

Zealand Pharma Announces Financial Results for the First Nine Months of 2022

Copenhagen, Denmark November 10, 2022 – 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 three and nine months ended September 30, 2022 and provided a corporate update.

Key strategic objectives achieved

Adam Steensberg, President and Chief Executive at Zealand Pharma said: "Zealand has continued to execute and deliver on key objectives in the third quarter. In September, we completed our stated objective of securing partnerships for our marketed products through a license and development agreement with Novo Nordisk, a global leader in diabetes, to commercialize Zegalogue®.

"Within our R&D pipeline of investigational therapeutic peptides we have seen further positive clinical data. In September we reported topline results from the Phase 3 EASE-1 trial showing that treatment of short bowel syndrome patients with twice weekly glepaglutide, our long-acting GLP-2 analogue, resulted in a statistically significant 5.13 liters/week reduction from baseline in the volume of parenteral support required. Importantly, approximately 1 in 8 patients treated with glepaglutide weaned off parenteral support within 24 weeks, while no placebo treated patients were able to wean off parenteral support, which we believe is differentiating from current treatments. We look forward to seeing the results of the ongoing glepaglutide EASE-2 and 3 long term extension trials and engaging with the regulatory authorities in preparation for an NDA submission. In obesity, our partner Boehringer Ingelheim, presented Phase 2 data for the dual GCGR/GLP-1R agonist BI 456906 in patients with type 2 diabetes, showing encouraging glycemic control through a reduction in HbA1c, as well as body weight loss. We are encouraged by these results and look forward to seeing the results from Boehringer's ongoing Phase 2 trial in patients with obesity, which we expect next year. We also made progress with our own early-stage clinical candidates in obesity.

"Finally, we strengthened our balance sheet with gross proceeds of DKK 786 million from a directed issue and private placement resulting in an adjusted cash position of DKK 1,515 million in early October."

Financial results for the first nine months of 2022

- **Revenue: DKK 80.1 million** (DKK 95.1 million in the first nine months of 2021).
- **Net operating expenses: DKK -675.7 million** (DKK -652.8 million in the first nine months of 2021).
- **Net operating result: DKK -596.2 million** (DKK -568.7 million in the first nine months of 2021).
- **Net financial items: DKK -53.4 million** (DKK 21.5 million in the first nine months of 2021).
- **Net result from Discontinued Operations: DKK -215.1 million** (DKK -193.7 million in the first nine months of 2021).
- **Cash, cash equivalents, and marketable securities: DKK 729.9 million** as of September 30, 2022 (September 30, 2021: DKK 1,049.0 million).

Highlights in the third quarter 2022

- **Announced positive topline results from the pivotal Phase 3 EASE-1 trial of glepaglutide, a long-acting GLP-2 analogue designed for subcutaneous delivery via auto-injector, in patients with short bowel syndrome (SBS).** Glepaglutide treatment met the primary endpoint with twice weekly dosing achieving a statistically significant reduction in weekly parenteral support volume by 5.13 Liters/week from baseline at 24 weeks. 66% of patients in the twice weekly group

had a clinically meaningful response (>20% reduction in parenteral support volume). In total 9 of 70 patients treated with glepaglutide were weaned off parenteral support, while no placebo treated patients were able to wean off parenteral support. Glepaglutide treatment appeared to be safe and was well-tolerated in the trial.

- **Reported results from the Boehringer Ingelheim-sponsored Phase 2 clinical trial of BI 456906, a glucagon receptor/glucagon-like peptide-1 receptor (GCGR/GLP-1R) dual agonist, in patients with type 2 diabetes (T2D) at the 58th Annual Meeting of the European Association for the Study of Diabetes (EASD).** Treatment with BI 456906 resulted in dose dependent HbA1c reductions, with a mean of up to -1.88% at Week 16 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%. The safety and tolerability profile, which included gastrointestinal disorders (such as nausea and vomiting) as the most frequently reported adverse events, was as is expected with higher increasing doses of GLP-1 receptor agonists. Most adverse events were reported during the dose-escalation phase of the trial, and therefore slower escalation schemes may mitigate the frequency of such events.
- **Presented results from the Phase 3 clinical trial of dasiglucagon in congenital hyperinsulinism (CHI) at the 60th Annual Meeting of the European Society for Paediatric Endocrinology (ESPE).** Dasiglucagon significantly reduced the requirement for intravenous glucose to maintain glycemia in newborns and infants with CHI (Part 1 of Phase 3 trial). Dasiglucagon reduced time in hypoglycemia and enabled discontinuation of intravenous glucose in most infants and limited the need for pancreatectomy (Part 2 of Phase 3 trial). Results support the potential for dasiglucagon to be a novel, effective, and well tolerated treatment for infants with CHI dependent on intravenous glucose.
- **Completed dose escalation in the ongoing Phase 1a single ascending dose (SAD) trial of ZP8396, a long-acting amylin analogue.** In this Phase 1 SAD trial, subcutaneous ZP8396 appeared to be well tolerated with no unexpected side effects and the single administration maximum tolerated dose (MTD) was reached. The pharmacokinetic (PK) profile is suitable for once weekly dosing. Zealand expects to initiate dosing in a Phase 1b multiple ascending dose (MAD) trial of ZP8396 by the end of 2022.
- **Announced a global license and development agreement with Novo Nordisk to commercialize ZEGALOGUE® (dasiglucagon) for injection.** Agreement includes an upfront payment, development, regulatory, manufacturing and sales-based milestones of up to DKK 290 million to Zealand in addition to high-single to low-double digit royalties on worldwide net sales by Novo Nordisk. Zealand will be responsible for certain planned development, regulatory, and manufacturing activities to support approval outside the U.S. to be reimbursed by Novo Nordisk.
- **Appointed Henriette Wennicke as Chief Financial Officer.** Henriette Wennicke brings broad finance and business experience at large organizations, including in healthcare, where she has led financial planning, R&D portfolio management and investor relations.
- **Completed voluntary delisting of its American Depositary Shares (ADSs) from the New York-based Nasdaq Global Select Market.** One ADS currently represents one ordinary share in Zealand and on suspension of trading the company's ADSs accounted for less than 1.5% of the total share capital. Trading in Zealand shares is consolidated to Nasdaq Copenhagen, the company's primary and most liquid stock exchange. The decision is part of Zealand's strategy to prioritize R&D and streamline corporate operations.

Events after the reporting date

- **Presented preclinical data at the Annual Meeting of the Obesity Society (Obesity Week)** on Zealand's amylin analogue (ZP8396); its first-in-class GLP-1R/GLP-2R dual agonist (dapiglutide); and the GIP analogue (ZP6590).

- **Reported results from the Boehringer Ingelheim-sponsored Phase 2 clinical trial of BI 456906 (GCGR/GLP-1R) in patients with T2D at Obesity Week.** BI 456906 resulted in dose-dependent bodyweight reductions of up to -9% at Week 16.
- **Phase 2 trial of BI 456906 in patients with non-alcoholic steatohepatitis (NASH)** conducted by Boehringer Ingelheim has completed patient enrollment.
- **Received gross proceeds of DKK 786 million from a directed issue and private placement.** Zealand issued a total of 4,975,000 new shares at a subscription price of DKK 158 per share.

Upcoming events

- **Initiate Phase 1b MAD trial of ZP8396**, a long-acting amylin analogue in development for obesity by the end of the fourth quarter 2022.
- **Interim Phase 3 data from EASE-SBS 2 and 3 long term extension trials of glepaglutide** expected by the end of the fourth quarter 2022, and first quarter of 2023, respectively.
- **Potential submission of new drug application (NDA)** with the U.S. Food and Drug Administration (FDA) for dasiglucagon treatment in the management of CHI in the first half of 2023, based on data from the full Phase 3 program.

Financial guidance for 2022

The company will no longer provide guidance on net product revenue, reflecting the completion of the asset purchase agreement for V-Go® with MannKind Corporation and the completion of the global license and development agreement for Zegalogue® with Novo Nordisk.

In 2022, Zealand expects revenue from existing license agreements. However, since such revenue is uncertain in terms of size and timing, Zealand does not intend to provide guidance on such revenue.

Net operating expenses in 2022 are expected to be DKK 1,000 million +/-10%*. This is unchanged from our updated guidance issued on March 30, 2022.

*Excluding discontinued operations

Conference call today at 4 PM CET / 10 AM ET

Zealand's management will host a conference call today at 4 PM CET / 10 AM ET to present results through the first nine months of 2022 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/BI2233344c2eff4f40be51448707df4e03>. 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/untoz3rk>. 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-cal>.

Total number of shares and voting rights in Zealand Pharma A/S as of September 30, 2022

Number of shares (nominal value of DKK 1 each): 46,538,186 which is an increase of 2,895,044 from 43,634,142 as reported on December 31, 2021.

Therefore, the current share capital is (nominal value in DKK): 46,538,186.

Number of voting rights: 46,538,186.

On October 4, 2022, The Group announced that a directed issue and private placement of 4,975,000 new shares had been completed. Please refer to note 17 for further information.

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 and partnerships with a number of blue-chip 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.

