



No. 54 / 2020

# Interim report for 9M 2020

Zealand Pharma continues to advance clinical programs and commercial launch capabilities and presents financial results for the first nine months of 2020

### Financial results for the first nine months of 2020

- Revenue: DKK 290.0 million / USD 45.6 million (DKK 29.8 million / USD 4.4 million in the first nine months of 2019).
- Net operating expenses: DKK -714.5 million / USD -112.3 million (DKK -431.5 million / USD -62.9 million in the first nine months of 2019).
- Net operating result: DKK -449.1 million / USD -70.6 million (DKK -402.1 million / USD -58.7 million in the first nine months of 2019).
- Cash, cash equivalents, and marketable securities: DKK 1,528.6 million / USD 240.4 million as of September 30, 2020 (September 30, 2019: DKK 1,543.2 million / USD 225.0 million).

# Business highlights for the third quarter of 2020 and subsequent events

- Completed phase 1a single-ascending dose trial of ZP7570 (pINN: dapiglutide) for short bowel syndrome (SBS), demonstrating safety and tolerability and a plasma half-life allowing for once weekly dosing. Today, Zealand Pharma announces the completion of a phase 1 single-ascending dose trial of dapiglutide in healthy subjects, our long acting GLP-1/GLP-2 dual agonist, as our next generation treatment of SBS. Dapiglutide was found to have a good safety and tolerability profile in the trial and we observed a plasma half-life allowing for once weekly dosing. Based on these results we initiated and dosed the first subjects in the phase 1b (multiple ascending dose) earlier this month. We plan to publish data from the phase 1 singe-ascending dose trial at a scientific conference in 2021.
- Operations in a COVID-19 world. During the COVID-19 pandemic, we have kept our research labs and major operations in Denmark and the United States running. We continue to progress with the regulatory process for the HypoPal® rescue pen, the buildout of Zealand Pharma US operations, the dasiglucagon phase 3-programs for congenital hyperinsulinism (CHI), the bi-hormonal artificial pancreas pump (BHAP) as well as the development work for our strategic partnerships. This progress has allowed us to maintain our timelines for the phase 3-data in CHI, which we are expecting this December. The impact in

.



this environment is on the speed of recruitment of patients for the phase 3-trial of glepaglutide in SBS (EASE-1) meaning current timelines for the data readout are uncertain. While we may still see phase 3 results in 2021, once we have more clarity on the timing for the data readout of the phase 3 glepaglutide trial we will make an announcement.

Build Global Medical Affairs function with world-renowned experts. In September, Zealand Pharma significantly
enhanced its capabilities in medical affairs with the appointments of Dr. Danilo Verge as Head of Global Medical Affairs and
Dr. David Kendall as Senior Global Advisor. Drs. Verge and Kendall each bring to Zealand Pharma decades of experience in
the global diabetes space. This is expected to enhance our ability to interact with key stakeholders.

# Emmanuel Dulac, President and Chief Executive Officer at Zealand Pharma, comments:

In discovery, we continue to leverage our innovative peptide platform as we advance the development of our pipeline. On the clinical front, we remain on track to report topline data for our first and largest phase 3-trial for dasiglucagon in congenital hyperinsulinism this December. We are also excited to announce favorable safety and tolerability results from our phase 1 single-ascending dose trial of dapiglutide, previously referred to as ZP7570, a GLP1/GLP2 dual peptide, which is our second asset being advanced for the treatment of short bowel syndrome. We have maintained the majority of the timelines for our programs throughout the COVID-19 pandemic, but we are seeing a slow recruitment of patients in our phase 3-trial for glepaglutide in SBS. We continue to work closely with investigators on moving the program forward and together with the many upcoming milestones across our several programs later this year and in 2021. We are also preparing for our first commercial launch of the dasiglucagon HypoPal® rescue pen, for which we expect to receive an approval decision from the Food and Drug Administration (FDA) in March 2021. I am very pleased with the way that we have continued to execute on our plans, kept our employees engaged, our labs open and trials running despite the pandemic.

# Financial guidance for 2020

Net product revenue from the sales of the V-Go® wearable insulin delivery device is expected to be within the range of DKK 150 - 175 million for the period beginning on April 2, 2020 and ending on December 31, 2020.

In 2020, Zealand Pharma expects revenue from existing license agreements. However, since such revenue is uncertain in terms of size and timing, Zealand Pharma does not intend to provide guidance on such revenue.

Net operating expenses in 2020 are expected to be within the range of DKK 950-1,000 million and remains unchanged from the operating expense guidance announced on August 13, 2020.

# **Update regarding COVID-19**

Zealand Pharma continues to monitor the COVID-19 pandemic and take precautions to keep our employees, patients, business and clinical partners safe. This is an ongoing exercise in monitoring the effects of the pandemic on all of our key stakeholders and responding appropriately. We maintain compliance with guidance from applicable government and health authorities. We have adapted the way we work to support our community's efforts to reduce the transmission of COVID-19 and protect our employees, while continuing to provide patient care and maintain business continuity.



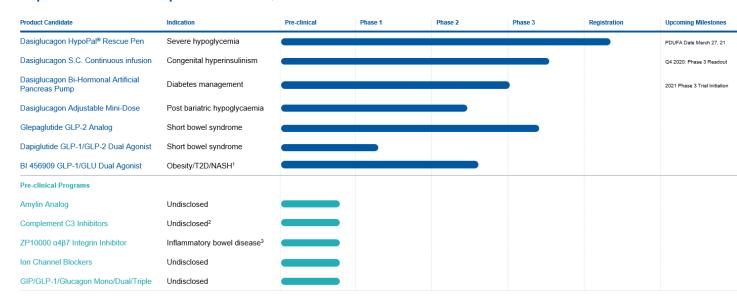
Zealand Pharma has taken measures to secure its discovery activities, which remain ongoing, while work in laboratories and offices has been organized to reduce the risk of COVID-19 transmission. The impact of COVID-19 on our research activities has thus far been minimal. Employees who can work from home have been doing so, while those needing to work in laboratory facilities are divided into shifts to reduce the number of people gathered at one time. Business travel has been minimized and online and teleconference technology is used to meet virtually rather than in person. We have continued our clinical trials while working with authorities, investigators, trial sites and contract research organizations to minimize site visits and ensure optimal trial follow-up.

The recent worsening of the pandemic has so far not affected our phase 3-program for dasiglucagon in congenital hyperinsulinism (CHI) and we expect topline data from the first phase 3-trial in December. The regulatory process for the HypoPal® rescue pen also progresses as planned and we currently do not anticipate changes to the timelines for the bi-hormonal artificial pancreas pump phase 3-program. However, the pandemic continues to compromise the speed of recruitment of patients for our phase 3-trial with glepaglutide for treatment of short bowel syndrome meaning timelines for data readout are uncertain.

Our research and development programs may be impacted if the pandemic continues to put increased pressure on hospital systems, slow recruitment of patients into the trials or cause lockdowns that affect our clinical trial sites if key external medical resources are diverted elsewhere.

Direct engagement with health care providers and patients has been reduced and transformed by leveraging virtual meetings, training, and support. Commercial activities in the U.S. are focused on continuing to support the business for the V-Go® wearable insulin delivery device, while ensuring a continued high level of service and support for existing patients.

# Pipeline as of September 30, 2020



<sup>1:</sup> Partnered with Boehringer Ingelheim. 2: Partnered with Alexion Pharmaceuticals. 3: Acquired Encycle Therapeutics, Inc.: future potential earn-outs of up to USD \$80 million contingent on successful achievement of development, regulatory and commercial milestones; payable in cash and/or ZEAL equity at Zealand's discretion.



### Metabolic diseases

Dasiglucagon is Zealand Pharma's lead drug in development to improve the treatment of metabolic diseases. Dasiglucagon is a stable glucagon analog being developed in four distinct indications:

### Dasiglucagon HypoPal® rescue pen for severe hypoglycemia

The New Drug Application (NDA) with the U.S. FDA was filed in Q1 2020, and the NDA was accepted for review in May 2020. Under the Prescription Drug User Fee Act (PDUFA), the FDA has set a target action date of March 27, 2021. In addition to the hiring of the President of Zealand Pharma U.S., key leaders across sales, marketing, market access and medical affairs have been onboarded to prepare for the potential launch in the U.S. market in 2021.

The ready-to-use dasiglucagon rescue pen, the HypoPal®, is designed to offer diabetes patients fast and effective treatment for severe hypoglycemia. In the pivotal and confirmatory phase 3-trials in adults and children, primary and all key secondary endpoints were successfully achieved with a median time to blood glucose recovery of 10 minutes.

### Dasiglucagon bi-hormonal artificial pancreas pump for automated diabetes management

Zealand Pharma is developing a 1 ml cartridge containing 4 mg/ml dasiglucagon, intended for use in bi-hormonal artificial pancreas pumps.

