



ZEALAND PHARMA

# Q1 2024 Presentation.

**Zealand Pharma**

May 16, 2024

# 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 pre-clinical and clinical trials and the reporting of data therefrom and the company’s Significant events and potential catalysts in 2024 and Financial Guidance for 2024. 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, patient recruitment 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 at third party manufacturers; dependency on third parties, for instance contract research or development organizations; unexpected growth in costs and expenses; our ability to effect the strategic reorganization of our businesses in the manner planned; failure to protect and enforce our data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; regulatory authorities may require additional information or further studies, or may reject, fail to approve or may delay approval of our drug candidates or expansion of product labeling; failure to obtain regulatory approvals in other jurisdictions; exposure to product liability and other claims; interest rate and currency exchange rate fluctuations; unexpected contract breaches or terminations; inflationary pressures on the global economy; and political uncertainty, including the ongoing military conflict in Ukraine and the uncertainty surrounding upcoming elections in the US.

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 presentation. 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.

# Solid start to 2024 with strong progress across obesity pipeline and PDUFA dates for rare disease assets

## Advancing differentiated obesity pipeline



**Petrelintide**  
amylin analog

- 16-week trial completed; on track for topline data in late Q2 2024



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

- DREAM trial completed; on track for topline data in mid-Q2 2024



**Survodutide<sup>1</sup>**  
dual GCG/GLP-1  
receptor agonist

- Boehringer announced positive topline data from Phase 2 trial in MASH

## Progressing rare disease assets to patients



**Dasiglucagon in congenital hyperinsulinism**

- PDUFA date for Part 1 set by US FDA on October 8, 2024<sup>2</sup>



**Glepaglutide in short bowel syndrome**

- PDUFA date set by US FDA on December 22, 2024

## Strengthening financial position



- Runway extended into 2027 through capital raise in January

Notes: 1. Survodutide is licensed to Boehringer Ingelheim from Zealand Pharma, with Boehringer solely responsible for development and commercialization globally (subject to Zealand's co-promotion rights in the Nordic countries): EUR 315 million outstanding potential development, regulatory and commercial milestones + high single to low double digit % royalties on global sales. 2. Part 1 of the New Drug Application for dasiglucagon in congenital hyperinsulinism relates to dosing of up to three weeks.

MASH=metabolic dysfunction-associated steatohepatitis (formerly NASH=non-alcoholic steatohepatitis); PDUFA=Prescription Drug User Fee Act; FDA=Food and Drug Administration.

# We are well on track to deliver on the most important priorities for the year 2024

## Petrelintide (amylin analog)

- Ph1b 16-week MAD clinical trial data
- Ph2b trial initiation



## Dapiglutide (GLP-1R/GLP-2R)

- Ph2a DREAM clinical trial data<sup>1</sup>
- Ph1b 13-week dose-titration clinical trial data