Safe Harbor / Forward-Looking Statements

This press release 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 preclinical and clinical trials and the reporting of data therefrom and the company's Upcoming Events and Financial Guidance for 2022. 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; political uncertainty, including due to the ongoing military conflict in Ukraine; and the direct and indirect impacts of the ongoing COVID-19 pandemic on our business, results of operations and financial condition. If any or all of such forward-looking statements prove to be incorrect, our actual results could differ materially and adversely from those anticipated or implied by such statements. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from our expectations in any forward-looking statement. All such forward-looking statements speak only as of the date of this press release and are based on information available to Zealand Pharma as of the date of this release. We do not undertake to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof. Information concerning pharmaceuticals (including compounds under development) contained within this material is not intended as advertising or medical advice.

NOTE: DKK/USD Exchange rates used: September 30, 2022 = 7.629 and September 30, 2021 = 6.422

V-Go® is a registered trademark of MannKind Corporation and Zegalogue® is a registered trademark of Novo Nordisk A/S

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Refocused Strategy

On March 30, 2022, Zealand announced a strategy to prioritize research and development and to seek strategic commercial partnering agreements. As part of this strategy, the company has restructured its commercial operations and expects the global cost base by the end of 2022 will be reduced by approximately 35% from 2021 levels. In addition, Zealand completed the sale of its V-Go® insulin delivery device to MannKind Corporation in the second quarter and announced a global license and development agreement with Novo Nordisk to commercialize Zegalogue® in the third quarter.

Pipeline Update

Rare Diseases

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

Third quarter 2022 update:

- Announced positive topline results from the pivotal Phase 3 EASE-SBS 1 trial in SBS patients with intestinal failure
- Expects interim Phase 3 data from EASE-SBS 2 by the end of the fourth quarter, and EASE-SBS 3 in the first quarter 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 short bowel syndrome (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-SBS 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 (PS) 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-SBS 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. While 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.

In total, 102 of 106 participating patients completed EASE-SBS-1, of which 96 continued into the ongoing long-term safety and efficacy extension trials, EASE-SBS 2 and EASE-SBS 3. In addition, EASE-SBS 4 is a Phase 3b trial to assess long-term effects of glepaglutide on intestinal fluid and energy uptake. The company expects efficacy and safety data from the full EASE-SBS Phase 3 program data to form the basis of a new drug application (NDA) with the U.S. Food and Drug Administration (FDA). For more information on the EASE-SBS trials, please visit ClinicalTrials.gov (IDs: [NCT03690206](https://ClinicalTrials.gov/ct2/show/study/NCT03690206), [NCT03905707](https://ClinicalTrials.gov/ct2/show/study/NCT03905707), [NCT04881825](https://ClinicalTrials.gov/ct2/show/study/NCT04881825), [NCT04991311](https://ClinicalTrials.gov/ct2/show/study/NCT04991311)).

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.

Dasiglucagon for congenital hyperinsulinism (CHI)

Third quarter 2022 update:

- Presented results at the 60th ESPE annual meeting from the Phase 3 trial of dasiglucagon in neonates and infants up to 12 months old, supporting the potential for dasiglucagon to be a novel, effective, and well tolerated treatment for infants with CHI dependent on intravenous glucose.
- NDA submission to FDA based on data from full Phase 3 program anticipated in the first half of 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 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. 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](#)) 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.

The company expects safety and efficacy data from the full Phase 3 program to form the basis of an NDA submission to the FDA for dasiglucagon treatment in the management of CHI in the first half of 2023. The FDA and the European Commission have both granted orphan drug designation to dasiglucagon for the treatment of CHI.

Obesity

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

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 82nd ADA Scientific Sessions.

Zealand intends to support a Phase 2 investigator-initiated clinical trial of dapiglutide in obesity anticipated to commence in early 2023.

ZP8396 (long-acting amylin analogue)

Third quarter 2022 update:

- Dose escalation complete in the Phase 1a SAD trial and subcutaneous ZP8396 appears to be well tolerated with no unexpected side effects and shows a PK profile suitable for once-weekly dosing
- Phase 1 MAD trial expected to begin by the end of 2022
- Preclinical data presented at Obesity Week in November confirm the feasibility of administering ZP8396 co-formulated with semaglutide or dapiglutide and achieving greater body weight loss when compared to monotherapy with either agent

Background:

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

Preclinical data presented at the 82nd ADA Scientific Sessions in June 2022, showed that ZP8396 significantly improved glycemic control in an in vivo model of type 2 diabetes. A second presentation demonstrated that aqueous formulation of ZP8396 at physiological pH induced significant body weight loss in an in vivo model of diet-induced obesity. Prior preclinical observations presented at the Obesity Society Annual Meeting in 2021 showed potent anti-obesity effects of ZP8396, with up to 20% weight loss in in vivo models when combined with GLP-1 analogue semaglutide. New preclinical data presented at the Obesity Society Annual Meeting in November 2022 showed body weight reduction was similar with ZP8396 and semaglutide administered as separate injections (loose combinations) compared with co-formulation. In addition, a second presentation showed that combination therapy with dual GLP-1R/GLP-2R agonist dapaglutide and ZP8396 achieved up to 19% weight loss in an in vivo model of diet induced obesity compared to body weight reductions of 12% with dapaglutide alone and 6% with ZP8396 alone.

Zealand has completed the subcutaneous dose escalation phase of the Phase 1a, First-in-Human, randomized, single ascending dose (SAD) trial to assess the safety, tolerability, pharmacokinetics, and pharmacodynamics of ZP8396 in healthy volunteers. In this Phase 1 SAD trial, subcutaneous ZP8396 appears to be well tolerated with no unexpected side effects and the single administration maximum tolerated dose (MTD) was reached. The pharmacokinetic (PK) profile is suitable for once-weekly dosing. Zealand expects to initiate dosing in a Phase 1b multiple ascending dose (MAD) trial of ZP8396 by the end of 2022.

BI 456906 (long-acting dual GCGR/GLP-1R agonist) in collaboration with Boehringer Ingelheim

Third quarter 2022 update:

- Reported results from the Boehringer Ingelheim-sponsored Phase 2 clinical trial in patients with T2D, showing dose dependent HbA1c reductions of up to -1.88% at Week 16 and dose-dependent bodyweight reductions of up to -9% at Week 16, presented at the 58th EASD annual meeting and Obesity Week, respectively.

Background:

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. BI 456906 is targeting treatment of obesity and associated metabolic diseases.

A Phase 2 randomized, placebo-controlled, double-blind trial evaluated BI 456906 in people with T2D on stable metformin background therapy. Participants received multiple rising doses of BI 456906 in one of six dose groups, placebo or open-label weekly semaglutide 1.0 mg for 16 weeks. Different doses of BI 456906 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, Boehringer Ingelheim presented results for the primary endpoint of change from baseline in HbA1c after 16 weeks of treatment. Treatment with BI 456906 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%.

At Obesity Week in November, Boehringer Ingelheim presented results for the secondary endpoint of change from baseline in bodyweight after 16 weeks of treatment. Treatment with BI 456906 led to dose-dependent decreases in bodyweight, with mean reductions of -1.9% to -9.0% at 16 weeks across the six dose groups, compared with -1.2% seen with placebo. Treatment with open-label weekly semaglutide at 1.0 mg led to a decrease in bodyweight of -5.4%. In addition, dose-dependent decreases in waist circumference were observed following treatment with BI 456906, with mean decreases of -1.80 cm to -12.89 cm at 16 weeks across the six dose groups, compared with -1.95 cm seen with placebo. Treatment with open-label weekly semaglutide at 1.0 mg led to a decrease in bodyweight of -3.63 cm.

In the Phase 2 trial, adverse events were reported in 78% of all participants receiving BI 456906. Drug-related adverse events were reported for 59% of BI 456906-treated participants and 38% of participants treated with open-label semaglutide and were most frequently GI disorders such as nausea and vomiting. Drug-related serious adverse events were reported for four participants treated with BI 456906 across dose groups, all of which resolved once treatment was stopped, and for no participants receiving placebo. Adverse events led to treatment discontinuation in 16% of patients receiving BI 456906, 5% receiving placebo and 4% receiving open label semaglutide. Slower dose escalations over a longer duration are expected to mitigate GI adverse events.

At Obesity Week in November 2021, results from the Phase 1b trial of BI 456906 ([NCT03591718](#)) in people with obesity or who are overweight demonstrated up to 13.7% weight loss and no unexpected safety findings following 16 weeks of dosing.

Boehringer Ingelheim is conducting three parallel Phase 2 trials to assess BI 456906: in diabetes (ClinicalTrials.gov ID: [NCT04153929](#)), obesity (ClinicalTrials.gov ID: [NCT04667377](#)), and non-alcoholic steatohepatitis, or NASH (ClinicalTrials.gov ID: [NCT04771273](#)). The NASH program has received Fast Track Designation from the U.S. FDA.

BI 456906 was co-invented by Boehringer Ingelheim and Zealand. Boehringer Ingelheim is funding all research, development and commercialization activities related to BI 456906. 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 holds 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's partner, Beta Bionics, initiated enrollment into the screening protocol for the Phase 3 Bihormonal iLet® Bionic Pancreas Pivotal Program in late 2021. Dosing of the first patients is anticipated to begin in early 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 evaluate mini-dose dasiglucagon to support this development program.