We are collaborating with Beta Bionics, developer of the iLet™, a pocket-sized, dual-chamber, autonomous, glycemic control system. The iLet mimics a biological pancreas by calculating and dosing insulin and/or glucagon (dasiglucagon) as needed, based on data from the diabetic person's continuous glucose monitor. Top-line results from a phase 2-trial in patients with Type 1 diabetes demonstrated that the bi-hormonal iLet using dasiglucagon provided superior glycemic control over the insulin-only iLet. During the bi-hormonal period, 90% of participants had a mean CGM glucose level of < 154 mg/dL, whereas only 50% of participants on the insulin-only iLet achieved this. Importantly these glycemic targets were achieved while time spent with blood glucose levels < 54 mg/dL was only 0.3% in the bi-hormonal and 0.6% in the insulin-only arm.

Beta Bionics has finalized screening of patients into a 440 patients insulin-only artificial pancreas pivotal trial with dosing of the first subjects expected in Q4 2020 (ClinicalTrials.gov identifier: NCT04200313). Following the completion of the insulin-only study the initiation of the bi-hormonal artificial pancreas pump phase 3-trial with dasiglucagon can commence, the timing for that initiation is expected in 2021.

### Dasiglucagon for congenital hyperinsulinism (CHI)

The potential for chronic dasiglucagon infusion delivered via a pump to prevent hypoglycemia in children with CHI is being evaluated in a phase 3-program. The aim is to reduce or eliminate the need for intensive hospital treatment, reduce the frequency of dangerous low blood glucose and need for constant feeding, and to potentially delay or eliminate the need for pancreatectomy. The U.S. FDA and the European Commission both granted orphan drug designation to dasiglucagon for the treatment of CHI.

Two phase 3-trials are ongoing with topline results from the first trial expected in December 2020. The first phase 3-trial is with 32 children with CHI aged 3 months to 12 years and enrollment was completed in August 2020. The second phase 3-trial in 12 children with CHI aged 7 days to one year of age is ongoing.

### Dasiglucagon adjustable mini-dose

Post bariatric hypoglycemia phase 2a dose-finding clinical proof of concept trial reported results in March 2020 that demonstrate mini doses of dasiglucagon significantly reduced meal-induced hypoglycemia compared to placebo in individuals who have undergone gastric bypass bariatric surgery.



A phase 2a low-dose dasiglucagon trial for prevention of insulin-induced hypoglycemia in people with type 1 diabetes is ongoing.

### Gastrointestinal diseases

### Glepaglutide

Zealand Pharma is developing treatments for gastrointestinal diseases, with current focus on short bowel syndrome. One of the leading programs in Zealand Pharma's pipeline is glepaglutide, a long-acting GLP-2 analog being developed in an auto-injector with potential for convenient weekly administration. The ongoing pivotal phase 3-trial seeks to establish the efficacy and safety of once- and twice-weekly administration of glepaglutide in patients with SBS. The primary endpoint is to evaluate the reduction in weekly parenteral support volume from baseline to week 24. Given renewed spike in COVID-19 and associated slow-down in recruitment data readout from the trial is uncertain. While we may still see phase 3 results in 2021, once we have more clarity on the timing for the data readout of the phase 3 glepaglutide trial we will make an announcement. The U.S. FDA granted orphan drug designation to glepaglutide for the treatment of Short Bowel syndrome (SBS).

### Dapiglutide (ZP7570)

Dapiglutide (pINN) is a potential first-in-class and long-acting GLP-1R/GLP-2R dual agonist designed to improve management of SBS beyond what is achievable with mono GLP-2 treatments. Dapiglutide may represent a next level of innovation for helping SBS patients to further realize their full potential for intestinal rehabilitation.

The phase 1a single-ascending dose, safety and tolerability trial in healthy volunteers was completed in Q3 2020 and dapiglutide was in the trial found to have a good safety and tolerability profile and we observed a plasma half-life allowing for once weekly dosing. Based on these results we have initiated and dosed the first subjects in the phase 1b (multiple ascending dose) safety and tolerability trial earlier in November 2020.

# Pre-Clinical programs

Zealand Pharma is pursuing multiple pre-clinical programs in inflammatory gastrointestinal and metabolic therapeutic areas.

Zealand Pharma regained the worldwide rights to a long-acting Amylin analog program from Boehringer Ingelheim, including the lead molecule that had been in development as a potential once-weekly treatment of obesity and Type 2 diabetes.

# Partner programs

### BI 456906: Long-acting GLP-1/GLU dual agonist for obesity and/or diabetes (with Boehringer Ingelheim)

The GLP-1/glucagon dual agonist activates two key gut hormone receptors simultaneously and may offer better blood sugar and weight-loss control than current single-hormone receptor agonist treatments. The lead molecule BI 456906 is targeting treatment of diabetes, obesity and non-alcoholic steatohepatitis (NASH). Boehringer Ingelheim initiated a phase 2-trial on April 30, based on the safety, tolerability, and favorable weight loss potential in individuals with a BMI up to 40 kg/m² observed in phase 1.

The phase 2-trial is a randomized, parallel group, dose-finding study of subcutaneously administered BI 456906, compared with placebo and open-label semaglutide in 410 patients with Type 2 diabetes mellitus. The main objective of the trial is to demonstrate a dose-relationship of BI 456906 on HbA1c from baseline to 16 weeks relative to placebo. Secondary objectives



are to assess the effect of BI 456906 on change in body weight. An open-label comparator (semaglutide) will allow for comparison of the effects against a pure GLP-1R agonist.

Boehringer Ingelheim is funding all research, development and commercialization activities related to the treatment. Zealand Pharma is eligible to receive up to EUR 386 million in milestone payments, of which EUR 345 million is outstanding, and high-single to low-double digit royalties on global sales.

### **Complement inhibitors (with Alexion Pharmaceuticals)**

Zealand Pharma and Alexion Pharmaceuticals announced in March 2019 that they will collaborate on the discovery and development of novel peptide therapies for complement-mediated diseases. Under the terms of the agreement, Alexion and Zealand Pharma entered an exclusive collaboration for the discovery and development of subcutaneously delivered peptide therapies directed to up to four complement pathway targets. The lead program is a long-acting inhibitor of Complement C3 which has the potential to treat a broad range of complement mediated diseases. Zealand Pharma will lead the joint discovery and research efforts through the preclinical stage, and Alexion will lead development efforts beginning with IND filing and phase 1-trials.

For the lead target, Zealand Pharma is eligible to receive up to USD 610 million in development and sales milestone payments, plus royalties on global sales in the high single to low double digits. In addition, Alexion has the option to select up to three additional targets with Zealand Pharma eligible for USD 15 million upfront per target plus development/regulatory milestones for each target selected similar to the lead target with slightly reduced commercial milestones and royalties.

# Conference call today at 4:00 pm CEST / 10:00 am EDT

Zealand Pharma's management will host a conference call today at 4:00 pm CEST to present results through the first nine months of 2020. Participating in the call will be Chief Executive Officer Emmanuel Dulac, Chief Financial Officer Matt Dallas, and Chief Medical and Development Officer Adam Steensberg. The presentation will be followed by a Q&A session.

The conference call will be conducted in English, and the dial-in numbers are:

Denmark +45 32 72 80 42 United Kingdom +44 (0) 844 571 8892 United States +1 631 510 7495 France +33 (0) 176700794 Netherlands +31 (0) 207143545

Passcode 1296466

A live audio webcast of the call, including an accompanying slide presentation, will be accessible from the Investor section of Zealand Pharma's website. Participants are advised to register for the webcast approximately 10 minutes before the start. A recording of the event will be available on the Investor section of Zealand Pharma's website following the call.

# **Upcoming events**

Zealand Pharma plans to publish results for the fourth quarter and full year 2020 on March 11, 2021.

The Annual General Meeting 2021 is planned for April 15, 2021, subject to the appropriate official notification.



# Total number of shares and voting rights in Zealand Pharma as of 30 September, 2020

Number of shares (nominal value of DKK 1 each): 39,778,961

Share capital (nominal value in DKK): 39,778,961

Number of voting rights: 39,778,961

### **About Zealand Pharma A/S**

Zealand Pharma A/S (Nasdaq: ZEAL) ("Zealand") is a biotechnology company focused on the discovery, development and commercialization of innovative peptide-based medicines. More than 10 drug candidates invented by Zealand Pharma have advanced into clinical development, of which two have reached the market. Zealand Pharma's robust pipeline of investigational medicines includes three candidates in late stage development, and one candidate being reviewed for regulatory approval in the United States. Zealand markets V-Go®, an all-in-one basal-bolus insulin delivery option for people with diabetes. License collaborations with Boehringer Ingelheim and Alexion Pharmaceuticals create opportunity for more patients to potentially benefit from Zealand Pharma-invented peptide therapeutics.

Zealand Pharma was founded in 1998 in Copenhagen, Denmark, and has presence throughout the U.S. that includes key locations in New York, Boston, and Marlborough (MA). For more information about Zealand Pharma's business and activities, please visit <a href="https://www.zealandpharma.com">www.zealandpharma.com</a>.

HypoPal® and V-Go® are registered trademarks of Zealand Pharma A/S.

