



ZEALAND PHARMA

# Q3 2023 Interim Report.

**Zealand Pharma**

November 9, 2023

# Forward-looking Statements



This presentation 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 2023.

The reader is cautioned not to rely on these forward-looking statements. Such forward-looking statements are subject to risks, uncertainties and inaccurate assumptions, which may cause actual results to differ materially from expectations set forth herein and may cause any or all of such forward-looking statements to be incorrect, and which include, but are not limited to, the occurrence of adverse safety events; risks of unexpected costs or delays; unexpected concerns that may arise from additional data, analysis or results obtained during clinical trials; failure to protect and enforce our data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; regulatory authorities may require additional information or further studies, or may fail to approve or may delay approval of our drug candidates or expansion of product labeling; failure to obtain regulatory approvals in other jurisdictions; exposure to product liability and other claims; interest rate and currency exchange rate fluctuations; unexpected contract breaches or terminations; inflationary pressures on the global economy; and political uncertainty, including due to the ongoing military conflict in Ukraine.

If any or all of such forward-looking statements prove to be incorrect, our actual results could differ materially and adversely from those anticipated or implied by such statements. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from our expectations in any forward-looking statement.

All such forward-looking statements speak only as of the date of this presentation 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.

# Q3 2023 saw strong progress across obesity pipeline and first PDUFA date for dasiglucagon in CHI

NON-EXHAUSTIVE



**Survodutide**  
dual GCGR/GLP-1R  
receptor agonist

**Announced details on  
Phase 3 program  
SYNCHRONIZE™**



**ZP 8396**  
amylin analog

**Presented 6-week trial results  
at ObesityWeek**



**Dapiglutide**  
dual GLP-1R/GLP-2R  
receptor agonist

**Initiated 13-week dose  
titration trial**

## Dasiglucagon in congenital hyperinsulinism



**Granted Priority Review with  
Dec-30, 2023 PDUFA date for  
up to three weeks of dosing**

## Solid financial position



**Recognized revenue for  
milestones from existing  
partners, with cash inflow  
expected in Q4 2023**

# In 2023 we have three key strategic objectives focused on maximizing the value potential of our pipeline

## 1 Progress rare disease assets toward regulatory submission

- ✓ **Dasiglucagon for congenital hyperinsulinism**



- **Glepaglutide for Short Bowel Syndrome**



## 2 Advance obesity portfolio

- ✓ **Survodutide<sup>1</sup> (GCGR/GLP-1R)**
  - ✓ Phase 2 data in obesity
  - ✓ Phase 3 decision
- ✓ **Dapiglutide (GLP-1R/GLP-2R)**
  - ✓ Initiate Phase 2a DREAM trial<sup>2</sup>
  - ✓ Initiate 13-wk dose-titration trial
- ✓ **ZP8396 (amylin)**
  - ✓ 6-wk MAD Phase 1 results
  - ✓ Initiate 16-wk dose-titration trial
- ✓ **ZP6590 (GIP)**
  - ✓ Ready for Phase 1

