



ZEALAND PHARMA

Medical Innovation Day Challenge.

Digital solutions for rescue treatment

Zealand Pharma

Case description, August 2019

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Zealand Pharma in brief



Danish Biotech

Founded in Copenhagen (HQ) in 1998,
opened U.S. subsidiary 2018



Leading Peptide Platform

A world leading peptide platform,
with two medicines on the market



Three Phase 3 Programs

Accelerating several late stage
programs to launch new products
into major markets in 2 to 4 years



Expanding Capabilities

Transforming into a fully integrated
biotech company with
U.S. commercial organization



Experienced Team

172 employees of which
83% are in R&D



Dual Nasdaq Listing

Traded in Copenhagen
and New York (ZEAL)

We change lives with next generation peptide therapeutics



Changing Lives

We work every day with patient communities and thought leaders to change the lives of people with severe medical conditions



Transforming Peptides

We leverage our 20 years of experience discovering and developing peptide drugs to transform peptide projects into next generation therapeutics



Engaging Partnerships

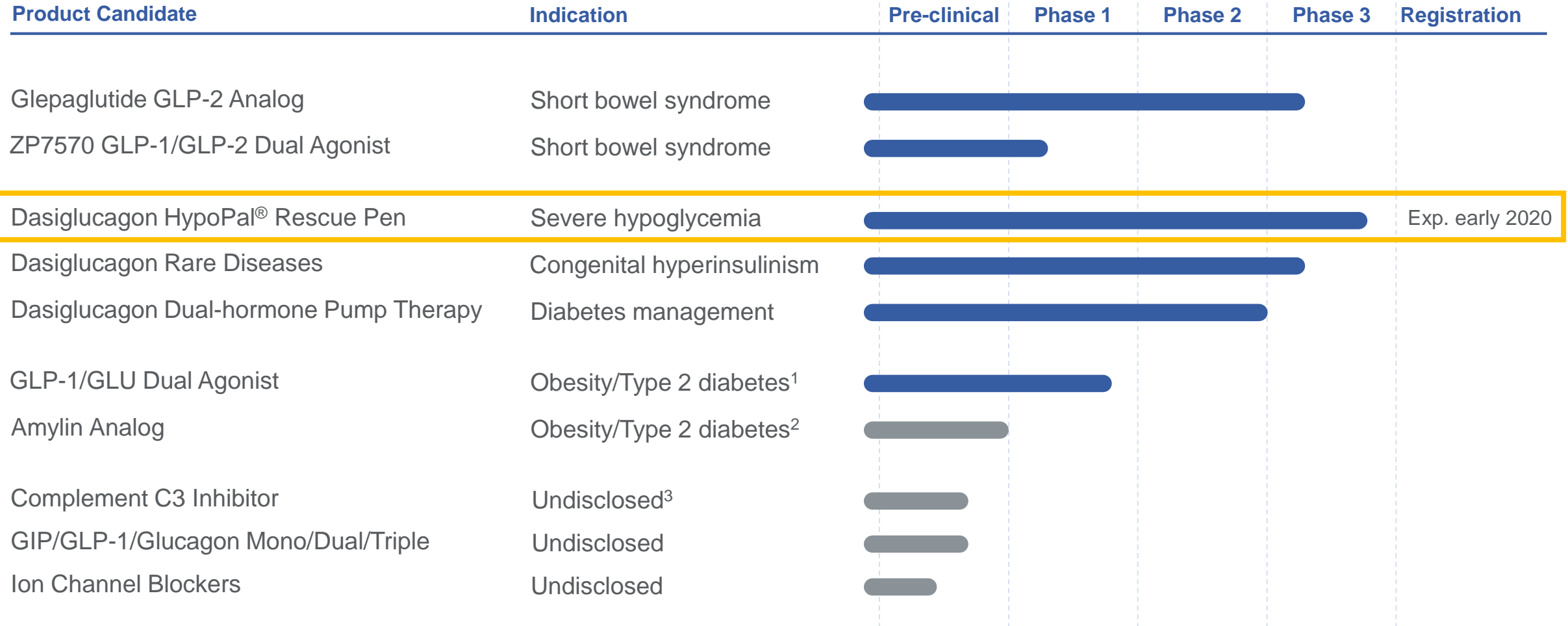
We engage with development and commercial partners to enhance innovation and expand opportunities across markets and therapeutics areas



Approaching Commercialization

We are building a fully integrated commercial organization with U.S. operations to market our own therapies for rare diseases

Three Phase 3 programs and a promising early pipeline



Dasiglucagon HypoPal[®] – a stable glucagon analog for fast rescue treatment of severe hypoglycemia



