and often are not recognized until launched against a target, we and our partners may be unable to anticipate these techniques or to implement adequate preventative measures. Further, we do not have any control over the operations of the facilities or technology of our cloud and service providers, including any third-party vendors that collect, process and store personal data on our behalf. Our systems, servers and platforms and those of our service providers may be vulnerable to computer viruses or physical or electronic break-ins that our or their security measures may not detect. Individuals able to circumvent such security measures may misappropriate our confidential or proprietary information, disrupt our operations, damage our computers or otherwise impair our reputation and business. We may need to expend significant resources and make significant capital investment to protect against security breaches or to mitigate the impact of any such breaches. There can be no assurance that we or our third-party providers will be successful in preventing cyber-attacks or successfully mitigating their effects. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our future therapeutic candidates could be delayed.

If, following the Recapitalization Share Exchange, securities or industry analysts do not publish or cease publishing research or reports about us, our business, or our market, or if they change their recommendations regarding our securities adversely, the price and trading volume of common stock could decline.

The trading market for common stock will be influenced by the research and reports that industry or securities analysts may publish about us, our business, market or competitors. Securities and industry analysts do not currently, and may never, publish research on us. If no securities or industry analysts commence coverage of us, our share price and trading volume would likely be negatively impacted. If any of the analysts who may cover us change their recommendation regarding our common stock adversely, or provide more favorable relative recommendations about our competitors, the price of our common stock would likely decline. If any analyst who may cover us were to cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our share price or trading volume to decline.

Comprehensive tax reform bills could adversely affect our business and financial condition.

The U.S. government recently enacted comprehensive federal income tax legislation that includes significant changes to the taxation of business entities. These changes include, among others, a permanent reduction to the corporate income tax rate. Notwithstanding the reduction in the corporate income tax rate, the overall impact of this tax reform is uncertain, and our business and financial condition could be adversely affected. This information statement/prospectus does not discuss any such tax legislation or the manner in which it might affect purchasers of our common stock. We urge our stockholders to consult with their legal and tax advisors with respect to any such legislation and the potential tax consequences of investing in our common stock.

ALLARITY A/S EXTRAORDINARY GENERAL MEETING OF SHAREHOLDERS

General

Allarity A/S is sending this information statement/prospectus to its shareholders to help them decide how to vote their Allarity A/S ordinary shares with respect to the matters to be considered at the Allarity A/S Extraordinary General Meeting. This information statement/prospectus provides Allarity A/S's shareholders with information they need to know to be able to vote or direct their vote to be cast at the Allarity A/S Extraordinary General Meeting.

Date, Time and Place

The Allarity A/S Extraordinary General Meeting will be held on November 22, 2021 at 10:00 a.m. Central European Time at the offices of Manzanti-Andersen Advokatpartnerselskab, Amaliegada 10, DK-1256, Copenhagen K. The Allarity A/S Extraordinary General Meeting will be held virtually via live webcast in English without the possibility of voting online. You will be able to attend the Allarity A/S Extraordinary General Meeting by following the instructions on *www.allarity.com/egm2021*.

Purpose of Allarity A/S Extraordinary General Meeting

Allarity A/S shareholders are being asked to vote on the following proposals:

1. The Recapitalization Share Exchange Proposals which includes votes on three separate resolutions consisting of (1.A) a resolution to approve the sale of substantially all of the assets, and the assumption of substantially all of the liabilities of Allarity A/S to Acquisition Sub in exchange for Delaware Common Stock; (1.B) a resolution to approve the share exchange swap program; and (1.C) a resolution to approve the declaration and payment of an extraordinary dividend of the Delaware Common Stock to shareholders who have not participated in the share exchange swap program.

2. the Nasdaq Pipe Proposal; and

3. the Incentive Plan Proposal.

The Recapitalization Share Exchange is conditioned upon the approval of each of the proposals. Failure to receive approval of any of the proposals provides each of Allarity A/S and Allarity Delaware with a right to terminate the Reorganization Agreement. If our shareholders do not approve each of the proposals, the reorganization may not be consummated. If the Recapitalization Share Exchange Proposals is not approved, each of the other proposals will not be presented to the shareholders for a vote.

Recommendation of the Allarity A/S Board of Directors

The Allarity A/S board of directors has unanimously determined that the Recapitalization Share Exchange, on the terms and conditions set forth in the Reorganization Agreement, are advisable and in the best interests of Allarity A/S and its shareholders and has directed that the proposals set forth in this information statement/prospectus be submitted to its shareholders for approval at the Allarity A/S Extraordinary General Meeting on the date and at the time and place set forth in this information statement/prospectus. The Allarity A/S board of directors unanimously recommends that Allarity A/S's shareholders vote "**FOR**" The Recapitalization Share Exchange Proposals, "**FOR**" the Nasdaq Pipe Proposal, and "**FOR**" the Incentive Plan Proposal.

Voting Power; Record Date

You will be entitled to vote or direct votes to be cast at the Allarity A/S Extraordinary General Meeting if you owned shares of Allarity A/S ordinary shares at the close of business on November 15, 2021, which is the record date for the Allarity A/S Extraordinary General Meeting. You are entitled to one vote for each share of Allarity A/S ordinary shares that you owned as of the close of business on the Allarity A/S record date. If your shares are held in "street name" or are in a margin or similar account, you should contact your broker, bank or other nominee to ensure that votes related to the shares you beneficially own are properly counted. On the record date, there were 403,791,200 ordinary shares outstanding.

Quorum and Required Vote for Proposals for the Allarity A/S Extraordinary General Meeting

Under the DCA, a quorum of a specific number of ordinary shares present in person or by proxy at the Allarity A/S Extraordinary General Meeting is not necessary to hold a valid meeting. Consequently, the required vote will be calculated based only on the number of ordinary shares that are present in person or by proxy at the Allarity A/S Extraordinary General Meeting even if less than a majority of the issued and outstanding ordinary shares are present in person or by proxy at the meeting.

The Recapitalization Share Exchange Proposals: Approval of Proposals 1.A and 1.D of The Recapitalization Share Exchange Proposals requires the affirmative vote of 66.67% of the votes cast and the share capital represented at the Allarity A/S Extraordinary General Meeting while a majority of the votes cast and the share capital represented at the Allarity A/S Extraordinary General Meeting is required to approve Proposal 1.B and 1.C of The Recapitalization Share Exchange Proposals.

The Nasdaq Pipe Proposal: The affirmative vote of a majority of the votes cast and the share capital represented at the Allarity A/S Extraordinary General Meeting is required to approve the Nasdaq Pipe Proposal. Notwithstanding the approval of the Nasdaq Pipe Proposal, if the reorganization is not consummated for any reason, the actions contemplated by the Nasdaq Pipe Proposal will not be effected.

The Incentive Plan Proposal: The affirmative vote of 66.67% of the votes cast and the share capital represented at the Allarity A/S Extraordinary Meeting is required to approve the Incentive Plan Proposal. Notwithstanding the approval of the Incentive Plan Proposal, if the reorganization is not consummated for any reason, the actions contemplated by the Incentive Plan Proposal will not be effected.

The Recapitalization Share Exchange is conditioned upon the approval of each of the proposals. Failure to receive approval of any of the proposals provides each of Allarity A/S and Allarity Delaware with a right to terminate the Reorganization Agreement. If our shareholders do not approve each of the proposals, the Recapitalization Share Exchange may not be consummated. If The Recapitalization Share Exchange Proposals is not approved, each of the other proposals (except the Adjournment Proposal) will not be presented to the shareholders for a vote.

It is important for you to note that in the event that any of The Recapitalization Share Exchange Proposals, the Nasdaq Pipe Proposal, or the Incentive Plan Proposal do not receive the requisite vote for approval, then the Recapitalization Share Exchange may not be consummated. If Allarity A/S does not consummate the Recapitalization Share Exchange, Allarity A/S will continue as an *Aktieselskab* organized under the laws of Denmark with its ordinary shares listed on the Nasdaq First North Growth Market in Stockholm.

Recommendation of the Allarity A/S Board of Directors

Allarity A/S's board of directors unanimously determined that the Reorganization Agreement and the transactions contemplated thereby, including the Recapitalization Share Exchange, were advisable, fair to, and in the best interests of, Allarity A/S and its shareholders. Accordingly, Allarity A/S's board of directors unanimously recommends that its shareholders vote "FOR" The Recapitalization Share Exchange Proposals and each of the other proposals hereby.

In considering the recommendation of the board of directors of Allarity A/S to vote in favor of approval of The Recapitalization Share Exchange Proposals, the Nasdaq Pipe Proposal, and the Incentive Plan Proposal, shareholders should keep in mind that certain members of the board of directors and executive officers of Allarity A/S have interests in such proposals that are different from, or in addition to, those of Allarity A/S shareholders generally. These interests include, among other things:

- All of the named executive officers and certain directors of Allarity A/S have received compensatory warrants to purchase Allarity A/S ordinary shares. As explained in the section titled "*The Reorganization Agreement — Treatment of Compensatory Warrants*," those warrants granted to our named executive officers and certain directors will convert into options to purchase approximately 673,268 Delaware Common Stock, representing approximately 1.8% of the common stock of Allarity Delaware issued and outstanding at the effective time, based on our anticipation of issuing approximately 8,075,824 shares of Delaware Common Stock in the Recapitalization Share Exchange. *See, SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT*.

- After the Recapitalization Share Exchange, we may enter into new employment agreements with our executive officers with potential increases in compensation and benefits. It has not yet been determined whether there will be any such agreements or, if so, what their terms would be.
- Under the terms of the employment agreements for our Chief Executive Officer Steve Carchedi, and our Senior Vice President-Corporate Development James G. Cullem, 1,761,937 of Mr. Carchedi's unvested warrants and 430,696 of Mr. Cullem's unvested warrants will accelerate and become vested when such warrants are converted into options to purchase Delaware Common Stock.
- Allarity A/S's officers and directors will receive continued indemnification and liability insurance after the reorganization.

Abstentions and Broker Non-Votes

Abstentions are considered present for the purposes of calculating the required vote for each proposal and will have the same effect as a vote "**AGAINST**" each of the proposals. Broker non-votes are otherwise present for the purposes of calculating the required vote for each proposal will have the same effect as a vote "**AGAINST**" each of the proposals.

Voting Your Shares

The Allarity A/S Extraordinary General Meeting will be held as a physical meeting with a live webcast in English. Shareholders wishing to attend the Allarity A/S Extraordinary General Meeting must notify Allarity A/S of their attendance prior to the meeting as set out in the convening notice. Shareholders may — instead of opting for physical attendance — vote by proxy or by mail prior to the meeting, and such shareholders can follow the general meeting online via live webcast in English with a link being made available on *www.allarity.com/egm2021*. Whether voting in person or by proxy or mail, the right to vote at the Allarity A/S Extraordinary General Meeting is determined on the basis of the shares held by the shareholder at the Allarity A/S record date. The shareholdings and voting rights are calculated on the basis of entries in the Allarity A/S shareholders' register and any notice of ownership received by Allarity A/S for the purpose of registration in the shareholders' register. Shareholders wishing to exercise their voting rights at the Allarity A/S Extraordinary General Meeting are encouraged to contact their depository bank well in advance of the Allarity A/S record date to ensure correct and sufficient registration.

Revoking Your Proxy

If you are a record owner of your shares and you give a proxy or voting instruction, you may change or revoke it at any time before it is exercised by doing any one of the following:

- you may send another proxy card with a later date;
- you may notify Allarity A/S's secretary in writing before the Allarity A/S Extraordinary General Meeting that you have revoked your proxy or voting instruction; or
- you may attend the Allarity A/S Extraordinary General Meeting, revoke your proxy or voting instruction, and vote in person as described above.

If your shares are held in "street name" or are in a margin or similar account, you should contact your broker for information on how to change or revoke your voting instructions.

No Additional Matters May be Presented at the Allarity A/S Extraordinary General Meeting

The Allarity A/S Extraordinary General Meeting has been called only to consider the approval of The Recapitalization Share Exchange Proposals, the Nasdaq Pipe Proposal, and the Incentive Plan Proposal. No other matters may be considered at the Allarity A/S Extraordinary General Meeting if they are not included in this information statement/prospectus, which serves as the notice of the Allarity A/S Extraordinary General Meeting.

Who Can Answer Your Questions About Voting

If you have any questions about how to vote or direct a vote in respect of your Allarity A/S ordinary shares, you may call +45 88 74 24 15 or email investorrelations@allarity.com.

Appraisal Rights

Appraisal rights are not available to holders of Allarity A/S ordinary shares in connection with the Recapitalization Share Exchange.

Proxy and Voting Solicitation Costs

Allarity A/S is soliciting your votes for the approval of the proposals. This solicitation is being made in accordance with Danish law by press release, publication on our website, but also may be made by mail, telephone or in person. Allarity A/S and its directors, officers and employees may also solicit proxies or votes in person. Allarity A/S will file with the SEC all scripts and other electronic communications as proxy soliciting materials. Allarity A/S will bear the cost of the solicitation.

Allarity A/S will ask banks, brokers and other institutions, nominees and fiduciaries to forward the proxy materials to their principals and to obtain their authority to execute proxies and voting instructions. Allarity A/S will reimburse them for their reasonable expenses.

ALLARITY A/S PROPOSALS

References in this section to "we," "us," "our," and "the Company" are intended to mean Allarity A/S Acquisition Corp.

PROPOSAL NO. 1 — THE RECAPITALIZATION SHARE EXCHANGE PROPOSALS

Holders of Allarity A/S ordinary shares are being asked to approve the Reorganization Agreement and the transactions contemplated thereby, including the Recapitalization Share Exchange. Allarity A/S shareholders should read carefully this information statement/prospectus in its entirety for more detailed information concerning the Reorganization Agreement, which is attached as Annex A to this information statement/prospectus. Please see the sections titled "*The Recapitalization Share Exchange*" and "*The Reorganization Agreement*" in this information statement/prospectus for additional information regarding the Recapitalization Share Exchange and a summary of certain terms of the Reorganization Agreement. You are urged to read carefully the Reorganization Agreement in its entirety before voting on this proposal. In order to consummate the Recapitalization Share Exchange, shareholders will be asked to vote upon the following proposals:

1.A. To consider and vote upon a resolution approving the sale of substantially all of the assets and the assumption of liabilities of Allarity A/S to Acquisition Sub in exchange for Allarity Delaware Common Stock.

1.B. To consider and vote upon a resolution approving the initiation by the board of directors of a share swap program as further described in an Offer Document to be prepared by Allarity A/S's Danish legal counsel involving, inter alia, the exchange of 0.02 shares of Delaware Common Stock for each Allarity A/S ordinary share and in connection therewith adopting the following resolution:

Proposal to decrease the Company's share capital from nominal DKK 20,189,560 to nominal DKK 400,000 against distributions to shareholders, payment of losses and/or transfers to a special reserve fund.

1.C. To consider and vote upon a resolution approving that the board of directors pursuant to its current authorization in the articles of association declare and pay an extraordinary dividend of 0.02 shares of Delaware Common Stock for each Allarity A/S ordinary share that has not exchanged their shares in the share swap program.

1.D. To amend the authorization in article 6.12 of the articles of association to the effect that the board of directors is authorized to issue warrants conferring the right to subscribe for up to nominal DKK 2,750,000 with an exercise price that is not below SEK 0.945 per share of nominal DKK 0.05. The proposed amended wording of paragraph 1 of 6.12 will thus be as follows:

The board of directors is authorized during the period until 30 August 2026 on one or more occasions to issue warrants to the board members, employees, advisors and consultants of the company or its subsidiaries entitling the holder to subscribe for shares for a total of up to nominal DKK 2,750,000 without pre-emptive rights for the company's shareholders. The exercise price for the warrants shall not be less than SEK 0.945. The board of directors shall determine the terms for the warrants and the distribution hereof.

In paragraph 2 of article 6.12, 2,049,006.75 is changed to 2,750,000.

Allarity A/S shareholders must approve Proposals 1.A, 1.B, 1.C and 1.D in order to approve Proposal No. 1.

Allarity A/S may consummate the Recapitalization Share Exchange only if Proposals 1.A and 1.D of The Recapitalization Share Exchange Proposals receives votes FOR Proposals 1.A and 1.D of at least 66.67% of the votes cast and the share capital represented at the Allarity A/S Extraordinary General Meeting and a majority of the votes cast and the share capital represented at the Allarity A/S Extraordinary General Meeting are voted FOR Proposals 1.B and 1.C of The Recapitalization Share Exchange Proposals.

United States Federal Income Tax Considerations

The following is a discussion of U.S. federal income tax considerations for holders of Allarity A/S ordinary shares that receive Delaware Common Stock in the Recapitalization Share Exchange. This discussion applies only to Allarity A/S ordinary shares that is held as a capital asset for U.S. federal income tax purposes (generally, property held for investment). This discussion does not describe all of the U.S. federal income tax consequences that may be

relevant to you in light of your particular circumstances, including the alternative minimum tax, the Medicare tax on certain investment income and the different consequences that may apply if you are subject to special rules that apply to certain types of investors, such as:

- banks and financial institutions;
- insurance companies;
- brokers and dealers in securities, currencies or commodities;
- dealers or traders in securities subject to a mark-to-market method of accounting with respect to shares of Allarity A/S Class A common stock;
- regulated investment companies and real estate investment trusts;
- governmental organizations and qualified foreign pension funds;
- persons holding Allarity A/S Class A common stock as part of a "straddle," hedge, integrated transaction or similar transaction;
- U.S. holders (as defined below) whose functional currency is not the U.S. dollar;
- partnerships or other pass-through entities for U.S. federal income tax purposes (and investors in such entities);
- certain former citizens or long-term residents of the United States;
- controlled foreign corporations and passive foreign investment companies; and
- tax-exempt entities.

If a partnership or entity treated as a partnership for U.S. federal income tax purposes holds Allarity A/S ordinary shares, the U.S. federal income tax treatment of the partners in the partnership will generally depend on the status of the partners and the activities of the partnership. Partners in partnerships holding Allarity A/S ordinary shares should consult their tax advisors.

This discussion is based on the Code and administrative pronouncements, judicial decisions and final, temporary and proposed Treasury regulations as of the date hereof, changes to any of which subsequent to the date of this information statement/prospectus may affect the tax consequences described herein. No assurance can be given that the IRS would not assert, or that a court would not sustain, a position contrary to any of the tax considerations described below. No advance ruling has been or will be sought from the IRS regarding any matter discussed in this summary. This discussion does not address any aspect of state, local or non-U.S. taxation, or any U.S. federal taxes other than income taxes (such as gift and estate taxes).

You are urged to consult your tax advisor with respect to the application of U.S. federal tax laws to your particular situation, as well as any tax consequences arising under the laws of any state, local or foreign jurisdiction.

U.S. Holders

This section applies to you if you are a "*U.S. holder*." A U.S. holder is a beneficial owner of Allarity A/S ordinary shares who or that is, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation (or other entity taxable as a corporation for U.S. federal income tax purposes) organized in or under the laws of the U.S., any state thereof or the District of Columbia;
- an estate the income of which is subject to U.S. federal income tax purposes regardless of its source; or
- a trust, if (A) a court within the U.S. is able to exercise primary supervision over the administration of such trust and one or more "United States persons" (within the meaning of the Code) have the authority to control all substantial decisions of the trust or (B) the trust validly elected to be treated as a United States person for U.S. federal income tax purposes.

Material U.S. Federal Income Tax Consequences of the Recapitalization Share Exchange as a Tax-Free Reorganization

The following is a general summary of the material anticipated U.S. federal income tax consequences of the Recapitalization Share Exchange. The discussion is based upon the Code, Treasury regulations, court decisions, published positions of the Internal Revenue Service ("IRS") and other applicable authorities, all as in effect on the date hereof and all of which are subject to change or differing interpretations (possibly with retroactive effect). The discussion is limited to U.S. persons who hold ordinary shares of Allarity A/S as capital assets for U.S. federal income tax purposes (generally, assets held for investment). This summary does not address all of the U.S. federal income tax consequences that may be relevant to a particular shareholder or to shareholders who may be subject to special treatment under U.S. federal income tax laws. No ruling has been or will be obtained from the IRS regarding any matter relating to the Reorganization. No assurance can be given that the IRS would not assert, or that a court would not sustain, a position contrary to any of the tax aspects described below. Prospective investors must consult their own tax advisers as to the U.S. federal income tax consequences of the Reorganization, as well as the effects of state, local and non-U.S. tax laws.

The federal income tax consequences with respect to the Recapitalization Share Exchange will be dependent upon the particular facts in existence prior to and at the time of the Recapitalization Share Exchange. In addition, the application of certain aspects of the federal income tax law to the proposed Recapitalization Share Exchange is unclear and subject to alternative interpretations.

The parties believe that the Recapitalization Share Exchange will be characterized for U.S. federal income tax purposes as a tax-free reorganization under Section 368(a) of the Code. It may, however, be treated as a taxable transaction in which Allarity A/S is deemed to have sold all of its assets for federal income tax purposes and the Allarity A/S shareholders are deemed to have exchanged their respective stock in a taxable sale. Even though the Recapitalization Share Exchange may qualify as a tax-free reorganization for U.S. federal income tax purposes for U.S. Holders, we anticipate that the Recapitalization Share Exchange will be characterized as a taxable transaction in Denmark. See, *Income Tax Considerations for Non-U.S. Holders.*

Requirements to Qualify as a Tax-Free Reorganization

Under Code Section 368(a)(1)(C), a transaction that results in an exchange of stock of an acquiring corporation, or stock of a corporation controlling the acquiring corporation, for substantially all of the assets of another corporations may qualify as a tax-free reorganization. In addition to the statutory requirements, the transaction needs to satisfy the continuity of proprietary interest, continuity of business enterprise, and business purpose requirements, all of which should be satisfied in the contemplated Recapitalization Share Exchange.

Federal Income Tax Consequence if the Recapitalization Share Exchange Qualifies as a Tax-Free Reorganization

Our counsel, Lewis Brisbois Bisgaard & Smith LLP has delivered an opinion that the statements set forth in this information statement/prospectus under the caption heading Federal Income Tax Considerations if the Recapitalization Share Exchange Qualifies as a Tax-Free Reorganization constitutes our opinion as to the material U.S. federal income tax consequences of the Recapitalization Share Exchange to U.S. Holders of Allarity A/S ordinary shares. Such opinion is filed as Exhibit 8.1 to the registration statement of which this information statement/prospectus forms a part and is based on customary assumptions, representations and covenants. If any of the assumptions, representations or covenants on which the opinion is based is or becomes incorrect, incomplete, inaccurate or is otherwise not complied with, the validity of the opinion described above may be adversely affected and the tax consequences of the Recapitalization Share Exchange could differ from those described herein. An opinion of counsel is not binding on the IRS or any court, and there can be no certainty that the IRS will not challenge the conclusions reflected in the opinion or that a court would not sustain such a challenge. Assuming the Recapitalization Share Exchange is consummated in accordance with the Reorganization Agreement and as described in this information statement/prospectus, the Recapitalization Share Exchange should qualify as a tax-free reorganizations as to Allarity Delaware within the meaning of Section 368(a) of the Code, and the U.S. federal income tax consequences of the Recapitalization Share Exchange can be summarized as follows:

- No gain or loss will be recognized by Allarity Delaware upon the Recapitalization Share Exchange.
- No gain or loss will be recognized by a U.S. Holder who receives Delaware Common Stock pursuant to the Recapitalization Share Exchange.

- The aggregate tax basis of Delaware Common Stock received by a U.S. Holder pursuant to the Recapitalization Share Exchange will be the same as the aggregate tax basis of the ordinary shares Allarity A/S surrendered in exchange therefor.
- The holding period of Delaware Common Stock received by a shareholder of Allarity A/S pursuant to the Recapitalization Share Exchange will include the holding period of Allarity A/S ordinary shares surrendered in exchange therefor.
- Allarity Delaware's tax basis in the Allarity A/S assets received by Allarity Delaware pursuant to the Recapitalization Share Exchange will equal the tax basis of such assets in the hands of Allarity A/S immediately prior to the Recapitalization Share Exchange, and Allarity Delaware's holding period of such assets will, in each instance, include the period during which the assets were held by Allarity A/S.

Because the Recapitalization Share Exchange involves parties that are tax residents of the U.S. and Denmark, the parties may seek relief from double taxation under the terms of the prevailing tax treaty between the U.S. and Denmark. Because the deferral of Denmark taxation on its tax residents is solely in the discretion of the Danish Tax Authorities upon application by the parties, it is uncertain whether the tax treaty between the U.S. and Denmark will provide any tax deferrals to tax residents of Denmark.

The tax consequences described above also assume that the IRS will apply Revenue Ruling 98-10 to treat the issuance of the Converted Options by Allarity Delaware in exchange for the Compensatory Warrants of Allarity A/S as "separate from" the acquisition of substantially all of the assets and the assumption of substantially all of the liabilities in exchange for the Delaware common stock issued in Recapitalization Share Exchange, but still "in pursuance of the plan of reorganization" as described therein.

Federal Income Tax Consequence if the Recapitalization Share Exchange Fails to Qualify as a Tax-Free Reorganization

If the Recapitalization Share Exchange fails to qualify as a tax-free reorganization for any reason, the transaction will be taxable to Allarity A/S shareholders that are also U.S. Holders. For example, the Recapitalization Share Exchange fails to qualify as a tax tree reorganization, Allarity A/S will be deemed to have sold all of its assets to Allarity Delaware in a taxable transaction, followed by a deemed liquidation of Allarity A/S and a distribution of the sales proceeds (the Delaware Common Stock) to Allarity A/S's shareholders. Based upon current market values, Allarity A/S anticipates that it would recognize a net gain for federal income tax purposes on such deemed sale which may be substantially off-set by the amount of taxes paid to Denmark. Each Allarity A/S shareholder who is a U.S. Holder would recognize gain or loss on the liquidating distribution in an amount equal to the difference between the fair market value of the Delaware Common Stock received in the Recapitalization Share Exchange and such shareholder's basis in its Allarity A/S stock. Allarity Delaware's basis in the purchased assets would include (i) its historic basis in the assets previously held by Allarity Delaware and (ii) the fair market value of the Allarity A/S assets as of the date of the Recapitalization Share Exchange. Allarity Delaware, after the Recapitalization Share Exchange, would not succeed to any net operating or capital loss carry forwards of Allarity A/S.

Reporting Requirements

An Allarity A/S shareholder who receives Delaware Common Stock as a result of the Recapitalization Share Exchange may be required to retain records pertaining to the Recapitalization Share Exchange. Each Allarity A/S shareholder who is required to file a federal income tax return and who is a "significant holder" that receives Delaware Common Stock in the Recapitalization Share Exchange will be required to file a statement with the holder's federal income tax return setting forth, among other things, the holder's basis in the Allarity A/S ordinary shares surrendered and the fair market value of the Delaware Common Stock and cash, if any, received in the Recapitalization Share Exchange. A "significant holder" is a holder of Allarity A/S shares who, immediately before the Recapitalization Share Exchange, owned at least 5% of the outstanding Allarity A/S ordinary shares.

Backup Withholding and Information Reporting

We may be required to withhold U.S. federal income tax at a rate of 24% from all distributions and redemption proceeds payable to shareholders who fail to provide us with their correct taxpayer identification number or to make required certifications, or who have been notified by the IRS that they are subject to backup withholding. Corporate

shareholders and certain other shareholders specified in the Code generally are exempt from such backup withholding. This withholding is not an additional tax. Any amounts withheld may be credited against the shareholder's federal income tax liability, provided the required information is furnished to the IRS.

The Foreign Account Tax Compliance Act

Sections 1471-1474 of the Code and the U.S. Treasury and IRS guidance issued thereunder (collectively, "FATCA") generally require us to obtain information sufficient to identify the status of each of its shareholders. If a shareholder fails to provide this information or otherwise fails to comply with FATCA, we may be required to withhold under FATCA at a rate of 30% with respect to that shareholder on our dividends and distributions and sale, redemption or exchange proceeds. We may disclose the information that we receive from (or concerning) our shareholders to the IRS, non-U.S. taxing authorities or other parties as necessary to comply with FATCA, related intergovernmental agreements or other applicable law or regulation. Investors are urged to consult their own tax advisers regarding the applicability of FATCA and any other reporting requirements with respect to the investor's own situation, including investments through an intermediary.

Income Tax Considerations for Non-U.S. Holders

We believe that a substantial majority of Allarity A/S shareholders are not "U.S. Holders" and therefore the United States Federal Income Tax Considerations would not be applicable to a substantial majority of Allarity A/S shareholders. Consequently, you are urged to consult your tax advisor with respect to the application of the tax laws in your country of tax residency as they may apply to your particular situation, as well as any tax consequences of the Recapitalization Share Exchange arising under the laws of any local or foreign jurisdiction.

Absent the application of the tax treaty between the U.S. and Denmark (the "U.S./Denmark Tax Treaty"), we do not believe that the Recapitalization Share Exchange will qualify as a tax free transaction under the laws of Denmark. Consequently, Denmark may tax Allarity A/S as if Allarity A/S sold all of its assets at fair market value and impose a capital gain tax on the difference between the fair market value of the assets and the tax basis Allarity A/S has in its assets. Under the U.S./Denmark Tax Treaty, Allarity Delaware may make an application to the Danish tax authority to have the tax imposed on the sale of Allarity A/S assets "deferred" until Allarity Delaware sells the assets purchased in the Recapitalization Share Exchange in a taxable transaction applicable under U.S. tax law in order to preserve the availability of foreign tax credits and other provisions intended to avoid "double taxation" of transactions covered by the treaty. Deferral of the payment of the tax is subject to the absolute discretion of the Danish tax authorities. Therefore, no assurances can be given that such deferment will be granted or that Allarity Delaware will apply for such deferment after further consultation with its tax advisers.

For Allarity A/S shareholders who are citizens or tax residents of Denmark, we also do not believe that the Recapitalization Share Exchange may be a tax free transaction to you. In this respect, the amount of tax you may owe will depend upon whether you participate in the proposed share swap program, or if you receive Delaware Common Stock in the Recapitalization Share Exchange as an extraordinary dividend. If you participate in the proposed share swap program to receive your Delaware Common Stock, Denmark may treat your transaction as a taxable sale of your ordinary shares at the value of the Delaware Common Stock received as consideration for the sale. You would then be taxed on the difference between the value of the Delaware Common Stock received and the tax basis you have in your ordinary shares sold in the share swap program as a capital gain. On the other hand, if you receive your Delaware Common Stock as an extraordinary dividend, you would pay a tax on the full value of the Delaware Common Stock you receive as a dividend. **You should consult your own tax advisor to determine whether you should participate in the share exchange swap program or wait to receive your shares of Delaware Common Stock as a fully taxable dividend subject to applicable withholding requirements.**

Recommendation of the Allarity A/S Board of Directors

ALLARITY A/S'S BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS THAT ITS SHAREHOLDERS VOTE "FOR" THE RECAPITALIZATION SHARE EXCHANGE PROPOSALS.

The existence of financial and personal interests of Allarity A/S's directors may result in a conflict of interest on the part of one or more of the directors between what they may believe is in the best interests of Allarity A/S and its shareholders and what they may believe is best for themselves in determining to recommend that shareholders vote for the proposals. See *"The Recapitalization Share Exchange — Interests of Certain Persons in the Recapitalization Share Exchange"* beginning on page 239 of this information statement/prospectus.

PROPOSAL NO. 2 — THE NASDAQ PIPE PROPOSAL

Overview

In connection with the Recapitalization Share Exchange, the shareholders of Allarity A/S who will become the shareholders of Allarity Delaware upon consummation of the Recapitalization Share Exchange are being asked to approve, for purposes of complying with applicable listing rules of the Nasdaq Stock Market, (a) the issuance 20,000 shares of Allarity Delaware Series A Convertible Preferred Stock that is initially convertible into 2,018,958 shares of Allarity Delaware Common Stock, and (b) the issuance of a common stock purchase warrant for an additional 2,018,958 shares of Allarity Delaware common stock, to 3i, LP, a Delaware limited partnership in the PIPE Investment.

Why Allarity A/S Needs Shareholder Approval

We are seeking shareholder approval in order to comply with Rule 5635(d) of the Nasdaq Stock Market listing rules ("Rule 5635(d)").

Under Rule 5635(d), shareholder approval is required prior to the issuance of shares of common stock in certain circumstances, including if the number of shares of common stock to be issued is, or will be upon issuance, equal to or in excess of 20% of the number of shares of common stock outstanding before the issuance. The shares of Allarity Delaware Series A Preferred Stock to be issued to 3i, LP, a Delaware limited partnership, that is convertible into shares of Allarity Delaware common stock and the common stock purchase warrant to be issued to 3i, LP, a Delaware limited partnership, in the PIPE Investment will represent greater than 20% of the number of shares of Allarity Delaware common stock before such issuance as of the effective time of the Recapitalization Share Exchange on an "as converted basis" and without giving effect to 4.99% beneficial ownership limitation. As a result, shareholder approval of the issuance of the Series A Convertible Preferred Stock and the common stock purchase warrant issued to 3i, LP, a Delaware limited partnership in the PIPE Investment is required under Rule 5635(d).

Description of the PIPE Investment Agreement

The following is a summary of the material terms and conditions of the agreements we have entered into with 3i, LP, a Delaware limited partnership, for an investment of $20 million in our Series A Convertible Preferred Stock conditioned upon, among other things, the consummation of the Recapitalization Share Exchange. The following summary is qualified in its entirety by reference to the complete text of each of the agreements. The full text of these agreements, or forms thereof, are filed as exhibits to the registration statement of which this information statement/prospectus forms a part, and the following descriptions are qualified in their entirety by the full text of such exhibits. Shareholders and other interested parties are urged to read such related agreements in their entirety prior to voting on the proposals presented at the Allarity A/S Extraordinary General Meeting.

Securities Purchase Agreement

On May 20, 2021, we entered into a Securities Purchase Agreement (the "SPA") with 3i, LP, a Delaware limited partnership for the purchase and sale of 20,000 shares of our Series A Convertible Preferred Stock (the "Preferred Shares") for $1,000 per share for an aggregate purchase price of $20 million. The closing of the PIPE Investment is conditioned upon, among other things, an effective registration statement covering the resale of the shares of our common stock to be issued upon conversion of the Preferred Shares (the "Conversion Shares"), the consummation of the Recapitalization Share Exchange, and the listing of the Conversion Shares on the Nasdaq Stock Market. At the closing of the PIPE Investment, 3i, LP will also be issued a common stock purchase warrant to purchase up to an additional $20 million of our common stock at an initial exercise price equal to the fixed conversion price of the Preferred Shares, or approximately 2,018,958 shares with an exercise price of $9.906, for a term of three years from the closing date of the PIPE Investment.

Under the terms of the SPA and the agreed upon form of Certificate of Designations (the "COD") setting forth the rights, preferences, privileges and restrictions for the Preferred Shares, the Preferred Shares will be entitled to convert into shares of our common stock at an initial fixed conversion price of $9.906 per share, subject to a beneficial ownership limitation of 4.99% which can adjusted to a beneficial ownership limitation of 9.99% upon 61 days prior written notice. For purposes of calculating the beneficial ownership limitation, 3i, LP's beneficial ownership of our common stock will be calculated under the rules promulgated under Section 13(d) of the Securities Exchange Act of

1934, as amended (the "Exchange Act"). If there were no beneficial ownership limitation in the COD, the Preferred Shares would be entitled to convert into 2,018,958 shares of our common stock immediately after the closing of the PIPE Investment, or 20% of our anticipated issued and outstanding shares of common stock.

Under the terms of the COD, the fixed conversion price of the preferred shares will be calculated at the closing of the PIPE Investment by dividing $80 million by the number of shares of common stock we issue in the Recapitalization Share Exchange at the effective time. We anticipate issuing 8,075,824 shares of our common stock at the effective time of the Recapitalization Share Exchange resulting in a fixed conversion price for the Preferred Shares, and the exercise price for the common stock purchase warrant, of $9.906. In the event that the volume weighted average price ("VWAP") for the five days prior to conversion of the Preferred Shares is less than the fixed conversion price, or other triggering events, the Preferred Shares are entitled to convert at a price equal to 90% of the five day VWAP, but not less than 20% of the fixed conversion price, or if thirty days after our common stock commences trading on the Nasdaq Stock Market the average daily dollar volume for the five days previous to conversion is less than $2,000,000, then the Preferred Shares are entitled to convert at the lower of the fixed conversion price equal to 80% of the five day VWAP, but not less than 20% of the fixed conversion price. In addition, the COD and the common stock purchase warrants provide for an adjustment to the conversion price and exercise of the warrant in the event of a "new issuance" of our common stock, or common stock equivalents, at a price less than the applicable conversion price of the Preferred Shares or exercise price of the common stock purchase warrant. The adjustment is a "full ratchet" adjustment in both the conversion price of the Preferred Shares and the exercise price of the common stock purchase warrant equal to the lower of the new issuance price or the then existing conversion price of the Preferred Shares or exercise price of the common stock purchase warrants, with few exceptions.

If certain defined "triggering events" defined in the COD occur, such as a breach of the Registration Rights Agreement, suspension of trading, or our failure to convert the Preferred Shares into common stock when a conversion right is exercised, or failure to issue our common stock when the common stock purchase warrant is exercised, then we may be required to redeem the Preferred Shares for cash. In addition, if thirty days after our common stock commences trading on the Nasdaq Stock Market the average daily dollar volume for the five days previous to conversion is less than $2,500,000, then the Preferred Shares shall be entitled to a one time dividend equal to an 8% increase in the stated value of the Preferred Share, or an $80 increase per share in stated value, resulting in a stated value of $1,080 per Preferred Share.

Registration Rights Agreement

Concurrently with the execution of the SPA, we entered into a Registration Rights Agreement (the "RRA") with 3i, LP in which we have agreed to register the shares of our common stock issuable upon conversion of the Preferred Shares and the exercise of the common stock purchase warrant with the SEC for resale. Under the RRA, we have agreed to file a registration statement on Form S-1 with the SEC within 15 business days of filing the registration statement of which this information statement/prospectus is a part, and to have the registration statement declared effective within 60 calendar days from the date we first register our common stock under the Exchange Act. The RRA also contains usual and customary liquidated damages provisions for failure to file and failure to have the registration statement declared effective by the SEC within the time periods specified.

Vote Required

The affirmative vote of a majority of the votes cast by holders of Allarity A/S ordinary shares present in person or represented by proxy at the Allarity A/S Extraordinary General Meeting is required to approve the Nasdaq Pipe Proposal.

Recommendation of the Allarity A/S Board of Directors

ALLARITY A/S'S BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS THAT ITS SHAREHOLDERS VOTE "FOR" THE NASDAQ PIPE PROPOSAL.

The existence of financial and personal interests of Allarity A/S's directors may result in a conflict of interest on the part of one or more of the directors between what they may believe is in the best interests of Allarity A/S and its shareholders and what they may believe is best for themselves in determining to recommend that shareholders vote for the proposals. See *"The Recapitalization Share Exchange — Interests of Certain Persons in the Recapitalization Share Exchange"* beginning on page 239 of this information statement/prospectus.

PROPOSAL NO. 3 — THE INCENTIVE PLAN PROPOSAL

Overview

In this Proposal No. 3, we are asking our shareholders to approve the 2021 Plan. Allarity Delaware's board of directors will adopt the 2021 Plan prior to the Allarity A/S Extraordinary General Meeting, in substantially the form of Annex B attached hereto, subject to shareholder approval at the Allarity A/S Extraordinary General Meeting. If shareholders approve this proposal, the 2021 Plan will become effective on the consummation of the Recapitalization Share Exchange. The 2021 Plan is described in more detail below.

General Information

The purpose of the 2021 Plan is to provide a means whereby we can secure and retain the services of employees, directors and consultants, to provide incentives for such persons to exert maximum efforts for our success and to provide a means by which such persons may be given an opportunity to benefit from increases in value of Allarity Delaware common stock through the granting of awards under the 2021 Plan.

Approval of the 2021 Plan by our shareholders is required, among other things, in order to comply with stock exchange rules requiring shareholder approval of equity compensation plans and allow the grant of incentive stock options ("ISOs") under the 2021 Plan. If this Incentive Plan Proposal is approved by our shareholders, the 2021 Plan will become effective as of the date of the closing of the Recapitalization Share Exchange. In the event that our shareholders do not approve this proposal, the 2021 Plan will not become effective.

Our equity compensation program, as implemented under the 2021 Plan, will allow us to be competitive with comparable companies in our industry by giving us the resources to attract and retain talented individuals to achieve our business objectives and build shareholder value. It is critical to our long-term success that the interests of employees and other service providers are tied to our success as "owners" of the business. Approval of the 2021 Plan will allow us to assume the Converted Options and to grant stock options and other equity awards at levels we determine to be appropriate in order to attract new employees and other service providers, retain existing employees and service providers and to provide incentives for such persons to exert maximum efforts for our success and ultimately increase shareholder value. The 2021 Plan allows us to utilize a broad array of equity incentives with flexibility in designing equity incentives, including traditional stock option grants, stock appreciation rights, restricted stock awards, restricted stock unit awards, other stock awards and performance awards to offer competitive equity compensation packages in order to retain and motivate the talent necessary for us to be competitive.

If the request to approve the 2021 Plan is approved by our shareholders, there will be up to approximately 1,168,330 shares, subject to adjustment for specified changes in our capitalization, available for grant under the 2021 Plan as of the effective time in addition to 43,044 shares allocated to the Converted Options in the Recapitalization Share Exchange. The Allarity A/S board of directors believes this pool size is necessary to provide sufficient shares for the assumption of the Converted Options and a level of grants that will attract, retain, and motivate employees and other participants.

Description of the 2021 Plan

We have adopted our 2021 Plan that will become effective on the effective time of the Recapitalization Share Exchange. Our 2021 Plan authorizes the award of stock options, RSAs, SARs, RSUs, cash awards, performance awards and stock bonus awards. We have initially reserved One Million One Hundred Sixty Eight Thousand Three Hundred Thirty (1,168,330) Shares, plus an amount derived by the difference between fifteen percent (15%) of the Company's issued and outstanding shares of Common Stock issued in the Company's Recapitalization Share Exchange covered by the Company's registration statement on Form S-4 (SEC File No. 333-258968) and One Million One Hundred Sixty Eight Thousand Three Hundred Thirty (1,168,330) Shares. The number of shares reserved for issuance under our 2021 Plan will increase automatically on January 1 of each of 2022 through 2031 by the number of shares equal to the lesser of 5% of the aggregate number of outstanding shares of our common stock as of the immediately preceding December 31, or a number as may be determined by our board of directors.

In addition, the following shares will again be available for issuance pursuant to awards granted under our 2021 Plan:

- shares subject to options or SARs granted under our 2021 Plan that cease to be subject to the option or SAR for any reason other than exercise of the option or SAR;
- shares subject to awards granted under our 2021 Plan that are subsequently forfeited or repurchased by us at the original issue price;
- shares subject to awards granted under our 2021 Plan that otherwise terminate without such shares being issued;
- shares subject to awards granted under our 2021 Plan that are surrendered, cancelled or exchanged for cash or a different award (or combination thereof); and
- shares subject to awards under our 2021 Plan that are used to pay the exercise price of an option or withheld to satisfy the tax withholding obligations related to any award.

Purpose. The purpose of our 2021 Plan is to provide incentives to attract, retain, and motivate eligible persons whose present and potential contributions are important to the success of the Company, and any Parents, Subsidiaries, and Affiliates that exist now or in the future, by offering them an opportunity to participate in the Company's future performance through the grant of Awards.

Administration. Our 2021 Plan is expected to be administered by our compensation committee, all of the members of which are outside directors as defined under applicable federal tax laws, or by our board of directors acting in place of our compensation committee. Subject to the terms and conditions of the 2021 Plan, the compensation committee will have the authority, among other things, to select the persons to whom awards may be granted, construe and interpret our 2021 Plan as well as to determine the terms of such awards and prescribe, amend and rescind the rules and regulations relating to the plan or any award granted thereunder. The 2021 Plan provides that the board of directors or compensation committee may delegate its authority, including the authority to grant awards, to one or more executive officers to the extent permitted by applicable law, *provided that* awards granted to non-employee directors may only be determined by our board of directors.

Eligibility. Our 2021 Plan provides for the grant of awards to our employees, directors, consultants, independent contractors and advisors.

Options. The 2021 Plan provides for the grant of both incentive stock options intended to qualify under Section 422 of the Code, and non-statutory stock options to purchase shares of our common stock at a stated exercise price. Incentive stock options may only be granted to employees, including officers and directors who are also employees. The exercise price of stock options granted under the 2021 Plan must be at least equal to the fair market value of our common stock on the date of grant. Incentive stock options granted to an individual who holds, directly or by attribution, more than ten percent of the total combined voting power of all classes of our capital stock must have an exercise price of at least 110% of the fair market value of our common stock on the date of grant. Subject to stock splits, dividends, recapitalizations or similar events, no more than 7,009.980 shares may be issued pursuant to the exercise of incentive stock options granted under the 2021 Plan.

Options may vest based on service or achievement of performance conditions. Our compensation committee may provide for options to be exercised only as they vest or to be immediately exercisable, with any shares issued on exercise being subject to our right of repurchase that lapses as the shares vest. The maximum term of options granted under our 2021 Plan is ten years from the date of grant, except that the maximum permitted term of incentive stock options granted to an individual who holds, directly or by attribution, more than ten percent of the total combined voting power of all classes of our capital stock is five years from the date of grant.

Restricted stock awards. An RSA is an offer by us to sell shares of our common stock subject to restrictions, which may lapse based on the satisfaction of service or achievement of performance conditions. The price, if any, of an RSA will be determined by the compensation committee. Holders of RSAs will have the right to vote and any dividends or stock distributions paid pursuant to unvested RSAs will be accrued and paid when the restrictions on such shares lapse. Unless otherwise determined by the compensation committee at the time of award, vesting will cease on the date the participant no longer provides services to us and unvested shares may be forfeited to or repurchased by us.

Stock appreciation rights. A SAR provides for a payment, in cash or shares of our common stock (up to a specified maximum of shares, if determined by our compensation committee), to the holder based upon the difference between the fair market value of our common stock on the date of exercise and a predetermined exercise price, multiplied by the number of shares. The exercise price of a SAR must be at least the fair market value of a share of our common stock on the date of grant. SARs may vest based on service or achievement of performance conditions, and may not have a term that is longer than ten years from the date of grant.

Restricted stock units. RSUs represent the right to receive shares of our common stock at a specified date in the future, and may be subject to vesting based on service or achievement of performance conditions. Payment of earned RSUs will be made as soon as practicable on a date determined at the time of grant, and may be settled in cash, shares of our common stock or a combination of both. No RSU may have a term that is longer than ten years from the date of grant.

Performance awards. Performance awards granted to pursuant to the 2021 Plan may be in the form of a cash bonus, or an award of performance shares or performance units denominated in shares of our common stock that may be settled in cash, property or by issuance of those shares subject to the satisfaction or achievement of specified performance conditions.

Stock bonus awards. A stock bonus award provides for payment in the form of cash, shares of our common stock or a combination thereof, based on the fair market value of shares subject such award as determined by our compensation committee. The awards may be granted as consideration for services already rendered, or at the discretion of the compensation committee, may be subject to vesting restrictions based on continued service or performance conditions.

Cash awards. A cash award is an award that is denominated in, or payable to an eligible participant solely in, cash.

Dividend equivalents rights. Dividend equivalent rights may be granted at the discretion of our compensation committee, and represent the right to receive the value of dividends, if any, paid by us in respect of the number of shares of our common stock underlying an award. Dividend equivalent rights will be subject to the same vesting or performance conditions as the underlying award and will be paid only at such time as the underlying award has become fully vested. Dividend equivalent rights may be settled in cash, shares or other property, or a combination of thereof as determined by our compensation committee.

Change of control. Our 2021 Plan provides that, in the event of a corporate transaction, as defined in the 2021 Plan, outstanding awards under our 2021 Plan shall be subject to the agreement evidencing the corporate transaction, any or all outstanding awards may be (a) continued by us, if we are the successor entity; or (b) assumed or substituted by the successor corporation, or a parent or subsidiary of the successor corporation, for substantially equivalent awards (including, but not limited to, a payment in cash or the right to acquire the same consideration paid to the stockholders of the company pursuant to the corporate transaction); (c) substituted by successor corporation of equivalent awards with substantially the same terms for such outstanding awards; (d) accelerated in full or in part as to the exercisability or vesting; (e) settled in the full value of such outstanding award in cash, cash equivalents, or securities of the successor entity (or its parent, if any) with a fair market value equal to the required amount, followed by the cancellation of such awards; or (f) cancelled for no consideration. If applicable, the number and kind of shares and exercise prices of awards being continued, assumed, or substituted shall be adjusted pursuant to the terms of the 2021 Plan.

Adjustment. In the event of a change in the number of outstanding shares of our common stock without consideration by reason of a stock dividend, extraordinary dividend or distribution, recapitalization, stock split, reverse stock split, subdivision, combination, consolidation reclassification, spin-off or similar change in our capital structure, appropriate proportional adjustments will be made to the number and class of shares reserved for issuance under our 2021 Plan; the exercise prices, number and class of shares subject to outstanding options or SARs; the number and class of shares subject to other outstanding awards; and any applicable maximum award limits with respect to incentive stock options.

Exchange, repricing and buyout of awards. Our compensation committee may, with the consent of the respective participants, issue new awards in exchange for the surrender and cancelation of any or all outstanding awards. Our compensation committee may also reduce the exercise price of options or SARs or buy an award previously granted with payment in cash, shares or other consideration, in each case, subject to the terms of the 2021 Plan.

Director compensation limits. No non-employee director may receive awards under our 2021 Plan with a grant date value that when combined with cash compensation received for his or her service as a director, exceeds $750,000 in a calendar year or $1,000,000 in the calendar year of his or her initial service.

Clawback; transferability. All awards will be subject to clawback or recoupment pursuant to any compensation clawback or recoupment policy adopted by our board of directors (or a committee thereof) or required by law during the term of service of the award holder, to the extent set forth in such policy or applicable agreement. Except in limited circumstances, awards granted under our 2021 Plan may generally not be transferred in any manner prior to vesting other than by will or by the laws of descent and distribution.

Amendment and termination. Our board of directors may amend our 2021 Plan at any time, subject to stockholder approval as may be required. Our 2021 Plan will terminate ten years from the date our board of directors adopts the plan, unless it is terminated earlier by our board of directors. No termination or amendment of the 2021 Plan may adversely affect any then-outstanding award without the consent of the affected participant, except as is necessary to comply with applicable laws.

U.S. Federal Income Tax Consequences

The following is a summary of the principal U.S. federal income tax consequences to participants and Allarity Delaware with respect to participation in the 2021 Plan, which will not become effective until the date of the closing of the Recapitalization Share Exchange. No awards will be issued under the 2021 Plan prior to the date of the closing of the Recapitalization Share Exchange. This summary is not intended to be exhaustive and does not discuss the income tax laws of any local, state or foreign jurisdiction in which a participant may reside. The information is based upon current U.S. federal income tax rules and therefore is subject to change when those rules change. Because the tax consequences to any participant may depend on his or her particular situation, each participant should consult the participant's tax adviser regarding the federal, state, local and other tax consequences of the grant or exercise of an award or the disposition of stock acquired under the 2021 Plan. The 2021 Plan is not qualified under the provisions of Section 401(a) of the Code and is not subject to any of the provisions of the Employee Retirement Income Security Act of 1974, as amended. Our ability to realize the benefit of any tax deductions described below depends on our generation of taxable income as well as the requirement of reasonableness and the satisfaction of our tax reporting obligations.

Nonstatutory Stock Options. Generally, there is no taxation upon the grant of a NSO. Upon exercise, a participant will recognize ordinary income equal to the excess, if any, of the fair market value of the underlying stock on the date of exercise of the stock option over the exercise price. If the participant is employed by us or one of our affiliates, that income will be subject to withholding taxes. The participant's tax basis in those shares will be equal to their fair market value on the date of exercise of the stock option, and the participant's capital gain holding period for those shares will begin on the day after they are transferred to the participant. Subject to the requirement of reasonableness, the deduction limits under Section 162(m) of the Code and the satisfaction of a tax reporting obligation, we will generally be entitled to a tax deduction equal to the taxable ordinary income realized by the participant.

*Incentive Stock Option*s. The 2021 Plan provides for the grant of stock options that are intended to qualify as "incentive stock options," as defined in Section 422 of the Code. Under the Code, a participant generally is not subject to ordinary income tax upon the grant or exercise of an ISO. If the participant holds a share received upon exercise of an ISO for more than two years from the date the stock option was granted and more than one year from the date the stock option was exercised, which is referred to as the required holding period, the difference, if any, between the amount realized on a sale or other taxable disposition of that share and the participant's tax basis in that share will be long-term capital gain or loss. If, however, a participant disposes of a share acquired upon exercise of an ISO before the end of the required holding period, which is referred to as a disqualifying disposition, the participant generally will recognize ordinary income in the year of the disqualifying disposition equal to the excess, if any, of the fair market value of the share on the date of exercise of the stock option over the exercise price. However, if the sales proceeds are less than the fair market value of the share on the date of exercise of the stock option, the amount of ordinary income recognized by the participant will not exceed the gain, if any, realized on the sale. If the amount realized on

a disqualifying disposition exceeds the fair market value of the share on the date of exercise of the stock option, that excess will be short-term or long-term capital gain, depending on whether the holding period for the share exceeds one year. For purposes of the alternative minimum tax, the amount by which the fair market value of a share of stock acquired upon exercise of an ISO exceeds the exercise price of the stock option generally will be an adjustment included in the participant's alternative minimum taxable income for the year in which the stock option is exercised. If, however, there is a disqualifying disposition of the share in the year in which the stock option is exercised, there will be no adjustment for alternative minimum tax purposes with respect to that share. In computing alternative minimum taxable income, the tax basis of a share acquired upon exercise of an ISO is increased by the amount of the adjustment taken into account with respect to that share for alternative minimum tax purposes in the year the stock option is exercised. We are not allowed a tax deduction with respect to the grant or exercise of an ISO or the disposition of a share acquired upon exercise of an ISO after the required holding period. If there is a disqualifying disposition of a share, however, we will generally be entitled to a tax deduction equal to the taxable ordinary income realized by the participant, subject to the requirement of reasonableness, the deduction limits under Section 162(m) of the Code and provided that either the employee includes that amount in income or we timely satisfy our reporting requirements with respect to that amount.

Restricted Stock Awards. Generally, the recipient of a restricted stock award will recognize ordinary income at the time the stock is received equal to the excess, if any, of the fair market value of the stock received over any amount paid by the recipient in exchange for the stock. If, however, the stock is subject to restrictions constituting a substantial risk of forfeiture when it is received (for example, if the employee is required to work for a period of time in order to have the right to transfer or sell the stock), the recipient generally will not recognize income until the restrictions constituting a substantial risk of forfeiture lapse, at which time the recipient will recognize ordinary income equal to the excess, if any, of the fair market value of the stock on the date it becomes vested over any amount paid by the recipient in exchange for the stock. A recipient may, however, file an election with the IRS, within 30 days following the date of grant, to recognize ordinary income, as of the date of grant, equal to the excess, if any, of the fair market value of the stock on the date the award is granted over any amount paid by the recipient for the stock. The recipient's basis for the determination of gain or loss upon the subsequent disposition of shares acquired from a restricted stock award will be the amount paid for such shares plus any ordinary income recognized either when the stock is received or when the restrictions constituting a substantial risk of forfeiture lapse. Subject to the requirement of reasonableness, the deduction limits under Section 162(m) of the Code and the satisfaction of a tax reporting obligation, we will generally be entitled to a tax deduction equal to the taxable ordinary income realized by the recipient of the restricted stock award.

Restricted Stock Unit Awards. Generally, the recipient of a restricted stock unit award will generally recognize ordinary income at the time the stock is delivered equal to the excess, if any, of (i) the fair market value of the stock received over any amount paid by the recipient in exchange for the stock or (ii) the amount of cash paid to the participant. The recipient's basis for the determination of gain or loss upon the subsequent disposition of shares acquired from a restricted stock unit award will be the amount paid for such shares plus any ordinary income recognized when the stock is delivered, and the participant's capital gain holding period for those shares will begin on the day after they are transferred to the participant. Subject to the requirement of reasonableness, the deduction limits under Section 162(m) of the Code and the satisfaction of a tax reporting obligation, we will generally be entitled to a tax deduction equal to the taxable ordinary income realized by the recipient of the restricted stock unit award.

Stock Appreciation Rights. Generally, the recipient of a stock appreciation right will recognize ordinary income equal to the fair market value of the stock or cash received upon such exercise. Subject to the requirement of reasonableness, the deduction limits under Section 162(m) of the Code and the satisfaction of a tax reporting obligation, we will generally be entitled to a tax deduction equal to the taxable ordinary income realized by the recipient of the stock appreciation right.

Tax Consequences to Allarity Delaware

Compensation of Covered Employees. Our ability to obtain a deduction for amounts paid under the 2021 Plan could be limited by Section 162(m) of the Code. Section 162(m) of the Code limits our ability to deduct compensation, for U.S. federal income tax purposes, paid during any year to a "covered employee" (within the meaning of Section 162(m) of the Code) in excess of $1.0 million.

Golden Parachute Payments. Our ability (or the ability of one of our subsidiaries) to obtain a deduction for future payments under the 2021 Plan could also be limited by the golden parachute rules of Section 280G of the Code, which prevent the deductibility of certain "excess parachute payments" made in connection with a change in control of an employer-corporation.

New Plan Benefits

The awards, if any, that will be made to eligible persons under the 2021 Plan are subject to the discretion of the compensation committee of our board of directors. Therefore, we cannot currently determine the benefits or number of shares subject to awards that may be granted in the future and a new plan benefits table is thus not provided.

Interests of Allarity A/S's Directors and Officers in the Incentive Plan Proposal

When you consider the recommendation of the Allarity A/S board of directors in favor of approval of the 2021 Plan, you should keep in mind that certain of Allarity A/S's board of directors and officers have interests in the 2021 Plan that are different from, or in addition to, your interests as a shareholder or warrant holder. See *"The Reorganization — Interests of Certain Persons in the Recapitalization Share Exchange"* beginning on page 239 of this information statement/prospectus.

Vote Required for Approval

The affirmative vote of a 66.67% of the votes cast by holders of Allarity A/S ordinary shares present in person or represented by proxy at the Allarity A/S Extraordinary General Meeting is required to approve the Incentive Plan Proposal. Notwithstanding the approval of the Incentive Plan Proposal, if the reorganization is not consummated for any reason, the actions contemplated by the Incentive Plan Proposal will not be effected.

Adoption of the Incentive Plan Proposal is conditioned on the approval of The Recapitalization Share Exchange Proposals and the Nasdaq Pipe Proposal at the special meeting.

Recommendation of Allarity A/S's Board of Directors

ALLARITY A/S'S BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS THAT SHAREHOLDERS VOTE "FOR" THE APPROVAL OF THE INCENTIVE PLAN PROPOSAL.

INFORMATION ABOUT ALLARITY A/S

References in this section to "we," "our," "us," the "Company," or "Allarity" generally refer to Allarity Therapeutics A/S and its consolidated subsidiaries, including Allarity Delaware and Acquisition Sub.

Allarity's Business

Overview

We are a clinical stage biopharmaceutical company targeting some of the greatest unmet needs in oncology by developing differentiated and novel therapeutic candidates together with our proprietary DRP® companion diagnostics in a precision medicine approach. Our business strategy includes a focus on leveraging our proprietary DRP® companion diagnostics platform to streamline the drug development process and to identify patients that will benefit from therapeutic candidates that other biotechnology or pharmaceutical companies have abandoned or shelved after initiating clinical trials under an IND application filed with the FDA, including candidates that have failed to achieve statistical significance on the original endpoints established in the clinical trials. We use our proprietary DRP® companion diagnostics platform to advance therapeutic candidates by targeting and evaluating patient sub-populations having gene signatures, determined by our DRP® companion diagnostics platform, that will potentially correlate with drug efficacy and patient response to treatment. While we have not yet successfully received regulatory or marketing approval for any of our therapeutic candidates or companion diagnostics, and while we believe that our approach has the potential to reduce the cost and time of drug development through the identification and selection of patient populations more likely to respond to therapy, our strategy involves risks and uncertainties that differ from other biotechnology companies that focus solely on new therapeutic candidates that do not have a history of failed clinical development. By utilizing our DRP® platform to generate a drug-specific companion diagnostic for each of our therapeutic candidates, if approved by the FDA, we believe our therapeutic candidates have the potential to advance the goal of personalized medicine by selecting the patients most likely to benefit from each of our therapeutic candidates and avoid the treatment of non-responder patients. All of our therapeutic candidates are clinical stage assets and the FDA has not yet approved any of our therapeutic candidates or any of our DRP® companion diagnostics. As used in this information statement/prospectus, statements regarding the use of our proprietary DRP® companion diagnostics or our proprietary DRP® platform or our observations that a therapeutic candidate may have anti-cancer or anti-tumor activity or is observed to be well tolerated in a patient population should not be construed to mean that we have resolved all issues of safety and/or efficacy for any of our therapeutic candidates or DRP® companion diagnostic. Issues of safety and efficacy for any therapeutic candidate companion diagnostic may only be determined by the U.S. FDA or other applicable regulatory authorities in jurisdictions outside the United States.

Our DRP® platform has been retrospectively validated by us using retrospective observational studies in 35 clinical trials that were conducted or sponsored by other companies. The FDA considers a retrospective observational study to be one in which the study identifies the population and determines the exposure/treatment from historical data (i.e. data generated prior to the initiation of the study) with the variables and outcomes of interest determined at the time the study is designed. See, *Framework for FDA's Real-World Evidence Program,* page 6 (December 2018), *https://www.fda.gov/media/120060/download*. The FDA has accepted our retrospective validation in support of two Investigational Device Exemption ("IDE") applications to conduct clinical trials, one with respect to LiPlaCis® and one with respect to stenoparib.

We anticipate submitting a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for our lead therapeutic candidate, dovitinib, a second-generation "pan"-tyrosine kinase inhibitor (TKI), before December 31, 2021, while continuing to expand patient enrollment in our ongoing Phase 2 clinical trials for our two other priority programs, stenoparib, a novel inhibitor of the key DNA damage repair enzyme poly-ADP-ribose polymerase (PARP), and IXEMPRA® (ixabepilone), a selective microtubule inhibitor. We may additionally conduct a near-term clinical trial for stenoparib to test the anti-viral activity of this therapeutic candidate as a potential treatment for SARS-CoV-2 (COVID-19) applications. We have not yet submitted an Investigational New Drug ("IND") application to the FDA to conduct such a trial and if we decide to do so, the FDA may not approve our IND application. We also intend to opportunistically acquire other promising oncology assets, which have undergone prior clinical trials by other pharmaceutical companies with clinical data that helps us evaluate whether these candidates will be well tolerated in the tested patient population, and in some cases, have observed anti-cancer or anti-tumor activity that would support additional clinical trials using our DRP® platform. We were founded in Denmark in 2004 by our chief scientific officer,

Steen Knudsen, Ph.D., and our Senior Vice President of Information Technologies, Thomas Jensen, both of whom were formerly academic researchers at the Technical University of Denmark working to advance novel bioinformatic and diagnostic approaches to improving cancer patient response to therapeutics.

Our clinical and commercial development team is advancing our pipeline of targeted oncology therapeutic candidates, all of which have previously succeeded at least though Phase 1 clinical demonstrating that the therapeutic candidate is well tolerated. Our three priority assets, dovitinib, stenoparib, and IXEMPRA® (ixabepilone) are all former drug candidates of large pharmaceutical companies. Our lead therapeutic candidate, dovitinib, is a selective inhibitor of several classes of tyrosine kinases, including FGFR and VEGFR, and was formerly developed by Novartis Pharmaceuticals through Phase 3 clinical trials in numerous indications. We anticipate submitting an NDA with the FDA before December 31, 2021, for the treatment of third line renal cell carcinoma (RCC or kidney cancer) in patients selected by our Dovitinib-DRP® companion diagnostic. Our anticipated NDA will be supported by a concomitant Pre-Market Approval (PMA) application to the FDA for approval of our dovitinib-specific DRP® companion diagnostic for use to select and treat patients likely to respond to dovitinib. Our second priority therapeutic candidate is stenoparib (formerly E7449), a novel inhibitor of the key DNA damage repair enzyme poly-ADP-ribose polymerase (PARP), which also has an observed inhibitory action against Tankyrases, another important group of DNA damage repair enzymes. Stenoparib was formerly developed by Eisai, Inc. (Eisai) through Phase 1 clinical trials, and we are currently advancing a Phase 2 clinical trial of this therapeutic candidate for the treatment of ovarian cancer at the Dana-Farber Cancer Institute (Boston, MA USA.) together with its stenoparib-specific DRP® companion diagnostic, for which the FDA has previously approved an Investigational Device Exemption (IDE) application.

Our third priority therapeutic candidate is IXEMPRA® (ixabepilone), a selective microtubule inhibitor, which has been shown to interfere with cancer cell division, leading to cell death. IXEMPRA® (ixabepilone) was formerly developed and brought to market by Bristol-Myers Squibb, is currently marketed and sold in the U.S. by R-PHARM US LLC, for the treatment of metastatic breast cancer treated with two or more prior chemotherapies. We are currently advancing IXEMPRA®, together with its drug-specific DRP® companion diagnostic, in a Phase 2 European clinical trial for the same indication, with the goal of eventually submitting an application for Marketing Authorization (MA) with the European Medicine Agency (EMA) to market IXEMPRA®, together with its drug-specific DRP® companion diagnostic, in the European market.

Our focused approach to address major unmet needs in oncology leverages our management's significant expertise in discovery, medicinal chemistry, manufacturing, clinical development, and commercialization. As a result, we have created substantial intellectual property around the composition of matter for our new chemical entities. The foundations of our approach include:

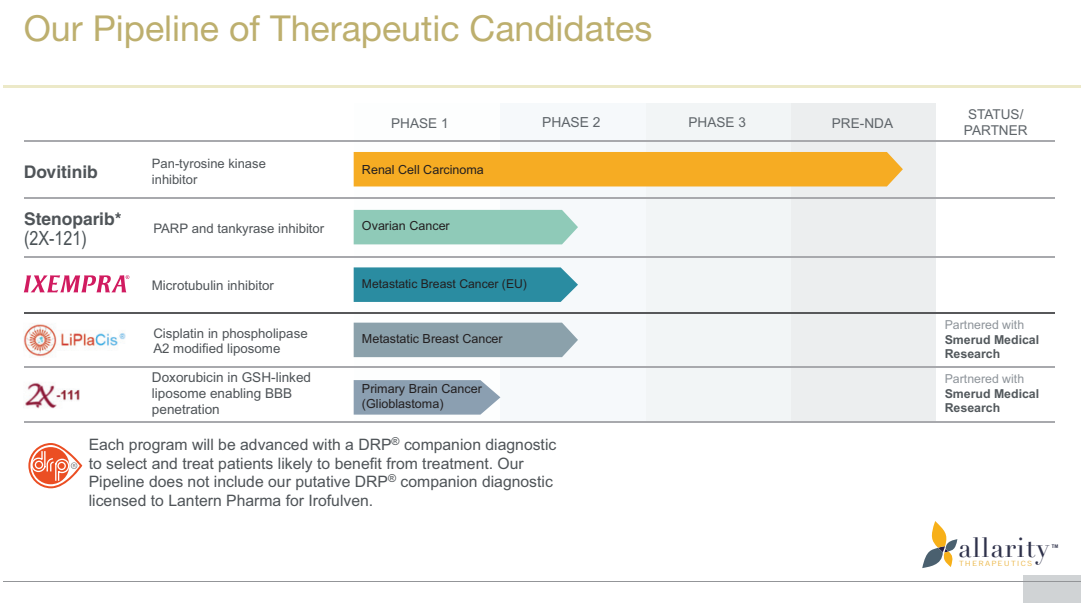
- ***The pursuit of clinical-stage assets:*** We strive to identify and pursue novel oncology therapeutic candidates that have advanced beyond Phase 1 clinical trials and are preferably Phase 2 to Phase 3 clinical stage assets. Accordingly, the assets we have acquired, and intend to acquire, have undergone prior clinical trials by other pharmaceutical companies with clinical data that helps us evaluate whether these candidates will be well tolerated in the tested patient population, and in some cases, have observed anti-cancer or anti-tumor activity that would support additional clinical trials using our DRP® platform. We often focus our acquisition efforts on therapeutic candidates that have been the subject of clinical trials conducted by large pharmaceutical companies. Further we intend to select therapeutic candidates for which we believe we can develop a drug-specific DRP® to advance together with the therapeutic candidate in further clinical trials as a companion diagnostic to select and treat the patients most likely to respond to the therapeutic candidate. We further consider whether the licensor or assignor can provide us substantial clinical grade active pharmaceutical ingredients (API) for the therapeutic candidate, at low-to-no cost, for our use in future clinical trials. The availability of API at low-to-no cost reduces both our future clinical trial costs and the lead time it takes us to start a new clinical trial for the therapeutic candidate. As an example, our lead therapeutic candidate, dovitinib, was developed by Novartis through Phase 2 clinical trials in numerous indications and in Phase 3 clinical trials for RCC before we acquired the therapeutic candidate, and it came with a substantial API supply to support our continuing advancement towards submitting an NDA to the FDA.

- ***Our proprietary DRP® companion diagnostics:*** We believe our proprietary and patented Drug Response Predictor (DRP®) platform provides us with a substantial clinical and commercial competitive advantage for each of therapeutic candidates in our pipeline. DRP® is a proprietary, predictive biomarker

technology that employs complex systems biology, bio-analytics with a proprietary clinical relevance filter to bridge the gap between *in vitro* cancer cell responsiveness to a given therapeutic candidate and *in vivo* likelihood of actual patient response to that therapeutic candidate. The DRP® platform has been retrospectively validated by us using retrospective observational studies in 35 clinical trials that were conducted or sponsored by other companies. We intend to develop and validate a drug-specific DRP® biomarker for each and every therapeutic candidate in our therapeutic candidate pipeline to serve as a companion diagnostic to select and treat patients most likely to respond to that therapeutic candidate. Our DRP® technology has also been peer-reviewed by numerous publications and we have patented DRP®s for more than 70 anti-cancer drugs.

- ***A precision oncology approach:*** Our focused strategy is to advance our pipeline of therapeutic candidates, together with DRP® companion diagnostics, to bring these therapeutic candidates, once approved, to market and to patients through a precision oncology approach. DRP® provides a gene expression fingerprint that we believe reveals whether a specific tumor in a specific patient is likely to respond to one of our therapeutic candidates and therefore can be used to identify those patients who are most likely to respond to a particular therapeutic treatment in order to guide therapy decisions and lead to better treatment outcomes. Our DRP® companion diagnostics may be used both to identify a susceptible patient population for inclusion in clinical trials during the drug development process (and to exclude the non-susceptible patient population), and further to select the optimal anti-cancer drug for individual patients in the treatment setting once an anti-cancer drug is approved and marketed. By including only patients that have tumors that we believe may respond to our therapeutic candidate in our clinical trials, we believe our proprietary DRP® companion diagnostics platform has the potential to improve the overall treatment response in our clinical trials and thereby improving our chances for regulatory approval to market our therapeutic candidate, while potentially reducing the time, cost, and risk of clinical development.

The following chart summarizes our therapeutic candidate pipeline:



Our lead therapeutic candidate, dovitinib (formerly TKI258), was designed to be a second-generation "pan"-tyrosine kinase inhibitor (TKI) with the ability to inhibit numerous classes of tumor-driving tyrosine kinases (both receptor and internal), including FGFR, VEGFR, PDGFR, c-Kit, Flt-3, and CSF-1. Numerous pan-TKIs are approved and in use for the treatment of cancers, including Sorafenib (NEXAR®, Bayer) and Lenvatinib (LENVIMA®, Eisai), and this class of drugs is increasingly showing promise in combination with immuno-oncology drugs, including checkpoint inhibitors. Dovitinib was previously developed by Novartis in 56 clinical trials, and through a Phase 3 clinical trial, where it showed therapeutic equivalence (with similar adverse events profile) to Bayer's Sorafenib for the treatment of third line RCC. Dovitinib also previously showed encouraging Phase 2 clinical trial results for the treatment of gastrointestinal stromal tumors (GIST), endometrial cancer, breast cancer, and liver cancer. We have retrospectively validated our DRP® companion diagnostic for dovitinib using clinical trial gene expression data (from patient biopsies) from prior Phase 2 and 3 clinical trials of this therapeutic candidate. In retrospective analysis

of these trials, patients selected with our Dovitinib-DRP® have an observed fifty percent (50%) increase in median overall survival when compared to DRP® negative patients. We plan to gain initial market approval for dovitinib, in the U.S., for the treatment of RCC, using our dovitinib-specific DRP® companion diagnostic to select and treat likely responder patients. Subsequently, we plan to expand approved indications for this therapeutic candidate to breast cancer, GIST, endometrial, and/or HCC, as well as pursue combination therapy approvals, such as dovitinib with a PD-1 inhibitor. We believe that dovitinib, if approved, could be broadly applicable and gain market share in the pan-TKI market as both a mono-therapy and combo-therapy product.

Our second priority therapeutic candidate, stenoparib, is a selective inhibitor of the key DNA damage repair enzyme poly-ADP-ribose polymerase (PARP), which also has, in clinically relevant doses, a unique inhibitory action against Tankyrases, another important group of DNA damage repair enzymes. DNA damage repair mechanisms are crucial to mammalian cell survival and replication, and so inhibition of key DNA damage repair enzymes, such as PARP, has clinically demonstrated to be therapeutically beneficial in the treatment of cancer. Tankyrases are enzymes involved in the stabilization and maintenance of telomeres (the ends of chromosomal DNA) during cell replication, and so disruption of Tankyrases is thought to provide an additional mechanism of impeding cancer cell growth. There are numerous PARP inhibitors currently approved and used for the treatment of cancers, primarily ovarian and breast cancers. Most of these approved PARP inhibitors use mutation of BRCA genes, which encode another important DNA damage repair enzyme as a biomarker for whether the patient will respond to a PARP inhibitor. The theory is that tumors already defective in BRCA, which are then treated with an inhibitor of PARP, will suffer higher cell/tumor death than tumors with active BRCA, effectively resulting from a synergistic inhibition of multiple DNA damage repair pathways. Stenoparib has demonstrated a superior therapeutic and toxicity profile compared to competitive PARP inhibitors and has the potential to be a beneficial drug, if approved. In addition to stenoparib's dual PARP and Tankyrase inhibitory activity, we believe stenoparib may cross the blood brain barrier (BBB) — potentially leading to treatment opportunities for primary brain cancers and brain metastases from tumors elsewhere in the body — exhibits superior cell export resistance, and shows less myelotoxicity than many other approved PARP inhibitors. Additionally, we have developed and retrospectively validated our Stenoparib-DRP® companion diagnostic using clinical trial biopsies from the prior Phase 1 clinical trial of this therapeutic candidate. In retrospective analysis of this trial, we have observed that patients selected with our Stenoparib-DRP® have a fourfold (4X) improvement in overall survival when compared to DRP® negative patients. Our putative Stenoparib-DRP® companion diagnostic identified a substantially broader responder patient subgroup than use of single biomarkers, including BRCA mutation, alone, thus potentially enabling the treatment of more patients. Currently marketed PARP inhibitors have generated over $2 billion of sales in the past few years, and sales are increasing as these agents are used in combination therapy approaches. Sales of PARP inhibitors are expected to reach $9 billion in 2026 for the treatment of ovarian cancer and pancreatic cancer alone, according to published industry sources. We plan to apply for initial market approval for stenoparib, in the U.S., for the treatment of advanced ovarian cancer, using our Stenoparib- DRP® companion diagnostic to select and treat likely responder patients. We are currently advancing a Phase 2 clinical trial for stenoparib for the treatment of advanced ovarian cancer at the Dana-Farber Cancer Institute (Boston, MA USA.) together with its Stenoparib-specific DRP® companion diagnostic, for which the FDA has previously approved an Investigational Device Exemption (IDE) application. We intend to expand enrollment of this clinical trial in 2021 and conclude our clinical trial and report our results in 2022. Additionally, pre-clinical testing of stenoparib for anti-viral activity against COVID-19 has yielded encouraging results, both as mono-therapy and in combination with the approved anti-viral remdesivir (Gilead), and we intend to initiate a further pre-clinical study of stenoparib's anti-viral activity against new variants of COVID-19. If the results of this pre-clinical study are positive, we may advance to a further clinical trial for stenoparib as an anti-viral agent against COVID-19 in early 2022. We have not yet submitted an Investigational New Drug ("IND") application to the FDA to conduct such a trial and if we decide to do so, the FDA may not approve our IND application. We believe that stenoparib, once approved, could marketed as both a mono-therapy and combo-therapy product. Eisai holds a first buy-back option for this asset.

Our third priority therapeutic candidate, IXEMPRA® (ixabepilone), is a selective microtubule inhibitor, which interferes with cancer cell division, through mitotic arrest, leading to cell death. Microtubules are polymers of the structural protein tubulin that form part of the cytoskeleton and provide structure and shape to mammalian cells. They are crucially involved in forming the mitotic spindle apparatus that ensures the proper segregation of duplicated chromosomes into daughter cells during cell division. IXEMPRA® was formerly developed and brought to market by Bristol-Myers Squibb (BMS) and is currently marketed and sold in the U.S. by R-PHARM US LLC for the treatment of metastatic breast cancer treated with two or more prior chemotherapies. There are numerous microtubule inhibitors currently approved and used for the treatment of numerous cancers such as ovarian and

breast, including Halaven® (eribulin mesylate), Taxotere® (docetaxel), and Abraxane® (nanoparticle albumin-bound paclitaxel). Currently marketed microtubule inhibitors have generated significant sales in the past few years. For example, sales of Halaven® (Eisai) alone were about $400 million in 2019. We have previously developed and retrospectively validated our Ixabepilone-DRP® companion diagnostic using clinical trial gene expression data from a prior Phase 2 clinical trial of IXEMPRA® by BMS. In retrospective analysis of this trial, patients selected with our putative Ixabepilone-DRP® companion diagnostic have an observed 58% increase in complete remission when compared to randomly selected patients treated with ixabepilone. We are currently advancing IXEMPRA®, together with its DRP® companion diagnostic, in a Phase 2 European clinical trial in metastatic breast cancer treated with two or more prior chemotherapies, with the goal of eventually submitting for marketing approval with the EMA for the European market. R-PHARM US, LLC, holds a first buy-back option for this asset.

We are also developing, primarily with others, several second priority therapeutic candidates, including LiPlaCis®, 2X-111, and Irofulven, each in combination with a drug-specific DRP® companion diagnostic in order to improve therapeutic benefit and patient outcomes by selecting and treating the patients most likely to respond to each drug. LiPlaCis® is an advanced, targeted liposomal formulation of Cisplatin, one of the world's most widely used chemotherapies. We exclusively in-licensed this drug from LiPlasome Pharma ApS. The specific LiPlaCis® formulation utilizes a proprietary phospholipase A (sPLA2-IIA) cleavage substrate for controlled, selective hydrolyzation, disruption and release of drug payload in the presence of tumor cells. This delivery vehicle may result in drug accumulation directly at tumor site, thereby potentially increasing drug targeting at the tumor and reducing negative, off target drug effects and toxicity that is well known for cisplatin. We have previously developed and retrospectively validated a DRP® companion diagnostic specific for cisplatin, which we believe enables us to identify and treat the patients most likely to respond to this therapeutic candidate. LiPlaCis® has previously shown encouraging results in a Phase 2 clinical trial in DRP®-selected patients with late stage metastatic breast cancer (mBC). In August 2019, the FDA approved our Investigational Device Exemption (IDE) application for use of our LiPlaCis®-DRP® companion diagnostic in a contemplated pivotal Phase 3 clinical trial in mBC. In June 2019, the FDA had provided feedback on our pending Investigational New Drug (IND) application and proposed Phase 3 clinical trial in mBC. In June of 2020, we out-licensed this program to Smerud Medical Research International, our long-time CRO partner in Europe, which we anticipate will further advance the clinical development of LiPlaCis®, together with its DRP® companion diagnostic, in late stage mBC or in a pediatric cancer indication, building on prior clinical trial results. The initiation, by Smerud, of the next Phase 2 clinical trial for this program is anticipated by early 2022, however the license agreement with SMERUD may be termininated if SMERUD does not obtain outside financing for the program by December 31, 2021.

2X-111 is an advanced, targeted liposomal formulation of Doxorubicin, one of the world's most widely used chemotherapies. We exclusively in-licensed this therapeutic candidate from 2BBB Medicines, B.V. The specific 2X-111 formulation, which exploits a glutathione enhanced PEG-liposomal delivery system, we believe may allow 2X-111 to cross the blood-brain barrier (BBB), thereby potentially enabling the treatment of primary brain tumors, such as glioblastoma multiforme (GBM), and secondary brain tumors that originated from cancers outside the brain, such as metastatic breast cancer. The treatment of such brain tumors is a significant unmet need in cancer care, given that patients with primary brain tumors and metastases have few or no meaningful therapy options. We have previously developed and retrospectively validated a DRP® companion diagnostic specific for doxorubicin, which may enable us to identify and treat the patients most likely to respond to this therapeutic candidate. 2X-111 has previously shown encouraging results in a Phase 2 trial (without use of a DRP® companion diagnostic) for the treatment of both GBM and brain metastases of mBC. In June of 2020, we out-licensed this program to Smerud Medical Research International, our long-time CRO partner in Europe, who intends to further advance the clinical development of 2X-111, together with our DRP® companion diagnostic, in GBM, building on prior clinical trial results. The initiation, by Smerud, of the next Phase 2 clinical trial for this program is anticipated by early 2022, however the license agreement with SMERUD may be termininated if SMERUD does not obtain outside financing for the program by December 31, 2021.

Irofulven (6-hydroxymethylacylfulvene), is a unique DNA damaging agent, is a semi-synthetic sesquiterpene derivative of illudin S, a natural toxin isolated from the Jack O'lantern mushroom (*Omphalotus illudens*). Until July 23, 2021, we exclusively in-licensed this therapeutic candidate from Lantern Pharma, Inc. Irofulven has two primary anti-tumor mechanisms of action: first, it produces bulky single strand DNA adducts that are only repairable by the transcription coupled nucleotide excision repair (TC-NER) pathway; and second, it stalls RNA polymerase II leading to transcription and cell cycle arrest and apoptosis. The therapeutic candidate was formerly developed, between 1995 and 2007, in 41 different clinical trials, including through Phase 3 clinical trials, which demonstrated Irofulven's single agent activity in a range of indications, including castration-resistance prostate cancer (CRPC), ovarian, liver,

and pancreatic cancer, and clinical activity in combination treatments targeting CRPC, colorectal and thyroid cancers. We have previously developed and patented a putative DRP® companion diagnostic specific for Irofulven, which we believe enables us to identify and treat the patients most likely to respond to this therapeutic candidate although we have not yet filed a PMA with the FDA for this companion diagnostic. In order to devote more of our development resources to our priority therapeutic candidates, on July 23, 2021, we terminated our drug development agreement for Irofulven and sold our inventory of API, our clinical data and records, and our know-how relating to Irofulven to Lantern Pharma, and granted a non-exclusive license to Lantern Pharma to use our putative DRP® companion diagnostic specific for Irofulven in exchange for $1m and future additional milestone and royalties. Although we may be entitled to future milestone payments and royalties if Lantern Pharma advances the development of Irofulven with or without our putative DRP® companion diagnostic specific for Irofulven, we will no longer devote any of our development resources to advance this therapeutic candidate.

We retain exclusive worldwide rights to all the therapeutic candidates in our pipeline, with the exception of IXEMPRA®, for which we have exclusive European rights and our putative DRP® companion diagnostic specific for Irofulven., which we have out-licensed to Lantern Pharma, Inc. We have a broad intellectual property portfolio comprised of more than 15 granted DRP® patents covering 70 different cancer drugs, and another19 DRP® patent applications pending covering 2 additional cancer drugs. We recently received allowance from the U.S. Patent and Trademark Office (USPTO) on 3 pending applications including our Dovitinib-DRP®, and our rolling patent strategy allows our DRP® patents to be listed for the drugs where they occur in the approval label. We also control remaining composition of matter, formulation, and methods of use patent coverage on dovitinib and stenoparib which extend out to 2028 or 2032 depending on the product and the relevant patents.

Our Team

Our Chief Executive Officer, Steve R. Carchedi, brings over 30 years of commercial experience in specialty pharmaceuticals, diagnostics, and precision medicine with fortune 500 organizations. He previously served as the Chief Executive Officer and President of Apexian Pharmaceuticals, Inc., an oncology discovery, and development company, and as Chief Executive Officer and President of Raphael Pharmaceuticals, Inc. (formerly Cornerstone Pharmaceuticals), an oncology discovery, and development company, where he raised over $20 million in investment. Prior to that, he served as Senior Vice President and President, Commercial Operations for Mallinckrodt Pharmaceuticals, managing a $2 billion business with 5 operating companies. He also served as Chief Marketing Officer for General Electric (GE) Healthcare-Molecular Diagnostics, where he was responsible for leading worldwide marketing for GE's $2.5 Billion Medical Diagnostics business. Prior to joining GE Healthcare, Mr. Carchedi held senior commercial leadership positions at Endo Pharmaceuticals, Enzon Pharmaceuticals, Johnson & Johnson, Eli Lilly & Company, and Bristol Myers Squibb. While at Enzon, he led the company's exit strategy resulting in a sale to Sigma Tau Pharmaceuticals in 2009 for over $327 million. While at Johnson & Johnson, he led the worldwide launch of VELCADE® (Bortezomib), which now treats Multiple Myeloma in over 80 countries, with global sales currently at $1.5 billion. While at Eli Lilly, he played a key role in commercializing GEMZAR® (Gemcitabine) and ALIMTA® (Pemetrexed Di-sodium), two of the leading chemotherapies on the market today, and led the development of Lilly's oncology strategy, which delivered $1.5 billion in annual sales.

Our clinical, senior management team has broad expertise and a successful track record of clinically developing and commercializing new medicines and developing and exploiting companion diagnostics to enable Personalized Medicine. Our Chief Medical Officer, Marie Foegh, M.D., Dr.Sc., brings more than thirty years of experience in the pharmaceutical and biotechnology industries, with a proven track record of medical leadership within clinical development and medical affairs. She previously served as the President of Henri Beaufour Institute, as a Medical Director for Ipsen Pharmaceuticals, and later as Vice President of Medical Affairs, Strategy and Development, Female Health Care, at Bayer Pharmaceuticals. Earlier in her career, she served as Vice President of Clinical Development, at Berlex Laboratories, and as Vice President of Clinical R&D, for Agile Therapeutics. During her career, Marie advanced numerous therapeutic products through development and regulatory approval, including Decapeptyl (prostate cancer); Somatuline (gastro-pancreatic-neuroendocrine tumors and acromegaly); Yaz (premenstrual dysphoric disorder, acne, oral contraceptive); Yasmin (oral contraceptive); and Menostar, a weekly transdermal patch (osteoporosis). She has deep expertise in clinical development and approval of human therapeutics, including regulatory filings and relationships with the FDA and EU EMA.

Our Chief Scientific Officer, Steen Knudsen, Ph.D., co-founded our company in 2004 and is the inventor and leading world expert in our DRP® platform, which is Allarity's core companion diagnostic technology. He is a former Professor of Systems Biology at Technical University of Denmark and has extensive expertise in mathematics, bioinformatics, biotechnology, and systems biology of tumors. He has developed and patented drug-specific DRP® biomarkers for more than 70 different cancer drugs, validated DRP® diagnostics in more than 35 clinical trials (retrospective) and has played a central role in the preparation and filing of all regulatory documents with the FDA for our drug programs and DRP® companion diagnostics, including PMA, IND, and IDE applications.

Strategy

We strive to deliver meaningful benefit to patients with serious unmet medical needs in oncology by developing potentially breakthrough therapies, together with our proprietary DRP® companion diagnostics, in a personalized medicine approach. The core elements of our strategy include:

- ***Advance the U.S. approval of our lead therapeutic candidate, dovitinib, for the initial RCC indication, followed by expansion to other promising indications.*** We are preparing to submit our first NDA to the FDA before December 31, 2021, for marketing approval of dovitinib for the treatment of third line renal cell carcinoma (RCC) in patients selected with our Dovitinib-DRP® companion diagnostic. Our NDA is based on data from a previous Phase clinical trial by Novartis demonstrating that dovitinib is as good as (or "non-inferior" to) Bayer's pan-TKI Sorafenib in this patient group. Our NDA is predicated on the use of our proprietary Dovitinib-DRP® companion diagnostic to select and treat patients most likely to respond to this therapeutic candidate, and we have submitted our PMA for the use our Dovitinib-DRP® companion diagnostic. We believe that the DRP® companion diagnostic for dovitinib, if approved, will be the first complex, gene expression signature approved by the FDA as a companion diagnostic to guide patient selection for cancer therapy. If the FDA approves our NDA for RCC, we also intend to initiate additional clinical trials for dovitinib, selecting patients with our Dovitinib-DRP® companion diagnostic, for the treatment of GIST, breast cancer, endometrial cancer, and/or liver cancer (HCC) — all indications for which the therapeutic candidate has clinical data in Phase 2 clinical trials that would support additional clinical trials — as well as potentially conduct a combination therapy clinical trial for dovitinib together with a PD-1 inhibitor.

- ***Accelerate enrollment in, and conclusion of, our ongoing Phase 2 clinical trials for stenoparib in ovarian cancer and IXEMPRA® in metastatic breast cancer***. Our ongoing, DRP®-guided Phase 2 clinical trial of stenoparib as a treatment for ovarian cancer, being conducted at the Dana-Farber Cancer Institute (Boston, MA USA.), has been adversely impacted by the COVID-19 pandemic. As the adverse effects from the COVID-19 pandemic diminish, we anticipate accelerating enrollment in our stenoparib Clinical trial and concluding the clinical trial, with data read out, sometime in 2022. Similarly, the recent start of our DRP®-guided Phase 2 clinical trial of IXEMPRA® as a treatment for metastatic breast cancer, being conducted at numerous locations in Europe, has been adversely impacted by the COVID-19 pandemic. As we continue to emerge from COVID-19 pandemic, we anticipate accelerating enrollment in our IXEMPRA® clinical trial within 2021, and concluding the clinical trial, with data read out, in late 2022.

- ***Advance the opportunistic potential of stenoparib as an anti-viral treatment for COVID-19.*** We have conducted, and continue to conduct, pre-clinical experiments — at the Pathogen and Microbiome Institute at Northern Arizona University (NAU), a leading U.S. infectious disease test center — to assess the potential anti-viral activity of stenoparib against COVID-19, as well as the variant B.1.1.7 ("British variant") and variant B.1.351 ("South African variant"). The current and planned in-vitro studies, focusing on SARS-CoV-2 lineage B.1.1.7 and B.1.351, follow previous positive pre-clinical test results demonstrating that stenoparib may be a potential treatment of SARS-CoV-2, the results of which were published in the peer-review journal mBio (mbio.asm.org) on 19 January 2021. The published data showed that stenoparib may inhibit SARS-CoV-2 as a single agent, and in addition that stenoparib, in combination with remdesivir, may also be active in inhibiting the virus. The concentration of stenoparib required for virus inhibition was lower in the combination study with remdesivir than in the single agent study. Based on the results of these pre-clinical studies, we have submitted a phase 2/3 protocol through the BARDA portal to be an arm in the NIH ACTIV clinical trials, a part of the U.S. government's "The National Strategy for the COVID-19 Response and Pandemic Preparedness," formerly known as "Operation Warp Speed."

We will continue to explore opportunities to advance stenoparib into clinical trials as a novel treatment for COVID-19 infection. We have not yet submitted an Investigational New Drug ("IND") application to the FDA to conduct such a trial and if we decide to do so, the FDA may not approve our IND application.

- ***Support the continuing, external clinical development of our secondary pipeline assets towards value inflection points***. We have previously out-licensed both LiPlaCis® and 2X-111, to our longtime CRO partner Smerud Medical Research International, in our efforts to advance the clinical development of these assets. Smerud intends to conduct expanded enrollment of a DRP®-guided Phase 2 clinical trial in Europe for LiPlaCis® and 2X-111, with the intent of establishing sufficient clinical results to garner the interest of a larger pharmaceutical acquirer or partner to advance the programs through Phase 3 clinical trials and, if approved, to market. We intend to support both of these clinical trials with our proprietary DRP® companion diagnostics and our clinical trial and regulatory expertise, however the license agreement with SMERUD may be termininated if SMERUD does not obtain outside financing for the program by December 31, 2021.

- ***Continue to leverage our deep insights in tumor biology and predictive diagnostics to pursue innovative clinical candidates.*** We have established, over many years, expertise, and capabilities in the evaluation of oncology therapeutics with coupled companion diagnostics utilizing our proprietary DRP® platform. We intend to leverage these capabilities to identify, acquire, and advance additional new, clinical stage assets that may benefit patients with serious unmet medical needs, through a precision medicine approach.

- ***Evaluate strategic opportunities to accelerate development timelines and maximize value of our therapeutic candidate pipeline.*** We currently own the exclusive worldwide development and commercial rights to each of our therapeutic candidates, with the exception of IXEMPRA®, for which we own exclusive European rights and Irofulven which is now being developed by Lantern Pharma. We intend to evaluate collaborations that could maximize the value of our therapeutic candidate pipeline, either through the evaluation of our therapeutic candidates in combination with compounds owned by third parties or through geographic collaborations outside of the U.S. that allow us to leverage the existing infrastructure of other companies. For example, there are a number of pharmaceutical companies in oncology markets in the Asia-Pacific, Middle East, and Latin America markets that we believe are interested in partnering with us, and or acquiring license rights from us, in order to develop and commercialize our oncology products in those substantial oncology therapeutics markets.

Companion Diagnostics

Overview of Our DRP® Companion Diagnostic Platform

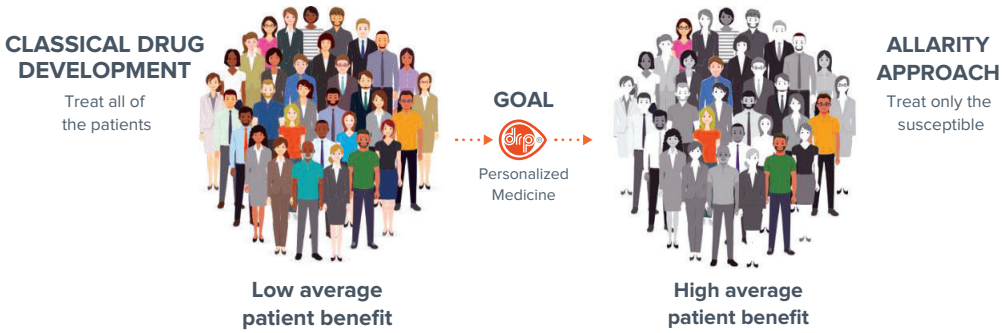
Our patented DRP® platform is a proprietary technology that enables the development of drug-specific companion diagnostics that are used to identify patients that will most likely respond to a particular cancer therapy. While our strategy is to use our DRP® platform to advance our own therapeutic candidates, we believe our DRP® platform could be used many other cancer drugs, both in clinical development and those on the market.

A companion diagnostic is an *in vitro* diagnostic device or test that provides information that is essential for the safe and effective use of a corresponding therapeutic product. After the companion diagnostic is approved for use by the FDA, the use of the companion diagnostic with an approved therapeutic product is stipulated in the instructions for use in the labeling of both the companion diagnostic and the corresponding therapeutic product.

In cancer therapy, personalized medicine, also known as precision medicine, aims to match therapeutic products to those patients (and only those patients) who will positively respond to that therapeutic product, to maximize the benefits and minimize risks from the therapeutic product received. Personalized medicine in the field of oncology therefore depends on (1) understanding the molecular pathophysiology of cancer and (2) the ability of companion diagnostics to accurately and reliably detect and measure molecular biomarkers. Consequently, these companion diagnostics inform both the clinical development of therapeutic candidates and the approved use of therapeutic products.

Our DRP® platform facilitates personalized medicine in cancer patients by addressing the crucial fact that the specific cancer tumor biology within a patient that determines whether a patient will (or will not) respond to a particular cancer drug is largely unique to that patient:

Personalized Therapy for Cancer Patients Requires Predictive Diagnostics to Select Likely Responders to a Given Drug



We believe our DRP® platform addresses the great complexity of cancer, and is fundamentally different from classical or competitive approaches, in that we let the tumor tell us what cellular mechanisms are important to its response (or resistance) to a given cancer drug:

How We Create a Drug-Specific DRP®

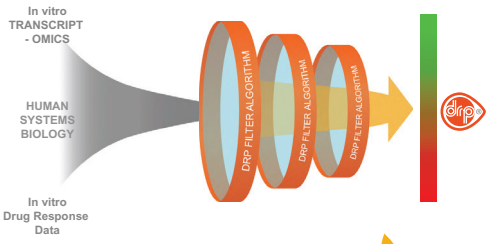
Cancer is Complex

"Systems biology" is used to **analyze all genes** (~25,000) expressed in a cancer cell/tumor, without bias towards current knowledge of relevant drug targets or pathways.

Graph of all 680 non-redundant proteins

The Tumor Tells us What is Important

From cancer cell line drug testing data as an "input", our **DRP® engine applies the system biology analysis** as a "filter" of human tumor biopsy data, to yield a 50 to 400 gene DRP® for that specific drug.

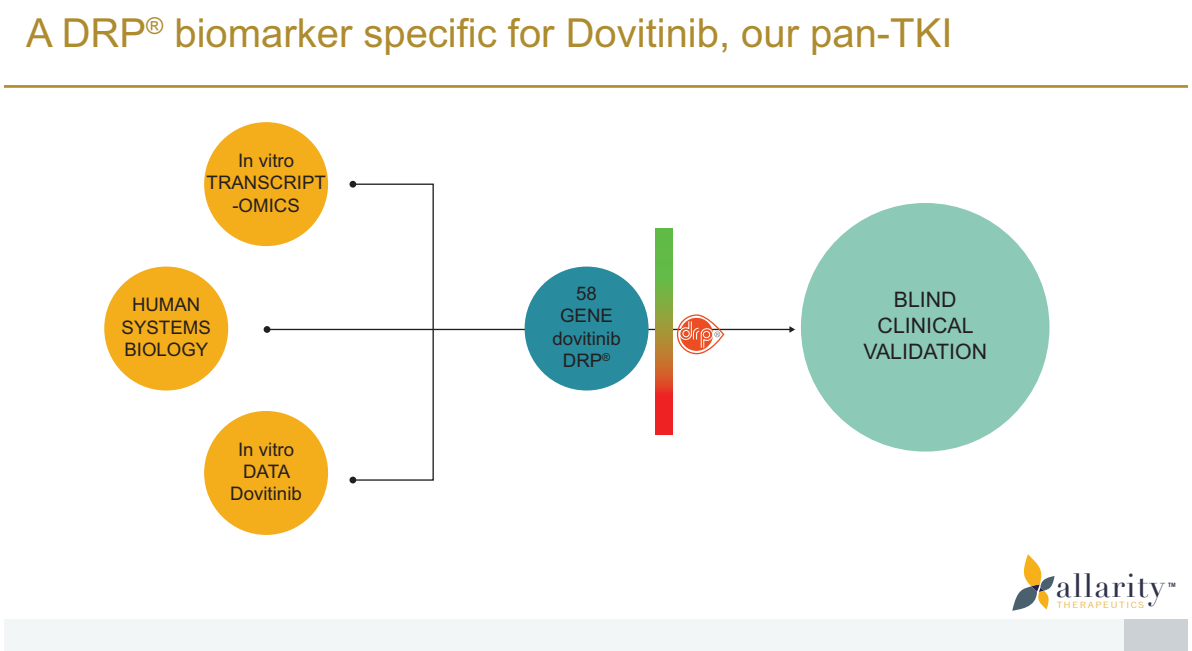


Our DRP® platform is a powerful bioinformatic engine that is based on advanced systems biology and transcriptomics, meaning that it analyzes all genes that are transcribed (*i.e.* expressed) as RNA and/or microRNA in a tumor and whether those transcribed genes are affected in response to treatment of the tumor (or cancer cells) with a given approved drug or therapeutic candidate. Our approach differs greatly from simple genetic tests, such as those for a critical mutation in a single gene, and provides a much deeper level of insight into a tumor's likelihood of responding to a particular approved drug or therapeutic candidate, that may not be observed by simply looking at a patient's DNA sequence information.

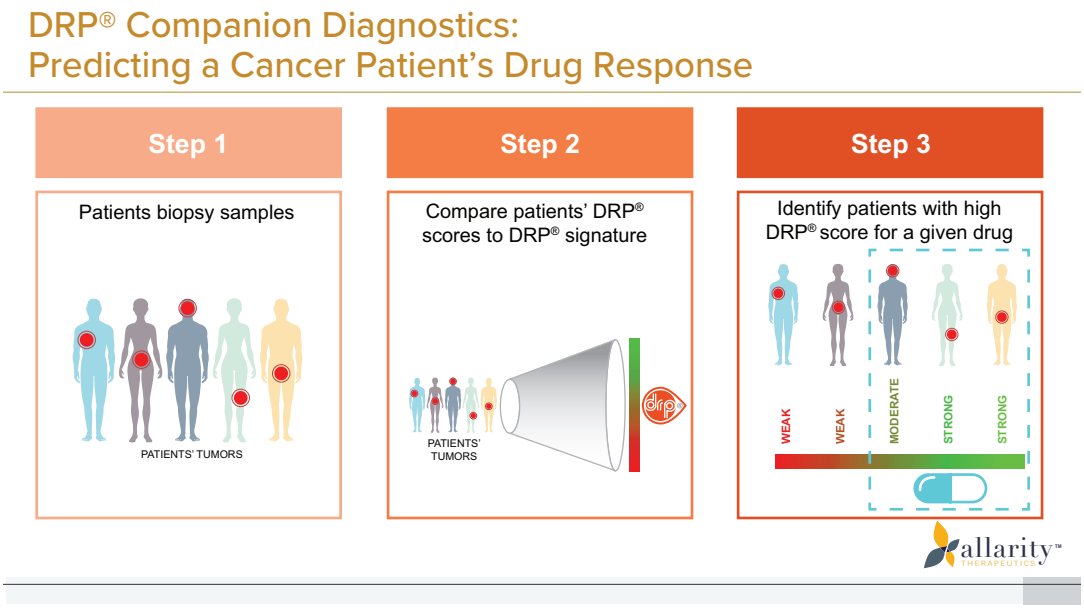
When we create a new, drug-specific DRP® companion diagnostic using our DRP® platform, we start with an established panel of cancer cell lines, which have been treated with the cancer drug or therapeutic candidate, to correlate the genetic expression profile of cell lines that are either sensitive or resistant to the drug or therapeutic candidate. In our development of a companion diagnostic, we usually use a well-known collection of 60 human tumor cell lines from the National Cancer Institute known as the "NCI-60" panel, however we also use proprietary cancer cell line panels. Gene expression profiles of the cancer cell lines are derived from a microarray (commercially available Affymetrix Gene Chips) to quantify the level of mRNA and/or microRNA that have been transcribed from genes in those cells. The advanced bioinformatic algorithm at the heart of our DRP® platform then identifies, from all mRNA and microRNA, the specific ones that are correlated with either drug or therapeutic candidate response or resistance, and the collection of these biomarkers becomes a "fingerprint" of response (or resistance) to that drug or therapeutic candidate. Our DRP® platform then applies what we believe to be a unique "biological relevance filter" — created from analyzing more than 3,000 actual biopsy samples from human clinical trials across a broad range of cancer types and cancer drug and therapeutic candidate types — to remove biomarkers that are not relevant to actual clinical response of tumors (from patients) and thus reduce the background noise from our observations. This process generates a putative DRP® companion diagnostic, specific for the drug or therapeutic candidate, which identifies a subpopulation of cancer patients most likely to respond to the drug or therapeutic candidate. Typically, between 50 and 400 biomarkers (*i.e.* expressed genes) comprise a putative DRP® companion diagnostic for a specific drug or therapeutic candidate.

However, before we can confidently use the DRP® companion diagnostic with real cancer patients, either in clinical trials for a therapeutic candidate or for an approved and on market drug, we must retrospectively validate the predictive power of the DRP® for that drug or therapeutic candidate by accessing tumor biopsies (or gene expression data from such biopsies) from prior clinical trials of the drug or therapeutic candidate, and then retrospectively predicting which patients will respond to the drug or therapeutic candidate. When possible, we do our analysis in a "blinded" manner, meaning that we have no access to patient information and whether they did or did not respond to the drug or therapeutic candidate. Using this protocol of analysis, we believe we are able to retrospectively validate whether our putative DRP® companion diagnostic would have correctly identified those patients who did respond to the drug or therapeutic candidate. At this stage, we also establish a cutoff score for the putative DRP® companion diagnostic, in order to capture most of the responsive patients while excluding most of the nonresponsive patients in the tested population. Typically, we set a DRP® cutoff score for a given cancer drug at 50%, although we may use a more stringent cutoff score for certain cancer types or drugs.

The following image shows an exemplary process flow for creation of our Dovitinib-DRP® companion diagnostic:



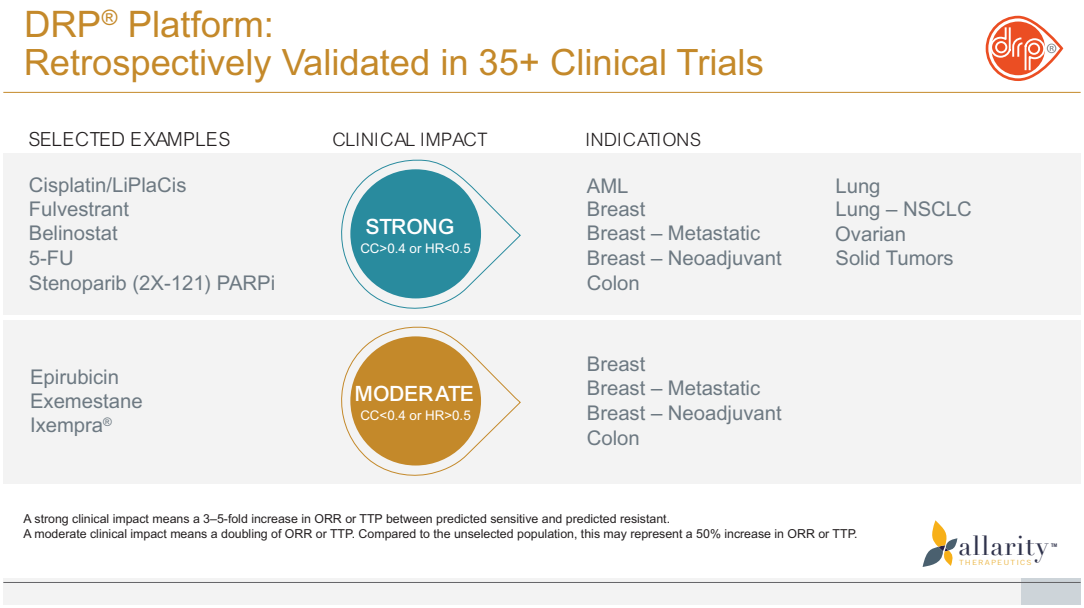
If we succeed with the final retrospective validation step, then our putative DRP® companion diagnostic is ready for submission as an Investigational Device Exemption ("IDE") to the FDA and, if approved, use with actual patients in clinical trials. Depending on the outcomes of our clinical trials, a Pre-Marketing Authorization ("PMA") application may be made with the FDA and, if approved, our DRP® companion diagnostic may be used with an approved drug in cancer therapy. The following image shows how to use a drug-specific DRP® companion diagnostic, in practice, to test whether a patient will or will not respond to a given cancer drug:



For example, we may receive, at our diagnostic laboratory (or a partner diagnostic laboratory), a biopsy sample from a hospital or cancer center where a patient is being treated. Often, this biopsy sample is formalin-fixed paraffin-embedded (FFPE). Generally, we prefer a recent biopsy to an older (*e.g.* diagnostic) biopsy, since tumors may change, at the molecular biology level, with each round of therapy they are treated with. Gene expression in tumor cells from the biopsy is determined in the same manner as in the cell lines previously described above. The expression levels of the relevant biomarkers (that comprise the DRP® companion diagnostic) in the patient's tumor are compared to the DRP® reference in order to assess how closely the patient's biomarker expression levels match the reference. We then apply the relevant DRP® score cutoff (e.g. 50%) for that drug to determine whether the patient has a high enough DRP® score to be identified as a likely responder for the drug.

Our DRP® platform has been retrospectively validated by us using retrospective observational studies in 35 clinical trials that were conducted or sponsored by other companies. The FDA considers a retrospective observational study to be one in which the study identifies the population and determines the exposure/treatment from historical data (i.e. data generated prior to the initiation of the study) with the variables and outcomes of interest determined at the time the study is designed. See, *Framework for FDA's Real-World Evidence Program,* page 6 (December 2018), *https://www.fda.gov/media/120060/download*. The FDA has accepted our retrospective validation in support of two Investigational Device Exemption ("IDE") applications to conduct clinical trials, one with respect to dovitinib and one with respect to stenoparib. We believe our DRP® platform has successfully generated drug-specific putative DRP® companion diagnostics for a broad range of cancer drugs and therapeutic candidates with different mechanisms-of-action (e.g. kinase inhibitors, chemotherapeutics, HDAC inhibitors, PARP inhibitors, hormone receptor inhibitors, etc.) and across both solid and hematological cancers. Although none of our putative DRP® companion diagnostics have yet been approved by the FDA for marketing, the following graphic illustrates some retrospective validations we have conducted

(a strong clinical impact suggests that use of the putative DRP® companion diagnostic may result in a 3X to 5X increase in therapeutic benefit for DRP®-selected patients, while a moderate clinical impact suggests that the DRP® companion diagnostic may provide a 2X increase in therapeutic benefit):



While these retrospective observational studies validate the ability of the DRP® platform to predict likely responders, few of these retrospective studies meet the criteria for proof of efficacy and safety required by the FDA. Usually, the FDA requires a sufficiently powered phase III clinical trial as we used for the putative Dovitinib DRP® companion diagnostic validation in renal cell carcinoma.

Although we believe our DRP® platform is very robust and retrospectively validated, we are not always successful in discovering a putative DRP® companion diagnostic in all cases. Generally, the limited number of failures we have encountered have been with cancer drugs with a mechanism-of-action that is not directly cytotoxic (*i.e.* it acts directly on the cancer cell leading to cell death), such as angiogenesis inhibitors that interfere with new blood vessel development to the tumor. Additionally, we have experienced some failures to develop a putative DRP® companion diagnostic for a given drug or therapeutic candidate when biopsy materials are too old, or when too many intervening treatments have taken place from the time of original biopsy to current treatment.

Our DRP® companion diagnostics have been patented for more than 70 anticancer agents across a broad range of cancer drugs. Studies involving our DRP® platform, and resulting putative DRP® companion diagnostics, have also been extensively published in peer reviewed literature and presented at major oncology conferences.

Advantages Over Other Biomarker Approaches

The realization of personalized medicine in cancer care has been hampered, in part, due to the general lack of FDA approved companion diagnostics to select and treat those cancer patients most likely to respond to a given drug (while avoiding treatment of those patients likely to not respond). This lack of suitable companion diagnostics we believe has largely resulted from an outdated and overly simplistic view of cancer, which fails to adequately address the great complexity of individual tumor responsiveness to a given drug or therapeutic candidate, and which relies entirely on what the oncology community knows about cancer biology without regard to the much greater body of what we do not know. Accordingly, historic and competitive companion diagnostic approaches mostly rely on a "knowledge-driven" approach that focus only on single biomarkers — and not on more informative and reliable, complex biomarker signatures — that rarely hold up in the clinic or on the market for use with actual patients.

Examples of competitive approaches and technologies and their shortcomings are:

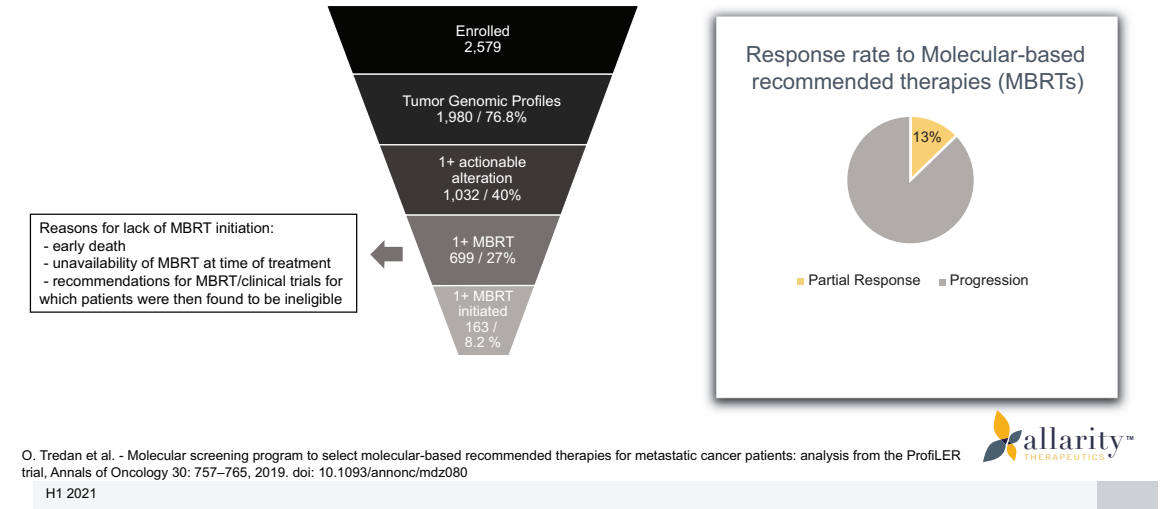
- ***Gene Mutation Sequencing***. A number of gene mutations have been identified which leads to an alteration in the expressed protein or enzyme, targeted by a drug, which results in the drug no longer binding (or sufficiently binding) to and inhibiting the target. Such mutations are common in kinases,

and thus can lead to failure of targeted kinase inhibitors binding to that target. Modern "Next Gen Sequencing" (NGS) of such genetic mutations is one current approach to identify patients who may or may not respond to a given cancer drug. NGS approaches have been commercialized by companies like Foundation Medicine, and are also increasingly being used by large cancer centers with their own NGS capabilities. We believe this approach is largely limited by failing to address complex tumor biology and mechanisms of drug response/resistance, much of which is currently unknown, and, accordingly, can only partially identify patient therapeutic response if it is linked to a single gene mutation. This approach is also limited to drugs that target proteins or enzymes that have mutations, and is thus not suitable for predicting response to drugs such as chemotherapeutics.

- ***Drug Target Expression Analysis***. This approach uses the level of expression of the actual drug target itself as a biomarker for whether a patient will (or will not) respond to a given drug. A common example is expression of the cell surface receptor tyrosine kinase HER2 used as a companion diagnostic for the HER2-targeting cancer drug Herceptin® for the treatment of breast cancer. We believe this approach is also largely limited by failing to address complex tumor biology and mechanisms of drug response/resistance, much of which is currently unknown. Indeed, many patients who are HER2 positive do not respond well to drugs targeting this receptor and/or patients that initially respond become resistant, indicating other, more complex underlying tumor biology.

- ***"Artificial Intelligence" (AI) or "Machine Learning" (ML) Approaches***. While there are many companies, including in the companion diagnostics space, currently employing technologies that leverage AI or ML, we believe these computer-based technologies are largely limited to the identification and/or design of potential new drug structures. Currently, we are not aware of any retrospectively or clinically validated, published, or approved companion diagnostic created by any AI-based or ML-based approach.

The Limitations of Single Biomarker Companion Diagnostics



In contrast to other alternative companion diagnostics technologies we believe our DRP® platform enjoys several, unique competitive advantages:

- ***Broadly Applicable***. We believe our DRP® platform can successfully generate a drug-specific companion diagnostic for most cancer drug types, including:
  - mechanisms-of-action as diverse as DNA damaging agents,
  - chemotherapeutics,
  - targeted kinase inhibitors, and
  - epigenetic enzyme inhibitors.

