

## **Zealand Pharma: on Track for Potential First Product Launch and Establishing Commercial Operations in the United States**

### **Full Year Results for 2020**

*Copenhagen, March 11, 2021* – Zealand Pharma A/S (“Zealand”) (NASDAQ: ZEAL) (CVR-no. 20 04 50 78), a biotechnology company focused on the discovery and development of innovative peptide-based medicines, announced financial results for the 12-month period from January 1 to December 31, 2020.

In 2020, a number of significant milestones were achieved by Zealand Pharma, including filing the company’s first New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for the dasiglucagon auto-injector and pre-filled syringe and establishing a commercial organization in the U.S. through the integration of staff and assets from the Valeritas acquisition and the hiring of key external talent. With the growth, Zealand’s total number of employees has increased by approximately 50%. In addition, the company continues to progress on the early and late-stage clinical pipeline and strengthened its balance sheet by securing a total of DKK 795 million in private placements.

#### **Financial results for the full year 2020**

- Revenue of DKK 353.3 million / USD 54.2 million (2019: DKK 41.3 million / USD 6.2 million).
- Net operating expenses of DKK 1,092.1 million / USD 166.9 million (2019: DKK 629.3 million / USD 94.2 million).
- Operating result for the year of DKK -792.4 million / USD -121.1 million (2019: DKK -587.9 million / USD -88.1 million).
- Cash including marketable securities amounted to DKK 1,257.6 million / USD 192.2 million at year-end (2019: DKK 1,380.5 million / USD 206.8 million).

#### **Business highlights and updates for Q4 2020 and the period thereafter**

- Dasiglucagon auto-injector and pre-filled syringe for severe hypoglycemia: Strengthened US commercial operations and continued to progress commercial launch readiness ahead of potential FDA approval.
- Announced data from first Phase 3 trial for dasiglucagon in congenital hyperinsulinism (CHI).
- Dapiglutide for the treatment of Short Bowel Syndrome: Dosed first patients in phase 1b multiple ascending dose study.
- Strengthened the US commercial model by adding robust business analytics capabilities and a modernized digital and virtual marketing mix.
- In January of 2021, secured a total of gross DKK 749.0 million through a direct issue and private placement of approximately 4.0 million new shares to institutional and professional investors, including participation from the CEO and CFO of Zealand Pharma.
- In March of 2021 the company hosted a virtual R&D day and Q&A session focusing on the company’s R&D strategy, peptide platform and early and late-stage clinical portfolio.

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

“2020 was a pivotal year for Zealand Pharma as transformed from a research and development-focused organization to a fully integrated commercial biopharmaceutical company. We continue to progress our

late-stage clinical pipeline across both our metabolic and gastrointestinal franchises and to advance our early-stage pipeline. We are on schedule with our US launch readiness activities in preparation for a potential FDA approval later this month and we are targeting the commercial launch of dasiglucagon auto-injector and pre-filled syringe for severe hypoglycemia in late June.”

“None of this would be possible without the support of the healthcare community, the patients enrolled in our clinical trials and the dedication and resilience of our employees. Their commitment to our mission has been exceptional this past year, overcoming the challenges presented by COVID-19. Amid a global pandemic, the Zealand team accomplished our strategic objectives of building our own commercial organization in the U.S. while continuing industry-leading research and development. I am proud of what the team has done and look forward to what we will accomplish together in 2021 and beyond.”

## Financial guidance

In 2021, Zealand Pharma expects net product revenue from the sales of its commercial products of DKK 220 million +/-10% compared to 2020 of DKK 161.3 million.

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% compared to 2020 of DKK 1,092.1 million.

## Pipeline

Zealand Pharma is a world leader in peptide drug discovery and design, building upon 20 years of experience in understanding and exploiting peptide design. If approved by the FDA, the dasiglucagon auto-injector and pre-filled syringe could become the first dasiglucagon-based medicine made available to people with severe hypoglycemia. Zealand is also developing dasiglucagon in congenital hyperinsulinism (CHI) and 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.

Zealand is conducting additional analyses and engaging with regulatory authorities to discuss the results of 17109 while awaiting the outcome of a second Phase 3 trial in neonates up to 12 months old with CHI. The Company also plans to initiate a Phase 2 study in 2021 evaluating a low dose of dasiglucagon administered by a pen in people with Type 1 diabetes as a non-caloric alternative to manage plasma glucose.

Zealand is collaborating with Beta Bionics on the iLet® bionic pancreas device, which also uses dasiglucagon, and the companies plan to initiate a pivotal Phase 3 trial in the second half of 2021, which will consist of one pivotal trial in adults with Type 1 diabetes (T1D) and one pivotal trial in children with T1D. Approximately 350 adults and 350 children 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.

