

# Zealand Pharma Announces Financial Results for the First Half of 2023.

*Strong progress across R&D pipeline and significant strengthening of the balance sheet*

- Boehringer Ingelheim to move into Phase 3 trials with GCGR/GLP-1R dual agonist survodutide (BI456906) in obesity following positive Phase 2 data
- Encouraging weight loss and tolerability data from long-acting amylin analog ZP8396
- Regulatory submission of NDA to the US FDA for dasiglucagon in congenital hyperinsulinism and submission of MAA to EMA for dasiglucagon for the treatment of severe hypoglycemia
- Strengthened balance sheet with DKK 1.5 billion, resulting in a runway to mid-2026

Copenhagen, Denmark, August 17, 2023 – Zealand Pharma A/S (Nasdaq: ZEAL) (CVR-no. 20045078), a biotechnology company focused on the discovery and development of innovative peptide-based medicines, today announced the interim report for the six months ended June 30, 2023 and provided a corporate update.

## Strong progress in obesity portfolio and execution of regulatory submissions for dasiglucagon

Adam Steensberg, President and Chief Executive Officer at Zealand Pharma said: "The first six months of 2023 have been phenomenal for Zealand Pharma, with impressive clinical data readouts from our obesity portfolio, including presentations at ADA for survodutide and our amylin analog ZP8396, regulatory submissions for dasiglucagon, and a strengthened balance sheet.

"We look forward to an eventful second half of the year as well, which we expect among other events will include the regulatory submission to the FDA for glipaglutide in SBS, a potential partnership agreement for dasiglucagon in CHI, and initiation by Boehringer Ingelheim of the Phase 3 program with survodutide in obesity."

## Key financial results for H1 2023

DKK million	H1 2023	H1 2022*
Revenue	24.0	36.3
Net operating expenses <sup>1</sup>	-388.1	-470.5
Net operating result	-364.0	-434.1
Net financial items	-152.0	-61.8
Cash position <sup>2</sup>	1,692	1,178
Funding available incl. undrawn committed RCF <sup>3</sup>	2,042	1,178

\*Comparative numbers are adjusted for discontinued operations.

Notes:

1. Net operating expenses consist of R&D, S&M, G&A and other operating items.
2. Cash position includes cash, cash equivalents and marketable securities.
3. RCF = Revolving Credit Facility provided by Danske Bank.

## Highlights in the second quarter 2023

### Obesity

- **Survodutide:** Presented results from Phase 2 dose-finding clinical trial with survodutide (formerly BI 456906), a glucagon/glucagon-like peptide-1 receptor (GCGR/GLP-1R) dual agonist, in people living with **overweight or obesity**. Survodutide achieved up to 18.7% mean weight loss from baseline after 46 weeks based on the actual maintenance dose. Up to 40% of people who reached the highest two doses of survodutide in the trial achieved a weight loss of at least 20%. The safety and tolerability profile of survodutide was in line with other incretin-based pharmacotherapies. The data were presented at the 2023 American Diabetes Association's (ADA) 83<sup>rd</sup> Scientific Sessions.
- **ZP8396:** Presented results from Phase 1a single ascending dose (SAD) trial of long-acting amylin analog ZP8396. Healthy participants with a mean BMI of 25.8 treated with ZP8396 had dose-dependent and sustained reductions in mean body weight of up to 4.2% from baseline. Placebo-treated participants had a mean body weight increase of 0.6%. The plasma half-life of ZP8396 was approximately 10 days, which supports once-weekly

dose administration. ZP8396 was well tolerated in this study, with no serious or severe adverse events (AEs) and no withdrawals. The data were presented at the ADA 83<sup>rd</sup> Scientific Sessions.

- **ZP8396: Initiated 16-week multiple ascending dose (MAD) trial with long-acting amylin analog ZP8396, Part 2 of the Phase 1b trial.** Based on the mild adverse event profile observed in the 6-week Part 1 of the MAD trial, Zealand has progressed ZP8396 into 16 weeks of dosing to explore significantly higher exposure levels of ZP8396 using a dose up-titration scheme.
- **Dapiglutide: Initiated DREAM, a Phase 2 investigator-led clinical trial of dapiglutide, a first-in-class GLP-1/GLP-2 receptor dual agonist in people with obesity.** The DREAM trial aims to evaluate the potential for weight loss following 12 weeks and gain key mechanistic insights into the effects of dapiglutide on inflammatory markers. Zealand expects the trial to complete in the first half of 2024.

#### Rare diseases

- **Dasiglucagon (CHI): Submitted new drug application (NDA) to the US Food and Drug Administration (FDA) for dasiglucagon for the treatment of congenital hyperinsulinism.** The submission is based on the results from two pivotal Phase 3 trials and interim results from an ongoing long-term extension trial.
- **Glepaglutide (SBS): Completed the interim analyses of EASE-2, EASE-3, and EASE-4 clinical trials of glepaglutide in patients with short bowel syndrome (SBS).** Zealand Pharma is on track to submit the NDA to the US FDA in the second half of 2023. The submission will be based on EASE-1 and interim results from EASE-2, EASE-3 and EASE-4.

#### Type 1 diabetes

- **Dasiglucagon (severe hypoglycemia): Submitted marketing authorization application (MAA) to the European Medicines Agency (EMA) for dasiglucagon for the treatment of severe hypoglycemia in adults, adolescents and children aged six years or older with diabetes.** Dasiglucagon injection was approved under the brand name Zegalogue® by the US FDA on March 22, 2021, for the treatment of severe hypoglycemia in pediatric and adult people with diabetes aged six years and above. In September 2022, Zealand entered into a global license and development agreement with Novo Nordisk to commercialize Zegalogue®. The MAA submission triggered a milestone payment to Zealand of DKK 15 million.

#### Financing

- **Strengthened balance sheet and extended runway to mid-2026.** In April, Zealand received gross proceeds of DKK 1.5 billion from a directed issue and private placement of 6,578,948 new shares. In May 2023, Zealand repaid the Oberland Capital loan in full and the loan agreement is now terminated. The repayment is refinanced through a new undrawn Credit Facility provided by Danske Bank and expected near-term upcoming milestones from existing partners.

#### Events after the reporting date

- **ZP8396: Announced topline results in July 2023 from 6-week MAD trial with long-acting amylin analog ZP8396, Part 1 of the Phase 1b trial.** Low doses of 0.6 and 1.2 mg ZP8396 administered once-weekly for six weeks led to 5.3% and 5.1% mean weight loss compared to 2.6%, 3.6% and 4.2% mean weight loss following single doses of 0.7, 1.4 and 2.4 mg ZP8396, reported from the SAD trial. Based on the mild AE profile observed in the 6-week MAD trial, Zealand has initiated Part 2 of the MAD trial, a 16-week study exploring significantly higher doses of ZP8396 using a dose up-titration scheme.
- **Survodutide: Announced advancement into three global Phase 3 trials in obesity.** On August 17, Boehringer Ingelheim announced their decision to advance to Phase 3 in people living with overweight or obesity with initiation expected in the second half of 2023.

#### Upcoming events next 12 months

- **Glepaglutide in SBS.** In the second half of 2023, Zealand anticipates submitting an NDA to the FDA for glepaglutide administered via autoinjector for the treatment of SBS with intestinal failure and engage in more detailed partnership discussions.
- **Dasiglucagon in CHI.** In the second half of 2023, Zealand aims to enter into a partnership agreement for the commercialization of dasiglucagon in CHI.
- **Survodutide in obesity.** Boehringer Ingelheim expects to start enrolment of patients in the Phase 3 clinical program with survodutide in people living with overweight or obesity in the second half of 2023, with details on the trials to be disclosed prior to their initiation.
- **Survodutide in NASH.** Boehringer Ingelheim and Zealand Pharma expect to report topline results from the Phase 2 trial with survodutide in NASH in the first half of 2024.

- **Dapiglutide, GLP-1/GLP-2 receptor dual agonist.** Zealand expects to initiate a 13-week dose titration trial in people with obesity in the second half of 2023. Topline results from the ongoing investigator-initiated Phase 2 trial DREAM are expected in the first half of 2024.
- **ZP8396, long-acting amylin analog.** In the first half of 2024, Zealand expects to report topline results from the 16-week MAD trial.
- **ZP6590, GIP analog.** Zealand expects to complete pre-clinical activities in 2023 and advance this program into first-in-human clinical trials in the first half of 2024.
- **ZP10068, Complement Inhibitor.** Zealand expects to complete pre-clinical activities in the second half of 2023 for the investigational long-acting complement inhibitor. Subsequent regulatory, clinical and development efforts will be led and conducted by Alexion.
- **ZP9830, Kv1.3 Ion Channel Blocker.** Zealand expects the Kv1.3 ion channel blocker to be Phase 1-ready in the first half of 2024 and to initiate first-in-human clinical trials in 2024.

