Zealand Pharma receives first FDA approval and prepares for launch of Zegalogue® (dasiglucagon) injection

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Share

Company announcement – No. 29/ 2021

Interim report for Q1 2021

Zealand Pharma receives first FDA approval and prepares for launch of Zegalogue® (dasiglucagon) injection

Financial results for the first quarter of 2021

- **Revenue: DKK 47.8 million / USD 7.5 million** (DKK 12.4 million / USD 1.8 million in the first three months of 2020).
- **Net operating expenses: DKK -284.8 million / USD -44.9 million** (DKK -189.7 million / USD -27.8 million in the first three months of 2020).
- **Net operating result: DKK -260.9 million / USD -41.1 million** (DKK -177.2 million / USD -26.0 million in the first three months of 2020).
- **Cash, cash equivalents, and marketable securities: DKK 1,604.1 million / USD 252.9 million** as of March 31, 2021 (March 31, 2020: DKK 1,290.6 million / USD 189.4 million).

Business highlights for the first quarter of 2021 and subsequent events

- **Received approval from U.S. Food and Drug Administration (FDA) for Zegalogue® (dasiglucagon) injection, for the treatment of severe hypoglycemia in people with diabetes.** Zegalogue has been approved in pediatric and adult patients with diabetes aged 6 years and above. The approval was based on efficacy results from three randomized, double-blind, placebo-controlled multicenter Phase 3 studies of Zegalogue in children aged

Profil de l'entreprise

Zealand Pharma
Industrie: Pharmaceuticals
Site Internet: https://zealandpharma.com

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placebo. In the main Phase 3 adult trial 99% of patients recovered within 15 minutes. In these Phase 3 trial results the most common adverse events reported (≥2%) were nausea, vomiting, headache, diarrhea and injection site pain in adults; and nausea, vomiting, headache and injection site pain in pediatric patients. The approval was received from the FDA four days ahead of the scheduled PDUFA date. Zealand is planning to launch Zegalogue in the U.S. in late June.

- **Zealand Pharma announced the initiation by partner Boehringer Ingelheim of two Phase 2 trials for BI 456906.** In April 2021, Zealand announced the initiation of two Phase 2 trials for the GLP-1/glucagon dual agonist for adults who are overweight or obese and for adults with non-alcoholic steatohepatitis (NASH). The compound is already being investigated in an ongoing Phase 2 study in people with type 2 diabetes mellitus. The new study is to investigate if there are additional benefits on both chronic weight management, and NASH to prevent progression to cirrhosis compared to currently available.
- **Five X Twenty-five ("5x25").** In March the company presented its five-year R&D strategy to roadmap the corporate goal of five commercialized products by 2025 ("5x25") augmenting our industry leading peptide platform with phage display, computerized molecular design and oral peptide technologies. In addition, the company demonstrated continued progression on Zealand's fully owned peptide pipeline with expansions into IBD and Obesity.
- **Announced the promotion of Christina Sonnenborg Bredal to Head of People & Organization.** Christina joined Zealand in 2020 and will now lead the Denmark and US People & Organization functions, as well as Internal Communications. The newly created position will optimize Zealand's people and organizational strategy globally and locally, accelerate its focus on developing talent, and optimize processes and communications as the company continues to grow. Christina will report to CEO Emmanuel Dulac and be a member of the company's Corporate Management Team.
- **Secured a total of DKK gross 749.0 million through a direct issue and private placement of new shares.** The financing, completed in January, provides Zealand with additional funding to continue supporting the Company's development pipeline and prepare the Company for the commercial launch of Zegalogue in the U.S. in late June of 2021.

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

"The recent FDA approval of Zegalogue was a landmark achievement for Zealand. It marks our evolution from a research and development focused organization to a fully

Zegalogue, the clinical and regulatory teams who advanced its development and ensured its full approval from the FDA, and the members of our growing commercial organization who are working to bring this treatment to the patients who need it most. The commercial launch of Zegalogue in late June, along with our noteworthy pipeline momentum, will position us well as we continue to work toward our vision of offering five commercialized products by 2025."

Financial guidance for 2021

There is no change from the financial guidance issued on March 11, 2021.