### Safe Harbor / Forward-Looking Statement

The above information contains forward-looking statements that provide our expectations or forecasts of future events such as the impact of the global COVID-19 pandemic on our business, new product introductions, clinical development activities and anticipated results, product approvals, financial performance and integration of a recently acquired business. Zealand Pharma may, in some cases, use terms such as "predicts," "believes," "potential," "proposed," "continue," "designed," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words or expressions referencing future events, conditions or circumstances that convey uncertainty of future events or outcomes to identify these forward-looking statements. Such forward-looking statements are subject to risks, uncertainties and inaccurate assumptions. This may cause actual results to differ materially from expectations and it may cause any or all of our forward-looking statements here or in other publications to be wrong. Factors that may affect future results include the impact of the global COVID-19 pandemic, interest rate and currency exchange rate fluctuations, delay or failure of clinical trials and other development activities, production problems, unexpected contract breaches or terminations, government-mandated or market-driven price decreases for Zealand Pharma's products, introduction of competing products, Zealand Pharma's ability to successfully market both new and existing products, exposure to product liability and other lawsuits, changes in reimbursement rules and governmental laws and related interpretation thereof, unexpected growth in costs and expenses, and Zealand Pharma's ability to integrate businesses in varying geographies with different commercial and operating characteristics. You will find a more detailed assessment of these risks, uncertainties and other risks that could cause actual events or results to materially differ from our current expectations in the Company's U.S. Securities and Exchange Commission filings and reports, including in the Company's Annual Report on Form 20-F for the year ended December 31, 2019, as supplemented by risks described herein.

Certain assumptions made by Zealand Pharma are required by Danish Securities Law for full disclosure of material corporate information. Some assumptions, including assumptions relating to sales associated with a product that is prescribed for unapproved uses, are made taking into account past performances of other similar drugs for similar disease states or past



performance of the same drug in other regions where the product is currently marketed. It is important to note that although physicians may, as part of their freedom to practice medicine in the United States, prescribe approved drugs for any use they deem appropriate, including unapproved uses, at Zealand Pharma, promotion of unapproved uses is strictly prohibited.

NOTE: DKK/USD Exchange rates used: September 30, 2020 = 6.3598 and September 30, 2019 = 6.8566.

### For further information, please contact:

Mads Kronborg Head of Investor Relations & Communication Phone: +45 5060 3707

Email: mkronborg@zealandpharma.com

### For U.S. Media

David Rosen Argot Partners Phone: 212-600-1902

Email: media@zealandpharma.com



# **Key figures** \*

DKK thousand

		Reviewed				Audited
INCOME STATEMENT AND COMPREHENSIVE INCOME	Note	Q3 2020	Q3 2019	Q1-Q3 2020	Q1-Q3 2019	FY 2019
Revenue		56,526	9,922	289,958	29,840	41,333
Gross margin		22,255	9,691	227,661	29,425	40,918
Research and development expenses		-139,332	-123,822	-430,991	-380,733	-561,423
Sales and marketing expenses		-97,429	0	-172,282	0	0
Administrative expenses		-40,567	-16,020	-111,232	-51,211	-67,881
Net operating expenses		-277,328	-139,842	-714,505	-431,944	-628,860
Operating result		-218,207	-130,062	-449,120	-402,135	-576,942
Net financial items		-9,746	15,521	-18,748	20,315	11,265
Result before tax		-227,953	-114,541	-467,869	-381,820	-576,677
Income tax	(1)	-621	1,313	1,686	3,954	5,136
Net result for the period	. ,	-228,574	-113,228	-466,183	-377,866	-571,541
Comprehensive result for the period		-228,574	-113,228	-466,183	-377,866	-571,541
Earnings/loss per share – basic/diluted (DKF	<b>(</b> )	-5.76	-3.44	-12.39	-11.49	-16.91
				September	September	December
STATEMENT OF FINANCIAL POSITION				30, 2020	30, 2019	31, 2019
Cash and cash equivalents				1,231,685	1,242,871	1,081,060
Marketable securities				296,909	300,370	299,448
Cash, cash equivalents and Marketable s	ecurities			1,528,594	1,543,241	1,380,508
Other assets				530,549	170,353	219,006
Total assets				2,059,143	1,713,594	1,599,514
Share capital ('000 shares)				39,779	35,865	36,055
Equity				1,590,003	1,409,193	1,242,673
Total liabilities				469,140	304,401	356,841
Equity ratio	(2)			0.77	0.82	0.78
CASH FLOW				Q1-Q3 2020	Q1-Q3 2019	FY 2019
Cash used in operating activities				-411,628	-241,240	-409,455
Cash used in investing activities				-200,799	-48,454	-51,666
Cash flow from financing activities				780,826	656,011	674,480
Purchase of property, plant and equipment				-29,491	-14,569	-21,036
Not each flow	(2)			444 440	255 000	420.404
Net cash flow	(3)			-441,119	-255,809	-430,491
				September	September	December
OTHER				30, 2020	30, 2019	31, 2019
Share price (DKK)				241.60	174.40	235.40
Market capitalization (MDKK)	(4)			9.588	6,255	8,487
Equity per share (DKK)	(5)			40.06	39.36	34.52
Average number of full time employees				322	166	173
Number of full time employees at the end of	the period			329	176	179

- Notes:

  \* The acquisition of the business from Valeritas is only reflected in key figures covering the period since April 2, 2020 being the acquisition date.

  (1) Zealand expects to be eligible to receive up to DKK 5.5 million in Danish corporate tax benefit related to R&D expenses incurred for 2020, of which DKK 4.1 million has been recognized for the period ended September 30, 2020.
- (2) Equity ratio is calculated as equity at the balance sheet date divided by total assets at the balance sheet date.
- (3) Free cash flow is calculated as the sum of cash flows from operating activities and purchase of property, plant and equipment.
- (4) Market capitalization is calculated as outstanding shares at the balance sheet date times the share price at the balance sheet date.
- (5) Equity per share is calculated as shareholders' equity divided by total number of shares less treasury shares.



# **Financial review**

Comparative figures for the corresponding period in 2019 are shown in brackets except for the financial position, which expresses the comparative figures as of December 31, 2019.

The condensed interim financial statements are prepared in accordance with IAS 34 *Interim Financial Reporting*, as issued by the International Accounting Standards Board (IASB) and as adopted by the EU, and additional requirements of the Danish Financial Statements Act. The interim condensed consolidated financial statements are presented in DKK, which is also the functional currency of the Company.

### Financial results

Revenue, cost of goods sold, and gross margin reported for V-Go are as of the closing of the Valeritas Asset Purchase on April 2, 2020 and do not include figures from the first quarter of 2020.

### Revenue

DKK thousand	September 30, 2020	September 30, 2019	Δ	$\Delta$ in percent
Sale of goods	103,968	0	103,968	100%
License and milestone revenue	185,990	29,840	156,150	523%
Total revenue	289,958	29,840	260,118	871%

Revenue for the nine months was driven by net sales of the V-Go wearable insulin delivery device, the phase 2 milestone payment triggered in June 2020 from our partnership agreement with Boehringer Ingelheim and revenue recognition related to our collaboration with Alexion.

# Gross margin

DKK thousand	September 30, 2020	September 30, 2019	Δ	$\Delta$ in percent
Gross margin	227,661	29,425	198,236	673%

The increase in gross margin is due to V-Go sales in 2020 and the revenue incurred as a result of the Boehringer Ingelheim phase 2 milestone.

# Research and development expenses

	September	September		
DKK thousand	30, 2020	30, 2019	Δ	$\Delta$ in percent
Research and development expenses	430,991	380,733	50,258	13%



The increase in research and development expenses mainly relates to the regulatory efforts to support the NDA filing for the dasiglucagon HypoPal rescue pen, the ongoing clinical development of the dasiglucagon and glepaglutide programs, as well as pre-clinical and research activities for the Zealand early stage pipeline.

# Sales and marketing expenses

DKK thousand	September 30, 2020	September 30, 2019	Δ	$\Delta$ in percent
Sales and marketing expenses	172,282	0	172,282	100%

Zealand's commercial activities commenced in 2020 with the acquisition of the Valeritas business in April 2020.

# Administrative expenses

DKK thousand	September 30, 2020	September 30, 2019	$\Delta$	∆ in percent
Administrative expenses	111,232	51,211	60,021	117%

The primary increase in administrative expenses is a result of the expansion of the company through the Valeritas acquisition including consulting and legal costs related to the transaction, new compensation expenses for employees brought on board as part of the acquisition, and administrative support for the V-Go program.

# Operating result

	September	September		
DKK thousand	30, 2020	30, 2019	Δ	∆ in percent
Operating result	-449,120	-402,135	-46,985	-12%

The operating result reflects gross margin, research and development expenses, sales and marketing and administrative expenses, as discussed above and other operating expenses explained in note 3.

# Financial income and financial expenses

DKK thousand	September 30, 2020	September 30, 2019	Δ	∆ in percent
Net financial items	-18,748	20,315	-39,063	-192%

Financial income and financial expenses, which we refer to collectively as net financial items, consist of interest income and expense, dividend, banking fees and impact from adjustments from changes in currencies. The decrease is primarily driven by unfavorable changes in currencies by DKK 9.0 million and unfavorable impact from fair value adjustment by DKK 5.2 million.



### Result before tax

DKK thousand	September 30, 2020	September 30, 2019	Δ	$\Delta$ in percent
Result before tax	-467,869	-381,820	-86,049	-23%

Result before tax reflects the operating result and net financial items, as discussed above.