- ***Retrospectively Validated***. The ability of the DRP® platform to generate reliable and accurate predictive DRP® companion diagnostics has been retrospectively validated in more than 35 clinical trials and 1 prospective clinical trial.
- ***Extensively Published***. Studies of our DRP® platform and putative companion diagnostics have been extensively published in peer-reviewed literature, including publications such as the British Journal of Cancer, Journal of the National Cancer Institute, Plos One, and Breast Cancer Research and Treatment, and have been presented at major oncology conferences, including ASCO, ESMO, and EACR.
- ***Accepted for Use in Clinical Trials by Regulatory Agencies***. Although none of our putative DRP® companion diagnostics has yet been approved by a regulatory agency for marketing, the U.S. FDA has previously granted 2 Investigational Device Exemptions (IDEs) approving the use of DRP® companion diagnostics for both stenoparib and LiPlaCis® in clinical trials. The FDA is also currently reviewing a Pre-Market Approval (PMA) application for the use of the Dovitinib-DRP® companion diagnostic as a marketed companion diagnostic for dovitinib in RCC. Similarly, the stenoparib, IXEMPRA® and LiPlaCis® DRP® companion diagnostics have been accepted for use in clinical trials by national regulatory agencies in Europe.
- ***Novel Companion Diagnostic***. The PMA currently being reviewed by the FDA for our Dovitinib-DRP® companion diagnostic, if approved by the FDA, we believe will become the first complex gene expression signature that is approved as a companion diagnostic to select and treat patients most likely to respond to a cancer drug.
- ***Trusted by Clinicians***. Prominent oncologists at leading cancer centers where we are conducting our DRP®-guided clinical trials, including the Dana-Farber Cancer Institute (Boston, MA, U.S.A.), Guy's Hospital (London, England), and Rigshospitalet (Copenhagen, Denmark), have used our putative DRP® companion diagnostics to select and treat likely responder patients and improve patient outcomes in a personalized medicine approach in such trials.

Priority Therapeutic Programs

Overview of Dovitinib (pan-TKI)

Our lead therapeutic candidate, dovitinib (formerly TKI258), is a potent and selective small molecule inhibitor targeting multiple tyrosine kinases. It inhibits fibroblast growth factor receptors (FGFR), along with vascular endothelial growth factor receptor (VEGFR) and platelet-derived growth factor receptor (PDGFR), among others. During clinical development, with dovitinib's unique pharmacological profile, the focus was originally on FGFR driven diseases, and also on those diseases where the additional anti-angiogenesis properties of dovitinib would offer a therapeutic advantage. As used in this section of this information statement/prospectus describing our therapeutic candidate dovitinib, statements regarding the use of our proprietary DRP® companion diagnostics or our proprietary DRP® platform or our observations that our therapeutic candidate dovitinib may have anti-cancer or anti-tumor activity or is observed to be well tolerated in a patient population should not be construed to mean that we have resolved all issues of safety and/or efficacy for our therapeutic candidate dovitinib or our putative Dovitinib-DRP® companion diagnostic. Issues of safety and efficacy for any therapeutic candidate companion diagnostic may only be determined by the U.S. FDA or other applicable regulatory authorities in jurisdictions outside the United States.

Dovitinib exhibits a dual mechanism of action including anti-tumor effects via its anti-proliferative activity as well as anti-angiogenic activity. Dovitinib is a potent inhibitor of the FGFR1 (inhibitory concentration 50% (IC50) of 8 nM), FGFR2 (IC50 of 40 nM) and FGFR3 (IC50 of 9 nM), as well as of the VEGFR 1, 2, and 3, PDGFRβ, c-Kit, RET, TrkA, CSF 1R, and FLT3 with IC50s of less than 40 nM. Stem cell factor (SCF), also termed KIT ligand or steel factor, has been shown to modulate tumor angiogenesis. In cultured human endothelial cells and c-Kit expressing cancer cells, dovitinib was observed to inhibit VEGF and SCF- stimulated mitogenesis; in a second model of angiogenesis driven by FGF-2, dovitinib was observed to potently inhibit neovascularization of Matrigel® plugs in vivo with an average effective dose (50% inhibition) (ED50) of 3 mg/kg. The effects on endothelial cells suggest that dovitinib may have potent anti-angiogenic activity. FGFR and PDGFR are also believed to play a role in the proliferation of certain tumor cells and supporting stromal cells. As a result of inhibition of target receptor tyrosine kinases (RTKs) by dovitinib,

other ligand- stimulated cellular functions are blocked, including activation of downstream signaling molecules, cellular proliferation, and survival. Anti-tumor effects for this agent may therefore be secondary to anti-angiogenesis, anti-proliferative activity against tumor cells, and anti- stromal activity.

Receptor tyrosine kinases (RTKs) such as VEGFR1,2,3, FGFR1,2,3, and PDGFRβ have been shown to play an important role in tumor angiogenesis (Dvorak 2003). VEGF is produced by both the host and the cancer cells and VEGF has a direct effect on endothelial cells, causing their proliferation, migration, invasion, and growth (Nagy et al 2002). Sunitinib and sorafenib, both multi-tyrosine kinase inhibitors that target the VEGF pathways, have become the standard of care for patients with advanced kidney cancer. Subsequently, other anti-angiogenic agents including, bevacizumab in combination with interferon alpha, pazopanib, axitinib and cabozantinib have also been approved by the FDA for advanced RCC.

The mTOR pathway has been shown to play an important role in angiogenesis through regulation of the synthesis of HIF and proteins that control cell proliferation, such as c-myc and cyclin D1. Based on favorable risk benefit ratio FDA has approved mTOR inhibitors such as temsirolimus and everolimus for advanced RCC that have demonstrated anti-angiogenesis and anti-tumor activities via action on HIF and stopping the production of cell-cycle regulators. All of these targeted therapies have been established as the preferred first or second line of therapies in patients with advanced RCC, with a median overall survival of up to 26 months, although sorafenib, the original prototype receptor tyrosine kinase inhibitor (RTKi) has been relegated to the 3rd line setting following failure of targeting of the VEGF and mTOR pathways.

Dovitinib was previously developed by Novartis, through a Phase 3 trial, where it showed therapeutic equivalence (with similar adverse events profile) to Bayer's Sorafenib for the treatment of third line RCC. Dovitinib also previously showed promising Phase 2 results in Novartis sponsored studies for the treatment of gastrointestinal stromal tumors (GIST), endometrial cancer, breast cancer, and liver cancer.

Pre-Clinical Studies

Dovitinib has demonstrated activity in a number of in vitro and in vivo models. It potently inhibits the activity of multiple receptor tyrosine kinases (RTKs) including PDGFRβ, CSF 1R, KIT, FLT3, VEGFRs 1-3, TrkA, RET, and FGFR (IC50 = 1-40 nM). Inhibition of these RTKs impedes tumor growth and progression through different mechanisms, including both direct anti- tumor effects and effects on host tissues, such as endothelial cells and supporting stromal cells, that are essential for tumor cell proliferation and metastasis.

The in vivo effects of dovitinib were shown to be a result of its direct anti-tumor effect and also its anti-angiogenic effect. Direct inhibition of RTK activation on tumor cells (PDGFRβ, FLT3, and FGFR3) was confirmed by a reduction in phosphorylation of these target RTKs, as well as signaling pathway components (ERK, STAT5, and AKT) in tumor xenografts. Target inhibition was observed for as long as 24 h after a single high dose of dovitinib. A decrease in tumor cell proliferation and induction of apoptosis, in combination with the anti-angiogenic effect of dovitinib, resulted in significant anti-tumor activity. The target RTK profile of dovitinib predicts for activity in many different types of solid and hematologic tumor models by acting on both endothelial cells and tumor cells. In the human tumor xenograft models tested, including colon, prostate, myeloma, AML, breast, and ovarian, dovitinib had anti-tumor effects on both small and large established tumor xenografts.

Studies in the RIP-Tag based experimental tumor model have shown that tumor angiogenesis can switch from VEGFR dependence to FGFR dependence under anti-VEGF therapy. This escape mechanism could explain treatment failure with agents targeting single angiogenic targets. Dovitinib combines potent anti-VEGFR2 and FGFR1-3 activity suggesting the possibility of enhanced response or duration of response in renal tumors compared to agents targeting VEGF only.

Dovitinib was evaluated in the mouse renal cell carcinoma Renca model. Renca cells (1 x 106 cells/mouse) were implanted s.c. into the right flank of Balb/c mice and treatment was started when the average tumor volume was ~70 mm3. Dovitinib was also evaluated in two models for human clear cell RCC: Caki-1, with VHLWT and 786-O with a deletion in the VHL gene and compared to sunitinib and sorafenib. In both human RCC models, dovitinib was at least as effective as the two clinically approved inhibitors at their MTDs.

Prior Clinical Trials

Dovitinib has been studied in 56 prior clinical trials, of which 23 were sponsored by Novartis, and 33 were investigator initiated. The sponsor initiated trials are summarized in the following table:

Study No. with CTKI258 as prefix	Indication/Design/Country	Study drug dose/schedule	N (total)	Comments	General Results
A1101	Advanced solid tumors P1 Dose escalation Japan	100 – 500 mg qd 5 days on/2 days off	28	6 patients treated at 500 mg in SCS	MTD determined to be the 500 mg dovitinib on an oral once daily, 5 days on, 2 days off schedule
A1201	Advanced scirrhous gastric carcinoma P2, single arm, multicenter Japan	500 mg qd 5 days on/2 days off	11	Evaluate the efficacy and safety. Early termination. Acceptable safety profile	Primary endpoint DCR at 8 weeks: 0%
A2101	Advanced solid tumors P1 Dose escalation, multicenter UK	25 – 100 mg qd 7 days on/7 days off and 100 – 175 qd 7 days on/7 days off then 28 day cycles continuous qd dosing	35	Dose and schedule not similar to pivotal study	MTD defined at 125 mg daily, orally
A2102	Acute myloid leukemia P1/2 Dose escalation, multicenter UK & US	50 – 600 mg qd 7 days on/7 days off then 28 day cycles continuous qd dosing	32	Dose and schedule not similar to pivotal study	2 DLT in 600 mg group
A2103	Multiple Myeloma P1/2 Dose escalation, multicenter US	50 – 500 mg qd x 14 days then 7 day rest followed by continuous qd dosing	21	MM pts had neutropenic DLTs not seen in solid tumor pts	Report combined with A2104
A2104	Multiple Myeloma P1/2 Dose escalation, multicenter UK	50 mg BID, 100 mg BID, and 325 mg qd continuous dosing on 28 day cycles	7	Hematological tumor toxicities differ from solid tumors	A2103 and A2104 were discontinued due to time and dose dependent accumulation at daily doses above 500 mg
A2105	Melanoma P1/2 Dose escalation, multicenter US	200 – 500 mg qd continuous dosing	47		MTD reached at 400 mg daily Study discontinued due to no clinical benefit
A2106	Solid tumor P1, single center, ADME Netherlands	500 mg radiolabeled dose day 1 followed by 400 mg qd continuous dosing	13	ADME	Terminal half life about 32 hours. Elimination via oxidative metabolism
A2107	Metastatic RCC P1/2, Dose escalation and expansion, multicenter US, EU, Taiwan	500 – 600 mg qd 5 days on/2 days off	87 5 pts at 600 mg and 82 pts at 500 mg	Supportive P1/2 in SCS and SCE + renal impairment (TKI258 renal impairment report – Nov 19, 2013)	MTD was 500 mg 5 days on/2 days off Disease Control (CR, PR, SD) 73.3% in the dovitinib 500 mg group per central reading

Study No. with CTKI258 as prefix	Population	Study drug dose/schedule	N (total)	Comments	General Results
A2112	Solid tumors P1, multicenter, crossover US	Arm 1 – Cycle 1: 500 mg single dose crossover Cycle 2+: CSF capsule 500 mg 5 on/2 off Arm 2 – Cycle 1: 300 mg daily, crossover for test meals Cycle 2+: FMI capsule 500 mg 5 on/2 off	60	Bioavailability Food Effect Capsules	Food had no effect on the systemic exposure of dovitinib (FMI capsules)
A2116	Solid tumors P1, multicenter, crossover US	Arm 1 – Cycle 1: 500 mg single dose crossover Cycle 2+: CSF capsule 500 mg 5 on/2 off Arm 2 – Cycle 1: 300 mg daily, crossover for test meals Cycle 2+: FMI tablet 500 mg 5 on/2 off	63	Bioavailability Food Effect Tablets	Food had no effect on the systemic exposure of dovitinib (FMI tablets)
A2119	Solid tumors P1, multicenter, drug-drug interaction (DDI) US	Cycle 1 DDI between dovitinib and the substrates of CYP1A2, CYP2C19, CYP2C9, and CYP3A4	39	DDI study	Dovitinib is a strong inducer of CYP1A2 and a moderate inhibitor f CYP2C19 and CYP3A4/5
A2120	Solid tumors, excluding breast cancer P1, multicenter, drug-drug interaction (DDI) US, EU	Cycle 1 DDI between dovitinib and the inhibitor of CYP1A2	45	DDI study	Fluvoxamine, a CYP1A2 inhibitor showed weak to moderate inhibition of dovitinib metabolism
A2124	Mild, moderate and severe hepatic impairment cohorts in Patients w/ Solid Tumors P1, multicenter, hepatic impairment US, EU	Single dose PK followed by multiple dose PK 400 mg or 500 mg	38 Normal 7 Mild 400 mg: 12 Mild 500 mg: 10 Moderate 400 mg: 9	Closure of the study before the tolerated dose was identified in any of the hepatic impaired group. In SCS	Dovitinib label: Excluding patients with moderate and severe hepatic impairment from treatment with dovitinib
A2128	Solid tumors P1, multicenter, crossover US	500 mg 5 on/2 off crossover in PK phase	175	Bioequivalence Capsules FMI vs. Tablets FMI	Bioequivlence established between capsules and tablets
A2201	Urothelial Cancer NA, EU Taiwan	500 mg qd 5 days on/2 days off	44	In SCS	ORR in FGR3 wildtype: 3.2% FGFR3 mutated: 0%
A2202	Metastatic Breast Cancer P2, multicenter NA, EU, Taiwan	500 mg qd 5 days on/2 days off	81	In SCS	No CR or PR SD: FGFR1+/HR+ 65.2% FGFR1-/HR+ 39.1%
A2204	Multiple myeloma P2, multicenter NA, EU, Australia, Turkey	500 mg qd 5 days on/2 days off	43	Hematological tumor toxicities differ from solid tumors	ORR 0% Terminsted after stage 1 according to protocol

Study No. with CTKI258 as prefix	Population	Study drug dose/schedule	N (total)	Comments	General Results
A2208	Hepatocellular carcinoma 1st line P2, multicenter Asia	500 mg qd X 5 days on/2 days off with Pop PK Vs Sorafenib 400 mg bid	165 (dovitinib 82, sorafenib 83)	Phase 2 randomized in SCS	HR 1.27
A2210	Metastatic breast cancer, HER2-, HR+ P2, randomized, double blind, placebo controlled Global	Fulvestrant + dovitinib 500 mg qd 5 days on/2 days off vs. Fulvestrant + Placebo	47 (fulvestrant+ dovitinib) 49 (fulvestrant+ placebo)	In SCS	PFS HR 0.681 (95% CI: 0.406, 1,143)
A2211	Endometrial cancer with or without FGFR2 mutation P2, multicenter, single arm Global	500 mg qd 5 days on/2 days off	53	In SCS	PFS at 28 weeks 31.8% in FGFR2 mutated 29.0% in FGFR2 wild type
A2302	Advanced RCC after failure of at least 1 VEGF and 1 mTOR targeted therapy	500 mg qd X 5 days on/2 days off with Pop PK Vs Sorafenib 400 mg bid	570 (dovitinib 284, sorafenib 286)	Phase 3, pivotal in SCS & SCE	
AIC02	GIST Progressed on imatinib EU	500 mg qd X 5 days on/2 days	38	Phase 2 Investigator initiated In SCS	DCR at 12 weeks 52.6%
KR01T	GIST Progressed on imatinib and sunitinib South Korea	500 mg qd X 5 days on/2 days	30	Phase 2 Investigator initiated No CSR only a publication Kang et. al., British Journal of Cancer (2013) 109, 2309 – 2315	DCR at 24 weeks 13%

We believe the clinical data in these trials justify further clinical trials for dovitinib in GIST, endometrial cancer, breast cancer, RCC, and hepatocellular carcinoma (HCC or liver cancer).

The studies in clear cell renal carcinoma, A2302 and A2107, are the pivotal and the supporting study, respectively, in the dovitinib NDA as well as PD02-044, the Dovitinib-DRP® validation study. The indication is treatment of patients with advanced RCC following two or more prior systemic therapies and who are selected for therapy with the Dovitinib-DRP® companion diagnostic.

A2107 is a Phase I/II study on a 5-day on/2-day off treatment schedule in heavily pretreated advanced RCC patients that are refractory to standard therapies. In the 20 patients treated in phase I with 500 mg (N = 15) or 600 mg (N = 5) dovitinib, the MTD was defined as 500 mg. Dovitinib was observed to be well tolerated and anti-tumor activity was observed after progression on both VEGF and mTOR inhibitors. In the Phase II portion of the study, 67 heavily pretreated patients were enrolled and received 500 mg dovitinib on a 5 days on/2 days off schedule, and had measurable, histologically or cytologically confirmed progressive advanced or metastatic RCC with predominant clear cell histology. Thirty-five patients were previously treated with at least 2 prior VEGF inhibitors (most often sunitinib and sorafenib) and one mTOR inhibitor (most often everolimus), and 55 patients received at least one VEGF and one mTOR inhibitor. ORR of 3% (90% CI 0.5-9.1), Disease Control Rate (DCR; CR, PR, and SD) of 55.2% and a median progression free survival of 3.7 (95% CI 3.0- 5.6) months according to both independent central review and local review.

A further Phase III registration trial CTKI258A2302 (study A2302), also referred to as the GOLD trial, was conducted in RCC. The pivotal Phase III trial was an open-label, randomized, multi-center study to compare the toleration and anti-cancer activity of dovitinib versus sorafenib in patients (N = 570) with metastatic RCC after failure of anti-angiogenic (VEGF- targeted and mTOR inhibitor) therapies. Supportive data will come from a Phase I/II dose escalation maximum tolerated dose (MTD) and dose expansion study CTKI258A2107 (study 2107) in patients with advanced or metastatic RCC (N = 82 at 500 mg).

Initially, dovitinib was investigated with a continuous daily dosing schedule. However, preliminary PK data suggested that over-proportional drug accumulation might occur with daily administration. Therefore, a 5 days on/2 days off dosing schedule was proposed for study A2107. At the tested dose levels of 500 mg and 600 mg, no over-proportional drug- accumulation was observed on Day 15 (steady state) with the 5 days on/2 days off regimen. Two patients presented with dose-limiting toxicities at 600 mg, and the MTD was established at 500 mg. Accordingly, Novartis selected the 500 mg 5 days on/2 days off regimen for the Phase III registration trial in the advanced RCC indication (study A2302).

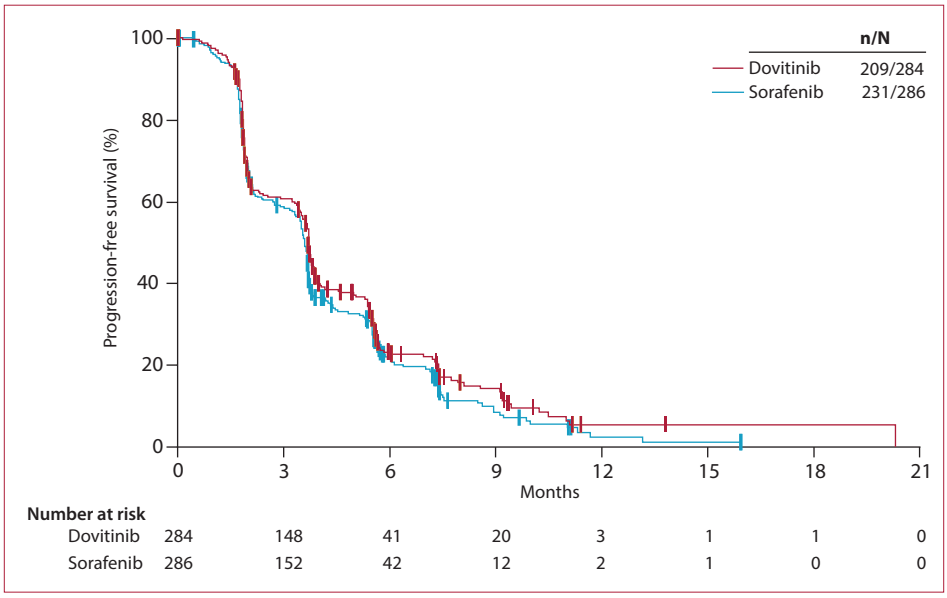
Based on the observed anti-tumor effect of dovitinib against advanced RCC in trial A2107 Novartis proceeded to a Phase III registration trial designed to show superiority over sorafenib. A2302 is the Phase III registration trial, also referred to as the GOLD trial. This pivotal Phase III trial was an open-label, randomized, multi-center study to compare the tolerability and anti-cancer activity of dovitinib versus sorafenib in patients (N = 570) with metastatic RCC after failure of anti-angiogenic (one VEGF- targeted and one mTOR inhibitor) and other therapies. The randomization was a 1:1 ratio to dovitinib 500 mg/day 5 days on/2 days off vs. sorafenib 400 mg BID. The trial failed its primary anti-cancer activity endpoint of superiority (to sorafenib) progression-free survival (PFS) as determined by central radiology assessment (the median PFS was 3.7 months and 3.6 months in the dovitinib and sorafenib arms, respectively and the HR 0.86 (95% CI: 0.72, 1.04)). The median overall survival was 11.9 months for the dovitinib arm and 11.2 months for the sorafenib arm, respectively (HR: 0.95; 95% CI: 0.78, 1.15). The study was published in *Lancet Oncology* in 2014 where it was concluded that "Dovitinib showed activity, but this was no better than that of sorafenib in patients with renal cell carcinoma who had progressed on previous VEGF-targeted therapies and mTOR inhibitors."

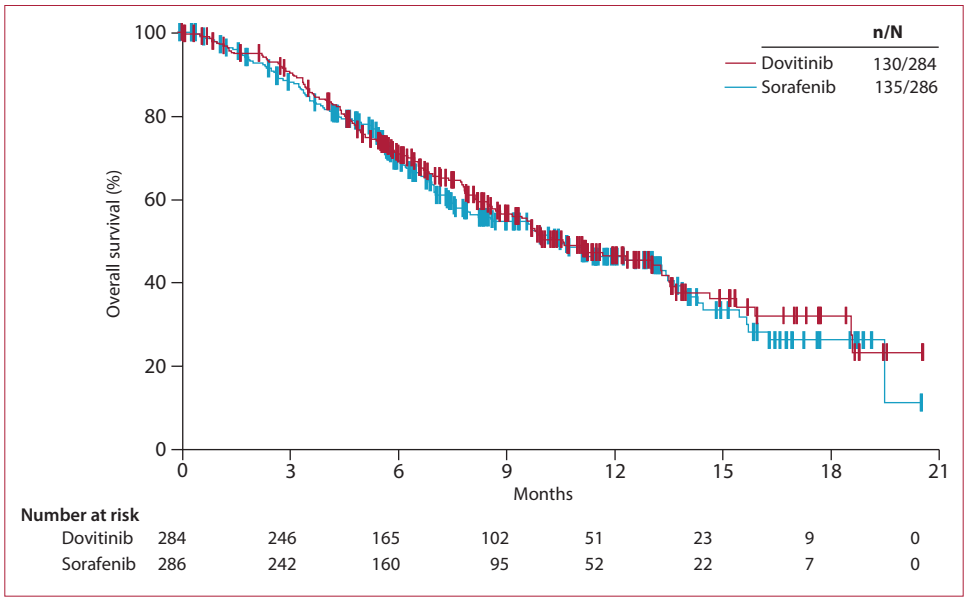
The A2302 trial had been designed to show superiority of dovitinib to sorafenib, and the superiority observed in terms of PFS and OS was not statistically significant. Subsequently, Novartis did not pursue further development. However, the trial established that dovitinib is non-inferior to sorafenib with respect to PFS and OS. Non-inferior is the statistical term describing a drug that is a drug that shows equivalent therapeutic benefit to its comparator drug.

The two key requirements for the non-inferiority approach are (i) the presence of assay sensitivity of the pivotal study, a finding that is readily demonstrable for the A2302 study, and (ii) the choice of non-inferiority margin, based upon a combination of statistical reasoning and clinical judgement by RCC-subspecialized practitioners offering their clinical perspective on the retention of efficacy needed for the intervention to be considered "efficacious" in that particular malignancy and specific disease setting. The non-inferiority margin for the hazard ratio, i.e., 1.153, was determined using studies that are all phase 3, randomized controlled trials (RCTs) where sorafenib was administered as second-line, third-line, or fourth-line treatment. As mentioned above, in the A2302 study, the point estimate of the hazard ratio on PFS was 0.86, and its two-sided 95% confidence interval was (0.72, 1.04). Since the upper bound margin of 95% CI in the unstratified analysis of PFS was 1.04, the non-inferiority of dovitinib to sorafenib is demonstrated because the upper limit (1.04) was less than the estimated margin of 1.153. Subgroup and sensitivity analyses of PFS were consistent with the primary analysis demonstrating the efficacy of dovitinib in this patient population. Patients with KPS ≥ 90 had a higher median PFS in the dovitinib group (median 18.4 months, 95% CI: 12.9, Not evaluable) than the sorafenib group (median 13.9, 95% CI:10.7, 15.5).

The post hoc non-inferiority analysis on the OS was performed using a hazard ratio (HR on OS; dovitinib/sorafenib as secondary endpoint) with a margin of 1.153 with the same hypothesis used for PFS. The OS between the dovitinib and sorafenib treatment groups, had a Hazard ratio of 0.94 with 95% CI: 0.779, 1.146%. Since the upper bound of the two-sided 95% confidence interval for the hazard ratio is <1.153, the results show that dovitinib is non-inferior to sorafenib.

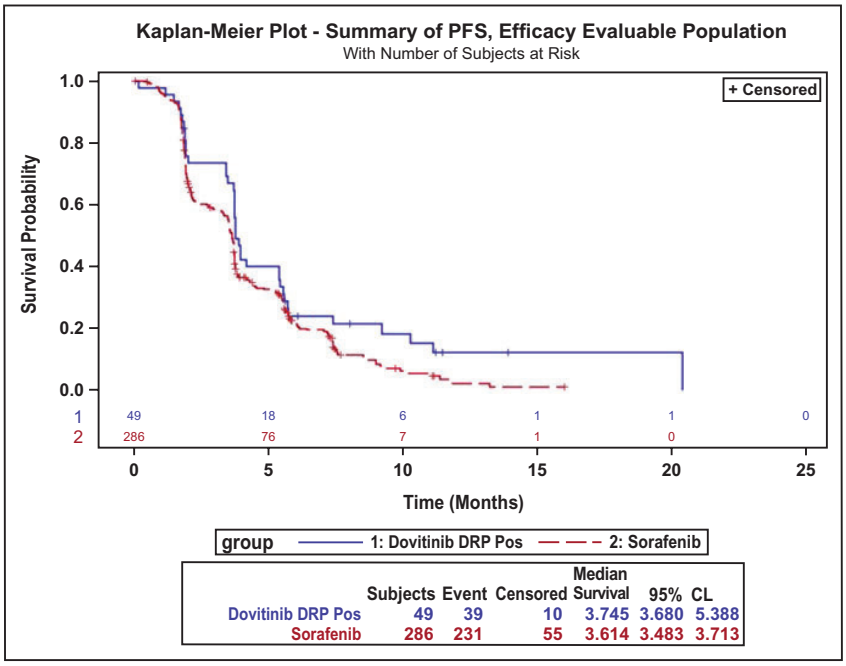
The figures below show the progression-free and overall survival from the A2302 Phase 3 trial):





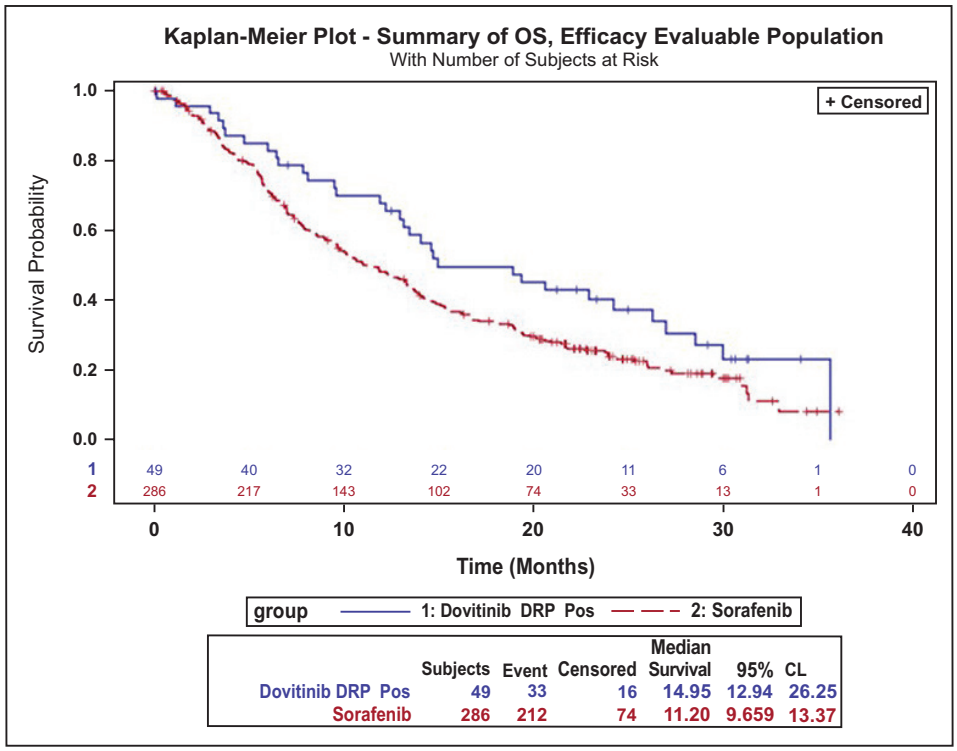
The PD02-044 study intended to identify patients who were more likely to benefit from treatment with dovitinib in the A2302 study and thus validating the Dovitinib-DRP®. Hundred and thirty five dovitinib-treated patients' renal biopsy tissue comprised the investigational arm of the "Dovitinib DRP Study". Of these 135 patients, 49 patients had a Dovitinib-DRP® score of >50%. The *key clinical outcomes* of PFS, OS, and ORR were compared between the 49 patients with a tumor DRP® score >50% and the sorafenib-treated control arm comprised of 286 patients. The protocol for the "Dovitinib DRP Clinical Performance Evaluation Study" was submitted with the PMA submission. The outcome on the efficacy outcome measure, PFS, revealed a 3.75 month median PFS for DRP®-selected dovitinib-treated patients versus 3.6 month median PFS for sorafenib-treated patients, yielding an *unadjusted* HR of 0.714 (95% CI 0.5051, 1.0103; p = 0.0572). These results show a marginal and non-significant improvement in median PFS for DRP®-selected dovitinib-treated patients. (Please refer to Figure 1 below.)

Figure 1: Kaplan Meier Plot — Summary of PFS, Efficacy Evaluable Population



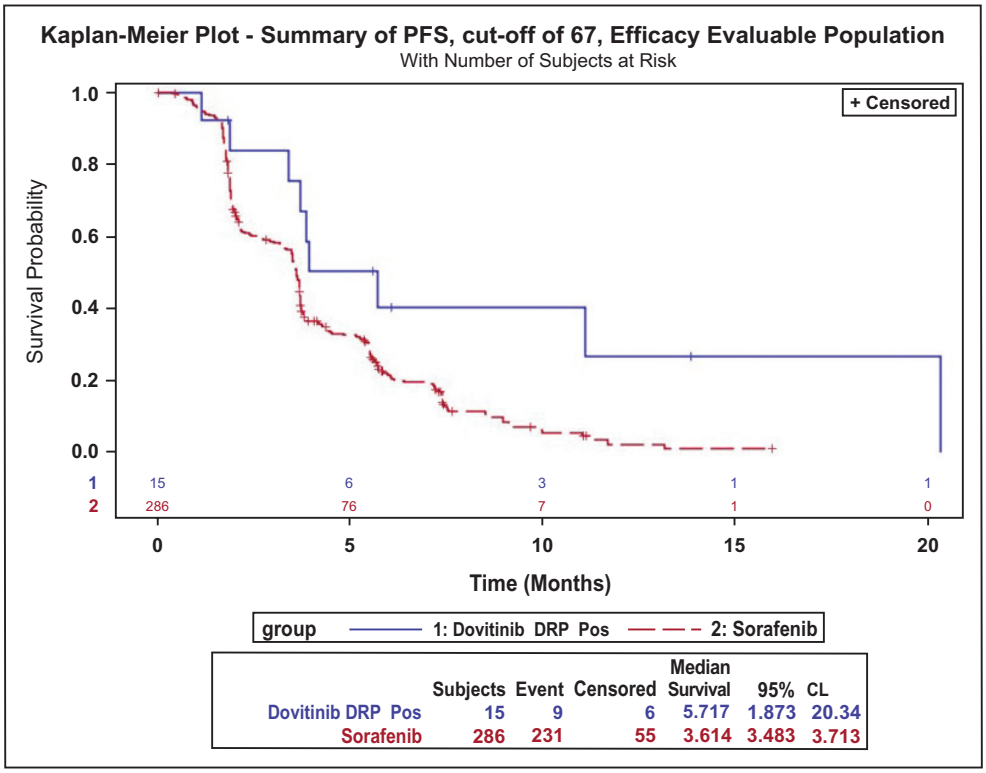
The results of the "Dovitinib DRP Study" on the other efficacy outcome measure OS, revealed a favorable outcome. It showed a 14.95 months median OS for DRP-selected dovitinib-treated patients *versus* an 11.20 months median OS for sorafenib-treated patients. Comparison of these medians yields an *unadjusted* HR of 0.685 (95% CI 0.4736, 0.9897; p = 0.0439) where the upper bound of the 95% CI does not cross unity, thereby revealing a statistically significant improvement in median OS for DRP-selected dovitinib-treated patients. (Please refer to Figure 2 below).

Figure 2: Kaplan Meier Plot — Summary of OS, Efficacy Evaluable Population



In an exploratory analysis of the effect of increasing DRP® score thresholds on clinical outcomes, it was shown that as the DRP® threshold increased, so did the clinical outcomes on PFS and OS. Specifically, when the DRP® score threshold increased from 50 to 67, the outcome on the primary efficacy endpoint, PFS, further improved to a 5.7 months median PFS for DRP®-selected dovitinib-treated patients *versus* 3.6 months median PFS for sorafenib-treated patients. Comparison of the median PFS values (resulting from this increase in the DRP threshold score) yields an *unadjusted* HR of 0.420 (95% CI 0.2054, 0.8585; p = 0.0174) and shows a statistically significant improvement in median PFS for DRP®-selected dovitinib-treated patients when the DRP® score threshold is increased. (Please refer to Figure 3 below).

Figure 3: Kaplan Meier Plot — Summary of PFS, Cut-Off of 67%, Efficacy Evaluable Population



The following tables summarize the adverse events observed in the prior Phase 3 trial in RCC:

Most frequently occurring AEs by MedDRA System Organ Class and Preferred Term:

ISS 6.2B TEAEs by MedDRA SOC and PT — Pooled RCC Studies, Safety Population (≥5%)

System Organ Class[1] Preferred Term[1]	Dovitinib (500 mg/day) N=362 n (%)	Sorafenib N=284 n (%)	Total N=646 n (%)
Subjects With ≥ 1 TEAE	**357 (98.6)**	**276 (97.2)**	**633 (98.0)**
Total Number Of TEAEs	**6195**	**3770**	**9965**
Blood And Lymphatic System Disorders	**74 (20.4)**	**39 (13.7)**	**113 (17.5)**
Anaemia	49 (13.5)	31 (10.9)	80 (12.4)
Gastrointestinal Disorders	**325 (89.8)**	**233 (82.0)**	**558 (86.4)**
Abdominal Pain	51 (14.1)	42 (14.8)	93 (14.4)
Abdominal Pain	41 (11.3)	24 (8.5)	65 (10.1)

System Organ Class[1] Preferred Term[1]	Dovitinib (500 mg/day) N=362 n (%)	Sorafenib N=284 n (%)	Total N=646 n (%)
Upper			
Constipation	72 (19.9)	73 (25.7)	145 (22.4)
Diarrhoea	247 (68.2)	134 (47.2)	381 (59.0)
Dry Mouth	27 (7.5)	13 (4.6)	40 (6.2)
Dyspepsia	40 (11.0)	14 (4.9)	54 (8.4)
Nausea	204 (56.4)	84 (29.6)	288 (44.6)
Stomatitis	51 (14.1)	57 (20.1)	108 (16.7)
Vomiting	177 (48.9)	49 (17.3)	226 (35.0)
General Disorders And Administration Site Conditions	**285 (78.7)**	**187 (65.8)**	**472 (73.1)**
Asthenia	92 (25.4)	48 (16.9)	140 (21.7)
Fatigue	141 (39.0)	99 (34.9)	240 (37.2)
General Physical Health Deterioration	28 (7.7)	20 (7.0)	48 (7.4)
Non-Cardiac Chest Pain	39 (10.8)	21 (7.4)	60 (9.3)
Oedema Peripheral	44 (12.2)	20 (7.0)	64 (9.9)
Pain	16 (4.4)	16 (5.6)	32 (5.0)
Pyrexia	63 (17.4)	44 (15.5)	107 (16.6)
Investigations	**165 (45.6)**	**129 (45.4)**	**294 (45.5)**
Blood Alkaline Phosphatase Increased	30 (8.3)	5 (1.8)	35 (5.4)
Gamma-Glutamyltransferase Increased	35 (9.7)	8 (2.8)	43 (6.7)
Weight Decreased	81 (22.4)	90 (31.7)	171 (26.5)
Metabolism And Nutrition Disorders	**217 (59.9)**	**132 (46.5)**	**349 (54.0)**
Decreased Appetite	133 (36.7)	101 (35.6)	234 (36.2)
Hyperkalaemia	20 (5.5)	12 (4.2)	32 (5.0)
Hypertriglyceridaemia	71 (19.6)	2 (0.7)	73 (11.3)
Musculoskeletal and Connective Tissue Disorders	**203 (56.1)**	**138 (48.6)**	**341 (52.8)**
Arthralgia	41 (11.3)	30 (10.6)	71 (11.0)
Back Pain	53 (14.6)	36 (12.7)	89 (13.8)
Bone Pain	18 (5.0)	14 (4.9)	32 (5.0)
Muscle Spasms	25 (6.9)	25 (8.8)	50 (7.7)
Musculoskeletal Chest Pain	21 (5.8)	14 (4.9)	35 (5.4)
Musculoskeletal Pain	21 (5.8)	11 (3.9)	32 (5.0)
Myalgia	42 (11.6)	17 (6.0)	59 (9.1)
Pain In Extremity	52 (14.4)	33 (11.6)	85 (13.2)
Nervous System Disorders	**163 (45.0)**	**84 (29.6)**	**247 (38.2)**
Dizziness	37 (10.2)	8 (2.8)	45 (7.0)
Dysgeusia	48 (13.3)	9 (3.2)	57 (8.8)
Headache	45 (12.4)	25 (8.8)	70 (10.8)
Psychiatric Disorders	**64 (17.7)**	**47 (16.5)**	**111 (17.2)**
Anxiety	19 (5.2)	13 (4.6)	32 (5.0)
Insomnia	23 (6.4)	21 (7.4)	44 (6.8)
Respiratory, Thoracic and Mediastinal Disorders	**187 (51.7)**	**133 (46.8)**	**320 (49.5)**
Cough	74 (20.4)	52 (18.3)	126 (19.5)
Dysphonia	26 (7.2)	26 (9.2)	52 (8.0)
Dyspnoea	91 (25.1)	58 (20.4)	149 (23.1)
Pleural Effusion	19 (5.2)	13 (4.6)	32 (5.0)

System Organ Class[1] Preferred Term[1]	Dovitinib (500 mg/day) N=362 n (%)	Sorafenib N=284 n (%)	Total N=646 n (%)
Skin And Subcutaneous Tissue Disorders	**188 (51.9)**	**198 (69.7)**	**386 (59.8)**
Alopecia	5 (1.4)	61 (21.5)	66 (10.2)
Dry Skin	35 (9.7)	26 (9.2)	61 (9.4)
Palmar-Plantar Erythrodysaesthesia Syndrome	39 (10.8)	118 (41.5)	157 (24.3)
Pruritus	19 (5.2)	30 (10.6)	49 (7.6)
Rash	72 (19.9)	48 (16.9)	120 (18.6)
Vascular Disorders	**118 (32.6)**	**95 (33.5)**	**213 (33.0)**
Hypertension	76 (21.0)	79 (27.8)	155 (24.0)

(1) MedDRA Version 16.0.

Note: All percentages are based on the number of subjects in the population and treatment group (N).

ISS 6.2B2 TEAEs by MedDRA SOC and PT — Pooled 500 mg Dosing Regimen Studies, Safety Population(>5%)

System Organ Class[1] Preferred Term[1]	Dovitinib (500 mg/day) N=664 n (%)
Subjects With ≥ 1 TEAE	**657 (98.9)**
Total Number Of TEAEs	**12443**
Blood And Lymphatic System Disorders	**156 (23.5)**
Anaemia	96 (14.5)
Neutropenia	37 (5.6)
Thrombocytopenia	47 (7.1)
Eye Disorders	**135 (20.3)**
Lacrimation Increased	35 (5.3)
Gastrointestinal Disorders	**600 (90.4)**
Abdominal Pain	112 (16.9)
Abdominal Pain Upper	84 (12.7)
Constipation	132 (19.9)
Diarrhoea	462 (69.6)
Dry Mouth	68 (10.2)
Dyspepsia	74 (11.1)
Nausea	379 (57.1)
Stomatitis	80 (12.0)
Vomiting	353 (53.2)
General Disorders And Administration Site Conditions	**527 (79.4)**
Asthenia	194 (29.2)
Fatigue	250 (37.7)
General Physical Health Deterioration	33 (5.0)
Non-Cardiac Chest Pain	46 (6.9)
Oedema Peripheral	90 (13.6)
Pyrexia	119 (17.9)
Infections And Infestations	**224 (33.7)**
Urinary Tract Infection	51 (7.7)

System Organ Class[1] Preferred Term[1]	Dovitinib (500 mg/day) N=664 n (%)
Investigations	**331 (49.8)**
Alanine Aminotransferase Increased	77 (11.6)
Aspartate Aminotransferase Increased	73 (11.0)
Blood Alkaline Phosphatase Increased	87 (13.1)
Blood Bilirubin Increased	34 (5.1)
Gamma-Glutamyltransferase Increased	73 (11.0)
Weight Decreased	145 (21.8)
Metabolism And Nutrition Disorders	**401 (60.4)**
Decreased Appetite	255 (38.4)
Dehydration	40 (6.0)
Hypertriglyceridaemia	109 (16.4)
Hypoalbuminaemia	43 (6.5)
Musculoskeletal And Connective Tissue Disorders	**323 (48.6)**
Arthralgia	57 (8.6)
Back Pain	90 (13.6)
Muscle Spasms	37 (5.6)
Musculoskeletal Pain	34 (5.1)
Myalgia	67 (10.1)
Pain In Extremity	89 (13.4)
Nervous System Disorders	**314 (47.3)**
Dizziness	70 (10.5)
Dysgeusia	83 (12.5)
Headache	110 (16.6)
Psychiatric Disorders	**134 (20.2)**
Insomnia	61 (9.2)
Respiratory, Thoracic And Mediastinal Disorders	**321 (48.3)**
Cough	117 (17.6)
Dysphonia	40 (6.0)
Dyspnoea	145 (21.8)
Skin And Subcutaneous Tissue Disorders	**353 (53.2)**
Dermatitis Acneiform	40 (6.0)
Dry Skin	63 (9.5)
Palmar-Plantar Erythrodysaesthesia Syndrome	56 (8.4)
Pruritus	43 (6.5)
Rash	152 (22.9)
Vascular Disorders	**207 (31.2)**
Hypertension	135 (20.3)
Hypotension	35 (5.3)

(1) MedDRA Version 16.0.

Note: All percentages are based on the number of subjects in the population and treatment group (N).

Table: Adverse Events with Incidence ≥ 3.5% (Grade 3/4), Regardless of Study Drug Relationship, By Preferred Term, Maximum Grade and Treatment (Safety Set)

	Dovitinib N=280		Sorafenib N=284	
Preferred Term	**All Grade n (%)**	**Grade 3/4 n (%)**	**All Grades n (%)**	**Grade 3/4 n (%)**
Total	275 (98.2)	215 (76.8)	276 (97.2)	199 (70.1)
Diarrhoea	190 (67.9)	20 (7.1)	134 (47.2)	13 (4.6)
Nausea	147 (52.5)	9 (3.2)	84 (29.6)	7 (2.5)
Vomiting	125 (44.6)	10 (3.6)	49 (17.3)	3 (1.1)
Fatigue	115 (41.1)	29 (10.4)	99 (34.9)	24 (8.5)
Decreased Appetite	93 (33.2)	5 (1.8)	101 (35.6)	14 (4.9)
Asthenia	65 (23.2)	14 (5.0)	48 (16.9)	11 (3.9)
Dyspnoea	64 (22.9)	16 (5.7)	58 (20.4)	22 (7.7)
Weight Decreased	63 (22.5)	4 (1.4)	90 (31.7)	1 (0.4)
Hypertension	55 (19.6)	22 (7.9)	79 (27.8)	45 (15.8)
Hypertriglyceridaemia	55 (19.6)	38 (13.6)	2 (0.7)	1 (0.4)
Rash	54 (19.3)	3 (1.1)	48 (16.9)	6 (2.1)
Cough	52 (18.6)	4 (1.4)	52 (18.3)	3 (1.1)
Constipation	51 (18.2)	0	73 (25.7)	3 (1.1)
Pyrexia	46 (16.4)	2 (0.7)	44 (15.5)	3 (1.1)
Back Pain	42 (15.0)	7 (2.5)	36 (12.7)	8 (2.8)
Abdominal Pain	38 (13.6)	10 (3.6)	42 (14.8)	4 (1.4)
Pain In Extremity	36 (12.9)	6 (2.1)	33 (11.6)	4 (1.4)
Anaemia	34 (12.1)	17 (6.1)	31 (10.9)	19 (6.7)
Dyspepsia	33 (11.8)	0	14 (4.9)	1 (0.4)
Palmar-Plantar Erythrodysaesthesia Syndrome	32 (11.4)	3 (1.1)	118 (41.5)	18 (6.3)
Stomatitis	30 (10.7)	1 (0.4)	57 (20.1)	6 (2.1)
Abdominal Pain Upper	30 (10.7)	3 (1.1)	24 (8.5)	3 (1.1)
Arthralgia	28 (10.0)	6 (2.1)	30 (10.6)	6 (2.1)
Myalgia	28 (10.0)	3 (1.1)	17 (6.0)	0
Dizziness	28 (10.0)	3 (1.1)	8 (2.8)	0
Oedema Peripheral	27 (9.6)	1 (0.4)	20 (7.0)	0
Gamma-Glutamyltransferase Increased	27 (9.6)	16 (5.7)	8 (2.8)	2 (0.7)
Headache	26 (9.3)	2 (0.7)	25 (8.8)	1 (0.4)
Blood Alkaline Phosphatase Increased	25 (8.9)	6 (2.1)	5 (1.8)	0
Dermatitis Acneiform	23 (8.2)	1 (0.4)	6 (2.1)	0
Dysphonia	22 (7.9)	0	26 (9.2)	1 (0.4)
Non-Cardiac Chest Pain	22 (7.9)	5 (1.8)	21 (7.4)	2 (0.7)
General Physical Health Deterioration	19 (6.8)	13 (4.6)	20 (7.0)	16 (5.6)
Musculoskeletal Chest Pain	17 (6.1)	1 (0.4)	14 (4.9)	2 (0.7)
Pleural Effusion	17 (6.1)	10 (3.6)	13 (4.6)	9 (3.2)
Lipase Increased	17 (6.1)	13 (4.6)	11 (3.9)	9 (3.2)
Bone Pain	15 (5.4)	2 (0.7)	14 (4.9)	4 (1.4)
Hyperkalaemia	14 (5.0)	4 (1.4)	12 (4.2)	5 (1.8)
Muscular Weakness	14 (5.0)	1 (0.4)	6 (2.1)	1 (0.4)
Paraesthesia	13 (4.6)	2 (0.7)	9 (3.2)	1 (0.4)
Malaise	13 (4.6)	1 (0.4)	7 (2.5)	0
Alanine Aminotransferase Increased	13 (4.6)	3 (1.1)	6 (2.1)	3 (1.1)
Musculoskeletal Pain	12 (4.3)	0	11 (3.9)	1 (0.4)
Gastrooesophageal Reflux Disease	12 (4.3)	1 (0.4)	4 (1.4)	0
Pain	11 (3.9)	5 (1.8)	16 (5.6)	5 (1.8)

Preferred Term	Dovitinib N=280 All Grade n (%)	Dovitinib N=280 Grade 3/4 n (%)	Sorafenib N=284 All Grades n (%)	Sorafenib N=284 Grade 3/4 n (%)
Pneumonia	11 (3.9)	6 (2.1)	15 (5.3)	10 (3.5)
Dehydration	11 (3.9)	7 (2.5)	12 (4.2)	5 (1.8)
Urinary Tract Infection	11 (3.9)	1 (0.4)	10 (3.5)	0
Aspartate Aminotransferase Increased	11 (3.9)	3 (1.1)	8 (2.8)	3 (1.1)
Hypotension	11 (3.9)	1 (0.4)	7 (2.5)	0
Blood Triglycerides Increased	11 (3.9)	8 (2.9)	1 (0.4)	0
Dysphagia	7 (2.5)	2 (0.7)	12 (4.2)	0
Haemoptysis	5 (1.8)	0	11 (3.9)	2 (0.7)
Alopecia	2 (0.7)	0	61 (21.5)	1 (0.4)
Erythema	1 (0.4)	0	15 (5.3)	1 (0.4)
Pain of Skin	1 (0.4)	0	11 (3.9)	1 (0.4)

— Preferred Terms Are Sorted In Descending Frequency Of All Grades Column, As Reported In Dovitinib Arm.
— A Patient with Multiple Occurrences Of An AE Under One Treatment Is Counted Only Once In The AE Category For That Treatment.
— A Patient with Multiple Adverse Events Is Counted Only Once In The Total Row.
— MedDRA Version 16.0 Has Been Used For The Reporting Of AEs. AEs Have Been Graded According To The CTCAE V4.03.

Anticipated NDA Filing for RCC

We are pursuing FDA approval for dovitinib for the treatment of advanced RCC as the first indication for this drug. The target population is ccRCC patients in the post-second-line setting whose RCC has progressed due to the failure of two or more prior systemic therapies and patients selected for therapy based on the Dovitinib-DRP® companion diagnostic.

We anticipate that the NDA will be supported primarily by data from one randomized Phase 3 trial (A2302) that compared dovitinib to sorafenib in patients with metastatic RCC after failure of VEGF- targeted therapies or mTOR inhibitors, plus supportive data from one Phase 1/2 trial (A2107) in patients with advanced or metastatic RCC. We conducted a pre-NDA meeting with the FDA on February 20, 2020, and subsequently received pre-NDA meeting Minutes on March 18, 2020. Our anticipated NDA includes a plan for a Phase 1/2A study of dovitinib for the treatment of pediatric solid tumors (phase 1) followed by a phase 2A in osteosarcoma and later any solid tumor with positive signals in the phase 1, as required under The RACE for Children Act (Title V, Sec. 504, FDA Reauthorization Act (FDARA), enacted August 18, 2017). The patients in the phase 2 settings will be selected with the Dovitinib-DRP®. We have previously conducted a pre-clinical animal model study of dovitinib showing that the drug has activity in this pediatric indication.

Our anticipated NDA includes use of our Dovitinib-DRP® as a companion diagnostic to select and treat patients most likely to respond to the drug. We expect our NDA application will be submitted in late 2021 and is supported by a Pre-Market Approval (PMA) application, for use of the DRP® as a companion diagnostic, which was submitted to the FDA on April 1, 2021, and is currently under review by the FDA.

Overview of Renal Cell Carcinoma (RCC)

Globally, the incidence of RCC varies widely from region to region, with the highest rates observed in the Czech Republic and North America. Approximately 338,000 new cases of kidney cancer were diagnosed worldwide in 2012 and 143,000 patients died from this malignancy. In the United States, there are approximately 74,000 new cases each year and almost 15,000 deaths from RCC on an annual basis. In the European Union, there were approximately 84,000 cases of RCC and 35,000 deaths due to kidney cancer in 2012.

Renal cell carcinomas arise from the proximal tubal epithelium. Alternatively known as clear- cell cancer or renal adenocarcinoma, RCC is characterized by a distinct clear or granular cell appearance visible by light microscopy.

The most common molecular abnormality in clear cell RCC is loss of Von Hippel-Lindau (VHL), which is found in about 50-70% of sporadic cases. Sporadic somatic and hereditary germ cell mutations cause the loss of the VHL protein 9Pvhl0 and VHL negatively regulates hypoxia inducible genes, such as those encoding Hypoxia-inducible factor (HIF 1)-alpha, vascular endothelial growth factor (VEGF), and platelet-derived growth factor (PDGF) ß and the glucose transporter GLUT-1.

Approximately 25% of the patients present with advanced disease at the time of diagnosis, including locally invasive or metastatic renal cell carcinoma, and 50% of the patients undergoing curative surgery can be expected to experience relapse at distant sites. Median survival for patients with metastatic disease is approximately 2 years with the 5-year overall survival < 10% that has only improved marginally to 11.7% in the 2007-2013 reporting period.

In the last decade and a half, the treatment of RCC has evolved from being predominantly cytokine-based to being grounded in the use of drugs targeting VEGF and PDGF, mammalian target of rapamycin (mTOR) pathways and immunotherapy.

Rationale for Targeting Multiple Kinases in RCC

In the first line setting of advanced RCC, the established therapeutic options include agents conferring VEGF pathway inhibition, (e.g., sunitinib, pazopanib, and cabozantinib), mTOR- pathway inhibition (everolimus, temsirolimus), high-dose interleukin (IL)-2, but more recently, this has shifted to a combination of immune-oncology agents or a combination of immunotherapy with a tyrosine kinase inhibitor.

In the second-line setting, following progression of disease on therapy, or intolerance of the first- line regimen, there are again a number of potential treatment options, including targeted drugs such as axitinib, cabozantinib, lenvatinib in combination with everolimus, and the checkpoint inhibitors nivolumab and iplimumab. The optimal sequence of therapy remains an area of active research, partially rooted in the observation that mRCC is a heterogeneous disease characterized by a variable natural history and response to initial and subsequent therapy.

In the third line RCC setting, there is an unmet need for companion diagnostics, like the Dovitinib-DRP®, to help guide therapeutic options and decisions in this patient group. Until recently, there was no newly approved drug in this setting. However, tivozanib was recently approved (March 2021) as a treatment option in the third line RCC setting.

Although these newly approved targeted agents represent significant progress in the treatment of advanced kidney cancer, the majority of advanced RCC patients become resistant or refractory to these therapies. There remains a large and significant unmet medical need for patients whose cancer progresses despite treatment with VEGF and mTOR inhibitors and immunotherapies. Thus, the development of novel therapies, particularly in combination with a predictive biomarker is an unmet medical need in third-line advanced RCC.

Currently, there is just one novel therapy in patients who have failed two previous systemic therapies, namely, the recently approved TKI tivozanib. In a retrospective analysis of 34 patients, third-line sorafenib appears to be active and well tolerated in mRCC after first-line sunitinib and second-line everolimus or temsirolimus. In addition, the most recently approved agent, axitinib, in second-line advanced RCC was also based on a Phase III trial comparing axitinib vs. sorafenib. Sorafenib was selected as an appropriate active comparator for the dovitinib Phase III trial (A2302) in patients who failed both anti-VEGF and mTOR therapies.

Existing pan-TKIs and Our Opportunity

Numerous pan-TKIs, including Nexavar® (sorafenib), Sutent® (sunitinib), Votrient® (pazopanib), and Lenvima® (lenvantib) are currently used in the treatment of RCC and numerous other indications. Fotivda® (tivozanib) was recently approved as a third line RCC treatment, however its use in clinical practice is yet to be established. The global kinase inhibitor market in 2019 was roughly $33 billion and, according to consensus estimates cited by Leerink, is poised to grow about 13% annually to surpass $50 billion by 2022. Sales of pan-TKIs substantially contribute to this total market. For example, sales of Sutent® were $1 billion in 2018, while sales of Nexavar® and Votrient® were each about $800 million that year. Additionally, sales of certain pan-TKIs, such as Lenvima®, are increasingly being driven, in part, by combination therapy with immune checkpoint inhibitors, such as PD-1 inhibitors (e.g. Merck's Keytruda®). In the RCC setting, sales of Nexavar® alone, for example, were $125 million in 2019. The global kidney cancer drugs market size was valued at $4.4 billion in 2016 and is expected to grow to $6.3 billion in 2022.

The table below lists the therapeutic benefit of pan-TKIs, as well as other agents, approved for the treatment of RCC:

Efficacy and MOA of currently available treatments for advanced renal cell carcinoma — FDA approved

Approval Date/pharma	Drug name	MOA	Trt Control/Line of treatment	ORR %	Median PFS	Median OS
Dec 2005 Bayer	Sorafenib	TKI: KIT, FLT3, RET, VEGFR1-3, PDGFRβ, c-CRAF, BRAF, mutantBRAF	Placebo 2nd-line	Not reported	5.5 M vs 2.8 M HR=0.44	HR=0.72 NS
Jan 2006 Pfizer	Sunitinib	TKI: VEGFR1-2, FLT3, IT, SCF, PDGFRα	IFN-alpha 1st-line Previously untreated	27.5 vs 5.3	10.8 M vs 5.1 M HR=0.42	26.4 vs 21.8 HR=0.72 NS
May 2007 Pfizer	Temsirolimus	m-Tor inhibitor	IFN-alpha 1st-line Previously untreated with poor prognostic factors	8.6 vs 4.8 NS	5.5 M vs 3.1 M HR=0.53	10.9 M vs. 7.3 M HR=0.73
March 2009 Novartis	Everolimus	m-Tor inhibitor	Placebo 2nd-line Previously treated with sunitinib or sorafenib	2 vs 0	4.9 M vs 1.9 M HR=0.33 P<0.0001	NS
July 2009 Genentech	Bevacizumab/ IFNα	VEGF inhibitor/cytokine	IFN-alpha 1st-line	30 vs 12	9.2 M vs 4.2 M HR=0.60	23 M vs 21 M HR=0.86 NS
Oct 2009 Novartis	Pazopanib	TKI: VEGFR1-3, PDGFRαβ, FGF1-3, Kit, Itk, Lck, c-Fms,	Placebo 1st or 2nd-line Trt naïve (54%) or one prior cytokine trt (46%)	30 vs 3	9.2 M vs 4.2 M HR=046	NS
Jan 2012 Pfizer	Axitinib	VEGFR1-3, PDGFRαβ, c-Kit	Sorafenib 2nd-line after failure of one prior systemic therapy	19.4 vs 9.4	6.7 M vs 4.7 M HR=0.67 p<0.0001	20.1 vs 19.2 HR=0.97 NS
Nov 2015 BMS	Nivolumab	PD-1 blocking AB	Everolimus 2nd or 3rd line treatment after 1 or 2 antiangiogenic therapies	21.5 vs 3.9	6.0 M vs 6.0 M HR=0.84 p<0.033 mostly 2nd line	25.8 M vs 19.7 M HR=0.73 p<0.0018

Approval Date/pharma	Drug name	MOA	Trt Control/Line of treatment	ORR %	Median PFS	Median OS
May 2016 Eisai	Lenvatinib + everolimus	TKI: VEGFR1-3, FGFR1-4, PDGFαβ, KIT, RET/m-Tor	Everolimus (monotherapy) or Lenvatinib (monotherapy) or Lenvatinib + Everolimus 2nd-line treatment after 1antiangiogenic therapy	19 vs 3	14.5 M (L+E) vs 5.5 M (E) vs 7.4 M (L) HR=0.37	18.5 M L+E) vs 16.5 M (E) and 17.8 M (L) Label Aug 2018: 25.5 M vs 15.4 M HR=0.67
Dec 2016 Exelixis	Cabozantinib	TKI: VEGFR1-3, KIT, TRBB, FLT-3, AXL, RET, MET, TIE-2	Everolimus 2nd-line treatment in patients with metastatic renal cell carcinoma who progressed after VEGFR-targeted therapy	17 vs 3 p<0.0001	7.4 M vs 3.8 M HR=0.58 p<0.0001	21.4 M vs 16.5 M HR 0.66 p<0.0003
Dec 2017 Exelixis	Cabozantinib	TKI: VEGFR1-3, KIT, TRBB, FLT-3, AXL, RET, MET, TIE-2	Sunitinib 1st-line treatment in patients with advanced renal cell carcinoma of intermediate or poor risk	20 vs 9	8.6 M vs 5.3 M HR=0.48 P<0.0008	26.6 M vs 21.2 M HR=0.80
Aug 2018 BMS	Nivolumab + ipilimumab	PD-1 blocking AB/CTLA-4 blocking AB	Sunitinib 1st-line treatment in patients with Intermediate- and Poor-Risk Advanced Renal Cell Carcinoma	41.6 vs 26.5 p<0.0001	11.6 M vs 8.4 M HR=0.82 NS	NR vs 26.6 M HR=0.63 p<0.0001
Apr 2019 Merck	Pembrolizumab + axitinib	PD-1 blocking AB/TKI	Sunitinib 1st-line treatment in patients with advanced renal cell carcinoma	59 vs 36 p<0.0001	15.1 M vs 11.1 M HR=0.69 p<0.0001	 HR=0.53 p=0.0001
May 2019 EMD Serono Pfizer	Avelumab + axitinib	PD-L1 blocking AB/TKI	Sunitinib 1st-line treatment in patients with advanced renal-cell carcinoma	19.4 vs 9.4	13.8 M vs 7.2 M HR=0.67 p<0.0001	20.1 M vs 19.2 M HR=0.97 NS

Approval Date/pharma	Drug name	MOA	Trt Control/Line of treatment	ORR %	Median PFS	Median OS
Jan 2021 BMS Exelixis	Nivolumab + cabozantinib	PD-1 blocking AB/TKI	Sunitinib 1st line treatment in patients with advanced renal cell carcinoma	56 vs 27 P<0.0001	16.6M vs 8.3M HR=0.51 p<0.0001	Not reached yet HR=0.60 p<0.001
Mar 2021 Aveo	Tivozanib	VEGFR1-3 c-kit, PDGFR-β and others	Sorafenib ≥3 line Treatment in relapsed or refractory advanced RCC	18 vs 8 NS	5.6M vs 3.9M HR=0.73 P=0.016	16.4M vs 19.2M HR=0.97 NS

The commercial success of pan-targeted kinase inhibitors has resulted in the development and FDA approval of seven tyrosine kinases for the treatment of RCC over the last 15 years. Adverse grade 3 – 4 events from this class of drugs include hypertension, liver toxicity, GI problems (nausea, vomiting, diarrhea), anemia, lymphocytopenia, thrombocytopenia, and fatigue. Other common adverse reactions include anorexia, mucositis, abdominal pain, palmar-plantar erythrodysesthesia and skin rash. These adverse events vary in frequency and severity among the different tyrosine kinases approved for RCC.

Additionally, most patients develop resistance to pan-TKIs via a number of mechanisms (i.e. genetic alterations, activation of other signaling pathways) or are non-responsive to a given pan-TKI. Accordingly, there continues to be a need for the development and approval of additional, new pan-TKIs, both for the treatment of RCC and other indications.

We believe that our pan-TKI, dovitinib, together with its DRP® companion diagnostic — which enables us to select and treat patients most likely to respond to this drug (while excluding those who will not), uniquely overcomes many of the limitations of current pan-TKIs and, once it is approved with its DRP® companion diagnostic by the FDA, has the potential to be a unique drug that can succeed and compete in the marketplace in numerous cancer indications. If approved by the FDA, the treating oncologist will have a novel diagnostic tool, the Dovitinib-DRP®, to evaluate a cancer patient's likelihood of responding to treatment with dovitinib and thus individualize the risk/benefit of this drug, versus other therapeutic options, for the patient.

Future Opportunities & Development Plans for Dovitinib

Overview of Hepatocellular Carcinoma (HCC) & Rationale for Targeting Multiple Kinases in HCC

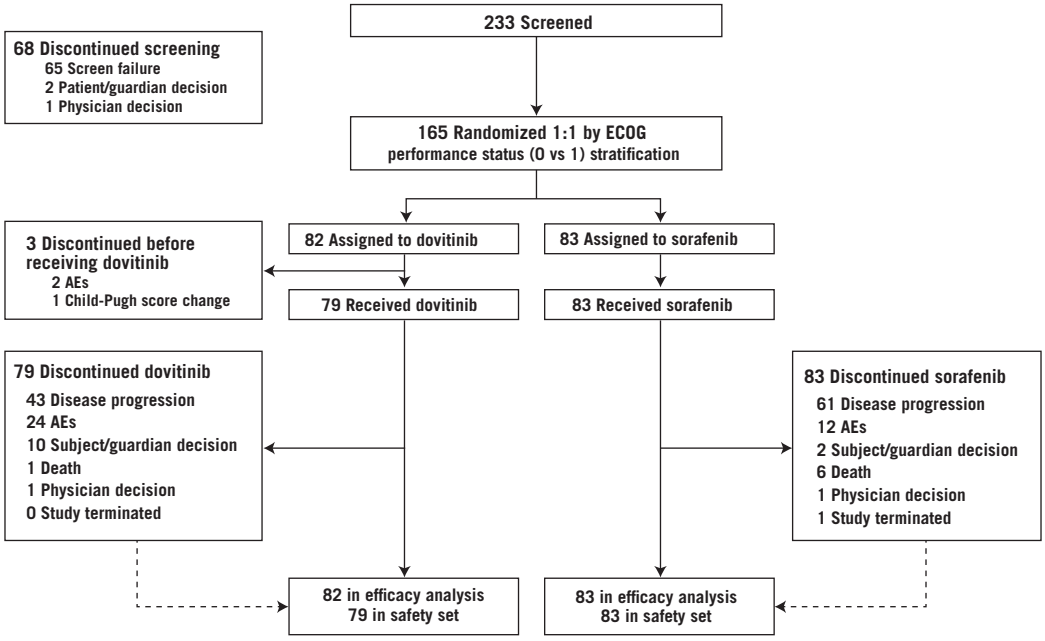
Overexpression of fibroblast growth factor receptors (FGFRs) FGFR1, FGFR2, FGFR3, or FGFR4 and corresponding FGF ligands (FGF2, FGF8, FGF17, or FGF18) have been observed in human hepatocellular carcinoma (HCC) tumors. HCC accounts for approximately 80% of primary liver cancer cases, the majority of which are diagnosed at an advanced stage of disease and are not candidates for surgical interventions. FGF2, a potent angiogenic factor in HCC, has been shown to augment vascular endothelial growth factor (VEGF)-mediated HCC development and angiogenesis, and perhaps may evade resistance to VEGFR modulating agents.

Sorafenib (Bayer) is a multi-kinase inhibitor of vascular endothelial growth factor receptor (VEGFR) and platelet-derived growth factor receptor (PDGFR). It was the first effective antiangiogenic therapy for advanced HCC, and remained the only approved treatment for a decade. Lenvatinib (Eisai) became the second approved pan-TKI for frontline treatment in HCC. This was followed in 2017 and 2019 by two additional TKIs approved as second line therapies. Combination therapy of an immune checkpoint inhibitor and an anti-VEGF antibody did, in 2020, replace sorafenib as first line standard therapy. Several studies are ongoing combining immunotherapy and a pan-TKI.

Dovitinib is a potent inhibitor of FGFRs, VEGFRs, and PDGFRb, with anti-tumor activity mediated by a dual mechanism of action, including antiproliferative and antiangiogenic effects. Preliminary anti-tumor activity for dovitinib has been reported in patients with metastatic renal cell carcinoma, metastatic melanoma, breast cancer, multiple myeloma, and acute myeloid leukemia. Dovitinib activity has been evaluated in multiple preclinical xenograft

models in HCC. In the sorafenib-sensitive PLC5 HCC model, dovitinib was observed to inhibit tumor growth in a dose-dependent manner. Furthermore, in patient-derived HCC xenograft models, dovitinib was observed to have anti-tumor activity superior to that of sorafenib and antiangiogenic effects that correlated with FGFR, PDGFRb, and VEGFR2 signaling pathway activation. These data supported a prior Phase 2, open-label, multicenter, randomized study conducted in the Asia-Pacific region evaluated the anti-cancer activity and toleration of dovitinib compared with sorafenib in patients with advanced HCC.

In the randomized Phase 2 study, dovitinib activity was not greater than that of sorafenib as frontline therapy in Asian-Pacific patients with advanced HCC. However, the median OS was similar for dovitinib and sorafenib (34.6 versus 36.7 weeks [8.0 versus 8.4 months]). Similarly, the median TTP as determined by the local investigator did not differ with dovitinib and sorafenib treatment in this study (17.6 versus 17.9 weeks [4.0 versus 4.1 months]). These results are similar to those of studies evaluating other tyrosine kinase inhibitors (TKIs) versus sorafenib, although differences in toxicity and OS have been observed. The following graphic summarizes the design of and enrollment in that study:



We have previously observed the ability of our Dovitinib-DRP® companion diagnostic to correctly identify HCC patients most likely to respond to the drug using biopsy data from the prior Phase 2 HCC trial. Given the promising prior activity of dovitinib in HCC, and the observed ability of our Dovitinib-DRP® companion diagnostic to select and treat the patients most likely to respond to the drug, we plan to conduct a future DRP®-guided Phase 2 clinical trial for HCC, following FDA approval of dovitinib in RCC as an initial indication, with a potential trial start date in 2022.

Clinical Development Plan for Dovitinib in HCC

We anticipate that this study would be performed as an open, uncontrolled Phase II study of dovitinib in up to 30 HCC patients stable on treatment with a PD-1 inhibitor. Patients with predicted high likelihood of responding to dovitinib using the Dovitinib-DRP® companion diagnostic will be included in the study. In this study, a high likelihood of response to dovitinib will be defined as the patient having a Dovitinib-DRP® score of >50%. However, this DRP® cutoff may be modified depending on the clinical outcome.

Once initiated, this study will be performed in accordance with the Simon two-stage design (Simon 1989). The patients will come to a screening visit within 2 weeks prior to first administration of dovitinib. Patients will receive a daily dose of 500 mg dovitinib 5 days on/2 days off as tablets administered in a 28 days cycle. The treatment will continue until disease progression or unacceptable toxicity. We anticipate that the clinical endpoint will be clinical response rate and objective response rate according to RECIST.

Patients will continue the treatment until the occurrence of: (i) disease progression, or (ii) unacceptable toxicity, or (iii) patient refusal/withdrawing of consent, or (iv) non-compliance to the protocol, or (v) physician decision to discontinue treatment, or treatment delay > 2 weeks (except in the case of perceived patient benefit). An End of Treatment visit will be conducted when administration of dovitinib is stopped. Patients with CR, PR or SD where treatment have been stopped will continue follow-up by phone every 12 weeks until death.

We anticipate commencing enrollment in this Phase 2 study in late 2022, following a favorable FDA decision on our currently planned NDA for dovitinib in RCC with patients selected with the Dovitinib-DRP®.

Development for Additional Indications

Based on prior Phase 2 clinical trials (conducted by Novartis) and our positive observation of the Dovitinib-DRP® using biopsy materials/data from such studies in endometrial cancer, in metastatic ER positive breast cancer (dovitinib in combination with fulvestrant), and gastrointestinalstromal tumor (GIST), these three indications are near term opportunities to further develop and, once approved, market dovitinib. Additionally, given the commercial success of the pan-TKI Lenvima® (Eisai) in combination with the PD-1 inhibitor Keytruda® (Merck), for the treatment of numerous indications, we believe there is an opportunity to further develop and, once approved, market dovitinib in combination with another approved PD-1 inhibitor, such as Opdivo® (BMS).

Additionally, we are developing a Protocol for a DRP®-guided Phase 2 trial of dovitinib for the treatment of pediatric osteosarcoma. This will be preceded by a Phase 1B dose escalation study in solid tumors in pediatric patients >=2 years of age. Current FDA regulations require, under The RACE for Children Act (Title V, Sec. 504, FDA Reauthorization Act (FDARA), enacted August 18, 2017) as part of an NDA submission for a drug, the concomitant submission of a clinical development plan for the drug in at least one pediatric cancer. Our planned study for pediatric osteosarcoma is based on previously conducted, pre-clinical animal model studies of dovitinib showing that the drug has promising activity in this pediatric indication, which is the most common primary malignant bone tumor in children and young adults. These pre-clinical studies were carried out in collaboration with the University of Illinois (Champaign, IL USA.)

The purpose of the pre-clinical studies was to investigate the capacity of dovitinib alone, and in combination with a specific checkpoint inhibition strategy (anti-PD-1), for slowing the progression of experimental pulmonary metastases in animal models of osteosarcoma. Two separate studies, performed contemporaneously in a syngeneic, mouse model of experimental pulmonary osteosarcoma metastases in mice using the K7M2 cell line, generated the following key results:

- Treatment with dovitinib, compared to control treatment (sucrose solution lacking dovitinib), increased the median survival time by 50%.
- Anti-tumor growth activity was also observed for dovitinib as a single agent in this model.

In addition, it was found that no significant anti-tumor activity was observed in mice treated with single-agent anti-PD-1 antibody at the investigated dosage and dosing schedule. Furthermore, the combination of dovitinib and anti-PD-1 antibody did not generate additive or synergistic anti-tumor activities equal or greater than observed by dovitinib alone in the mouse osteosarcoma model.

DRP® Companion Diagnostic for Dovitinib

We are developing dovitinib together with a DRP® companion diagnostic, which we believe will enable us to select the patients most likely to respond to the drug in our clinical trials. A Pre-Market Approval (PMA) application for our Dovitinib-DRP® companion diagnostic was filed with the FDA on April 1, 2021, and we anticipate approval of this PMA to coincide with the approval of our NDA. The Dovitinib-DRP® companion diagnostic, which comprises 58 expressed genes, was initially developed using cell line testing in the NCI60 panel. The sensitivity of the 60 cell lines to dovitinib was determined. The observed difference in sensitivity was correlated to the observed baseline gene expression in the 60 cell lines and 58 genes were identified as positively correlated or negatively correlated.

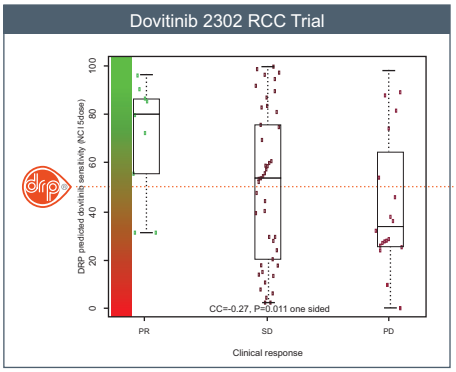
The putative Dovitinib-DRP® companion diagnostic, developed through our DRP® platform using gene expression data from cancer cell line testing data, was positively observed using biopsy materials from five Phase 2 trials of the drug and single Phase 3 trial of the drug, sponsored by Novartis AG, that were conducted worldwide from 2010-2015 (clinicaltrial.gov numbers NCT01223027, NCT01379534, NCT01232296, NCT01478373, NCT00958971, NCT01528345).

The following table shows the primary and secondary endpoints, respectively, in our analysis using a DRP® score cut-off of 50% is a single Phase 3 trial sponsored by Novartis AG. All observed measures show an improvement in the DRP® selected patients from the dovitinib arm when compared to the sorafenib arm:

Efficacy Parameter	Dovitinib Dovitinib Score > 50% N = 49	Sorafenib Unselected N = 286	p-value	HR
Median PFS, Months	3.75	3.61	0.0572	0.71
(95% CI)	(3.68,5.39)	(3.48,3.71)		(0.51,1.01)
Median OS, Months	15.0	11.2	0.04	0.69
(95% CI)	(12.94,26.25)	(9.66,13.37)		(0.48,0.99)

Our Dovitinib DRP® Potentially Identifies Responsive Patients

Dovitinib DRP® potentially predicted response in biopsies from the Novartis Phase 3 in RCC

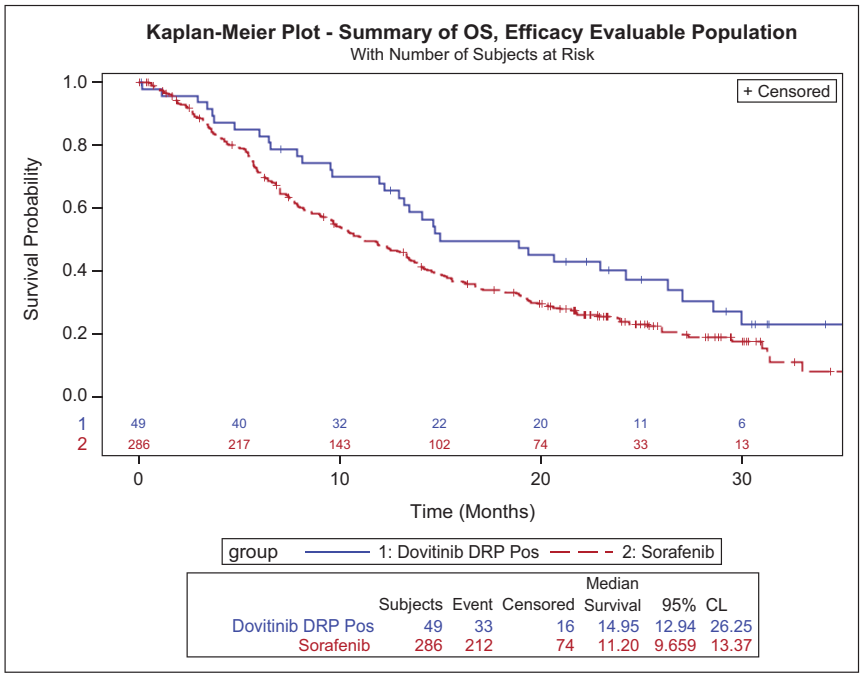


All comers URR* : **8%**
(median PFS 3.7 months)

Response rate above DRP® cutoff of 50: **18%**
(median PFS 5 months)

*URR stands for unconfirmed response rate

188 patients consented in the dovitinib group, of these 135 passed established biomarker quality criteria. The DRP-dovitinib divided the patients into two groups, sensitive (n=49, DRP score >50%) or resistant (n=86, DRP score < 50%) to dovitinib. The DRP sensitive population was compared to the unselected sorafenib group (N=286). The graphic below shows a Kaplan-Meier curve of overall survival in these two groups.



A statistically significant improvement in overall survival of patients selected with Dovitinib-DRP® and treated with Dovitinib, when compared to patients treated with Sorafenib, is considered a strong argument in favor of regulatory approval of Dovitinib and its companion diagnostic Dovitinib-DRP®. Such evidence can be based on retrospective analysis of an already conducted clinical trial if the selection of patients is unbiased and the biomarker analysis is blinded and based on a prior statistical analysis plan. The U.S. FDA has the following requirements for such a prospectively defined retrospective analysis:

- Pre-specification of the primary analysis endpoint(s) occurs prior to study unblinding or any unblinded interim analysis.
- The banked samples are from an adequate, well-conducted, well-controlled study.
- The study is of adequate size such that treatment effects in one or more marker-defined subgroups of interest can be determined.
- The test result can be ascertained in a very large proportion of the study subjects.
- The IVD has acceptable analytical performance.
- The pre-specified retrospective analysis plan is considered acceptable by FDA.

Users of the assay are blinded to the study's clinical outcomes.

We additionally observed that, as expected, the Dovitinib-DRP® does not select responders or patients with longer PFS or OS in the sorafenib arm of the Phase 3 RCC study. This demonstrates that the DRP® is highly drug specific, and thus the Dovitinib-DRP® cannot be used to select responders to sorafenib. Certain details of our Dovitinib-DRP® were published as an e-Poster at the European Association for Cancer Research (EACR) 2021 Virtual Congress held from 9 – 12 June 2021, and at the European Society for Medical Oncology (ESMO) 2021 Virtual Congress taking place from September 16 until September 21, 2021.

We further tested the predictive power of the Dovitinib-DRP® companion diagnostic in other Phase 2 study cohorts from which pre-treatment or diagnostic biopsies have been obtained, as follows:

- HCC (NCT01232296): Trial A2208 consisted of 82 patients treated frontline with dovitinib and 82 patients treated frontline with sorafenib. Archival tumor slides or fresh biopsy slides were available for 8 patients from the dovitinib arm and 10 patients from the sorafenib arm.
- Endometrial (NCT01379534): Trial A2211 consisted of 53 patients treated second-line with dovitinib. Archival tumor slides or tumor blocks were available for 44 patients, of which 35 met the QC criteria during lab analysis.
- GIST (NCT01478373): Trial AIC02 consisted of 38 enrolled patients treated second line dovitinib, biopsies were available and met QC for 16 patients.
- Breast cancer combination trial of fulvestrant +/- dovitinib in locally advanced or metastatic breast cancer patients who had evidence of disease progression (NCT01528345, A2210). 47 patients were randomized to fulvestrant+dovitinib, of which 21 had available biopsies that met QC.
- Breast cancer monotherapy (NCT00958971, A2202): 1-3 prior therapies in the metastatic setting, N=57 biopsies of which 19 meet QC.

In cohorts from GIST trial IC02 (second line dovitinib, N=16 biopsies) and breast cancer trial A2202 (1-3 prior therapies in the metastatic setting, N=57 biopsies of which 19 meet QC) there was no positive association between clinical outcome and DRP®-Dovitinib prediction. But the 95% confidence interval of the OS and PFS hazard ratios included those hazard ratios observed for the other cohorts and the RCC phase III cohort.

In summary, based on these studies, we believe our putative Dovitinib-DRP® companion diagnostic accurately and reliably identifies responder patients (with RCC, HCC, breast cancer (ER positive) and endometrial cancer) to this therapeutic candidate, and we plan to use this DRP® companion diagnostic for all of our clinical programs to advance clinical development of dovitinib for these indications including RCC.

Overview of Stenoparib (PARP inhibitor)

Mechanisms of Action

PARP is an enzyme discovered more than 40 years ago that produces large, branched chains of poly(ADP) ribose (PAR) from NAD. In humans, there are 17 members of the PARP gene family, but most of these are poorly characterized. Of the 17 PARP family members, only PARP1 and PARP 2 are known to be involved in DNA repair. PARP is an abundant nuclear enzyme that is activated by DNA strand breaks to synthesize poly(ADP-ribose) from NAD. The main function of PARP is the maintenance of genomic integrity by facilitating DNA repair through the BER pathway. BER is one mechanism by which cancer cells counteract the DNA damage elicited by cytotoxic agents or radiation and thus develop resistance to chemo-or radiation therapies. PARP inhibition may provide a novel mechanism to sensitize refractory tumors to chemotherapy and radiotherapy.

PARP inhibition has shown anti-tumor activity in homologous DNA repair-defective tumors, such as those with BRCA1 and BRCA2 mutations. Also, it is well established that cells deficient in homologous recombination are particularly sensitive to DNA-crosslinking agents, including the platinum salts (cisplatin and carboplatin); their BRCA-selective effects are mediated by a similar mechanism to that of PARP inhibitors. Therefore, as platinum salts are frequently used for the treatment of ovarian cancer, including some individuals with BRCA1 or BRCA2 mutations, the combination with PARP inhibitors and DNA agents is an interesting combination that should be explored in clinical trials.

As used in this section of this information statement/prospectus describing our therapeutic candidate stenoparib, statements regarding the use of our proprietary DRP® companion diagnostics or our proprietary DRP® platform or our observations that our therapeutic candidate Stenoparib may have anti-cancer or anti-tumor activity or is observed to be well tolerated in a patient population should not be construed to mean that we have resolved all issues of safety and/or efficacy for our therapeutic candidate Stenoparib or our putative Stenoparib-DRP® companion diagnostic. Issues of safety and efficacy for any therapeutic candidate companion diagnostic may only be determined by the U.S. FDA or other applicable regulatory authorities in jurisdictions outside the United States.

Stenoparib is a potent inhibitor of both PARP1 and PARP2 enzymes, as demonstrated in both *in vitro* and *in vivo* studies. Development of stenoparib as single agent and in combination is supported by preclinical studies. Stenoparib inhibited proliferation in subsets of cells in cell line panels derived from a variety of tumors. Stenoparib, administered as a monotherapy, demonstrated potent tumor growth inhibition in several animal models with tumors featuring underlying defects in DNA repair, including BRCA mutant breast cancer. In addition, stenoparib demonstrated *in vivo* activity as a single agent in models of B cell lymphoma and AML.

Apart from being a potent PARP1/2 inhibitor, stenoparib also inhibits PARP5a/5b, otherwise known as tankyrase1 and 2 (TNKS1 and 2), important regulators of canonical Wnt/β-catenin signaling and maintenance of chromosomal telomerase integrity. Thus, stenoparib inhibited Wnt/β-catenin signaling in colon cancer cell lines, likely through TNKS inhibition. Consistent with this possibility, stenoparib stabilized axin and TNKS proteins resulting in β-catenin de-stabilization and significantly altered expression of Wnt target genes. This indicates a potential for treating several cancers where aberrant activation of Wnt/β-catenin signaling can be part of the carcinogenesis and tumor progression.

Temozolomide (TMZ) is a chemotherapeutic agent with an activity that can be enhanced by PARP inhibition. PARP inhibition has also been shown to overcome resistance of cells to TMZ. Potentiation of TMZ activity was observed in orthotopic models of melanoma and glioblastoma. In xenograft models, stenoparib inhibition of PARP was observed in tumor tissue by using the PARP pharmacodynamic assay to measure PAR levels.

The predictive biomarker Ataxia-Telangiectasis Mutated (ATM) was selected for use in B cell lymphoma by demonstrating that stenoparib sensitivity was increased through ATM loss in these cells. Certain hematological indications are known to up-regulate P-glycoprotein (P-gp), which is implicated in the development of multidrug resistance leading to therapeutic failure and poor outcome. Stenoparib activity is not affected by P-gp over-expression, thus offering a potential advantage in the clinic.

Pre-Clinical Studies

PARP utilizes nicotinamide adenine dinucleotide (NAD) as substrate to catalyze the polymerization and transfer of poly(ADP-ribose) (PAR) to acceptor proteins. The posttranslational modification through addition of PAR results in modulation of target protein function. Stenoparib is a nicotinamide mimetic, competitive PARP inhibitor that inhibits PARP1 and PARP2 equipotently.

In cell based assays, stenoparib potently inhibited proliferation of the BRCA1 mutant human breast cancer cell line MDA-MB-436. Additionally, stenoparib inhibited proliferation in the human hematologic cell lines: SR (B cell lymphoma) and MV-4-11-luc2/AcGFP (acute myeloid leukemia (AML)). In the murine leukemia cell line P388, P-glycoprotein (P-gp) overexpression had very little impact on inhibition of proliferation by stenoparib.

Oral administration of stenoparib for 28 days significantly inhibited tumor growth in vivo in the subcutaneous MDA-MB-436 xenograft model without any significant body weight loss. A dose- responsive pharmacodynamic effect on PARP activity in MDA-MB-436 xenograft tumor tissue was observed following administration of a single stenoparib dose. The decrease in PARP activity was sustained over several hours. These results demonstrate monotherapy activity of stenoparib in a BRCA mutant breast cancer model. Single agent activity was also observed in the AML MV-4-11-luc2/AcGFP survival model. Treatment with stenoparib resulted in decreased tumor burden as measured by luciferase signal, and reduction in disease translated to a statistically significant survival benefit.

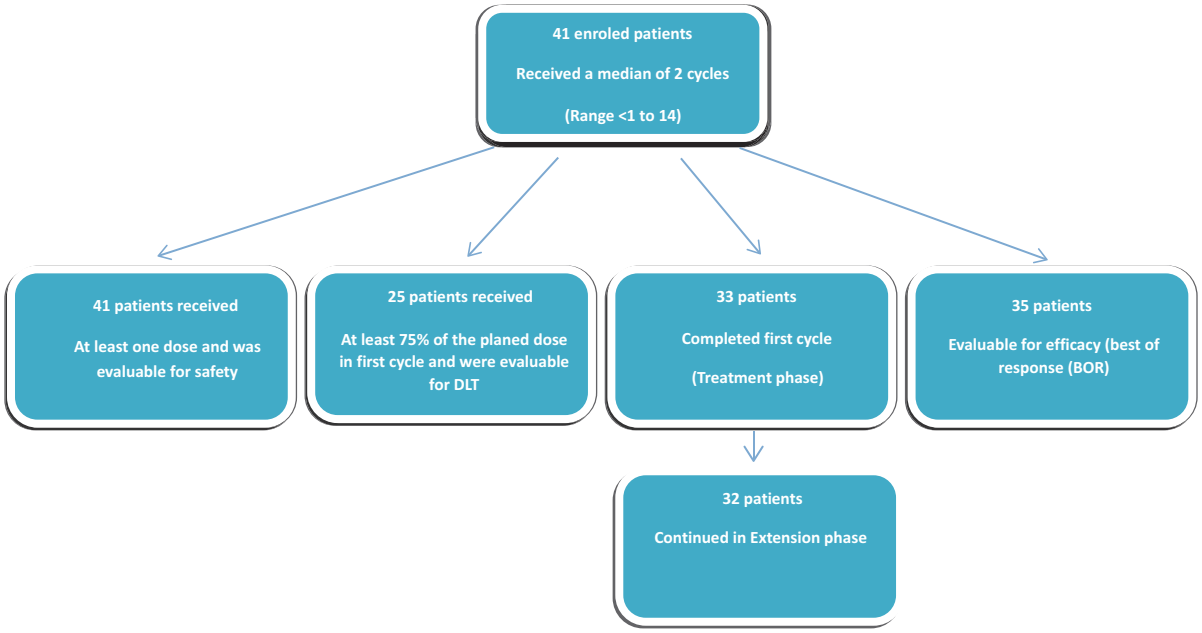
In addition to activity as monotherapy, stenoparib demonstrated potentiation of the anti-tumor effects of temozolomide (TMZ), eribulin mesylate (E7389) and carboplatin. In intracranial survival models of melanoma (murine melanoma B16 cell line) and glioblastoma (human glioblastoma multiforme SJGBM2 cell line), the addition of stenoparib to TMZ resulted in a significantly increased survival benefit versus that derived from TMZ alone.

Prior Clinical Trials

The initial planned first-in-human study of stenoparib (conducted by Eisai, Inc.) was an open-Label, Multi center, Phase 1 study of PARP Inhibitor stenoparib (formerly E7449) as single agent in subjects with advanced solid tumors or with B-cell malignancies and in combination with TMZ or with Carboplatin and Paclitaxel in Subjects with Advanced Solid Tumors. The first part (Phase 1) of the study started January 31, 2012 and was completed with the last patient visit July 14, 2015. Further clinical evaluation was stopped, as it was decided to stop the clinical development for the reasons described below. Preliminary data after treating the first 28 patients have been presented at ESMO conference 2014. The final data including the retrospective/prospective Stenoparib-DRP® selection results were presented at ASCO 2018.

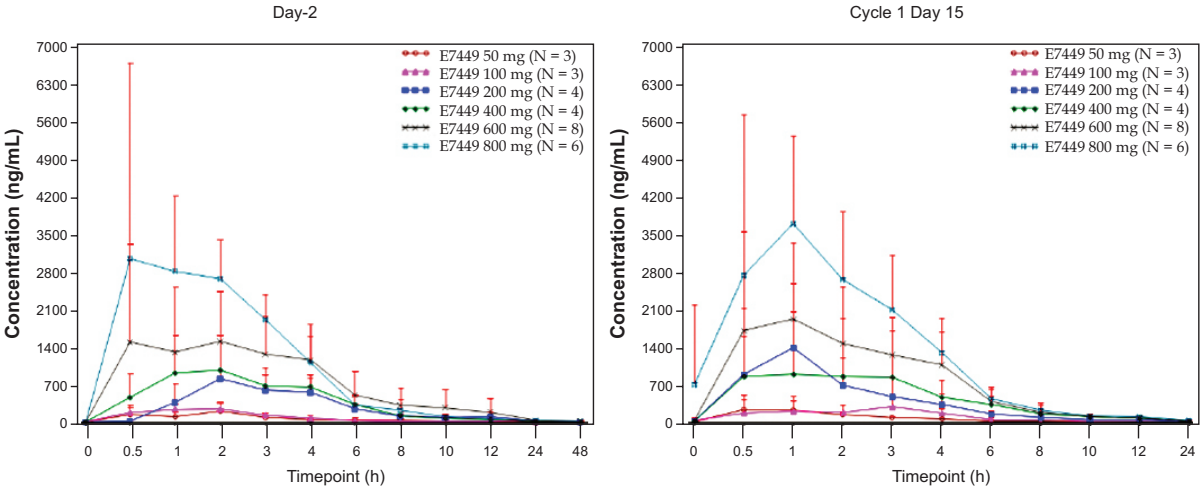
The study was conducted as Phase 1 single-agent arm (Arm 1) and standard 3+3 dose escalation was performed. During dose escalation, sequential cohorts of 3 to 6 subjects (dose escalation cohorts) were administered increasing doses of 50 mg, 100 mg, 200 mg, 400 mg, 600 mg, and 800 mg (Table 5-1). Forty-one subjects were enrolled and 33 completed the 'Treatment phase' (received first cycle of treatment) while 8 subjects discontinued. Thirty-two subjects continued in the 'Dose Extension Phase'. During the Dose Extension Phase, the primary reason for discontinuation of study treatment was disease progression (27 subjects due to objective disease progression, which was defined as treatment completion). Two subjects in the 600 mg dose group discontinued study treatment due to AEs with AE being the primary reason for discontinuation as recorded from the disposition page of the Case Report Form (CRF).

All 41 subjects received at least 1 dose of stenoparib and were included in the safety, PK, and pharmacodynamics analyses. Twelve (12) subjects who received the 600 mg dose of stenoparib in both fed and fasted states were analyzed for food effect.



After a single or multiple oral dose, stenoparib was moderately well absorbed with tmax ranging from 0.5 to 4 hours across subjects and dose groups. The elimination half-life was approximately 8 hours with less than 1.5% of the administered dose recovered in urine. Accumulation based on AUC was minimal (less than 1.2 fold) upon 15 days of dosing across the range of doses.

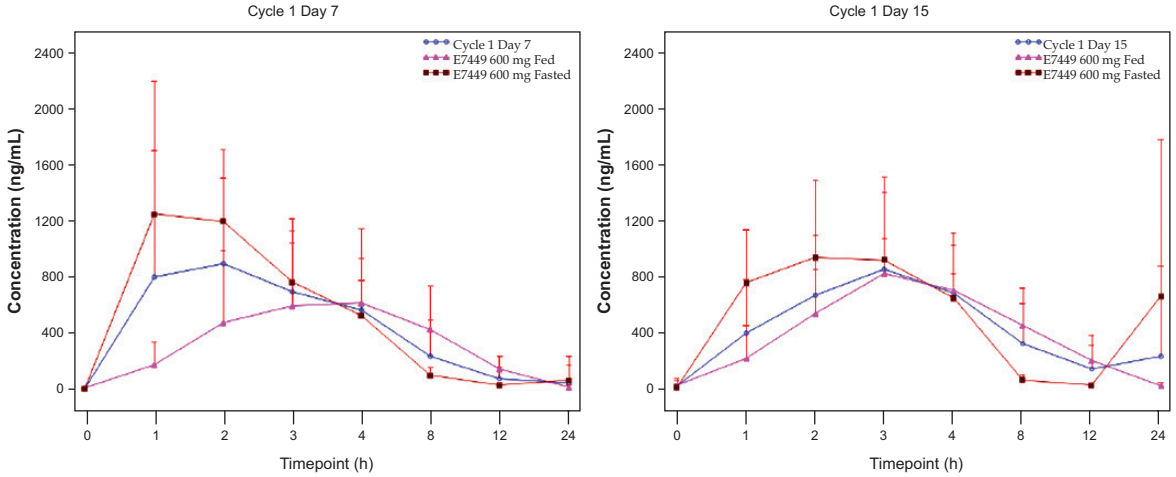
Stenoparib exposure (both Cmax and AUC) appeared to be approximately dose proportional following single or multiple oral doses between 50 mg and 800 mg, with slight deviation at the 400 mg and 600 mg doses. At the 600 mg dose, food delayed stenoparib absorption as evidenced by a shift in tmax by 2 hours, reduced Cmax by 60%, and increased AUC by 10%. The interpatient pharmacokinetic variability is large both with and without food. Thus, the effect of food with the decrease in Cmax, and increase in AUC.



The above figure shows a Linear Plot of Mean (+SD) E7449 plasma concentration versus nominal time (hours) by treatment fasting and after food intake.

Dose dependent inhibition of PARP activity, as demonstrated by percent change in PAR levels, was observed. Maximal inhibition of PARP activity was observed at the MTD dose (600 mg) of single agent stenoparib. Evaluation of PAR levels at the MTD dose of stenoparib (600 mg) in the food effect cohort demonstrated that PAR levels show maximal decrease at 2 to 4 hours post-dose with up to 90% inhibition in PAR levels (from baseline) observed. Sustained PARP inhibition was observed with a 70% or greater decrease in PAR levels observed at 24 hours post-dose. Greater decrease in PAR levels was observed with increasing plasma concentration of stenoparib and with the maximal inhibition observed corresponding to the peak plasma concentration in measurements obtained at Day -2 and Cycle 1 Day 15. A greater decrease in PAR levels was observed with a corresponding higher Cmax when stenoparib was administered without food than when administered with food. No significant changes in percent DNA in tail were observed.

In the finalized Phase 1 study, the majority of subjects (35/41; 85.4%) received up to 8 cycles of treatment with 26 subjects (63.4%) who received up to 2 cycles (<1 cycle = 7, 1 cycle = 5, and 2 cycles = 14); mean number of treatment cycles overall were 3.8 (median = 2 cycles, range: 0 i.e. <1 to 14). The overall median duration of treatment for all dose groups was 57 days (range: 1 to 392 days) with an overall median dose intensity of 11% (range: 1% to 111%) in terms of percentage of planned dose.



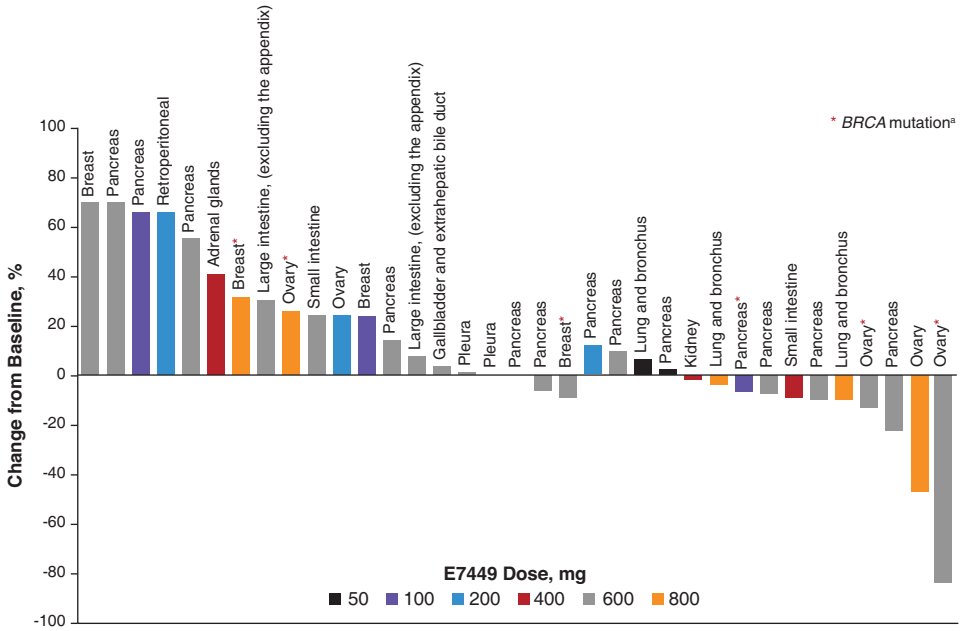
In the completed Phase 1 study the following safety results were reported:

- DLTs were reported in 5 of the 25 DLT evaluable subjects, 4 of these occurred at the 800 mg QD dose (1 Grade 3 fatigue and 3 Grade 2 fatigue resulting in administration of less than 75% of the planned dosage of stenoparib) and 1 occurred at the 600 mg QD dose (Grade 3 anaphylactic reaction). Based on assessment of DLTs, the MTD and RP2D of single agent stenoparib treatment was 600 mg administered orally QD in 28-day cycles.
- The mean number of treatment cycles received by the 41 subjects treated at the different dose levels of stenoparib was 3.8 (median = 2 cycles, range: <1 to 14). The overall median duration of treatment for all dose groups was 57 days (range: 1 to 392 days).
- No deaths due to AEs were reported during the study. Nonfatal SAEs were reported in 58.5% subjects overall. The majority of SAEs were considered not related to stenoparib treatment and were reported in not more than 1 subject overall; SAEs reported in more than 2 subjects overall were fatigue (n=3) and lower respiratory tract infection (n=3). Treatment related SAEs included fatigue (n=3), anemia (n=1), anaphylactic reaction (n=1), drug hypersensitivity (n=1), depression (n=1), pyrexia (n=1), and transaminases increased (n=1).
- TEAEs occurred in all study subjects. The most frequently reported (>30% of subjects overall) TEAEs were fatigue, chromaturia, decreased appetite, nausea, diarrhea, constipation, and vomiting. The majority of TEAEs were reported to be Grade 1 or 2 in severity. Overall, Grade 3 events were reported in 27 subjects (65.9%) and the most frequently reported Grade 3 event was fatigue (n=7, 17.1%). A single Grade 4 AE of non-treatment-related hypokalemia was reported in a subject in the 200 mg dose group. No Grade 5 (fatal) events were reported. (Table 5-3)

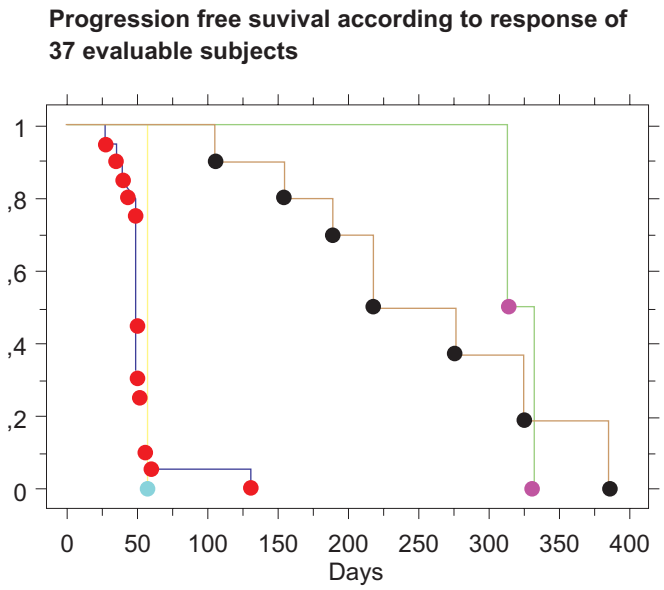
- The most common treatment-related TEAE was fatigue (63%), followed by chromaturia (49%), nausea (34%), diarrhea (29%), and maculo-papular rash (27%). The majority of treatment-related AEs were Grade 1 or 2 in severity. With the exception of treatment-related fatigue that was reported to be Grade 3 in severity for 4 subjects (2 subjects each in the 600 mg and 800 mg dose groups), all other Grade 3 treatment-related events were reported in not more than 2 subjects overall (Table 5-4).
- The study treatment was discontinued due to AEs in 17% subjects (1/3 subjects in 50 mg, 4/21 subjects in 600 mg, and 2/6 subjects in 800 mg dose groups). The events leading to treatment discontinuation included fatigue (n=3), diarrhea (n=2), muscular weakness (n=2), nausea (n=1), photosensitivity reaction (n=1), decreased appetite (n=1), paresthesia (n=1), and anaphylactic reaction (n=1). A total of 24 of 41 subjects (59%) required dose interruptions to manage treatment emergent toxicity. Dose reductions due to AEs were required in 14.6% subjects overall (1/4 subjects in 400 mg, 2/21 subjects in 600 mg, and 3/6 subjects in 800 mg dose groups).
- Skin rash was considered as an event of special interest for stenoparib. Overall, 41.5% experienced AEs of skin rash with the highest incidence observed in the 800 mg dose group (66.7%) followed by the 600 mg dose group (47.6%). No serious events of skin rash were reported. All but 1 event of Grade 3 erythematous rash reported with the 600 mg dose group.

Preliminary anti-cancer activity assessment was a secondary objective of Phase 1. Of the total 41 subjects who received single agent stenoparib treatment, best overall response (BOR) could not be assessed for 6 subjects including 5 subjects who discontinued study treatment prior to the first posttreatment tumor evaluation and 1 subject who did not have any target lesion (i.e., measurable disease). None of the 35 subjects assessed had a BOR of CR based on investigator assessment using RECIST 1.1. The overall objective response rate (ORR; CR + PR) was 4.9% (n=2) with 2 PR out of 41 (both in ovarian cancer), and 31.7% SD (13 out of 41), and disease control rate lasting more than 23 weeks was 24.4% (CR+PR+SD: N=10). Both PRs were predicted by the DRP® for stenoparib after analyzing biopsies from 13 of the patients. A waterfall plot of the individual responses of 35 subjects from the safety cohort is presently below:

Anti-cancer activity according to dose groups



PFS for the whole population was 55 days. A Kaplan Meier plot of progression free survival of subjects with PR (green line), SD (orange line), NE (yellow line) and PD (blue line) is below:



The study was published in the British Journal of Cancer in 2020. It concluded that the drug stenoparib "showed good tolerability, promising antitumour activity and significant concentration-dependent PARP inhibition," and that "The results support further clinical investigation." Nevertheless Eisai decided to pursue other priorities and for undisclosed reasons offered the therapeutic candidate to us because we had developed a Stenoparib-DRP® response predictor that we believe could identify the infrequent responding patients.

DRP®-Guided Phase 2 Trials

We have previously conducted an open label, single arm Phase 2 study to investigate the toleration and anti-cancer activity of stenoparib in patients with metastatic breast cancer. Patients were selected by having a Stenoparib-DRP® score of >80%. Stenoparib was administered as a once daily oral dose of 600 mg in 21-days cycles (study SMR-3475/2X-1001). The study was initiated in June 2018 and discontinued in June 2020 due to inconclusive results. Fourteen patients were enrolled and received at least 1 dose of stenoparib. The median of number of previous chemotherapies were 6. There were 3 patients with 'stable disease' response after receiving the treatment, and 1 patient maintained stable disease for more than 26 weeks until the date of disease progression. The overall CBR in evaluable population was 9.1%, PFS was 6 weeks, and OC was 8 months. The most common AE was Fatigue (n = 11; 79%), the second most common AE was decreased appetite and nausea, respectively (n = 8; 57%). There were 8 SAEs reported by 5 patients, 6 events were unrelated, 1 was unlikely to be related, and 1 event (urinary tract infection) was possibly related to the treatment. The data from this mBC trial suggest that a diagnostic biopsy cannot be used for predicting likelihood of drug response, using the Stenoparib-DRP® companion diagnostic, in heavily pre-treated mBC patients, and that new biopsies are needed. By terminating the mBC study, Allarity has decided to focus on advancing stenoparib in indications with a higher likelihood of success, including ovarian and pancreatic cancer.

We are further currently conducting a DRP®-guided Phase 2, open label, single arm study to investigate the toleration and anti-cancer activity of the PARP inhibitor, stenoparib in patients with advanced ovarian cancer. The protocol (2X-1002) addresses unmet medical needs in ovarian cancer patients that have progressed on previous PARPi therapy without requiring repeat platinum treatment and in selecting both HR proficient and HR mutated patients/tumors with high likelihood of responding. The primary endpoint is ORR as determined by RECIST 1.1. Secondary endpoints are CBR, PFS and OS. This study is being conducted at the Dana-Farber Cancer Institute (Boston, MA, USA.) and Guy's Hospital (London, England). Patients are selected by using the Stenoparib-DRP® with a score of >50%. Stenoparib is administered as a once daily oral dose of 600 mg in a 28-days cycle (study 2X-1002). The study was initiated in April 2019 and 10 subjects that were required to be enrolled independent of DRP® score have received at least 1 dose of stenoparib and are included in the safety SAE reporting. Stenoparib-DRP®-selected patients will be enrolled from June 2021. The delay in enrolling Stenoparib-DRP®- selected patients has mainly been

due to COVID-19 pandemic issues. Since the Phase 2 studies currently are ongoing, anti-cancer activity data from these are too early to report. We anticipate expanded enrollment in this trial in 2021 and anticipate patient enrolment completed mid 2022 and initial data read out in 2022 as well. If results allow we will continue with a pivotal Phase 2 for accelerated approval.

Overview of Ovarian Cancer

Ovarian Cancer (OC) is a lethal disease with a 5 year survival rate of 20-30% for advanced OC. It is the second leading cause of cancer related deaths in women. A large proportion of patients with OC are diagnosed at an advanced tumor stage. The outcome after chemotherapy for advanced OC becomes poorer and poorer each time a new treatment is introduced following progression on the previous treatment. Approximately 14,000 OC patients die each year due to disease progression.

Treatment of OC (as well as breast cancer (BC)) advanced when the genes BRCA1 and BRCA2 were cloned in the early 1990s and allowing identification of high risk individuals. These genes encode proteins that are involved in DNA homologous recombination (HR). Patients harboring germline BRCA1/2 mutations carry a defective copy of the gene in every cell, which increases the likelihood of cancer developing if the remaining copy becomes defective through somatic mutation or epigenetic inactivation. However, there are also patients with germline mutations in other HR pathway genes and patients who do not carry an inherited germline mutation but have tumors with sporadic HRD mutations. Data from the Cancer Genome Atlas (TCGA) demonstrates that approximately fifty percent of high grade serous ovarian cancers have aberrations in HR repair.

Epidemiological studies have shown an association between germline BRCA1/2 (gBRCA1/2) mutations and the development of OC, (BC), and to a lesser extent pancreatic and endometrial cancers. Mutation frequencies are estimated to be approximately 15-20% for those diagnosed with OC and 5% for those diagnosed with BC (15). In a recent publication it was shown that for BRCA1 and 2 carriers, cumulative risk for BC by age 80 was 72% and 69%, respectively. For OC, cumulative risk was 44% and 17%, respectively.

The peak incidence of BC occurred in the 41-50-year age group (28.3 per 1000 person-years) for BRCA1 and in the 51-60-year group (30.6 per 1000) for BRCA2 mutation carriers. The incidence of OC was 3.6 times higher for BRCA1 than BRCA2 carriers, with the peak incidence of cancer occurring regardless of mutation type among women in the 61-70-year age group (29.4 per 1,000 in BRCA1 carriers). For BRCA1 and 2 carriers, BC risk increased with the number of first- and second- degree relatives with breast cancer. In contrast, OC risk did not vary with respect to family history of this disease. DNA repair pathways involving BRCA1/2 engage in single or double stranded DNA breaks, which can occur from damage caused by ultraviolet light, the generation of reactive oxygen species, ambient or therapeutic irradiation, day- to-day replication errors or chemical exposure. Cells lacking a functional BRCA1/2 are also deficient in HR and show a high-degree of chromosomal instability as well as increased sensitivity to ionizing radiation and chemotherapeutic agents that lead to double-stranded breaks.

Rationale for Targeting PARP in Ovarian Cancer

Poly(ADP-ribose) polymerases (PARPs) are a family of DNA-dependent nuclear enzymes catalyzing the transfer of ADP-ribose moieties from cellular nicotinamide-adenine-dinucleotide (NAD+) to a variety of target proteins. There are 17 PARP family member proteins identified through sequence homology of the catalytic domain. PARP1, 2 and 3 have all been implicated in DNA repair, with PARP1 being the most abundant. PARP inhibitors are designed to compete with NAD+ for the substrate binding to PARP and inhibit PARP activity. Cells containing dysfunctional BRCA1 or BRCA2 have been shown to become profoundly sensitized to the inhibition of PARP enzymatic activity, resulting in chromosomal instability, cell cycle arrest and subsequent apoptosis. PARP inhibition is thought to induce synthetic lethality, which describes a process where at least two genetic lesions that individually are not lethal become lethal when combined in the same cell. For example, cells that are deficient in HR, which is not lethal in itself, are hypersensitive to a reduction in PARP activity by PARP inhibitors. However, disruption to other proteins involved in HR DNA repair other than in BRCA may have the same effect on PARP inhibitor sensitivity.

A further important mechanism of action for PARP inhibition is the trapping of the PARP1 and PARP2 enzymes at damaged DNA causing cytotoxicity and cell death. Recent studies have revealed a more complex web of fundamental cellular processes that PARP1 is involved in crucial cell processes other than in DNA damage repair, such as chromatin remodeling and transcription or regulation of the cell cycle.

There are currently three PARP inhibitors approved, in a number of countries but not all yet, for either monotherapy or maintenance therapy or both in patients with advanced OC. Two are approved in patients with BRCA 1 and 2 mutations with advanced OC having undergone therapy with >3 chemotherapies (Olaparib) or >2 chemotherapies (Rucaparib). Two PARPi (niraparib and olaparib) are approved as maintenance therapy in patients with advanced OC who are in complete or partial response to platinum-based chemotherapy.

The effectiveness of PARP inhibitors as monotherapy or as maintenance therapy has substantially improved the progression free survival and may be promising for overall survival in OC patients. PARP inhibitors as single agents or as potential enhancers of cytotoxic agents that provoke DNA damage, such as alkylating agents and chemotherapy, have been investigated in a number of studies, including olaparib, rucaparib, niraparib, veliparib, and talazoparib, where the two latter PARPi are still under development.

There is a current unmet need for treatment of patients with OC who have progressed on PARPi treatment. Our ongoing Phase 2 study in ovarian cancer allows for enrollment of patients previously treated with a PARPi. We intend to use our Stenoparib-DRP® to select patients from this group that will have a high likelihood of responding to our PARPi, Stenoparib.

Future Opportunities & Development Plans for Stenoparib

Overview of Pancreatic Ductal Adenocarcinoma (PDAC) & Rationale for Targeting PARP in PDAC

PDAC is the third leading cause of cancer related death in the United States (2018). Initial presentation of the disease is typically with metastasis, and the overall 5-year survival for all stages combined is 8%. Molecular analysis has revealed four subtypes of PDAC giving clinicians further insight into treating this deadly disease. One subtype that has been elucidated and termed "unstable" is significant for the presence of DNA damage repair deficiency and can be targeted by several old and emerging therapies. One such therapy that may be considered are PARP inhibitors.

There have been reports of responses seen to PARP inhibitors in individuals with pancreatic cancer, and there are clinical trials currently (NCT03140670, NCT02184195, NCT01585805) for this patient population. One PARPi (olaparib) was approved by the FDA in December 2019 for the treatment of BRCA1/2 mutated PDAC. Due to the relatively common DNA repair pathway mutations in PDAC tumors, PARP inhibition may be a potential therapeutic option in individuals with advanced PDAC with the HRD phenotype.

Development Plan for Stenoparib in PDAC

This study would be performed as an open, uncontrolled Phase II study of stenoparib in up to 30 advanced PDAC patients. Patients with predicted high likelihood of responding to stenoparib, after inclusion in the pre-screening protocol using the Stenoparib-DRP® companion diagnostic will be included in the study. In this study, a high likelihood of response to stenoparib will be defined as the patient having a Stenoparib-DRP® score of at least 80% or greater. However, this DRP® cutoff can be modified depending on the clinical outcome.

The study will be performed in accordance with the Simon two-stage design (Simon 1989). The patients will come to a screening visit within 2 weeks prior to first administration of stenoparib. Patients will receive a daily dose of 600 mg stenoparib as hard gelatin capsules administered in a 28 days cycle. The treatment will continue until disease progression or unacceptable toxicity. The clinical endpoint will be objective response rate (ORR), as determined by RECIST 1.1.

Patients will continue the treatment until the occurrence of: (i) disease progression, or (ii) unacceptable toxicity, or (iii) patient refusal/withdrawing of consent, or (iv) non-compliance to the protocol, or (v) physician decision to discontinue treatment, or treatment delay > 2 weeks (except in the case of perceived patient benefit). An End of Treatment visit will be conducted when administration of stenoparib is stopped. Patients with CR, PR or SD where treatment have been stopped will continue follow-up by phone every 12 weeks until death.