## Financial guidance for 2023

- Guidance unchanged from March 2, 2023

DKK million	2023 Guidance	2022 Actual
Revenue anticipated from existing and new license and partnership agreements	No guidance due to uncertain size and timing	104
Net operating expenses <sup>4</sup>	800-900	941

Notes:

4. Financial guidance based on foreign exchange rates as of August 17, 2023.

## Conference call today at 2 PM CET / 8 AM ET

Zealand's management will host a conference call today at 2:00 PM CET / 8:00 AM ET to present results through the first six months of 2023 followed by a Q&A session. Participating in the call will be Chief Executive Officer, Adam Steensberg; Chief Financial Officer, Henriette Wennicke; and Chief Medical Officer, David Kendall. The conference call will be conducted in English.

Telephone dial-in information and a unique personal access PIN will be provided upon registration at <https://register.vevent.com/register/B108d950a0d12f438da>

[57a04a02449f692](https://www.zealandpharma.com/events/57a04a02449f692). A live listen-only audio webcast of the call, including an accompanying slide presentation, will be accessible at <https://edge.media-server.com/mmc/p/5hqhqe4j>. Participants are advised to register for the call or webcast approximately 10 minutes before the start. A recording of the event will be available following the call on the Investor section of Zealand's website at <https://www.zealandpharma.com/events/>.

## About Zealand Pharma A/S

Zealand Pharma A/S (Nasdaq: ZEAL) ("Zealand") is a biotechnology company focused on the discovery and development of peptide-based medicines. More than 10 drug candidates invented by Zealand have advanced into clinical development, of which two have reached the market and three candidates are in late-stage development. The company has development partnerships with a number of pharma companies as well as commercial partnerships for its marketed products.

Zealand was founded in 1998 and is headquartered in Copenhagen, Denmark, with a presence in the U.S. that includes Boston. For more information about Zealand's business and activities, please visit [www.zealandpharma.com](http://www.zealandpharma.com).

## Forward-looking Statements

This company announcement and interim report contains "forward-looking statements", as that term is defined in the Private Securities Litigation Reform Act of 1995 in the United States, as amended, even though no longer listed in the United States this is used as a definition to provide Zealand Pharma's expectations or forecasts of future events regarding the research, development and commercialization of pharmaceutical products, the timing of the company's pre-clinical and clinical trials and the reporting of data therefrom and the company's Upcoming Events and Financial Guidance for 2023. 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, unexpected costs or delays in clinical trials and other development activities due to adverse safety events or otherwise; unexpected concerns that may arise from additional data, analysis or results obtained during

clinical trials; our ability to successfully market both new and existing products; changes in reimbursement rules and governmental laws and related interpretation thereof; government-mandated or market-driven price decreases for our products; introduction of competing products; production problems; unexpected growth in costs and expenses; our ability to effect the strategic reorganization of our businesses in the manner planned; 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 reject, fail to approve or may delay approval of our drug candidates or expansion of product labeling; failure to obtain regulatory approvals in other jurisdictions; exposure to product liability and other claims; interest rate and currency exchange rate fluctuations; unexpected contract breaches or terminations; inflationary pressures on the global economy; and political uncertainty, including due to the ongoing military conflict in Ukraine. 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/company announcement and are based on information available to Zealand Pharma as of the date of this release/announcement. 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 pharmaceuticals (including compounds under development) contained within this material is not intended as advertising or medical advice.

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## Contacts:

Adam Lange  
Investor Relations Officer  
Zealand Pharma  
Email: [ALange@zealandpharma.com](mailto:ALange@zealandpharma.com)

Anna Krassowska, PhD  
Vice President, Investor Relations & Corporate  
Communications  
Zealand Pharma  
Email: [AKrassowska@zealandpharma.com](mailto:AKrassowska@zealandpharma.com)

## R&D Pipeline

Therapeutic area	Product candidate*	Pre-clinical	Phase 1	Phase 2	Phase 3	Registration
Rare diseases	Dasiglucagon: S.C. Continuous Infusion	Congenital Hyperinsulinism				
	Glepaglutide (GLP-2 Analog)	Short Bowel Syndrome				
Obesity	Survodutide (GCGR/GLP-1R Dual Agonist) <sup>1</sup> 	Obesity, NASH and T2D				
	Dapiglutide (GLP-1/GLP-2 Dual Agonist)	Obesity				
	ZP 8396 (Amylin Analog)	Obesity				
	ZP 6590 (GIP Receptor Agonist)	Obesity				
Type 1 diabetes	Dasiglucagon: Bi-Hormonal Artificial Pancreas Systems	Type 1 Diabetes management				
	Dasiglucagon: Mini-Dose Pen	T1D exercise-induced hypoglycemia				
Inflammation	ZP 10068 (Complement C3 Inhibitor) <sup>2</sup> 	Undiscl.				
	ZP 9830 (Kv1.3 Ion Channel Blocker)	Undiscl.				
	ZP 10000 (α4β7 Integrin Inhibitor)	IBD				

\*) Investigational compounds whose safety and efficacy have not been evaluated or approved by the FDA or any other regulatory authority

1) Co-invented by Boehringer Ingelheim and Zealand: EUR 345 million outstanding potential development, regulatory and commercial milestones + high single to low double digit % royalties on global sales to Zealand

2) Licensed to Alexion: USD \$610 million potential development, regulatory and commercial milestones + high single to low double digits % royalties on net sales

### Rare diseases

#### Dasiglucagon for congenital hyperinsulinism (CHI)

##### Second quarter 2023 update:

- Submission of the NDA to the US FDA on June 30, 2023.

##### Background:

Dasiglucagon is a glucagon analog that is stable in aqueous solution and is thus suitable for chronic pump use. The Phase 3 program comprises three clinical trials evaluating the potential for chronic dasiglucagon infusion delivered subcutaneously via a pump to prevent hypoglycemia in children with CHI. The FDA and the European Commission have both granted orphan drug designation to dasiglucagon for the treatment of CHI.

The global, 2-part, Phase 3 trial 17103 (ClinicalTrials.gov ID: [NCT04172441](https://clinicaltrials.gov/ct2/show/study/NCT04172441)) evaluated the efficacy of dasiglucagon in reducing glucose requirements in 12 children (ranging in age from 7 days to 12 months) with persistent CHI requiring continuous intravenous glucose administration to prevent or manage hypoglycemia.

In Part 1 of the Phase 3 trial, dasiglucagon significantly reduced the requirement for intravenous (IV) glucose to maintain glycemia in newborns and infants with CHI. Dasiglucagon significantly reduced the mean IV glucose infusion rate (GIR) in the last 12 hours of the 48 hour treatment period by 55% as compared to placebo (4.3 mg/kg/min for dasiglucagon and 9.4 mg/kg/min for placebo with a treatment difference of 5.2 mg/kg/min; p=0.0037). Dasiglucagon also reduced GIR over the entire 48-hour treatment period by 3.5 mg/kg/min compared to placebo (p=0.0107). Dasiglucagon treatment resulted in a

reduction of 31 g/day in total carbohydrate intake (IV and gastric) compared to placebo (107 g/day for dasiglucagon vs. 138 g/day for placebo; p = 0.024), a 22% reduction in carbohydrate calories. Dasiglucagon was observed to be well tolerated in Part 1 of the trial, with skin reactions and gastrointestinal disturbances as the most frequently reported adverse events (no serious adverse events reported).

In the 21-day open-label Part 2 of the Phase 3 trial, dasiglucagon reduced time in hypoglycemia and enabled discontinuation of intravenous glucose in most infants and limited the need for pancreatectomy. Continuous subcutaneous infusion of dasiglucagon enabled reduction and either periodic or permanent discontinuation of IV glucose infusion in 10 out of 12 infants during the study period. Seven infants, who did not require pancreatectomy, were completely weaned off IV glucose at the completion of the trial. During the 21-day treatment with dasiglucagon, continuous glucose monitoring (CGM) measures of hypoglycemia trended lower with median time <70 mg/dL reduced from 7.0% to 5.2% and <54 mg/dL reduced from 1.9% to 0.88%. There was no increase in hyperglycemia. The safety profile of dasiglucagon in Part 2 was consistent with Part 1, with no adverse event requiring discontinuation of treatment and no serious adverse events reported.

The open-label Phase 3 trial 17109 (ClinicalTrials.gov ID: [NCT03777176](https://clinicaltrials.gov/ct2/show/study/NCT03777176)) evaluated the efficacy of dasiglucagon in reducing hypoglycemia in 32 children (ranging in age from 3 months to 12 years) with CHI with more than three hypoglycemic events per week despite previous near-total pancreatectomy and/or maximum medical therapy. Data reported in December 2020 showed that 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, dasiglucagon treatment resulted in a 40–50% reduction in hypoglycemia compared to SOC alone, when assessed by blinded continuous glucose monitoring.

The Phase 3 trial 17106 (ClinicalTrials.gov ID: [NCT03941236](#)) is evaluating the long-term safety of dasiglucagon in 42 of the 44 children older than 1 month with CHI who completed either of the Phase 3 trials 17103 or 17109.

