

Interim report for H1 2020

Zealand Pharma announces acceleration of U.S. commercial operations through the completion of the Valeritas acquisition; FDA acceptance of New Drug Application submission for the dasiglucagon HypoPal[®] rescue pen; pipeline progress including completion of patient enrollment in first Phase 3 trial of dasiglucagon in CHI; and completion of a direct issue and private placement for DKK 657.7 million.



Interim report for H1 2020

Zealand Pharma A/S (Nasdaq: ZEAL) (CVR No. 20045078), a biotechnology company changing lives with innovative peptide-based medicines, today announced financial results for the first half of 2020.

Financial results for the first half of 2020

- **Revenue: DKK 233.4 million / USD 35.3 million** (DKK 19.9 million / USD 3.0 million in the first six months of 2019).
- **Net operating expenses: DKK -437.2 million / USD -65.7 million** (DKK -292.0 million / USD -44.5 million in the first six months of 2019).
- **Net operating result: DKK -230.9 million / USD -34.7 million** (DKK -272.1 million / USD -41.5 million in the first six months of 2019).
- **Cash, cash equivalents, and marketable securities: DKK 1,644.9 million / USD 247.2 million** as of June 30, 2020 (June 30, 2019: DKK 1,142.1 million / USD 174.1 million).

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

In the first half of 2020, Zealand Pharma made significant progress towards its goal of leveraging our innovative peptide platform to address unmet needs in metabolic and gastrointestinal diseases. The New Drug Application for the dasiglucagon HypoPal[®] rescue pen was accepted in May and is under review by the U.S. FDA, with a target action date of March 27, 2021. As we await an approval decision, we are accelerating the build-out of our commercial team, bolstered by the acquisition of the Valeritas assets and commercial infrastructure, including the already marketed V-Go[®] wearable insulin delivery device. We are also expanding our commercial operations in the U.S. through the establishment of a new U.S. headquarters in Boston and the appointment of a new President of Zealand Pharma U.S.

We also continue to execute on our clinical development pipeline, remaining on track for the Phase 3 clinical trial readout of dasiglucagon in congenital hyperinsulinism which is expected later this year. Despite previously announced delays in enrollment due to the circumstances created globally by the COVID-19 pandemic, we are enrolling in our Phase 3 trial of glepaglutide in short bowel syndrome, with expected results still slated for 2021. Underscoring our commercial preparations and development efforts is a solid balance sheet, recently strengthened by an additional DKK 657.7 million raised through a direct issue and



private placement as well as a EUR 20.0 million milestone payment from our Boehringer Ingelheim GLP-1/glucagon dual agonist partnership program that was triggered in June.

Business highlights for the first half of 2020

- **Accelerated U.S. commercial operations through acquisition and integration of business assets of Valeritas Holdings, Inc., opening of new Boston office, and appointing new U.S. leadership.** We made strong progress against our objective to establish U.S. commercial operations in order to launch our late stage assets by acquiring substantially all of the business assets of Valeritas Holdings, Inc., including the marketed V-Go® wearable insulin delivery device. We successfully integrated 110 employees, supporting systems, processes and the majority of established contracts in Q2 since we closed with a cash transaction of USD 23.0 million on April 2. In June, Zealand announced the appointment of Frank Sanders as President of Zealand Pharma U.S., and in July announced the opening of a new U.S. headquarters in Boston.
- **Announced FDA acceptance of New Drug Application (NDA) for the dasiglucagon HypoPal® rescue pen for treatment of severe hypoglycemia.** In March, Zealand announced the submission of the NDA to the U.S. Food and Drug Administration (FDA), and in May, the Company announced the FDA's acceptance of the filing. Under the Prescription Drug User Fee Act (PDUFA), the FDA has set a target action date of March 27, 2021.
- **Completed randomization in the first Phase 3 study of dasiglucagon for the treatment of congenital hyperinsulinism (CHI.)** Randomization was completed in the study with 32 children with CHI aged 3 months to 12 years, with results expected late this year. The first neonates have been dosed in the second Phase 3 study with 12 children with CHI from 7 days up to one year of age.
- **Initiated a Phase 2 low-dose dasiglucagon trial for prevention of insulin-induced hypoglycemia in people with type 1 Diabetes in June.** The 20 patient dose finding study supports our efforts to develop a mini-dose pen for the treatment and prevention of mild to moderate hypoglycemia. (ClinicalTrials.gov Identifier: NCT04449692).
- **Presented positive clinical data and health economic outcome data with use of regular human insulin delivered by the V-Go® in adults with type 2 diabetes and presented clinical and non-clinical evidence for dasiglucagon rescue therapy at the 80th Scientific Sessions of the American Diabetes Association.** In June, Zealand presented data showing that in older adults with type 2 diabetes, use of human regular insulin delivered by V-Go® demonstrated similar glycemic control with no increased hypoglycemia risk compared to use of rapid acting insulin analogs. Zealand also presented additional results from two Phase 3 clinical studies with dasiglucagon for the treatment for severe hypoglycemia as well as one preclinical pharmacokinetics/pharmacodynamics (PK/PD) study investigating aqueous versus dimethyl sulfoxide (DMSO) formulations of glucagon and the pharmacodynamics of dasiglucagon in aqueous solution.
- **Announced a two-year research agreement with Intomics A/S.** In June, Zealand entered into a research agreement with Intomics, broadening Zealand's access to 'Big Data', artificial intelligence and machine learning in the discovery and development of next generation peptide therapeutics. From its competences with AI, machine learning, and network biology, Intomics has developed the inBio Discover™ platform, which has been used for accelerating R&D, including identification of novel targets, discovery of biomarkers, patient stratification, and precision medicine.
- **Phase 2 trial initiated in late April with BI 456906, a long-acting GLP-1/glucagon dual agonist, for the treatment of type 2 diabetes and obesity, by partner Boehringer Ingelheim and first patient dosed in June.** Dosing of the first patient in the Phase 2 trial triggered a EUR 20 million milestone payment due to Zealand in Q3 of 2020. Boehringer



Ingelheim has also informed Zealand that they intend to expand development of BI 456906 to also include treatment of non-alcoholic steatohepatitis (NASH).