Anticipated clinical trials sites and Principal Investigators would include Dr. Dan Von Hoff (U.S.) and Dr. Deb Sarker (UK). We anticipate commencing enrollment in this Phase 2 study in either late 2022 or first half of 2023, following conclusion of our current, ongoing Phase 2 study of stenoparib in ovarian cancer.

Development for Additional Indications

We have developed a protocol for a Phase II, open label clinical study to investigate anti-tumor effect and tolerability of stenoparib in docetaxel-pretreated metastatic castration-resistant prostate cancer (mCRPC) patients selected by the Stenoparib-DRP® companion diagnostic. Patients would receive 600 mg stenoparib as single oral agent in a 21-days cycle in in mCRPC patients who progressed on AR-targeted therapy (abiraterone acetate, enzalutamide or investigational AR-targeted agent) and docetaxel-pretreated metastatic castration-resistant prostate cancer patients selected by the Stenoparib-DRP® companion diagnostic. Up to 30 mCRPC patients with predicted high probability of response to stenoparib, as determined by a Stenoparib-DRP®) score of >80%, will be enrolled and treated. Anti-tumor effect of stenoparib is based on objective response rate defined as complete response (CR), partial response (PR) or stable disease (SD) of > 9 weeks according to RECIST 1.1 for patients with measurable disease and defined as stable disease > 9 weeks including PSA and bone metastases according to PCWG3. This Phase II trial would likely have trial sites in the U.S. and in the EU/Denmark.

Development as a COVID-19 Treatment

We are also opportunistically exploring the potential anti-viral activity of stenoparib as a potential new treatment for COVID-19. We initiated our pre-clinical testing of stenoparib as an anti-viral, following publications showing that the PARP inhibitor, Mefuparib (CVL218), has promising antiviral activity against the virus that causes COVID-19. CVL218 was more potent than remdesivir (an antiviral therapy developed by Gilead Sciences, which was recently approved by the FDA for treatment of COVID-19) in blocking COVID-19 infection of cells, and equally as potent as Remdesivir in blocking replication of virus once it has entered the cells.

We have conducted, and continue to conduct, pre-clinical experiments — at the Pathogen and Microbiome Institute at Northern Arizona University (NAU), a leading U.S. infectious disease test center — to assess the potential anti-viral activity of stenoparib against COVID-19, as well as the variant B.1.1.7 ("British variant") and variant B.1.351 ("South African variant"). The current and planned in-vitro studies, focusing on SARS-CoV-2 lineage B.1.1.7 and B.1.351, follow previous positive pre-clinical test results with stenoparib as a treatment of SARS-CoV-2 first announced on 26 August 2020, and since published in the peer-review journal mBio (mbio.asm.org) on 19 January 2021. The previously announced data showed that stenoparib inhibits SARS-CoV-2 as a single agent, and in addition that stenoparib, in combination with remdesivir, was also active in inhibiting the virus. The concentration of stenoparib required for virus inhibition was lower in the combination study with remdesivir than in the single agent study. We are continuing to explore the Biden administration opportunities through NIH as well as BARDA opportunities to advance stenoparib into clinical trials as a novel treatment for COVID-19 infection. We have not yet submitted an Investigational New Drug ("IND") application to the FDA to conduct such a trial and if we decide to do so, the FDA may not approve our IND application.

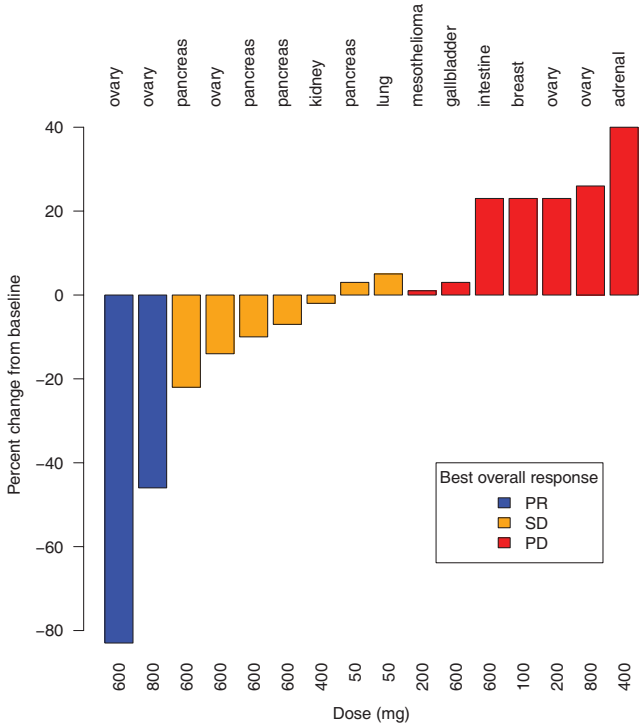
DRP® Companion Diagnostic for Stenoparib

We are developing stenoparib together with its validated DRP® companion diagnostic, which enables us to select the patients most likely to respond to the drug in our clinical trials. An Investigation Device Exemption (IDE) for our Stenoparib-DRP® was granted by the FDA (G180165) in 2018. The Stenoparib-DRP®, which comprises 414 expressed genes, was initially developed using a panel of 61 cancer cell lines (provided by Eisai) treated with stenoparib. This putative DRP® contains biomarkers that reflect the mechanism of action of PARP and Tankyrase inhibition by stenoparib, as well as capturing much unknown tumor biology, and is largely independent of BRCA mutation.

The putative Stenoparib-DRP®, developed through our DRP® platform using gene expression data from cancer cell line testing data, was retrospectively validated using biopsy materials from the Phase 1 trial of the drug (formerly E7449), sponsored by Eisai, that was conducted in the United Kingdom (UK) from 2012-2015 (clinicaltrial.gov number NCT01618136). Of 41 patients enrolled in the Phase 1 study, 35 had response assessment. Of these, 2 had PR (5% ORR) and 13 had SD. Biopsies and BRCA analysis were voluntary and available from 16, and 7 patients, respectively. Of the 16 patients with biopsies, 13 passed our QC in the lab and were assayed on the Affymetrix HG-U133Plus2 array.

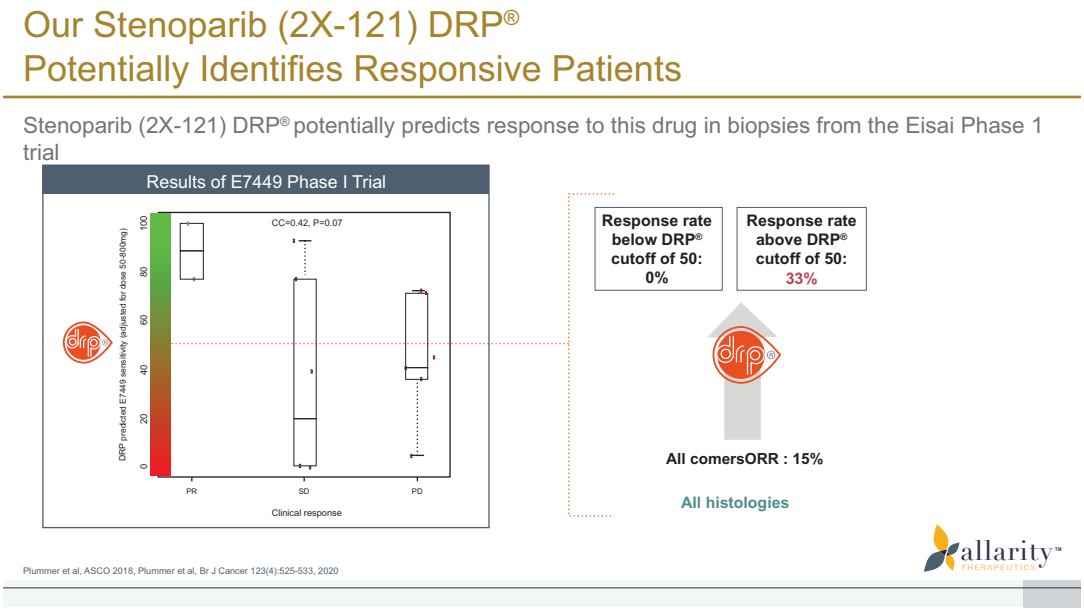
A statistical analysis plan was completed before initiation of retrospective blinded prediction of stenoparib sensitivity on the 13 samples.

Waterfall plot of 16 Phase 1 patients for which biopsies were available



Before blinded retrospective analysis of mixed histology biopsies from the Phase I trial of stenoparib, two crucial choices were made: 1) to use a reference population of 819 breast cancer biopsies, and 2) to use as cutoff the population median of the Phase 1 biopsies. Both choices turned out to be excellent, because the population median of the Phase 1 biopsies was very close to the population median of the breast cancer reference population, and when applied to the Phase 1 biopsies both medians separated the samples in identical populations with a clear difference in response rate and PFS.

It was decided that the breast cancer reference population with a cutoff of 50% would be used for the proposed Phase II trial. This has the added advantage of being the exact same parameters used for the blinded analysis of the Phase I trial. The only difference is that DRP has been locked and retrospectively validated between Phase I and proposed Phase II. The following figure shows the unblinded comparison of dose-adjusted predicted sensitivity to stenoparib and clinical response to stenoparib (the highest scoring SD patient is actually a long-term progression-free pancreatic cancer survivor (still alive at last check at 406 days, and progression-free at last evaluation at 321 days):



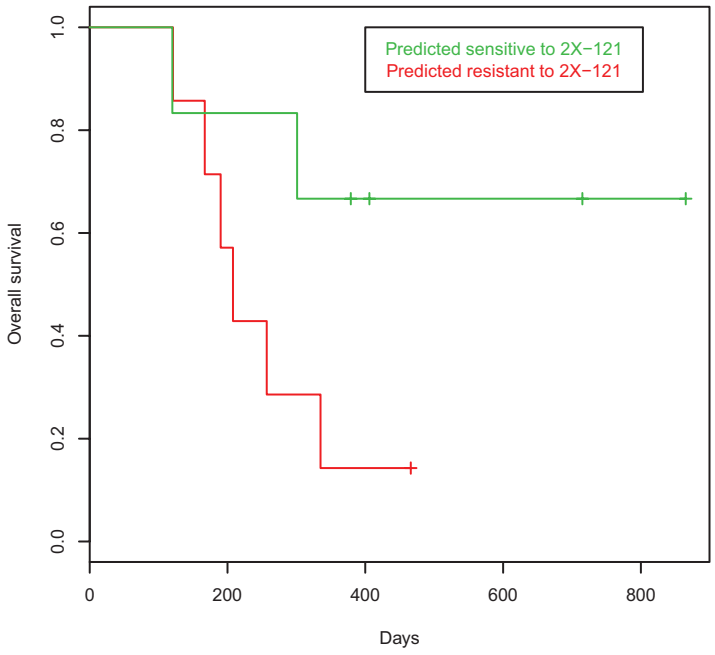
Clinical performance of the Stenoparib-DRP® at the pre-specified cutoff of 50 in ovarian cancer

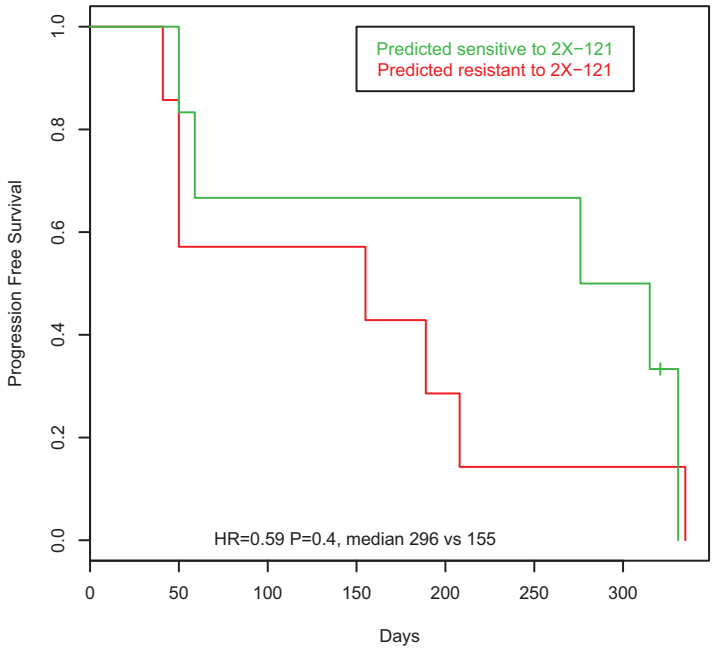
Ovarian only (N=3)	Responders (PR)	Non-responders (SD+PD)
DRP® positive (top 50%)	2	0
DRP® negative (bottom 50%)	0	1
Overall precision: 100% correct prediction		
Sensitivity: 100% of responders correctly predicted		
Specificity: 100% of non-responders correctly predicted		

Clinical performance of the Stenoparib-DRP® at the pre-specified cutoff of 50 for all histologies

All histologies (N=13)	Responders (PR)	Non-responders (SD+PD)
DRP® positive (top 50%)	2	4
DRP® negative (bottom 50%)	0	7
Overall precision: 69% correct prediction		
Sensitivity: 100% of responders correctly predicted		
Specificity: 64% of non-responders correctly predicted		

The following figures show Kaplan-Meier curves of overall survival (OS) and progression free survival (PFS) in two populations, those above a dose-adjusted cutoff of 50 (N=6), and those below a cutoff of 50 (N=7). The hazard ratio is 0.26 (P=0.04 one sided) and the median survival in the predicted resistant group (below cutoff) is 208 days. More than half of the patients remain alive in the group predicted sensitive.





Additionally, BRCA mutation status considered, but was only available for 7 patients in the trial (NCT01618136), of which 6 are BRCA mutated. Of these 6, 1 responds to stenoparib, giving a response rate of 1/6 or 16% in the BRCA mutated population. This equals the response rate observed in the unselected 13 patients analyzed with DRP® score. Thus, BRCA mutation does not appear to be a predictor of response in this small trial.

In sum, our retrospectively validated Stenoparib-DRP® companion diagnostic correctly identifies responder patients to this drug, and we plan use this DRP® companion diagnostic for all of our clinical programs to advance stenoparib, including our ongoing Phase 2 ovarian cancer study.

Existing PARP Inhibitors and Our Opportunity

Numerous PARP inhibitors, including Lynparza® (olaparib), Rubraca® (rucaparib camsylate), Zejula® (niraparib) and Talzenna® (talazoparib tosylate) have been approved by the FDA for multiple oncology indications, including ovarian, breast, prostate, and pancreatic cancer. Sales of these FDA-approved PARP inhibitors were approximately $1.7 billion in 2019 and are forecasted to be over $7.0 billion in 2025, with Lynparza (olaparib) accounting for $1.2 billion and over $4.0 billion in the 2019 and 2025 totals, respectively.

Despite the commercial success of PARP inhibitors, broader adoption is limited by their high rates of GI and bone marrow toxicity which is largely a result of off-target cell killing. Adverse grade 3-4 events from this class of drugs include anemia, thrombocytopenia, neutropenia and alopecia. Other common adverse reactions include nausea, vomiting, diarrhea, fatigue, and decreased appetite.

We believe Stenoparib is distinguished among the PARP class of drugs by the following features and advantages:

- It is a dual inhibitor of Tankyrases 1 and 2, which provides a likely dual cancer cell killing mechanism by interference with Wnt signaling pathways and chromosomal telomerase maintenance and stability.
- It lacks myelotoxicity, a common limiting adverse event among PARP inhibitors, at the established MTD.
- It is resistant to P-glycoprotein (PgP) mediated export from target cancer cells, resulting in higher accumulation of drug in target cells.
- It can cross the Blood-Brain Barrier (BBB), enabling the potential treatment of primary brain tumors, such as glioblastoma multiforme (GBM), and brain metastases from other body tumors, such as malignant breast cancer.

Additionally, the use of our Stenoparib-DRP® companion diagnostic to identify and treat only those patients most likely to respond to the drug (while excluding those patients most likely to be unresponsive to the drug), gives us a substantial advantage in increasing patient response rates, avoiding adverse events in patients that are not likely to benefit from our drug, and providing health economics advantages.

Furthermore, our DRP® for stenoparib identifies a broader group of potential responder patients than can be identified by the competitive biomarker approach of only assessing BRCA 1 and 2 mutation status in order to select and treat patients. The DRP® for stenoparib comprises 414 genes, including Wnt-beta-catenin and a number of DNA repair pathways, and thus is a broader assessment of the tumor responsiveness to the drug than determining mutation in one or two BRCA genes.

Overview of IXEMPRA® (microtubule inhibitor)

Mechanisms of Action

Ixabepilone (IXEMPRA®) is a semisynthetic derivative of epothilone B, with improved in vitro metabolic stability. It is a novel antineoplastic agent that stabilizes microtubule dynamics, resulting in blockade of cancer cells in mitosis during cell division, leading to cell death. Ixabepilone induces a distinct pathway of cellular apoptosis via activation of caspase-2, whereas other tubulin agents, such as the taxanes, act via caspase-9. Ixabepilone is a poor substrate for efflux transporters such as the multidrug resistance-related protein (MRP1) and P-glycoprotein (P-gp) that are involved in drug-resistance mechanisms. Epothilones have a tubulin-binding mode distinct from that of other microtubule- stabilizing agents. Ixabepilone's tubulin-binding mode affects the microtubule dynamics of multiple β-tubulin isoforms, including the class III isoform of β-tubulin (β-III tubulin), the expression of which has been implicated in clinical taxane resistance. As used in this section of this information statement/prospectus describing our therapeutic candidate IXEMPRA®, statements regarding the use of our proprietary DRP® companion diagnostics or our proprietary DRP® platform or our observations that our therapeutic candidate IXEMPRA® may have anti-cancer or anti-tumor activity or is observed to be well tolerated in a patient population should not be construed to mean that we have resolved all issues of safety and/or efficacy for our therapeutic candidate IXEMPRA® or our putative IXEMPRA®-DRP® companion diagnostic. Issues of safety and efficacy for any therapeutic candidate companion diagnostic may only be determined by the U.S. FDA or other applicable regulatory authorities in jurisdictions outside the United States.

Ixabepilone has anti-tumor activity in vivo against a broad spectrum of tumor types, including tumors that overexpress P-gp and are resistant to multiple agents including taxanes, anthracyclines, and vinca alkaloids. Ixabepilone demonstrated synergistic in vivo activity in combination with capecitabine. In addition to direct anti-tumor activity, ixabepilone demonstrated antiangiogenic activity in vivo.

The nonclinical pharmacokinetic (PK) studies performed with ixabepilone were directed toward the preliminary assessment of the absorption, distribution, metabolism, and excretion of the drug. Ixabepilone was (a) orally bioavailable with bioavailability ranging from 8 to 40% in mice, rats, and dogs; (b) extensively distributed extravascularly; (c) moderately bound to serum protein; (d) extensively metabolized to many metabolites and the metabolite profile was similar among species including humans; (e) metabolized by CYP3A4/5; (f) cleared primarily via oxidative metabolism and then mostly excreted in the feces; (g) neither a CYP inhibitor nor a CYP inducer at clinically relevant concentrations.

Pre-Clinical Studies

The results from the in vitro cytotoxicity studies against extensive panels of human-tissue specific, taxane-sensitive and taxane-resistant (including MDR, β-III tubulin over- expression, and tubulin mutation mechanisms), cancer cell lines demonstrate that ixabepilone has potent and broad-spectrum antineoplastic activity. The effectiveness of ixabepilone in vitro is paralleled by equally broad-spectrum activity observed in vivo. Ixabepilone demonstrated a broad spectrum of in vivo anti-tumor activity in taxane- sensitive and taxane-resistant human cancer xenograft models. Less frequent dosing schedules allowed higher doses of ixabepilone to be given and performed better than the more frequent dosing schedules. Against a total of 35 human tumor xenografts grown in mice, representing a wide array of tumor types, ixabepilone demonstrated anti-tumor activities, producing 1 LCK or greater anti-cancer activity in 33 of 35 tumors. Ixabepilone demonstrated the ability to overcome drug resistance due to the Pgp-mediated multidrug resistance (MDR) phenotype in vivo, reversing the MDR resistance of 2 established MDR models: the 16C/ADR breast carcinoma models and the HCT116/VM46 human colon carcinoma model. Ixabepilone also demonstrated anti-tumor activity both in vitro and in vivo against a human tumor model that over expresses MRP1 (Pat-7), producing in vitro IC90 values of 7.4 nM (compared with 150 nM for paclitaxel) and an in vivo activity of 2.9 LCK (compared with 0.8 LCK for paclitaxel).

Ixabepilone suppresses the dynamic instability of αβ-III microtubules and αβ-II microtubules. This is in contrast to paclitaxel which had no suppressive effect on the dynamic instability of αβ-III microtubules, but suppressed the dynamic instability of αβ-II microtubules. Thus, ixabepilone should be more effective than paclitaxel at inhibiting proper formation of the mitotic spindle and disrupting mitosis in tumor cells with high expression of β-III tubulin. On this basis, ixabepilone is expected to be more active on tumors that are resistant to paclitaxel because of over expression of β-III tubulin.

The in vitro and in vivo cardiovascular safety pharmacology studies conducted with ixabepilone indicated that it is unlikely that ixabepilone will affect electrocardiographic parameters at anticipated plasma concentrations in patients. Ixabepilone induced drug- related clinical signs consistent with peripheral neuropathy in rodents. In a comparative study in rats, ixabepilone and paclitaxel induced peripheral neuropathy that was similar in nature and characterized by decreases in sensory and motor maximal nerve conduction velocities and reductions in sensory and compound nerve-response amplitudes. There were no ixabepilone-related CNS or respiratory findings.

The combination of ixabepilone with a number of approved anticancer therapeutic agents produced anti-tumor activities that were markedly greater than the best achievable responses from the individual single agents administered at their MTD alone. Such therapeutic synergism was observed with capecitabine, cetuximab, bevacizumab, or trastuzumab. Modest anti-cancer activity enhancement was observed when combined with irinotecan. However, no therapeutic advantage was observed when combined with gefitinib, gemcitabine, or paclitaxel).

The pharmacokinetic characteristics of ixabepilone in mice, rats, and dogs are comparable to those in humans, indicating the acceptability of those species for the toxicological assessment of ixabepilone. Serum protein binding of ixabepilone was moderate in rat, dog, and human serum.

In both animals and humans, ixabepilone was extensively metabolized via oxidative metabolism and eliminated mainly through fecal excretion. Only metabolites formed through oxidation of ixabepilone were found in animals and humans. All of the metabolites identified in humans were present in the species used in the toxicological evaluation of ixabepilone. The total amount of metabolites, as a percentage of the total radioactive dose in excreta (urine and feces), was high in all species studied. The known degradants of ixabepilone, BMS-249798, BMS-326412, and BMS-567637, were detected in plasma and excreta across species. The metabolite and degradant profiles in plasma are similar among humans, rats, and dogs, with unchanged ixabepilone being the most abundant drug-related component. Although the pharmacologic activity of individual metabolites is not known, a mixture of in vitro metabolites of ixabepilone was not active in in vitro cytotoxicity assays.

Ixabepilone is a substrate of CYP3A4 and CYP3A5. The PK of ixabepilone may be affected by the co-administration of agents that inhibit or induce CYP3A4. Ixabepilone is an inhibitor of CYP3A4, but it does not inhibit any of the other common CYP enzymes. Ixabepilone is not an inducer of CYP enzymes in vitro. Based on the efficacious plasma concentration and the in vitro inhibition and induction characteristics, ixabepilone is not expected to affect the PK of co-administered agents that are metabolized by CYP enzymes.

Nonclinical toxicity studies identified the principal target-organ, genetic, and developmental toxicities of ixabepilone. Ixabepilone principally affected tissues having rapid-cell division, including the GI, hematopoietic and lymphoid systems, and the male reproductive system. In mice and rats, peripheral neuropathy was also a prominent effect. Ixabepilone-induced toxicities were generally reversible following a 1-month, post dose recovery period, except for delayed testicular effects in rats and dogs and peripheral neuropathy in rats and mice. In rats, females were generally more severely affected than males, consistent with higher systemic exposures in females. When administered daily for 2 weeks or once every 21 days for 6 or 9 months, ixabepilone toxicity was similar to that observed in the single-dose, 5-day, and 1-month intermittent dose (QWx5) toxicity studies, with the exception of loss of bony trabeculae of the femoral growth plate in rats, which was not seen in any other studies. The increased growth-plate thickness observed in the rat is not likely to be a safety risk for the treatment of cancer in adult human populations, because in the rat, unlike humans, the growth plates do not fuse upon reaching sexual maturity.

Ixabepilone was not mutagenic in the Ames bacterial mutation assay. Ixabepilone was not clastogenic in the in vitro cytogenetics assay in primary human lymphocytes, but did increase the incidence of polyploid lymphocytes at high concentrations. However, ixabepilone was clastogenic (induction of micronuclei) in the in vivo rat micronucleus study. These findings were similar to other microtubule-stabilizing drugs and result in a benefit-risk analysis in the indicated patient population that supports the use of these drugs for a cancer indication. Ixabepilone did not affect mating or fertility in a rat reproduction study, and induced embryo-fetal toxicity in rats and rabbits only at doses that also caused maternal toxicity. Since clinical administration of ixabepilone occurs at doses associated with minimal to mild clinical side effects, administration during pregnancy may pose a risk for fetal toxicity.

The single- and repeat-dose IV toxicity studies with ixabepilone adequately predicted the clinical toxicities that were subsequently observed in humans. In both experimental animals and humans, ixabepilone toxicities were primarily manifested in the GI, hematopoietic, and peripheral nervous systems. These effects were expected and consistent with the toxicity produced by other microtubule-stabilizing anticancer drugs. In general, the nonclinical species were more sensitive to ixabepilone-induced toxicity than human subjects. In vitro, vincristine and paclitaxel were more potent than ixabepilone in inhibiting mitochondrial axonal transport in fetal dorsal root ganglion culture, whereas in mice and rats, paclitaxel and ixabepilone induced axonal degeneration or decreases in nerve conduction velocities that were similar in nature and severity. Based on the intended use of ixabepilone in treating advanced breast cancer and other solid tumors, the scope and results of the nonclinical pharmacology, pharmacokinetics, toxicity, and exposure studies support the continuous IV administration of ixabepilone on a once every 21-day cycle in this patient population.

Prior Clinical Trials

Ixabepilone (IXEMPRA®) was originally developed through Phase 3 clinical trials and brought to market by Bristol-Myers Squibb (BMS). In Phase 1 clinical trials of ixabepilone as monotherapy, objective responses were demonstrated in a variety of tumor types, including breast, colon, head and neck, ovarian, endometrial, vulvar, and peritoneal cancers, melanoma, and non-Hodgkin's lymphoma.

Dose-limiting toxicities observed in Phase 1 clinical trials of ixabepilone as monotherapy included sensory neuropathy, neutropenia, myalgia, and fatigue. Adverse events (AEs) reported in Phase 1 studies in which ixabepilone was used in combination with other chemotherapy agents (*e.g.*, carboplatin [CA163007], doxorubicin [CA163008], and irinotecan [CA163025]) were similar qualitatively and in frequency to that observed in monotherapy studies; no toxicities unique to combination therapies were reported.

The PK of ixabepilone are linear, based on consistent total body clearance and apparent terminal elimination half-life across doses from 15 mg/m^2 to 57 mg/m^2. The coadministration of ketoconazole increases ixabepilone exposure in patients. Ketoconazole or other potent CYP3A4 inhibitors such as itraconazole, clarithromycin, atazanavir, nefazodone, saquinavir, telithromycin, ritonavir, amprenavir, indinavir, nelfinavir, delavirdine, or voriconazole should be avoided. If alternative treatment cannot be administered, a dose adjustment should be considered, and patients should be monitored closely for acute toxicities. Pharmacokinetics results indicate that exposure to ixabepilone is increased by 22%, 30%, and 81% in patients with mild, moderate, or severe hepatic dysfunction, respectively. After coadministration of ixabepilone and capecitabine, PK differences are minor and are not expected to affect the toleration profile or anti-cancer activity of either ixabepilone or capecitabine.

In a Phase 1/2 clinical trial (CA163031) evaluating ixabepilone in combination with capecitabine for the treatment of metastatic breast cancer (MBC), common toxicities included fatigue, nausea, hand-foot syndrome, and sensory neuropathy.

Phase 2 clinical trials demonstrated the activity of ixabepilone in advanced breast cancer, non- small cell, small-cell lung cancers, prostate cancer, gastric, and other malignancies. The most notable toxicities reported in Phase 2 trials of ixabepilone as monotherapy are peripheral neuropathy, neutropenia, myalgia, arthralgia, alopecia, and fatigue. The peripheral neuropathy has been predominantly sensory, cumulative in nature, and reversible upon discontinuation of ixabepilone.

In a large, international Phase 3 clinical trial (CA16304612) in patients with taxane-resistant and anthracycline-pretreated or resistant metastatic or locally advanced breast cancer, ixabepilone in combination with capecitabine resulted in a statistically significant improvement in progression-free survival (PFS) and response rate (RR) compared to capecitabine monotherapy, per the independent radiology review committee (IRRC). Another similar, large, multicenter, international randomized, Phase 3 clinical trial (CA16304813) compared ixabepilone in combination with capecitabine to capecitabine alone in patients with metastatic or locally advanced breast cancer previously treated with anthracyclines and taxanes. CA163048, in which OS was the primary endpoint, demonstrated statistically significant and clinically meaningful superiority in PFS and improved RR over capecitabine alone that translated into a modest improvement in overall survival (OS) favoring the combination which did not meet statistical significance. These studies were conducted in 29 countries, with more than 300 clinical investigators and over 1,200 treated patients. The studies included dozens of trial sites spread throughout European countries.

Based on the Phase 3 clinical trials, ixabepilone was approved by the FDA in 2007 for the treatment of metastatic breast cancer in the following settings:

- In combination with capecitabine for the treatment of metastatic or locally advanced breast cancer in patients after failure of an anthracycline and a taxane.
- As monotherapy for the treatment of metastatic or locally advanced breast cancer in patients after failure of an anthracycline, a taxane, and capecitabine.

Despite the positive Phase 3 clinical trial results leading to approval of Ixabepilone in the U.S., the drug has not yet been approved in Europe, due to the EMA's determination of insufficient risk-benefit for Ixabepilone under the European socialized medicine pricing structure. Subsequently, IXEMPRA® was out-licensed to us to pursue approval in Europe using our IXEMPRA®-DRP®-selected patient population in order to show statistical significance in further clinical trials that the therapeutic candidate has sufficient risk-benefit under European standards to support a pricing structure that would be appropriate.

As of March 2009, more than 3,144 patients have been treated with ixabepilone in BMS- sponsored Phase 1, 2, and 3 clinical trials. In addition, the Cancer Therapy Evaluation Program (CTEP) program of the U.S. National Cancer Institute (NCI) independently conducted a number of clinical studies. These studies demonstrated the activity of ixabepilone in a variety of tumor types, including breast, hormone-refractory prostate, pancreatic, renal cell, non- small cell and small-cell lung cancers, and non-Hodgkin's lymphoma.

DRP®-Guided Phase 2 Clinical Trial

We are currently conducting a DRP®-guided, Phase 2, open label, single arm clinical trial — in Europe — to investigate the toleration and anti-cancer activity of IXEMPRA® as monotherapy in patients with metastatic or locally advanced breast cancer after failure of an anthracycline, a taxane, and capecitabine. This clinical trial, with an enrollment target of 60 IXEMPRA®-DRP®-selected patients, is being conducted at numerous sites in Europe, including Belgium, England, Denmark, Finland, Poland and Germany. Patients are selected by using the putative IXEMPRA®-DRP® companion diagnostic at a cut-off score of sixty-seven percent (67%), and IXEMPRA® is administered at 40 mg/m^2 infused intravenously over 3 hours every 3 weeks (in accordance with the U.S. label of the drug). Dose reduction is required in certain patients with elevated AST, ALT, or bilirubin. The trial was initiated in April 2021. Thus far, no DRP®-selected patients have been enrolled and dosed in the trial, partially due to delays resulting from the ongoing COVID-19 pandemic. The clinical trial's goal is to provide a superior clinical benefit to DRP®-selected patients receiving IXEMPRA®, as compared to historical clinical data from breast cancer patients treated with IXEMPRA® but not selected with the putative DRP® companion diagnostic for the drug. Since the Phase

2 clinical trials currently are ongoing, data from these trials is not yet available to report. We anticipate expanded enrollment in this trial in 2021 and anticipate trial completion and data read out in 2022. We have entered into a cost sharing arrangement with Smerud Medical Research International, our CRO for the Phase 2 clinical trial, where our CRO has agreed to accept a single digit royalty on any proceeds we generate from the commercialization or disposition of IXEMPRA® in exchange for the anticipated costs our CRO would incur in conducting the Phase 2 clinical trial up to an agreed upon maximum amount of costs incurred.

Overview of Metastatic Breast Cancer

Breast cancer is the most frequent malignancy in women worldwide, and the second most common cancer worldwide, with an estimated 1.8 million new diagnoses per year. In the U.S., breast cancer has the highest prevalence among all cancers. The Surveillance, Epidemiology, and End Results ("SEER") Program at National Cancer Institute estimates that in 2020, there will be 276,000 new cases of breast cancer in the U.S. alone, and more than 40,000 deaths. Treatment options for breast cancer depend on many factors, including the stage of cancer. Breast cancer is a heterogeneous disease which is grouped into several clinical subtypes based on the expression of three proteins: ER, progesterone receptor ("PR") and HER2. Both ER and PR are hormone receptors, and tumors that express either of these receptors are referred to as hormone receptor-positive. The American Cancer Society estimates that approximately 75-80% of all breast cancers express estrogen receptor ("ER+") highlighting the central role of ER signaling in driving a large majority of breast cancer. Although early-stage non-metastatic disease is curable in approximately 70-80% of patients, advanced breast cancer with distant organ metastases is considered incurable with currently available therapies. Advanced breast cancer comprises inoperable locally advanced breast cancer, which has not spread to distant organs, and metastatic (stage IV) breast cancer; common sites of spread are bone, lungs, liver, and brain. Currently, it is a treatable but virtually incurable disease, with metastases including to the brain being the cause of death in almost all patients, and a median overall survival of two to three years. Patients with metastatic breast cancer receive treatments that aim to relieve their symptoms and to prolong quality-adjusted life expectancy.

Treatment often continues until the cancer starts growing again or until side effects become unacceptable. If this happens, other drugs might be tried. The types of drugs used for stage IV (metastatic) breast cancer depend on the hormone receptor status and the HER2 status of the cancer. Women with hormone receptor-positive (estrogen receptor-positive or progesterone receptor-positive) cancers are often treated first with hormone therapy (tamoxifen or an aromatase inhibitor). This may be combined with a targeted drug such as a CDK4/6 inhibitor, everolimus or a PI3K inhibitor. Women who haven't yet gone through menopause are often treated with tamoxifen or with medicines that keep the ovaries from making hormones along with other drugs. Because hormone therapy can take months to work, chemo is often the first treatment for patients with serious problems from their cancer spread, such as breathing problems. Chemotherapy is the main treatment for women with hormone receptor-negative (ER-negative and PR-negative) cancers. These breast cancers are either HER2 positive or triple negative.

Trastuzumab (Herceptin®) may help women with HER2-positive cancers live longer if it's given along with chemo or with other medications such as hormonal therapy or other anti-HER2 drugs. Pertuzumab (Perjeta®), another targeted drug, might be added as well. Other options might include targeted drugs such as lapatinib (which may be given with certain chemo drugs or hormone therapy) or ado-trastuzumab emtansine (Kadcyla®). For HER2-negative patients, treatment depends on specific gene mutation status. Women who have a BRCA mutation are typically treated with chemotherapy (and hormone therapy, if the cancer is hormone receptor-positive). An option after getting chemotherapy is treatment with a PARP inhibitor, such as olaparib or talazoparib. Women who have a PIK3CA mutation are typically treated with alpelisib, a targeted PI3K inhibitor that can be used along with fulvestrant to treat postmenopausal women with advanced hormone receptor positive breast cancer.

For women that have triple-negative breast cancer (TNBC) — HER2 negative, ER negative, and PR negative — the immunotherapy dug atezolizumab (Tecentriq®) if often used, along with albumin-bound paclitaxel (Abraxane®) in patients with advanced triple-negative breast cancer with tumors expressing the PD-L1 protein (which is expressed is about 20% of triple-negative breast cancers.) For women with TNBC and a BRCA mutation whose cancer no longer responds to common breast cancer chemo drugs, platinum drugs (like cisplatin or carboplatin) may be considered.

According to the current estimates, the global therapeutics market for treatment of breast cancer was valued at over $19 billion in 2018 and is expected to reach over $40 billion by the year 2026, at a CAGR of 10.6%. By way of example, in 2019, worldwide sales for endocrine and targeted therapies treating ER+ breast cancer patients totaled $9.6 billion. Given the incidence rate and cost of treatment, by 2027 the market size for adjuvant therapy, first line treatments and second line treatments could total $25 billion, $8 billion and $4 billion, respectively. Accordingly, the potential market for treatment of mBC, including treatment of brain metastases (for which there is currently no approved therapy) is large and growing.

Rationale for Targeting Microtubules in mBC

IXEMPRA® is approved and on market in the U.S. as third- or fourth-line treatment of metastatic breast cancer in the following settings:

- In combination with capecitabine for the treatment of metastatic or locally advanced breast cancer in patients after failure of an anthracycline and a taxane.
- As monotherapy for the treatment of metastatic or locally advanced breast cancer in patients after failure of an anthracycline, a taxane, and capecitabine.

Accordingly, the clinical benefit of IXEMPRA®, a microtubule inhibitor, in these patient groups is already established. We seek to gain approval of this drug in Europe, for the same mBC patient groups, in connection with our putative IXEMPRA®-DRP® companion diagnostic, used to select and treat the most likely responder patients for the drug, in order to yield a superior therapeutic benefit in selected patients. Further, use of our putative DRP® companion diagnostic is expected to provide an improved benefit versus risk ratio, which we believe should support an EMA approval. IXEMPRA® was previously rejected by the EMA on basis of the risk versus benefit ratio.

Future Opportunities & Development Plans for IXEMPRA®

Potential Development for Neoadjuvant mBC Setting

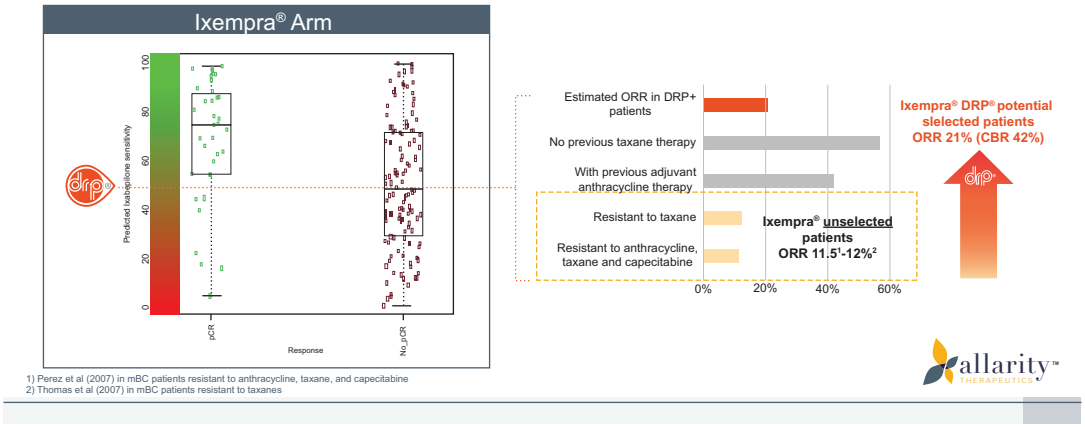
Since the retrospective validation of the IXEMPRA®-DRP® companion diagnostic showed a 58% increase in complete remission of patients treated with IXEMPRA® (see below) as adjuvant therapy, there is a potential to expand the IXEMPRA® drug plus a DRP® companion diagnostic combination to this setting as an attractive alternative to the commonly used paclitaxel. The neoadjuvant mBC setting is a substantially larger market opportunity than the third- or fourth-line mBC setting.

DRP® Companion Diagnostic for IXEMPRA®

We are developing IXEMPRA® together with its retrospectively validated DRP® companion diagnostic, which we believe enables us to select the patients most likely to respond to the drug in our clinical trials. Our Phase 2 clinical trial protocol, including use of the putative IXEMPRA®-DRP® companion diagnostic is in process of being approved by the regulatory agencies in the countries where we are conducting the clinical trial, and is already approved for use in clinical trials in Belgium, Finland, Denmark, UK and Poland. The putative IXEMPRA-DRP® companion diagnostic, which comprises 198 expressed genes, was initially retrospectively validated using gene expression data from patient biopsies in the prior Phase 2 clinical trial of ixabepilone in neoadjuvant breast cancer setting that was conducted by BMS (NCT00455533). In retrospective analysis of this trial, patients selected with our putative IXEMPRA®-DRP® companion diagnostic was observed to have a 58 percent (58%) increase in complete remission when compared to randomly selected patients treated with ixabepilone.

Our IXEMPRA® DRP® Potentially Identifies Responsive Patients

IXEMPRA® DRP® potentially predicts response to this drug in published data from biopsies from a trial of ixabepilone in neoadjuvant BC



1) Perez et al (2007) in mBC patients resistant to anthracycline, taxane, and capecitabine
2) Thomas et al (2007) in mBC patients resistant to taxanes

In sum, we believe our retrospectively validated putative IXEMPRA®-DRP® companion diagnostic accurately and reliably identifies responder patients to this drug, and we plan to use this DRP® companion diagnostic for all of our clinical programs to advance IXEMPRA®, including our ongoing Phase 2 clinical trial for mBC.

Existing Microtubule Inhibitors & Our Opportunity

A number of microtubule inhibitors are approved and on market for the treatment of multiple cancer types. These approved drugs include docetaxel (Taxotere®), eribulin (Halaven®), ixabepilone (IXEMPRA®), paclitaxel (Taxol®, Abraxane®), and vinorelbine (Navelbine®). Docetaxel, paclitaxel, and albumin-bound paclitaxel are also

called taxanes. Currently marketed microtubule inhibitors have generated several $billions of sales in the past few years. For example, sales of Halaven® (Eisai) alone were about $400 million in 2019, and sales of vinorelbine exceeded $110 million in 2018. The following table (2019) summarizes many of the approved microtubule inhibitors:

Drug	Main indications	Dose	Combinations
Vinblastine 1961*	Hodgkin's disease, non-Hodgkin lymphoma, histiocytic lymphoma, mycosis fungoides, testis, Kaposi's sarcoma, choriocarcinoma, breast, kidney	3.7 mg/m^2 – 18.5 mg/m^2	Monotherapy, mechlorethamine, doxorubicin, vincristine, bleomycin, etoposide, dacarbazine, brentuximab, cisplatin, ifosfamide, methotrexate, mitomycine
Vincristine 1963*	Leukemias, lymphomas, myeloma, breast, lung, head & neck, sarcomas, Wilms' tumor, neuroblastoma, retinoblastoma, medulloblastoma,	0.8 mg/m^2 – 2 mg	Monotherapy, doxorubicin, carboplatin mechlorethamine, vinblastine, bleomycin, etoposide, cyclophosphamide, procarbazine, topotecan, dactinomycin, leucovorin, actinomycin D
Vindesine 1982***	ALL, CML, melanoma, breast	3 mg/m^2 – 4 mg/m^2	Monotherapy, cisplatin
Vinorelbine 1994*	NSCLC, Hodgkin's disease, non-Hodgkin lymphoma, rhabdomyosarcoma, Wilm's tumor, neuroblastoma	25 mg/m^2 – 30 mg/m^2	Monotherapy, cisplatin
Vinflunine 2009**	Urothelial carcinoma	280 mg/m^2 – 320 mg/m^2	Monotherapy
Vincristine Liposomal 2012*	Philadelphia chromosome-negative ALL	2.25 mg/m^2	Monotherapy
Paclitaxel 1992*	Ovarian, breast, lung, gastric, Kaposi's sarcoma	100 mg/m^2 – 210 mg/m^2	Monotherapy, cisplatin, doxorubicin
Docetaxel 1996*	Breast, lung, prostate, gastric, head & neck	75 mg/m^2 – 100 mg/m^2	Monotherapy, cyclophosphamide, cisplatin, 5-fluorouracil
Nab-Paclitaxel 2005*	Breast, lung, pancreas	100 mg/m^2 – 260 mg/m^2	Monotherapy, carboplatin, gemcitabine
Cabazitaxel 2010*	Prostate	20 mg/m^2 – 25 mg/m^2	Monotherapy
lxabepilone 2007*	Breast	40 mg/m^2	Capecitabine

Anti-tubulin agents first approved by FDA(*), EMA(**) or in other countries (***). ALL: acute lymphoblastic leukemia; CML: chronic myelogenous leukemia; NSCLC: non-small-cell lung carcinoma

According to the National Comprehensive Cancer Network (NCCN) guidelines for treatment of metastatic breast cancer, in the second line metastatic breast cancer (mBC) setting, for patients who are HER2 negative, ixabepilone in combination with capecitabine is a therapeutic option, along with other microtubule inhibitors, such as eribulin, cyclophosphamide, docetaxel, and epirubicin. The choice of a particular microtubule therapeutic is made by the treating oncologist, and the current lack of suitable companion diagnostics to guide therapy selection has hampered the introduction of personalized medicine to this patient group. Our current clinical program for ixabepilone in metastatic breast cancer is focused on a third-line monotherapy in patients selected with the IXEMPRA®-DRP® companion diagnostic.

Despite the success of microtubule inhibitors as a class in the treatment of cancer, the expanded use of these drugs has been limited by certain toxicities, that include neutropenia and neurotoxicity, and the development of tumor resistance to the drugs after long-term use. For example, among taxane-naıve patients, primary resistance to taxanes is a critical factor for disease progression. More than one-third of patients with metastatic breast cancer do not respond to first-line anthracyclines or taxanes. Taxane resistance rates of up to 55% in anthracycline-pretreated patients and up to one-third in anthracycline-naıve patients have been reported. Second-line, the same spectrum of outcomes can be expected.

Drug resistance is attributed to heterogeneity of tumors. Each patient has his/her own tumor with different characteristics and therefore different therapy outcomes. The variabilities include but are not limited to different genetic, epigenetic, transcriptomic and proteomic properties. The genotypic changes include mutations, gene amplifications, deletions, chromosomal rearrangements, transpositions of the genetic elements, translocations and microRNA alterations. Genomic instability generates a great level of intercellular genetic heterogeneity in cancer.

We believe that our microtubule inhibitor, IXEMPRA®, together with its DRP® companion diagnostic, can overcome many of the limitations of current microtubule inhibitors and has the potential to be a leading drug in its class that can succeed and compete in the marketplace for the treatment of mBC, and potentially other indications. The use of the IXEMPRA®-DRP® companion diagnostic to select and treat only those mBC patients most likely to respond to the drug (while excluding treatment of likely non-responders) can mitigate toxicity events in non-responder patients, while increasing therapeutic benefit in the identified responder patient population. The success of our IXEMPRA® program will establish the ability of our DRP® platform to expand oncology markets for approved cancer therapeutics through a personalized medicine approach using DRP® companion diagnostics.

Secondary Therapeutic Programs

Overview of LiPlaCis® (targeted, liposomal cisplatin)

Mechanisms of Action

Cisplatin (or cisplatinum or *cis*-diamminedichloroplatinum (II)) is a chemotherapeutic drug that has been used, since the 1970's, in the treatment of various types of human cancers such as ovarian, lung, head and neck, testicular and bladder. Cisplatin has demonstrated anti-cancer activity against various types of cancers such as germ cell tumors, sarcomas, carcinomas as well as lymphomas. The mechanism of action of cisplatin has been associated with ability to crosslink with the urine bases on the DNA to form DNA adducts, preventing repair of the DNA leading to DNA damage and subsequently induces apoptosis (programmed cell death) within cancer cells. However, the drug exhibits certain level of resistance including increased repair of the damaged DNA, reduction in the accumulation of the drug intracellular and cytosolic inactivation of cisplatin.

The drug is also characterized by various toxic side effects including nausea, nephrotoxicity, cardiotoxicity, hepatotoxicity and neurotoxicity. Due to various side effects as well as drug resistance, other anti-cancer drugs that contain platinum such as carboplatin and oxaliplatin, among others, have been used in combination with cisplatin in chemotherapeutic treatment of cancer. In addition to the cytotoxic effects, cisplatin has immunosuppressive and radio-sensitizing properties. As used in this section of this information statement/prospectus describing our therapeutic candidate LiPlaCis®, statements regarding the use of our proprietary DRP® companion diagnostics or our proprietary DRP® platform or our observations that our therapeutic candidate LiPlaCis® may have anti-cancer or anti-tumor activity or is observed to be well tolerated in a patient population should not be construed to mean that we have resolved all issues of safety and/or efficacy for our therapeutic candidate LiPlaCis® or our putative Cisplatin-DRP® companion diagnostic. Issues of safety and efficacy for any therapeutic candidate companion diagnostic may only be determined by the U.S. FDA or other applicable regulatory authorities in jurisdictions outside the United States.

LiPlaCis® is a novel, targeted liposomal formulation of the anti-cancer drug cisplatin. Liposomes are closed spherical vesicles, having an interior aqueous space entrapped by a bilayer lipid membrane. LiPlaCis® liposomes have cisplatin encapsulated in the interior aqueous space of the liposomes and the bilayer membrane is constituted by 3 phospholipids. The use of liposomes as drug carriers has been limited due to the rapid clearance of these carriers from the blood stream by the reticuloendothelial system. The addition of polyethylenglycol (PEG) polymers to the surface of the liposomes leads to reduced clearance rates. As a result, the use of liposomes is now recognized as a promising strategy for tumor-targeted drug delivery. Due to the leaky tumor vasculature and the incomplete lymphatic

drainage system of tumors, long circulatory liposomes may be preferentially trapped and therefore accumulate in cancer tissues. The preferential entrapment and accumulation of the liposomes in the cancer tissue is also known as the enhanced permeability and retention effect (EPR-effect). As a consequence of the trapping of liposomes, significantly more drug substance is present at the site of the tumor compared to administration of plain drug products.

However, it has also been realized that the degradation of liposomes and release of the encapsulated drug(s) after the liposomes accumulate in the tumor are critical elements to the success of liposomal drug delivery. This is in particular the case for hydrophilic drugs such as cisplatin, which do not readily diffuse across the liposomal membrane. Such hydrophilic drugs require that tumor-specific degradation of the liposomal carrier takes place before the drug can be released and exert its cytotoxic action on the cancer cells. In fact, the absence of a trigger mechanism in the tumor tissue was proposed as the explanation for the lack of anti-tumor activity in clinical trials using cisplatin containing Stealth® liposomes (SPI-077)(PEGylated liposomes). In these studies, a high level of cisplatin was found in the tumor tissue inside the liposomes, but it was not bioavailable.

LiPlaCis® includes a tumor-specific targeting mechanism on the surface of its liposomes, which triggers the release of cisplatin specifically in tumor tissue. Secretory sPLA2 is a small secreted and phospholipid-degrading enzyme, which is overexpressed in cancer tissue compared to normal tissue. Until now, 10 catalytically active isoforms of sPLA2 have been identified, of which the Group II sPLA2 isoform seems to be the most predominant form in cancer. In normal tissue, Group II sPLA2 has been found to be expressed in cartilage, digestive tract (stomach, duodenum, jejunum, ileum and colon), and in prostate-, parotid- and lacrimal glands. This enzyme breaks down the LiPlaCis® once it accumulates in the cancer tissue due to the EPR-effect. The lipid composition of the LiPlaCis® is designed to be specifically susceptible to degradation by sPLA2. This leads to tumor-specific release of the encapsulated drug substance in the target tissue. sPLA2 has shown to be overexpressed in a wide range of tumors such as stomach, breast, gastric, liver, lung and pancreatic cancers. It has been shown that sPLA2 expression is increased with advancing stage of cancer disease and that enhanced expression of sPLA2 may be related to tumor progression.

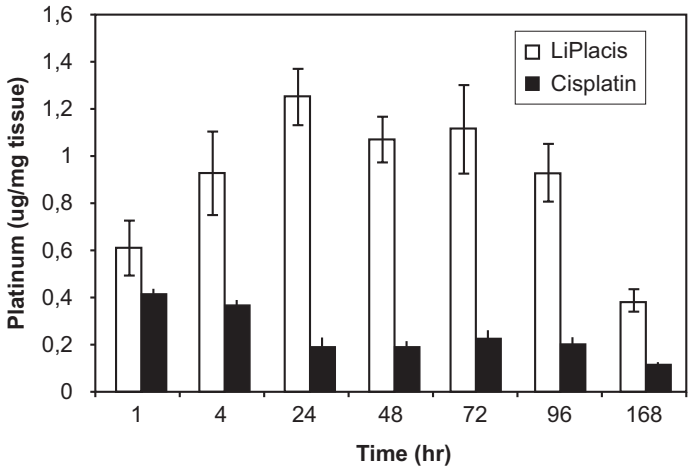
LiPlaCis® enables the targeted transport of high concentrations of encapsulated anti-cancer drugs to cancer tissue. After IV administration, LiPlaCis® will naturally extravasate and accumulate in the extracellular space of the tumor tissue. The secretion of sPLA2 into the extracellular space of the cancer tissue provides further support to the overall concept of achieving a tumor-specific degradation of the LiPlaCis® after extravasation. The targeted delivery of cisplatin to tumors that is achieved by LiPlaCis® has the benefits of transporting this mutagenic and toxic chemotherapeutic to cancer cells while avoiding exposure to healthy cells. The tumor-specific degradation of the liposomal drug carriers by overexpressed sPLA2 offers a novel way to achieve a targeted and triggered release of the encapsulated drugs in the cancer tissue without any prior knowledge of the position and size of the tumor, *e.g.* undetected metastases.

Pre-Clinical Studies

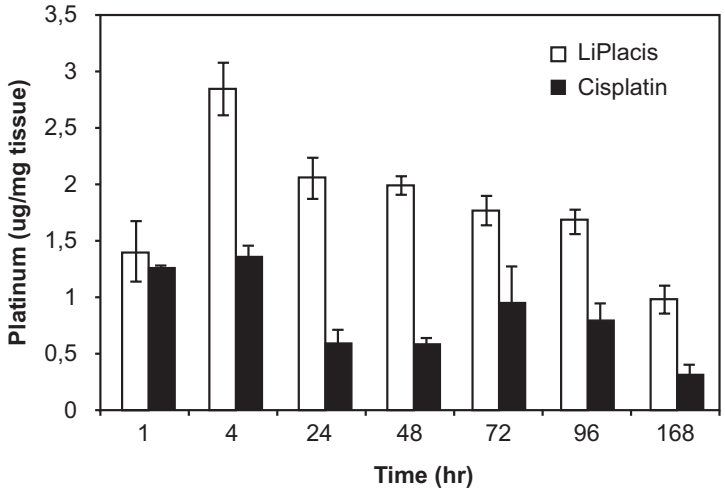
The cytotoxic effects of LiPlaCis® and Stealth® liposomes (SPI-077) with encapsulated cisplatin were tested in the HT-29 human colon cancer cell line and compared to free cisplatin (Study No LPE00392). After a 6-hour incubation with free cisplatin or one of the two liposomal formulations of cisplatin (in conditioned media from COLO 205 cells secreting sPLA2), the HT-29 colon cancer cells were grown in fresh media and the number of cells was evaluated after 72 hours. The concentration of sPLA2 in the cancer cell media was 60 ng/mL during the 6 hours incubation period. A significant cytotoxic activity was observed for LiPlaCis® against the HT-29 colon cancer cells. In contrast, only a marginal cytotoxicity was observed for the Stealth® liposomes (SPI-077) loaded with cisplatin. This demonstrated that neither sPLA2 nor any other enzymes or proteins in the cancer cell media were able to degrade the stable Stealth® liposomes (SPI-077) formulation. The lack of cytotoxic activity of the Stealth® liposomes (SPI-077) against the colon cancer cells is consistent with earlier studies and demonstrates that cisplatin stays inside the stable Stealth® liposomes (SPI-077) as a non-bioavailable form and therefore cannot exert a cytotoxic effect against the cancer cells.

In a bio-distribution study, LiPlaCis® and free cisplatin were administered (3 mg/kg) to tumor bearing mice (Study No. LPE0041). COLO205 tumor cells were implanted subcutaneously and allowed to grow to approximately 200 mm3 before the mice were randomized to a single dose bolus with IV treatment (via tail vein) with either LiPlaCis® or free cisplatin. The concentrations of platinum in plasma were determined using inductively coupled plasma mass spectrometry (ICP-MS) as a function of time. The plasma level of platinum (Pt) after administration of LiPlaCis® showed a remarkably prolonged blood circulation. In contrast, free cisplatin was cleared rapidly from circulation.

A selective and high accumulation of LiPlaCis® in the tumor tissue is critical in order to increase the anti- tumor activity of encapsulated cisplatin. In this study, tumors were removed at 1, 4, 24, 48, 72, and 168 hours post-injection. Pt was determined by ICP-MS after tumor samples were dissolved in nitric acid (HNO3). As a consequence of the long circulation time of LiPlaCis in the blood compared to free cisplatin, a preferential accumulation of LiPlaCis in the tumor tissue takes place due to the EPR-effect. This is shown in the following graph:



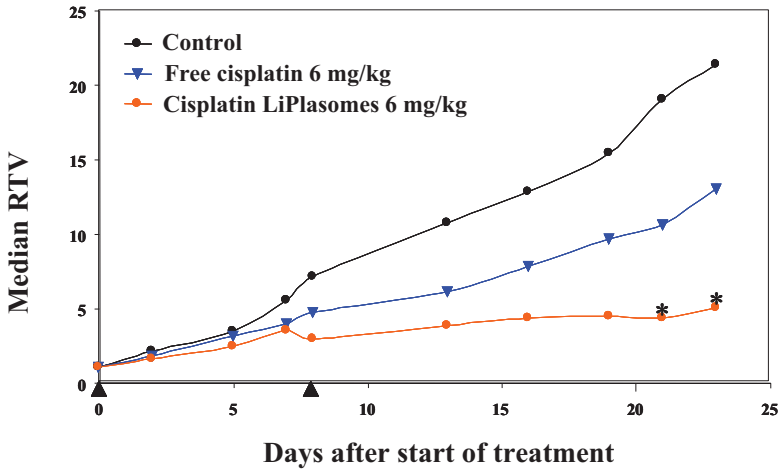
Bio-distribution of LiPlaCis® and cisplatin in liver, kidney and spleen were also investigated in Study No. LPE00141 by measuring the concentration of Pt. The Pt levels in liver in the LiPlaCis® group reach a maximum after 4 hours and decline over the remaining part of the study. In kidney, increased concentrations of Pt were seen in both the cisplatin and LiPlaCis® group already after 1 hour. Where the Pt in the LiPlaCis® group remained high over the study period, the Pt levels decreased over time in the cisplatin group, reflecting the different PK properties, as shown in the following graph:



The highest concentrations of Pt in case of LiPlaCis® was seen in the spleen where the was a continuous increase of platinum until 72 hours post-injection before the levels started to decline. The same distribution in liver, kidney and spleen have been observed for SPI-077.

The in vivo anti-tumor activity of LiPlaCis® and free cisplatin using equivalent doses was tested using the MT-3 breast carcinoma xenograft model in nude mice (Study No. LPE00041). The tumor cells were implanted subcutaneously and allowed to grow to approximately 100 mm3 before the mice were randomized either to a control

group or to treatment with LiPlaCis® or free cisplatin at 6 mg/kg. Each mouse received 2 doses of randomized drug injected into the tail vein at Days 0 and 8. LiPlaCis® showed significantly better anti-tumor activity when compared to free cisplatin ($p<0.05$), as shown in the following chart:



A pronounced, overexpressed sPLA2 in the tumor tissue suggests that sPLA2 degradable LiPlaCis® formulation is superior for targeted and triggered delivery of a high cytotoxic concentration of cisplatin to the target tumor tissue.

As a result of the well characterized toxicity of cisplatin, the active ingredient of LiPlaCis®, the standard battery of safety pharmacology studies was not performed.

Prior Clinical Trials

A Phase I dose-escalating, open label, non-randomized clinical trial to evaluate the safety and tolerability of LiPlaCis® in patients with advanced or refractory tumors was previously conducted. The location of the clinical investigation was Erasmus Medical Center, Rotterdam and Leiden University Medical Center, Leiden, both in the Netherlands under the supervision of Drs. De Jonge and Gelderblom, respectively. First Subject First Visit (FPFV) was May 20, 2008.

Initially, 3 patients were included in a cohort/dose level. Per cohort/dose level the second and third patient could be entered simultaneously after evaluation of the first week of the first cycle of the first patient in that cohort. If a DLT occurred in 1 of the 3 patients within a cohort, 3 additional patients were to be treated at that level. If a DLT occurred in 2/3 or 2/6 patients, the next lower dose level was to be expanded to at least 6 patients. The MTD was defined as the dosing regimen in which ≥ 2 patients experienced a DLT during the first cycle in a cohort of 3 or 6 patients. The RD was defined as the dose at which no more than 1 out of 6 patients experienced a DLT in the first cycle. The RD would normally be the dose level below the MTD (MTD-1).

The starting dose was 10 mg. LiPlaCis® was to be administered to subsequent cohorts with increases of 20 – 100% from the previous dose level. Once the last patient in a specific cohort had completed the first cycle, a clinical (telephone) conference was organized between the investigators and the sponsor to discuss dose-escalation. The same panel was to decide on the MTD and the RD to be used in future phase 2 clinical trials with LiPlaCis®.

18 patients were treated and dose levels 10, 20, 40, 80 and 120 mg without reaching the MTD. All patients received the planned dose at all dosing cycles, except for 1 patient in the 10 mg dose group who received slightly less in the first treatment cycle due to a blocked infusion line. Overall median (range) exposure to LiPlaCis® was 100 (20-400) mg. Overall median (range) treatment duration was 43 (1-295) days.

The LiPlaCis® infusion was interrupted in 5 patients (10, 20 and 80 mg) because of an allergic reaction and in 1 patient because of an acute infusion reaction (120 mg). In 1 patient, infusion was delayed because of hypertension (80 mg) and in 1 patient because of increased creatinine following the previous cycle (120 mg). Only one DLT was reported; this was a Grade 3 infusion-related reaction in the first treatment cycle of a patient in the 10 mg dose group. Therefore, it was concluded that the MTD had not been reached in the study.

All patients experienced one or more treatment emergent adverse event (TEAEs). Most of the LiPlaCis®-related AEs were of mild to moderate severity, i.e. in 72% (13/18) of the patients. The following table summarizes observed TEAEs:

	LiPlaCis Dose Level					
System Organ Class Preferred term	**All levels (n=18)**	**10 mg (n=6)**	**20 mg (n=3)**	**40 mg (n=3)**	**80 mg (n=3)**	**120 mg (n=3)**
Number of patients with any event (%)	17 (94.4)	5 (83.3)	3 (100)	3 (100)	3 (100)	3 (100)
Blood and Lymphatic System Disorders	1 (5.6)	0	0	0	0	1 (33.3)
Anemia	1 (5.6)	0	0	0	0	1 (33.3)
Hemolytic uremic syndrome	1 (5.6)	0	0	0	0	1 (33.3)
Thrombocytopenic purpura	1 (5.6)	0	0	0	0	1 (33.3)
Ear and labyrinth disorders	1 (5.6)	0	0	0	0	1 (33.3)
Deafness	1 (5.6)	0	0	0	0	1 (33.3)
Gastrointestinal disorders	13 (72.2)	3 (50.0)	2 (66.7)	2 (66.7)	3 (100)	3 (100)
Abdominal distension	3 (16.7)	1 (16.7)	0	1 (33.3)	0	1 (33.3)
Diarrhea	1 (5.6)	0	1 (33.3)	0	0	0
Dry mouth	1 (5.6)	1 (16.7)	0	0	0	0
Eructation	1 (5.6)	1 (16.7)	0	0	0	0
Nausea	10 (55.6)	3 (50.0)	1 (33.3)	1 (33.3)	3 (100)	2 (66.7)
Vomiting	5 (27.8)	1 (16.7)	1 (33.3)	0	2 (66.7)	1 (33.3)
General disorders and administration site conditions	8 (44.4)	3 (50.0)	2 (66.7)	1 (33.3)	1 (33.3)	1 (33.3)
Fatigue	7 (38.9)	3 (50.0)	2 (66.7)	0	1 (33.3)	1 (33.3)
Infusion related reaction	3 (16.7)	1 (16.7)	0	0	1 (33.3)	1 (33.3)
Malaise	1 (5.6)	0	0	1 (33.3)	0	0
Immune system disorders	3 (16.7)	2 (33.3)	1 (33.3)	0	0	0
Hypersensitivity	3 (16.7)	2 (33.3)	1 (33.3)	0	0	0
Investigations	3 (16.7)	0	1 (33.3)	0	0	2 (66.7)
Blood creatinine increased	3 (16.7)	0	1 (33.3)	0	0	2 (66.7)
Metabolism and nutrition disorders	5 (27.8)	1 (16.7)	2 (66.7)	1 (33.3)	0	1 (33.3)
Anorexia	5 (27.8)	1 (16.7)	2 (66.7)	1 (33.3)	0	1 (33.3)
Musculoskeletal and connective tissue disorders	2 (11.1)	2 (33.3)	0	0	0	0
Back pain	1 (5.6)	1 (16.7)	0	0	0	0
Muscle spasms	1 (5.6)	1 (16.7)	0	0	0	0
Pain in extremity	1 (5.6)	1 (16.7)	0	0	0	0
Nervous system disorders	5 (27.8)	2 (33.3)	1 (33.3)	1 (33.3)	0	1 (33.3)
Dysgeusia	1 (5.6)	1 (16.7)	0	0	0	0
Headache	2 (11.1)	0	1 (33.3)	0	0	1 (33.3)
Restless legs syndrome	1 (5.6)	0	0	1 (33.3)	0	0
Syncope	1 (5.6)	1 (16.7)	0	0	0	0
Psychiatric disorders	2 (11.1)	0	0	0	1 (33.3)	1 (33.3)
Anxiety	1 (5.6)	0	0	0	1 (33.3)	0
Insomnia	1 (5.6)	0	0	0	0	1 (33.3)
Renal and urinary disorders	1 (5.6)	1 (16.7)	0	0	0	0
Renal impairment	1 (5.6)	1 (16.7)	0	0	0	0
Skin and subcutaneous tissue disorders	2 (11.1)	2 (33.3)	0	0	0	0
Dry skin	1 (5.6)	1 (16.7)	0	0	0	0
Rash	1 (5.6)	1 (16.7)	0	0	0	0
Urticaria	1 (5.6)	1 (16.7)	0	0	0	0
Patients who died	0	0	0	0	0	0

The most frequently reported LiPlaCis®-related AEs were nausea (10/18; 56%) and fatigue (7/18; 39%), followed by vomiting (5/18; 28%), anorexia (5/18; 28%), abdominal distension (3/18; 17%), infusion- related reaction (3/18; 17%), hypersensitivity (3/18; 17%) and increased blood creatinine (3/18; 17%). There was no apparent relationship between dose group and incidence of LiPlaCis®-related AEs. Individual creatinine data showed no particular increase from baseline at doses up to and including 80 mg in any of the patients. At the 120 mg dose level, one 78-year old male had initial rise in serum creatinine on cycles 1 and 2 Day 8, after which the levels decreased again towards baseline. This was the patient who also developed hemolytic uremic syndrome. Another patient at the 120 mg dose level had pre-existing chronic renal insufficiency and had fluctuating serum creatinine during the trial. In both patients the toxicity was at most of grade 2. In general, no trends could be detected at any dose level with respect to cumulative changes over time for the laboratory parameters, vital signs and other physical examination parameters evaluated.

Severe TEAEs were reported for 5 patients (28%), which were considered LiPlaCis® related in 3 patients (17%): 1 patient in the 10 mg dose group with Grade 3 fatigue and infusion-related reaction, 1 patient in the 80 mg group with Grade 3 infusion-related reaction and 1 patient in the 120 mg dose group with Grade 3 hemolytic uremic syndrome and Grade 4 thrombocytopenia as part of this syndrome. The following table summarizes the observed severe TEAEs:

	LiPlaCis Dose Level											
System Organ Class **Prefrred term**	**All levels (n=18)**		**10 mg (n=6)**		**20 mg (n=3)**		**40 mg (n=3)**		**80 mg (n=3)**		**120 mg (n=3)**	
	All	Rel*	All	Rel*	All	Rel*	All	Rel*	All	Rel*	All	Rel*
Number of patients with any event	5	3	2	1	0	0	0	0	2	1	1	1
Blood and Lymphatic System Disorders	1	1	0	0	0	0	0	0	0	0	1	1
Hemolytic uremic syndrome	1	1	0	0	0	0	0	0	0	0	1	1
Thrombocytopenic purpura	1	1	0	0	0	0	0	0	0	0	1	1
General disorders and administration site conditions	2	2	1	1	0	0	0	0	1	1	0	0
Fatigue	2	1	1	1	0	0	0	0	1	0	0	0
Infusion related reaction	2	2	1	1	0	0	0	0	1	1	0	0
Metabolism and nutrition disorders	1	0	0	0	0	0	0	0	1	0	0	0
Hyperkaliemia	1	0	0	0	0	0	0	0	1	0	0	0
Hyponatremia	1	0	0	0	0	0	0	0	1	0	0	0
Musculoskeletal and connective tissue disorders	1	0	1	0	0	0	0	0	0	0	0	0
Flank pain	1	0	1	0	0	0	0	0	0	0	0	0
Pain in extremity	1	0	1	0	0	0	0	0	0	0	0	0
Vascular disorders	3	0	1	0	0	0	0	0	1	0	1	0
Hypertension	1	0	0	0	0	0	0	0	1	0	0	0
Jugular vein thrombosis	1	0	1	0	0	0	0	0	0	0	0	0
Superior vena caval occlusion	1	0	0	0	0	0	0	0	0	0	1	0

In total 9 patients (50%) experienced one or more SAEs and in 4 patients (22%) one or more of these SAEs were considered LiPlaCis®-related. Increased blood creatinine (Grade 1-2) was the most frequently reported SAE, namely for 4/18 (22%) patients. This SAE was considered LiPlaCis®-related in 3/18 (17%) patients (n=1 at 20 mg and n=2 at 120 mg) and led to early study discontinuation in 1 patient (120 mg dose group). The other LiPlaCis®-related SAEs were Grade 3 infusion-related reaction (n=1 at 10 mg) and Grade 3 hemolytic uremic syndrome with Grade 4 thrombocytopenia (n=1 at 120 mg); both led to early study discontinuation. One other Grade 3 infusion-related reaction experienced by 1 patient in the 80 mg dose group, which was not an SAE, led to early study discontinuation. So, in total, the study was discontinued early in 4 patients because of LiPlaCis®-related AEs, 2 patients with infusion-related reaction (n=1 at 10 mg and n=1 at 80 mg), 1 patient with hemolytic uremic syndrome and thrombocytopenia (n=1 at 120 mg) and 1 patient with increased blood creatinine (120 mg dose group). There were no deaths in the study.

Clinical Study Report conclusions from the 18 patients in this Phase 1 clinical trial were:

- The MTD was not reached in the study with only one DLT reported at the lowest dose level.
- LiPlaCis®, administered IV, every 3 weeks in an infusion volume of 500 ml, is tolerated up to the studied dose of 120 mg with mild to moderate toxicities.
- Infusion related grade 2-3 symptoms (flushing, febrile reaction, palpitations, feeling unwell, hypotension) was seen in two patients (one patient at 10 mg and one patient at 80 mg).
- The recommended infusion duration is ≥ 120 minutes.
- The most frequently observed LiPlaCis®-related AEs were mild to moderate nausea, vomiting, fatigue and anorexia.
- There was no apparent relationship between dose group and incidence of LiPlaCis®-related AEs.
- There were no deaths on the study and there were no LiPlaCis®-related Grade 4 AEs, except for thrombocytopenia Grade 4, which was considered part of a hemolytic uremic syndrome Grade 3 in 1 patient.
- Renal toxicity was only seen in patients with pre-existing renal insufficiency or as part of hemolytic-uremic syndrome. However, renal function should be monitored closely in future studies with LiPlaCis® at higher dose levels especially in patients with pre-existing renal insufficiency.
- In general, no trends could be detected at any dose level with respect to cumulative changes over time for the laboratory parameters, vital signs and other physical examination parameters evaluated.

DRP®-Guided Phase 2 Clinical Trial

We have conducted a DRP®-guided Phase 2, open label, non-randomized dose escalation clinical trial (LiPlaCis/P1/002; NCT01861496), with a non-randomized extension part, in late-stage metastatic breast cancer patients (with several lines of prior therapy). There were three trial sites all in Denmark. A total of 53 patients were enrolled and treated in this study, all of whom were selected as likely responder patients using the LiPlaCis®-DRP® at a cutoff score of thirty-three percent (33%). The patients were selected from a screening study of 1,200 patients screened for their eligibility to participate in future trial upon reoccurrence of their breast cancer.

LiPlaCis® was initially administered at a fixed dose independent of body surface area and given day 1 and day 8 every 3 weeks. Drug was administered as a 2 hour infusion day 1 and day 8 every 3 weeks for up to 3 cycles or more if the patient benefited from the treatment upon the investigator's judgement and if there was no evidence of progressive disease or unacceptable toxicity. The treatment included hydration program, prophylaxis against infusion reaction and anti-emetic regimen. The treatment doses were assigned by the trial sponsor according to a detailed dose escalation plan with 3-6 patients per dose level. The first patient was treated with LiPlaCis® 60 mg on day 1 and on day 8.

The dose steps were:

Step 1: 60 mg on day 1 and on day 8. Total dose of 120 mg per cycle.

Step 2: 90 mg on day 1 and on day 8. Total dose of 180 mg per cycle.

Step 3: 120 mg on day 1 and on day 8. Total dose of 240 mg per cycle.

Step 4: 90 mg on day 1, 90 mg on day 8 and 45 mg on day 15 was given as discussed and agreed by the Safety Data Committee. Total dose of 225 mg per cycle.

Following decision between PI and sponsor, two dose steps were conducted between dose step 4 and dose step 5 for the Proof of Concept phase with pharmacodynamics (PD):

Step A- completed: 60 mg on day 1 and on day 8. Total dose of 120 mg per cycle.

Step B- completed: 90 mg on day 1 and on day 8. Total dose of 180 mg per cycle.

Step 5: 75 mg on day 1 and 75 mg on day 8. Total dose of 150 mg per cycle.

Step 5 continued: 40 mg/m^2 body surface area (BSA) on day 1 and on day 8 of each 21 days cycle with a maximum dose of 80 mg.

A total of 53 patients with mBC were enrolled based on general inclusion criteria and due to their DRP score, 2 of the mBC patients in the dose escalation phase and the remaining in the dose expansion phase, where the last patient was enrolled on October 25, 2019. Most patients (94.3%) experienced one or more treatment emergent adverse events (TEAEs), that are considered LiPlaCis® related. Most of the LiPlaCis®-related AEs were of mild to moderate severity. The most frequently reported LiPlaCis®-related AEs were fatigue (29/53; 54.7%), followed by nausea (25/53; 47.2%), hypomagnesemia (19/53; 35.8%), increased blood cholesterol (17/53; 32.1%), and followed by vomiting (16/53; 30.2%, decreased appetite (14/53; 26.4%), and any renal disorder (9/53 17.0%). Infusion-related reaction rate was high in the first dose levels (9/20; 45.0%) but decreased to 9/53; 17.0%), since no infusion-related reactions were registered in the 2 last dose levels assumable due to a common premedication scheme which was introduced to prevent infusion-related reactions.

A total of 29 patients (54.7%) experienced one or more AEs of grade 3 or more and in 13 patients (24.5%) one or more of these were considered LiPlaCis®-related. Seven AEs of grade 3 or more were observed in more than one patient (anemia, increased blood cholesterol, hyperglycemia, hypokalemia, hyponatremia, thromboembolism, and hypertension), and 4 of these were considered LiPlaCis®-related (anemia, increased blood cholesterol, hypokalemia, and thromboembolism).

In total 21 patients (39.6%) experienced one or more SAEs and in 11 patients (20.1%) one or more of these SAEs were considered LiPlaCis®-related. Four SAEs were reported for renal failure, while each of hypomagnesemia, and infusion related fever were reported with 2 SAEs. Other LiPlaCis®-related SAEs were: one incident of nausea, one of anorexia, one pyelonephritis, and one thromboembolic event. In one patient, a fatal SAE of thrombotic thrombytopenic purpura/hemolytic uremic syndrome was considered LiPlaCis®-related. Further, 2 patients died during treatment, one due to disease progression, and one due to renal failure secondary to undetected hydronephrosis.

Interim anti-cancer activity results were presented at ASCO 2018. All patients had received at least 2 prior chemotherapies. All patients had received 75 mg LiPlaCis® on days 1 and 8 every 3 weeks with anti-cancer activity evaluation every 6 wks. Anti-cancer activity was measured as progression-free survival (PFS) and objective response rate (ORR) against outcome of latest prior treatment. Patients with a Cisplatin-DRP® Score >67% were compared to patients with a DRP® score of >33% and <=67%. Twelve patients had been included with a planned enrollment of 20 evaluable patients. Two patients did not receive a full cycle due to early death, deemed unrelated to LiPlaCis by the safety committee. ORR in the intention to treat group (n = 12) was 17%. Ten patients are evaluable for response 6 had a DRP score >67% and 4 had a score of >33% and <=67%. LiPlaCis® was the 8th line of treatment for advanced disease (median). Two patients had partial remissions (PR), 5 had stable disease (SD) and three had progressive disease (PD). Five of the 6 patients with a Cisplatin-DRP® score >67% were platinum-naïve and all 5 had clinical benefit with a median PFS of 25 weeks vs 17 weeks in latest prior treatment (hazard ratio (HR) 0.19, p = 0.04). Three out of the 5 had better anti-cancer activity or longer response than with any previous medical treatment for advanced disease and ORR was 40% (both patients with PR had a DRP score >67%). Two patients with a Cisplatin-DRP® score of >33% and <=67% were platinum naïve. They had a significant shorter PFS compared to the 5 platinum-naïve with a DRP® score >67% (25 weeks vs. 8 weeks; HR of 4e-10, p = 0.008). LiPlaCis®, therefore, shows promising anti-cancer activity in mBC patients with a Cisplatin-DRP® score >67%.

The Clinical Study Report (CSR) from this trial is not yet complete, but we anticipate it will be completed by mid-year 2021. A randomized, pivotal Phase 3 clinical trial was discussed with the FDA at a Pre-IND meeting in 2019.

Rationale for Liposomal Cisplatin in mBC

According to the National Comprehensive Cancer Network (NCCN) guidelines for treatment of metastatic breast cancer, in the second line setting, for mBC patients who are HER2 negative, cisplatin and carboplatin are among preferred therapy options for tumors that have a BRCA 1 or 2 mutation. Other preferred therapy options include anthracyclines (doxorubicin or liposomal doxorubicin), taxanes (e.g. paclitaxel), anti-metabolites (capecitabine or gemcitabine) and/or microtubule inhibitors (e.g. vinorelbine or eribulin). The choice of a particular therapeutic is made by the treating oncologist, and the current lack of suitable companion diagnostics to guide therapy selection has hampered the introduction of personalized medicine to this patient group.

Despite the success of cisplatin in the mBC setting, the drug has substantial toxicity that is disfavored by both oncologists and patients. The side effects associated with cisplatin treatment can be severe and may include toxicity to the kidney and nervous system, hearing difficulties, nausea, vomiting, and several others. Additionally, cisplatin resistance may be attributed to heterogeneity of tumors, as well as changes to tumor biology resulting from prior lines of therapy. Each patient has his/her own tumor with different characteristics and therefore different therapy outcomes. The variabilities include but are not limited to different genetic, epigenetic, transcriptomic and proteomic properties. The genotypic changes include mutations, gene amplifications, deletions, chromosomal rearrangements, transpositions of the genetic elements, translocations and microRNA alterations. Genomic instability generates a great level of intercellular genetic heterogeneity in cancer.

We believe that our targeted, liposomal formulation of cisplatin, LiPlaCis®, together with its DRP® companion diagnostic, can overcome many of the limitations of naked cisplatin and has the potential to be an important drug in its class that can succeed and compete in the marketplace for the treatment of mBC, and potentially other indications. The use of the LiPlaCis®-DRP® companion diagnostic to select and treat only those mBC patients most likely to respond to the drug (while excluding treatment of likely non-responders) can mitigate toxicity events in non-responder patients, while increasing therapeutic benefit in the identified responder patient population. Additionally, the tumor-targeted, liposomal delivery of cisplatin that is accomplished with LiPlaCis® can reduce off-target, systemic toxicity that is frequent with this chemotherapeutic.

Future Opportunities & Development Plans for LiPlaCis®

In June of 2020, we out-licensed our LiPlaCis® program to Smerud Medical Research International, our long-time CRO partner in Europe, which will further advance LiPlaCis®, together with its DRP® companion diagnostic, in late stage mBC or a pediatric cancer indication, building on prior clinical trial results. The initiation, by Smerud, of the next Phase 2 clinical trial for this program is anticipated by early 2022, however the license agreement with SMERUD may be termininated if SMERUD does not obtain outside financing for the program by December 31, 2021.

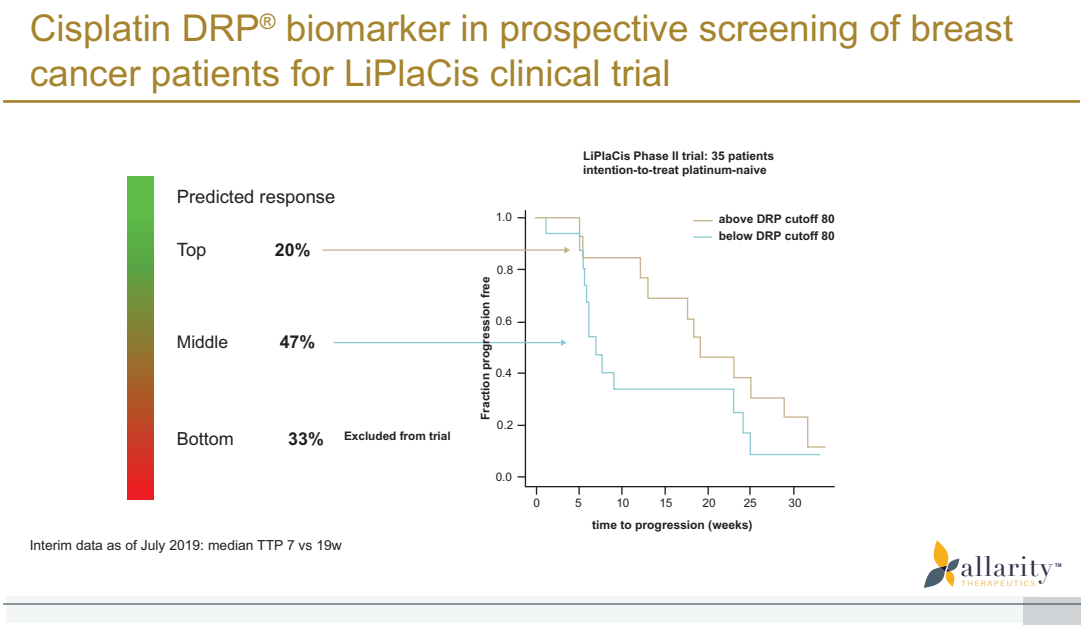
The expanded Phase 2 clinical trial to be conducted by Smerud will screen up to 225 metastatic breast cancer (mBC) patients — if mBC is decided upon as a priority indication — using the DRP® companion diagnostic for the drug, to select and enroll, (on a rolling basis) approximately 45 mBC patients identified as high likely responders to LiPlaCis® in order to have at least 50 patients (inclusive of the 17 patients with a LiPlaCis®-DRP® companion diagnostic score of >80% already treated and evaluated by Allarity in its prior Phase 2 clinical trial) evaluable for anti-cancer activity (Objective Response Rate (ORR) per RECIST). Smerud's clinical development plan may further include additional, optional, clinical trials to assess, for example, the potential utility of LiPlaCis® for treatment of pediatric cancers. Cisplatin is currently used for the treatment of certain pediatric cancers, but results in well documented ototoxicity (ear/hearing damage) that is highly undesirable in these young patients. LiPlaCis®, by virtue of its tumor-targeted delivery of cisplatin, may reduce ototoxicity in this patient group. We will support Smerud in these studies by providing LiPlaCis®-DRP® companion diagnostic analysis for screened patients.

In addition to mBC, cisplatin is also approved for and used as a chemotherapy in a number of other cancers, including testicular cancer, ovarian cancer, cervical cancer, bladder cancer, head and neck cancer, esophageal cancer, lung cancer, mesothelioma, brain tumors and neuroblastoma. In pediatric cancers, cisplatin is well known to cause ototoxicity (hearing damage), and liposomal formulations of cisplatin have potential to ameliorate such ototoxicity. Accordingly, there are many future market opportunities for LiPlaCis® following initial approval for mBC or other priority indication.

DRP® Companion Diagnostic for LiPlaCis®

We are developing LiPlaCis® together with our prospectively validated DRP® companion diagnostic for cisplatin, which enables us to select the patients most likely to respond to the drug in our clinical trials. In August 2019, the FDA approved our Investigational Device Exemption (IDE) application for use of our Cisplatin-DRP® companion diagnostic in a planned pivotal Phase 3 clinical trial of LiPlaCis® in mBC. In June 2019, we announced that the FDA had provided feedback on our pending Investigational New Drug (IND) application and proposed pivotal Phase 3 clinical trial in mBC using the Cisplatin-DRP®. The Cisplatin-DRP®, which comprises 205 expressed genes, was initially developed using gene expression data from the National Cancer Institute NCI60 panel of cancer cell lines.

The Cisplatin-DRP® was retrospectively validated in two Non-small cell lung cancer (NSCLC) cohorts. Molecular prediction of adjuvant cisplatin anti-cancer activity in NSCLC showed a significant prediction at 3 year survival from surgery in univariate (HR = 0.138 (95% CI:0.035–0.537), p = 0.004) and multivariate analysis (HR = 0.14 (95% CI:0.030–0.6), p = 0.0081).



The Clinical Study Report (CSR) from this trial is not yet complete, but we anticipate it will be completed by mid-year 2021.

In sum, we believe our retrospectively and prospectively validated putative LiPlaCis®-DRP® companion diagnostic accurately and reliably identifies responder patients to LiPlaCis®, and we plan to use this DRP® companion diagnostic for all of our clinical programs to advance LiPlaCis®, including the planned, expanded Phase 2 clinical trial for mBC being advanced by our licensee, Smerud Medical Research International.

Existing Liposomal Formulations of Cisplatin & Our Opportunity

Worldwide annual sales of platinum-based anticancer drugs are of the order of $2 billion (2006). There are currently six platinum drugs with marketing approval in various regions throughout the world: cisplatin, carboplatin, oxaliplatin, nedaplatin, lobaplatin, and heptaplatin. Among these six drugs, cisplatin remains one of the most widely used.

There are currently no approved, targeted liposomal formulations of cisplatin on the market. Several companies have previously advanced development of liposomal cisplatin, but failed to secure regulatory approval to bring such drugs to market. Examples include Lipoplatin® (Regulon, Inc.), which has been previously granted an Orphan Drug designation by EMA for pancreatic cancer, but which has not achieved approval or advanced to market in the EU, U.S, or other major oncology market.

Accordingly, LiPlaCis® has the potential to be a novel product with the potential, together with its DRP® companion diagnostic, to gain substantial market share not only in mBC but in the numerous other indications where cisplatin is currently used, including testicular cancer, ovarian cancer, cervical cancer, bladder cancer, head and neck cancer, esophageal cancer, lung cancer, mesothelioma, brain tumors and neuroblastoma.

Overview of 2X-111 (targeted, liposomal doxorubicin)

Mechanisms of Action

2X-111 is an advanced, targeted liposomal formulation of doxorubicin, one of the world's most widely used chemotherapies. The specific 2X-111 formulation, which exploits a unique, glutathione enhanced PEG-liposomal delivery system, allows the drug to cross the blood-brain barrier (BBB), thereby enabling the treatment of primary brain tumors, such as glioblastoma multiforme (GBM), and secondary brain tumors that originated from cancers outside the brain, such as metastatic breast cancer.

Doxorubicin is a type of chemotherapy drug called an anthracycline. It slows or stops the growth of cancer cells by blocking an enzyme called topo isomerase 2, which is necessary for DNA replication. Topo isomerase 2 is an enzyme that cuts both strands of the DNA helix simultaneously in order to manage DNA tangles and supercoils. Cancer cells need this enzyme to divide and grow. Doxorubicin is approved and in use for a number of cancer types, including breast cancer, bladder cancer, Kaposi's sarcoma, lymphoma, and acute lymphocytic leukemia. It is often used together with other chemotherapy agents.

Liposomes are closed spherical vesicles, having an interior aqueous space entrapped by a bilayer lipid membrane. 2X-111 liposomes have doxorubicin encapsulated in the interior aqueous space of the liposomes and the bilayer membrane is constituted by 3 phospholipids. The use of liposomes as drug carriers has been limited due to the rapid clearance of these carriers from the blood stream by the reticuloendothelial system. The addition of polyethylenglycol (PEG) polymers to the surface of the liposomes leads to reduced clearance rates. As a result, the use of liposomes is now recognized as a promising strategy for tumor-targeted drug delivery. Due to the leaky tumor vasculature and the incomplete lymphatic drainage system of tumors, long circulatory liposomes may be preferentially trapped and therefore accumulate in cancer tissues. The preferential entrapment and accumulation of the liposomes in the cancer tissue is also known as the enhanced permeability and retention effect (EPR-effect). As a consequence of the trapping of liposomes, significantly more drug substance is present at the site of the tumor compared to administration of plain drug products.

Most PEG-liposomal cancer drugs cannot pass the BBB and therefore cannot be used for treatment of primary or secondary brain tumors. The delicate metabolic homeostasis of the central nervous system is largely maintained by the BBB, which plays a key role in excluding potentially neurotoxic and exogenous compounds from the brain, while still allowing the penetration and uptake of essential nutrients. Many potentially highly efficacious anticancer drugs are currently not available to treat brain tumors because they do not adequately cross the BBB, and therefore do not reach the brain.

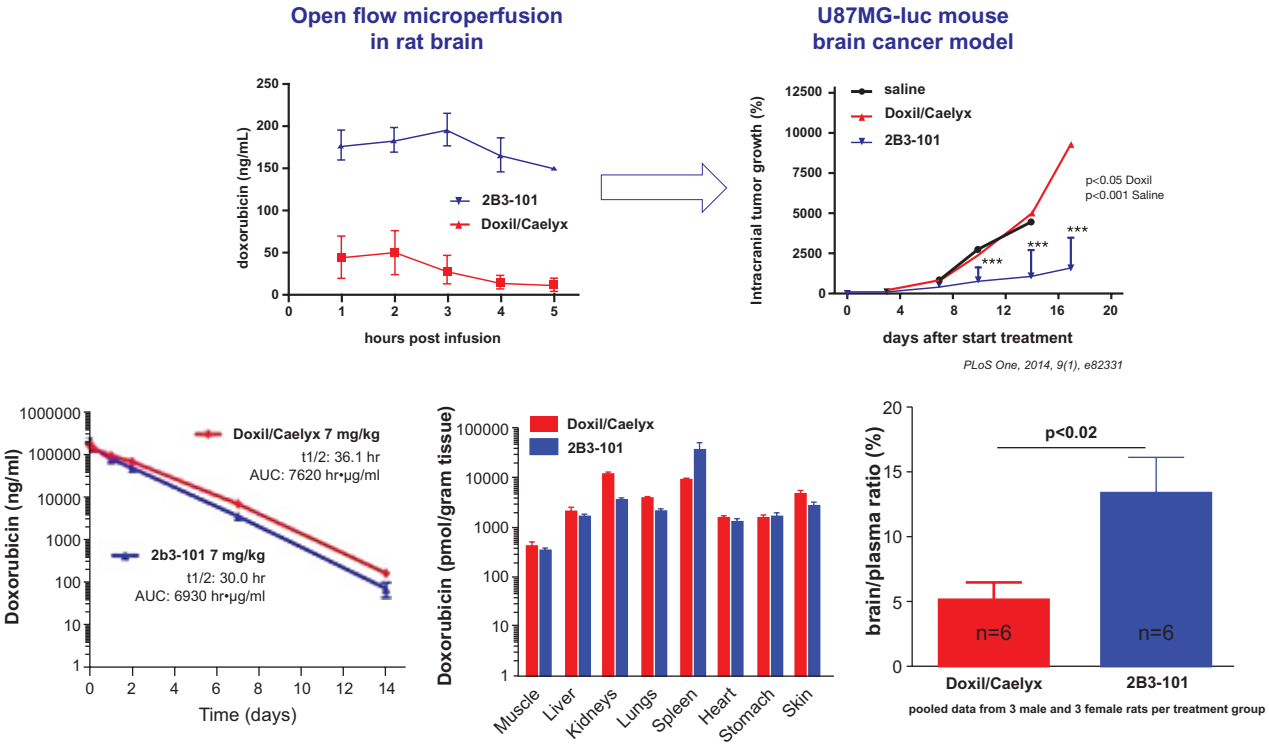
Glutathione is an endogenous tri-peptide with antioxidant-like properties in the brain and its active (sodium-dependent) transport receptor is highly expressed on the BBB. The unique 2X-111 glutathione-modified PEG-liposome enables transport of encapsulated drugs, such as doxorubicin past the BBB, enhancing the delivery of such drugs to the brain. As used in this section of this information statement/prospectus describing our therapeutic candidate 2X-111, statements regarding the use of our proprietary DRP® companion diagnostics or our proprietary DRP® platform or our observations that our therapeutic candidate 2X-111 may have anti-cancer or anti-tumor activity or is observed to be well tolerated in a patient population should not be construed to mean that we have resolved all issues of safety and/or efficacy for our therapeutic candidate 2X-111® or our putative Doxorubicin-DRP® companion diagnostic. Issues of safety and efficacy for any therapeutic candidate companion diagnostic may only be determined by the U.S. FDA or other applicable regulatory authorities in jurisdictions outside the United States.

Pre-Clinical Studies

Preclinical studies have been performed in order to determine the anti-cancer activity and toleration of 2X-111 both systemically and in the CNS prior to the start of the human clinical trials. 2X-111 showed significantly better tumor growth inhibition and survival benefit in rodents with brain tumors as compared to normal PEGylated liposomal doxorubicin (Caelyx®/Doxil®). In a systemic breast cancer animal model, the tumor suppression was equal between

2X-111 and Caelyx®/Doxil®. Moreover, compared to Caelyx®/Doxil®, enhanced doxorubicin delivery by 2X-111 across the BBB was observed, with a favorable pharmacokinetic and safety profile in animal models. The following graphs represent some of the preclinical observations:

Non-clinical: improved brain uptake of doxorubicin in brain cancer model



Prior Clinical Trials

2X-111 (formerly 2B3-101) was previously evaluated in Phase I/IIa, multi-center, open-label, dose-escalation clinical trial sponsored by 2-BBB Medicines, B.V. (NCT01818713; NCT01386580). Dieta Brandsma, MD, PhD, Division of Neuro-Oncology, Netherlands Cancer Institute in Amsterdam was the Coordinating Investigator. There were numerous trial sites in the Netherlands, Belgium, and France.

The purpose of this study was the determination of safety, tolerability, and PK of 2X-111 both as single agent and in combination with trastuzumab. Furthermore, the study aimed to explore the preliminary anti-tumor activity of 2X-111 as single agent in patients with solid tumors and brain metastases or recurrent malignant glioma, as well as in patients with various forms of breast cancer in combination with trastuzumab in Her2+ breast cancer patients with brain metastases. The study was performed in two phases: a dose escalation phase following a standard "3+3" design to determine dose-limiting toxicities (DLT) and a safe dose (MTD) of 2X-111, followed by four expanded study arms where patients were treated at the MTD in order to confirm the Recommended Phase II Dose (RP2D).

Eighty-four (84) patients were enrolled in this study, including 37 in the dose escalation phase and an additional 47 patients in the expansion safety cohorts. Only patients who meet all of the inclusion and exclusion criteria were enrolled. Two populations were used to analyze the study data including:

- Safety (SAF): Patients who received at least one dose of 2X-111 were evaluable for safety analysis.
- Intention to Treat (ITT): All patients in the SAF who have received at least one dose of trial medication were evaluable for ITT analysis.

To be eligible to participate in this study, candidates must have met the following eligibility criteria:

1. Patients with pathologically confirmed diagnosis of advanced, recurrent solid tumors and unequivocal evidence of brain metastases that were refractory to standard therapy or for whom no standard therapy existed or with unequivocal evidence of newly diagnosed un- treated brain metastases and controlled extra cranial disease, which per the multi-disciplinary team decision did not require immediate radiotherapy, surgery, or standard systemic chemotherapy. Brain metastases may have been stable, progressive, symptomatic or asymptomatic brain metastasis/es. Stable or decreasing doses of steroids (e.g. dexamethasone) for a minimum of 7 days prior to baseline MRI or non-enzyme inducing antiepileptic drugs were allowed.

2. Patients with pathology confirmed diagnosis of advanced, recurrent primary malignant (grade III and IV) glioma that were refractory to standard therapy or for whom no standard therapy existed. Stable or decreasing doses of steroids (e.g. dexamethasone) for a minimum of 7 days prior to baseline MRI or non-enzyme inducing antiepileptic drugs were allowed.

2X-111 in combination with trastuzumab dose-escalation phase:

3. Patients with histologically-confirmed Her2+ (IHC 3+ or fluorescence in situ hybridization [FISH] amplified; by clinical assay on either primary or metastatic tumor) adenocarcinoma of the breast with unequivocal evidence of brain metastases that were refractory to standard therapy or for whom no standard therapy exist or with unequivocal evidence of newly diagnosed untreated brain metastases and controlled extra cranial disease, which per the multi-disciplinary team decision did not require immediate radiotherapy, surgery, or standard systemic chemotherapy could be included to this escalation phase as well.

Breast cancer brain metastases study arm of the expansion phase:

4. Patients with pathologically confirmed diagnosis of advanced, recurrent breast cancer with at least one progressive and/or new metastatic brain lesion, that were refractory to standard therapy or for whom no standard therapy exists. Stable or decreasing dosages of steroids (e.g. dexamethasone) for 7 days prior to baseline MRI and/or non-enzyme inducing antiepileptic drugs were allowed.

5. Patients with pathologically confirmed diagnosis of advanced breast cancer with newly diagnosed, untreated, brain metastases and controlled extracranial disease, which per the multi-disciplinary team decision do not require immediate radiotherapy, surgery, or standard systemic chemotherapy.

6. Once the MTD of 2B3-101 with trastuzumab has been determined, patients with histologically-confirmed Her2+ (IHC 3+ or fluorescence in situ hybridization [FISH] amplified; by clinical assay on either primary or metastatic tumor) adenocarcinoma of the breast with at least one progressive and/or new metastatic brain lesion, that were refractory to standard therapy or for which no standard therapy exist or with unequivocal evidence of newly diagnosed untreated brain metastases and controlled extra cranial disease, which per the multi-disciplinary team decision do not require immediate radiotherapy, surgery, or standard systemic chemotherapy, could be included to this expansion phase as well.

SCLC brain metastases study arm of the expansion phase:

7. Patients with pathologically confirmed diagnosis of advanced, recurrent SCLC with at least one progressive and/or new metastatic brain lesion, that were refractory to standard therapy or for whom no standard therapy exists. Stable or decreasing dosages of steroids (e.g. dexmethasone) for 7 days prior to baseline MRI and/or use of non-enzyme inducing antiepileptic drugs were allowed.

8. Patients with pathologically confirmed diagnosis of advanced SCLC with newly diagnosed, untreated, brain metastases and controlled extra cranial disease, which per the multi-disciplinary team decision do not require immediate radiotherapy, surgery, or standard systemic chemotherapy.

Melanoma brain metastases study arm of the expansion phase:

9. Patients with pathologically confirmed diagnosis of advanced, recurrent melanoma with at least one progressive and/or new metastatic brain lesion, that were refractory to standard therapy or for whom no standard therapy exists. Stable or decreasing dosages of steroids (e.g. dexamethasone) for 7 days prior to baseline MRI and/or use of non-enzyme inducing antiepileptic drugs were allowed.

10. Patients with pathologically confirmed diagnosis of advanced melanoma with newly diagnosed, untreated, brain metastases and controlled extra cranial disease, which per the multi-disciplinary team decision do not require immediate radiotherapy, surgery, or standard systemic chemotherapy.

Recurrent malignant glioma study arm of the expansion phase:

11. Patients with histologically proven glioma grade IV, which were progressive following first line treatment with surgery or biopsy followed by fractionated radiotherapy with concurrent temozolomide as chemotherapy.

12. Patients with recurrent histologically confirmed malignant (WHO grade III and IV) glioma or histologically confirmed low-grade (WHO grade II) glioma with radiographic evidence of malignant transformation by MRI, that were refractory to standard therapy, or for whom no standard therapy exists or did not require immediate standard therapy per the multi- disciplinary team decision.

13. Patients in both groups should have stable or decreasing dosage of steroids (e.g. dexamethasone) for a minimum of 7 days prior to baseline MRI. Non-enzyme inducing antiepileptic drugs are allowed.

In the single agent dose-escalation phase, patients eligible for the study were assigned to a dose level cohort. The starting dose was 5 mg/m^2, which was equal to 1/10 of the human equivalent dose of the LD10 of 2X-111 in rats. Dose levels for subsequent cohorts were 10, 20, 30 mg/m^2 and steps of 10 mg/m^2 thereafter. Patients received a single IV dose of 2X-111 on day 1 of each cycle. In order to minimize the risk of infusion reactions 5% of the total dose of 2B3-101 (in mg) was infused slowly over the first 30 minutes. If tolerated, the infusion was completed over the next hour for a total infusion time of 90 minutes. Each treatment cycle consisted of 21 days.

In the combination with trastuzumab dose-escalation phase, patients were assigned to a 2X-111 dose level cohort. The starting dose of 2X-111 was 40 mg/m^2 every 3 weeks. This dose has been selected based upon safety information from patients treated with 2X-111 at this dose level, as well as upon previous treatment with PEGylated liposomal doxorubicin in combinations trastuzumab.

In both cases, dose-escalation was conducted in steps of 10 mg/m^2 up to the MTD level determined for 2X-111 as single agent. The trastuzumab dose remained fixed to a loading dose of 8 mg/kg at day 1 and 6 mg/kg every 3 weeks at the subsequent cycles throughout the determination of the MTD. All patients received a single IV dose of 2X-111 on day 1 of each cycle. In order to minimize the risk of infusion reactions 5% of the total dose of 2X-111 (in mg) was infused slowly over the first 30 minutes. As long as 2X-111 was well tolerated, the remaining 95% of the infusion thereafter were administered over the next 60 min, resulting in a total infusion time of 90 minutes. The infusion of trastuzumab followed 30 minutes after the completion of the 2B3-101 infusion.

In the breast cancer brain metastases study arm of the expansion phase, each treatment cycle equally also consisted of 21 days. On day 1 of each cycle patients received a single IV 50 mg/m^2 dose of 2X-111 as single agent, or a dose of 2X-111 at the MTD of 2B3-101 in combination with trastuzumab (if different). In order to minimize the risk of infusion reactions 5% of the total dose (in mg) was infused slowly over the first 30 minutes. As long as 2X-111 was well tolerated, the remaining 95% of the infusion was thereafter administered over the next 60 minutes, resulting in a total infusion time of 90 minutes. A trastuzumab infusion followed 30 minutes after the completion of the 2X-111 infusion, if applicable. Each treatment cycle consisted of 21 days.

In the SCLC brain metastases study arm of the expansion phase, each treatment cycle also consisted of 21 days. Patients received a single IV 50 mg/m^2 dose of 2X-111 on day 1 of each cycle. In order to minimize the risk of infusion reactions 5% of the total dose of 2X-111 (in mg) was infused slowly over the first 30 minutes. If tolerated, the infusion was then completed over the next hour for a total infusion time of 90 minutes. Each treatment cycle consisted of 21 days.

In the melanoma brain metastases study arm of the expansion phase, each treatment cycle also consisted of 21 days. Patients received a single IV 50 mg/m^2 dose of 2X-111 on day 1 of each cycle. In order to minimize the risk of infusion reactions 5% of the total dose of 2X-111 (in mg) was infused slowly over the first 30 minutes. If tolerated, the infusion was completed over the next hour for a total infusion time of 90 minutes. Each treatment cycle consisted of 21 days.

In the recurrent malignant glioma study arm of the expansion phase, each treatment cycle consists of 28 days. Patients received a single IV 60 mg/m^2 dose of 2X-111 on day 1 of each cycle. In order to minimize the risk of infusion reactions 5% of the total dose of 2X-111 (in mg) was infused slowly over the first 30 minutes. If tolerated, the infusion was completed over the next hour for a total infusion time of 90 minutes. Each treatment cycle consisted of 28 days.

Infusion or hypersensitivity reactions were expected with the first or subsequent dose of 2X-111 and/or trastuzumab. In case of an infusion reaction it was recommended to follow the below infusion scheme not only for the continued infusion but also for all future infusions with 2X-111 in the patients that experience such a reaction:

- (Re)-start the 2X-111 infusion with 10 mL/hour for the first 15 minutes and increase the infusion rate every 15 to 30 minutes as follows: 20 mL/hour, 50 mL/hour, 100 mL/hour and finally 200 mL/hour.
- In addition, (pre) medication such as hydrocortisone, ranitidine, cimetidine, antiemetics, and diphenhydramine in line with existing local institutional guidelines all were allowed.

Patients who received 2X-111 in combination with trastuzumab participated in an intensified cardiac program including ECG, LVEF, cTnT and NT-proBNP measurements before start of every treatment cycle.

The following table summarizes the demographic characteristics of patients enrolled in each of the DEP and EPP stages:

Characteristic	Statistic	DEP	EPP
Age (years)	Mean (s.d.)	52.2 (10.6)	51.6 (11.5)
	Median (min, max)	52 (31, 73)	53 (25, 81)
Weight (kg)	Mean (s.d.)	75.1 (13.6)	81.7 (18.2)
	Median (min, max)	71 (41, 103)	82.0 (51, 126)
Height (cm)	Mean (s.d.)	172.1 (11.1)	172.4 (9.4)
	Median (min, max)	172 (153, 197)	170 (147, 191)
Body Surface Area (kg/m^2)	Mean (s.d.)	1.889 (0.211)	2.001 (0.242)
	Median (min, max)	1.873 (1.34, 2.29)	2.038 (1.60, 2.59)
Gender (N)	Female (%)	25 (67.6)	31 (66)
	Male (%)	12 (32.4)	16 (34)
Ethnicity (N)	Black (%)	1 (2.7)	1 (2.1)
	Caucasian/white (%)	34 (91.9)	44 (93.6)
	Oriental (%)	0 (0.0)	2 (4.3)
	Other (%)	2 (5.4)	0 (0)
Tumour Type (N)	BC (%)	13 (35.1)	15 (31.9)
	Mal. Glioma (%)	13 (35.1)	20 (42.6)
	Melanoma (%)	1 (2.7)	5 (10.6)
	Other (%)	7 (18.9)	0 (0)
	SCLC (%)	3 (8.1)	7 (14.9)
Her2/Neu on BC (N)	Negative (%)	1 (2.7)	7 (14.9)
	Positive (%)	12 (32.4)	8 (17.0)
Progesterone receptor on BC (N)	Negative (%)	9 (24.3)	11 (23.4)
	Positive (%)	4 (10.8)	4 (8.5)
Estrogen receptor on BC (N)	Negative (%)	6 (16.2)	7 (14.9)
	Positive (%)	7 (18.9)	8 (17.0)

Preliminary anti-cancer activity for solid tumors was assessed according to RECIST 1.1 criteria. The preliminary anti-cancer activity for recurrent malignant gliomas was assessed according to the RANO criteria. In order to evaluate the anti-cancer activity of the treatment, appropriate imaging procedures were performed to accurately assess the tumor size at baseline, at the last day (day 21 or in case of patients with recurrent malignant glioma enrolled in the dose expansion phase day 28) of every even cycle (e.g. cycle 2, 4, 6 etc.), and at withdrawal from study treatment. Unless not done within 14 days before start of treatment the MRI of the brain was performed to assess brain lesion sizes. Unless not done within 28 days before baseline, a CT/MRI-scan of chest/abdomen/pelvis was performed to assess solid tumor sizes. If corticosteroid treatment (e.g. dexamethasone or methylprednisolone) or increase in corticosteroid treatment was required between screening and the first cycle of 2X-111, the baseline MRI was re-performed after a minimum of 7 days of stable or decreasing doses of the corticosteroids. The first cycle of drug was not initiated until baseline MRI has been performed.

CT/MRI-scans of the chest/abdomen/pelvis were only obtained from patients with solid tumors and brain metastases. These assessments were not required for patients with recurrent malignant glioma. Identified lesions were consistently followed using the unique lesion number assigned at baseline. All tumor measurements were obtained using the same diagnostic procedure used at baseline. For each course in which a tumor assessment was made, standard tumor response criteria were applied and the response for that course documented in the patient file. All identified lesions at screening/baseline were followed using the same imaging procedure. A bone scan was only obtained if clinically indicated during the study if the patient developed symptoms or signs of bone metastases. If bone metastases were known to be present at screening, bone scintigraphy was performed in addition to and at the same time as the CT/MRI-scans throughout the study. All lesions were followed during treatment (i.e. target lesions as well as non-target lesions). All CT/MRI Images from patients enrolled in the dose expansion arms of the study were sent electronically to a central repository system.

Safety was assessed by means of physical examination, neurological examination (and a brain MRI if a neurological deficit was leading to WHO > 2), weight, vital signs, ECOG performance status, MMSE, HDS, laboratory evaluations (hematology, biochemistry and urinalysis and N-terminal Pro-Brain Natriuretic Peptide (NT-ProBNP) and cardiac Troponin T (cTnT)), electrocardiograms (ECG), LVEF (MUGA/ECHO)), and recording of concurrent illness/therapy and adverse events.

Clinical anti-cancer activity was assessed by best overall response (OR) by both, investigator and computer-based methods. Overall, both methodologies reported similar results with the majority of best overall survival (OS) reported being stable diseases (SDs) while some partial responses (PRs) also being observed.

In the Dose Escalation Phase (DEP) group and in the glioma only patients, SD was the best OR recorded for 26.5% and 23.5% of the patients, as reported by the computer and investigator, respectively. At the same time, in the DEP group and for other solid tumors and across all single and combination arms, one PR (2.9%) was reported by the computer in the 2X-111 50 mg/m^2 + trastuzumab group. However, this response was deemed as SD by the investigator. The rate of SDs reported for this other (non-glioma) solid tumor group, was 23.3% and 20.6% for the computer and investigator, respectively.

In the Expansion Phase (EPP) group and for the glioma patients, both the computer and the investigator methods recorded the best OR as an SD rate of 17.8%. In the solid tumors group, the same SD rate of 26.7% was reported by both methods of assessment also. In addition, PR was also reported, 2.2% by the investigator and 4.4% by the computer.

The following tables summarize best overall responses by dose group and by cohort:

	Dose groups in mg/m²										
	5	10	20	30	40	50	60	70	40+T	50+T	Total
	N (%)										
RANO: Malignant Glioma											
PD											
Computer				1 (33.3)		1 (33.3)					**2 (5.9)**
Investigator				2 (66.7)		1 (33.3)					**3 (8.8)**
SD											
Computer				1 (33.3)	2 (66.7)	1 (33.3)	3 (42.9)	2 (100)			**9 (26.5)**
Investigator					2 (66.7)	1 (33.3)	3 (42.9)	2 (100)			**8 (23.5)**
RECIST: Solid tumour											
PD											
Computer	3 (100)	2 (66.7)	2 (100)	1 (33.3)	1 (33.3)		4 (57.1)	1 (50)	1 (33.3)	1 (20)	**16 (47.1)**
Investigator	3 (100)	2 (66.7)	2 (100)	1 (33.3)	1 (33.3)		4 (57.1)	1 (50)	1 (33.3)	1 (20)	**16 (47.1)**
PR											
Computer										1 (20)	**1 (2.9)**
SD											
Computer		1 (33.3)				1 (33.3)			2 (66.7)	3 (60)	**7 (20.6)**
Investigator		1 (33.3)				1 (33.3)			2 (66.7)	4 (80)	**8 (23.5)**
Total [N; %]	**3 (100)**	**3 (100)**	**2 (100)**	**3 (100)**	**3 (100)**	**3 (100)**	**7 (100)**	**2 (100)**	**3 (100)**	**5 (100)**	**34 (100)**

	Dose groups in mg/m²						
	60 prog. Glioma	60 Glioma	50 Breast new	50 Breast rec.	50 SCLC	50 Melanoma	Total
	N (%)						
RANO: Malignant Glioma							
PD							
Computer	5 (62.5)	5 (50)					**10 (22.2)**
Investigator	5 (62.5)	5 (50)					**10 (22.2)**
SD							
Computer	3 (37.5)	5 (50)					**8 (17.8)**
Investigator	3 (37.5)	5 (50)					**8 (17.8)**
RECIST: Solid tumour							
PD							
Computer			4 (50)	3 (42.9)	3 (42.9)	3 (60)	**13 (28.9)**
Investigator			4 (50)	1 (14.3)	5 (71.4)	4 (80)	**14 (31.1)**
PR							
Computer				1 (14.3)		1 (20)	**2 (4.4)**
Investigator				1 (14.3)			**1 (2.2)**
SD							
Computer			4 (50)	3 (42.9)	4 (57.1)	1 (20)	**12 (26.7)**
Investigator			4 (50)	5 (71.4)	2 (28.6)	1 (20)	**12 (26.7)**
Total [N; %]	**8 (100)**	**10 (100)**	**8 (100)**	**7 (100)**	**7 (100)**	**5 (100)**	**45 (100)**

Finally, analysis of the three exploratory populations revealed that SDs are the predominant best OR. In the glioma patient group receiving 2X-111 greater or equal to 40 mg/m^2, 16 out of the 27 patients experienced PD. In the breast-patient-group receiving 2X-111 greater or equal to 40 mg/m^2, 2 out of 24 patients experienced PR according to the computer or investigator method of assessment, respectively and at the same time, 12 or 15 out of 24 experienced an

SD. In the Her2+ breast patient group receiving 2X-111 greater or equal to 40 mg/m^2 in combination with trastuzumab, 2 or 1 out of 16 patients experienced PR according to the computer or investigator method of assessment, respectively and at the same time, 10 or 12 out of 24 experienced an SD. The following table summarizes those results:

	Dose groups in mg/m^2 > = 40 mg		
	Glioma	**Breast**	**Her2+**
		N (%)	
RANO: Malignant Glioma			
PD			
Computer	11 (40.7)		
Investigator	11 (40.7)		
SD			
Computer	16 (59.3)		
Investigator	16 (59.3)		
RECIST: Solid tumour			
PD			
Computer	1 (3.7)[38]	10 (41.7)	4 (25)
Investigator	1 (3.7)[38]	8 (33.3)	3 (18.8)
PR			
Computer		2 (8.3)	2 (12.5)
Investigator		1 (4.2)	1 (6.3)
SD			
Computer		12 (50)	10 (62.5)
Investigator		15 (62.5)	12 (75)
Total	**27 (100)**	**24 (100)**	**16 (100)**

All patients have reported at least one treatment emergent adverse event (grade I to IV) but all of them were manageable and none of them have been considered unexpected based on the previous experience from treatment with liposomal doxorubicin (Doxil/Caelyx) and/or non-clinical safety information with Allarity.

The number of infusions administered as single agent or in combination with trastuzumab to the individual patients ranged from 1 to 10. Long-term toxicity data (> 2 infusions of 2X-111) were available from 34 patients, all but one of these patients were treated with doses more or equal to 40 mg/m^2. One patient has received 10 infusions. The maximum total dose of 2X-111 delivered to date is 240 mg/m^2. Following treatment with 2X-111 infusion related reactions were reported in 27% of the patients in the Dose Escalation and 34% in the EPP. All infusion related reactions (dyspnea, chest pain, back pain, fatigue, headache, flushing, chills, tachycardia) that were observed in this study with 2X-111 were in between grade 1 to 3, but no grade 4 reactions. After modification of the initial infusion rate (5% given over the first 30 min and the remaining 95% over 60 min) at a dose of 30 mg/m^2, infusion reaction grade 1-2 has been reduced and reported in 16 out of 68 treated patients (23%), the majority still without any premedication. In all patients experiencing an infusion reaction the infusions were continued after a shorter treatment interruption. Only one case was reported as SAE (grade 2 bronchospasm). With respect to hematological toxicity, neutropenia was observed in 40.5%, leukocytopenia in 24.3% and thrombocytopenia in 18.9% of patients in the DEP. In EPP neutropenia occurred in 31.9%, leukocytopenia in 8.5% and thrombocytopenia in 4.3% of patients. In all patients with hematologic side effects the subsequent dose has been withheld for 1-2 weeks, per protocol and in 1 case also a dose reduction by 10 mg/m^2.

