

77 Based on our unique expertise in peptides, and with Lyxumia® now selling in the marketplace, we are advancing new innovative medicines for the benefit of patients and all our stakeholders

**Zealand Pharma A/S Annual Report 2013** 

# **Our values**

We speak our minds and dare to

challenge

challenge ourselves everyday

We approach idea and and receptive way

every new opportunity in an open

for our and the

We care

discover medicine

dedicated and determined to excel in our goals colleagues people for whom we

We are

### Who we are

At Zealand, we are **peptide medicine experts.** 

We have built a world-leading position in the invention, design and development of **innovative peptides**. Our activities are focused in the growing field of cardio-metabolic diseases, and we have a particularly strong presence in diabetes, a worldwide pandemic.

The first Zealand invented medicine, **Lyxumia**® (lixisenatide) for Type 2 diabetes, was launched in 2013, marketed internationally by Sanofi, a global leader in diabetes.

To follow Lyxumia®, we are advancing a broad pipeline of proprietary and partnered assets, including six clinical and several preclinical peptide drug candidates.

Our strategy is to grow the value of our product portfolio and pipeline, building on our R&D peptide capabilities. We retain a diligent approach to risk and apply a partnering model for the commercialisation of our products. Our current partners include Sanofi, Helsinn, Boehringer Ingelheim, Eli Lilly and AbbVie.

A dynamic and uniquely skilled team of dedicated people and an agile organisation are some of our key competitive strengths.

We are driven by our ambition and zeal to provide novel peptide medicines and therapeutic solutions that can make a major positive difference in patients' lives.

This is the Zealand approach to creating revolutionary health solutions.

#### Other facts and figures

**Cash position** 

Cash position (end 2013): DKK 311 (EUR 41) million.

2014 financial guidance

Royalties on sales of Lyxumia®;

Expected milestones of DKK 97 (EUR 13) million, of which DKK 82 (EUR 11) million

Net operating expenses of DKK 200-210 (EUR 27-28) million.

Market Cap

Listed on NASDAQ OMX Copenhagen (ZEAL.CO). Market Cap (per 14 March 2014: DKK 1.7 billion (EUR 226 million).

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Setting the scene for accellerated growth

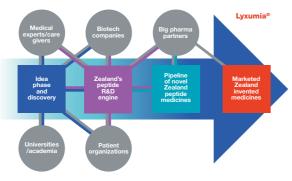


Financial highlights and key figures 2013









Financial guidance and business outlook for 2014

### **Pipeline** overview

**15** 

Indication	Discovery and Preclinical	Phase I	Phase II	Phase III	Registration	
Type 2 diabetes	Lyxumia <sup>®</sup> (Lix	tisenatide)				
Type 2 diabetes	Lyxumia®/ La	antus <sup>e</sup> combination	product			
Diabetes/ Obesity	ZP2929					
Myocardial Ischemic Reper- fusion Injury	Danegaptide					
Inflammatory Bowel Disease	ZP1848 <sup>1</sup>					
Chemotherapy- induced diarrhea	Elsiglutide					
Acute Kidney Injury	ZP1480 (ABT	-719)				

Short-to mid-term value drivers

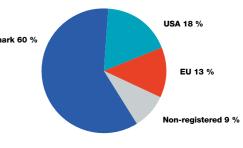
LixiLan

Other mid-term

Strong basis for long-term value growth

value drivers

36 Shareholder information



Geographical distribution of Zealand share ownership

**Financial** statements Royalty expenses Gross profit Research and development expenses Administrative expenses Other operating income -185,618 Operating result

# Setting the scene for accellerated growth

#### Dear shareholders.

#### 2013 and the start of 2014 - an important and eventful period for Zealand

The launch of Lyxumia® marks kev transition to a durable revenue stream

In 2013, Lyxumia® (lixisenatide) was approved in Europe, Japan and several overseas markets for the treatment of Type 2 diabetes. This first marketed peptide medicine from Zealand's pipeline is being rolled out country by country by Sanofi, one of the world's leading diabetes companies, as price and reimbursement negotiations with national health authorities are finalized. Due to the differentiating characteristics of Lyxumia® and Sanofi's internationally renowned market position, we are confident about future sales. The launch of Lyxumia® marks the key transition to a durable revenue stream for Zealand and constitutes an important foundation for growing Zealand's peptide expertise and pipeline towards continued value creation.

**US regulatory filing in 2015** To avoid the risk of potentially compromising the integrity of ELIXA, the ongoing cardiovascular outcome study of lixisenatide, Sanofi decided in September 2013 to withdraw the New Drug Application (NDA) for lixisenatide in the US, which included interim results from ELIXA. Sanofi's decision was not related to safey issues with the product or deficiencies in the NDA, and resubmission is planned for 2015, after completion of ELIXA. The study is designed to show cardiovascular benefits from treatment with Lyxumia®, and we believe a positive outcome will expand the entire GLP-1 agonist market and also differentiate this medicine further from its competitors. Despite Sanofi's decision resulting in a two-year delay in the US launch of Lyxumia® and a negative impact on Zealand's share price in 2013, we believe it has strengthened the overall prospects for the product.

Fixed-ratio Lantus®/Lyxumia® combination on clear path towards regulatory filing late 2015

In early 2014, Sanofi initiated the LixiLan clinical Phase III development program for the fixed-ratio single injection combination of Lyxumia® with Lantus®, the most prescribed basal insulin worldwide. This event marked a significant milestone for Zealand, providing a USD 15 million payment, confirming Sanofi's commitment and setting this important diabetes product on a clear path towards regulatory filings as early as the end of 2015. The LixiLan Phase III program is expected to be completed in the 2<sup>nd</sup> half of 2015.

New collaboration with Lilly - 3<sup>rd</sup> global diabetes company to partner with Zealand

We also signed a new partnership with Lilly in the US to advance novel peptide therapeutics as a new approach in the treatment of diabetes and obesity. Lilly is the third large global diabetes company, beyond Sanofi and Boehringer Ingelheim, to now work with Zealand, and this collaboration is a further validation of our core strengths in designing and developing innovative diabetes medicines for the 21st century. Within our diabetes franchise, we also announced promising results for a late-stage preclinical asset, a liquid formulated glucagon analogue to treat severe hypoglycemia in diabetes.

BI collaboration: New lead replaces ZP2929

Together with Boehringer Ingelheim, we announced a change in the lead development program on novel dual-acting glucagon/GLP-1 agonists to treat Type 2 diabetes and/or obesity. A new lead candidate will replace ZP2929 with unchanged financial conditions, while Zealand has taken over the full control of the continued Phase I development of ZP2929.

Important clinical advances for danegaptide and elsiglutide in Phase II

Zealand's pipeline of other proprietary and partnered peptide medicines in development also advanced in 2013. With danegaptide, our important new peptide in cardiovascular medicine, we initiated a Phase II Proof-of-Concept study. Under our partnership with Helsinn, a worldwide leader company in cancer supportive care, preparations began for the advancement of elsiglutide into Phase IIb studies following supportive results from a Phase IIa study for the prevention of chemotherapy induced diarrhea in colorectal cancer patients.

#### 2014 and beyond: Short-, mid- and long-term value drivers

Zealand is well-positioned and financed for further advances and value growth

We are confident Zealand is well positioned and financed for further advances and value growth in 2014 and beyond. In 2014, we expect to see incrementally growing sales of Lyxumia® and related royalty revenue. We also look forward to Sanofi advancing the Phase III development of the Lantus®/Lyxumia® combination product towards completion in 2015. For our proprietary diabetes pipeline, we are working to advance ZP2929 in clinical Phase I development and complete pre-clinical development of our glucagon product and proceed into clinical development. This peptide medicine is designed for application in an easy-to-use rescue pen and, we believe, holds the potential to significantly improve the treatment of severe hypoglycemia.

Phase II PoC results for danegaptide expected in the 2<sup>nd</sup> half 2015 Outside our diabetes franchise, we will continue the enrolment of patients into the clinical Phase II study with danegaptide. The study is designed to show the efficacy of this Zealand peptide medicine in preventing heart damage from myocardial ischemic reperfusion injuries. If positive, results will also show potential for danegaptide in other types of reperfusion injuries, such as organ transplantation and stroke. Study results are expected in the 2<sup>nd</sup> half 2015. With elsiglutide, Helsinn will begin a Phase IIb study in 2014, which is planned to be completed in 2015. We see both peptide medicines representing potentially significant improvements to patients' lives.

Additional partner alliances expected to accelerate pipeline growth Zealand is a world-leading and recognized expert in the discovery, design and development of peptide-based medicines and patient centric innovation is at our core. Still, we cannot do it alone and we will continue to join forces with leading healthcare companies who have the resources to undertake large clinical studies and to market our medicines globally. In the near future, we intend to establish additional alliances that allow us to develop new, breakthrough medicines in a cost effective manner, thereby sharing the financial risks, whilst being equally rewarded. This will augment Zealand's skills, provide additional opportunities to accelerate growth in our pipeline and make our innovative treatments available to patients, thereby also rewarding our shareholders.

Our employees make Zealand successful It is the significant work of our employees that makes Zealand successful and we thank them for their passion, hard work and innovative ideas as they join us in fulfilling Zealand's mission to discover and develop peptide medicines that improve people's lives.

We thank you for your trust in us and look forward to sharing further advances with you in 2014.



David Horn Solomon President and Chief Executive Officer Daniël Jan Ellens Chairman. Board of Directors

# Financial highlights...



Mats Blom Senior Vice President and Chief Financial Officer

Revenue in 2013 was made up of initial sales royalties following the launch of Lyxumia® by Sanofi in March 2013. With the first Zealand invented medicine now on the market, the way is paved for sustained revenue to our company. Still, as market presence is built on a country by country basis, sales in this first years after launch are typically limited.



As no milestone payments were recognized from our partners in 2013, we saw a decrease in revenue from previous years. Revenue in 2011 and 2012 was entirely milestone driven, and this type of revenue varies greatly from year to year.

# 200 150 100 2009 2010 2011 2012 2013 Administrative expenses Net R&D (research and development expenses adjusted for other operating income)

#### **Operating result**

After two years with positive results, the negative operating result for 2013 was mainly a consequence of no recognized milestones for the period. R&D expenses were 10 % lower than in 2012. Due to a fall in other operating income in the form of cost reimbursements under our collaboration with BI, net R&D expenses increased 7 %. Administrative expenses was 24 % higher than in 2012 but unchanged compared to 2011.

#### Cash, cash equivalents and securities

End 2013, Zealand had cash and securities of DKK 311 (EUR 41) million. In early 2014, an additional DKK 82 (EUR 11) million was received as a milestone payment from Sanofi upon first study protocol approval relating to the LixiLan Phase III program.

#### **Average number of employees**

It is Zealand's intention to retain a dynamic and agile organization focusing on our core competences in the invention, design and development of peptide medicines. On 14 March, the number of full time employees (FTE) was 91.