Net product revenue from the sales of commercial products is expected to be DKK 220 million +/- 10%.

In 2021, 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 2021 are expected to be DKK 1,250 million +/-10%.

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

of people gathered at one time. Business travel has been minimized and online and video conference 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. In late April, Zealand Pharma in Denmark commenced a gradual return to office program, which currently allows up to 60% occupancy, consistent with local health authority guidelines and practice including frequent testing, sanitizing, and other protective measures.

COVID-19 restrictions have not affected our phase 3-program for dasiglucagon in congenital hyperinsulinism (CHI) and we expect topline data from the second Phase 3 trial in 2021. Commercial activities ahead of the Zegalogue launch are continuing as planned and we currently do not anticipate changes to the timelines for the bi-hormonal artificial pancreas pump Phase 3 program. The pandemic impacted the speed of patient recruitment for our Phase 3 trial with glepaglutide for treatment of short bowel syndrome, and results are expected in 2022.

Our research and in particular our 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. In addition to preparing for the launch of Zegalogue in late June, our commercial team is also 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.

Metabolic diseases

indications:

Zegalogue® (dasiglucagon) for severe hypoglycemia

Zegalogue (dasiglucagon) injection was approved by the U.S. FDA on March 22, 2021 for the treatment of severe hypoglycemia in people with diabetes. Zegalogue will be available in both an auto injector and a prefilled syringe for patients with diabetes age 6 or older. The approval was based on results from three pivotal trials in adults and children with diabetes, showing a media time to blood glucose recovery from severe hypoglycemia of 10 minutes following injection of 0.6 mg/0.6 mL of Zegalogue. In these Phase 3 trial results the most common adverse events reported (≥2%) were nausea, vomiting, headache, diarrhea, and injection site pain in adults; and nausea, vomiting, headache and injection site pain in pediatric patients.

Zegalogue is expected to launch in the U.S. in late June 2021.

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

We plan to initiate the pivotal Phase 3 trial in the second half of 2021. Approximately 350 adults and 350 children with type 1 diabetes will be randomized into the trials. The primary outcome measure is superiority on HbA1c of the bihormonal iLet configuration using dasiglucagon over the insulin only iLet configuration at week 26. Overall, the program has been designed to demonstrate the clinical outcome of utilizing dasiglucagon in the bihormonal iLet versus an insulin-only iLet, while also comparing these results to intensified usual care.

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 FDA and the European Commission both granted orphan drug designation to dasiglucagon for the treatment of CHI.

We announced data from the first Phase 3 trial in the program, trial 17109, in December 2020. This trial evaluated children from 3 months to 12 years old with more than three hypoglycemic events per week despite previous near-total pancreatectomy and/or maximum medical therapy. Dasiglucagon on top of standard of care (SOC) did not significantly reduce the rate of hypoglycemia compared to SOC alone when assessed by the primary endpoint, intermittent self-measured plasma glucose. However, hypoglycemia was reduced by 40–50% with dasiglucagon as compared to SOC alone when assessed by blinded continuous glucose monitoring. Dasiglucagon treatment was assessed to be well tolerated in the study and 31 out of 32 patients continued into the long-term extension study.

to 12 months old with CHI. Results from the 17109 trial are expected in 2021.

Dasiglucagon adjustable mini-dose

We are developing a dasiglucagon mini-dose pen for potential treatment of exercise-induced hypoglycemia in people living with Type 1 Diabetes and for people that suffers from meal-induced hypoglycemia following gastric bypass surgery.

Trials conducted in hospital settings have demonstrated the clinical potential for using low doses of dasiglucagon to correct moderate hypoglycemia. Top-line results of a post bariatric hypoglycemia Phase 2a dose-finding clinical proof of concept trial were reported in 2020 and demonstrate that mini doses of dasiglucagon significantly reduced meal-induced hypoglycemia compared to placebo in individuals who had undergone gastric bypass bariatric surgery. Top-line results from a Phase 2a dose-finding trial in people with type 1 diabetes will be presented at the American Diabetes Association congress in June 2021. Our patient Phase 2 trials in both indications are planned for initiation in the second quarter this year.