Palmar plantar erythrodysthesia (PPE) was reported in 45.9% of patients in DEP and 55.3% in EPP. However, no hand-foot syndrome grade 4 or 5 was reported. Grade 3 hand-foot syndrome was present in approximately 21.6% in DEP and 23.4% in EPP. While hand-foot syndrome caused by 2X-111 was reversible within one or two weeks, it caused dose delays and dose reductions in several patients. However, a favorable safety profile was observed and 2X-111 was relatively well tolerated in both patients with BCBM from solid tumors and patients with recurrent malignant gliomas.

Overview of Glioblastoma Multiforme (GBM)

Malignant brain tumors account for approximately 190,000 new cases and 40,000 deaths per year globally. In the U.S., gliomas account for 81% of all malignant brain tumors where glioblastoma (GBM) (WHO grade IV) is the most aggressive form and represents the most prevalent (54%) form of all gliomas and 46% of all primary malignant brain tumors. The majority of GBM (95%) has histologically been classified as primary GBM mostly in elderly without any clinical history of lower grade gliomas. Secondary GBM develops from lower grade gliomas in younger patients (age <45 years) in the course of many months to years of disease. Today the distinction is based on isocitrate dehydrogenase (IDH) mutations.

The prognosis of newly diagnosed GBM is poor with overall survival (OS) rates in the U.S. at 1-year, 2-year, and 5-year survival of 37.2%, 8.8%, and 5.1%, respectively. The current standard of care is tumor resection followed by radiotherapy combined with chemotherapy with temozolomide (TMZ) and then continuing with TMZ maintenance, and results in median OS of 14.6 months, which does not seem to have been relevantly improved over the past several decades. Thus, the therapeutic results are still not satisfactory, and new and more efficacious therapies are needed. Only a subgroup of GBM patients (approximately 32%), who have a methylated MGMT (O6-methylguanine-DNA methyltransferase) promotor, may benefit from TMZ treatment. The MGMT gene is involved in DNA repair, and epigenetic silencing by promotor methylation has previously been shown to be associated with longer survival in patients receiving alkylating agents. It has been shown that TMZ treatment improves OS from 15.3 to 21.7 months in patients with MGMT silencing, while patients with unmethylated MGMT promotors had no significant benefit from TMZ.

In most GBM patients the disease will progress sooner or later, however there is no clear recommendations for second line treatment. Depending on the clinical picture of each individual patient the treatment of recurrent GBM includes a second surgical procedure with or without implantation of carmustine wafers, nitrosoureas, TMZ treatment, the VEGF-blocking antibody bevacizumab (Avastin®) alone or in combination with the topoisomerase 1 inhibitor irinotecan, and, in some countries, systemic chemotherapy (e.g. carmustine plus irinotecan). In a Danish study of bevacizumab in combination with irinotecan an overall response rate (ORR) of 30%, median PFS of 5 months, and median OS of 7.5 months was observed. However, the treatment options for recurrent GBM are limited and the prognosis is poor. Patients should therefore be encouraged to participate in clinical trials.

Rationale for Liposomal Doxorubicin in GBM

Several studies on established glioma cell lines have shown promising levels of therapeutic activity of doxorubicin. In the last decade, treatment of GBM with pegylated liposomal doxorubicin (Doxil®/Caelyx®) has been assessed in three small studies. The treatment has been shown to result in a modest positive effect (1.5 months) on survival. However, this effect has not been considered sufficient to justify the use of Doxil®/Caelyx® as a standard treatment option in patients with brain tumors according to treating clinicians and regulatory agencies.

Existing PEG-liposomal formulations of doxorubicin, such as Doxil®/Caelyx®, do not readily pass the BBB and therefore do not deliver sufficient levels of the drug to brain tumors in order to provide meaningful therapeutic benefit. Likewise, doxorubicin itself does not pass the BBB.

The FDA granted orphan drug designation for 2X-111 for the treatment of glioma on August 16, 2010 (FDA/103119). Additionally, on September 21, 2010 the orphan drug designation of 2X-111 for the treatment of glioma was approved by the EMA (EMA/OD/031/10).

2X-111 is a novel PEG-liposomal formulation of doxorubicin, which, by virtue of the glutathione modification on the liposomal surface, is able to pass the BBB and deliver therapeutically sufficient levels of doxorubicin to brain tumors. Accordingly, 2X-111 has the potential to be a new and beneficial therapeutic option for the treatment of GBM.

Rationale for Liposomal Doxorubicin in Breast Cancer (Brain Metastases)

Brain metastases are diagnosed in approximately 15% of unselected patients with advanced breast cancer. Over time, it has become increasingly clear that the biology of the primary tumor influences the pattern of metastatic spread, including the likelihood of relapse in the central nervous system (CNS). As many as half of patients with HER2-positive advanced breast cancer will develop brain metastases at some point in the course of their disease.

Within the HER2-positive subset, hormone receptor status appears to further define the risk of CNS relapse, with patients having hormone receptor-negative/HER2-positive tumors experiencing increased risk developing metastases in the CNS as the first site of relapses, compared with patients with hormone receptor-positive/HER2-positive tumors. Furthermore, patients with metastatic, triple-negative (ER, PR and HER2 negative) breast cancer are equally at high risk, with 25–46% of patients developing brain metastases at some point in the course of their disease. The timing of the CNS relapse also appears to vary by tumor subtype. Patients with non-luminal tumors (e.g. triple-negative cancers) appear to experience a shorter time to relapses in the CNS compared to patients with luminal tumors.

In a historical series of unselected patients with breast cancer brain metastases treated with whole-brain radiotherapy (WBRT), the median survival has been reported to be approximately five to six months. More recent analyses have identified performance status of the patient and the biologic tumor subtype as major drivers of prognosis. For example, in a multi-institutional retrospective database of over 400 patients with breast cancer brain metastases, a prognostic model (the Diagnosis-Specific Graded Prognostic Assessment, DSGPA) using these factors (plus age) was able to distinguish between patients experiencing a two-year median survival versus those with 3.4 months median survival.

Across multiple retrospective studies, the most striking differences consistently noted have been between patients with HER2-positive breast cancer (who carry the most favorable prognosis) and patients with triple-negative breast cancer. Based on several lines of evidence, it is likely that improved systemic tumor control is a major contributing factor to this difference. First, although one must interpret retrospective data cautiously because of issues with patient selection, it has been observed by multiple investigators that patients with HER2-positive tumors who continue on anti-HER2 therapy following the diagnosis of brain metastases do far better than those who receive either no therapy, or chemotherapy without HER2-directed therapy. Second, as many as half of the patients with HER2-positive brain metastases die primarily from CNS progression of their disease (as opposed to systemic progression). Accordingly, the need for a brain-targeted therapy for the treatment of brain metastases is warranted in this patient population. This is distinguished from patients with triple-negative brain metastases, where patients most commonly die of uncontrolled systemic disease.

Existing PEG-liposomal formulations of doxorubicin, such as Doxil®/Caelyx®, do not readily pass the BBB and therefore do not deliver sufficient levels of the drug to brain tumors in order to provide meaningful therapeutic benefit. Likewise, doxorubicin itself does not pass the BBB.

2X-111 is a novel PEG-liposomal formulation of doxorubicin, which, by virtue of the glutathione modification on the liposomal surface, is able to pass the BBB and deliver therapeutically sufficient levels of doxorubicin to brain tumors. Accordingly, 2X-111 has the potential to a new and beneficial therapeutic option for the treatment of brain metastases of breast cancer.

Future Opportunities & Development Plans for 2X-111

In June of 2020, we out-licensed our 2X-111 program to Smerud Medical Research International, our long-time CRO partner in Europe, which will further advance 2X-111, together with its DRP® companion diagnostic, in GBM, building on prior clinical trial results. The initiation, by Smerud, of the next Phase 2 clinical trial for this program is anticipated by early 2022, however the license agreement with SMERUD may be termininated if SMERUD does not obtain outside financing for the program by December 31, 2021.

The expanded Phase 2 clinical trial to be conducted by Smerud will screen up to 300 glioblastoma (GBM) patients for 2X-111 followed by the enrollment (on a rolling basis) of approximately 40 GBM patients identified, using the DRP® companion diagnostic for the drug, as high likely responders to 2X-111, in order to have at least 30 patients evaluable for anti-cancer activity (Objective Response Rate (ORR) per RECIST). Smerud's clinical development plan may further include additional, optional, clinical trials to assess, for example, the potential utility of 2X-111 for treatment of pediatric brain cancers. We will support Smerud in these studies by providing Doxorubicin-DRP® companion diagnostic analysis for screened patients.

In addition to GBM, and brain metastases of breast cancer, there are many future market opportunities for 2X-111 for the treatment of other primary brain cancers, including astrocytomas, ependymomas, medulloblastomas, and oligodendrogliomas, and additional distal cancers that metastasize to brain, including lung, colon, kidney and melanoma.

DRP® Companion Diagnostic for 2X-111

We are developing 2X-111, together with our retrospectively validated DRP® companion diagnostic for doxorubicin, which enables us to select the patients most likely to respond to the drug in our clinical trials. The FDA has previously approved our Investigational Device Exemption (IDE) applications for use DRP® companion diagnostics in clinical trials of two of our priority programs: Stenoparib and LiPlaCis®. Accordingly, we are confident the FDA will approve an eventual IDE for our Doxorubicin-DRP® companion diagnostic for U.S. clinical trials of 2X-111. The Doxorubicin-DRP®, which comprises 299 expressed genes, was initially developed using gene expression data from the National Cancer Institute NCI60 cancer cell lines panel.

The putative Doxorubicin-DRP®, developed through our DRP® platform using gene expression data from cancer cell line testing data, was retrospectively validated using biopsy materials from the screening of breast cancer patients for our LiPlaCis® trial (clinicaltrial.gov number NCT01861496). A total of 140 patients received epirubicin and were included in the analysis. The study population was diagnosed with primary BC between 1986 and 2015 and received epirubicin in the locally advanced or metastatic setting between May 1997 and November 2016. The hazard ratio for DRP scores differing by 50 percentage points was 0.55 (95% CI –0.93, one-sided). The results were published in Breast Cancer Res Treat. 2018 Aug 11.

In sum, our retrospectively validated Doxorubicin-DRP® companion diagnostic correctly identifies responder patients to 2X-111 and we plan use this DRP® companion diagnostic for all of our clinical programs to advance 2X-111 including the planned, expanded Phase 2 GBM clinical trial being advanced by our licensee, Smerud Medical Research International.

Existing Liposomal Doxorubicin Drugs & Our Opportunity

There has not been a therapeutically meaningful new drug for the treatment of GBM since bevacizumab (Avastin®) was approved, by the FDA, in 2009 as a monotherapy for patients who have progressed on prior therapy. Prior to introduction of bevacizumab in the GBM treatment landscape, TMZ was approved, by the FDA in 2005, for the treatment of adult patients with newly diagnosed GBM concomitantly with radiotherapy and then as maintenance treatment. Nearly 20 years later, TMZ remains the only front-line therapy for GBM, and its effectiveness is limited. Similarly, the effectiveness of benefit of second-line therapeutic bevacizumab remains limited. Accordingly, there is pressing need for new and innovative therapies for the treatment of this aggressive and incurable cancer.

There is no currently approved, available therapy for the treatment of brain metastases of breast cancer, and these metastases remain fatal to breast cancer patients. Accordingly, there is pressing need for new and innovative therapies for the treatment of this aggressive and incurable metastatic cancer.

Worldwide annual sales TMZ exceeded $1 billion annually in 2009. The global GBM drugs market to projected to reach nearly $1.8 billion by 2027, expanding at a CAGR of 12.8% during the forecast period, driven by rising geriatric population, growing incidence cases and clinical pipeline of new products. The global breast cancer therapeutics market has been valued at over $19 billion in 2018 and is expected to reach over $40 billion by the year 2026, at a CAGR of 10.6%. Since an estimated 10-15% of breast cancer patients will develop brain metastases, which are fatal, the estimated annual market for new therapeutics to treat such brain metastases will exceed $4 billion by 2026.

While there are several approved PEG-liposomal doxorubicin formulations (e.g. Doxil®/Caelyx®) currently marketed for the treatment of numerous cancer, including breast cancer, these drugs do not pass the BBB. There are currently no approved, targeted liposomal formulations of doxorubicin on the market that are capable of passing the BBB and therefore treating both primary and secondary brain tumors. Accordingly, 2X-111 has the potential to be a novel, beneficial product with the potential, together with its DRP® companion diagnostic, to gain substantial market share not only in GBM and breast cancer (brain metastases) but as a new therapy for the numerous other primary and second brain tumors.

Overview of Our Prior Therapeutic Candidate Irofulven (DNA damaging agent) and Our Out-licensed Putative DRP® Companion Diagnostic

Mechanisms of Action

Irofulven (6-hydroxymethylacylfulvene) is a unique DNA damaging agent that is a semi-synthetic sesquiterpene derivative of illudin S, a natural toxin isolated from the Jack O'lantern mushroom (*Omphalotus illudens*). Irofulven has two primary anti-tumor mechanisms of action: first, it produces bulky single strand DNA adducts that are only repairable by the transcription coupled nucleotide excision repair (TC-NER) pathway; and second, it stalls RNA polymerase II leading to transcription and cell cycle arrest and apoptosis.

Irofulven is a prodrug. The active metabolite is created by the reduction of the unsaturated α−β ketone by the NADPH-dependent Prostaglandin Reductase 1 (PTGR1). This metabolite is unstable and highly reactive, binding to either protein or DNA. The DNA binding is primarily to the 3-N of deoxyadenosine (98%) with the remainder binding to 7-N deoxyguanine. The resulting bulky single strand adducts can cause single strand DNA breaks and S-phase double strand DNA breaks. The GG-NER, BER and MMR pathways do not detect or remove Irofulven-DNA adducts, which either persist into, or are created during, S-phase of cancer cell duplication and create double strand DNA breaks which may be repaired by Homologous Recombination.

Irofulven is more active *in vitro* against tumor cells of epithelial origin and is more resistant than other alkylating agents to deactivation by p53 loss and MDR15. Irofulven showed impressive anticancer results in xenograft models, shows synergy with topoisomerase I inhibitors, and has demonstrated activity against cell lines that are resistant to other therapies. Irofulven has significant scope for combination with other therapies, including PARP inhibitors, checkpoint inhibitors (e.g. PD-1 inhibitors) and standard chemotherapeutic regimes, and is synergistic with other therapies targeting the TC-NER pathway and other DNA damage pathways.

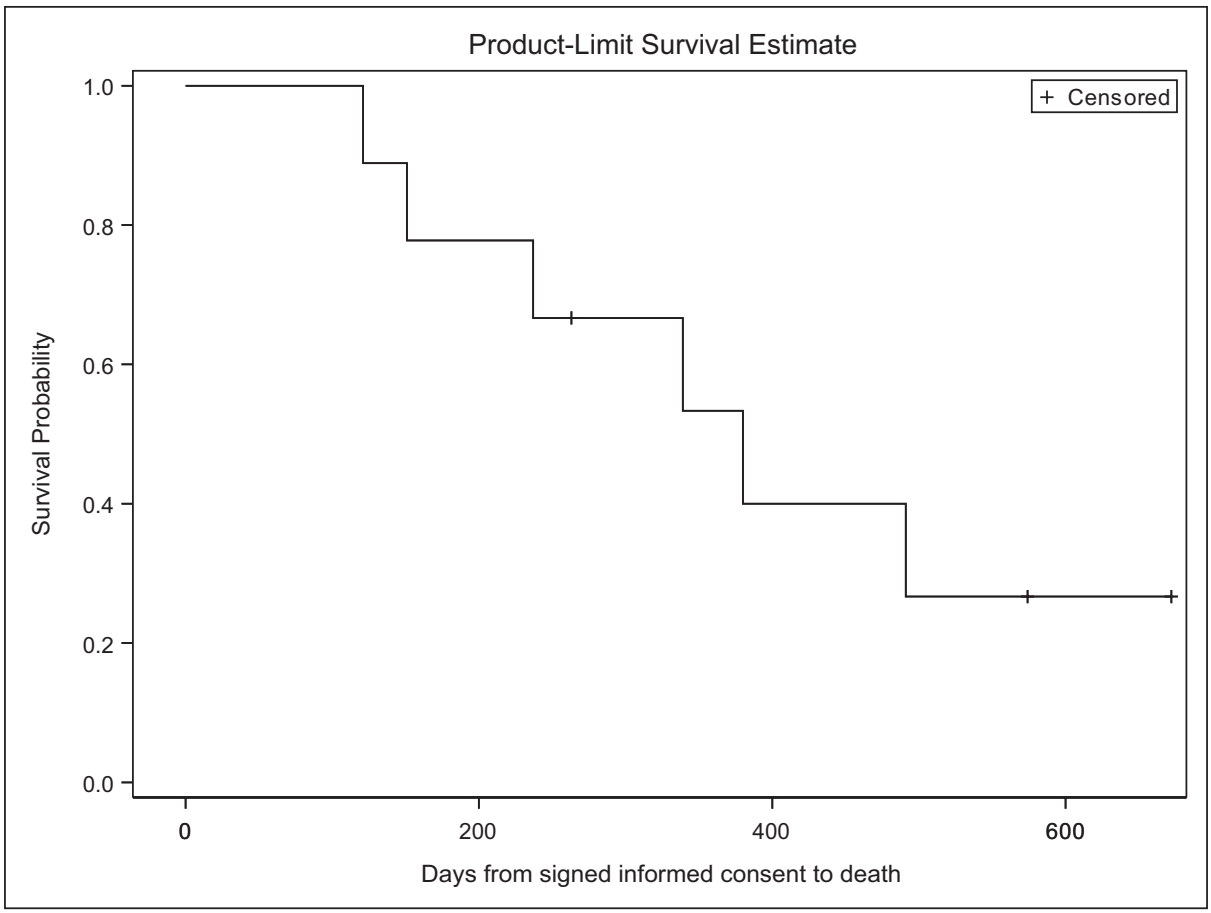
Irofulven causes apoptosis in sensitive tumor cell lines. Activation of caspases 3, 7, 8, and 9 has been well documented in Irofulven-treated tumor cell lines. Irofulven also causes upregulation of ATM/Chk2 and ATR-dependent FANCD2 mono-ubiquitination. In all cases, however, the functional linkage(s) between irofulven adducts (both DNA and protein) and subsequent pathway activation steps are, at present, not fully understood.

DRP®-Guided Phase 2 Clinical Trial

Prior to July 23, 2021, and our sale of Irofulven to Lantern Pharma, Inc., we commenced a DRP®-guided Phase 2 clinical trial of Irofulven in androgen receptor (AR)-targeted and Docetaxel-Pretreated Metastatic Castration-Resistant Prostate Cancer (mCRPC) patients using our putative Irofulven-DRP® companion diagnostic to select and treat patients most likely to respond to the drug (study SMR-365). This trial was not completed and was an open-label, non-randomized, multi-center study in patients with docetaxel and AR-targeted therapy pre-treated mCRPC. Up to 27 mCRPC patients with predicted high probability of response to Irofulven (as determined by the Irofulven-DRP® companion diagnostic) were included. A high likelihood of Irofulven response was defined as a patient having an Irofulven-DRP® score of >80%. This study was suspended in 2019 when we internally deprioritized Irofulven. We had previously developed and patented a putative DRP® companion diagnostic specific for Irofulven, which we believe enables us to identify and treat the patients most likely to respond to this therapeutic candidate although we have not yet filed a PMA with the FDA for this companion diagnostic. In order to devote more of our development resources to our priority therapeutic candidates, on July 23, 2021, we terminated our drug development agreement for Irofulven and sold our inventory of Irofulven active pharmaceutical ingredients, ("API"), our clinical data and records ("Data"), and our know-how relating to Irofulven to Lantern Pharma, and granted a non-exclusive license to use our putative DRP® companion diagnostic specific for Irofulven. Although we may be entitled to future milestone payments and royalties if Lantern Pharma advances the development of Irofulven with or without our putative DRP® companion diagnostic specific for Irofulven, we will no longer devote any of our development resources to advance this therapeutic candidate.

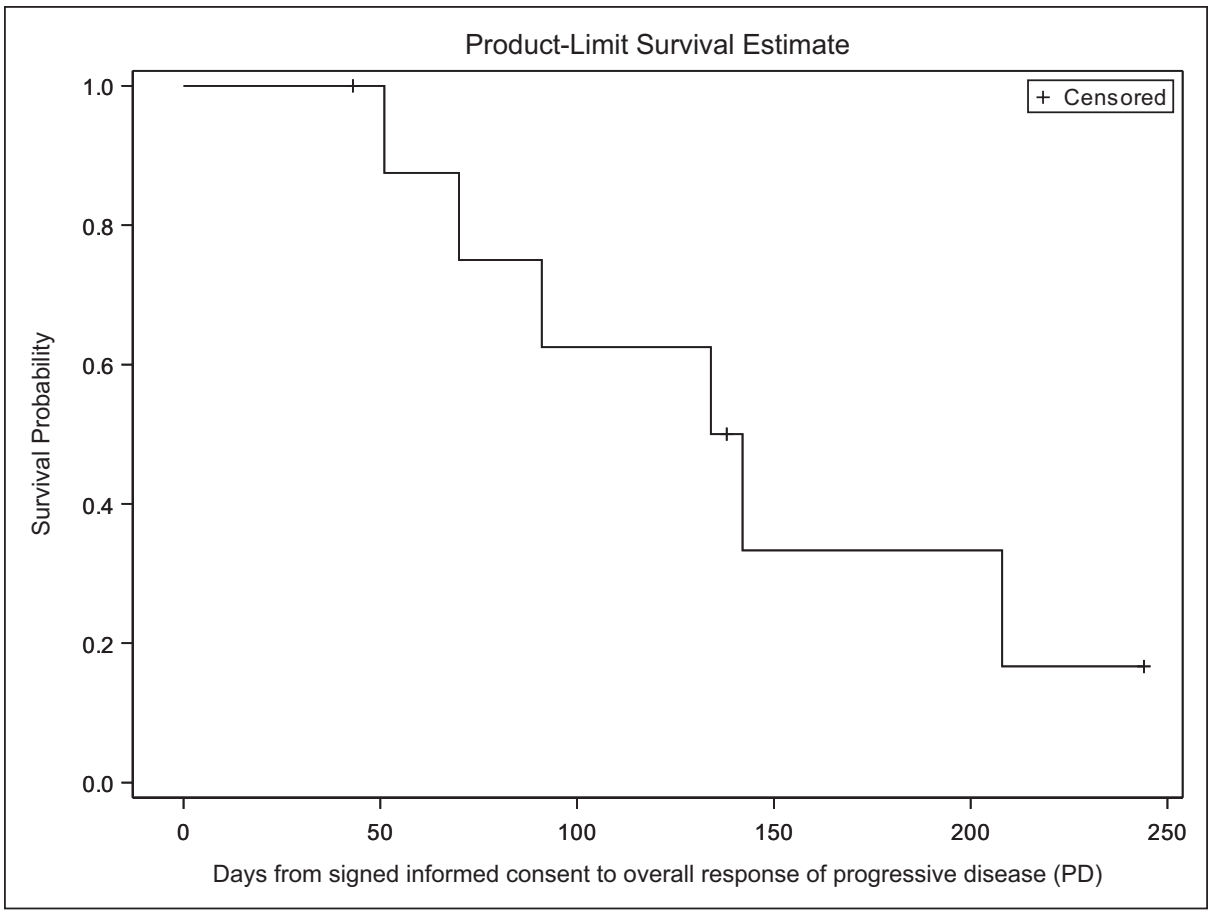
Study SMR-3165. Time (days) from enrolment to death of any cause.

The LIFETEST Procedure



Study SMR-3165. Time (days) from enrolment to overall response of progressive disease (PD).

The LIFETEST Procedure



Overview of Our PRP® (Patient Response Predictor)

Collections of drug-specific putative DRP® companion diagnostics can be grouped together to form a panel of putative DRP® companion diagnostics that we believe can help guide therapeutic decision making for a given patient, in a true personalized medicine approach. For example, putative DRP® companion diagnostics for a number of cancer drugs with a similar mechanism-of-action, for example chemotherapeutics such as cisplatin, doxorubicin, and irofulven can be grouped together, by drug type (e.g. DNA damaging agents) in a panel to help identify which of these chemotherapeutics is most likely to benefit a particular patient. Similarly, putative DRP® companion diagnostics for a number of cancer drugs with differing mechanism-of-action, such as fulvestrant, cisplatin, and dovitinib, can be grouped together, by cancer type (e.g. drugs that treat metastatic breast cancer) in a panel to help identify which of these drugs is most likely to benefit a particular patient. We call such panels of putative DRP® companion diagnostics Patient Response Predictors (PRP®s).

We believe PRP®s, once approved, have the potential to achieve the true promise of personalized cancer care, specifically to pre-screen a given cancer patient for their likelihood of responding to a range of therapeutic options, then selecting the drug(s) most likely to benefit that patient, while avoiding the prescription of therapeutics that are not likely to benefit that patient. In practice, the treating oncologist and/or cancer center would provide us with a tumor biopsy from a given patient (or gene expression data from such biopsy) and we would then run a PRP® analysis, as requested by the oncologist, resulting in a PRP® report, provided to the oncologist and the patient, identifying the therapy options most likely to benefit the patient. This report would be somewhat analogous to currently marketed predictive diagnostic panels and reports, such as FoundationOne® (Foundation Medicine, Inc.), but with a different underlying technology base and therapeutic response predictive power.

An example of such a PRP® product for multiple myeloma was published in 2018 where the sensitivity of 67 patients to 14 drugs was predicted. A.J. Vangsted *et al.*, Gene 644 80-86)

We continue to explore the strategic and market potential of such PRP® panels. Market introduction and penetration of such personalized medicine diagnostic tests and reports is challenging and subject to close scrutiny of regulatory agencies such as the FDA, and also are very capital intensive to develop, bring to market, and expand sales. Accordingly, development of a potential PRP® product and business is not currently part of our priority strategy.

Intellectual Property

Our commercial success depends in large part on our ability to obtain and maintain patent protection in the U.S. and other major oncology markets and countries for our investigational products and our DRP® companion diagnostics, to operate without infringing valid and enforceable patents and proprietary rights of others, and to prevent others from infringing on our proprietary or intellectual property rights. We seek to protect our proprietary position by (1) filing, in the U.S. and certain other regions/countries (include the EU), patent applications intended to cover our DRP® companion diagnostics and their use with a particular therapeutic to guide patient therapy decision making, and maintaining any issued DRP® patents in our major markets; (2) maintaining and advancing, and where possible expanding, existing patents and patent applications covering the composition-of-matter of our investigational products, their methods of use and related discoveries, their formulations and methods of manufacture, and related technologies, inventions and improvements that may be commercially important to our business; and (3) filing, in the U.S. and certain other regions/countries, new patent applications on novel therapeutic uses of our investigational products, alone or together with their DRP® companion diagnostics. We may also rely on trade secrets and know-how to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection, and which is difficult to reverse engineer. We also intend to take advantage of regulatory protection afforded through data exclusivity, market exclusivity and patent term extensions where available.

We have investigational products, and putative DRP® companion diagnostics, for a number of therapeutic targets, although none of our companion diagnostics have yet received FDA or other regulatory agency approval. As of September 27, 2021, our company-owned patent portfolio consists of:

- 15 DRP® companion diagnostics patents granted covering 70 different cancer drugs, including 7 issued patents in the U.S. and 3 issued patents in the EU. Our issued patents cover, among others, DRP® companion diagnostics for Dovitinib, LiPlaCis®, 2X-111, and Irofulven. Our issued patent portfolio includes patents granted in the U.S., EU, China, Japan, Canada and Australia.

- 19 DRP® companion diagnostics patent applications pending covering 2 additional drugs, including pending applications in the U.S., EU, China, Japan, Canada, India and Australia. Our pending patent applications cover, among others, DRP® companion diagnostics for IXEMPRA® and for Stenoparib.

- Over 50 granted patents and pending patent applications, for composition-of-matter, methods of use, formulation, and methods of manufacturing, for many of our pipeline assets, including Dovitinib, Stenoparib, LiPlaCis® and 2X-111. These granted patents and applications generally cover the U.S. and EU, as well as numerous additional major world cancer therapeutics markets; although existing and remaining patent/application coverage varies from drug program to drug program. In some instances we own and control such pre-existing patent/application portfolios (such as for Dovitinib) and in some instances the original drug owner/licensor owns and controls such pre-existing patent/application portfolios (such as for Stenoparib).

- 1 International patent application pending covering novel anti-viral uses of Stenoparib as a therapeutic for treatment of COVID-19 infection.

- The term of any patents that issue from our company-owned (or controlled) U.S. and foreign patent applications will vary in accordance with the laws of each jurisdiction, but is typically 20 years from the earliest non-provisional application filing date. Expiration dates for certain patents covering our portfolio assets ranges between 2028 and 2032. Expiration dates for the DRP® companion diagnostic patents that cover our current pipeline programs will typically expire between 2030 and 2040. Any patents that may issue in the future from our company-owned (or controlled) pending patent applications are projected

to expire between 2031 and 2041, unless extended or otherwise adjusted. Generally, the older and more developed the drug program the earlier the patent portfolio on the product will expire. For example, remaining patent portfolio term for dovitinib is less than remaining patent term for stenoparib. Such product patent portfolio expiration is independent from continuing patent coverage provided by DRP® companion diagnostics for each product.

- In countries or regions, such as the U.S. and EU, where regulatory approval of a companion diagnostic together with its drug, on the label, is available, approved DRP® companion diagnostics will substantially extend patent and product protection well after the core product patents (e.g. composition-of-matter) have expired.

We have obtained or are pursuing patent protection for our proprietary drug response predictor (DRP®) technology, a unique diagnostic platform, with a particular focus on the application of the DRP® technology to treat renal cell carcinoma, ovarian cancer, and metastatic breast cancer. Specifically, the DRP® technology is being applied to select patients to be treated with dovitinib, stenoparib, or ixabepilone. Our patent portfolio also includes patents and applications in-licensed from Novartis International AG ("Novartis") that protect dovitinib compositions and methods of its use for treatment, as well as patents and applications in-licensed from Eisai Co., Ltd. ("Eisai") that protect stenoparib compositions and methods of its use for treatment. Our in-licensed patent on the composition of matter for dovitinib expired on September 11, 2021. Because we are developing dovitinib in combination with a DRP® companion diagnostic, we do not believe the expiration of our composition of matter patent for dovitinib will materially adversely effect our ability to receive FDA approval of our anticipated NDA for dovitinib or our PMA for our DRP® companion diagnostic.

DOVITINIB

Our dovitinib patent portfolio, which includes pending U.S. and foreign patents and patent applications, is positioned to protect aspects of our business in the United States and in key foreign jurisdictions. The following is a brief summary of the dovitinib patent portfolio, which includes in-licensed patent families, as well as patent families owned by us.

In-licensed patents:

- Patents granted in the United States (US 9,545,402), Australia (AU 2011273519), Canada (CA 2,801,826), China (CN 106943355), Europe (EP 2588086), and Japan (JP 2013-517282), which correspond to International Patent Application No. PCT/EP2011/060949, protect pharmaceutical dovitinib compositions and methods for producing pharmaceutical compositions containing dovitinib. The patents are scheduled to expire beginning in 2031.

- Patents granted in the United States (US 8,741,903), Europe (EP 2558095), and Australia (AU 2011239999), which correspond to International Patent Application No. PCT/EP2011/055906, protect methods of treating hepatocellular carcinoma or liver cancer with dovitinib. The patents are scheduled to expire beginning in 2031.

Owned patents:

- We have patent rights covering the use of the DRP® technology in conjunction with dovitinib in the United States (US 10,835,531). Patent rights outside the U.S. will be pursued in key foreign jurisdictions, including Australia, Canada, China, Europe, India, Japan, Brazil, Mexico, Egypt, and Saudi Arabia, in connection with International Patent Application No. PCT/EP2020/066724. National applications will be filed starting in November 2021. This portfolio is scheduled to expire in 2040.

STENOPARIB

Our stenoparib patent portfolio, which includes pending U.S. and foreign patents and patent applications, is positioned to protect aspects of our business in the United States and in key foreign jurisdictions. The following is a brief summary of the stenoparib patent portfolio, which includes patent families in-licensed from Eisai, as well as patent applications owned by Allarity.

In-licensed patents:

- Patents corresponding to International Patent Application No. PCT/US2008/078606 that are In-licensed from Eisai include composition of matter claims directed to genera and species encompassing stenoparib. Patents have issued in the United States (US 8,236,802 and US 8,894,989) and in key foreign jurisdictions including, e.g., Europe (EP 2209375), Canada (CA 2,700,903), China (CN 102083314B), Japan (JP 5439380), and South Korea (KR 10-1596526). The patents are scheduled to expire in 2028.

Owned patents:

- We are pursuing patent protection for the use of our DRP® technology in conjunction with stenoparib via International Patent Application No. PCT/EP2019/062508, which has been filed in the United States, Australia, Canada, China, Europe, India, and Japan. This portfolio is scheduled to expire in 2039.

IXABEPILONE

Our ixabepilone patent portfolio, which is owned by us, is based on protecting our DRP® technology in the United States and in key foreign jurisdictions. Patent applications corresponding to International Patent Application No. PCT/EP2021/052132, which seeks to cover the use of the DRP® technology in conjunction with ixabepilone, will be pursued in the United States and in key foreign jurisdictions, including Australia, Canada, China, Europe, India, Japan, Brazil, Mexico, Egypt, and Saudi Arabia. National applications will be filed starting in July 2022. This portfolio is scheduled to expire in 2041. We do not own or control any patents relating to ixabepilone itself in the EU market, where such patents have previously expired.

LiPlaCis®

We also have obtained patent rights to LiPlaCis®, which is a third-generation liposomal formulation of cisplatin. Our LiPlaCis® patent portfolio, which includes pending U.S. and foreign patents and patent applications, is positioned to protect aspects of our business in the United States and in key foreign jurisdictions. The following is a brief summary of our LiPlaCis® patent portfolio, which includes patent families in-licensed from LiPlasome Pharma ApS, as well as patents and applications owned by us.

In-licensed patents:

Patent applications corresponding to International Patent Application No. PCT/DK2010/050237 include composition of matter claims directed to LiPlaCis® (US 13/497,031) and allowed claims to a method of treating cancer by administration of LiPlaCis® (US 16/630,836; issue date expected in Q4 of 2021). This portfolio is scheduled to expire in 2030.

A patent corresponding to International Patent Application No. PCT/DK2010/050283 with composition of matter claims directed to LiPlaCis® has issued in the United States (US 9,820,941). This portfolio is scheduled to expire in 2030.

Patent applications directed to a treatment regimen using LiPlaCis® are also pending in the United States, Australia, Canada, China, and Japan. These applications correspond to U.S. Patent Application Publication No. 2019/0231795. This portfolio is scheduled to expire in 2039.

Owned Patents:

We own the rights to the use of our DRP® technology in conjunction with LiPlaCis®. Patents to this technology have issued in the United States (US 10,907,214), Europe (EP 3342879), and Hong Kong (HK 1255416). Patent applications are also pending in Australia, Canada, China, Europe, and India. This portfolio is scheduled to expire beginning in 2038.

2X-111

Our 2X-111 patent portfolio, which includes U.S. and foreign patents, is positioned to protect aspects of our business in the United States and in key foreign jurisdictions. The following is a brief summary of the 2X-111 patent portfolio, which includes patent families in-licensed from 2BBB Medicines, B.V., as well as patent and patent applications owned by Allarity.

In-licensed patents:

Our 2X-111 patent portfolio includes the following patent families in-licensed from 2BBB Medicines, B.V.: (1) drug conjugates, which patents are issued and in force until March 2028; (2) liposomal delivery system, which patents are issue and in force until December 2025; and modified drug delivery system, which patents are issued and in force until February 2030. Generally, the issued patents of each patent family cover most of the European Union countries, including, among others, Germany, Spain, United Kingdom, Italy, France, and Turkey. Patents within family (3) have also been granted in Australia, Canada, China, Japan and New Zealand.

Owned patents:

We own exclusive, global rights to the use of our DRP® technology in conjunction with doxorubicin, which is the active therapeutic ingredient of 2X-111. A patent to this technology has issued in the United States (US 10,900,089). Patent applications are also pending in Australia, Canada, China, Europe, Hong Kong, and India. This portfolio is scheduled to expire in 2038.

The patent positions for biotechnology and pharmaceutical companies like us are generally uncertain and can involve complex legal, scientific and factual issues. Changes in either the patent laws or their interpretation in the U.S. and other countries may diminish our ability to protect our investigational products and/or DRP® companion diagnostics and enforce the patent rights that we own, and could affect the value of such intellectual property and the business. With respect to our company-owned (or controlled) intellectual property, we cannot guarantee that the patent applications we are currently pursuing or may file in the future will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Our competitors may independently develop similar investigational products or technologies that are outside the scope of the rights granted under any company-owned (or controlled) patents that may issue. We cannot be sure that any patents granted to us will be commercially useful in protecting our products or their methods of use or manufacture. Moreover, even issued patents do not guarantee us the right to commercialize our products. For example, third parties may have blocking patents that could be used to prevent us from commercializing or manufacturing our investigational products and/or our DRP® companion diagnostics.

Because of the extensive time required for development, testing and regulatory review of an investigational product, it is possible that, before a product can be commercialized, any patent protection for such product may expire or remain in force for only a short period following commercialization, thereby reducing the commercial advantage the patent provides. In the U.S., the term of a patent covering an FDA-approved product may, in certain cases, be eligible for a patent term extension under the Hatch-Waxman Act as compensation for the loss of patent term during the FDA regulatory review process. The period of extension may be up to five years, but cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent among those eligible for an extension may be extended and the amount of available extension to any PTE-eligible patent depends on a variety of factors, including the date on which the patent issues and certain dates related to the regulatory review period. Possible extensions may be available in Europe and in certain other jurisdictions to extend the term of a patent that covers an approved product. While we intend to seek patent term extensions in any jurisdictions where they are available to us, there is no guarantee that the applicable authorities, including the FDA or the USPTO, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions.

We cannot be sure that any patents will issue from any pending or future company-owned (or controlled) patent applications. Even if patents do issue, we cannot be sure that the claims of these patents will be held valid or enforceable by a court of law or governmental agency, will provide us with any significant protection against competitive products, or will afford us a commercial advantage over competitive products. For example:

- we might not have been the first to file patent applications for the inventions covered by our pending patent applications and any patents that issue therefrom;
- others may independently develop similar or alternative technologies without infringing our intellectual property rights;
- some or all of our pending patent applications may not result in issued patents or the claims that issue may be narrow in scope and not provide us with a competitive advantage;

- any patents that issue from any of our pending patent applications may be challenged by a third-party and invalidated;
- any patents that issue from our pending patent applications may be subject to post-grant proceedings, oppositions or other administrative or court proceedings that may result in a reduction in their scope or their loss altogether;
- we may not develop proprietary technologies or investigational products that are patentable; and
- the patents of others may prevent us from discovering, developing or commercializing our investigational products.

The defense and prosecution of intellectual property infringement suits, post-grant proceedings, oppositions and related legal and administrative proceedings are costly, time-consuming to pursue and divert resources. The outcome of these types of proceedings is uncertain and could significantly harm our business.

The development of our investigational products and the commercialization of any resulting drugs may be impacted by patents of other companies or by companies engaged in the development of competitive programs or those with significantly greater resources. This could result in the expenditure of significant legal fees and management resources.

We also rely on certain trade secrets to protect our technology and therapeutic candidates, especially where we do not believe patent protection is appropriate or obtainable, or where maintaining such technology as a trade secret provides us greater competitive advantage than obtaining a patent would. However, trade secrets are often difficult to protect, especially outside of the U.S. While we believe that we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, partners and other advisors may unintentionally or willfully disclose our trade secrets to others, including competitors. Enforcing a claim that a third-party illegally disclosed, obtained or is using our trade secrets would be expensive and time-consuming, and the outcome would be unpredictable. Even if we are able to maintain our trade secrets as confidential, our competitors may independently develop information that is equivalent or similar to our trade secrets.

License Agreement with Novartis Pharma for Dovitinib

On April 6, 2018, we in-licensed the exclusive worldwide rights to all therapeutic and/or diagnostic uses related to cancer in humans for dovitinib from Novartis Pharma AG ("Novartis") pursuant to a license agreement. Upon execution of the agreement, we paid Novartis a one-time, non-refundable, non-creditable payment of $1 million. Pursuant to the agreement, we are solely responsible for the development of dovitinib during the term of the agreement.

Development Milestone Payments

Pursuant to the agreement, we have agreed to make milestone payments to Novartis in connection with the development of dovitinib by us or our affiliates, or by a third-party (a "Program Acquirer") that assumes control of the dovitinib development program from us corresponding to: (i) upon enrollment of half of the patients required in a Phase 2 clinical trials in certain countries in accordance with agreed upon protocols; (ii) Upon dosing of the first patient in the first Phase 3 clinical trial; (iii) upon submission of the first NDA with the FDA; (iv) submission of an MAA to the EMA or any other Regulatory Authority in certain countries; (v) upon receipt of the first authorization by the FDA to market and sell a licensed product; and (vi) upon receipt of a MAA (including a respective pricing and reimbursement approval) for a licensed product in one or more specified European countries. If all milestones have been achieved, we may be obligated to pay Novartis up to a maximum of $26 million. We anticipate paying a mid level seven figure payment upon submission of our planned NDA with the FDA.

Royalty Payments

In addition to the milestone payments described above, we have agreed to pay Novartis royalties based on annual incremental sales of product derived from dovitinib in an amount between five percent (5%) and ten percent (10%) of annual sales of between $0 and $250 million, between six percent (6%) and thirteen percent (13%) of annual sales between $250 million and $500 million, between seven percent (7%) and thirteen percent (13%) of annual sales between $500 million and $750 million, and between thirteen percent (13%) and fifteen percent (15%) of annual sales in excess of $750 million.

We are obligated to pay royalties under the agreement on a country-by-country and product-by-product basis for a period that commences with the first commercial sale of a product until the later of (i) the expiration of the last to expire valid claim of any licensed patent covering such licensed product in such country; or, (ii) the expiration of regulatory-based exclusivity for such licensed product in such country or (iii) the ten (10) year anniversary of the date of first commercial sale of such licensed product in such country. However, the agreement may be sooner terminated without cause by us upon 120 days prior written notice, or upon written notice of a material breach of the agreement by Novartis that is not cured within 30 days. Novartis also has the right to terminate the agreement upon written notice of a material breach of the agreement by us that is not cured within 30 days or in the event that we file for bankruptcy.

License Agreement with Eisai for Stenoparib

On July 6, 2017, we in-licensed the exclusive worldwide rights to any and all preventative, therapeutic and/or diagnostic uses related to cancer in humans and by amendment to the agreement on December 11, 2020, viral infections in humans (including, but not limited to, coronaviruses) for stenoparib from Eisai, Inc. ("Eisai") pursuant to a license agreement. Upon the execution of the agreement in 2017, we paid Eisai a one-time, non-refundable and non-creditable payment of $1 million. Pursuant to the license agreement, we are solely responsible for the development of stenoparib during the term of the agreement. The agreement also provides for a joint development committee consisting of six (6) members, three (3) appointed by us and three (3) appointed by Eisai. One of our members of the joint development committee is designated chair of the committee and has the power to break any deadlock in decisions by the committee that must be made by a majority vote with each representative having one (1) vote. The purpose of the committee is to implement and oversee development activities for stenoparib pursuant to the clinical development plan, serves as a forum for exchanging data, information and development strategy.

Development Milestone Payments

Pursuant to the agreement, we have agreed to make milestone payments to Eisai in connection with the development of stenoparib by us or our affiliates, or by a third-party (a "Program Acquirer") that assumes control of the stenoparib development program from us corresponding to: (i) successful completion of a Phase 2 clinical trial; (ii) Upon dosing of the first patient in the first Phase 3 clinical trial; (iii) upon submission of the first NDA with the FDA; (iv) submission of an MAA to the EMA; (v) submission of an NDA to the MHLW in Japan; (vi) upon receipt of authorization by the FDA to market and sell a licensed product; (vii) upon receipt of approval of an MAA by the EMA for a licensed product; and (viii) upon receipt of approval by the MHLW in Japan for a licensed product. If all milestones have been achieved, we may be obligated to pay Eisai up to a maximum of $94 million. In addition, we have agreed to pay Eisai a one-time sales milestone payment in the amount of $50 million the first time our annual sales of licensed product is $1 billion or more.

Royalty Payments

In addition to the milestone payments described above, we have agreed to pay Eisai royalties based on annual incremental sales of product derived from stenoparib in an amount between five percent (5%) and ten percent (10%) of annual sales of between $0 and $100 million, between six percent (6%) and ten percent (10%) of annual sales between $100 million and $250 million, between seven percent (7%) and eleven percent (11%) of annual sales between $250 million and $500 million, and between eleven percent (11%) and fifteen percent (15%) of annual sales in excess of $500 million.

We are obligated to pay royalties under the agreement on a country-by-country and product-by-product basis for a period that commences with the first commercial sale of a product until the later of (i) the expiration of the last to expire valid claim of any licensed patent covering such licensed product in such country; or, (ii) the expiration of regulatory-based exclusivity for such licensed product in such country or (iii) the fifteen (15) year anniversary of the date of first commercial sale of such licensed product in such country. However, the agreement may be sooner terminated without cause by us upon 120 days prior written notice, or upon written notice of a material breach of the agreement by Eisai that is not cured within 90 days (30 days for a payment default). Eisai also has the right to terminate the agreement upon written notice of a material breach of the agreement by us that is not cured within 90 days (30 days for a payment default) or in the event that we file for bankruptcy. By an amendment effective as of August 3, 2021, and executed by Eisai on August 23, 2021, Eisai also has the right to terminate the agreement if we do not complete a Phase 2 clinical trial before December 31, 2022, unless we elect to pay a one million dollar ($1,000,000) extension payment.

Option to Reacquire Rights to Stenoparib

For the period of time commencing with enrollment of the first five (5) patients in a Phase 2 clinical trial pursuant to the clinical development plan and ending ninety (90) days following successful completion of such Phase 2 clinical trial, Eisai has the option to reacquire our licensed rights to develop stenoparib for a purchase price equal to the fair market value of our rights, giving effect to the stage of development of stenoparib that we have completed under the agreement. We commenced a Phase 2 clinical trial in April 2019 and as of the date of this information statement/prospectus, Eisai has not indicated an intention to exercise its repurchase option.

Development, Option and License Agreement with R-Pharm for IXEMPRA®

On March 1, 2019, we entered into an option to in-license the rights to any and all therapeutic and/or diagnostic uses in humans for IXEMPRA® in the European Union (Great Britain but excluding Switzerland and Lichtenstein) (the "Territory") from R-Pharm U.S. Operating, LLC ("R-Pharm"), pursuant to a Development, Option and License Agreement (the "Option"). Upon the execution of the agreement we paid R-Pharm a non-refundable, non-creditable option payment of one hundred thousand dollars ($100,000) and agreed to an anniversary payment of two hundred fifty thousand dollars ($250,000) on or before March 1, 2020, which we have paid. Upon exercise of the option by us, we have agreed to pay R-Pharm an exercise payment of two hundred fifty thousand dollars ($250,000). By an amendment to the agreement dated May 28, 2021, the term of the option will expire on September 1, 2022, if not exercised by us before then. As a condition to the exercise of the Option, we are required to offer R-Pharm a right to re-acquire the licensed rights from us on terms to be mutually agreed upon, including the payment to us of the fair market value of the licensed rights. Pursuant to the Option, we are solely responsible for the development of IXEMPRA® during the term of the Option within the Territory. The agreement also provides for a joint development committee consisting of four (4) members, two (2) appointed by us and two (2) appointed by R-Pharm. Decisions by the committee that must be made by a unanimous consent of the parties, with us having the tie breaking vote on matters involving our DRP Biomarker, patient selection in the mBC clinical trial and the commercialization plan and R-Pharm having the tie breaking vote on all other matters. The purpose of the committee is to implement and oversee development activities for IXEMPRA® pursuant to the clinical development plan, serves as a forum for exchanging data, information and development strategy.

Development Milestone Payments

Pursuant to the agreement, once we have exercised the Option, we have agreed to make milestone payments to R-Pharm in connection with the development of IXEMPRA® by us or our affiliates, or by a third-party (a "Program Acquirer") that assumes control of the IXEMPRA® development program from us corresponding to: (i) upon receipt of regulatory approval for the Product for the treatment of the first indication in the first country in the Territory; and (ii) upon receipt of regulatory approval for the Product for the treatment of each additional indication in the first country in the Territory for each such additional indication. If all milestones have been achieved, and assuming only one additional indication in the second milestone is achieved, we may be obligated to pay R-Pharm up to a maximum of $12.5 million.

Royalty Payments

In addition to the milestone payments described above, once we have exercised the Option, we have agreed to pay R-Pharm royalties based on annual incremental sales of product derived from IXEMPRA® in an amount between five percent (5%) and eight percent (8%) of annual sales of between $0 and $30 million, and between eight percent (8%) and twelve percent (12%) of annual sales over $30 million.

After the Option is exercised, we would be obligated to pay royalties under the agreement on a country-by-country and product-by-product basis for a period that commences with the first commercial sale of a product until the later of (i) the expiration of the last to expire valid claim of any licensed patent covering such licensed product in such country; or, (ii) the expiration of regulatory-based exclusivity for such licensed product in such country or (iii) the seven (7) year anniversary of the date of first commercial sale of such licensed product in such country. However, the agreement may be sooner terminated without cause by us upon 90 days prior written notice, or upon written notice of a material breach of the agreement by R-Pharm that is not cured within 90 days (30 days for a payment default). R-Pharm also has the right to terminate the agreement upon written notice of a material breach of the agreement by us that is not cured within 90 days (30 days for a payment default) or in the event that we file for bankruptcy.

Drug License and Development Agreement for Irofulven

From May 2015 until July 23, 2021, we in-licensed various rights to Irofulven from Lantern Pharma, Inc. pursuant to a drug license and development agreement.

Pursuant to the agreement, we were responsible for the development of Irofulven pursuant to a defined clinical development plan. The agreement also provides for a joint development committee, including representatives from Lantern Pharma and us, to regularly discuss, plan and inform the development of products under the agreement. In 2018, we commenced a DRP®-guided Phase 2 clinical trial of Irofulven in androgen receptor (AR)-targeted and Docetaxel-Pretreated Metastatic Castration-Resistant Prostate Cancer (mCRPC) patients using our putative Irofulven-DRP® companion diagnostic to select and treat patients most likely to respond to the drug (study SMR-365). This trial was not completed and was an open-label, non-randomized, multi-center study in patients with docetaxel and AR-targeted therapy pre-treated mCRPC. Up to 27 mCRPC patients with predicted high probability of response to Irofulven (as determined by the Irofulven-DRP® companion diagnostic) were included. A high likelihood of Irofulven response was defined as a patient having an Irofulven-DRP® score of >80%. This study was suspended in 2019, when we deprioritized Irofulven as a therapeutic candidate in order to devote more of our development resources to our priority therapeutic candidates, and on July 23, 2021, we terminated our drug development agreement for Irofulven and sold our inventory of API, our clinical data and records, and our manufacturing know-how relating to Irofulven to Lantern Pharma, and granted a non-exclusive license to Lantern Pharma to use our putative DRP® companion diagnostic specific for Irofulven. Although we may be entitled to future milestone payments and royalties if Lantern Pharma advances the development of Irofulven with or without our putative DRP® companion diagnostic specific for Irofulven, we will no longer devote any of our development resources to advance this therapeutic candidate.

Asset Purchase Agreement between Allarity Therapeutics A/S and Lantern Pharma, Inc. for Irofulven

On July 23, 2021, we entered into an Asset Purchase Agreement with Lantern Pharma, Inc. relating to our inventory of Irofulven active pharmaceutical ingredients ("API"), our clinical research data relating to Irofulven developed by us during the drug development program under the May 2015 Drug License and Development Agreement for Irofulven (the "Data") and terminated our obligation to further advance the development of Irofulven under the May 2015 agreement. Under the Asset Purchase Agreement, Lantern Pharma agreed to pay us $1 million on closing of the transaction, and additional amounts (i) when the inventory of Irofulven API is recertified with a longer shelf life, (ii) upon the initiation of treatment of the first patient in an investigator-led "compassionate use" ERCC2/3 mutation subgroup study using Irofulven in certain agreed upon investigators; and (iii) upon the initiation of treatment of the second patient within an agreed upon time period after the closing of the transaction in any human clinical trial of Irofulven initiated by Lantern Pharma. In addition to the sale of our inventory of Irofulven API and Data to Lantern Pharma, we also granted Lantern Pharma a non-exclusive, worldwide license to use our putative Irofulven DRP® companion diagnostic to advance the development and commercialization of Irofulven and other Illudins (sesquiterpenes with anti-tumor properties produced by some mushrooms). We have also agreed not to engage in any drug development program for Illudins or any of its analogues or any use thereof for a period of five (5) years.

Milestone Payments

Under the Asset Purchase Agreement, we would also be entitled to receive certain milestone payments relating to our out-licensed putative Irofulven DRP® companion diagnostic upon the occurrence of the following events: (i) upon the first use of our putative Irofulven DRP® companion diagnostic in a clinical trial for Irofulven; and (ii) upon the first regulatory approval of our putative Irofulven DRP® companion diagnostic as a companion diagnostic for use with an approved drug. In addition to the milestone payments relating to our putative Irofulven DRP® companion diagnostic, we would also be entitled to receive certain milestone payments relating to the development and commercialization of Irofulven upon the occurrence of the following events: (i) upon the first filing for regulatory approval for commercialization of Irofulven in the United Kingdom, Germany, France and Italy, or upon the first and second filings for regulatory approval for commercialization of Irofulven in countries located in the European Union that are not Germany, France or Italy; (ii) upon the first filing for regulatory approval for commercialization of Irofulven in the United States; (iii) upon receiving the first regulatory approval for commercialization of Irofulven in the United Kingdom, Germany, France and Italy, or upon the first and second receipts for regulatory approval for commercialization of Irofulven in countries located in the European Union that are not Germany, France or

Italy, (iv) upon receiving the first regulatory approval for commercialization of Irofulven in the United States. If all milestones have been achieved, then we would be entitled to receive up to $16 million in milestone payments under the Asset Purchase Agreement.

Royalty Payments

In addition to the milestone payments described above, Lantern Pharma has agreed to pay us royalties based on annual incremental net sales of product derived from Irofulven, on a country by country basis, in an amount between two percent (2%) and seven percent (7%) of annual sales of between $0 and $50 million, between three percent (3%) and eight percent (8%) of annual sales between $50 million and $150 million, between four percent (4%) and nine percent (9%) of annual sales between $150 million and $300 million, and between five percent (5%) and ten percent (10%) of annual sales in excess of $300 million.

The royalty amounts we are entitled to receive may be subject to reduction in the event of generic competition, patent expiry, or if products are (i) sold in the form of a combination product containing one or more active pharmaceutical ingredients which are not Irofulven or (ii) sold under a bundled or capitated arrangement with one or more products which are not Irofulven or (iii) sold under an arrangement whereby the sale of the product is only available with or conditioned upon the purchase of other products.

License Agreement with 2-BBB Medicines B.V. for 2X-111

On March 27, 2017, we in-licensed the exclusive worldwide rights to the central nervous system ("CNS") and/or cerebrocardiovascular drug application, including the (preventive) treatment of peripheral effects of agents causing CNS disease or symptoms, including cancer, for 2X-111 from 2-BBB Medicines B.V. ("2-BBB") pursuant to a license agreement. Upon execution of the agreement, we paid 2-BBB a one-time, non-refundable, non-creditable payment of $500,000. Pursuant to the agreement, we are solely responsible for the development of 2X-111 during the term of the agreement.

Development and Sales Milestone Payments

Pursuant to the agreement, we have agreed to make milestone payments to 2-BBB in connection with the development of 2X-111 by us or our affiliates, or by a third-party (a "Program Acquirer") that assumes control of the 2X-111 development program from us corresponding to: (i) upon enrollment of the first ten patients required in a Phase 2 clinical trial; (ii) upon the successful completion of a Phase 2 clinical trial; (iii) upon dosing of the first patient in the first Phase 3 clinical trial; (iv) upon submission of the first NDA with the FDA; (v) submission of an MAA to the EMA in the European Union; (vi) upon submission of an NDA in the first of either China or India; (vii) upon receipt of the first authorization by the FDA to market and sell a licensed product; (viii) upon receipt of a MAA for a licensed product in the European Union; and (ix) upon receipt of regulatory approval in the first of either China or India. If all development milestones have been achieved, we may be obligated to pay 2-BBB up to a maximum of $27.75 million which could increase to $55.5 million if 2-BBB successfully expands the field of our license agreement to include all preventative, therapeutic and/or diagnostic uses related to cancer in humans. In addition to the development milestones described above, we have agreed to make a mid-level seven figure one-time payment upon our sales of a licensed product reaching $500,000,000 annually and a low eight figure payment upon the first and second time our sales of a licensed product reaches $1 Billion annual. If all sales milestones have been achieved, we would be obligated to pay 2-BBB up to a maximum of $22.5 million which could increase to $45 million if 2-BBB successfully expands the field of our license agreement to include all preventative, therapeutic and/or diagnostic uses related to cancer in humans.

Royalty Payments

In addition to the milestone payments described above, we have agreed to pay 2-BBB royalties based on annual incremental sales of product derived from 2X-111 in an amount between five percent (5%) and ten percent (10%) of annual sales of between $0 and $100 million, between six percent (6%) and thirteen percent (13%) of annual sales between $100 million and $250 million, and between seven percent (7%) and thirteen percent (13%) of annual sales in excess of $250 million. We are obligated to pay royalties under the agreement on a product-by-product and country-by-country basis, from the period of time commencing on the first commercial sale of any product in such country and expiring upon the latest of (a) the expiration of the last valid claim of a patent within (i) the 2-BBB intellectual property and/or (ii) the joint intellectual property in such country (if, but only if, such joint intellectual

property arose from activities under the clinical development plan) , or (b) the tenth (10th) anniversary of the date of first commercial sale of such product in such country. However, the agreement may be sooner terminated without cause by us upon 120 days prior written notice, or upon written notice of a material breach of the agreement by 2-BBB that is not cured within 90 days. 2-BBB also has the right to terminate the agreement upon written notice of a material breach of the agreement by us that is not cured within 90 days (30 days for a payment default) or in the event that we file for bankruptcy. 2-BBB also has the right to terminate the agreement in the event we challenge a 2-BBB patent and we have the right to terminate the agreement upon 30 days' notice for specified safety reason.

Out-License Agreement with SMERUD

In June of 2020, we out-licensed our secondary LiPlaCis® and 2X-111 programs to Smerud Medical Research International, our long-time CRO partner in Europe, for further Phase 2 clinical development of each program together with its DRP® companion diagnostic. The initiation, by Smerud, of the next Phase 2 clinical trials for these programs is anticipated by early 2022. Smerud will, initially, advance LiPlaCis® for the treatment of metastatic breast cancer (mBC) and advance 2X-111 for the treatment of glioblastoma multiforme (GBM). We will support Smerud in these studies by providing DRP® companion diagnostic analysis for screened patients in each trial.

By an amendment to the license agreement effective as of September 28, 2021, Smerud must secure sufficient funding (whether by investment and/or by grants) for each program by/before December 31, 2021 (or other date as extended by agreement), otherwise either party has the right to terminate the license. Pursuant to the agreement, we will be entitled to regulatory approval milestones, totally approximately $30 million, for the two programs combined, upon the occurrence of the following: (i) mid level seven figure payment upon approval of LiPlaCis® in the U.S.; (ii) mid level seven figure payment upon approval of LiPlaCis® in the European Union; (iii) a lower mid level seven figure payment upon regulatory approval of LiPlaCis® in Japan; (iv) a lower mid level seven figure payment upon regulatory approval of LiPlaCis® in China; (v) mid level seven figure payment upon approval of 2X-111 in the U.S.; (vi) mid level seven figure payment upon approval of 2X-111 in the European Union; and (vii) a lower mid level seven figure payment upon regulatory approval of 2X-111 in China.

In addition to development milestone payments we are entitled to tiered royalties on sales of each program once it/they are approved and on sale during the royalty term which is determined on a product-by-product and country-by-country basis, as the period of time commencing on the first commercial sale of any product in such country and expiring upon the latest of (a) the expiration of the last valid claim of a patent within (i) out intellectual property and/or (ii) the joint intellectual property in such country (if, but only if, such joint intellectual property arose from activities under the clinical development plan defined in the agreement), or (b) the fifteenth (15th) anniversary of the date of first commercial sale of such licensed drug in such country. For LiPlaCis® we will be entitled between seven percent (7%) and twelve percent (12%) of sales up to $250,000,000 and between twelve percent (12%) and seventeen percent (17%) of sales above $250,000,000. For 2X-111, we will be entitled to royalties between ten percent (10%) and fifteen percent (15%) of sales up to $250,000,000 and between twelve percent 12% and eighteen percent (18%) of sales above $250,000,000.

Our agreement with Smerud will continue on a product-by-product and country-by-country basis until the expiration of the applicable royalty term described above. Our agreement with Smerud may be terminated by either party for material breach or non-performance upon ninety (90) days prior written notice, of termination for convenience upon one hundred twenty (120) prior written notice. Either party may also terminate the agreement immediately upon written notice if Smerud fails to obtain funding for the clinical trials by December 31, 2021, subject to an agreement to extend the funding deadline to another date.

Amended and Restated License Agreement with LiPlasome Pharma ApS for LiPlaCis®

In January 2021, we entered into an Amended and Restated License Agreement with LiPlasome Pharma ApS ("LiPlasome") for the perpetual, exclusive, world-wide rights to develop, use and market LiPlaCis® for any indication which superseded all prior license and development agreements between us and LiPlasome. Under the agreement, we agreed to pursue a commercialization event for LiPlaCis® and acknowledging that our out-license agreement with Smerud described above was such an event. We have further agreed to share equally with LiPlasome any proceeds we receive from Smerud under our out-license agreement with Smerud, In the event that the out-license agreement with Smerud is terminated, we have agreed to pursue another commercialization event. We have no other payment obligations with LiPlasome under the agreement.

The agreement may be terminated by either party upon the material breach of the agreement by the other party if such breach is not cured within 30 days. LiPlasome may terminate the agreement in the event our out-license agreement with Smerud is terminated and we have not entered into another commercialization event within six months.

Manufacturing and Supply

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of our investigational products for preclinical and clinical testing, as well as for commercial manufacture if any of our investigational products obtain marketing approval. We also rely, and expect to continue to rely, on third parties to package, label, store and distribute our investigational products, as well as for our commercial products if marketing approval is obtained. We believe that this strategy allows us to maintain a more efficient infrastructure by eliminating the need for us to invest in our own manufacturing facilities, equipment and personnel while also enabling us to focus our expertise and resources on the development of our investigational products.

To date, we have obtained APIs and drug product for our investigational products from either the original drug owner/licensee or from single-source third-party clinical manufacturing organizations (CMOs). We are in the process of developing our supply chain for each of our investigational products and intend to put in place framework agreements under which CMOs will generally provide us with necessary quantities of API and drug product on a project-by-project basis based on our development needs, and which agreements will provide us with intellectual property rights necessary to conduct the business. We may use a different CMO for each investigational product and will consider further diversification of drug product and supply organizations as circumstances warrant. Overall, as we advance our investigational products through development, we will start by seeking multiple sources for raw materials and address other potential points in concern over time.

Commercialization

We intend to retain significant development and commercial rights to our investigational products and, if marketing approval is obtained, to commercialize our investigational products on our own, or potentially with a partner, in the U.S. and other regions, either globally or on a region-by-region basis. We do not intend to build the necessary infrastructure and sales, marketing and commercial product distribution capabilities for the U.S., and potentially other regions, following further advancement of our investigational products. We instead prefer to build appropriate partnerships with marketing, sales, and distribution partners to effect launch and market penetration for each of our therapeutic programs. However, as we near approval and commercial launch of each program, we will assess the suitability of marketing and sales partners and reserve the right to potentially develop and implement our own infrastructure to support the commercial success of our programs. Clinical data, the size of the addressable patient population and the size of the commercial infrastructure and manufacturing needs and economics related to the foregoing may all influence or alter our commercialization plans.

Competition

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, development experience and scientific knowledge provide us with competitive advantages, we face potential competition from many different sources, including large pharmaceutical and biotechnology companies, academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for the research, development, manufacturing and commercialization of cancer therapies. Any investigational products that we successfully develop and commercialize will compete with new therapies that may become available in the future. Similarly, our core DRP® platform technology, and any drug-specific DRP® companion diagnostics that we develop and commercialize, will compete with new companion diagnostic technologies that may become available in the future.

We compete in the segments of the pharmaceutical, biotechnology and other related markets that develop small molecules and drug conjugates, together with companion diagnostics, as treatments for cancer patients. There are many other companies that have commercialized and/or are developing such treatments for cancer including large pharmaceutical and biotechnology companies, such as AstraZeneca plc, Bristol-Myers Squibb Company ("BMS"), Merck, Pfizer in partnership with Merck KGaA, Regeneron Pharmaceuticals, Inc. in partnership with Sanofi

Genzyme ("Sanofi") and Roche. There are also many other companies that are developing, have developed, and/or have commercialized patient-selective, companion diagnostic technologies/approaches for cancer patients, such as Foundation Medicine, Inc., Kura Oncology, Inc., and Lantern Pharma, Inc.

For our Dovitinib program, we are aware of a number of companies that are currently marketing approved pan-TKIs and/or developing pan-TKIs that are or may be competitive to our drug, such as Big Pharma companies Eisai, Bayer, Pfizer, Novartis, and smaller pharmaceutical players Exelixis, Mirati Therapeutics, and Aveo Oncology. To our knowledge, there is currently no approved or in development pan-TKI, for the treatment of RCC or other indications, that has an identical therapeutic profile to dovitinib, with or without its Dovitinib-DRP® companion diagnostic.

For our Stenoparib program, we are aware of a number of companies that are currently marketing approved PARP inhibitors and/or developing PARP inhibitors that are or may be competitive to our drug, such as Big Pharma companies AstraZeneca, BMS, Novartis, and GlaxoSmithKline (GSK), and smaller pharmaceutical players BeiGene and Clovis Oncology. To our knowledge, there is currently no approved or in development PARP inhibitor, for the treatment of ovarian cancer or other indications, that has an identical therapeutic profile to stenoparib, with or without its Stenoparib-DRP® companion diagnostic.

For our IXEMPRA® program, we are aware of a number of companies that are currently marketing approved microtubule inhibitors and/or developing microtubule inhibitors that are or may be competitive to our drug, such as Big Pharma companies Eisai and Sanofi, and smaller pharmaceutical players like Celgene and Veru Pharma. To our knowledge, there is currently no approved or in development microtubule inhibitor, for the treatment of metastatic breast cancer (mBC) or other indications, that has an identical therapeutic profile to IXEMPRA®, with or without its IXEMPRA®-DRP® companion diagnostic.

For our LiPlaCis® program, we are aware of a number of companies that are currently or have been developing liposomal formulations of cisplatin that are or may be competitive to our drug, such as Regulon, Inc. To our knowledge, there is currently no approved liposomal formulation of cisplatin. Furthermore, to our knowledge, there is no in development liposomal formulation of cisplatin, for the treatment of mBC or other indications, that has an identical therapeutic profile to LiPlaCis®, with our without its Cisplatin-DRP® companion diagnostic.

For our 2X-111 program, we are aware of a number of companies that are currently marketing approved liposomal formulations of doxorubicin and/or developing liposomal formulations of doxorubicin that are or may be competitive to our drug, such as Janssen Pharmaceuticals, Baxter, and Teva, and Zydus Cadilla. To our knowledge, there is currently no approved or in development Glutathione-modified liposomal formulation of doxorubicin, for the treatment of GBM or other indications, that has an identical therapeutic profile to 2X-111, with our without its Doxorubicin-DRP® companion diagnostic.

For our Irofulven-DRP® companion diagnostic that we have out-licensed to Lantern Pharma, we are aware of a number of companies that are currently marketing approved DNA damaging chemotherapeutics and/or developing DNA damaging chemotherapeutics that are or may be competitive to Irofulven. Many approved chemotherapeutics are now generic, and sold by companies such as Teva Pharmaceuticals and Baxter. Some smaller pharmaceutical companies, such as Alkido Pharma and Lantern Pharma, are attempting to develop novel chemotherapeutics. Lantern Pharma, for example, is pre-clinically attempting to develop novel analogues of Irofulven. To our knowledge, there is currently no approved or in development DNA damaging agent, for the treatment of mCRPC or other indications, that has an identical therapeutic profile to Irofulven, with our without its Irofulven-DRP® companion diagnostic.

For our core DRP® platform technology (and its resulting drug-specific DRP® companion diagnostics), we are aware of a number of companies that are currently marketing approved companion diagnostic platforms, or are attempting to develop such platforms, that are or may be competitive to (although distinct from) our DRP® platform, such as Foundation Medicine and Lantern Pharma. To our knowledge, there is currently no approved or developmental diagnostic technology or platform — for the development of drug-specific companion diagnostics to guide selection and treatment of cancer patients most likely to respond to a given drug — that is as broadly applicable, robust, and highly validated as our DRP® platform.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Mergers

and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and enrolling subjects for our clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

We could see a reduction or elimination of our commercial opportunity if our competitors develop and commercialize therapeutic products that are safer or more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we or our collaborators may develop. Similarly, it is possible that our commercial opportunity may be reduced by the development and commercialization of competing companion diagnostic products that are superior to our DRP® companion diagnostics. Our competitors also may obtain FDA or foreign regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. The key competitive factors affecting the success of all of our investigational products, if approved, are likely to be their degree of anti-cancer activity, tolerability profile, convenience and price, the effectiveness of companion diagnostics (if required), the level of biosimilar or generic competition and the availability of reimbursement from government and other third-party payors. All of these factors will be impacted by the value and superiority of our DRP® companion diagnostics over any competing companion diagnostic approaches that currently exist or evolve in the oncology market.

Government Regulation

Government authorities in the U.S. at the federal, state and local level and in other countries regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug and biological products. Generally, before a new drug can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority. Similar regulations and approvals exist in the EU and other major oncology therapeutic markets.

U.S. Drug Development

In the U.S., the FDA regulates drugs under the Food, Drug, and Cosmetic Act ("FDCA"). Similarly, in the European Union (EU), the European Medicines Agency (EMA) regulates the clinical trial, approval, and marketing of drugs. Drugs also are subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. or EU requirements at any time during the product development process, approval process or post-market may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's or EMA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Our therapeutic candidates are considered small molecule drugs and must be approved by the FDA through the new drug application ("NDA"), and similarly by the EMA under an equivalent process, before they may be legally marketed in the U.S. The process generally involves the following:

- completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with GLP;
- submission to the FDA of an Investigational New Drug (IND) application, which must become approved and effective before human clinical trials may begin;
- submission to the FDA of an Investigational Device Exemption (IDE) application, which must become approved and effective before a drug-specific DRP® companion diagnostic can be used in human clinical trials;

- approval by an independent Institutional Review Board (IRB) or ethics committee at each clinical trial site before each trial may be initiated;
- performance of adequate and well controlled human clinical trials in accordance with applicable IND regulations, GCP requirements and other clinical trial-related protocols and regulations to establish substantial evidence of the safety and efficacy of the investigational product for each proposed indication;
- submission to the FDA of a New Drug Application (NDA) after completion of all pivotal trials;
- submission to the FDA of a Pre-Market Approval (PMA) application to allow use of a DRP® companion diagnostic on the market together with its approved drug;
- determination by the FDA within 60 days of its receipt of an NDA to accept the filing for substantive review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the drug will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- potential FDA audit of the pre-clinical study and/or clinical trial sites that generated the data in support of the NDA filing;
- FDA review and approval of the NDA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the drug in the U.S.; and
- compliance with any post-approval requirements, including the potential requirement to implement a REMS and the potential requirement to conduct post-approval studies.

The data required to support an NDA are generated in two distinct developmental stages: pre-clinical and clinical. The pre-clinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for any current and future therapeutic candidates will be granted on a timely basis, or at all, whether in the U.S, EU, or other region/country.

Pre-Clinical Studies and IND/IDE

The preclinical developmental stage generally involves laboratory evaluations of drug chemistry, formulation and stability, as well as studies to evaluate toxicity in animals, which support subsequent clinical testing. The sponsor must submit the results of the preclinical studies, together with manufacturing information, retrospective data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before human clinical trials may begin. Similarly, and IDE is a request for authorization from the FDA to use a diagnostic — in our case a DRP® companion diagnostic — to screen, select, and treat specific patients in a human clinical trial.

Pre-clinical studies include laboratory evaluation of product chemistry and formulation, as well as *in vitro* and animal studies to assess the potential for adverse events and in some cases to establish a rationale for therapeutic use. The conduct of pre-clinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies. An IND sponsor must submit the results of the pre-clinical tests, together with manufacturing information, retrospective data, any available clinical data or literature and plans for clinical studies, among other things, to the FDA as part of an IND. Similarly, an IDE sponsor must submit information about the prior development and validation of the diagnostic, including results of the pre-clinical tests, together with manufacturing information, retrospective data, any available clinical data or literature and plans for clinical studies, among other things, to the FDA as part of an IDE. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence. Similarly, submission of an IDE for a DRP® companion diagnostic may not result in the FDA allowing use of such DRP® in an approved clinical trial.

Clinical Trials

The clinical-stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB must also approve the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Clinical development in other major oncology markets, such as the EU, is subject to similar requirements and regulations.

A sponsor who wishes to conduct a clinical trial outside of the U.S. may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of an NDA. The FDA will generally accept a well-designed and well conducted foreign clinical trial not conducted under an IND if the clinical trial is conducted in compliance with GCP and. the FDA is able to validate the data through an onsite inspection, if deemed necessary. An NDA based solely on foreign clinical data meeting U.S. criteria for marketing approval may be approved if (1) the foreign data are applicable to the U.S. population and U.S. medical practice, (2) the studies have been performed by clinical investigators of recognized competence and (3) the FDA is able to validate the data through an onsite inspection or other appropriate means, if deemed necessary.

Clinical trials in the U.S. generally are conducted in three sequential phases, known as Phase 1, Phase 2 and Phase 3, and may overlap.

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the therapeutic candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, tolerability and safety of the drug.

- Phase 2 clinical trials involve studies in disease-affected patients to determine the dose and dosing schedule required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, possible adverse effects and safety risks are identified, and a preliminary evaluation of efficacy is conducted.

- Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product approval. These trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, are conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA. Sponsor is also responsible for submitting written IND safety reports, including reports of serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the drug, findings from animal or *in vitro* testing that suggest a significant risk for human subjects, and any clinically significant increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Clinical development in other major oncology markets, such as the EU, is subject to similar requirements and regulations.

Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated check-points based on access to certain data from the trial.

Concurrent with clinical trials, companies may complete additional animal safety studies and also must develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process, as performed by the manufacturing facility, must be capable of consistently producing quality batches of our therapeutic candidates. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that our therapeutic candidates do not undergo unacceptable deterioration over their labeled shelf life.

We may be required to develop and implement additional clinical trial policies and procedures designed to help protect subjects from the COVID-19 virus. For example, in March 2020, the FDA issued a guidance, which the FDA subsequently updated, on conducting clinical trials during the pandemic, which describes a number of considerations for sponsors of clinical trials impacted by the pandemic, including the requirement to include in the clinical trial report contingency measures implemented to manage the clinical trial, and any disruption of the clinical trial as a result of the COVID-19 pandemic; a list of all subjects affected by the COVID-19-pandemic related study disruption by unique subject identifier and by investigational site and a description of how the individual's participation was altered; and analyses and corresponding discussions that address the impact of implemented contingency measures (e.g., participant discontinuation from investigational product and/or study, alternative procedures used to collect critical safety and/or efficacy data) on the safety and efficacy results reported for the clinical trial. In June 2020, FDA also issued a guidance on good manufacturing practice considerations for responding to COVID-19 infection in employees in drug products manufacturing, including recommendations for manufacturing controls to prevent contamination of drugs. Clinical development in other major oncology markets, such as the EU, may be subject to similar requirements and regulations in view of the COVID-19 pandemic.

NDA Review Process

Following completion of the clinical trials, data is analyzed to assess whether the investigational product is safe and effective for the proposed indicated use or uses. The results of pre-clinical studies and clinical trials are then submitted to the FDA as part of an NDA, along with proposed labeling, chemistry and manufacturing information to ensure product quality and other relevant data. In short, the NDA is a request for approval to market the drug in the U.S. for one or more specified indications and must contain proof of safety and efficacy for a drug. Concomitantly, a PMA is submitted to the FDA as part of NDA approval that is conditioned on use of a companion diagnostic. In short, the PMA is a request for approval to market the companion diagnostic in the U.S., together with and required for prescription of the drug, for one or more specified indications and must contain clinical evidence of safety and efficacy and sufficient validation of the companion diagnostic used to select patients for treatment with the drug.

The NDA application must include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of FDA. FDA approval of an NDA must be obtained before a drug may be legally marketed in the U.S. Similarly, FDA approval of a PMA must be obtained before a DRP® companion diagnostic may be legally marketed in the U.S.

Under the Prescription Drug User Fee Act ("PDUFA"), as amended, each NDA must be accompanied by a user fee. FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual program fee for each marketed human drug. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA reviews all submitted NDAs before it accepts them for filing and may request additional information rather than accepting the NDA for filing. The FDA must make a decision on accepting an NDA for filing within 60 days of receipt. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has 10 months, from the filing date, in which to complete its initial review of a new molecular-entity NDA and respond to the applicant, and six months from the filing date of a new molecular-entity NDA designated for priority review. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs, and the review process is often extended by FDA requests for additional information or clarification. Similarly, the FDA must decide on accepting a PMA for review within 45 days of receipt. After acceptance, the FDA will begin substantive review of the PMA. During the review process, FDA will notify the PMA applicant via major/minor deficiency letters of any information needed by FDA to complete the review of the application. FDA may refer the PMA to an outside panel of experts (advisory committee). In general, all PMAs for the first-of-a-kind device are taken before the appropriate advisory panel for review and recommendation.

Before approving an NDA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP requirements. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA also may audit data from clinical trials to ensure compliance with GCP requirements. Additionally, the FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by recommendations of an advisory committee, but it considers such recommendations when making decisions on approval. The FDA likely will reanalyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. After the FDA evaluates an NDA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A Complete Response Letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The Complete Response Letter may require additional clinical data, additional pivotal Phase 3 clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, preclinical studies and/or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data.

Similarly, an IDE application is considered approved 30 days after it has been received by the FDA, unless the FDA otherwise informs the sponsor via email prior to 30 calendar days from the date of receipt, that the IDE is approved, approved with conditions, or disapproved. In cases of disapproval, a sponsor has the opportunity to respond to the deficiencies

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S., or more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making the product available in the U.S. for this type of disease or condition will be recovered from sales of the product.

Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years from

the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety or providing a major contribution to patient care or in instances of drug supply issues. However, competitors may receive approval of either a different product for the same indication or the same product for a different indication but that could be used off-label in the orphan indication. Orphan drug exclusivity also could block the approval of one of our therapeutic candidates for seven years if a competitor obtains approval before we do for the same product, as defined by the FDA, for the same indication we are seeking approval, or if a therapeutic candidate is determined to be contained within the scope of the competitor's product for the same indication. If one of our therapeutic candidates designated as an orphan drug receives marketing approval for an indication broader than that which is designated, it may not be entitled to orphan drug exclusivity. Orphan drug status in the European Union (EU) has similar, but not identical, requirements and benefits.

Expedited Development and Review Programs

The FDA has a fast track program that is intended to expedite or facilitate the process for reviewing new drugs that meet certain criteria. Specifically, new drugs are eligible for fast track designation if they are intended to treat a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to both the product and the specific indication for which it is being studied. The sponsor can request the FDA to designate the product for fast track status any time before receiving NDA approval, but ideally no later than the pre-NDA meeting with the FDA.

Any product submitted to the FDA for marketing, including under a fast track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it treats a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies.

A product may also be eligible for accelerated approval, if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality ("IMM"), which is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. FDA may withdraw drug approval or require changes to the labeled indication of the drug if confirmatory post-market trials fail to verify clinical benefit or do not demonstrate sufficient clinical benefit to justify the risks associated with the drug. If the FDA concludes that a drug shown to be effective can be safely used only if distribution or use is restricted, it may require such post-marketing restrictions as it deems necessary to assure safe use of the product.

Additionally, a drug may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints. The benefits of breakthrough therapy designation include the same benefits as fast track designation, plus intensive guidance from the FDA to ensure an efficient drug development program. Fast track designation, priority review, accelerated approval and breakthrough therapy designation do not change the standards for approval, but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Post-Approval Requirements

Following approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping requirements, requirements to report adverse events and comply with promotion and advertising requirements, which include restrictions on promoting drugs for unapproved uses or patient populations, known as "off-label promotion," and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such uses. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Further, if there are any modifications to the drug, including

changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA or NDA supplement, which may require the development of additional data or preclinical studies and clinical trials.

The FDA may also place other conditions on approvals including the requirement for REMS, to assure the safe use of the product. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market, or product recalls;
- fines, warning letters, or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications;
- suspension or revocation of product approvals;
- product seizure or detention;
- refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Marketing and promotion of approved drugs in other major oncology markets, such as the EU, are subject to similar requirements and regulations.

Other U.S. Regulatory Matters

Pharmaceutical manufacturers are subject to various healthcare laws, regulation, and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Our conduct, including those of our employees, as well as our business operations and relationships with third parties, including current and future arrangements with healthcare providers, third-party payors, customers, and others may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, which may constrain the business or financial arrangements and relationships through which we research, as well as, sell, market, and distribute any products for which we obtain marketing approval. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- The federal Anti-Kickback Statute, which makes it illegal for any person or entity, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Moreover, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act.

- The federal false claims, including the civil False Claims Act that can be enforced by private citizens through civil whistleblower or *qui tam* actions, and civil monetary penalties law prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government.
- HIPAA prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters.
- HIPAA, as amended by HITECH, and their implementing regulations also impose obligations on covered entities such as health insurance plans, healthcare clearinghouses, and certain healthcare providers and their respective business associates and their covered subcontractors, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.
- The federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to CMS information regarding certain payments and other transfers of value to physicians, as defined by such law, and teaching hospitals as well as information regarding ownership and investment interests held by physicians and their immediate family members; additionally, the Substance Use-Disorder Prevention that Promoted Opioid Recovery and Treatment for Patients and Communities Act, under the provision titled "Fighting the Opioid Epidemic with Sunshine," in part, extends the reporting and transparency requirements for physicians under the Physician Payments Sunshine Act to physician assistants, nurse practitioners, and other mid-level practitioners, with reporting requirements going into effect in 2022 for payments made, or ownership and investment interests held, in 2021.
- Analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, state laws that require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state and local laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and require the registration of their sales representatives, state laws that require biotechnology companies to report information on the pricing of certain drug products, and state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Pricing and rebate programs must also comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the Affordable Care Act. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws. In addition, the distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act as well as other applicable consumer safety requirements.

The failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in significant civil, criminal and administrative penalties, including damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings, injunctions, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals or refusal to allow a firm to enter into supply contracts, including government contracts.

Marketing, promotion, and sale of approved drugs in other major oncology markets, such as the EU, are subject to similar requirements and regulations. For example, in the EU, safeguarding the privacy, security and transmission of individually identifiable health information is subject to the General Data Protection Regulation (GDPR) and laws, which are widely considered to be the most stringent in the world.

U.S. Patent-Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of any future therapeutic candidates, some of our U.S. patents, if issued, may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits restoration of the patent term of up to five years as compensation for patent term lost during product development and FDA regulatory review process. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent-term restoration period is generally one-half the time between the effective date of an IND or the issue date of the patent, whichever is later, and the submission date of an NDA plus the time between the submission date of an NDA or the issue date of the patent, whichever is later, and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA.

Market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the U.S. to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application ("ANDA"), or a 505(b)(2) NDA submitted by another company for a generic version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness or generate such data themselves.

European Union Drug Development

Similar to the United States, the various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls. Although the EU Clinical Trials Directive 2001/20/EC has sought to harmonize the EU clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the EU, the EU Member States have transposed and applied the provisions of the Directive differently. This has led to significant variations in the member state regimes. Under the current regime, before a clinical trial can be initiated, it must be approved in each of the EU countries where the trial is to be conducted by two distinct bodies: the National Competent Authority ("NCA"), and one or more Ethics Committees ("ECs"). Under the current regime all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the Member State where they occurred.

The EU clinical trials legislation currently is undergoing a transition process mainly aimed at harmonizing and streamlining clinical-trial authorization, simplifying adverse-event reporting procedures, improving the supervision of clinical trials and increasing their transparency. Recently enacted Clinical Trials Regulation EU No 536/2014 ensures that the rules for conducting clinical trials in the EU will be identical. In the meantime, Clinical Trials Directive 2001/20/EC continues to govern all clinical trials performed in the EU.

European Union Drug Review and Approval

In the European Economic Area ("EEA"), which comprises the 28 Member States of the European Union and three European Free Trade Association States (Norway, Iceland and Liechtenstein), medicinal products can only be commercialized after obtaining a Marketing Authorization ("MA"). There are two types of MAs.

- The Community MA is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use, of the EMA, and is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced-therapy medicines such as gene-therapy, somatic cell-therapy or tissue-engineered medicines and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.

- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member States through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure. Under the Decentralized Procedure an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member State ("RMS"). The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics ("SOPC"), and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Member States Concerned) for their approval. If the Member States Concerned raise no objections, based on a potential serious risk to public health, to the assessment, SOPC, labeling or packaging proposed by the RMS, the product is subsequently granted a national MA in all the Member States (i.e., in the RMS and the Member States Concerned).

Under the above-described procedures, before granting the MA, EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy. Similar to the U.S. patent term-restoration, Supplementary Protection Certificates ("SPCs") serve as an extension to a patent right in Europe for up to five years. SPCs apply to specific pharmaceutical products to offset the loss of patent protection due to the lengthy testing and clinical trials these products require prior to obtaining regulatory marketing approval.

Coverage and Reimbursement

Sales of our therapeutic products and DRP® companion diagnostics, if approved, will depend, in part, on the extent to which our products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the U.S., for example, principal decisions about reimbursement for new products are typically made by CMS. CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. However, no uniform policy of coverage and reimbursement for drug products exists. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of our products will be made on a payor-by-payor basis.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical therapeutic candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific therapeutic candidates on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. We may need to conduct expensive pharmacoeconomic studies to demonstrate the medical necessity and cost effectiveness of our products. As

a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. Additionally, coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Unlike Medicare Part A and B, Part D coverage is not standardized. While all Medicare drug plans must give at least a standard level of coverage set by Medicare, Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan likely will be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private third-party payors often follow Medicare coverage policy and payment limitations in setting their own payment rates.

In addition, where a drug product requires a companion diagnostic (in our case, a DRP® companion diagnostic), then companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics. In general, insurance payors will cover and reimburse a companion diagnostic where sufficient clinical proof is provided to support that use of the companion diagnostic improves healthcare outcomes and/or reduces healthcare expenses associated with a given drug.

In addition, in most foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the U.S. and generally prices tend to be significantly lower.

Healthcare Reform

The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price-controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. For example, the Affordable Care Act substantially changed the way healthcare is financed by both the government and private insurers, and continues to significantly impact the U.S. pharmaceutical industry. The Affordable Care Act contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal healthcare programs. The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the HHS Secretary as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. The Affordable Care Act made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs from 15.1% of average manufacturer price ("AMP"), to 23.1% of AMP and adding a new rebate calculation for "line extensions" (i.e., new formulations,

such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The Affordable Care Act also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by enlarging the population potentially eligible for Medicaid drug benefits. Additionally, for a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer.

There remain judicial and Congressional challenges to certain aspects of the Affordable Care Act, as well as efforts by the administration to repeal or replace certain aspects of the Affordable Care Act. Since January 2017, there have been several executive orders and other directives designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the Affordable Care Act have passed. In 2017, the Tax Act repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the Affordable Care Act's mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. The Bipartisan Budget Act of 2018, among other things, amended the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare Part D drug plans. In December 2018, CMS published a new final rule permitting further collections and payments to and from certain ACA-qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. In April 2020, the U.S. Supreme Court reversed a federal circuit decision that previously upheld Congress' denial of $12.0 billion in "risk corridor" funding. In December 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, in December 2019, the U.S. Court of Appeals for the Fifth Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. On June 17, 2021, the U.S. Supreme Court reversed the decision of the Fifth Circuit holding that the state plaintiff's lacked standing to challenge the individual mandate under Article III, Section 2 of the U.S. Constitution. It is unclear how future litigation and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act and our business. We will continue to evaluate the effect that the Affordable Care Act and its possible repeal and replacement has on our business. Complying with any new legislation, resulting in a material adverse effect on our business.

Other legislative changes have been proposed and adopted in the U.S. since the Affordable Care Act was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2030 unless additional congressional action is taken. The CARES Act, which was signed into law in March 2020, and designed to provide financial support and resources to individuals and businesses affected by COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020, through December 31, 2020, and extended the sequester by one year, through 2030, in order to offset the added expense of the 2020 suspension. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and accordingly, our financial operations.

Additionally, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drug products. For example, at the federal level, the administration's budget proposals for fiscal year 2021 includes a $135.0 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the administration sent "principles" for drug pricing to Congress, calling for

legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Additionally, the administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. Although a number of these and other measures may require additional authorization to become effective, Congress and the administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. For example, on July 24, 2020, the administration announced four executive orders to lower drug prices, including allowing importation of certain drugs, changing how drug rebates are negotiated by middlemen, like pharmacy benefit managers, and directing such rebates to be passed to patients as point-of-sale discounts, and requiring Medicare to pay certain Part B drugs at the lowest price available in economically comparable countries (the details of which were released on September 13, 2020 and also expanded the policy to cover certain Part D drugs). The president has delayed the effective date of the international drug pricing order, pending discussion with major drug companies. How these executive orders will be implemented and their impact on the industry remain uncertain. Additionally, the FDA recently released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. It is possible that additional governmental action is taken in response to the ongoing COVID-19 pandemic, which may impact our business. We are unable to predict the future course of federal or state healthcare legislation in the U.S. directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. These and any further changes in the law or regulatory framework that reduce our revenue or increase our costs could also have a material and adverse effect on our business, financial condition and results of operations.

Facilities

Our principal executive office is located in Cambridge, MA USA., where we lease at-will, month-to-month share space in a technology park, where we are not bound by any lease. This office is sufficient to support our U.S.-based executive team members, all of whom are based on the East Coast of the U.S., including our CEO, CMO, CFO, and SVP of Corporate Development. Our principal laboratory and R&D facility is located in Hoersholm, Denmark (just north of Copenhagen), where we have a modest space in a technology park, with a facility lease currently in force until January 31, 2023. We believe that these existing facilities will be adequate for our current needs and that suitable additional or alternative space will be available in the future on commercially reasonable terms, if required.

Human Capital

As of June 30, 2021, we had 13 employees, all of whom were full-time and most of which were engaged in research and development activities. Of our employees, the majority are located in Hoersholm, Denmark. Among our executive management team members, one is located near Boston, MA USA, two are located near Philadelphia, PA USA, and one is located near New York City, NY USA. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

We recognize that attracting, motivating and retaining talent at all levels is vital to our continued success. Our employees are a significant asset and we aim to create an environment that is equitable, inclusive and representative in which our employees can grow and advance their careers, with the overall goal of developing, expanding and retaining our workforce to support our current pipeline and future business goals. By focusing on employee retention and engagement, we also improve our ability to support our clinical-stage platform, business and operations, and also protect the long-term interests of our securityholders. Our success also depends on our ability to attract, engage and retain a diverse group of employees. Our efforts to recruit and retain a diverse and passionate workforce include providing competitive compensation and benefits packages and ensuring we listen to our employees.

We value agility, passion and teamwork, and are building a diverse environment where our employees can thrive and one that inspires exceptional contributions and professional and personal development in order to achieve our mission to significantly change the practice of oncology. Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors

and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives. We are committed to providing a competitive and comprehensive benefits package to our employees. Our benefits package provides a balance of protection along with the flexibility to meet the individual health and wellness needs of our employees.

We plan to continue to develop our efforts related to attracting, retaining and motivating our workforce as we grow and develop and hire more employees.

Legal Proceedings

From time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not currently a party to any material legal proceedings or any threatened legal proceedings. Regardless of outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

INFORMATION ABOUT ALLARITY DELAWARE AND ALLARITY ACQUISITION SUB

Allarity Delaware is a Delaware corporation and a directly wholly owned subsidiary of Allarity A/S, which was formed on April 6, 2021 for the purpose of effecting a reorganization with Allarity A/S that is described in this information statement/prospectus as a Recapitalization Share Exchange. Allarity Delaware does not own any material assets or operate any business. Allarity Acquisition Subsidiary, Inc. ("Acquisition Sub") is a Delaware corporation and a directly wholly owned subsidiary of Allarity Delaware formed on June 24, 2021, for the purpose of effecting the Recapitalization Share Exchange that is described in this information prospectus. Acquisition Sub does not own any material assets or operation any business. After the Recapitalization Share Exchange, substantially all of the assets and liabilities of Allarity A/S will be transferred to Acquisition Sub in exchange for the voting common stock of Allarity Delaware which will be distributed to the Shareholders of Allarity A/S either by an exchange offer or by extraordinary dividend and then Allarity A/S will liquidate and dissolve.

MANAGEMENT OF ALLARITY A/S AND ALLARITY DELAWARE

MANAGEMENT OF ALLARITY A/S

Directors and Executive Officers

The below lists Allarity A/S's current officers and directors, as well as their respective ages as of December 31, 2020. Upon consummation of the Reorganization Share Exchange, the following directors and officers will continue their respective positions.

Name	Age	Title
Steve R. Carchedi	59	Chief Executive Officer and Director
Jens E. Knudsen	53	Chief Financial Officer
James G. Cullem	52	Senior Vice President, Corporate Development
Steen Knudsen	59	Chief Scientific Officer
Marie Foegh	78	Chief Medical Officer
Thomas H. Jensen	42	Senior Vice President, Information Technology
Duncan Moore	61	Chairman
Søren G. Jensen	58	Director
Gail Maderis	63	Director

Steve R. Carchedi has been our Chief Executive Officer and a director since September 2019. Mr. Carchedi brings more than 30 years of commercial industry experience focused in oncology from several leading multinational pharmaceutical biotech companies. Mr. Carchedi was previously President & Chief Executive Officer and member of the board of directors of Apexian Pharmaceuticals, an early stage oncology discovery and development company focused in novel targets to treat cancer from 2016 to 2019. He also served as Chief Executive Officer and member of the board of directors of Raphael Pharmaceuticals (formerly Cornerstone Pharmaceuticals), an oncology company focused in cancer metabolism, from 2014 to 2016. From 2012 to 2013, Mr. Carchedi also served as the Senior Vice President and President, Commercial Operations (North America) for Mallinckrodt Pharmaceuticals and led the company's listing on NYSE. In addition, Mr. Carchedi was the Chief Marketing Officer at General Electric from 2010 to 2012, the Franchise Vice President for Sales and Marketing at Johnson & Johnson from 2005 to 2008, a Director of the Oncology Product Group-Global Oncology Franchise Leader at Eli Lilly & Company from 1998 to 2003, and a Director of Marketing Strategy, Business Development, and Product Planning at Bristol Myers Squibb from 1989 to 1998. Mr. Carchedi also currently serves on the Board of Directors of Drummond Scientific Company, a privately held global manufacturer and distributor of precision laboratory equipment that serves the pharmaceutical and laboratory industries and previously served on the board of directors of Sunesis Pharmaceuticals 2013 to 2021 and Bionumerik Pharmaceuticals from 2012 to 2017. In addition to his executive experience, Mr. Carchedi was Co-Chair of the BioNJ Personalized Medicine & Diagnostics Committee Council (CMOC) from 2010 to 2012, the Ontario Institute of Cancer Research Commercial Committee (OICR) from 2007 to 2008, and the Pharmaceutical Industry Board of the American Pediatric Family Foundation from 2006 to 2008. Mr. Carchedi received a B.S. in Marketing from West Chester University and an MBA in Marketing from Drexel University. Mr. Carchedi is well qualified to serve as our director because of his experience serving on the board of directors and executive experience as CEO with public and private companies in the biotechnology sector and over 30 years of commercial industry experience.

Jens E. Knudsen has been our Chief Financial Officer since November 2020. Mr. Knudsen has over 30 years of experience leading financial organizations from previous positions as a Vice President of Finance and Controller in numerous public and private companies, including in the life sciences sector. Before joining Allarity in November 2020, Mr. Knudsen served as Vice President of Finance & Operations at Metabo Corporation from June 2012 to September 2020. Prior to that, he served as Controller at multiple companies, including Eurand Pharmaceuticals, Inc. from April 2008 to June 2012, Beijing Med-Pharm Corporation from June 2005 to April 2008, and Eximias Pharmaceutical Corporation from May 2004 to June 2005. Mr. Knudsen is a member of the American Institute of Certified Public Accountants and the Pennsylvania Institute of Certified Public Accountants. He received his Bachelor degree in Economic and Business from the Copenhagen Business School, is a Certified Public Accountant (CPA) and holds a Master degree in Business Administration from Philadelphia University.

James G. Cullem has been our Senior Vice President, Corporate Development since October 2019. Mr. Cullem is an experienced biotechnology executive and previously served as our Vice President, Corporate Development from August 2014 to September 2019. He brings 20+ years of diverse experience in life sciences organizational management, business development & licensing, intellectual property & technology transfer/commercialization, partnership creation/management, and strategic planning as a member of executive teams. During his tenure, Mr. Cullem has been responsible for the identification and acquisition of most of our lead clinical oncology assets, including big pharma therapeutics dovitinib (from Novartis) and stenoparib (from Eisai). He leads the company's business development discussions as well as clinical program out-licensing and partnership negotiations, both in the U.S. and worldwide. Mr. Cullem has experience in designing and negotiating a broad span of life science deals, has founded and led several early-stage biotech companies, and is a catalyst for businesses taking the next step in the fields of precision medicine and predictive/companion diagnostics, novel drug targets, proteomics and genomics, and clinical-stage cancer therapeutic development. He holds a B.S. degree in Biochemistry from The University of California at Davis, a Juris Doctorate (JD) degree from The University of New Hampshire Franklin Pierce School of Law, specializing in patent & I.P. law, and is a registered patent attorney before the United States Patent & Trademark Office.

Steen Knudsen has been our Chief Scientific Officer since 2006. Dr. Knudsen is a co-founder of Allarity Therapeutics A/S and the inventor of DRP®, the Drug Response Prediction Platform, which is Allarity's core technology and companion diagnostics platform. Dr. Knudsen is also a former Professor of Systems Biology with extensive expertise in mathematics, bioinformatics, biotechnology, and systems biology. He co-founded the Company in 2004 and served as our CEO from 2004 to 2006. Dr. Knudsen also previously served as a member on our Board of Directors from 2016 to 2020. In addition, Dr. Knudsen also currently serves as the Chief Executive Officer of MPI, Inc., an operating subsidiary of Company in the U.S. Dr. Knudsen holds an M.Sc. degree in Engineering from the Technical University of Denmark and a Ph.D. degree in Microbiology from the University of Copenhagen. He received Postdoctoral training in computational biology from Harvard Medical School.

Marie Foegh has been our Chief Medical Officer since January 2018 and previously served as Chief Medical Officer of our first U.S. subsidiary, 2X-Oncology, Inc. (later Oncology Venture US, Inc.) from 2016 to 2018. Dr. Foegh brings thirty years of experience in the pharmaceutical and biotechnology industries to our senior management team and has a strong track record leading successful clinical development of therapeutics, including regulatory and medical affairs. She is also Adjunct Clinical Professor at Georgetown University, Department of Medicine and Adjunct Professor at New York Medical College, Department of Pharmacology. Dr. Foegh was the Chief Medical Officer and cofounder of Ell Imaging, LLC, an ultrasound device company, from 2014 to 2016. She serves as the Chair of the Board of Directors at the device company Injecto A/S since 2014. Dr. Foegh leads clinical development of our current precision medicine oncology pipeline, including our lead assets stenoparib, dovitinib, and Ixempra®. Dr. Foegh previously led the successful development and regulatory approval of more than 10 novel drug products in the U.S. and U.K., within oncology, endocrinology and cardiology. Dr. Foegh has fluency in regulatory interactions with the FDA and EMEA, including INDs, NDAs, IDEs (for predictive biomarkers and/or companion diagnostics), and product issues. She also manages interactions with the oncology key opinion leaders including our Scientific Advisory Board. Dr. Foegh holds both a Medical Doctorate (M.D.) degree and a Doctorate of Science (Dr.Sc.) degree from Copenhagen University, Denmark, and is a member of the American College of Physicians (ACP), American Medical Association (AMA), the American Society of Clinical Oncology, and the American College of Obstetricians and Gynecologists (ACOG).

Thomas H. Jensen has been our Senior Vice President, Information Technology since June 2020, and previously served as Chief Technology Officer from 2004 to June 2020. Mr. Jensen co-founded Allarity Therapeutics A/S in 2004. Mr. Jensen also established and currently leads our laboratories in Denmark. Alongside nurturing our global laboratories, Mr. Jensen is instrumental in building our investor relations operations, securing operational financing, and fostering the business growth of Allarity Therapeutics. Amongst Mr. Jensen's accolades are his inventions of molecular biological guidelines combined with techniques for high quality reproducible RNA extraction and downstream processing. This allows for high resolution analysis of cancer patients' biopsies. Mr. Jensen's inventions are an important foundation of the DRP® -Drug Response Prediction platform. Mr. Jensen holds a Bachelor of Science degree in Biology from the Technical University of Denmark, and conducted further studies in Biology at the University of Copenhagen.

Duncan Moore has been a director since 2018 and was appointed as our Chairman at the same time. Dr. Moore has previously served as chairman of Oncology Venture Sweden AB (publ) since 2015. Dr. Moore is currently a partner in the company East West Capital Partners and has previously worked as Global Head of Healthcare Research at Morgan Stanley where he was employed from 1990 to 2006, latterly as a Managing Director. Dr. Moore is a board member of Forward Pharma Nasdaq; FWP, as well as privately held Lamellar Biomedical and Cycle Pharma. Dr. Moore has over twenty years' experience in capital markets analysis within health care. Dr. Moore holds a PhD in Biochemistry from the University of Cambridge where he was also a post-doctoral research fellow. He also has a degree in Biochemistry and Microbiology from the University of Leeds. Dr. Moore is well qualified to serve on our board of directors based on the above qualifications and his extensive experience in capital markets within the healthcare industry.

Søren G. Jensen has been a director since September 2020. Mr. Jensen is a current Member of the European Parliament for the Danish Liberal Party (Venstre) and was previously a member of the Danish Parliament for the Danish Liberal Party (Venstre) from 2015 to 2019, of which he was the Group Chairman from 2015 to 2018 and an appointed State Auditor of the Danish Parliament from 2015 to 2018. Mr. Jensen currently serves as the Chairman of TecLeaf ApS, CSR Invest ApS, and is also currently the chief executive officer of SGJ Holstebro ApS and CSR Invest ApS. In addition, Mr. Jensen also serves on the board of various non-profit organizations, and is currently a board member for Fulton Foundation and Samfonden, and the Chairman for Memorial Park for the Battle of Jutland 1916. Mr. Jensen holds an MSc degree in Economics from the University of Aarhus. Mr. Jensen is well qualified to serve on our board of directors due to his experience serving on the board of directors of private and non-profit companies.

Gail Maderis has been a director since October 2020. Since 2015, Ms. Maderis has also served as the President & CEO of Antiva Biosciences, Inc., a venture-backed biopharmaceutical company pioneering topical therapies to treat the pre-cancerous lesions caused by HPV. Previously, Ms. Maderis led BayBio, Northern California's life science industry organization as its President and CEO from 2019 to 2015. From 2003-2009, she served as President and CEO of FivePrime Therapeutics, a protein discovery company focused on immuno-oncology. Prior to her tenure at FivePrime Therapeutics, Ms. Maderis held senior executive positions at Genzyme Corporation, including founder and president of Genzyme Molecular Oncology. Ms. Maderis also practiced management and strategy consulting with Bain & Co. She currently serves on the corporate boards of DURECT Corporation (DRRX), Valitor, Inc. and Antiva Biosciences, as well as on the non-profit boards of BIO (Emerging Company and Health Sections), CLSI, The Termeer Foundation, and the University of California Berkeley Foundation Board of Trustees. Ms. Maderis received a BS in business from UC Berkeley, and an MBA from Harvard Business School. Ms. Maderis is well qualified to serve on our board of directors due to her operational, industry and leadership experience in the biopharmaceutical industry as CEO of FivePrime Therapeutics, President of Genzyme Molecular Oncology and her current position at Antiva, and her insight into business and policy trends impacting the biopharma industry.

Involvement in Certain Legal Proceedings

To the best of our knowledge, during the past ten years, none of our directors or executive officers were involved in any of the following: (1) any bankruptcy petition filed by or against any business of which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time; (2) any conviction in a criminal proceeding or being subject to a pending criminal proceeding (excluding traffic violations and other minor offenses); (3) being subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining, barring, suspending or otherwise limiting his involvement in any type of business, securities or banking activities; and (4) being found by a court of competent jurisdiction (in a civil action), the SEC or the Commodities Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended or vacated.

Executive Compensation and Director Compensation

Summary Compensation Table

The following table provides information regarding total compensation awarded to, earned by, and paid to Allarity A/S's named executive officers for services rendered to Allarity A/S in all capacities for the fiscal year ended December 31, 2020. For purposes of this section, compensatory warrants granted to named executive officers, employees and directors of Allarity A/S are also referred to as "options."

Name and Principal Position	Year	Salary	Bonus[1]	Option Awards[2]	All Other Compensation ($)	Total
Steve R. Carchedi, *Chief Executive Officer*	2020	$ 425,000	$ 283,333	$ —	$ 9,945[3]	$ 718,278[3]
Henrik Moltke,[4] *Chief Financial Officer*	2020	$ 195,000	$ 42,600	$ —	$ 25,000[4]	$ 262,600[4]
Jens E. Knudsen,[5] *Chief Financial Officer*	2020	$ 41,667	$ —	$ 230,667	$ —	$ 272,334[5]
Marie Foegh *Chief Medical Officer*	2020	$ 288,000	$ —	$ —	$ —	$ 288,000
James G. Cullem,[6] *Senior Vice President, Corporate Development*	2020	$ 235,000	$ —	$ 158,515	$ —	$ 393,515

(1) The bonuses reported in this column for 2020 consist of cash payment.

(2) The amounts reported in this column represent the aggregate grant date fair value of service-based option grants awarded to the named executive officer during 2020, calculated based on a Black Scholes model. Such grant date fair values do not take into account any estimated forfeitures related to service-vesting conditions. This calculation assumes that the named executive officer will perform the requisite service for the award to vest in full as required by SEC rules. The assumptions used in calculating the grant date fair values of the equity awards reported in this column are set forth in Note 7 of Allarity A/S's Audited Consolidated Financial Statements for the twelve months ended December 31, 2020 appearing elsewhere in this information statement/prospectus. The amounts reported in this column reflect the accounting cost for these equity awards and do not correspond to the actual economic value that may be realized by named executive officers upon the vesting of the stock options, the exercise of the stock options or the sale of the securities underlying such stock options.

(3) Consists of life insurance premium.

(4) Served as Chief Financial Officer until October 30, 2020. Includes pension payment received by Mr. Moltke. Total compensation reflects pro-rata compensation from January 1, 2020 until his resignation.

(5) Mr. Knudsen was appointed as Chief Financial Officer in November 2020. Total compensation reflects pro-rata compensation since appointment in November 2020.

Outstanding Equity Awards as of December 31, 2020

The following table sets forth information regarding outstanding equity awards held by Allarity A/S's named executive officers as of December 31, 2020.

Name	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price (SEK)	Option Expiration Date
Steve R. Carchedi, *Chief Executive Officer*	09/15/2019	1,761,938	1,761,937[1]	—	2.20	09/15/2029
Henrik Moltke *Chief Financial Officer*[2]	[2]	[2]	[2]	[2]	[2]	[2]
Jens E. Knudsen, *Chief Financial Officer*	11/1/2020	55,000	1,925,000[3]	—	2.42	10/31/2033
Marie Foegh *Chief Medical Officer*	—	—	—	—	—	—
James G. Cullem, *Senior Vice President, Corporate Development*	10/1/2019	626,467	783,083[4]	—	1.41	09/30/2032

(1) This option vests as to 25% on 6 months from start date, 25% on 12 month anniversary, 25% on 24 month anniversary and 25% on 36 month anniversary.

(2) Mr. Moltke resigned in October 2020.

(3) This option vests as to 1/36 of the shares underlying the option on a monthly basis, which vesting commenced November 2020.

(4) This option vests as to 1/36 of the shares underlying the option on a monthly basis, which vesting commenced on October 2019.

Pension Benefits

Except as set forth in the Summary Compensation Table above, Allarity A/S's named executive officers did not participate in, or otherwise receive any benefits under, any pension or retirement plan sponsored by Allarity A/S during the fiscal year ended December 31, 2020.

Nonqualified Deferred Compensation

Allarity A/S's named executive officers did not participate in, nor earn any benefits under, a nonqualified deferred compensation plan sponsored by Allarity A/S during the fiscal year ended December 31, 2020.

Service Agreements

Allarity A/S has service agreements with the following named executive officers, which are dated on or about September 2019. Upon the consummation of the Recapitalization Share Exchange, Allarity Delaware intends to enter into new agreements with its named executive officers. Below are descriptions of the service agreements between Allarity A/S and the specified named executive officers.

Term and Termination. The service agreements with each of the named executive officers provide for at-will employment and may be terminated in writing with thirty (30) days prior written notice. In the event the named executive officer is terminated without cause by Allarity A/S or for good reason by the respective named executive officer, the service agreements provide for (i) severance payment based on base salary and period of employment for Mr. Carchedi, and (ii) severance payment equal to six (6) month pay at the base salary rate for termination without cause, and twelve (12) month pay at the base salary rate in the event of change of control for Mr. Cullem. In addition, under the service agreement with Mr. Carchedi, he is also entitled to a percentage of annual bonus target upon termination for cause by Allarity A/S or for good reason by Mr. Carchedi.

Base Salary. The service agreements provide for the initial annual base salaries set forth below:

Named Executive Officer	Initial Annual Base Salary
Steve R. Carchedi	$ 425,000
James G. Cullem	$ 235,000

Annual Bonus. Each named executive officer is eligible to receive a discretionary annual cash bonus (the "Annual Bonus") representing up to a certain percentage of their base salaries, as follows:

Named Executive Officer	Annual Bonus
Steve R. Carchedi	up to 50% of annual base salary
James G. Cullem	up to 30% of annual base salary

The Annual Bonus payable is dependent on the achievement of individual and corporate performance targets, metrics and/or management-by-objectives to be determined and approved by Company's board of directors, and such named executive officer's continued performance of services through the scheduled annual incentive compensation payment date of the applicable bonus year.

Equity Awards. The service agreements provide for the following granting of compensation options, which vesting is subject to continuous service and a vesting schedule. The services agreements also provide that upon change of control, the unvested options will be fully vested.

Name	Number of Shares	Vesting Schedules
Steve R. Carchedi	3,523,875	25% on 6 months from start date, 25% on 12 month anniversary, 25% on 24 month anniversary and 25% on 36 month anniversary
	2% of the outstanding shares	Upon completion of 24 months of continuous service, Allarity A/S agreed to grant compensation options to purchase a total of 2% of the then outstanding shares of Allarity A/S on a fully diluted basis, which warrants shall be fully vested as of the grant date
James G. Cullem	1,409,550	1/36 per month

Benefits. Each of the named executive officers is eligible to participate in Allarity A/S's standard employee benefit plans and programs.

Offer Letter

Allarity A/S provided an offer letter to Mr. Knudsen in October 2020 relating to his proposed services as Chief Financial Officer. The offer letter provides for (a) an annual base salary of $250,000, (2) discretionary incentive compensation of up to 30% of annual base salary, and (3) equity compensation of up to one percent (1%) of the then outstanding shares subject to a vesting schedule. In connection with Mr. Knudsen's employment, subject to continuous service, the Board approved grant of options for 1,980,000 ordinary shares subject to a vesting schedule of 1/36 per month. The offer letter states that Mr. Knudsen's services may be terminated at any time. Mr. Knudsen is also entitled to severance payment equal to twelve (12) month pay at the base salary rate in the event of change of control.

Stock Options

As of December 31, 2020, Allarity A/S had five (5) equity-settled stock option plans which were approved at extraordinary general meetings of shareholders of Allarity A/S. As of December 31, 2020, options to purchase 10,775,971ordinary shares were outstanding, of which 6,008,140 were exercisable at December 31, 2020. All options granted have a term of ten (10) years from date of grant. If an employee does not have a contractual agreement that provides otherwise, all options vest 1/36 per month.

As of August 6, 2021, Allarity A/S had 46,287,002 compensatory warrants conferring the right to subscribe for Allarity A/S ordinary shares. At the effective time of the Recapitalization Share Exchange, each warrant (option) to purchase Allarity A/S ordinary shares held by the officers, directors, employees and consultants (each, a "Compensatory Warrant") that is outstanding immediately prior to the effective time, whether vested or unvested, will be converted into an option (each, a "Converted Option") to purchase a number of shares of Allarity Delaware Common Stock

equal to the product (rounded down to the nearest whole number) of (a) the number of ordinary shares of Allarity A/S subject to such Compensatory Warrant immediately prior to the effective time multiplied by (b) the exchange ratio, at an exercise price per share (rounded up to the nearest whole cent) equal to (i) the exercise price per share of such Compensatory Warrant immediately prior to the effective time divided by (ii) the exchange ratio and then converted into U.S. dollars; provided, however, that the exercise price and the number of shares of Delaware Common Stock purchasable pursuant to the Converted Options will be determined in a manner consistent with the requirements of Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"); provided, further, however, that in the case of any Converted Option to which Section 422 of the Code applies, the exercise price and the number of shares of Delaware Common Stock purchasable pursuant to such option will be determined in accordance with the foregoing, subject to such adjustments in a manner consistent with Treasury Regulation Section 1.424-1, such that the Converted Option will not constitute a modification of such Converted Option for purposes of Section 409A or Section 424 of the Code. Except as specifically provided above, following the effective time, each Converted Option will continue to be governed by the same terms and conditions (including vesting and exercisability terms) as were applicable to the corresponding former Compensatory Warrant immediately prior to the effective time.

Other Benefits

Allarity A/S's named executive officers are eligible to participate in Allarity A/S's health and welfare plans to the same extent as all full-time employees.

Allarity A/S generally has not provided perquisites or personal benefits except in limited circumstances, and except as set forth above under "Summary Compensation Table," it did not provide any perquisites or personal benefits to its named executive officers in fiscal year ended December 31, 2020.

Employee Benefit Plans

Equity-based compensation has been and will continue to be an important foundation in executive compensation packages as Allarity A/S believes it is important to maintain a strong link between executive incentives and the creation of stockholder value. Allarity A/S believes that performance and equity-based compensation can be an important component of the total executive compensation package for maximizing stockholder value while, at the same time, attracting, motivating and retaining high-quality executives. Formal guidelines for the allocations of cash and equity-based compensation have not yet been determined, but it is expected that the 2021 Equity Incentive Plan ("2021 Plan") described in Proposal No. 3 will be an important element of Allarity Delaware's compensation arrangements for both executive officers and directors.

2021 Equity Incentive Plan

We have adopted our 2021 Plan that will become effective on the effective time of the Recapitalization Share Exchange. Our 2021 Plan authorizes the award of stock options, RSAs, SARs, RSUs, cash awards, performance awards and stock bonus awards. We have initially reserved One Million One Hundred Sixty Eight Thousand Three Hundred Thirty (1,168,330) Shares, plus an amount derived by the difference between fifteen percent (15%) of the Company's issued and outstanding shares of Common Stock issued in the Company's Recapitalization Share Exchange covered by the Company's registration statement on Form S-4 (SEC File No. 333-258968) and One Million One Hundred Sixty Eight Thousand Three Hundred Thirty (1,168,330) Shares. The number of shares reserved for issuance under our 2021 Plan will increase automatically on January 1 of each of 2022 through 2031 by the number of shares equal to the lesser of 5% of the aggregate number of outstanding shares of our common stock as of the immediately preceding December 31, or a number as may be determined by our board of directors.