## 3 Engage in strategic partnership discussions

### Rare disease programs

- Focus on companies with rare disease commercial infrastructure

### Obesity programs

- Focus on companies with global development and commercial infrastructure

### Other programs

- Focus on companies with therapeutic area leadership

## Other significant activities

- ✓ **Zegalogue<sup>®3</sup>**
  - MAA submission in EU by Zealand

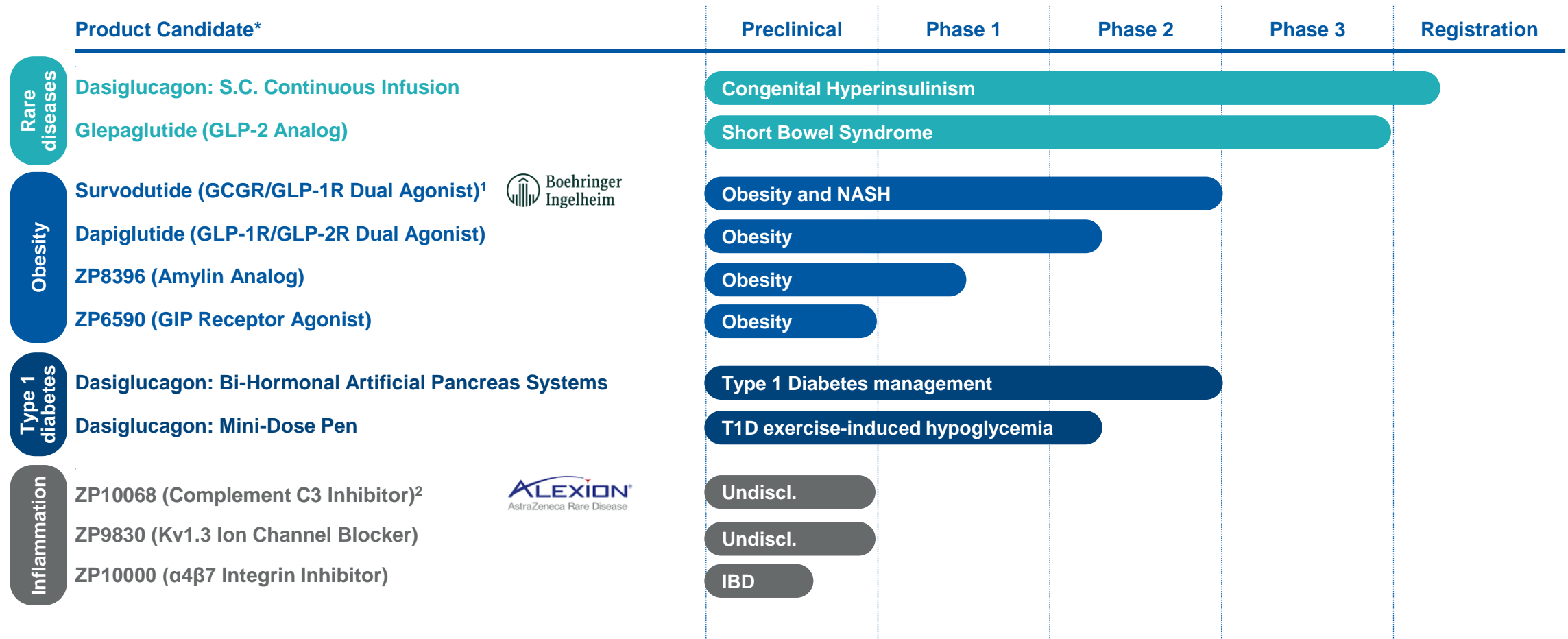


- **Dasiglucagon (in BHAP systems)**
  - Initiate Phase 3 program<sup>4</sup>

- ✓ **ZP10068<sup>5</sup> (complement C3 inhibitor)**
  - Ready for Phase 1

<sup>1</sup>Conducted by Boehringer Ingelheim; <sup>2</sup>DREAM is an investigator-led trial; <sup>3</sup>Licensed to Novo Nordisk; <sup>4</sup>With Beta Bionics; <sup>5</sup>Discovery and development agreement with Alexion, AstraZeneca Rare Disease.