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. EASE-SBS 1 is the pivotal Phase 3 trial with a planned enrolment of 129 patients with SBS that seeks to establish the efficacy and safety of once- and twice-weekly administration of glepaglutide. They will be treated for six months whereafter they are offered a further 2-year treatment with glepaglutide in an extension trial, EASE-SBS 2. The primary endpoint is the absolute reduction in parenteral support

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 found to have a good safety and tolerability profile. Results showed 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) safety and tolerability trial. This ongoing trial is evaluating once-weekly doses of dapiglutide and results of this trial expected later this year.

Pre-Clinical programs

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

Later this year we expect to initiate a Phase 1 clinical trial with our long-acting Amylin analog ZP8396 that is being developed 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).

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.

Last month, with our partner Boehringer Ingelheim, we initiated two new Phase 2 trials of BI 456906 for adults who are overweight or obese and for adults with NASH. The first Phase 2 randomized double-blind placebo-controlled dose-finding trial will evaluate BI 456906 in people with obesity or who are overweight with a BMI 27 kg/m^2 or higher without diabetes. Participants will receive a subcutaneous injection of either BI 456906 or placebo once a week for the duration of the trial. The primary endpoint of this trial is the percentage change in body weight at week 46 compared to placebo. The other Phase 2 randomized double-blind placebo-controlled dose-finding trial will evaluate BI 456906 in people with NASH and liver fibrosis (F2/F3) with and without diabetes. The primary endpoint of this trial is the histological improvement of steatohepatitis without worsening of fibrosis after 48 weeks of treatment. Participants will receive a weekly subcutaneous injection of either different doses of BI 456906 or placebo for the duration of the trial.

Boehringer Ingelheim is funding all research, development and commercialization activities related to the treatment. Zealand Pharma is eligible to receive up to EUR 345 million in outstanding milestone payments, 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

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. We are looking to initiate a Phase 1 trial of the C3 inhibitor in 2022.

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 pm CEST / 10 am EDT

Zealand Pharma's management will host a conference call today at 4 pm CEST to present results through the first three months of 2021. 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 with the presenters.

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

Denmark	+45 32 720 417
United Kingdom	+44 (0) 844 481 9752
United States	+1 646 741 3167
France	+33 (0) 170700781
Netherlands	+31 (0) 207956614
Passcode	1868806

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.

Total number of shares and voting rights in Zealand Pharma as of March 31, 2021

Number of shares (nominal value of DKK 1 each): 43,428,192 which as increase of 3,650,842 from 39,799,706 as reported at the end of 2020.

Therefore, the current Share capital is (nominal value in DKK): 43,428,192

Number of voting rights: 43,428,192

About Zealand Pharma A/S

Zealand Pharma A/S (Nasdaq: ZEAL) ("Zealand") is a biotechnology company focused on the discovery, development, and commercialization of peptide-based medicines. More than 10 drug candidates invented by Zealand have advanced into clinical development, of which two have reached the market. Zealand's robust pipeline of investigational medicines includes three candidates in late-stage development. Zealand markets V-Go®, a basal-bolus insulin delivery option for people with diabetes, and has received FDA approval for Zegalogue, (dasiglucagon), the first and only glucagon analogue for the treatment severe hypoglycemia in pediatric and adult patients with diabetes aged 6 and above. License collaborations with Boehringer Ingelheim and Alexion Pharmaceuticals create opportunity for more patients to potentially benefit from Zealand-invented peptide investigational agents currently in development.

Zealand 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's business and activities, please visit http://www.zealandpharma.com.