In addition, the following shares will again be available for issuance pursuant to awards granted under our 2021 Plan:

- shares subject to options or SARs granted under our 2021 Plan that cease to be subject to the option or SAR for any reason other than exercise of the option or SAR;
- shares subject to awards granted under our 2021 Plan that are subsequently forfeited or repurchased by us at the original issue price;
- shares subject to awards granted under our 2021 Plan that otherwise terminate without such shares being issued;

- shares subject to awards granted under our 2021 Plan that are surrendered, cancelled or exchanged for cash or a different award (or combination thereof); and
- shares subject to awards under our 2021 Plan that are used to pay the exercise price of an option or withheld to satisfy the tax withholding obligations related to any award.

Purpose. The purpose of our 2021 Plan is to provide incentives to attract, retain, and motivate eligible persons whose present and potential contributions are important to the success of the Company, and any Parents, Subsidiaries, and Affiliates that exist now or in the future, by offering them an opportunity to participate in the Company's future performance through the grant of Awards.

Administration. Our 2021 Plan is expected to be administered by our compensation committee, all of the members of which are outside directors as defined under applicable federal tax laws, or by our board of directors acting in place of our compensation committee. Subject to the terms and conditions of the 2021 Plan, the compensation committee will have the authority, among other things, to select the persons to whom awards may be granted, construe and interpret our 2021 Plan as well as to determine the terms of such awards and prescribe, amend and rescind the rules and regulations relating to the plan or any award granted thereunder. The 2021 Plan provides that the board of directors or compensation committee may delegate its authority, including the authority to grant awards, to one or more executive officers to the extent permitted by applicable law, provided that awards granted to non-employee directors may only be determined by our board of directors.

Eligibility. Our 2021 Plan provides for the grant of awards to our employees, directors, consultants, independent contractors and advisors.

Options. The 2021 Plan provides for the grant of both incentive stock options intended to qualify under Section 422 of the Code, and non-statutory stock options to purchase shares of our common stock at a stated exercise price. Incentive stock options may only be granted to employees, including officers and directors who are also employees. The exercise price of stock options granted under the 2021 Plan must be at least equal to the fair market value of our common stock on the date of grant. Incentive stock options granted to an individual who holds, directly or by attribution, more than ten percent of the total combined voting power of all classes of our capital stock must have an exercise price of at least 110% of the fair market value of our common stock on the date of grant. Subject to stock splits, dividends, recapitalizations or similar events, no more than 7,009.980 shares may be issued pursuant to the exercise of incentive stock options granted under the 2021 Plan.

Options may vest based on service or achievement of performance conditions. Our compensation committee may provide for options to be exercised only as they vest or to be immediately exercisable, with any shares issued on exercise being subject to our right of repurchase that lapses as the shares vest. The maximum term of options granted under our 2021 Plan is ten years from the date of grant, except that the maximum permitted term of incentive stock options granted to an individual who holds, directly or by attribution, more than ten percent of the total combined voting power of all classes of our capital stock is five years from the date of grant.

Restricted stock awards. An RSA is an offer by us to sell shares of our common stock subject to restrictions, which may lapse based on the satisfaction of service or achievement of performance conditions. The price, if any, of an RSA will be determined by the compensation committee. Holders of RSAs will have the right to vote and any dividends or stock distributions paid pursuant to unvested RSAs will be accrued and paid when the restrictions on such shares lapse. Unless otherwise determined by the compensation committee at the time of award, vesting will cease on the date the participant no longer provides services to us and unvested shares may be forfeited to or repurchased by us.

Stock appreciation rights. A SAR provides for a payment, in cash or shares of our common stock (up to a specified maximum of shares, if determined by our compensation committee), to the holder based upon the difference between the fair market value of our common stock on the date of exercise and a predetermined exercise price, multiplied by the number of shares. The exercise price of a SAR must be at least the fair market value of a share of our common stock on the date of grant. SARs may vest based on service or achievement of performance conditions, and may not have a term that is longer than ten years from the date of grant.

Restricted stock units. RSUs represent the right to receive shares of our common stock at a specified date in the future, and may be subject to vesting based on service or achievement of performance conditions. Payment of earned RSUs will be made as soon as practicable on a date determined at the time of grant, and may be settled in cash, shares of our common stock or a combination of both. No RSU may have a term that is longer than ten years from the date of grant.

Performance awards. Performance awards granted to pursuant to the 2021 Plan may be in the form of a cash bonus, or an award of performance shares or performance units denominated in shares of our common stock that may be settled in cash, property or by issuance of those shares subject to the satisfaction or achievement of specified performance conditions.

Stock bonus awards. A stock bonus award provides for payment in the form of cash, shares of our common stock or a combination thereof, based on the fair market value of shares subject such award as determined by our compensation committee. The awards may be granted as consideration for services already rendered, or at the discretion of the compensation committee, may be subject to vesting restrictions based on continued service or performance conditions.

Cash awards. A cash award is an award that is denominated in, or payable to an eligible participant solely in, cash.

Dividend equivalents rights. Dividend equivalent rights may be granted at the discretion of our compensation committee, and represent the right to receive the value of dividends, if any, paid by us in respect of the number of shares of our common stock underlying an award. Dividend equivalent rights will be subject to the same vesting or performance conditions as the underlying award and will be paid only at such time as the underlying award has become fully vested. Dividend equivalent rights may be settled in cash, shares or other property, or a combination of thereof as determined by our compensation committee.

Change of control. Our 2021 Plan provides that, in the event of a corporate transaction, as defined in the 2021 Plan, outstanding awards under our 2021 Plan shall be subject to the agreement evidencing the corporate transaction, any or all outstanding awards may be (a) continued by us, if we are the successor entity; or (b) assumed or substituted by the successor corporation, or a parent or subsidiary of the successor corporation, for substantially equivalent awards (including, but not limited to, a payment in cash or the right to acquire the same consideration paid to the stockholders of the company pursuant to the corporate transaction); (c) substituted by successor corporation of equivalent awards with substantially the same terms for such outstanding awards; (d) accelerated in full or in part as to the exercisability or vesting; (e) settled in the full value of such outstanding award in cash, cash equivalents, or securities of the successor entity (or its parent, if any) with a fair market value equal to the required amount, followed by the cancellation of such awards; or (f) cancelled for no consideration. If applicable, the number and kind of shares and exercise prices of awards being continued, assumed, or substituted shall be adjusted pursuant to the terms of the 2021 Plan.

Adjustment. In the event of a change in the number of outstanding shares of our common stock without consideration by reason of a stock dividend, extraordinary dividend or distribution, recapitalization, stock split, reverse stock split, subdivision, combination, consolidation reclassification, spin-off or similar change in our capital structure, appropriate proportional adjustments will be made to the number and class of shares reserved for issuance under our 2021 Plan; the exercise prices, number and class of shares subject to outstanding options or SARs; the number and class of shares subject to other outstanding awards; and any applicable maximum award limits with respect to incentive stock options.

Exchange, repricing and buyout of awards. Our compensation committee may, with the consent of the respective participants, issue new awards in exchange for the surrender and cancelation of any or all outstanding awards. Our compensation committee may also reduce the exercise price of options or SARs or buy an award previously granted with payment in cash, shares or other consideration, in each case, subject to the terms of the 2021 Plan.

Director compensation limits. No non-employee director may receive awards under our 2021 Plan with a grant date value that when combined with cash compensation received for his or her service as a director, exceeds $750,000 in a calendar year or $1,000,000 in the calendar year of his or her initial service.

Clawback; transferability. All awards will be subject to clawback or recoupment pursuant to any compensation clawback or recoupment policy adopted by our board of directors (or a committee thereof) or required by law during the term of service of the award holder, to the extent set forth in such policy or applicable agreement. Except in limited circumstances, awards granted under our 2021 Plan may generally not be transferred in any manner prior to vesting other than by will or by the laws of descent and distribution.

Amendment and termination. Our board of directors may amend our 2021 Plan at any time, subject to stockholder approval as may be required. Our 2021 Plan will terminate ten years from the date our board of directors adopts the plan, unless it is terminated earlier by our board of directors. No termination or amendment of the 2021 Plan may adversely affect any then-outstanding award without the consent of the affected participant, except as is necessary to comply with applicable laws.

2020 Non-Employee Director Compensation

The following table sets forth information concerning the compensation of Allarity A/S non-employee directors for the year ended December 31, 2020. Mr. Carchedi also served as a director of Allarity A/S.Mr. Carchedi's compensation as named executive officer is set forth above under "Summary Compensation Table."

Name	Fees Earned or Paid in Cash $	Option Awards[1][2] $	Total $
Duncan Moore	$ 45,000	$ —	$ 45,000
Søren G. Jensen[3]	$ 10,516	$ 1,982	$ 12,498
Gail Maderis[4]	$ 10,516	$ 1,982	$ 12,498
Dr. Magnus Persson[5]	$ —	$ —	$ —

(1) Amounts reported represent the aggregate grant date fair value of stock options granted to such non-employee directors and have been computed based on a Black Scholes model and excludes the effect of estimated forfeitures. The assumptions used in calculating the grant date fair values of the equity awards reported in this column are set forth in Note 7of Allarity A/S's Audited Consolidated Financial Statements for the twelve months ended December 31, 2020 appearing at the end of this information statement/prospectus. The amounts reported in this column reflect the accounting cost for these equity awards and do not correspond to the actual economic value that may be realized by the directors upon the vesting of the stock options, the exercise of the stock options or the sale of the securities underlying such stock options.

(2) The table below lists the aggregate number of shares subject to option awards outstanding for each of Allarity A/S's non-employee directors as of December 31, 2020.

Name	Number of Shares Subject to Outstanding Options
Duncan Moore	—
Søren G. Jensen.	20,000
Gail Maderis	20,000
Dr. Magnus Persson	—

(3) Appointed in September 2020. Compensation reflects pro-rata compensation. Options are subject to monthly vesting for two years.

(4) Appointed in October 2020. Compensation reflects pro-rata compensation. Options are subject to monthly vesting for two years.

(5) Resigned on or about October 2020.

Non-Employee Director Compensation Policy

Under Allarity A/S's current policy, non-employee directors' compensation package consists of an annual cash retainer of $45,000, and an option grant to purchase 20,000 ordinary shares for their service as directors.

Emerging Growth Company Status

Allarity Delaware is an "emerging growth company," as defined in the JOBS Act. As an emerging growth company it will be exempt from certain requirements related to executive compensation, including the requirements to hold a nonbinding advisory vote on executive compensation and to provide information relating to the ratio of total compensation of its President and Chief Executive Officer to the median of the annual total compensation of all of its employees, each as required by the Investor Protection and Securities Reform Act of 2010, which is part of the Dodd-Frank Act.

Executive Compensation Following the Business Combination

Following the Recapitalization Share Exchange, the Compensation Committee will oversee the compensation policies, plans and programs and review and determine compensation to be paid to executive officers, directors and other senior management, as appropriate. The compensation policies followed by Allarity Delaware will be intended to provide for compensation that is sufficient to attract, motivate and retain executives of Allarity Delaware and potential other individuals and to establish an appropriate relationship between executive compensation and the creation of stockholder value.

MANAGEMENT OF ALLARITY DELAWARE AFTER THE RECAPITALIZATION SHARE EXCHANGE

References in this section to "we," "our," "us" and the "Company" generally refer to Allarity Delaware and its consolidated subsidiaries after the Recapitalization Share Exchange.

Executive Officers and Directors After the Recapitalization Share Exchange

The current executive officers and directors of Allarity A/S are the current officers and directors of the Allarity Delaware. Upon the consummation of the Recapitalization Share Exchange, the business and affairs of Allarity Delaware will continue to be managed by or under the direction of its board of directors. The directors and executive officers of Allarity A/S will continue to be the directors and executive officers of Allarity Delaware. The name, age and biographical summary of each of the directors and executive officers are set forth in the section in titled "Management Allarity A/S."

Family Relationships and Arrangements

There are no family relationships among any of Allarity Delaware's directors or executive named officers. There are no arrangements or understandings with any other person under which our directors and officers was elected or appointed as a director or executive officer.

Involvement in Certain Legal Proceedings

To the best of our knowledge, during the past ten years, none of our directors or executive officers were involved in any of the following: (1) any bankruptcy petition filed by or against any business of which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time; (2) any conviction in a criminal proceeding or being subject to a pending criminal proceeding (excluding traffic violations and other minor offenses); (3) being subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining, barring, suspending or otherwise limiting his involvement in any type of business, securities or banking activities; and (4) being found by a court of competent jurisdiction (in a civil action), the SEC or the Commodities Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended or vacated.

Board Composition, Committees, and Independence

Allarity Delaware's business and affairs is managed under the direction of its board of directors. Mr. Moore will serve as Chair of the Allarity Delaware board of directors. The primary responsibilities of the Allarity Delaware board of directors is to provide oversight, strategic guidance, counseling and direction to Allarity Delaware's management. The board of directors of Allarity Delaware will meet on a regular basis and additionally as required under the Nasdaq rules.

In accordance with the terms of Allarity Delaware's Bylaws, subject to the rights of holders of any series of Preferred Stock, the board of directors may establish the authorized number of directors from time to time by resolution. The board of directors consists of four (4) members and is divided into three (3) classes, Class I, Class II and Class III, with members of each class serving staggered three-year terms. The Allarity Delaware board of directors is divided into the following classes:

- Class I, consists of Mr. Jensen, whose term will expire at Allarity Delaware's first annual meeting of stockholders to be held after the consummation of the Recapitalization Share Exchange;
- Class II, consists of Ms. Maderis, whose term will expire at Allarity Delaware's second annual meeting of stockholders to be held after the consummation of the Recapitalization Share Exchange; and
- Class III, consists of Messrs. Moore and Carchedi, whose terms will expire at Allarity Delaware's third annual meeting of stockholders to be held after the consummation of the Recapitalization Share Exchange.

Director Independence

Nasdaq listing standards require that a majority of our board of directors be independent. In addition, applicable Nasdaq rules require that, subject to specified exceptions, each member of a listed company's audit and compensation committees be independent within the meaning of the applicable Nasdaq rules. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act. The board of directors has undertaken a review of the independence of each director. Based on information provided by each director concerning her or his background, employment and affiliations, the board of directors of Allarity Delaware has determined that none of the directors, other than Mr. Carchedi, has any relationships that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of the directors is "independent" as that term is defined under the Nasdaq listing standards. In making these determinations, the board of directors considered the current and prior relationships that each non-employee director has with Allarity Delaware and all other facts and circumstances the board of directors of deemed relevant in determining their independence, including the beneficial ownership of securities of Allarity Delaware by each non-employee director and the transactions described in the section titled "*Certain Relationships and Related Party Transactions*."

Role of the Allarity Delaware Board of Directors in Risk Oversight

One of the key functions of the board of directors is informed oversight of Allarity Delaware's risk management process. The board of directors does not anticipate having a standing risk management committee, but rather anticipates administering this oversight function directly through the Allarity Delaware board of directors as a whole, as well as through various standing committees of the Allarity Delaware board of directors that address risks inherent in their respective areas of oversight. In particular, the Allarity Delaware board of directors is responsible for monitoring and assessing strategic risk exposure and Allarity Delaware's audit committee will have the responsibility to consider and discuss Allarity Delaware's major financial risk exposures and the steps its management will take to monitor and control such exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The audit committee will also monitor compliance with legal and regulatory requirements. Allarity Delaware's compensation committee will also assess and monitor whether Allarity Delaware's compensation plans, policies and programs comply with applicable legal and regulatory requirements.

Board Committees

In anticipation of the consummation of the Recapitalization Share Exchange, the board of directors has established an audit committee, compensation committee, and nominating and corporate governance committee. The board of directors has also adopted new charters for each of these committees, which comply with the applicable requirements of current SEC and Nasdaq rules. Following the consummation of the Recapitalization Share Exchange, copies of the charters for each committee will be available at *www.allarity.com*.

Audit Committee

The audit committee consists of Ms. Maderis, Mr. Jensen and Mr. Moore, each of whom the board of directors has determined satisfies the independence requirements under Nasdaq listing standards and Rule 10A-3(b)(1) of the Exchange Act. The chair of the audit committee is Mr. Moore, who the board of directors has determined is an "audit committee financial expert" within the meaning of SEC regulations. Each member of the audit committee can read and understand fundamental financial statements in accordance with applicable requirements. In arriving at these determinations, the board of directors has examined each audit committee member's scope of experience and the nature of their employment in the corporate finance sector.

The primary purpose of the audit committee will be to provide assistance to the board of directors of Allarity Delaware in fulfilling the board of directors responsibility to the Allarity Delaware's stockholders relating to the Allarity Delaware's accounting and financial reporting practices, system of internal control, the audit process, the quality and integrity of its financial reporting, and Allarity Delaware's process for monitoring compliance with laws and regulations and its code of conduct. Specific responsibilities of the audit committee are to:

- Appoint, compensate, and oversee the work of any independent auditor;
- Resolve any disagreements between management and the independent auditor regarding financial reporting;

- Pre-approve all audit and permitted non-audit services by the independent auditor;
- Retain independent counsel, independent registered accounting firm, or other advisors or consultants to advise and assist the Audit Committee in carrying out its duties, without needing to seek approval for the retention of such advisors or consultants from the Board, and determine the appropriate compensation for any such advisors or consultants retained by the Audit Committee;
- Seek any information it requires from employees of Allarity Delaware's or any direct or indirect subsidiary of Allarity Delaware (each, a "Subsidiary"), all of whom are directed to cooperate with the Audit Committee's requests, or external parties;
- Meet with any officer or employee of the Allarity Delaware (or any Subsidiary), the independent auditor or outside counsel, as necessary, or request that any such persons meet with any members of, or advisors or consultants to, the Audit Committee; and
- Oversee that management has established and maintained processes to assure compliance by the Allarity Delaware with applicable laws, regulations and corporate policy.

Compensation Committee

The compensation committee consists of Ms. Maderis, Mr. Jensen and Mr. Moore. The chair of the compensation committee is Ms. Maderis. The board of directors has determined that each member of the compensation committee is independent under the Nasdaq listing standards and a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act.

The primary purpose of the compensation committee is to discharge the responsibilities of the board of directors relating to compensation of Allarity Delaware's directors and executive officers, to assist the board of directors in establishing appropriate incentive compensation and equity-based plans and to administer such plans, and to oversee the annual process of evaluation of the performance of Allarity Delaware's management. Specific responsibilities of the compensation committee are to:

- Establish a compensation policy for executive officers designed to (i) enhance the profitability of the Allarity Delaware and increase stockholder value, (ii) reward executive officers for their contribution to the Allarity Delaware's growth and profitability, (iii) recognize individual initiative, leadership, achievement, and other contributions and (iv) provide competitive compensation that will attract and retain qualified executives.
- Subject to variation where appropriate, the compensation policy for executive officers shall include (i) base salary, which shall be set on an annual or other periodic basis, (ii) annual or other time or project based incentive compensation, which shall be awarded for the achievement of predetermined financial, project, research or other designated objectives of the Allarity Delaware as a whole and of the executive officers individually and (iii) long-term incentive compensation in the forms of equity participation and other awards with the goal of aligning, where appropriate, the long-term interests of executive officers with those of the Allarity Delaware's stockholders and otherwise encouraging the achievement of superior results over an extended time period.
- Review competitive practices and trends to determine the adequacy of the executive compensation program.
- Annually review and recommend to the board of directors corporate goals and objectives relevant to CEO compensation, evaluate the CEO's performance in light of those goals and objectives, and recommend to the board of directors the CEO's compensation levels based on this evaluation; the CEO may not be present during any deliberations or voting with respect to the CEO's compensation.
- Annually review and approve compensation of executive officers of the Allarity Delaware other than the CEO.
- Annually review and approve compensation of directors of the Allarity Delaware, including with respect to any equity based plan.

- As deemed necessary or appropriate, approve employment contracts, severance arrangements, change in control provisions and other agreements.
- Approve and administer cash incentives and deferred compensation plans for executive officers (including any modification to such plans) and oversight of performance objectives and funding for executive incentive plans.
- Approve and oversee reimbursement policies for directors and executive officers.
- Periodically review and make recommendations to the board of directors with respect to equity based plans that are subject to approval by the board of directors. The compensation committee shall oversee the Allarity Delaware's compliance with the requirement under Nasdaq rules that, with limited exceptions, stockholders approve equity compensation plans. Subject to such stockholder approval, or as otherwise required by the Exchange Act, or other applicable law, the compensation committee shall have the power to manage all equity based plans.
- If the Allarity Delaware is required by applicable Securities and Exchange Commission ("SEC") rules to include a Compensation Discussion and Analysis ("CD&A") in its SEC filings, review the CD&A prepared by management, discuss the CD&A with management and, based on such review and discussions, recommend to the board of directors that the CD&A be included in the Allarity Delaware's Annual Report on Form 10-K, proxy statement, or any other applicable filing as required by the SEC.
- Review all compensation policies and practices for all employees to determine whether such policies and practices create risks that are reasonably likely to have a material adverse effect on the Allarity Delaware.
- Recommend to the board of directors that the stockholders of the Allarity Delaware approve, on an advisory basis, the compensation of the named executive officers of the Allarity Delaware, as disclosed in the Allarity Delaware's proxy statement, if such proposal will be contained in the Allarity Delaware's proxy statement.
- Recommend to the board of directors the frequency of holding a vote on the compensation of the Allarity Delaware's named executive officers, if such proposal will be contained in the Allarity Delaware's proxy statement.
- Periodically review executive supplementary benefits and, as appropriate, the organization's retirement, benefit, and special compensation programs involving significant cost.
- Make regular reports to the board of directors.
- Annually review and reassess the adequacy of the compensation committee Charter and recommend any proposed changes to the board of directors for approval.
- Annually evaluate its own performance.
- Oversee the annual process of performance evaluations of the Allarity Delaware's management.
- Fulfill such other duties and responsibilities as may be assigned to the compensation committee, from time to time, by the board of directors and/or the Chairman of the board of directors.

Nominating and Corporate Governance Committee

The nominating and corporate governance committee consists of Ms. Maderis, Mr. Jensen and Mr. Moore. The chair of the nominating and corporate governance committee is Mr. Jensen. The board of directors has determined that each member of the nominating and corporate governance committee is independent under the Nasdaq listing standards.

The primary purpose of the nominating and corporate governance committee is (1) to assist the board of directors by identifying qualified candidates for director, and to recommend to the board of directors the director nominees for the next annual meeting of shareholders; (2) to lead the board of directors in its annual review of the board of directors'

performance; (3) to recommend to the board of directors director nominees for each board of directors committee; and (4) develop and recommend to the board of directors corporate governance guidelines applicable to Allarity Delaware. Specific responsibilities of the nominating and corporate governance committee are to:

- Evaluate the current composition, organization and governance of the board of directors and its committees, and make recommendations to the board of directors for approval.
- Annually review for each director and nominee, the particular experience, qualifications, attributes or skills that contribute to the board of directors' conclusion that the person should serve or continue to serve as a director for the Allarity Delaware, as well as how the directors' skills and background enable them to function well together as a board of directors.
- Determine desired member skills and attributes and conduct searches for prospective directors whose skills and attributes reflect those desired. Evaluate and propose nominees for election to the board of directors. At a minimum, nominees for service on the board of directors must meet the threshold requirements set forth in the *Nominating and Corporate Governance Committee Policy Regarding Qualifications of Directors*. Each nominee will be considered both on his or her individual merits and in relation to existing or other potential members of the board of directors, with a view to establishing a well-rounded, diverse, knowledgeable, and experienced board of directors.
- Administer the annual board of directors' performance evaluation process, including conducting surveys of director observations, suggestions and preferences.
- Evaluate and make recommendations to the board of directors concerning the appointment of directors to board of directors committees, the selection of board of directors committee chairs, and proposal of the slate of directors for election to the board of directors.
- Consider bona fide candidates recommended by shareholders for nomination for election to the board of directors in accordance with Section 2.12 of Allarity Delaware's Bylaws.
- As necessary in the nominating and corporate governance committee's judgment from time to time, retain and compensate third-party search firms to assist in identifying or evaluating potential nominees to the board of directors.
- Evaluate and recommend termination of membership of individual directors in accordance with the board of directors' governance principles, for cause or for other appropriate reasons.
- Oversee the process of succession planning for the Chief Executive Officer and, as warranted, other senior officers of the Allarity Delaware.
- Develop, adopt and oversee the implementation of a Code of Business Conduct and Ethics for all directors, executive officers and employees of the Allarity Delaware.
- Review and maintain oversight of matters relating to the independence of board of directors and committee members, keeping in mind the independence standards of the Sarbanes-Oxley Act of 2002 and the rules of The Nasdaq Stock Market LLC.
- Oversee and assess the effectiveness of the relationship between the board of directors and Allarity Delaware management.
- Form and delegate authority to subcommittees when appropriate, each subcommittee to consist of one or more members of the nominating and corporate governance committee. Any such subcommittee, to the extent provided in the resolutions of the nominating and corporate governance committee and to the extent not limited by applicable law, shall have and may exercise all the powers and authority of the nominating and corporate governance committee.
- Make regular reports to the board of directors concerning its activities.
- Annually review and reassess the adequacy of the nominating and corporate governance charter and the appendices thereto and recommend any proposed changes to the board of directors for approval.

- Annually evaluate its own performance.
- Maintain appropriate records regarding its process of identifying and evaluating candidates for election to the board of directors.
- Fulfill such other duties and responsibilities as may be assigned to the nominating and corporate governance committee, from time to time, by the board of directors and/or the Chairman of the board of directors.

None of the members of the compensation committee has ever been an executive officer or employee of Allarity Delaware. None of Allarity Delaware's executive officers currently serve, or has served during the last completed fiscal year, on the compensation committee or board of directors of any other entity that has one or more executive officers that will serve as a member of the Allarity Delaware board of directors or compensation committee.

Executive and Director Compensation

Allarity Delaware has not and will not pay compensation of any kind, including finder's and consulting fees, to the named executive officers and directors, or any of their respective affiliates, for services rendered in connection with the consummation of the Recapitalization Share Exchange.

Following the Recapitalization Share Exchange, directors or members of our management team may be paid director, consulting, management or other fees from Allarity Delaware with any and all amounts being fully disclosed to stockholders, to the extent then known, in the proxy solicitation materials furnished to our stockholders in connection with the proposed Recapitalization Share Exchange.

Executive Compensation

Any compensation to be paid to our executive officers will be determined by a compensation committee constituted solely by independent directors.

It is anticipated that subject to the closing of the investment with 3i, LP's, Allarity Delaware will enter into employment agreements with the following executive officers which will provide for the following compensation terms:

Executive Officers and Position	Initial Annual Base Salary
Steve R. Carchedi, Chief Executive Officer	$ 475,000
Jens E. Knudsen, Chief Financial Officer	$ 287,500
Marie Foegh, Chief Medical Officer	$ 331,200
Steen Knudsen, Chief Scientific Officer	$ 275,000
Thomas Jensen, Senior Vice President, Information Technology	$ 216,200
James G. Cullem, Senior Vice-President/Corporation Development	$ 270,250

Executive Officer	Discretionary Annual Bonus for Calendar Year 2021[(1)]
Steve R. Carchedi, Chief Executive Officer	up 55% of annual base salary
Jens E. Knudsen, Chief Financial Officer	up to 30% of annual base salary
Marie Foegh, Chief Medical Officer	up to 40% of annual base salary
Steen Knudsen, Chief Scientific Officer	up to 40% of annual base salary
Thomas Jensen, Senior Vice President, Information Technology	up to 30% annual base salary
James G. Cullem, Senior Vice-President/Corporation Development	Up to 40% annual base salary

(1) +/- 20% at the discretion of the board and/or compensation committee

The annual bonus payable will be dependent on the achievement of individual and corporate performance targets, metrics and/or management-by-objectives to be determined and approved by Allarity Delaware board of directors and/or compensation committee, and such executive officer's continued performance of services through the scheduled annual incentive compensation payment date of the applicable bonus year. The annual bonus may be paid in cash or equity at the discretion of the board and/or compensation committee.

Director Compensation

Directors of Allarity Delaware will be entitled to an annual director fee of $35,000, and an annual grant of 12,500 shares of common stock, which will vest at the earlier of (1) twelve (12) months, or (2) next annual meeting so long as the director has served on the board of directors for at least six (6) months. In addition, a director who serves as a lead independent director or chair or on a committee of the board of directors will receive the following additional annual fee:

Position	Annual Chair/ Lead Fee	Annual Member Fee
Chairman of the Board or Lead Independent Director	$ 30,000	$ —
Audit Committee	$ 15,000	$ 7,500
Compensation Committee	$ 10,000	$ 5,000
Nominating and Corporate Governance Chair	$ 8,000	$ 4,000

Annual fees may be paid in cash or equity at the option of the director. In addition, new directors who join the board of directors will receive an initial grant of 25,000 shares of common stock, subject to thirty-six (36) month vesting.

Converted Stock Options

At the effective time of the Reorganization Share Exchange, Allarity Delaware will issue stock options to all holders of the Compensatory Warrants of Allarity A/S. The description of the manner in which the options will be converted is set forth in the section titled "Management of Allarity A/S-Executive Compensation and Director Compensation-Stock Options."

2021 Equity Incentive Plan

In connection with the Reorganization Share Exchange, the Board of Directors of Allarity A/S has approved the 2021 Plan and is submitting the 2021 Plan for shareholder approval at the Allarity A/S Extraordinary General Meeting. Allarity Delaware's board of directors will adopt the 2021 Plan prior to the Allarity A/S Extraordinary General Meeting, subject to shareholder approval at the Allarity A/S Extraordinary General Meeting. If the 2021 is approved then the 2021 Plan will become effective as of the date of the closing of the Recapitalization Share Exchange. In the event that the shareholders do not approve this proposal, the 2021 Plan will not become effective.

The description of the 2021 Plan is set forth in the section in titled "PROPOSAL NO. 3 — The Incentive Proposal" and in "Management of Allarity A/S-Executive Compensation and Director Compensation-2021 Equity Incentive Plan."

Limitation on Liability and Indemnification of Directors and Officers

Allarity Delaware's certificate of incorporation limits a director's liability to the fullest extent permitted under the DGCL. The DGCL provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability:

- for any breach of the director's duty of loyalty to the corporation or its stockholders;
- for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;
- for unlawful payment of dividend or unlawful stock purchase or redemption pursuant to the provisions of Section 174 of the DGCL; and
- for any transaction from which the director derived an improper personal benefit.

If the DGCL is amended to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of the directors will be eliminated or limited to the fullest extent permitted by the DGCL, as so amended.

Delaware law and the bylaws provide that Allarity Delaware will, in certain situations, indemnify its directors and officers and may indemnify other employees and other agents, to the fullest extent permitted by law. Any indemnified person is also entitled, subject to certain limitations, to advancement, direct payment, or reimbursement of reasonable expenses (including attorneys' fees and disbursements) in advance of the final disposition of the proceeding.

In addition, Allarity Delaware intends to enter into separate indemnification agreements with its directors and officers. These agreements, among other things, require Allarity Delaware to indemnify its directors and officers for certain expenses, including attorneys' fees, judgments, fines, and settlement amounts incurred by a director or officer in any action or proceeding arising out of their services as one of its directors or officers or any other company or enterprise to which the person provides services at its request.

Allarity Delaware plans to maintain a directors' and officers' insurance policy pursuant to which its directors and officers are insured against liability for actions taken in their capacities as directors and officers. We believe these provisions in the Certificate of Incorporation and bylaws and these indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers, or control persons, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Code of Business Conduct and Ethics for Employees, Executive Officers, and Directors

Following the closing of the Recapitalization Share Exchange, the board of directors will adopt a Code of Business Conduct and Ethics, or the Code of Conduct, applicable to all of Allarity Delaware's employees, executive officers and directors. The Code of Conduct will be available at the investors section of Allarity Delaware's website at *www.allarity.com*. Information contained on or accessible through this website is not a part of this information statement/prospectus, and the inclusion of such website address in this information statement/prospectus is an inactive textual reference only. Any amendments to the Code of Conduct, or any waivers of its requirements, are expected to be disclosed on its website to the extent required by applicable rules and exchange requirements.

SELECTED HISTORICAL FINANCIAL INFORMATION

The following selected historical financial information of Allarity Therapeutics A/S set forth below should be read in conjunction with "*Allarity Therapeutics Management's Discussion and Analysis of Financial Condition and Results of Operations*" and Allarity Therapeutics A/S, historical financial statements and the related notes thereto contained elsewhere in this information statement/prospectus.

The selected consolidated statements of operations and comprehensive loss data for the year ended December 31, 2020 and 2019, and the selected consolidated balance sheet data as of December 31, 2020 and 2019 are each derived from Allarity Therapeutics A/S' audited consolidated financial statements appearing elsewhere in this information statement/prospectus. The selected consolidated statements of operations and comprehensive loss data for the six months ended June 30, 2021 and 2020, and the selected consolidated balance sheet data as of June 30, 2021, are derived from Allarity Therapeutics A/S' unaudited condensed consolidated financial statements appearing elsewhere in this information statement/prospectus. The Allarity Therapeutics A/S unaudited interim condensed consolidated financial statements were prepared on the same basis as its audited annual financial statements and include all adjustments, consisting only of normal recurring adjustments that are considered necessary for a fair statement of the financial information set forth in those statements. The historical results are not necessarily indicative of the results to be expected in the future.

	As of December 31, 2020	As of December 31, 2019	As of June 30, 2021
Consolidated Balance Sheet Data:			
Total assets	$ 33,403	$ 31,607	$ 38,780
Total liabilities	$ 6,552	$ 10,704	$ 9,960
Total stockholders' equity	$ 26,851	$ 20,903	$ 28,820

	Year Ended December 31, 2020	Year Ended December 31, 2019	Period from January 1 to June 30, 2021	Period from January 1 to June 30, 2020
Consolidated Statements of Operation and Comprehensive Loss Data				
Revenue	$ —	$ 120	$ —	—
Operating expenses				
Research and development	5,126	6,367	3,755	2,221
General and administrative	4,101	3,870	3,521	2,292
Impairment	—	7,494	—	—
Total operating expenses	9,227	17,731	7,276	4,513
Loss from operations	(9,227)	(17,611)	(7,276)	(4,513)
Other (income) expense				
Interest income	—	(7)	—	—
Interest expense	227	3,312	509	336
(Gain) loss on investment	(708)	—	180	(411)
Foreign exchange (gain) loss, net	(62)	(80)	80	(86)
Fair value adjustment on derivative liabilities	(2,131)	(1,859)	(30)	(1,061)
Change in fair value of convertible debt	681	—	298	47
Total other (income) expense	(1,993)	1,366	1,037	(747)
Loss before income taxes	(7,234)	(18,977)	(8,313)	(3,766)
Income tax benefit	2,161	4,577	655	829
Net loss	(5,073)	(14,400)	(7,658)	(2,937)
Net loss attributable to non-controlling interests	(15)	(87)	—	(15)
Net loss attributable to Allarity A/S., common stockholders	(5,058)	(14,313)	(7,658)	(2,922)

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis provide information which Allarity Therapeutics' management believes is relevant to an assessment and understanding of Allarity Therapeutics A/S' consolidated results of operations and financial condition. You should read the following discussion and analysis of Allarity Therapeutics' financial condition and results of operations together with the section titled "Selected Historical Financial Information of Allarity Therapeutics" and Allarity Therapeutic A/S' audited consolidated financial statements and notes thereto and unaudited condensed consolidated financial statements and notes thereto included elsewhere in this information statement/prospectus. In addition to historical financial information, this discussion contains forward-looking statements based upon Allarity Therapeutics' current expectations that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under "Risk Factors" and elsewhere in this information statement/prospectus. Unless otherwise indicated or the context otherwise requires, references in this Management's Discussion and Analysis of Financial Condition and Results of Operations section to "Allarity Therapeutics," "we," "us," "our," and other similar terms refer to Allarity Therapeutics A/S and its consolidated subsidiaries.

We caution readers not to place undue reliance on any forward-looking statements made by us, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the SEC, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

Overview

We are a biopharmaceutical company focused on discovering and developing highly targeted anti-cancer drug candidates. Through the use of its Drug Response Predictor (DRP®) platform, the Company identifies the value in drug assets that have otherwise been discontinued by identifying patient populations where these drugs are active. The Company's three lead drug candidates are: the tyrosine kinase inhibitor (TKI) dovitinib, the poly-ADP-ribose polymerase (PARP) inhibitor stenoparib, and the microtubule inhibitor agent IXEMPRA.

Risks and Uncertainties

The Company is subject to risks common to companies in the biotechnology industry, including but not limited to, risks of failure of preclinical studies and clinical trials, the need to obtain marketing approval for any drug product candidate that it may identify and develop, the need to successfully commercialize and gain market acceptance of its product candidates, dependence on key personnel and collaboration partners, protection of proprietary technology, compliance with government regulations, development by competitors of technological innovations, and the ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including preclinical and clinical testing and regulatory approval prior to commercialization. Even if the Company's research and development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

Impacts of COVID-19 on our Business — Update

In March 2020, the World Health Organization declared COVID-19 a global pandemic. COVID-19 has had a modest impact on our operations as it caused some unexpected delays in our clinical program activities as clinical trials were delayed. Management is unable to estimate the future financial effects, if any, to our business as a result of COVID-19 because of the high level of uncertainties and unpredictable outcomes of this disease.

We are continuing to evaluate the impact of COVID-19 pandemic on our business and are taking proactive measures to protect the health and safety of our employees, as well as to maintain business continuity. Based on guidance issued by federal, state and local authorities, we transitioned to a remote work model for our employees, effective March 16, 2020. We believe that the measures we are implementing are appropriate, reflecting both regulatory and public health guidance, to maintain business continuity. We will continue to closely monitor and seek to comply with guidance from governmental authorities and adjust our activities as appropriate.

The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trial, healthcare systems or the global economy as a whole. However, these effects could harm our operations, and we will continue to monitor the COVID-19 situation closely.

Financial Operations Overview

Since our inception in September of 2004, we have focused substantially all of our resources on conducting research and development activities, including drug discovery and preclinical studies, establishing and maintaining our intellectual property portfolio, the manufacturing of clinical and research material, hiring personnel, raising capital and providing general and administrative support for these operations. In recent years, we have recorded very limited revenue from collaboration activities, or any other sources. We have funded our operations to date primarily from convertible notes and the issuance and sale of our ordinary shares.

We have incurred net losses in each year since inception. Our net losses were $5.07 million and $14.4 million for 2020 and 2019, respectively. Our net losses were $7.6 million and $2.9 million for the six months ended June 30, 2021 and 2020, respectively. As of June 30, 2021, we had an accumulated deficit of $45 million. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur significant expenses and increasing operating losses over at least the next several years. We expect our expenses will increase substantially in connection with our ongoing activities, as we:

- advance drug candidates through clinical trials;
- pursue regulatory approval of drug candidates;
- operate as a public company;
- continue our preclinical programs and clinical development efforts;
- continue research activities for the discovery of new drug candidates; and
- manufacture supplies for our preclinical studies and clinical trials.

Components of Operating Expenses

Research and Development Expenses

Research and development expenses include:

- expenses incurred under agreements with third-party contract organizations, and consultants;
- costs related to production of drug substance, including fees paid to contract manufacturers;
- laboratory and vendor expenses related to the execution of preclinical trials;
- employee-related expenses, which include salaries, benefits and stock-based compensation: and
- maintenance and renewal fees for patents.

We expense all research and development costs in the periods in which they are incurred. Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks and estimates of services performed using information and data provided to us by our vendors and third-party service providers. Non-refundable advance payments for goods or services to be received in future periods for use in research and development activities are deferred and accounted for as prepaid expenses. The prepayments are then expensed as the related goods are delivered and as services are performed.

To date, the majority of these expenses have been incurred to advance our lead drug candidates, dovitinib, stenoparib, and IXEMPRA®.

We expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in research and development activities related to developing our drug candidates, as our drug candidates advance into later stages of development, and as we begin to conduct clinical trials. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the

successful development of our drug candidates is highly uncertain. As a result, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our drug candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related costs, facilities costs, depreciation and amortization expenses and professional services expenses, including legal, human resources, audit and accounting services. Personnel-related costs consist of salaries, benefits and stock-based compensation. Facilities costs consist of rent and maintenance of facilities. Legal costs incurred in connection with patents are accounted for as general and administrative expenses. We expect our general and administrative expenses to increase for the foreseeable future due to anticipated increases in headcount to advance our drug candidates and as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the SEC, Nasdaq Stock Market, additional insurance expenses, investor relations activities and other administrative and professional services.

Other Income (Expenses), Net

Other income (expense) of ($2 million) recognized in the year ended December 31, 2020 consisted primarily of a ($2.1 million) fair value adjustment to derivative liabilities, a ($708 thousand) gain on our equity investment in Lantern Pharma, and a $62 thousand gain on foreign exchange transactions, offset by $227 thousand in interest expenses and a $681 thousand increase in the fair value of convertible debt.

Other income (expense) of $1.37 million recognized in the year ended December 31, 2019 consisted primarily of a ($1.86 million) fair value adjustment to derivative liabilities, a gain of ($80 thousand) on foreign exchange transactions and $7 thousand in interest income, offset by $3.3 million in interest expense.

Changes in fair value of our derivative liabilities and convertible debt are measured using level 3 inputs as described in our consolidated financial statements.

Results of Operations

Comparison of Three and Six months Ended June 30, 2021 and 2020

The following table summarizes our results of operations for the three and six months ended June 30, 2021 and 2020 (in thousands):

	For the three months ended June 30,		Increase/	For the six months ended June 30,		Increase/
	2021	2020	(Decrease)	2021	2020	(Decrease)
	(In thousands)			(In thousands)		
Operating expenses:						
Research and development	$ 2,098	$ 652	$ 1,446	$ 3,755	$ 2,221	$ 1,534
General and administrative	2,497	1,281	1,216	3,521	2,292	1,229
Total operating expenses	$ 4,595	$ 1,933	$ 2,662	$ (7,276)	$ (4,513)	$ 2,763

Research and Development Expenses

We currently do not track our research and development costs by product candidate. A breakdown by nature of type of expense for the three and six month periods ended June 30, 2021 and June 30, 2020 is provided below.

	For the three months ended June 30,		Increase/	For the six months ended June 30,		Increase/
	2021	2020	(Decrease)	2021	2020	(Decrease)
	(In thousands)			(In thousands)		
Research study expenses	428	258	170	1,197	1,248	(51)
Recovery of R&D costs	—	(15)	15	—	(15)	15
Manufacturing & supplies	487	16	471	793	54	739
Contractors	863	101	762	1,079	307	772
Patents	—	—	—	67	66	1
Staffing	248	248	—	496	465	31
Amortization	32	36	(4)	68	72	(4)
Other	40	8	32	55	24	31
	$ 2,098	**$ 652**	$ 1,446	**$ 3,755**	**$ 2,221**	$ 1,534

For the three month period ended June 30, 2021 versus June 30, 2020:

The increase of $1.4 million in research and development cost was due to an increase of $170 thousand in research study expenses, a decrease of $15 thousand in recovery of R&D costs, an increase of $471 thousand in Manufacturing and supplies, an increase of $762 thousand in Contractors; a decrease of $4 thousand in amortization, and an increase of $32 thousand in other expenses. Overall, the increase was because activity during the 3 months ended June 30, 2020 was paused or significantly slowed due to Covid-19. Research and development in the 3 months ended June 30, 2021 increased as activity in the clinical trials coming back to a pre-pandemic level. Manufacturing & supplies and contractor costs has increased in preparation of our NDA filing for Dovitinib.

For the six month period ended June 30, 2021 versus June 30, 2020:

The increase of $1.5 million in research and development cost was due to a decrease of $51 thousand in research study expenses, a decrease of $15 thousand in recovery of R&D costs, an increase of $739 thousand in manufacturing and supplies, an increase of $772 thousand in Contractors; an increase of $1 thousand in patent expenses, an increase of $31 thousand in staffing expenses, a decrease of $4 thousand in amortization, and an increase of $31 thousand in other expenses. Overall, the increase was because activity during the 6 months ended June 30, 2020 was paused or significantly slowed due to Covid-19. Manufacturing & supplies and contractor costs increased in preparation of our NDA filing for Dovitinib.

General and Administrative Expenses

General and administrative expenses increased by $1.2 million for the three months ended June 30, 2021 compared to the same period in 2020. The increase was primarily due to an increase in professional fees of $997 thousand, an increase in staffing costs of $201 thousand and an increase in other expenses of $18 thousand. Professional fees increased as the Company prepared its prospectus to file with the SEC in its effort to move it's listing to the US Nasdaq.

General and administrative expenses increased by $1.23 million for the six months ended June 30, 2021, compared to the same period in 2020 primarily for the same reasons as the increase in cost in the three months ended June 30, 2021.

Year Ended December 31, 2020 and 2019

	December 31,		Increase/
	2020	2019	(Decrease)
	(In thousands)		
Operating expenses:			
Research and development	$ 5,126	$ 6,367	$ (1,241)
General and administrative	4,101	3,870	231
Impairment	—	7,494	(7,494)
Total operating expenses	(9,227)	(17,731)	(8,504)

Research and Development Expenses

A breakdown by nature of type of expense for the years ended December 31, 2020 and December 31, 2019 is provided below.

In ($1,000's of USD)	Year ended December 31, 2020	2019	Increase/ (Decrease)
Research study expenses	2,119	2,843	(724)
Recovery of R&D costs	(22)	(315)	293
Manufacturing & supplies	332	530	(198)
Contractors	1,106	1,668	(562)
Patents	198	180	18
Staffing	954	1,226	(272)
Amortization	149	152	(3)
Other	290	83	207
TOTAL:	**5,126**	**6,367**	(1,241)

The decrease of $1.2 million in research and development cost was due to a decrease of $724 thousand in research study expenses, a decrease of $293 thousand in recovery of R&D costs, a decrease of $198 thousand in manufacturing and supplies, a decrease of $562 thousand in contractors, an increase of $18 thousand in patent costs, a decrease of $272 thousand in staffing; a decrease of $3 thousand in amortization, and an increase of $207 thousand in other expenses. Overall, the decrease was related to the Covid-19 pandemic as most R&D activity was paused or significantly slowed for the majority of 2020.

General and Administrative Expenses

General and administrative expenses increased by $231 thousand for the year ended December 31, 2020 compared to the same period in 2019. This was due to $830 thousand increase in staffing, professional fees and insurance offset by a decrease in other expenses and communications $500 thousand.

Impairment Expenses

Impairment expenses decreased by $7.5 million for the year ended December 31, 2020 compared to the same period in 2019. During 2019 the Company wrote off LiplaCis a deprioritized product no longer part of our 3 top priority products; Dovitinib, Stenoparib and Ixempra.

Liquidity, Capital Resources and Plan of Operations

Since our inception through June 30, 2021, our operations have been financed primarily by the sale of convertible promissory notes and the sale and issuance of our ordinary shares. As of June 30, 2021, we had $6.6 million in cash and investments, and an accumulated deficit of $45 million.

In the six months ended June 30, 2021 we received $12.1 million in gross proceeds from the issuance of 121.3 million units of one common share and one share purchase warrant; and proceeds from convertible debt of $1.2 million. We also received a bridge loan of $2.9 million in the six months ended June 30, 2021 and repaid $2.9 million in June 2021.

In 2020, we received $3 million in net proceeds from the sale and issuance of convertible notes. We also received $4 million in proceeds from share issuance.

Our primary use of cash is to fund operating expenses, which consist of research and development as well as regulatory expenses related to our lead drug candidate, dovitinib, and clinical programs for stenoparib and IXEMPRA®, and to a lesser extent, general and administrative expenses. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

As of August 6, 2021, the Company's cash deposits of $6.2 million were determined to be insufficient to fund its current operating plan and planned capital expenditures for at least the next 12 months. These conditions give rise to a substantial doubt over the Company's ability to continue as a going concern.

Management's plans to mitigate the conditions or events that raise substantial doubt include additional funding through public equity, private equity, debt financing, collaboration partnerships, or other sources. There are no assurances, however, that the Company will be successful in raising additional working capital, or if it is able to raise additional working capital, it may be unable to do so on commercially favorable terms. The Company's failure to raise capital or enter into other such arrangements if and when needed would have a negative impact on its business, results of operations and financial condition and its ability to develop its product candidates.

The Company has also entered into a Securities Purchase Agreement with 3i, LP, a Delaware limited partnership that provides for a $20 million equity investment in the Company. Please refer to the subsequent event disclosures in note 25 for further information.

We expect to incur substantial expenses in the foreseeable future for the development and potential commercialization of our drug candidates and ongoing internal research and development programs. At this time, we cannot reasonably estimate the nature, timing or aggregate amount of costs for our development, potential commercialization, and internal research and development programs. However, in order to complete our current and future preclinical studies and clinical trials, and to complete the process of obtaining regulatory approval for our drug candidates, as well as to build the sales, marketing and distribution infrastructure that we believe will be necessary to commercialize our drug candidates, if approved, we may require substantial additional funding in the future.

Cash Flows

The following table summarizes our cash flows for the periods indicated:

(In thousands)	Year Ended December 31, 2020	Year Ended December 31, 2019	Six months Ended June 30, 2021	Six months Ended June 30, 2020
Net Cash used in operating activities	$ (7,251)	$ (10,113)	$ (6,646)	$ (3,907)
Net Cash (used in) provided by investing activities	(3)	229	—	—
Net Cash provided by financing activities	6,033	11,202	13,062	2,019
Net (decrease) increase in cash and cash equivalents	$ (1,221)	$ 1,318	$ 6,416	$ (1,888)

Operating Activities

During the six months ended June 30, 2021, cash used in operating activities of $6.6 million was attributable to a net loss of $7.7 million, $310 thousand of deferred income taxes and offset by $1.6 million in non-cash charges. The non-cash charges consisted of a reduction from fair value adjustments of convertible debt of $383 thousand and fair value decrease of the derivative liability of $30 thousand. This was offset by foreign currency gain of $4 thousand, non-cash interest of $451 thousand, stock-based compensation of $628 thousand and depreciation of $18 thousand. The cash used in operating assets and liabilities of $360 thousand was primarily because of an increase in income taxes receivable of $345 thousand, an increase in current assets of $230 thousand and a decrease in operating lease liabilities of $47 thousand, offset by a decrease in accounts payable of $151 thousand, decrease in prepaid expenses of $93 thousand, and a decrease in accrued liabilities of $15 thousand.

During the six months ended June 30, 2020, cash used in operating activities of $3.9 million was attributable to a net loss of $2.9 million, $829 thousand of deferred income taxes and $618 thousand in non-cash charges. This was offset by a $477 thousand net change in net operating assets and liabilities. The non-cash charges consisted of foreign currency gain of $86 thousand, a reduction from fair value adjustments of the convertible debt of $475 thousand and fair value adjustments of the derivative liability of $1 million. This was offset by non-cash interest of $31 thousand, stock-based compensation of $392 thousand and depreciation of $22 thousand. The change in operating assets and liabilities of $477 thousand was primarily due to a $649 thousand decrease in income taxes receivable, a $340 thousand decrease in other current assets, a $95 thousand decrease in accounts receivable, and a $72 thousand decrease in prepaid expenses, offset by a decrease in accounts payable of $471 thousand, a decrease in accrued liabilities of $164 thousand, and a decrease in operating lease liabilities of $42 thousand.

In 2020, cash used in operating activities of $7 million was attributable to a net loss of $5.1 million, $1.3 million in deferred income taxes, and a $708 thousand gain on equity investment. This was offset by $0.6 million in non-cash charges and a net change of $445 thousand in our net operating assets and liabilities. The non-cash charges consisted

of a $2.1 million increase in fair value adjustment of the derivative liability, a decrease of $681 thousand in fair value adjustment of convertible term loan, $616 thousand in expense related to share-based compensation, $187 thousand in non-cash interest and $46 thousand in depreciation and amortization. The change in operating assets and liabilities was primarily due to a $605 thousand decrease in accounts receivable and other current assets, offset by a decrease in income taxes receivable of $71 thousand, a decrease in prepaid expenses of $97 thousand, decrease in accounts payable of $62 thousand, decrease in accrued liabilities of $36 thousand and a decrease in operating lease liability of $88 thousand.

In 2019 cash used in operating activities of $10.1 million was attributable to a net loss of $14.4 million and $3.8 million increase in deferred income taxes. This was partially offset by $6 million in non-cash charges and a net change of $2.1 million in our net operating assets and liabilities. The non-cash charges consisted of impairment write-off of our IPR&D in the amount of $7.5 million, a $1.9 million increase in fair value adjustment of the derivative liability, and $333 thousand in expense related to share-based compensation and depreciation of $51 thousand. The change in operating assets and liabilities was primarily due to $1.6 million increase in accounts payable and accrued liabilities, increase of $500 thousand of income tax receivable, and decrease of $217 thousand in prepaid expenses. This is offset by an increase of $101 thousand in accounts receivable and other current assets and a decrease of $121 thousand in operating lease liability and deferred revenue.

Investing Activities

During the six months ended June 30, 2021 and June 30, 2020, the Company did not generate any cash flows with respect to investing activities.

In 2020, cash used by investing activities of $3 thousand was used to purchase equipment.

In 2019, cash provided by investing activities of $229 thousand comprised of $237 thousand in proceeds received from the sale of an equity investment offset by a use of cash of $8 thousand to purchase equipment.

Financing Activities

During the six months ended June 30, 2021, cash provided by financing activities of $13 million was related to proceeds from share issuance of $12.1 million and convertible loan proceeds of $1.2 million, offset by $250 thousand in share issuance costs and $23 thousand repayment of our line of credit. We also received and repaid $2.9 million in loan funding during the six months ended June 30, 2021.

During the six months ended June 30, 2020, cash provided by financing activities of $2 million was related to proceeds from share issuance of $1.6 million and convertible loan proceeds of $1 million, offset by $533 thousand for repayment of loan and $136 thousand of share issuance costs.

In 2020, cash provided by financing activities of $6.0 million was related to net proceeds of $4 million from the issuance of common shares, $3 million from convertible debt, and $84 thousand from line of credit, partially offset by repayment of a loan of $533 thousand and share issuance costs of $223 thousand.

In 2019, cash provided by financing activities of $11.2 million was related to net proceeds of $13.6 million from the issuance of common shares, and $8.7 million from loan proceeds, partially offset by loan repayment of $5.1 million, share issuance costs of $4.4 million, and purchase of non-controlling interests for $802 thousand.

Contractual Obligations and Commitments

The following table summarizes our commitments and contractual obligations as of June 30, 2021:

	Payments Due By Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
			(In thousands)		
Line of credit	$ 58	$ 58	$ —	$ —	$ —
Operating lease obligations	$ 160	$ 98	$ 62	$ —	$ —

The following table summarizes our commitments and contractual obligations as of December 31, 2020:

	Payments Due By Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
			(In thousands)		
Line of credit	$ 84	$ 84	$ —	$ —	$ —
Operating lease obligations	$ 376	$ 109	$ 267	$ —	$ —
Convertible debt	$ 1,327	$ 1,327	$ —	$ —	$ —

We enter into agreements in the normal course of business with vendors for preclinical studies, clinical trials and other service providers for operating purposes. We have not included these payments in the table of contractual obligations above since these contracts are generally cancellable at any time by us following a certain period after notice and therefore, we believe that our non-cancellable obligations under these agreements are not material.

Off-Balance Sheet Arrangements

The Company does not have any off-balance sheet arrangements.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of financial condition and results of operations is based upon our unaudited condensed consolidated financial statements for the three and six month periods ended June 30, 2021 and June 30, 2020, and our audited consolidated financial statements for the years ended December 31, 2020 and December 31, 2019, which have been prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. On an on-going basis, we evaluate our critical accounting policies and estimates. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable in the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions and conditions.

While our significant accounting policies are described in the notes to our consolidated financial statements for the years ended December 31, 2020 and December 31, 2019 and there have been no changes to our significant accounting policies during the six months ended June 30, 2021, we believe that the following critical accounting policies are most important to understanding and evaluating our reported financial results.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting years. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the fair value of the convertible loan, the accrual for research and development expenses, revenue recognition, fair values of acquired intangible assets and impairment review of those assets, share based compensation expense, and income taxes. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. Estimates are periodically reviewed in light of reasonable changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates or assumptions.

Acquired In-Process Research and Development (IPR&D)

Acquired IPR&D represents the fair value assigned to research and development assets that the Company acquires and have not been completed at the acquisition date. The fair value of IPR&D acquired in a business combination is recorded on the consolidated balance sheets at the acquisition-date fair value and is determined by estimating the costs to develop the technology into commercially viable products, estimating the resulting revenue from the projects, and discounting the projected net cash flows to present value. IPR&D is not amortized, but rather is reviewed for impairment on an annual basis or more frequently if indicators of impairment are present, until the project is completed, abandoned or transferred to a third-party. The projected discounted cash flow models used to estimate

the fair value of partnered assets and cost approach model used to estimate proprietary assets as part of the Company's IPR&D reflect significant assumptions regarding the estimates a market participant would make in order to evaluate a drug development asset, including the following:

- Estimates of obsolescence of development expenditure;
- Probability of successfully completing clinical trials and obtaining regulatory approval;
- Estimates of future cash flows from potential milestone payments and royalties related to out-licensed product sales; and
- A discount rate reflecting the Company's weighted average cost of capital and specific risk inherent in the underlying assets.

Once brought into use, intangible assets are amortized over their estimated useful economic lives, which for acquired IPR&D assets is over the remaining life of the relevant patents.

Research contract costs and accruals

The Company has entered into various research and development contracts with companies both inside and outside of the United States. These agreements are generally cancellable, and related payments are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies or trials, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Convertible note:

The Company accounts for certain convertible notes issued during the year ended December 31, 2020 under the fair value option ("FVO") election of ASC 825, Financial Instruments ("ASC-825") as discussed below.

The convertible notes accounted for under FVO wherein the financial instrument is initially measured at its issue-date estimated fair value and then subsequently re-measured at estimated fair value on a recurring basis at each reporting period date. The estimated fair value adjustments are based upon a discounted cash flow valuation technique using a weighted cost of capital of 15% and are recognized as other income (expense) in the accompanying consolidated statement of operations and the portion of the fair value adjustment attributed to a change in the instrument-specific credit risk is recognized as a component of other comprehensive income ("OCI").

Warrants

When the Company issues warrants, it evaluates the proper balance sheet classification of the warrant to determine whether the warrant should be classified as equity or as a derivative liability on the consolidated balance sheets. In accordance with ASC 815-40, Derivatives and Hedging-Contracts in the Entity's Own Equity (ASC 815-40), the Company classifies a warrant as equity so long as it is "indexed to the Company's equity" and several specific conditions for equity classification are met. A warrant is not considered indexed to the Company's equity, in general, when it contains certain types of exercise contingencies or adjustments to exercise price. If a warrant is not indexed to the Company's equity or it has net cash settlement that results in the warrants to be accounted for under ASC 480, Distinguishing Liabilities from Equity, or ASC 815-40, it is classified as a derivative liability which is carried on the consolidated balance sheet at fair value with any changes in its fair value recognized immediately in the statement of operations. Warrants are fair valued using the Black-Scholes option pricing model. The Black-Scholes option pricing model requires the use of highly subjective and complex assumptions, including the option's expected term and the price volatility of the underlying stock, to determine the fair value of the award. As of December 31, 2020 and 2019, the Company had warrants that were classified as equity and warrants that were classified as liabilities.

Share-based compensation

The Company accounts for share-based compensation in accordance with ASC 718, Compensation — Stock Compensation ("ASC 718"). ASC 718 requires companies to estimate the fair value of equity-based payment awards on the date of grant. The value of the portion of the award that is ultimately expected to vest is recognized as an expense over the requisite service period in the Company's consolidated statements of operations and comprehensive loss.

The Company records the expense for option awards using either a graded or straight-line vesting method. The Company accounts for forfeitures as they occur. For share based awards granted to non-employee consultants, the measurement date for non-employee awards is the date of grant. The compensation expense is then recognized over the requisite service period, which is the vesting period of the respective award.

The Company reviews stock award modifications when there is an exchange of original award for a new award. The Company calculates for the incremental fair value based on the difference between the fair value of the modified award and the fair value of the original award immediately before it was modified. The Company immediately recognizes the incremental value as compensation cost for vested awards and recognizes, on a prospective basis over the remaining requisite service period, the sum of the incremental compensation cost and any remaining unrecognized compensation cost for the original award on the modification date.

The fair value of stock options ("options") on the grant date is estimated using the Black-Scholes option-pricing model using the single-option approach. The Black-Scholes option pricing model requires the use of highly subjective and complex assumptions, including the option's expected term and the price volatility of the underlying stock, to determine the fair value of the award. The Company applies the Black-Scholes model as it believes it is the most appropriate fair value method for all equity awards.

Contingencies

Liabilities for loss contingencies arising from claims, assessments, litigation, fines, penalties and other sources are recorded when it is probable that a liability has been incurred and the amount can be reasonably estimated. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential loss range is probable and reasonably estimable under the provisions of the authoritative guidelines that address accounting for contingencies. The Company expenses costs as incurred in relation to such legal proceedings as general and administrative expense within the consolidated statements of operations and comprehensive loss.

Qualitative and Quantitative Disclosures about Market Risk

Interest Rate Risk

We had cash of $6.6 million as of June 30, 2021, consisting of cash. We had no cash equivalents at June 30, 2021. To date, fluctuations in interest income have not been significant.

We do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate risk exposure. We have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates. A hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our consolidated financial statements.

Recently Issued Accounting Pronouncements

See the sections titled "*Recently Issued Accounting Pronouncements*" in Note 1(j) to the Company's unaudited interim condensed consolidated financial statements for the three and six month periods ended June 30, 2021 and June 30, 2020 and in "*Significant Accounting Policies — Accounting pronouncements not yet adopted*" in Note 2 to the Company's consolidated financial statements for the year ended December 31, 2020 and December 31, 2019, respectively, appearing elsewhere herein.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table and accompanying footnotes set forth information regarding (1) the actual beneficial ownership of Allarity A/S ordinary shares as of September 17, 2021, and (2) expected beneficial ownership of shares of Allarity Delaware Common Stock immediately following the consummation of the Recapitalization Share Exchange based on the Exchange Ratio by:

- each person who is known to be the beneficial owner of more than 5% of the outstanding Allarity A/S ordinary shares or is expected to be the beneficial owner of more than 5% of any class of shares of Allarity Delaware Common Stock Post-Recapitalization Share Exchange;
- our current executive officers and each of our current directors;
- our executive officers or directors Post-Recapitalization Share Exchange; and
- all of our executive officers and directors as a group Pre-Recapitalization Share Exchange, and all of our executive officers and directors Post-Recapitalization Share Exchange.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC. A person is a "beneficial owner" of a security if that person has or shares "voting power," which includes the power to vote or to direct the voting of the security, or "investment power," which includes the power to dispose of or to direct the disposition of the security or has the right to acquire such powers within sixty (60) days.

The beneficial ownership of ordinary shares Pre-Recapitalization Share Exchange is based on 403,791,200 shares of Allarity A/S ordinary shares issued and outstanding as of September 17, 2021. The beneficial ownership Post-Recapitalization Share Exchange assumes the exercise of vested options and warrants such security holder had a right to acquire immediately before the closing of the Recapitalization Share Exchange and such options that vested as a result of the Recapitalization Share Exchange.

The expected beneficial ownership of shares of our Common Stock Post-Recapitalization Share Exchange excludes any common stock underlying any convertible preferred stock issued or owned by 3i, LP, a Delaware limited partnership, subsequent to closing of the Recapitalization Share Exchange as a result of their beneficial ownership limitation of 4.99%. 3i, LP's beneficial ownership limitation may be adjusted to a beneficial ownership limitation of 9.99% upon 61 days prior written notice. We have not received notice to increase adjustment as of the date hereof. If there were no beneficial ownership limitation in the COD, the Preferred Shares would be entitled to convert into 2,018,958 shares of our Common Stock immediately after the closing of the PIPE Investment, or 20% of our anticipated issued and outstanding shares of Common Stock of Allarity Delaware.

Unless otherwise noted in the footnotes to the following table, and subject to applicable community property laws, the persons and entities named in the table have sole voting and investment power with respect to their beneficially owned Common Stock. Additionally, except as set forth in the footnote, the following table does not reflect record or beneficial ownership of any shares of Allarity A/S ordinary shares issuable upon exercise of warrants, options or convertible preferred stock, as such securities are not exercisable or convertible within sixty (60) days of September 17, 2021.

Name of Beneficial Owner[1]	Pre-Recapitalization Share Exchange		Post-Recapitalization Share Exchange[2][3]	
	Number of Shares of Allarity A/S Beneficially Owned	Percentage of Class	Number of Shares of Allarity Delaware Beneficially Owned	Percentage of Class
5% and Greater Holders:				
Sass & Larsen ApS[4]	54,211,969	13.43%	1,084,239	13.43%
Directors and Named Executive Officers Pre- and Post-Recapitalization Share Exchange:				
Steve R. Carchedi[5]	6,095,272	1.49%	157,144	1.91%
Jens E. Knudsen[6]	993,335	*	19,867	*
James G. Cullem[7]	3,027,460	*	78,569	*
Marie Foegh	1,449,432	*	28,989	*
Duncan Moore[10]	1,355,851	*	27,117	*
Søren Gade Jensen[8]	254,166	*	5,083	*
Gail Maderis[9]	114,166	*	2,283	*
All directors and executive officers as a group (7 individuals)	13,289,680	3.21%	319,052	3.83%

* Less than one percent (1%).

(1) Unless otherwise noted, the business address of each of the following entities or individuals is c/o Allarity Therapeutics, Inc., 210 Broadway, Suite 201, Cambridge, MA 02139.

(2) The calculations for Post-Recapitalization of Share Exchange assume options and warrants which granted the reporting person(s) a right to acquire ordinary shares of Allarity A/S within sixty (60) days of September 17, 2021 were exercised and the ordinary shares or options held by such reporting person(s), if any, are automatically converted into Delaware Common Stock at the exchange ratio equal to the quotient of the number of Allarity A/S ordinary shares outstanding in Allarity A/S divided by fifty (50) or 0.02 shares in Allarity Delaware for each Allarity A/S ordinary share in Allarity A/S in connection with the Recapitalization Share Exchange. In each case, with the share amounts rounded down to the nearest whole number on a holder-by-holder basis. In addition, assumes vesting of all options that are subject to accelerated vesting pursuant to contractual rights.

(3) Excludes shares of Common Stock that may be issued to and acquired by 3i in the PIPE investment.

(4) Interests shown include 973,432 ordinary shares held in the name of Leon Sass. Leon Sass and Benny Sass are the beneficial owners of Sass & Larsen ApS. Leon Sass and Benny Sass each own 50% of Sass & Larsen ApS.

(5) Interests shown include ordinary shares issuable upon exercise of vested options within sixty (60) days. Post-Recapitalization Share Exchange ownership includes 1,761,937 ordinary shares underlying options which shall vest at closing, but excludes ordinary shares underlying options subject to vesting.

(6) Interests shown include ordinary shares issuable upon exercise of vested options within sixty (60) days.

(7) Interests shown include (i) 509,450 ordinary shares and (ii) 2,518,010 ordinary shares issuable upon exercise of vested options within sixty (60) days. Post-Recapitalization Share Exchange ownership includes 391,542 ordinary shares underlying options which shall vest at closing, but excludes ordinary shares underlying options subject to vesting.

(8) Interests shown include (i) 140,000 ordinary shares, and (ii) 114,166 ordinary shares issuable upon exercise of options within sixty (60) days.

(9) Interests shown include ordinary shares issuable upon exercise of vested options within sixty (60) days.

(10) Interests shown include (i) 850,222 ordinary shares, and (ii) (222,222 ordinary shares issuable upon exercise of options within sixty (60) days.

THE RECAPITALIZATION SHARE EXCHANGE

The following is a discussion of the Recapitalization Share Exchange and the material terms of the Reorganization Agreement among Allarity Delaware, Acquisition Sub and Allarity A/S. You are urged to read carefully the Reorganization Agreement in its entirety, a copy of which is attached as Annex A to this information statement/prospectus. This summary does not purport to be complete and may not contain all of the information about the Reorganization Agreement that is important to you. We encourage you to read the Reorganization Agreement carefully and in its entirety. This section is not intended to provide you with any factual information about Allarity Delaware or Allarity A/S. Such information can be found elsewhere in this information statement/prospectus.

Terms of the Recapitalization Share Exchange

Transaction Structure

Allarity A/S's and Allarity Delaware's boards of directors have approved the Reorganization Agreement. Pursuant to the Reorganization Agreement, Allarity Delaware, a direct wholly owned subsidiary of Allarity A/S, by and through a direct wholly owned subsidiary of Allarity Delaware, will purchase substantially all of the assets and assume substantially all of the liabilities of Allarity A/S in exchange for the common stock of Allarity Delaware (the "Delaware Common Stock"). Allarity A/S will then distribute the Delaware Common Stock issued as consideration for the assets and liabilities of Allarity A/S to holders of Allarity A/S ordinary shares, first through a voluntary share exchange swap program for an amount equal to the Exchange Ratio, and thereafter by an extraordinary dividend in the amount of the Exchange Ratio to holders of Allarity A/S ordinary shares that did not participate in the share exchange swap program. Allarity A/S will then liquidate and dissolve in accordance with Part 14 of the DCA. Other than the Converted Options specifically provided for in Section 206 of the Reorganization Agreement, neither Allarity Delaware nor Acquisition Sub will be assuming any equity-based compensation arrangement or employee bonuses based upon the sale or disposition of Allarity A/S' therapeutic candidates.

Consideration for the Recapitalization Share Exchange

The number of shares of Allarity Delaware voting common stock that will be issued in exchange for substantially all of the assets and liabilities of Allarity A/S and subsequently distributed to the shareholders of Allarity A/S is determined by an exchange ratio of 0.02 share of Delaware Common Stock for each ordinary share of Allarity A/S (the "Exchange Ratio") issued and outstanding at the Closing. As of the date of this information statement, prospectus, we anticipate issuing approximately 8,075,824 shares of Delaware Common Stock in the Recapitalization Share Exchange.

Shareholders of Allarity A/S will then be given the opportunity to exchange their ordinary shares of Allarity A/S for an amount of Delaware Common Stock equal to the Exchange Ratio rounded down to the nearest whole number during the share exchange swap program and any fractional interest will be settled in cash. Any shares of Delaware Common Stock remaining after the share exchange swap program expires will be distributed to the remaining shareholders of Allarity A/S by an extraordinary dividend or liquidating distribution, subject to any required withholding for taxes. No fractional shares will be issued in the Share Exchange Recapitalization and any fractional interest will be settled in cash.

At the effective time, each warrant (option) conferring the right to subscribe for Allarity A/S ordinary shares held by the officers, directors, employees and consultants (each, a "Compensatory Warrant") that is outstanding immediately prior to the effective time, whether vested or unvested, will be assumed by Allarity Delaware and converted into an option (each, a "Converted Option") to purchase a number of shares of Delaware Common Stock equal to the product (rounded down to the nearest whole number) of (a) the number of ordinary shares of Allarity A/S subject to such Compensatory Warrant immediately prior to the effective time multiplied by (b) the exchange ratio, at an exercise price per share (rounded up to the nearest whole cent) equal to (i) the exercise price per share of such Compensatory Warrant immediately prior to the effective time divided by (ii) the exchange ratio and converted into U.S. dollars; provided, however, that the exercise price and the number of shares of Delaware Common Stock purchasable pursuant to the Converted Options will be determined in a manner consistent with the requirements of Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"); provided, further, however, that in the case of any Converted Option to which Section 422 of the Code applies, the exercise price and the number of shares of Delaware Common Stock purchasable pursuant to such option will be determined in accordance with the foregoing, subject to such adjustments in a manner consistent with Treasury Regulation Section 1.424-1, such that the Converted

Option will not constitute a modification of such Converted Option for purposes of Section 409A or Section 424 of the Code. Except as specifically provided above, following the effective time, each Converted Option will continue to be governed by the same terms and conditions (including vesting and exercisability terms) as were applicable to the corresponding former Compensatory Warrant immediately prior to the effective time.

Recommendation of the Allarity A/S Board of Directors and Reasons for the Recapitalization Share Exchange

The Allarity A/S board of directors, in evaluating the Recapitalization Share Exchange, consulted with Allarity A/S's executive management and its legal counsel, and financial, accounting and other advisors. In reaching its unanimous resolution (i) that the terms and conditions of the Reorganization Agreement and the Recapitalization Share Exchange contemplated thereby, are advisable, fair to and in the best interests of Allarity A/S and its shareholders and (ii) to recommend that Allarity A/S's shareholders adopt the Reorganization Agreement and approve the transactions contemplated thereby, including the Recapitalization Share Exchange, Allarity A/S's board of directors considered and evaluated a number of reasons. In light of the number and wide variety of factors considered in connection with its evaluation of the Recapitalization Share Exchange, Allarity A/S's board of directors did not consider it practicable to, and did not attempt to, quantify or otherwise assign relative weights to the specific reasons that it considered in reaching its determination and supporting its decision. This explanation of Allarity A/S's reasons for the Recapitalization Share Exchange and all other information presented in this section is forward-looking in nature and, therefore, should be read in light of the factors discussed under "*Cautionary Note Regarding Forward-Looking Statements; Market, Ranking and Other Industry Data*" beginning on page 3 of this information statement/prospectus.

The Board considered a number of reasons pertaining to the Recapitalization Share Exchange as generally supporting its decision to enter into the Reorganization Agreement and the transactions contemplated thereby, including:

- ***Substantial Investment of $20 million.*** The PIPE Investment of $20 million from 3i, LP, a Delaware limited partnership, is conditioned upon the consummation of the Recapitalization Share Exchange and a listing of the Delaware Common Stock on the Nasdaq Stock Market and will represent the largest investment by an institutional investor in Allarity A/S ever made.

- ***Enhanced Shareholder Value through Access to Capital.*** The Recapitalization Share Exchange presents an opportunity to enhance long-term value for shareholders, through attracting deeper and growing pools of passive investment capital in the U.S, like 3i, LP, a Delaware limited partnership that primarily invest in U.S. listed companies.

- ***Redomiciling to the U.S.*** The Recapitalization Share Exchange will redomicile the company as a U.S.-based biopharmaceutical company, which we believe will level the playing field with our principal competitors, many of which are U.S.-based companies;

- ***Executive Management.*** We will continue to use our proprietary DRP® predictive biomarker platform to generate drug-specific companion diagnostics from our research facilities in Denmark while maintaining executive offices in the U.S. for our U.S. based senior executives.

- ***Comparable Peer Group.*** Following the Recapitalization Share Exchange, shares of our common stock will be listed on the Nasdaq Stock Market and we will report our consolidated financial results in U.S. dollars instead of SEK and in accordance with U.S. GAAP instead of IFRS, and will file reports with the SEC making it easier for the market to compare our business, pipeline of therapeutic candidates, and prospects with our peer group of U.S. listed comparable companies.

- ***Broadening Investor Base Enhancing Market Capitalization.*** We believe that our listing on the Nasdaq Stock Market and enhancing our comparability to our U.S. peers will enable a broader range of potential investors to invest in our shares and may result in a market capitalization closer to other U.S. listed biopharmaceutical companies with a comparable pipeline of therapeutic candidates.

- ***Delaware Incorporation.*** Redomiciling in Delaware will provide for greater comparability to other U.S. public companies, many of which are incorporated in Delaware.

- ***Shareholder Approval.*** The Recapitalization Share Exchange is subject to obtaining the approval of our shareholders.

- ***U.S. Listing on the Nasdaq Stock Market.*** The consummation of the Recapitalization Share Exchange is conditioned upon the listing of the Delaware Common Stock of the Nasdaq Stock Market.

The Allarity A/S board of directors also considered a variety of uncertainties and risks and other potentially negative factors concerning the Recapitalization Share Exchange, including, but not limited to, the following:

- ***Benefits Not Achieved.*** The risk that the potential benefits of the Recapitalization Share Exchange may not be fully achieved, or may not be achieved within the expected timeframe.
- ***Possible Liquidation of Allarity A/S.*** The risks and costs to Allarity A/S if the Recapitalization Share Exchange is not completed, including the risk of diverting management focus and resources to other capital raising opportunities, which could result in Allarity A/S being unable to raise the additional capital it requires to advance its therapeutic candidates forcing Allarity A/S to liquidate its assets and dissolve; and Allarity A/S warrants to expire worthless.
- ***Shareholder Vote.*** The risk that Allarity A/S's shareholders may fail to provide the respective votes necessary to effect the Recapitalization Share Exchange.
- ***Taxable Transaction.*** Although the Recapitalization Share Exchange in intended to be a tax free reorganization for U.S. holders, it is likely to be construed as a taxable transaction in Denmark imposing a tax on both Allarity A/S and a tax on each of our shareholders who receive shares of Delaware Common Stock in the transaction.
- ***Limitations of Review***. The Board considered that they were not obtaining an opinion from any independent investment banking or accounting firm that the Recapitalization Share Exchange is fair to Allarity A/S or its shareholders from a financial point of view.
- ***Closing Conditions.*** The fact that completion of the Recapitalization Share Exchange is conditioned on the satisfaction of certain closing conditions that are not within Allarity A/S's control, including approval by Allarity A/S's shareholders and approval by the Nasdaq Stock Market of the initial listing application in connection with the Recapitalization Share Exchange.
- ***Litigation.*** The possibility of litigation challenging the Recapitalization Share Exchange or that an adverse judgment granting permanent injunctive relief could indefinitely enjoin consummation of the Recapitalization Share Exchange.
- ***Fees and Expenses.*** The fees and expenses associated with completing the Recapitalization Share Exchange.
- ***Other Risks.*** Various other risks associated with the Recapitalization Share Exchange described under "*Risk Factors*" beginning on page 26 of this information statement/prospectus.

In addition to considering the factors described above, Allarity A/S's board of directors also considered:

- ***Interests of Certain Persons.*** Some officers and directors of Allarity A/S may have interests in the Recapitalization Share Exchange as individuals that are in addition to, and that may be different from, the interests of Allarity A/S's shareholders (see "*— Interests of Certain Persons in the Recapitalization Share Exchange"* below). Our independent directors reviewed and considered these interests during the negotiation of the Recapitalization Share Exchange and in evaluating and unanimously approving, as members of the board of directors, the Reorganization Agreement and the transactions contemplated therein, including the Recapitalization Share Exchange.

The Allarity A/S board of directors concluded that the potential benefits that it expected Allarity A/S and its shareholders to achieve as a result of the Recapitalization Share Exchange outweighed the potentially negative factors associated with the Recapitalization Share Exchange. Accordingly, Allarity A/S's board of directors unanimously determined that the Reorganization Agreement and the transactions contemplated thereby, including the Recapitalization Share Exchange, were advisable, fair to, and in the best interests of, Allarity A/S and its shareholders.

Interests of Certain Persons in the Recapitalization Share Exchange

In considering the recommendation of the board of directors of Allarity A/S to vote in favor of approval of the Recapitalization Share Exchange Proposals, the Nasdaq Pipe Proposal, and the Incentive Plan Proposal, shareholders should keep in mind that certain members of the board of directors and executive officers of Allarity A/S have interests in such proposals that are different from, or in addition to, those of Allarity A/S shareholders generally. These interests include, among other things:

- All of the executive officers and directors of Allarity A/S have received warrants conferring the right to subscribe for Allarity A/S ordinary shares. As explained in the section titled "*The Reorganization Agreement — Treatment of Compensatory Warrants*," those warrants will convert into options to purchase approximately 9.5% of the common stock of Allarity Delaware issued and outstanding at the effective time assuming all vested and unvested Converted Options are exercised. *See, SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT***.**
- After the Recapitalization Share Exchange, we may enter into new employment agreements with our executive officers with potential increases in compensation and benefits. It has not yet been determined whether there will be any such agreements or, if so, what their terms would be.
- Under the terms of the employment agreement for our Chief Executive Officer Steve Carchedi, some of Mr. Carchedi's unvested warrants will accelerate and become vested when such warrants are converted into options to purchase Delaware Common Stock.
- Allarity A/S's officers and directors will receive continued indemnification and liability insurance after the reorganization.

At any time at or prior to the Recapitalization Share Exchange, subject to applicable securities laws (including with respect to material nonpublic information), our directors, officers, employees and advisors or respective affiliates may purchase Allarity A/S ordinary shares in the market or at a lower price from institutional and other investors. The purpose of such share purchases would be to increase the likelihood of approving the proposals.

Entering into any such arrangements may have a depressive effect on our share price (*e.g.*, by giving an investor or holder the ability to effectively purchase shares at a price lower than market, such investor or holder may therefore become more likely to sell the shares he or she owns, either at or prior to the Recapitalization Share Exchange). If such transactions are effected, the consequence could be to cause the Recapitalization Share Exchange to be consummated in circumstances where such consummation could not otherwise occur. Purchases of shares by the persons described above would allow them to exert more influence over the approval of the proposals to be presented at the Allarity A/S Extraordinary General Meeting and would likely increase the chances that such proposals would be approved. Allarity A/S will file or submit a Current Report on Form 8-K to disclose any material arrangements entered into or significant purchases made by any of the aforementioned persons that would affect the vote on the proposals to be put to the Allarity A/S Extraordinary General Meeting. Any such report will include descriptions of any arrangements entered into or significant purchases by any of the aforementioned persons.

The existence of financial and personal interests of one or more of Allarity A/S's directors may result in a conflict of interest on the part of such director(s) between what he, she or they may believe is in the best interests of Allarity A/S and its shareholders and what he, she or they may believe is best for himself or themselves in determining to recommend that shareholders vote for the proposals. In addition, Allarity A/S's officers have interests in the Recapitalization Share Exchange that may conflict with your interests as a shareholder.

Accounting Treatment of the Recapitalization Share Exchange

The Recapitalization Share Exchange will be accounted for as a "reverse recapitalization" in accordance with GAAP. Under this method of accounting Allarity A/S will be treated as the "acquired" company for financial reporting purposes. This determination is primarily based on the fact that subsequent to the Recapitalization Share Exchange, the shareholders of Allarity A/S are expected to have a majority of the voting power of Allarity Delaware, Allarity A/S will comprise all of the ongoing operations of Allarity Delaware, the existing directors of Allarity A/S will comprise a majority of the board of directors of Allarity Delaware, and Allarity A/S's senior management will comprise all of the senior management of Allarity Delaware. Accordingly, for accounting purposes, the Recapitalization Share Exchange

will be treated as the equivalent of Allarity A/S issuing shares for the net assets of Allarity Delaware, accompanied by a recapitalization. The net assets of Allarity Delaware will be stated at historical costs. No goodwill or other intangible assets will be recorded. Operations prior to the Recapitalization Share Exchange will be those of Allarity A/S.

Accounting Treatment of the Series A Convertible Preferred Stock

The PIPE Investment of $20 million comprises 20,000 shares of Series A Convertible Preferred Stock with a stated value of $1,000 per share to be converted to approximately 2,018,958 common stock at an expected conversion price of $9.91 and approximately 2,018,958 detachable warrants to purchase common shares at $9.91 each. Upon closing of the investment, the Series A Preferred shares will be accounted for as mezzanine equity pursuant to ASC 480 and the warrants will be accounted for as a liability. The $20 million will be allocated to the warrants on a fair value basis and the residual value to the preferred shares.

Public Trading Markets

Allarity A/S ordinary shares are currently listed on the Nasdaq First North Growth Market in Stockholm, Sweden under the symbol "ALLR.ST." Upon the consummation of the Recapitalization Share Exchange and the listing of Delaware Common Stock on the Nasdaq Stock Market under the symbol "ALLR," the ordinary shares of Allarity A/S will no longer be listed on the Nasdaq First North Growth Market in Stockholm.

THE REORGANIZATION AGREEMENT

The following is a summary of the material provisions of the Reorganization Agreement. A copy of the Reorganization Agreement is attached as Annex A to this information statement/prospectus and is incorporated by reference into this information statement/prospectus. You are encouraged to read the Reorganization Agreement, including the exhibits attached thereto, in its entirety for a more complete description of the terms and conditions of the reorganization.

The representations, warranties and covenants contained in the Reorganization Agreement were made only for purposes of that agreement and as of specific dates, were solely for the benefit of the parties to the Reorganization Agreement, and may be subject to limitations agreed upon by the contracting parties, including being qualified by confidential disclosures made for the purposes of allocating contractual risk between the parties to the Reorganization Agreement instead of establishing these matters as facts, and may be subject to standards of materiality applicable to the contracting parties that differ from those applicable to investors. Accordingly, you should not rely on the representations and warranties as characterizations of the actual state of affairs of Allarity A/S without considering the entirety of the disclosure about Allarity A/S as set forth in this information statement/prospectus. Moreover, information concerning the subject matter of the representations and warranties may change after the date of the Reorganization Agreement, which subsequent information may or may not be fully reflected in this information statement/prospectus or in other public disclosures by Allarity A/S.

Allarity Delaware's Purchase of Allarity A/S Assets in Exchange for Delaware Common Stock

On May 20, 2021, Allarity A/S entered into a Plan of Reorganization and Asset Purchase Agreement, which was subsequently amended and restated on September 23, 2021, (the "Reorganization Agreement") with Allarity Delaware, a direct wholly owned subsidiary of Allarity A/S, and on behalf of Allarity Acquisition Subsidiary, Inc. ("Acquisition Sub") which is a direct, wholly owned subsidiary of Allarity Delaware. Pursuant to the Reorganization Agreement, Allarity Delaware will capitalize Acquisition Sub with share of Delaware Common Stock to be used to purchase the assets of Allarity A/S. Acquisition Sub will then exchange all of the Delaware Common Stock received in its capitalization for substantially all of the assets of Allarity A/S, and will assume substantially all of the liabilities of Allarity A/S. Allarity A/S will then distribute the Delaware Common Stock it received in exchange for its assets to its shareholders, first in a share exchange swap program and then as an extraordinary dividend to its shareholders who have not participated in the share exchange swap program. Allarity A/S will then commence an orderly liquidation and dissolution under Part 14 of the DCA. As a result of the transaction, all of the shareholders of Allarity A/S will own substantially the same percentage ownership of Allarity Delaware as they owned in Allarity A/S and all of the business owned by Allarity A/S will be owned and conducted by Allarity Delaware through its direct wholly owned subsidiary Acquisition Sub. Other than the Converted Options specifically provided for in Section 206 of the Reorganization Agreement, neither Allarity Delaware nor Acquisition Sub will be assuming any equity-based compensation arrangement or employee bonuses based upon the sale or disposition of Allarity A/S' therapeutic candidates.

The terms of the Reorganization Agreement, which contains customary representations and warranties, covenants, closing conditions and other terms relating to the reorganization and the other transactions contemplated thereby, are summarized below.

Closing and Effective Time of the Recapitalization Share Exchange

Unless the parties otherwise mutually agree, the closing of the Recapitalization Share Exchange will take place as promptly as practicable (and no later than five business days) after the date on which all of the closing conditions have been satisfied or waived (other than those conditions that by their terms are to be satisfied at the closing) (such date, the "closing date").

On the closing date, Allarity A/S and Allarity Delaware will effect the asset purchase, liability assumption, and share exchange and distribution by filing executed and acknowledged resolutions approving the transaction and proposals presented at the Allarity A/S Extraordinary General Meeting. The time at which the Recapitalization Share Exchange will be the date on which all of the Delaware Common Stock issued in the transaction has been distributed to Allarity A/S shareholders by dividend and is sometimes referred to in this information statement/prospectus as the "effective time".

Determination of the Number of Common Stock to be Issued

The number of shares of Allarity Delaware voting common stock that will be issued in the transaction is determined by an exchange ratio of 0.02 share of Delaware Common Stock for each ordinary share of Allarity A/S issued and outstanding at the closing (the "Exchange Ratio"). As of the date of this information statement, prospectus, we anticipate issuing approximately 8,075,824 shares of Delaware Common Stock in the Recapitalization Share Exchange.

Distribution of Common Stock to Shareholders

Immediately after the Allarity A/S Extraordinary General Meeting where the Recapitalization Share Exchange has been approved, Allarity A/S will offer its shareholders an opportunity to exchange their ordinary shares for shares of Delaware Common Stock in proportion to the Exchange Ratio rounded down to the nearest whole share and any fractional interest will be settled in cash and thereafter will distribute the remaining shares of Delaware Common Stock received in the transaction to the shareholders who did not participate in the share exchange swap program as an extraordinary dividend in proportion to the Exchange Ratio and any fractional interest will be settled in cash.

As of the date of this information statement/prospectus, we anticipate distributing approximately 8,075,824 share of Delaware Common Stock to the shareholders of Allarity A/S in the Recapitalization Share Exchange. The exact number of shares of Delaware Common Stock to be distributed to the shareholders of Allarity A/S will be finally calculated in accordance with the methodology and procedures set forth in the Reorganization Agreement at the Closing.

Treatment of Compensatory Warrants Held by Directors, Officers and Employees of Allarity A/S

At the effective time, each warrant (option) conferring the right to subscribe for Allarity A/S ordinary shares held by the officers, directors, employees and consultants (each, a "Compensatory Warrant") that is outstanding immediately prior to the effective time, whether vested or unvested, will be converted into an option (each, a "Converted Option") to purchase a number of shares of Allarity Delaware Common Stock equal to the product (rounded down to the nearest whole number) of (a) the number of ordinary shares of Allarity A/S subject to such Compensatory Warrant immediately prior to the effective time multiplied by (b) the exchange ratio, at an exercise price per share (rounded up to the nearest whole cent) equal to (i) the exercise price per share of such Compensatory Warrant immediately prior to the effective time divided by (ii) the exchange ratio and converted into U.S. dollars; provided, however, that the exercise price and the number of shares of Delaware Common Stock purchasable pursuant to the Converted Options will be determined in a manner consistent with the requirements of Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"); provided, further, however, that in the case of any Converted Option to which Section 422 of the Code applies, the exercise price and the number of shares of Delaware Common Stock purchasable pursuant to such option will be determined in accordance with the foregoing, subject to such adjustments in a manner consistent with Treasury Regulation Section 1.424-1, such that the Converted Option will not constitute a modification of such Converted Option for purposes of Section 409A or Section 424 of the Code. Except as specifically provided above, following the effective time, each Converted Option will continue to be governed by the same terms and conditions (including vesting and exercisability terms) as were applicable to the corresponding former Compensatory Warrant immediately prior to the effective time.

Intended U.S. Tax Treatment

For U.S. federal income tax purposes, it is intended that the Recapitalization Share Exchange qualify as a "reorganization" within the meaning of Section 368(a) of the Code, and the regulations promulgated thereunder and we obtained an opinion from our legal counsel, Lewis Brisbois Bisgaard & Smith LLP, to that effect.

Representations and Warranties

The Reorganization Agreement contains customary representations and warranties and covenants of Allarity A/S, Allarity Delaware and Acquisition Sub relating to, among other things, their ability to enter into the Reorganization Agreement and their respective outstanding capitalization. These representations and warranties are subject to materiality, knowledge and other similar qualifications in many respects and expire at the effective time. These representations and warranties have been made solely for the benefit of the other parties to the Reorganization Agreement.

In the Reorganization Agreement, Allarity A/S and Allarity Delaware make certain representations and warranties (with certain exceptions set forth in the disclosure schedule to the Reorganization Agreement) relating to, among other things:

- proper corporate organization;
- authorization, execution, delivery and enforceability of the agreement and other transaction documents;
- absence of conflicts;
- charter documents and corporate records;
- related-party transactions;
- subsidiaries;
- absence of certain changes or events;
- approval of the board and the shareholders; and
- other customary representations and warranties.

Conduct of Business Pending the Reorganization; Covenants

Each of Allarity A/S, Allarity Delaware and Acquisition Sub have agreed that, prior to the closing date, it will conduct its business in the ordinary course of business consistent with past practices and preserve intact its business relationships with key employees, material suppliers and other material third parties.

In addition to the general covenants above, Allarity A/S has agreed that, prior to the closing date or the earlier termination of the Reorganization Agreement, subject to specified exceptions, it will not, and will cause its subsidiaries not to, without the written consent of Allarity Delaware (which may not be unreasonably withheld, conditioned or delayed):

- amend, or propose to amend its charter documents;
- (i) split, combine, or reclassify any of its securities or its subsidiary's securities, (ii) repurchase, redeem, or otherwise acquire, or offer to repurchase, redeem, or otherwise acquire, any of its securities or its subsidiary's securities, or (iii) declare, set aside, or pay any dividend or distribution (whether in cash, stock, property, or otherwise) in respect of, or enter into any contract with respect to the voting of, any shares of its capital stock (other than dividends from its direct or indirect wholly-owned subsidiaries);
- except with certain exceptions, issue, sell, pledge, dispose of, or encumber any of its securities or its subsidiary's securities, other than the issuance of shares of its ordinary shares upon the exercise of any equity aware outstanding as of the date of the Reorganization Agreement in accordance with its terms;
- except with certain exceptions (i) increase the compensation payable or that could become payable by it or any of its subsidiaries to directors, officers, or employees, other than increases in compensation made to non-officer employees in the ordinary course of business consistent with past practice, (ii) promote any officers or employees, except in connection with its annual or quarterly compensation review cycle or as the result of the termination or resignation of any officer or employee, or (iii) establish, adopt, enter into, amend, terminate, exercise any discretion under, or take any action to accelerate rights under any of its employee plans or any plan, agreement, program, policy, trust, fund, or other arrangement that would be an employee plan if it were in existence as of the date of the Reorganization Agreement, or make any contribution to any of its employee plans, other than contributions required by law, the terms of such employee plans as in effect or that are made in the ordinary course of business consistent with past practice;
- acquire, by asset acquisition, consolidation, acquisition of stock or assets, or otherwise, any business or person or division thereof or make any loans, advances, or capital contributions to or investments in any person;

- (i) except with certain exceptions, transfer, license, sell, lease, or otherwise dispose of (whether by way of asset acquisition, consolidation, sale of stock or assets, or otherwise) or pledge, encumber, mortgage, or otherwise subject to any lien (other than a permitted lien), any assets, including the capital stock or other equity interests in any subsidiary; *provided, that* the foregoing shall not prohibit it and its subsidiaries from transferring, selling, leasing, or disposing of obsolete equipment or assets being replaced, or granting non-exclusive licenses under the its IP, in each case in the ordinary course of business consistent with past practice, or (ii) adopt or effect a plan of complete or partial liquidation, dissolution, restructuring, recapitalization, or other reorganization;

- except with certain exceptions, repurchase, prepay, or incur any indebtedness for borrowed money or guarantee any such indebtedness of another person, issue or sell any debt securities or options, warrants, calls, or other rights to acquire any of its debt securities or any debt securities of its subsidiaries, guarantee any debt securities of another person, enter into any "keep well" or other contract to maintain any financial statement condition of any other person (other than any wholly-owned subsidiary of it) or enter into any arrangement having the economic effect of any of the foregoing, other than in connection with the financing of ordinary course trade payables consistent with past practice;

- except with certain exceptions, enter into or amend or modify in any material respect, or consent to the termination of (other than at its stated expiration date), any of its material contracts or any lease with respect to material real estate or any other contract or lease that, if in effect as of the date the Reorganization Agreement would constitute a material contract or lease with respect to material real estate;

- institute, settle, or compromise any legal action involving the payment of monetary damages of any amount exceeding $100,000 in the aggregate, other than (i) any legal action brought against Allarity Delaware or Acquisition Sub arising out of a breach or alleged breach of this Agreement by Allarity Delaware or Acquisition Sub, and (ii) the settlement of claims, liabilities, or obligations reserved against on its balance sheet; *provided, that* neither it nor any of its subsidiaries shall settle or agree to settle any legal action which settlement involves a conduct remedy or injunctive or similar relief or has a restrictive impact on its business;

- make any material change in any method of financial accounting principles or practices, in each case except for any such change required by a change to, or in, GAAP or applicable Law;

- (i) settle or compromise any material tax claim, audit, or assessment for an amount materially in excess of the amount reserved or accrued on its balance sheet, (ii) make or change any material tax election, change any annual tax accounting period, or adopt or change any method of tax accounting, (iii) amend any material tax Returns or file claims for material tax refunds, or (iv) enter into any material closing agreement, surrender in writing any right to claim a material tax refund, offset or other reduction in tax liability or consent to any extension or waiver of the limitation period applicable to any material tax claim or assessment relating to it or its subsidiaries;

- enter into any material agreement, agreement in principle, letter of intent, memorandum of understanding, or similar contract with respect to any joint venture, strategic partnership, or alliance;

- except with certain exceptions, take any action to exempt any person from, or make any acquisition of its securities by any person not subject to, any state takeover statute or similar statute or regulation that applies to it with respect to a takeover proposal or otherwise, including the restrictions on "business combinations" set forth in Section 203 of the DGCL, except for Allarity Delaware, Acquisition Sub, or any of their respective subsidiaries or affiliates, or the transactions contemplated by the Reorganization Agreement;

- except with certain exceptions, abandon, allow to lapse, sell, assign, transfer, grant any security interest in otherwise encumber or dispose of any material IP, or grant any right or license to any material IP other than pursuant to non-exclusive licenses entered into in the ordinary course of business consistent with past practice;

- terminate or modify in any material respect, or fail to exercise renewal rights with respect to, any material insurance policy;

- engage in any transaction with, or enter into any agreement, arrangement or understanding with, any affiliate or other person covered by Item 404 of Regulation S-K promulgated by the SEC that would be required to be disclosed pursuant to Item 404 of Regulation S-K promulgated by the SEC;
- adopt or implement any stockholder rights plan or similar arrangement; or
- agree or commit to do any of the foregoing.

Allarity Delaware and Acquisition Sub have agreed that, prior to the closing date or the earlier termination of the Reorganization Agreement, subject to specified exceptions, it will not, without the written consent of Allarity A/S (which may not be unreasonably withheld, conditioned or delayed):

- amend its charter documents in a manner that would adversely affect Allarity A/S or the holders of Allarity A/S ordinary shares relative to the other holders of Allarity Delaware common stock;
- (i) split, combine, or reclassify any of its securities or its subsidiary's securities in a manner that would adversely affect Allarity A/S or the holders of Allarity A/S ordinary shares relative to the other holders of Allarity Delaware common stock, (ii) repurchase, redeem, or otherwise acquire, or offer to repurchase, redeem, or otherwise acquire, any its securities or its subsidiary's securities, or (iii) declare, set aside, or pay any dividend or distribution (whether in cash, stock, property, or otherwise) in respect of, or enter into any contract with respect to the voting of, any shares of its capital stock (other than dividends from its direct or indirect wholly-owned Subsidiaries and ordinary quarterly dividends, consistent with past practice with respect to timing of declaration and payment);
- issue, sell, pledge, dispose of, or encumber any of its securities or its subsidiary's securities, other than (i) the issuance of shares of common stock upon the exercise of any of its equity awards outstanding as of the date of the Reorganization Agreement in accordance with its terms, (ii) the issuance of shares of common stock in connection with or upon the exercise of any of its equity awards granted after the date hereof in the ordinary course of business, and (iii) sales or issuances of shares of common stock or convertible securities in the amount of the PIPE Investment;
- acquire, by asset acquisition, consolidation, acquisition of stock or assets, or otherwise, any business or person or division thereof or make any loans, advances, or capital contributions to or investments in any person, in each case that would reasonably be expected to prevent, impede, or materially delay the consummation of the asset acquisition or other transactions contemplated by the Reorganization Agreement;
- adopt or effect a plan of complete or partial liquidation, dissolution, restructuring, recapitalization, or other reorganization; or
- agree or commit to do any of the foregoing.

Additional Agreements

Information statement; Registration Statement

As soon as reasonably practicable, Allarity A/S and Allarity Delaware agreed to prepare and file with the SEC this information statement/prospectus. Each of Allarity A/S and Delaware agree to use their respective reasonable best efforts to cause this information statement/prospectus to be declared effective under the Securities Act as soon as reasonably practicable after filing. Allarity A/S shall cause this information statement/prospectus to be distributed to its shareholders of record, as promptly as practicable, following this information statement/prospectus becoming declared effective under the Securities Act. Allarity Delaware will cause all documents that it is responsible for filing with the SEC or other regulatory authorities in connection with the reorganization to (i) comply as to form with all applicable SEC requirements and (ii) otherwise comply in all material respects with all applicable law.

Allarity A/S Shareholder Meeting

Allarity A/S has agreed to convene and hold an extraordinary general meeting of its shareholders as soon as reasonably practicable after the date on which this information statement/prospectus is declared effective.

Employees and Employee Benefit Plans

Under the terms of the Reorganization Agreement, Allarity Delaware has agreed to employ the employees of Allarity A/S on substantially the same terms and conditions, including compensation levels and employee benefits, as such employees had while employed by Allarity A/S.

Stock Exchange Listing

Allarity Delaware has agreed to cause the common stock to be issued in connection with the Recapitalization Share Exchange to be approved for listing on the Nasdaq Stock Market as promptly as practicable following the issuance thereof, subject to official notice of issuance, prior to the closing date.

Other Covenants and Agreements

The Reorganization Agreement contains other covenants and agreements, including covenants related to:

- Allarity Delaware providing indemnification agreements and liability insurance for all of the officers and directors of Allarity A/S;
- All parties using reasonable best efforts to consummate the transactions contemplated by the Reorganization Agreement; and
- prompt notification of certain matters; and
- confidentiality and publicity relating to the Recapitalization Share Exchange;

Conditions to Closing

Mutual

Consummation of the Recapitalization Share Exchange is conditioned upon the satisfaction or, to the extent permitted by applicable law, waiver by the party for whose benefit such condition exists, of each of the following conditions:

- No provisions of any applicable law, and no order by any governmental authority shall restrain or prohibit or impose any condition on the consummation of the closing.
- There shall not be any action brought by any governmental authority to enjoin or otherwise restrict or make illegal the consummation of the closing.
- The share of common stock to be issued in the Recapitalization Share Exchange shall have been approved for listing on the Nasdaq stock Market, subject to official notice of issuance.
- Allarity A/S shareholder approval shall have been duly obtained by the requisite vote.
- Allarity Delaware's stockholders approval shall have been duly obtained by the requisite vote.
- This information statement/prospectus shall have become effective under the Securities Act and no stop order suspending the effectiveness of this information statement/prospectus shall have been issued and no proceedings for that purposes shall have been initiated or threatened by the SEC and not withdrawn.
- All waiting periods applicable to the consummation of the asset acquisition shall have expired or been terminated and all required filings shall have been made and all required approvals obtained (or waiting periods expired or terminated) under applicable antitrust laws.

Notwithstanding the foregoing, none of the mutual closing conditions listed above may be waived due to the parties' charter or organizational documents, applicable law or otherwise and only first and last conditions listed above are subject to the possibility of a waiver by the parties.

Termination

The Reorganization Agreement may be terminated and/or abandoned at any time prior to the closing, whether before or after approval of the proposals being presented to Allarity A/S's shareholders, by:

- the mutual consent of all parties.
- by any party if the asset acquisition has not been consummated on or before December 31, 2021, (the "**End Date**"); *provided, however,* that the right to terminate the Agreement shall not be available to any party whose material breach of any representation, warranty, covenant, or agreement set forth in the Agreement has been a contributing cause of, or a contributing factor that resulted in, the failure of the asset acquisition to be consummated on or before the End Date;
- if any governmental entity of competent jurisdiction shall have enacted, issued, promulgated, enforced, or entered any law or order making illegal, permanently enjoining, or otherwise permanently prohibiting the consummation of the asset acquisition, the issuance of the Delaware Common Stock, or the other transactions contemplated by the Agreement, and such law or order shall have become final and non-appealable;
- if this Agreement has been submitted to the shareholders of Allarity A/S for adoption at a duly convened shareholder meeting and the requisite vote shall not have been obtained at such meeting (unless such shareholder meeting has been adjourned or postponed, in which case at the final adjournment or postponement thereof); or
- if the requisite vote of Allarity Delaware stockholders is not obtained.

Effect of Termination

In the event of termination by either Allarity A/S or Allarity Delaware, all further obligations of the parties shall terminate.

Recommendation of the Board

THE ALLARITY A/S BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS THAT SHAREHOLDERS VOTE "FOR" THE APPROVAL OF THE RECAPITALIZATION SHARE EXCHANGE PROPOSALS.

Related Agreements

This section describes certain additional agreements entered into or to be entered into relating to or pursuant to the Reorganization Agreement, but does not purport to describe all of the terms thereof. The following summary is qualified in its entirety by reference to the complete text of each of the agreements. The full text of the related agreements, or forms thereof, are filed as exhibits to the registration statement of which this information statement/prospectus forms a part, and the following descriptions are qualified in their entirety by the full text of such exhibits. Shareholders and other interested parties are urged to read such related agreements in their entirety prior to voting on the proposals presented at the Allarity A/S Extraordinary General Meeting.

The following is a summary of the material terms and conditions of the agreements we have entered into with 3i, LP, a Delaware limited partnership, for an investment of $20 million in our Series A Convertible Preferred Stock conditioned upon, among other things, the consummation of the Recapitalization Share Exchange. The following summary is qualified in its entirety by reference to the complete text of each of the agreements. The full text of these agreements, or forms thereof, are filed as exhibits to the registration statement of which this information statement/prospectus forms a part, and the following descriptions are qualified in their entirety by the full text of such exhibits. Shareholders and other interested parties are urged to read such related agreements in their entirety prior to voting on the proposals presented at the Allarity A/S Extraordinary General Meeting.

Securities Purchase Agreement

On May 20, 2021, we entered into a Securities Purchase Agreement (the "SPA") with 3i, LP, a Delaware limited partnership for the purchase and sale of 20,000 shares of our Series A Convertible Preferred Stock (the "Preferred Shares") for $1,000 per share for an aggregate purchase price of $20 million. The closing of the PIPE Investment

is conditioned upon, among other things, an effective registration statement covering the resale of the shares of our common stock to be issued upon conversion of the Preferred Shares (the "Conversion Shares"), the consummation of the Recapitalization Share Exchange, and the listing of the Conversion Shares on the Nasdaq Stock Market. At the closing of the PIPE Investment, 3i, LP will also be issued a common stock purchase warrant to purchase up to an additional $20 million of our common stock at an initial exercise price equal to the fixed conversion price of the Preferred Shares, or approximately 2,018,958 shares, with an exercise price of $9.906 for a term of three years from the closing date of the PIPE Investment.

Under the terms of the SPA and the agreed upon form of Certificate of Designations (the "COD") setting forth the rights, preferences, privileges and restrictions for the Preferred Shares, the Preferred Shares will be entitled to convert into shares of our common stock at an initial fixed conversion price of $9.906 per share, subject to a beneficial ownership limitation of 4.99% which can adjusted to a beneficial ownership limitation of 9.99% upon 61 days prior written notice. For purposes of calculating the beneficial ownership limitation, 3i, LP's beneficial ownership of our common stock will be calculated under the rules promulgated under Section 13(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). If there were no beneficial ownership limitation in the COD, the Preferred Shares would be entitled to convert into 2,018,958 share of our common stock immediately after the closing of the PIPE Investment, or 20% of our anticipated issued and outstanding shares of common stock.

Under the terms of the COD, the fixed conversion price of the preferred shares will be calculated at the closing of the PIPE Investment by dividing $80 million by the number of shares of common stock we issue in the Recapitalization Share Exchange at the effective time. We anticipate issuing 8,075,824 shares of our common stock at the effective time of the Recapitalization Share Exchange resulting in a fixed conversion price for the Preferred Shares, and the exercise price for the common stock purchase warrant, of $9.906. In the event that the volume weighted average price ("VWAP") for the five days prior to conversion of the Preferred Shares is less than the fixed conversion price, or other triggering events, the Preferred Shares are entitled to convert at a price equal to 90% of the five day VWAP, but not less than 20% of the fixed conversion price, or if thirty days after our common stock commences trading on the Nasdaq Stock Market the average daily dollar volume for the five days previous to conversion is less than $2,000,000, then the Preferred Shares are entitled to convert at the lower of the fixed conversion price equal to 80% of the five day VWAP, but not less than 20% of the fixed conversion price. In addition, the COD and the common stock purchase warrants provide for an adjustment to the conversion price and exercise of the warrant in the event of a "new issuance" of our common stock, or common stock equivalents, at a price less than the applicable conversion price of the Preferred Shares or exercise price of the common stock purchase warrant. The adjustment is a "full ratchet" adjustment in both the conversion price of the Preferred Shares and the exercise price of the common stock purchase warrant equal to the lower of the new issuance price or the then existing conversion price of the Preferred Shares or exercise price of the common stock purchase warrants, with few exceptions.

If certain defined "triggering events" defined in the COD occur, such as a breach of the Registration Rights Agreement, suspension of trading, or our failure to convert the Preferred Shares into common stock when a conversion right is exercised, or failure to issue our common stock when the common stock purchase warrant is exercised, then we may be required to redeem the Preferred Shares for cash. In addition, if thirty days after our common stock commences trading on the Nasdaq Stock Market the average daily dollar volume for the five days previous to conversion is less than $2,500,000, then the Preferred Shares shall be entitled to a one time dividend equal to an 8% increase in the stated value of the Preferred Share, or an $80 increase per share in stated value, resulting in a stated value of $1,080 per Preferred Share.

Registration Rights Agreement

Concurrently with the execution of the SPA, we entered into a Registration Rights Agreement (the "RRA") with 3i, LP in which we have agreed to register the shares of our common stock issuable upon conversion of the Preferred Shares and the exercise of the common stock purchase warrant with the SEC for resale. Under the RRA, we have agreed to file a registration statement on Form S-1 with the SEC within 15 business days of filing the registration statement of which this information statement/prospectus is a part, and to have the registration statement declared effective within 60 calendar days from the date we first register our common stock under the Exchange Act. The RRA also contains usual and customary liquidated damages provisions for failure to file and failure to have the registration statement declared effective by the SEC within the time periods specified.

COMPARISON OF SHAREHOLDERS' RIGHTS

If the Recapitalization Share Exchange Proposals are approved, the rights of Allarity A/S shareholders will no longer be governed by the Articles of Association of Allarity A/S but instead will be governed by the Certificate of Incorporation and Bylaws of Allarity Delaware.

The following table sets forth a summary of the principal differences between Allarity A/S's shareholders' rights under its existing articles of association and under the Certificate of Incorporation and Bylaws of Allarity Delaware. This summary is qualified by reference to the complete text of Allarity Delaware's Certificate of Incorporation and Bylaws, copies of which have been filed as exhibits to the registration statement of which this information statement/ prospectus is a part. We urge you to read the Certificate of Incorporation and Bylaws in its entirety for a complete description of the rights and preferences of the common stock of Allarity Delaware.

	Allarity A/S Existing Articles of Association	Allarity Delaware Certificate of Incorporation ("COI") and Bylaws
Name Change	Allarity A/S's current name is Allarity Therapeutics A/S	Under the COI, the business of Allarity A/S will under the name Allarity Therapeutics, Inc.
Purpose	The existing articles of association provides that the purpose of Allarity A/S shall be to develop new medicinal products and new diagnostic tools and to own and hold shares in its subsidiaries and portfolio companies.	The COI will provide that the purpose of corporation will be to engage in any lawful act or activity for which a corporation may be organized under the DGCL.
Authorized/ Outstanding Shares	The existing articles of association establishes the share capital at DKK 20,189,560 denominated as DKK 0.05 per share.	The COI, as amended provides for authorized capital stock consisting of (i) 30,000,000 share of common stock, par value $0.0001, and 500,000 share of preferred stock, par value $0.0001.
Rights of Ordinary Share v. Common Stock	Under the existing articles of association shareholder rights are substantially similar to the Delaware COI and Bylaws except for the following: Shareholders have preemptive rights unless they approve an issuance of shares without preemptive rights; While each ordinary share is entitled to one vote on all matters submitted for shareholder approval, there is no minimum quorum requirement to hold a meeting of shareholders.	Under the COI and Bylaw, holders of common stock have the following right: Voting: each share of common stock is entitled to one vote on all matters submitted for approval by the stockholders. Dividends: each share of common stock is entitled to dividends if, when and as declared by the board of directors, subject to any rights, preferences and restrictions of any preferred stock. Distributions upon liquidation: each share of common stock is entitled to its pro rata share of net assets of the corporation upon its liquidation, subject to any rights, preferences and restrictions of any preferred stock. Preemptive Rights: holders of common stock will not have preemptive rights on the issuance of additional shares of capital stock
Blank Check Preferred Stock	The existing articles of association do not permit the board of directors to issue any preference shares without shareholder approval.	The COI authorize the issuance of up to 5,000,000 shares of "blank check" preferred stock, par value $0.0001 per share, the rights, preferences and privileges of which may be designated from time to time by our board of directors without stockholder approval.

	Allarity A/S Existing Articles of Association	Allarity Delaware Certificate of Incorporation ("COI") and Bylaws
Director Classification	The existing articles of association provides that Allarity A/S is managed by a board of directors with three to seven members elected by the general meeting for one year at a time.	The COI provides for three classes of directors, with the term for Class I directors expiring after one year, the term for Class II directors expiring after two years and the term for Class III directors expiring after three years.
Actions by Shareholders	All matters requiring shareholder approval must be submitted for shareholder approval at a meeting of shareholders.	The COI and bylaws provide that no action shall be taken by the shareholders except at an annual or special meeting of shareholders called in accordance with the bylaws, and no action shall be taken by the shareholders by written consent.
Bylaws Amendment	Any amendment to Allarity A/S's articles of association requires the affirmative vote of at least two thirds of the votes cast and the share capital represented at an extraordinary general meeting.	The COI provide that the board of directors may amend the bylaws without shareholder approval and stockholders also may amend the bylaws by adopting a resolution to amend the bylaws at any annual or special meeting of stockholders.
Amendments	The existing Articles of Association may be amended only by shareholder vote.	The COI provides that any amendment to certain provisions of the COI will require the approval of the holders of at least $66\frac{2}{3}\%$ of then-outstanding shares of capital stock entitled to vote in an election of directors, voting together as a single class. The board of directors or the shareholders may amend the bylaws.

DESCRIPTION OF ALLARITY DELAWARE CAPITAL STOCK

As a result of the Recapitalization Share Exchange, Allarity A/S shareholders who receive shares of Delaware Common Stock in the transactions will become Allarity Delaware shareholders. Your rights as Allarity Delaware shareholders will be governed by Delaware law and Allarity Delaware's Certificate of Incorporation and bylaws. The following description of the material terms of Allarity Delaware capital stock, including the common stock to be issued in the Recapitalization Share Exchange, reflects the anticipated state of affairs upon completion of the Recapitalization Share Exchange. We urge you to read the applicable provisions of Delaware law and Allarity Delaware's forms Certificate of Incorporation and bylaws carefully and in their entirety because they describe your rights as a holder of shares of Delaware Common Stock.

The following is a description of the material terms of, and is qualified in its entirety by, Allarity Delaware's certificate of incorporation and bylaws, each of which will be in effect upon the consummation of the Recapitalization Share Exchange, the forms of which are filed as exhibits to the registration statement of which this information statement/prospectus forms a part.

Allarity Delaware's purpose is to engage in any lawful act or activity for which corporations may now or hereafter be organized under the DGCL. Upon the consummation of the Recapitalization Share Exchange, Allarity Delaware's authorized capital stock will consist of 30,000,000 shares of common stock, par value $0.0001 per share, and 500,000 shares of preferred stock, par value $0.0001 per share. 20,000 shares of preferred stock, designated Series A Convertible Preferred Stock, will be issued to 3i, LP, a Delaware limited partnership immediately after the Recapitalization Share Exchange. Unless our board of directors determines otherwise, we will issue all shares of our capital stock in uncertificated form.

As of the date of this information statement/prospectus, Allarity Delaware had only one share of common stock, par value $0.0001 per share, issued and outstanding which is held by Allarity A/S. Immediately after the Recapitalization Share Exchange, and after giving effect to the PIPE investment and other related transactions, we expect that we will have approximately 8,095,824 shares of capital stock outstanding, consisting of 8,075,824 shares of common stock and 20,000 shares of Series A Convertible Preferred Stock.

Common stock

Holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of shareholders, including the election or removal of directors, except for any directors who are elected exclusively by the holders of a class of our preferred stock that entitles that class of stock to elect one or more directors. The holders of our common stock do not have cumulative voting rights in the election of directors.