### **Glepaglutide (long-acting GLP-2 analog) for short bowel syndrome (SBS)**

#### **Second quarter 2023 update:**

- Presentation of EASE-1 results at the ASPEN 2023 Nutrition Science & Practice Conference in April 2023 and Digestive Diseases Week in May 2023.
- Completion of interim analyses for the EASE-2, EASE-3 and EASE-4 clinical trials of glepaglutide in patients with short bowel syndrome and intestinal failure to support regulatory submission expected in the second half of 2023.

#### **Background:**

Glepaglutide is a long-acting GLP-2 analog that is stable in aqueous solution and can be administered as a ready-to-use liquid formulation. Zealand is developing glepaglutide as a ready-to-use, fixed dose product designed for subcutaneous delivery via auto-injector for the potential treatment of SBS. The Phase 3 program includes four clinical trials evaluating the potential for glepaglutide to reduce or eliminate the need for parenteral support in patients with SBS.

EASE-1 is a randomized, double-blind Phase 3 trial that enrolled a total of 106 SBS patients with intestinal failure who were dependent on parenteral support for at least three days per week. Patients were evenly randomized to receive treatment with 10 mg glepaglutide administered either once or twice weekly, or placebo. The primary endpoint in the trial was the absolute change in weekly parenteral support volume from baseline at 24 weeks.

In EASE-1, glepaglutide given twice weekly significantly reduced the total weekly volume of parenteral support at 24 weeks as compared to placebo ( $p=0.0039$ ). When administered once weekly, glepaglutide treatment also resulted in a numeric reduction in weekly parenteral support, however this did not achieve statistical significance. At 24 weeks, the average reduction in parenteral support from baseline was 5.13 Liters/week for patients treated with glepaglutide twice weekly and was 3.13 Liters/week for patients treated with glepaglutide once weekly. Placebo treatment resulted in a reduction in parenteral support of 2.85 Liters/week. Clinical response, defined as a patient

achieving at least 20% reduction in weekly parenteral support volume from baseline at both 20 and 24 weeks, was significantly higher with twice weekly glepaglutide compared to placebo ( $p=0.0243$ ). Among patients receiving glepaglutide twice weekly, 65.7% achieved a clinical response, whereas 45.7% and 38.9% of patients achieved a clinical response in the once weekly and placebo treatment groups, respectively.

In the twice weekly dosing group, 14% of patients ( $n=5$ ) were completely weaned off parenteral support (enteral autonomy). In total, 9 patients treated with glepaglutide achieved enteral autonomy, while no placebo-treated patients were able to discontinue parenteral support. Glepaglutide appeared to be safe and was well-tolerated in the trial. The most frequently reported adverse events were injection site reactions and gastrointestinal events. These results were presented at the ASPEN 2023 Nutrition Science & Practice Conference in April 2023 and Digestive Diseases Week in May 2023.

In total, 102 of 106 participating patients completed EASE-1, of which 96 continued into the ongoing two-year, long-term safety and efficacy extension trial, EASE-2. EASE-2 is a randomized, double-blind trial in which SBS patients continued their assigned treatment from EASE-1 with glepaglutide 10 mg once or twice weekly. Patients who received placebo in EASE-1 were re-randomized to treatment with either glepaglutide 10 mg once or twice weekly. In an interim analysis conducted at six months, clinical response to glepaglutide across the key efficacy endpoints was generally maintained or showed continued improvement. Data also demonstrated that additional patients on both doses weaned off parenteral support successfully.

Patients who complete EASE-2 are eligible to participate in EASE-3, evaluating glepaglutide administered once weekly using an auto-injector. An interim analysis of EASE-3, conducted with the first 43 patients rolled over from EASE 2, showed that the reduction in prescribed PS was generally maintained.

Glepaglutide appeared to be safe and well-tolerated in EASE-2 and EASE-3, with a profile consistent with that observed in EASE-1. Both EASE-2 and EASE-3 long-term extension trials are ongoing.

In addition, EASE-4 is a Phase 3b trial to assess long-term effects of glepaglutide on intestinal fluid and energy uptake. Zealand has completed the interim analysis of the trial and expects to present results from this study at a future scientific conference.

For more information on the EASE trials, please visit ClinicalTrials.gov (IDs: [NCT03690206](#), [NCT03905707](#), [NCT04881825](#), [NCT04991311](#)).

The company expects efficacy and safety data from the full EASE Phase 3 program to form the basis of an NDA



submission with the FDA in the second half of 2023. FDA has granted orphan drug designation to glepaglutide for the treatment of SBS.

Phase 2 data have shown the potential of glepaglutide to increase intestinal absorption in people with SBS and were published in the journal *The Lancet Gastroenterology & Hepatology* in 2019.

## Obesity

### ZP8396 (long-acting amylin analog)

#### Second quarter 2023 update:

- Presentation of detailed results from Phase 1a SAD trial in healthy participants at ADA 83<sup>rd</sup> Scientific Sessions in June 2023, showing mean weight loss of 4.2% from baseline (4.8% placebo adjusted) with ZP8396 2.4 mg treatment.
- Announcement of topline results in July 2023 of the Phase 1b MAD trial Part 1, showing mean weight loss of 5.3% and 5.1% after administration once-weekly for six weeks of relatively low doses of 0.6 and 1.2 mg ZP8396 (placebo: 0.4% mean weight loss).
- Initiation of the 16-week Phase 1b MAD trial Part 2, exploring significantly higher doses of ZP8396 using a dose up-titration scheme.

#### Background:

ZP8396 is a long-acting amylin analog designed to improve solubility and allow for co-formulation with other peptides, including GLP-1 analogs. Amylin analogs hold potential as both mono and combination therapies for obesity and type 2 diabetes.

Zealand has completed a Phase 1a, first-in-human, randomized, single ascending dose (SAD) trial to assess the safety, tolerability, pharmacokinetics, and pharmacodynamics of ZP8396 in healthy volunteers (ClinicalTrials.gov ID: [NCT05096598](#)). Healthy participants with a mean BMI of 25.8 were randomized (6:2) within seven dose cohorts and treated with either subcutaneous ZP8396 or placebo. After one week, participants treated with ZP8396 had reductions in mean body weight of 2.6%, 3.6% and 4.2% from baseline following single doses of 0.7, 1.4 and 2.4 mg ZP8396. Body weight reductions were well-sustained during the additional five weeks of observation without further doses of ZP8396. Placebo-treated participants had a mean body weight increase of 0.6% after one week that continued to increase in most participants during the follow-up period. The plasma half-life of ZP8396 was 230 hours, or approximately 10 days, which supports once-weekly dose administration. ZP8396 was well tolerated in this study, with no serious or severe adverse

events (AEs) and no withdrawals. The detailed results were presented at the ADA 83<sup>rd</sup> Scientific Sessions in June 2023.

Zealand is conducting a Phase 1b, randomized, multiple ascending dose (MAD) clinical trial of ZP8396 in normal weight and overweight healthy participants (ClinicalTrials.gov ID: [NCT05613387](#)). The MAD trial consists of Part 1 and Part 2. Part 1 includes 20 participants receiving six once-weekly subcutaneous doses of ZP8396 or placebo. Part 2 includes 48 participants receiving 16 once-weekly doses of ZP8396 or placebo using a dose up-titration scheme. In July 2023, Zealand reported topline results from the 6-week MAD trial Part 1. Low doses of 0.6 mg and 1.2 mg ZP8396 administered once-weekly for six weeks led to 5.3% and 5.1% mean weight loss from baseline. In the 6-week trial, ZP8396 was judged to be well tolerated, with no serious or severe AEs and no withdrawals. The most common AEs were related to the gastrointestinal system, were all mild and most occurred within two days of the first dose. Based on the mild adverse event profile, Zealand has initiated Part 2 of the MAD trial, exploring significantly higher doses of ZP8396 using a dose up-titration scheme, and expects results from the 16-week study in the first half of 2024.

### Dapiglutide (long-acting GLP-1R/GLP-2R dual agonist)

#### Second quarter 2023 update:

- Initiation of a Phase 2 investigator-led clinical trial in collaboration with Zealand in people with obesity (DREAM).

#### Background:

Dapiglutide is a long-acting dual GLP-1R/GLP-2R agonist for the potential treatment of obesity. Phase 1 results of dapiglutide in healthy volunteers demonstrated dose-dependent weight loss of up to 4.3% from baseline body weight after only four weeks of treatment. Dapiglutide also delayed gastric emptying, and reduced plasma glucose and insulin concentrations, in a dose-dependent manner. The pharmacokinetics (PK) showed dose proportionality with a low inter-subject variability and a mean half-life of 123-129 hours across the four dose cohorts and supported that dapiglutide is suitable for once-weekly dosing. No trial participants developed anti-drug antibodies. Multiple weekly doses of dapiglutide were well-tolerated and the safety profile was as expected for GLP-1 and GLP-2 receptor agonists. These results were presented at the ADA 82<sup>nd</sup> Scientific Sessions in June 2022.