## Survodutide<sup>2</sup> (GCGR/GLP-1R)



- Ph2 MASH clinical trial data
- Ph3 obesity trial enrollment<sup>3</sup>



## Deliver on rare disease and inflammation pipeline

### Regulatory decisions for rare disease assets

- Dasiglucagon for CHI
- Glepaglutide for SBS

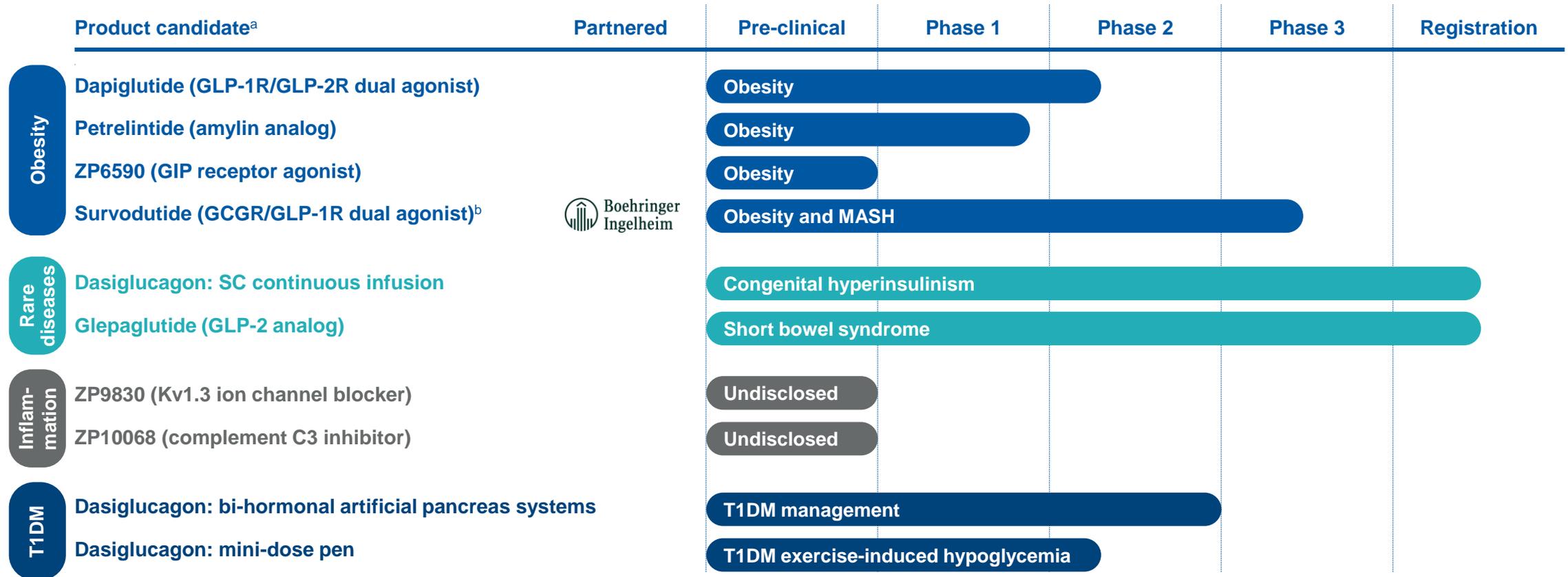
### First-in-human trial initiation with inflammation assets

- ZP9830 (Kv1.3 Ion Channel Blocker)
- ZP10068 (Complement C3 Inhibitor)

Notes: 1. DREAM is an investigator-led trial. 2. Survodutide is licensed to Boehringer Ingelheim from Zealand Pharma, with Boehringer solely responsible for development and commercialization globally (subject to Zealand's co-promotion rights in the Nordic countries). 3. SYNCHRONIZE™.

MAD=multiple ascending dose; MASH=metabolic dysfunction-associated steatohepatitis (formerly NASH=non-alcoholic steatohepatitis); CHI=congenital hyperinsulinism; SBS=short bowel syndrome.

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



<sup>a</sup>Investigational compounds whose safety and efficacy have not been evaluated or approved by the U.S. Food and Drug Administration (FDA) or any other regulatory authority.

<sup>b</sup>Survodutide is licensed to Boehringer Ingelheim from Zealand Pharma, with Boehringer solely responsible for development and commercialization globally (subject to Zealand's co-promotion rights in the Nordic countries); EUR 315 million outstanding potential development, regulatory and commercial milestones + high single to low double digit % royalties on global sales.

GCGR=glucagon receptor; GIP=gastric inhibitory polypeptide; GLP-1R=glucagon-like peptide-1 receptor; GLP-2=glucagon-like peptide-2; GLP-2R=glucagon-like peptide-2 receptor; MASH=metabolic dysfunction-associated steatohepatitis (formerly NASH, or nonalcoholic steatohepatitis); SC=subcutaneous; T1DM=type 1 diabetes mellitus.