### Income tax

DKK thousand	September 30, 2020	September 30, 2019	Δ	∆ in percent
Income tax	1,686	3,954	-2,268	-57%

The net income tax benefit is mainly impacted by DKK 4.1 million related to the Danish tax credit scheme (Skattekreditordningen) under which companies may annually obtain payment of the tax base of losses originating from R&D expenses of up to DKK 25.0 million (tax value of DKK 5.5 million) and offset by income tax expenses in USA.

No deferred tax asset regarding the Danish parent company has been recognized in the statement of financial position due to uncertainty as to whether tax losses carried forward can be utilized within the near term.

# Net result and comprehensive result

DKK thousand	September 30, 2020	September 30, 2019	Δ	∆ in percent
Net result and comprehensive result	-466,183	-377,866	-88,317	23%

The increase is primarily a result of the increases in Research and development and sales and marketing expenses.

# Liquidity and capital resources

# Equity

DKK thousand	September 30, 2020	December 31,2019	Δ	$\Delta$ in percent
Equity	1,590,003	1,242,673	347,330	28%
Equity ratio	77%	78%	N/A	N/A

Equity ratio is calculated as equity at the balance sheet date divided by total assets at the balance sheet date. The increase in equity mainly stems driven by from the direct issue and private placement in June of DKK 657.7 million, the private placement in March of DKK 137.2 million, and issue of shares related to exercise of warrants of DKK 38.8 million offset by the loss for the period and costs incurred in connection with the capital increases.



# Cash, cash equivalents and Marketable securities

DKK thousand	September 30, 2020	December 31, 2019	Δ	$\Delta$ in percent
Cash, cash equivalents and Marketable securities	1,528,594	1,380,508	148,086	11%

The increase in cash and cash equivalents is due to capital increases resulting from a private placement in March, a financing completed in June as well as the EUR 20.0 million Boehringer Ingelheim milestone triggered in June. The year over year increase in cash and cash equivalents is partially offset by the increase in cash used for operations as well as the USD 24.5 million payment for the Valeritas asset purchase agreement.

### Cash flow

DKK thousand	September 30, 2020	September 30, 2019	Δ	$\Delta$ in percent
Cash used in operating activities	-411,628	-241,240	-170,388	71%
Cash used in investing activities	-200,799	-48,454	-152,345	314%
Cash flow from financing activities	780,826	656,011	124,815	19%
Net cash flow	-441,119	-255,809	-185,310	72%

The increase in cash used in operating activities from the same period in 2019 is mainly related to our research and development and sales and marketing expenses increasing as a result of the regulatory and pre-commercial activities for the HypoPal Rescue Pen as well as the commercial activities and support for the V-Go wearable insulin delivery device. Cash used in operating activities for the nine months ended September 30, 2019 was positively impacted by the upfront payment from the Alexion license agreement received in Q1 2019.

Cash used in investing activities in the first nine months of 2020 related mainly to the acquisition of Valeritas business of DKK 167.7 million. Cash flow from investing activities for the nine months ended September 30, 2019 was primarily related to the Beta Bionics investment and the payment from Royalty Pharma for royalty expenses related to the sale of future royalty and milestones (remainder balance from the 2018 transaction).

Cash from financing activities increased primarily as a result of the March private placement and June financing in an aggregate amount of DKK 794.9 million. Cash from financing activities for the nine months ended September 30, 2019 was mainly related to a capital increase as part of the agreement with Alexion and a private placement completed in Q3 2019.

### Risk factors

This interim report contains forward-looking statements, including forecasts of future expenses as well as expected business related events. Such statements are subject to risks and uncertainties as various factors, some of which are beyond the control of Zealand, may cause actual results and performance to differ materially from the forecasts made in this interim report. Without being exhaustive, such factors include e.g. the impact of the global COVID-19 pandemic, interest rate and currency exchange rate fluctuations, delay or failure of clinical trials and other development activities, production problems, unexpected contract breaches or terminations, government-mandated or market-driven price decreases for Zealand's products, introduction of competing products, Zealand's ability to successfully market both new and existing products, exposure to product liability and other lawsuits, changes in reimbursement rules and governmental laws and related interpretation thereof, unexpected growth in costs and expenses, and Zealand's ability to integrate businesses in varying geographies with different commercial and operating characteristics. In particular, the global COVID-19 pandemic could potentially materially adversely impact our



business and financial performance, including the timing of our clinical trials, projected regulatory approval timelines, our supply chain and sales of our approved products, as well as our Financial Guidance for 2020 in this interim report, particularly because the COVID-19 pandemic continues to evolve, and its breadth and significance on our business and financial performance is uncertain. A more extensive description of risk factors can be found in the 2019 Annual Report under the section Risk management and internal control.



# Management's statement on the interim report

The Board of Directors and the Management have considered and adopted the interim report of Zealand Pharma A/S for the three and nine months periods ended September 30, 2020.

The condensed consolidated interim financial statements are prepared in accordance with IAS 34 *Interim Financial Reporting*, as issued by the International Accounting Standards Board (IASB) and as adopted by the EU, and additional requirements of the Danish Financial Statements Act. In our opinion, the interim report gives a true and fair view of the Group's assets, equity and liabilities and financial position at September 30, 2020 as well as of the results of the Group's operations and cash flow for the period January 1 – September 30, 2020.

Moreover, in our opinion, the Management's Review gives a true and fair view of the development in the Company's operations and financial conditions, of the net result for the periods and the financial position while also describing the most significant risks and uncertainty factors that may affect the Group.

Copenhagen, November 12, 2020

# Management

Emmanuel Dulac
President and
Chief Executive Officer

Matthew Dallas Senior Vice President and Chief Financial Officer Adam Sinding Steensberg Executive Vice President and Chief Medical Officer

### **Board of Directors**

Alf Gunnar Martin Nicklasson

Chairman

Kirsten Aarup Drejer Vice Chairman Jeffrey Berkowitz Board member

Bernadette Mary Connaughton

Board member

Leonard Kruimer Board member

Employee elected

Alain Munoz Board member

Michael John Owen Board member Gertrud Koefoed Rasmussen Board member Iben Louise Gjelstrup Board member Employee elected

Jens Peter Stenvang

Nikolaj Frederik Beck Board member Employee elected

Board member Employee elected



# Independent auditor's report

### To the shareholders of Zealand Pharma A/S

We have reviewed the interim condensed consolidated financial statements of Zealand Pharma A/S for the three and nine month periods ended September 30, 2020, which comprise a condensed consolidated statement of profit or loss and statement of other comprehensive income for the three and nine month periods ended September 30, 2020, statement of financial position at September 30, 2020, and statement of changes in equity and statement of cash flow for the nine month period ended September 30, 2020, and notes. The interim condensed consolidated financial statements are prepared in accordance with IAS 34 *Interim Financial Reporting*, as issued by the International Accounting Standards Board (IASB) and as adopted by the EU, and additional requirements of the Danish Financial Statements Act.

### Management's responsibility for the interim condensed consolidated financial statements

Management is responsible for the preparation of interim condensed consolidated financial statements in accordance with IAS 34 *Interim Financial Reporting*, as issued by the International Accounting Standards Board (IASB) and as adopted by the EU, and additional requirements of the Danish Financial Statements Act and for such internal control as Management determines is necessary to enable the preparation of interim condensed consolidated financial statements that are free from material misstatement, whether due to fraud or error.

### Auditor's responsibility

Our responsibility is to express a conclusion on the interim condensed consolidated financial statements. We conducted our review in accordance with the International Standard on Review of Interim Financial Information Performed by the Independent Auditor of the Entity and additional requirements applicable in Denmark.

This requires us to conclude whether anything has come to our attention that causes us to believe that the interim condensed consolidated financial statements, taken as a whole, are not prepared, in all material respects, in accordance with IAS 34 *Interim Financial Reporting*, as issued by the International Accounting Standards Board (IASB) and as adopted by the EU, and additional requirements of the Danish Financial Statements Act. This standard also requires us to comply with ethical requirements.

A review of the interim condensed consolidated financial statements in accordance with the International Standard on Review of Interim Financial Information Performed by the Independent Auditor of the Entity is a limited assurance engagement. The auditor performs procedures primarily consisting of making enquiries of Management and others within the company, as appropriate, applying analytical procedures and evaluate the evidence obtained.

The procedures performed in a review are substantially less that those performed in an audit conducted in accordance with the International Standards on Auditing. Accordingly, we do not express an audit opinion on the interim condensed consolidated financial statements.

### Conclusion

Based on our review, nothing has come to our attention that causes us to believe that these interim condensed consolidated financial statements are not prepared, in all material respects, in accordance with IAS 34 *Interim Financial Reporting*, as issued by the International Accounting Standards Board (IASB) and as adopted by the EU, and additional requirements of the Danish Financial Statements Act.

Copenhagen, November 12, 2020

ΕY

Godkendt Revisionspartnerselskab CVR no. 30 70 02 28

Christian Schwenn Johansen State Authorized Public Accountant mne33234 Rasmus Bloch Jespersen State Authorized Public Accountant mne35503



# Interim condensed consolidated financial statements

Interim condensed consolidated statement of profit or loss for the three and nine months periods ended September 30, 2020 and 2019.