A Phase 2 investigator-led randomized, double-blind, placebo-controlled clinical trial in up to 54 people living with overweight and obesity, named DREAM, aims to evaluate the potential for weight loss and gain key mechanistic insights into the effects of dapiglutide on inflammatory markers following a 12-week treatment period. Zealand

expects topline results from the trial in the first half of 2024. Please visit [ClinicalTrials.gov](https://ClinicalTrials.gov) for further information (ID: [NCT05788601](https://ClinicalTrials.gov/record/NCT05788601)).

Separately, Zealand expects to initiate a 13-week dose titration trial in people with obesity in the second half of 2023.

### **Survodutide (long-acting dual GCGR/GLP-1R agonist) in collaboration with Boehringer Ingelheim**

#### **Second quarter 2023 update:**

- Presentation of detailed results from the Boehringer Ingelheim-sponsored Phase 2 clinical trial in people living with overweight or obesity at the ADA 83<sup>rd</sup> Scientific Sessions in June 2023, showing dose-dependent reductions in body weight of up to 18.7% at Week 46.
- Announcement by Boehringer Ingelheim in August 2023 of decision to advance survodutide to Phase 3 development in people living with overweight or obesity, expected to be initiated in the second half of 2023.

#### **Background:**

Survodutide (formerly BI 456906) is a long-acting dual GCGR/GLP-1R agonist for once-weekly subcutaneous administration that activates two key gut hormone receptors simultaneously and may offer better efficacy than current single-hormone receptor agonist treatments. Survodutide is targeting the treatment of obesity and associated metabolic diseases.

A Phase 2 randomized, placebo-controlled, double-blind, trial evaluated survodutide compared to placebo in people with overweight or obesity ([ClinicalTrials.gov ID: NCT04667377](https://ClinicalTrials.gov/record/NCT04667377)). Participants received multiple rising doses of survodutide in one of four dose groups or placebo and included 20 weeks of dose escalation and 26 weeks of maintenance. Based on the planned maintenance dose assigned at randomization regardless of whether the planned dose was reached during the dose escalation phase, survodutide achieved up to 14.9% mean weight loss from baseline after 46 weeks. An analysis based on the actual maintenance dose regardless of assignment at randomization, showed up to 18.7% mean weight loss after 46 weeks. Bodyweight reductions with survodutide had not reached a plateau at week 46, suggesting additional weight loss could be achieved with longer treatment duration. Up to 40% of people who reached the highest two doses of survodutide, 3.6 mg and 4.8 mg, achieved a weight loss of at least 20%.

Serious adverse events were reported by 4.2% of participants on survodutide versus 6.5% of those on placebo. Treatment discontinuation due to adverse events occurred in 24.6% and 3.9% of participants on survodutide and placebo,

respectively, mainly due to gastrointestinal adverse events. Most treatment discontinuations due to adverse events occurred during the rapid 20-week dose-escalation phase with up-titration every second week. Thus, the safety and tolerability profile of survodutide was in line with other incretin-based pharmacotherapies. The treatment discontinuation rate of survodutide was also roughly similar to the treatment discontinuation rates seen with other incretin-based pharmacotherapies in previous Phase 2 studies in type 2 diabetes (T2D) and obesity. Boehringer Ingelheim and Zealand Pharma expect that treatment discontinuations due to adverse events can be mitigated with more gradual dose escalation over a longer duration in Phase 3. The detailed results from the Phase 2 trial were presented at the ADA 83<sup>rd</sup> Scientific Sessions in June 2023.

Boehringer Ingelheim announced on August 17, 2023 plans to advance survodutide to Phase 3 in people living with overweight or obesity, with further details on the trials to be disclosed prior to their initiation.

A Phase 2 randomized, placebo-controlled, double-blind trial evaluated survodutide in people with T2D on stable metformin background therapy ([ClinicalTrials.gov ID: NCT04153929](https://ClinicalTrials.gov/record/NCT04153929)). Participants received multiple rising doses of survodutide in one of six dose groups, placebo or open-label weekly semaglutide 1.0 mg for 16 weeks. Different doses of survodutide were escalated every 1–2 weeks to ensure that 10 weeks were spent on a maintenance dose.

At the 58th EASD annual meeting in September 2022, Boehringer Ingelheim presented results for the primary endpoint of change from baseline in HbA1c after 16 weeks of treatment. Treatment with survodutide led to dose-dependent decreases in HbA1c, with mean reductions of -0.93% to -1.88% at 16 weeks across the six dose groups, compared with -0.25% seen with placebo. Treatment with open-label weekly semaglutide at 1.0 mg led to a decrease in HbA1c of -1.47%.

A third Phase 2 trial is assessing survodutide in non-alcoholic steatohepatitis, or NASH ([ClinicalTrials.gov ID: NCT04771273](https://ClinicalTrials.gov/record/NCT04771273)). The NASH program has received Fast Track Designation from the US FDA. In people living with overweight and obesity, it is estimated that 75% have nonalcoholic fatty liver disease (NAFLD) and 34% have NASH. Boehringer Ingelheim and Zealand Pharma expect to report topline results from the Phase 2 trial with survodutide in NASH in the first half of 2024.

Survodutide was co-invented by Boehringer Ingelheim and Zealand. Boehringer Ingelheim is funding all research, development and commercialization activities related to survodutide. Zealand is eligible to receive up to EUR 345 million in outstanding milestone payments and high-single to low-double digit royalties on global sales.



## Type 1 Diabetes Management

### Dasiglucagon for Bihormonal Artificial Pancreas systems

#### Background:

Zealand is developing a pre-filled dasiglucagon cartridge intended for use in Bihormonal Artificial Pancreas systems, which hold potential to improve the management of type 1 diabetes (T1D). Zealand is collaborating with Beta Bionics, developer of the Bihormonal iLet® Bionic Pancreas (iLet Duo™), a pocket-sized, dual chamber (insulin and glucagon), autonomous, glycemic control system. The iLet Duo™ is an investigational device, limited by federal (or United States) law to investigational use only. The iLet® Bionic Pancreas platform is designed to use adaptive, self-learning, control algorithms, together with continuous glucose monitoring and pump technology, to autonomously compute and administer doses of insulin and/or glucagon and mimic the body's natural ability to maintain tight glycemic control.

Zealand anticipates that Beta Bionics will begin the Phase 3 Bihormonal iLet® Bionic Pancreas Pivotal Program in the second half of 2023. The Phase 3 program consists of three planned studies designed to support the marketing applications for the iLet Duo and an NDA for the use of dasiglucagon in Bihormonal Artificial Pancreas systems for the treatment of T1D. The pivotal study plan includes an initial crossover trial of approximately 60 participants to assess safety and efficacy of the bihormonal and insulin-only configurations of the iLet® Bionic Pancreas. Subsequently, the companies plan to initiate full-scale, randomized, controlled pivotal trials in 350 adult and 350 pediatric participants with T1D to assess the efficacy of the iLet Duo™ as compared to the insulin-only system.

### Dasiglucagon mini-dose pen

#### Background:

Zealand is developing a dasiglucagon mini-dose pen for the potential treatment of exercise-induced hypoglycemia in people living with T1D and for people who suffer from meal-induced hypoglycemia following gastric bypass surgery (post bariatric hypoglycemia, or PBH). Four investigator-initiated trials conducted in collaboration with Zealand evaluated mini-dose dasiglucagon to support this development program.

Investigators from the Steno Diabetes Center Copenhagen conducted a Phase 2 trial using the dasiglucagon mini-dose pen in people with T1D in free-living conditions (ClinicalTrials.gov ID: [NCT04764968](#)). The trial results were published online in April 2023 in the journal *Diabetologia* and showed that dasiglucagon administered by pen improved glycemic control and reduced carbohydrate intake among the study participants. These data build on two prior clinical studies conducted in hospital settings with

results that show the potential for using low doses of dasiglucagon to correct moderate hypoglycemia: a Phase 2a dose-finding trial in people with T1D (ClinicalTrials.gov ID: [NCT04449692](#)) presented at the ADA Scientific Sessions in 2021, and a Phase 2a trial in PBH (ClinicalTrials.gov ID: [NCT03984370](#)) published in the journal *Diabetes Care* in 2022.

A Phase 2 trial in PBH conducted in an out-patient setting (ClinicalTrials.gov ID: [NCT04836273](#)) has been completed and met the primary endpoint.

### Inflammation

Zealand is pursuing multiple pre-clinical programs in inflammatory diseases which will be detailed more as they progress through development.

### Complement inhibitors (collaboration with Alexion, AstraZeneca Rare Disease)

Zealand and Alexion are collaborating 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, ZP10068, is an investigational 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 pre-clinical stage, and Alexion will lead development efforts beginning with Investigational New Drug (IND) filing and Phase 1 trials. In 2023, Zealand expects to complete activities to support advancing ZP10068 into clinical studies. Subsequent regulatory, clinical, and development efforts will be led and conducted by Alexion.