At the 82nd ADA Scientific Sessions in June, investigators from the Steno Diabetes Center Copenhagen presented results from the Phase 2 trial using the dasiglucagon mini-dose pen in people with T1D in free-living conditions (ClinicalTrials.gov ID: [NCT04764968](#)). Dasiglucagon administered by pen improved glycemic control and reduced carbohydrate intake among the study participants. These data build on prior clinical studies conducted in hospital settings that show the potential for using low doses of dasiglucagon to correct moderate hypoglycemia: Results from the Phase 2a dose-finding trial in people with T1D (ClinicalTrials.gov ID: [NCT04449692](#)) were presented at the ADA Scientific Sessions in 2021, and results of the Phase 2a trial in PBH (ClinicalTrials.gov ID: [NCT03984370](#)) were published in the journal *Diabetes Care* in 2022.

The Phase 2 trial in PBH conducted in an out-patient setting (ClinicalTrials.gov ID: [NCT04836273](#)) has been completed and met the primary endpoint. Zealand is encouraged by the results and anticipates that the investigator will submit data for presentation at a scientific congress in 2023, at which time Zealand expects to provide an update on plans for the program.

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 is a long-acting inhibitor of Complement C3 which has the potential to treat a broad range of complement mediated diseases. Zealand will lead the joint discovery and research efforts through the preclinical stage, and Alexion will lead development efforts beginning with Investigational New Drug (IND) filing and Phase 1 trials.

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 development/regulatory milestones for each target selected similar to the lead target with slightly reduced commercial milestones and royalties.

Key figures

DKK thousand

INCOME STATEMENT AND COMPREHENSIVE INCOME		Note	Q3 2022	Q3 2021*	Q1-Q3 2022	Q1-Q3 2021*	FY 2021*
Revenue			43,714	54,188	80,061	95,114	108,546
Gross margin			43,137	54,258	79,484	84,144	97,576
Research and development expenses			-145,076	-139,457	-451,988	-421,793	-582,270
Sales and Marketing expenses			-6,166	-11,127	-28,644	-51,341	-62,600
Administrative expenses			-53,998	-62,226	-177,050	-179,680	-235,609
Net operating expenses			-205,240	-212,810	-657,682	-652,814	-880,479
Other operating items, net			27	73	-17,986	8	-1,414
Operating result			-162,076	-158,479	-596,184	-568,662	-784,317
Net financial items			8,418	16,071	-53,421	21,520	25,430
Result before tax			-153,658	-142,408	-649,605	-547,142	-758,887
Income tax		(1)	1,776	998	5,056	2,944	3,949
Net result for the period from continuing operations			-151,882	-141,410	-644,549	-544,198	-754,938
Net result for the period from discontinued operations			3,540	-57,477	-215,138	-193,689	-263,211
Net result for the period			-148,342	-198,887	-859,687	-737,887	-1,018,149
Earnings/loss per share from continuing operations – basic/diluted (DKK)			-3.29	-3.28	-14.46	-12.73	-17.61
Earnings/loss per share – basic/diluted (DKK)			-3.21	-4.61	-19.28	-17.26	-23.75
STATEMENT OF FINANCIAL POSITION					September 30, 2022	September 30, 2021	December 31, 2021
Cash and cash equivalents		(2)			493,755	753,599	1,129,103
Marketable securities		(2)			236,131	295,379	299,042
Cash, cash equivalents and Marketable securities					729,886	1,048,978	1,428,145
Other assets					361,722	611,721	639,484
Total assets					1,091,608	1,660,699	2,067,629
Share capital					46,538	43,582	43,634
Equity					366,440	1,185,746	927,803
Total liabilities					725,168	474,953	1,139,826
CASH FLOW					Q1-Q3 2022	Q1-Q3 2021	FY 2021
Cash (used in)/provided by operating activities					-669,927	-904,257**	-1,211,971
Cash (used in)/provided by investing activities					178,566	-6,255	-18,121
Cash (used in)/provided by financing activities					-178,535	686,440**	1,332,751
Purchase of property, plant and equipment					-5,083	-5,854	-22,133
Of which cash (used in)/provided by discontinued operations					-31,788	-324,815	-371,956
Free cash flow		(3)			-675,010	-929,585	-1,234,104
OTHER					September 30, 2022	September 30, 2021	December 31, 2021
Share price (DKK)					173.8	185.0	145.1
Market capitalization (MDKK)		(4)			7,750	7,911	6,220
Equity ratio (%)		(5)			34	71	45
Equity per share (DKK)		(6)			8.22	27.73	21.26
Average number of employees					271	345	346
Number of full-time employees at the end of the period					203	346	355

Notes:

* Comparatives adjusted to reflect the effect of discontinued operations. For further details refer to note 2.

** DKK 19,474 reclassified from cash from financing activities to cash used in operating activities compared to reported figures from Q3, 2021.

(1) Zealand expects to be eligible to receive up to DKK 5.5 million in Danish corporate tax benefit related to R&D expenses incurred for 2022, of which DKK 4.1 million has been recognized for the nine months ended September 30, 2022, which is setoff against recognized tax expense in the US.

(2) As of September 30, 2022, the groups marketable securities (DKK 236.1 million) and a part of the groups cash (DKK 151.2 million) is restricted. Please refer to note 10 for further information.

(3) Free cash flow is calculated as the sum of cash flows from operating activities and purchase of property, plant and equipment.

(4) Market capitalization is calculated as weighted outstanding shares at the balance sheet date times the share price at the balance sheet date.

(5) Equity ratio is calculated as equity at the balance sheet date divided by total assets at the balance sheet date.

(6) Equity per share is calculated as shareholders' equity divided by weighted total number of ordinary shares less weighted treasury shares.

Financial review

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

Financial results

Revenue

DKK thousand	Q1-Q3 2022	Q1-Q3 2021	Δ	Δ in percent
Sale of services	770	0	770	N/A
License and milestone revenue	79,291	95,114	-15,823	-17%
Revenue from continuing operations	80,061	95,114	-15,053	-16%
Sale of goods from discontinued operations	87,314	143,438	-56,124	-39%
Total revenue	167,375	238,552	-71,177	-30%

License and milestone revenue is related to milestones from the collaboration partners with a slight decrease due to milestones being triggered in Q3, 2021.

Sale of goods from discontinued operations is related to sales of the V-Go insulin delivery device, Zegalogue via own sales force and the one-off sale of the entire inventory of Zegalogue finished goods as a result of the commencement of the partnership with Novo Nordisk. V-GO was divested in Q2, 2022, and the commercial rights to Zegalogue were transferred to Novo Nordisk in Q3, 2022.

Gross margin

DKK thousand	Q1-Q3 2022	Q1-Q3 2021	Δ	Δ in percent
Gross margin from continuing operations	79,484	84,144	-4,660	-6%
Gross margin from discontinued operations	16,753	59,433	-42,680	-72%
Gross margin in total	96,237	143,577	-47,340	-33%

The decrease in gross margin is due to the decrease in license and milestone revenue as described above.

Gross margin from discontinued operations is related to sales of the V-Go insulin delivery device and Zegalogue via own sales force which is accounted for as discontinued operations as a result of the company's refocused strategy. V-GO was divested in Q2, 2022, and the commercial rights to Zegalogue were transferred to Novo Nordisk in Q3, 2022.

Research and development expenses

DKK thousand	Q1-Q3 2022	Q1-Q3 2021	Δ	Δ in percent
Research and development expenses from continuing operations	451,988	421,793	30,195	7%
Research and development expenses from discontinued operations	4,156	4,473	-317	-7%
Research and development expenses in total	456,144	426,266	29,878	7%

The increase in research and development expenses is primarily related to activities with our late-stage clinical programs for dasiglucagon and glepaglutide.

Research and development expense from discontinued operations is related to the efforts to sell the V-Go insulin delivery device and Zegalogue via own sales force which is accounted for as discontinued operations as a result of the company's refocused strategy. V-GO was divested in Q2, 2022, and the commercial rights to Zegalogue were transferred to Novo Nordisk in Q3, 2022.

Sales and marketing expenses

DKK thousand	Q1-Q3 2022	Q1-Q3 2021	Δ	Δ in percent
Sales and marketing expenses from continuing operations	28,644	51,341	-22,697	-44%
Sales and marketing expenses from discontinued operations	125,629	230,346	-104,717	-45%
Sales and marketing expenses in total	154,273	281,687	-127,414	-45%

The decrease in total sales and marketing expenses is due to reduced commercial efforts related to Zegalogue following the company's restructuring announcement on March 30, 2022.

Sales and marketing expenses from discontinued operations are related to the efforts to sell the V-Go insulin delivery device and Zegalogue via own sales force which is accounted for as discontinued operations as a result of the company's refocused strategy. V-GO was divested in Q2, 2022 and the commercial rights to Zegalogue were transferred to Novo Nordisk in Q3, 2022.

Administrative expenses

DKK thousand	Q1-Q3 2022	Q1-Q3 2021	Δ	Δ in percent
Administrative expenses from continuing operations	177,050	179,680	-2,630	-1%
Administrative expenses from discontinued operations	15,348	18,575	-3,227	-17%
Administrative expenses in total	192,398	198,255	-5,857	-3%

Administrative expenses decreased due to cost reduction efforts included as a part of the companies announced restructuring on March 30, 2022.

Administrative expenses from discontinued operations are related to the efforts to sell the V-Go insulin delivery device and Zegalogue via own sales force which is accounted for as discontinued operations as a result of the company's refocused strategy. V-GO was divested in Q2, 2022 and the commercial rights to Zegalogue were transferred to Novo Nordisk in Q3, 2022.