# In late Q2 2024, we expect topline results with petrelintide from the Phase 1b 16-week trial

## A potentially best-in-class amylin analog



Targeting **GLP-1RA-like weight reduction**; high quality weight loss with preservation of lean mass



**Unique, non-incretin mechanism** that reduces food intake by increasing satiety and restoring leptin sensitivity



Potential for **improved tolerability** vs. GLP-1RAs

## The 16-week trial is exploring significantly higher doses using an up-titration scheme<sup>1</sup>

### Trial design

- N=48, men and women aged 18-64 years (BMI 27.0-39.9 kg/m<sup>2</sup>)
- Duration = 16 weeks
- Dose strengths = significantly higher than in previous MAD Part 1 and SAD, thus much higher than 2.4 mg<sup>2</sup>

### Topline data

- %-change in body weight from baseline to week 16
- Safety and tolerability profile



Phase 2b planned for initiation in H2 2024

Source: 1. ClinicalTrials.gov (NCT05613387).

GLP-1RA=glucagon-like peptide-1 receptor agonist; MAD=multiple ascending dose; SAD=single ascending dose; TEAEs=treatment-emergent adverse events.

# In mid-Q2 2024, we expect topline results with dapiglutide from the investigator-led trial DREAM

## A first-in-class GLP-1R/GLP-2R dual agonist



**Safety and tolerability** similar to other GLP-1RA-based weight-loss medications



Potential **cardioprotective benefits** from GLP-1 agonism and additional **anti-inflammatory** effect from GLP-2 agonism



Potential for **regenerative** effects to address organ damage associated with low-grade inflammation, e.g., **MASH** and **Alzheimer's disease**

## DREAM evaluating effects on body weight, gut permeability and inflammation<sup>1</sup>

### Trial design

- N=54, men and women aged 18-75 years (BMI  $\geq 30$  kg/m<sup>2</sup>)
- Duration = 12 weeks
- Dose strengths = up to 6.0 mg (similar to 4-week MAD)<sup>2</sup>

### Topline data

- %-change in body weight from baseline to week 12
- Safety and tolerability profile



Topline data from DREAM (low doses) in Q2 2024



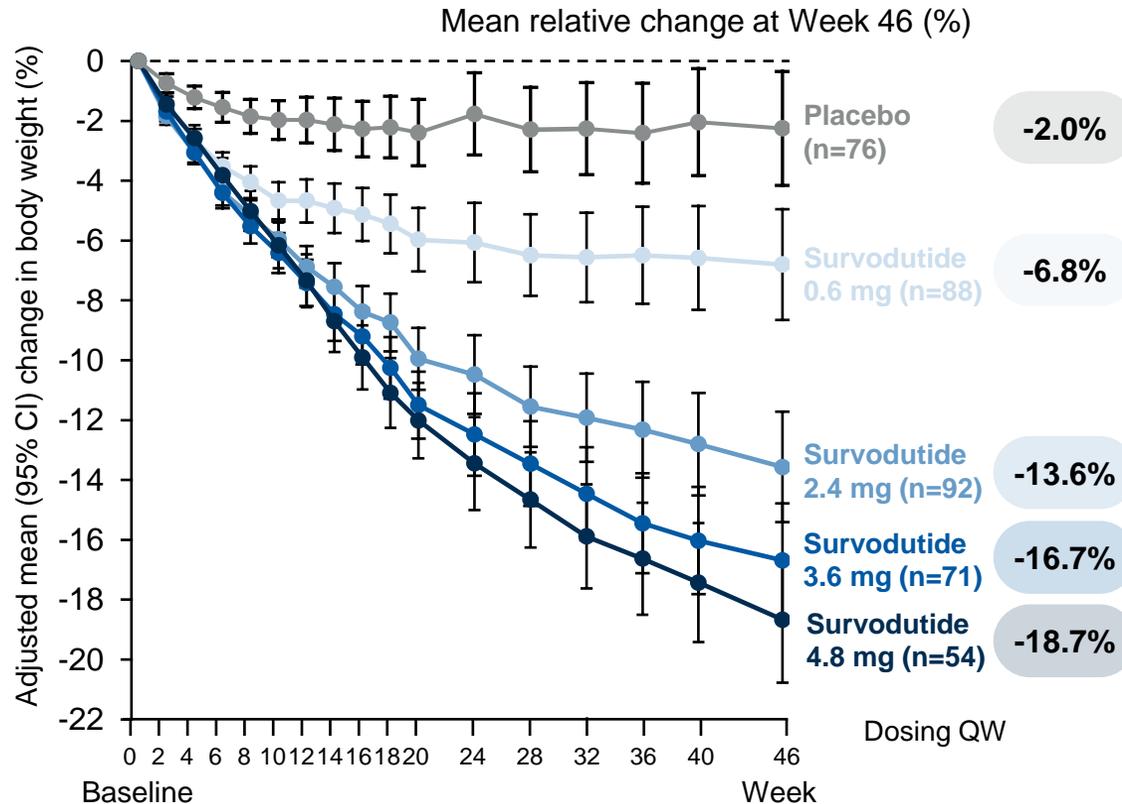
Topline data from Phase 1b 13-week dose-titration trial (high doses) in H2 2024