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 USD 15 million upfront per target plus potential development/regulatory milestones for each target selected similar to the lead target with slightly reduced commercial milestones and royalties.

# Financial highlights and key figures.

<b>Financial highlights (DKK thousand)</b>	<b>Note</b>	<b>Q2-23</b>	<b>Q2-22*</b>	<b>H1-23</b>	<b>H1-22*</b>
<b>Revenue</b>	2	<b>10,407</b>	<b>25,390</b>	<b>24,036</b>	<b>36,347</b>
Research and development expenses		-155,564	-151,359	-297,827	-306,912
Sales and marketing expenses		-7,135	-10,470	-11,751	-22,478
Administrative expenses		-48,275	-70,337	-90,759	-123,052
Net other operating items	3	5,202	1,715	12,263	-18,013
<b>Net operating expenses</b>		<b>-205,773</b>	<b>-230,451</b>	<b>-388,074</b>	<b>-470,455</b>
Net financial items	4	-125,684	-194,873	-152,334	-61,839
<b>Result before tax</b>		<b>-321,050</b>	<b>-399,934</b>	<b>-516,373</b>	<b>-495,947</b>
Corporate tax		1,548	2,306	3,239	3,280
<b>Net result for the period from continuing operations</b>		<b>-319,502</b>	<b>-397,628</b>	<b>-513,134</b>	<b>-492,667</b>
Net result for the period from discontinued operations		-	-90,872	-	-218,678
<b>Net result for the period</b>		<b>-319,502</b>	<b>-488,500</b>	<b>-513,134</b>	<b>-711,345</b>
Earnings/loss per share from continuing operations - basic/diluted (DKK)		-5.50	-9.77	-9.36	-14.03
				<b>Jun-30, 2023</b>	<b>Dec-31, 2022</b>
<b>Statement of financial position (DKK thousand)</b>	<b>Note</b>				
Cash, cash equivalents and marketable securities				1,692,374	1,177,845
Total assets				2,049,678	1,539,806
Total shareholders' equity				1,727,435	815,911
				<b>H1-23</b>	<b>H1-22</b>
<b>Cash flow (DKK thousand)</b>	<b>Note</b>				
Undrawn borrowing facilities	(1)			350,000	-
Cash (used in)/provided by operating activities				-372,480	-543,920
Cash (used in)/provided by investing activities				-1,260,893	101,399
Cash (used in)/provided by financing activities				897,384	-154,942
Purchase of property, plant and equipment				-3,686	-4,759
Free cash flow	(2)			-376,166	-548,679
				<b>Jun-30, 2023</b>	<b>Dec-31, 2022</b>
<b>Other</b>	<b>Note</b>				
Share price (DKK)				244.6	201.4
Number of shares ('000 shares)				58,642	51,702
Market capitalization (MDKK)	(2)			14,251	9,305
Equity ratio (%)	(2)			84%	53%
Equity per share (DKK)	(2)			29.65	17.66
Average number of full time employees				221	247
Number of full-time employees at the end of period				236	196

\* Comparatives numbers for Q2 and H1 2022 are adjusted to reflect the effect of discontinued operations. For further details refer to note 2.8 in the 2022 Annual Report.

1) In May 2023, Zealand entered a new DKK 350 million revolving credit facility provided by Danske Bank as refinancing following the repayment of the Oberland loan, refer to note 6.

2) For basis of calculation refer to 2022 Annual Report p. 110.

# Financial Review.

- Net operating expenses in H1 of DKK -388 million are mainly driven by the progression of the late-stage rare disease assets and the obesity pipeline.
- Financial items in H1 2023 of DKK -152 million mainly represent costs associated with the final repayment and termination of the loan with Oberland Capital.
- Runway to mid-2026 following the directed issue and private placement in April 2023 bringing in gross proceeds of DKK 1.5 billion.

## Revenue

Revenue in H1 2023 of DKK 24 million is mainly driven by the license and development agreement for Zegalogue® with Novo Nordisk A/S, signed in September 2022.

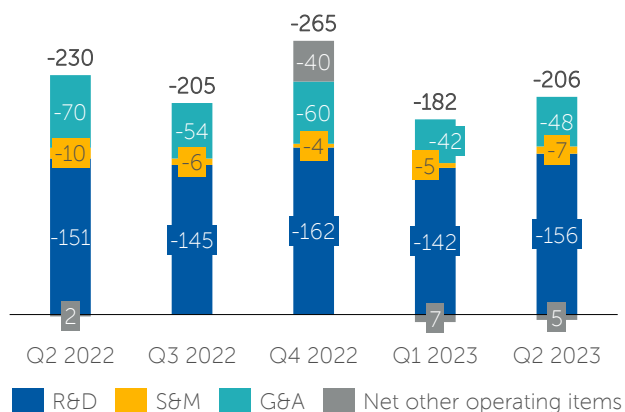
## Net operating expenses

Research and development expenses in H1 2023 of DKK -298 million are mainly driven by the progression of the late-stage rare disease assets and the obesity pipeline. The spend is slightly below H1 2022 due to timing of clinical activities.

Selling and marketing expenses of DKK -12 million and administrative expenses of DKK -91 million in H1 2023 are significantly below H1 2022 due to cost reduction efforts following the announced restructuring on March 30, 2022.

Net other operating items of DKK 12 million in H1 2023 are related to a reversal of inventory write-down associated with Zegalogue®.

**OPEX by quarter**  
DKK million



## Financial items

Financial items in H1 2023 of DKK -152 million are mainly driven by the final repayment and termination of the loan with Oberland Capital in May 2023. Interest expenses and banking fees in H1 2023 of DKK -20 million, mainly related to interest payments on the now terminated Oberland loan agreement, are partly offset by interest income of DKK 18 million related to the funds from the Oberland loan, which were placed on an investment account and interest on marketable securities.

In H1 2023, the investment in Beta Bionics was subject to a fair value adjustment of DKK -15 million.

## Equity

On June 30, 2023, equity was DKK 1,724 million, reflecting a significant increase compared to June 30, 2022, mainly driven by the proceeds from the directed issue and private placement of new shares in April 2023 and partly offset by the loss for the period.

## Cash position

Cash, cash equivalents and marketable securities as of June 30, 2023 was DKK 1.7 billion and DKK 2.0 billion including a DKK 350 million new Revolving Credit Facility provided by Danske Bank, reflecting a significant increase compared to the DKK 1.2 billion in cash position as of December 31, 2022. This development in the first half of 2023 is mainly driven by the DKK 1.5 billion in gross proceeds from the directed issue and private placement of new shares in April 2023 and partly offset by cash used in operating activities during the period (DKK -372 million) and repayment of the Oberland loan (DKK -526 million).

The final repayment and termination of the loan agreement with Oberland Capital in May 2023 was refinanced through a new Revolving Credit Facility provided by Danske Bank and expected near-term upcoming milestones from existing partners. For further information on the capital increase in April, repayment of the Oberland loan in May, and the new Revolving Credit Facility, please refer to note 6.

Zealand expects the new funds to provide cash runway to mid-2026 and expects to advance the clinical pipeline and as such reach several potential key milestones within this timeframe.

Zealand's cash is intended to:

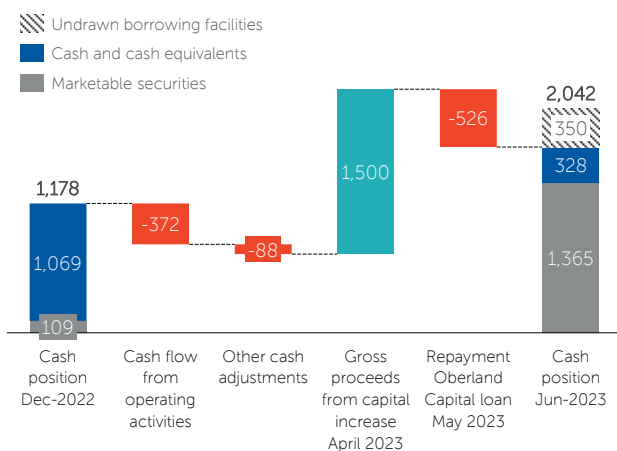
- Support the remaining late-stage rare disease assets, and pursue a strong strategic partner for future commercialization

- Advance the clinical-stage candidates, including the obesity/metabolic disease portfolio that includes the clinical-stage GLP-1/GLP-2 dual agonist dapiglutide, the amylin analog ZP8396, and the non-clinical stage GIP analog ZP6590
- Progress additional peptide candidates from non-clinical development into early clinical development
- Continue the early discovery and research to develop additional peptide candidates
- Strengthen the Zealand's capital base and cash preparedness (general corporate purposes)

On March 12, 2023, Zealand provided a statement on the closure of Silicon Valley Bank (SVB). On closure, Zealand's cash deposits in SVB were DKK 162.6 million, however the closure eventually had no impact as all depositors were granted access to their money from March 13. In the light of this event, Zealand has implemented an even higher diversification in its management of funds.