# ... and key figures 2013

DKK '000	Note	2013	2012	2011	2010	2009
Income statement and comprehensive						
income						
Revenue		6,574	223,565	142,284	87,357	25,319
Royalty expenses		-872	-15,933	-112	-11,203	-74
Gross profit		5,702	207,632	142,172	76,154	25,245
Research and development expenses		-164,467	-182,759	-126,938	-140,075	-93,047
Administrative expenses		-34,155	-27,611	-34,905	-39,732	-16,735
Initial public offering expenses		7,000	0	0	-5,820	0
Other operating income		7,302	35,135	28,435	777	3,971
Operating result		-185,618	32,397	8,764	-108,696	-80,566
Net financial items		1,942	3,975	4,613	4,062	4,215
Net result (after tax)		-183,676	36,372	13,377	-104,634	-76,351
Comprehensive income		<b>-183,676</b> -8.10	<b>36,372</b> 1.61	<b>13,377</b> 0.60	<b>-104,634</b> -5.92	-76,351 -4.45
Earnings per share – basic (DKK)  Earnings per share – diluted (DKK)		-8.10 -8.10	1.60	0.60	-5.92 -5.92	-4.45 -4.45
Cash and cash equivalents Securities Total assets Share capital ('000 shares) Shareholder's equity Equity / assets ratio		286,178 24,383 346,913 23,193 316,141 0.91	358,847 126,940 522,404 23,193 491,015 0.94	278,265 149,358 470,861 23,193 441,397 0.94	383,228 49,673 451,890 22,871 407,108 0.90	144,540 0 159,978 17,682 132,924 0.84
Cash flow Depreciation Change in working capital Investments in fixed assets		5,911 -3,643 -4,569	5,319 13,782 -8,849	4,129 -30,943 -11,475	3,334 15,194 -4,236	3,686 9,712 -3,574
Free cash flow	1	-174,187	59,688	-12,637	-60,216	-65,028
Other						
Share price (DKK)		59,00	84.00	57.00	70.00	n/a
Market capitalization (MDKK)		1,368,387	1,948,216	1,322,004	1,600,970	n/a
Equity per share (DKK)	2	13,97	21.70	19.51	18.24	7.76
Average number of employees		111	104	91	72	69
	١	C	7	6	C	6
Compounds in clinical development (year end Products on the market	)	6	7	6	6	0

<sup>&</sup>lt;sup>1</sup> Free cash flow is calculated as cash flow from operating activities less purchase of property, plant and equipment

 $<sup>^2</sup>$  Equity per share is calculated as shareholders equity divided by total number of shares less treasury shares

# Key events in 2013 and post year end

# Our strategy

**Maximize** 

mitigate

risk

Sustain

focused

#### Lyxumia® (lixisenatide) - Sanofi

**Feb** European approval FDA acceptance of the New Drug Application (NDA) filed for lixisenatide in the US

Mar First European launch

**June** Approval in Japan

Sanofi withdrew the NDA for lixisenatide in the US in order to resubmit in 2015 after completion of the ELIXA cardiovascular outcome study

Dec Data presented at the IDF World Diabetes congress support flexibility in the timing of Lyxumia® administration

**Feb'14** Report of 2013 initial Lyxumia® royalty revenue: DKK 6.5 (€ 0.85) million (Q4: DKK 3.2 (EUR 0.43) million)

# Lantus®/Lyxumia® fixed-ratio combination – Sanofi

**Feb** Sanofi delays the expected start of the LixiLan Phase III development program (previously planned for start mid 2013)

Sanofi assigns priority to a Fixed-Ratio combination of Lantus®/Lyxumia® over the Fix-Flex device for start of Phase III

**June** Sanofi announces expected start of the LixiLan Phase III program in first half of 2014

Jan'14 Approval of the first LixiLan Phase III study protocol; milestone payment of USD 15 (DKK 82) million to Zealand from Sanofi

**Feb'14** LixiLan Phase III program started – US regulatory submission targeted for late 2015

# **ZP2929 and Boehringer Ingelheim** collaboration

Jan'14 Change of development program on novel dual-acting glucagon/GLP-1 receptor agonists to a new lead compound – ZP2929 will continue in Phase I development outside the collaboration under Zealand's sole control

#### **Danegaptide**

Mar Decision to start a large single centre Phase II Clinical Proof-of-Concept study to evaluate this potential first-in-class peptide therapeutic in the prevention of ischemic reperfusion injuries

Start of patient dosing in the Phase II PoC study: Completion targeted for the 2<sup>nd</sup> half of 2015

#### **Elsiglutide**

Helsinn decides to advance into Phase IIb development based on favourable results from Phase IIa

#### Other pipeline events and partnering

June Partnership with D. E. Shaw Research:

Potentially adding a new dimension to peptide drug design

Preclinical data presented at ADA support the outlook for ZP-GA-1 as a potential new treatment of diabetic hypoglycemia in the form of an easy-to-use pen and/or in an artificial pancreas

Aug Partnership with Lilly – Third diabetes collaboration:
Joint design and development of novel peptide
therapeutics for Type 2 diabetes and obesity

GLP-1/gastrin dual agonist:
Preclinical data presented at EASD show potential for this compound as a novel approach for the treatment and/or prevention of Type 2 diabetes

#### Zealand's organisation

Sep

Jan Agneta Svedberg appointed as new Chief Operating Officer

Sep Dr. Torsten Hoffmann appointed as new Chief Scientific Officer

# Our strategy defines the path towards achieving Zealand's corporate mission:

To discover and develop proprietary innovative peptide medicines and health solutions that improve people's lives.

To support our mission, we have defined a corporate strategy which builds on three fundamental pillars of our business:

# Design and develop novel peptide therapeutics to improve patients' lives

- We have a patient-centric approach to the invention of new medicines and accompanying health solutions.
- Our activities are driven by focused innovation and leading competencies in the field of peptide drug design and development.
- We aim to expand and advance our activities and value creation through investments in both proprietary and acquired/in-licensed pipeline assets.

# Generate maximum value and mitigate development risk through partnerships

- We have in-house capabilities to take drug candidates through Phase II clinical Proof-of-Concept studies.
- To leverage our internal competencies and ensure an optimal balance between drug development risk and value creation, our business model is based on synergistic partnering; with big pharma, biotech and academia.
- As our company matures, we will increasingly engage in partnerships that build on sharing financing and risk to add further value to our pipeline, including the retention of strategic product rights and partial commercial rights into late-stage development.

#### Sustain an R&D-focused and agile operating model

Zealand intends to remain focused on R&D, retaining an organizational structure that
ensures high operational agility and rapid decision making to maximise productivity and
effects a seamless and dynamic transition from invention to clinical development.

# Our Business model

Our business model is built on partnering. Through partnerships and collaborations we can leverage our core R&D competences, expand our activities and optimize the value in our pipeline while retaining a balanced risk-reward approach. This is why we are ZealAND patients; ZealAND big pharma and biotech companies; ZealAND medical experts and care givers; and ZealAND academia.

# The starting place for our business is world-leading expertise in the field of peptide medicines

Zealand has a fundamentally strong basis for its business activities founded on its world-leading competences and expertise in the field of peptide drug design and development. This is evident from the number of peptides synthesized since the company's inception 15 years ago (approximately 5,900 peptides) as well as by the approx. 800 active patents on Zealand peptide compounds, approx. 250 of which have been issued, and the nine therapeutic candidates that we have taken into clinical development.

#### Peptide based medicines - A growing market

Peptides have several advantages as medicines. They play important roles in regulating human physiologic functions. Peptides have a high biologic specificity and selectivity, physiological medicines based on peptides offers advantageous efficacy and safety profiles.

Peptide medicines have in general benefits over protein based medicines in terms of administration routes and manufacturing costs. Peptide based medicines are a growing class with still unexplored potential in several disease areas. Currently, there are many marketed peptide products, several with blockbuster status these include Capoxone, Victoza, Sandostatin, Forteo, Zoladex.

Source: Transparency Market Research, Peptide Therapeutics Market Global Industry Analysis, Size, Share, Growth, Trends and Forecast 2012-2018

#### **Key elements of our business model**

From idea generation to commercialisation of Zealand invented peptide medicines and associated health solutions, we rely on partnerships. This approach is key in meeting our overall strategic objectives. Our business model helps us to optimize the scope of our activities and the value of our pipeline while retaining an agile organization focused within our core expertise area of design and development of innovative peptide based therapeutics.

The size and structure of our R&D organization ensures a dynamic and interactive development process. We believe this adds optimal speed to the transition of novel peptide therapeutics from preclinical to clinical development.

# The Zealand business model Medical experts/care givers Biotech companies Big pharma partners Big pharma partners Pipeline of novel Zealand peptide R&D engine Redicines Marketed Zealand invented medicines

Patient

niversitie

Zealand believes that inventing and developing revolutionary health solutions requires a thorough understanding of patients and their needs as well as strong science and IP protection. We therefore interact with relevant stakeholders, including patient organizations and caregivers throughout the invention and development of a new medicine.

We have a comprehensive toolbox of peptide technologies in house which we can apply to novel peptide therapeutics. We do, however, acknowledge that many new opportunities in terms of new peptide design and formulary techniques reside outside our company. This is why we engage in collaborations with biotech companies and academia in the pre-clinical phase to ensure access to the newest techniques. The current collaboration with D.E. Shaw research is an example of our approach to leveraging the expertise of others.

We have in-house capabilities to take new peptide drug candidates in selected indications from idea phase to clinical Proof-of-Concept. For such proprietary clinical programs, however, study activities are still conducted in collaboration with leading hospital, clinical centers and via Contract Research Organizations helping us to leverage our work. This approach is essential also, to establish strong and valuable contacts at medical centers and retain a network of relevant medical key opinion leaders. An example is the Phase II clinical study we have ongoing with danegaptide, which is conducted in collaboration with Rigshospitalet, one of the world's leading cardiac centers.

As a partnering company, Zealand intends to stay focused on invention and early development of new health solutions, with a partner eventually being responsible for the later stage development as well as commercialisation.

# IP and Region DK/DI

Zealand's peptide

**R&D** engine

medicines

Stability

#### Zealand's integrated approach to peptide R&D

We believe that an integrated approach is essential in advancing programs at a high speed and with the lowest risk possible, and we take advantage of being an agile and flexible organization with focus on R&D activities. When an idea matures into a project, activities to find the best lead candidate are initiated. This is an iterative process where all disciplines in the company continuously provide input to allow for the most valuable assets to be advanced into the clinic.

# Revolutionary health solutions: The Zealand approach

Our corporate tag line "revolutionary health solutions" is a reflection of our ambition to design and develop innovative peptide medicines and accompanying solutions which can significantly improve patients' lives.

#### **Product**

#### **Revolutionary attributes**

#### Lixisenatide (Lyxumia®)

### Type 2 diabetes (licensed to Sanofi)

When lixisenatide was invented by Zealand in 1999 as the first once-daily GLP-1 receptor agonist (RA), the class represented a novel approach in the treatment of Type 2 diabetes with significant benefits over existing types of anti-diabetic treatment:

- Effective only upon food intake, leading to lower risk of hypos and better beta cell preservation.
- First ever diabetes product with weight reducing effect.
- GLP-1 receptors are presented in heart tissue, leaving the class with potentially beneficial CV effects a truly revolutionary aspect.

Lixisenatide has a pronounced lowering effect on post-prandial glucose, uniquely complementing basal insulin as an important new combination therapy to offer patients.

#### **Danegaptide**

### Ischemia reperfusion injuries (IRI)

(Zealand proprietary product)

Danegaptide is a first-in-class Zealand-invented therapeutic peptide which can protect cells from injury.