# Our R&D pipeline addresses unmet medical needs across several therapeutic areas

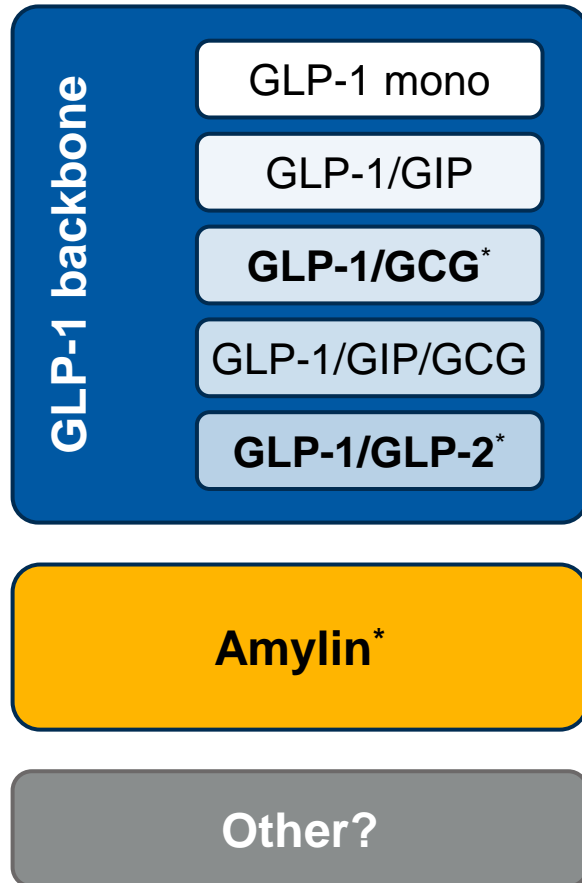


\* Investigational compounds whose safety and efficacy have not been evaluated or approved by the FDA or any other regulatory authority

<sup>1</sup> Co-invented by Boehringer Ingelheim and Zealand: EUR 345 million outstanding potential development, regulatory and commercial milestones, including EUR 30 million recognized in the third quarter of 2023, plus high single to low double digit % royalties on global sales to Zealand.

<sup>2</sup> Licensed to Alexion: USD 610 million potential development, regulatory and commercial milestones + high single to low double digits % royalties on net sales.

# The success of future weight loss therapies will be determined by differentiation on multiple fronts



## Examples of differentiation factors

- Effects on comorbidities to obesity such as CVD, NASH, T2DM, CKD, and OA
- Improved tolerability by addressing GI side effects during weight loss and weight maintenance
- Unique non-incretin mechanisms – for example, amylin increasing satiety in contrast to decreasing appetite
- Offer greater convenience through dosing regimen and/or delivery, for example orals versus injectables
- Develop fixed or loose ‘flexible-use’ combinations for patient segments that need even greater weight loss, serving different patient needs

\*Zealand Pharma clinical development pipeline.

CKD=chronic kidney disease; CVD=cardiovascular disease; GCC=glucagon; GI=gastrointestinal; GIP=gastric inhibitory polypeptide; GLP-1=glucagon-like peptide-1; GLP-2=glucagon-like peptide-2; NASH=nonalcoholic steatohepatitis; OA=osteoarthritis; T2DM=type 2 diabetes mellitus.

# The Phase 3 program with survodutide in obesity includes three global registrational trials



	Inclusion criteria	Study design	Primary endpoint
<b>SYNCHRONIZE™-1</b> Efficacy and Safety in Patients with obesity without T2DM	<ul style="list-style-type: none"> <li>HbA1c &lt;6.5% (no history of diabetes)</li> <li>BMI ≥30 or BMI ≥27 with comorbidities*</li> </ul>	<ul style="list-style-type: none"> <li>N = 600</li> <li>1:1:1 ratio (active 3.6mg, active 6.0mg or placebo)</li> <li>Trial duration: 76 weeks</li> </ul>	<ul style="list-style-type: none"> <li>Percentage change in BW from baseline to Week 76</li> <li>Achievement of BW reduction ≥5% from baseline to Week 76</li> </ul>
<b>SYNCHRONIZE™-2</b> Efficacy and Safety in Patients with obesity with T2DM	<ul style="list-style-type: none"> <li>HbA1c ≥6.5%, &lt;10%</li> <li>BMI ≥27</li> <li>Treated for T2DM with either diet and exercise alone or stable treatment</li> </ul>	<ul style="list-style-type: none"> <li>N = 600</li> <li>1:1:1 ratio (active 3.6mg, active 6.0mg or placebo)</li> <li>Trial duration: 76 weeks</li> </ul>	<ul style="list-style-type: none"> <li>Percentage change in BW from baseline to Week 76</li> <li>Achievement of BW reduction ≥5% from baseline to Week 76</li> </ul>
<b>SYNCHRONIZE™-CVOT</b> Long-term CV safety in Patients with obesity and established CVD/CKD or risk factors for CVD	<ul style="list-style-type: none"> <li>BMI ≥27 with CVD and/or at least two weight-related risk factors for CVD or</li> <li>BMI ≥30 with CVD or CKD and/or at least two weight-related factors for CVD</li> </ul>	<ul style="list-style-type: none"> <li>N = 4,935</li> <li>1:1:1 ratio (active 3.6mg, active 6.0mg or placebo)</li> <li>Trial duration: up to 114 weeks</li> </ul>	<ul style="list-style-type: none"> <li>Time to first occurrence of any of five major adverse cardiac events (5P-MACE) to demonstrate non-inferiority</li> </ul>