We aspire to offer the HypoPal[®] Rescue Pen as the fastest treatment option for severe hypoglycemia



For illustration only

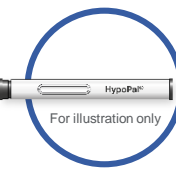
Fast onset of action confirmed in Phase 3

One dose from age 6 in a ready-to-use autoinjector¹

Preferred mode of administration by patients, care givers and HCPs²

Expected U.S. launch in H1 2021

Severe hypoglycemia is one of the most feared complications for diabetes patients on insulin therapy¹



6 million people

With diabetes are on insulin therapy in the U.S.²

Up to 40% of type 1 diabetes patients

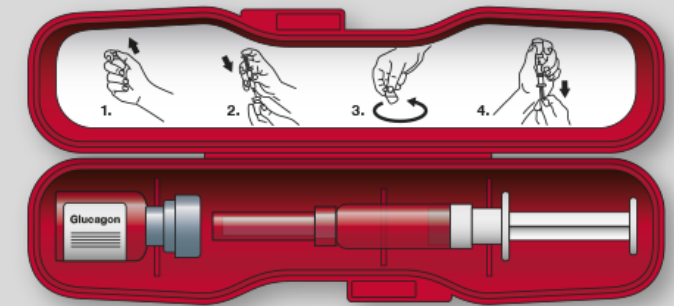
Experience severe hypoglycemia every year³

~300,000 hospitalizations

Occur annually in the U.S. due to severe hypoglycemia⁴

Underutilization of currently available glucagon rescue kits

- >85% of trained caregivers failed to deliver full dose of glucagon⁵
- Not stable as a ready-to-use liquid formulation⁶
- 6-10 steps from reconstitution to injection⁶
- Underutilization despite training⁷

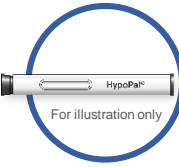


Glucagon Emergency kit, Eli Lilly^a

¹ Kalra 2013, UK Hypoglycemia Study Group; ² cdc.gov and diabetes.org and www.diabetesselfmanagement.com/diabetes-resources/tools-tech/insulin-pumps; ³ International Hypoglycemia Study Group. *Diabetes Care*. 2015;38:1583–1591; ⁴ National Diabetes Statistics Report. CDC. 2014; ⁵ Needle-free nasal delivery of glucagon is superior to injectable delivery in simulated hypoglycaemia rescue, ePoster # 867, EASD 2015, Stockholm; ⁶ Glucagon for injection Eli Lilly 2012. GlucaGen HypoKit Instruction for use Novo Nordisk 2016. Pontiroli A. *Journal of Diabetes Science and Technology* 2015, Vol. 9(1) 38–43; ⁷ Harris G, et al. *Practical Diabetes Int* 2001; 18(1); 22-25.;

^a The Glucagon Emergency kit design is a trademark of Eli Lilly and Company

The U.S. market for rescue treatments is heavily underpenetrated; ~3m patients at risk, and only ~1m kits sold annually



In the U.S. ~3 million or 14% of diabetes patients are on insulin only therapy

Type 1 Diabetes

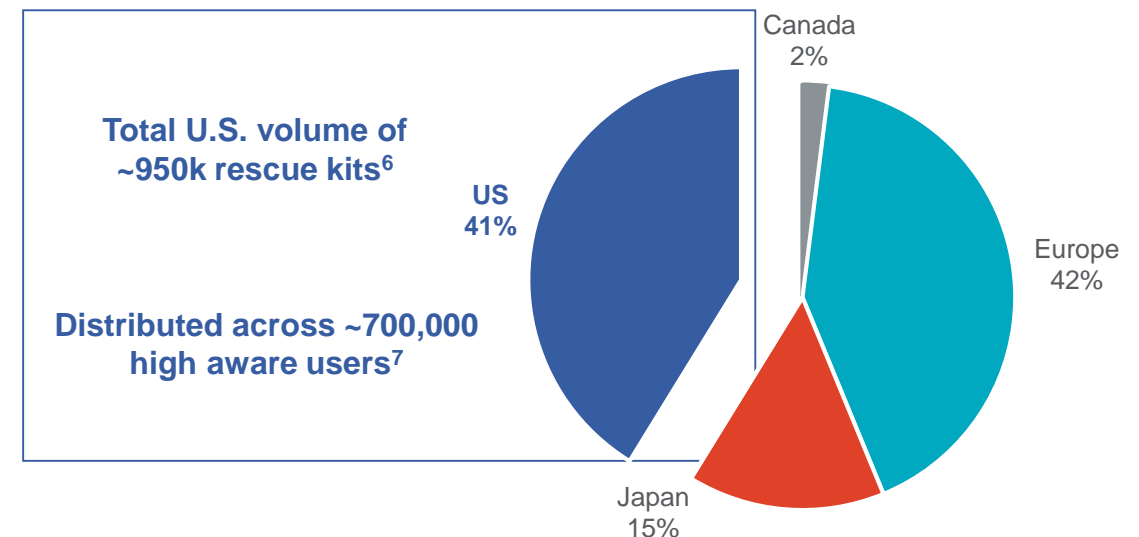
- ~1.25 million patients in the U.S. growing at 3% per year¹