Danegaptide has shown a unique ability to reduce tissue damage and infarct sizes in models of IRI, and the peptide has also shown to be very safe. A clinical Phase II Proof-of-Concept study is now ongoing to evaluate the therapeutic effect of danegaptide in the prevention of IRI in patients with a myocardial infarction.

Cardiac IRI can lead to severely reduced cardiac function and increased cardiac event risk. Treatment options are limited, and we believe danegaptide thus represents significant possible value as the first medicinal approach to improving quality of life for these patients.

If danegaptide can demonstrate positive effect in protecting against cardiac IRI, this will open the potential for broader use of this Zealand peptide also in other forms of IRI, including organ transplants and stroke.

#### **Elsiglutide**

### Chemotherapy-induced diarrhea

(partnership with Helsinn)

Elsiglutide was invented by Zealand as a novel GLP-2 receptor agonist, a new and upcoming class of medicines with unique characteristics to enhance the function of the gastero-intestinal tract.

In a clinical Phase II study, this peptide has shown the ability to reduce diarrhea in cancer patients treated with chemotherapy. No effective treatment of this condition exists today, leading to reduced quality of life for many cancer patients and non-optimal cancer treatment.

If the clinical effect of elsiglutide can be firmly established, it opens the possibility not only of significantly improving quality of life for cancer patients, but also for a more effective cancer treatment. This would have a major beneficial impact on patients lives.

# Glucagon analoque optimized for liquid formulation

#### Severe hypoglycemia in diabetes

(Zealand proprietary product)

Zealand's innovative team of peptide specialists have invented a glucagon analoque optimized for liquid formulation and with attractive therapeutic properties. This opens the potential for its application in a easy-to-use rescue pen for improved treatment of severe hypoglycemia in diabetes.

Glucagon plays an important role in upregulating blood sugar levels. The peptide is however highly unstable in liquid formulation, and current rescue kits to treat hypoglycemia are therefore based on powder versions of glucagon. This requires a cumbersome handling procedure for relatives in a critial situation.

We believe that an easy-to-use rescue pen with a liquid formulation of glucagon has the potential to revolutionize the way severe hypoglycemia is treated today with an important positive impact on quality of life for diabetes patients and their relatives.

Further, a liquid formulated glucagon analogue holds potential for use in an artificial closed-loop pancreatic system, which would represent a very important advance in the treatment of diabetes patients.

# Key performance indicators

Essential for Zealand's success is our ability to constantly innovate and grow our product portfolio and pipeline of novel attractive medicines, and to ensure an increasing revenue stream and ensure financial solidity.

### Zealand key performance indicators for 2014 and onwards

# Grow the value of our pipeline, advancing novel medicines towards the market

- Pipeline advances in terms of shifts to the next stage of development (two per year)
- Speed of transition from preclinical to clinical development (One IND per two years)

#### Increase the proprietary (unpartnered) part of the pipeline

 Number of pipeline assets where Zealand retains full or partial rights and thus substantial value upside

#### **Grow the portfolio of partnerships**

 Number of big pharma partnerships (offering late stage clinical and commercial strength, financing and risk mitigation)

#### **Generate growing revenues and retain solid financial position**

- Royalty revenue growth (quarter/quarter, year/year)
- Sum of total potential milestone payments from partners
- Retain a cash position corresponding to at least 18 months of net operational expenses

# Financial guidance and business outlook for 2014

# Pipeline overview

#### Financial guidance for 2014

In 2014, Zealand will receive revenue from milestone payments and royalties on Lyxumia<sup>®</sup> sales. Guidance on milestone payments amount to DKK 97 (EUR 13) million, including DKK 82 (EUR 11) million received from Sanofi in January 2014 and a time based milestone payment from Helsinn of DKK 15 (EUR 2) million to be received in fourth quarter of 2014.

The timing of other potential milestone based payments is largely outside Zealand's control and therefore not included in our guidance at this point. Guidance on royalties cannot be provided, since Sanofi has given no guidance on expected Lyxumia<sup>®</sup> sales in 2014.

Net operating expenses for 2014 are expected at a range of DKK 200-210 (EUR 27-28) million.

#### **Expectations for our business in 2014**

#### Lyxumia® (lixisenatide)

- Further commercial roll-out by Sanofi (quarterly updates)
- Publication of results from on-going phase IV studies to further elucidate the product's therapeutic profile
- . Completion of treatment in the CV outcome study, ELIXA

#### Lyxumia<sup>®</sup>/Lantus<sup>®</sup>

 Publication of results from phase IIb study of fixed-ratio combination (323 patients)

#### **ZP2929**

• Advance phase I clinical development of ZP2929

#### **Danegaptide**

- Continue enrolment in phase II clinical Proof-of-Concept study (600 patients)
- Results are expected in the 2<sup>nd</sup> half of 2015

#### **Elsiglutide**

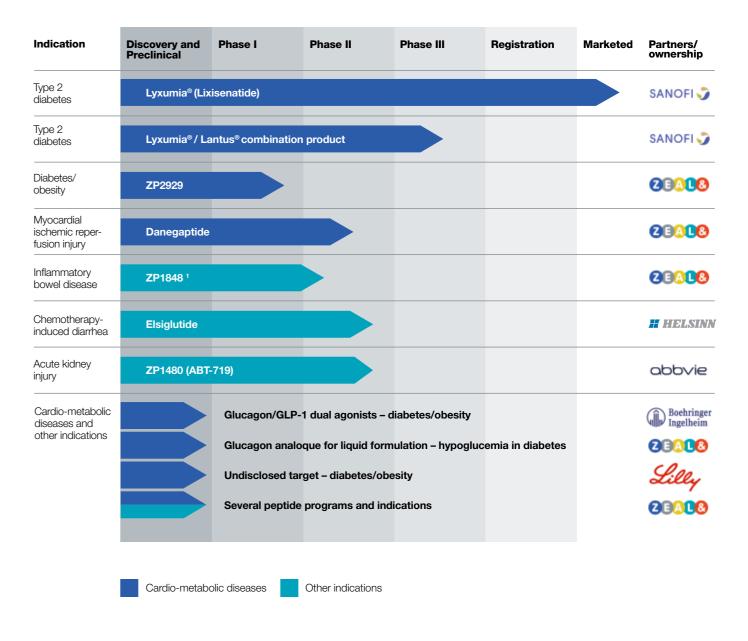
• Start of clinical phase Ilb study

#### Other expected pipeline news

- ZP1480 (ABT-719): Advancement in Phase IIb development for the prevention of acute kidney injury
- Start clinical Phase I with novel liquid formulated glucagon analogue
- Selection and advancement of new lead glucagon/GLP-1 candidate under collaboration with BI
- Expand portfolio of partnerships

# We are advancing a broad pipeline of proprietary and partnered assets, including six clinical and several preclinical peptide drug candidates.

Our pipeline reflects our therapeutic focus on cardio-metabolic diseases. All peptide medicines in our pipeline are invented in-house.



<sup>&</sup>lt;sup>1</sup> ZP1848 will be advanced into Phase II development only under a partnership.

# Our partnership portfolio

#### Financial support, risk mitigation and validation

P	a	r	tı	1	е	r	

#### Collaboration

#### **Financial terms**



Sanofi sanofi.com Global license agreement to develop and commercialize lixisenatide (Lyxumia®) and any combination product, which include lixisenatide Financing: All covered by Sanofi

**Milestones to Zealand:** USD 275 million, of which USD 160 million is outstanding.

**Royalties to Zealand:** Tiered, low double-digit percentages on sales of Lyxumia<sup>®</sup> and fixed, low-double digit percentage on sales of combination products, which include lixisenatide.



Helsinn Healthcare helsinn.com

Worldwide exclusive agreement on the development and commercialisation of elsiglutide within a specific field in cancer supportive care Financing: All covered by Helsinn

**Milestones to Zealand:** Up to EUR 140 million, of which EUR 14 million has been received.

**Royalties to Zealand:** High single digit percentages of Helsinn's global sales of elsiglutide. Zealand has an option to obtain commercial rights to elsiglutide in the Nordic countries.



Abbvie abbvie.com

License agreement on ZP1480 (ABT-719)

Financing: All covered by AbbVie

**Royalties to Zealand:** Low single digit percentage on global sales of the product.



Boehringer Ingelheim boehringer-Ingelheim.com Global license and collaboration agreement to develop and commercialize glucagon/GLP-1 dual acting agonists for the treatment of Type 2 diabetes and/or obesity

Financing: All covered by Boehringer Ingelheim

**Milestones to Zealand:** Up to EUR 376 million, of which EUR 365 million remaining, in total for potential development, regulatory and commercial events relating to the lead candidate – additional, potential milestones for other products from the collaboration.

**Royalties to Zealand:** Ranging from high single to low double digits on global sales of products from the collaboration.



Eli Lilly lilly.com Collaboration agreement to design and develop novel therapeutic peptides for Type 2 diabetes and obesity **Financing:** The companies will share the funding, risk and reward of the program.

# Pipeline descriptions

#### Lyxumia® (lixisenatide) for Type 2 diabetes - Marketed (licensed to Sanofi)

#### Description

# Lyxumia® (lixisenatide) is a once-daily prandial GLP-1 receptor agonist, invented by Zealand and with global commercial rights licensed to Sanofi. The product has a pronounced effect on post-prandial glucose and is indicated for use in combination with basal insulin, including Lantus® (insulin glargine), the world's most prescribed basal insulin, and/or oral anti-diabetic medicines.

#### Status

Approved and launched by Sanofi in Europe (March 2013), Japan (September) and several other countries. In the US, an NDA is planned submitted in 2015 after completion of the ELIXA CV study.

#### Key events/milestones

Quarterly sales numbers.

Additional launches in new markets.

Results from ELIXA study outcome.

US NDA submission.

#### Lantus®/Lyxumia® combination product for Type 2 diabetes – In Phase III (licensed to Sanofi)

#### Description

# Fixed-ratio combination of Lantus® and Lyxumia® administered once-daily in a disposable pen.

#### Status

LixiLan Phase III clinical development program started in January 2014. Evaluated in large Phase IIb study in 323 patients.

#### Key events/milestones

Presentation of Phase IIb results in 2014.
Completion of the LixiLan Phase III program.
US NDA submission.

#### ZP2929 for Type 2 diabetes and/or obesity - In Phase I (Zealand proprietary asset)

#### Description

# ZP2929 is a once-daily glucagon/GLP-1 dual-acting peptide agonist for the treatment of diabetes and/or obesity.

ZP2929 has shown, in preclinical studies, to improve glycemic control (HbA1c) equivalent to that of marketed GLP-1s, while showing a superior and sustained weight loss.

#### Status

The continued development program for ZP2929 is under strategic review. The program is conducted under an initial new drug application (IND) with the FDA.

#### **Kev events/milestones**

As a next step Zealand will present its preferred strategy for the continued Phase I development and design to the FDA, including results from additional preclinical studies.

#### Danegaptide for ischemia reperfusion injuries - In Phase II (Zealand proprietary asset)

#### Product/disease indication

# A novel Zealand invented dipeptide gap junction modifier with cardioprotective properties.

#### Status

# Zealand is evaluating danegaptide in a Phase II Clinical Proof-of-Concept study for its effect in the protection against ischemic reperfusion injuries. The study is expected to enroll up to 600 patients with an acute myocardial infarction (STEMI), undergoing PCI.