- **Secured a total of DKK gross 657.7 million through a direct issue and private placement of new shares.** The financing, completed in June, provides Zealand with additional funding to continue supporting the Company's development pipeline and prepare the Company for the potential commercial launch of dasiglucagon in the U.S. in 2021, pending regulatory approval.

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 expects revenue from existing license agreements. However, since such revenue is uncertain in terms of size and timing, Zealand 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 to the operating expense guidance announced on May 14, 2020, which reflected an increase in guidance for 2020 net operating expenses from DKK 790-810 million due to the acquisition of the business activities from Valeritas effective since April 2, 2020. The acquisition increased Zealand Pharma's personnel by 110 employees in the U.S. and added the V-Go program to the Zealand commercial portfolio.

Update regarding COVID-19

Zealand 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 has taken measures to secure its discovery activities, which remain ongoing, while work in laboratories and facilities 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 together at one time. Business travel has been minimized and online and teleconference technology is used to meet virtually rather than in person.















Consistent with our announcement on April 2, 2020, we have continued our clinical trials while working with authorities, investigators, trial sites and CROs to minimize site visits and ensure optimal trial follow-up.

While we have continued our clinical trials, several clinical sites paused enrollment of new patients to accommodate the pressure on hospital systems caused by the COVID-19 outbreak. Several of these sites have re-opened for new patient enrollment and we expect this development to continue over the coming months assuming that the pressure on hospital systems remains reduced and any further COVID-19 outbreaks do not cause lockdowns that affect our clinical trial sites.

Direct engagement with health care providers and patients has been reduced and has been 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 (acquired on April 2, 2020), while ensuring a continued high level of service and support for patients who have already been prescribed the device. We anticipate a reduced ability to meet with V-Go[®] stakeholders will impact V-Go[®] sales.

Pipeline as of June 30, 2020

Dasiglucagon HypoPal [®] Rescue Pen		Severe hypoglycemia		PDUFA Date March 27, 2021 Q4 2020: Phase 3 Readout 2021: Phase 3 Trial Initiation
Dasiglucagon S.C. Continuous Infusion		Congenital hyperinsulinism		
Dasiglucagon Dual-hormone Pump		Diabetes management		
Dasiglucagon Adjustable Mini-Dose		Post bariatric hypoglycemia		
Glepaglutide GLP-2 Analog		Short bowel syndrome		2H 2021: Phase 3 Readout Q4 2020: Phase 1a Results
ZP7570 GLP-1/GLP-2 Dual Agonist		Short bowel syndrome		
BI 456906 GLP-1/GLU Dual Agonist		Obesity/Type 2 diabetes/NASH ¹		
Amylin Analog		Undisclosed		
Complement C3 Inhibitor		Undisclosed ²		
ZP10000 α4β7 Integrin Inhibitor		Inflammatory bowel disease ³		
Ion Channel Blockers		Undisclosed		
GIP/GLP-1/Glucagon Mono/Dual/Triple		Undisclosed		

¹ Partnered with Boehringer Ingelheim. Zealand eligible for EUR 345m in outstanding milestones; ² Partnered with Alexion Pharmaceuticals: Zealand eligible for USD 610m in outstanding milestones. ³ Acquired Cycle Therapeutics, Inc.: future potential earn-outs of up to USD 80m 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'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 by the FDA 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 on boarded 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, the primary and all key secondary endpoints were successfully achieved with a median time to blood glucose recovery of 10 minutes. Results from a pediatric Phase 3 study announced in September 2019 demonstrated that the median time to blood glucose recovery was 10 minutes for dasiglucagon in children.

Dasiglucagon dual-hormone artificial pancreas for automated diabetes management



Zealand is developing a 1 ml cartridge containing 4 mg/ml dasiglucagon, intended for use in dual-hormone 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 bihormonal iLet using dasiglucagon provided superior glycemic control over the insulin-only iLet. During the bihormonal 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 bihormonal and 0.6% in the insulin-only arm.

Beta Bionics has finalized screening of patients into the 440 patient insulin-only bionic pancreas pivotal trial with dosing of the first subjects expected in Q3 (ClinicalTrials.gov Identifier: NCT04200313). Measures to accommodate COVID19 precautions have caused a slight delay in initiation of the Insulin-Only Phase 3 trial which will push initiation of the bi-hormonal bionic pancreas Phase 3 trial with dasiglucagon into 2021.

Dasiglucagon for congenital hyperinsulinism (CHI)

The potential of 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 studies are ongoing with results expected in 2020. The first Phase 3 study is with 32 children with CHI age 3 months to 12 years and enrollment was completed in August. The second Phase 3 study is with 12 children with CHI age 7 days to one year of age.

Dasiglucagon adjustable mini-dose

Post bariatric hypoglycemia Phase 2 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 2 low-dose dasiglucagon trial for prevention of insulin-induced hypoglycemia in people with type 1 diabetes is ongoing.