Other operating items

DKK thousand	Q1-Q3 2022	Q1-Q3 2021	Δ	Δ in percent
Other operating income from continuing operations	1,854	614	1,240	202%
Other operating expenses from continuing operations	-19,840	-606	-19,234	-3,174%
Other operating income from discontinued operations	21,338	0	21,338	N/A
Other operating expenses from discontinued operations	-92,315	0	-92,315	N/A
Other operating items in total	-88,963	8	-88,971	-1,112,138%

Other operating expenses from continuing operations have increased due to employee-related restructuring costs incurred with the March 30, 2022, company announcement.

The development in other operating income from discontinued operations primarily relates to the reversal of the loss on Zegalogue finished goods triggered by the license and development agreement with Novo Nordisk.

Other operating expenses from discontinued operations comprise the net loss on the divestment of the V-GO activities, employee-related restructuring cost and recognition of a loss for Zegalogue inventory following the March 30, 2022, company announcement.

For further information, please refer to note 4.

Operating result

DKK thousand	Q1-Q3 2022	Q1-Q3 2021	Δ	Δ in percent
Operating result from continuing operations	-596,184	-568,662	-27,522	-5%
Operating result from discontinued operations	-199,357	-193,961	-5,396	-3%
Operating result in total	-795,541	-762,623	-32,918	-4%

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

The operating result from discontinued operations is related to the efforts to sell the V-Go insulin delivery device and Zegalogue via own sales force which is accounted for as discontinued operations as a result of the company's refocused strategy. V-GO was divested in Q2, 2022, and the commercial rights to Zegalogue were transferred to Novo Nordisk in Q3, 2022.

The development in operating result from discontinued operations comprise the upsides from the cost decrease in sales and marketing cost due to the initiatives implemented with the March 30, 2022, company announcement and the reversal of reserve for loss Zegalogue finished goods inventory. This is offset by a decrease in gross margin from sales, the recognised restructuring costs and the net loss from the divestment of the V-GO disposal group.

Financial items

DKK thousand	Q1-Q3 2022	Q1-Q3 2021	Δ	Δ in percent
Financial income	130,776	29,427	101,349	344%
Financial expenses	-184,197	-7,907	-176,290	-2,230%
Financial items in total	-53,421	21,520	-74,941	-348%

The increase in financial income is due to higher currency exchange adjustments on cash position caused by the change in USD/DKK exchange rate (DKK 29.4 million) and a fair value adjustment of prepayment option on the Oberland loan (DKK 71.1 million).

The higher financial expenses comprise an increase in interest expenses (DKK 26.4 million) and loss on settlement of borrowings (DKK 144.9 million) associated with the partial prepayment of the loan with Oberland, please refer to note 15 for further information.

Result before tax

DKK thousand	Q1-Q3 2022	Q1-Q3 2021	Δ	Δ in percent
Result before tax from continuing operations	-649,605	-547,142	-102,463	-19%

Result before tax from discontinued operations	-199,357	-193,961	-5,396	-3%
Result before tax in total	-848,962	-741,103	-107,859	-15%

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

Income tax

DKK thousand	Q1-Q3 2022	Q1-Q3 2021	Δ	Δ in percent
Income tax from continuing operations	5,056	2,944	2,112	72%
Income tax from discontinued operations	-15,781	272	-16,053	-5,902%
Income tax in total	-10,725	3,216	-13,941	-433%

The net income tax (expense) is mainly impacted by an impairment of deferred taxes in US as a result of the company's restructuring announcement on March 30, 2022.

The tax income from continuing operations is related to the corporate tax benefit on R&D expenses that the group expects to be eligible to collect.

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

Net result

DKK thousand	Q1-Q3 2022	Q1-Q3 2021	Δ	Δ in percent
Net result from continuing operations	-644,549	-544,198	-100,351	-18%
Net result from discontinued operations	-215,138	-193,689	-21,449	-11%
Net result	-859,687	-737,887	-121,800	-17%

The decrease in the net result from continuing operations is primarily due to the impact of the net financial items incurred as part of the company's restructuring including the amendment for the Oberland agreement signed on May 10, 2022.

Net result from discontinued operations is related to the efforts to sell the V-Go insulin delivery device and Zegalogue via own sales force which is accounted for as discontinued operations as a result of the company's refocused strategy. V-GO was divested in Q2, 2022, and the commercial rights to Zegalogue were transferred to Novo Nordisk in Q3, 2022. The decrease in the net result from discontinued operations is caused by the costs incurred following the March 30, 2022, restructuring announcement and the divestment of V-GO partly offset by the lower costs due to lower activity level.

Liquidity and capital resources

Equity

DKK thousand	September 30, 2022	December 31, 2021	Δ	Δ in percent
Equity	366,440	927,803	-561,363	-61%
Equity ratio	34%	45%	N/A	N/A

Equity ratio is calculated as equity at the balance sheet date divided by total assets at the balance sheet date. The decrease in equity was mainly driven by the loss for the period partly offset by the capital raise in June.

Subsequent to the period end, the Company announced completion of a directed issue and private placement of 4.975.000 new ordinary shares raising gross proceeds of DKK 786 million.

Cash, cash equivalents and Marketable securities

DKK thousand	September 30, 2022	December 31, 2021	Δ	Δ in percent
Cash, cash equivalents and Marketable securities	729,886	1,428,145	-698,259	-49%

The decrease in cash, cash equivalents and marketable securities is mainly driven by cash spent in the period and repayment of portion of the loan to Oberland. The impact is partly offset by cash received from capital market financings and receivables related to the company's commercial programs, proceeds from the completed sale of V-Go® insulin delivery device to MannKind Corporation and the positive effect from the development in the USD/DKK exchange rate.

Subsequent to the period end, the Company announced completion of a directed issue and private placement of 4.975.000 new ordinary shares raising gross proceeds of DKK 786 million.

Cash flow

DKK thousand	Q1-Q3 2022	Q1-Q3 2021	Δ	Δ in percent
Cash from (used in) operating activities	-669,927	-904,257*	253,804	27%
Cash from (used in) investing activities	178,566	-6,255	184,420	2,955%
Cash from (used in) financing activities	-178,535	686,440*	-884,449	-125%

*DKK 19,474 reclassified from cash from financing activities to cash used in operating activities compared to reported figures from Q3, 2021.

The decrease in cash used in operating activities from the same period in 2021 is mainly related to reductions in sales and marketing and administrative expenses as a result of decreased commercial activities and support for Zegalogue and the V-Go wearable insulin delivery device.

Cash from investing activities increased with the consideration received from the deal with MannKind in Q2, 2022, and proceeds received from marketable securities as they mature.

Cash from financing activities decreased from the same period in 2021 due to the financing that took place in January 2021 and the repayment of USD 50m of the Oberland loan in May 2022. These effects are partly offset by the June 2022 capital market financing.

Contrary to previous periods, it is managements judgement, that there are no substantial doubt that the groups' interim condensed consolidated financial statement can be prepared under the going concern assumption. It is management assessment that the company's non-restricted cash and cash equivalents of DKK 342.6 million as of September 30, 2022 together with the gross proceeds of DKK 786.0 million from private placement of new shares on October 4, 2022 as described in note 17 will be sufficient to fund our operating activities as planned for at least 12 months from the balance sheet date.

Risk factors

This interim report contains forward-looking statements, including forecasts of future expenses as well as expected business-related events. Such statements are subject to risks and uncertainties as various factors, some of which are beyond the control of Zealand, may cause actual results and performance to differ materially from the forecasts made in this interim report. Without being exhaustive, such factors include e.g. the impact of the global COVID-19 pandemic, interest rate and currency exchange rate fluctuations, larger scale uncertainty about the state of the global economy and the possibility of a global slowdown in economic growth, the effects of potentially increasing inflation on the global economy, costs in general or performance of the equity markets that will make raising capital more difficult, the ongoing conflict in Ukraine, delay or failure of clinical trials, the views of regulatory authorities and changing standards and other development activities, production problems, unexpected contract breaches or terminations, government-mandated or market-driven price decreases for Zealand's products, introduction of competing products, Zealand's ability to successfully market both new and existing products, exposure to product liability and other lawsuits, changes in reimbursement rules and governmental laws and related interpretation thereof, unexpected growth in costs and expenses, and Zealand's ability to integrate businesses in varying geographies with different commercial and operating characteristics. In particular, the global COVID-19 pandemic could potentially materially adversely impact our business and financial performance, including the timing of our clinical trials, projected regulatory approval timelines, our supply chain and sales of our approved products, as well as our Financial Guidance for 2022 in this interim report, particularly because the COVID-19 pandemic continues to evolve, and its breadth and significance on our business and financial performance is uncertain. In addition, Zealand's classification as a going concern may hamper the ability to raise additional capital or may mean that it will have to take additional cost saving measures that may cause further delays in the progress of its pre-clinical and clinical programs beyond the internal or publicized projected dates. A more extensive description of risk factors can be found in the 2021 Annual Report under the section Risk management and internal control.

Management's statement on the interim report

The Board of Directors and the Management have considered and adopted the interim report of Zealand Pharma A/S for the three- and nine-months periods ended September 30, 2022.

The condensed consolidated interim 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 condensed consolidated interim financial statements give a true and fair view of the Group's assets, equity and liabilities and financial position as of September 30, 2022 as well as of the results of the Group's operations and cash flow for the three and nine month periods ended September 30, 2022.