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

Safe Harbor / Forward-Looking Statement

expectations or forecasts of future events regarding the research, development and commercialization of pharmaceutical products. These forward-looking statements may be identified by words such as “aim,” “anticipate,” “believe,” “could,” “estimate,” “expect,” “forecast,” “goal,” “intend,” “may,” “plan,” “possible,” “potential,” “will,” “would” and other words and terms of similar meaning. You should not place undue reliance on these statements, or the scientific data presented. The reader is cautioned not to rely on these forward-looking statements. Such forward-looking statements are subject to risks, uncertainties and inaccurate assumptions, which may cause actual results to differ materially from expectations set forth herein and may cause any or all of such forward-looking statements to be incorrect, and which include, but are not limited to, the occurrence of adverse safety events; risks of unexpected costs or delays; unexpected concerns that may arise from additional data, analysis or results obtained during clinical trials; failure to protect and enforce our data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; regulatory authorities may require additional information or further studies, or may fail to approve or may delay approval of our drug candidates or expansion of product labeling; failure to obtain regulatory approvals in other jurisdictions; product liability claims; and the direct and indirect impacts of the ongoing COVID-19 pandemic on our business, results of operations and financial condition. If any or all of such forward-looking statements prove to be incorrect, our actual results could differ materially and adversely from those anticipated or implied by such statements. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from our expectations in any forward-looking statement. All such forward-looking statements speak only as of the date of this press release and are based on information available to Zealand Pharma as of the date of this release. We do not undertake to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof. Information concerning

NOTE: DKK/USD Exchange rates used: March 31, 2021 = 6.3430 and March 31, 2020 = 6.8158.

For further information, please contact:

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For U.S. Media

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Key figures *

DKK thousand

		Reviewed		Audited
INCOME STATEMENT AND COMPREHENSIVE INCOME	**Note**	**Q1 2021**	**Q1 2020**	**FY 2020**
Revenue		47,819	12,417	353,314
Gross margin		**24,077**	**12,417**	**262,749**
Research and development expenses		-135,308	-164,541	-604,081
Sales and marketing expenses		-81,931	0	-285,256
Administrative expenses		-67,574	-25,076	-202,771
Net operating expenses		**-284,813**	**-189,617**	**-1,092,108**
Operating result		**-260,901**	**-177,203**	**-792,361**
Net financial items		19,839	-3,245	-47,292
Result before tax		**-241,062**	**-180,447**	**-839,653**
Income tax	(1)	-1,122	931	-7,076
Net result for the period		**-242,184**	**-179,516**	**-846,729**
Comprehensive result for the period		**-239,436**	**-179,543**	**-837,752**
Earnings/loss per share – basic/diluted (DKK)		-5.78	-4.98	-22.07

STATEMENT OF FINANCIAL POSITION	**March 31, 2021**	**March 31, 2020**	**December 31, 2020**
Cash and cash equivalents	1,307,554	999,707	960,221
Marketable securities	296,566	290,935	297,345
Cash, cash equivalents and Marketable securities	**1,604,120**	**1,290,642**	**1,257,566**

Equity		1,002,740	1,210,092	1,229,011
Total liabilities		505,080	346,203	532,638
Equity ratio	(2)	0.77	0.78	0.70
CASH FLOW		**Q1 2021**	**Q1 2020**	**FY 2020**
Cash used in operating activities		-368,132	-212,383	-688,716
Cash used in investing activities		-4,828	-18,698	-196,807
Cash flow from financing activities		703,536	144,632	760,941
Purchase of property, plant and equipment		-4,480	-3,701	-25,044
Net cash flow	(3)	-372,612	-216,084	-713,760
OTHER		**March 31, 2021**	**March 31, 2020**	**December 31, 2020**
Share price (DKK)		**204.4**	**233.6**	**220.60**
Market capitalization (MDKK)	(4)	**8,603**	**8,617**	**8,464**
Equity per share (DKK)	(5)	**40.04**	**33.01**	**32.04**
Average number of full time employees		**334**	**188**	**297**
Number of full time employees at the end of the period		**335**	**191**	**329**

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 2021, of which DKK 1.4 million has been recognized for the period ended March 31, 2021.

(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

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

DKK thousand	March 31, 2021	March 31, 2020
Sale of goods	42,115	0
License and milestone revenue	5,704	12,417
Total revenue	**47,819**	**12,417**

Revenue for the three months was due to sales of V-Go in 2021 that were not part of the comparative period in 2020, offset by lower license and milestone revenue recognition related to our collaboration with Alexion.