Upon our liquidation, dissolution or winding up and after payment in full of all amounts required to be paid to creditors and to the holders of preferred stock having liquidation preferences, if any, the holders of our common stock (and the holders of any preferred stock that may then be outstanding, to the extent required by our certificate of incorporation, including any certificate of designation with respect to any series of preferred stock) will be entitled to receive pro rata our remaining assets available for distribution, unless holders of a majority of the outstanding shares of common stock approve a different treatment of the shares. Holders of our common stock do not have preemptive, subscription, redemption or conversion rights. Our common stock will not be subject to further calls or assessment by us. There will be no redemption or sinking fund provisions applicable to our common stock. All shares of our common stock that will be outstanding at the effective time will be fully paid and non-assessable. The rights, powers, preferences and privileges of holders of our common stock will be subject to those of the holders of our Series A Convertible Preferred Stock and any other shares of preferred stock we may authorize and issue in the future.

Preferred Stock

Our Certificate of Incorporation will authorize our board of directors to establish one or more series of preferred stock (including convertible preferred stock). Unless required by law or by the Nasdaq Stock Market, the authorized shares of preferred stock will be available for issuance without further action by you. Our board of directors may

determine, with respect to any series of preferred stock, the powers including preferences and relative participations, optional or other special rights, and the qualifications, limitations or restrictions thereof, of that series, including, without limitation:

- the designation of the series;
- the number of shares of the series, which our board of directors may, except where otherwise provided in the preferred stock designation, increase (but not above the total number of authorized shares of the class) or decrease (but not below the number of shares then outstanding);
- whether dividends, if any, will be cumulative or non-cumulative and the dividend rate of the series;
- the dates at which dividends, if any, will be payable;
- the redemption rights and price or prices, if any, for shares of the series;
- the terms and amounts of any sinking fund provided for the purchase or redemption of shares of the series;
- the amounts payable on shares of the series in the event of any voluntary or involuntary liquidation, dissolution or winding-up of our affairs;
- whether the shares of the series will be convertible into shares of any other class or series, or any other security, of ours or any other corporation, and, if so, the specification of the other class or series or other security, the conversion price or prices or rate or rates, any rate adjustments, the date or dates as of which the shares will be convertible and all other terms and conditions upon which the conversion may be made;
- restrictions on the issuance of shares of the same series or of any other class or series; and
- the voting rights, if any, of the holders of the series.

We could issue a series of preferred stock that could, depending on the terms of the series, impede or discourage an acquisition attempt or other transaction that some, or a majority, of the holders of our common stock might believe to be in their best interests or in which the holders of our common stock might receive a premium for your common stock over the market price of the common stock. Additionally, the issuance of preferred stock may adversely affect the rights of holders of our common stock by restricting dividends on our common stock, diluting the voting power of our common stock or subordinating the liquidation rights of our common stock. As a result of these or other factors, the issuance of preferred stock could have an adverse impact on the market price of our common stock.

The Series A Convertible Preferred Stock to be issued in the PIPE Investment

The following is a summary of the material terms and conditions of the agreements we have entered into with 3i, LP, a Delaware limited partnership, for an investment of $20 million in our Series A Convertible Preferred Stock conditioned upon, among other things, the consummation of the Recapitalization Share Exchange. The following summary is qualified in its entirety by reference to the complete text of each of the agreements. The full text of these agreements, or forms thereof, are filed as exhibits to the registration statement of which this information statement/prospectus forms a part, and the following descriptions are qualified in their entirety by the full text of such exhibits. Shareholders and other interested parties are urged to read such related agreements in their entirety prior to voting on the proposals presented at the Allarity A/S Extraordinary General Meeting.

On May 20, 2021, we entered into a Securities Purchase Agreement (the "SPA") with 3i, LP, a Delaware limited partnership for the purchase and sale of 20,000 shares of our Series A Convertible Preferred Stock (the "Preferred Shares") for $1,000 per share for an aggregate purchase price of $20 million. The closing of the PIPE Investment is conditioned upon, among other things, an effective registration statement covering the resale of the shares of our common stock to be issued upon conversion of the Preferred Shares (the "Conversion Shares"), the consummation of the Recapitalization Share Exchange, and the listing of the Conversion Shares on the Nasdaq Stock Market. At the closing of the PIPE Investment, 3i, LP will also be issued a common stock purchase warrant to purchase up to an additional $20 million of our common stock at an initial exercise price equal to the fixed conversion price of the Preferred Shares, or approximately 2,018,958 shares, with an exercise price of $9.906, for a term of three years from the closing date of the PIPE Investment.

Under the terms of the SPA and the agreed upon form of Certificate of Designations (the "COD") setting forth the rights, preferences, privileges and restrictions for the Preferred Shares, the Preferred Shares have a liquidation preference equal to an amount per Preferred Share equal to the sum of (i) the Black Scholes Value (as defined in the Warrants) with respect to the outstanding portion of all Warrants held by such Holder (without regard to any limitations on the exercise thereof) as of the date of such event and (ii) the greater of (A) 125% of the Conversion Amount of such Preferred Share on the date of such payment and (B) the amount per share such Holder would receive if such Holder converted such Preferred Share into Common Stock immediately prior to the date of such payment, and will be entitled to convert into shares of our common stock at an initial fixed conversion price of $9.906 per share, subject to a beneficial ownership limitation of 4.99% which can adjusted to a beneficial ownership limitation of 9.99% upon 61 days prior written notice. For purposes of calculating the beneficial ownership limitation, 3i, LP's beneficial ownership of our common stock will be calculated under the rules promulgated under Section 13(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). If there were no beneficial ownership limitation in the COD, the Preferred Shares would be entitled to convert into 2,018,958 share of our common stock immediately after the closing of the PIPE Investment, or 20% of our anticipated issued and outstanding shares of common stock.

Under the terms of the COD, the fixed conversion price of the preferred shares will be calculated at the closing of the PIPE Investment by dividing $80 million by the number of shares of common stock we issue in the Recapitalization Share Exchange at the effective time. We anticipate issuing 8,075,824 shares of our common stock at the effective time of the Recapitalization Share Exchange resulting in a fixed conversion price for the Preferred Shares, and the exercise price for the common stock purchase warrant, of $9.906. In the event that the volume weighted average price ("VWAP") for the five days prior to conversion of the Preferred Shares is less than the fixed conversion price, or other triggering events, the Preferred Shares are entitled to convert at a price equal to 90% of the five day VWAP, but not less than 20% of the fixed conversion price, or if thirty days after our common stock commences trading on the Nasdaq Stock Market the average daily dollar volume for the five days previous to conversion is less than $2,000,000, then the Preferred Shares are entitled to convert at the lower of the fixed conversion price equal to 80% of the five day VWAP, but not less than 20% of the fixed conversion price. In addition, the COD and the common stock purchase warrants provide for an adjustment to the conversion price and exercise of the warrant in the event of a "new issuance" of our common stock, or common stock equivalents, at a price less than the applicable conversion price of the Preferred Shares or exercise price of the common stock purchase warrant. The adjustment is a "full ratchet" adjustment in both the conversion price of the Preferred Shares and the exercise price of the common stock purchase warrant equal to the lower of the new issuance price or the then existing conversion price of the Preferred Shares or exercise price of the common stock purchase warrants, with few exceptions.

If certain defined "triggering events" defined in the COD occur, such as a breach of the Registration Rights Agreement, suspension of trading, or our failure to convert the Preferred Shares into common stock when a conversion right is exercised, or failure to issue our common stock when the common stock purchase warrant is exercised, then we may be required to redeem the Preferred Shares for cash. In addition, if thirty days after our common stock commences trading on the Nasdaq Stock Market the average daily dollar volume for the five days previous to conversion is less than $2,500,000, then the Preferred Shares shall be entitled to a one time dividend equal to an 8% increase in the stated value of the Preferred Share, or an $80 increase per share in stated value, resulting in a stated value of $1,080 per Preferred Share.

Dividends

The DGCL permits a corporation to declare and pay dividends out of "surplus" or, if there is no "surplus," out of its net profits for the fiscal year in which the dividend is declared and/or the preceding fiscal year. "Surplus" is defined as the excess of the net assets of the corporation over the amount determined to be the capital of the corporation by the board of directors. The capital of the corporation is typically calculated to be (and cannot be less than) the aggregate par value of all issued shares of capital stock. Net assets equals the fair value of the total assets minus total liabilities. The DGCL also provides that dividends may not be paid out of net profits if, after the payment of the dividend, capital is less than the capital represented by the outstanding stock of all classes having a preference upon the distribution of assets.

Declaration and payment of any dividend will be subject to the discretion of our board of directors. The time and amount of dividends will be dependent upon our financial condition, operations, cash requirements and availability, debt repayment obligations, capital expenditure needs and restrictions in our debt instruments, industry trends, the provisions of Delaware law affecting the payment of distributions to shareholders and any other factors our board of directors may consider relevant.

We have no current plans to pay dividends on our common stock. Any decision to declare and pay dividends in the future will be made at the sole discretion of our board of directors and will depend on, among other things, our results of operations, cash requirements, financial condition, contractual restrictions and other factors that our board of directors may deem relevant. Because we will be a holding company and will have no direct operations, we will only be able to pay dividends from funds we receive from our operating subsidiaries. In addition, our ability to pay dividends may be limited by the agreements governing any indebtedness that we or our subsidiaries incur in the future.

Annual Shareholder Meetings

Our bylaws will provide that annual shareholder meetings will be held at a date, time and place, if any, as exclusively selected by our board of directors. To the extent permitted under applicable law, we may conduct meetings by remote communications, including by webcast.

Dissenters' Rights of Appraisal and Payment

Under the DGCL, with certain exceptions, our shareholders will have appraisal rights in connection with a reorganization or consolidation of we may undertake in the future. Pursuant to the DGCL, shareholders who properly request and perfect appraisal rights in connection with such reorganization or consolidation will have the right to receive payment of the fair value of their shares as determined by the Delaware Court of Chancery.

Shareholders' Derivative Actions

Under the DGCL, any of our shareholders may bring an action in our name to procure a judgment in our favor, also known as a derivative action; provided that the shareholder bringing the action is a holder of our shares at the time of the transaction to which the action relates or such shareholder's stock thereafter devolved by operation of law.

Exclusive Forum

Our certificate of incorporation provides that unless we consent to the selection of an alternative forum, any (1) derivative action or proceeding brought on our behalf, (2) action asserting a claim of breach of a fiduciary duty owed by any director, officer, shareholder or employee to us or our shareholders, (3) action asserting a claim arising pursuant to any provision of the DGCL or certificate of incorporation or bylaws or (4) action asserting a claim governed by the internal affairs doctrine or otherwise related to our internal affairs shall, to the fullest extent permitted by law, be exclusively brought in the Court of Chancery of the State of Delaware or, if such court does not have subject matter jurisdiction thereof, another state or federal court located within the State of Delaware. Any person or entity purchasing or otherwise acquiring any interest in shares our capital stock shall be deemed to have notice of and consented to the forum provisions in our certificate of incorporation. In addition, the provisions described above will not apply to suits brought to enforce a duty or liability arising under the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Furthermore, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. We intend for this provision to apply to any complaints asserting a cause of action under the Securities Act despite the fact that Section 22 of the Securities Act creates concurrent jurisdiction for the federal and state courts over all actions brought to enforce any duty or liability created by the Securities Act or the rules and regulations promulgated thereunder. There is uncertainty as to whether a court would enforce this provision with respect to claims under the Securities Act where the state courts have concurrent jurisdiction and our stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Limitations on Liability and Indemnification of Officers and Directors

The DGCL authorizes corporations to limit or eliminate the personal liability of directors to corporations and their shareholders for monetary damages for breaches of directors' fiduciary duties, subject to certain exceptions. Our certificate of incorporation includes a provision that eliminates the personal liability of directors for monetary damages for any breach of fiduciary duty as a director, except to the extent such exemption from liability or limitation thereof is not permitted under the DGCL. The effect of these provisions is to eliminate our rights and the rights of our shareholders, through shareholders' derivative suits on our behalf, to recover monetary damages from a director

for breach of fiduciary duty as a director, including breaches resulting from grossly negligent behavior. However, exculpation does not apply to any director if the director has acted in bad faith, knowingly or intentionally violated the law, authorized illegal dividends or redemptions or derived an improper benefit from his or her actions as a director.

Our bylaws provide that we must indemnify and advance expenses to our directors and officers to the fullest extent authorized by the DGCL. We are also expressly authorized to carry directors' and officers' liability insurance providing indemnification for our directors, officers and certain employees for some liabilities. We believe that these indemnification and advancement provisions and insurance are useful to attract and retain qualified directors and executive officers.

The limitation of liability, advancement and indemnification provisions in our certificate of incorporation and bylaws may discourage shareholders from bringing a lawsuit against directors for breach of their fiduciary duty.

These provisions also may have the effect of reducing the likelihood of derivative litigation against directors and officers, even though such an action, if successful, might otherwise benefit us and our shareholders. In addition, your investment may be adversely affected to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

There is currently no pending material litigation or proceeding involving any of our directors, officers or employees for which indemnification is sought.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Certain Relationships and Related Person Transactions — Allarity A/S

Below is a description of transactions since January 1, 2018, to which Allarity A/S was a party or will be a party, in which:

- the amounts involved exceeded or will exceed the lesser of (1) $120,000, or (2) 1% of the average of Allarity A/S's total assets for the last two completed fiscal years; and
- any person who will be a directors or executive officer, or any member of the immediate family of, or person sharing the household with, the foregoing persons, had or will have a direct or indirect material interest.

During our fiscal years ended December 31, 2020, 2019 and 2018, we paid our Chief Scientific Officer and founder, Steen Knudsen, employee compensation of $156,000, $150,000 and $150,000, respectively. Dr. Knudsen is employed as our full time Chief Scientific Officer as an annual compensation of approximately DKK 1,022,000, ($156,000) and will continue as our Chief Scientific Officer after the consummation of the Recapitalization Share Exchange at the same rate of compensation.

During our fiscal year ended December 31, 2018, we paid our Senior Vice President, Corporate Development, Mr. Cullem, employee compensation of $152,000.

Indemnification Agreements

Our certificate of incorporation contains provisions limiting the liability of directors, and bylaws provide that we will indemnify each of our directors and officers to the fullest extent permitted under Delaware law. In addition, we will enter into an indemnification agreement with each of our directors and executive officers, which requires us to indemnify them. For more information regarding these agreements, see "*MANAGEMENT OF ALLARITY DELAWARE AFTER THE RECAPITALIZATION SHARE EXCHANGE — Executive Compensation — Limitation on Liability and Indemnification of Directors and Officers*."

Related Person Transactions Policy Following the Recapitalization Share Exchange

Upon the consummation of the Recapitalization Share Exchange, we will adopt a new written related person transactions policy that sets forth our policies and procedures regarding the identification, review, consideration and oversight of "related person transactions." For purposes of policy only, a "related person transaction" is a transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which we or any of our subsidiaries are participants involving an amount that exceeds the lesser of (a) $120,000 or (b) 1% of the average of our total assets for the last two completed fiscal years, in which any "related person" has a material interest.

Transactions involving compensation for services provided to us as an employee, consultant or director will not be considered related person transactions under this policy. A related person is any executive officer, director, nominee to become a director or a holder of more than 5% of any class of our voting securities (including our common stock), including any of their immediate family members and affiliates, including entities owned or controlled by such persons.

Under the policy, the related person in question or, in the case of transactions with a holder of more than 5% of any class of our voting securities, an officer with knowledge of a proposed transaction, must present information regarding the proposed related person transaction to our audit committee (or, where review by our audit committee would be inappropriate, to another independent body of our board of director) for review. To identify related person transactions in advance, we will rely on information supplied by our executive officers, directors and certain significant shareholders. In considering related person transactions, our audit committee will take into account the relevant available facts and circumstances, which may include, but are not limited to:

- the risks, costs, and benefits to us;
- the impact on a director's independence in the event the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the terms of the transaction;

- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties.
- our audit committee will approve only those transactions that it determines are fair and in our best interests. All of the transactions described above were entered into prior to the adoption of such policy.

PRICE RANGE OF SECURITIES AND DIVIDENDS

Price Range of Allarity A/S Securities

Allarity A/S's ordinary shares are traded on the Nasdaq First North Growth Market in Stockholm under the symbol ALLR.ST. and trades in SEK. The following table sets forth, for the periods indicated, the high and low sales prices for Allarity A/S ordinary shares and dividends declared per share of Allarity A/S ordinary shares as reported on the Nasdaq First North Growth Market converted into U.S. Dollars at a conversion rate of 8.2 SEK for 1 USD.

	Allarity A/S Ordinary Shares		
	High	Low	Dividends Declared
2021			
First Quarter	$ 0.18	$ 0.07	None
2020:			
Fourth Quarter	$ 0.25	$ 0.08	None
Third Quarter	$ 0.26	$ 0.16	None
Second Quarter	$ 0.52	$ 0.14	None
First Quarter			
2019:			
Fourth Quarter	$ 0.29	0.18	None
Third Quarter	$ 0.69	0.26	None
Second Quarter	$ 1.20	0.35	None
First Quarter	$ 0.85	0.42	None

Allarity Delaware Securities

Historical market price information regarding Allarity Delaware is not provided because there is no public market for Allarity Delaware securities.

Dividends

Allarity A/S has not paid any cash dividends on the Allarity A/S ordinary shares to date and does not intend to pay cash dividends prior to the completion of the Recapitalization Share Exchange.

EXPERTS

The financial statements of Allarity A/S as of December 31, 2020 and 2019 and for the years then ended included in this information statement/prospectus have been so included in reliance on the report (which contains an explanatory paragraph relating to the Company's ability to continue as a going concern as described in Note 1 to the financial statements) of PricewaterhouseCoopers Statsautoriseret Revisionspartnerselskab, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

In connection with the acceptance of the audit and the inclusion of PwC's opinion on our financial statements for the two years ended December 31, 2020, PwC and we completed an independence assessment to evaluate the services and relationships with us and our affiliates that may bear on PwC's independence under the SEC and the Public Company Accounting Oversight Board (United States) (PCAOB) independence rules. Certain services provided to us and an affiliate of ours were identified that are inconsistent with the auditor independence rules provided in Rule 2-01 of Regulation S-X.

The services identified included: (i) PwC provided valuation services on two occasions between June 4, 2020, and July 13, 2020, by providing two independent assurance statements required under Section 37(1) of the Danish Companies Act filed with the Danish Business Authority relating to the value of non-controlling interests in two of our subsidiaries we purchased; and (ii) PwC provided XBRL services to us and two of our subsidiaries between April 1, 2020, and May 7, 2021, relating to our 2019 and 2020 IFRS audited financial statements and the statutory audits of two of our subsidiaries for which PwC filed with the Danish Business Authority. All of these services were terminated prior to the commencement of PwC's professional engagement period for our U.S. GAAP financial statement audits for the years ended December 31, 2020 and 2019.

For the services identified, PwC provided to our audit committee and management an overview of the facts and circumstances surrounding the services, including the entities involved, the nature and scope of the services provided and an approximation of the fees earned related to the services. Additionally, it was noted that the services were permissible under the local independence regulations that applied and SEC and PCAOB independence was not contemplated at the time PwC performed the services, the fees are not material to PwC or to us and the results of the services are not subject to PwC's audit of the U.S. GAAP financial statements.

Considering the facts presented, our audit committee concluded that the services provided would not impact PwC's application of objective and impartial judgement on any matters encompassed within the audit engagement performed by PwC for our U.S. GAAP financial statements for the years ended December 31, 2020 and 2019. Furthermore, our audit committee concluded that a reasonable investor with knowledge of the relevant facts and circumstances would reach the same conclusion.

CHANGE IN REGISTERED PUBLIC ACCOUNTING FIRM

PricewaterhouseCoopers Statsautoriseret Revisionspartnerselskab, Copenhagen, Denmark ("PwC"), our current independent registered public accounting firm, notified us on August 16, 2021 that they declined to stand for re-election as our independent registered public accounting firm with respect to the audit of our financial statements for the year ending December 31, 2021, effective upon the consummation of the Recapitalization Share Exchange.

PwC's reports on our financial statements for the fiscal years ended December 31, 2020, and December 31, 2019, did not contain an adverse opinion or a disclaimer of opinion, and neither such report was qualified or modified as to uncertainty, audit scope, or accounting principle, except for the reports on our financial statements for the fiscal years ended December 31, 2020, and December 31, 2019, contained a paragraph stating that there was substantial doubt about our ability to continue as a going concern.

During the fiscal years ended December 31, 2020, and December 31, 2019, and subsequent interim periods through the date of this information statement/prospectus, (i) there were no disagreements with PwC on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreement, if not resolved to the satisfaction of PwC, would have caused PwC to make reference thereto in its reports on the financial statements for such years, and (ii) there were no reportable events as described in paragraph (a)(1)(v) of Item 304 of Regulation S-K, other than the material weakness in the internal control over financial reporting relating to (i) a lack of accounting resources required to fulfill US GAAP and SEC reporting requirements, (ii) a lack of comprehensive US GAAP accounting policies and financial reporting procedures, and (iii) a lack of segregation of duties given the size of our finance and accounting team as described in Risk Factors section of this information statement/prospectus. See, RISK FACTORS-*We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weakness, or if we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business and stock price*.

We have provided PwC with a copy of the above disclosures. A copy of PwC's letter to the U.S. Securities and Exchange Commission required by Item 304(a) of Regulation S-K is included as Exhibit 16.1 to the registration statement of which this information statement forms a part.

LEGAL MATTERS

The legality of shares of Delaware Common Stock offered by this information statement/prospectus will be passed upon for Allarity Delaware by Lewis Brisbois Bisgaard & Smith LLP. Manzanti-Andersen Advokatpartnerselskab has represented Allarity Delaware with respect to Danish law in connection with the Recapitalization Share Exchange.

There is no material litigation, arbitration or governmental proceeding currently pending against Allarity A/S, Allarity Delaware, or any members of their management teams in their capacity as such, and neither has been subject to any such proceeding in the twelve months preceding the date of this information statement/prospectus.

OTHER MATTERS

As of the date of this information statement/prospectus, the Allarity A/S board of directors does not know of any matters that will be presented for consideration at the Allarity A/S Extraordinary General Meeting other than as described in this information statement/prospectus. If any other matters properly come before the Allarity A/S Extraordinary General Meeting, or any adjournment or postponement thereof, and are voted upon, any proxy presented at the Allarity A/S Extraordinary General Meeting will be deemed to confer discretionary authority on the individuals that it names as proxies to vote the shares represented by the proxy as to any of these matters.

APPRAISAL RIGHTS

Holders of Allarity A/S ordinary shares are not entitled to appraisal rights in connection with the Recapitalization Share Exchange under Danish law.

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Allarity Therapeutics A/S

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Allarity Therapeutics A/S and its subsidiaries (the "Company") as of December 31, 2020 and 2019, and the related consolidated statements of operations and comprehensive loss, of stockholders' equity and of cash flows for the years then ended, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt about the Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred significant losses and has an accumulated deficit that raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers Statsautoriseret Revisionspartnerselskab

Copenhagen, Denmark

August 20, 2021

We served as the Company's auditor since 2006

ALLARITY THERAPEUTICS A/S
CONSOLIDATED BALANCE SHEETS
As at December 31, 2020 and 2019
(U.S. dollars in thousands, except for share and per share data and where otherwise noted)

	2020 $	2019 $
ASSETS		
Current assets		
Cash and cash equivalents	298	1,524
Accounts receivable	—	95
Other current assets	335	821
Prepaid expenses	174	77
Income tax receivable	908	826
Total current assets	1,715	3,343
Non-current assets:		
Investment	845	137
Property, plant and equipment, net	21	37
Operating lease assets	331	400
Intangible assets, net	30,491	27,690
Total assets	**33,403**	31,607
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Line of credit	84	—
Accounts payable	2,116	2,178
Accrued liabilities	1,840	1,876
Income taxes payable	57	43
Operating lease liabilities	109	86
Loan	—	536
Convertible debt	1,327	—
Total current liabilities	5,533	4,719
Non-current liabilities		
Derivative liabilities	149	3,793
Non-current operating lease liabilities	267	341
Deferred tax	603	1,851
Total liabilities	6,552	10,704
Commitments and contingencies (Note 24)		
Stockholders' equity		
Common stock, par value $0.01 (DKK 0.05, shares issued and outstanding at December 31, 2020 and 2019 were 212,601,044 and 121,336,079 respectively	1,624	924
Additional paid-in capital	61,284	50,623
Accumulated other comprehensive income (loss)	1,375	(1,086)
Accumulated deficit	(37,432)	(32,374)
Total stockholders' equity attributable to Allarity A/S common stockholders	26,851	18,087
Non-controlling interest in consolidated subsidiaries	—	2,816
Total stockholders' equity	26,851	20,903
Total liabilities & stockholders' equity	**33,403**	31,607

The accompanying notes are an integral part of the consolidated financial statements.

ALLARITY THERAPEUTICS A/S
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
For the years ended December 31, 2020 and 2019
(U.S. dollars in thousands, except for share and per share data and where otherwise noted)

	2020 $	2019 $
Revenue	—	120
Operating expenses:		
Research and development	5,126	6,367
General and administrative	4,101	3,870
Impairment	—	7,494
Total operating expenses	9,227	17,731
Loss from operations	(9,227)	(17,611)
Other (income) expenses		
Interest income	—	(7)
Interest expenses	227	3,312
Gain on investment	(708)	—
Foreign exchange (gains), net	(62)	(80)
Fair value adjustment of derivative liabilities	(2,131)	(1,859)
Change in fair value of convertible debt	681	—
Net other (income) expenses	(1,993)	1,366
Net loss for the year before tax benefit	(7,234)	(18,977)
Income tax benefit	2,161	4,577
Net loss	(5,073)	(14,400)
Net loss attributable to non-controlling interests	(15)	(87)
Net loss attributable to Allarity A/S common stockholders	**(5,058)**	(14,313)
Basic and diluted net loss per common share	**(0.03)**	(0.23)
Weighted-average number of common shares outstanding, basic and diluted	**172,723,125**	63,407,230
Net loss	(5,073)	(14,400)
Other comprehensive loss, net of tax:		
Change in cumulative translation adjustment	2,452	(465)
Change in fair value attributable to instrument specific credit risk	9	—
Total other comprehensive loss	(2,612)	(14,865)
Less comprehensive loss attributable to non-controlling interests	(15)	(165)
Comprehensive loss attributable to Allarity A/S common stockholders	**(2,597)**	(14,700)

The accompanying notes are an integral part of the consolidated financial statements.

ALLARITY THERAPEUTICS A/S
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For the years ended December 31, 2020 and 2019
(U.S. dollars in thousands, except for share and per share data and where otherwise noted)

	Common Shares		Additional Paid in Capital	Accumulated Other Comprehensive Loss	Retained Earnings (Accumulated Deficit)	Stockholders' Equity	Non-Controlling Interest (net of OCI)	Total
	Number	Value $	$	$	$	$	$	$
Balance at December 31, 2018	50,311,278	397	39,847	(699)	(18,061)	21,484	3,352	24,836
Shares issued for cash	48,420,891	360	13,197	—	—	13,557	—	13,557
Fair value of investor warrants	—	—	(3,514)	—	—	(3,514)	—	(3,514)
Debt conversion	22,603,910	167	5,620	—	—	5,787	—	5,787
Share issuance costs	—	—	(4,429)	—	—	(4,429)	—	(4,429)
Acquisition of non-controlling Interest ("NCI")	—	—	(431)	—	—	(431)	(371)	(802)
Share based compensation	—	—	333	—	—	333	—	333
Currency translation adjustment	—	—	—	(387)	—	(387)	(78)	(465)
Loss for the year	—	—	—	—	(14,313)	(14,313)	(87)	(14,400)
Balance at December 31, 2019	121,336,079	924	50,623	(1,086)	(32,374)	18,087	2,816	20,903
Shares issued for cash	18,067,963	141	2,889	—	—	3,030	—	3,030
Debt conversion	25,546,633	203	2,799	—	—	3,002	—	3,002
Settlement of Financing Facility (Note 14(b))	9,330,000	67	2,437	—	—	2,504	—	2,504
Acquisition of NCI	38,320,369	289	2,572	—	—	2,861	(2,861)	—
Share issuance costs	—	—	(652)	—	—	(652)	—	(652)
Share based compensation	—	—	616	—	—	616	—	616
Currency translation adjustment	—	—	—	2,452	—	2,452	60	2,512
Fair value of instrument specific Credit risk	—	—	—	9	—	9	—	9
Loss for the year	—	—	—	—	(5,058)	(5,058)	(15)	(5,073)
Balance, December 31, 2020	**212,601,044**	**1,624**	**61,284**	**1,375**	**(37,432)**	**26,851**	**—**	**26,851**

The accompanying notes are an integral part of the consolidated financial statements.

ALLARITY THERAPEUTICS A/S
CONSOLIDATED STATEMENTS OF CASH FLOWS
For the years ended December 31, 2020 and 2019
(U.S. dollars in thousands, except for share and per share data and where otherwise noted)

	2020 $	2019 $
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	(5,073)	(14,400)
Adjustments to reconcile net income (loss) to net cash (used in) provided by operating activities:		
Depreciation and amortization	46	51
Intangible asset impairment	—	7,494
Share-based compensation	616	333
Non-cash lease expense	40	34
Non-cash interest	187	
Gain on investment	(708)	—
Foreign currency gain, net	(68)	(67)
Fair value adjustment of convertible debt	681	—
Fair value adjustment of derivative liabilities	(2,131)	(1,859)
Deferred income taxes	(1,286)	(3,760)
Changes in operating assets and liabilities:		
Accounts receivable	95	(95)
Other current assets	510	(6)
Income taxes receivable	(71)	500
Prepaid expenses	97	217
Accounts payable	(62)	237
Accrued liabilities	(36)	1,329
Operating lease liability	(88)	(74)
Deferred revenue	—	(47)
Net cash used in operating activities	(7,251)	(10,113)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(3)	(8)
Proceeds from sale of equity investment	—	237
Net cash used in investing activities	(3)	229
CASH FLOWS FROM FINANCING ACTIVITIES:		
Line of credit	84	—
Proceeds from share issuance	3,703	13,557
Share issuance costs	(223)	(4,429)
Settlement of derivative financial liability	—	(673)
Purchase of non-controlling interests	—	(802)
Proceeds from convertible loan	3,002	—
Loan proceeds	—	8,658
Repayment of loan	(533)	(5,109)
Net cash provided in financing activities	6,033	11,202
Net increase (decrease) in cash	(1,221)	1,318
Effect of exchange rate changes on cash	(5)	(31)
Cash, beginning of year	1,524	237
Cash, end of year	298	1,524
Supplemental disclosure of cash flow information		
Cash paid for income taxes	—	22
Cash paid for interest	40	47
Supplemental disclosure of non-cash investing and financing activities:		
Conversion of convertible debt to equity	3,163	5,787
Conversion of derivative liability to equity	1,412	—
Acquisition of NCI	1,873	—
Non-cash share issuance costs	429	—

The accompanying notes are an integral part of the consolidated financial statements.

1. Nature of the business

(a) Organization

Allarity Therapeutics A/S (the "Company") is a public limited company domiciled in Denmark. The Company was incorporated under the laws of Denmark on 9 September 2004 The Company's principal operations are located at Venlighedsvej 1, 2970 Horsholm, Denmark. The Company's United States operations are located at 210 Broadway #201, Cambridge, MA 012139, United States of America.

(b) Principal Activities

Allarity Therapeutics A/S develops drugs for the personalized treatment of cancer using drug specific companion diagnostics (cDx) generated by its proprietary drug response predictor technology, DRP®. The Company is a merged company (the "Merger") between two prior affiliated companies, the drug development company Oncology Venture Sweden AB and the predictive diagnostic development company Medical Prognosis Institute A/S. Pursuant to the Merger, effective 21 August 2018 the Company obtained control of 100% shares and voting interests of Oncology Venture Sweden AB, a company based in Sweden, listed on Spotlight, Stockholm, Sweden and specializing in the research and development of anti-cancer drugs via its wholly owned Danish subsidiary, Oncology Venture ApS. The Merger was accounted for as a business combination with the Company being the acquirer and all assets acquired and liabilities assumed were recognized at fair value.

Allarity Therapeutics A/S (Nasdaq First North Growth Market Stockholm: ALLR) develops drugs for the personalized treatment of cancer using drug-specific companion diagnostics (cDx) generated by its proprietary drug response predictor technology, DRP®.

(c) Risks and Uncertainties

The Company is subject to risks common to companies in the biotechnology industry, including but not limited to, risks of failure of preclinical studies and clinical trials, the need to obtain marketing approval for any drug product candidate that it may identify and develop, the need to successfully commercialize and gain market acceptance of its product candidates, dependence on key personnel and collaboration partners, protection of proprietary technology, compliance with government regulations, development by competitors of technological innovations, and the ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including preclinical and clinical testing and regulatory approval prior to commercialization. Even if the Company's research and development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

The accompanying consolidated financial statements have been prepared on going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business. The accompanying financial statements do not reflect any adjustments relating to the recoverability and reclassifications of assets and liabilities that might be necessary if the Company is unable to continue as a going concern. The Company expects its costs and expenses to increase as it continues to develop its product candidates and progress its current clinical programs and cost associated with being a public company.

Pursuant to the requirements of Accounting Standard Codification (ASC) 205-40, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern, management must evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of management's plans that have not been fully implemented as of the date of these financial statements, and (1) is probable that the plan will be effectively implemented within one year after the date the financial statements are issued, and (2) it is probable that the plan, when implemented, will

1. Nature of the business (cont.)

mitigate the relevant condition or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date the financials are issued. Certain elements of the Company's operating plan to alleviate the conditions that raise substantial doubt are outside of the Company's control and cannot be included in management's evaluation under the requirements of Accounting Standard Codification (ASC) 205-40.

Since inception, the Company has devoted substantially all of its efforts to business planning, research and development, clinical expenses, recruiting management and technical staff, and securing funding via collaborations. The Company has historically funded its operations with proceeds received from its collaboration arrangements, sale of equity capital and proceeds from sales of convertible notes.

The Company has incurred significant losses and has an accumulated deficit of $37.4 million as of December 31, 2020. Management expects to continue to generate operating losses in the foreseeable future, particularly as the Company advances its preclinical activities and clinical trials for its product candidates in development. The Company plans to seek additional funding through public equity, private equity, debt financing, collaboration partnerships, or other sources. There are no assurances, however, that the Company will be successful in these endeavours. If the Company is unable to obtain funding, the Company could be forced to delay, reduce, or eliminate its research and development programs, or reduce product candidate expansion, which could adversely affect its business prospects. As of August 20, 2021, our cash which includes the proceeds of our rights offering in June 2021 is insufficient to fund our current operating plan and planned capital expenditures for at least the next 12 months. These conditions give rise to a substantial doubt over the Company's ability to continue as a going concern.

As of June 10, 2021, the Company has completed a unit offering in exchange for gross proceeds of approximately $12.459 million (SEK 102.8 million). The Company has also entered into a Securities Purchase Agreement with 3i, LP, a Delaware limited partnership that provides for a $20 million equity investment in the Company. Please refer to the subsequent event disclosures in note 25 for further information.

Although management continues to pursue its funding plans, there is no assurance that the Company will be successful in obtaining sufficient funding to fund continuing operations on terms acceptable to the Company, if at all. Further, at the date of this filing the above noted 3i $20 million equity investment cannot be asserted as probable and is subject to close of the transaction. Accordingly, based upon cash on hand at the issuance date of these financial statements which includes proceeds of the rights offering of $12.459 million, the Company does not have sufficient funds to finance its operations for at least twelve months from the issuance date and therefore has concluded that substantial doubt exists about the Company's ability to continue as a going concern.

Impact of Covid-19 on our Business

In March 2020, the World Health Organization declared the novel strain of coronavirus (COVID-19) a pandemic and recommended containment and mitigation measures worldwide. The COVID-19 pandemic has been evolving, and to date has led to the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures.

As a result of COVID-19, all of the Company's clinical trials were experiencing significant delays throughout the year ended December 31, 2020. The Company has been slowly ramping up its clinical trial sites in 2021. Management continues to closely monitor the impact of the COVID-19 pandemic on all aspects of the business, including how it will impact operations and the operations of customers, vendors, and business partners. The extent to which COVID-19 impacts the future business, results of operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted with confidence at this time, such as the continued duration of the outbreak, new information that may emerge concerning the severity or other strains of COVID-19 or the effectiveness of actions to contain COVID-19 or treat its impact, among others. If the Company or any of

1. Nature of the business (cont.)

the third parties with which it engages, however, were to experience shutdowns or other business disruptions, the ability to conduct business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on business, results of operations and financial condition. The estimates of the impact on the Company's business may change based on new information that may emerge concerning COVID-19 and the actions to contain it or treat its impact and the economic impact on local, regional, national, and international markets. Management have not identified any triggering events which would result in any significant impairment losses in the carrying values of assets as a result of the pandemic and are not aware of any specific related event or circumstance that would require management to revise estimates reflected in these consolidated financial statements.

Emerging Growth Companies

Section 102(b)(1) of the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act") exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that an emerging growth company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. The Company has chosen to not make an election to opt out of new or revised accounting standards.

2. Summary of Significant Accounting Policies

(a) Basis of Presentation

The accompanying consolidated financial statements have been prepared on an accrual basis of accounting, in accordance with accounting principles generally accepted in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

(b) Organization and Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries:

Name	Country of Incorporation
Oncology Venture Product Development ApS	Denmark
OV-SPV2 ApS	Denmark
MPI Inc.	United States
Oncology Venture US Inc.	United States

All intercompany transactions and balances, including unrealized profits from intercompany sales, have been eliminated upon consolidation.

2. Summary of Significant Accounting Policies (cont.)

(c) Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting years. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the fair value of the convertible loan, the accrual for research and development expenses, revenue recognition, fair values of acquired intangible assets and impairment review of those assets, the useful life of property, plant and equipment, share based compensation expense, provisions for contingencies and litigation, and income tax uncertainties and valuation allowances. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. Estimates are periodically reviewed in light of reasonable changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known and if material, their effects are disclosed in the notes to the consolidated financial statements. Actual results could differ from those estimates or assumptions.

(d) Foreign currency and currency translation

The functional currency is the currency of the primary economic environment in which an entity's operations are conducted. The Company and its subsidiaries operate mainly in Denmark and the United States. The functional currencies of the Company's subsidiaries are their local currency.

The Company's reporting currency is the U.S. dollar. The Company translates the assets and liabilities of its Denmark subsidiaries into the U.S. dollar at the exchange rate in effect on the balance sheet date. Revenues and expenses are translated at the average exchange rate in effect during each monthly period. Unrealized translation gains and losses are recorded as a cumulative translation adjustment, which is included in the consolidated statements of shareholders' equity as a component of accumulated other comprehensive (loss) income.

Monetary assets and liabilities denominated in currencies other than the functional currency are remeasured into the functional currency at rates of exchange prevailing at the balance sheet dates. Non-monetary assets and liabilities denominated in foreign currencies are re-measured into the functional currency at the exchange rates prevailing at the date of the transaction. Exchange gains or losses arising from foreign currency transactions are included in the determination of net loss for the respective periods.

Adjustments that arise from exchange rate changes on transactions denominated in a currency other than the local currency are included in other comprehensive income (loss) in the consolidated statements of operations and comprehensive loss as incurred. The Company recorded a foreign exchange gain (loss) of $2,452 and ($465) included in accumulated other comprehensive loss for the years ended December 31, 2020, and 2019, respectively.

(e) Concentrations of credit risk and of significant suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash. The Company maintains its cash in financial institutions in amounts that could exceed government-insured limits. The Company does not believe it is subject to additional credit risks beyond those normally associated with commercial banking relationships. The Company is dependent on third-party manufacturers to supply products for research and development activities in its programs. In particular, the Company relies and expects to continue to rely on a small number of manufacturers to supply its requirements for supplies and raw materials related to these programs. These programs could be adversely affected by a significant interruption in these manufacturing services or the availability of raw materials.

2. Summary of Significant Accounting Policies (cont.)

(f) Cash and Cash Equivalents

Cash and cash equivalents consist primarily of highly liquid investments with original maturities of three months or less at date of purchase to be cash equivalents. The Company had no cash equivalents or restricted cash on December 31, 2020, and 2019.

(g) Property, plant and equipment

Property, plant and equipment are stated at cost, less accumulated depreciation. Depreciation expense is recognized using the straight-line method over the estimated useful lives of the respective assets as follows:

	Estimated Useful Economic Life
Leasehold property improvements	Lesser of lease term or useful life
Laboratory equipment	5 years
Furniture and office equipment	3 years

Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in loss from operations. As of December 31, 2020, and 2019, there have been no significant asset retirements to date. Expenditures for repairs and maintenance that do not improve or extend the lives of the respective assets are charged to expense as incurred.

(h) Grants

Grants are recognized when the conditions for receipt are met and there is reasonable assurance that the grant will be received.

Grants that are receivable as compensation for expenses or losses already incurred or for the purpose of giving immediate financial support to the Group with no future related costs are recognized in profit or loss in the period in which they become receivable.

(i) Impairment of long-lived assets

Long-lived assets consist of property, plant and equipment, and intangible assets. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. An impairment loss would be recognized as a loss from operations when estimated undiscounted future cash flows expected to result from the use of an asset group or the estimated return on investment are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset group over its fair value, determined based on discounted cash flow or return on investment calculations

(j) Business Combinations

Business combinations are accounted for in accordance with ASC Topic 805 “Business Combinations”. The total purchase price of an acquisition is allocated to the underlying identifiable net assets, based on their respective estimated fair values as of the acquisition date. Determining the fair value of assets acquired and liabilities assumed requires management’s judgment and often involves the use of significant estimates and assumptions, including assumptions with respect to future cash inflows and outflows, probabilities of success, discount rates, and asset lives, among other items. Assets acquired and liabilities assumed are recorded at their estimated fair values.

2. Summary of Significant Accounting Policies (cont.)

(k) Non-controlling interest

These financial statements reflect the application of ASC 810, Consolidations, which establishes accounting and reporting standards that require: (i) the ownership interest in subsidiaries held by parties other than the parent to be clearly identified and presented in the consolidated balance sheet within shareholder's (deficit) equity, but separate from the parent's (deficit) equity; (ii) the amount of consolidated net income attributable to the parent and the non-controlling interest to be clearly identified and presented on the face of the consolidated statement of operations and (iii) changes in a parent's ownership interest while the parent retains its controlling financial interest in its subsidiary to be accounted for consistently.

Our consolidated financial statements include all assets, liabilities, incidental service revenues, and expenses of less-than-100%-owned affiliates that we control or for which we are the primary beneficiary. We record a non-controlling interest for the allocable portion of income or loss and comprehensive income or loss to which the non-controlling interest holders are entitled based upon their ownership share of the affiliate. Distributions made to the holders of non-controlling interests are charged to the respective non-controlling interest balance. Losses attributable to the non-controlling interest in an affiliate may exceed our interest in the affiliate's equity. The excess and any further losses attributable to the non-controlling interest shall be attributed to those interests. The non-controlling interest shall continue to be attributed its share of losses even if that attribution results in a deficit non-controlling interest balance.

(l) Acquired Patents

Acquired patents are measured in the balance sheet at the lower of cost less accumulated amortization and impairment charges, if any. The legal costs incurred to renew or extend the term of the acquired patents are expensed as incurred. As of December 31, 2020 and 2019, the Company has not recognized any impairment charges with respect to its acquired patents.

Cost comprises the acquisition price and the depreciation period are estimated at 6 years with no residual value. Depreciation methods, useful lives and residual values are reviewed every year.

(m) Acquired In-Process Research and Development (IPR&D)

Acquired IPR&D represents the fair value assigned to research and development assets that the Company acquired as part of a business combination and have not been completed at the acquisition date. The fair value of IPR&D acquired in a business combination is recorded on the consolidated balance sheets at the acquisition-date fair value and is determined by estimating the costs to develop the technology into commercially viable products, estimating the resulting revenue from the projects, and discounting the projected net cash flows to present value. IPR&D is not amortized, but rather is reviewed for impairment on an annual basis or more frequently if indicators of impairment are present, until the project is completed, abandoned or transferred to a third-party. The projected discounted cash flow models used to estimate the fair value of partnered assets and cost approach model used to estimate proprietary assets as part of the Company's IPR&D reflect significant assumptions regarding the estimates a market participant would make in order to evaluate a drug development asset, including the following:

- Estimates of obsolescence of development expenditure;
- Probability of successfully completing clinical trials and obtaining regulatory approval;
- Estimates of future cash flows from potential milestone payments and royalties related to out-licensed product sales; and
- A discount rate reflecting the Company's weighted average cost of capital and specific risk inherent in the underlying assets.

2. Summary of Significant Accounting Policies (cont.)

Once brought into use, intangible assets are amortized over their estimated useful economic lives using the economic consumption method if anticipated future revenues can be reasonably estimated. The straight-line method is used when revenues cannot be reasonably estimated. The Company recorded an impairment loss on IPR&D of $0 and $7,494 during the years ended December 31, 2020 and December 31, 2019 respectively.

(n) Fair value measurements of financial instruments

The carrying value of the Company's financial instruments of cash, trade receivables, other receivables, accounts payable and accrued liabilities, bank overdraft and loan approximate their fair value due to their short-term nature. The Company's other financial instruments include an equity investment, convertible debt and derivative liabilities. The equity investment is adjusted to fair market value at the end of every period based upon unadjusted quoted prices. The convertible debt and derivative liabilities are fair valued at the end of every period using level 3 inputs.

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Accounting Standards Codification ("ASC") Topic 820, Fair Value Measurement ("ASC 820"), establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances. ASC 820 identifies fair value as the exchange price, or exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a three-tier fair value hierarchy that distinguishes between the following:

- Level 1 — Unadjusted quoted prices in active markets for identical assets or liabilities.
- Level 2 — Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3 — Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

(o) Segment and geographic information

Operating segments are defined as components of a business for which separate discrete financial information is available for evaluation by the chief operating decision maker in deciding how to allocate resources and assess performance. The Company and its chief operating decision maker, the Company's Chief Executive Officer, view the Company's operations and manage its business as a single operating segment. The Company operates in two geographic areas: Denmark and the United States however, as at December 31, 2020, the Company has neither revenues nor assets outside of Denmark.

2. Summary of Significant Accounting Policies (cont.)

(p) Leases

The Company determines if an arrangement is a lease at inception by establishing if the contract conveys the right to control the use of identified property, plant, or equipment for a period of time in exchange for consideration. Operating leases are included non-current assets and current and long-term operating lease liabilities in the Company's consolidated balance sheets. The Company has not entered into any financing leases.

ROU assets represent the Company's right to use and control an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As the Company's leases do not provide an implicit rate, the Company uses its collateralized incremental borrowing rate for an equivalent lease term, based on the information available at commencement date in determining the present value of lease payments. The ROU asset also includes lease payments made before the lease commencement date and excludes any lease incentives. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option.

The components of a lease shall be split into three categories, if applicable: lease components (e.g., land, building, etc.), non-lease components (e.g., common area maintenance, maintenance, consumables, etc.), and non-components (e.g., property taxes, insurance, etc.). The fixed and in-substance fixed contract consideration (including any related to non-components) must then be allocated based on fair values to the lease components and non-lease components. The Company's facilities operating leases may have lease and non-lease components to which the Company has elected to apply a practical expedient to account for each lease component and related non-lease component as one single component. In addition, the Company has elected to not recognize right of use assets or lease liabilities for low value leases or leases with a term of 12 months or less for all asset classes. This results in a right-of-use asset being recorded on the consolidated balance sheets. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

(q) Service revenue recognition

The Company's revenues are generated primarily through minor revenue associated with research and development services provided to pharmaceutical and biotechnology companies. The terms of these arrangements may include (i) the grant of intellectual property rights (IP licenses) to therapeutic drug candidates against specified targets, (ii) performing research and development services to optimize drug candidates, and (iii) the grant of options to obtain additional research and development services or licenses for additional targets, or to optimize product candidates, upon the payment of option fees.

The Company has adopted Financial Accounting Standards Board (the "FASB") Accounting Standards Codification ("ASC") Topic 606—Revenue from Contracts with Customers ("ASC 606"). This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. In determining the appropriate amount of revenue to be recognized under ASC 606, the Company performs the following steps:

(i) identify the promised goods or services in the contract;

(ii) determine whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract;

(iii) measurement of the transaction price, including the constraint on variable consideration;

(iv) allocation of the transaction price to the performance obligations; and

(v) recognition of revenue when (or as) the Company satisfies each performance obligation.

2. Summary of Significant Accounting Policies (cont.)

(r) Research and development costs

Research and development costs are expensed as incurred. Research and development expenses are comprised of costs incurred in performing research and development activities, including salaries, share-based compensation and benefits, facilities costs and laboratory supplies, depreciation, amortization and impairment expense, manufacturing expenses and external costs of outside vendors engaged to conduct preclinical development activities and clinical trials. Typically, upfront payments and milestone payments made for the licensing of technology are expensed as research and development in the period in which they are incurred. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed. There were no milestone payments paid or due in either of the years ended December 31, 2020 and 2019.

(s) Research contract costs and accruals

The Company has entered into various research and development contracts with companies in Europe, the United States, and other countries. These agreements are generally cancellable, and related payments are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies or trials, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

(t) Research and development incentives and receivable

The Company, through its subsidiaries in Denmark, receives reimbursements of certain research and development expenditures as part of a European agency's research and development cost reliefs program. Management has assessed the Company's research and development activities and expenditures to determine which activities and expenditures are likely to be eligible under the research and development incentive program described above. At each period end, management estimates the reimbursement available to the Company based on available information at the time. The Company recognizes a receivable for the research and development incentives when the relevant expenditure has been incurred, the associated conditions have been satisfied and there is reasonable assurance that the reimbursement will be received. The Company records these research and development expense reimbursements as a reduction to research and development expenses in the consolidated statements of operations and comprehensive loss, as the research and development cost reimbursements are not dependent on the Company generating future taxable income, the Company's ongoing tax status, or tax position. The research and development incentives receivable represent an amount due in connection with the above program. The Company has recorded government grants received as a reduction to research and development expense of $22 and $315 for the years ended December 31, 2020 and 2019, respectively.

(u) Investments

The Company's investments in equity securities are measured at fair value in the balance sheet with changes in fair value recognized in net income. For investments in equity securities that are traded in an active market, fair value is equivalent to the market value at the balance sheet date and changes in fair value are recognized in operating income. Pursuant to ASC 321-10-35-2, the Company has elected to apply the measurement alternative and measure other investments in equity securities for which fair value cannot be determined reliably initially at cost, less impairment, if any, plus or minus changes resulting from observable price changes.

2. Summary of Significant Accounting Policies (cont.)

(v) Convertible note:

The Company accounts for certain convertible notes issued during the year ended December 31, 2020 under the fair value option election of ASC 825, Financial Instruments ("ASC-825") wherein the financial instrument is initially measured at its issue-date estimated fair value and then subsequently re-measured at estimated fair value on a recurring basis at each reporting period date. The estimated fair value adjustment is recognized as other income (expense) in the accompanying consolidated statement of operations and the portion of the fair value adjustment attributed to a change in the instrument-specific credit risk is recognized as a component of other comprehensive income ("OCI").

(w) Warrants

When the Company issues warrants, it evaluates the proper balance sheet classification to determine classification as either equity or as a derivative liability on the consolidated balance sheets. In accordance with ASC 815-40, Derivatives and Hedging-Contracts in the Entity's Own Equity (ASC 815-40), the Company classifies a warrant as equity so long as it is "indexed to the Company's equity" and several specific conditions for equity classification are met. A warrant is not considered indexed to the Company's equity, in general, when it contains certain types of exercise contingencies or adjustments to exercise price. If a warrant is not indexed to the Company's equity or it has net cash settlement that results in the warrants to be accounted for under ASC 480, Distinguishing Liabilities from Equity, or ASC 815-40, it is classified as a derivative liability which is carried on the consolidated balance sheet at fair value with any changes in its fair value recognized immediately in the statement of operations. As of December 31, 2020 and 2019, the Company had warrants outstanding for share based compensation that were classified as equity, and outstanding investor warrants that were classified as derivative liabilities.

(x) Share-based compensation

The Company accounts for share-based compensation in accordance with ASC 718, Compensation — Stock Compensation ("ASC 718"). ASC 718 requires companies to estimate the fair value of equity-based payment awards on the date of grant. The value of the portion of the award that is ultimately expected to vest is recognized as an expense over the requisite service period in the Company's consolidated statements of operations and comprehensive loss.

The Company records the expense for option awards using a graded and straight line method. The Company accounts for forfeitures as they occur. For share based awards granted to non-employee consultants, the measurement date for non-employee awards is the date of grant. The compensation expense is then recognized over the requisite service period, which is the vesting period of the respective award.

The Company reviews all stock award modifications including when there is an exchange of original award for a new award. In the case of stock award modifications, the Company calculates for the incremental fair value based on the difference between the fair value of the modified award and the fair value of the original award immediately before it was modified. The Company immediately recognizes the incremental value as compensation cost for vested awards and recognizes, on a prospective basis over the remaining requisite service period, the sum of the incremental compensation cost and any remaining unrecognized compensation cost for the original award on the modification date.

The fair value of stock options ("options") on the grant date is estimated using the Black-Scholes option-pricing model using the single-option approach. The Black-Scholes option pricing model requires the use of highly subjective and complex assumptions, including the option's expected term and the price volatility of the underlying stock, to determine the fair value of the award. The Company applies the Black-Scholes model as it believes it is the most appropriate fair value method for all equity awards and for the Employee Share Purchase Plan (the "ESPP"). The Black-Scholes model requires a number of assumptions, of which the most significant are the share price, expected volatility and the expected award term.

2. Summary of Significant Accounting Policies (cont.)

Expected term of options granted is calculated using the simplified method being the average between the vesting period and the contractual term to the expected term of the options in effect at the time of grant. The Company has historically not paid dividends and has no foreseeable plans to pay dividends and, therefore, uses an expected dividend yield of zero in the option pricing model. The risk-free interest rate is based on the yield of U.S. treasury bonds with equivalent terms.

The Company classifies share-based compensation expense in its consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

(y) Accumulated other comprehensive (Loss)

Accumulated other comprehensive loss includes net loss as well as other changes in shareholders' equity (deficit) that result from transactions and economic events other than those with shareholders. The Company records unrealized gains and losses related to foreign currency translation and instrument specific credit risk as components of other accumulated comprehensive loss in the consolidated statements of operations and comprehensive loss.

(z) Contingencies

Liabilities for loss contingencies arising from claims, assessments, litigation, fines, penalties and other sources are recorded when it is probable that a liability has been incurred and the amount can be reasonably estimated. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential loss range is probable and reasonably estimable under the provisions of the authoritative guidelines that address accounting for contingencies. The Company expenses costs as incurred in relation to such legal proceedings as general and administrative expense within the consolidated statements of operations and comprehensive loss.

(aa) Income taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company's tax returns. Deferred tax assets and liabilities are determined on the basis of the differences between the consolidated financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that will more likely than not be realized upon ultimate settlement. Any provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits that are considered appropriate. The Company recognizes interest and penalties related to uncertain tax positions in other (income) expenses.

2. Summary of Significant Accounting Policies (cont.)

(bb) Computation of Loss per Share

The Company computes net (loss) income per share in accordance with ASC Topic 260, "Earnings Per Share" ("ASC 260") and related guidance, which requires two calculations of net (loss) income attributable to the Company's shareholders per share to be disclosed: basic and diluted.

Basic loss per share is derived by dividing net loss applicable to common stockholders by the weighted average number of shares of common stock outstanding during each period. Diluted loss per share includes the effect, if any, from the potential exercise or conversion of securities, such as warrants, and convertible debt, which would result in the issuance of incremental shares of common stock unless such effect is anti-dilutive. In calculating the basic and diluted net loss per share applicable to common stockholders, the weighted average number of shares remained the same for both calculations due to the fact that when a net loss exists, dilutive shares are not included in the calculation.

(cc) Recently adopted accounting pronouncements

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework — Changes to the Disclosure Requirements for Fair Value Measurement (ASU 2018-13), which modifies the disclosure requirements on fair value measurements with respect to Level 3 rollforwards, timing of liquidation of investments in certain entities that calculate net asset value, and measurement uncertainty. This standard became effective for the Company on January 1, 2020. The adoption of this standard has not had a material impact on our consolidated financial statements as of December 31, 2020 but, will result in increased disclosure related to our convertible debt rollforward balances in future periods.

In June 2016, the FASB issued ASU No. 2016-13, Measurement of Credit Losses on Financial Instruments ("ASU 2016-13"). ASU 2016-13 changes how companies account for credit losses for most financial assets and certain other instruments. For trade receivables, loans and held-to-maturity debt securities, companies are required to recognize an allowance for credit losses rather than reducing the carrying value of the asset. This standard became effective for the Company on January 1, 2020. The adoption of this standard resulted in the recognition of the fair value of instrument specific credit risk in our consolidated financial statements.

In November 2018, the FASB issued ASU No. 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606. This standard became effective for the Company on January 1, 2020 and makes targeted improvements for collaborative arrangements as follows:

- Clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC 606, Revenue from Contracts with Customers, when the collaborative arrangement participant is a customer in the context of a unit of account. In those situations, all the guidance in ASC 606 should be applied, including recognition, measurement, presentation and disclosure requirements:
- Adds unit-of-account guidance to ASC 808, Collaborative Arrangements, to align with the guidance in ASC 606 (that is, a distinct good or service) when an entity is assessing whether the collaborative arrangement or a part of the arrangement is within the scope of ASC 606; and
- Precludes a company from presenting transactions with collaborative arrangement participants that are not directly related to sales to third parties with revenue recognized under ASC 606 if the collaborative arrangement participant is not a customer.

The adoption of this standard did not have a material impact on our consolidated financial statements.

In February 2016 the FASB issued ASU 2016-02: Leases. The ASU introduces a lessee model that results in most leases impacting the balance sheet. The ASU addresses other concerns related to the current lease model. Under ASU 2016-02, lessees will be required to recognize for all leases with terms longer than 12 months, at the commencement date of the lease, a lease liability, which is a lessee's obligation to make lease payments arising from a

2. Summary of Significant Accounting Policies (cont.)

lease measured on a discounted basis, and a right-to-use (ROU) asset, which is an asset that represents the lessee's right to use or control the use of a specified asset for the lease term. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition.

In July 2018, the FASB issued ASU 2018-10 "Codification Improvements to Topic 842, Leases." This ASU affects narrow aspects of the guidance issued in the amendments in ASU 2016-02 including those regarding residual value guarantees, rate implicit in the lease, lessee reassessment of lease classification, lessor reassessment of lease term and purchase option, variable lease payments that depend on an index or a rate, investment tax credits, lease term and purchase option, transition guidance for amounts previously recognized in business combinations, certain transition adjustments, transition guidance for leases previously classified as capital leases under Topic 840, transition guidance for modifications to leases previously classified as direct financing or sales-type leases under Topic 840, transition guidance for sale and leaseback transactions, impairment of net investment in the lease, unguaranteed residual asset, effect of initial direct costs on rate implicit in the lease, and failed sale and leaseback transactions.

The Company adopted ASC 2018-10 Topic 842 effective January 1, 2019 and elected the short-term lease recognition exemption for all leases that qualify. For those leases that qualify, the Company will not recognize ROU assets or lease liabilities, and this includes not recognizing ROU assets or lease liabilities for existing short-term leases of those assets in transition. This practical expedient was elected to not separate lease and non-lease components for its office space leases. The adoption of this new standard resulted in the recognition of a ROU asset and lease liability.

(dd) Recently issued accounting pronouncements not yet adopted:

In May 2021, the FASB issued ASU No. 2021-04 — Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options — to clarify the accounting by issuers for modifications or exchanges of equity-classified warrants. The framework applies to freestanding written call options, such as warrants, that were and remain equity classified by the issuer after the modification and are not in the scope of another Codification Topic. The framework applies regardless of whether the modification is through an amendment to the existing terms or issuance of a replacement warrant. The effect of the modification of the warrant is measured as the difference in its fair value immediately before and after the modification. The effect is recognized in the same manner as if cash had been paid as consideration. Additionally, other modifications may need to be accounted for as a cost to the issuing entity based on the substance of the transaction. The Update is effective prospectively for fiscal years beginning after December 15, 2021 including interim periods therein, with early adoption permitted. The Company is currently evaluating the impact of this standard on its consolidated financial statements and related disclosures.

In August 2020, the FASB issued ASU No. 2020-06, Debt — Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity, which simplifies accounting for convertible instruments by removing major separation models required under current U.S. GAAP. ASU No. 2020-06 removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception and it also simplifies the diluted earnings per share calculation in certain areas. ASU No. 2020-06 is effective for public companies for annual periods beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted for annual periods beginning after December 15, 2020, and interim periods within those fiscal years. The Company is currently evaluating the impact of this standard on its consolidated financial statements and related disclosures.

In December 2019, the FASB issued ASU 2019-12, "Income Taxes — Simplifying the Accounting for Income Taxes". The ASU simplifies the accounting for income taxes by removing certain exceptions to the general principles as well as clarifying and amending existing guidance to improve consistent application. The amendments to this ASU are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. Depending on the amendment, adoption may be applied on the retrospective, modified retrospective or prospective basis. The Company does not expect that the adoption of this standard will have a significant impact upon its consolidated financial statements.

(U.S. dollars in thousands, except for share and per share data and where otherwise noted)

3. Accounts Receivable

The Company's accounts receivable is comprised of the following:

	December 31,	
	2020 $	2019 $
Trade receivables	—	95
Less: Allowance for doubtful accounts	—	—
Net trade receivables	—	95

4. Other Current Assets

The Company's other current assets are comprised of the following:

	December 31,	
	2020 $	2019 $
Deposits	68	60
Grant receivable	50	315
Salary deposit	51	24
Value added tax ("VAT") receivable	166	406
Employee receivables	—	14
Sales taxes recoverable	—	2
	335	821

5. Prepaid Expenses

	December 31,	
	2020 $	2019 $
Prepaid insurance	152	14
Other prepayments	22	63
	174	77

6. Investment

The Company owns 43,898 common shares in Lantern Pharma Inc. (NasdaqCM) ("Lantern" or "Lantern shares") as a result of a prior license agreement made with Lantern Pharma in 2017. During June 2020 Lantern Pharma became publicly listed. As at December 31, 2020 the fair market value of the shares was $845.

	December 31,	
	2020 $	2019 $
Opening balance	137	137
Gain recognition	708	—
Ending balance	**845**	137

7. Property, plant and equipment

Property, plant and equipment are recorded at historical cost, net of accumulated depreciation. Components of property, plant and equipment, net are summarized as follows (in thousands):

	As of December 31,	
	2020	**2019**
Laboratory equipment	364	327
Less: accumulated depreciation	(343)	(290)
	21	37

The Company's property, plant and equipment is pledged as collateral to its line of credit loan as disclosed in Note 10.

Depreciation expense was $21 and $26 for the years ended December 31, 2020 and 2019, respectively.

8. Operating lease assets

The facilities of the Company are leased under various operating lease agreements for periods ending no later than 2023. The Company also has the option to extend the term of certain facility lease agreements and these are included in the calculation of right-of-use assets.

Under ASC 842, as a practical expedient, the Company has elected to only recognize on the balance sheet all leases with durations greater than 12 months, including non-cancellable operating leases. The aggregated present value of lease agreements is recorded as a long-term operating lease asset. The corresponding lease liabilities are split between current and long-term lease liabilities.

Upon implementation of ASC 842, effective January 1, 2019, the Company recorded right-of-use assets obtained in exchange for lease obligations of $512 on our opening balance sheet. All of our leases qualify as operating leases. The following table summarizes the presentation in our consolidated balance sheets of our operating lease assets:

	As of December 31,	
Balance sheet location (in $1,000's)	**2020**	**2019**
Assets:		
Operating lease assets	$ 331	$ 400
Liabilities:		
Current operating lease liabilities	$ 109	$ 86
Non-current operating lease liabilities	267	341
	$ 376	$ 427

Future minimum lease payments under non-cancellable operating leases as of December 31, 2020, are as follows:

	December 31,	
	2020	**2019**
Short-term lease liabilities	$ 109	$ 86
Long-term lease liabilities	267	341
Net present value of future minimum lease payments	**$ 376**	$ 427
Weighted average of remaining operating lease term (years)	**3**	4
Weighted average of operating lease discount rate	**10%**	**10%**

(U.S. dollars in thousands, except for share and per share data and where otherwise noted)

8. Operating lease assets (cont.)

Future minimum lease payments under non-cancellable operating leases as at December 31, 2020, are as follows:

2021	$ 141
2022	146
2023	151
	438
Imputed interest	(62)
Total	$ 376

Operating lease costs for the Company's premises and virtual offices for the years ended December 31, 2020 and 2019 were $27 and $38 respectively.

9. Intangible assets

Intangible assets, net of accumulated amortization, impairment charges and adjustments are summarized as follows:

	As of December 31, 2020			As of December 31, 2019		
	Cost	Accumulated Amortization*	Net	Cost	Accumulated Amortization*	Net
IPR&D Assets	$ 38,876	$ (8,399)	$ 30,477	$ 35,275	$ (7,624)	$ 27,651
Acquired patents	78	(64)	14	78	(39)	39
Total intangible assets	$ 38,954	$ (8,463)	$ 30,491	$ 35,353	$ (7,663)	$ 27,690

* **Accumulated Amortization of IPR&D Assets includes impairment charges as described below.**

The Company's IPR&D assets have been classified as indefinite-lived intangible assets. Individually material development projects in progress are as follows:

	December 31,	
	2020 $	2019 $
Stenoparib	27,522	24,970
Dovitinib	2,955	2,681
Total	**30,477**	27,651

Impairments

In November 2019 management reassessed its projects and determined to reprioritize its research and development efforts. Consequently, during the year ended December 31, 2019 the Company recognized impairment losses of $7,494 on certain of its IPR&D assets. Written down IPR&D assets, although written down to zero, may ultimately be out licensed.

10. Line of credit

Effective 1 July 2016 the Company established a line of credit with Nordea Bank in the amount of $84 bearing interest at 8.75%. The Company's assets, up to an amount of $84 have been provided as collateral against the line of credit. As of December 31, 2020, the Company was indebted in the amount of $84 (December 31, 2019 – $0).

(U.S. dollars in thousands, except for share and per share data and where otherwise noted)

11. Accrued liabilities

The Company's accrued liabilities are comprised of the following:

	December 31,	
	2020 $	2019 $
Development cost liability (Note 24)	1,191	300
Payroll accruals	316	716
Hospital expense accruals	—	265
Accrued Board member fees	119	69
Accrued audit and legal	84	117
Accrued liabilities	130	409
	1,840	1,876

12. Loan

Effective September 24, 2019 the Company received a loan of $512 bearing interest at 3% per month and due on November 30, 2019. The lender agreed to extend the due date of the loan with no penalty and the balance of the loan, including interest of $62 was paid as of January 7, 2020. The loan agreement included the Company's commitment to complete a rights offering and issue common shares which was completed in 2019.

13. Convertible debt

On 31 March 2020 the Company entered into an agreement to issue up to $10,100 (SEK 100,000) (the "Commitment") to be funded in tranches ("Tranches") of ten non-interest bearing notes ("Notes") into common shares of the Company, each with a par value of $1,010 (SEK 10,000), under the following terms:

a) Fees payable include 5% of the $10,100 Commitment in 2 equal installments of $252, paid on the disbursement of each of the first and second Tranches; and a further 5% of the principal of the notes is to be deducted from the payment of each Tranche.

b) The Conversion Price of the Notes is 95% of the lowest closing volume weighted average price as reported by Bloomberg ("VWAP") of the shares during the applicable pricing period preceding the conversion date. Conversion of the Loan Amount shall be made at a rate equal to the Conversion Price. The Conversion Price cannot be below par value. The number of new Shares issued by the Company to the Investor upon conversion of the Loan Amount shall be calculated as the Loan Amount divided by the Conversion Price. If the Conversion Price is equal to or less than $0.01 (0.05 DKK), the Investor will not be required to convert such Note. If the Investor (contrary to the clear intention in the Agreement) claims repayment of one or more Tranches and not to convert into Shares the Company shall be entitled to deduct the commitment fee in connection with the repayment.

c) The loan is due for repayment in full 12 months from the date of issuance; or immediately repayable in the event of default, a change of control or a material adverse event. The Investor may in its sole discretion decide to convert the Loan in full or in part (in multiples of $4 (SEK 25) in 1,000's) into new shares.

d) Default interest accrues on the overdue amount from the due date up to the date of actual payment at 8% per annum; calculated on a 360 day year and accrues and compounds on a daily basis.

(U.S. dollars in thousands, except for share and per share data and where otherwise noted)

13. Convertible debt (cont.)

The Company accounted for the Notes issued during the year ended December 31, 2020 under the FVO election whereby the financial instrument is initially measured at its issue-date estimated fair value and subsequently re-measured at estimated fair value on a recurring basis at each reporting date. The estimated fair value adjustment is presented as a single line item within other income (expense) in the accompanying consolidated statements of operations under the caption "change in fair value of convertible notes and derivative liabilities".

We determined the fair value of the Notes using a discounted cash flow valuation technique with a weighted average cost of capital of 15%. Therefore, they are categorized as Level 3 in accordance with ASC 820, "Fair Value Measurements and Disclosures". (Note 23) Following is a roll forward of the fair values from date of issuance to December 31, 2020:

Beginning fair value balance on issue date	$	4,670
Change in fair value (loss) reported in statement of operations		(681)
Conversion of notes to common shares		(2,662)
Ending fair value balance – December 31, 2020	$	1,327

The Company estimates the change in fair value attributable to the instrument specific credit risk of the Notes at 1% under the fair value option and accordingly has recognized a gain of $9 in other comprehensive income.

14. Derivative Liabilities

(a) Investor Warrants

The exercise price of our investor warrants described below is denominated in SEK; however, the functional currency of the Company is DKK. Consequently, the value of the proceeds on exercise is not fixed and will vary based on foreign exchange rate movements. The investor warrants when issued other than as compensation for goods and services are therefore a derivative for accounting purposes and are required to be recognized as a derivative liability and measured at fair value at each reporting period. Any changes in fair value from period to period are recorded as non-cash gain or loss in the consolidated statements of comprehensive loss. Upon exercise, the holders will pay the Company the respective exercise price for each investor warrant exercised in exchange for one common share of the Company and the fair value at the date of exercise and the associated non-cash liability will be reclassified to share capital. The non-cash liability associated with any investor warrants that expire unexercised will be recorded as a gain in the consolidated statements of comprehensive loss. There are no circumstances in which the Company would be required to pay any cash upon exercise or expiry of the investor warrants.

In connection with subscriptions of Offer Units in the rights issue carried out April/May 2019, 20,166,221 investor warrants ("TO1 warrants") have been granted to investors in connection with subscription of Offer Units in the rights issued carried out April/May 2019. All Warrants were vested as per the grant date. A warrant gives the right, during a fixed period to subscribe for nominal $0.01 (DKK 0.05) common share in the Company at $0.9 (SEK 7.5) (the "Exercise Price"), converted into DKK using the official exchange rate between DKK and SEK on the exercise day. All TO1 warrants were expired in the period ended December 31, 2020.

In connection with subscriptions of Offer Units in the rights issue carried out October — December 2019, 50,341,080 investor warrants ("TO2 warrants") have been granted to investors in connection with subscription of Offer Units in the rights issued carried out October — December 2019. All Warrants were vested as per the grant date. A warrant gives the right, during a fixed period to subscribe for nominal $0.01 (DKK 0.05) common share in the Company $0.7 (SEK 6,0) (the "Exercise Price"), converted into DKK using the official exchange rate between

(U.S. dollars in thousands, except for share and per share data and where otherwise noted)

14. Derivative Liabilities (cont.)

DKK and SEK on the exercise day. Each warrant carries the right to subscribe for one common share. Investors in the Rights Issue will have the possibility to exercise their warrants in five two-week windows during the 24-months period during which the warrants may be exercised. These periods are: April 1, 2020 – April 15, 2020, September 1, 2020 – September 15, 2020, February 1, 2021 – February 15, 2021, May 1, 2021 – May 15, 2021 and September 1, 2021 – September 15, 2021.

The table below summarizes the number of investor warrants that were outstanding, their weighted average exercise price ("WAEP") as at December 31, as well as the movements during the year.

	2020		2019	
	Number	Weighted Average Exercise Price	Number	Weighted Average Exercise Price
Outstanding at January 1	70,507,301	$ 0.69	—	—
Granted	3,996,864	$ 0.36	70,507,301	$ 0.68
Expired	(20,166,221)	$ 0.82	—	—
Outstanding at December 31	50,341,080	$ 0.71	70,507,301	$ 0.69
Exercisable at December 31	50,341,080	$ 0.71	70,507,301	$ 0.69

(b) Financing Facility

Effective November 29, 2018 the Company established a convertible debt facility (the "Facility") for funding of up to SEK 200 million to be funded in up to 20 tranches of SEK 10 million each over a 24 month term and bearing interest at 2% per annum. Five of the tranches receivable under the Facility were at the discretion of the investor and the Facility was convertible into shares and warrants at 50% of the nominal amount of the notes.

The Company has evaluated the terms of the Financing Facility in accordance with ASC 815-40-15 and ASC 815-40-25 and determined that the instrument is a derivative. Accordingly, the accounting treatment is the same as that described for Investor Warrants in Note 14(a) above.

On June 3, 2019 the Company settled one of the five tranches with a cash payment of $673 (SEK 6,4 million) and in February 2020 the balance of the committed tranches were settled by receipt of $1 million (SEK 10,5 million) from the investor in cash, in exchange for a subscription of 9,330,000 common shares in the Company (Settlement Shares) valued at $2.5 million and the issuance of 3,996,864 investor warrants (Settlement Warrants) valued at $625 as of the February 23, 2020 grant date.

All Settlement Warrants immediately vested on the grant date. A warrant gives the right, during a fixed period to subscribe for nominal $0.01 (DKK 0.05) common share in the Company at $0.4 (SEK 3,3) (the "Exercise Price"), converted into DKK using the official exchange closing rate between DKK and SEK on the last business day prior to the exercise. Each warrant carries the right to subscribe for one common share over 36 months.

(U.S. dollars in thousands, except for share and per share data and where otherwise noted)

14. Derivative Liabilities (cont.)

(c) Valuation of Derivative Liabilities

The derivative liabilities are measured at fair value at each reporting period and the reconciliation of changes in fair value is presented in the following tables:

	Financing Facility*		T01 Warrants Warrants issued May 2019		T02 Warrants Warrants issued December 2019	
	December 31, 2020 $	December 31, 2019 $	December 31, 2020 $	December 31, 2019 $	December 31, 2020 $	December 31, 2019 $
Balance beginning	2,138	2,935	14	—	1,641	—
Issued during the year	—	—	—	1,741	—	1,773
Change in fair value	(524)	—	(14)	(1,727)	(1,594)	(132)
Partial settlement – cash	—	(673)	—	—	—	—
Amount transferred to Equity*	(1,412)	—	—	—	—	—
Translation effect	(100)	(124)	—	—	—	—
Balance – end of year	102	2,138	—	14	47	1,641
Fair value per warrant issuable	0.026	—	—	0.001	0.001	0.033

* The December 31, 2019 $2,935 estimated fair value of the Financing Facility comprises the $673 cash settlement paid by the Company in June 2019, and the $2,262 market value of 9,330,000 common shares and 3,996,864 warrants issued on settlement of the Facility on February 23, 2020. The 3,996,864 warrants are exchangeable into one common share each at $0.34 (SEK 3.3) for 36 months.

The fair value of the Company's derivative warrant liabilities were estimated initially and on a quarterly basis using the Black-Scholes option pricing model and based on the following assumptions (see Note 16 for a detailed description of the assumptions):

	Warrants issued February 2020		Warrants issued May 2019	Warrants issued December 2019	
	Settlement Warrants for the termination of Financing Facility		T01 Warrants	T02 Warrants	
	December 31, 2020	Grant date February 23, 2020	December 31, 2019	December 31, 2020	December 31, 2019
Exercise price	$0.40 – (SEK 3.3)	$0.34 – (SEK 3.3)	$0.80 – (SEK 7.5)	$0.73 – (SEK 6.0)	$0.64 – (SEK 6.0)
Share price	$0.10 – (SEK 0.80)	$0.27 – (SEK 2.61)	$0.18 – (SEK 1.70)	$0.10 – (SEK 0.80)	$0.18 – (SEK 1.70)
Risk-free interest	(0.41)%	(0.38)%	(0.68)%	(0.57)%	(0.68)%
Expected dividend yield	(0)%	(0)%	(0)%	(0)%	(0)%
Contractual life (years)	2.17	3.00	0.42	0.71	1.71
Expected volatility	106.50%	104.10%	97.90%	106.50%	97.90%

As of December 31, 2020, the effect of an increase or a decrease of 5% of the volatility used, which is the significant unobservable input in the fair value estimate, would result in a loss of $30 or a profit of $26 of respectively.

As at December 31, 2020, the effect of a 5% strengthening of the U.S. dollar against the SEK, would result in a profit of $7. An assumed 5% weakening of the U.S. dollar against the SEK would have an equal but opposite effect on the basis that all other variables remained constant.

15. Stockholders' Equity and Non-controlling Interests

(a) Stockholders' Equity

i. Capital structure

As of December 31, 2020 and 2019 respectively the Company's total issued and outstanding common shares were 212,601,044 and 121,336,079 respectively with a par value $0.01 (DKK 0.05). The shares are fully paid in. The shares are not divided into classes, and no shares enjoy special rights.

ii. Share issuances

During the year ended December 31, 2020 the Company issued:

(a) 18,067,963 common shares in exchange for $2,869 in cash and recognized $652 in share issuance costs;

(b) 9,330,000 common shares and 3,996,864 warrants in exchange for $1,092 in cash in settlement of the Financing Facility dated February 23, 2020; the fair value of the common shares of $2,504 was recorded in equity and the $625 fair value of the warrants was recorded as a derivative liability which was adjusted to market at the end of every period; as at December 31, 2020, the fair value of the warrants is $102;

(c) 25,546,633 common shares valued at $3,002 on conversion of debt;

(d) 25,936,599 common shares valued at $3,906 in exchange for 37% of the NCI in OV SPV2 ApS; and

(e) 12,383,770 common shares valued at $2,029 in exchange for 16.09% of the NCI in OV US Inc.

During the year ended December 31, 2019 the Company issued:

(f) 48,420,891 common shares in exchange for $13,557, inclusive of 230,000 common shares issued on the exercise of warrants for $18, and recognized $4,429 in share issuance costs; and

(g) 22,603,910 common shares valued at $5,787, on conversion of debt.

(b) Non-controlling interests

The following provides a reconciliation of the beginning and ending balances of the Company's non-controlling interests in OV-SPV2 ApS and OV US Inc. for the years ended December 31, 2020 and 2019:

(US$ in thousands)	OV-SPV2 ApS Non-controlling Interest	OV US Inc. Non-controlling interest	Total Non-controlling Interest
Balance at December 31, 2018:	$ 2,550	$ 802	$ 3,352
Acquisition of 8% of OV-SPV2 ApS for cash of $802	(371)	—	(371)
Income (loss) for 2019	(77)	(10)	(87)
Foreign currency translation	(60)	(18)	(78)
Balance at December 31, 2019	2,042	774	2,816
Acquisition of 37% of OV-SPV2 ApS for shares (see (d) above)	(2,103)	—	(2,103)
Acquisition of 16.09% of OV US Inc. for shares (see (e) above)	—	(758)	(758)
Income (Loss) for 2020	17	(32)	(15)
Foreign currency translation	44	16	60
Balance at December 31, 2020	**$ —**	**$ —**	**$ —**

* See Statement of Stockholders' Equity and above disclosure for detail.

16. Share-based payments

Share based payments in the legal form of warrants have been granted to members of the executive management, members of the board of directors, employees and external consultants.

Warrant plan #7

On December 18, 2020 the Board of Directors approved an equity-settled stock option plan which provides an employee and a member of the executive management of the Group with the option to purchase 3,389,550 common shares of the Company at market price on the date of grant. Warrants were granted with monthly vesting over 36 months until September 1, 2022 respectively October 1, 2023 provided they remain within the Group's employment. Vested warrants are exercisable over a fixed period of time from grant date up to and including September 30, 2032 respectively October 31, 2033.

Warrant plan #6

On October 18, 2019 the Board of Directors approved an equity-settled stock option plan which provides board of directors and members of the executive management of the Group with the option to purchase 5,638,199 common shares of the Company at market price on the date of grant. Warrants were granted with monthly vesting over 36 months until September 1, 2022 provided they remain within the Group's employment. Vested warrants are exercisable over a fixed period of time from grant date up to and including September 30, 2032.

Additional Executive Plan

Effective September 15, 2019 the Company established a warrant compensation plan to grant the CEO a right to subscribe a total of two percent of the then outstanding shares of the Company on a fully diluted basis upon completion of twenty-four months of continuous employment. The warrants will be fully vested as of the date of grant. As of December 31, 2020, the total estimated amount of warrants payable is 4,313,602. The warrants have been valued with the Black-Scholes model using an expected volatility of 70% – 80.6%; expected life of 120 months; risk free interest rate of (0.32%) – (0.45%); an expected dividend yield of 0%; and an exercise price of $0.15 – $0.30.

Warrant plan #5

On February 24, 2017 the Board of Directors approved an equity-settled stock option plan which provides board of directors and members of the executive management of the Group with the option to purchase 696,220 common shares of the Company at market price on the date of grant. Warrants were granted with either immediate vesting, or monthly vesting over 36 months until July 1, 2019 provided the recipient remains within the Group's employment. Vested warrants are exercisable over a fixed period of time from grant date up to and including July 1, 2021.

Warrant plan #4

On February 18, 2016, the Board of Directors approved an equity-settled stock option plan, which provides key management personnel with the option to purchase 633,780 common shares of the Company at market price on the date of grant. Warrants were granted with monthly vesting over 36 months from July 1, 2016 until July 1, 2019, provided the recipient remains within the Group's employment. Vested warrants are exercisable over a fixed period of time from grant date up to and including July 1, 2021.

Warrant plan #3

On December 17, 2014, the Board of Directors approved an equity-settled stock option plan, which provides key management personnel and with the option to purchase 570,000 common shares of the Company at market price on the date of grant. Warrants were granted with 50% immediately vesting upon grant, 25% vesting on December 17, 2015 and 25% vesting on July 3, 2016, provided the recipient remains within the Group's employment. Vested warrants are exercisable over a fixed period of time from grant date up to and including July 1, 2021.

(U.S. dollars in thousands, except for share and per share data and where otherwise noted)

16. Share-based payments (cont.)

All share-based payment warrant plans

During 2020, the total charge to profit or loss amounted to $616 (2019: $333) of which $616 (2019: $333) are recognized as general and administrative expenses. As of December 31, 2020 and 2019, the total unrecognized compensation cost relating to unvested options granted was $510 and $939, respectively, which is expected to be realized over a period of 2.7 and 2.7 years, respectively. The Company will issue shares upon exercise of warrants from shares reserved under the plans.

The table below summarizes the number of options that were outstanding, their weighted average exercise price and contractual term as at December 31, as well as the movements during the period.

	Number of Shares	Weighted Average Exercise Price	Weighted Average Contractual Term (in years)
Balance on January 1, 2019	3,309,040	$ 0.08	—
Granted	5,638,199	0.23	—
Exercised	(230,000)	0.08	—
Balance on December 31, 2019	8,717,239	0.18	10
Granted	3,389,550	0.22	—
Forfeited	(1,350,818)	0.26	—
Outstanding as of December 31, 2020	10,775,971	$ 0.20	9.3
Options exercisable at December 31, 2020	6,008,140	$ 0.18	7.3

The intrinsic value of warrants outstanding at December 31, 2020 and 2019 was $0. No warrants expired in either of the years ended December 31, 2020 or 2019. The weighted average share price at the date of exercise of warrants in 2019 was $0.35. And, the intrinsic value per share of exercised shares in 2019 was $0.27 per share. The exercise price for warrants outstanding at the end of 2020 is $0.09 – $0.30 (2019: $0.08 – $0.24).

The weighted average grant date fair value of warrants granted in 2020 was $0.12 (2019: $0.20) per share. The total fair value of warrants vested during the years December 31, 2020 and 2019, was $616 and $333 respectively.

The estimate of the grant date fair value of each warrant issued is based on a Black Scholes model. The assumptions used in our valuation are summarized as follows:

	For the Years ended December 31,	
	2020	2019
Expected volatility	80.6%	70%
Weighted average share price	$ 0.14	$ 0.23
Expected life (in years)	10 – 11	10 – 12
Expected dividend yield	0%	0%
Risk-free interest rate	(0.41)%	(0.36)%

Expected Term — The expected term is based upon the historical exercise patterns of warrants.

Expected volatility — Was determined based upon the expected term of the warrants which is based upon the historical exercise patterns of warrants.

Risk-Free Interest Rate — The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the date of grant for zero-coupon U.S. Treasury notes with maturities approximately equal to the share-based awards' expected term.

16. Share-based payments (cont.)

Dividend Rate — The expected dividend is zero as the Company has not paid nor does it anticipate paying any dividends on its common stock in the foreseeable future.

Fair Value of Common Stock — The fair value of the Company's common stock is used to estimate the fair value of the share-based awards at grant date.

17. License and Development Agreements

a) License Agreement with Novartis Pharma for Dovitinib

We hold the exclusive worldwide rights to all therapeutic and/or diagnostic uses related to cancer in humans for dovitinib from Novartis Pharma AG ("Novartis") pursuant to a license agreement. Pursuant to the agreement, we are solely responsible for the development of dovitinib during the term of the agreement.

Development Milestone Payments

Pursuant to the agreement, we have agreed to make milestone payments to Novartis in connection with the development of dovitinib by us or our affiliates, or by a third-party (a "Program Acquirer") that assumes control of the dovitinib development program from us corresponding to: (i) upon enrollment of half of the patients required in a Phase 2 clinical trials in certain countries in accordance with agreed upon protocols; (ii) Upon dosing of the first patient in the first Phase 3 clinical trial; (iii) upon submission of the first NDA with the FDA; (iv) submission of an MAA to the EMA or any other Regulatory Authority in certain countries; (v) upon receipt of the first authorization by the FDA to market and sell a licensed product; and (vi) upon receipt of a MAA (including a respective pricing and reimbursement approval) for a licensed product in one or more specified European countries. If all milestones have been achieved, we may be obligated to pay Novartis up to a maximum of $26 million.

Royalty Payments

In addition to the milestone payments described above, we have agreed to pay Novartis royalties based on annual incremental sales of product derived from dovitinib in an amount between five percent (5%) and ten percent (10%) of annual sales of between $0 and $250 million, between six percent (6%) and thirteen percent (13%) of annual sales between $250 million and $500 million, between seven percent (7%) and thirteen percent (13%) of annual sales between $500 million and $750 million, and between thirteen percent (13%) and fifteen percent (15%) of annual sales in excess of $750 million.

We are obligated to pay royalties under the agreement on a country-by-country and product-by-product basis for a period that commences with the first commercial sale of a product until the later of (i) the expiration of the last to expire valid claim of any licensed patent covering such licensed product in such country; or, (ii) the expiration of regulatory-based exclusivity for such licensed product in such country or (iii) the ten (10) year anniversary of the date of first commercial sale of such licensed product in such country. However, the agreement may be sooner terminated without cause by us upon 120 days prior written notice, or upon written notice of a material breach of the agreement by Novartis that is not cured within 30 days. Novartis also has the right to terminate the agreement upon written notice of a material breach of the agreement by us that is not cured within 30 days or in the event that we file for bankruptcy.

b) License Agreement with Eisai for Stenoparib

We hold the exclusive worldwide rights to any and all preventative, therapeutic and/or diagnostic uses related to cancer in humans and by amendment to the agreement on December 11, 2020, viral infections in humans (including, but not limited to, coronaviruses) for stenoparib from Eisai, Inc. ("Eisai") pursuant to a license agreement. Pursuant to the license agreement, we are solely responsible for the development of stenoparib during the term of the agreement. The agreement also provides for a joint development committee consisting of six (6) members, three (3) appointed by us and three (3) appointed by Eisai. One of our members of the joint development committee is designated chair

17. License and Development Agreements (cont.)

of the committee and has the power to break any deadlock in decisions by the committee that must be made by a majority vote with each representative having one (1) vote. The purpose of the committee is to implement and oversee development activities for stenoparib pursuant to the clinical development plan, serves as a forum for exchanging data, information and development strategy.

Development Milestone Payments

Pursuant to the agreement, we have agreed to make milestone payments to Eisai in connection with the development of stenoparib by us or our affiliates, or by a third-party (a "Program Acquirer") that assumes control of the stenoparib development program from us corresponding to: (i) successful completion of a Phase 2 clinical trial; (ii) Upon dosing of the first patient in the first Phase 3 clinical trial; (iii) upon submission of the first NDA with the FDA; (iv) submission of an MAA to the EMA; (v) submission of an NDA to the MHLW in Japan; (vi) upon receipt of authorization by the FDA to market and sell a licensed product; (vii) upon receipt of approval of an MAA by the EMA for a licensed product; and (viii) upon receipt of approval by the MHLW in Japan for a licensed product. If all milestones have been achieved, we may be obligated to pay Eisai up to a maximum of $94 million.

Royalty Payments

In addition to the milestone payments described above, we have agreed to pay Eisai royalties based on annual incremental sales of product derived from stenoparib in an amount between five percent (5%) and ten percent (10%) of annual sales of between $0 and $100 million, between six percent (6%) and ten percent (10%) of annual sales between $100 million and $250 million, between seven percent (7%) and eleven percent (11%) of annual sales between $250 million and $500 million, and between eleven percent (11%) and fifteen percent (15%) of annual sales in excess of $500 million.

We are obligated to pay royalties under the agreement on a country-by-country and product-by-product basis for a period that commences with the first commercial sale of a product until the later of (i) the expiration of the last to expire valid claim of any licensed patent covering such licensed product in such country; or, (ii) the expiration of regulatory-based exclusivity for such licensed product in such country or (iii) the fifteen (15) year anniversary of the date of first commercial sale of such licensed product in such country. However, the agreement may be sooner terminated without cause by us upon 120 days prior written notice, or upon written notice of a material breach of the agreement by Eisai that is not cured within 90 days (30 days for a payment default). Eisai also has the right to terminate the agreement upon written notice of a material breach of the agreement by us that is not cured within 90 days (30 days for a payment default) or in the event that we file for bankruptcy. Eisai also has the right to terminate the agreement as we did not complete a Phase 2 clinical trial before July 6, 2021, unless we elect to pay a very low seven digit extension payment.

Option to Reacquire Rights to Stenoparib

For the period of time commencing with enrollment of the first five (5) patients in a Phase 2 clinical trial pursuant to the clinical development plan and ending ninety (90) days following successful completion of such Phase 2 clinical trial, Eisai has the option to reacquire our licensed rights to develop stenoparib for a purchase price equal to the fair market value of our rights, giving effect to the stage of development of stenoparib that we have completed under the agreement. We commenced a Phase 2 clinical trial April 15, 2019 and as of the date of these consolidated financial statements, Eisai has not indicated an intention to exercise its repurchase option.

c) Development, Option and License Agreement with R-Pharm for IXEMPRA®

On March 1, 2019, the Company entered into an option to in-license the rights to any and all therapeutic and/or diagnostic uses in humans for IXEMPRA® in the European Union (Great Britain but excluding Switzerland and Lichtenstein) (the "Territory") from R-Pharm U.S. Operating, LLC ("R-Pharm"), pursuant to a Development, Option

17. License and Development Agreements (cont.)

and License Agreement (the "Option"). By an amendment to the agreement dated June 15, 2021 for no consideration, the term of the option will expire on September 1, 2022, if not exercised by us before then. As a condition to the exercise of the Option, we are required to offer R-Pharm a right to re-acquire the licensed rights from us on terms to be mutually agreed upon, including the payment to us of the fair market value of the licensed rights. Pursuant to the Option, we are solely responsible for the development of IXEMPRA® during the term of the Option within the Territory. The agreement also provides for a joint development committee consisting of four (4) members, two (2) appointed by us and two (2) appointed by R-Pharm. Decisions by the committee that must be made by a unanimous consent of the parties, with us having the tie breaking vote on matters involving our DRP Biomarker, patient selection in the mBC clinical trial and the commercialization plan and R-Pharm having the tie breaking vote on all other matters. The purpose of the committee is to implement and oversee development activities for IXEMPRA® pursuant to the clinical development plan, serves as a forum for exchanging data, information and development strategy.

Development Milestone Payments

Pursuant to the agreement, once we have exercised the Option, we have agreed to make milestone payments to R-Pharm in connection with the development of IXEMPRA® by us or our affiliates, or by a third-party (a "Program Acquirer") that assumes control of the IXEMPRA® development program from us corresponding to: (i) upon receipt of regulatory approval for the Product for the treatment of the first indication in the first country in the Territory; and (ii) upon receipt of regulatory approval for the Product for the treatment of each additional indication in the first country in the Territory for each such additional indication. If all milestones have been achieved, and assuming only one additional indication in the second milestone is achieved, we may be obligated to pay R-Pharm up to a maximum of $12.5 million.

Royalty Payments

In addition to the milestone payments described above, once we have exercised the Option, we have agreed to pay R-Pharm royalties based on annual incremental sales of product derived from IXEMPRA® in an amount between five percent (5%) and eight percent (8%) of annual sales of between $0 and $30 million, and between eight percent (8%) and twelve percent (12%) of annual sales over $30 million.

After the Option is exercised, we would be obligated to pay royalties under the agreement on a country-by-country and product-by-product basis for a period that commences with the first commercial sale of a product until the later of (i) the expiration of the last to expire valid claim of any licensed patent covering such licensed product in such country; or, (ii) the expiration of regulatory-based exclusivity for such licensed product in such country or (iii) the seven (7) year anniversary of the date of first commercial sale of such licensed product in such country. However, the agreement may be sooner terminated without cause by us upon 90 days prior written notice, or upon written notice of a material breach of the agreement by R-Pharm that is not cured within 90 days (30 days for a payment default). R-Pharm also has the right to terminate the agreement upon written notice of a material breach of the agreement by us that is not cured within 90 days (30 days for a payment default) or in the event that we file for bankruptcy.

d) Development costs and Out-License Agreement with Smerud

In June of 2020, the Company out-licensed its secondary LiPlaCis® and 2X-111 programs to Smerud Medical Research International, the Company's long-time CRO partner in Europe, for further Phase 2 clinical development of each program together with its DRP® companion diagnostic. The initiation, by Smerud, of the next Phase 2 clinical trials for these programs is anticipated by early 2022. Smerud will, initially, advance LiPlaCis® for the treatment of metastatic breast cancer (mBC) and advance 2X-111 for the treatment of glioblastoma multiforme (GBM). The Company will support Smerud in these studies by providing DRP® companion diagnostic analysis for

(U.S. dollars in thousands, except for share and per share data and where otherwise noted)

17. License and Development Agreements (cont.)

screened patients in each trial. Under the license, Smerud must secure sufficient funding (whether by investment and/or by grants) for each program by/before October 1, 2021 (as extended by Amendment), otherwise either party has the right to terminate the license. The Company is eligible to receive regulatory approval milestones, totaling close to $30 million, for the two programs combined. In addition to development milestone payments we are entitled to tiered royalties on sales of each program once it/they are approved and on sale during the royalty term which is determined on a product-by-product and country-by-country basis, as the period of time commencing on the first commercial sale of any product in such country and expiring upon the latest of (a) the expiration of the last valid claim of a patent within (i) out intellectual property and/or (ii) the joint intellectual property in such country (if, but only if, such joint intellectual property arose from activities under the clinical development plan defined in the agreement), or (b) the fifteenth (15th) anniversary of the date of first commercial sale of such licensed drug in such country. For LiPlaCis® will be entitled between seven percent (7%) and twelve percent (12%) of sales up to $250,000,000 and between twelve percent (12%) and seventeen percent (17%) of sales above $250,000,000. For 2X-111, we will be entitled to royalties between ten percent (10%) and fifteen percent (15%) of sales up to $250,000,000 and between twelve percent 12% and eighteen percent (18%) of sales above $250,000,000. The license includes industry-standard development diligence requirements and termination (e.g. for uncured material breach by either party) provisions.

18. Revenue

	Year ended December 31,	
	2020	**2019**
	$	**$**
Research and development services	—	109
Other	—	11
Total	—	120

19. Tax

The reconciliation of the statutory rate to the effective tax rate is as follows:

Reconciliation of effective tax rate:	**2020** **$**	**2019** **$**
Tax computed on the loss before tax at a tax rate of 22.0%	(1,592)	(4,175)
Foreign rate differential	4	10
Non-deductible expenses, share-based payments	135	73
Non-deductible expenses, other	151	2
Tax value of derivative warrants	(491)	(436)
Tax deduction on exercise of employee warrants	—	(8)
Special tax deduction on research and development expenses	(323)	(17)
Other adjustments	(123)	(47)
Adjustment of tax concerning previous years	3	(522)
Change in valuation allowance	75	543
Effective tax rate (30%/24%)	(2,161)	(4,577)

(U.S. dollars in thousands, except for share and per share data and where otherwise noted)

19. Tax (cont.)

The components of income (loss) before income taxes were as follows:

	Year ended December 31,	
	2020	2019
(in $1,000's)	**$**	**$**
Denmark	(7,003)	(18,102)
Sweden	(4)	136
United States	(227)	(1,011)
	(7,234)	(18,977)

The components of the (benefit) provision for income taxes from operations were as follows:

	Year ended December 31,	
	2020	2019
(in $1,000's)	**$**	**$**
Current:		
Denmark	(908)	(826)
Sweden	30	—
United States	3	9
Total	(875)	(817)
Deferred:		
Denmark	(1,286)	(3,760)
Sweden	—	—
United States	—	—
Total	(1,286)	(3,760)
	(2,161)	(4,577)

	2020	2019
Deferred tax comprises:	**$**	**$**
Property, plant and equipment	21	16
Intangible assets	(5,869)	(5,324)
Net operating losses	6,163	4,301
Total deferred tax	315	(1,007)
Valuation allowance	(920)	(844)
Net deferred tax liabilities	**(603)**	(1,851)

	2020	2019
Tax on profit/loss for the year:	**$**	**$**
Current income tax expense (benefit)	(36)	530
Change in deferred tax	(1,286)	(3,760)
Adjustment of tax concerning previous years	3	(522)
Tax received under the tax credit scheme	(842)	(825)
Tax expense (benefit) on profit/loss for the year	**(2,161)**	(4,577)

Under the growth plan adopted by the Danish Parliament in 2013 companies with losses resulting from research and development costs may receive payment of the tax base of losses of up to DKK 25 million. During the years ended December 31, 2020 and December 31, 2019 the Company received tax recoveries of $825 and $1,341 respectively.

Tax losses carried forward of approximately $28.2 million can be carried forward indefinitely. Deferred tax has been provided at 22% corresponding to the statutory tax rate applied.

(U.S. dollars in thousands, except for share and per share data and where otherwise noted)

19. Tax (cont.)

As of December 31, 2020, the Company does not believe it has any uncertain tax positions that would result in the Company having a liability to the taxing authorities.

20. Related parties

Transactions with related parties

During the years ended December 31, 2020 and December 31, 2019, the Company's former CEO and certain of his family members provided research and development and investor relations services to the Company and were compensated in the amount of $156 and $349 respectively.

Acquisition of NCI

On June 8, 2020 the Company issued 25,936,599 shares in the Company at a value of $3,906 to Sass Larsen, an entity with significant influence over the Company in exchange for the purchase of the remaining 37% interest in OV SPV2 ApS.

On July 13, 2020 the Company acquired the remaining ownership (16.09%) in Oncology Venture US Inc. for 12,383,770 common shares valued at $2,029 out of which Sass Larsen was issued 3,281,250 common shares in the Company valued at $538.

21. Segment information

The Company is domiciled in Denmark and operates as one operating segment. Our Chief Executive Officer (CEO), as the chief operating decision-maker, manages and allocates resources to the operations of our Company on a total Company basis. Managing and allocating resources on a total company basis enables our CEO to assess the overall level of resources available and how to best deploy these resources across functions, therapeutic areas and research and development projects that are in line with our long-term company-wide strategic goals. Consistent with this decision-making process, our CEO uses consolidated, single-segment financial information for purposes of evaluating performance, forecasting future period financial results, allocating resources and setting incentive targets. The Company has neither revenues from external customers outside Denmark, nor non-current assets in other geographical areas than Denmark.

22. Basic and diluted net loss per share

Basic net loss per share is computed based on the weighted average number of ordinary shares outstanding during each period. Diluted net loss per share is computed based on the weighted average number of ordinary shares outstanding during the period plus potential shares (deriving from warrants and convertible notes) considered outstanding during the period, in accordance with ASC 260-10 as determined under the treasury stock method. Basic and diluted net loss per share attributable to common shareholders was as follows:

	Years Ended December 31,	
	2020	**2019**
Numerator:		
Net loss attributable to common shareholders	$ (5,073)	$ (14,400)
Denominator:		
Weighted average common shares outstanding – basic and diluted	163,238,991	63,407,230
Net loss per share attributable to common shareholders – basic and diluted	$ (0.03)	$ (0.23)

(U.S. dollars in thousands, except for share and per share data and where otherwise noted)

22. Basic and diluted net loss per share (cont.)

The Company's unvested restricted shares and restricted share units have been excluded from the computation of basic net loss per share attributable to common shareholders.

The Company's potentially dilutive securities, which include warrants and shares issuable upon conversion of convertible debt, have been excluded from the computation of diluted net loss per share attributable to common shareholders as the effect would be to reduce the net loss per share attributable to common shareholders. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common shareholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to common shareholders for the periods indicated because including them would have had an anti-dilutive effect:

	As of December 31,	
	2020	2019
Warrants	8,523,918	4,387,223
Convertible debt	960,216	—
	9,484,134	4,387,223

23. Financial Instruments

The following tables present information about the Company's financial instruments measured at fair value on a recurring basis and indicate the level of the fair value hierarchy used to determine such fair values:

	Fair Value Measurements as of December 31, 2020 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Investment	$ 845	$ —	$ —	$ 845
Liabilities:				
Convertible debt	$ —	$ —	$ (1,327)	$ (1,327)
Financing Facility	—	—	(102)	(102)
Derivative warrants	—	—	(47)	(47)
	$ —	$ —	$ (1,476)	$ (1,476)

	Fair Value Measurements as of December 31, 2019 Using:			
	Level 1	Level 2	Level 3*	Total
Assets:				
Investment	$ —	$ —	$ 137	$ 137
Liabilities:				
Financing Facility	$ —	$ —	$ (2,138)	$ (2,138)
Derivative warrants	—	—	(1,655)	(1,655)
	$ —	$ —	$ (3,793)	$ (3,793)

The following method was used to estimate the fair values of our financial instruments:

The carrying amount of level 1 financial instruments approximates fair value because of the short maturity of the instruments. Financial assets and liabilities are considered Level 3 when their fair values are determined using pricing models, discounted cash flow methodologies, or similar techniques, and at least one significant model assumption or input is unobservable. Level 3 financial assets also include investment securities in 2020 for which there is limited market activity such that the determination of fair value requires significant judgment or estimation.

(U.S. dollars in thousands, except for share and per share data and where otherwise noted)

23. Financial Instruments (cont.)

The Company reviews the fair value hierarchy classification on a quarterly basis. Changes in the ability to observe valuation inputs may result in a reclassification of levels for certain securities within the fair value hierarchy. The Company's policy is to recognize transfers into and out of levels within the fair value hierarchy at the date the actual event or change in circumstances that caused the transfer occurs. When a determination is made to classify an asset or liability within Level 3, the determination is based upon the significance of the unobservable inputs to the overall fair value measurement. There were no transfers between level 1 or level 2 during the years ended December 31, 2020 and December 31, 2019. The following table provides a reconciliation of the beginning and ending balances of the item measured at fair value on a recurring basis in the table above that used significant unobservable inputs (Level 3):

	Year ended December 31,	
Level 3	**2020**	**2019**
Beginning balance – assets:	$ 137	$ —
Transfers into level 3	—	137
Transfers out of level 3 to level 1	(137)	—
Ending balance – assets:	$ —	$ 137
Beginning balance – liabilities:	$ 3,793	$ —
Gains included in net loss	845	—
Transfers out of level 3	(845)	—
Issuance of convertible debt (Note 13)	4,670	—
Issuance of investor warrants (Note 14(a)	—	3,514
Issuance of Financing Facility (Note 14(b))	—	2,935
	8,463	6,449
Financing Facility adjustments (Note 14(b)):		
Fair value	(524)	—
Translation effect	(100)	(124)
Cash (partial) settlement	—	(673)
Converted to equity on settlement	(1,412)	—
Fair value adjustments:		
TO1 Warrants (Note 14(a))	(14)	(1,727)
TO2 Warrants (Note 14(a))	(1,594)	(132)
Convertible debt (Note 13)	(681)	—
Debt conversion (Note 13)	(2,662)	—
Ending balance – liabilities	$ 1,476	$ 3,793

24. Commitments and Contingencies

Development costs

The Company is contingently liable for development costs of Smerud Medical Research International ("Smerud") in the approximate amount of $1,191 which has been accrued as of December 31, 2020 and will be payable only if Smerud is unable to identify investors to fund development of in licensed products from the Company by October 1, 2021.

25. Subsequent Events

For its consolidated financial statements as of December 31, 2020 and for the year then ended, the Company evaluated subsequent events through August 20, 2021, the date on which those financial statements were issued.

(a) Rights Issue

Effective May 19, 2021, the Company approved the issuance of common shares with preferential rights to the Company's existing shareholders on record as of May 20, 2021 (the "Rights Issue"). The Rights Issue consists of up to a maximum of 120,891,157 units of one common share and one share purchase warrant for $0.10 (SEK 0.85) per unit. The attached warrants are exercisable for $0.20 (1.70 SEK) each and expire on April 15, 2023. Pursuant to the Rights Issue, gross proceeds of approximately 100 million SEK are fully guaranteed.

(b) Plan of Reorganization and US Nasdaq Listing

On April 6, 2021, the Company incorporated Allarity Therapeutics, Inc., a Delaware corporation, ("Allarity Delaware") as a direct wholly owned subsidiary of the Company for the sole purpose of entering into a Plan of Reorganization and Asset Purchase Agreement with Allarity Delaware in order to reorganize the Company as a holding company listed on the US Nasdaq Stock Market and complete a 50 to 1 share reverse split, resulting in an immediate decrease in the outstanding shares used to calculate the weighted average common shares outstanding for basic and diluted net income per share. The reorganization is a common control transaction and there will be no change in control over the assets of the ultimate parent. Consequently, Allarity Delaware will record all assets and liabilities acquired from Allarity Therapeutics A/S at historical cost. The recapitalization share exchange is conditioned upon the approval the Company's shareholder and an effective registration statement filed with the US Securities and Exchange Commission.

As of the date of these financial statements, the Company anticipates that approximately 7,801,262 shares of Delaware common stock will be issued in the recapitalization share exchange to the Company's shareholders.

(c) PIPE Investment

On May 20, 2021, the Company entered into an Investment Agreement (the "Investment Agreement") with 3i, LP, a Delaware Limited Partnership (the "Investor") whereby the Company agreed to issue and sell the Investor 20,000 shares of Allarity Delaware Series A Convertible Preferred Stock (the "Preferred Stock") and common stock purchase warrants (the "Warrants") for an additional $20 million (the "PIPE Investment"). The PIPE Investment is conditioned upon, and will occur simultaneously with, the consummation of the Recapitalization Share Exchange and the approval of Allarity Delaware's application to list its common stock on the US Nasdaq Stock Market.

The Preferred Stock may convert over time into at approximately 20% of the Company's issued and outstanding shares however, conversion of the Preferred Shares and exercise of the Warrants; is limited to 4.99% of the Company's issued and outstanding shares.

As of the date of these financial statements the Company expects the conversion price of the Preferred Stock to be between $7.47 and $10.25 per share. However, if the volume weighted average price for Allarity Delaware common stock on the US Nasdaq Stock Market falls below the fixed conversion price for the preferred stock, then the preferred stock would be entitled to convert at an alternate conversion price between 80% to 90% of the volume weighted average price at the time of conversion with a similar adjustment for the exercise price for the warrants.

Lastly, in the event that the average daily US dollar volume of shares of Allarity Delaware common stock traded on the US Nasdaq Stock Market falls below $2.5 million, then holders of the convertible preferred stock will be entitled to a one-time special dividend of 8% of the stated value of the preferred stock ($1.6 million) payable in shares of common stock upon conversion of the convertible preferred stock. The Company is in the process of assessing the accounting treatment of the special dividend.

25. Subsequent Events (cont.)

(d) Loan

Effective March 22, 2021 the Company received a loan of up to $2.9 million (SEK 25 million), net of a 3% loan origination fee of $87 (SEK 750 thousand), bearing interest at 3% per month, and due on June 23, 2021. In exchange for the loan, the Company committed to complete a rights offering and issue common shares.

The rights offering was completed before June 23, 2021 as described in these financial statements. As of June 23, 2021, the loan balance and interest of $2,817 and $197 respectively were paid to the lender.

(e) Sale of Irofulven

On July 23, 2021, the Company and Lantern Pharma Inc. ("Lantern") entered into an exclusive agreement under which Lantern will reacquire global rights to Irofulven ("LP-100") and assume full authority to manage and guide future clinical development and commercialization. The Company received an upfront payment of $1,000 from Lantern. The agreement voids all prior obligations from the original 2015 in-license agreement and provides for additional development and regulatory milestone fees, and tiered royalties on future sales of Irofulven.

If all milestones have been achieved, then we would be entitled to receive up to $16 million in milestone payments under the Asset Purchase Agreement. In addition to the milestone payments, Lantern Pharma has agreed to pay us royalties of mid-single digits, based on annual incremental net sales of product derived from Irofulven, on a country by country basis, in an amount equal to percentages of annual sales based on a tiered progression.

26. Event Subsequent to Original Issuance of Financial Statements (Unaudited)

In connection with the reissuance of the financial statements, the Company has evaluated subsequent events through November 4, 2021, the date the financial statements were available to be reissued.

a) TO 2 and TO 3 Warrants

In accordance with the terms of the Company's 145,003,680 outstanding TO 3 Warrants, exercisable for $0.20 (SEK 1.7) per share, the Company's Board of Directors can determine an extraordinary and final exercise window of 10 trading days in which warrants shall be exercised provided, however, that the price of the Company's shares increases to SEK 2.0 or more calculated as average volume weighted price (VWAP) over 10 trading days. On August 26, 2021, the Board of Directors set an extraordinary and final exercise period for the Company's TO 3 Warrants, starting on August 30, 2021, and ending on September 13, 2021. Any warrants unexercised after September 13, 2021, expired without compensation or payment of any kind to the warrant holders.

In total, 13,719,266 warrants of series TO 3 were exercised, corresponding to approximately 9.5 percent of the total number of outstanding warrants, for subscription of 13,719,266 shares at a subscription price of SEK 1.7 per share. Through the exercise of the warrants, Allarity received approximately U.S. $2.7 million (SEK 23.3 million) before issuing costs amounting to approximately U.S. $162 thousand (SEK 1.4 million).

In total, 8,820 warrants of series TO 2 were exercised, corresponding to approximately 0.02 percent of the total number of outstanding warrants, for subscription of 8,820 shares at a subscription price of SEK 6.0 per share. Through the exercise of the TO 2 warrants, Allarity received approximately U.S. $6 thousand (SEK 53,000) before issuing costs. The final exercise period for the warrants of series TO 2 took place from September 1 up to and including September 15, 2021.

26. Event Subsequent to Original Issuance of Financial Statements (Unaudited) (cont.)

b) License Agreement with Eisai for Stenoparib

Subsequent to August 20, 2021, the terms of our agreement with Eisai have been revised to provide Eisai the right to terminate the agreement if we do not complete a Phase 2 clinical trial before December 31, 2022, unless we elect to pay a very low seven digit extension payment.

c) Development costs and Out-License Agreement with Smerud

Subsequent to August 20, 2021, the terms of our agreement with Smerud have been revised to extend the time Smerud has to obtain the minimum funding under the agreement from October 1, 2021, to December 31, 2021.

ALLARITY THERAPEUTICS A/S
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)
(U.S. dollars in thousands, except for share and per share data and where otherwise noted)

	June 30, 2021 Restated (See Note 1(e)) $	December 31, 2020 $
ASSETS		
Current assets:		
Cash and cash equivalents	6,598	298
Other current assets	631	335
Prepaid expenses	15	174
Income tax receivable	1,253	908
Total current assets	8,497	1,715
Non-current assets:		
Investment	641	845
Property, plant and equipment, net	10	21
Operating lease assets	131	331
Intangible assets, net	29,501	30,491
Total assets	**38,780**	33,403
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Line of credit	58	84
Accounts payable	2,268	2,116
Accrued liabilities	1,855	1,840
Income taxes payable	56	57
Lease liabilities	98	109
Convertible debt	—	1,327
Total current liabilities	4,335	5,533
Non-current liabilities		
Derivative liabilities	5,270	149
Lease liabilities	62	267
Deferred tax	293	603
Total liabilities	9,960	6,552
Stockholders' equity		
Common stock, par value DKK 0.05; shares issued and outstanding at June 30, 2021 and December 31, 2020 were 365,173,471 and 212,601,044 respectively	2,851	1,624
Additional paid-in capital	67,933	61,284
Obligation to issue shares	2,606	—
Accumulated other comprehensive income (loss)	520	1,375
Accumulated Deficit	(45,090)	(37,432)
Total stockholders' equity	28,820	26,851
Total liabilities & stockholders' equity	**38,780**	33,403

See accompanying notes to consolidated financial statements.

ALLARITY THERAPEUTICS A/S
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)
(U.S. dollars in thousands, except for share and per share data and where otherwise noted)

	Three months ended June 30,		Six months ended June 30,	
	2021 $	2020 $	2021 $	2020 $
Operating expenses:				
Research and development	2,098	652	3,755	2,221
General and administrative	2,497	1,281	3,521	2,292
Total operating expenses	4,595	1,933	7,276	4,513
Loss from operations	(4,595)	(1,933)	(7,276)	(4,513)
Interest expenses	382	374	509	336
Loss (gain) on investment	67	(411)	180	(411)
Foreign exchange losses (gains), net	(1)	10	80	(86)
Fair value adjustment of derivative liabilities	(75)	(158)	(30)	(1,061)
Change in fair value of convertible debt	98	475	298	475
Net other income (expenses)	471	290	1,037	(747)
Net loss for the period before tax benefit	(5,066)	(2,223)	(8,313)	(3,766)
Income tax benefit	373	261	655	829
Net loss	(4,693)	(1,962)	(7,658)	(2,937)
Net loss attributable to non-controlling interests	—	(14)	—	(15)
Net loss attributable to Allarity A/S common stockholders	**(4,693)**	(1,948)	**(7,658)**	(2,922)
Basic and diluted net loss per common share	**(0.02)**	(0.01)	**(0.03)**	(0.02)
Weighted-average number of common shares outstanding, basic and diluted	**250,859,128**	140,303,961	**238,832,128**	132,665,515
Net loss				
Other comprehensive loss, net of tax:	(4,693)	(1,962)	(7,658)	(2,937)
Change in cumulative translation adjustment	(304)	311	(846)	82
Change in fair value attributable to instrument specific credit risk	(3)	6	(9)	6
Total comprehensive loss	(5,000)	(1,645)	(8,513)	(2,849)
Less comprehensive gain (loss) attributable to non-controlling interests	—	(14)	—	(15)
Comprehensive loss attributable to Allarity A/S common stockholders	**(5,000)**	(1,631)	**(8,513)**	(2,834)

See accompanying notes to consolidated financial statements.