Type 2 Diabetes

- ~22 million² patients in the U.S. growing 3-5%³ per year
- ~1.65 million are on insulin therapy only⁴
- ~3 million are on combination therapy – OADs/insulin⁵

Less than 1 million rescue treatments are currently sold in the U.S. (2016)

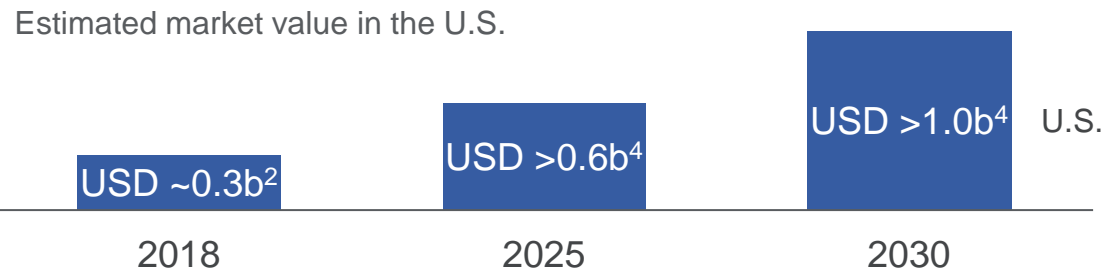
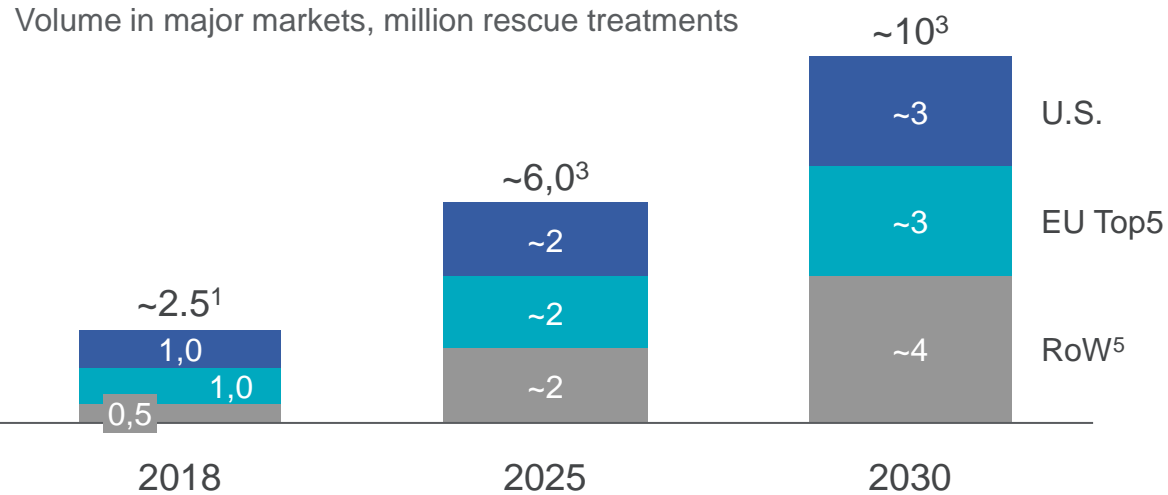
Volume of rescue kits by geography (2.3 m rescue kits in total)⁶



With improved treatment options, the glucagon rescue market could reach > USD 1 billion in the U.S. alone



Significant growth expected for rescue treatments



Major growth drivers for glucagon rescue treatments

- Increasing number of insulin-treated diabetes patients
- Increasing awareness of severe hypoglycemia among T1D and T2D patients
- Faster rescue and ease of administration⁶

Dasiglucagon as the potential fastest rescue treatment for severe hypoglycemia

8 ¹ Estimate based on IMS Health data, 2016 volume of glucagon rescue kit market; ² Based on IMS Health data, 2016 value; ³ 2016 U.S. volume (IMS Health) forecasted with an increase in T1D prevalence of 3% per year (JDRF) and increased adoption of rescue treatments with new options available; ⁴ Based on estimated WAC price; ⁵ Rest of World estimate include China, Japan and Canada; ⁶ Vast majority of parents of T1DM children or adolescents struggled to use the current rescue kit. Source: Harris 2001;

The Medical Innovation Day Challenge

Background

As stated above the current market for glucagon rescue treatments is highly underpenetrated, partly due to the complexity of administering currently available glucagon rescue kits. Hence, many patients suffering from Type 1 or Type 2 diabetes do not have a glucagon rescue treatment readily at hand in case of a hypoglycemic event.