Gross margin

DKK thousand	March 31, 2021	March 31, 2020
Gross margin	**24,077**	**12,417**

The increase in gross margin is due to sales of V-Go in 2021 that were not part of the comparative period in 2020.

Research and development expenses

DKK thousand	March 31, 2021	March 31, 2020
Research and development expenses	**135,308**	**164,651**

The decrease in research and development expenses mainly relates to capitalization of pre-launch Zegalogue inventory and Zegalogue clinical studies and regulatory efforts in 2020 that were completed by Q1 2021 and resulted in our FDA approval.

Sales and marketing expenses	81,931	0

The increase in sales and marketing expenses is relating to our V-Go and Zegalogue sales force. This was not part of the comparative period in 2020.

Administrative expenses

DKK thousand	March 31, 2021	March 31, 2020
Administrative expenses	67,574	25,076

The primary increase in administrative expenses is a result of the increase in activities as a result of the Valeritas acquisition in April of 2020.

Operating result

DKK thousand	March 31, 2021	March 31, 2020
Operating result	-260,901	-177,203

The operating result reflects gross margin, research and development expenses, sales and marketing and administrative expenses, as discussed above.

Financial income and financial expenses

DKK thousand	March 31, 2021	March 31, 2020
Net financial items	19,839	-3,245

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 positive development is primarily driven by an increase in the USD exchange rate compared to December 31, 2020.

Result before tax

DKK thousand	March 31, 2021	March 31, 2020
Result before tax	-241,062	-180,447

DKK thousand	March 31, 2021	March 31, 2020
Income tax	-1,122	931

The net income tax expense is mainly impacted by the taxable income in US offset by the tax deduction in Denmark.

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

DKK thousand	March 31, 2021	March 31, 2020
Net result	-242,184	-179,516

The increase is primarily a result of the increases in sales and marketing as well as administrative expenses partially offset by revenue from the sales of V-Go which were not part of the comparative period in 2020.

Liquidity and capital resources

Equity

DKK thousand	March 31, 2021	December 31, 2020
Equity	1,662,746	1,229,311
Equity ratio	77%	70%

Equity ratio is calculated as equity at the balance sheet date divided by total assets at the balance sheet date. The increase in equity was mainly driven by a capital increase in January 2021 offset by the loss for the period

Cash, cash equivalents and Marketable securities

DKK thousand	March 31, 2021	December 31, 2020
Cash, cash equivalents and Marketable securities	1,604,120	1,257,566

The increase was mainly driven by a capital increase in January 2021 of gross DKK 748.9 million offset by the expenses for the period.

Cash used in operating activities	-368,131	-212,383	
Cash used in investing activities	-4,828	-18,698	
Cash flow from financing activities	703,536	144,632	
Net cash flow	-372,612	-216,084	

The increase in cash used in operating activities from the same period in 2020 is mainly related to our research and development, increase in administrative expenses due to the increase in employees as a consequence of the Valeritas acquisition and sales and marketing expenses increasing as a result of the regulatory and pre-commercial activities for the Zegalogue launch as well as the commercial activities and support for the V-Go wearable insulin delivery device.

Cash used in investing activities in the first three months of 2021 related mainly to acquisition of tangible assets.

Cash from financing activities increased primarily as a result of the January financing with an aggregate amount of gross DKK 748.9 million. Cash from financing activities for the three months ended March 31, 2020 was mainly related to a private placement of gross DKK 137.2 million

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

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 2021 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 2020 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 months periods ended March 31, 2021.

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 March 31, 2021 as well as of the results of the Group's operations and cash flow for the period January 1 – March 31, 2021.

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, May 12, 2021

Management

Alf Gunnar Martin Nicklasson Chairman	Kirsten Aarup Drejer Vice Chairman	Jeffr Boa
Bernadette Mary Connaughton Board member	Leonard Kruimer Board member	Alai Boa
Michael John Owen Board member	Gertrud Koefoed Rasmussen Board member Employee elected	Iber Boa Emp
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 interim condensed consolidated financial statements of Zealand Pharma A/S for the three months period ended March 31, 2021, which comprise a condensed consolidated income statement and statement of other comprehensive income for the three months period ended March 31, 2021, statement of financial position at March 31, 2021, and statement of changes in equity and statement of cash flow for the three months period ended March 31, 2021, 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 responsibilities 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

Auditor's responsibilities

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

Copenhagen, May 12, 2021

EY

Godkendt Revisionspartnerselskab

CVR no. 30 70 02 28

Christian Schwenn Johansen State Authorized Public Accountant mne33234	Rasmus Bloch Jespe State Authorized Pub mne35503

Interim condensed consolidated financial statements

Interim condensed consolidated income statement for the three months periods ended March 31, 2021 and 2020.