	Reviewed			
Note	Q3 2020	Q3 2019	YTD 2020	YTD 2019
2	56,526	9,922	289,958	29,840
	-34,271	0	-62,297	0
	0	-231	0	-415
	22,255	9,691	227,661	29,425
	-139 332	-123 822	-430 991	-380,733
		0	•	0
		-16 020		-51,211
3	- ,	89		384
	-218,207	-130,062	-449,120	-402,135
	4,070	17,101	1,265	27,398
4	-13,816	-1,580	-20,014	-7,083
	-227,953	-114,541	-467,869	-381,820
	-621	1,313	1,686	3,954
	-228,574	-113,228	-466,183	-377,866
5	-5.76	-3.44	-12.39	-11.49
	3	Note Q3 2020  2 56,526 -34,271 0 22,255  -139,332 -97,429 -40,567 3 36,866 -218,207  4,070 4 -13,816 -227,953 -621 -228,574	Note         Q3 2020         Q3 2019           2         56,526 -34,271 0 0 -231         9,922 -34,271 0 -231           22,255         9,691           -139,332 -97,429 0 -40,567 -16,020 3 36,866 89         -16,020 -130,062           4,070 4 -13,816 -1,580 -227,953 -114,541         17,101 -1,580 -1,580 -114,541           -227,953 -114,541         -113,228	Note         Q3 2020         Q3 2019         YTD 2020           2         56,526 -34,271 0         9,922 -62,297 0         289,958 -62,297 0         -62,297 0           22,255         9,691         227,661           -139,332 -97,429 0         -123,822 -40,567 -16,020 -111,232         -430,991 -172,282 -111,232           3         36,866 89 37,724         89 37,724           -218,207 4         -130,062 -13,816 -1,580 -20,014         -449,120 -20,014           4         -13,816 -1,580 -20,014         -20,014 -467,869           -621 1,313 1,686         -228,574 -113,228 -466,183

Interim condensed consolidated statement of other comprehensive income (loss) for the three and nine months periods ended September 30, 2020 and 2019.

Reviewed					
DKK thousand	Note	Q3 2020	Q3 2019	YTD 2020	YTD 2019
Net result for the period Other comprehensive income to be reclassified to profit or loss in subsequent periods:		-228,574	-113,228	-466,183	-377,866
Adjustment of foreign currency fluctuations on subsidiaries		2,733	0	2,405	0
Comprehensive result for the period		-225,841	-113,228	-463,777	-377,866



# Interim condensed consolidated statements of cash flow for the nine months periods ended September 30, 2020 and 2019 and for the twelve month period ended December 31, 2019

		Reviewed		Audited
DKK thousand	Note	YTD 2020	YTD 2019	FY 2019
DRK thousand	NOLE	110 2020	110 2019	1 1 2019
Operating result		-449,120	-402,135	-587,942
Bargain purchase	3,20	-36,692	0	0
Depreciation and amortization		25,567	6,176	13,682
Adjustments for other non-cash items		44,977	13,418	12,019
Change in working capital		43,133	-13,224	10,873
Financial income received		901	5,100	5,413
Financial expenses paid		-5,862	-1,362	-3,390
Deferred revenue	2	-34,532	150,787	139,890
Income tax paid/received		0	0	93
Cash flow from operating activities		-411,628	-241,240	-409,455
Acquisition of Valeritas business, net of cash acquired	20	-167,725	0	0
Royalty paid regarding sale of future royalty and milestones		0	-6,575	0
Deposits paid		-3,583	-4,531	-6,250
Purchase of other investments	9	0	-22,804	-22,804
Purchase of property, plant and equipment	7	-29,491	-14,569	-21,036
Purchase of intangible assets		0	0	-2,480
Sale of property, plant and equipment		0	25	25
Dividends on securities		0	0	878
Cash flow from investing activities		-200,799	-48,454	-51,666
Proceeds from issuance of shares related to exercise of				
warrants	15	38,832	29,283	52,468
Proceeds from issuance of shares	15	794,929	645,145	645,145
Costs related to issuance of shares		-42,689	-13,977	-14,444
Lease installments	8	-10,246	-4,440	-8,689
Cash flow from financing activities		780,826	656,011	674,480
Decrease/increase in cash and cash equivalents		168,399	366,318	213,359
Cash and cash equivalents by beginning of period		1,081,060	860,635	860,635
Exchange rate adjustments		-17,775	15,918	7,066
Cash and cash equivalents by end of period		1,231,685	1,242,871	1,081,060



# Interim condensed consolidated statements of financial position as of September 30, 2020 and December 31, 2019

		Reviewed	Audited
		September 30,	December 31,
DKK thousand	Note	2020	2019
ASSETS			
Non-current assets		75.454	0.400
Intangible assets	6	75,154	2,480
Property, plant and equipment	7	94,315	39,708
Right-of-use assets	8	131,966	85,632
Deposits		16,261	9,012
Corporate tax receivable		4,125	0
Deferred tax assets	_	510	0
Other investments	9	33,007	35,632
Total non-current assets		355,338	172,464
Current assets			
Inventories	10	75,162	0
Trade receivables	11	44,238	751
Prepaid expenses	12	39,896	30,755
Corporate tax receivable		6,725	7,101
Other receivables	13	9,190	7,935
Marketable securities	9	296,909	299,448
Cash and cash equivalents	14	1,231,685	1,081,060
Total current assets		1,703,805	1,427,050
Total assets		2,059,143	1,599,514
EQUITY AND LIABILITIES			
Share capital	15	39,779	36,055
Share premium		3,457,526	2,650,142
Translation reserve		2,405	0
Accumulated loss		-1,909,707	-1,443,524
Equity		1,590,003	1,242,673
Deferred revenue		45,191	83,639
Deferred tax liabilities		11,163	0
Lease liabilities	8	119,290	78,068
Non-current liabilities		175,644	161,707
Trade payables	16	61,703	57,533
Corporate tax payables	10	1,775	614
Lease liabilities	8	14,218	7,692
Deferred revenue	J	58,589	56,251
Discount and rebate liabilities		28,289	0
Other liabilities	17	128,922	73,044
Current liabilities	.,	293,496	195,134
Total liabilities		469,140	356,841
Total equity and liabilities		2,059,143	1,599,514



# Interim condensed consolidated statements of changes in equity for the nine month periods ended September 30, 2020 and September 30, 2019

		Reviewed			
DKK thousand	Share	Share	Translation	Retained	
	capital	premium	reserve	Loss	Total
Equity at January 1, 2019	30,787	1,979,493	0	-893,999	1,116,281
Restatement 1)	0	-22,015	0	22,015	0
Restated equity at January 1, 2019 Other comprehensive income for the	30,787	1,957,478	0	-871,984	1,116,281
period	0	0	0	0	0
Net loss for the period	0	0	0	-377,866	-377,866
Share-based compensation expenses	0	10,327	0	0	10,327
Capital increase	5,078	669,350	0	0	674,428
Costs related to capital increases	0	-13,977	0	0	-13,977
Equity at September 30, 2019	35,865	2,623,178	0	-1,249,850	1,409,193
Equity at January 1, 2020	36,055	2,650,142	0	-1,443,524	1,242,673
Other comprehensive income for the	30,033	2,030,142	· ·	-1,443,324	1,242,073
period	0	0	2,405	0	2,405
Net loss for the period	0	0	0	-466,183	-466,183
Share-based compensation expenses	0	20,037	0	0	20,037
Capital increase, see note 15	3,724	830,037	0	0	833,761
Costs related to capital increases	0	-42,689	0	0	-42,689
Equity at September 30, 2020	39,779	3,457,526	2,405	-1,909,707	1,590,003

<sup>1.</sup> Reclassification between share premium and retained loss arising from restatement of warrants. See note 1 in the Annual Report for 2019.



# Note 1 - Basis of preparation and changes to the Group's accounting policies

# Basis of preparation

The interim condensed consolidated financial statements of Zealand Pharma A/S ("the Company") have been prepared in accordance with IAS 34, Interim Financial Reporting, as issued by the International Accounting Standards Board (IASB) and as adopted by EU and and additional requirements of the Danish Financial Statements Act. The interim condensed consolidated financial statements are presented in Danish kroner (DKK) which is also the functional currency of the parent company.

The accounting policies used in the interim condensed consolidated financial statements are consistent with those used in the Company's Annual report for the year ended December 31, 2019 except for the newly applied accounting policies following the acquisition of the business activities from Valeritas as disclosed in note 20, which has also implied adoption of new standards effective as of January 1, 2020 as discussed below.

# New standards, interpretations and amendments adopted by the Group

A few amendments apply for the first time in 2020, but do not have an impact on the interim condensed consolidated financial statements of the Group:

### Amendments to IFRS 3: Definition of a Business

The amendment to IFRS 3 clarifies that to be considered a business, an integrated set of activities and assets must include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create output. Furthermore, it clarified that a business can exist without including all of the inputs and processes needed to create outputs.

### Amendments to IFRS 7, IFRS 9 and IAS 39: Interest Rate Benchmark Reform

The amendments to IFRS 9 and IAS 39 *Financial Instruments: Recognition and Measurement* provide a number of reliefs, which apply to all hedging relationships that are directly affected by interest rate benchmark reform. A hedging relationship is affected if the reform gives rise to uncertainties about the timing and or amount of benchmark-based cash flows of the hedged item or the hedging instrument.

