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**PRESS RELEASE**

**REGULATED INFORMATION – INSIDE INFORMATION**

9 February 2021, 2:30 pm CET



## **SEQUANA MEDICAL LAUNCHES EQUITY PLACEMENT**

**Ghent, Belgium, 9 February 2021 – Sequana Medical NV (Euronext Brussels: SEQUA)** (the "**Company**" or "**Sequana Medical**"), an innovator in the treatment of diuretic-resistant fluid overload in liver disease, malignant ascites and heart failure, announces today the launch of an equity offering to raise an amount of approximately up to EUR 17.5 million by means of a private placement via an accelerated bookbuild offering (the "**Offering**"), with the possibility to increase the size of the Offering.

Sequana Medical currently envisages using the net proceeds of the Offering:

- for its ongoing studies:
  - POSEIDON, the North American pivotal study of the **alfapump**<sup>®</sup> in liver disease for which further interim results are expected in H1 2021, with the primary endpoint read-out planned for Q1 2022. The study cost is estimated to be approximately EUR 11 million of which EUR 2.7 million has been spent up to H1 2020;
  - RED DESERT, the repeated dose study of the **alfapump DSR**<sup>®</sup> (Direct Sodium Removal) in diuretic-resistant heart failure patients for which top line results are expected in H1 2021. The study cost is estimated to be approximately EUR 2.2 million of which EUR 1.0 million has been spent up to H1 2020;
- to initiate:
  - SAHARA DESERT, the study to evaluate the dosing and frequency of the **alfapump DSR**<sup>®</sup> therapy in decompensated heart failure patients with residual congestion which is expected to commence in H1 2021 with interim results planned by end 2021. The study cost is estimated to be approximately EUR 2.2 million;
  - the development of the proprietary **DSR**<sup>®</sup> infusate which is expected to commence in Q1 2021 with an estimated cost of approximately EUR 1.6 million; and
- for working capital and other general corporate purposes.

The net proceeds from the Offering are expected to extend the current cash runway of the Company from H2 2021 into Q1 2022.

### **Details of the Offering**

The accelerated bookbuilding procedure will commence immediately. The Company will announce the results of the Offering as soon as possible after closing of the bookbuilding in a subsequent press release (including the final number of the new shares to be issued and the offer price).

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Trading in Sequana Medical shares on Euronext Brussels will be suspended during the bookbuilding period. Trading in the shares is expected to resume following the publication of the results of the Offering.

KBC Securities NV ("**KBC Securities**") and Van Lanschot Kempen Wealth Management N.V. ("**Kempen & Co**") are acting as Joint Global Coordinators of the Offering, with Belfius Bank NV/SA, together with its subcontractor Kepler Cheuvreux S.A. ("**Belfius**"), acting as Joint Bookrunner of the Offering (jointly, the "**Underwriters**").

Optiverder B.V. (an experienced investor in growth companies, who intends to submit an order in the Offering for an amount of EUR 4.25 million), as well as an existing experienced medical device investor and certain other private investors are supportive of the Offering and committed to submit orders in the Offering for an aggregate amount of approximately EUR 7.3 million. The Offering is open to institutional, qualified, professional and/or other investors as permitted under applicable private placement exemptions, and any final allocation to investors, as the case may be, will be made based on customary objective and pre-identified criteria. No guarantee will be or has been given as to the final allocation to any of the aforementioned investors, shareholders or other persons, that any allocation will be made to them, or as to the size of any such allocation.

In relation to the Offering, the Company and the members of the executive management have agreed with the Underwriters to a market customary 180-days standstill period on future share issuances, waivable by the Joint Global Coordinators on behalf of the Underwriters and subject to customary exceptions.

**For more information, please contact:**

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**About Sequana Medical**

Sequana Medical is a commercial stage medical device company developing the **alfapump**<sup>®</sup> platform for the treatment of fluid overload in liver disease, malignant ascites and heart failure where diuretics are no longer effective. Fluid overload is a fast growing complication of advanced liver disease driven by NASH (non-alcoholic steatohepatitis) related cirrhosis and a common complication in heart failure with diuretic

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resistance being widespread in both of these indications. The U.S. market for the **alfapump**<sup>®</sup> resulting from NASH-related cirrhosis is forecast to exceed €3 billion annually within the next 10-20 years. The heart failure market for the **alfapump DSR**<sup>®</sup> (Direct Sodium Removal) is estimated to be over €5 billion annually in the U.S. and EU5 by 2026. Both indications leverage Sequana Medical's **alfapump**<sup>®</sup>, a unique, fully implanted wireless device that automatically pumps fluid from the abdomen into the bladder, where it is naturally eliminated through urination.