DKK thousand	Note
Revenue	2
Cost of goods sold	
Gross margin	
Research and development expenses	
Sales and marketing expenses	3
Administrative expenses	3
Operating expenses	
Other operating items, net	
Operating result	
Financial income	4
Financial expenses	5
Result before tax	
Income tax (expense) benefit	
Net result for the period	
Earnings/(loss) per share – basic/diluted (DKK)	6

Interim condensed consolidated statement of comprehensive income (loss) for the three months periods ended March 31, 2021 and 2020.

DKK thousand	Note
Net result for the period	
Other comprehensive income to be reclassified to profit or loss in subsequent periods:	
Exchange differences on translation of foreign operations	

Interim condensed consolidated statements of cash flow for the three months periods ended March 31, 2021 and 2020 and for the twelve months period ended December 31, 2020

		Reviewed
DKK thousand	**Note**	**YTD 2021**
Net result for the period		-242,184
Bargain purchase		0
Adjustments for other non-cash items		-49,586
Change in working capital		-69,696
Interest received		0
Interest paid		-962
Deferred revenue	2	-5,704
Income tax paid/received		0
Cash flow from operating activities		**-368,132**
Acquisition of Valeritas business, net of cash acquired		0
Change in deposits		-348
Purchase of property, plant and equipment	8	-4,480
Cash flow from investing activities		**-4,828**
Proceeds from issuance of shares related to exercise of share-based compensation	16	3,911
Proceeds from issuance of shares	16	748,974
Costs related to issuance of shares		-46,453
Lease installments	9	-2,896
Cash flow from financing activities		**703,536**
Decrease/increase in cash and cash equivalents		**330,576**
Cash and cash equivalents by beginning of period		960,221
Exchange rate adjustments		16,757
Cash and cash equivalents by end of period		**1,307,554**

Interim condensed consolidated statements of financial position as of March 31, 2021 and December 31, 2020

		Review
DKK thousand	**Note**	**March**
ASSETS		
Non-current assets		
Intangible assets	7	
Property, plant and equipment	8	
Right-of-use assets	9	
Deposits		
Corporate tax receivable		
Prepaid expenses		
Deferred tax assets		
Other investments	10	

Trade receivables	12	
Prepaid expenses	13	
Corporate tax receivable		
Other receivables	14	
Marketable securities	10	
Cash and cash equivalents	15	1,
Total current assets		**1,**
Total assets		**2,**
EQUITY AND LIABILITIES		
Share capital	16	
Share premium	17	4,
Translation reserve		
Accumulated loss		-2,
Equity		**1,**
Deferred revenue		
Other liabilities		
Lease liabilities	9	
Non-current liabilities		
Trade payables	18	
Corporate tax payables		
Lease liabilities	9	
Deferred revenue		
Discount and rebate liabilities		
Other liabilities	19	
Current liabilities		
Total liabilities		
Total equity and liabilities		**2,**

Interim condensed consolidated statements of changes in equity for the three months periods ended March 31, 2021 and 2020

DKK thousand	Share capital	Share premium	R Translat rese
Equity at January 1, 2020	**36,055**	**2,650,142**	
Other comprehensive income	0	0	
Net loss for the period	0	0	
Share-based compensation	0	4,766	
Capital increase	833	146,665	
Costs related to capital increases	0	-2	
Equity at March 31, 2020	**36,888**	**2,801,571**	
Equity at January 1, 2021	**39,800**	**3,470,787**	**8,**
Other comprehensive income	0	0	2,
Net loss for the period	0	0	
Share-based compensation	0	8,038	
Treasury shares, see note 17	0	-41,600	

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 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 financial statement for the year ended December 31, 2020.