Gastrointestinal diseases

Glepaglutide

Zealand is developing treatments for gastrointestinal diseases, with current focus on short bowel syndrome (SBS). One of the leading programs in Zealand's pipeline is glepaglutide, a long-acting GLP-2 analog being developed in an auto-injector with potential for convenient weekly administration. The 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. Trial results are expected in H2 2021. Orphan drug designation is granted in the U.S.



ZP7570

ZP7570 is a potential first-in-class and long-acting GLP-1R/GLP-2R dual agonist. ZP7570 is designed to improve management of SBS beyond what is achievable with mono GLP-2 treatments, and may represent a next level of innovation for helping SBS patients to further realize full potential for intestinal rehabilitation. Results from the Phase 1a single-ascending dose, safety and tolerability trial are expected in 2020, and we plan to initiate the Phase 1b multiple-ascending dose, safety and tolerability trial in 2021.

Pre-Clinical Programs

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

Zealand 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 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 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 entered into 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 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 studies.

For the lead target, Zealand 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 eligible for \$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.

Protagonist Therapeutics License Agreement

In 2012, we entered into a research collaboration agreement with Protagonist Therapeutics, Inc., or Protagonist Therapeutics, and one of its affiliates, which agreement was terminated in 2014. At that time, Protagonist Therapeutics elected to assume the responsibility for the development and commercialization of compounds previously developed, and we assigned to Protagonist Therapeutics certain intellectual property arising from the collaboration. We also granted Protagonist Therapeutics an exclusive license to certain background intellectual property rights of Zealand that relate to the products they assumed.

Under the terms of the terminated agreement and related agreements, we are entitled to receive payments in respect of certain development, regulatory and commercial milestone events, as well as a low single-digit royalty on worldwide net sales of products developed under the agreement, if further developed and commercialized by Protagonist Therapeutics. Through June 30, 2020, we had received USD 1 million of such milestone payments and we may be entitled to receive up to USD 128 million of additional milestone payments under the agreement if certain development, regulatory and commercial milestone events occur.

On 23 January 2020 Protagonist Therapeutics filed a demand for arbitration with the International Court of Arbitration of the International Chamber of Commerce (ICC) seeking a declaration that it has no past, present or future milestone or royalty payment obligations with respect to the compound it is advancing, PTG-300, alleging that the compound is not within the set of compounds



to which such payment obligations apply. Protagonist Therapeutics is also seeking costs, fees, and expenses of the proceeding, including attorneys' fees, repayment of the USD 1 million of payments previously paid and pre-judgment interest. We are defending against this demand on the basis that payments are required for PTG-300 under our agreements and, as to the demand for repayment that the payments made were voluntary and are non-reimbursable. We have also filed counterclaims demanding payment of an additional milestone now due in the amount of USD 1 million, USD 2 million or USD 3 million, depending on the number of patients to be enrolled in the Phase III clinical trials for PTG-300, and seeking a declaration confirming our right to the payments due under our agreements, as well as the costs, fees and expenses of the proceeding, including attorneys' fees, and pre-judgment interest. The arbitration remains pending as of the date of this report.

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

Zealand's management will host a conference call today at 4:00 pm CEST to present results through the first half 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 **1775754**

A live audio webcast of the call, including an accompanying slide presentation, will be accessible from the Investor section of Zealand'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's website following the call.

Upcoming events

Zealand Pharma plans to publish results for the third quarter 2020 on November 12, 2020.

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About Zealand Pharma A/S

Zealand Pharma A/S (Nasdaq: ZEAL) a biopharmaceutical company, is developing next generation peptide-based medicines to change the lives of people living with metabolic and gastrointestinal diseases. The Company has one FDA-approved product, V-



Go®, an all-in-one basal-bolus insulin delivery option for people with diabetes and is using its peptide platform to develop a diverse pipeline of drug candidates. Its lead candidate in the metabolic franchise, the dasiglucagon HypoPal Rescue Pen, is under review by the U.S. FDA, with potential commercialization in 2021 pending regulatory approval. Dasiglucagon is also in development for three additional metabolic indications, with one late stage program for congenital hyperinsulinism. Zealand also has a late stage product in its gastrointestinal franchise, glepaglutide, which is being evaluated in a Phase 3 study for patients with short bowel syndrome. Zealand is headquartered in Copenhagen, Denmark, with offices in the U.S. including locations in New York, Boston, and Marlborough (MA).

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 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'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. 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 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, promotion of unapproved uses is strictly prohibited.

NOTE: DKK/USD Exchange rates used: June 30, 2020 = 6.6553 and June 30, 2019 = 6.5585