Notes:

SYNCHRONIZE-1 (ClinicalTrials.gov ID: NCT06066515), SYNCHRONIZE-2 (ClinicalTrials.gov ID: NCT06066528). SYNCHRONIZE-CVOT (ClinicalTrials.gov ID: NCT06077864).

Inclusion criteria for all three trials include Age ≥18 years. Comorbidities = dyslipidemia, hypertension, obstructive sleep apnea, others. T2DM = type 2 diabetes mellitus. CVD = cardiovascular disease. CKD = chronic kidney disease.

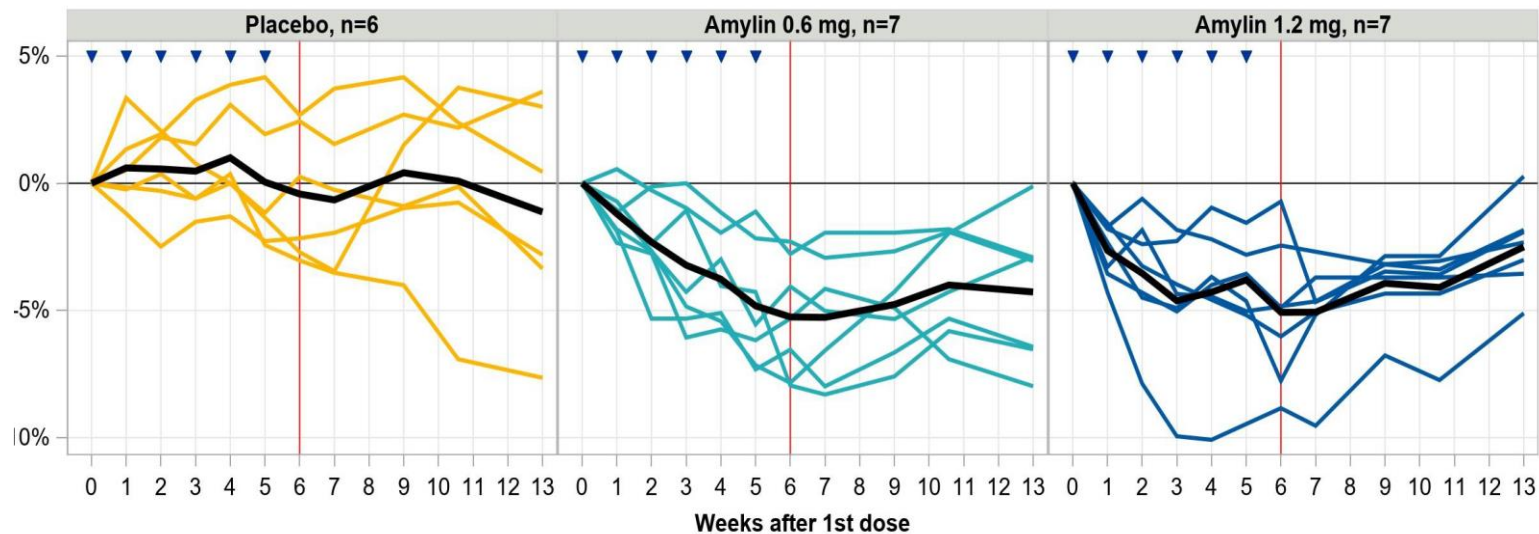
5P-MACE includes cardiovascular death, non-fatal stroke, non-fatal myocardial infarction, ischemia-related coronary revascularization or heart failure.

