# ZEALAND PHARMA

interesting and a start of the

# Annual Report.

2022

**Zealand Pharma** 

March 2, 2023

## **Forward Looking Statement**



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 2022.

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; political uncertainty, including due to the ongoing military conflict in Ukraine; and the direct and indirect impacts of the 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 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.

# In 2022 we delivered on our strategic objectives and achieved significant pipeline progress





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



**Engage in strategic Progress rare disease assets** Advance obesity portfolio partnership discussions toward regulatory filings **Dasiglucagon for congenital** BI 456906<sup>2</sup> (GCGR/GLP-1R) **Rare disease programs** hyperinsulinism Phase 2 data in obesity and • Focus on companies with rare Phase 3 decision disease commercial infrastructure Dapiglutide (GLP-1/GLP-2) **Obesity programs** Initiate Phase 2a obesity trial Focus on companies with global and 13-week dose-titration trial development and commercial **Glepaglutide for Short Bowel** infrastructure ZP8396 (amylin) Syndrome 6-week MAD Phase 1 results and Other programs initiate 16-week dose-titration trial · Focus on companies with **ZP6590 (GIP)** therapeutic area leadership Advance into Phase 1 Other significant activities Zegalogue<sup>®1</sup> Dasiglucagon (in BHAP systems)

MAA submission in EU by Zealand

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**Dasiglucagon (in BHAP systems)** Initiate Phase 3 program<sup>3</sup> **ZP10068<sup>4</sup> (complement C3 inhibitor)** Ready for Phase 1

## Dasiglucagon has potential to address shortcomings of current management of CHI

#### CHI is an ultra-rare disease in newborns and children

- 1 in 28-50,000 newborns per year are diagnosed with genetically determined CHI in the US and EU<sup>1,2</sup>
- CHI can cause serious episodes of hypoglycemia during childhood<sup>2,3</sup>

### Severe episodes of hypoglycemia may result in brain damage

- Hypoglycemia can cause seizures in ~50% of the patients<sup>4</sup>
- Lack of proper management within days can increase the risk of permanent brain injury and neurocognitive impairment<sup>3,4</sup>

### Significant impact on the patient and caregivers' quality of life

• Complex care requirements can cause lengthy and frequent hospitalizations and make daily social activities difficult<sup>4,5</sup>

### **Dasiglucagon for subcutaneous infusion\***

- Current treatments for CHI are associated with significant limitations
   and clinical barriers
- Glucagon analog designed to allow for continuous subcutaneous (s.c.) infusion via pump<sup>6</sup>

<sup>1</sup> Arnoux JB et al. 2011 Orphanet J Rare Dis;6:63; <sup>2</sup> Yau et al. Plos One 2020;15(2):e0228417; <sup>3</sup>Thornton PS et al., J Pediatr. 2015;167(2):238-45; <sup>4</sup>Banerjee I et al., Orphanet J Rare Dis. 2022;17:61; <sup>5</sup>Pasquini TLS et al. Front Endocrinol 2022:13;876903; <sup>6</sup>Zealand Pharma has entered a collaborative development and supply agreement with DEKA Research & Development Corporation and affiliates for infusion pump system.



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

## **Opportunity to treat up to 800 patients with diffuse CHI at ultra-rare disease price levels in the US**



## Patients eligible for dasiglucagon treatment in the US



## Ultra-rare disease therapy analogues with clear clinical value command premium prices in US<sup>5</sup>



#### Annual treatment cost (k\$)

#### Patient population

<sup>1</sup>Arya et al. Plos One 2014;9:e98054; <sup>2</sup>Arnoux JB et al. 2011 Orphanet J Rare Dis;6:63; <sup>3</sup>Yau et al. Plos One 2020;15(2):<sup>4</sup> Based on KOL interviews (2022); <sup>5</sup> Zealand Pharma Payer & Pricing Research, December 2022 <u>Indications by product</u>: Procysbi (nephropathic cystinosis); Naglazyme (Marateaux Lamy syndrome); Ultomoris (atypical hemolytic uremic syndrome); Kanuma (lysosomal acid lipase deficiency); Luxturna (biallelic RPE65 mutation-associated retinal dystrophy); Elaprase (Hunter syndrome); Aldurazyme (Hurler and Hurler-Scheie forms of Mucopolysaccharidosis I)

## **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 + 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

## **Glepaglutide continues to be evaluated in Phase 3 long term extension studies in SBS**





## **Obesity is a complex metabolic disease requiring additional treatment options**



### 650 million adults and 124 million children and adolescents suffering from obesity<sup>1</sup>



### Zealand Pharma's peptide approach

Dual agonists (one molecule – two actions)

• BI 456906 – GLU/GLP-1 receptor agonist

Dapiglutide – GLP1/GLP2 receptor agonist



### Co-formulation or loose combo of mono agonists

ZP 8396 – Amylin analog
ZP 6590 – GIP receptor agonist



## **Targeting obesity with differentiated candidates**



## Dual pharmacology with a GLP-1 receptor agonist foundation

### GLP-1

- Increase insulin sensitivity
- Delay gastric emptying
- Decrease appetite

### + Glucagon

- Increase energy expenditure
- Reduce hepatic fat content
- Stimulate lipolysis in fat tissue



### + GLP-2

- Improve intestinal barrier function
- Delay gastric emptying
- Improve tolerability to GLP-1



### Single pharmacology as combinable alternative modality



Aim: achieve increased weight loss and/or provide supplementary effects to address specific needs of obese/overweight subpopulations

Obesity and fatty liver

Obesity and "leaky gut" / inflammation

Monotherapy or combination

Increase tolerance to GLP-1

## **Profit & Loss**



DKK million	2022	2021
Revenue	104.0	108.5
Gross margin	104.0	97.6
Research and Development expenses	-614.0	-581.5
Sales and Marketing Expenses	-32.3	-62.6
General and Administrative Expenses	-237.2	-235.6
Other Operating Items	-57.6	-2.2
Net Operating Expenses	-941.1	-881.9
Operating Result	-837.2	-784.3
Net Financial Items	-134.9	25.4
Result before tax	-972.0	-758.9
Тах	6.4	3.9
Net result for the year from continued operations	-965.6	-754.9
Discontinued Operations	-236.5	-263.2
Net result for the year	-1,202.1	-1,018.1

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

- Revenue of DKK 104 million in 2022 driven by development agreement with Alexion and the Novo Nordisk partnership agreement
- Total operating expenses of DKK 941 million slightly above last year driven by the progression of our R&D activities, and one-off costs related to restructuring cost on continued operations and insurance from US delisting
- The loss in net financial items relate to the Oberland loan agreement
- All income and expenses related to the commercialization of V-Go and Zegalogue are accounted for as discontinued operations



## Strong cash position allows for investments in R&D



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### **2023 financial guidance**

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