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Key figures *

DKK thousand

INCOME STATEMENT AND COMPREHENSIVE INCOME	Note	Reviewed				Audited
		Q2 2020	Q2 2019	H1 2020	H1 2019	FY 2019
Revenue		221,016	19,918	233,432	19,918	41,333
Gross margin		192,990	19,734	205,406	19,734	40,918
Research and development expenses		-127,006	-135,423	-291,658	-256,910	-561,423
Sales and Marketing expenses		-74,853	0	-74,853	0	0
Administrative expenses		-45,592	-20,736	-70,665	-35,191	-67,881
Net operating expenses		-247,451	-156,206	-437,176	-292,101	-628,860
Operating result		-53,710	-136,288	-230,912	-272,072	-576,942
Net financial items		-5,846	-2,171	-9,003	4,794	11,265
Result before tax		-59,556	-138,459	-239,915	-267,278	-576,677
Income tax	(1)	1,375	1,333	2,306	2,641	5,136
Net result for the period		-58,181	-137,126	-237,609	-264,637	-571,541
Comprehensive result for the period		-58,481	-137,126	-237,937	-264,637	-571,541
Earnings/loss per share – basic/diluted (DKK)		-1.57	-4.33	-6.49	-8.47	-16.91
				June 30, 2020	June 30, 2019	December 31, 2019
STATEMENT OF FINANCIAL POSITION						
Cash and cash equivalents				1,350,986	840,802	1,081,060
Marketable securities				293,982	301,292	299,448
Cash, cash equivalents and Marketable securities				1,644,968	1,142,094	1,380,508
Other assets				626,806	87,305	219,006
Total assets				2,271,774	1,229,399	1,599,514
Share capital ('000 shares)				39,734	31,815	36,055
Equity				1,799,922	966,778	1,242,673
Total liabilities				471,852	262,621	356,841
Equity ratio	(2)			0.79	0.79	0.78
				H1 2020	H1 2019	FY 2019
CASH FLOW						
Cash outflow/inflow from operating activities				-313,518	-90,687	-409,455
Cash outflow/inflow from investing activities				-186,428	-29,852	-51,666
Cash outflow/inflow from financing activities				770,249	102,517	674,480
Purchase of property, plant and equipment				-14,392	-419	-21,036
Free cash flow	(3)			-327,910	-91,127	-430,491
				June 30, 2020	June 30, 2019	December 31, 2019
OTHER						
Share price (DKK)				227.40	142.70	235.40
Market capitalization (MDKK)	(4)			8,449	4,540	8,487
Equity per share (DKK)	(5)			48.44	30.45	34.52
Average number of employees				320	163	173
Number of full time employees at the end of the period				313	172	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 2.8 million has been recognized for the period ended June 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 reviewed condensed consolidated interim financial statements of the Company have been prepared in accordance with IAS 34, Interim Financial Reporting, as issued by the International Accounting Standards Board, or the IASB. The reviewed condensed consolidated interim 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 and gross margin

Revenue for the six months ended June 30, 2020 was DKK 233.4 million of which DKK 149.1 million was a result of the milestone payment triggered in June from our partnership agreement with Boehringer Ingelheim. Revenue from our partnership with Alexion during the period was DKK 26.2 million versus DKK 18.3 million for the same period in 2019. Revenue from sales of the V-Go wearable insulin device was DKK 58.1 million. Cost of goods sold for the period beginning April 2 and ending June 30, 2020 was DKK 28.0 million relating to V-Go sales.

Research and development expenses

Research and development expenses for the six months ended June 30, 2020 amounted to DKK 291.7 million, an increase of 14% versus the same period in 2019, in which research and development expenses were DKK 256.9 million. The costs mainly relate to the regulatory efforts to support the NDA filing for the dasiglucagon HypoPal rescue pen, clinical development of dasiglucagon and glerpaglutide programs, as well as pre-clinical research activities.

Sales and marketing expenses

Sales and marketing expenses consist of expenses for selling, product demonstration samples, trade shows, and similar items. Sales and marketing expenses for the six months ended June 30, 2020 amounted to DKK 74.9 million versus DKK 0.0 million in 2019. The increase originates from Zealand's commercial activities that commenced in connection with the acquisition of the Valeritas business and appointment of a new commercial U.S. leadership.

Administrative expenses

Administrative expenses consist of administrative personnel, company premises, investor relations and similar items. Administrative expenses for the six months ended June 30, 2020 amounted to DKK 70.7 million, an increase of 101% versus the six months ended June 30, 2019, which amounted to DKK 35.2 million. The increase is due to higher consultancy and legal costs of which DKK 7.1 million relates to the acquisition of the Valeritas business, but also expenses for integration of acquired activities, new company headquarter and increased compensation expenses.

Operating result

Operating result reflects gross margin, research and development expenses, sales and marketing and administrative expenses, as discussed above. The operating result for the six months ended June 30, 2020 was DKK -230.9 million compared to DKK -272.1 million for the same period in 2019.

Financial income and financial expenses

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. Net financial items for the six months ended June 30, 2020 amounted to DKK -9.0 million (expense) as compared to DKK 4.8 million (income) for the same period in 2019. The decrease is primarily driven by the unfavorable impact from fair value adjustment by DKK 6.3 million, increase in interest expense and banking fees by DKK 2.7 million and by unfavorable changes in currencies by DKK 5.5 million.

Result before tax

Result before tax reflects operating result and net financial items, as discussed above. Result before tax for the six months ended June 30, 2020 was DKK -239.9 million, compared to DKK -267.3 million for the same period in 2019.

Income tax

During the six months ended June 30, 2020, we recognized DKK 2.3 million in net income tax benefit. The net income tax benefit is mainly impacted by DKK 2.8 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).

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

Net result for the period consists of result before tax and income tax, and comprehensive result for the period consists of net result for the period and other comprehensive income. Net result and comprehensive result for the six months ended June 30,

2020 amounted to DKK -237.6 million compared to DKK -264.6 million for the same period in 2019. The increase is primarily a result of the Boehringer Ingelheim milestone payment of DKK 149.1 million offset by an increase in Research and development and sales and marketing expenses.

Liquidity and capital resources

Equity

Equity as of June 30, 2020 was DKK 1,799.9 million corresponding to an equity ratio of 79%. The equity as of December 31, 2019 was DKK 1,242.7 million corresponding to an equity ratio of 78%. 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 32.6 million offset by the loss for the period and costs incurred in connection with the capital increases.