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

Copenhagen, November 10, 2022

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

Nikolaj Frederik Beck
Board member
Employee elected

Independent auditor's report

To the shareholders of Zealand Pharma A/S

We have reviewed the interim condensed consolidated financial statements of Zealand Pharma A/S for the three and nine-month periods ended September 30, 2022, which comprise a condensed consolidated income statement and statement of comprehensive income for the three and nine-month periods ended September 30, 2022, statement of financial position as at September 30, 2022, and statement of changes in equity and statement of cash flow for the nine-month period ended September 30, 2022, 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, November 10, 2022

EY

Godkendt Revisionspartnerselskab
CVR no. 30 70 02 28

Christian Schwenn Johansen
State Authorized Public Accountant
mne33234

Rasmus Bloch Jespersen
State Authorized Public Accountant
mne35503

Interim condensed consolidated financial statements

Interim condensed consolidated income statement for the three- and nine-months periods ended September 30, 2022 and 2021.

DKK thousand	Note	Q3 2022	Q3 2021	Q1-Q3 2022	Q1-Q3 2021	FY 2021
Revenue	3	43,714	54,188	80,061	95,114	108,546
Cost of providing services		-577	0	-577	0	0
Royalty expenses		0	70	0	-10,970	-10,970
Gross margin		43,137	54,258	79,484	84,144	97,576
Research and development expenses		-145,076	-139,457	-451,988	-421,793	-582,270
Sales and marketing expenses		-6,166	-11,127	-28,644	-51,341	-62,600
Administrative expenses		-53,998	-62,226	-177,050	-179,680	-235,609
Total Operating expenses		-205,240	-212,810	-657,682	-652,814	-880,479
Other operating income	4	27	126	1,854	614	759
Other operating expenses	4	0	-53	-19,840	-606	-2,173
Operating result		-162,076	-158,479	-596,184	-568,662	-784,317
Financial income	5	18,885	18,548	130,776	29,427	41,211
Financial expenses	5	-10,467	-2,477	-184,197	-7,907	-15,781
Result before tax		-153,658	-142,408	-649,605	-547,142	-758,887
Income tax	6	1,776	998	5,056	2,944	3,949
Net result for the period from continuing operations		-151,882	-141,410	-644,549	-544,198	-754,938
Net result for the period from discontinued operations	2	3,540	-57,477	-215,138	-193,689	-263,211
Net result for the period		-148,342	-198,887	-859,687	-737,887	-1,018,149
Earnings/loss per share from continuing operations – basic/diluted (DKK)	7	-3.29	-3.28	-14.46	-12.73	-17.61
Earnings/loss per share from discontinuing operations – basic/diluted (DKK)	7	0.08	-1.33	-4.82	-4.53	-6.14
Earnings/loss per share – basic/diluted (DKK)	7	-3.21	-4.61	-19.28	-17.26	-23.75

Interim condensed consolidated statement of comprehensive income (loss) for the three- and nine-months periods ended September 30, 2022 and 2021.

DKK thousand	Note	Q3 2022	Q3 2021	Q1-Q3 2022	Q1-Q3 2021	FY 2021
Net result for the period		-148,342	-198,887	-859,687	-737,887	-1,018,149
Exchange differences on translation of foreign operations		-511	1,990	4,376	3,794	5,178
Comprehensive result for the period		-148,853	-196,897	-855,311	-734,093	-1,012,971

Interim condensed consolidated statements of cash flow for the nine-months periods ended September 30, 2022 and 2021.

DKK thousand	Note	Q1-Q3 2022	Q1-Q3 2021	FY 2021
Net result for the period		-859,687	-737,887	-1,018,149
Adjustments for other non-cash items	8	192,960	33,015*	47,615
Change in working capital		63,806	-130,223*	-166,325
Interests received		3,045	0	0
Interest paid		-20,004	-5,347	-3,296
Change in deferred revenue	3	-51,483	-16,844	-30,185
Income tax paid/received		1,436	-46,971	-41,631
Cash used in operating activities		-669,927	-904,257	-1,211,971
Payments of deposits		-434	-401	4,012
Purchase of marketable securities		-693,174	0	0
Proceeds from sale of marketable securities		772,405	0	0
Proceeds from sale of V-GO	2	104,852	0	0
Purchase of property, plant and equipment		-5,083	-5,854	-22,133
Cash used in investing activities		178,566	-6,255	-18,121
Repayment of borrowings	15	-436,088	0	0
Proceeds from borrowings		0	0	647,906
Proceeds from issuance of shares related to exercise of share-based compensation		1,177	21,149	26,070
Proceeds from issuance of shares		274,775	748,975	748,975
Costs related to issuance of shares		-8,153	-46,894	-46,894
Purchase of treasury shares		0	-28,595	-28,590
Repayment of leasing liabilities		-10,246	-8,195*	-14,716
Cash from financing activities		-178,535	686,440	1,332,751
Decrease/increase in cash and cash equivalents		-669,896	-224,072	102,659
Cash and cash equivalents at beginning of period		1,129,103	960,221	960,221
Exchange rate adjustments		34,548	17,450	66,223
Cash and cash equivalents at end of period		493,755	753,599	1,129,103

* Reclassifications of DKK 19,474 from leasing liabilities to adjustments for other non-cash items and DKK 34,004 from Change in working capital to adjustments for other non-current transactions have occurred compared to reported figures from Q3, 2021.

Interim condensed consolidated statements of financial position as of September 30, 2022 and December 31, 2021

DKK thousand	Note	Reviewed	Audited
		September 30, 2022	December 31, 2021
ASSETS			
Non-current assets			
Intangible assets	2	2,531	53,790
Property, plant and equipment	2	62,655	86,454
Right-of-use assets	2	119,564	134,994
Other investments	9	33,857	26,907
Deposits	2	11,614	12,638
Corporate tax receivable	6	4,125	1,268
Deferred tax assets	6	0	13,525
Prepaid expenses		16,456	16,457
Other financial assets	9	6,921	0
Total non-current assets		257,723	346,033
Current assets			
Inventories	2, 12	0	118,436
Trade receivables		33,560	73,025
Prepaid expenses		41,475	64,626
Corporate tax receivable	6	24,724	21,562
Other receivables		4,240	15,802
Marketable securities (restricted)	9, 10	236,131	0
Marketable securities	9	0	299,042
Cash (restricted)	10	151,171	0
Cash and cash equivalents		342,584	1,129,103
Total current assets		833,885	1,721,596
Total assets		1,091,608	2,067,629

Interim condensed consolidated statements of financial position as of September 30, 2022 and December 31, 2021

DKK thousand	Note	Reviewed	Audited
		September 30, 2022	December 31, 2021
EQUITY AND LIABILITIES			
Share capital	13	46,538	43,634
Translation reserve		18,531	14,155
Retained earnings		301,371	870,014
Equity		366,440	927,803
Borrowings	15	368,520	647,906
Deferred revenue		0	14,551
Other liabilities		18,426	18,426
Lease liabilities	2	112,295	124,626
Non-current liabilities		499,241	805,509
Trade payables		36,158	64,558
Lease liabilities	2	14,905	14,897
Deferred revenue		16,100	53,033
Rebate and product return liabilities		7,159	28,695
Other liabilities		151,605	173,134
Current liabilities		225,927	334,317
Total liabilities		725,168	1,139,826
Total shareholders' equity and liabilities		1,091,608	2,067,629

Interim condensed consolidated statements of changes in equity for the nine-months periods ended September 30, 2022 and 2021

DKK thousand	Reviewed			Total
	Share capital	Translation reserve	Retained* earnings	
Equity at January 1, 2021	39,800	8,977	1,180,534	1,229,311
<i>Other comprehensive income for the period</i>	0	3,794	0	3,794
Net result for the period	0	0	-737,887	-737,887
Share-based compensation	0	0	37,492	37,492
Acquisition of treasury shares	0	0	-70,195	-70,195
Capital increase	3,782	0	766,342	770,124
Costs related to capital increases	0	0	-46,893	-46,893
Equity at September 30, 2021	43,582	12,771	1,129,393	1,185,746
Equity at January 1, 2022	43,634	14,155	870,014	927,803
<i>Other comprehensive income for the period</i>	0	4,376	0	4,376
Net result for the period	0	0	-859,687	-859,687
Share-based compensation	0	0	26,149	26,149
Capital increase	2,904	0	273,048	275,952
Costs related to capital increase	0	0	-8,153	-8,153
Equity at September 30, 2022	46,538	18,531	301,371	366,440

*Columns Treasury shares, Share premium and Retained losses from the Company's annual financial statements for the year ended December 31, 2021 have been merged into the column Retained earnings to ease accessibility of information.

For the period January 1, 2021 – September 30, 2021 the following amounts have been transferred (DKK thousand):

From Share premium to Retained earnings: Equity at January 1, 2021 (3,470,787), Share-based compensation (37,492), Treasury shares (-70,195), Capital increase (766,342) and costs related to capital increase (-46,893). In total/Equity at September 30, 2021: 4,157,533.

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

Basis of preparation

The interim condensed consolidated financial statements of Zealand Pharma A/S (The 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 Company's annual financial statement for the year ended December 31, 2021 except for discontinued operations which are relevant account policies for the current interim period.

Discontinued operations

A discontinued operation is a component of the entity that has been disposed of or is classified as held for sale and that represents a separate major line of business or geographical area of operations, is part of a single coordinated plan to dispose of such a line of business or area of operations, or is a subsidiary acquired exclusively with a view to resale. The results of discontinued operations are presented separately in the statement of profit or loss. Comparatives in the statement of profit and loss for previous periods are restated to reflect the result of discontinued operations.