#### **Key events/milestones**

Results are expected in the 2<sup>nd</sup> half of 2015.

# Short-to mid-term value drivers: Lyxumia® and the Lantus®/Lyxumia® combination product

#### **ZP1848** for inflammatory bowel disease - Ready for Phase II (Zealand proprietary asset)

#### Product/disease indication

# A GLP-2 peptide agonist demonstrating regenerative effect on the intestinal epithelial surface and an ability to enhance bowel function.

#### **Status**

Completed Phase Ib and ready for Phase II

#### Key events/milestones

It is part of Zealand's current prioritization to only advance ZP1848 under a partnership.

#### Elsiglutide for chemotherapy induced diarrhea - In Phase II (partnership with Helsinn)

#### **Description**

# A novel, potent and selective GLP-2 peptide receptor agonist in development for the prevention of chemotherapy induced diarrhea.

#### **Status**

Helsinn has evaluated elsiglutide in a clinical Phase Ila Proof-of-Concept study for the prevention of chemotherapy induced diarrhea in colorectal cancer patients. Based on favorable results from this study, Helsinn is preparing the advance of elsiglutide into a Phase Ilb dose-finding study.

#### **Key events/milestones**

Initiation of Phase IIb by Helsinn later in 2014.

Conduction of large observational multicenter, multinational study to better understand the incidence of chemotherapy induced diarrhea in colorectal and breast cancer patients.

#### ZP1480 (ABT-719) for acute kidney injury - In Phase II (licensed to Abbvie)

#### **Product/disease indication**

# An MSH melanocortin peptide agonist for the prevention of acute kidney injury following major surgery.

#### **Status**

Abbvie is conducting a Phase IIb program to confirm positive results from an earlier study of ZP1480 in the prevention of acute kidney injury.

#### **Key events/milestones**

Results from Phase IIb program.

#### **Preclinical programs**

Our preclinical activities include around 10 peptide programs and a number of early stage projects. The majority of projects relate to the therapeutic field of cardio-metabolic indications, and new projects are targeting other disease areas, where peptide therapeutics promise to have large potential.

Two of the preclinical projects are under partnerships. One covers our collaboration with Boehringer Ingelheim on novel glucagon/GLP-1 dual agonists for the treatment of diabetes and/or obesity, which is progressing towards the selection of a new lead candidate from the portfolio of novel compound designs invented under the two-year

research agreement of the collaboration (completed in June 2013), including compounds designed for once-weekly dosing. Another is our collaboration with Lilly on joint design and development of potentially novel therapeutic peptides against an undisclosed target with therapeutic relevance for the treatment of Type 2 diabetes and obesity.

One late-stage proprietary preclinical program covers our novel glucagon analogue for the treatment of severe hypoglycemia (episodes of critically low blood sugar levels) in diabetic patients. This Zealand invented peptide analogue has shown unique physico-chemical properties as well as efficacy and a

pharmacokinetic profile similar to native glucagon, making it suitable for a liquid formulation. These properties leave the potential for its use in a easy-to-use rescue pen and potentially as an essential component in an artificial pancreatic system. Zealand is currently preparing for the advancement of this medicine into clinical development.

Another advanced preclinical program is our dual acting GLP-1-gastrin agonist for the treatment of diabetes. This peptide has potentially disease preventive properties as it has demonstrated in preclinical animal models its potential to preserve pancreatic beta-cell function and insulin secretion.

# Lyxumia® 10 µg OD SC

asy-to-Use Once-Daily prandial GLP-1

Lyxumia® 20 μg on SC

injection was advanced into pivotal Phase III development by Sanofi in early 2014. The program is expected to complete in the 2<sup>nd</sup> half of 2015, and regulatory submissions could begin as early as the end of 2015.

Global roll-out of Lyxumia® as a new treatment of

filing in the US is expected in 2015.

Type 2 diabetes is expected to lead to increasing royalty

The fixed-ratio combination of Lyxumia® with Lantus®, the

most prescribed basal insulin world-wide, in a single daily

revenues to Zealand in the coming years. Regulatory

Lyxumia<sup>®</sup> – Once-daily prandial GLP-1 receptor agonist for Type 2 diabetes, invented by Zealand and marketed by Sanofi

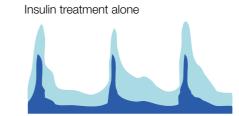
In March 2013, Lyxumia® was launched in the first markets by Sanofi, who holds global development and commercial rights to the product under a license agreement with Zealand. Lyxumia® is currently approved in over 40 countries worldwide for the treatment of Type 2 diabetes, with commercial launches ongoing in Europe, Japan, Mexico and other markets.

Zealand is entitled to royalties based on Sanofi's global sales of Lyxumia<sup>®</sup>. In 2013, initial royalty revenue amounted to EUR 0.9 million (DKK 6.5 million), and Sanofi continues the commercial roll-out of the product.

# Why lowering of post-prandial (meal related) glucose levels is important?

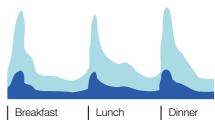
Lowering of both post-prandial (meal related) and fasting blood sugar levels is important for good diabetes management. Basal insulin mainly has effect on fasting glucose when adding the treatment with a prandial GLP-1 agonist. This has a proven effect on post-prandial glucose such as Lyxumia® and therefore would have a strong therapeutic rationale.

#### Expected benefits on fasting and post-prandial glucose



Treatment with basal insulin is effective in controlling blood sugar, mainly via effect on fasting (in between meals) glucose levels. Basal insulin is however, not very effective on meal related glucose peaks, also referred to as post-prandial glucose (PPG).

Insulin + GLP-1 treatment



Adding a GLP-1 agonist with pronounced effect on PPG complements basal insulin in normalizing blood sugar levels over the course of the day.

Blood glucose profile

Blood glucose under treatment

#### Lyxumia®'s profile makes it particularly well suited for use as add-on to basal insulin, incl. Lantus®

Lyxumia® (lixisenatide) is associated with a significant lowering of HbA1C (glycosylated hemoglobin), a beneficial effect on body weight and a predominant effect on lowering meal related glucose (post-prandial glucose, PPG). This profile makes Lyxumia® particularly well suited for use as add-on therapy to basal insulin, including Lantus® (insulin glargine). Lantus® is Sanofi's leading diabetes product and the most prescribed basal insulin world-wide with annual sales of EUR 5.7 billion in 2013.

In February 2013, FDA accepted a New Drug Application (NDA) filed by Sanofi for lixisenatide in the US. The filing included interim results from the ongoing cardio-vascular outcome study on lixisenatide, ELIXA.

In September, Sanofi announced its decision to withdraw the application and instead plan for resubmission in 2015, after completion of the ELIXA CV study.

The decision to withdraw the lixisenatide application followed discussions with the FDA regarding its proposed process for the review of interim data. Sanofi believes that potential public disclosure of early interim data, even with safeguards, could potentially compromise the integrity of the ongoing ELIXA study. Sanofi's decision was not related to safety issues or deficiencies in the NDA.

# ELIXA – Lyxumia<sup>®</sup> (lixisenatide) CV outcome study: Completion in 2015

#### Filing for submission of lixisenatide in the US is expected in 2015 after completion of the ELIXA CV safety study

The evaluation of <u>lixisenatide</u> in acute coronary syndrome (ELIXA) study is an event-driven cardiovascular (CV) outcome study in Type 2 diabetic patients with high CV risk.

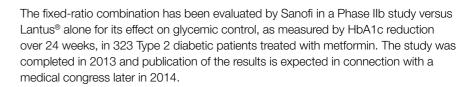
The primary objective of the ELIXA study is to demonstrate that lixisenatide can reduce CV morbidity and mortality (composite endpoint of CV death, non-fatal myocardial infarction (MI), non-fatal stroke, hospitalization for unstable angina) compared to placebo in Type 2 diabetic patients who recently experienced an acute coronary syndrome (ACS) event.

The ELIXA study started in June 2010 with a target enrollment of 6,000 patients. As of August, 2013, the study was fully enrolled and study completion is expected in 2015, with results available that same year.

Europe

#### Lyxumia® (lixisenatide) and Lantus®/Lyxumia® combination product - Development timeline





The fixed-ratio single injection combination of Lyxumia® with

In February 2014, Sanofi announced the initiation of the LixiLan Phase III clinical development program for the fixed-ratio combination.

#### The LixiLan program comprises two studies:

- LixiLan-O (O = Oral) is investigating the effect of treatment with the fixed-ratio combination of Lyxumia® and Lantus® in people with Type 2 diabetes (1,125 patients) versus treatment with either Lantus® or Lyxumia® alone. The first patient was screened for this study in February 2014.
- **LixiLan-L** (L = Lantus) is investigating the effect of treatment with the fixed-ratio combination of Lyxumia® and Lantus® on HbA1c levels in people with Type 2 diabetes (700 patients) versus treatment with Lantus® alone. The first patient was screened for this study at the end of January 2014.

Completion of the LixiLan studies is expected in the 2<sup>nd</sup> half of 2015 and the planned timing for regulatory filings leaves the potential for the fixed-ratio combination of Lyxumia<sup>®</sup> and Lantus<sup>®</sup> to be the first fixed-ratio combination of a basal insulin with a GLP-1 agonist in a single daily injection to be marketed in the US.

#### Over 380 million people worldwide have diabetes

l ixil an

The number of people with Type 2 diabetes is increasing all over the world. Today, 382 million people have diabetes worldwide and this number is expected to increase by 55% to 592 million by 2035. If insufficiently treated, diabetes will lead to a number of disabling and life-threatening health problems, including serious diseases affecting the heart and blood vessels, the eyes, the kidneys, the liver and the nervous system. An estimated 175 million people with diabetes are currently undiagnosed.

Source: International Diabetes Federation

1999	2003	2007	2010	2011	2012	2013			2014
									<del></del>
Zealand invents lixisenatide	License collaboration with Sanofi on lixisenatide including global development and marketing rights	Phase Ilb study for lixisenatide completed by Sanofi	Amendment of Sanofi partnership to include combination products, including lixisenatide  Lixisenatide shows first positive results from global GetGoal Phase III program in	Additional positive results from GetGoal, showing significant HbA1c reduction, a pronounced lowering of post-prandial glucose and a beneficial effect on body weight from treatment with Lyxumia® Lyxumia® (lixisenatide) filed	Global Phase III GetGoal program for lixisenatide completed by Sanofi  Lyxumia® (lixisenatide) filed for regulatory approval in Japan	Lyxumia® (lixisenatide) formally approved in Europe  European approval FDA acceptance of the New Drug Application (NDA) filed for lixisenatide in the US	Sanofi withdraws the NDA for lixisenatide in the US in order to resubmit in 2015 after completion of the ELIXA cardiovascular outcome study	Sanofi assigns priority to a Fixed-Ratio combination of Lantus®/Lyxumia® over the Fix-Flex device for start of Phase III First commercial sales of Lyxumia® (lixisenatide) in Europe	Report of 2013 initial Lyxumia® royalty revenue: DKK 6.5 (€ 0.85) million (Q4: DKK 3.2 (EUR 0.43) million)  LixiLan Phase III program started – US regulatory submission targeted for late 2015

Zealand Pharma Annual Report 2013 Zealand Pharma Annual Report 2013 Zealand Pharma Annual Report 2013

# Other mid-term value drivers: Danegaptide and elsiglutide

Danegaptide is a proprietary Zealand asset with the potential to become the first medical treatment for ischemic reperfusion injuries – An area of large unmet medical need. Ongoing Phase II Proof-of-Concept study to read out in the 2<sup>nd</sup> half of 2015.