### Cash position compared to FY22

DKK million



### Events after the reporting date

On August 17, 2023 Boehringer Ingelheim announced their decision to advance to Phase 3 in people living with overweight or obesity with initiation expected in the second half of 2023. Zealand is eligible to receive a one-time milestone payment upon Phase 3 initiation.

### Outlook for the year

There are no changes to the outlook for the year and guidance is confirmed. Net operating expenses for the year are still expected between DKK 800-900 million. For further information refer to p. 10 in the 2022 Annual Report.

# Interim financial statements.

## Unaudited interim condensed consolidated financial statements H1 2023:

Interim income statement for H1, 2023 .....	5
Interim statement of comprehensive loss for H1, 2023 .....	6
Interim statements of financial position as of H1, 2023 .....	7
Interim statements of cash flow for H1, 2023.....	8
Interim statements of changes in equity as of H1, 2023 .....	9
Notes to the interim condensed consolidated financial statements.....	10
1. Basis of preparation and changes to the Group's accounting policies .....	10
2. Revenue .....	11
3. Net other operating items .....	11
4. Net financial items.....	12
5. Inventory .....	12
6. Financial instruments.....	13
7. Cash and cash equivalents .....	14
8. Share capital.....	14
9. Capital Management .....	15
10. Contingent assets and liabilities .....	15
11. Significant events after the reporting period .....	15
Statement by the Executive Management and the Board of Directors .....	16
Independent auditor's report.....	17



# Interim income statement for H1, 2023.

DKK thousand	Note	Q2-23 (reviewed)	Q2-22* (reviewed)	H1-23 (reviewed)	H1-22* (reviewed)
<b>Revenue</b>	2	<b>10,407</b>	<b>25,390</b>	<b>24,036</b>	<b>36,347</b>
Research and development expenses		-155,564	-151,359	-297,827	-306,912
Sales and marketing expenses		-7,135	-10,470	-11,751	-22,478
Administrative expenses		-48,275	-70,337	-90,759	-123,052
Net other operating items	3	5,202	1,715	12,263	-18,013
<b>Net operating expenses</b>		<b>-205,773</b>	<b>-230,451</b>	<b>-388,074</b>	<b>-470,455</b>
<b>Operating result (EBIT)</b>		<b>-195,365</b>	<b>-205,061</b>	<b>-364,039</b>	<b>-434,108</b>
Financial income	4	11,760	-41,614	19,197	111,891
Financial expenses	4	-137,445	-153,259	-171,531	-173,730
<b>Result before tax</b>		<b>-321,050</b>	<b>-399,934</b>	<b>-516,373</b>	<b>-495,947</b>
Corporate tax		1,548	2,306	3,239	3,280
<b>Net result for the period from continuing operations</b>		<b>-319,502</b>	<b>-397,628</b>	<b>-513,134</b>	<b>-492,667</b>
Net result for the period from discontinued operations*		-	-90,872	-	-218,678
<b>Net result for the period</b>		<b>-319,502</b>	<b>-488,500</b>	<b>-513,134</b>	<b>-711,345</b>
Earnings/loss per share from continuing operations -		-5.50	-9.77	-9.36	-14.03
Earnings/loss per share from discontinued operations -		-	-1.27	-	-2.24
Earnings/loss per share - basic/diluted (DKK)		-5.50	-11.04	-9.36	-16.27

\* Comparatives numbers for Q2 and H1 2022 are adjusted to reflect the effect of discontinued operations. For further details refer to note 2.8 in the 2022 Annual Report.

# Interim statement of comprehensive loss for H1, 2023.

DKK thousand	Note	Q2-23 (reviewed)	Q2-22 (reviewed)	H1-23 (reviewed)	H1-22 (reviewed)
Net result for the period		-319,502	-488,500	-513,134	-711,345
Other comprehensive income					
<i>Items that will be reclassified to income statement when certain conditions are met (net of tax):</i>					
Exchange differences on translation of foreign operations		-26	2,861	3,759	4,887
<b>Total comprehensive result for the period</b>		<b>-319,528</b>	<b>-485,639</b>	<b>-509,374</b>	<b>-706,458</b>

# Interim statements of financial position as of H1, 2023.

DKK thousand	Note	Jun-30, 2023	Dec-31, 2022
<b>Assets</b>		(reviewed)	(audited)
Property, plant and equipment		48,819	50,528
Right-of-use assets		108,432	114,960
Other investments	6	16,194	30,943
Corporate tax receivable		2,750	-
Deferred tax assets		1,983	2,017
Other receivables		20,499	18,105
Other financial assets	6	7,131	6,901
<b>Total non-current assets</b>		<b>205,808</b>	<b>223,454</b>
Inventory	5	12,823	1,286
Trade and other receivables		117,077	115,622
Corporate tax receivable		21,596	21,599
Marketable securities	6,7	1,364,688	108,611
Cash and cash equivalents	7	327,686	1,069,234
<b>Total current assets</b>		<b>1,843,870</b>	<b>1,316,352</b>
<b>Total assets</b>		<b>2,049,678</b>	<b>1,539,806</b>
<b>Shareholders equity and liabilities</b>			
Share capital	8	58,642	51,702
Currency translation reserve		18,376	14,617
Retained earnings		1,650,417	749,592
<b>Total shareholders' equity</b>		<b>1,727,435</b>	<b>815,911</b>
Other payables		19,058	19,058
Borrowings including embedded derivatives	6	-	401,346
Lease liabilities		102,074	108,000
<b>Total non-current liabilities</b>		<b>121,132</b>	<b>528,404</b>
Lease liabilities		14,787	14,729
Trade and other payables		186,324	180,762
<b>Total current liabilities</b>		<b>201,111</b>	<b>195,491</b>
<b>Total liabilities</b>		<b>322,243</b>	<b>723,895</b>
<b>Total shareholders' equity and liabilities</b>		<b>2,049,678</b>	<b>1,539,806</b>

# Interim statements of cash flow for H1, 2023.

DKK thousand	Note	H1-23 (reviewed)	H1-22 (reviewed)
Net result for the period		-513,134	-711,345
Adjustment for other non-cash items		180,147	106,683
Changes in working capital		-35,053	77,929
Financial income received		15,665	1,226
Financial expenses paid		-20,341	-17,713
Corporate taxes paid/received		236	-700
<b>Cash flow from/(used in) operating activities</b>		<b>-372,480</b>	<b>-543,920</b>
Proceeds from sale of marketable securities		204,744	673,995
Purchase of marketable securities	6	-1,461,951	-672,449
Purchase of property, plant and equipment		-3,686	-4,759
Divestment of activities		-	104,852
Change in deposits		-	-240
<b>Cash flow from/(used in) investing activities</b>		<b>-1,260,893</b>	<b>101,399</b>
Repayment of borrowings	6	-525,764	-417,340
Lease installments		-6,351	-4,225
Proceeds from issuance of shares	8	1,500,000	274,776
Purchase of treasury shares	8	-41,600	-
Proceeds from issuance of shares related to exercise of share-based compensation	8	42,422	-
Costs related to issuance of shares		-71,323	-8,153
<b>Cash flow from/(used in) financing activities</b>		<b>897,384</b>	<b>-154,942</b>
<b>(Decrease)/increase in cash and cash equivalents</b>		<b>-735,989</b>	<b>-597,463</b>
Cash and cash equivalents at beginning of period		1,069,234	1,129,103
Exchange rate adjustments		-5,559	21,602
<b>Cash and cash equivalents at end of period</b>	7	<b>327,686</b>	<b>553,242</b>

# Interim statements of changes in equity as of H1, 2023.

DKK thousand	Share capital	Translation reserve	Retained earnings*	Total
<b>Shareholder's equity at Jan-1, 2023</b>	51,702	14,617	749,592	815,911
<i>Other comprehensive income for the period</i>	-	3,759	-	3,759
Net result for the period	-	-	-513,134	-513,134
Acquisition of treasury shares	-	-	-81,045	-81,045
Share-based compensation	-	-	30,935	30,935
Capital increase	6,940	-	1,535,392	1,542,332
Costs related to capital increase	-	-	-71,323	-71,323
<b>Shareholder's equity at Jun-30, 2023 (reviewed)</b>	<b>58,642</b>	<b>18,376</b>	<b>1,650,417</b>	<b>1,727,435</b>
<b>Shareholder's equity at Jan-1, 2022</b>	<b>43,634</b>	<b>14,155</b>	<b>870,014</b>	<b>927,803</b>
<i>Other comprehensive income for the period</i>	-	4,887	-	4,887
Net result for the period	-	-	-711,345	-711,345
Share-based compensation	-	-	16,979	16,979
Capital increase	2,893	-	271,883	274,776
Costs related to capital increase	-	-	-8,153	-8,153
<b>Shareholder's equity at Jun-30, 2022 (reviewed)</b>	<b>46,527</b>	<b>19,042</b>	<b>439,378</b>	<b>504,947</b>

\*Treasury shares, Share premium, Warrant compensation expenses and Retained losses have been merged into the column Retained earnings to ease accessibility of information.