Source: 1. ClinicalTrials.gov (NCT05788601). 2. Data presented by Agersnap at the 82nd ADA Scientific Sessions, June 3–7, 2022, New Orleans, LA. MASH=metabolic dysfunction-associated steatohepatitis (formerly NASH=non-alcoholic steatohepatitis); GLP-1RA=glucagon-like peptide-1 receptor agonist; GLP-2=glucagon-like peptide-2; MAD=multiple ascending dose.

# Survodutide\* glucagon/GLP-1 receptor dual agonist shows best-in-class potential in MASH Phase 2 trial



## Phase 2 trial in people with overweight or obesity<sup>1</sup>



**SYNCHRONIZE™ Phase 3 clinical program in obesity ongoing<sup>2</sup>**

## Phase 2 biopsy-driven trial in people with MASH<sup>3</sup>



Participants showing **improvement in MASH** without worsening of fibrosis (stages F1-F3): **83.0% with survodutide** vs. 18.2% with placebo (p<0.0001)



**Statistically significant improvement in liver fibrosis** with survodutide in secondary endpoint



Survodutide treatment did not show unexpected safety or tolerability issues, including at the higher dose of 6.0 mg



Full data to be presented at the EASL congress in Milan, Italy on June 7, 2024



**Further development in MASH planned**

\*Survodutide is licensed to Boehringer Ingelheim from Zealand Pharma, with Boehringer solely responsible for development and commercialization globally (subject to Zealand's co-promotion rights in the Nordic countries).

Source: 1. Figure adapted from Le Roux et al. Oral presentation (51-OR) at ADA 83<sup>rd</sup> Scientific Sessions, June 23–26, 2023, San Diego, CA. Analysis based on dose reached at the end of treatment regardless of the dose assigned at randomization. 2. ClinicalTrials.gov accessed February 2024; 3. Boehringer Ingelheim press release February 26, 2024.

MASH=metabolic dysfunction-associated steatohepatitis (formerly NASH=non-alcoholic steatohepatitis); CI=confidence interval; QW=once-weekly; GCG=glucagon; GLP-1=glucagon-like peptide-1.

# Dasiglucagon is being developed to address a high unmet medical need for the management of CHI

US FDA has accepted the resubmission<sup>1</sup> of NDA Part 1 with a PDUFA goal date of October 8, 2024



Two Phase 3 trials in neonates and children up to 12 years of age demonstrated clinical potential



PDUFA date for NDA Part 1 for up to three weeks of dosing set by US FDA for October 8, 2024



Submission of NDA Part 2 for use beyond three weeks<sup>2</sup> of dosing expected in the second half of 2024



Partnering discussions ongoing



Investigational compound and device<sup>3</sup> whose safety and efficacy have not been evaluated or approved by the FDA or any other regulatory authority.

Notes: 1. The US FDA issued a Complete Response Letter (CRL) in December 2023 due to inspection findings at a third-party manufacturing facility that were not specific to dasiglucagon. 2. To be supported by additional analyses from existing CGM datasets included as a secondary outcome measure in the Phase 3 program. 3. Zealand Pharma has entered a collaborative development and supply agreement with DEKA Research & Development Corporation and affiliates for infusion pump system.