Elsiglutide, in partnership with Helsinn, has shown favourable clinical Phase IIa results and the next step in development is a Phase IIb dose-finding study, planned to start in the 2<sup>nd</sup> half 2014

# **Danegaptide – A potential first-in-class medicinal treatment** for ischemic reperfusion injuries

Danegaptide is a small dipeptide invented by Zealand, which has demonstrated both anti-arrhythmic and cytoprotective (cell-preserving) properties.

Danegaptide
- a novel, small peptide
therapeutic invented by
Zealand

In a pre-clinical model of reperfusion injuries related to acute myocardial infarction (AMI), i.e. an acute blood clot in the heart, danegaptide has demonstrated dose-dependant significant reductions in infarct size. The safety of danegaptide has been evaluated in an extensive Phase I program, including three individual studies in 153 subjects. Results showed that the compound was safe and well tolerated.

In November 2013, we advanced danegaptide in development with the initiation of a Phase II Clinical Proof-of-Concept study. The study objective is to assess the efficacy and safety of danegaptide in reducing tissue damage from reperfusion injuries in patients with an acute myocardial infarction (ST-segment elevation myocardial infarction, STEMI) when added to standard treatment in the form of balloon dilatation (primary PCI).

The study is a randomized, double-blind, placebo-controlled study, which will be conducted at Rigshospitalet in Copenhagen. It is expected to enroll up to 600 STEMI patients, who will be randomized to treatment with either a high or a low dose of danegaptide or placebo in connection with a PCI procedure.

The primary study endpoint is assessing the therapeutic effect of danegaptide in the reduction of tissue damage, measured as myocardial salvage index three months after the PCI procedure, by use of magnetic resonance imaging. The myocardial salvage index is a documented, strong prognostic marker for cardiac outcome (e.g. death and heart failure). Secondary study endpoints include clinical events of heart failure, re-hospitalizations for heart failure, pharmacodynamic effects and safety of danegaptide when added to the standard treatment of STEMI patients.

The Phase II study is expected to complete in the 2<sup>nd</sup> half of 2015. Results will be decisive to define the future value of danegaptide

The Phase II Proof-of-Concept study is expected to complete in the 2<sup>nd</sup> half of 2015. Study results will be decisive in demonstrating danegaptide's effect in the protection of cardiac tissue against ischemic reperfusion injuries, an area of large unmet medical needs. In addition, the outcome of this study will help define danegaptide's futher potential as a possible general therapy for the prevention of reperfusion injuries, e.g. injuries caused by reperfusion in connection with organ transplantation, kidney injuries and stroke.

#### Interview with Dr. Thomas Engstrøm: Ischemic reperfusion injury represent a serious therapeutic challenge



**Dr. Thomas Engstrøm**PhD, DMSc, Chief Physician,
the Heart Center, Rigshospitalet,
Copenhagen University Hospital
and lead investigator on
the danegaptide study

- Q You and the team at Rigshospitalet have extensive experience in the treatment of patients with cardiac disease, including acute myocardial infarction (AMI) How would you describe treatment outcomes today?
- A Over the past few decades, we have seen significant advances in the treatment of patients with an AMI, i.e. a blood clot in the heart, which has brought the patient survival rate up to 90% from previously around 40%. This has been achieved to a large extent via interventional procedures, referred to as percutaneous coronary intervention (PCI), where a balloon catheter inserted into the clotted vessel to open for blood flow (reperfusion). In most developed parts of the world, PCI has become the standard treatment of AMI, and in some countries, including Denmark, the time to treatment has also been reduced to a minimum via optimal logistics and hospital set-ups, important to salvage more cardiac tissue.

Despite the advances in the treatment of AMI, we are left with a serious therapeutic challenge: while reperfusion of the ischemic myocardial tissue via timely PCI procedures is key to saving patient lives, the return of blood flow in itself causes additional injuries to the heart. Such injuries, which are generally referred to as myocardial reperfusion injuries result in decreased cardiac function and quality of life for patients treated for AMI including an elevated risk of heart failure.

- What options do we have today to prevent or treat myocardial reperfusion injuries?
- A Our team at Rigshospitalet has played an active role over the last many years in finding treatment options to reduce reperfusion injuries. So far, we have found a few therapeutic procedures which may bring some benefit to patients, but we do not yet have any established treatment available to significantly prevent or treat cardiac reperfusion injuries.

Thus we still see a large unmet need for novel preventive therapies, which can help improve the overall clinical outcome and quality of life for patients presenting with an AMI.

- Q How do you see the route forward in terms of treatment opportunities for ischemic reperfusion injuries and improved prospects for patients?
- A Finding a way to effectively prevent or reduce reperfusion injuries would be an important advance in the treatment of AMI. It would ensure a better overall treatment outcome with reduced risk of another cardiac event, significantly improving quality of live for patients. This would be beneficial also from a Health Economic point of view. Danegaptide, which we are currently evaluating in a Phase II Proof-of-Concept study in collaboration with Zealand, represents a relevant medicinal approach. In the study, we are exploring if treatment with this peptide molecule in addition to PCI may reduce reperfusion injuries and meet our needs.

#### **Ischemic reperfusion injury - A serious cardiac condition**

Coronary heart disease is the leading cause of death and disability worldwide. According to the WHO, the condition led to 7,254,000 deaths worldwide (12.8 % of all deaths) in 2008. The detrimental effects of coronary heart disease can be attributable to acute myocardial ischemic reperfusion injury (IRI). IRI typically arises in patients presenting with an acute ST-segment elevation myocardial infarction (STEMI), In 2020, the incidence of STEMI is predicted to be 756.700 in US, EU and Japan combined. The treatment of acute myocardial infarction (AMI) is aimed at enabling the return of blood flow to the ischemic myocardium, thereby limiting the size of the infarct. Treatment options include percutaneous coronary intervention (PCI) with or without thrombectomy, stent implantation and, and in some cases, coronary artery bypass grafting (CABG). Approximately 80 % of STEMI patients undergo PCI procedure, now established in most western countries as the standard treatment of MI.

Source: WHO: The Atlas of Heart Diseases and Stroke. Datamonitor: Stakeholder Insight: Acute Coronary Syndrome 2010

# Strong basis for long-term value growth: World-leading peptide competences and focused drug innovation

#### Elsiglutide – For the prevention of chemotherapy induced diarrhea, an area of large unmet medical needs

and selective GLP-2 peptide agonist invented by Zealand

**Elsiglutide is a novel, potent** Elsiglutide is a GLP-2 receptor agonist, invented by Zealand. Designed for once-daily subcutaneous or intravenous administration, this peptide drug candidate has shown the ability to normalize gastrointestinal function via stimulation of the small intestinal mucosa.

> Global development and commercial rights to elsiglutide in the field of cancer supportive care are licensed to Helsinn Healthcare, which is developing this therapeutic for the prevention of chemotherapy induced diarrhea (CID). Helsinn is a private pharmaceutical company based in Switzerland with a worldwide leading position in cancer supportive

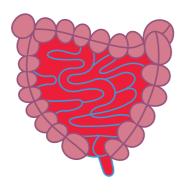
Initiation of phase IIb study

Helsinn has completed a randomized, double-blind, placebo-controlled Phase IIa Proof-of-Concept study with elsiglutide in 138 patients with colorectal cancer receiving chemotherapy. Based on the favourable results from the Phase IIa study, Helsinn made a decision in 2013 to advance clinical development of elsiglutide and is preparing for the initiation of a Phase IIb dose-finding study in the 2<sup>nd</sup> half 2014.



As part of the elsiglutide development program, Helsinn has undertaken a large international, multicenter, prospective, cohort observational study in US and EU to assess the incidence of chemotherapy-induced diarrhea in colorectal and breast cancer patients.

Results from the study together with the outcomes on the planned Phase IIb study will be important to optimally design the full clinical Phase III development program for elsiglutide.



#### Chemotherapy induced diarrhea (CID) - A major challenge in cancer therapy today

Many cancer patients who receive chemotherapy, in particular 5-fluorouracil (5-FU)-based chemotherapy, suffer from severe diarrhea induced by damages to their intestines caused by their chemotherapy. CID can lead to serious adverse events resulting in hospitalization, non-optimal cancer treatment and severely reduced quality of life for the patients.

Source: Healthways, Chemotherapy Induced Diarrhea, Care Guide Update 2010

Peptide-based therapeutics represent a large field of novel and untapped opportunities in several disease areas.

Based on leading and validated peptide design and development competences and a patient-focused approach to drug innovation, Zealand stands in a strong position to explore and benefit long-term from these opportunities.



Dr. Torsten Hoffmann. Executive Vice President and Chief Scientific Officer

#### **Interview with Dr. Torsten Hoffmann:**

- You have more than 20 years' experience, including high ranking managerial and global network positions, from academia and big pharma – what attracted you to Zealand?
- A Zealand is unique in many ways: We have our first invented medicine, Lyxumia®, on the market and six other novel peptide therapeutics are in clinical development – a significant achievement for an organization of our size with limited operational spend. We have a talented and dedicated team of scientists with leading expertise in peptide drug R&D, and we believe in "small is beautiful". Zealand's agile organizational set-up is in my view optimal to support a dynamic and constructive feedback loop between preclinical and clinical development – a key driver in moving successfully from therapeutic target selection all the way to clinical Proof-of-Concept.
- How do you see the future potential for peptide based medicines and what role do you expect Zealand to play?
- A Peptide medicines have become a widely recognized therapeutic class, and going forward, I see the application of peptides moving far beyond what we currently know. New attractive routes to explore include novel molecular designs that will lead to medicines with superior therapeutic attributes such as extended pharmacological action, improved pharmacokinetic profiles as well as enhanced cell- and tissue-specific targeting properties.

Zealand is a pioneer in peptide drug design and development, and our leading position sets a solid foundation for our future scientific endeavors. One example of novel approaches, we are currently exploring at Zealand, are peptide conjugates.

Another way to leverage Zealand's competences is to extend our therapeutic focus beyond the cardio-metabolic field; e.g. into inflammation, where we believe peptide based therapies have significant untapped potential.

- You have a dedicated focus on innovation as a key driver in building long-term pipeline value – what initiatives have you taken to boost innovation at Zealand?
- **A** I am impressed by our researchers at Zealand by their skills, innovation and drive. To further motivate the entire R&D organization, I have established an entrepreneurial governance structure to seed and fund the best ideas in a non-bureaucratic manner. The intension is to relieve the idea generators from milestone pressure in the early project phase.

- **Q** How do you see Zealand's product pipeline and R&D activities developing over the coming years?
- A We intend to grow our pipeline from both internal R&D and external sources to leverage our competences and increase the value of Zealand. We will continue to build on partnerships for a risk-balanced approach to advancing our products towards the market yet, as we start to see accelerating revenues from the sales of Lyxumia® and potentially the Lantus®/Lyxumia® single product combination, we will extend investments into the proprietary part of our pipeline.

For our internally sourced programs, we accelerate those therapeutic peptides towards clinical development which we believe represent the most important potential improvements to patients' lives. In addition, we are always scouting the external landscape of innovative technologies and molecules to further grow our R&D platform and clinical pipeline.