Survodutide was co-invented by Boehringer Ingelheim and Zealand Pharma. Boehringer Ingelheim funds all research, development and commercialization activities.

# Very low doses of ZP8396 delivered >5% weight loss after 6 weeks

*ZP8396 in a low 0.6 mg dose delivered average weight loss of 5.3% after six once-weekly doses*

## Part 1 of Phase 1b multiple ascending dose trial with ZP8396<sup>1</sup>



Mean: -0.4%

Mean: -5.3%

Mean: -5.1%

- Healthy lean and overweight people randomized (7:3) and treated with either ZP8396 or placebo (mean BMI 25.4)
- Weight loss up to mean of 5.3% and 5.1% after six once-weekly doses of 0.6 mg and 1.2 mg ZP8396, respectively



# In Part 1 of MAD trial, ZP8396 was well tolerated with no serious or severe AEs and no withdrawals

*All related adverse events were mild, transient and most had an onset within two days of the first dose*

## Treatment-emergent adverse events (TEAEs) in Part 1 of Phase 1b MAD trial with ZP8396<sup>1</sup>

No. of subjects (events)	Placebo n = 6	ZP8396 0.6 mg n = 7	ZP8396 1.2 mg n = 7
<b>Total AEs</b>	<b>5 (28)</b>	<b>6 (23)</b>	<b>7 (29)</b>
Mild	5 (24)	6 (23)	7 (29)
Moderate	3 (4)	0	1 (2)
Severe	0	0	0
<b>Serious</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>Metabolism and nutrition disorders</b>	<b>1 (1)</b>	<b>6 (9)</b>	<b>6 (8)</b>
<b>Gastrointestinal disorders</b>	<b>3 (7)</b>	<b>2 (6)</b>	<b>5 (9)</b>

- Nausea occurred in three subjects treated with ZP8396, with one also reporting vomiting; no other subjects reported vomiting
- No injection site reactions were reported, and no subjects developed anti-drug antibodies

# Results from Part 2 of the trial, exploring higher doses of ZP8396 over 16 weeks are expected in H1 2024



**We are investigating significantly higher doses of ZP8396...**



**...over a longer duration of 16 weeks...**



**...using an up-titration scheme...**



**...in 48 people with overweight or obesity\* ...**

# Priority review for dasiglucagon in CHI for up to three weeks of dosing with PDUFA date December 30, 2023

*To make dasiglucagon available to infants and children with CHI as soon as possible, the US FDA recommended conducting the review of the NDA in two parts*



## **Part 1**

- Up to three weeks of dosing
- Priority Review with PDUFA date Dec-30, 2023

## **Part 2**

- Longer dosing beyond three weeks
- Good progress on preparing extensive analyses from existing CGM datasets, with submission expected in H1 2024