Revenue from delivery of services

Revenue from delivery of services is recognised in the accounting period in which the services are rendered. Amount is recognised net of any pass-through cost incurred on behalf of the customer. The assessment of if a cost is incurred on behalf of the customer is made by evaluating the nature of its promise to the customer including whether the specified good or service to be provided to the customer are controlled by the Company before that good or service is transferred to the customer.

New standards, interpretations and amendments adopted by the Group

IASB has issued a number of new and amended standards which are not yet effective. The Group has not early adopted any standard, interpretation or amendment that has been issued but is not yet effective. Several amendments apply for the first time in 2022, but do not have an impact on the interim condensed consolidated financial statements of the Group.

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.

Judgements and estimates applied

Discontinued operation

On March 30, 2022, the group announced its intention to exit the US sales activities including the V-Go activity. The activities were successfully divested on May 29, 2022 through an asset purchase agreement with MannKind Corporation. On September 7, 2022, the group announced the transfer of the commercial rights for Zegalogue to Novo Nordisk effectively ending all efforts to commercialize the group's products via own sales force. Management has determined that the activities around commercialization of products via own sales force met all the criteria for classification as a discontinued operation as of September 7, 2022. Accordingly, the activities, including the divestment of the V-GO disposal group, has been classified as a discontinued operation in the condensed consolidated interim income statement for all periods presented. Reference is made to note 2 for further information.

Going concern

Contrary to previous periods, it is management's judgement, that there are no substantial doubts that the group's interim condensed consolidated financial statement can be prepared under the going concern assumption. It is management's assessment that the company's non-restricted cash and cash equivalents of DKK 342.6 million as of September 30, 2022 together with the gross proceeds of DKK 786.0 million from private placement of new shares on October 4, 2022 as described in note 17 will be sufficient to fund our operating activities as planned for at least 12 months from the balance sheet date.

On October 4, 2022 Zealand Pharma announced the completion of a private placement of new shares. Reference is made to note 17.

Revenue from Novo Nordisk

On September 7, 2022, The Group announced a global license and development agreement with Novo Nordisk. Under the agreement The Group have received DKK 25.0 million in upfront payments and is eligible for up to DKK 45.0 million in development milestones and DKK 220.0 million in sales-based milestones. Management have applied judgement in identifying the distinct performance obligations from the agreement and determining the transaction price in accordance with IFRS 15 – revenue from contracts with customers. The transaction price has been allocated between the performance obligations based on the estimated amount that The Group expects to be entitled to in exchange for fulfilling the performance obligation. Based on the estimates The Group has recognised DKK 27.8 million as consideration for the license. The remaining consideration will be recognised as performance obligations are delivered and milestones are triggered.

For further information, please refer to note 3.

Valuation of Zegalogue inventory

Following the March 30, 2022, restructuring announcement management elected to write off all Zegalogue inventories, except what was forecasted to be sold in 2022, due to the uncertainties about the future sales channels for the product. With the agreement with Novo Nordisk, the prior period write-off related to finished goods was reversed as these items were transferred to Novo as a part of the agreement. Due to uncertainties whether the raw material will be utilized in the production of future products to Novo Nordisk, it is management estimate that the net realisable value of the raw material is zero as of September 30, 2022. Please refer to note 12 for further information.

Valuation of US deferred tax assets

On March 30, 2022 the group announced intentions to exit US sales activities and thus reduce US operations significantly and in Q2 V-Go was divested leading to US being projected for a negative taxable income for 2022. As a result, management has revaluated the groups US deferred tax assets and concluded to measure them at zero due to the uncertainties around when and if the deferred tax assets can be utilized. Please refer to note 6 for further information.

Valuation of Oberland prepayment option

As of December 31, 2021, it was estimated that the fair value of the prepayment option on the loan from Oberland was immaterial under the circumstances present at the time. Following the March 30th, 2022, restructuring announcement where Zealand announced their intention to scale back their commercial efforts, it became clear that Zealand would not be able to comply with the revenue covenants from the contract, which was a prerequisite to release the proceeds from the loan for use. As of March 31, 2022, the prepayment option was estimated at a fair value of DKK 142.1 million using third party valuation experts. The amount was recognized as a financial income. During Q2, 2022, the prepayment option was partially utilized and expensed and the remaining loan amount was released from any revenue related covenants. As a consequence, the fair value of the prepayment option is estimated to be immaterial as of September 30, 2022.

Modification of Oberland loan agreement

During the financial year, the loan agreement with Oberland have been amended twice. It is managements judgement that the amendments comprise terms which are substantially different from the term applicable prior to the amend. Consequently, the modification has been accounted for as an extinguishment of the loan subject to the original terms and recognition of a new liability. As a result, previously capitalized loan costs have been expensed. Management have estimated that any difference between the fair value of the new liability as of the time of the amendments and the principal amount of the loan to be immaterial. Please refer to note 15 for further information.

For further information regarding significant accounting estimates and judgments see note 1 in the Annual Report for 2021.

Note 2 – Discontinued operations

On March 30, 2022, the group announced its intension to exit the US sales activities including the V-Go activity. The activities was successfully divested on May 29, 2022 through an asset purchase agreement with MannKind Corporation. On September 7, 2022, the group announced the transfer of the commercial rights for Zegalogue to Novo Nordisk effectually ending all efforts to commercialize the groups products via own sales force. Management has determined that the activities around commercialization of products via own sales force met all the criteria for classification as a discontinued operation as of September 7, 2022. Accordingly, the activities, including the effect of the divestment of the V-GO disposal group, has been presented separately as a discontinued operation in the interim income statement.

The results and the cash flow of the discontinued activities are presented below as a discontinued operations for the interim period ended September 30, 2022 and September 30, 2021:

DKK thousand	Q3 2022	Q3 2021	Q1-Q3 2022	Q1-Q3 2021	FY 2021
Revenue	22,668	52,219	87,314	143,438	184,021
Cost of goods sold	-27,157	-28,743	-70,561	-84,005	-107,844
Gross margin	-4,489	23,476	16,753	59,433	76,177
Research and development expenses	-76	-1,841	-4,156	-4,473	-6,183
Sales and marketing expenses	-11,206	-67,697	-125,629	-230,346	-312,669
Administrative expenses	-1,961	-7,262	-15,348	-18,575	-25,378
Total Operating expenses	-13,243	-76,800	-145,133	-253,394	-344,230
Other operating income	21,338	0	21,338	0	0
Other operating expenses	-0	0	-92,315	0	0
Result before tax	3,606	-53,324	-199,357	-193,961	-268,053
Income tax	-66	-4,153	-15,781	272	4,842
Net result from discontinued operations	3,540	-57,477	-215,138	-193,689	-263,211

DKK thousand	Q1-Q3 2022	Q1-Q3 2021	FY 2021
Cash flows from discontinued operations			
Net cash inflow (outflow) from operating activities	-135,532	-322,233	-368,052
Net cash inflow (outflow) from investing activities	104,808	-874	-1,585
Net cash (outflow) from financing activities	-1,064	-1,708	-2,319
Net cash increase (decrease) generated from the discontinued operation	-31,788	-324,815	-371,956

All assets and liabilities included in the V-Go disposal group was derecognized as of May 29, 2022 with the closure of the asset purchase agreement with MannKind. As a result, no assets or liabilities are classified as held for sale in relation to the discontinued operation as of September 30, 2022.

The derecognized assets and liabilities, recognized consideration and net impact on profit and loss from the divestment of V-Go are presented below:

DKK thousand	May 29, 2022
Assets included in disposal group	
Intangible assets	52,082
Property, plant and equipment	20,586
Right-of-use assets	8,128
Deposits and prepayments	1,871
Inventories	79,872
Total assets of disposal group	162,539
Liabilities directly associated with assets included in disposal group	
Lease liabilities	8,837
Total liabilities of disposal group	8,837
Net assets of disposal group	153,702
<i>Consideration:</i>	
Cash consideration*	111,553
Other financial assets	6,573
Total consideration	118,126
Net loss - recognized as other operating expenses from discontinued operations	-35,576

*As of September 30, 2022, DKK 104.9 million of the cash consideration was received. The remaining DKK 6.6 million is included in a settlement account that will be settled upon completion of transition period.

Note 3 - Revenue

Revenue can be specified as follows:

DKK thousand	Q3 2022	Q3 2021	Q1-Q3 2022	Q1-Q3 2021	FY 2021
Alexion Pharmaceuticals Inc.	15,136	6,497	51,483	16,753	30,185
Boehringer Ingelheim International GmbH	0	22,311	0	22,311	22,311
Novo Nordisk	27,808	0	27,808	0	0
Protagonist Therapeutics Inc.	0	25,380		25,381	25,381
Sanofi-Aventis Deutschland GmbH	0	0	0	30,669	30,669
Total license and milestone revenue	42,944	54,188	79,291	95,114	108,546
Total revenue from sale of services	770	0	770	0	0
Total sale of goods revenue net	22,668	45,881	87,314	143,348	184,021
- Hereof related to discontinued operations	-22,668	-45,881	-87,314	-143,348	-184,021
Sale of goods revenue net from continuing operations	0	0	0	0	0
Total revenue from continuing operations	43,714	54,188	80,061	95,114	108,546
Total revenue recognized over time	15,136	6,497	51,483	16,753	30,185
Total revenue recognized at a point in time	28,578	47,691	28,578	78,361	78,361

License revenue for the first nine months of 2022 is related to the research and development agreement with Alexion Pharmaceuticals and the global license and development agreement with Novo Nordisk. Under the agreement with Novo Nordisk an upfront fee of DKK 25.0 million was received upon signing in Q3, 2022, and the group is eligible to receive up to DKK 45.0 million in development milestones. DKK 27.8 million has been recognised upon signing while the remaining of the contract value will be recognised as performance obligations are fulfilled and milestones are triggered.