I have no doubts that we have both the internal competences and the necessary resources to grow Zealand into becoming one of the leading innovators of novel peptide therapeutics in the pharmaceutical industry sector. I am excited to be part of the Zealand team at this important time.

# Core competences in peptide drug innovation and development

#### Peptide experts

At Zealand, we understand how peptides work. This enables us to provide novel peptide therapies and solutions to improve patients' lives.

We are deeply knowledgeable about peptide drug discovery and development, and have built a world-leading position in the field. We have an experienced and integrated R&D organization, broadly recognized for its capabilities, and with all main functions in-house, including:

- Identification of novel biological targets and testing of their therapeutic relevance (idea generation);
- Innovation, design, modification and optimization of peptides;
- Solutions to the challenges of turning peptides into durable, stable and cost-effective drugs;
- Preclinical and clinical development of novel drugs targeting diabetes/metabolic diseases and related disorders.

#### What are peptides?

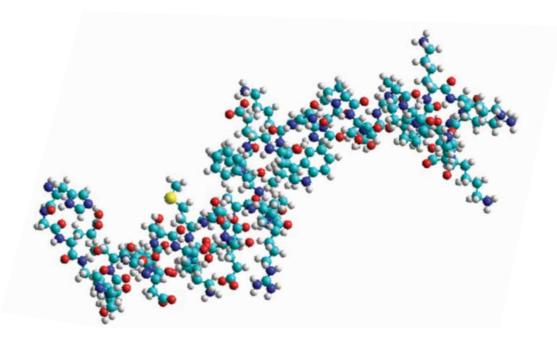
Peptides are naturally occurring biological molecules. They are found in all living organisms and play an active key role in many complex biological systems. Like proteins, peptides are built of amino acids and are formed (synthesized) naturally from transcription of a sequence of the generic code, DNA.

For a peptide to exert its effect it usually binds to a receptor specific for that peptide which is located in the membrane of relevant cells and organs. Many receptors penetrate the cell membrane and consists of an extracellular domain where the peptide binds, and an intracellular domain through which the peptide exerts its function upon binding and activation of the receptor. An example is the glucagon receptor which is located on the liver and on adipose tissue. Upon activation of the liver receptors by natural glucagon, or a peptide analog (a synthesized molecule mimicking the effect of natural glucagon), the release of glucose into the blood stream is activated through a series of biological processes which may prevent inadequate low blood sugar levels i.e. hypo-glycemia as it is sometimes observed in insulin treated patents with Type 2 diabetes.

#### Peptides as drugs

Compared with small chemical entity drugs, peptide based drugs possess certain favorable characteristics, including:

- Higher potency; peptide based drugs generally are very active on their target receptor, which translates into a high effect at a low dose;
- Higher selectivity; peptides have a very tight fit to their receptors, which makes them
  much more selective than smaller molecules. This means that peptides tend to bind only
  to their target receptor and therefore are less likely to be associated with serious adverse
  side effects;
- Naturally occurring biologics better safety: peptides are naturally degraded in the blood stream by circulating enzymes to their component amino acids.



Lixisenatide ZP10 (Lyxumia®), Zealand's first invented peptide medicine.

# Risk management and internal control

At Zealand, we constantly monitor and assess both the overall risk of doing business in the pharmaceutical biotech industry and the particular risks associated with our current activities and corporate profile, including scientific and development risks, partner interest risks, commercial and financial risks.

Doing business in the pharmaceutical and biotech industry involves major financial risk. The development period for novel medicines typically stretches over many years; costs are high and the probability of reaching the market relatively low due to developmental and regulatory hurdles.

Zealand's management is responsible for implementing adequate systems and policies on risk management and internal control and to assess the overall risks and specific risks associated with Zealand's business and operations and seek to ensure that such risks are managed best possible in a responsible and efficient manner.

Risks of particular importance to Zealand are scientific and development risks, partner interest risks and commercial as well as financial risks. Risk and mitigation plans are monitored by management and this continuous risk assessment is an integral part of the quarterly reporting to the Board of Directors.

#### Scientific and development risks

During the course of the research and development process Zealand regularly assesses these risks through a quarterly risk assessment of all the company's research and development projects conducted by management in collaboration with the department heads and project managers and presented to the Board of Directors. Each project is described and progress is measured based on milestones. An individual risk analysis for each of the projects is conducted and a prioritizing of the project portfolio is performed.

#### Commercial risks

On a regular basis, our Clinical and Scientific Advisory Board provides input to the risks in Zealand's research and development portfolio as well as in individual projects.

From early on in the research phase and all the way through development, risks related to patent protection, market size, competition, development time and costs and partner interest are assessed to make sure that final products are potentially commercially viable. Any major changes in the commercial potential for a drug candidate can lead to reduced value prospects and eventually discontinued development.

Partner interest risks Zealand has ongoing discussions with potential industry partners in order to gauge and encourage interest in the research programs. The aim is to ensure that Zealand focuses on programs that are attractive to partners. Entering into collaborations with partners can bring significant benefits but also potentially involve risks. In addition, full control of the products is often given over to the collaborator. In order to mitigate these risks Zealand strives to foster a close and open dialogue with its partners thereby building strong partnerships that work effectively.

#### Financial risks

Financial risks such as cash and treasury management, liquidity forecasts and financing opportunities are managed in accordance with the Finance Policy and regularly assessed by the company's management and reported to the audit committee and the Board of Directors. See also p. 62; Note 14 - Financial and operational risk.

#### Risk management and internal control related to financial reporting

Zealand has a number of internal control and risk management systems in place to ensure that its financial statements provide a true and fair view and are in accordance with the International Financial Reporting Standards as adopted by the EU and Danish disclosure requirements for listed companies. On a yearly basis, an evaluation with special emphasis on risk management and internal control related to the financial reporting is done to ensure that risks are managed in a responsible and efficient manner.

Zealand has several policies and procedures in key areas of financial reporting. The internal control and risk management systems are designed to mitigate, detect and correct material misstatements rather than eliminate the risks identified in the financial reporting process.

A review and prioritization of material accounting items is also performed. Items in the financial statements that are based on estimates or that are generated through complex processes carry a relatively higher risk for error. Zealand performs continual risk assessments to identify such items and to assess the scope and related risk.

The policies and procedures are approved by the Board of Directors and on a daily basis the responsibility is of the Executive Management. The Board of Directors has established an audit committee with an advisory role relative to the Board of Directors. Considering Zealand's legal structure, size and the fact that operations are carried out at one single site, the Board of Directors have concluded that it is not relevant to establish an internal audit function in Zealand.

#### **Description of management** reporting systems and internal control systems

Zealand has management reporting and internal control systems in place that enable it to monitor performance, strategy, operations, business environment, organization, procedures, funding, risk and internal control. The company believes that the reporting and internal controls are adequate to avoid misstatements in the financial reporting.

A full description of the risk management and internal control system in relation to financial reporting is included in the statutory report on Corporate Governance, cf. section 107b of the Danish Financial Statements Act, which can be found on the company's website:

zealandpharma.com/investors/corporategovernance

# *Corporate* governance

# Corporate Social Responsibility

Zealand follows Danish securities law, and as a company listed on NASDAQ OMX Copenhagen, we are guided by the Corporate Governance Recommendations designated by NASDAQ OMX Copenhagen.

NASDAQ OMX Copenhagen has incorporated the Recommendations by the Danish Committee of Corporate Governance, and Zealand intends to meet these recommendations in all respects of material relevance to our company. As part of our Corporate Governance policy we apply the "comply or explain" principle as recommended.

Zealand regularly reviews its rules, policies and practices related to the overall governance of our company with the purpose of ensuring that we meet our obligations to shareholders, employees, regulatory authorities and other stakeholders, while serving to maximize long-term value.

**Recommendations** It is the view of management that Zealand complies with the recommendations set **section 3.4.8** forward with one single exception which is highlighted and explained below:

> The remuneration committee will be using the same external advisors as the Executive Management, even if this is against the Corporate Governance recommendations. The reason is that the Board of Directors is of the conviction that the external advisors will provide professional and unbiased advice in both their capacities as advisers to the Executive Management and to the remuneration committee.

Zealand's statutory report on Corporate Governance, which has been prepared in accordance with the Danish Financial Statements Act, section 107b, is available in full at the company's website:

#### zealandpharma.com/investors/corporategovernance

The statuary report includes our policy and objectives in relation to diversity in accordance with the Danish Financial Statements Act, section 99b.

**Our report on Corporate Social Responsibility focuses** on areas which are unique to Zealand's business as a research and development driven biotechnology company with a diverse range of strategic partnerships. The report is available on our website.

Zealand's policies with regards to Corporate Social Responsibility (CSR) cover many areas of our operations. In 2013 Zealand updated its CSR status report describing the status and activities within the following areas:

- Labour practices & decent work;
- Occupational health & safety;
- · Animal rights;
- Environmental sustainability;
- Anti-corruption & pharmaceutical ethics.

These focus areas are an amalgamation of existing Zealand values and policies together with the principles of the United Nations Global Compact where they apply to the scope of the company's business.

The CSR report puts particular emphasis on those areas which are unique to Zealand's business as a biotechnology and research corporation with a diverse range of strategic partnerships. However, given that we do not directly market or commercialize any medicinal products, there are many issues specific to the pharmaceutical industry which consequently do not fall within the scope of our CSR activities.

Zealand has in accordance with the Danish Financial Statements Act, section 99a, prepared a statutory report on CSR, which can be found on the company's website:

zealandpharma.com/investors/csr

# Executive Management



**Mats Blom** 

Senior Vice President and Chief Financial Officer

Born: 1965

Mr. Blom joined Zealand in March 2010. Prior to joining Zealand Mr. Blom served as the CFO of Swedish Orphan International, a leading European orphan drug company, acquired by Biovitrum of Sweden in 2009.

Mr. Blom has held CFO positions at Active Biotech and Anoto which are both publicly listed on Nasdaq OMX in Stockholm. He has several years of experience as a management consultant at Gemini Consulting and at the Transaction Services division of Ernst&Young.

Mr. Blom has a BA in Business Administration and Economics from the University of Lund followed by an MBA from I.E.S.E University of Navarra, Barcelona.

Chairman of the board: Medical Need AB

Ownership: 129,050 warrants 90,246 shares



**David Horn Solomon** 

President and Chief Executive Officer

Born: 1960

Dr. David Horn Solomon joined Zealand in September 2008 from a position as Chief Operating Officer of Vital Sensors.

From 2003 to 2006, Dr. Solomon led healthcare investing at Carrot Capital Healthcare Ventures.

He has served as a faculty member at Columbia University's College of Physicians and Surgeons in New York, NY and has had leadership positions at biotechnology, pharmaceutical and medical device companies, including Remedy Pharmaceuticals, Inc. and Critical Diagnostics Inc., both in New York

Dr. Solomon received his doctorate at Cornell University Medical College and the Sloan-Kettering division of its Graduate School of Medical Sciences, in New York City.

Member of the board: BioAlliance Pharma S.A.

Ownership: 387,150 warrants 30,600 shares



Arvind M. Hundal

Senior Vice President and Chief Business Officer

Born: 1963

Dr. Hundal joined Zealand in 2009 and was appointed Chief Business Officer in September 2011. Prior to joining Zealand, Dr. Hundal served as a member of the Strategic Planning Business Development organization at Astra Zeneca, and most recently as Business Development Director at 7TM Pharma A/S.