In the U.S., the Company's key growth market, the **alfapump**<sup>®</sup> has been granted breakthrough device designation by the FDA for recurrent or refractory ascites due to liver cirrhosis. Interim data from the ongoing North American pivotal study (POSEIDON) showed positive outcomes against all primary endpoints of the study. This study is intended to support a future marketing application of the **alfapump**<sup>®</sup> in the U.S. and Canada. In Europe, the **alfapump**<sup>®</sup> is CE-marked for the management of refractory ascites due to liver cirrhosis and malignant ascites and is included in key clinical practice guidelines. Over 800 **alfapump**<sup>®</sup> systems have been implanted to date. Building on its proven **alfapump**<sup>®</sup> platform, Sequana Medical is developing the **alfapump DSR**<sup>®</sup>, a breakthrough, proprietary approach to fluid overload due to heart failure. Clinical proof-of-concept was achieved in a first-in-human single dose DSR<sup>®</sup> study and further supported by strong interim safety and efficacy results from the ongoing repeated dose **alfapump DSR**<sup>®</sup> study (RED DESERT) in heart failure patients.

Sequana Medical is headquartered in Ghent, Belgium. For further information, please visit [www.sequanamedical.com](http://www.sequanamedical.com).

**Important Regulatory Disclaimers:**

*The **alfapump**<sup>®</sup> system is not currently approved in the United States or Canada. In the United States and Canada, the **alfapump**<sup>®</sup> system is currently under clinical investigation (POSEIDON Study) and is being studied in adult patients with refractory or recurrent ascites due to cirrhosis. For more information regarding the POSEIDON clinical study see [www.poseidonstudy.com](http://www.poseidonstudy.com). The DSR<sup>®</sup> therapy is still in development and it should be noted that any statements regarding safety and efficacy arise from ongoing pre-clinical and clinical investigations which have yet to be completed. The DSR<sup>®</sup> therapy is not currently approved for clinical research in the United States or Canada. There is no link between the DSR<sup>®</sup> therapy and ongoing investigations with the **alfapump**<sup>®</sup> system in Europe, the United States or Canada.*

**Important information:**

*The information contained in this announcement is for general information only and does not purport to be full or complete. This announcement does not constitute, or form part of, an offer to sell or issue, or any solicitation of an offer to purchase or subscribe for shares, and any purchase of, subscription for or application for, shares. This announcement and the information contained herein are not for publication, distribution or release in, or into, directly or indirectly, the United States of America, Australia, Canada,*

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*Any offer of securities to which this announcement relates is only addressed to and directed at persons in the United Kingdom and member states of the European Economic Area (the "EEA") (each a "Member State") who are "qualified investors" within the meaning of Article 2(e) of Regulation 2017/1129 of the European Parliament and of the Council of 14 June 2017 on the prospectus to be published when securities are offered to the public or admitted to trading on a regulated market, and repealing Directive 2003/71/EC, as amended from time to time, to the extent implemented in the relevant Member State of the EEA) and any implementing measure in each relevant Member State of the EEA or, for the United Kingdom, as it forms part of retained EU law as defined in the EU (Withdrawal) Act 2018 (the "Prospectus Regulation") ("Qualified Investors"), or such other investors as shall not constitute an offer to the public within the meaning of Article 3.1 of the Prospectus Regulation. Each person in the United Kingdom or a Member State who initially acquires any of the Company's securities or to whom any offer of the Company's securities may be made and, to the extent applicable, any funds on behalf of which such person is acquiring the Company's securities that are located in the United Kingdom or a Member State will be deemed to have represented, acknowledged and agreed that it is a Qualified Investor.*

*In addition, any offer of securities to which this announcement relates is in the United Kingdom, being distributed only to, and is directed only at, (i) persons who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended from time to time (the "Order"), (ii) high net worth entities etc. falling within Article 49(2)(a) to (d) of the Order, and (iii) any other person to whom it may otherwise lawfully be communicated (all such persons together being referred to as "relevant persons"). The offering of securities to which this announcement relates will only be available to, and any invitation, offer or agreement to subscribe for, purchase, or otherwise acquire securities will be engaged in only with relevant persons. Any person who is not a relevant person should not act or rely on this announcement or any of its*