### Amendments to IAS 1 and IAS 8: Definition of Material

The amendments provide a new definition of material that states "information is material if omitting, misstating or obscuring it could reasonably be expected to influence decisions that the primary users of general purpose financial statements make on the basis of those financial statements, which provide financial information about a specific reporting entity."

The amendments clarify that materiality will depend on the nature or magnitude of information, either individually or in combination with other information, in the context of the financial statements. A misstatement of information is material if it could reasonably be expected to influence decisions made by the primary users.



# Significant judgements estimates

In the preparation of the interim condensed consolidated financial statements, the Company's management ("Management") makes several accounting estimates that form the basis for the presentation, recognition and measurement of the Company's assets and liabilities.

In the application of the Company's accounting policies, Management is required to make judgments, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates. The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period, or in the period of the revision and future periods if the revision affects both current and future periods. The estimates used are based on assumptions assessed as reasonable by Management; however, estimates are inherently uncertain and unpredictable. The assumptions can be incomplete or inaccurate, and unexpected events or circumstances might occur. Furthermore, the Company is subject to risks and uncertainties that might result in deviations in actual results compared with estimates.

For further information regarding significant accounting estimates and judgments related to revenue recognition please see note 1 in the Annual Report for 2019. Additionally, new significant accounting estimates and judgments have been applied regarding Gross to net accruals and business combinations. Gross to net accruals is relating to the discounts and rebates arising from our V-Go sales in USA and is described under newly applied accounting policies below. The purchase price allocation is described in general terms in the section on Business combinations under newly applied accounting policies and specifically for the Valeritas acquisition in note 20.

# Newly applied accounting policies

The following accounting policies have been applied for the first time in the interim condensed consolidated reporting for the period ended September 30, 2020 because of the acquisition of the Valeritas business as disclosed in note 20.

### Revenue from contracts with customers (extended)

Sale of Goods

Revenue from sale of goods is recognized at a point in time when control of the goods are transferred to the customer and recorded net of adjustments for managed care rebates, wholesale distributions fees, cash discounts, prompt pay discounts, and co-pay card redemptions, all of which are established at the time of sale.

In order to prepare the consolidated financial statements, the company is required to make estimates regarding the amounts earned or to be claimed on the related product sales, including the following:

- managed care and Medicare rebates, which are based on the estimated end user pay or mix and related contractual rebates;
- distribution fees, prompt pay discounts and other discounts, which are recorded based on specified payment terms, and which vary by customer and other incentive programs; and
- Co-pay card redemption charges which are based on the net transaction costs of prescriptions filled via a company-subsidized card program and other incentive programs.



Zealand believes its estimates related to managed care rebates and Medicare rebates, distribution fees, prompt pay and other discounts, and co-pay card redemption do not have a high degree of estimation complexity or uncertainty as the related amounts are settled within a relatively short period of time.

The Group has concluded that it is the principal in this revenue arrangements since it controls the goods before transferring them to the customer.

### **Return Reserve**

We record allowances for product returns as a reduction of revenue at the time product sales are recorded. Several factors are considered in determining whether an allowance for product returns is required, including the customers' return rights and our historical experience with returns and the amount of product sales in the distribution channel not consumed by patients and subject to return. We rely on historical return rates to estimate returns. In the future, as any of these factors and/or the history of product returns change, adjustments to the allowance for product returns will be reflected

### Cost of goods sold

Cost of goods sold includes raw materials, labor costs, manufacturing overhead expenses and reserves for anticipated scrap and inventory obsolescence.

### Sales and marketing expenses (extended)

Sales and marketing expenses include expenses for sales personnel and expenses related to company premises in the US used for sales activities. Other significant expenses include product demonstration samples, trade show expenses, professional fees for our contracted customer support center and other consultants, insurance, facilities and information technology expenses. Overhead expenses have been allocated to sales and marketing expenses according to the number of employees in each department, based on the respective employees' associated undertakings.

### Impairment testing

Each year, the assets are reviewed in order to assess whether there are indications of impairment. If such indications exist, the recoverable amount, determined as the higher amount of the fair value of the asset adjusted for expected costs to sell and the value in use of the asset, is calculated. The value in use is calculated based on the estimated future cash flows, discounted by using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset.

If the recoverable amount of an asset or its cash-generating unit is lower than the carrying amount, an impairment charge is recognized in respect of the asset. The impairment loss is recognized in the income statement. In addition, for goodwill and other intangible assets with indefinite useful lives, impairment tests are performed at each balance sheet date, regardless of whether there are any indications of impairment. For acquisitions, the first impairment test is performed before the end of the year of acquisition.

### Inventories

Raw materials, work in progress and finished goods are stated at the lower of cost and net realizable value. Cost comprises direct materials, direct labor and an appropriate proportion of variable and fixed overhead expenditure, the latter being allocated on the basis of normal operating capacity. Costs of purchased inventory are determined after deducting rebates and discounts. Net realizable value is the estimated selling price in the ordinary course of business less the estimated costs of completion and the estimated costs necessary to make the sale.

### Trade receivables write-down

On initial recognition, receivables are measured at fair value. The Group holds the trade receivables with the objective to collect the contractual cash flows and therefore measures them subsequently at amortized cost.



Trade receivables are written down for expected credit losses. The Group applies the simplified approach in IFRS 9 to measuring expected credit losses which uses a lifetime expected loss allowance for trade receivables and contract assets. A write-down is recognized in sales and marketing expenses.

### **Business combinations**

Business combinations are accounted for using the acquisition method of accounting. At the date of the acquisition, the Company initially recognizes the fair value of the identifiable assets acquired, the liabilities assumed and any non-controlling interest in the acquired business.

The consideration transferred is measured at fair value at the date of acquisition and the excess of the consideration transferred over the fair value of net identifiable assets of the business acquired is recorded as goodwill. In circumstances where the consideration transferred is less than the fair value of net identifiable assets of the business acquired, the difference is recognized directly in the consolidated statement of profit or loss as a bargain purchase.

Where the settlement of any part of cash consideration is deferred, the amounts payable in the future are discounted to their present value. Contingent consideration is classified either as equity or a financial liability and is recognized at fair value on the acquisition date. Amounts classified as a financial liability are subsequently remeasured to fair value in accordance with IFRS 9 (Financial Instruments), with changes in fair value recognized in the consolidated statement of comprehensive loss as an administrative expense.

Business combinations require management making an assessment of the fair value of the net assets acquired as well as an assessment regarding whether control exists. Management judgement is particularly involved in the recognition and measurement of the following items at fair value:

- intellectual property: this may include patents, licenses, trademarks and similar rights for currently marketed products, and also the rights and scientific knowledge associated with projects that are currently in research or development phases, and requires the projection of estimated future cash inflows and outflows and relevant risks, the terminal value of these assets, discount rates and weighted average costs of capital,
- working capital items such as trade receivables, inventory (raw materials, work in process, parts and finished goods), prepaid expenses, trade payables, and fixed assets
- Guarantees, warranties, indemnities, rights, claims, counterclaims etc. set off against third parties relating to the
  acquired assets or assumed liabilities, including rights under vendors' and manufacturers' warranties, indemnities,
  guaranties and avoidance claims and causes of action under any applicable Law, employee liabilities and other
  contingencies

In all cases, management makes an assessment based on the underlying economic substance of the items concerned, and not only on the contractual terms, in order to fairly present these items. In making these assessments, management relies to a significant extent on the work of valuation experts. However, the assessments are highly subjective and sensitive to the assumptions used.

In accordance with IFRS 3, if a business combination indicates a bargain gain all applied assumptions will be reassessed by Management before recognition.

Directly attributable acquisition-related costs are expensed as incurred within the consolidated statement of comprehensive loss.

Customer relationships and IP rights acquired through business combinations are measured at fair value at the acquisition date and amortized on a systematic basis over their useful life 8 and 10 years respectively (unless the asset has an indefinite useful life, in which case it is not amortized).

### Note 2 - Revenue



### Revenue can be specified as follows:

DKK thousand	Q3 2020	Q3 2019	Q1-Q3 2020	Q1-Q3 2019
Alexion Pharmaceuticals Inc.	10,645	8,267	36,870	26,528
Boehringer Ingelheim International GmbH	0	0	149,120	0
Undisclosed counterpart	0	1,655	0	3,312
Total license and milestone revenue	10,645	9,922	185,990	29,840
Total sale of goods revenue net (V-Go sales)	45,881	0	103,968	0
Total revenue	56,526	9,922	289,958	29,840
Total revenue recognized over time	10,645	9,922	36,870	29,840
Total revenue recognized at a point in time	45,881	0	253,088	0

License revenue for the first nine months of 2020 of DKK 37.1 million relate to the research and development agreement with Alexion Pharmaceuticals entered into in March 2019. Under the agreement DKK 103.8 million is accounted for as deferred revenue at September 30, 2020.

Milestone revenue for the first nine months of 2020 of DKK 149.1 million relate to the license agreement with Boehringer Ingelheim entered into in 2011. No deferred revenue related to this agreement is recognized at September 30, 2020 as payments are not received before the achievement of pre-specified development, regulatory and commercial milestones for the lead product are met. For further information about the agreements please see note 2 in the Annual Report 2019.