CHI=congenital hyperinsulinism; NDA=new drug application; PDUFA=Prescription Drug User Fee Act; FDA=Food and Drug Administration; CGM=continuous glucose monitoring.

# Glepaglutide has best-in-class potential as a next-generation GLP-2 therapy for patients with SBS

US FDA has accepted the NDA submission with a PDUFA goal date of December 22, 2024



Significantly reduced weekly PS volume at 24 weeks versus placebo in the EASE-1 trial in SBS<sup>1</sup>



Expected 10 mg twice-weekly subcutaneous dosing; Ready-to-use auto-injector with needle protection



PDUFA date with US FDA on December 22, 2024



Partnering discussions ongoing



Glepaglutide is an investigational product whose safety and efficacy has not been evaluated or approved by the FDA or any other regulatory authority.

Notes: 1. Results presented by Palle B. Jeppesen at the ASPEN 2023 Nutrition Science & Practice Conference in April 2023. SBS=short bowel syndrome; PS=parenteral support; PDUFA=Prescription Drug User Fee Act; FDA=Food and Drug Administration.

# Q1 2024 Profit & Loss

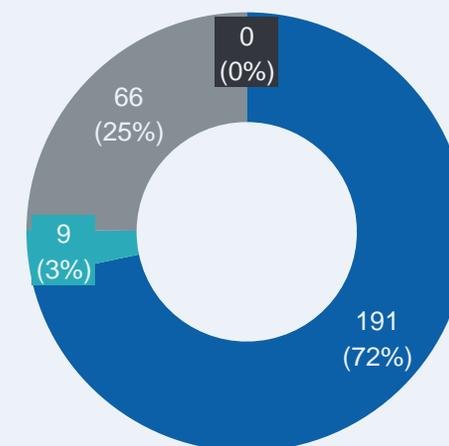
DKK million	Q1 2024	Q1 2023
Revenue	15.1	13.6
<b>Gross profit</b>	<b>10.5</b>	<b>13.6</b>
Research and development expenses	-190.9	-142.3
Sales and marketing expenses	-9.2	-4.6
General and administrative expenses	-66.2	-42.5
Other operating Items	-	7.1
<b>Net operating expenses</b>	<b>-266.3</b>	<b>-182.3</b>
<b>Operating result</b>	<b>-255.8</b>	<b>-168.7</b>
Net financial items	25.9	-26.7
<b>Result before tax</b>	<b>-230.0</b>	<b>-195.3</b>
Tax	1.4	1.7
<b>Net result for the period</b>	<b>-228.6</b>	<b>-193.6</b>

## P&L reflecting Zealand's investment in its differentiated assets targeting obesity

- Revenue of DKK 15 million is mainly driven by the license and development agreement with Novo Nordisk for Zegalogue®.
- Total operating expenses of DKK 266 million are higher than last year, primarily driven by the increase in R&D expenses (72% of OPEX allocated to R&D) due to the clinical advancement of the obesity pipeline and activities supporting the regulatory review by the US FDA of the late-stage rare disease assets.
- Net financial items of DKK 26 million are mainly driven by interest income from excess liquidity invested in marketable securities