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*contents.*

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*No announcement or information regarding the offering, listing or securities of the Company referred to above may be disseminated to the public in jurisdictions where a prior registration or approval is required for such purpose. No steps have been taken, or will be taken, for the offering or listing of securities of the Company in any jurisdiction where such steps would be required, except for the admission of the offered shares on the regulated market of Euronext Brussels. The issue, exercise, or sale of, and the subscription for or purchase of, securities of the Company are subject to special legal or statutory restrictions in certain jurisdictions. The Company is not liable if the aforementioned restrictions are not complied with by any person.*

*Certain statements, beliefs and opinions in this announcement are forward-looking, which reflect the Company's or, as appropriate, the Company directors' current expectations and projections concerning future events such as the Company's results of operations, financial condition, liquidity, performance, prospects, growth, strategies and the industry in which the Company operates. By their nature, forward-looking statements involve a number of risks, uncertainties, assumptions and other factors that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. These risks, uncertainties, assumptions and factors could adversely affect the outcome and financial effects of the plans and events described herein. A multitude of factors including, but not limited to, changes in demand, competition and technology, can cause actual events, performance or results to differ significantly from any anticipated development. Forward-looking statements contained in this announcement regarding past trends or activities are not guarantees of future performance and should not be taken as a representation that such trends or activities will continue in the future. In addition, even if actual results or developments are consistent with the forward-looking statements contained in this announcement, those results or developments may not be indicative of results or developments in future periods. No representations and warranties are made as to the accuracy or fairness of such forward-looking statements. As a result, the Company expressly disclaims any obligation or undertaking to release any update or revisions to any forward-looking statements in this announcement as a result of any change in expectations or any change in events, conditions, assumptions or circumstances on which these forward-looking statements are based. Neither the Company nor its advisers or representatives nor any of its subsidiary undertakings or any such person's officers or employees guarantees that the assumptions*

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*underlying such forward-looking statements are free from errors nor does either accept any responsibility for the future accuracy of the forward-looking statements contained in this announcement or the actual occurrence of the forecasted developments. You should not place undue reliance on forward-looking statements, which speak only as of the date of this announcement.*

**Information to Distributors:**

*Solely for the purposes of the product governance requirements contained within: (a) EU Directive 2014/65/EU on markets in financial instruments, as amended from time to time ("MiFID II"); (b) Articles 9 and 10 of Commission Delegated Directive (EU) 2017/593 supplementing MiFID II; and (c) local implementing measures (together, the "MiFID II Product Governance Requirements"), and disclaiming all and any liability, whether arising in tort, contract or otherwise, which any 'manufacturer' (for the purposes of the MiFID II Product Governance Requirements) may otherwise have with respect thereto, the offered shares have been subject to a product approval process, which has determined that the offered shares are: (i) compatible with an end target market of retail investors and investors who meet the criteria of professional clients and eligible counterparties, each as defined in MiFID II; and (ii) eligible for distribution through all distribution channels as are permitted by MiFID II (the "Target Market Assessment"). Notwithstanding the Target Market Assessment, distributors should note that: the price of the offered shares may decline and investors could lose all or part of their investment; the offered shares offer no guaranteed income and no capital protection; and an investment in the offered shares is compatible only with investors who do not need a guaranteed income or capital protection, who (either alone or in conjunction with an appropriate financial or other adviser) are capable of evaluating the merits and risks of such an investment and who have sufficient resources to be able to bear any losses that may result therefrom. The Target Market Assessment is without prejudice to the requirements of any contractual, legal or regulatory selling restrictions in relation to the Offering. Furthermore, it is noted that, notwithstanding the Target Market Assessment, the Underwriters will only procure investors who meet the criteria of professional clients and eligible counterparties.*

*For the avoidance of doubt, the Target Market Assessment does not constitute: (a) an assessment of suitability or appropriateness for the purposes of MiFID II; or (b) a recommendation to any investor or group of investors to invest in, or purchase, or take any other action whatsoever with respect to the offered shares.*

*Each distributor is responsible for undertaking its own target market assessment in respect of the offered shares and determining appropriate distribution channels.*

*KBC Securities, Kempen & Co and Belfius are acting exclusively for the Company and no one else in connection with the Offering. In connection with such matters, they, their affiliates and their respective directors, officers, employees and agents will not regard any other person as their client, nor will they be*

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*responsible to any other person for providing the protections afforded to their clients or for providing advice in relation to the Offering or any other matters referred to in this announcement.*

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*Note: **alfapump**<sup>®</sup> is a registered trademark. **DSR**<sup>®</sup> and **alfapump DSR**<sup>®</sup> are registered trademarks in the Benelux.*