New standards, interpretations and amendments adopted by the Group

A few amendments apply for the first time in 2021, but do not have an impact on the interim condensed consolidated financial statements of the Group.

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

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 see note 1 in the Annual Report for 2020.

Information on COVID-19

Our business, operations and clinical studies were, of course, impacted by the effects of COVID-19. Although our clinical studies continued without interruption during 2021 and 2020, there were delays and increased total costs arising from the implications of COVID-19.
However, we have not recognized any write-offs, impairments of assets, or losses to onerous contracts due to COVID-19.

The COVID-19 pandemic is also having an effect on other aspects of our business, including: our third-party manufacturers, and other third parties; albeit with no material effect or impact. The COVID-19 pandemic may, in the long-term, affect the productivity of our staff; our ability to attract, integrate, manage and retain qualified personnel or key employees; our global supply chains and relationships with vendors and other parties; significant disruption of global financial markets; and reduced ability to secure additional funding. We continuously monitor the COVID-19 pandemic and its potential impact on our business and financials.

Note 2 - Revenue

Revenue can be specified as follows:

DKK thousand	
Alexion Pharmaceuticals Inc.	
Total license and milestone revenue	

Total revenue recognized over time	
Total revenue recognized at a point in time	

License revenue for the first three months of 2021 of DKK 5.7 million relate to the research and development agreement with Alexion Pharmaceuticals entered into in March 2019. Under the agreement DKK 92.1 million is accounted for as deferred revenue at March 31, 2021.

Sale of goods revenue for the first three months of 2021 of DKK 42.1 million relate to V-Go. The net sales comprise of gross sales of DKK 82.3 million and discounts and rebates of DKK -40.2 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.

Net sales in US for the three months period ended March 31, 2021 comprise DKK 47.8 million including license revenues and sale of goods. No other countries accounts for more than 10% of the net total sales.

Note 3 – Administrative, sale and marketing expenses

The increase in administrative, sale and marketing expenses in Q1 2021 over Q1 2020 is due to the acquisition of Valeritas in April 2020.

Note 4 – Financial income

Recognized financial income can be specified as follows:

DKK thousand	
Interest income and banking fees	
Currency exchange adjustments	
Financial expenses	

Note 5 - Financial expenses

Recognized financial expenses can be specified as follows:

DKK thousand	

Note 6 - 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	
Net earnings/loss for the period	
Net earnings/loss used in the calculation of basic earnings/loss per share	
Weighted average number of ordinary shares	
Weighted average number of treasury shares	
Weighted average number of ordinary shares used in the calculation of basic/diluted loss per share	
Earnings/loss per share – basic/diluted (DKK)	

The following potential ordinary shares are anti-dilutive and are therefore average number of ordinary shares for the purpose of diluted earnings/lo

	March 31, 2021	March 31 202
Outstanding warrants under the 2010 Employee incentive program	0	5,45
Outstanding warrants under the 2015 Employee incentive program	1,827,171	1,593,21
Outstanding warrants under the 2020 Employee incentive program	63,217	
Outstanding Performance Share Units (PSUs) under the LTIP 2019 program	19,765	19,76
Outstanding Restricted Share Units (RSUs) under the LTIP 2020 program	27,466	
Total outstanding warrants/PSUs/RSUs	**1,937,619**	**1,618,43**

For further information on the Employee incentive programs please see note 6 in the Annual Report for 2020.

Note 7 – Intangible assets

Intangible assets of DKK 58.0 million recognized as at March 31, 2021 as compared to DKK 57.5 million as of December 31, 2020. The increase is primarily due to currency translation.

Plant and machinery
Other fixtures and fittings
Building improvements
Assets under construction
Carrying amount

The decrease from DKK 85.0 million at December 31, 2020 to DKK 84.5 million as at March 31, 2021 is primarily related to depreciations off set by smaller additions.

Note 9 - Right of use assets and lease liabilities

Right-of-use-assets of DKK 126.0 million and lease liability of DKK 128.7 million were recognized as at March 31, 2021 as compared to DKK 128.0 million and DKK 130.1 million, respectively, as of December 31, 2020. The decrease is primarily related to depreciations and payments.