Sale of goods revenue net from the acquisition date of April 2, 2020 of DKK 104.0 million relate to V-Go, which is a product line developed by Valeritas Inc. that was acquired as part of the business combination as described in note 20. The net sales comprises of gross sales of DKK 192.8 million and discounts and rebates of DKK -88.8 million.

Zealand is managed and operated as one business unit, which is reflected in the organizational structure and internal reporting. No separate lines of business or separate business entities have been identified with respect to any of the product candidates or geographical markets and no segment information is currently included in the internal reporting. All V-Go related costs can be identified in the financial statement lines cost of goods sold (DKK 62.3 million for the nine months period ended September 30, 2020) and sales and marketing expenses (DKK 163.6 million for the nine months period ended September 30, 2020).

Net revenue in Germany for the nine months period ended September 30, 2020 comprise DKK 149.1 million in license revenue whereas net sales in US for the nine months period ended September 30, 2020 comprise DKK 140.8 million including license revenues and sale of goods. No other countries accounts for more than 10% of the net total sales.



# Note 3 – Other operating income

Recognized other operating income can be specified as follows:

DKK thousand	Q3 2020	Q3 2019	Q1-Q3 2020	Q1-Q3 2019
Bargian purchase	36,692	0	36,692	0
Other	174	89	1,032	384
Other operating income	36,866	89	37,724	384

The bargain purchase recognized is relating to Valeritas business described in note 20 on business combinations.

# Note 4 - Financial expenses

Recognized financial expenses can be specified as follows:

DKK thousand	Q3 2020	Q3 2019	Q1-Q3 2020	Q1-Q3 2019
Interest expenses and banking fees	-134	-503	-279	-922
Fair value adjustments	0*	0	-5,164	0
Other financial expenses	-1,256	-657	-5,583	-1,555
Currency exchange adjustments	-12,426	-420	-8,988	-4,606
Financial expenses	-13,816	-1,580	-20,014	-7,083

<sup>\*</sup>Fair value adjustments for the 3 months period in Q3 is a net income and therefore not included in the table as it is recognized under financial income.

# Note 5 - Earnings/Loss per share

The earnings/loss and weighted average number of ordinary shares used in the calculation of basic and diluted earnings/loss per share are as follows:

DKK thousand	Q3 2020	Q3 2019	Q1-Q3 2020	Q1-Q3 2019
Net earnings/loss for the period  Net earnings/loss used in the calculation of basic	-228,574	-113,228	-466,183	-377,866
earnings/loss per share	-228,574	-113,228	-466,183	-377,866
Weighted average number of ordinary shares	39,750,959	32,956,731	37,701,621	32,956,731
Weighted average number of treasury shares	-64,223	-64,223	-64,223	-64,223
Weighted average number of ordinary shares used in the calculation of basic/diluted loss per	00 000 700	00 000 500	07.007.000	00 000 500
share	39,686,736	32,892,508	37,637,398	32,892,508
			40.00	
Earnings/loss per share – basic/diluted (DKK)	-5.76	-3.44	-12.39	-11.49



The following potential ordinary shares are anti-dilutive and are therefore excluded from the weighted average number of ordinary shares for the purpose of diluted earnings/loss per share:

	September 30, 2020	September 30, 2019
Outstanding warrants under the 2010 Employee incentive program	0	87,359
Outstanding warrants under the 2015 Employee	O	07,559
incentive program	1,941,209	1,768,073
Outstanding warrants under the 2020 Employee incentive program	63,217	0
Outstanding Performance Share Units (PSUs)	10.765	10.765
under the LTIP 2019 program Outstanding Restricted Share Units (RSUs) under	19,765	19,765
the LTIP 2020 program	27,466	0
Total outstanding warrants	2,051,657	1,875,197

For further information on the Employee incentive programs please see note 6 in the Annual Report for 2019.

# Note 6 – Intangible assets

Intangible assets of DKK 75.2 million recognized as at September 30, 2020 as compared to DKK 2.5 million as of December 31, 2019. The increase is primarily related to the acquisition of the Valeritas business (DKK 82.1 million) described in note 20 on business combinations.

# Note 7 – Property, plant and equipment

DKK thousand	September 30, 2020	December 31, 2019
Plant and machinery	42,785	13,457
Other fixtures and fittings	9,413	8,337
Building improvements	35,828	3,913
Assets under construction	6,289	14,001
Carrying amount	94,315	39,708

The increase from DKK 39.7 million as at December 31, 2019 to DKK 94.3 million as at September 30, 2020 is primarily related to tooling, machinery and equipment for the production lines to procedure V-Go and leasehold improvements purchased as part of the Valeritas acquisition (DKK 41.1 million) described in note 20 on business combinations and new leasehold improvements in Søborg (DKK 29.2 million).



# Note 8 - Right of use assets and lease liabilities

Right-of-use-assets of DKK 132.0 million and lease liability of DKK 133.5 million were recognized as at September 30, 2020 as compared to DKK 85.6 million and DKK 85.8 million, respectively, as of December 31, 2019. The increase is primarily related to the office spaces at the headquarters in Søborg, Denmark (DKK 24.2 million) and lease agreement on the assumed Valeritas domicile (DKK 12.3 million) transferred in connection with the acquisition of the Valeritas business described in note 20 on business combinations.

### Note 9 - Financial instruments

As of September 30, 2020 and December 31, 2019, the following financial instruments are measured at fair value through profit or loss:

DKK thousand	September 30, 2020	December 31, 2019
Marketable securities	296,909	299,448
Other investments	33,007	35,632
Financial assets measured at fair value	329,916	335,080

The fair value of marketable securities and other investments is based on Level 1 and Level 3, respectively, in the fair value hierarchy. No financial assets are based on Level 2.

Other investments consist of a USD 5.2 million (December 31, 2019: USD 5.3 million) investment in Beta Bionics, Inc., the developer of iLet™, a fully integrated dual-hormone pump (bionic pancreas) for autonomous diabetes care. The fair value of the investment in Beta Bionics, Inc. is based on the capital contributions made by either Zealand or other investors, and investee's current business plan, and is classified as level 3 fair values in the fair value hierarchy due to the use of unobservable inputs. For further information please see note 15 in the Annual Report 2019.

Management has for the purpose of measuring the fair value at September 30, 2020 obtained information about recent capital contributions made and other progress achieved already or in the short-term that can be used as firm evidence for a revised valuation. Management has obtained a valuation report from Beta Bionics supporting the fair value at September 30, 2020.

A net fair value adjustment of DKK 5.2 million from marketable securities and other investments have been recognized in financial expenses, as of September 30, 2020 (September 30, 2019: DKK 6.9 million in financial income).

There were no transfers between levels 1, 2 and 3 for recurring fair value measurements during the interim periods ended September 30, 2019 and 2020, respectively.



### Note 10 - Inventories

DKK thousand	September 30 202	
Raw materials	15,26	2 0
Work in progress	27,57	0
Finished goods	32,33	0 0
Inventories	75,16	2 0

Inventories relate to the V-Go product. The increase is due to the acquisition of the Valeritas business described in note 20 on business combinations.

### Note 11 – Trade receivables

The increase in Trade receivables from DKK 0.8 million at December 31, 2019 to DKK 44.2 million at September 30, 2020 is mainly related to receivables from V-Go sales.

# Note 12 – Prepaid expenses

The increase in Prepaid expenses from DKK 30.8 million at December 31, 2019 to DKK 39.9 million at September 30, 2020 is mainly relating to timing differences.

### Note 13 - Other receivables

DKK thousand	September 30, 2020	December 31, 2019
VAT	7,265	5,437
Other	1,925	2,498
Total other receivables	9,190	7,935

Other receivables is mainly related to VAT receivables in Denmark.



# Note 14 - Cash and cash equivalents

DKK thousand	September 30, 2020	December 31, 2019
DKK	724,287	732,405
USD	347,509	306,748
EUR	159,889	41,907
Total cash and cash equivalents	1,231,685	1,081,060

# Note 15 - Changes in share capital

The following changes have occurred in the share capital during the respective year-to-date interim periods:

	No. of shares
Share capital at January 1, 2019	30,786,827
Capital increase on March 15, 2019 (issue of shares related to exercise of warrants)	72,000
Capital increase on March 25, 2019 (private placement and directed issue of shares)	802,859
Capital increase on April 5, 2019 (issue of shares related to exercise of warrants)	18,250
Capital increase on May 28, 2019 (issue of shares related to exercise of warrants)	45,539
Capital increase on June 14, 2019 (issue of shares related to exercise of warrants)	89,315
Capital increase on August 23, 2019 (issue of shares related to exercise of warrants) Capital increase on September 5, 2019 (issue of shares related to exercise of	16,500
warrants)	3,975,000
Capital increase on September 13, 2019 (issue of shares related to exercise of warrants)	59,171
Share capital at September 30, 2019	35,865,461
Share capital at January 1, 2020	36,054,661
Capital increase on March 20, 2020 (issue of shares related to exercise of warrants)	91,475
Capital increase on March 26, 2020 (private placement and directed issue of shares)	741,816
Capital increase on April 15, 2020 (issue of shares related to exercise of warrants)	29,372
Capital increase on May 26, 2020 (issue of shares related to exercise of warrants)	90,871
Capital increase on June 12, 2020 (issue of shares related to exercise of warrants)	41,495
Capital increase on June 18, 2020 (private placement and directed issue of shares)	2,684,461
Capital increase on August 21, 2020 (issue of shares related to exercise of warrants) Capital increase on September 11, 2020 (issue of shares related to exercise of	30,959
warrants)	13,851
Share capital at September 30, 2020	39,778,961



# Note 16 – Trade payables

The decrease in Trade payables from DKK 57.5 million at December 31, 2019 to DKK 61.7 million at September 30, 2020 is mainly relating to timing differences.