# Notes to the interim condensed consolidated financial statements.

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

### Basis of preparation

The interim condensed consolidated financial statements of Zealand Pharma A/S (The Group) have been prepared in accordance with IAS 34, Interim Financial Reporting, 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 Group's annual financial statement for the year ended December 31, 2022.

### Going concern assessment

Management's judgement and assessment of the Group's ability to continue as a going concern includes evaluation of the Group's operational cash flow requirements for the forthcoming 12 months from the balance sheet date and future sources and uses of cash. Following the capital increase completed in April 2023 the Group received gross proceeds of DKK 1.5 billion. On this basis the interim condensed consolidated financial statements are prepared using the going concern assumption.

### New standards, interpretations and amendments adopted by the Group

Several amendments apply for the first time in 2023, but do not have an impact on the interim condensed consolidated financial statements of the Group. The Group has not early adopted any standard, interpretation or amendment that has been issued but is not yet effective.

### Significant accounting estimates and judgements

The preparation of the interim condensed consolidated financial statements requires Management to make judgments and estimates that affect the reported amounts of revenues, expenses, assets and liabilities, and the accompanying disclosures. In applying our accounting policies, Management is required to make judgements and estimates 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 to be reasonable by Management. However, estimates are inherently uncertain and unpredictable. The assumptions may be incomplete or inaccurate, and unexpected events or circumstances may occur. Furthermore, we are subject to risks and uncertainties that may result in deviations in actual results compared with estimates.

Except for the items listed below, no material changes in significant accounting estimates and judgements have occurred since the Annual Report 2022. Please refer to note 1.4 in the 2022 Annual Report for further information:

- Estimate of net realizable value of Zegalogue<sup>®</sup> raw materials (Inventory). Refer to note 5.
- Estimate of fair value on investment in Beta Bionics (Other investments). Refer to note 6.
- Estimate of fair value of Oberland's call option for repayment of loan (Borrowings including embedded derivatives). Refer to note 6.
- Judgement in assessing operational cash-flow and capital requirements for the forthcoming 12 months from the balance sheet date. Refer to the going concern assessment above.

## 2. Revenue

Revenue can be specified as follows:

DKK thousand	Q2-23 (reviewed)	Q2-22* (reviewed)	H1-23 (reviewed)	H1-22* (reviewed)
Alexion Pharmaceuticals Inc.	914	25,390	2,704	36,346
Novo Nordisk A/S	9,493	-	21,332	-
<b>Total revenue from license and collaboration agreements</b>	<b>10,407</b>	<b>25,390</b>	<b>24,036</b>	<b>36,346</b>
Total sale of goods revenue net	-	24,816	-	64,647
- Hereof related to discontinued operations	-	-24,816	-	-64,647
<b>Sale of goods revenue from continuing operations</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>Total revenue from continuing operations</b>	<b>10,407</b>	<b>25,390</b>	<b>24,036</b>	<b>36,346</b>
Total revenue recognized over time	10,407	25,390	24,036	36,346
Total revenue recognized at a point in time from discontinued operations	-	24,816	-	64,647

\* Comparatives numbers for Q2 and H1 2022 are adjusted to reflect the effect of discontinued operations. For further details refer to note 2.8 in the 2022 Annual Report.

## 3. Net other operating items

Net other operating items can be specified as follows:

DKK thousand	Q2-23 (reviewed)	Q2-22 (reviewed)	H1-23 (reviewed)	H1-22 (reviewed)
Proceeds from insurance claims	-	1,849	-	1,849
Restructuring costs	-	-134	-	-19,120
Loss on sale of fixed assets	-	-	-	-742
Reversal of inventory write-down	5,202	-	12,263	-
<b>Net other operating items in total</b>	<b>5,202</b>	<b>1,715</b>	<b>12,263</b>	<b>-18,013</b>

All restructuring costs in Q2 and H1 2022 were incurred as a result of the March 30, 2022, company announcement on refocused strategy.

As of June 30, 2023 management has estimated the net realizable value of raw materials to be DKK 12.8 million as all materials are expected to be utilized in the production under the supply agreement with Novo Nordisk, and therefore a reversal of inventory write-down of DKK 12.3 million has been made in H1, 2023 of which DKK 5.2 million relates to Q2, 2023. Reference is made to note 5.

#### 4. Net financial items

Financial items include interests, as well as foreign exchange rate adjustments, fair value adjustments of other investments, embedded derivatives and marketable securities and dividends from marketable securities.

<b>DKK thousand</b>	<b>Q2-23</b> (reviewed)	<b>Q2-22</b> (reviewed)	<b>H1-23</b> (reviewed)	<b>H1-22</b> (reviewed)
Interest income	13,038	1,684	17,747	1,684
Interest expenses and banking fees	-8,653	-7,518	-20,446	-26,355
Loss on settlement of borrowings, including embedded derivatives under Oberland loan	-135,588	-144,729	-135,588	-144,729
Fair value adjustment of lender's call option	-1,128	-	1,161	-
Fair value adjustment of prepayment option	-	-71,050	-	71,050
Fair value adjustment of marketable securities	-100	-1,013	289	-2,646
Fair value adjustment of other investments	229	-	-14,519	2,259
Fair value adjustment of other financial assets	-50	-	-	-
Amortization of loan costs	-287	-	-943	-
Exchange rate adjustments	6,854	27,753	-35	36,898
<b>Financial items in total</b>	<b>-125,685</b>	<b>-194,873</b>	<b>-152,334</b>	<b>-61,839</b>
<b>Presentation in income statement:</b>				
Financial income	11,760	-41,614	19,197	111,891
Financial expenses	-137,445	-153,259	-171,531	-173,730

Interest income mainly comprise interest related to the USD 50 million from the Oberland loan which was placed on an investment account and interest on marketable securities.

Interest expenses and banking fees mainly consists of interest payments due to the loan agreement with Oberland.

Loss on settlement of borrowings relates to the settlement of the Oberland loan on May 10, 2023. Fair value adjustment of lender call option (embedded derivative) relates to the value adjustments of Oberland's option to call for repayment of the loan under certain conditions. Please refer to note 6 for further information.

Fair value adjustment on other investments comprises the accounting impact of the investment in Beta Bionics as described in note 6.

Exchange rate adjustments primarily relates to USD deposits.

#### 5. Inventory

In Q1 and Q2, 2023 a reversal of Zegalogue® inventory write-down has been made as the raw materials are expected to be utilized under the license and development agreement with Novo Nordisk. The adjustments affect net other operating items in H1, 2023 by DKK 12.3 million of which DKK 5.2 million relates to Q2, 2023, see note 3.

For further information regarding significant accounting estimates and judgements, refer to note 1.4 in the 2022 Annual Report.

## 6. Financial instruments

As of June 30, 2023, and December 31, 2022, the following financial instruments are measured at fair value through profit or loss. The fair value of marketable securities is measured using inputs categorized as Level 1 and 2 in the fair value hierarchy, whereas the other investments and other financial assets is based on inputs categorized as Level 3 in the fair value hierarchy. Embedded derivatives is measured using inputs categorized as Level 3 in the fair value hierarchy.

No transfers occurred between the levels of the fair value hierarchy in the six months ending 30 June 2023.

DKK thousand	Jun-30, 2023 (reviewed)	Dec-31, 2022 (audited)
<b>Assets measured at fair value:</b>		
Marketable securities (Level 1)	1,146,383	-
Marketable securities (Level 2)	218,305	108,611
Other investments (Level 3)	16,194	30,943
Other financial assets (Level 3)	7,131	6,901
<b>Financial assets measured at fair value through profit and loss</b>	<b>1,388,013</b>	<b>146,455</b>
<b>Liabilities measured at fair value:</b>		
Embedded derivatives, lender's call option (Level 3)	-	80,603
<b>Financial liabilities measured at fair value through profit and loss</b>	<b>-</b>	<b>80,603</b>
	<b>Financial assets (Level 3)</b>	<b>Financial liabilities (Level 3)</b>
<b>Carrying amount at start of period</b>	<b>37,844</b>	<b>80,603</b>
Fair value adjustments through profit and loss	-14,519	-1,161
Exchange rate effect through other comprehensive income	-	-1,916
Derecognition of call option on settlement of Oberland Capital loan	-	-77,526
<b>Carrying amount at end of period</b>	<b>23,325</b>	<b>-</b>

### Investment in marketable securities

As of June 30, 2023 Zealand has placed DKK 1,365 million into low risk marketable securities in line with the Group's treasury policy.