Under the agreement with Alexion Pharmaceuticals, DKK 16.1 million is accounted for as deferred revenue as of September 30, 2022.

Revenue from sale of goods for the first nine months of 2022 comprise DKK 21.3 million related to the transfer of Zegalogue finished goods to Novo Nordisk following the global license and development agreement as announced in Q3 2022 and DKK 66.0 million for the sale of V-GO and Zegalogue products sold via own sales force. Following the divestment of V-GO and the global license and development agreement for Zegalogue such sales are accounted for as discontinued operations. Please refer to note 2 for further information. The net sales of goods comprise of gross sales of DKK 164.7 million and discounts and rebates of DKK -77.4 million (DKK 270.3 million and DKK -127.0 million respectively for the nine months ended September 30, 2021 and DKK 354.6 million and DKK -157.0 million respectively for the financial year ended December 31, 2021).

Zealand is managed and operated as one business unit, which is reflected in the organizational structure and internal reporting. Beside from the V-Go activities which is presented separately as discontinued operations and disposal group held for sale, no separate lines of business or separate business entities have been identified with respect to any of the product candidates or geographical markets and no segment information is currently included in the internal reporting.

Note 4 – Other operating items

Recognized other operating income and expenses can be specified as follows:

DKK thousand	Q3 2022	Q3 2021	Q1-Q3 2022	Q1-Q3 2021	FY 2021
Proceeds from insurance claims	0	0	1,849	0	0
Government grants	27	126	5	614	759
Loss on sale of fixed assets	0	-53	-742	-606	-2,173
Restructuring costs – continuing operations	0	0	-19,098	0	0
Other operating items from continuing operations	27	73	-17,986	8	-1,414
Restructuring costs	0	0	-56,738	0	0
Reversal of prior periods inventory write-off	21,338	0	21,338	0	0
Divestment of V-GO	0	0	-35,577	0	0
Other operating items from discontinued operations	21,338	0	-70,977	0	0
Presentation in income statement:					
Other operating income	27	126	1,854	614	759
Other operating expenses	0	-53	-19,840	-606	-2,173
Discontinued operations	21,338	0	-70,977	0	0

Restructuring costs from discontinued operations comprises severance costs (DKK -13.8 million), reversal of costs related to forfeited share-based incentive programs (DKK 2.7 million) and an allowance for loss on Zegalogue inventories (DKK -45.6 million) while restructuring costs from continuing operations comprises severance costs (DKK -30.3 million) and reversal of costs related to forfeited share-based incentive programs (DKK 11.2 million). All restructuring costs were incurred as a result of the March 30, 2022, company announcement.

The partial reversal of prior periods inventory write-off of DKK 21.3 million relates to the Zegalogue finished goods inventory that was transferred to Novo Nordisk in Q3, 2022, as a result of the global license and development agreement as announced in Q3, 2022.

Note 5 – Financial items

Recognized financial items can be specified as follows:

DKK thousand	Q3 2022	Q3 2021	Q1-Q3 2022	Q1-Q3 2021	FY 2021
Interest income	1,379	0	3,060	0	44
Interest expenses and banking fees	-10,349	-2,477	-36,705	-6,329	-4,091
Loss on settlement of borrowings	-172	0	-144,901	0	0
Fair value adjustments of other investments	0	0	2,259	0	-8,217
Fair value adjustments of prepayment option	0	0	71,050	0	0
Fair value adjustment of marketable securities	54	602	-2,591	-1,578	1,852
Currency exchange adjustments	17,506	17,946	54,407	29,427	39,315
Other financial expenses	0	0	0	0	-3,473
Financial items in total	8,418	16,071	-53,421	21,520	25,430
Presentation in income statement:					
Financial income	18,885	18,548	130,776	29,427	41,211
Financial expenses	-10,467	-2,477	-184,197	-7,907	-15,781

Fair value adjustments of prepayment option relate to the prepayment option included in the loan agreement with Oberland. As of December 31, 2021, it was assessed that the fair value of the option was immaterial under the circumstances present at the time. Following the March 30th, 2022, restructuring announcement where Zealand announced their intention to scale back their commercial efforts, it became clear that Zealand would not be able to comply with the revenue covenants from the contract, which was a prerequisite to release the proceeds from the loan for use. As of March 31, 2022, the prepayment option was valued at a fair value of DKK 142.1 million which was recognized as a financial income. During Q2, 2022, the prepayment option was partially utilized and the remaining loan amount was released from any revenue related covenants. As a consequence, the fair value of the prepayment option is assessed to be immaterial as of September 30, 2022.

Loss on settlement of borrowings both relates to the utilization of the prepayment option from the loan agreement with Oberland and comprise the partial utilization of the prepayment option, the premium paid and the capitalized loan costs which have been fully expensed. Reference is made to note 15 for further information.

Note 6 – Income tax

Recognised income tax is based on the groups' projected effective tax rate for the year adjusted for separate events.

Tax from continuing operations recognized in 2022 comprise tax income of DKK 4.1 million relating to corporate tax benefit in Denmark, and a tax income of DKK 0.9 million related to prior year taxes in Denmark.

Tax from discontinued operations for the first nine months of 2022 relates to revaluation of the deferred tax assets related to US. Following the March 30, 2022 restructuring announcement the group expects reduced activities in the US going forward. As a result, the value of the groups tax asset related to US activities have been remeasured leading to an impairment of the tax asset of DKK 14.6 million.

As of September 30, 2022, no deferred tax assets are recognized for the group due to uncertainties about when the assets can be utilized.

Receivable taxes relate to receivable tax benefits in Denmark and prepaid taxes in US.

Note 7 - Earnings/Loss per share

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

DKK thousand	Q3 2022	Q3 2021	Q1-Q3 2022	Q1-Q3 2021	FY 2021
Net earnings/loss used in the calculation of basic/diluted earnings per share from continuing operations	-151,882	-141,410	-644,549	-544,198	-754,938
Net earnings/loss used in the calculation of basic/diluted earnings per share from discontinuing operations	3,540	-57,477	-215,138	-193,689	-263,211
Total net earnings/loss	-148,342	-198,887	-859,687	-737,887	-1,018,149
Weighted average number of ordinary shares	46,530,186	43,552,583	44,917,346	43,053,533	43,192,383
Weighted average number of treasury shares	-248,848	-401,599	-327,075	-290,848	-322,988
Weighted average number of ordinary shares used in the calculation of basic/diluted loss per share	46,281,338	43,150,984	44,590,271	42,762,6845	42,869,395
Earnings/loss per share from continuing operations – basic/diluted (DKK)	-3.29	-3.28	-14.46	-12.73	-17.61
Earnings/loss per share from discontinued operations – basic/diluted	0.08	-1.33	-4.82	-4.53	-6.14
Total earnings/loss per share – basic/diluted	-3.21	-4.61	-19.28	-17.26	-23.75

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

	September 30, 2022	September 30, 2021	December 31, 2021
Outstanding warrants under the 2015 Employee incentive program	1,013,688	1,526,779	1,413,977
Outstanding warrants under the 2020 Employee incentive program	10,490	63,217	63,217
Outstanding Performance Share Units (PSUs) under the LTIP 2019 program	0	19,765	16,703
Outstanding Restricted Share Units (RSUs) under the LTIP 2020 program	7,008	27,466	23,548

Outstanding Performance Share Units (PSUs) under the LTIP 2021 program	88,734	282,852	255,058
Outstanding Restricted Share Units (RSUs) under the LTIP 2021 program	147,886	452,450	436,541
Outstanding warrants under the LTIP 2022 program	833,165	0	0
Outstanding Performance Share Units (PSUs) under the LTIP 2022 program	266,223	0	0
Outstanding Restricted Share Units (RSUs) under the LTIP 2022 program	139,920	0	0
Total outstanding warrants/PSUs/RSUs	2,507,114	2,372,529	2,209,044

Total number of outstanding warrants, PSUs and RSUs for long-term incentive programs currently unexercised or under vesting have been negatively impacted by 401,696 from the termination of employees end of March 2022 in connection with the restructuring.

Note 8 – Adjustments for non-cash items

DKK thousand	Q1-Q3 2022	Q1-Q3 2021	FY 2021
Depreciation, amortization and impairment losses	96,734	30,774	40,249
Financial items	53,421	-21,520	-25,430
Share-based compensation	26,149	37,492	53,504
Income tax	10,725	-3,216	-8,791
Other non-cash items	5,931	-10,515	-11,917
Adjustments for non-cash items in total	192,960	33,015	47,615

Depreciation, amortization and impairment losses for Q1-Q3, 2022, includes the net loss on the V-GO divestment (DKK 35.6 million) and the net allowance for loss on Zegalogue inventory (DKK 24.3 million).