ALLARITY THERAPEUTICS A/S
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For the Three and Six months Ended June 30, 2021 and 2020
(Unaudited)
(U.S. dollars in thousands, except for share and per share data and where otherwise noted)

For the Three months ended March 31, 2020 and June 30, 2020	Common Shares Number	Common Shares Value $	Additional Paid-in Capital $	Obligation to Issue Shares $	Accumulated Other Comprehensive Loss $	Retained Earnings (Accumulated Deficit) $	Stockholders' Equity $	Non-Controlling Interest (net of OCI) $	Total $
Balance at December 31, 2019	121,336,079	924	50,623	—	(1,086)	(32,374)	18,087	2,816	20,903
Settlement of Financing Facility	9,330,000	67	2,437	—	—	—	2,504	—	2,504
Share issuance costs	—	—	(105)	—	—	—	(105)	—	(105)
Share based compensation	—	—	188	—	—	—	188	—	188
Cumulative translation adjustment	—	—	—	—	(229)	—	(229)	—	(229)
Net loss for the period	—	—	—	—	—	(974)	(974)	(1)	(975)
Balance at March 31, 2020	130,666,079	991	53,143	—	(1,315)	(33,348)	19,471	2,815	22,286
Debt conversion	12,638,305	95	1,826	—	—	—	1,921	—	1,921
Acquisition of NCI	25,936,599	196	1,907	—	—	—	2,103	(2,103)	—
Share issuance costs	—	—	(79)	—	—	—	(79)	—	(79)
Share based compensation	—	—	204	—	—	—	204	—	204
Cumulative translation adjustment	—	—	—	—	311	—	311	60	371
Fair value of instrument specific credit risk	—	—	—	—	6	—	6	—	6
Net loss for the period	—	—	—	—	—	(1,948)	(1,948)	(14)	(1,962)
Balance at June 30, 2020	169,240,983	1,282	57,001	—	(998)	(35,296)	21,989	758	22,747

For the Three Months Ended March 31, 2021 and June 30, 2021 (Restated (See Note 1(e))	Common Shares Number	Common Shares Value $	Additional Paid-in Capital $	Obligation to Issue Shares $	Accumulated Other Comprehensive Loss $	Retained Earnings (Accumulated Deficit) $	Stockholders' Equity $	Non-Controlling Interest (net of OCI) $	Total $
Balance at December 31, 2020	212,601,044	1,624	61,284	—	1,375	(37,432)	26,851	—	26,851
Debt conversion	26,440,475	215	2,169	—	—	—	2,384	—	2,384
Share based compensation	—	—	195	—	—	—	195	—	195
Cumulative translation adjustment	—	—	—	—	(542)	—	(542)	—	(542)
Fair value of instrument specific credit risk	—	—	—	—	(6)	—	(6)	—	(6)
Net loss for the period	—	—	—	—	—	(2,965)	(2,965)	—	(2,965)
Balance at March 31, 2021	239,041,519	1,839	63,648	—	827	(40,397)	25,917	—	25,917
Debt conversion	4,969,135	40	456	—	—	—	496	—	496
Units issued for cash	121,162,817	972	11,153	—	—	—	12,125	—	12,125
Fair value of investor warrants	—	—	(5,151)	—	—	—	(5,151)	—	(5,151)
Share issuance costs	—	—	(2,606)	2,606	—	—	—	—	—
Share based compensation	—	—	433	—	—	—	433	—	433
Cumulative translation adjustment	—	—	—	—	(304)	—	(304)	—	(304)
Fair value of instrument specific credit risk	—	—	—	—	(3)	—	(3)	—	(3)
Net loss for the period	—	—	—	—	—	(4,693)	(4,693)	—	(4,693)
Balance at June 30, 2021	**365,173,471**	**2,851**	**67,933**	**2,606**	**520**	**(45,090)**	**28,820**	**—**	**28,820**

See accompanying notes to consolidated financial statements.

ALLARITY THERAPEUTICS A/S
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(U.S. dollars in thousands, except for share and per share data and where otherwise noted)

	Six months ended June 30,	
	2021 $	2020 $
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss for the period	(7,658)	(2,937)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	18	22
Share-based compensation	628	392
Non-cash lease expense	58	20
Non-cash interest	451	31
Loss (gain) on investment	180	(411)
Foreign currency loss (gain), net	(4)	(86)
Fair value adjustment of convertible debt	383	475
Fair value adjustment of derivative liabilities	(30)	(1,061)
Deferred income taxes	(310)	(829)
Changes in operating assets and liabilities:		
Accounts receivable	—	95
Other current assets	(230)	338
Income taxes	(345)	649
Prepaid expenses	93	72
Accounts payable	151	(471)
Accrued liabilities	15	(164)
Operating lease liability	(47)	(42)
Net cash used in operating activities	(6,646)	(3,907)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Bank debt	(23)	88
Proceeds from share issuance	12,125	1,593
Share issuance costs	(250)	(136)
Proceeds from convertible loan	1,200	1,007
Loan proceeds	2,945	—
Repayment of loan (Note 9)	(2,934)	(533)
Net cash provided by financing activities	13,062	2,019
Net increase (decrease) in cash	6,416	(1,888)
Effect of exchange rate changes on cash	(116)	755
Cash, beginning of period	298	1,524
Cash, end of period	6,598	391
Supplemental information		
Cash paid for income taxes	—	20
Cash paid for interest	293	24
Supplemental disclosure of non-cash investing and financing activities:		
Conversion of convertible debt to equity	2,825	914
Conversion of debt to equity	55	—
Conversion of derivative liability to equity	—	911
Non-cash share issuance costs	2,356	48

See accompanying notes to consolidated financial statements.

1. Nature of Business and Summary of Significant Accounting Policies

(a) Organization

Allarity Therapeutics A/S (the "Company") is a limited liability company domiciled in Denmark. The Company was incorporated under the laws of Denmark on 9 September 2004. The Company's principal operations are located at Venlighedsvej 1, 2970 Horsholm, Denmark. The Company's United States operations are located at 210 Broadway #201, Cambridge, MA 012139, United States of America.

(b) Principal Activities

Allarity Therapeutics A/S develops drugs for the personalized treatment of cancer using drug specific companion diagnostics (cDx) generated by its proprietary drug response predictor technology, DRP®. The Company is a merged company (the "Merger") between two prior affiliated companies, the drug development company Oncology Venture Sweden AB and the predictive diagnostic development company Medical Prognosis Institute A/S. Pursuant to the Merger, effective 21 August 2018 the Company obtained control of 100% shares and voting interests of Oncology Venture Sweden AB, a company based in Sweden, listed on Spotlight, Stockholm, Sweden and specializing in the research and development of anti-cancer drugs via its wholly owned Danish subsidiary, Oncology Venture ApS. The Merger was accounted for as a business combination with the Company being the acquirer and all assets acquired and liabilities assumed were recognized at fair value.

Allarity Therapeutics A/S (Nasdaq First North Growth Market Stockholm: ALLR) develops drugs for the personalized treatment of cancer using drug-specific companion diagnostics (cDx) generated by its proprietary drug response predictor technology, DRP®.

(c) Liquidity and Going Concern

The accompanying consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business. The accompanying financial statements do not reflect any adjustments relating to the recoverability and reclassifications of assets and liabilities that might be necessary if the Company is unable to continue as a going concern.

Pursuant to the requirements of Accounting Standard Codification (ASC) 205-40, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern, management must evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of management's plans that have not been fully implemented as of the date of these financial statements, and (1) is probable that the plan will be effectively implemented within one year after the date the financial statements are issued, and (2) it is probable that the plan, when implemented, will mitigate the relevant condition or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date the financials are issued. Certain elements of the Company's operating plan to alleviate the conditions that raise substantial doubt are outside of the Company's control and cannot be included in management's evaluation under the requirements of Accounting Standard Codification (ASC) 205-40.

Since inception, the Company has devoted substantially all of its efforts to business planning, research and development, clinical expenses, recruiting management and technical staff, and securing funding via collaborations. The Company has historically funded its operations with proceeds received from its collaboration arrangements, sale of equity capital and proceeds from sales of convertible notes.

The Company has incurred significant losses and has an accumulated deficit of $45 million as of June 30, 2021. As of August 20, 2021, our cash which includes the proceeds of our rights offering in June 2021 is insufficient to fund our current operating plan and planned capital expenditures for at least the next 12 months. These conditions give rise to a substantial doubt over the Company's ability to continue as a going concern.

1. Nature of Business and Summary of Significant Accounting Policies (cont.)

Management's plans to mitigate the conditions or events that raise substantial doubt include additional funding through public equity, private equity, debt financing, collaboration partnerships, or other sources. There are no assurances, however, that the Company will be successful in raising additional working capital, or if it is able to raise additional working capital, it may be unable to do so on commercially favorable terms. The Company's failure to raise capital or enter into other such arrangements if and when needed would have a negative impact on its business, results of operations and financial condition and its ability to develop its product candidates.

The Company has entered into a Securities Purchase Agreement with 3i, LP, a Delaware limited partnership that provides for a $20 million equity investment in the Company. Please refer to the subsequent event disclosures in note 19 for further information.

Although management continues to pursue its funding plans, there is no assurance that the Company will be successful in obtaining sufficient funding to fund continuing operations on terms acceptable to the Company, if at all. Further, at the date of this filing the above noted 3i $20 million equity investment cannot be asserted as probable and is subject to close of the transaction. Accordingly, based upon cash on hand at the issuance date of these financial statements the Company does not have sufficient funds to finance its operations for at least twelve months from the issuance date and therefore has concluded that substantial doubt exists about the Company's ability to continue as a going concern.

(d) Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP"). The accompanying interim financial statements as of June 30, 2021 and for the three and six months ended June 30, 2021 and 2020, and related interim information contained within the notes to the financial statements, are unaudited. In management's opinion, the unaudited interim consolidated financial statements have been prepared on the same basis as the Company's audited financial statements and include all adjustments (including normal recurring adjustments) necessary for a fair statement of the financial statements. These interim financial statements should be read in conjunction with the Company's audited financial statements and accompanying notes included elsewhere in this Form S-4 for the year ended December 31, 2020. The results for the three and six months ended June 30, 2021 are not necessarily indicative of the results expected for the full fiscal year or any interim period.

(e) Restatement for error

Pursuant to ASC 718, we have determined that the fair value of the 24,112,523 financial advisor warrants should be recorded as equity rather an as a derivative liability. As a result, we have reduced the fair value of investor warrant amounts in our Condensed Statement of Stockholders' Equity by $1,026 from $6,177 to $5,151. There has been no impact to our Condensed Consolidated Statements of Operations and Comprehensive Loss or our Condensed Consolidated Statements of Cash Flows.

(U.S. dollars in thousands, except for share and per share data and where otherwise noted)

1. Nature of Business and Summary of Significant Accounting Policies (cont.)

Adjustments made to the line items in the Company's Condensed Consolidated Balance Sheets and Condensed Consolidated Statements of Stockholders' Equity as at June 30, 2021 relate to:

(in $1,000's)	June 30, 2021 As originally presented $	Increase/ (Decrease) $	June 30, 2021 (Restated) $
Balance Sheet			
Derivative liabilities	6,296	(1,026)	**5,270**
Total liabilities	10,986	(1,026)	**9,960**
Total stockholders' equity	27,794	1,026	**28,820**
Additional paid-in capital	66,907	1,026	**67,933**
Statement of Stockholders' Equity			
Additional paid-in capital	66,907	1,026	**67,933**
Stockholders' Equity	27,794	1,026	**28,820**

(f) Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries:

Name	Country of Incorporation
Oncology Venture Product Development ApS	Denmark
OV-SPV2 ApS	Denmark
MPI Inc.	United States
Oncology Venture US Inc.	United States
Allarity Therapeutics, Inc.	United States
Allarity Acquisition Subsidiary, Inc.	United States

All intercompany transactions and balances, including unrealized profits from intercompany sales, have been eliminated upon consolidation.

(g) Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting years. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the fair value of the convertible loan, the accrual for research and development expenses, revenue recognition, fair values of acquired intangible assets and impairment review of those assets, the useful life of property, plant and equipment, share based compensation expense, provisions for contingencies and litigation, and income tax uncertainties and valuation allowances. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. Estimates are periodically reviewed in light of reasonable changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known and if material, their effects are disclosed in the notes to the consolidated financial statements. Actual results could differ from those estimates or assumptions.

1. Nature of Business and Summary of Significant Accounting Policies (cont.)

(h) Computation of Earnings (Loss) per Share

The Company computes net (loss) income per share in accordance with ASC Topic 260, "Earnings Per Share" ("ASC 260") and related guidance, which requires two calculations of net (loss) income attributable to the Company's shareholders per share to be disclosed: basic and diluted. Basic loss per share is derived by dividing net loss applicable to common stockholders by the weighted average number of shares of common stock outstanding during each period. Diluted loss per share includes the effect, if any, from the potential exercise or conversion of securities, such as warrants, and convertible debt, which would result in the issuance of incremental shares of common stock unless such effect is anti-dilutive. In calculating the basic and diluted net loss per share applicable to common stockholders, the weighted average number of shares remained the same for both calculations due to the fact that when a net loss exists, dilutive shares are not included in the calculation.

(i) Conversion of foreign currencies

The functional currency is the currency of the primary economic environment in which an entity's operations are conducted. The Company and its subsidiaries operate mainly in Denmark and the United States. The functional currencies of the Company's subsidiaries are their local currency.

The Company's reporting currency is the U.S dollar. The Company translates the assets and liabilities of its Denmark subsidiaries into the U.S. dollar at the exchange rate in effect on the balance sheet date. Revenues and expenses are translated at the average exchange rate in effect during each monthly period. Unrealized translation gains and losses are recorded as a cumulative translation adjustment, which is included in the consolidated statements of shareholders' equity as a component of accumulated other comprehensive (loss) income.

Monetary assets and liabilities denominated in currencies other than the functional currency are re-measured into the functional currency at rates of exchange prevailing at the balance sheet dates. Non-monetary assets and liabilities denominated in foreign currencies are re-measured into the functional currency at the exchange rates prevailing at the date of the transaction. Exchange gains or losses arising from foreign currency transactions are included in the determination of net profit or loss for the respective periods.

Adjustments that arise from exchange rate changes on transactions denominated in a currency other than the local currency are included in other comprehensive income (loss) in the consolidated statements of operations and comprehensive loss as incurred.

(j) Accumulated other comprehensive income (loss)

Accumulated other comprehensive income (loss) includes all changes in equity except those resulting from investments by owners and distributions to owners, including accumulated foreign currency translation, and changes in instrument specific credit risk. During the three months ended June 30, 2021 and 2020 the Company recorded accumulated foreign currency translation losses of $304 and gains of $311 respectively and instrument specific credit risk losses of $3 and gains of $6 respectively. During the six months ended June 30, 2021 and 2020 the Company recorded accumulated foreign currency translation losses of $846 and gains of $82 and instrument specific credit risk losses of $9 and gains of $6 respectively. These amounts have been recorded as a separate component of stockholders' equity (deficit).

(k) Contingencies

Liabilities for loss contingencies arising from claims, assessments, litigation, fines, penalties and other sources are recorded when it is probable that a liability has been incurred and the amount can be reasonably estimated. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential loss range is probable and

1. Nature of Business and Summary of Significant Accounting Policies (cont.)

reasonably estimable under the provisions of the authoritative guidelines that address accounting for contingencies. The Company expenses costs as incurred in relation to such legal proceedings as general and administrative expense within the consolidated statements of operations and comprehensive loss.

(l) Recently Issued Accounting Pronouncements

Changes to GAAP are established by the Financial Accounting Standards Board (the "FASB") in the form of accounting standards updates ("ASUs") to the FASB's Accounting Standards Codification.

The Company considers the applicability and impact of all ASUs. ASUs not listed below were assessed and determined not to be applicable or are expected to have minimal impact on the Company's consolidated financial position and results of operations.

Adopted

In December 2019, the FASB issued ASU 2019-12, "Income Taxes — Simplifying the Accounting for Income Taxes". The ASU simplifies the accounting for income taxes by removing certain exceptions to the general principles as well as clarifying and amending existing guidance to improve consistent application. The amendments to this ASU are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. Depending on the amendment, adoption may be applied on the retrospective, modified retrospective or prospective basis. The Company has adopted this standard on a prospective basis with no significant impact upon its consolidated financial statements.

Not Yet Adopted

In May 2021, the FASB issued ASU No. 2021-04 — Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options — to clarify the accounting by issuers for modifications or exchanges of equity-classified warrants. The framework applies to freestanding written call options, such as warrants, that were and remain equity classified by the issuer after the modification and are not in the scope of another Codification Topic. The framework applies regardless of whether the modification is through an amendment to the existing terms or issuance of a replacement warrant. The effect of the modification of the warrant is measured as the difference in its fair value immediately before and after the modification. The effect is recognized in the same manner as if cash had been paid as consideration. Additionally, other modifications may need to be accounted for as a cost to the issuing entity based on the substance of the transaction. The Update is effective prospectively for fiscal years beginning after December 15, 2021 including interim periods therein, with early adoption permitted. The Company is currently evaluating the impact of this standard on its consolidated financial statements and related disclosures.

In August 2020, the FASB issued ASU No. 2020-06, Debt — Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity, which simplifies accounting for convertible instruments by removing major separation models required under current U.S. GAAP. ASU No. 2020-06 removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception and it also simplifies the diluted earnings per share calculation in certain areas. ASU No. 2020-06 is effective for public companies for annual periods beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted for annual periods beginning after December 15, 2020, and interim periods within those fiscal years. The Company has not early adopted this standard and is currently evaluating the impact of this standard on its consolidated financial statements and related disclosures.

2. Other Current Assets

The Company's other current assets are comprised of the following:

	June 30, 2021 $	December 31, 2020 $
Deposits	56	68
Grant receivable	—	50
Salary deposit	66	51
Value added tax ("VAT") receivable	472	166
Other	37	—
Net other current assets	**631**	335

3. Prepaid Expenses

	June 30, 2021 $	December 31, 2020 $
Prepaid insurance	15	152
Other prepayments	—	22
	15	174

4. Investment

The Company owns 43,898 common shares in Lantern Pharma Inc. (NasdaqCM) ("Lantern" or "Lantern shares") as a result of a prior license agreement made with Lantern Pharma in 2017. During June 2020 Lantern Pharma became publicly listed. As at June 30, 2021 the fair market value of the shares was $641. Accordingly, for the three months ended June 30, 2021 the Company has recognized a finance loss on the Lantern shares of $67 and a foreign exchange gain of $10 (2020: finance gain of $411 and foreign exchange loss of $8). For the six months ended June 30, 2021 the Company has recognized a finance loss on the Lantern shares of $180 and a $24 foreign exchange (2020: finance gain of $411 and foreign exchange loss of $8).

5. Property, plant and equipment, net

Property, plant and equipment, net consisted of the following (in thousands):

	June 30, 2021	December 31, 2020
Laboratory equipment	338	338
Less: accumulated depreciation	(328)	(317)
	10	21

Depreciation expense was for the three months ended June 30, 2021 and 2020 was $32 and 36 respectively; and for the six months ended June 30, 2021 and 2020 was $68 and $72 and respectively.

(U.S. dollars in thousands, except for share and per share data and where otherwise noted)

6. Intangible assets

Intangible assets, net of accumulated amortization, impairment charges and adjustments are summarized as follows:

	As of June 30, 2021			As of December 31, 2020		
	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
IPR&D Assets	$ 38,876	$ (9,375)	$ 29,501	$ 38,876	$ (8,399)	$ 30,477
Acquired patents	99	(99)	—	99	(85)	14
Total intangible assets	$ 38,975	$ (9,474)	$ 29,501	$ 38,975	$ (8,484)	$ 30,491

The Company's IPR&D assets have been classified as indefinite-lived intangible assets. Individually material development projects in progress are as follows:

	June 30, 2021 $	December 31, 2020 $
Stenoparib	26,641	27,522
Dovitinib	2,860	2,955
	29,501	**30,477**

7. Accrued liabilities

The Company's accrued liabilities are comprised of the following:

	June 30, 2021 $	December 31, 2020 $
Development cost liability	1,153	1,191
Payroll accruals	407	316
Accrued Board member fees	6	119
Accrued audit and legal	47	84
Accrued liabilities	242	130
	1,855	**1,840**

8. Line of credit

Effective July 1, 2016 the Company established a line of credit with Nordea Bank in the amount of $84 bearing interest at 8.75%. The Company's assets, up to an amount of $84 have been provided as security against the line of credit. As at June 30, 2021 the Company was indebted in the amount of $58 (December 31, 2020 – $84).

9. Loan

2021 Loan

Effective March 22, 2021 the Company received a loan of up to $2.9 million (SEK $25 million), net of a 3% loan origination fee of $87 (SEK 750 thousand), bearing interest at 3% per month, and due on June 23, 2021. In exchange for the loan, the Company committed to complete a rights offering and issue common shares.

(U.S. dollars in thousands, except for share and per share data and where otherwise noted)

9. Loan (cont.)

The rights offering was completed before June 23, 2021 as described in these financial statements. As of June 23, 2021, the loan balance of $2,817 and interest of $284 were paid to the lender.

2019 Loan

Effective September 24, 2019 the Company received a loan of $512 bearing interest at 3% per month and due on November 30, 2019. The lender agreed to extend the due date of the loan with no penalty and the balance of the loan, including interest of $62 was paid as of January 7, 2020. The loan agreement included the Company's commitment to carry out a common share subscription which was cancelled upon repayment of the loan on January 7, 2020.

10. Convertible debt

On 31 March 2020 the Company entered into an agreement to issue up to $10,100 (SEK 100,000) (the "Commitment") to be funded in tranches ("Tranches") of ten non-interest bearing notes ("Notes") into new shares of the Company, each with a par value of $1,010 (SEK 10,000); 5% of each Tranche is deductible and the conversion price of the Notes is 95% of the lowest closing volume weighted average price as reported by Bloomberg ("VWAP").

The Company accounted for the Notes issued under the FVO election whereby the financial instrument is initially measured at its issue-date estimated fair value and subsequently re-measured at estimated fair value on a recurring basis at each reporting date. The estimated fair value adjustment is presented as a single line item within other income (expense) in the accompanying consolidated statements of operations under the caption "change in fair value of convertible notes and derivative liabilities.

We determined the fair value of the Notes using a discounted cash flow valuation technique with a weighted average cost of capital of 15%. The Company estimates the change in fair value attributable to the instrument specific credit risk of the Notes at 1% under the fair value option and accordingly has recognized a gain of $3 in other comprehensive income during the three month period ended June 30, 2021 (2020: $Nil).

Finance costs of $98 related to the Notes have been recognized in the Company's statement of operations for the three months ended June 30, 2021 and $298 for the six months ended June 30, 2021 (for the three months and six months ended June 30, 2020 – $475).

The roll forward of the Notes as of June 30, 2021 and December 31, 2020 is as follows:

	June 30, 2021 $	December 31, 2020 $
Opening fair value*	1,327	—
Convertible debt issued in the period	1,200	4,670
Change in fair value (loss) reported in statement operations	298	(681)
Conversion of notes to common shares	(2,825)	(2,662)
Ending fair value balance	—	1,327

10. Convertible debt (cont.)

An effective interest rate determines the fair value of the Notes. The notes are unlisted and therefore, they are categorized as Level 3 in accordance with ASC 820, "Fair Value Measurements and Disclosures." The estimated fair value of the Net carrying amount of liability component of the Notes as of June 30, 2021 and December 31, 2020 was $Nil and $1,327 respectively.

The Company estimates the change in fair value attributable to the instrument specific credit risk of the Notes at 1% under the fair value option and accordingly has recognized a gain of $3 in other comprehensive income.

11. Derivative Liabilities (Restated (See Note 1(e))

(a) Investor Warrants

The exercise price of our investor warrants described below is denominated in SEK; however, the functional currency of the Company is DKK. Consequently, the value of the proceeds on exercise is not fixed and will vary based on foreign exchange rate movements. The investor warrants when issued other than as compensation for goods and services are therefore a derivative for accounting purposes and are required to be recognized as a derivative liability and measured at fair value at each reporting period. Any changes in fair value from period to period are recorded as non-cash gain or loss in the consolidated statements of comprehensive loss. Upon exercise, the holders will pay the Company the respective exercise price for each investor warrant exercised in exchange for one common share of the Company and the fair value at the date of exercise and the associated non-cash liability will be reclassified to share capital. The non-cash liability associated with any investor warrants that expire unexercised will be recorded as a gain in the consolidated statements of comprehensive loss. There are no circumstances in which the Company would be required to pay any cash upon exercise or expiry of the investor warrants.

In connection with subscriptions of Offer Units in the rights issue carried out April/May 2019, 20,166,221 investor warrants ("TO1 warrants") have been granted to investors. All Warrants were vested as per the grant date. A warrant gives the right, during a fixed period to subscribe for nominal $0.01 (DKK 0.05) common share in the Company at $0.9 (SEK 7.5) (the "Exercise Price"), converted into DKK using the official exchange rate between DKK and SEK on the exercise day. All TO1 warrants were expired in the period ended December 31, 2020.

In connection with subscriptions of Offer Units in the rights issue carried out October — December 2019, 50,341,080 investor warrants ("TO2 warrants") have been granted to investors. All Warrants were vested as per the grant date. A warrant gives the right, during a fixed period to subscribe for nominal $0.01 (DKK 0.05) common share in the Company $0.69 (SEK 6,0) (the "Exercise Price"), converted into DKK using the official exchange rate between DKK and SEK on the exercise day. Each warrant carries the right to subscribe for one common share. Investors in the Rights Issue will have the possibility to exercise their warrants in five two-week windows during the 24-months period during which the warrants may be exercised. These periods are: April 1, 2020 – April 15, 2020, September 1, 2020 – September 15, 2020, February 1, 2021 – February 15, 2021, May 1, 2021 – May 15, 2021 and September 1, 2021 – September 15, 2021.

In connection with subscriptions of Offer Units in the rights issue carried out in June 2021, 121,162,817 investor warrants ("TO3 warrants") have been granted to investors. All Warrants were vested as per the grant date and expire April 15, 2023 and are exercisable for $0.20 (SEK 1,70).

(U.S. dollars in thousands, except for share and per share data and where otherwise noted)

11. Derivative Liabilities (Restated (See Note 1(e)) (cont.)

The table below summarizes the number of investor warrants that were outstanding, their weighted average exercise price ("WAEP") as at June 30, 2021 and December 31, 2020, as well as the movements during the respective periods:

	Six months ended June 30, 2021		Year ended December 31, 2020	
	Number	Weighted Average Exercise Price	Number	Weighted Average Exercise Price
Outstanding, opening	54,337,944	$ 0.71	70,507,301	$ 0.69
Granted	120,891,157	0.20	3,996,864	$ 0.36
Expired	—	—	(20,166,221)	$ 0.82
Outstanding, ending	175,229,101	$ 0.67	54,337,944	$ 0.71
Exercisable, ending	175,229,101	$ 0.67	54,337,944	$ 0.71

(b) Financing Facility

Effective November 29, 2018 the Company established a convertible debt facility (the "Facility") for funding of up to SEK 200 million to be funded in up to 20 tranches of SEK 10 million each over a 24 month term and bearing interest at 2% per annum. Five of the tranches were receivable under the Facility at the discretion of the investor and the Facility was convertible into shares and warrants at 50% of the nominal amount of the notes.

The Company has evaluated the terms of the Financing Facility in accordance with ASC 815-40-15 and ASC 815-40-25 and determined that the instrument is a derivative. Accordingly, the accounting treatment is the same as that described in Note 12(a) above.

On June 3, 2019 the Company settled one of the five tranches and in February 2020 the balance of the committed tranches were settled by receipt of $1 million (SEK 10,5 million) from the investor in cash, in exchange for a subscription of 9,330,000 common shares in the Company (Settlement Shares) valued at $2.5 million and the issuance of 3,996,864 investor warrants at an exercise price of $0.38 each (Settlement Warrants) valued at $0.6 million as of the February 23, 2020 grant date.

All Settlement Warrants immediately vested on the grant date. A warrant gives the right, during a fixed period to subscribe for nominal $0.01 (DKK 0.05) common share in the Company at $0.4 (SEK 3,3) (the "Exercise Price"), converted into DKK using the official exchange closing rate between DKK and SEK on the last business day prior to the exercise. Each warrant carries the right to subscribe for one common share over 36 months.

As at June 30, 2021, the weighted average contractual life of all of the investor warrants described in this Note 11 (a) and (b) is 1.54 years. The weighted average exercise price for the warrants as at the end of June 30, 2021, is $0.33 each.

(U.S. dollars in thousands, except for share and per share data and where otherwise noted)

11. Derivative Liabilities (Restated (See Note 1(e)) (cont.)

(c) Valuation of Derivative Liabilities

The derivative liabilities are measured at fair value at each reporting period and the reconciliation of changes in fair value is presented in the following tables:

	Financing Facility*		T01 Warrants Warrants issued May 2019	T02 Warrants Warrants issued December 2019		T03 Warrants Warrants issued June 2021
	June 30, 2021 $	December 31, 2020 $	December 31, 2020 $	June 30, 2021 $	December 31, 2020 $	June 30, 2021 $
Balance beginning	102	2,138	14	47	1,641	—
Issued during the period	—	—	—	—	—	5,151
Change in fair value	20	(524)	(14)	(46)	(1,594)	—
Amount transferred to Equity*	—	(1,412)	—	—	—	—
Translation effect	(3)	(100)	—	(1)	—	—
Balance – end of year	119	102	—	—	47	5,151
Fair value per warrant issuable at period end	0.03	0.026	—	—	0.0009	0.04

* The December 31, 2019 $2,935 estimated fair value of the Financing Facility comprises the $673 cash settlement paid by the Company in June 2019, and the $2,262 market value of 9,330,000 common shares and 3,996,864 warrants issued on settlement of the Facility on February 23, 2020. The 3,996,864 warrants are exchangeable into one common share each at $0.34 (SEK 3.3) for 36 months.

The fair value of the Company's derivative warrant liabilities were estimated using the Black-Scholes option pricing model and based on the following assumptions:

	Warrants issued February 2020		Warrants issued December 2019		Warrants issued June 2021
	Settlement Warrants for the termination of Financing Facility		T02 Warrants		T03 Warrants
	June 30, 2021	December 31, 2020	June 30, 2021	December 31, 2020	June 30, 2021
Exercise price	$0.38 – (SEK3.3)	$0.40 – (SEK3.3)	$0.69 – (SEK6.0)	$0.73 – (SEK6.0)	$0.20 – (SEK1.70)
Share price	$0.10 – (SEK0.92)	$0.10 – (SEK0.80)	$0.10 – (SEK0.92)	$0.10 – (SEK0.80)	$0.10 – (SEK0.92)
Risk-free interest	(0.52)%	(0.41)%	(0.52)%	(0.57)%	(0.52)%
Expected dividend yield	(0)%	(0)%	(0)%	(0)%	(0)%
Contractual life (years)	1.67	2.17	0.21	0.71	1.79
Expected volatility	104.20%	106.50%	104.20%	106.50%	104.20%

The Company measured its derivative warrant liabilities on a recurring basis using level 3 inputs (see Note 17).

12. Stockholders' Equity (Restated (See Note 1(e))

On June 30, 2021 the share capital consists of 365,173,471 common shares of par value $0.01 (DKK 0.05) each (December 31, 2020: 212,601,044 shares of par value $0.01 (DKK 0.05 each)). The shares are fully paid in. The shares are not divided into classes, and no shares enjoy special rights.

During the three months ended June 30, 2021 the Company issued:

(a) Units consisting of 120,891,157 common shares and 120,891,157 common share purchase warrants for $0.10 (SEK 0.85) per unit; valued at $12,125. The attached warrants are exercisable for $0.20 (SEK 1,70) each and expire on April 15, 2023; The obligation to issue shares of $2,606 represents share issuance costs which were paid in Units on July 14, 2021 to the financial advisors of the May 14, 2021 rights issue. The payment comprised 24,112,523 Units based on the offering price of the Unit offering of $0.10 per Unit;

(U.S. dollars in thousands, except for share and per share data and where otherwise noted)

12. Stockholders' Equity (Restated (See Note 1(e)) (cont.)

(b) 271,660 common shares valued at $16 upon the exercise of common stock purchase warrants; and

(c) 4,969,135 common shares valued at $496 upon conversion of debt.

During the six months ended June 30, 2021 the Company issued:

(a) Units consisting of 120,891,157 common shares valued at $12,125 upon the issuance of 120,891,157 units of one common share and one share purchase warrant for $0.10 (SEK 0.85) per unit. Terms of the Units and the obligation to issue shares of $2,606 are as described above in the three months ended June 30, 2021;

(b) 271,660 common shares valued at $16 upon the exercise of common stock purchase warrants; and

(c) 31,409,610 common shares valued at $2,880 upon conversion of debt.

During the three months ended June 30, 2020 the Company issued:

(a) 12,638,305 common shares valued at $1,921 on conversion of debt; and

(b) 25,936,599 common shares valued at $2,103 in exchange for 37% of the NCI in OV SPV2 ApS.

During the six months ended June 30, 2020 the Company issued:

(a) 9,330,000 common shares and 3,996,864 warrants in exchange for $1,092 in cash in settlement of the Financing Facility dated February 23, 2020; the fair value of the common shares of $2,504 was recorded in equity and the $625 fair value of the warrants was recorded as a derivative liability which was adjusted to market at the end of every period and as at June 30, 2021 the fair value of the warrants is $95;

(b) 12,638,305 common shares valued at $1,921 on conversion of debt; and

(c) 25,936,599 common shares valued at $2,103 in exchange for 37% of the NCI in OV SPV2 ApS.

13. Share-based payments

Share based payments in the legal form of warrants have been granted to members of the executive management, members of the board of directors, employees and external consultants.

All share-based payment warrant plans

During the three months ended June 30, 2021, the total charge to profit or loss amounted to $518 (2020: $196) and are recognized as general and administrative expenses. During the six months ended June 30, 2021, the total charge to profit or loss amounted to $628 (2020: $392) and are recognized as general and administrative expenses. Total compensation cost of $254 for non-vested warrants as at June 30, 2021 will be recognized through October 31, 2023.

The table below summarizes the number of options that were outstanding, their weighted average exercise price ("WAEP") as at June 30, 2021 and December 31, 2020, as well as the movements during the periods.

	June 30, 2021		December 31, 2020	
	Number	Weighted Average Exercise Price	Number	Weighted Average Exercise Price
Opening balance	10,775,971	$ 0.20	8,717,239	$ 0.18
Granted	—	—	3,389,550	$ 0.22
Forfeited	(271,660)	0.20	(1,350,818)	$ 0.26
Ending balance outstanding	10,504,311	$ 0.20	10,775,971	$ 0.20
Ending balance, exercisable	6,888,718	$ 0.18	6,008,140	$ 0.18

(U.S. dollars in thousands, except for share and per share data and where otherwise noted)

13. Share-based payments (cont.)

No warrants expired in either the three or six month period ended June 30, 2021 or the year ended December 31, 2020. No warrants were granted in the three or six month period ended June 30, 2021. The weighted average remaining contractual life for the warrants outstanding as at June 30, 2021 was 8.9 years (December 31, 2020: 9.3 years).

The exercise price for warrants outstanding at the end of June 30, 2021 is $0.08 – $0.28 (2020: $0.09 – $0.30).

14. Related Party Transactions

Transactions with related parties

During the three and six months ended June 30, 2021, the Company's former CEO and members of his family provided research and development and investor relations services to the Company and were compensated in the amount of $42 and $42 respectively (2020: $37 and $75 respectively).

15. Segments

The Company is domiciled in Denmark and operates as one operating segment. Our Chief Executive Officer (CEO), as the chief operating decision-maker, manages and allocates resources to the operations of our Company on a total Company basis. Managing and allocating resources on a total company basis enables our CEO to assess the overall level of resources available and how to best deploy these resources across functions, therapeutic areas and research and development projects that are in line with our long-term company-wide strategic goals. Consistent with this decision-making process, our CEO uses consolidated, single-segment financial information for purposes of evaluating performance, forecasting future period financial results, allocating resources and setting incentive targets. The Company has neither revenues from external customers outside Denmark, nor non-current assets in other geographical areas than Denmark.

16. Basic and diluted net loss per share

Basic net income loss per share is computed based on the weighted average number of ordinary shares outstanding during each period. Diluted net income per share is computed based on the weighted average number of ordinary shares outstanding during the period plus potential shares (deriving from warrants and convertible notes) considered outstanding during the period, in accordance with ASC 260-10 as determined under the treasury stock method.

	Three month period ended June 30,		Six month period ended June 30,	
	2021	2020	2021	2020
Numerator:				
Net loss attributable to common shareholders	$ (4,693)	$ (1,962)	(7,658)	(2,937)
Denominator:				
Weighted average common shares outstanding – basic and diluted	250,859,128	140,303,961	238,832,128	132,665,515
Net loss per share attributable to common shareholders – basic and diluted	$ (0.02)	$ (0.01)	$ (0.03)	$ (0.02)

The Company's unvested restricted shares and restricted share units have been excluded from the computation of basic net loss per share attributable to common shareholders.

(U.S. dollars in thousands, except for share and per share data and where otherwise noted)

16. Basic and diluted net loss per share (cont.)

The Company's potentially dilutive securities, which include warrants and shares issuable upon conversion of convertible debt, have been excluded from the computation of diluted net loss per share attributable to common shareholders as the effect would be to reduce the net loss per share attributable to common shareholders. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common shareholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to common shareholders for the periods indicated because including them would have had an anti-dilutive effect:

	Three month period ended June 30,		Six month period ended June 30,	
	2021	2020	2021	2020
Warrants	10,629,897	8,717,239	10,629,897	8,717,239
Convertible debt	—	2,259,504	—	2,259,504
	10,629,897	10,976,743	10,629,897	10,976,743

17. Financial Instruments (Restated (See Note 1(e))

The following tables present information about the Company's financial instruments measured at fair value on a recurring basis and indicate the level of the fair value hierarchy used to determine such fair values:

	Fair Value Measurements as of June 30, 2021 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Investment	$ 641	$ —	$ —	$ 641
Liabilities:				
Derivative warrants	$ —	$ —	$ (5,270)	$ (5,270)
	$ —	$ —	$ (5,270)	$ (5,270)

	Fair Value Measurements as of December 31, 2020 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Investment	$ 845	$ —	$ —	$ 845
Liabilities:				
Convertible debt	$ —	$ —	$ (1,327)	$ (1,327)
Financing Facility	—	—	(102)	(102)
Derivative warrants	—	—	(47)	(47)
	$ —	$ —	$ (1,476)	$ (1,476)

The following method was used to estimate the fair values of our financial instruments:

The carrying amount of level 1 financial instruments approximates fair value because of the short maturity of the instruments. Financial assets and liabilities are considered Level 3 when their fair values are determined using pricing models, discounted cash flow methodologies, or similar techniques, and at least one significant model assumption or input is unobservable. Level 3 financial assets also include investment securities in 2020 for which there is limited market activity such that the determination of fair value requires significant judgment or estimation.

(U.S. dollars in thousands, except for share and per share data and where otherwise noted)

17. Financial Instruments (Restated (See Note 1(e)) (cont.)

The Company reviews the fair value hierarchy classification on a quarterly basis. Changes in the ability to observe valuation inputs may result in a reclassification of levels for certain securities within the fair value hierarchy. The Company's policy is to recognize transfers into and out of levels within the fair value hierarchy at the date the actual event or change in circumstances that caused the transfer occurs. When a determination is made to classify an asset or liability within Level 3, the determination is based upon the significance of the unobservable inputs to the overall fair value measurement. There were no transfers between level 1 or level 2 during the six months ended June 30, 2021 and the year ended December 31, 2020. The following table provides a reconciliation of the beginning and ending balances of the item measured at fair value on a recurring basis in the table above that used significant unobservable inputs (Level 3):

Level 3	June 30, 2021	December 31, 2020
Beginning balance	$ 1,476	$ 3,793
Gains included in net loss	—	845
Transfers out of level 3	—	(845)
Issuance of convertible debt	1,200	4,670
Issuance of investor warrants	5,151	—
	7,827	8,463
Financing Facility:		
Fair value adjustment	20	(524)
Translation effect	(3)	(99)
Converted to equity on settlement	—	(1,413)
Fair value adjustments:		
TO1 Warrants	—	(14)
TO2 Warrants	(46)	(1,594)
Translation effect	(1)	—
Convertible debt	298	(681)
Debt conversion	(2,825)	(2,662)
Ending balance	$ 5,270	$ 1,476

18. Commitments and Contingencies

Development costs

The Company is contingently liable for development costs of Smerud Medical Research International ("Smerud") in the approximate amount of $1,191 which has been accrued as of June 30, 2021 and will be payable only if Smerud is unable to identify investors to fund development of in licensed products from the Company by October 1, 2021.

On November 10, 2020 the Company entered into a cost sharing agreement with Smerud for the development of Ixempra whereby Smerud will be entitled to 7.5% royalties on future revenue in exchange for funding half of the development costs. As of June 30, 2021 Smerud has performed work valued at $52 and is entitled to a very low amount of future royalties.

19. Subsequent Events

For its interim consolidated financial statements as of June 30, 2021 and for the six months then ended, the Company evaluated subsequent events through August 20, 2021, the date on which those financial statements were issued.

(a) Plan of Reorganization and US Nasdaq Listing

On April 6, 2021, the Company incorporated Allarity Therapeutics, Inc., a Delaware corporation, ("Allarity Delaware") as a direct wholly owned subsidiary of the Company for the sole purpose of entering into a Plan of Reorganization and Asset Purchase Agreement with Allarity Delaware in order to reorganize the Company as a holding company listed on the US Nasdaq Stock Market and complete a 50 to 1 share reverse split, resulting in an immediate decrease in the outstanding shares used to calculate the weighted average common shares outstanding for basic and diluted net income per share. The reorganization is a common control transaction and there will be no change in control over the assets of the ultimate parent. Consequently, Allarity Delaware will record all assets and liabilities acquired from Allarity Therapeutics A/S at historical cost. The recapitalization share exchange is conditioned upon the approval the Company's shareholder and an effective registration statement filed with the US Securities and Exchange Commission.

As of the date of these financial statements, the Company anticipates that approximately 7,801,262 shares of Delaware common stock will be issued in the recapitalization share exchange to the Company's shareholders.

(b) PIPE Investment

On May 20, 2021, the Company entered into an Investment Agreement (the "Investment Agreement") with 3i, LP, a Delaware Limited Partnership (the "Investor") whereby the Company agreed to issue and sell the Investor 20,000 shares of Allarity Delaware Series A Convertible Preferred Stock (the "Preferred Stock") and common stock purchase warrants (the "Warrants") for an additional $20 million (the "PIPE Investment"). The PIPE Investment is conditioned upon, and will occur simultaneously with, the consummation of the Recapitalization Share Exchange and the approval of Allarity Delaware's application to list its common stock on the US Nasdaq Stock Market.

The Preferred Stock may convert over time into at approximately 20% of the Company's issued and outstanding shares however, conversion of the Preferred Shares and exercise of the Warrants; is limited to 4.99% of the Company's issued and outstanding shares.

As of the date of these financial statements the Company expects the conversion price of the Preferred Stock to be between $7.47 and $10.25 per share. However, if the volume weighted average price for Allarity Delaware common stock on the US Nasdaq Stock Market falls below the fixed conversion price for the preferred stock, then the preferred stock would be entitled to convert at an alternate conversion price between 80% to 90% of the volume weighted average price at the time of conversion with a similar adjustment for the exercise price for the warrants.

Lastly, in the event that the average daily US dollar volume of share of Allarity Delaware common stock traded on the US Nasdaq Stock Market falls below $2.5 million, then holders of the convertible preferred stock will be entitled to a one-time special dividend of 8% of the stated value of the preferred stock ($1.6 million) payable in shares of common stock upon conversion of the convertible preferred stock. The Company is in the process of assessing the accounting treatment of the special dividend.

(c) Sale of Irofulven

On July 23, 2021, the Company and Lantern Pharma Inc. ("Lantern") entered into an exclusive agreement under which Lantern will reacquire global rights to Irofulven ("LP-100") and assume full authority to manage and guide future clinical development and commercialization. The Company received an upfront payment of $1,000 from Lantern. The agreement voids all prior obligations from the original 2015 in-license agreement and provides for additional development and regulatory milestone fees, and tiered royalties on future sales of Irofulven.

19. Subsequent Events (cont.)

If all milestones have been achieved, then we would be entitled to receive up to $16 million in milestone payments under the Asset Purchase Agreement. In addition to the milestone payments, Lantern Pharma has agreed to pay us royalties in the low mid-digits based on annual incremental net sales of product derived from Irofulven, on a country-by-country basis, in an amount equal to percentages of annual sales based on a tiered progression.

20. Events Subsequent to Original Issuance of Financial Statements

In connection with the reissuance of the financial statements, the Company has evaluated subsequent events through November 4, 2021, the date the financial statements were available to be reissued.

a) TO 2 and TO 3 Warrants

In accordance with the terms of the Company's 145,003,680 outstanding TO 3 Warrants, exercisable for $0.20 (SEK 1.7) per share, the Company's Board of Directors can determine an extraordinary and final exercise window of 10 trading days in which warrants shall be exercised provided, however, that the price of the Company's shares increases to SEK 2.0 or more calculated as average volume weighted price (VWAP) over 10 trading days. On August 26, 2021, the Board of Directors set an extraordinary and final exercise period for the Company's TO 3 Warrants, starting on August 30, 2021, and ending on September 13, 2021. Any warrants unexercised after September 13, 2021, expired without compensation or payment of any kind to the warrant holders.

In total, 13,719,266 warrants of series TO 3 were exercised, corresponding to approximately 9.5 percent of the total number of outstanding warrants, for subscription of 13,719,266 shares at a subscription price of SEK 1.7 per share. Through the exercise of the warrants, Allarity received approximately U.S. $2.7 million (SEK 23.3 million) before issuing costs amounting to approximately U.S. $162 thousand (SEK 1.4 million).

In total, 8,820 warrants of series TO 2 were exercised, corresponding to approximately 0.02 percent of the total number of outstanding warrants, for subscription of 8,820 shares at a subscription price of SEK 6.0 per share. Through the exercise of the TO 2 warrants, Allarity received approximately U.S. $6 thousand (SEK 53,000) before issuing costs. The final exercise period for the warrants of series TO 2 took place from September 1 up to and including September 15, 2021.

b) License Agreement with Eisai for Stenoparib

Subsequent to August 20, 2021, the terms of our agreement with Eisai have been revised to provide Eisai the right to terminate the agreement if we do not complete a Phase 2 clinical trial before December 31, 2022, unless we elect to pay a very low seven digit extension payment.

c) Development costs and Out-License Agreement with Smerud

Subsequent to August 20, 2021, the terms of our agreement with Smerud have been revised to extend the time Smerud has to obtain the minimum funding under the agreement from October 1, 2021, to December 31, 2021.

Execution Version

Annex A

AMENDED AND RESTATED

PLAN OF REORGANIZATION AND ASSET PURCHASE AGREEMENT

By and Among

Allarity Therapeutics, Inc.

a Delaware corporation

Allarity Acquisition Subsidiary

a Delaware Corporation

and

Allarity Therapeutics A/S

an *Aktieselskab* organized under the laws of Denmark

Dated as of May 20, 2021

As amended as of September 23, 2021

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AMENDED AND RESTATED PLAN OF REORGANIZATION AND ASSET PURCHASE AGREEMENT

This Amended and Restated Plan of Reorganization and Asset Purchase Agreement (this "**Agreement**"), was entered into as of May 20, 2021, and is hereby entered into as of September 23, 2021, by and among Allarity Therapeutics A/S, an *Aktieselskab* organized under the laws of Denmark (the "**Company**"), Allarity Therapeutics, Inc., a Delaware corporation ("**Parent**"), and Allarity Acquisition Subsidiary, a Delaware corporation to be organized under the laws of Delaware and a wholly-owned Subsidiary of Parent ("**Acquisition Sub**"). Capitalized terms used herein (including in the immediately preceding sentence) and not otherwise defined herein shall have the meanings set forth in Section 8.01 hereof.

RECITALS

WHEREAS, the Parent will capitalized the Acquisition Sub with shares of Parent Common Stock (as defined below) in exchange for the common stock of the Acquisition Sub and the parties intend that Acquisition Sub will acquire all of the assets and assume all of the liabilities the Company in exchange for the Parent Common Stock and the Company will distribute the Parent Common Stock received as the purchase price for the Company's assets and assumption of liabilities to the holders the Company Ordinary Shares (as defined below) first by a share exchange "swap" program and then pro rata as a special dividend to shareholders who have not exchanged their ordinary shares for Parent Common Stock and thereafter will dissolve and liquidate in accordance with Part 14 of Danish Companies Act (the "**DCA**") on the terms and subject to the conditions set forth herein;

WHEREAS, the Board of Directors of the Company (the "**Company Board**") has: (a) determined that it is in the best interests of the Company and the holders of the Company's ordinary shares, nominal value DKK 0.05 per share (the "**Company Ordinary Shares**"), and declared it advisable, to enter into this Agreement with Parent and Acquisition Sub; (b) approved the execution, delivery, and performance of this Agreement and, subject to the approval of the Company's shareholders, execution of the Asset Purchase Agreement (the "**Asset Purchase Agreement**") attached hereto as Exhibit A, the consummation of the transactions contemplated hereby (the "**Asset Acquisition**"); and (c) resolved, subject to the terms and conditions set forth in this Agreement and the execution of the Asset Purchase Agreement, to recommend adoption of the Asset Acquisition by the shareholders of the Company; in each case, in accordance with the DCA;

WHEREAS, the respective Boards of Directors of Parent (the "**Parent Board**"), and, prior to execution of the Asset Purchase Agreement, the Acquisition Sub (the "**Acquisition Sub Board**") will each have: (a) determined that it is in the best interests of Parent or Acquisition Sub, as applicable, and their respective stockholders, and declared it advisable, to enter into this Agreement; and (b) approved the execution, delivery, and performance of this Agreement and, subject to the execution of the Asset Purchase Agreement, the consummation of the transactions contemplated hereby, including the Asset Acquisition; in each case, in accordance with the Delaware General Corporation Law (the "**DGCL**");

WHEREAS, the Parent Board has resolved to recommend that the holders of shares of Parent's common stock, par value $0.001 per share (the "**Parent Common Stock**") approve the issuance of shares of Parent Common Stock in connection with the Asset Purchase Agreement on the terms and subject to the conditions set forth in this Agreement (the "**Parent Stock Issuance**");

WHEREAS, for U.S. federal income Tax purposes, the parties intend that the Asset Acquisition qualify as a "reorganization" within the meaning of Section 368(a) of the Internal Revenue Code of 1986, as amended (the "**Code**"), and that this Agreement be, and is hereby, adopted as a plan of reorganization within the meaning of Section 368(a) of the Code; and

WHEREAS, the parties desire to make certain representations, warranties, covenants, and agreements in connection with the Asset Acquisition and the other transactions contemplated by this Agreement and also to prescribe certain terms and conditions to the Asset Acquisition.

NOW, THEREFORE, in consideration of the foregoing and of the representations, warranties, covenants, and agreements contained in this Agreement, the parties, intending to be legally bound, agree as follows:

ARTICLE I
THE ASSET ACQUISITION

Section 1.01 The Asset Acquisition. On the terms and subject to the conditions set forth in this Agreement, and in accordance with the DCA and further subject to the execution of the Asset Purchase Agreement, at the Effective Time: (a) the Company will sale, transfer and assigned substantially all of its assets to the Acquisition Sub and the Acquisition Sub will assume substantially all of the Company's liabilities solely in exchange for the Parent Common Stock (the "**Asset Acquisition**"); (b) the Parent Common Stock issued as consideration for the Asset Acquisition will be distributed to the Company's shareholders first in a share exchange wherein each shareholder of the Company will be given the opportunity to exchange each share of the Company's ordinary shares for shares of Parent Common Stock in an amount equal to the Exchange Ratio provided for in Section 2.01(b) rounded down to the nearest whole share (the "**Parent Common Stock Exchange**" pursuant to a Company share buy-back program and then the remaining shares of Parent Common Stock will be distributed pro rata to the Company's remaining shareholders by extraordinary or liquidating dividend (the "**Parent Common Stock Dividend**") subject to any applicable tax withholding requirements; (c) pursuant to Part 14 of the DCA, the Company will dissolve and liquidate; and (d) the Acquisition Sub will continue the business operations of the Company as a Subsidiary of Parent (sometimes referred to herein as the "**Surviving Corporation**"). For the sake of clarity, the Parent shall not assume any liabilities of the Company as a part of the Asset Acquisition.

Section 1.02 Closing. Upon the terms and subject to the conditions set forth herein, the closing of the Asset Acquisition (the "**Closing**") will take place at 9:00 am Pacific Time or as soon as practicable (and, in any event, within five (5) Business Days) after the satisfaction or, to the extent permitted hereunder, waiver of all conditions to the Asset Acquisition set forth in ARTICLE VI (other than those conditions that by their nature are to be satisfied at the Closing, but subject to the satisfaction or, to the extent permitted hereunder, waiver of all such conditions), unless this Agreement has been terminated pursuant to its terms or unless another time or date is agreed to in writing by the parties hereto. The Closing shall take place at the offices of Lewis Brisbois Bisgaard & Smith LLP, 633 West 5th Street, Suite 4000, Los Angeles, California, 90071, or remotely by exchange of documents and signatures (or their electronic counterparts), unless another place is agreed to in writing by the parties hereto. The actual date of the Closing is hereinafter referred to as the "**Closing Date**."

Section 1.03 Effective Time. Subject to the provisions of this Agreement, at the Closing, the Company, Parent, and Acquisition Sub will cause the resolution of the Company, (by shareholders acting at a general meeting and/or their respective board of directors) approving the Asset Acquisition and to be executed, acknowledged, and filed with any applicable governmental agency in Denmark and shall make all other filings or recordings required under the DCA. The Asset Acquisition will become effective on the date the Parent Common Stock Dividend has been paid to the Company's shareholders (the effective time of the Asset Acquisition being hereinafter referred to as the "**Effective Time**").

Section 1.04 Effects of the Asset Acquisition. The Asset Acquisition shall have the effects set out in this Agreement and in the applicable provisions of the DCA. Without limiting the generality of the foregoing, and subject thereto, from and after the Effective Time, all property, rights, privileges, immunities, powers, franchises, licenses, and authority of the Company shall vest in the Surviving Corporation, and all debts, liabilities, obligations, restrictions, and duties of each of the Company, except for any excluded liabilities, shall become the debts, liabilities, obligations, restrictions, and duties of the Surviving Corporation.

ARTICLE II
EFFECT OF THE ASSET ACQUISITION ON CAPITAL STOCK; PURCHASE PRICE EXCHANGE OF CERTIFICATES

Section 2.01 Effect of the Asset Acquisition on Capital Stock. At the Effective Time, as a result of the Asset Acquisition and without any action on the part of Parent, Acquisition Sub, or the Company or the holder of any capital stock of Parent, Acquisition Sub, or the Company:

(a) Cancellation of Certain Company Ordinary Shares. Each share of Company Ordinary Shares that is owned by Parent or the Company (as treasury stock or otherwise) or any of their respective direct or indirect wholly-owned Subsidiaries as of immediately prior to the Effective Time (the "**Cancelled Shares**") will automatically be cancelled and retired and will cease to exist, and no Parent Common Stock Dividend will be paid or other consideration delivered in Asset Acquisition.

(b) Purchase Price in Parent Common Stock. The Purchase Price to be paid in exchange for all of the assets of the Company, and the assumption of all of the Company's liabilities shall be a number of shares of Parent Common Stock determined on the basis of each share of Company Ordinary Shares issued and outstanding immediately prior to the Effective Time (other than Cancelled Shares) will be converted into the right to receive: (i) 0.02 (the "**Exchange Ratio**") of a share of Parent Common Stock held by the Acquisition Sub (the "**Asset Acquisition Consideration**") as their pro rata amount of the Parent Common Stock Exchange and Parent Common Stock Dividend rounded down to the nearest whole number. Consequently, the value of the Asset Acquisition Consideration shall be equal to an amount calculated by multiplying the number of issued and outstanding Company Ordinary Shares entitled to the Parent Common Stock Exchange and Parent Common Stock Dividend by the ten trading day average of the closing price for the Company's Ordinary Shares on the First North Growth Market immediately prior to the Effective Time.

(c) Fractional Shares. No certificates or scrip representing fractional shares of Parent Common Stock shall be issued upon the payment of the Parent Common Stock Exchange or Parent Common Stock Dividend to the holders of the Company's Ordinary Shares pursuant to Section 2.01(b) and such fractional share interests shall not entitle the owner thereof to vote or to any other rights of a holder of shares of Parent Common Stock. Any fractional interest, calculated on a holder by holder basis, will be settled in cash.

Section 2.02 Asset Acquisition Consideration, Parent Common Stock Exchange and Parent Common Stock Dividend Payment Procedures.

(a) Exchange Agent. Prior to the Effective Time, Parent and Acquisition Sub shall appoint an exchange agent, which may be the Company, (the "**Exchange Agent**") to act as the agent for the purpose of paying the Asset Acquisition Consideration to the Company and the payment of the Parent Common Stock Exchange and Parent Common Stock Dividend to the holders of the Company's Ordinary shares. At or immediately prior to the Effective Time, Parent shall deposit, or cause the Surviving Corporation to deposit, with the Exchange Agent certificates representing the shares of Parent Common Stock to be issued as Asset Acquisition Consideration (or make appropriate alternative arrangements if uncertificated shares of Parent Common Stock represented by book-entry shares will be issued). Such shares of Parent Common Stock are referred to collectively in this Agreement as the "**Exchange Fund**."

(b) Procedures for the Payment of the Parent Common Stock Exchange and Parent Common Stock Dividend. Prior to the Effective Time, the Company shall provide the Exchange Agent with information relating to all record holder of shares of Company Ordinary Shares on the record date for the Parent Common Stock Exchange and the Parent Common Stock Dividend and at the Effective Time, for all shareholders who are entitled to receive the Asset Acquisition Consideration through the payment of the Parent Common Stock Dividend. The Company and the Exchange Agent shall then determine the correct allocation of the Asset Acquisition Consideration to be paid to each holder of the Company's Ordinary Shares as payment for the Parent Common Stock Exchange and payment of the Parent Common Stock Dividend and shall cause the Parent Common Stock paid to the Company pursuant to the Asset Purchase Agreement to be distributed to holders of the Company's Ordinary Shares through the payment of the Parent Common Stock Exchange and Parent Common Stock Dividend.

(c) Termination of Exchange Fund. Any portion of the Exchange Fund that remains unclaimed by the holders of shares of Company Ordinary Shares six (6) months after the Effective Time shall be returned to Parent, upon demand, and any such holder who has not claimed the payment of any portion of the Parent Common Stock Dividend prior to that time shall thereafter look only to Parent (subject to abandoned property, escheat, or other similar Laws), as general creditors thereof, for payment of the Asset Acquisition Consideration without any interest. Notwithstanding the foregoing, Parent shall not be liable to any holder of shares of Company Ordinary Shares for any amounts paid to a public official pursuant to applicable abandoned property, escheat, or similar Laws. Any amounts remaining unclaimed by holders of shares of Company Ordinary Shares two (2) years after the Effective Time (or such earlier date, immediately prior to such time when the amounts would otherwise escheat to or become property of any Governmental Entity) shall become, to the extent permitted by applicable Law, the property of Parent free and clear of any claims or interest of any Person previously entitled thereto.

Section 2.03 Adjustments. Without limiting the other provisions of this Agreement, if at any time during the period between the date of this Agreement and the Effective Time, any change in the outstanding shares of capital stock of the Company or the Parent Common Stock shall occur (other than the issuance of additional shares of capital stock of the Company in its previously announced shareholder rights offering or as otherwise permitted by this Agreement), including by reason of any reclassification, recapitalization, stock split (including a reverse stock split), or combination, exchange, readjustment of shares, or similar transaction, or any stock dividend or distribution paid in

stock, the Exchange Ratio and the amount payable as Asset Acquisition Consideration pursuant to this Agreement shall be appropriately adjusted to reflect such change; *provided, however*, that this sentence shall not be construed to permit Parent or the Company to take any action with respect to its securities that is prohibited by the terms of this Agreement.

Section 2.04 Withholding Rights. Each of the Exchange Agent, Parent, Acquisition Sub, and the Surviving Corporation shall be entitled to deduct and withhold from the consideration otherwise payable to any Person pursuant to this ARTICLE II such amounts as may be required to be deducted and withheld with respect to the making of such payment under any Tax Laws. To the extent that amounts are so deducted and withheld by the Exchange Agent, Parent, Acquisition Sub, or the Surviving Corporation, as the case may be, such amounts shall be treated for all purposes of this Agreement as having been paid to the Person in respect of which the Exchange Agent, Parent, Acquisition Sub, or the Surviving Corporation, as the case may be, made such deduction and withholding.

Section 2.05 Lost Certificates. If any Certificate shall have been lost, stolen, or destroyed, upon the making of an affidavit of that fact by the Person claiming such Certificate to be lost, stolen, or destroyed and, if required by Parent, the posting by such Person of a bond, in such reasonable amount as Parent may direct, as indemnity against any claim that may be made against it with respect to such Certificate, the Exchange Agent will issue, in exchange for such lost, stolen, or destroyed Certificate, the Asset Acquisition Consideration to be paid in respect of the shares of Company Ordinary Shares formerly represented by such Certificate as contemplated under this ARTICLE II.

Section 2.06 Treatment of Stock Options (Warrants) and Other Stock-Based Compensation Issued Under a Company Stock Plan.

(a) Company Stock Options (Warrants). As of the Effective Time, each option (warrant) to acquire shares of Company Ordinary Shares (each, a "**Company Stock Option**") that was issued to an officer, director, employee or consultant of the Company for services and which is issued and outstanding under any Company Stock Plan immediately prior to the Effective Time, whether or not then vested or exercisable, shall be, by virtue of the Asset Acquisition and without any action on the part of the holder thereof, or any other Person, converted into a Parent Stock Option in accordance with this Section 2.06. Each such Parent Stock Option as so assumed and converted shall continue to have, and shall be subject to, the same terms and conditions as applied to the Company Stock Option immediately prior to the Effective Time. As of the Effective Time, each such Parent Stock Option as so converted shall be an option to acquire that number of whole shares of Parent Common Stock (rounded down to the nearest whole share) equal to the product of: (i) the number of shares of Company Ordinary Shares subject to such Company Stock Option; and (ii) the Exchange Ratio, at an exercise price per share of Parent Common Stock (rounded up to the nearest whole cent) equal to the quotient obtained by dividing (A) the exercise price per share of Company Ordinary Shares of such Company Stock Option by (B) the Exchange Ratio; *provided, that* the exercise price and the number of shares of Parent Common Stock subject to the Parent Stock Option shall be determined in a manner consistent with the requirements of Section 409A of the Code, and, in the case of Company Stock Options that are intended to qualify as incentive stock options within the meaning of Section 422 of the Code, consistent with the requirements of Section 424(a) of the Code.

(b) Reserved.

(c) Resolutions and Other Company Actions. At or prior to the Effective Time, the Company, the Company Board, and the compensation committee of such board, as applicable, shall adopt any resolutions and take any actions (including obtaining any employee consents) that may be necessary to effectuate the provisions of paragraphs Section 2.06(a) and Section 2.06(b) of this Section 2.06.

(d) Parent Actions. At or prior to the Effective Time, Parent shall reserve for future issuance a number of shares of Parent Common Stock at least equal to the number of shares of Parent Common Stock that will be subject to Parent Equity Awards as a result of the actions contemplated by this Section 2.06. As soon as practicable after the Effective Time, if and to the extent necessary to cause a sufficient number of shares of Parent Common Stock to be registered and issuable with respect to the Parent Equity Awards, Parent shall prepare and issue the Parent Equity Awards to such officers, directors, employees and consultants entitled thereto under this Section 2.06 and prepare and file with the SEC a registration statement on Form S-8 (or any successor or other appropriate form) with respect to the shares of Parent Common Stock subject to the Parent Equity Awards.

Section 2.07 **Tax Treatment.** For U.S. federal income Tax purposes, it is intended that the Asset Acquisition qualify as a "reorganization" within the meaning of Section 368(a) of the Code, and the regulations promulgated thereunder, that this Agreement will constitute a "plan of reorganization" for purposes of Sections 354 and 361 of the Code.

ARTICLE III
REPRESENTATIONS AND WARRANTIES OF THE COMPANY

Except as set forth in the correspondingly numbered Section of the Company Disclosure Letter that relates to such Section or in another Section of the Company Disclosure Letter to the extent that it is reasonably apparent on the face of such disclosure that such disclosure is applicable to such Section, the Company hereby represents and warrants to Parent and Acquisition Sub as follows:

Section 3.01 **Organization; Standing and Power; Charter Documents; Subsidiaries.**

(a) Organization; Standing and Power. The Company and each of its Subsidiaries is a corporation, limited liability company, or other legal entity duly organized, validly existing, and in good standing (to the extent that the concept of "good standing" is applicable in the case of any jurisdiction outside the United States) under the Laws of its jurisdiction of organization, and has the requisite corporate, limited liability company, or other organizational, as applicable, power and authority to own, lease, and operate its assets and to carry on its business as now conducted. Each of the Company and its Subsidiaries is duly qualified or licensed to do business as a foreign corporation, limited liability company, or other legal entity and is in good standing (to the extent that the concept of "good standing" is applicable in the case of any jurisdiction outside the United States) in each jurisdiction where the character of the assets and properties owned, leased, or operated by it or the nature of its business makes such qualification or license necessary, except where the failure to be so qualified or licensed or to be in good standing, would not reasonably be expected to have, individually or in the aggregate, a Company Material Adverse Effect.

(b) Charter Documents. The copy of Articles of Association (the "**Charter Documents**") of the Company as most recently filed with the applicable governmental authority are true, correct, and complete copies of such documents as in effect as of the date of this Agreement. The Company has delivered or made available to Parent a true and correct copy of the Charter Documents of each of the Company's Subsidiaries. Neither the Company nor any of its Subsidiaries is in violation of any of the provisions of its Charter Documents.

(c) Subsidiaries. Section 3.01(c)(i) of the Company Disclosure Letter lists each of the Subsidiaries of the Company as of the date hereof and its place of organization. Section 3.01(c)(ii) of the Company Disclosure Letter sets forth, for each Subsidiary that is not, directly or indirectly, wholly-owned by the Company: (i) the number and type of any capital stock of, or other equity or voting interests in, such Subsidiary that is outstanding as of the date hereof; and (ii) the number and type of shares of capital stock of, or other equity or voting interests in, such Subsidiary that, as of the date hereof, are owned, directly or indirectly, by the Company. All of the outstanding shares of capital stock of, or other equity or voting interests in, each Subsidiary of the Company that is owned directly or indirectly by the Company have been validly issued, are fully paid and non-assessable, and are free and clear of all Liens, including any restriction on the right to vote, sell, or otherwise dispose of such capital stock or other equity or voting interests, except for any Liens: (A) imposed by applicable securities Laws; or (B) arising pursuant to the Charter Documents of any non-wholly-owned Subsidiary of the Company. Except for the capital stock of, or other equity or voting interests in, its Subsidiaries, the Company does not own, directly or indirectly, any capital stock of, or other equity or voting interests in, any Person.

Section 3.02 **Capital Structure.**

(a) Capital Stock. The registered share capital of the Company consists of: (i) 241,783,314 shares of Company Ordinary Shares denominated as DKK 0.05 per share. As of the date of this Agreement, 241,783,314 shares of Company Ordinary Shares were issued and outstanding (not including shares held in treasury) and there are no other classes of shares that are authorized, issued or outstanding. Since December 31, 2020, and through the date hereof, no additional shares of Company Ordinary Shares have been issued. No Subsidiary of the Company owns any shares of Company Ordinary Shares.

(b) Stock Awards.

(i) As of the date of this Agreement, there are no shares of Company Ordinary Shares reserved for issuance pursuant to Company Equity Awards not yet granted under the Company Stock Plans. As of the date of this Agreement, 6,913,425 shares of Company Ordinary Shares were reserved for issuance pursuant to outstanding Company Stock Options and Section 3.02(b)(i) of the Company Disclosure Letter sets forth as of the date of this Agreement a list of each outstanding Company Equity Award granted under the Company Stock Plans and: (A) the name of the holder of such Company Equity Award; (B) the number of shares of Company Ordinary Shares subject to such outstanding Company Equity Award; (C) if applicable, the exercise price, purchase price, or similar pricing of such Company Equity Award; (D) the date on which such Company Equity Award was granted or issued; (E) the applicable vesting, repurchase, or other lapse of restrictions schedule, and the extent to which such Company Equity Award is vested and exercisable as of the date hereof; and (F) with respect to Company Stock Options, the date on which such Company Stock Option expires. All shares of Company Ordinary Shares subject to issuance under the Company Stock Plans, upon issuance in accordance with the terms and conditions specified in the instruments pursuant to which they are issuable, will be duly authorized, validly issued, fully paid, and non-assessable.

(ii) Except for the Company Stock Plans and as set forth in Section 3.02(b)(ii) of the Company Disclosure Letter, there are no Contracts to which the Company is a party obligating the Company to accelerate the vesting of any Company Equity Award as a result of the transactions contemplated by this Agreement (whether alone or upon the occurrence of any additional or subsequent events). Other than the Company Equity Awards, as of the date hereof, there are no outstanding: (A) securities of the Company or any of its Subsidiaries convertible into or exchangeable for Voting Debt or shares of capital stock of the Company; (B) options, warrants, or other agreements or commitments to acquire from the Company or any of its Subsidiaries, or obligations of the Company or any of its Subsidiaries to issue, any Voting Debt or shares of capital stock of (or securities convertible into or exchangeable for shares of capital stock of) the Company; or (C) restricted shares, restricted stock units, stock appreciation rights, performance shares, profit participation rights, contingent value rights, "phantom" stock, or similar securities or rights that are derivative of, or provide economic benefits based, directly or indirectly, on the value or price of, any shares of capital stock of the Company, in each case that have been issued by the Company or its Subsidiaries (the items in clauses (A), (B), and (C), together with the capital stock of the Company, being referred to collectively as "**Company Securities**"). All outstanding shares of Company Ordinary Shares, all outstanding Company Equity Awards, and all outstanding shares of capital stock, voting securities, or other ownership interests in any Subsidiary of the Company, have been issued or granted, as applicable, in compliance in all material respects with all applicable securities Laws.

(iii) There are no outstanding Contracts requiring the Company or any of its Subsidiaries to repurchase, redeem, or otherwise acquire any Company Securities or Company Subsidiary Securities. Neither the Company nor any of its Subsidiaries is a party to any voting agreement with respect to any Company Securities or Company Subsidiary Securities.

(c) Voting Debt. No bonds, debentures, notes, or other indebtedness issued by the Company or any of its Subsidiaries: (i) having the right to vote on any matters on which stockholders or equity holders of the Company or any of its Subsidiaries may vote (or which is convertible into, or exchangeable for, securities having such right); or (ii) the value of which is directly based upon or derived from the capital stock, voting securities, or other ownership interests of the Company or any of its Subsidiaries, are issued or outstanding (collectively, "**Voting Debt**").

(d) Company Subsidiary Securities. As of the date hereof, there are no outstanding: (i) securities of the Company or any of its Subsidiaries convertible into or exchangeable for Voting Debt, capital stock, voting securities, or other ownership interests in any Subsidiary of the Company; (ii) options, warrants, or other agreements or commitments to acquire from the Company or any of its Subsidiaries, or obligations of the Company or any of its Subsidiaries to issue, any Voting Debt, capital stock, voting securities, or other ownership interests in (or securities convertible into or exchangeable for capital stock, voting securities, or other ownership interests in) any Subsidiary of the Company; or (iii) restricted shares, restricted stock units, stock appreciation rights, performance shares, profit participation rights, contingent value rights, "phantom" stock, or similar securities or rights that are derivative of, or provide economic benefits based, directly or indirectly, on the value or price of, any capital stock or voting securities of, or other ownership interests in, any Subsidiary of the Company, in each case that have been issued by a Subsidiary of the Company (the items in clauses (i), (ii), and (iii), together with the capital stock, voting securities, or other ownership interests of such Subsidiaries, being referred to collectively as "**Company Subsidiary Securities**").

Section 3.03 Authority; Non-Contravention; Governmental Consents; Board Approval; Anti-Takeover Statutes.

(a) Authority. The Company has all requisite corporate power and authority to enter into and to perform its obligations under this Agreement and, subject to, in the case of the consummation of the Asset Acquisition, adoption of this Agreement by the affirmative vote of two thirds of the holders of shares of Company Ordinary Shares that are present in person or by proxy at a meeting of shareholders (the "**Requisite Company Vote**"), to consummate the transactions contemplated by this Agreement. The execution and delivery of this Agreement by the Company and, upon the execution of the Asset Acquisition, the consummation by the Company of the transactions contemplated hereby have been duly authorized by all necessary corporate action on the part of the Company and no other corporate proceedings on the part of the Company are necessary to authorize the execution and delivery of this Agreement or to consummate the Asset Acquisition and the other transactions contemplated hereby, subject only, in the case of consummation of the Asset Acquisition, to the receipt of the Requisite Company Vote. The Requisite Company Vote is the only vote or consent of the holders of any class or series of the Company's capital stock necessary to approve and adopt this Agreement, approve the Asset Acquisition, and consummate the Asset Acquisition and the other transactions contemplated hereby. This Agreement has been duly executed and delivered by the Company and, assuming due execution and delivery by Parent and Acquisition Sub, constitutes the legal, valid, and binding obligation of the Company, enforceable against the Company in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, moratorium, and other similar Laws affecting creditors' rights generally and by general principles of equity.

(b) Non-Contravention. The execution, delivery, and performance of this Agreement by the Company, and the consummation by the Company of the transactions contemplated by this Agreement, including the Asset Acquisition, do not and will not: (i) subject to obtaining the Requisite Company Vote, contravene or conflict with, or result in any violation or breach of, the Charter Documents of the Company or any of its Subsidiaries; (ii) assuming that all Consents contemplated by clauses (i) through (v) of Section 3.03(c) have been obtained or made and, in the case of the consummation of the Asset Acquisition, obtaining the Requisite Company Vote, conflict with or violate any Law applicable to the Company, any of its Subsidiaries, or any of their respective properties or assets; (iii) result in any breach of or constitute a default (or an event that with notice or lapse of time or both would become a default) under, result in the Company's or any of its Subsidiaries' loss of any benefit or the imposition of any additional payment or other liability under, or alter the rights or obligations of any third-party under, or give to any third-party any rights of termination, amendment, acceleration, or cancellation, or require any Consent under, any Contract to which the Company or any of its Subsidiaries is a party or otherwise bound as of the date hereof; or (iv) result in the creation of a Lien (other than Permitted Liens) on any of the properties or assets of the Company or any of its Subsidiaries, except, in the case of each of clauses (ii), (iii), and (iv), for any conflicts, violations, breaches, defaults, loss of benefits, additional payments or other liabilities, alterations, terminations, amendments, accelerations, cancellations, or Liens that, or where the failure to obtain any Consents, in each case, would not reasonably be expected to have, individually or in the aggregate, a Company Material Adverse Effect.

(c) Governmental Consents. No consent, approval, order, or authorization of, or registration, declaration, or filing with, or notice to (any of the foregoing being a "**Consent**"), any supranational, national, state, municipal, local, or foreign government, any instrumentality, subdivision, court, administrative agency or commission, or other governmental authority, or any quasi-governmental or private body exercising any regulatory or other governmental or quasi-governmental authority (a "**Governmental Entity**") is required to be obtained or made by the Company in connection with the execution, delivery, and performance by the Company of this Agreement or the consummation by the Company of the Asset Acquisition and other transactions contemplated hereby, except for: (i) the filing of the resolution approving the Asset Acquisition with the applicable Governmental Entity; (ii) the filing with the Securities and Exchange Commission ("**SEC**") of (A) the Form S-4, and the declaration of its effectiveness under the Securities Act of 1933, as amended (the "**Securities Act**"), and (B) such reports under the Securities Exchange Act of 1934, as amended (the "**Exchange Act**") as may be required in connection with this Agreement, the Asset Acquisition, and the other transactions contemplated by this Agreement; (iii) such Consents as may be required under (A) the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (the "**HSR Act**") or (B) any other Laws that are designed or intended to prohibit, restrict, or regulate actions having the purpose or effect of monopolization or restraint of trade or significant impediments or lessening of competition or creation or strengthening of a dominant position through Asset Acquisition or acquisition ("**Foreign Antitrust Laws**" and, together with the HSR Act, the "**Antitrust Laws**"), in any case that are applicable to the transactions contemplated by this Agreement; (iv) such Consents as may be required under applicable state securities or "blue sky" Laws and the securities Laws of any foreign country

or the rules and regulations of any applicable stock exchange; (v) the other Consents of Governmental Entities listed in Section 3.03(c) of the Company Disclosure Letter (the "**Other Governmental Approvals**"); and (vi) such other Consents which if not obtained or made would not reasonably be expected to have, individually or in the aggregate, a Company Material Adverse Effect.

(d) Board Approval. The Company Board, by resolutions duly adopted by a unanimous vote at a meeting of all directors of the Company duly called and held and, not subsequently rescinded or modified in any way, has: (i) determined that this Agreement and the transactions contemplated hereby, including the Asset Acquisition, upon the terms and subject to the conditions set forth herein, are fair to, and in the best interests of, the Company and the Company's stockholders; (ii) approved and declared advisable this Agreement, including the execution, delivery, and performance thereof, and the consummation of the transactions contemplated by this Agreement, including the Asset Acquisition, upon the terms and subject to the conditions set forth herein; (iii) directed that this Agreement be submitted to a vote of the Company's stockholders for adoption at the Company Stockholders Meeting; and (iv) resolved to recommend that Company stockholders vote in favor of adoption of this Agreement in accordance with the DCA (collectively, the "**Company Board Recommendation**").

(e) Anti-Takeover Statutes. No "fair price," "moratorium," "control share acquisition," "supermajority," "affiliate transactions," "business combination," or other similar anti-takeover statute or regulation enacted under any federal, state, local, or foreign laws applicable to the Company is applicable to this Agreement, the Asset Acquisition, or any of the other transactions contemplated by this Agreement.

ARTICLE IV
REPRESENTATIONS AND WARRANTIES OF PARENT

Except as set forth in the correspondingly numbered Section of the Parent Disclosure Letter that relates to such Section or in another Section of the Parent Disclosure Letter to the extent that it is reasonably apparent on the face of such disclosure that such disclosure is applicable to such Section, Parent represents and warrants to the Company as follows:

Section 4.01 Organization; Standing and Power; Charter Documents; Subsidiaries.

(a) Organization; Standing and Power. Each of Parent and its Subsidiaries is a corporation, limited liability company, or other legal entity duly organized, validly existing, and in good standing (to the extent that the concept of "good standing" is applicable in the case of any jurisdiction outside the United States) under the Laws of its jurisdiction of organization, and has the requisite corporate, limited liability company, or other organizational, as applicable, power and authority to own, lease, and operate its assets and to carry on its business as now conducted. Each of Parent and its Subsidiaries is duly qualified or licensed to do business as a foreign corporation, limited liability company, or other legal entity and is in good standing (to the extent that the concept of "good standing" is applicable in the case of any jurisdiction outside the United States) in each jurisdiction where the character of the assets and properties owned, leased, or operated by it or the nature of its business makes such qualification or license necessary, except where the failure to be so qualified or licensed or to be in good standing, would not reasonably be expected to have, individually or in the aggregate, a Parent Material Adverse Effect.

(b) Charter Documents. The copies of the Certificate of Incorporation and By-Laws of Parent as most recently provided to the Company are true, correct, and complete copies of such documents as in effect as of the date of this Agreement. Parent has delivered or made available to the Company a true and correct copy of the Charter Documents of Acquisition Sub that are intended to be Charter Documents of Acquisition Sub on the Closing Date. The Parent is not in violation of any of the provisions of its Charter Documents.

(c) Subsidiaries. All of the outstanding shares of capital stock of, or other equity or voting interests in, each Subsidiary of Parent have been validly issued and are owned by Parent, directly or indirectly, free of pre-emptive rights, are fully paid and non-assessable, and are free and clear of all Liens, including any restriction on the right to vote, sell, or otherwise dispose of such capital stock or other equity or voting interests, except for any Liens: (i) imposed by applicable securities Laws; or (ii) arising pursuant to the Charter Documents of any non-wholly-owned Subsidiary of Parent. Except for the capital stock of, or other equity or voting interests in, its Subsidiaries, Parent does not own, directly or indirectly, any capital stock of, or other equity or voting interests in, any Person.

Section 4.02 Capital Structure.

(a) Capital Stock. The authorized capital stock of Parent consists of: (i) 20,000,000 shares of Parent Common Stock, par value $0.0001, and (ii) 5,000,000 shares of preferred stock, par value $0.001 per share, of Parent (the "**Parent Preferred Stock**"). As of the date of this Agreement: (A) one (1) share of Parent Common Stock was issued and outstanding and (B) no shares of Parent Preferred Stock were issued and outstanding or held by Parent in its treasury. All of the outstanding shares of capital stock of Parent are, and all shares of capital stock of Parent which may be issued as contemplated or permitted by this Agreement, including the shares of Parent Common Stock constituting the Asset Acquisition Consideration, will be, when issued, duly authorized, validly issued, fully paid, and non-assessable, and not subject to any pre-emptive rights. No Subsidiary of Parent owns any shares of Parent Common Stock.

(b) Stock Awards.

(i) As of the date of this Agreement, the Parent intends to reserve an amount equal to approximately fifteen percent (15%) of the issued and outstanding shares of Parent Common Stock as of the Effective Date for issuance pursuant to Parent Equity Awards not yet granted under the Parent Stock Plans. As of the date of this Agreement, no shares of Parent Common Stock were reserved for issuance pursuant to outstanding Parent Stock Options. All shares of Parent Common Stock subject to issuance under the Parent Stock Plans, including the Parent Equity Awards constituting Asset Acquisition Consideration to be issued pursuant to Section 2.06, upon issuance in accordance with the terms and conditions specified in the instruments pursuant to which they are issuable, will be duly authorized, validly issued, fully paid, and non-assessable.

(ii) As of the date hereof, there are no outstanding Contracts requiring Parent or any of its Subsidiaries to repurchase, redeem, or otherwise acquire any Parent Securities or Parent Subsidiary Securities. Neither Parent nor any of its Subsidiaries is a party to any voting agreement with respect to any Parent Securities or Parent Subsidiary Securities.

(c) Voting Debt. No bonds, debentures, notes, or other indebtedness issued by Parent or any of its Subsidiaries: (i) having the right to vote on any matters on which stockholders or equity holders of Parent or any of its Subsidiaries may vote (or which is convertible into, or exchangeable for, securities having such right); or (ii) the value of which is directly based upon or derived from the capital stock, voting securities, or other ownership interests of Parent or any of its Subsidiaries, are issued or outstanding (collectively, "**Parent Voting Debt**").

(d) Parent Subsidiary Securities. As of the date hereof, there are no outstanding: (i) securities of Parent or any of its Subsidiaries convertible into or exchangeable for Parent Voting Debt, capital stock, voting securities, or other ownership interests in any Subsidiary of Parent; (ii) options, warrants, or other agreements or commitments to acquire from Parent or any of its Subsidiaries, or obligations of Parent or any of its Subsidiaries to issue, any Parent Voting Debt, capital stock, voting securities, or other ownership interests in (or securities convertible into or exchangeable for capital stock, voting securities, or other ownership interests in) any Subsidiary of Parent; or (iii) restricted shares, restricted stock units, stock appreciation rights, performance shares, profit participation rights, contingent value rights, "phantom" stock, or similar securities or rights that are derivative of, or provide economic benefits based, directly or indirectly, on the value or price of, any capital stock or voting securities of, or other ownership interests in, any Subsidiary of Parent, in each case that have been issued by a Subsidiary of Parent (the items in clauses (i), (ii), and (iii), together with the capital stock, voting securities, or other ownership interests of such Subsidiaries, being referred to collectively as "**Parent Subsidiary Securities**").

Section 4.03 Authority; Non-Contravention; Governmental Consents; Board Approval.

(a) Authority. The Parent has all requisite corporate power and authority to enter into and to perform its obligations under this Agreement and, subject to, in the case of the consummation of the Asset Acquisition: (i) the adoption of this Agreement by Parent as the sole stockholder of Acquisition Sub; and (ii) the need to obtain the affirmative vote or consent of majority of the outstanding shares of the Parent Common Stock to the Parent Stock Issuance and the affirmative vote of a majority of the holders of shares of Acquisition Sub's common stock that are present in person or by proxy at a meeting of shareholders (the "**Requisite Parent Vote**"), to consummate the transactions contemplated by this Agreement. The execution and delivery of this Agreement by Parent and the consummation by Parent of the transactions contemplated by this Agreement have been duly authorized by all necessary corporate action on the part of Parent and no other corporate proceedings on the part of Parent are necessary to authorize the execution

and delivery of this Agreement or upon the execution of the Asset Acquisition to consummate the Asset Acquisition, the Parent Stock Issuance, and the other transactions contemplated by this Agreement, subject only, in the case of consummation of the Asset Acquisition, to: (i) the adoption of this Agreement by Parent as the sole stockholder of Acquisition Sub; and (ii) the need to obtain the Requisite Parent Vote. This Agreement has been duly executed and delivered by Parent and, assuming due execution and delivery by the Company, constitutes the legal, valid, and binding obligation of Parent, enforceable against Parent in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, moratorium, and other similar Laws affecting creditors' rights generally and by general principles of equity.

(b) Non-Contravention. The execution, delivery, and performance of this Agreement by Parent and the consummation by Parent and Acquisition Sub of the transactions contemplated by this Agreement, do not and will not: (i) contravene or conflict with, or result in any violation or breach of, the Charter Documents of Parent or Acquisition Sub; (ii) assuming that all of the Consents contemplated by clauses (i) through (v) of Section 4.03(c) have been obtained or made, and in the case of the consummation of the Asset Acquisition, upon the execution of the Asset Acquisition, obtaining the Requisite Parent Vote, conflict with or violate any Law applicable to Parent or Acquisition Sub or any of their respective properties or assets; (iii) result in any breach of or constitute a default (or an event that with notice or lapse of time or both would become a default) under, result in Parent's or any of its Subsidiaries' loss of any benefit or the imposition of any additional payment or other liability under, or alter the rights or obligations of any third-party under, or give to any third-party any rights of termination, amendment, acceleration, or cancellation, or require any Consent under, any Contract to which Parent or any of its Subsidiaries is a party or otherwise bound as of the date hereof; or (iv) result in the creation of a Lien (other than Permitted Liens) on any of the properties or assets of Parent or any of its Subsidiaries, except, in the case of each of clauses (ii), (iii), and (iv), for any conflicts, violations, breaches, defaults, loss of benefits, additional payments or other liabilities, alterations, terminations, amendments, accelerations, cancellations, or Liens that, or where the failure to obtain any Consents, in each case, would not reasonably be expected to have, individually or in the aggregate, a Parent Material Adverse Effect.

(c) Governmental Consents. No Consent of any Governmental Entity is required to be obtained or made by Parent or Acquisition Sub in connection with the execution, delivery, and performance by Parent and Acquisition Sub of this Agreement or the consummation by Parent and Acquisition Sub of the Asset Acquisition, the Parent Stock Issuance, and the other transactions contemplated hereby, except for: : (i) the filing of the resolution approving the Asset Acquisition with the applicable Governmental Entity; (ii) the filing with the Securities and Exchange Commission ("**SEC**") of (A) the Form S-4, and the declaration of its effectiveness under the Securities Act of 1933, as amended (the "**Securities Act**"), and (B) such reports under the Securities Exchange Act of 1934, as amended (the "**Exchange Act**") as may be required in connection with this Agreement, the Asset Acquisition, and the other transactions contemplated by this Agreement; (iii) such Consents as may be required under (A) the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (the "**HSR Act**") or (B) any other Laws that are designed or intended to prohibit, restrict, or regulate actions having the purpose or effect of monopolization or restraint of trade or significant impediments or lessening of competition or creation or strengthening of a dominant position through Asset Acquisition or acquisition ("**Foreign Antitrust Laws**" and, together with the HSR Act, the "**Antitrust Laws**"), in any case that are applicable to the transactions contemplated by this Agreement; (iv) such Consents as may be required under applicable state securities or "blue sky" Laws and the securities Laws of any foreign country or the rules and regulations of any applicable stock exchange; (v) the other Consents of Governmental Entities listed in Section 4.03(c) of the Parent Disclosure Letter (the "**Other Governmental Approvals**"); and (vi) such other Consents which if not obtained or made would not reasonably be expected to have, individually or in the aggregate, a Parent Material Adverse Effect.

(d) Board Approval.

(i) The Parent Board by resolutions duly adopted by a unanimous written consent of all directors of Parent duly called and held and, not subsequently rescinded or modified in any way, has (A) determined that this Agreement and the transactions contemplated hereby, including the Asset Acquisition, and the Parent Stock Issuance, upon the terms and subject to the conditions set forth herein, are fair to, and in the best interests of, Parent and the Parent's stockholders, (B) approved and declared advisable this Agreement, including the execution, delivery, and performance thereof, and the consummation of the transactions contemplated by this Agreement, including the Asset Acquisition and the Parent Stock Issuance, upon the terms and subject to the conditions set forth herein, (C) directed that the Parent Stock Issuance be submitted to a vote of the Parent's stockholders for adoption by written consent, and (D) resolved to recommend that Parent's stockholders vote in favor of approval of the Parent Stock Issuance (collectively, the "**Parent Board Recommendation**").

Section 4.04 **Acquisition Sub.** Acquisition Sub: (a) has engaged in no business activities other than those related to the transactions contemplated by this Agreement; and (b) when formed, will be a direct, wholly-owned Subsidiary of Parent.

ARTICLE V
COVENANTS

Section 5.01 **Conduct of Business of the Company.** During the period from the date of this Agreement until the Effective Time, the Company shall, and shall cause each of its Subsidiaries, except as expressly contemplated by this Agreement, as required by applicable Law, or with the prior written consent of Parent (which consent shall not be unreasonably withheld, conditioned, or delayed), to conduct its business in the ordinary course of business consistent with past practice, and, to the extent consistent therewith, the Company shall, and shall cause each of its Subsidiaries to, use its reasonable best efforts to preserve substantially intact its and its Subsidiaries' business organization, to keep available the services of its and its Subsidiaries' current officers and employees, to preserve its and its Subsidiaries' present relationships with customers, suppliers, distributors, licensors, licensees, and other Persons having business relationships with it. Without limiting the generality of the foregoing, between the date of this Agreement and the Effective Time, except as otherwise expressly contemplated by this Agreement, or as required by applicable Law, the Company shall not, nor shall it permit any of its Subsidiaries to, without the prior written consent of Parent (which consent shall not be unreasonably withheld, conditioned, or delayed):

(a) amend or propose to amend its Charter Documents;

(b) (i) split, combine, or reclassify any Company Securities or Company Subsidiary Securities, (ii) repurchase, redeem, or otherwise acquire, or offer to repurchase, redeem, or otherwise acquire, any Company Securities or Company Subsidiary Securities, or (iii) declare, set aside, or pay any dividend or distribution (whether in cash, stock, property, or otherwise) in respect of, or enter into any Contract with respect to the voting of, any shares of its capital stock (other than dividends from its direct or indirect wholly-owned Subsidiaries);

(c) except as specifically set forth in the Parent Disclosure Letter, issue, sell, pledge, dispose of, or encumber any Company Securities or Company Subsidiary Securities, other than the issuance of shares of Company Ordinary Shares upon the exercise of any Company Equity Award outstanding as of the date of this Agreement in accordance with its terms;

(d) except as specifically set forth in the Parent Disclosure Letter and except as required by applicable Law or by any Company Employee Plan or Contract in effect as of the date of this Agreement (i) increase the compensation payable or that could become payable by the Company or any of its Subsidiaries to directors, officers, or employees, other than increases in compensation made to non-officer employees in the ordinary course of business consistent with past practice, (ii) promote any officers or employees, except in connection with the Company's annual or quarterly compensation review cycle or as the result of the termination or resignation of any officer or employee, or (iii) establish, adopt, enter into, amend, terminate, exercise any discretion under, or take any action to accelerate rights under any Company Employee Plans or any plan, agreement, program, policy, trust, fund, or other arrangement that would be a Company Employee Plan if it were in existence as of the date of this Agreement, or make any contribution to any Company Employee Plan, other than contributions required by Law, the terms of such Company Employee Plans as in effect on the date hereof, or that are made in the ordinary course of business consistent with past practice;

(e) acquire, by Asset Acquisition, consolidation, acquisition of stock or assets, or otherwise, any business or Person or division thereof or make any loans, advances, or capital contributions to or investments in any Person;

(f) (i) except as specifically set forth in the Parent Disclosure Letter, transfer, license, sell, lease, or otherwise dispose of (whether by way of Asset Acquisition, consolidation, sale of stock or assets, or otherwise) or pledge, encumber, mortgage, or otherwise subject to any Lien (other than a Permitted Lien), any assets, including the capital stock or other equity interests in any Subsidiary of the Company; *provided, that* the foregoing shall not prohibit the Company and its Subsidiaries from transferring, selling, leasing, or disposing of obsolete equipment or assets being replaced, or granting non-exclusive licenses under the Company IP, in each case in the ordinary course of business consistent with past practice, or (ii) adopt or effect a plan of complete or partial liquidation, dissolution, restructuring, recapitalization, or other reorganization;

(g) except as specifically set forth in the Parent Disclosure Letter, repurchase, prepay, or incur any indebtedness for borrowed money or guarantee any such indebtedness of another Person, issue or sell any debt securities or options, warrants, calls, or other rights to acquire any debt securities of the Company or any of its Subsidiaries, guarantee any debt securities of another Person, enter into any "keep well" or other Contract to maintain any financial statement condition of any other Person (other than any wholly-owned Subsidiary of it) or enter into any arrangement having the economic effect of any of the foregoing, other than in connection with the financing of ordinary course trade payables consistent with past practice;

(h) except as specifically set forth in the Parent Disclosure Letter, enter into or amend or modify in any material respect, or consent to the termination of (other than at its stated expiry date), any Company Material Contract or any Lease with respect to material Real Estate or any other Contract or Lease that, if in effect as of the date hereof would constitute a Company Material Contract or Lease with respect to material Real Estate hereunder;

(i) institute, settle, or compromise any Legal Action involving the payment of monetary damages by the Company or any of its Subsidiaries of any amount exceeding $100,000 in the aggregate, other than (i) any Legal Action brought against Parent or Acquisition Sub arising out of a breach or alleged breach of this Agreement by Parent or Acquisition Sub, and (ii) the settlement of claims, liabilities, or obligations reserved against on the Company Balance Sheet; *provided, that* neither the Company nor any of its Subsidiaries shall settle or agree to settle any Legal Action which settlement involves a conduct remedy or injunctive or similar relief or has a restrictive impact on the Company's business;

(j) make any material change in any method of financial accounting principles or practices, in each case except for any such change required by a change to, or in, GAAP or applicable Law;

(k) (i) settle or compromise any material Tax claim, audit, or assessment for an amount materially in excess of the amount reserved or accrued on the Company Balance Sheet, (ii) make or change any material Tax election, change any annual Tax accounting period, or adopt or change any method of Tax accounting, (iii) amend any material Tax Returns or file claims for material Tax refunds, or (iv) enter into any material closing agreement, surrender in writing any right to claim a material Tax refund, offset or other reduction in Tax liability or consent to any extension or waiver of the limitation period applicable to any material Tax claim or assessment relating to the Company or its Subsidiaries;

(l) enter into any material agreement, agreement in principle, letter of intent, memorandum of understanding, or similar Contract with respect to any joint venture, strategic partnership, or alliance;

(m) except in connection with actions permitted by Section 5.04 hereof, take any action to exempt any Person from, or make any acquisition of securities of the Company by any Person not subject to, any state takeover statute or similar statute or regulation that applies to Company with respect to a Takeover Proposal or otherwise, including the restrictions on "business combinations" set forth in Section 203 of the DGCL, except for Parent, Acquisition Sub, or any of their respective Subsidiaries or Affiliates, or the transactions contemplated by this Agreement;

(n) except as specifically set forth in the Parent Disclosure Letter, abandon, allow to lapse, sell, assign, transfer, grant any security interest in otherwise encumber or dispose of any material Company IP, or grant any right or license to any material Company IP other than pursuant to non-exclusive licenses entered into in the ordinary course of business consistent with past practice;

(o) terminate or modify in any material respect, or fail to exercise renewal rights with respect to, any material insurance policy;

(p) engage in any transaction with, or enter into any agreement, arrangement or understanding with, any Affiliate of the Company or other Person covered by Item 404 of Regulation S-K promulgated by the SEC that would be required to be disclosed pursuant to Item 404 of Regulation S-K promulgated by the SEC;

(q) adopt or implement any stockholder rights plan or similar arrangement; or

(r) agree or commit to do any of the foregoing.

Section 5.02 Conduct of the Business of Parent. During the period from the date of this Agreement until the Effective Time, Parent shall, and shall cause each of its Subsidiaries, except as expressly contemplated by this Agreement, as set forth in Section 5.02 of the Parent Disclosure Letter, as required by applicable Law, or with the prior written consent of the Company (which consent shall not be unreasonably withheld, conditioned, or delayed), conduct its business in the ordinary course of business. Without limiting the generality of the foregoing, between the date of this Agreement and the Effective Time, except as otherwise expressly contemplated by this Agreement, as set forth in Section 5.02 of the Parent Disclosure Letter, or as required by applicable Law, Parent shall not, nor shall it permit any of its Subsidiaries to, without the prior written consent of the Company (which consent shall not be unreasonably withheld, conditioned, or delayed):

(a) amend its Charter Documents in a manner that would adversely affect the Company or the holders of Company Ordinary Shares relative to the other holders of Parent Common Stock;

(b) (i) split, combine, or reclassify any Parent Securities or Parent Subsidiary Securities in a manner that would adversely affect the Company or the holders of Company Ordinary Shares relative to the other holders of Parent Common Stock, (ii) repurchase, redeem, or otherwise acquire, or offer to repurchase, redeem, or otherwise acquire, any Parent Securities or Parent Subsidiary Securities, or (iii) declare, set aside, or pay any dividend or distribution (whether in cash, stock, property, or otherwise) in respect of, or enter into any Contract with respect to the voting of, any shares of its capital stock (other than dividends from its direct or indirect wholly-owned Subsidiaries and ordinary quarterly dividends, consistent with past practice with respect to timing of declaration and payment);

(c) issue, sell, pledge, dispose of, or encumber any Parent Securities or Parent Subsidiary Securities, other than (i) the issuance of shares of Parent Common Stock upon the exercise of any Parent Equity Awards outstanding as of the date of this Agreement in accordance with its terms, (ii) the issuance of shares of Parent Common Stock in connection with or upon the exercise of any Parent Equity Awards granted after the date hereof in the ordinary course of business, and (iii) sales or issuances of shares of Parent Common Stock or convertible securities in the amount of the PIPE Investment;

(d) acquire, by Asset Acquisition, consolidation, acquisition of stock or assets, or otherwise, any business or Person or division thereof or make any loans, advances, or capital contributions to or investments in any Person, in each case that would reasonably be expected to prevent, impede, or materially delay the consummation of the Asset Acquisition or other transactions contemplated by this Agreement;

(e) adopt or effect a plan of complete or partial liquidation, dissolution, restructuring, recapitalization, or other reorganization; or

(f) agree or commit to do any of the foregoing.

Section 5.03 Preparation of Proxy/Information Statement and Form S-4.

(a) Proxy/Information Statement and Form S-4. In connection with the Company Stockholders Meeting, as soon as reasonably practicable following the date of this Agreement, the Company and Parent shall prepare and file with the SEC the Proxy/Information Statement and the Form S-4 (which shall include the Proxy/Information Statement). The Company and Parent shall each use its reasonable best efforts to: (i) cause the Form S-4 to be declared effective under the Securities Act as promptly as practicable after its filing; (ii) ensure that the Form S-4 complies in all material respects with the applicable provisions of the Securities Act and the Exchange Act; and (iii) keep the Form S-4 effective for so long as necessary to complete the Asset Acquisition. Parent shall notify the Company promptly of the time when the Form S-4 has become effective or any supplement or amendment to the Form S-4 has been filed, and of the issuance of any stop order or suspension of the qualification of the shares of Parent Common Stock issuable in connection with the Asset Acquisition for offering or sale in any jurisdiction. Each of Parent and the Company shall use its reasonable best efforts to: (A) cause the Proxy/Information Statement to be mailed to the Company's stockholders as promptly as practicable after the Form S-4 is declared effective under the Securities Act, and (B) ensure that the Proxy/Information Statement complies in all material respects with the applicable provisions of the Securities Act and Exchange Act. Parent shall also take any other action (other than qualifying to do business in any jurisdiction in which it is not now so qualified) required to be taken under the Securities Act, the Exchange Act, any applicable foreign or state securities or "blue sky" Laws, and the rules and regulations thereunder in connection with the issuance of Parent Stock in the Asset Acquisition, and the Company shall furnish to Parent all information concerning the Company as may be reasonably requested in connection with any such actions.

(b) Furnishing of Information. Parent and the Company shall furnish to the other party all information concerning such Person and its Affiliates required by the Securities Act or the Exchange Act to be set forth in the Form S-4 or the Proxy/Information Statement. Each of Parent and the Company shall promptly correct any information provided by it for use in the Form S-4 or the Proxy/Information Statement if and to the extent that such information shall have become false or misleading in any material respect. Each of Parent and the Company shall take all steps necessary to amend or supplement the Form S-4 or the Proxy/Information Statement, as applicable, and to cause the Form S-4 or Proxy/Information Statement, as so amended or supplemented, to be filed with the SEC and disseminated to the holders of Company Ordinary Shares to the extent required by applicable Law.

Section 5.04 Company Stockholders Meeting. The Company shall take all action necessary to duly call, give notice of, convene, and hold the Company Stockholders Meeting as soon as reasonably practicable after the Form S-4 is declared effective, and, in connection therewith, the Company shall mail the Proxy/Information Statement to the holders of Company Ordinary Shares in advance of such meeting.

Section 5.05 Parent Stockholders Meeting; Approval by Sole Stockholder of Acquisition Sub.

(a) Parent Stockholders Meeting. Parent shall take all action necessary to duly call, give notice of, convene, and hold a meeting of Parent's stockholders (or solicitation of written consents) (the "**Parent Stockholders Meeting**") as soon as reasonably practicable after the Form S-4 is declared effective, and, in connection therewith, Parent shall use reasonable best efforts to: (i) obtain from the holder of Parent Common Stock written consents approving the Parent Stock Issuance; and (ii) take all other actions necessary or advisable to secure the vote or consent of the holders of Parent Common Stock required by applicable Law to obtain such approval.

(b) Approval by Sole Stockholder. Promptly following the execution and delivery of this Agreement, Parent, as sole stockholder of Acquisition Sub, shall adopt this Agreement and approve the Asset Acquisition, in accordance with the DCA.

Section 5.06 Notices of Certain Events. Subject to applicable Law, the Company shall notify Parent and Acquisition Sub, and Parent and Acquisition Sub shall notify the Company, promptly of: (a) any notice or other communication from any Person alleging that the consent of such Person is or may be required in connection with the transactions contemplated by this Agreement; (b) any notice or other communication from any Governmental Entity in connection with the transactions contemplated by this Agreement; and (c) any event, change, or effect between the date of this Agreement and the Effective Time which individually or in the aggregate causes or is reasonably likely to cause or constitute: (i) a material breach of any of its representations, warranties, or covenants contained herein, or (ii) the failure of any of the conditions set forth in ARTICLE VI of this Agreement to be satisfied; provided that, (any failure to give notice in accordance with the foregoing with respect to any breach shall not be deemed to constitute a violation of this Section 5.08 or the failure of any condition set forth in ARTICLE VI to be satisfied, or otherwise constitute a breach of this Agreement by the party failing to give such notice, in each case unless the underlying breach would independently result in a failure of the conditions set forth in ARTICLE VI to be satisfied; and provided, further, that) the delivery of any notice pursuant to this Section 5.06 shall not cure any breach of, or noncompliance with, any other provision of this Agreement or limit the remedies available to the party receiving such notice.

Section 5.07 Employees; Benefit Plans.

(a) Comparable Salary and Benefits. During the period commencing at the Effective Time and ending on the date which is six months from the Effective Time (or if earlier, the date of the employee's termination of employment with Parent and its Subsidiaries), and to the extent consistent with the terms of the governing plan documents, Parent shall cause the Surviving Corporation and each of its Subsidiaries, as applicable, to provide the employees of the Company and its Subsidiaries who remain employed immediately after the Effective Time (collectively, the "**Company Continuing Employees**") with annual base salary or wage level, annual target bonus opportunities (excluding equity-based compensation or bonuses based upon the sale or disposition of the Company's drug candidates), and employee benefits (excluding any retiree health or defined benefit retirement benefits) that are, in the aggregate, substantially comparable to the annual base salary or wage level, annual target bonus opportunities (excluding equity-based compensation), and employee benefits (excluding any retiree health or defined benefit retirement benefits) provided by the Company and its Subsidiaries on the date of this Agreement.

(b) Crediting Service. With respect to any "employee benefit plan" as defined in Section 3(3) of ERISA maintained by Parent or any of its Subsidiaries, excluding any retiree health plans or programs maintained by Parent or any of its Subsidiaries, any defined benefit retirement plans or programs maintained by Parent or any of its Subsidiaries, and any equity compensation arrangements maintained by Parent or any of its Subsidiaries (collectively, "**Parent Benefit Plans**") in which any Company Continuing Employees will participate effective as of the Effective Time, and subject to the terms of the governing plan documents, Parent shall, or shall cause the Surviving Corporation to, credit all service of the Company Continuing Employees with the Company or any of its Subsidiaries, as the case may be as if such service were with Parent, for purposes of eligibility to participate (but not for purposes of vesting or benefit accrual, except for vacation, if applicable) for full or partial years of service in any Parent Benefit Plan in which such Company Continuing Employees may be eligible to participate after the Effective Time; *provided, that* such service shall not be credited to the extent that: (i) such crediting would result in a duplication of benefits; or (ii) such service was not credited under the corresponding Company Employee Plan.

(c) Employees Not Third-Party Beneficiaries. This Section 5.07 shall be binding upon and inure solely to the benefit of each of the parties to this Agreement, and nothing in this Section 5.07, express or implied, shall confer upon any Company Employee, any beneficiary, or any other Person any rights or remedies of any nature whatsoever under or by reason of this Section 5.07. Nothing contained herein, express or implied: (i) shall be construed to establish, amend, or modify any benefit plan, program, agreement, or arrangement; (ii) shall alter or limit the ability of the Surviving Corporation, Parent, or any of their respective Affiliates to amend, modify, or terminate any benefit plan, program, agreement, or arrangement at any time assumed, established, sponsored, or maintained by any of them; or (iii) shall prevent the Surviving Corporation, Parent, or any of their respective Affiliates from terminating the employment of any Company Continuing Employee following the Effective Time. The parties hereto acknowledge and agree that the terms set forth in this Section 5.07 shall not create any right in any Company Employee or any other Person to any continued employment with the Surviving Corporation, Parent, or any of their respective Subsidiaries or compensation or benefits of any nature or kind whatsoever, or otherwise alters any existing at-will employment relationship between any Company Employee and the Surviving Corporation.

Section 5.08 Directors' and Officers' Indemnification and Insurance.

(a) Indemnification. Parent and Acquisition Sub agree that all rights to indemnification, advancement of expenses, and exculpation by the Company now existing in favor of each Person who is now, or has been at any time prior to the date hereof or who becomes prior to the Effective Time an officer or director of the Company or any of its Subsidiaries (each an "**Indemnified Party**") as provided in the Charter Documents of the Company, in each case as in effect on the date of this Agreement, or pursuant to any other Contracts in effect on the date hereof and disclosed in Section 5.08 of the Company Disclosure Letter, shall be assumed by the Surviving Corporation in the Asset Acquisition, without further action, at the Effective Time and shall survive the Asset Acquisition and shall remain in full force and effect in accordance with their terms. For a period of three years from the Effective Time, the Surviving Corporation shall, and Parent shall cause the Surviving Corporation to, maintain in effect the exculpation, indemnification, and advancement of expenses equivalent to the provisions of the Charter Documents of the Company as in effect immediately prior to the Effective Time with respect to acts or omissions by any Indemnified Party occurring prior to the Effective Time, and shall not amend, repeal, or otherwise modify any such provisions in any manner that would adversely affect the rights thereunder of any Indemnified Party; provided that all rights to indemnification in respect of any claim made for indemnification within such period shall continue until the disposition of such action or resolution of such claim.

(b) Insurance. The Surviving Corporation shall, and Parent shall cause the Surviving Corporation to: (i) obtain as of the Effective Time "tail" insurance policies with a claims period of three years from the Effective Time with at least the same coverage and amounts and containing terms and conditions that are not less advantageous to the Indemnified Parties, in each case with respect to claims arising out of or relating to events which occurred before or at the Effective Time (including in connection with the transactions contemplated by this Agreement); provided, however, that in no event will the Surviving Corporation be required to expend an annual premium for such coverage in excess of 100% percent of the last annual premium paid by the Company or any of its Subsidiaries for such insurance prior to the date of this Agreement, which amount is set forth in Section 5.08(b) of the Company Disclosure Letter (the "**Maximum Premium**"). If such insurance coverage cannot be obtained at an annual premium equal to or less than the Maximum Premium, the Surviving Corporation will obtain, and Parent will cause the Surviving Corporation to obtain, the greatest coverage available for a cost not exceeding an annual premium equal to the Maximum Premium.

(c) Survival. The obligations of Parent, Acquisition Sub, and the Surviving Corporation under this Section 5.08 shall survive the consummation of the Asset Acquisition and shall not be terminated or modified in such a manner as to adversely affect any Indemnified Party to whom this Section 5.08 applies without the consent of such affected Indemnified Party (it being expressly agreed that the Indemnified Parties to whom this Section 5.08 applies shall be third-party beneficiaries of this Section 5.08, each of whom may enforce the provisions of this Section 5.08).

(d) Assumptions by Successors and Assigns; No Release or Waiver. In the event Parent, the Surviving Corporation, or any of their respective successors or assigns: (i) consolidates with or merges into any other Person and shall not be the continuing or surviving corporation or entity in such consolidation or Asset Acquisition; or (ii) transfers all or substantially all of its properties and assets to any Person, then, and in either such case, proper provision shall be made so that the successors and assigns of Parent or the Surviving Corporation, as the case may be, shall assume all of the obligations set forth in this Section 5.08. The agreements and covenants contained herein shall not be deemed to be exclusive of any other rights to which any Indemnified Party is entitled, whether pursuant to Law, Contract, or otherwise. Nothing in this Agreement is intended to, shall be construed to, or shall release, waive, or impair any rights to directors' and officers' insurance claims under any policy that is or has been in existence with respect to the Company or its officers, directors, and employees, it being understood and agreed that the indemnification provided for in this Section 5.08 is not prior to, or in substitution for, any such claims under any such policies.

Section 5.09 Reasonable Best Efforts.

(a) Governmental and Other Third-Party Approval; Cooperation and Notification. Upon the terms and subject to the conditions set forth in this Agreement (including those contained in this Section 5.09), each of the parties hereto shall, and shall cause its Subsidiaries to, use its reasonable best efforts to take, or cause to be taken, all actions, and to do, or cause to be done, and to assist and cooperate with the other parties in doing, all things necessary, proper, or advisable to consummate and make effective, and to satisfy all conditions to, in the most expeditious manner practicable (and in any event no later than the End Date), the Asset Acquisition and the other transactions contemplated by this Agreement, including: (i) the obtaining of all necessary Permits, waivers, and actions or nonactions from Governmental Entities and the making of all necessary registrations, filings, and notifications (including filings with Governmental Entities) and the taking of all steps as may be necessary to obtain an approval or waiver from, or to avoid an action or proceeding by, any Governmental Entities; (ii) the obtaining of all necessary consents or waivers from third parties; and (iii) the execution and delivery of any additional instruments necessary to consummate the Asset Acquisition and to fully carry out the purposes of this Agreement. The Company and Parent shall, subject to applicable Law, promptly: (A) cooperate and coordinate with the other in the taking of the actions contemplated by clauses (i), (ii), and (iii) immediately above; and (B) supply the other with any information that may be reasonably required in order to effectuate the taking of such actions. Each party hereto shall promptly inform the other party or parties hereto, as the case may be, of any communication from any Governmental Entity regarding any of the transactions contemplated by this Agreement. If the Company, on the one hand, or Parent or Acquisition Sub, on the other hand, receives a request for additional information or documentary material from any Governmental Entity with respect to the transactions contemplated by this Agreement, then it shall use reasonable best efforts to make, or cause to be made, as soon as reasonably practicable and after consultation with the other party, an appropriate response in compliance with such request, and, if permitted by applicable Law and by any applicable Governmental Entity, provide the other party's counsel with advance notice and the opportunity to attend and participate in any meeting with any Governmental Entity in respect of any filing made thereto in connection with the transactions contemplated by this Agreement.

(b) Governmental Antitrust Authorities. Without limiting the generality of the undertakings pursuant to Section 5.09(a) hereof, the parties hereto shall: (i) provide or cause to be provided as promptly as reasonably practicable to Governmental Entities with jurisdiction over the Antitrust Laws (each such Governmental Entity, a "**Governmental Antitrust Authority**") information and documents requested by any Governmental Antitrust Authority as necessary, proper, or advisable to permit consummation of the transactions contemplated by this Agreement as promptly as practicable following the date of this Agreement and thereafter to respond as promptly as practicable to any request for additional information or documentary material that may be made under applicable Antitrust Laws; and (ii) subject to the terms set forth in Section 5.09(c) hereof, use their reasonable best efforts to take such actions as are necessary or advisable to obtain prompt approval of the consummation of the transactions contemplated by this Agreement by any Governmental Entity or expiration of applicable waiting periods.

(c) Actions or Proceedings. In the event that any administrative or judicial action or proceeding is instituted (or threatened to be instituted) by a Governmental Entity or private party challenging the Asset Acquisition or any other transaction contemplated by this Agreement, or any other agreement contemplated hereby, the Company shall cooperate in all respects with Parent and Acquisition Sub and shall use its reasonable best efforts to contest and resist any such action or proceeding and to have vacated, lifted, reversed, or overturned any Order, whether temporary, preliminary, or permanent, that is in effect and that prohibits, prevents, or restricts consummation of the transactions contemplated by this Agreement. Notwithstanding anything in this Agreement to the contrary, none of Parent, Acquisition Sub, or any of their respective Affiliates shall be required to defend, contest, or resist any action or proceeding, whether judicial or administrative, or to take any action to have vacated, lifted, reversed, or overturned any Order, in connection with the transactions contemplated by this Agreement.

Section 5.10 Public Announcements. The initial press release with respect to this Agreement and the transactions contemplated hereby shall be a release mutually agreed to by the Company and Parent. Thereafter, each of the Company and Parent agrees that no public release, statement, announcement, or other disclosure concerning the Asset Acquisition and the other transactions contemplated hereby shall be issued by any party without the prior written consent of the other party (which consent shall not be unreasonably withheld, conditioned, or delayed), except as may be required by: (a) applicable Law, (b) court process, (c) the rules or regulations of any applicable United States or foreign securities exchange, or (d) any Governmental Entity to which the relevant party is subject or submits; provided, in each such case, that the party making the release, statement, announcement, or other disclosure shall use its reasonable best efforts to allow the other party reasonable time to comment on such release, statement, announcement, or other disclosure in advance of such issuance.

Section 5.11 Anti-Takeover Statutes. If any "control share acquisition," "fair price," "moratorium," or other anti-takeover Law becomes or is deemed to be applicable to Parent, the Acquisition Sub, the Company, the Asset Acquisition, or any other transaction contemplated by this Agreement, then each of the Company and the Company Board on the one hand, and Parent and the Parent Board on the other hand, shall grant such approvals and take such actions as are necessary so that the transactions contemplated hereby may be consummated as promptly as practicable on the terms contemplated hereby and otherwise act to render such anti-takeover Law inapplicable to the foregoing.

Section 5.12 Stock Exchange Matters.

(a) Listing of Parent Common Stock. Parent shall use its reasonable best efforts to cause the shares of Parent Common Stock to be issued in connection with the Asset Acquisition (including shares of Parent Common Stock to be reserved for issuance upon exercise of Parent Equity Awards to be issued pursuant to Section 2.06) to be listed on the Nasdaq Stock Market (or such other stock exchange as may be mutually agreed upon by the Company and Parent), subject to official notice of issuance, prior to the Effective Time.

(b) Delisting; Deregistration of Company Ordinary Shares. To the extent requested by Parent, prior to the Effective Time, the Company shall cooperate with Parent and use its reasonable best efforts to take, or cause to be taken, all actions, and do or cause to be done all things, reasonably necessary, proper or advisable on its part under applicable Laws and the rules and policies of the First North Growth Market to enable the delisting of the shares of Company Ordinary Shares from First North Growth Market as promptly as practicable after the Effective Time.

Section 5.13 Obligations of Acquisition Sub. Parent will take all action necessary to file the Certificate of Incorporation for Acquisition Sub with the State of Delaware and thereafter cause Acquisition Sub to perform its obligations under this Agreement and to consummate the Asset Acquisition on the terms and conditions set forth in this Agreement.