In addition, Zealand is broadening its pipeline of metabolic therapies to also target obesity and non-alcoholic steatohepatitis (NASH). Alongside partner Boehringer Ingelheim (BI), Zealand progressed the clinical development of BI-456909 in 2020 with the initiation of a Phase 2 trial in type 2 diabetes and obesity and has plans to also pursue development in NASH.

Zealand also made progress in the clinical development of its gastrointestinal program, with Short Bowel Syndrome (SBS) as the foundation of this franchise. Though COVID-19 impacted patient recruitment for the Phase 3 trial of glepaglutide in SBS, the trial continues to enroll patients. EASE-SBS 1 is the pivotal

Phase 3 trial with a planned enrolment of 129 patients with SBS. 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 achieved by the end of the trial, with results expected in 2022.

The Company also completed the first Phase 1 trial for dapiglutide, a potential next generation of SBS treatment, and initiated another Phase 1 multiple-ascending dose trial. This ongoing trial is evaluating once-weekly doses of dapiglutide and Zealand is currently at the second dose level with results of this trial expected later this year.

In its early pipeline, Zealand regained the worldwide rights to the amylin-analog program from BI, and the Company expects to start clinical development for this program in 2021. The Company's continued collaboration with Alexion Pharmaceuticals is focused on preventing the detrimental effects of overactive C3 function in patients with complement driven diseases such as C3G, and the companies will look to initiate a Phase 1 trial of their C3 inhibitor in 2022.

In Zealand's GIP-program, which has potential for development in multiple major diseases and comprises mono-, dual-, and triple-agonists, the company selected the lead molecule and progressed towards clinical development while also progressing its Alpha4Beta7-program, which has the potential to provide Zealand's first-ever oral peptide therapeutic, and a Kv1.3 ion channel blocker toward Phase 1 initiation.

## **Zealand Pharma's Annual Report 2020**

This announcement is a summary and is qualified by, and should be read in conjunction with, Zealand's Annual Report for 2020, published on March 11, 2021. A PDF version of the Annual Report will be available for download from Zealand's website.

## **Conference call March 11, 2021, at 4:00 PM CET (10:00 AM EDT)**

Zealand's management will host a conference call on March 11, 2021 at 4:00 PM CET (10:00 AM EDT) to present the full-year results and the Annual Report for 2020. Presenting during the call will be President and Chief Executive Officer Emmanuel Dulac, Senior Vice President and Chief Financial Officer Matt Dallas, and Executive Vice President and Chief Medical 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, Copenhagen ..... +45 32 72 04 17  
United Kingdom..... +44 (0) 844 481 9752  
United States..... +1 646 741 3167  
France, Paris ..... +33 (0) 170 700 781  
Netherlands, Amsterdam ..... +31 (0) 207 956 614

Confirmation Code: .....**3077735**

A live audio webcast of the call, including an accompanying slide presentation, will be available via the following link, <https://edge.media-server.com/mmc/p/7daetm5k>, also accessible from the Investor section of Zealand's website ([www.zealandpharma.com](http://www.zealandpharma.com)). 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.

**For further information, please contact:**

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NOTE: Exchange rates used: 31 Dec 2020 = 6.54 and 31 Dec 2019 = 6.67

### About Zealand Pharma A/S

Zealand Pharma A/S (Nasdaq: ZEAL) ("Zealand") is a biotechnology company focused on the discovery, development and commercialization of innovative peptide-based medicines. More than 10 drug candidates invented by Zealand 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, and one candidate being reviewed for regulatory approval in the United States. Zealand markets V-Go<sup>®</sup>, an all-in-one basal-bolus insulin delivery option for people with diabetes. License collaborations with Boehringer Ingelheim and Alexion Pharmaceuticals create opportunity for more patients to potentially benefit from Zealand-invented peptide therapeutics. 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 [www.zealandpharma.com](http://www.zealandpharma.com).

### Forward-Looking Statements

*This announcement may contain forward-looking statements, including "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995, that are based on the beliefs and assumptions and on information currently available to management of Zealand, including with respect to the company's anticipated revenue and expenses for 2021 and potential product approval by the FDA. All statements other than statements of historical fact contained in this announcement are forward-looking statements, including statements regarding the anticipated final terms of the Investment. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other comparable terminology. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause Zealand's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These risks and uncertainties include, but are not limited to, the risks and uncertainties set forth in the "Risk Factors" section of the Zealand's Annual Report on Form 20-F for the year ended December 31, 2019 filed with the SEC on March 13, 2020 and subsequent reports that Zealand has filed or will file with the SEC. Forward-looking statements represent Zealand's beliefs and assumptions only as of the date of this announcement. Although Zealand believes that the expectations reflected in the forward-looking statements are reasonable, it cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, Zealand assumes no obligation to publicly update any forward-looking statements for any reason after the date of this announcement to conform any of the forward-looking statements to actual results or to changes in its expectations.*