Note 9 - Financial instruments

As of September 30, 2022, and December 31, 2021, the following financial instruments are measured at fair value through profit or loss:

DKK thousand	September 30, 2022	December 31, 2021
Marketable securities (Level 1)	118,129	299,042
Marketable securities (Level 2)	118,002	0
Other investments (Level 3)	33,857	26,907
Other financial assets (Level 3)	6,921	0
Financial assets measured at fair value	276,909	325,949

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 are based on inputs categorized as Level 3 in the fair value hierarchy. No transfers occurred between the levels of the fair value hierarchy in the nine months to 30 September 2022.

Marketable securities consist of investments in debt instruments (corporate bonds and asset-backed securities) and equity instruments (commercial papers and money market funds). For marketable securities categorized as Level 2, the valuation is mainly based on observable terms (e.g. maturity, interest rate, credit rating etc.).

Other investments consist of a USD 5.4 million (December 31, 2021: USD 5.4 million) investment in Beta Bionics, Inc., the developer of iLet™, a fully integrated dual-hormone pump (bionic pancreas) for autonomous diabetes care.

In determining fair value, Zealand is using valuations from third party specialists combined with considerations around the impact of any recent share capital issuances by Beta Bionics as an indicator of the fair value of the shares. In particular, Beta Bionics closed a series C financing in February, 2022, which is used as the basis for determining fair value.

Based on an updated valuation report and the development in the USD/DKK exchange rate the fair value of the investment in Beta Bionics has developed from DKK 26.9 million on December 31, 2021, to DKK 33.9 million on September 30, 2022. The gain has been recognized as finance income.

Other financial assets comprise the sales-related milestones from the divestment of V-Go. A maximum of four milestones of USD 2.5m each can be achieved under the contract based on annual sales. The fair value has been determined using the risk-adjusted net present value method using a discount rate of 10% and an estimated probability of 50% and 25% respectively to reach the first two sales-related milestones.

DKK thousand	Q3 2022	Q3 2021	Q1-Q3 2022	Q1-Q3 2021
Financial instruments categorized as level 3 in the fair value hierarchy				
Carrying amount at start of period	38,565	33,427	26,907	32,333
Additions during the period	0	0	6,573	0
Charges to profit and loss:				
Fair value adjustments	142	0	2,401	0
Exchange rate adjustments	2,071	1,255	4,897	2,349
Carrying amount at end of period	40,778	34,682	40,778	34,682

Note 10 – Restricted cash and marketable securities

Under the second amendment to the Oberland loan agreement signed on September 20, 2022, the outstanding principal of \$50 million is to be held in a designated deposit account controlled by Oberland.

The cash and securities can be released in chunks of USD 10.0 million upon request from the group.

Note 11 – Capital Management

The Company's capital management objectives and policies are unchanged from the ones described in the Annual report of the Company for 2021 with the exception of the company's commercial objectives. On March 30, 2022 the company announced that it will discontinue to support commercial operations in the United States and will prioritize research and development. With the implementation of this strategy the company will cease generating revenue from the product sales of its commercial programs and will instead look to out-license, sell, or partner their commercial and late-stage assets as a way of providing for the company's near and long-term capital requirements.

At the Zealand Annual Meeting held on April 6, 2022, the shareholders granted the company the ability during the period until 15 April 2026 to raise loans against issuance of convertible debt instruments with access to conversion to shares in the Company (convertible debt instruments) of up to a total of nominally DKK 10,850,136 without pre-emption rights for existing shareholders in accordance with the adopted new Articles 8.13-8.15 of the Company's Articles of Association.

In June of 2022 the company received gross proceeds of DKK 274.8 million from a directed issue and private placement. Zealand issued a total of 2,892,368 new shares at a subscription price of DKK 95 per share.

In August 2022 the company announced Voluntary Delisting of American Depositary Shares from the U.S.-Based Nasdaq Global Select Market.

Subsequent to the quarter, the company received gross proceeds of DKK 786 million from a directed issue and private placement. Zealand issued a total of 4,975,000 new shares at a subscription price of DKK 158 per share.

Note 12 - Inventories

DKK thousand	September 30, 2022	December 31, 2021
Raw materials	0	35,816
Work in progress	0	29,588
Finished goods	0	53,032
Inventories	0	118,436

The development in inventories relates to the decision to discontinue the efforts to sell V-Go and Zegalogue via own sales force. For further information related to V-Go please refer to note 2.

With the March 30, 2022, restructuring announcement an allowance for loss on Zegalogue inventory of DKK 45.6 million were recognized due to uncertainties around the future sales channels for the product. The allowance is included as discontinued operations under other operating expenses as a restructuring cost. As all Zegalogue finished goods was transferred to Novo Nordisk as a result of the global license and development agreement announced in Q3, 2022, a partial reversal of the inventory allowance of DKK 21.3 million was recognised under other operating income from discontinued operations in Q3, 2022.

As of September 30, 2022, Zegalogue related raw materials at costs amounts to DKK 28.7 million. Due to uncertainties if the raw materials will be utilized in the production under the supply agreement with Novo Nordisk, management have estimated the net realisable value to be immaterial. As a result, the inventory is measured at zero as of the reporting date.

Note 13 - Changes in share capital

The following changes have occurred in the share capital during the interim period:

	No. of shares (thousand)
Share capital at January 1, 2022	43,634
Increase due to issue of 2,892,368 new shares on June 1, 2022 at a subscription price of DKK 95 per share	2,892
Increase due to issue of 3,874 new shares on August 18, 2022 at a subscription price of DKK 100.8 per share	4
Increase due to issue of 7,802 new shares on September 8, 2022 at a subscription price of DKK 100.8 per share	8
Share capital at September 30, 2022	46,538

On October 4, 2022, The Group announced that a directed issue and private placement of 4,975,000 new shares had been completed. Please refer to note 17 for further information.

Note 14 – Treasury shares

The total number of treasury shares as of September 30, 2022 is 231,881 (December 31, 2021: 418,247). Treasury shares are allocated to long term incentive compensation plans. The development in the number of treasury shares is due to the vesting of employees RSUs and PSUs.

Note 15 – Borrowings

As further discussed in note 25 of the 2021 annual report, Zealand entered into a USD 100 million loan agreement with Oberland in December 2021.

On September 20, 2022, Zealand entered into an agreement no. II to amend certain terms of the Oberland loan and amendment No. I dated May 9. The amendments were as follows:

- Prepayment of 50% of the principal which including a prepayment premium of 20% amounts to 60 MUSD
- The outstanding principal of \$50 million to be held in a designated deposit account.
- The funds can be released in increments of \$10 million upon request
- 50% prepayment option premium irrespective of the date of prepayment
- Potential for a further \$75 million incremental capital following specific events

Management considers the amendments to comprise terms which are substantially different from the term applicable prior to the amend. Consequently, the modification has been accounted for as an extinguishment of the loan subject to the original terms and recognition of a new liability.

Under the amended terms, Management estimates that fair value of the prepayment option for the remaining outstanding amount is insignificant due to the fact that release from the liquidity covenant a market participant would not benefit from prepaying the loan due to the fact that the funds are available for use for a market participant.

In the first nine months of 2022 DKK 144.9 million was recognised as loss on settlement of borrowings under financial expenses. The amount comprises utilization of the prepayment option (DKK 71.1 million), premium on settlement of debts (DKK 64.9 million) and derecognition of capitalized loan costs (DKK 8.9 million). The cash outflow from debts of DKK 436.1 million comprises the premium on settlement of debts (DKK 64.9 million), repayment of USD 51.2 million (DKK 365.4 million) and a prepayment of USD 0.8 million (DKK 5.8 million) which will be offset against future repayments.

On 20 September 2022, the Company entered into the Second Amendment to the Note Purchase Agreement to address certain non-financial events of default by Zealand, which Oberland Capital waived pursuant to the amendment.

The Second Amendment introduced two conditions for the release of the \$50 million held in a Zealand Pharma A/S account that is controlled by Oberland Capital, one of which was satisfied. Upon satisfaction of the second condition, which relates to the fulfillment of certain post-closing obligations, Zealand may transfer funds from such account in increments of \$10 million for purposes of operating Zealand's business in the ordinary course upon prior notice to Oberland Capital.

There are currently no other outstanding events of default under the Note Purchase Agreement.

Note 16 - Contingent assets, liabilities, other contractual obligations and collateral provided

Contingent assets

As of September 30, 2022, Zealand is still eligible for a payment from Sanofi of up to USD 10.0 million which is expected in 2023. However, it is Management's opinion that the amount of any payment cannot be determined on a sufficiently reliable basis, and therefore the company has not recognized an asset in the statement of financial position of the Group.

Contingent liabilities and contractual obligations

As of September 30, 2022, total contractual obligations related to agreements with CRO's and CMO's amounted to DKK 268.1 million (DKK 71.4 million for 2022 and DKK 196.7 million for the years 2023 up to and including 2026).

Zealand may be required to pay future development, regulatory and commercial milestones related to the acquisition of Encycle Therapeutics. Refer to note 13 in the Annual Report 2021.

Collateral provided

The Group has provided floating charge collateral with all assets which can be collateralized including shares in subsidiaries.

Note 17 - Significant events after the reporting period

Private placement of new shares

On October 4, 2022, The Group announced that a directed issue and private placement of 4,975,000 new shares had been completed at a subscription price of DKK 158 per share.

The gross proceed from the issue was DKK 786 million and Zealand intends to use the net proceeds to help fund continued development of Zealand's proprietary pipeline of investigational peptide-based therapeutics, support pre-commercial activities, and general corporate purposes.