Marketable securities, cash and cash equivalents

As of June 30, 2020, marketable securities, cash and cash equivalents amounted to DKK 1,644.9 million as compared to DKK 1,380.5 million as of December 31, 2019. The increase in cash and cash equivalents is a consequence of capital increase from private placements and warrants exercised during the period offset by the cash used for operations and the Valeritas acquisition.

Cash flow

Cash used in operating activities for the six months ended June 30, 2020 was DKK -313.5 million, as compared to cash outflow generated by operations of DKK -90.7 million for the same period in 2019. The increase 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 six months ended June 30, 2019 was positively impacted by the upfront payment from the Alexion license agreement received in Q1 2019.

Cash used in investing activities for the six months ended June 30, 2020 amounted to DKK -186.4 million, as compared to DKK -29.9 million for the same period in 2019. Cash used in investing activities in H1 2020 related mainly to the acquisition of Valeritas of DKK 167.7 million. Cash flow from investing activities for the six months ended June 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 flow from financing activities for the six months ended June 30, 2020 was DKK 770.2 million, compared to cash from financing activities of DKK 102.5 million for the same period in 2019. Cash from financing activities increased primarily as a result of the private placements in aggregate amount of DKK 794.9 million. Cash from financing activities for the six months ended June 30, 2019 was mainly related to a capital increase as part of the agreement with Alexion.

The total cash flow for the six months ended June 30, 2020 was DKK 270.3 million compared to DKK -18.0 million for the same period in 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 six month periods ended June 30, 2020.

The report has been prepared in accordance with IAS 34 as issued by the International Accounting Standards Board (IASB) and as adopted by the EU and the additional Danish disclosure requirements for listed companies.

In our opinion, the interim report gives a true and fair view of the Group's assets, equity and liabilities and financial position at June 30, 2020 as well as of the results of the Group's operations and cash flow for the period January 1 – June 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 period and the financial position while also describing the most significant risks and uncertainty factors that may affect the Group.

Copenhagen, August 13, 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

Alain Munoz
Board member

Michael John Owen
Board member

Gertrud Koefoed Rasmussen
Board member
Employee elected

Iben Louise Gjelstrup
Board member
Employee elected

Jens Peter Stenvang
Board member
Employee elected

Nikolaj Frederik Beck
Board member
Employee elected

Independent auditor's report

To the shareholders of Zealand Pharma A/S

We have reviewed the condensed consolidated interim financial statements of Zealand Pharma A/S for the three and six month periods ended June 30, 2020, which comprise a condensed consolidated income statement, balance sheet, statement of changes in equity, cash flow statement and notes. 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.

Management's responsibility for the condensed consolidated interim financial statements

Management is responsible for the preparation of condensed interim 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 condensed consolidated interim 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 condensed consolidated interim 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 condensed consolidated interim 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 condensed consolidated interim 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 than those performed in an audit conducted in accordance with the International Standards on Auditing. Accordingly, we do not express an audit opinion on the condensed consolidated interim financial statements.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that these condensed consolidated interim 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, August 13, 2020

EY

Godkendt Revisionspartnerselskab
CVR no. 30 70 02 28

Christian Schwenn Johansen
State Authorized Public Accountant
mne33234

Rasmus Bloch Jespersen
State Authorized Public Accountant
mne35503

Condensed reviewed consolidated interim financial statements

Condensed reviewed consolidated statement of profit and loss for the three and six months periods ended June 30, 2020 and 2019.

DKK thousand	Note	Reviewed			
		Q2 2020	Q2 2019	H1 2020	H1 2019
Revenue	2	221,016	19,918	233,432	19,918
Cost of goods sold		-28,026	0	-28,026	0
Royalty expenses		0	-184	0	-184
Gross margin		192,990	19,734	205,406	19,734
Research and development expenses		-127,006	-135,423	-291,658	-256,910
Sales and marketing expenses		-74,853	0	-74,853	0
Administrative expenses		-45,592	-20,736	-70,665	-35,191
Other operating income		751	137	858	295
Operating result		-53,710	-136,288	-230,912	-272,072
Financial income		2,180	2,763	904	10,296
Financial expenses	3	-8,026	-4,934	-9,907	-5,502
Result before tax		-59,556	-138,459	-239,915	-267,278
Income tax		1,375	1,333	2,306	2,641
Net result for the period		-58,181	-137,126	-237,609	-264,637
Earnings/loss per share – basic/diluted (DKK)	4	-1.57	-4.33	-6.49	-8.47

Condensed reviewed consolidated statements of other comprehensive income (loss) for the three and six months periods ended June 30, 2020 and 2019.