Dr. Hundal has more than 20 years' experience in the life sciences sector, including 15 years in business development positions. She has worked on both in- and out-licensing across the industry from pre-seed to public organizations; including university technology developments, spinout biotechnology, and top tier pharmaceutical companies.

Dr. Hundal has a BS from King's
College London, a PhD from the
Institute of Genetics at Glasgow
University, and subsequently completed
a post-doctoral fellowship at the
University of Texas Southwestern
Medical Center, in Dallas.

Ownership: 129,050 warrants



**Torsten Hoffmann** 

Executive Vice President and Chief Scientific Officer

Born: 1967

Effective from 1 October 2013, Dr. Torsten Hoffmann joined Zealand from Roche, where he spent 16 years in several managerial positions, including as Head of Discovery Chemistry in the Pharma Research division of the company's headquarters in Basel.

Torsten is the author of more than 75 research publications, published conference reports and patent applications. In addition, the work of the Discovery Chemistry Department at Roche which Torsten led over the past eight years has been documented in more than 280 peer reviewed publications and 540 patent applications.

Torsten studied chemistry at the Heinrich-Heine University in Düsseldorf and received his doctorate at the Eidgenössische Technishe Hochshule in Zürich, which was followed by a position as post-doc at the Scripps Research Institute in California. He has received several prizes and awards and has been listed in Marquis Who's Who.

Ownership: 0 warrants



**Agneta Svedberg** 

Senior Vice President and Chief Operating Officer

Born: 1963

Effective from 1 February 2013, Agneta Svedberg joined Zealand from Cantargia AB, a Swedish biotech company, where she has held a position as Chief Executive Officer. She has more than 20 years of experience in drug development from different leadership functions in both biotech and big pharma companies, including more than ten years with Genmab A/S in Copenhagen, where she was Global Head of Clinical Development and held various senior management positions, the last year as Copenhagen site Manager with responsibility for 200 people.

Prior to this, Agneta Svedberg was Head of Clinical Development (Europe) at Oxigene Europe AB and also held managerial positions at Pharmacia & Upjohn AB in Sweden.

Agneta Svedberg holds a M.Sc. in Radiation Physics from Lund University and an Executive MBA from Lund University School of Economics and Management, Sweden.

Ownership: 67,012 warrants

# **Board** of Directors



Hanne Heidenheim Bak

MSc pharm.

Born: 1953

Board member since 2012

Employee elected

Project director

Ownership: 54,000 warrants 20,109 shares

Board member since 2012

Michael J. Owen

PhD Biochemestry

Independent

Born: 1951

Member of the board: **BLINK Therapeutics** Ossianix, Inc.

Advisor: Kymab Ltd Qure Invest SaRL CRT Pioneer Fund LP

Ownership: None



MA Economics

**Peter Benson** 

Born: 1955

Board member since 2007

Independent

Managing partner: Sunstone Capital

Member of the board: Virogates A/S. Asante Solutios Inc. Imix Holding AB Alligator AB

Ownership: None



**Daniël Jan Ellens** 

PhD Molecular Biology M.B.A.

Born: 1948

Chairman of the board since 2013

(Chairman 2007-2012 Board member since 2005)

Independent

Venture Partner: Life Sciences Partners

President: Elkerim GmbH

Chairman of the board: Prosensa B.V. Hybrigenics SA Kreatech Holding B.V.

Ownership: 134,024 warrants 16,500 shares



**Alain Munoz** 

MD Cardiology and Anaesthesiology

Born: 1949

Board member since 2005 (resigned 2006), re-elected 2007

Non-independent

Co-Chairman of Zealand's Clinical and Scientific Advisory Board

Advisor: Kurma Biofund

Member of the board: Valneva Auris medical AG Medesis SA Hybrigenics SA

Ownership: 7,000 shares



(Electronics)

Born: 1948

Vice Chairman of the board since 2013

(Chairman 2012-2013)

Board member since 2011

Independent

Chairman of the board: AVT Business School A/S Scania (DK) Scania (NO) JL Rungsted Holding Trifina Holding ApS K/S Vimmelskaftet 39-41 IT University of Copenhagen

Ownership: 14,285 shares



**Helle Størum** 

MSc Business Administration Diploma in Basic Pharmaceutical Medicine

Born: 1967

Board member since 2008

Employee elected

Associate director, Business development

Ownership: 15,000 warrants 3,000 shares



**Christian Thorkildsen** 

Cand.pharm. PMP

Born: 1968

Board member since 2006

Employee elected

Project director

Ownership: 54,000 warrants 23,329 shares



**Jutta af Rosenborg** 

State-Authorized Public Accountant, MSc Business Administration and Auditing

Born: 1958

Chairman of the Audit Committee

Board member since 2011

Independent

Member of the board: Auriga Industries A/S, (Chairman of the Audit Committee) Det Danske Klasselotteri A/S Aberdeen Asset Management Plc

Ownership: None



Florian Reinaud

MD Emergency Medicine and Internal Medicine

Born: 1973

Board member since 2010

Independent

Partner: Innovation Capital

Member of the board: FAB Pharma, SAS Kuros Biosurgery AG Orthopedic Synergy Inc.

Ownership: None

# Shareholder information

Zealand is listed on the NASDAQ OMX Copenhagen stock exchange under the ticker symbol ZEAL. The company has a market capitalization of DKK 1.7 billion and form part of the NASDAQ OMX Copenhagen Midcap index.

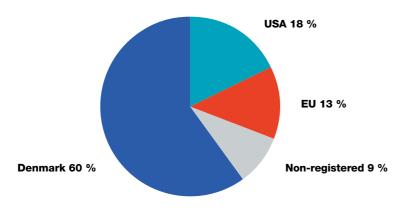
The nominal value of Zealand's share capital is DKK 23,193,047 divided into 23,193,047 shares with a nominal value of DKK 1 each. The share capital has remained unchanged in 2013. All Zealand shares are ordinary shares belonging to one class.

# The number of Zealand shareholders increased 134 % in 2013

On 31 December 2013, Zealand had 4,507 registered shareholders, who held a total of 21,055,753 shares, representing 91 % of the total outstanding share capital of the company. This corresponds to a 134 % increase in number of registered shareholders in 2013 (31 December 2012: 1,925 registered shareholders). In the first months of 2014, the number of registered shareholders has remained almost unchanged with 4,526 on 14 March.

Almost 40 % of Zealand's shares are held by investors outside Denmark, with the United States, France and the United Kingdom representing the largest non-Danish shareholdings. During the period until 2 November 2015 the Board of Directors is authorized to increase the Company's share capital by issuance of up to 11,163,953 new shares.

#### Geographical distribution of Zealand share ownership



#### **Major shareholders**

Sunstone BI Funds and Life Science Ventures Fund Copenhagen, Denmark	25.7 %
LD Pension (Lonmodtagernes Dyrtidsfond) Copenhagen, Denmark	11.3 %
Innovation Capital (former CDC Innovation) Paris, France	11.0 %
LSP Amsterdam, The Netherlands	5.5 %
A/S Dansk Erhvervsinvestering Copenhagen, Denmark	5.2 %

### The Zealand share price fell 30 % in 2013

Zealand's share price was DKK 59 at the close of 2013 compared to DKK 84 at the end of 2012, corresponding to a 30 % fall in valuation over the course of the year (2012 performance: +47.4 %). In comparison, the OMX Copenhagen Midcap index increased +53 %, the MSCI Europe Biotech Index +60 %, and the Nasdaq US Biotech Index +61 % in 2013.

### 23 % share price increase in 2014

Since the beginning of 2014, our share price has increased 23 % to close at DKK 72.5 on 14 March.

The underperformance of our shares in 2013 was mainly a consequence of announcements by Sanofi of 1) a six months' delay to the start of Phase III development of the Lantus®/Lyxumia® combination product in February and 2) the decision to withdraw the NDA for Lyxumia® in the US and refile in 2015 after completion of the ELIXA CV study. Following each of these announcements, our share price fell 20 %. The launch of Lyxumia® in Europe and Japan as the first Zealand product to be marketed and positive news relating to other pipeline activities, including Helsinn's decision to advance elsiglutide into Phase IIb, our start of Phase II development of danegaptide and a new partnership with Eli Lilly in diabetes and obesity, did not have sufficient positive effect on our share price to counterbalance the news from Sanofi.

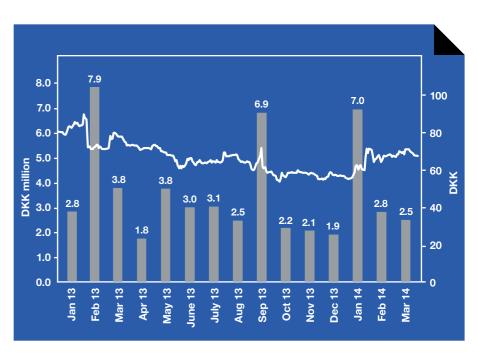
In 2014, the announced start of the LixiLan Phase III program for the Lantus®/Lyxumia® combination product and a related milestone payment to Zealand from Sanofi of USD 15 (DKK 82) million has positively impacted on our share price.

# Share liquidity increased significantly in 2013

On a very positive note, 2013 saw a further significant improvement in the liquidity of the Zealand stock. The average daily turnover on NASDAQ OMX Copenhagen was DKK 3.5 million in 2013, and increase of 95 % compared to 2012. The average daily number of shares traded in 2013 was 47,306 compared to 19,827 in 2012.

Into 2014 (until 14 March), liquidity has improved further, with an increase of almost 30 % in the average daily turnover to DKK 4.5 million compared to 2013.

## 2013 Share performance and turnover



Average daily turnover (lhs)

Share price (rhs)

#### **Investor Relations in Zealand**

In line with the disclosure requirements for companies listed on NASDAQ OMX Copenhagen, Zealand issues company announcements to inform the investor markets of material news relating to the company and its activities and to report interim financial reports. In addition, Zealand issues press releases to inform of business news of non-material character, and Investor News are used to inform of IR news and events.

**Direct access to** Zealand's objective is to be open, accessible and proactive in its interactions with the management investor community, and our main IR activities include the following: direct access to the management team via conference calls and webcasts, Capital Market Days, conference attendance and roadshows in both the US and the main cities in Europe.

Coverage by six banks Zealand is currently covered by [six] sell-side analysts, representing international banks, French specialist banks and Scandinavian banks. A list of names and contact details can be found at **zealandpharma.com/investors** 

IR Newsletters In addition, we issue online IR newsletters on a regular basis to update on recent news flow and the status of our activities. Under the investor section of Zealand's website: **zealandpharma.com/investors** we provide access to relevant information in the form of all our news releases, our IR newsletters. investor slide presentations, our IR event calendar, and recent financial and annual reports. Zealand can also be followed on Twitter, Facebook and LinkedIn.

#### to get news and IR newsletters directly

Register on our website Zealand intends in the future to shift more and more to online communication and information provision in order to protect the environment and save money which can be invested into our R&D activities. Therefore, we request all our shareholders to register their email address via our homepage under http://zealandpharma.com/investors/ shareholder-portal. To receive news releases and IR Newsletters directly, all interested stake holders can register by using the e-mail alert link at zealandpharma.com/investors/news



Hanne Leth Hillman Vice President, Head of IR & Corporate Communications

When we say that we care about IR, we are serious about it. Only via direct, transparent and active dialogue can we improve the communication with our stakeholders and we therefore encourage all with an interest in Zealand to contact us with any questions, comments or requests relating to our business and pipeline.