Note 10 - Financial instruments

As of March 31, 2021 and December 31, 2020, the following financial instruments are measured at fair value through profit or loss:

DKK thousand
Marketable securities
Other investments
Financial assets measured at fair value

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 5.4 million (December 31, 2020: USD 5.4 million) investment in Beta Bionics, Inc., the developer of iLet™, a fully integrated dual-hormone pump (bionic pancreas) for autonomous diabetes care.

In determining fair value, Zealand considered the impact of any recent share capital issuances by Beta Bionics as an indicator of the fair value of the shares. In particular, Beta Bionics undertook a capital offering in June 2019 and subsequent infliction points was used as the basis for determining fair value. Measurement is considered a level 3 measurement.

million in financial income).

There were no transfers between levels 1, 2 and 3 for recurring fair value measurements during the interim periods ended March 31, 2021 and 2020, respectively.

Note 11 - Inventories

DKK thousand	
Raw materials	
Work in progress	
Finished goods	
Inventories	

In 2021 a reversal of previous periods estimated write-down on prelaunch inventory with a net positive income statement effect of DKK 17.1 million on research and development expenses was recognized, as a consequence of our FDA approval.

Note 12 – Trade receivables

The increase in Trade receivables from DKK 46.5 million at December 31, 2020 to DKK 62.4 million at March 31, 2021 is mainly related to extended payment terms with our larger customers.

Note 13 – Prepaid expenses

The increase in Prepaid expenses from DKK 48.3 million at December 31, 2020 to DKK 60.3 million at March 31, 2021 is mainly relating to timing differences.

Note 14 - Other receivables

DKK thousand	
VAT	
Other	
Other receivables	

Other receivables are mainly related to VAT receivables in Denmark and Sweden.

Note 15 - Cash and cash equivalents

USD
EUR
Total cash and cash equivalents

Note 16 - Changes in share capital

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

Share capital at January 1, 2020
Increase due to issue of new shares
Share capital at March 31, 2020

Share capital at January 1, 2021
Increase due to issue of new shares
Share capital at March 31, 2021

Note 17 – Treasury shares

As part of the capital increase made in January 2021, a total of 200,000 shares were purchased through a share swap transaction. As the payment is not due yet, a liability of DKK 41.6 million is recognized under other liabilities. Refer to note 19

The total number of treasury shares at March 31, 2021 is 264,223 and will be used for long term incentive compensation plans.

Note 18 – Trade payables

The decrease in Trade payables from DKK 70.4 million at December 31, 2020 to DKK 46.7 million at March 31, 2021 is mainly relating to timing differences.

Note 19 - Other liabilities

DKK thousand
Employee benefits
Royalty payable to third party
Treasury shares purchase – See note 17
CRO liabilities
Other payables
Total other liabilities

the payout of bonus in Q1 2021.

Note 20 - Contingent assets, liabilities and contractual obligations

Contingent assets

At March 31, 2021, Zealand is still eligible for a payment from Sanofi of up to USD 15.0 million, of which up to USD 5.0 million is expected in 2021 and USD 10.0 million in 2022. However, it is Management's opinion that the amount of any payment cannot be determined on a sufficiently reliable basis, and therefore the company has not recognized an asset in the statement of financial position of the Group.

Contingent liabilities and contractual obligations

At March 31, 2021, total contractual obligations related to agreements with CROs amounted to DKK 342.8 million (DKK 166.2 million for 2021 and DKK 176.5 million for the years 2022 up to and including 2025).

Zealand may be required to pay future development, regulatory and commercial milestones related to the acquisition of Encycle Therapeutics. Refer to note 13 in the 2020 Annual Report.

Note 21 - Significant events after the reporting period

In May 2021, Sanofi has informed that they reached the first milestone resulting in a milestone payment to Zealand of up to USD 5.0 million. This will in accordance with our accounting policies be recognized as revenue in Q2 2021.

[Rakshit Choudhary : de directeur des opérations à ...]

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25 avr. 2024 13h30 HE

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