Section 5.14 Further Assurances. At and after the Effective Time, the officers and directors of the Surviving Corporation shall be authorized to execute and deliver, in the name and on behalf of the Company or Acquisition Sub, any deeds, bills of sale, assignments, or assurances and to take and do, in the name and on behalf of the Company or Acquisition Sub, any other actions and things to vest, perfect, or confirm of record or otherwise in the Surviving Corporation any and all right, title, and interest in, to and under any of the rights, properties, or assets of the Company acquired or to be acquired by the Surviving Corporation as a result of, or in connection with, the Asset Acquisition.

Section 5.15 Share Exchange and Extraordinary Dividend; Dissolution and Liquidation of the Company. Immediately after the Requisite Company Vote, the Company shall offer its shareholders the opportunity to exchange their ordinary shares DKK 0.5 for Parent Stock Issuance and thereafter declare an extraordinary dividend in order to distribute any remaining Parent Stock Issuance to the remaining shareholders of the Company, less any withholding required for the payment of Taxes. Promptly after completion of the share exchange offering and the payment of the extraordinary dividend, the Company shall take all necessary steps to dissolve and liquidate the Company under Part 14 of the DCA.

ARTICLE VI
CONDITIONS

Section 6.01 Conditions to Each Party's Obligation to Effect the Asset Acquisition. The respective obligations of each party to this Agreement to effect the Asset Acquisition is subject to the satisfaction or waiver (where permissible pursuant to applicable Law) on or prior to the Closing of each of the following conditions:

(a) Company Stockholder Approval. This Agreement and the Asset Acquisition and the transactions contemplated hereby will have been duly adopted by the Requisite Company Vote.

(b) Parent Stockholder Approval. The Parent Stock Issuance will have been approved by the Requisite Parent Vote.

(c) Listing. The shares of Parent Common Stock issuable as Asset Acquisition Consideration pursuant to this Agreement shall have been approved for listing on the Nasdaq Stock Market, subject to official notice of issuance.

(d) Form S-4. The Form S-4 shall have become effective under the Securities Act and shall not be the subject of any stop order.

(e) Regulatory Approvals. All waiting periods applicable to the consummation of the Asset Acquisition shall have expired or been terminated and all required filings shall have been made and all required approvals obtained (or waiting periods expired or terminated) under applicable Antitrust Laws.

(f) No Injunctions, Restraints, or Illegality. No Governmental Entity having jurisdiction over any party hereto shall have enacted, issued, promulgated, enforced, or entered any Laws or Orders, whether temporary, preliminary, or permanent, that make illegal, enjoin, or otherwise prohibit consummation of the Asset Acquisition, the Parent Stock Issuance, or the other transactions contemplated by this Agreement.

(g) [Reserved]

Section 6.02 Frustration of Closing Conditions. Neither the Company, Parent, or Acquisition Sub may rely, as a basis for not consummating the Asset Acquisition or the other transactions contemplated by this Agreement, on the failure of any condition set forth in Section 6.01 to be satisfied if such failure was caused by such party's breach in any material respect of any provision of this Agreement.

ARTICLE VII
TERMINATION, AMENDMENT, AND WAIVER

Section 7.01 Termination by Mutual Consent. This Agreement may be terminated at any time prior to the Closing (whether before or after the receipt of the Requisite Company Vote or the Requisite Parent Vote) by the mutual written consent of Parent and the Company.

Section 7.02 Termination by Either Parent or the Company. This Agreement may be terminated by either Parent or the Company at any time prior to the Closing (whether before or after the receipt of the Requisite Company Vote or the Requisite Parent Vote):

(a) if the Asset Acquisition has not been consummated on or before December 31, 2021, (the "**End Date**"); *provided, however,* that the right to terminate this Agreement pursuant to this Section 7.02(a) shall not be available to any party whose material breach of any representation, warranty, covenant, or agreement set forth in this Agreement has been a contributing cause of, or a contributing factor that resulted in, the failure of the Asset Acquisition to be consummated on or before the End Date;

(b) if any Governmental Entity of competent jurisdiction shall have enacted, issued, promulgated, enforced, or entered any Law or Order making illegal, permanently enjoining, or otherwise permanently prohibiting the consummation of the Asset Acquisition, the Parent Stock Issuance, or the other transactions contemplated by this Agreement, and such Law or Order shall have become final and non-appealable;

(c) if this Agreement has been submitted to the stockholders of the Company for adoption at a duly convened Company Stockholders Meeting and the Requisite Company Vote shall not have been obtained at such meeting (unless such Company Stockholders Meeting has been adjourned or postponed, in which case at the final adjournment or postponement thereof); or

(d) if the Parent Stock Issuance has been submitted to the stockholders of Parent for approval and the Requisite Parent Vote shall not have been obtained.

Section 7.03 Termination by Parent. This Agreement may be terminated by Parent at any time prior to the Closing if there shall have been a breach of any representation, warranty, covenant, or agreement on the part of the Company set forth in this Agreement such that the conditions to the Closing of the Asset Acquisition set forth in Section 6.01 would not be satisfied and, in either such case, such breach is incapable of being cured by the End Date.

Section 7.04 Termination by the Company. This Agreement may be terminated by the Company at any time prior to the Closing if there shall have been a breach of any representation, warranty, covenant, or agreement on the part of Parent or Acquisition Sub set forth in this Agreement such that the conditions to the Closing of the Asset Acquisition set forth Section 6.01 would not be satisfied and, in either such case, such breach is incapable of being cured by the End Date.

Section 7.05 Notice of Termination; Effect of Termination. The party desiring to terminate this Agreement pursuant to this ARTICLE VII (other than pursuant to Section 7.01) shall deliver written notice of such termination to each other party hereto specifying with particularity the reason for such termination, and any such termination in accordance with this Section 7.05 shall be effective immediately upon delivery of such written notice to the other party. If this Agreement is terminated pursuant to this ARTICLE VII, it will become void and of no further force and effect, with no liability on the part of any party to this Agreement (or any stockholder, director, officer, employee, agent, or Representative of such party) to any other party hereto.

Section 7.06 Amendment. At any time prior to the Effective Time, this Agreement may be amended or supplemented in any and all respects, whether before or after receipt of the Requisite Company Vote or the Requisite Parent Vote, by written agreement signed by each of the parties hereto; *provided, however,* that: (a) following the receipt of the Requisite Company Vote, there shall be no amendment or supplement to the provisions of this Agreement which by Law would require further approval by the holders of Company Ordinary Shares without such approval.

Section 7.07 Extension; Waiver. At any time prior to the Effective Time, Parent or Acquisition Sub, on the one hand, or the Company, on the other hand, may: (a) extend the time for the performance of any of the obligations of the other party(ies); (b) waive any inaccuracies in the representations and warranties of the other party(ies) contained in this Agreement or in any document delivered under this Agreement; or (c) unless prohibited by applicable Law, waive compliance with any of the covenants, agreements, or conditions contained in this Agreement. Any agreement on the part of a party to any extension or waiver will be valid only if set forth in an instrument in writing signed by such party. The failure of any party to assert any of its rights under this Agreement or otherwise will not constitute a waiver of such rights.

ARTICLE VIII
MISCELLANEOUS

Section 8.01 Definitions. For purposes of this Agreement, the following terms will have the following meanings when used herein with initial capital letters:

"**Acquisition Sub**" has the meaning set forth in the Preamble.

"**Acquisition Sub Board**" means the Board of Directors of Acquisition Sub.

"**Affiliate**" means, with respect to any Person, any other Person that directly or indirectly controls, is controlled by, or is under common control with, such first Person. For the purposes of this definition, "control" (including,

the terms "controlling," "controlled by," and "under common control with"), as applied to any Person, means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of that Person, whether through the ownership of voting securities, by Contract, or otherwise.

"**Agreement**" has the meaning set forth in the Preamble.

"**Antitrust Laws**" has the meaning set forth in Section 3.03(c).

"**Asset Acquisition**" has the meaning set forth in Section 1.01.

"**Asset Acquisition Consideration**" has the meaning set forth in Section 2.01(b).

"**Book-Entry Share**" has the meaning set forth in Section 2.01(c).

"**Business Day**" means any day, other than Saturday, Sunday, or any day on which banking institutions located in New York City, New York, USA are authorized or required by Law or other governmental action to close.

"**Cancelled Shares**" has the meaning set forth in Section 2.01(a).

"**Certificate**" means a share certificate for the Company's Ordinary Shares.

"**Charter Documents**" means: (a) with respect to a corporation, the charter, articles or certificate of incorporation or articles of association, as applicable, and bylaws or memorandum of association thereof; (b) with respect to a limited liability company, the certificate of formation or organization, as applicable, and the operating or limited liability company agreement, as applicable, thereof; (c) with respect to a partnership, the certificate of formation and the partnership agreement; and (d) with respect to any other Person the organizational, constituent and/or governing documents and/or instruments of such Person.

"**Closing**" has the meaning set forth in Section 1.02.

"**Closing Date**" has the meaning set forth in Section 1.02.

"**Code**" has the meaning set forth in the Recitals.

"**Company**" has the meaning set forth in the Preamble.

"**Company Balance Sheet**" means the consolidated balance sheet of Allarity Therapeutics A/S as of December 31, 2020.

"**Company Board**" has the meaning set forth in the Recitals.

"**Company Board Recommendation**" has the meaning set forth in Section 3.03(d).

"**Company Ordinary Shares**" has the meaning set forth in the Recitals.

"**Company Continuing Employees**" has the meaning set forth in Section 5.07(a).

"**Company Disclosure Letter**" means the disclosure letter, dated as of the date of this Agreement and delivered by the Company to Parent concurrently with the execution of this Agreement.

"**Company Employee**" means an employee of the Company or any of its Subsidiaries as of the Effective Date.

"**Company Employee Plans**" means any employee benefit plan adopted by the Company.

"**Company Equity Award**" means a Company Stock Option or a Company Restricted Share granted under one of the Company Stock Plans, as the case may be.

"**Company IP**" means any Intellectual Property or rights thereto owned or licensed by the Company.

"**Company IP Agreements**" means all licenses, sublicenses, consent to use agreements, settlements, coexistence agreements, covenants not to sue, waivers, releases, permissions, and other Contracts, whether written or oral, relating to Intellectual Property and to which the Company or any of its Subsidiaries is a party, beneficiary, or otherwise bound.

"**Company Material Adverse Effect**" means any event, circumstance, development, occurrence, fact, condition, effect, or change (each, an "**Effect**") that is, or would reasonably be expected to become, individually or in the aggregate, materially adverse to: (a) the business, results of operations, condition (financial or otherwise), or assets of the Company and its Subsidiaries, taken as a whole; or (b) the ability of the Company to timely perform its obligations under this Agreement or consummate the transactions contemplated hereby on a timely basis; *provided, however,* that, for the purposes of clause (a), a Company Material Adverse Effect shall not be deemed to include any Effect (alone or in combination) arising out of, relating to, or resulting from: (i) changes generally affecting the economy, financial or securities markets, or political conditions; (ii) the execution and delivery, announcement, or pendency of the transactions contemplated by this Agreement, including the impact thereof on relationships, contractual or otherwise, of the Company and its Subsidiaries with employees, suppliers, customers, Governmental Entities, or other third Persons (it being understood and agreed that this clause shall not apply with respect to any representation or warranty that is intended to address the consequences of the execution and delivery of this Agreement or the announcement or the pendency of this Agreement); (iii) any changes in applicable Law or GAAP or other applicable accounting standards, including interpretations thereof, (iv) acts of war, sabotage, terrorism, or military actions, or the escalation thereof; (v) natural disasters, epidemics, pandemics, or disease outbreaks (including the COVID-19 virus or other force majeure events; (vi) general conditions in the industry in which the Company and its Subsidiaries operate; (vii) any failure, in and of itself, by the Company to meet any internal or published projections, forecasts, estimates, or predictions in respect of revenues, earnings, or other financial or operating metrics for any period (it being understood that any Effect underlying such failure may be deemed to constitute, or be taken into account in determining whether there has been or would reasonably be expected to become, a Company Material Adverse Effect, to the extent permitted by this definition and not otherwise excepted by another clause of this proviso); (viii) any change, in and of itself, in the market price or trading volume of the Company's securities (it being understood that any Effect underlying such change may be deemed to constitute, or be taken into account in determining whether there has been or would reasonably be expected to become, a Company Material Adverse Effect, to the extent permitted by this definition and not otherwise excepted by another clause of this proviso); or (ix) actions taken as required or specifically permitted by the Agreement or actions or omissions taken with Parent's consent; *provided further*, *however*, that any Effect referred to in clauses (i), (iii), (iv), (v), or (vi) immediately above shall be taken into account in determining whether a Company Material Adverse Effect has occurred or would reasonably be expected to occur if it has a disproportionate effect on the Company and its Subsidiaries, taken as a whole, compared to other participants in the industries in which the Company and its Subsidiaries conduct their businesses (in which case, only the incremental disproportionate adverse effect may be taken into account in determining whether a Company Material Adverse Effect has occurred).

"**Company Material Contract**" means any contract that would have a material effect on the business, financial condition, or results of operations of the Company, taken as a whole.

"**Company-Owned IP**" means all Intellectual Property owned by the Company or any of its Subsidiaries.

"**Company Restricted Share**" has the meaning set forth in Section 2.06(b).

"**Company Securities**" has the meaning set forth in Section 3.02(b)(ii).

"**Company Stock Option**" has the meaning set forth in Section 2.06(a).

"**Company Stock Plans**" means the plans adopted by the Company for the issuance of warrants to Officers, Directors and employees of the Company and in each case as amended.

"**Company Stockholders Meeting**" means the general or extraordinary meeting of the stockholders of the Company to be held to consider the adoption of this Agreement.

"**Company Subsidiary Securities**" has the meaning set forth in Section 3.02(d).

"**Consent**" has the meaning set forth in Section 3.03(c).

"**Contracts**" means any contracts, agreements, licenses, notes, bonds, mortgages, indentures, leases, or other binding instruments or binding commitments, whether written or oral.

"**DCA**" has the meaning set forth in the Recitals.

"**DGCL**" has the meaning set forth in the Recitals.

"**Effect"** has the meaning set forth in the definition of "Company Material Adverse Effect."

"**Effective Time**" has the meaning set forth in Section 1.03.

"**End Date**" has the meaning set forth in Section 7.02(a).

"**ERISA**" means the Employee Retirement Income Security Act of 1974, as amended.

"**Exchange Act**" has the meaning set forth in Section 4.03(c).

"**Exchange Agent**" has the meaning set forth in Section 2.02(a).

"**Exchange Fund**" has the meaning set forth Section 2.02(a).

"**Exchange Ratio**" has the meaning set forth in Section 2.01(b).

"**Foreign Antitrust Laws**" has the meaning set forth in Section 3.03(c).

"**Form S-4**" means a registration statement under the Securities Act on Form S-4 registering the Parent Stock Issuance related to the Asset Acquisition.

"**GAAP**" means Generally Accepted Accounting Principles in the United States.

"**Governmental Antitrust Authority**" has the meaning set forth in Section 5.09(b).

"**Governmental Entity**" has the meaning set forth in Section 3.03(c).

"**HSR Act**" has the meaning set forth in Section 3.03(c).

"**Indemnified Party**" has the meaning set forth in Section 5.08(a).

"**Intellectual Property**" means any and all of the following arising pursuant to the Laws of any jurisdiction throughout the world: (a) trademarks, service marks, trade names, and similar indicia of source or origin, all registrations and applications for registration thereof, and the goodwill connected with the use of and symbolized by the foregoing; (b) copyrights and all registrations and applications for registration thereof; (c) trade secrets and know-how; (d) patents and patent applications; (e) internet domain name registrations; and (f) other intellectual property and related proprietary rights.

"**IRS**" means the United States Internal Revenue Service.

"**Knowledge**" means: (a) with respect to the Company and its Subsidiaries, the actual knowledge of each of the Company's Chairman, Chief Executive Officer, or Chief Financial Officer (b) with respect to Parent and its Subsidiaries, the actual knowledge of each of the Company's Chairman, Chief Executive Officer, or Chief Financial Officer; in each case, after due inquiry.

"**Laws**" means any federal, state, local, municipal, foreign, multi-national or other laws, common law, statutes, constitutions, ordinances, rules, regulations, codes, Orders, or legally enforceable requirements enacted, issued, adopted, promulgated, enforced, ordered, or applied by any Governmental Entity.

"**Lease**" means all leases, subleases, licenses, concessions, and other agreements (written or oral) under which the Company or any of its Subsidiaries holds any Leased Real Estate, including the right to all security deposits and other amounts and instruments deposited by or on behalf of the Company or any of its Subsidiaries thereunder.

"**Leased Real Estate**" means all leasehold or subleasehold estates and other rights to use or occupy any land, buildings, structures, improvements, fixtures, or other interest in real property held by the Company or any of its Subsidiaries.

"**Legal Action**" means any legal, administrative, arbitral, or other proceedings, suits, actions, investigations, examinations, claims, audits, hearings, charges, complaints, indictments, litigations, or examinations.

"**Liability**" means any liability, indebtedness, or obligation of any kind (whether accrued, absolute, contingent, matured, unmatured, determined, determinable, or otherwise, and whether or not required to be recorded or reflected on a balance sheet under GAAP).

"**Liens**" means, with respect to any property or asset, all pledges, liens, mortgages, charges, encumbrances, hypothecations, options, rights of first refusal, rights of first offer, and security interests of any kind or nature whatsoever.

"**Maximum Premium**" has the meaning set forth in Section 5.08(b).

"**Nasdaq First North Growth Market**" means the First North Growth Market in Stockholm operated by the Nasdaq.

"**Nasdaq Stock Market**" means the Nasdaq Stock Market LLC.

"**Order**" means any order, judgment, decree or enforcement action by any Governmental Entity.

"**Other Governmental Approvals"** has the meaning set forth in Section 3.03(c).

"**Parent**" has the meaning set forth in the Preamble.

"**Parent Benefit Plans**" has the meaning set forth in Section 5.07(b).

"**Parent Board**" has the meaning set forth in the Recitals.

"**Parent Board Recommendation**" has the meaning set forth in Section 4.03(d)(i).

"**Parent Common Stock**" has the meaning set forth in the Recitals.

"**Parent Disclosure Letter**" means the disclosure letter, dated as of the date of this Agreement and delivered by Parent and Acquisition Sub to the Company concurrently with the execution of this Agreement.

"**Parent Equity Award**" means a Parent Stock Option.

"**Parent Material Adverse Effect**" means any Effect that is, or would reasonably be expected to become, individually or in the aggregate, materially adverse to: (a) the business, results of operations, condition (financial or otherwise), or assets of Parent and its Subsidiaries, taken as a whole; or (b) the ability of Parent to timely perform its obligations under this Agreement or consummate the transactions contemplated hereby on a timely basis.

"**Parent Preferred Stock**" has the meaning set forth in Section 4.02(a).

"**Parent Restricted Share**" means any Parent Common Stock subject to vesting, repurchase, or other lapse of restrictions granted under any Parent Stock Plan.

"**Parent Securities**" means any equity or debt securities of the Parent.

"**Parent Stockholders Meeting**" means the special meeting of the stockholders (or the solicitation of written consents) of Parent to be held to consider the approval of the Parent Stock Issuance.

"**Parent Stock Issuance**" has the meaning set forth in the Recitals.

"**Parent Stock Option**" means any option to purchase Parent Common Stock granted pursuant to Section 2.06 of this Agreement.

"**Parent Stock Plans**" means the following plans, in each case as amended: The Allarity Therapeutics, Inc. 2021 Incentive Stock Plan.

"**Parent Subsidiary Securities**" means any equity or debt security of a Subsidiary of Parent.

"**Parent Voting Debt**" has the meaning set forth in Section 4.02(c).

"**Permits**" means any authorizations issued by a Governmental Entity.

"**Permitted Liens**" means: (a) statutory Liens for current Taxes or other governmental charges not yet due and payable or the amount or validity of which is being contested in good faith (provided appropriate reserves required pursuant to GAAP have been made in respect thereof); (b) mechanics', carriers', workers', repairers', and similar statutory Liens arising or incurred in the ordinary course of business for amounts which are not delinquent or which are being contested by appropriate proceedings (provided appropriate reserves required pursuant to GAAP have been made in respect thereof); (c) zoning, entitlement, building, and other land use regulations imposed by Governmental Entities

having jurisdiction over such Person's owned or leased real property, which are not violated by the current use and operation of such real property; (d) covenants, conditions, restrictions, easements, and other similar non-monetary matters of record affecting title to such Person's owned or leased real property, which do not materially impair the occupancy or use of such real property for the purposes for which it is currently used in connection with such Person's businesses; (e) any right of way or easement related to public roads and highways, which do not materially impair the occupancy or use of such real property for the purposes for which it is currently used in connection with such Person's businesses; and (f) Liens arising under workers' compensation, unemployment insurance, social security, retirement, and similar legislation.

"**Person**" means any individual, corporation, limited or general partnership, limited liability company, limited liability partnership, trust, association, joint venture, Governmental Entity, or other entity or group (which term will include a "group" as such term is defined in Section 13(d)(3) of the Exchange Act).

"**Pipe Investment**" means the $20 million purchase of Parent Preferred Stock by 3i LP and its co-investors.

"**Proxy/Information Statement**" has the meaning set forth in Section 3.17.

"**Real Estate**" means the Owned Real Estate and the Leased Real Estate.

"**Representative(s)**" means a Person who is an agent for a party to this Agreement.

"**Requisite Company Vote**" has the meaning set forth in Section 3.03(a).

"**Requisite Parent Vote**" has the meaning set forth in Section 4.03(a).

"**SEC**" means the United States Securities and Exchange Commission.

"**Securities Act**" has the meaning set forth in Section 3.03(c).

"**Subsidiary**" of a Person means a corporation, partnership, limited liability company, or other business entity of which a majority of the shares of voting securities is at the time beneficially owned, or the management of which is otherwise controlled, directly or indirectly, through one or more intermediaries, or both, by such Person.

"**Surviving Corporation**" has the meaning set forth in Section 1.01.

"**Taxes**" means all federal, state, local, foreign and other income, gross receipts, sales, use, production, ad valorem, transfer, franchise, registration, profits, license, lease, service, service use, withholding, payroll, employment, unemployment, estimated, excise, severance, environmental, stamp, occupation, premium, property (real or personal), real property gains, windfall profits, customs, duties or other taxes, fees, assessments, or charges of any kind whatsoever, together with any interest, additions or penalties with respect thereto and any interest in respect of such additions or penalties.

"**Tax Returns**" means any return, declaration, report, claim for refund, information return or statement, or other document relating to Taxes, including any schedule or attachment thereto, and including any amendment thereof.

"**Voting Debt**" has the meaning set forth in Section 3.02(c).

Section 8.02 Interpretation; Construction.

(a) The table of contents and headings herein are for convenience of reference only, do not constitute part of this Agreement and shall not be deemed to limit or otherwise affect any of the provisions hereof. Where a reference in this Agreement is made to a Section, Exhibit, Article, or Schedule, such reference shall be to a Section of, Exhibit to, Article of, or Schedule of this Agreement unless otherwise indicated. Unless the context otherwise requires, references herein: (i) to an agreement, instrument, or other document means such agreement, instrument, or other document as amended, supplemented, and modified from time to time to the extent permitted by the provisions thereof; and (ii) to a statute means such statute as amended from time to time and includes any successor legislation thereto and any regulations promulgated thereunder. Whenever the words "include," "includes," or "including" are used in this Agreement, they shall be deemed to be followed by the words "without limitation," and the word "or" is not exclusive. The word "extent" in the phrase "to the extent" means the degree to which a subject or other thing extends, and does not simply mean "if." A reference in this Agreement to $ or dollars is to U.S. dollars and a reference to DKK is to Danish Kroner. The definitions of terms herein shall apply equally to the singular and plural forms of the terms defined. The words "hereof," "herein," "hereby," "hereto," and "hereunder" and words of similar

import when used in this Agreement shall refer to this Agreement as a whole and not to any particular provision of this Agreement. References to "this Agreement" shall include the Company Disclosure Letter and Parent Disclosure Letter.

(b) The parties have participated jointly in negotiating and drafting this Agreement. In the event that an ambiguity or a question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the parties, and no presumption or burden of proof shall arise favoring or disfavoring any party by virtue of the authorship of any provision of this Agreement.

Section 8.03 Survival. None of the representations and warranties contained in this Agreement or in any instrument delivered under this Agreement will survive the Effective Time. This Section 8.03 does not limit any covenant or agreement of the parties contained in this Agreement which, by its terms, contemplates performance after the Effective Time.

Section 8.04 Governing Law. This Agreement and all Legal Actions (whether based on contract, tort, or statute) arising out of, relating to, or in connection with this Agreement or the actions of any of the parties hereto in the negotiation, administration, performance, or enforcement hereof, shall be governed by and construed in accordance with the internal laws of the State of Delaware without giving effect to any choice or conflict of law provision or rule (whether of the State of Delaware or any other jurisdiction) that would cause the application of Laws of any jurisdiction other than those of the State of Delaware.

Section 8.05 Notices. All notices, requests, consents, claims, demands, waivers, and other communications hereunder shall be in writing and shall be deemed to have been given upon the earlier of actual receipt or (a) when delivered by hand providing proof of delivery; (b) when received by the addressee if sent by a nationally recognized overnight courier (receipt requested); or (c) on the date sent by email if sent during normal business hours of the recipient, and on the next Business Day if sent after normal business hours of the recipient. Such communications must be sent to the respective parties at the following addresses (or to such other Persons or at such other address for a party as shall be specified in a notice given in accordance with this Section 8.05):

If to Parent or Acquisition Sub, to:	Allarity Therapeutics, Inc. 210 Broadway, Ste 201 Cambridge, MA 02139, USA Attention: Steve Carchedi, CE0 Email: scarchedi@allarity.com
with a copy (which will not constitute notice to Parent or Acquisition Sub) to:	Lewis Brisbois Bisgaard & Smith LLP 633 West 5th Street, Ste 4000 Los Angeles, CA 90071 Attention: Scott E. Bartel, Esq. Email: scott.bartel@lewisbrisbois.com
If to the Company, to:	Allarity Therapeutics A/S Venlighedsvej 1 2970 Horsholm, Denmark Attention: Steve Carchedi, CEO Email: scarchedi@allarity.com
with a copy (which will not constitute notice to the Company) to:	Mazanti-Andersen Amaliegade 10 DK-1256 Kobenhavn K, Denmark Attention: Lars Luthjohan Jensen Email: llj@mazanti.dk

Section 8.06 Entire Agreement. This Agreement (including all exhibits, annexes, and schedules referred to herein), the Company Disclosure Letter, and the Parent Disclosure Letter constitute the entire agreement among the parties with respect to the subject matter of this Agreement and supersede all other prior agreements and understandings, both written and oral, among the parties to this Agreement with respect to the subject matter of this Agreement. In the event of any inconsistency between the statements in the body of this Agreement, the Parent Disclosure Letter, and the Company Disclosure Letter (other than an exception expressly set forth as such in the Parent Disclosure Letter or Company Disclosure Letter), the statements in the body of this Agreement will control.

Section 8.07 No Third-Party Beneficiaries. Except as provided in Section 5.08 hereof (which shall be to the benefit of the Persons referred to in such section), this Agreement is for the sole benefit of the parties hereto and their permitted assigns and respective successors and nothing herein, express or implied, is intended to or shall confer upon any other Person or entity any legal or equitable right, benefit, or remedy of any nature whatsoever under or by reason of this Agreement.

Section 8.08 Severability. If any term or provision of this Agreement is invalid, illegal, or unenforceable in any jurisdiction, such invalidity, illegality, or unenforceability shall not affect any other term or provision of this Agreement or invalidate or render unenforceable such term or provision in any other jurisdiction. Upon such determination that any term or other provision is invalid, illegal, or unenforceable, the parties hereto shall negotiate in good faith to modify this Agreement so as to effect the original intent of the parties as closely as possible in a mutually acceptable manner in order that the transactions contemplated hereby be consummated as originally contemplated to the greatest extent possible.

Section 8.09 Assignment. This Agreement shall be binding upon and shall inure to the benefit of the parties hereto and their respective successors and permitted assigns. Neither Parent or Acquisition Sub, on the one hand, nor the Company on the other hand, may assign its rights or obligations hereunder without the prior written consent of the other party (Parent in the case of Parent and Acquisition Sub), which consent shall not be unreasonably withheld, conditioned, or delayed; *provided, however,* that prior to the Effective Time, Acquisition Sub may, without the prior written consent of the Company, assign all or any portion of its rights under this Agreement to Parent or to one or more of Parent's direct or indirect wholly-owned subsidiaries. No assignment shall relieve the assigning party of any of its obligations hereunder.

Section 8.10 Remedies Cumulative. Except as otherwise provided in this Agreement, any and all remedies expressly conferred upon a party to this Agreement will be cumulative with, and not exclusive of, any other remedy contained in this Agreement, at Law, or in equity. The exercise by a party to this Agreement of any one remedy will not preclude the exercise by it of any other remedy.

Section 8.11 Specific Performance.

(a) The parties hereto agree that irreparable damage would occur if any provision of this Agreement were not performed in accordance with the terms hereof and that the parties shall be entitled to an injunction or injunctions to prevent breaches or threatened breaches of this Agreement or to enforce specifically the performance of the terms and provisions hereof in any federal court located in the State of Delaware or any Delaware state court, in addition to any other remedy to which they are entitled at Law or in equity.

(b) Each party further agrees that: (i) no such party will oppose the granting of an injunction or specific performance as provided herein on the basis that the other party has an adequate remedy at law or that an award of specific performance is not an appropriate remedy for any reason at law or equity; (ii) no such party will oppose the specific performance of the terms and provisions of this Agreement; and (iii) no other party or any other Person shall be required to obtain, furnish, or post any bond or similar instrument in connection with or as a condition to obtaining any remedy referred to in this Section 8.11, and each party irrevocably waives any right it may have to require the obtaining, furnishing, or posting of any such bond or similar instrument.

Section 8.12 Counterparts; Effectiveness. This Agreement may be executed in any number of counterparts, all of which will be one and the same agreement. This Agreement will become effective when each party to this Agreement will have received counterparts signed by all of the other parties. A signed copy of this Agreement delivered by facsimile, e-mail or other means of electronic transmission shall be deemed to have the same legal effect as delivery of an original signed copy of this Agreement.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the date first written above by their respective officers thereunto duly authorized.

COMPANY

Allarity Therapeutics A/S

By: /s/
Name: Steve Carchedi
Title: CEO

PARENT

Allarity Therapeutics, Inc.

By: /s/
Name: Steve Carchedi
Title: CEO

EXHIBIT A

ASSET PURCHASE AGREEMENT

This Asset Purchase Agreement (this "Agreement"), dated as of September [ ], 2021, is entered into between Allarity Therapeutics A/S, an *Aktieselskab* organized under the laws of Denmark ("Seller"), and Allarity Therapeutics, Inc., a Delaware corporation ("Parent"), and Allarity Acquisition Subsidiary, Inc., a Delaware corporation to be organized under the laws of Delaware and a wholly-owned Subsidiary of Parent ("Acquisition Sub" or "Buyer"). Capitalized terms used in this Agreement have the meanings given to such terms herein, as such definitions are identified by the cross-references set forth in Exhibit A attached hereto.

RECITALS

WHEREAS, Seller is engaged in the business of oncology drug discovery and development with companion diagnostics using Seller's proprietary DRP® companion diagnostic platform (the "**Business**"); and

WHEREAS, Seller wishes to sell and assign to Buyer, and Buyer wishes to purchase and assume from Seller, substantially all the assets, and certain specified liabilities, of the Business, subject to the terms and conditions set forth herein;

NOW, THEREFORE, in consideration of the mutual covenants and agreements hereinafter set forth and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

ARTICLE IX
PURCHASE AND SALE

Section 9.01 Purchase and Sale of Assets. Subject to the terms and conditions set forth herein, at the Closing, Seller shall sell, convey, assign, transfer, and deliver to Buyer, and Buyer shall purchase from Seller, all of Seller's right, title, and interest in, to, and under all of the tangible and intangible assets, properties, and rights of every kind and nature and wherever located (other than the Excluded Assets), which relate to, or are used or held for use in connection with, the Business (collectively, the "**Purchased Assets**"), including the following:

(a) all cash and cash equivalents;

(b) all accounts receivable held by Seller ("**Accounts Receivable**");

(c) all inventory, finished goods, raw materials, work in progress, packaging, supplies, parts, and other inventories ("**Inventory**");

(d) all Contracts (the "**Assigned Contracts**") set forth on Section 1.01(d) of the disclosure schedules attached hereto (the "**Disclosure Schedules**"). The term "**Contracts**" means all contracts, leases, licenses, instruments, notes, commitments, undertakings, indentures, joint ventures, and all other agreements, commitments, and legally binding arrangements, whether written or oral;

(e) all furniture, fixtures, equipment, machinery, tools, vehicles, office equipment, supplies, computers, telephones, and other tangible personal property (the "**Tangible Personal Property**");

(f) all prepaid expenses, credits, advance payments, claims, security, refunds, rights of recovery, rights of set-off, rights of recoupment, deposits, charges, sums, and fees (including any such item relating to the payment of Taxes);

(g) all of Seller's rights under warranties, indemnities, and all similar rights against third parties to the extent related to any Purchased Assets;

(h) all insurance benefits, including rights and proceeds, arising from or relating to the Business, the Purchased Assets, or the Assumed Liabilities;

(i) originals or, where not available, copies, of all books and records, including books of account, ledgers, and general, financial, and accounting records, machinery and equipment maintenance files, customer lists, customer purchasing histories, price lists, distribution lists, supplier lists, production data, quality control records and procedures, customer complaints and inquiry files, research and development

files, records, and data (including all correspondence with any federal, state, local, or foreign government or political subdivision thereof, or any agency or instrumentality of such government or political subdivision, or any arbitrator, court, or tribunal of competent jurisdiction (collectively, "**Governmental Authority**")), sales material and records, strategic plans and marketing, and promotional surveys, material, and research ("**Books and Records**");

(j) all rights, title and interests in and to any subsidiary or other corporate entity owned by the Seller;

(k) any and all other tangible or intangible property or choses in actions; and

(l) all goodwill and the going concern value of the Purchased Assets and the Business.

Section 9.02 Excluded Assets. Notwithstanding the foregoing, the Purchased Assets shall not include the assets, properties, and rights specifically set forth on Section 1.02 of the Disclosure Schedules (collectively, the "**Excluded Assets**").

Section 9.03 Assumed Liabilities.

(a) Subject to the terms and conditions set forth herein, Buyer shall assume and agree to pay, perform, and discharge only the following Liabilities of Seller (collectively, the "**Assumed Liabilities**"), and no other Liabilities:

(i) all trade accounts payable of Seller to third parties in connection with the Business that remain unpaid and are not delinquent as of the Closing Date;

(ii) all Liabilities in respect of the Assigned Contracts; and

(iii) those Liabilities of Seller set forth on Section 1.03(a)(iii) of the Disclosure Schedules.

For purposes of this Agreement, "**Liabilities**" means liabilities, obligations, or commitments of any nature whatsoever, whether asserted or unasserted, known or unknown, absolute or contingent, accrued or unaccrued, matured or unmatured, or otherwise.

(b) Notwithstanding any provision in this Agreement to the contrary, Buyer shall not assume and shall not be responsible to pay, perform, or discharge any Liabilities of Seller or any of its Affiliates of any kind or nature whatsoever other than the Assumed Liabilities (the "**Excluded Liabilities**"). For the sake of clarity, Buyer is not assuming any equity-based compensation awards or bonuses based upon the sale or disposition of the Seller's, or Seller's Affiliate", drug candidates. For purposes of this Agreement: (i) "**Affiliate**" of a Person means any other Person that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, such Person; and (ii) the term "**control**" (including the terms "controlled by" and "under common control with") means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by contract, or otherwise. For the sake of clarity, Parent is not assuming any liabilities of the Seller as a consequence of this Agreement.

Section 9.04 Purchase Price. The aggregate purchase price for the Purchased Assets shall be [ ] shares of the Parent's Common Stock (the "**Purchase Price**"), plus the assumption of the Assumed Liabilities. Buyer shall transfer the Purchase Price to the Seller at the Closing.

Section 9.05 Allocation of Purchase Price. The Purchase Price and the Assumed Liabilities shall be allocated among the Purchased Assets for all purposes (including Tax and financial accounting) as shown on the allocation schedule set forth on Section 1.05 of the Disclosure Schedules (the "**Allocation Schedule**"). The Allocation Schedule shall be prepared in accordance with Section 1060 of the Internal Revenue Code of 1986, as amended. Buyer and Seller shall file all returns, declarations, reports, information returns and statements, and other documents relating to Taxes (including amended returns and claims for refund) ("**Tax Returns**") in a manner consistent with the Allocation Schedule.

Section 9.06 Withholding Tax. Buyer shall be entitled to deduct and withhold from the Purchase Price all Taxes that Buyer may be required to deduct and withhold under any provision of Tax Law. All such withheld amounts shall be treated as delivered to Seller hereunder.

Section 9.07 Third-party Consents. To the extent that Seller's rights under any Purchased Asset may not be assigned to Buyer without the consent of another Person which has not been obtained, this Agreement shall not constitute an agreement to assign the same if an attempted assignment would constitute a breach thereof or be unlawful, and Seller, at its expense, shall use its reasonable best efforts to obtain any such required consent(s) as promptly as possible. If any such consent shall not be obtained or if any attempted assignment would be ineffective or would impair Buyer's rights under the Purchased Asset in question so that Buyer would not in effect acquire the benefit of all such rights, Seller, to the maximum extent permitted by Law and the Purchased Asset, shall act after the Closing as Buyer's agent in order to obtain for it the benefits thereunder and shall cooperate, to the maximum extent permitted by Law and the Purchased Asset, with Buyer in any other reasonable arrangement designed to provide such benefits to Buyer.

Section 9.08 Option to Purchase up to 8,000,000 Ordinary Shares of Seller. Simultaneously with the Closing, Buyer shall have an option to purchase up to 8,000,000 ordinary shares, at an exercise price of DKK 0.05, (the "Ordinary Shares") and upon exercise of Buyer's option Seller shall sell to Buyer the Ordinary Shares for a subscription price of DKK O.05 or the equivalent amount in U.S. Dollars.

ARTICLE X
CLOSING

Section 10.01 Closing. Subject to the terms and conditions of this Agreement, the consummation of the transactions contemplated by this Agreement (the "**Closing**") shall take place concurrently with the Closing for the Amended and Restated Plan of Reorganization and Asset Purchase Agreement, dated September 23, 2021, entered into by the parties to this Agreement (the "Plan of Reorganization") at the place specified in the Plan of Reorganization, or remotely by exchange of documents and signatures (or their electronic counterparts), or at such other time or place or in such other manner as Seller, Parent and Buyer may mutually agree upon in writing. The date on which the Closing is to occur is herein referred to as the "**Closing Date**."

Section 10.02 Closing Deliverables.

(a) At the Closing, Seller shall deliver to Buyer the following:

(i) a bill of sale in form and substance satisfactory to Buyer (the "**Bill of Sale**") and duly executed by Seller, transferring the Tangible Personal Property included in the Purchased Assets to Buyer;

(ii) an assignment and assumption agreement in form and substance satisfactory to Buyer (the "**Assignment and Assumption Agreement**") and duly executed by Seller, effecting the assignment to and assumption by Buyer of the Purchased Assets and the Assumed Liabilities;

(iii) a certificate of the Secretary (or equivalent officer) of Seller certifying as to (A) the resolutions of the board of directors and the shareholders of Seller, which authorize the execution, delivery, and performance of this Agreement, the Bill of Sale, the Assignment and Assumption Agreement, and the other agreements, instruments, and documents required to be delivered in connection with this Agreement or at the Closing (collectively, the "**Transaction Documents**") and the consummation of the transactions contemplated hereby and thereby, and (B) the names and signatures of the officers of Seller authorized to sign this Agreement and the other Transaction Documents;

(iv) such other customary instruments of transfer or assumption, filings, or documents, in form and substance reasonably satisfactory to Buyer, as may be required to give effect to the transactions contemplated by this Agreement; and

(b) At the Closing, Buyer shall deliver to Seller the following:

(i) the Purchase Price (less any amounts which may be withheld for outstanding Tax Liabilities);

(ii) the Assignment and Assumption Agreement duly executed by Buyer; and

(iii) a certificate of the Secretary (or equivalent officer) of Buyer certifying as to (A) the resolutions of the board of directors of Buyer, which authorize the execution, delivery, and performance of this Agreement and the Transaction Documents and the consummation of the

transactions contemplated hereby and thereby, and (B) the names and signatures of the officers of Buyer authorized to sign this Agreement and the other Transaction Documents; and

ARTICLE XI
REPRESENTATIONS AND WARRANTIES OF SELLER

Seller represents and warrants to Buyer that the statements contained in this Article III are true and correct as of the date hereof.

Section 11.01 Organization and Authority of Seller. Seller is an *Aktieselskab* organized under the laws of Denmark. Seller has full corporate power and authority to enter into this Agreement and the other Transaction Documents to which Seller is a party, to carry out its obligations hereunder and thereunder, and to consummate the transactions contemplated hereby and thereby. The execution and delivery by Seller of this Agreement and any other Transaction Document to which Seller is a party, the performance by Seller of its obligations hereunder and thereunder, and the consummation by Seller of the transactions contemplated hereby and thereby have been duly authorized by all requisite corporate, board, and shareholder action on the part of Seller. This Agreement and the Transaction Documents constitute legal, valid, and binding obligations of Seller enforceable against Seller in accordance with their respective terms.

ARTICLE XII
REPRESENTATIONS AND WARRANTIES OF BUYER

Buyer represents and warrants to Seller that the statements contained in this Article IV are true and correct as of the date hereof.

Section 12.01 Organization and Authority of Buyer. Buyer is a corporation duly organized, validly existing, and in good standing under the Laws of the State of Delaware. Buyer has full corporate power and authority to enter into this Agreement and the other Transaction Documents to which Buyer is a party, to carry out its obligations hereunder and thereunder, and to consummate the transactions contemplated hereby and thereby. The execution and delivery by Buyer of this Agreement and any other Transaction Document to which Buyer is a party, the performance by Buyer of its obligations hereunder and thereunder, and the consummation by Buyer of the transactions contemplated hereby and thereby have been duly authorized by all requisite corporate action on the part of Buyer. This Agreement and the Transaction Documents constitute legal, valid, and binding obligations of Buyer enforceable against Buyer in accordance with their respective terms.

ARTICLE XIII
COVENANTS

Section 13.01 Receivables. From and after the Closing, if Seller or any of its Affiliates receives or collects any funds relating to any Accounts Receivable or any other Purchased Asset, Seller or its Affiliate shall remit such funds to Buyer within [five (5)/[NUMBER]] business days after its receipt thereof. From and after the Closing, if Buyer or its Affiliate receives or collects any funds relating to any Excluded Asset, Buyer or its Affiliate shall remit any such funds to Seller within [five (5)/[NUMBER]] business days after its receipt thereof.

Section 13.02 Transfer Taxes. All sales, use, registration, and other such Taxes and fees (including any penalties and interest) incurred in connection with this Agreement and the other Transaction Documents, if any, shall be borne and paid by Buyer when due. Seller shall, at its own expense, timely file any Tax Return or other document with respect to such Taxes or fees (and Buyer shall cooperate with respect thereto as necessary).

Section 13.03 Further Assurances. Following the Closing, each of the parties hereto shall, and shall cause their respective Affiliates to, execute and deliver such additional documents, instruments, conveyances, and assurances and take such further actions as may be reasonably required to carry out the provisions hereof and give effect to the transactions contemplated by this Agreement and the other Transaction Documents.

ARTICLE XIV
INDEMNIFICATION

Section 14.01 Survival. All representations, warranties, covenants, and agreements contained herein and all related rights to indemnification shall survive the Closing.

Section 14.02 Indemnification by Seller. Subject to the other terms and conditions of this Article VI, Seller shall indemnify and defend each of Buyer and its Affiliates and their respective Representatives (collectively, the "**Buyer Indemnitees**") against, and shall hold each of them harmless from and against, any and all losses, damages, liabilities, deficiencies, Actions, judgments, interest, awards, penalties, fines, costs, or expenses of whatever kind, including reasonable attorneys' fees (collectively, "**Losses**"), incurred or sustained by, or imposed upon, the Buyer Indemnitees based upon, arising out of, or with respect to:

(a) any inaccuracy in or breach of any of the representations or warranties of Seller contained in this Agreement, any other Transaction Document, or any schedule, certificate, or exhibit related thereto, as of the date such representation or warranty was made or as if such representation or warranty was made on and as of the Closing Date (except for representations and warranties that expressly relate to a specified date, the inaccuracy in or breach of which will be determined with reference to such specified date);

(b) any breach or non-fulfillment of any covenant, agreement, or obligation to be performed by Seller pursuant to this Agreement, any other Transaction Document, or any schedule, certificate, or exhibit related thereto;

(c) any Excluded Asset or any Excluded Liability; or

(d) any Third-party Claim based upon, resulting from, or arising out of the business, operations, properties, assets, or obligations of Seller or any of its Affiliates (other than the Purchased Assets or Assumed Liabilities) conducted, existing, or arising on or prior to the Closing Date. For purposes of this Agreement, "**Third-party Claim**" means notice of the assertion or commencement of any Action made or brought by any Person who is not a party to this Agreement or an Affiliate of a party to this Agreement or a Representative of the foregoing.

Section 14.03 Indemnification by Buyer. Subject to the other terms and conditions of this Article VI, Buyer shall indemnify and defend each of Seller and its Affiliates and their respective Representatives (collectively, the "**Seller Indemnitees**") against, and shall hold each of them harmless from and against any and all Losses incurred or sustained by, or imposed upon, the Seller Indemnitees based upon, arising out of, or with respect to:

(a) any inaccuracy in or breach of any of the representations or warranties of Buyer contained in this Agreement, any other Transaction Document, or any schedule, certificate, or exhibit related thereto, as of the date such representation or warranty was made or as if such representation or warranty was made on and as of the Closing Date (except for representations and warranties that expressly relate to a specified date, the inaccuracy in or breach of which will be determined with reference to such specified date);

(b) any breach or non-fulfillment of any covenant, agreement, or obligation to be performed by Buyer pursuant to this Agreement; or

(c) any Assumed Liability.

Section 14.04 Indemnification Procedures. Whenever any claim shall arise for indemnification hereunder, the party entitled to indemnification (the "**Indemnified Party**") shall promptly provide written notice of such claim to the other party (the "**Indemnifying Party**"). In connection with any claim giving rise to indemnity hereunder resulting from or arising out of any Action by a Person who is not a party to this Agreement, the Indemnifying Party, at its sole cost and expense and upon written notice to the Indemnified Party, may assume the defense of any such Action with counsel reasonably satisfactory to the Indemnified Party. The Indemnified Party shall be entitled to participate in the defense of any such Action, with its counsel and at its own cost and expense. If the Indemnifying Party does not assume the defense of any such Action, the Indemnified Party may, but shall not be obligated to, defend against such Action in such manner as it may deem appropriate, including settling such Action, after giving notice of it to the Indemnifying Party, on such terms as the Indemnified Party may deem appropriate and no action taken by the Indemnified Party in accordance with such defense and settlement shall relieve the Indemnifying Party of its indemnification obligations herein provided with respect to any damages resulting therefrom. The Indemnifying Party shall not settle any Action without the Indemnified Party's prior written consent (which consent shall not be unreasonably withheld or delayed).

Section 14.05 Cumulative Remedies. The rights and remedies provided in this Article VI are cumulative and are in addition to and not in substitution for any other rights and remedies available at law or in equity or otherwise.

ARTICLE XV
MISCELLANEOUS

Section 15.01 Notices. All notices, claims, demands, and other communications hereunder shall be shall be given or made in accordance with the notice provisions in the Plan of Reorganization.

Section 15.02 Interpretation; Headings. This Agreement shall be construed without regard to any presumption or rule requiring construction or interpretation against the party drafting an instrument or causing any instrument to be drafted. The headings in this Agreement are for reference only and shall not affect the interpretation of this Agreement.

Section 15.03 Severability. If any term or provision of this Agreement is invalid, illegal, or unenforceable in any jurisdiction, such invalidity, illegality, or unenforceability shall not affect any other term or provision of this Agreement.

Section 15.04 Entire Agreement. This Agreement and the other Transaction Documents constitute the sole and entire agreement of the parties to this Agreement with respect to the subject matter contained herein and therein, and supersede all prior and contemporaneous understandings and agreements, both written and oral, with respect to such subject matter. In the event of any inconsistency between the statements in the body of this Agreement and those in the other Transaction Documents, the Exhibits, and the Disclosure Schedules (other than an exception expressly set forth as such in the Disclosure Schedules), the statements in the body of this Agreement will control.

Section 15.05 Successors and Assigns. This Agreement shall be binding upon and shall inure to the benefit of the parties hereto and their respective successors and permitted assigns. Neither party may assign its rights or obligations hereunder without the prior written consent of the other party, which consent shall not be unreasonably withheld or delayed. Any purported assignment in violation of this Section shall be null and void. No assignment shall relieve the assigning party of any of its obligations hereunder.

Section 15.06 Amendment and Modification; Waiver. This Agreement may only be amended, modified, or supplemented by an agreement in writing signed by each party hereto. No waiver by any party of any of the provisions hereof shall be effective unless explicitly set forth in writing and signed by the party so waiving. No failure to exercise, or delay in exercising, any right or remedy arising from this Agreement shall operate or be construed as a waiver thereof; nor shall any single or partial exercise of any right or remedy hereunder preclude any other or further exercise thereof or the exercise of any other right or remedy.

Section 15.07 Governing Law. This Agreement and all Legal Actions (whether based on contract, tort, or statute) arising out of, relating to, or in connection with this Agreement or the actions of any of the parties hereto in the negotiation, administration, performance, or enforcement hereof, shall be governed by and construed in accordance with the internal laws of the State of Delaware without giving effect to any choice or conflict of law provision or rule (whether of the State of Delaware or any other jurisdiction) that would cause the application of Laws of any jurisdiction other than those of the State of Delaware.

Section 15.08 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together shall be deemed to be one and the same agreement. A signed copy of this Agreement delivered by facsimile, email, or other means of electronic transmission shall be deemed to have the same legal effect as delivery of an original signed copy of this Agreement.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the date first written above by their respective officers thereunto duly authorized.

ALLARITY THERAPEUTICS A/S

By _____

Steve Carchedi
CEO

ALLARITY THERAPEUTICS, INC and ALLARITY ACQUISITION SUBSIDIARY, INC.

By _____

Steve Carchedi
CEO

EXHIBIT A

DEFINITIONS CROSS-REFERENCE TABLE

The following terms have the meanings set forth in the location in this Agreement referenced below:

Term	Section
Accounts Receivable	Section 1.01(b)
Actions	Section 3.12(a)
Affiliate	Section 1.03(b)
Agreement	Preamble
Allocation Schedule	Section 1.05
Assigned Contracts	Section 1.01(d)
Assignment and Assumption Agreement	Section 2.02(a)(ii)
Assumed Liabilities	Section 1.03(a)
Balance Sheet	Section 3.03
Balance Sheet Date	Section 3.03
Bill of Sale	Section 2.02(a)(i)
Books and Records	Section 1.01(i)
Business	Recitals
Buyer	Preamble
Buyer Indemnitees	Section 6.02
Closing	Section 2.01
Closing Date	Section 2.01
Contracts	Section 1.01(d)
Control	Section 1.03(b)
Disclosure Schedules	Section 1.01(d)
Encumbrance	Section 3.02
Excluded Assets	Section 1.02
Excluded Liabilities	Section 1.03(b)
Financial Statements	Section 3.03
Governmental Authority	Section 1.01(i)
Governmental Order	Section 3.02
Indemnified Party	Section 6.04
Indemnifying Party	Section 6.04
Inventory	Section 1.01(c)
Law	Section 3.02
Liabilities	Section 1.03(a)
Losses	Section 6.02
[Material Customers]	[Section 3.11(a)]
[Material Suppliers]	[Section 3.11(b)]
Person	Section 3.02
Purchased Assets	Section 1.01
Purchase Price	Section 1.04
Representatives	Section 5.01
Restricted Business	Section 5.02(a)
Restricted Period	Section 5.02(a)
Seller	Preamble
Seller Indemnitees	Section 6.03

Term	Section
Tangible Personal Property	Section 1.01(e)
Taxes	Section 3.14
Tax Returns	Section 1.05
Territory	Section 5.02(a)
Third-party Claim	Section 6.02(d)
Transaction Documents	Section 2.02(a)(v)
[Transition Services Agreement]	[Section 2.02(a)(iii)]

ALLARITY THERAPEUTICS, INC.

2021 Equity Incentive Plan

1. PURPOSE. The purpose of this Plan is to provide incentives to attract, retain, and motivate eligible persons whose present and potential contributions are important to the success of the Company, and any Parents, Subsidiaries, and Affiliates that exist now or in the future, by offering them an opportunity to participate in the Company's future performance through the grant of Awards. Capitalized terms not defined elsewhere in the text are defined in Section 28.

2. SHARES SUBJECT TO THE PLAN.

2.1. Number of Shares Available. Subject to Sections 2.6 and 21 and any other applicable provisions hereof, the total number of Shares reserved and available for grant and issuance pursuant to this Plan as of the date of adoption of the Plan by the Board, is [One Million One Hundred Sixty Eight Thousand Three Hundred Thirty (1,168,330) Shares, plus an amount derived by the difference between fifteen percent (15%) of the Company's issued and outstanding shares of Common Stock issued in the Company's Recapitalization Share Exchange covered by the Company's registration statement on Form S-4 (SEC File No. 333- _____) and One Million One Hundred Sixty Eight Thousand Three Hundred Thirty (1,168,330) Shares. For the sake of clarity, the initial number of Shares reserved and available for grant as of the date of adoption of the Plan by the Board is an amount equal to fifteen percent (15%) of the Company's issued and outstanding shares of Common Stock issued in the Company's Recapitalization Share Exchange covered by the Company's registration statement on Form S-4 (SEC File No. 333- _____)].

2.2. Lapsed, Returned Awards. Shares subject to Awards, and Shares issued under the Plan under any Award, will again be available for grant and issuance in connection with subsequent Awards under this Plan to the extent such Shares: (a) are subject to issuance upon exercise of an Option or SAR granted under this Plan but which cease to be subject to the Option or SAR for any reason other than exercise of the Option or SAR, (b) are subject to Awards granted under this Plan that are forfeited or are repurchased by the Company at the original issue price, (c) are subject to Awards granted under this Plan that otherwise terminate without such Shares being issued or (d) are surrendered pursuant to an Exchange Program. To the extent an Award under the Plan is paid out in cash or other property rather than Shares, such cash payment will not result in reducing the number of Shares available for issuance under the Plan. Shares used to satisfy the tax withholding obligations related to an RSU will become available for future grant or sale under the Plan. Shares used to pay the exercise price of an Award or withheld to satisfy the tax withholding obligations related to an Award will become available for grant and issuance in connection with subsequent Awards under this Plan. For the avoidance of doubt, Shares that otherwise become available for grant and issuance because of the provisions of this Section 2.2 will not include Shares subject to Awards that initially became available because of the substitution clause in Section 21.2 hereof.

2.3. Minimum Share Reserve. At all times the Company will reserve and keep available a sufficient number of Shares as will be required to satisfy the requirements of all outstanding Awards granted under this Plan.

2.4. Automatic Share Reserve Increase. The number of Shares available for grant and issuance under the Plan will be increased on January 1st of each of 2022 through 2031, by the lesser of (a) Five percent (5%) of the number of shares of all classes of the Company's common stock issued and outstanding on each December 31 immediately prior to the date of increase or (b) such number of Shares determined by the Board.

2.5. ISO Limitation. No more than Seven Million Nine Thousand Nine Hundred Eighty (7,009.980) Shares will be issued pursuant to the exercise of ISOs granted under the Plan.

2.6. Adjustment of Shares. If the number or class of outstanding Shares is changed by a stock dividend, extraordinary dividend or distribution (whether in cash, shares, or other property, other than a regular cash dividend), recapitalization, stock split, reverse stock split, subdivision, combination, consolidation, reclassification, spin-off, or similar change in the capital structure of the Company, without consideration, then (a) the number and class of Shares reserved for issuance and future grant under the Plan set forth in Section 2.1, including Shares reserved under sub-clauses (a)-(e) of Section 2.1, (b) the Exercise Prices of and number and class of Shares subject to outstanding Options and SARs, (c) the number and class of Shares subject to other outstanding Awards, and (d) the maximum number and

class of Shares that may be issued as ISOs set forth in Section 2.5, will be proportionately adjusted, subject to any required action by the Board or the stockholders of the Company and in compliance with applicable securities or other laws, provided that fractions of a Share will not be issued.

If, by reason of an adjustment pursuant to this Section 2.6, a Participant's Award Agreement or other agreement related to any Award, or the Shares subject to such Award, covers additional or different shares of stock or securities, then such additional or different shares, and the Award Agreement or such other agreement in respect thereof, will be subject to all of the terms, conditions, and restrictions which were applicable to the Award or the Shares subject to such Award prior to such adjustment.

3. ELIGIBILITY. ISOs may be granted only to Employees. All other Awards may be granted to Employees, Consultants, Directors, and Non-Employee Directors, provided that such Consultants, Directors, and Non-Employee Directors render bona fide services not in connection with the offer and sale of securities in a capital-raising transaction.

4. ADMINISTRATION.

4.1. Committee Composition; Authority. This Plan will be administered by the Committee or by the Board acting as the Committee. Subject to the general purposes, terms, and conditions of this Plan, and to the direction of the Board, the Committee will have full power to implement and carry out this Plan, except, however, the Board will establish the terms for the grant of an Award to Non-Employee Directors. The Committee will have the authority to:

(a) construe and interpret this Plan, any Award Agreement, and any other agreement or document executed pursuant to this Plan;

(b) prescribe, amend, and rescind rules and regulations relating to this Plan or any Award;

(c) select persons to receive Awards;

(d) determine the form and terms and conditions, not inconsistent with the terms of the Plan, of any Award granted hereunder. Such terms and conditions include, but are not limited to, the Exercise Price, the time or times when Awards may vest and be exercised (which may be based on performance criteria) or settled, any vesting acceleration or waiver of forfeiture restrictions, the method to satisfy tax withholding obligations or any other tax liability legally due, and any restriction or limitation regarding any Award or the Shares relating thereto, based in each case on such factors as the Committee will determine;

(e) determine the number of Shares or other consideration subject to Awards;

(f) determine the Fair Market Value in good faith and interpret the applicable provisions of this Plan and the definition of Fair Market Value in connection with circumstances that impact the Fair Market Value, if necessary;

(g) determine whether Awards will be granted singly, in combination with, in tandem with, in replacement of, or as alternatives to, other Awards under this Plan or any other incentive or compensation plan of the Company or any Parent, Subsidiary, or Affiliate;

(h) grant waivers of Plan or Award conditions;

(i) determine the vesting, exercisability, and payment of Awards;

(j) correct any defect, supply any omission or reconcile any inconsistency in this Plan, any Award or any Award Agreement;

(k) determine whether an Award has been vested and/or earned;

(l) determine the terms and conditions of any, and to institute any Exchange Program;

(m) reduce, waive or modify any criteria with respect to Performance Factors;

(n) adjust Performance Factors to take into account changes in law and accounting or tax rules as the Committee deems necessary or appropriate to reflect the impact of extraordinary or unusual items, events, or circumstances to avoid windfalls or hardships;

(o) adopt terms and conditions, rules, and/or procedures (including the adoption of any subplan under this Plan) relating to the operation and administration of the Plan to accommodate requirements of local law and procedures outside of the United States or to qualify Awards for special tax treatment under laws of jurisdictions other than the United States;

(p) exercise discretion with respect to Performance Awards;

(q) make all other determinations necessary or advisable for the administration of this Plan; and

(r) delegate any of the foregoing to a subcommittee or to one or more executive officers pursuant to a specific delegation as permitted by applicable law, including Section 157(c) of the Delaware General Corporation Law.

4.2. Committee Interpretation and Discretion. Any determination made by the Committee with respect to any Award will be made in its sole discretion at the time of grant of the Award or, unless in contravention of any express term of the Plan or Award, at any later time, and such determination will be final and binding on the Company and all persons having an interest in any Award under the Plan. Any dispute regarding the interpretation of the Plan or any Award Agreement will be submitted by the Participant or Company to the Committee for review. The resolution of such a dispute by the Committee will be final and binding on the Company and the Participant. The Committee may delegate to one or more executive officers the authority to review and resolve disputes with respect to Awards held by Participants who are not Insiders, and such resolution will be final and binding on the Company and the Participant.

4.3. Section 16 of the Exchange Act. Awards granted to Participants who are subject to Section 16 of the Exchange Act must be approved by two or more "non-employee directors" (as defined in the regulations promulgated under Section 16 of the Exchange Act).

4.4. Documentation. The Award Agreement for a given Award, the Plan, and any other documents may be delivered to, and accepted by, a Participant or any other person in any manner (including electronic distribution or posting) that meets applicable legal requirements.

4.5. Foreign Award Recipients. Notwithstanding any provision of the Plan to the contrary, in order to comply with the laws and practices in other countries in which the Company, its Subsidiaries, and Affiliates operate or have Employees or other individuals eligible for Awards, the Committee, in its sole discretion, will have the power and authority to: (a) determine which Subsidiaries and Affiliates will be covered by the Plan; (b) determine which individuals outside the United States are eligible to participate in the Plan, which may include individuals who provide services to the Company, Subsidiary or Affiliate under an agreement with a foreign nation or agency; (c) modify the terms and conditions of any Award granted to individuals outside the United States or foreign nationals to comply with applicable foreign laws, policies, customs, and practices; (d) establish subplans and modify exercise procedures, vesting conditions, and other terms and procedures to the extent the Committee determines such actions to be necessary or advisable (and such subplans and/or modifications will be attached to this Plan as appendices, if necessary); and (e) take any action, before or after an Award is made, that the Committee determines to be necessary or advisable to obtain approval or comply with any local governmental regulatory exemptions or approvals, provided, however, that no action taken under this Section 4.5 will increase the Share limitations contained in Section 2.1 hereof. Notwithstanding the foregoing, the Committee may not take any actions hereunder, and no Awards will be granted, that would violate the Exchange Act or any other applicable United States securities law, the Code, or any other applicable United States governing statute or law.

5. OPTIONS. An Option is the right but not the obligation to purchase a Share, subject to certain conditions, if applicable. The Committee may grant Options to eligible Employees, Consultants, and Directors and will determine whether such Options will be Incentive Stock Options within the meaning of the Code ("***ISOs***") or Nonqualified Stock Options ("***NSOs***"), the number of Shares subject to the Option, the Exercise Price of the Option, the period during which the Option may vest and be exercised, and all other terms and conditions of the Option, subject to the following terms of this section.

5.1. Option Grant. Each Option granted under this Plan will identify the Option as an ISO or an NSO. An Option may be, but need not be, awarded upon satisfaction of such Performance Factors during any Performance Period as are set out in advance in the Participant's individual Award Agreement. If the Option is being earned upon the satisfaction of Performance Factors, then the Committee will: (a) determine the nature, length, and starting date of any Performance Period for each Option; and (b) select from among the Performance Factors to be used to measure the performance, if any. Performance Periods may overlap and Participants may participate simultaneously with respect to Options that are subject to different performance goals and other criteria.

5.2. Date of Grant. The date of grant of an Option will be the date on which the Committee makes the determination to grant such Option, or a specified future date. The Award Agreement and a copy of this Plan will be delivered to the Participant within a reasonable time after the granting of the Option.

5.3. Exercise Period. Options may be vested and exercisable within the times or upon the conditions as set forth in the Award Agreement governing such Option, provided, however, that no Option will be exercisable after the expiration of ten (10) years from the date the Option is granted and provided further that no ISO granted to a person who, at the time the ISO is granted, directly or by attribution owns more than ten percent (10%) of the total combined voting power of all classes of stock of the Company or of any Parent or Subsidiary ("***Ten Percent Stockholder***") will be exercisable after the expiration of five (5) years from the date the ISO is granted. The Committee also may provide for Options to become exercisable at one time or from time to time, periodically or otherwise, in such number of Shares or percentage of Shares as the Committee determines.

5.4. Exercise Price. The Exercise Price of an Option will be determined by the Committee when the Option is granted, provided that: (a) the Exercise Price of an Option will be not less than one hundred percent (100%) of the Fair Market Value of the Shares on the date of grant, and (b) the Exercise Price of any ISO granted to a Ten Percent Stockholder will not be less than one hundred ten percent (110%) of the Fair Market Value of the Shares on the date of grant. Payment for the Shares purchased may be made in accordance with Section 11 and the Award Agreement and in accordance with any procedures established by the Company.

5.5. Method of Exercise. Any Option granted hereunder will be vested and exercisable according to the terms of the Plan and at such times and under such conditions as determined by the Committee and set forth in the Award Agreement. An Option may not be exercised for a fraction of a Share. An Option will be deemed exercised when the Company receives: (a) notice of exercise (in such form as the Committee may specify from time to time) from the person entitled to exercise the Option (and/or via electronic execution through the authorized third-party administrator), and (b) full payment for the Shares with respect to which the Option is exercised (together with applicable withholding taxes). Full payment may consist of any consideration and method of payment authorized by the Committee and permitted by the Award Agreement and the Plan. Shares issued upon exercise of an Option will be issued in the name of the Participant. Until the Shares are issued (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company), no right to vote or receive dividends or any other rights as a stockholder will exist with respect to the Shares, notwithstanding the exercise of the Option. The Company will issue (or cause to be issued) such Shares promptly after the Option is exercised. No adjustment will be made for a dividend or other right for which the record date is prior to the date the Shares are issued, except as provided in Section 2.6 of the Plan. Exercising an Option in any manner will decrease the number of Shares thereafter available, both for purposes of the Plan and for sale under the Option, by the number of Shares as to which the Option is exercised.

5.6. Termination of Service. If the Participant's Service terminates for any reason except for Cause or the Participant's death or Disability, then the Participant may exercise such Participant's Options only to the extent that such Options would have been exercisable by the Participant on the date Participant's Service terminates no later than three (3) months after the date Participant's Service terminates (or such shorter or longer time period as may be determined by the Committee, with any exercise of an ISO beyond three (3) months after the date Participant's employment terminates deemed to be the exercise of an NSO), but in any event no later than the expiration date of the Options.

(a) Death. If the Participant's Service terminates because of the Participant's death (or the Participant dies within three (3) months after Participant's Service terminates other than for Cause or because of the Participant's Disability), then the Participant's Options may be exercised only to the extent that such Options would have been exercisable by the Participant on the date Participant's Service terminates and must be exercised by the

Participant's legal representative, or authorized assignee, no later than twelve (12) months after the date Participant's Service terminates (or such shorter or longer time period as may be determined by the Committee), but in any event no later than the expiration date of the Options.

(b) Disability. If the Participant's Service terminates because of the Participant's Disability, then the Participant's Options may be exercised only to the extent that such Options would have been exercisable by the Participant on the date Participant's Service terminates and must be exercised by the Participant (or the Participant's legal representative or authorized assignee) no later than twelve (12) months after the date Participant's Service terminates (or such shorter or longer time period as may be determined by the Committee, with any exercise beyond (a) three (3) months after the date Participant's employment terminates when the termination of Service is for a Disability that is not a "permanent and total disability" as defined in Section 22(e)(3) of the Code or (b) twelve (12) months after the date Participant's employment terminates when the termination of Service is for a Disability that is a "permanent and total disability" as defined in Section 22(e)(3) of the Code, deemed to be exercise of an NSO), but in any event no later than the expiration date of the Options.

(c) Cause. Unless otherwise determined by the Committee, if the Participant's Service terminates for Cause, then Participant's Options (whether or not vested) will expire on the date of termination of Participant's Service if the Committee has reasonably determined in good faith that such cessation of Services has resulted in connection with an act or failure to act constituting Cause (or such Participant's Services could have been terminated for Cause (without regard to the lapsing of any required notice or cure periods in connection therewith) at the time such Participant terminated Service), or at such later time and on such conditions as are determined by the Committee, but in any event no later than the expiration date of the Options. Unless otherwise provided in an employment agreement, Award Agreement, or other applicable agreement, Cause will have the meaning set forth in the Plan.

5.7. Limitations on ISOs. With respect to Awards granted as ISOs, to the extent that the aggregate Fair Market Value of the Shares with respect to which such ISOs are exercisable for the first time by the Participant during any calendar year (under all plans of the Company and any Parent or Subsidiary) exceeds one hundred thousand dollars ($100,000), such Options will be treated as NSOs. For purposes of this Section 5.7, ISOs will be taken into account in the order in which they were granted. The Fair Market Value of the Shares will be determined as of the time the Option with respect to such Shares is granted. In the event that the Code or the regulations promulgated thereunder are amended after the Effective Date to provide for a different limit on the Fair Market Value of Shares permitted to be subject to ISOs, such different limit will be automatically incorporated herein and will apply to any Options granted after the effective date of such amendment.

5.8. Modification, Extension or Renewal. The Committee may modify, extend, or renew outstanding Options and authorize the grant of new Options in substitution therefor, provided that any such action may not, without the written consent of a Participant, impair any of such Participant's rights under any Option previously granted. Any outstanding ISO that is modified, extended, renewed, or otherwise altered will be treated in accordance with Section 424(h) of the Code. Subject to Section 18 of this Plan, by written notice to affected Participants, the Committee may reduce the Exercise Price of outstanding Options without the consent of such Participants, provided, however, that the Exercise Price may not be reduced below the Fair Market Value on the date the action is taken to reduce the Exercise Price.

5.9. No Disqualification. Notwithstanding any other provision in this Plan, no term of this Plan relating to ISOs will be interpreted, amended, or altered, nor will any discretion or authority granted under this Plan be exercised, so as to disqualify this Plan under Section 422 of the Code or, without the consent of the Participant affected, to disqualify any ISO under Section 422 of the Code.

6. RESTRICTED STOCK UNITS. A Restricted Stock Unit ("***RSU***") is an award to an eligible Employee, Consultant, or Director covering a number of Shares that may be settled by issuance of those Shares (which may consist of Restricted Stock) or in cash. All RSUs will be made pursuant to an Award Agreement.

6.1. Terms of RSUs. The Committee will determine the terms of an RSU including, without limitation: (a) the number of Shares subject to the RSU, (b) the time or times during which the RSU may be settled, (c) the consideration to be distributed on settlement, and (d) the effect of the Participant's termination of Service on each

RSU, provided that no RSU will have a term longer than ten (10) years. An RSU may be awarded upon satisfaction of such performance goals based on Performance Factors during any Performance Period as are set out in advance in the Participant's Award Agreement. If the RSU is being earned upon satisfaction of Performance Factors, then the Committee will: (i) determine the nature, length, and starting date of any Performance Period for the RSU; (ii) select from among the Performance Factors to be used to measure the performance, if any; and (iii) determine the number of Shares deemed subject to the RSU. Performance Periods may overlap and Participants may participate simultaneously with respect to RSUs that are subject to different Performance Periods and different performance goals and other criteria. The Committee may adjust the performance goals to account for changes in law and accounting and to make such adjustments as the Committee deems necessary or appropriate to reflect the impact of extraordinary or unusual items, events or circumstances to avoid windfalls or hardships, including without limitation (i) restructurings, discontinued operations, extraordinary items, and other unusual or non-recurring changes, (ii) an event either not directly related to the operations of the Company or not within the reasonable control of the Company's management, or (iii) a change in accounting standards required by generally accepted accounting principles.

6.2. Form and Timing of Settlement. Payment of earned RSUs will be made as soon as practicable after the date(s) determined by the Committee and set forth in the Award Agreement. The Committee, in its sole discretion, may settle earned RSUs in cash, Shares, or a combination of both. The Committee may also permit a Participant to defer payment under a RSU to a date or dates after the RSU is earned, provided that the terms of the RSU and any deferral satisfy the requirements of Section 409A of the Code to the extent applicable.

6.3. Termination of Service. Except as may be set forth in the Participant's Award Agreement, vesting ceases on such date Participant's Service terminates (unless determined otherwise by the Committee).

7. RESTRICTED STOCK AWARDS. A Restricted Stock Award is an offer by the Company to sell to an eligible Employee, Consultant, or Director Shares that are subject to restrictions ("***Restricted Stock***"). The Committee will determine to whom an offer will be made, the number of Shares the Participant may purchase, the Purchase Price, the restrictions under which the Shares will be subject, and all other terms and conditions of the Restricted Stock Award, subject to the Plan.

7.1. Restricted Stock Purchase Agreement. All purchases under a Restricted Stock Award will be evidenced by an Award Agreement. Except as may otherwise be provided in an Award Agreement, a Participant accepts a Restricted Stock Award by signing and delivering to the Company an Award Agreement with full payment of the Purchase Price, within thirty (30) days from the date the Award Agreement was delivered to the Participant. If the Participant does not accept such Award within thirty (30) days, then the offer to purchase such Restricted Stock Award will terminate, unless the Committee determines otherwise.

7.2. Purchase Price. The Purchase Price for Shares issued pursuant to a Restricted Stock Award will be determined by the Committee and may be less than Fair Market Value on the date the Restricted Stock Award is granted. Payment of the Purchase Price must be made in accordance with Section 11 of the Plan, and the Award Agreement and in accordance with any procedures established by the Company.

7.3. Terms of Restricted Stock Awards. Restricted Stock Awards will be subject to such restrictions as the Committee may impose or are required by law. These restrictions may be based on completion of a specified period of Service with the Company or upon completion of Performance Factors, if any, during any Performance Period as set out in advance in the Participant's Award Agreement. Prior to the grant of a Restricted Stock Award, the Committee will: (a) determine the nature, length, and starting date of any Performance Period for the Restricted Stock Award; (b) select from among the Performance Factors to be used to measure performance goals, if any; and (c) determine the number of Shares that may be awarded to the Participant. Performance Periods may overlap and a Participant may participate simultaneously with respect to Restricted Stock Awards that are subject to different Performance Periods and having different performance goals and other criteria.

7.4. Termination of Service. Except as may be set forth in the Participant's Award Agreement, vesting ceases on such date Participant's Service terminates (unless determined otherwise by the Committee).

8. STOCK BONUS AWARDS. A Stock Bonus Award is an award to an eligible Employee, Consultant, or Director of Shares for Services to be rendered or for past Services already rendered to the Company or any Parent, Subsidiary, or Affiliate. All Stock Bonus Awards will be made pursuant to an Award Agreement. No payment from the Participant will be required for Shares awarded pursuant to a Stock Bonus Award.

8.1. Terms of Stock Bonus Awards. The Committee will determine the number of Shares to be awarded to the Participant under a Stock Bonus Award and any restrictions thereon. These restrictions may be based upon completion of a specified period of Service with the Company or upon satisfaction of performance goals based on Performance Factors during any Performance Period as set out in advance in the Participant's Stock Bonus Agreement. Prior to the grant of any Stock Bonus Award the Committee will: (a) determine the restrictions to which the Stock Bonus Award is subject, including the nature, length, and starting date of any Performance Period for the Stock Bonus Award; (b) select from among the Performance Factors, if any, to be used to measure performance goals; and (c) determine the number of Shares that may be awarded to the Participant. Performance Periods may overlap and a Participant may participate simultaneously with respect to Stock Bonus Awards that are subject to different Performance Periods and different performance goals and other criteria.

8.2. Form of Payment to Participant. Payment may be made in the form of cash, whole Shares, or a combination thereof, based on the Fair Market Value of the Shares earned under a Stock Bonus Award on the date of payment, as determined in the sole discretion of the Committee.

8.3. Termination of Service. Except as may be set forth in the Participant's Award Agreement, vesting ceases on such date Participant's Service terminates (unless determined otherwise by the Committee).

9. STOCK APPRECIATION RIGHTS. A Stock Appreciation Right ("***SAR***") is an award to an eligible Employee, Consultant, or Director that may be settled in cash or Shares (which may consist of Restricted Stock) having a value equal to (a) the difference between the Fair Market Value on the date of exercise over the Exercise Price multiplied by (b) the number of Shares with respect to which the SAR is being settled (subject to any maximum number of Shares that may be issuable as specified in an Award Agreement). All SARs will be made pursuant to an Award Agreement.

9.1. Terms of SARs. The Committee will determine the terms of each SAR including, without limitation: (a) the number of Shares subject to the SAR, (b) the Exercise Price and the time or times during which the SAR may be exercised and settled, (c) the consideration to be distributed on exercise and settlement of the SAR, and (d) the effect of the Participant's termination of Service on each SAR. The Exercise Price of the SAR will be determined by the Committee when the SAR is granted and may not be less than Fair Market Value of the Shares on the date of grant. A SAR may be awarded upon satisfaction of Performance Factors, if any, during any Performance Period as are set out in advance in the Participant's individual Award Agreement. If the SAR is being earned upon the satisfaction of Performance Factors, then the Committee will: (i) determine the nature, length, and starting date of any Performance Period for each SAR; and (ii) select from among the Performance Factors to be used to measure the performance, if any. Performance Periods may overlap and Participants may participate simultaneously with respect to SARs that are subject to different Performance Factors and other criteria.

9.2. Exercise Period and Expiration Date. A SAR will be exercisable within the times or upon the occurrence of events determined by the Committee and set forth in the Award Agreement governing such SAR. The SAR Agreement will set forth the expiration date, provided that no SAR will be exercisable after the expiration of ten (10) years from the date the SAR is granted. The Committee may also provide for SARs to become exercisable at one time or from time to time, periodically or otherwise (including, without limitation, upon the attainment during a Performance Period of performance goals based on Performance Factors), in such number of Shares or percentage of the Shares subject to the SAR as the Committee determines. Except as may be set forth in the Participant's Award Agreement, vesting ceases on the date Participant's Service terminates (unless determined otherwise by the Committee). Notwithstanding the foregoing, the rules of Section 5.6 also will apply to SARs.

9.3. Form of Settlement. Upon exercise of a SAR, a Participant will be entitled to receive payment from the Company in an amount determined by multiplying (a) the difference between the Fair Market Value of a Share on the date of exercise over the Exercise Price, by (b) the number of Shares with respect to which the SAR is exercised. At the discretion of the Committee, the payment from the Company for the SAR exercise may be in cash, in Shares of equivalent value, or in some combination thereof. The portion of a SAR being settled may be paid currently or on a deferred basis with such interest, if any, as the Committee determines, provided that the terms of the SAR and any deferral satisfy the requirements of Section 409A of the Code to the extent applicable.

9.4. Termination of Service. Except as may be set forth in the Participant's Award Agreement, vesting ceases on the date Participant's Service terminates (unless determined otherwise by the Committee).

10. PERFORMANCE AWARDS.

10.1. Types of Performance Awards. A Performance Award is an award to an eligible Employee, Consultant, or Director that is based upon the attainment of performance goals, as established by the Committee, and other terms and conditions specified by the Committee, and may be settled in cash, Shares (which may consist of, without limitation, Restricted Stock), other property, or any combination thereof. Grants of Performance Awards will be made pursuant to an Award Agreement that cites Section 10 of the Plan. The Committee may adjust the performance goals to account for changes in law and accounting and to make such adjustments as the Committee deems necessary or appropriate to reflect the impact of extraordinary or unusual items, events or circumstances to avoid windfalls or hardships, including without limitation (i) restructurings, discontinued operations, extraordinary items, and other unusual or non-recurring changes, (ii) an event either not directly related to the operations of the Company or not within the reasonable control of the Company's management, or (iii) a change in accounting standards required by generally accepted accounting principles.

(a) Performance Shares. The Committee may grant Awards of Performance Shares, designate the Participants to whom Performance Shares are to be awarded, and determine the number of Performance Shares and the terms and conditions of each such Award. Each Performance Share will have an initial value equal to the Fair Market Value of as Share on the date of grant. Performance Shares will consist of a unit valued by reference to a designated number of Shares, the value of which may be paid to the Participant by delivery of Shares or, if set forth in the instrument evidencing the Award, of such property as the Committee will determine, including, without limitation, cash, Shares, other property, or any combination thereof, upon the attainment of performance goals, as established by the Committee, and other terms and conditions specified by the Committee. The amount to be paid under an Award of Performance Shares may be adjusted on the basis of such further consideration as the Committee will determine in its sole discretion.

(b) Performance Units. The Committee may grant Awards of Performance Units, designate the Participants to whom Performance Units are to be awarded, and determine the number of Performance Units and the terms and conditions of each such Award. Performance Units will consist of a unit valued by reference to a designated amount of property other than Shares, which value may be paid to the Participant by delivery of such property as the Committee will determine, including, without limitation, cash, Shares, other property, or any combination thereof, upon the attainment of performance goals, as established by the Committee, and other terms and conditions specified by the Committee.

(c) Cash-Settled Performance Awards. The Committee may also grant cash-settled Performance Awards to Participants under the terms of this Plan. Such awards will be based on the attainment of performance goals using the Performance Factors within this Plan that are established by the Committee for the relevant performance period.

10.2. Terms of Performance Awards. The Committee will determine, and each Award Agreement will set forth, the terms of each Performance Award including, without limitation: (a) the amount of any cash bonus, (b) the number of Shares deemed subject to an award of Performance Shares, (c) the Performance Factors and Performance Period that will determine the time and extent to which each award of Performance Shares will be settled, (d) the consideration to be distributed on settlement, and (e) the effect of the Participant's termination of Service on each Performance Award. In establishing Performance Factors and the Performance Period the Committee will: (i) determine the nature, length, and starting date of any Performance Period; (ii) select from among the Performance Factors to be used; and (iii) determine the number of Shares deemed subject to the award of Performance Shares. Each Performance Share will have an initial value equal to the Fair Market Value of a Share on the date of grant. Prior to settlement the Committee will determine the extent to which Performance Awards have been earned. Performance Periods may overlap and Participants may participate simultaneously with respect to Performance Awards that are subject to different Performance Periods and different performance goals and other criteria.

10.3. Termination of Service. Except as may be set forth in the Participant's Award Agreement, vesting ceases on the date Participant's Service terminates (unless determined otherwise by the Committee).

11. PAYMENT FOR SHARE PURCHASES. Payment from a Participant for Shares purchased pursuant to this Plan may be made in cash or by check or, where expressly approved for the Participant by the Committee and where permitted by law (and to the extent not otherwise set forth in the applicable Award Agreement):

(a) by cancellation of indebtedness of the Company to the Participant;

(b) by surrender of shares of the Company held by the Participant that have a Fair Market Value on the date of surrender equal to the aggregate exercise price of the Shares as to which said Award will be exercised or settled;

(c) by waiver of compensation due or accrued to the Participant for services rendered or to be rendered to the Company or a Parent or Subsidiary of the Company;

(d) by consideration received by the Company pursuant to a broker-assisted or other form of cashless exercise program implemented by the Company in connection with the Plan;

(e) by any combination of the foregoing; or

(f) by any other method of payment as is permitted by applicable law.

The Committee may limit the availability of any method of payment, to the extent the Committee determines, in its discretion, such limitation is necessary or advisable to comply with applicable law or facilitate the administration of the Plan.

12. GRANTS TO NON-EMPLOYEE DIRECTORS.

12.1. General. Non-Employee Directors are eligible to receive any type of Award offered under this Plan except ISOs. Awards pursuant to this Section 12 may be automatically made pursuant to policy adopted by the Board, or made from time to time as determined in the discretion of the Board. No Non-Employee Director may receive Awards under the Plan that, when combined with cash compensation received for service as a Non-Employee Director, exceed Seven Hundred Fifty Thousand Dollars ($750,000) in value (as described below) in any calendar year; provided, however, that a Non-Employee Director may receive up to One Million Dollars ($1,000,000) in value in his or her initial year of service as a Non-Employee Director. The value of Awards for purposes of complying with this maximum will be determined as follows: (a) for Options and SARs, grant date fair value will be calculated using the Company's regular valuation methodology for determining the grant date fair value of Options for reporting purposes, and (b) for all other Awards other than Options and SARs, grant date fair value will be determined by either (i) calculating the product of the Fair Market Value per Share on the date of grant and the aggregate number of Shares subject to the Award, or (ii) calculating the product using an average of the Fair Market Value over a number of trading days and the aggregate number of Shares subject to the Award as determined by the Committee. Awards granted to an individual while he or she was serving in the capacity as an Employee or while he or she was a Consultant but not a Non-Employee Director will not count for purposes of the limitations set forth in this Section 12.1.

12.2. Eligibility. Awards pursuant to this Section 12 will be granted only to Non-Employee Directors. A Non-Employee Director who is elected or re-elected as a member of the Board will be eligible to receive an Award under this Section 12.

12.3. Vesting, Exercisability and Settlement. Except as set forth in Section 21, Awards will vest, become exercisable, and be settled as determined by the Board. With respect to Options and SARs, the exercise price granted to Non-Employee Directors will not be less than the Fair Market Value of the Shares at the time that such Option or SAR is granted.

12.4. Election to Receive Awards in Lieu of Cash. A Non-Employee Director may elect to receive his or her annual retainer payments and/or meeting fees from the Company in the form of cash or Awards or a combination thereof, if permitted, and as determined, by the Committee. Such Awards will be issued under the Plan. An election under this Section 12.4 will be filed with the Company on the form prescribed by the Company.

13. WITHHOLDING TAXES.

13.1. Withholding Generally. Whenever Shares are to be issued in satisfaction of Awards granted under this Plan or a tax event occurs, the Company may require the Participant to remit to the Company, or to the Parent, Subsidiary, or Affiliate, as applicable, employing the Participant an amount sufficient to satisfy applicable U.S. federal, state, local, and international income tax, social insurance, payroll tax, fringe benefits tax, payment on account or other tax liability legally due from the Participant (the tax-related items, the "***Tax-Related Items***") prior to the delivery of Shares pursuant to exercise or settlement of any Award. Whenever payments in satisfaction of Awards granted under this Plan are to be made in cash, such payment will be net of an amount sufficient to satisfy applicable withholding obligations for Tax-Related Items. Unless otherwise determined by the Committee, the Fair Market Value of the Shares will be determined as of the date that the taxes are required to be withheld and such Shares will be valued based on the value of the actual trade or, if there is none, the Fair Market Value of the Shares as of the previous trading day.

13.2. Stock Withholding. The Committee, or its delegate(s), as permitted by applicable law, in its sole discretion and pursuant to such procedures as it may specify from time to time and to limitations of local law, may require or permit a Participant to satisfy such Tax Related Items legally due from the Participant, in whole or in part by (without limitation) (a) paying cash, (b) having the Company withhold otherwise deliverable cash or Shares having a Fair Market Value equal to the Tax-Related Items to be withheld, (c) delivering to the Company already-owned shares having a Fair Market Value equal to the Tax-Related Items to be withheld, or (d) withholding from the proceeds of the sale of otherwise deliverable Shares acquired pursuant to an Award either through a voluntary sale or through a mandatory sale arranged by the Company. The Company may withhold or account for these Tax-Related Items by considering applicable statutory withholding rates or other applicable withholding rates, including up to the maximum permissible statutory tax rate for the applicable tax jurisdiction, to the extent consistent with applicable laws.

14. TRANSFERABILITY. Unless determined otherwise by the Committee, an Award may not be sold, pledged, assigned, hypothecated, transferred, or disposed of in any manner other than by will or by the laws of descent or distribution. If the Committee makes an Award transferable, including, without limitation, by instrument to an inter vivos or testamentary trust in which the Awards are to be passed to beneficiaries upon the death of the trustor (settlor) or by gift or by domestic relations order to a Permitted Transferee, such Award will contain such additional terms and conditions as the Committee deems appropriate. All Awards will be exercisable: (a) during the Participant's lifetime only by the Participant or the Participant's guardian or legal representative; (b) after the Participant's death, by the legal representative of the Participant's heirs or legatees; and (c) in the case of all awards except ISOs, by a Permitted Transferee. Notwithstanding any contrary provision of the Plan, the Committee shall have all discretion and authority to determine and implement the terms and conditions of any Award Transfer Program instituted pursuant to this Section 14 and shall have the authority to amend the terms of any Award participating, or otherwise eligible to participate in, the Award Transfer Program, including (but not limited to) the authority to (a) amend (including to extend) the expiration date, post-termination exercise period and/or forfeiture conditions of any such Award, (b) amend or remove any provisions of the Award relating to the Award holder's continued service to the Company or its Parent or any Subsidiary, (c) amend the permissible payment methods with respect to the exercise or purchase of any such Award, (d) amend the adjustments to be implemented in the event of changes in the capitalization and other similar events with respect to such Award, and (e) make such other changes to the terms of such Award as the Committee deems necessary or appropriate in its sole discretion.

15. PRIVILEGES OF STOCK OWNERSHIP; RESTRICTIONS ON SHARES.

15.1. Voting and Dividends. No Participant will have any of the rights of a stockholder with respect to any Shares until the Shares are issued to the Participant, except for any Dividend Equivalent Rights permitted by an applicable Award Agreement. Any Dividend Equivalent Rights will be subject to the same vesting or performance conditions as the underlying Award. In addition, the Committee may provide that any Dividend Equivalent Rights permitted by an applicable Award Agreement will be deemed to have been reinvested in additional Shares or otherwise reinvested. After Shares are issued to the Participant, the Participant will be a stockholder and have all the rights of a stockholder with respect to such Shares, including the right to vote and receive all dividends or other distributions made or paid with respect to such Shares; provided, that if such Shares are Restricted Stock, then any new, additional or different securities the Participant may become entitled to receive with respect to such Shares by virtue of a stock dividend, stock split or any other change in the corporate or capital structure of the Company will be subject to

the same restrictions as the Restricted Stock; provided, further, that the Participant will have no right to such stock dividends or stock distributions with respect to Unvested Shares, and any such dividends or stock distributions will be accrued and paid only at such time, if any, as such Unvested Shares become vested Shares. The Committee, in its discretion, may provide in the Award Agreement evidencing any Award that the Participant will be entitled to Dividend Equivalent Rights with respect to the payment of cash dividends on Shares underlying an Award during the period beginning on the date the Award is granted and ending, with respect to each Share subject to the Award, on the earlier of the date on which the Award is exercised or settled or the date on which it is forfeited provided, that no Dividend Equivalent Right will be paid with respect to the Unvested Shares, and such dividends or stock distributions will be accrued and paid only at such time, if any, as such Unvested Shares become vested Shares. Such Dividend Equivalent Rights, if any, will be credited to the Participant in the form of additional whole Shares as of the date of payment of such cash dividends on Shares.

15.2. Restrictions on Shares. At the discretion of the Committee, the Company may reserve to itself and/or its assignee(s) a right to repurchase (a "***Right of Repurchase***") a portion of any or all Unvested Shares held by a Participant following such Participant's termination of Service at any time within ninety (90) days (or such longer or shorter time determined by the Committee) after the later of the date Participant's Service terminates and the date the Participant purchases Shares under this Plan, for cash and/or cancellation of purchase money indebtedness, at the Participant's Purchase Price or Exercise Price, as the case may be.

16. CERTIFICATES. All Shares or other securities whether or not certificated, delivered under this Plan will be subject to such stock transfer orders, legends, and other restrictions as the Committee may deem necessary or advisable, including restrictions under any applicable U.S. federal, state, or foreign securities law, or any rules, regulations, and other requirements of the SEC or any stock exchange or automated quotation system upon which the Shares may be listed or quoted, and any non-U.S. exchange controls or securities law restrictions to which the Shares are subject.

17. ESCROW; PLEDGE OF SHARES. To enforce any restrictions on a Participant's Shares, the Committee may require the Participant to deposit all certificates representing Shares, together with stock powers or other instruments of transfer approved by the Committee, appropriately endorsed in blank, with the Company or an agent designated by the Company to hold in escrow until such restrictions have lapsed or terminated, and the Committee may cause a legend or legends referencing such restrictions to be placed on the certificates. Any Participant who is permitted to execute a promissory note as partial or full consideration for the purchase of Shares under this Plan will be required to pledge and deposit with the Company all or part of the Shares so purchased as collateral to secure the payment of the Participant's obligation to the Company under the promissory note, provided, however, that the Committee may require or accept other or additional forms of collateral to secure the payment of such obligation and, in any event, the Company will have full recourse against the Participant under the promissory note notwithstanding any pledge of the Participant's Shares or other collateral. In connection with any pledge of the Shares, the Participant will be required to execute and deliver a written pledge agreement in such form as the Committee will from time to time approve. The Shares purchased with the promissory note may be released from the pledge on a pro rata basis as the promissory note is paid.

18. REPRICING; EXCHANGE AND BUYOUT OF AWARDS. Without prior stockholder approval the Committee may (a) reprice Options or SARs (and where such repricing is a reduction in the Exercise Price of outstanding Options or SARs, the consent of the affected Participants is not required provided written notice is provided to them, notwithstanding any adverse tax consequences to them arising from the repricing), and (b) with the consent of the respective Participants (unless not required pursuant to Section 5.9 of the Plan), pay cash or issue new Awards in exchange for the surrender and cancellation of any, or all, outstanding Awards.

19. SECURITIES LAW AND OTHER REGULATORY COMPLIANCE. An Award will not be effective unless such Award is in compliance with all applicable U.S. and foreign federal and state securities and exchange control and other laws, rules, and regulations of any governmental body, and the requirements of any stock exchange or automated quotation system upon which the Shares may then be listed or quoted, as they are in effect on the date of grant of the Award and also on the date of exercise or other issuance. Notwithstanding any other provision in this Plan, the Company will have no obligation to issue or deliver certificates for Shares under this Plan prior to: (a) obtaining any approvals from governmental agencies that the Company determines are necessary or advisable and/or (b) completion of any registration or other qualification of such Shares under any state, federal, or foreign law or ruling of any governmental body that the Company determines to be necessary or advisable. The Company will

be under no obligation to register the Shares with the SEC or to effect compliance with the registration, qualification, or listing requirements of any foreign or state securities laws, exchange control laws, stock exchange, or automated quotation system, and the Company will have no liability for any inability or failure to do so.

20. NO OBLIGATION TO EMPLOY. Nothing in this Plan or any Award granted under this Plan will confer or be deemed to confer on any Participant any right to continue in the employ of, or to continue any other relationship with, the Company or any Parent, Subsidiary, or Affiliate or limit in any way the right of the Company or any Parent, Subsidiary, or Affiliate to terminate Participant's employment or other relationship at any time.

21. CORPORATE TRANSACTIONS.

21.1. Assumption or Replacement of Awards by Successor. In the event that the Company is subject to a Corporate Transaction, outstanding Awards acquired under the Plan shall be subject to the agreement evidencing the Corporate Transaction, which need not treat all outstanding Awards in an identical manner. Such agreement, without the Participant's consent, shall provide for one or more of the following with respect to all outstanding Awards as of the effective date of such Corporate Transaction:

(a) The continuation of an outstanding Award by the Company (if the Company is the successor entity).

(b) The assumption of an outstanding Award by the successor or acquiring entity (if any) of such Corporate Transaction (or by its parents, if any), which assumption, will be binding on all selected Participants; provided that the exercise price and the number and nature of shares issuable upon exercise of any such option or stock appreciation right, or any award that is subject to Section 409A of the Code, will be adjusted appropriately pursuant to Section 424(a) of the Code and/or Section 409A of the Code, as applicable.

(c) The substitution by the successor or acquiring entity in such Corporate Transaction (or by its parents, if any) of equivalent awards with substantially the same terms for such outstanding Awards (except that the exercise price and the number and nature of shares issuable upon exercise of any such option or stock appreciation right, or any award that is subject to Section 409A of the Code, will be adjusted appropriately pursuant to Section 424(a) of the Code and/or Section 409A of the Code, as applicable).

(d) The full or partial acceleration of exercisability or vesting and accelerated expiration of an outstanding Award and lapse of the Company's right to repurchase or re-acquire shares acquired under an Award or lapse of forfeiture rights with respect to shares acquired under an Award.

(e) The settlement of the full value of such outstanding Award (whether or not then vested or exercisable) in cash, cash equivalents, or securities of the successor entity (or its parent, if any) with a fair market value equal to the required amount, followed by the cancellation of such Awards; provided however, that such Award may be cancelled if such Award has no value, as determined by the Committee, in its discretion.

Subject to Section 409A of the Code, such payment may be made in installments and may be deferred until the date or dates the Award would have become exercisable or vested. Such payment may be subject to vesting based on the Participant's continued service, provided that the vesting schedule shall not be less favorable to the Participant than the schedule under which the Award would have become vested or exercisable. For purposes of this Section 21.1(e), the fair market value of any security shall be determined without regard to any vesting conditions that may apply to such security.

(f) The cancellation of outstanding Awards in exchange for no consideration.

The Board shall have full power and authority to assign the Company's right to repurchase or re-acquire or forfeiture rights to such successor or acquiring corporation. In addition, in the event such successor or acquiring corporation (if any) refuses to assume, convert, replace or substitute Awards, as provided above, pursuant to a Corporate Transaction, then the Committee will notify each Participant in writing or electronically that such Participant's

Award will, if exercisable, be exercisable for a period of time determined by the Committee in its sole discretion, and such Award will terminate upon the expiration of such period. Awards need not be treated similarly in a Corporate Transaction and treatment may vary from Award to Award and/or from Participant to Participant.

21.2. Assumption of Awards by the Company. The Company, from time to time, also may substitute or assume outstanding awards granted by another company, whether in connection with an acquisition of such other company or otherwise, by either: (a) granting an Award under this Plan in substitution of such other company's award, or (b) assuming such award as if it had been granted under this Plan if the terms of such assumed award could be applied to an Award granted under this Plan. Such substitution or assumption will be permissible if the holder of the substituted or assumed award would have been eligible to be granted an Award under this Plan if the other company had applied the rules of this Plan to such grant. In the event the Company assumes an award granted by another company, the terms and conditions of such award will remain unchanged (except that the Purchase Price or the Exercise Price, as the case may be, and the number and nature of Shares issuable upon exercise or settlement of any such Award will be adjusted appropriately pursuant to Section 424(a) of the Code). In the event the Company elects to grant a new Option in substitution rather than assuming an existing option, such new Option may be granted with a similarly adjusted Exercise Price. Substitute Awards will not reduce the number of Shares authorized for grant under the Plan or authorized for grant to a Participant in a calendar year.

21.3. Non-Employee Directors' Awards. Notwithstanding any provision to the contrary herein, in the event of a Corporate Transaction, the vesting of all Awards granted to Non-Employee Directors will accelerate and such Awards will become exercisable (as applicable) in full prior to the consummation of such event at such times and on such conditions as the Committee determines.

22. ADOPTION AND STOCKHOLDER APPROVAL. This Plan will be submitted for the approval of the Company's stockholders, consistent with applicable laws, within twelve (12) months before or after the date this Plan is adopted by the Board.

23. TERM OF PLAN/GOVERNING LAW. Unless earlier terminated as provided herein, this Plan will become effective on the Effective Date and will terminate ten (10) years from the date this Plan is adopted by the Board. This Plan and all Awards granted hereunder will be governed by and construed in accordance with the laws of the State of Delaware (excluding its conflict of laws rules).

24. AMENDMENT OR TERMINATION OF PLAN. The Board may at any time terminate or amend this Plan in any respect, including, without limitation, amendment of any form of Award Agreement or instrument to be executed pursuant to this Plan, provided, however, that the Board will not, without the approval of the stockholders of the Company, amend this Plan in any manner that requires such stockholder approval, provided further that a Participant's Award will be governed by the version of this Plan then in effect at the time such Award was granted. No termination or amendment of the Plan will affect any then-outstanding Award unless expressly provided by the Committee. In any event, no termination or amendment of the Plan or any outstanding Award may adversely affect any then outstanding Award without the consent of the Participant, unless such termination or amendment is necessary to comply with applicable law, regulation, or rule.

25. NONEXCLUSIVITY OF THE PLAN. Neither the adoption of this Plan by the Board, the submission of this Plan to the stockholders of the Company for approval, nor any provision of this Plan will be construed as creating any limitations on the power of the Board to adopt such additional compensation arrangements as it may deem desirable, including, without limitation, the granting of stock awards and bonuses otherwise than under this Plan, and such arrangements may be either generally applicable or applicable only in specific cases.

26. INSIDER TRADING POLICY. Each Participant who receives an Award will comply with any policy adopted by the Company from time to time covering transactions in the Company's securities by Employees, officers, and/or Directors of the Company, as well as with any applicable insider trading or market abuse laws to which the Participant may be subject.

27. ALL AWARDS SUBJECT TO COMPANY CLAWBACK OR RECOUPMENT POLICY. All Awards, subject to applicable law, will be subject to clawback or recoupment pursuant to any compensation clawback or recoupment policy adopted by the Board or required by law during the term of Participant's employment or other service with the Company that is applicable to officers, Employees, Directors or other service providers of the Company, and in addition to any other remedies available under such policy and applicable law, may require the cancellation of outstanding Awards and the recoupment of any gains realized with respect to Awards.

28. DEFINITIONS. As used in this Plan, and except as elsewhere defined herein, the following terms will have the following meanings:

28.1. "***Affiliate***" means (a) any entity that, directly or indirectly, is controlled by, controls, or is under common control with, the Company, and (b) any entity in which the Company has a significant equity interest, in either case as determined by the Committee, whether now or hereafter existing.

28.2. "***Award***" means any award under the Plan, including any Option, Performance Award, Cash Award, Restricted Stock, Stock Bonus, Stock Appreciation Right, or Restricted Stock Unit.

28.3. "***Award Agreement***" means, with respect to each Award, the written or electronic agreement between the Company and the Participant setting forth the terms and conditions of the Award, and country-specific appendix thereto for grants to non-U.S. Participants, which will be in substantially a form (which need not be the same for each Participant) that the Committee (or in the case of Award agreements that are not used for Insiders, the Committee's delegate(s)) has from time to time approved, and will comply with and be subject to the terms and conditions of this Plan.

28.4. "***Award Transfer Program***" means any program instituted by the Committee which would permit Participants the opportunity to transfer any outstanding Awards to a financial institution or other person or entity approved by the Committee.

28.5. "***Board***" means the Board of Directors of the Company.

28.6. "***Cause***" means (i) an unauthorized use or disclosure by Participant of the Company's confidential information or trade secrets, which use or disclosure causes material harm to the Company or is reasonably likely to cause material harm to the Company, (ii) a material breach of any agreement between Participant and the Company, (iii) a material failure to comply with the Company's written policies or rules that has caused or is reasonably likely to cause material injury to the Company, its successor, or its affiliates, or any of their business, (iv) conviction of, or plea of "guilty" or "no contest" to, a felony under the laws of the United States or any state thereof, (v) willful misconduct that has caused or is reasonably likely to cause material injury to the Company, its successor, or its affiliates, or any of their businesses, (vi) embezzlement, (vii) failure to cooperate with the Company in any investigation or formal proceeding if the Company has requested Participant's reasonable cooperation, (viii) violation of any applicable federal, state or foreign statutes or laws that govern or regulate employment, pharmaceutical drugs or securities, including but not limited to the laws enforced by the federal Equal Employment Opportunity Commission, Department of Labor, Food and Drug Administration, Securities and Exchange Commission and Department of Justice or (ix) a continued failure to perform assigned duties after receiving written notification of such failure from the Company's Chief Executive Officer; provided that Participant must be provided with written notice of Participant's termination for "Cause" and Participant must be provided with a thirty (30) day period following Participant's receipt of such notice to cure the event(s) that trigger "Cause," with the Company's Chief Executive Officer making the final determination whether Participant has cured any Cause. The determination as to whether a Participant is being terminated for Cause shall be made in good faith by the Company and shall be final and binding on the Participant. This definition does not in any way limit the Company's or any Parent's or Subsidiary's ability to terminate a Participant's employment or services at any time. Notwithstanding the foregoing, the foregoing definition of "Cause" may, in part or in whole, be modified or replaced in each individual employment agreement, Award Agreement, or other applicable agreement with any Participant, provided that such document explicitly supersedes the definition provided in this Section.

28.7. "***Code***" means the United States Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder.

28.8. "***Committee***" means the Compensation Committee of the Board or those persons to whom administration of the Plan, or part of the Plan, has been delegated as permitted by law.

28.9. "***Common Stock***" means the common stock of the Company.

28.10. "***Company***" means ALLARITY THERAPEUTICS, Inc., a Delaware corporation, or any successor corporation.

28.11. "***Consultant***" means any natural person, including an advisor or independent contractor, engaged by the Company or a Parent, Subsidiary, or Affiliate to render services to such entity.

28.12. "***Corporate Transaction***" means the occurrence of any of the following events: (a) any "Person" (as such term is used in Sections 13(d) and 14(d) of the Exchange Act) becomes the "beneficial owner" (as defined in Rule 13d-3 of the Exchange Act), directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the total voting power represented by the Company's then-outstanding voting securities, provided, however, that for purposes of this subclause (a) the acquisition of additional securities by any one Person who is considered to own more than fifty percent (50%) of the total voting power of the securities of the Company will not be considered a Corporate Transaction; (b) the consummation of the sale or disposition by the Company of all or substantially all of the Company's assets; (c) the consummation of a merger or consolidation of the Company with any other corporation, other than a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or its parent) at least fifty percent (50%) of the total voting power represented by the voting securities of the Company or such surviving entity or its parent outstanding immediately after such merger or consolidation; (d) any other transaction which qualifies as a "corporate transaction" under Section 424(a) of the Code wherein the stockholders of the Company give up all of their equity interest in the Company (except for the acquisition, sale or transfer of all or substantially all of the outstanding shares of capital stock of the Company), or (e) a change in the effective control of the Company that occurs on the date that a majority of members of the Board is replaced during any twelve (12) month period by members of the Board whose appointment or election is not endorsed by a majority of the members of the Board prior to the date of the appointment or election. For purposes of this subclause (e), if any Person is considered to be in effective control of the Company, the acquisition of additional control of the Company by the same Person will not be considered a Corporate Transaction. For purposes of this definition, Persons will be considered to be acting as a group if they are owners of a corporation that enters into a merger, consolidation, purchase, or acquisition of stock, or similar business transaction with the Company. Notwithstanding the foregoing, to the extent that any amount constituting deferred compensation (as defined in Section 409A of the Code) would become payable under this Plan by reason of a Corporate Transaction, such amount will become payable only if the event constituting a Corporate Transaction would also qualify as a change in ownership or effective control of the Company or a change in the ownership of a substantial portion of the assets of the Company, each as defined within the meaning of Code Section 409A, as it has been and may be amended from time to time, and any proposed or final Treasury Regulations and IRS guidance that has been promulgated or may be promulgated thereunder from time to time.

28.13. "***Director***" means a member of the Board.

28.14. "***Disability***" means in the case of incentive stock options, total and permanent disability as defined in Section 22(e)(3) of the Code and in the case of other Awards, that the Participant is unable to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment that can be expected to result in death or can be expected to last for a continuous period of not less than twelve (12) months.

28.15. "***Dividend Equivalent Right***" means the right of a Participant, granted at the discretion of the Committee or as otherwise provided by the Plan, to receive a credit for the account of such Participant in an amount equal to the cash, stock, or other property dividends in amounts equal equivalent to cash, stock, or other property dividends for each Share represented by an Award held by such Participant.

28.16. "***Effective Date***" means the effective time of the Company's Recapitalization Share Exchange described in the Company's Form S-4 Registration Statement (SEC File No. : 333-), subject to approval of the Plan by the Company's stockholders.

28.17. "***Employee***" means any person, including officers and Directors, providing services as an employee to the Company or any Parent, Subsidiary, or Affiliate. Neither service as a Director nor payment of a director's fee by the Company will be sufficient to constitute "employment" by the Company.

28.18. "***Exchange Act***" means the United States Securities Exchange Act of 1934, as amended.

28.19. "***Exchange Program***" means a program pursuant to which (a) outstanding Awards are surrendered, cancelled, or exchanged for cash, the same type of Award, or a different Award (or combination thereof); or (b) the exercise price of an outstanding Award is increased or reduced.

28.20. "***Exercise Price***" means, with respect to an Option, the price at which a holder may purchase the Shares issuable upon exercise of an Option and with respect to a SAR, the price at which the SAR is granted to the holder thereof.

28.21. "***Fair Market Value***" means, as of any date, the value of a Share, determined as follows:

(a) if such common stock is publicly traded and is then listed on a national securities exchange, its closing price on the date of determination on the principal national securities exchange on which the common stock is listed or admitted to trading as reported in *The Wall Street* Journal or such other source as the Committee deems reliable;

(b) if such common stock is publicly traded but is neither listed nor admitted to trading on a national securities exchange, the average of the closing bid and asked prices on the date of determination as reported in *The Wall Street Journal* or such other source as the Committee deems reliable; or

(c) by the Board or the Committee in good faith.

28.22. "***Insider***" means an officer or Director of the Company or any other person whose transactions in the Company's common stock are subject to Section 16 of the Exchange Act.

28.23. [RESERVED]

28.24. "***IRS***" means the United States Internal Revenue Service.

28.25. "***Non-Employee Director***" means a Director who is not an Employee of the Company or any Parent, Subsidiary, or Affiliate.

28.26. "***Option***" means an award of an option to purchase Shares pursuant to Section 5.

28.27. "***Parent***" means any corporation (other than the Company) in an unbroken chain of corporations ending with the Company if each of such corporations other than the Company owns stock possessing fifty percent (50%) or more of the total combined voting power of all classes of stock in one of the other corporations in such chain.

28.28. "***Participant***" means a person who holds an Award under this Plan.

28.29. "***Performance Award***" means an Award as defined in Section 10 and granted under the Plan, the payment of which is contingent upon achieving certain performance goals established by the Committee.

28.30. "***Performance Factors***" means any of the factors selected by the Committee and specified in an Award Agreement, from among the following measures, either individually, alternatively or in any combination, applied to the Company as a whole or any business unit or Subsidiary, either individually, alternatively, or in any combination, on a GAAP or non-GAAP basis, and measured, to the extent applicable on an absolute basis or relative to a pre-established target, to determine whether the performance goals established by the Committee with respect to applicable Awards have been satisfied:

(a) profit before tax;

(b) billings;

(c) revenue;

(d) net revenue;

(e) earnings (which may include earnings before interest and taxes, earnings before taxes, net earnings, stock-based compensation expenses, depreciation, and amortization);

(f) operating income;

(g) operating margin;

(h) operating profit;

(i) controllable operating profit or net operating profit;

(j) net profit;

(k) gross margin;

(l) operating expenses or operating expenses as a percentage of revenue;

(m) net income;

(n) earnings per share;

(o) total stockholder return;

(p) market share;

(q) return on assets or net assets;

(r) the Company's stock price;

(s) growth in stockholder value relative to a pre-determined index;

(t) return on equity;

(u) return on invested capital;

(v) cash flow (including free cash flow or operating cash flows);

(w) cash conversion cycle;

(x) economic value added;

(y) individual confidential business objectives;

(z) contract awards or backlog;

(aa) overhead or other expense reduction;

(bb) credit rating;

(cc) strategic plan development and implementation;

(dd) succession plan development and implementation;

(ee) improvement in workforce diversity;

(ff) customer indicators and/or satisfaction;

(gg) new product invention or innovation;

(hh) attainment of research and development milestones;

(ii) improvements in productivity;

(jj) bookings;

(kk) attainment of objective operating goals and employee metrics;

(ll) sales;

(mm) expenses;

(nn) balance of cash, cash equivalents, and marketable securities;

(oo) completion of an identified special project;

(pp) completion of a joint venture or other corporate transaction;

(qq) employee satisfaction and/or retention;

(rr) research and development expenses;

(ss) working capital targets and changes in working capital; and

(tt) any other metric that is capable of measurement as determined by the Committee.

The Committee may provide for one or more equitable adjustments to the Performance Factors to preserve the Committee's original intent regarding the Performance Factors at the time of the initial award grant, such as but not limited to, adjustments in recognition of unusual or non-recurring items such as acquisition related activities or changes in applicable accounting rules. It is within the sole discretion of the Committee to make or not make any such equitable adjustments.

28.31. "***Performance Period***" means one or more periods of time, which may be of varying and overlapping durations, as the Committee may select, over which the attainment of one or more Performance Factors will be measured for the purpose of determining a Participant's right to, and the payment of, a Performance Award.

28.32. "***Performance Share***" means an Award as defined in Section 10 and granted under the Plan, the payment of which is contingent upon achieving certain performance goals established by the Committee.

28.33. "***Performance Unit***" means an Award as defined in Section 10 and granted under the Plan, the payment of which is contingent upon achieving certain performance goals established by the Committee.

28.34. "***Permitted Transferee***" means any child, stepchild, grandchild, parent, stepparent, grandparent, spouse, former spouse, sibling, niece, nephew, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law (including adoptive relationships) of the Employee, any person sharing the Employee's household (other than a tenant or employee), a trust in which these persons (or the Employee) have more than 50% of the beneficial interest, a foundation in which these persons (or the Employee) control the management of assets, and any other entity in which these persons (or the Employee) own more than 50% of the voting interests.

28.35. "***Plan***" means this ALLARITY THERAPEUTICS, Inc. 2021 Equity Incentive Plan.

28.36. "***Purchase Price***" means the price to be paid for Shares acquired under the Plan, other than Shares acquired upon exercise of an Option or SAR.

28.37. "***Restricted Stock Award***" means an Award as defined in Section 6 and granted under the Plan, or issued pursuant to the early exercise of an Option.

28.38. "***Restricted Stock Unit***" means an Award as defined in Section 9 and granted under the Plan.

28.39. "***SEC***" means the United States Securities and Exchange Commission.

28.40. "***Securities Act***" means the United States Securities Act of 1933, as amended.

28.41. "***Service***" will mean service as an Employee, Consultant, Director, or Non-Employee Director, to the Company or a Parent, Subsidiary, or Affiliate, subject to such further limitations as may be set forth in the Plan or the applicable Award Agreement. An Employee will not be deemed to have ceased to provide Service in the case of (a) sick leave, (b) military leave, or (c) any leave of absence approved by the Company; provided however, that such leave is for a period of not more than 90 days (x) unless reemployment upon the expiration if such leave is guaranteed by contract or statute, or (y) unless provided otherwise pursuant to formal policy adopted from time to time by the Company and issued and promulgated to employees in writing. In the case of any Employee on an approved leave of absence or a reduction in hours worked (for illustrative purposes only, a change in schedule from that of full-time to part-time), the Committee may make such provisions respecting suspension of or modification to vesting of the Award while on leave from the employ of the Company or a Parent, Subsidiary or Affiliate or during such change in working hours as it may deem appropriate, except that in no event may an Award be exercised after the expiration of the term set forth in the applicable Award Agreement. In the event of military or other protected leave, if required by applicable laws, vesting will continue for the longest period that vesting continues under any other statutory or Company approved leave of absence and, upon a Participant's returning from military leave (under conditions that would entitle him or her to protection upon such return under the Uniform Services Employment and Reemployment Rights Act), he or she will be given vesting credit with respect to Awards to the same extent as would have applied had the Participant continued to provide Service to the Company throughout the leave on the same terms as he or she was providing Service immediately prior to such leave. An employee shall have terminated employment as of the date he or she ceases to provide Service (regardless of whether the termination is in breach of local employment laws or is later found to be invalid) and employment shall not be extended by any notice period or garden leave mandated by local law, *provided*, *however*, that a change in status between an Employee, Consultant, Director or Non-Employee Director shall not terminate the Participant's Service, unless determined by the Committee, in its discretion or to the extent set forth in the applicable Award Agreement. The Committee will have sole discretion to determine whether a Participant has ceased to provide Service and the effective date on which the Participant ceased to provide Service. An employee will have terminated employment as of the date he or she ceases to provide Service (regardless of whether the termination is in breach of local employment laws or is later found to be invalid) and employment will not be extended by any notice period or garden leave mandated by local law, provided, however, that a change in status from an Employee to a Consultant or Non-Employee Director (or vice versa) will not terminate the Participant's Service, unless determined by the Committee, in its discretion. The Committee will have sole discretion to determine whether a Participant has ceased to provide Service and the effective date on which the Participant ceased to provide Service.

28.42. "***Shares***" means shares of the Common Stock and the common stock of any successor entity of the Company.

28.43. "Stock Appreciation Right" means an Award defined in Section 8 and granted under the Plan.

28.44. "***Stock Bonus***" means an Award defined in Section 7 and granted under the Plan.

28.45. "***Subsidiary***" means any corporation (other than the Company) in an unbroken chain of corporations beginning with the Company if each of the corporations other than the last corporation in the unbroken chain owns stock possessing fifty percent (50%) or more of the total combined voting power of all classes of stock in one of the other corporations in such chain.

28.46. "***Treasury Regulations***" means regulations promulgated by the United States Treasury Department.

28.47. "***Unvested Shares***" means Shares that have not yet vested or are subject to a right of repurchase in favor of the Company (or any successor thereto).