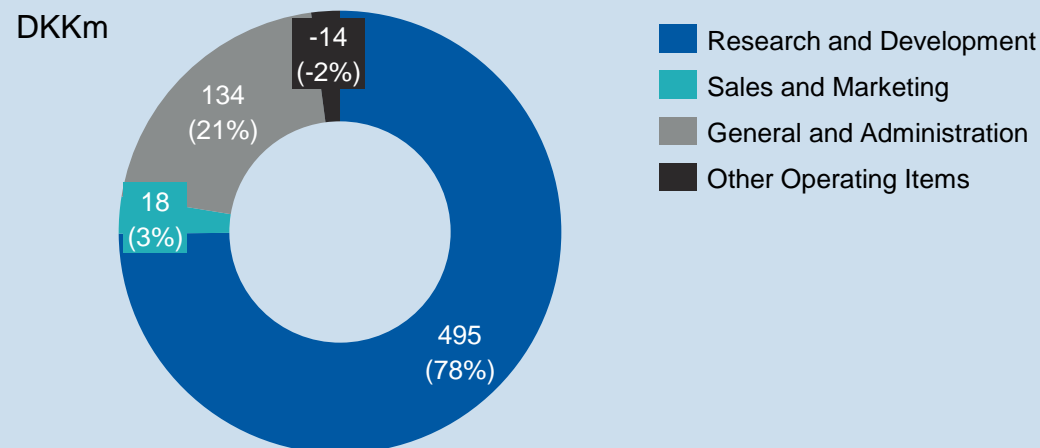
# Q3 2023 YTD Profit & Loss

DKK million	Q3-23 YTD	Q3-22 YTD
Revenue	319.6	80.1
<b>Gross margin</b>	<b>319.6</b>	<b>80.1</b>
Research and Development expenses	-494.7	-452.0
Sales and Marketing Expenses	-17.8	-28.6
General and Administrative Expenses	-134.4	-177.1
Other Operating Items	13.8	-18.0
<b>Net Operating Expenses</b>	<b>-633.2</b>	<b>-675.7</b>
<b>Operating Result</b>	<b>-313.6</b>	<b>-595.6</b>
Net Financial Items	-124.8	-53.4
<b>Result before tax</b>	<b>-443.5</b>	<b>-649.6</b>
Tax	4.6	5.1
<b>Net result for the period from continued operations</b>	<b>-439.0</b>	<b>-644.5</b>
Discontinued Operations	-	-215.1
<b>Net result for the period</b>	<b>-439.0</b>	<b>-859.7</b>

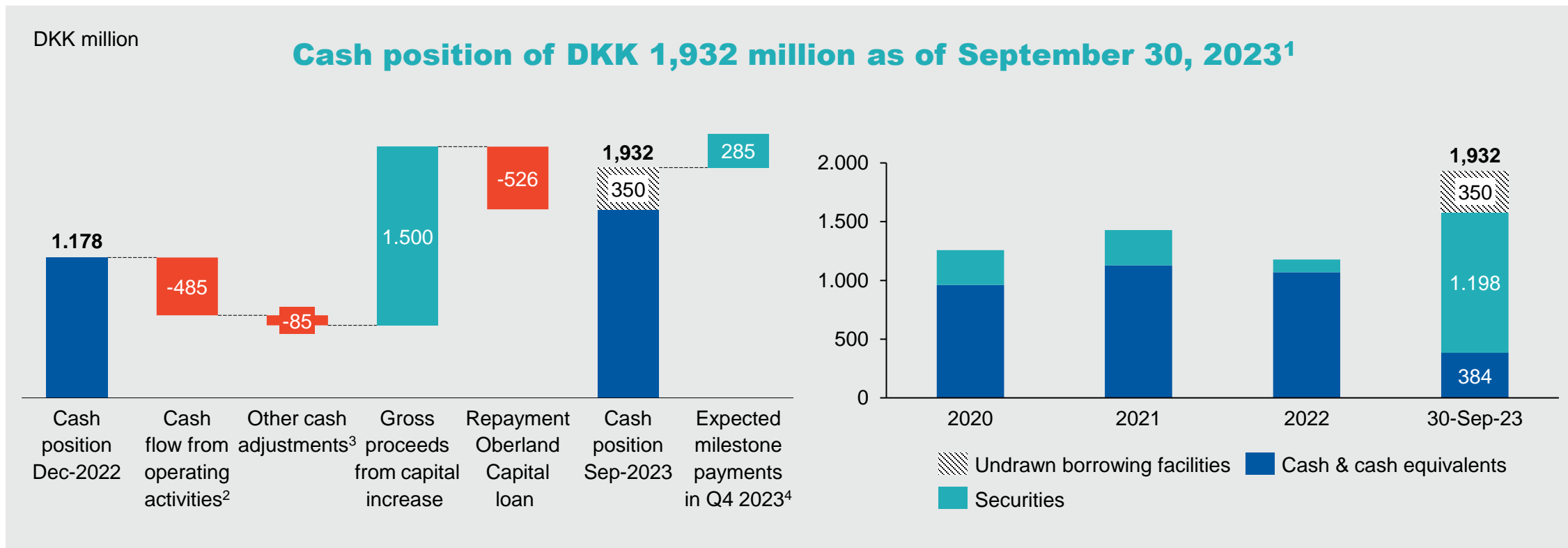
## P&L reflecting Zealand's ambition to be leading peptide drug discovery and development company while commercializing products through partnerships