Zealand Pharma is developing a fast, reliable and easy-to-use glucagon rescue therapy in an auto-injector with the potential to relief patients of the burden and fear associated with hypoglycemic events.

To increase awareness among patients and caregivers of the advantages of having a ready-to-use glucagon rescue therapy available at all times as well as how and when to use the therapy, Zealand Pharma wants to explore digital solutions for improved patient/HCP* connectivity. A solution that would provide valuable information to patients, caregivers and HCPs while also providing Zealand Pharma access to insightful data and knowledge of patient and HCP profiles, needs and preferences, usage of therapy, etc.

The Medical Innovation Day Challenge

Challenge Statement:

What could a blue-print 1st generation connected health service solution that can be implemented for the HypoPal[®] rescue pen look like?

The team could consider one or more of the following questions:

- How can Zealand support an effective treatment decision process through digital patient connectivity?
- What information could Zealand share to increase disease awareness, intention for use, and personalized relevant information?
- How could Zealand obtain information on e.g. patient/HCP profiles, preferences, and user experience to improve offerings and targeting?
- What key stakeholders should be connected in the 1st generation solutions and what are the pros/cons for including each segment?
- What could a 2nd and 3rd connected health service solution look like where we gradually introduce more features/stakeholders?
- How can we over time provide evidence that the use experience of glucagon treatment is an important factor for patients and payers?
- Which existing systems or platforms could be leveraged in order not to build a new system from scratch?

Values and goals expected from solving the challenge

Values and goals:

- Use of data and technology to optimize patient health, HCP interaction, and increase awareness of the risk of hypoglycemia
- Increase the proportion of patients with readily available rescue treatments and correct administration in a rescue situation
- Establish loyalty and preference among patients and prescribers
- Obtain information on patient/HCP profiles, preferences, real time data, frequency of use, etc. for product improvement and targeting
- Enable automated refills and prescriptions

Considerations for the challenge:

- Zealand Pharma is a smaller biotech company with limited access to resources. Hence, we are looking for a pragmatic and step-wise solution that e.g. builds upon already existing systems or platforms from other companies or digital service providers
- The solution should be a clear benefit to the patients. Numerous applications already exists for diabetes patients to manage their disease on a daily basis, but only few are successful in providing added value to the patients and hence receiving broader uptake
- The solution could entail connectivity of several parties; the patients, the caregivers (e.g. parent or nurse), the health care professional, the manufacturer (Zealand), the insurance companies, the patient organizations, etc.
- Due to the highly regulated nature of the health care market legal aspects should be taken into account, e.g. in terms of patient access, information sharing and data protection
- The US market is main focus, but broader use of the solution would be an advantage

Relevant links

Info on hypoglycemia

<http://diabetes.org/living-with-diabetes/treatment-and-care/blood-glucose-control/hypoglycemia-low-blood.html>

Link to Zealand Pharma and our dasiglucagon HypoPal® rescue pen in development

<https://www.zealandpharma.com/dasiglucagon-rescue>

Other ready-to-use glucagon treatments in development

<https://www.prnewswire.com/news-releases/baqsimi-glucagon-nasal-powder-3-mg-the-first-and-only-nasally-administered-glucagon-to-treat-severe-hypoglycemia-in-adults-and-children-with-diabetes-ages-four-years-and-older-approved-by-fda-300890782.html>

<https://www.xerispharma.com/news/press-release/xeris-pharmaceuticals-pdufa-date-extension-for-gvoke™>

Examples of existing diabetes management apps and digital innovations

<https://www.healthline.com/health/diabetes/top-iphone-android-apps#diabetes-connect>

https://www.closeconcerns.com/knowledgebase/r/1c21a00d?utm_source=Closer+Look+Subscribers+2018&utm_campaign=9e613e2a6f-2019-03-08_%28HTML_LINKS%29_WIR_3%2F4-3%2F803_08_2019&utm_medium=email&utm_term=0_c55d924bf1-9e613e2a6f-412246273

<https://social.eyeforpharma.com/commercial/its-you-were-virtually-there>