### Note 17 - Other liabilities

DKK thousand	September 30, 2020	December 31, 2019
Employee benefits	67,202	36,082
Royalty payable to third party	6,274	6,843
CRO liabilities	8,718	0
Other payables	46,728	30,119
Total other liabilities	128,922	73,044

The increase in other liabilities is mainly related to increase in employee related accruals in the US due to increase in activities (DKK 16.2 million), increased vacation and bonus accruals in Denmark (DKK 14.8 million) and accruals regarding ongoing CRO work (DKK 8.7 million).

# Note 18 - Contingent assets, liabilities and contractual obligations

### **Contingent assets**

Zealand is still eligible for a payment from Sanofi of up to USD 15.0 million in total, expected during 2020 and 2022. However, it is Management's opinion that the amount of any payment cannot be determined on a sufficiently reliable basis, and has therefore not recognized an asset in the financial position of the Group.

### **Contingent liabilities and contractual obligations**

At September 30, 2020, total contractual obligations related to agreements with CROs amounted to DKK 251.1 million (DKK 83.9 million for 2020 and DKK 167.2 million for the years 2021-24).

Zealand may be required to pay future development, regulatory and commercial milestones related to the acquisition of Encycle Therapeutics. For further information, please see Note 12 in the Annual Report for 2019.

As of September 30, 2020 Zealand has committed inventory purchase orders of DKK 21.1 million (September 30, 2019 DKK 0).

# Note 19 - Long-term incentive and warrant programs

On September 14, 2020, Zealand granted 63,217 new warrants and 5,864 RSUs to employees in the United States.

### **Grant of warrants**

The warrant program is an incentive scheme reflecting Zealand's objective to attract and retain first-rate employees and to help ensure shared short- and long-term interests for the management and employees with shareholders of Zealand.



A total of 63,217 warrants have been granted, giving the rights to subscribe for up to 63,217 new Zealand shares with a nominal value of DKK 1 each, corresponding to 0.2% of Zealand's total outstanding share capital. The exercise price is DKK 216.80, calculated as the closing price of Zealand's shares on Nasdaq Copenhagen on September 11, 2020.

The warrants will vest annually over a three-year period, and the exercise of the warrants may take place, in whole or in part, in defined time windows from September 14, 2021 up to and including September 13, 2030.

The exercise time windows are defined as four times a year during a four-week window following the time of publication of either Zealand's annual report or quarterly or semi-annual reports (three, six and nine months respectively).

The total new warrants granted have a combined market value of DKK 5,676,887 calculated on the basis of the Black–Scholes model. The cost of each warrant is DKK 89.80 based on Black-Scholes parameters for U.S. grants based with an average volatility of 45.6%, an average risk-free interest rate of -0.495%, and a share price of DKK 216.80.

### Long-term incentive program

Zealand's LTIP is intended to drive long-term performance, align management's interests with those of Zealand's shareholders, and support the attraction, retention and motivation of first-rate executive talent. The members of the Executive Management and Corporate Management are eligible to receive an annual grant of restricted share units (RSUs) free of charge. The 2020 RSU grants have a three-year vesting period from September 14, 2020 to September 13, 2023. Each vested RSU entitles the holder to receive one share in Zealand at no cost, provided the holders continued employment throughout the vesting period.

This grant of RSUs under the LTIP will have an estimated aggregate theoretical value of DKK 1.3 million, while each RSU has a value of DKK 220.50.

The value of the RSUs is determined as the simple average of the closing price of the Zealand share on Nasdaq Copenhagen A/S for a period of five trading days prior to the grant date.

### Note 20 - Business combinations

### Acquisition of medical technology business from Valeritas, Inc.

On April 2, 2020 (or "the acquisition date") Zealand acquired substantially all of the medical technology business from Valeritas Holdings, Inc. (or "Valeritas") pursuant to the terms of the stalking horse asset purchase agreement previously entered into with Valeritas and following approval by the U.S. Bankruptcy Court for the District of Delaware on March 20, 2020.

Valeritas was a U.S. based commercial-stage company whose activities comprised development, production and sale of wearable disposable insulin pumps and has therefore been acquired to accelerate Zealand's plans for establishing U.S. operations to support the anticipated launch of the dasiglucagon HypoPal® rescue pen.

The acquisition comprises all medical technology business related tangible and intangible assets that pursuant to the Bankruptcy Code was transferred to Zealand free and clear of all claims, liabilities and encumbrances including the Valeritas workforce. Additionally, the acquisition includes most of the working capital assets and selected liabilities.

Under IFRS 3, Business Combinations, the acquisition has been accounted for as a business combination using the acquisition method. The interim condensed consolidated financial statements include the results of Valeritas for the nine months period ended September 30, 2020 from the acquisition date.



The consideration transferred was DKK 167.7 million (USD 24.5 million), and the fair values of the identifiable assets and liabilities of Valeritas as at the date of acquisition were:

DKK thousand	Fair value recognized on acquisition
Assets	
Physician Relationship	68,459
V-Go IP	13,692
Property, plant and equipment	41,138
Right-of-use assets	14,299
Inventories	55,796
Trade receivables	50,603
Other assets	10,132
Cash and cash equivalents	66
Liabilities	
Deferred tax liability	-11,880
Trade payables	-4,050
Lease liabilities	-14,046
Other liabilities	-19,792
Total identifiable net assets at fair value	204,417
Bargain purchase recognized	-36,692
Purchase consideration transferred	167,725
Analysis of cash flows on acquisition: Net cash acquired with the subsidiary (included in cash flows from investing activities)	66
Cash paid	-167,725
Net cash flow on acquisition	-167,659

The fair value attributable to intangible assets (DKK 82.2 million as of the acquisition date) consists of the value arising from the existing Valeritas physician network and relationships, valued at DKK 68.5 million which is based on the estimated cost it would require to establish similar network and relationships, or a so-called with/without valuation method, and intellectual property related to the V-Go technology, valued at DKK 13.7 million using an excess earnings model. The valuations is calculated using cash flow projections from financial budget approved by Corporate Management covering a 10 year period. The discount rate applied to the cash flow projections is 13%. The growth rate used to extrapolate the cash flows of the unit beyond the 10 year period is -50% which reflects our estimate of the expected lifetime of the product of 10 years with a significant decrease in revenues afterwards.

The calculation of the fair value of intangible assets is most sensitive to the revenue and gross margin growths.



Revenue and gross margin: Revenue and gross margin are based on historical trends. The revenue growth applied in the calculation is between 1-20% in the 10-year budget period with the first years having the highest revenue growth in percentage.

Operating costs: Operating costs are based on historical trends and industry knowledge. Operating costs over the 10-year budget period has been adjusted to incorporate the allocation related to shared efforts of future product launches.

Trade receivables have been measured at the contractual amount expected to be received which approximates the fair value of DKK 50.6 million. The amounts have not been discounted, as maturity on receivables is generally very short and the discounted effect therefore immaterial.

The acquisition resulted in a bargain purchase gain of DKK 36.7 million which was recognized within other operating income in the consolidated income statement. The gain arose as the fair value of the net assets acquired (DKK 204.4 million) exceeded the fair value of the purchase consideration (DKK 167.7 million). The gain is primarily attributable to the Company purchasing the medical technology business of Valeritas out of bankruptcy. Valeritas encountered operational and financial difficulties in late 2019 and filed for Bankruptcy in February 2020.

Specifically, the fair value of the tangible and financial assets acquired (DKK 147.5 million), such as inventories, trade receivables, and property, plant and equipment, represents a significant component of the purchase price prior to consideration of the fair value of the identified intangible assets.

Acquisition-related costs of DKK 7.1 million have been expensed and are included in administrative expenses in profit or loss and are part of operating cash flows in the statement of cash flows for the nine months periods ended September 30, 2020 that have all been incurred in the three months period ended March 31, 2020.

Adjustments may be applied to the various net asset categories when full alignment to Zealand accounting policies is finalized. Consequently, adjustments may be applied for a period of up to twelve months from the acquisition date in accordance with IFRS 3.

The Valeritas business acquisition has contributed with net revenues of approximately DKK 104.0 million and profit and loss of approximately DKK -108.8 million to the Group for the interim period ending September 30, 2020 since the acquisition on April 2, 2020.

The 2019 Financial Statement audit for Valeritas has not yet been completed and it is impractical to include the revenue and profit and loss of the combined entities (the acquired assets transferred to several Zealand entities) for the current period as though the acquisition date was as of the beginning of the annual reporting period.

# Note 21 - Significant events after the reporting period

No significant events have occurred after the end of the reporting period.