DKK thousand	Note	Reviewed			
		Q2 2020	Q2 2019	H1 2020	H1 2019
Net result for the period		-58,181	-137,126	-237,609	-264,637
Adjustment of foreign currency fluctuations on subsidiaries		-300	0	-328	0
Comprehensive result for the period		-58,481	-137,126	-237,937	-264,637

Condensed reviewed consolidated statements of cash flow for the six months periods ended June 30, 2020 and 2019 and audited December 31, 2019

DKK thousand	Note	Reviewed		Audited
		H1 2020	H1 2019	FY 2019
Operating result		-230,912	-272,072	-587,942
Depreciation and amortization		6,167	6,176	13,682
Adjustments for other non-cash items		26,513	12,515	12,019
Change in working capital		-86,552	1,139	10,873
Financial income received		897	3,372	5,413
Financial expenses paid		-3,406	-870	-3,390
Deferred revenue	2	-26,225	159,053	139,890
Income tax paid/received		0	0	93
Cash flow from operating activities		-313,518	-90,687	-409,455
Acquisition of Valeritas business, net of cash acquired	19	-167,725	0	0
Royalty expenses regarding sale of future royalty and milestones		0	-6,575	0
Change in deposits		-4,311	-59	-6,250
Purchase of other investments	8	0	-22,804	-22,804
Purchase of property, plant and equipment	6	-14,392	-439	-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		-186,428	-29,852	-51,666
Proceeds from issuance of shares related to exercise of warrants	14	32,561	20,959	52,468
Proceeds from issuance of shares	14	794,929	85,585	645,145
Costs related to issuance of shares		-41,960	0	-14,444
Lease installments	7	-15,281	-4,027	-8,689
Cash flow from financing activities		770,249	102,517	674,480
Decrease/increase in cash and cash equivalents		270,303	-18,022	213,359
Cash and cash equivalents at beginning of period		1,081,059	860,635	860,635
Exchange rate adjustments		-376	-1,811	7,066
Cash and cash equivalents at end of period		1,350,986	840,802	1,081,059

Condensed reviewed consolidated statements of financial position as of June 30, 2020 and audited December 31, 2019

DKK thousand	Note	Reviewed	Audited
		June 30, 2020	December 31, 2019
ASSETS			
Non-current assets			
Intangible assets	5	40,641	2,480
Property, plant and equipment	6	94,960	39,708
Right-of-use assets	7	135,949	85,632
Deposits		16,989	9,012
Corporate tax receivable		2,750	0
Deferred tax assets		765	0
Other investments	8	34,581	35,632
Total non-current assets		326,635	172,464
Current assets			
Inventories	9	69,727	0
Trade receivables	10	180,422	751
Prepaid expenses	11	34,661	30,755
Corporate tax receivable		6,725	7,101
Other receivables	12	8,636	7,935
Marketable securities	8	293,982	299,448
Cash and cash equivalents	13	1,350,986	1,081,060
Total current assets		1,945,139	1,427,050
Total assets		2,271,774	1,599,514
EQUITY AND LIABILITIES			
Share capital	14	39,734	36,055
Share premium		3,441,647	2,650,142
Translation reserve		-328	0
Accumulated loss		-1,681,131	-1,443,524
Equity		1,799,922	1,242,673
Deferred revenue		61,308	83,639
Lease liabilities	7	122,596	78,068
Non-current liabilities		183,904	161,707
Trade payables	15	67,592	57,533
Corporate tax payables		0	614
Lease liabilities	7	14,289	7,692
Deferred revenue		52,450	56,251
Discount and rebate liabilities		25,255	0
Other liabilities	16	128,362	73,044
Current liabilities		287,948	195,134
Total liabilities		471,852	356,841
Total equity and liabilities		2,271,774	1,599,514

Condensed reviewed consolidated statements of changes in equity as of June 30, 2020 and June 30, 2019

DKK thousand	Reviewed				
	Share capital	Share premium	Translation reserve	Retained 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	30,787	1,957,478	0	-871,984	1,116,281
<i>Other comprehensive income for the period</i>	0	0	0	0	0
Net loss for the period	0	0	0	-264,637	-264,637
Share-based compensation expenses	0	8,590	0	0	8,590
Capital increase	1,028	105,516	0	0	106,544
Costs related to capital increases	0	0	0	0	0
Equity at June 30, 2019	31,815	2,071,584	0	-1,136,621	966,778
Equity at January 1, 2020	36,055	2,650,142	0	-1,443,524	1,242,673
<i>Other comprehensive income for the period</i>	0	0	-328	0	-328
Net loss for the period	0	0	0	-237,609	-237,609
Share-based compensation expenses	0	10,320	0	0	10,320
Capital increase, see note 16	3,679	823,811	0	0	827,490
Costs related to capital increases	0	-42,625	0	0	-42,625
Equity at June 30, 2020	39,734	3,441,647	-328	-1,681,131	1,799,922

1. 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 reviewed condensed consolidated interim 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 additional Danish requirements for submission of interim reports for companies listed on Nasdaq Copenhagen. The reviewed condensed consolidated interim financial statements are presented in Danish kroner (DKK) which is also the functional currency of the parent company.

The accounting policies used in the reviewed condensed consolidated interim 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 19, 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 reviewed condensed consolidated interim 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, significant accounting estimates and judgements relating to the preliminary purchase price allocation have been made following the acquisition of the Valeritas business, which is described in general terms in the section on Business combinations under newly applied accounting policies and specifically for the Valeritas acquisition in note 19.

Newly applied accounting policies

The following accounting policies have been applied for the first time in the condensed consolidated interim reporting for the period ended June 30, 2020 because of the acquisition of the Valeritas business as disclosed in note 19.

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 and 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 other intangible assets acquired through business combinations are measured at fair value at the acquisition date and amortized on a systematic basis over their useful life (unless the asset has an indefinite useful life, in which case it is not amortized).