- Revenue of DKK 320 million is driven by milestones from BI\* for survodutide and Sanofi for lixisenatide, and the agreement with Novo Nordisk for Zegalogue®
- Total operating expenses of DKK 633 million are slightly lower than last year, driven by lower S&M and G&A expenses due to cost reduction efforts following the announced restructuring on March 30, 2022, partially offset by higher R&D expenses. 78% of OPEX allocated to R&D driven by the progression of the late-stage rare disease assets towards regulatory submission and clinical advancement of the obesity pipeline
- The loss in net financial items relates primarily to the final repayment and termination of the loan agreement with Oberland Capital

## Q3 2023 YTD OPEX composition



# Solid cash position allows for investments in R&D



Notes

1. Cash position includes cash, cash equivalents and marketable securities, as well as undrawn borrowing facilities.
2. Cash flow from operating activities excludes the loss from the repayment of the loan with Oberland Capital.
3. Other cash adjustments include cash flow from investing activities, financing activities (excl. the capital raise in April 2023 and repayment of the Oberland Capital loan in May 2023), and exchange rate adjustments.
4. Cash inflow from milestone payments from Boehringer Ingelheim and Sanofi expected in Q4 2023.

# 2023 financial guidance confirmed

DKK million	2023 Guidance	2022 Actual
Revenue anticipated from existing and new license and partnership agreements	No guidance due to uncertain size and timing	104
Net operating expenses <sup>1</sup>	800 - 900	941

Notes

1. Net operating expenses consist of R&D, S&M, G&A and other operating items  
 Financial guidance based on foreign exchange rates as of November 9, 2023

# Multiple future events and catalysts across several therapeutic areas

NON-EXHAUSTIVE

## Q4 2023

**Survodutide**  
Initiation of Ph3 trials

**Glepaglutide (SBS)**  
Regulatory submission to US FDA

**Dasiglucagon (CHI)**  
PDUFA date for Part 1 of NDA with US FDA

## 2024

**Survodutide**  
Topline results from Ph2 trial in NASH

**ZP8396 (amylin)**  
Topline results from MAD Part 2

**Dapiglutide**  
Topline results from Ph2 IIT DREAM

**ZP6590 (GIP)**  
Initiation of first-in-human clinical trials

**ZP10068 (complement C3 inhibitor)**  
Initiation of first-in-human clinical trials

**ZP9830 (Kv1.3 Ion Channel Blocker)**  
Initiation of first-in-human clinical trials

Potential partnership agreements across therapeutics areas

Obesity

Rare diseases

Inflammation

# Obesity R&D Event on December 5, 2023 in London



**Professor Daniel Drucker**

Targeting obesity and low-grade inflammation with GLP-1/GLP-2



**Professor Louis Aronne**

Amylin as a next-generation weight loss therapy, representing an alternative to GLP-1



**Professor Carel Le Roux**

Targeting obesity and NASH with glucagon/GLP-1

**Register for in-person or virtual attendance:**

**<https://www.zealandpharma.com/event/zealand-pharmas-obesity-rd-event/>**



# Q&A session.