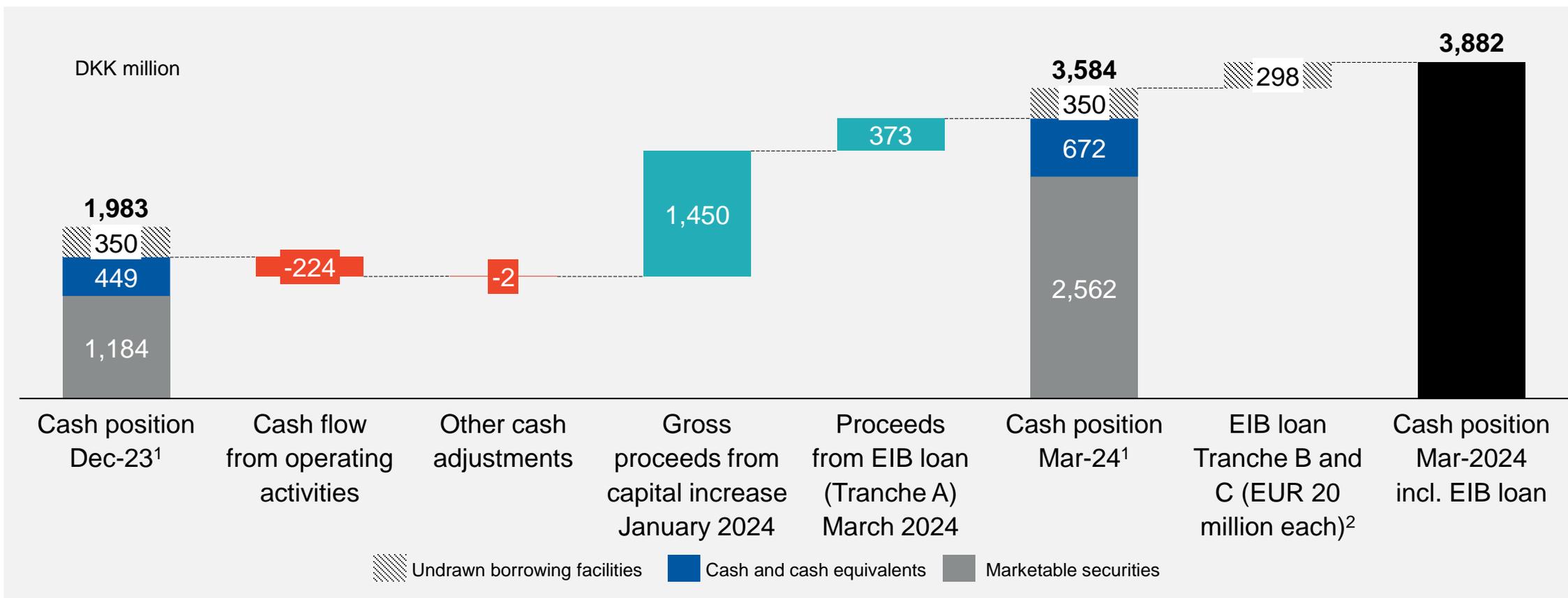
### Q1 2024 OPEX composition DKKm

- Research and Development
- Sales and Marketing
- General and Administration
- Other Operating Items



# Solid cash position allows for investments in R&D

DKK 3.9 billion cash position, including the EIB loan, ensures runway into 2027



Notes

1. Cash position includes cash, cash equivalents and marketable securities. Undrawn borrowing facilities comprise DKK 350 million Revolving Credit Facility provided by Danske Bank.

2. The two tranches are subject to pre-specified milestones being met.

# 2024 financial guidance

DKK million	2024 Guidance	2023 Actual
Revenue anticipated from existing and new license and partnership agreements	No guidance due to uncertain size and timing	343
Net operating expenses <sup>1</sup>	1,100 – 1,200	896

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 May 16, 2024.

# Significant events and potential catalysts in 2024

NON-EXHAUSTIVE

## Q2 2024

### Petrelintide

Topline results from 16-week Phase 1b MAD trial

### Dapiglutide

Topline results from Phase 2a investigator-led trial DREAM

### Survodutide<sup>1</sup>

Presentation of results from Phase 2 MASH trial at EASL congress

## H2 2024

### Petrelintide

Initiation of Phase 2b trial

### Dapiglutide

Topline results from 13-week Phase 1b dose-titration trial

### Survodutide<sup>1</sup>

Enrollment of Phase 3 SYNCHRONIZE program<sup>2</sup>

### Dasiglucagon (CHI)

Submission to US FDA of analyses supporting chronic use

### Dasiglucagon (CHI)

Potential US regulatory approval for Part 1 of NDA

### Glepaglutide (SBS)

Potential US regulatory approval

### ZP9830 (Kv1.3 Ion Channel Blocker)

Initiation of first-in-human clinical trials

Legend:

Obesity

Rare diseases

Inflammation

Potential partnership agreements across therapeutics areas

# Q&A.