### Fair value measurement of other investments

Other investments consist of an 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 considers the value per share from the most recent closed financing round, adjusted for valuation infliction points through the balance sheet date, including (i) discount for lack of marketability, (ii) information obtained from third party valuation reports, and (iii) company announcements.

Fair value of the investment amounted to DKK 16.2 million as of 30 June, 2023 (DKK 30.9 million as of December 31, 2022). The fair value adjustment of DKK -14.5 million in H1, 2023 is included in financial items off which DKK 0.2 million relates to Q2, 2023, see note 4.

### Fair value measurement of lender's call option (Oberland Capital loan)

Fair value of the lender call option is determined as the difference between the present value of the probability weighted contractual cash flow upon the occurrence of a call option trigger event and the present value of the contractual cash flows without a call option trigger event occurring, discounted at the expected internal rate of return of 14.3%. It is assumed that any

call option trigger event will result in full repayment of the loan. As of December 31, 2022, the likelihood of a lender call option trigger event within the next two years was assessed as realistic and fair value of the option was assessed to DKK 80.6 million. At the time of settlement on May 10, 2023, the fair value of the option amounted to DKK 77.5 million and is included in financial items under 'Loss on settlement of borrowings, including embedded derivatives under Oberland loan' in note 4. The fair value change, DKK 1.2 million, is included in financial items, while the effect of changes to the exchange rate, DKK 1.9 million, is included in other comprehensive income. Valuation is based on unobservable data (level 3).

#### Settlement of Oberland Capital loan

On April 20, 2023, Oberland Capital exercised an option in the loan agreement to provide an additional loan of USD 12.5 million on similar terms as the existing loan, bringing the total principal amount to USD 62.5 million. The additional loan of USD 12.5 million was not provided in cash.

On May 10, 2023, Zealand settled the Oberland Capital loans in a one-time payment of USD 77.3 million (DKK 525.7 million). With this final repayment, the Group's loan agreement with Oberland Capital is now fully terminated. As a result of the settlement Zealand in 2023 recognized a net loss of USD 19.9 million (DKK 135.6 million) under financial items, including derecognition of Oberland Capital's call option with a carrying value as of May 10, 2023, of USD 11.4 million (DKK 77.5 million).

With the final repayment, Oberland has released all rights to collateral provided for under the loan agreement.

#### Refinancing with new credit facility

The repayment of the Oberland Capital loan has been refinanced through a new DKK 350 million Revolving Credit Facility provided by Danske Bank. The facility matures in 2 years from June, 2023 where any outstanding amount must be repaid in full, and carries an interest of CIBOR + fixed margin.

#### Other fair value measurements

For information about fair value measurements of other financial assets and marketable securities, please refer to note 3.7 and 4.3 of the 2022 Annual Report.

## 7. Cash and cash equivalents

#### Restricted cash and cash equivalents

As of December 31, 2022, DKK 348.6 million was held as restricted cash subject to certain conditions following the second amendment to the Oberland loan agreement. With the final repayment of the Oberland loan agreement on May 10, 2023 all previous restrictions have been released. For further information, please refer to note 4.4 of the 2022 Annual Report.

#### Pledges provided in relation to revolving credit facility in Danske Bank

As security for the undrawn revolving credit facility of DKK 350 million, as disclosed in note 6, the Group has provided pledge over Zealand's designated custody accounts under management by Danske Asset Management and pledge over Zealand's designated cash accounts attached to the custody accounts. As of June 30, 2023 marketable securities and cash and cash equivalents held in these pledged accounts amount to DKK 446.0 million and DKK 3.8 million, respectively.

## 8. Share capital

	<b>Jun-30, 2023</b>	<b>Dec-31, 2022</b>
<b>DKK thousand</b>	(reviewed)	(audited)
<b>Share capital at January 1, 2023</b>	51,702	43,634
Shares issued for cash	6,579	7,867
Exercise of warrants	361	201
<b>Share capital at June 30, 2023</b>	<b>58,642</b>	<b>51,702</b>



Total new shares in H1, 2023 were issued at a weighed average subscription price of DKK 222.3.

New shares from exercise of warrants in H1, 2023 were issued at a weighed average subscription price of DKK 117.7. Total proceeds from exercise of share-based compensation amounts to DKK 42.4 million.

On March 30, 2023 Zealand announced an issue of 6,578,948 new ordinary shares at a subscription price of DKK 228 per new share resulting in gross proceeds of DKK 1.5 billion. The capital increase was completed in April 2023.

### **Treasury shares**

In Q2, 2023 the number of treasury shares has increased by 300,000 to a total of 378,633 treasury shares, equivalent to 0.6% of the share capital. The treasury shares are allocated to performance share units (PSUs) and restricted stock units (RSUs).

As of June 30, 2023 payable treasury shares amount to DKK 81.0 million included in trade and other payables. The payable amount as of December 31, 2022 of DKK 41.6 million has been settled and paid in full during H1, 2023.

### **Potential dilutive effects**

In the calculation of the diluted loss per share for H1, 2023 2,110,903 potential ordinary shares related to share-based payment instruments have been excluded as they are anti-dilutive (2,190,503 for 2022).

## **9. Capital Management**

The Group's capital management objectives and policies are unchanged from the ones described in the 2022 Annual Report. On March 12 and 13, 2023 the company provided statements on the closure of Silicon Valley Bank (SVB), and in the light of that line of events Zealand is seeking to achieve an even higher diversification in its management of funds. For further information refer to note 4.1 in the 2022 Annual Report.

On March 30, 2023 Zealand announced an issue of 6,578,948 new ordinary shares at a subscription price of DKK 228 per new share resulting in gross proceeds of DKK 1.5 billion. The capital increase was completed in April 2023.

On June 30, 2023 Zealand entered a new DKK 350 million Revolving Credit Facility provided by Danske Bank. The facility matures in 2 years from June, 2023 where any outstanding amount must be repaid in full, and carries an interest of CIBOR + fixed margin.

## **10. Contingent assets and liabilities**

Zealand is entitled to potential milestone payments and royalties on successful commercialization of products developed under license and collaboration agreements with partners. Since the size and timing of such payments are uncertain until the milestones are reached or sales are generated, the agreements may qualify as contingent assets. However, it is impossible to measure the value of contingent assets, and as such, no assets have been recognized.

As part of the license and collaboration agreements that Zealand has entered into, once a product is developed and commercialized, Zealand may be required to make milestone and royalty payments. It is not possible to measure the value of such future payments, but Zealand expects to generate future income from such products which will exceed any milestone and royalty payments due, and as such, no liabilities have been recognized. Refer to note 6.4 and 6.8 in the Annual Report 2022.

## **11. Significant events after the reporting period**

On August 17, 2023 Boehringer Ingelheim announced their decision to advance to Phase 3 in people living with overweight or obesity with initiation expected in the second half of 2023. Zealand is eligible to receive a one-time milestone payment upon Phase 3 initiation.

# Statement by the Executive Management and the Board of Directors

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, 2023.

The interim condensed consolidated financial statements are prepared in accordance with IAS 34 *Interim Financial Reporting* as adopted by the EU, and additional requirements of the Danish Financial Statements Act. In our opinion, the interim condensed consolidated financial statements give a true and fair view of the Group's assets,

equity and liabilities and financial position as of June 30, 2023 as well as of the results of the Group's operations and cash flow for the three- and six-month periods ended June 30, 2023.

Moreover, in our opinion, the Management's Review gives a fair view of the development in the Group'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, August 17, 2023*

## Management

### **Adam Sinding Steensberg**

President and  
Chief Executive Officer

### **Henriette Wennicke**

Executive Vice President and  
Chief Financial 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

### **Anneline Nansen**

Board member  
Employee elected

### **Iben Louise Gjelstrup**

Board member  
Employee elected

### **Jens Peter Stenvang**

Board member  
Employee elected

### **Frederik Barfoed 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- and six-month periods ended June 30, 2023, which comprise income statement and statement of comprehensive loss for the three- and six-month periods ended June 30, 2023, statement of financial position as of June 30, 2023, statement of cash flow and statement of changes in equity for the six-month period ended June 30, 2023, and notes, including accounting policies. The interim condensed consolidated financial statements are prepared in accordance with IAS 34 Interim Financial Reporting, 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 adopted by the EU, and additional requirements of the Danish Financial Statements Act and for such internal control as Management determines is necessary to enable the preparation of interim condensed consolidated financial statements that are free from material misstatement, whether due to fraud or error.

## Auditor's 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 adopted by the EU, and additional requirements of the Danish Financial Statements Act. This standard also requires us to comply with relevant 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 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 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 adopted by the EU, and additional requirements of the Danish Financial Statements Act.

*Copenhagen, August 17, 2023*

EY Godkendt Revisionspartnerselskab

Christian Schwenn Johansen  
State Authorized Public Accountant  
mne33234

Rasmus Bloch Jespersen  
State Authorized Public Accountant  
mne35503