Note 2 - Revenue

Recognized revenue can be specified as follows for all agreements:

DKK thousand	Q2 2020	Q2 2019	H1 2020	H1 2019
Alexion Pharmaceuticals Inc.	13,809	18,261	26,225	18,261
Boehringer Ingelheim International GmbH	149,120	0	149,120	0
Undisclosed counterpart	0	1,657	0	1,657
Total license and milestone revenue	162,929	19,918	175,345	19,918
V-Go (former Valeritas product)	58,087	0	58,087	0
Total sale of goods revenue net	58,087	0	58,087	0
Total revenue	221,016	19,918	233,432	19,918
Total revenue recognized over time	13,809	19,918	26,225	19,918
Total revenue recognized at a point in time	207,207	0	207,207	0

License revenue for the first six months of 2020 of DKK 26.2 million relate to the research and development agreement with Alexion Pharmaceuticals entered into in March 2019. Under the agreement DKK 113.8 million is accounted for as deferred revenue at June 30, 2020.

Milestone revenue for the first six 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 June 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 for first six months of 2020 of DKK 58.1 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 19. The net sales comprises of gross sales of DKK 104.2 million and discounts and rebates of DKK -46.1 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 28.0 million) and sales and marketing expenses (DKK 74.9 million).

Net revenue in Germany comprise DKK 149.1 million in license revenue whereas net sales in US comprise DKK 71.9 million including license revenues and sale of goods. No other countries accounts for more than 10% of the net total sales.

Note 3 - Financial expenses

Recognized financial expenses can be specified as follows:

DKK thousand	Q2 2020	Q2 2019	H1 2020	H1 2019
Interest expenses and banking fees	-1,962	-302	-3,574	-870
Fair value adjustment	0	0	-6,333	0
Currency exchange adjustments	-6,064	-4,632	0	-4,632
Financial expenses	-8,026	-4,934	-9,907	-5,502

Note 4 - 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	Q2 2020	Q2 2019	H1 2020	H1 2019
Net earnings/loss for the period	-58,181	-137,126	-237,609	-264,637
Net earnings/loss used in the calculation of basic earnings/loss per share	-58,181	-137,126	-237,609	-264,637
Weighted average number of ordinary shares	37,221,031	31,712,834	36,671,353	31,312,379
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 share	37,156,808	31,648,611	36,607,130	31,248,156
Earnings/loss per share – basic/diluted (DKK)	-1.57	-4.33	-6.49	-8.47

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:

	June 30, 2020	June 30, 2019
Outstanding warrants under the 2010 Employee incentive program	0	146,359
Outstanding warrants under the 2015 Employee incentive program	2,021,621	1,986,510
Outstanding Performance Share Units (PSUs) under the LTIP 2019 program	19,765	0
Outstanding Restricted Share Units (RSUs) under the LTIP 2020 program	21,602	0
Total outstanding warrants	2,062,988	2,132,869

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

Note 5 – Intangible assets

Intangible assets of DKK 40.6 million recognized as at June 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 38.7 million) described in note 19 on business combinations.

Note 6 – Property, plant and equipment

DKK thousand	June 30, 2020	December 31, 2019
Plant and machinery	46,910	13,457
Other fixtures and fittings	9,935	8,337
Building improvements	34,190	3,913
Assets under construction	3,925	14,001
Carrying amount	94,960	39,708

The increase from DKK 39.7 million as at December 31, 2019 to DKK 95.0 million as at June 30, 2020 is primarily related to tooling, machinery and equipment for the production lines to procedures V-Go and leasehold improvements purchased as part of the Valeritas acquisition (DKK 41.1 million) described in note 19 on business combinations and new leasehold improvements in Søborg (DKK 29.2 million).

Note 7 - Right of use assets and lease liabilities

Right-of-use-assets of DKK 135.9 million and lease liability of DKK 136.9 million were recognized as at June 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 19 on business combinations.

Note 8 - Financial instruments

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

DKK thousand	June 30, 2020	December 31, 2019
Marketable securities	293,982	299,448
Other investments	34,581	35,632
Financial assets measured at fair value	328,563	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 June 30, 2020 obtained information about capital contributions made during the three months period ended June 30, 2020 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 June 30, 2020.

A net fair value adjustment of DKK -6.5 million from marketable securities have been recognized in financial income and expenses, respectively, for H1 2020 (H1 2019: DKK 3.0 million in total).

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

Note 9 - Inventories

DKK thousand	June 30, 2020	December 31, 2019
Raw materials	8,385	0
Work in progress	38,726	0
Finished goods	22,616	0
Inventories	69,727	0

Inventories is related to the V-Go product. The increase is due to the acquisition of the Valeritas business described in note 19 on business combinations.

Note 10 – Trade receivables

The increase in Trade receivables from DKK 0.8 million at December 31, 2019 to DKK 180.4 million at June 30, 2020 is mainly related to the Boehringer Ingelheim milestone payment of DKK 149.1 million in June 2020 and the receivables from V-Go sales.

Note 11 – Prepaid expenses

The increase in Prepaid expenses from DKK 30.8 million at December 31, 2019 to DKK 34.7 million at June 30, 2020 is mainly relating to periodical movements.

Note 12 - Other receivables

DKK thousand	June 30, 2020	December 31, 2019
VAT	7,558	5,437
Other	1,078	2,498
Total other receivables	8,636	7,935

Other receivables is mainly related to VAT receivables in Denmark.

Note 13 - Cash and cash equivalents

DKK thousand	June 30, 2020	December 31, 2019
DKK	1,221,830	732,405
USD	98,019	306,748
EUR	31,137	41,907
Total cash and cash equivalents	1,350,986	1,081,060

Note 14 - 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
Share capital at June 30, 2019	31,814,790
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
Share capital at June 30, 2020	39,734,151

Note 15 – Trade payables

The increase in Trade payables from DKK 57.5 million at December 31, 2019 to DKK 67.6 million at June 30, 2020 is mainly related to increased V-Go operating expenses as a consequence of the acquisition of the Valeritas business described in note 19 on business combinations.

Note 16 - Other liabilities

DKK thousand	June 30, 2020	December 31, 2019
Severance payment	0	170
Employee benefits	59,828	36,082
Royalty payable to third party	6,576	6,843
Return liabilities	2,178	0
Other payables	59,780	29,949
Total other liabilities	128,362	73,044

The increase in Other liabilities is related to increase in employee related accruals in the US due to the acquisition of the Valeritas business (DKK 19.4 million) described in note 19 on business combinations, increased vacation accruals in Denmark due to new revised Holiday Act (DKK 8.1 million), Return and other V-Go related accruals (DKK 2.2 million) and deferral employee tax payments in Denmark (DKK 14.0 million) as part of to Government coronavirus financial support.

Note 17 - Contingent assets, liabilities and contractual obligations

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.

At June 30, 2020, total contractual obligations related to agreements with CROs amounted to DKK 291.8 million (DKK 139.2 million for 2020 and DKK 152.6 million for the years 2021-23).

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.

Note 18 - Long-term incentive and warrant programs

On April 15, 2020, Zealand granted 631,288 new warrants to Executive Management, Corporate Management and employees in Denmark and the United States.

The 631,288 warrants give the right to subscribe for up to 631,288 new Zealand shares with a nominal value of DKK 1 each, corresponding to 1.6% of Zealand's total outstanding share capital. The exercise price is DKK 224.40, based on the closing price of Zealand's shares on Nasdaq Copenhagen on April 14, 2020.

268,156 warrants granted to U.S. management and employees will vest annually over a three-year period, and the exercise of the warrants may take place, in full or in part, in defined time windows from April 15, 2021 up to and including April 14, 2030. 363,132 warrants granted to Danish management and employees will vest at the three-year anniversary of the grant date, and the exercise of the warrants may take place, in whole or in part after the three-year period, in defined time windows from April 15, 2023 up to and including April 14, 2030.

The exercise time windows for all granted warrants are defined as four times a year during a four-week window following the time of publication of either the 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 59,688,553 million calculated on the basis of the Black-Scholes model. The cost of each warrant is DKK 93.40 based on Black-Scholes parameters for U.S. grants based with a four-year historic volatility of 45.5%, an average risk-free interest rate of -0.337%, and a share price of DKK 224.40. The grants to Danish employees have a 10-year lifetime and vest over three years. The cost of the warrants issued to Danish employees is DKK 95.40. The Black-Scholes parameters used are a four-year historic volatility of 44.7%, a risk-free interest rate of -0.31% and a share price of DKK 224.40. Total cost for this warrant program will be recognized over the vesting period starting at April 15, 2020, i.e. in the period ending June 30, 2020.

April 15, 2020 implementation of an updated long-term incentive program (LTIP) for Zealand's Executive and Corporate Management was announced.

The updated LTIP is to align with selected European and U.S. biotech peers, and is intended to drive long-term performance, align management's interests with those of Zealand's shareholders, and to support the attraction, retention and motivation of first-rate executive talent.

Under the LTIP, the Executive Management and Corporate Management are eligible to receive annual grant of restricted share units (RSUs) free of charge instead of PSUs. The grant cannot exceed 25% of the annual base salary at grant for Executive Management.

The 2020 RSU grants have a three-year vesting period from April 15, 2020 to April 14, 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.

The first grant of RSUs under the LTIP will have an estimated aggregate theoretical value of DKK 4.0 million, while each RSU has a value of DKK 185.90. 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 following the publication of Zealand's annual report for the preceding financial year.

Note 19 - 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 public 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 consideration transferred was DKK 167.7 million (USD 23.0 million in acquisition costs and USD 1.5 million in cure costs). As at the time of the interim reporting for the three and six months periods ended June 30, 2020, the purchase price allocation has not been completed in full and key areas are still remaining to be addressed, including identification and valuation of intellectual property rights related to the V-Go product, other intangibles, including physician relationships etc. For the interim reporting for the three and six months periods ended June 30, 2020, It has not been practically possible for the company to complete the entire purchase price allocation due to the timing and complexity of the transaction. Below is disclosure of 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	
Unallocated intangible assets	38,677
Property, plant and equipment	41,138
Right-of-use assets	14,229
Inventories	54,573
Trade receivables	50,603
Other assets	10,132
Cash and cash equivalents	66
Liabilities	
Trade payables	-7,855
Lease liabilities	-14,046
Other liabilities	-19,792
Total identifiable net assets at fair value	167,725
Purchase consideration transferred	167,725
<i>Analysis of cash flows on acquisition:</i>	
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 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 six-months periods ended June 30, 2020 since the acquisition date.

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.

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 three and the six months periods ended June 30, 2020 that have all been incurred in the three months periods ended March 31, 2020.

As the purchase price allocation is not completed yet, adjustments may be applied to the various net asset categories as a result of final fair value measurement, in addition to adjustments related to V-Go product acquired and physician relationships. 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 58.1 million and profit and loss of approximately DKK -49.8 million to the Group for the interim period ending June 30, 2020 since the acquisition on April 2, 2020.

The revenue and profit or loss of the combined entities (the acquired asset were transferred to several Zealand entities) for the current reporting period as though the acquisition date had been as of the beginning of the annual reporting period is impracticable to disclose as the 2019 Financial Statements for Valeritas have not been audited.

Note 20 - Significant events after the reporting period

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