Please contact us We encourage our share holders, investors, analysts and other stakeholders to contact us with any questions or enquiries relating to Zealand:

> IR and Corporate Communications Phone: +45 50 60 00

E-mail: investor@zealandpharma.com

#### Financial and IR calendar 2014

Jan 9-10	Oddo MidCap Investor Conference Lyon
Jan 13-15	JP Morgan Healthcare Investor Conference San Francisco
Mar 4-5	Credit Suisse One-on-One Healthcare Conference London
Mar 20	Interim report for Q4 2013 and Annual Report 2013
Mar 31-Apr 1	Marcus Evans Discovery Summit 2014 Lisbon Chaired by Zealand's CSO, Dr. Torsten Hoffmann
April 29	Interim report for 1Q 2014 and Annual General Meeting Zealand headquarters
May 6	Capital Markets Day New York
May 7-8	Deutsche Bank 39th Annual Health Care Conference Boston
June 2-5	Jefferies 2014 Global Healthcare Conference New York
June 3	Danish Shareholder Association's Investor Forum Aarhus, Denmark
June 9-12	Goldman Sachs 35th Annual Global Healthcare Conference California
June 12	The Society of Financial Analysts' Company Forum Day 2014 Copenhagen
June 13-17	American Diabetes Association (ADA) 74th Scientific Sessions San Francisco
August 21	Interim report for 1H 2014
September 15-19	50th EASD Annual Meeting Vienna
November 7	Interim report for 9m 2014
November 19-20	Jefferies Global Healthcare Conference London

In addition to the above, Zealand has planned several road shows to meet investors in the main cities in Europe and in the US.

### Financial review

#### Financial review for the period 1 January - 31 December 2013

(Comparative figures for the same period last year are shown in brackets)

Income statement The net result for the year 2013 was a loss of DKK -183.7 million (36.4) in line with expectations. The major reason for the decreased result compared to 2012 was that no milestones payments were received in 2013.

**Revenue** Revenue amounted to DKK 6.6 million (223.6), consisting of royalty payments based on sales of Lyxumia® under the agreement with Sanofi. During 2013 no milestone payments were received. Milestone payments 2012 were related to the license agreements with the company's partners Sanofi, Boehringer Ingelheim, Helsinn Healthcare and former partner Action Pharma.

#### Royalty expenses

Royalty expenses for the year were DKK 0.9 million (15.9) and relates to royalty paid to third parties on recieved Lyxumia® sales royalties from Sanofi.

#### Research and development expenses

Research and development expenses amounted to DKK 164.5 million (182.8). The decrease relates to an increase in salaries and headcount with DKK 6.0 million, a decrease in incentive programs of DKK -1.8 million and decrease by DKK -24.6 million in other R&D costs mainly due to lower costs related to ZP2929 and the collaboration agreement with Boehringer Ingelheim . These costs have been refunded with DKK 6.6 million (34.2) and recorded as other operating income, see below.

#### **Administrative expenses**

Administrative expenses amounted to DKK 34.2 million (27.6). This is mainly a result of increased salaries and headcount of DKK 5.8 million and an increase of DKK 2.8 million in consultancy costs.

Other operating income Other operating income amounted to DKK 7.3 million (35.1) mainly associated with income under the license and collaboration agreement with Boehringer Ingelheim, relating to funding of incurred development costs of ZP2929 and costs related to the research collaboration.

Operating result Operating result for the period was a loss of DKK -185.6million (32.4).

#### Net financial items

Net financial items amounted to DKK 1.9 million (4.0). Net financial items consist of interest income, banking fees and changes in exchange rates.

#### Result from ordinary activities before tax

Result from ordinary activities before tax came to a loss of DKK -183.7 million (36.4).

#### Tax on ordinary activities

With a negative result from ordinary activities, no tax has been recorded for the period. No deferred tax asset has been recognized in the statement of financial position due to uncertainty as to when tax losses can be utilized.

Net result and Net result and comprehensive income both amounted to DKK -183.7 million (36.4) in **comprehensive income** each case due to the factors described above.

#### Allocation of result

No dividend has been proposed and the year's net loss of DKK -183.7 million (36.4) has been transferred to retained earnings.

**Equity** Equity amounts to DKK 316.1 million (491.0) at the end of the year, corresponding to an equity ratio of 91 % (94). The decrease in equity is a result of the net loss for the year.

#### Capital expenditure

Investments in plant and equipment for the period amounted to DKK 4.6 million (8.8) mainly related to new laboratory equipment.

#### Cash flow

Cash flow from operating activities amounted to DKK -169.6 million (68.5), and cash flow from investing activities to DKK 96.8 million (13.4) of which DKK 148.8 million (119.8) relates to disposal of securities. Cash flow from financing activities amounted to DKK 0.0 million (0.0). The total cash flow for the full year of 2013 amounted to DKK -72.8 million (82.0).

#### Cash and cash equivalents

As of 31 December 2013, cash and cash equivalents including securities amounted to DKK 310.6 million (485.9).

### sheet date

**Events after the balance** In January 2014 Sanofi confirmed plans to start Phase III development of LixiLan in the 1st quarter of 2014. DKK 82 (EUR 11) million milestone payment to Zealand was triggered relating to the approval of the first Phase III study protocol for LixiLan by a Health Authority.

#### Financial outlook for 2014

In 2014, Zealand will have revenue from milestone payments and royalties on Lyxumia® sales. Guidance on milestone payments amount to DKK 97 (EUR 13) million, including DKK 82 (EUR 11) million received from Sanofi in January 2014 and a time based milestone payment from Helsinn of DKK 15 (EUR 2) million to be received in Q4 2014. The timing of other potential milestone based payments is largely outside Zealand's control and therefore not included in our guidance at this point.

Guidance on royalties cannot be provided, since Sanofi has given no guidance on expected Lyxumia® sales in 2014.

Net operating expenses for 2014 are expected at a range of DKK 200-210 (EUR 27-28)

# Statement of the Board of Directors and Executive Management

Today the Board of Directors and Executive Management have discussed and approved the Annual Report of Zealand Pharma A/S for the financial year 1 January - 31 December 2013.

The Annual Report has been prepared in accordance with International Financial Reporting Standards as adopted by the EU and Danish disclosure requirements for listed companies.

In our opinion the financial statements give a true and fair view of the Company's financial position as of 31 December 2013 and of the results of the Company's operations and cash flows for the financial year 1 January - 31 December 2013.

In our opinion the management's review includes a fair review about the development of the Company's operations and economical conditions, the results for the year and the Company's financial position as well as a review of the more significant risks and uncertainty the Company faces, in accordance with the Danish disclosure requirements for listed companies.

We recommend that the Annual Report be approved at the annual general meeting.

Glostrup, 20 March 2014

#### **Executive Management**

David Horn Solomon

President and Chief Executive Officer Mats Blom

Senior Vice President and Chief Financial Officer

#### **Board of Directors**

Chairman

Jutta af Rosenborg

Board Member

Michael J. Owen Board Member

Jørgen Lindegaard Vice Chairman

Tunkyand

Alain Munoz Board Member

Helle Størum Board Member Employee elected

Welle Sta

Board Member

Peter Benson

Board Member

Christian Thorkildsen Board Member Employee elected

Hanne Heidenheim Bak Board Member Employee elected

Hamus H. Bah

# Independent auditors report

#### To the shareholders of Zealand Pharma A/S

#### **Report on Financial Statements**

We have audited the Financial Statements of Zealand Pharma A/S for the financial year 1 January to 31 December 2013, which comprise income statement, statement of comprehensive income, statement of financial position, statement of changes in equity, cash flow statement and notes, including summary of material accounting policies, for Zealand Pharma A/S. Financial Statements are prepared in accordance with International Financial Reporting Standards as adopted by the EU and Danish disclosure requirements for listed companies.

### Board of Directors and Executive management's Responsibility for the Financial Statements

Board of Directors and Executive Management is responsible for the preparation of Financial Statements that give a true and fair view in accordance with International Financial Reporting Standards as adopted by the EU and Danish disclosure requirements for listed companies, and for such internal control as Board of Directors and Executive Management determines is necessary to enable the preparation of Financial Statements that are free from material misstatement, whether due to fraud or error.

#### **Auditor's Responsibility**

Our responsibility is to express an opinion on the Financial Statements based on our audit. We conducted our audit in accordance with International Standards on Auditing and additional requirements under Danish audit regulation. This requires that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance whether the Financial Statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the Financial Statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the Financial Statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the Company's preparation of Financial Statements that give a true and fair view in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by Board of Directors and Executive Management, as well as evaluating the overall presentation of the Financial Statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

The audit has not resulted in any qualification.

#### **Opinion**

In our opinion, the Financial Statements give a true and fair view of the Company's financial position at 31 December 2013 and of the results of the Company's operations and cash flows for the financial year 1 January to 31 December 2013 in accordance with International Financial Reporting Standards as adopted by the EU and Danish disclosure requirements for listed companies.

#### Statement on Management's Review

We have read Management's Review in accordance with the Danish Financial Statements Act. We have not performed any procedures additional to the audit of the Financial Statements. On this basis, in our opinion, the information provided in Management's Review is consistent with the Financial Statements.

Copenhagen, 20 March 2014

PricewaterhouseCoopers
Statsautoriseret Revisionspartnerselskab

Di i

Kim Füchsel State Authorised Public Accountant Henrik Ødegaard State Authorised Public Accountant

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# Financial statements

Income statement			
DKK '000	Note	2013	2012
Revenue	2	6,574	223,565
Royalty expenses	3	-872	-15,933
Gross profit	•	5,702	207,632
Research and development expenses		-164,467	-182,759
Administrative expenses		-34,155	-27,611
Other operating income	4	7,302	35,135
Operating result		-185,618	32,397
Financial income	5	3,185	5,666
Financial expenses	6	-1,243	-1,691
Result from ordinary activities before	ore tax	-183,676	36,372
Tax on ordinary activities	7	0	(
Net result for the year		-183,676	36,372
Statement of comprehensi	ve income		
Net result for the year		-183,676	36,372
Other comprehensive income		0	(
Comprehensive income for the year	r	-183,676	36,372
Earnings per share			
Basic	18	-8.10	1.61
Diluted	18	-8.10	1.60

Statement of financial position				
DKK '000	Note		2013	2012
Assets				
Plant and machinery	8		16,014	18,736
Other fixtures and fittings, tools and equip	ment 8		409	517
Leasehold improvements	8		1,459	2,15
Fixed assets under construction	8		2,180	(
Investments in subsidiaries	9		0	1,496
Deposits			2,570	2,554
Non current assets total			22,632	25,454
Trade receivables			11	(
Prepaid expenses			3,642	3,648
Other receivables			10,067	7,518
Securities			24,383	126,940
Cash and cash equivalents			286,178	358,847
Current assets total			324,281	496,950
Total assets			346,913	522,404
Liabilities and equity			<b>346,913</b> 23,193	
<b>Liabilities and equity</b> Share capital				23,193
<b>Liabilities and equity</b> Share capital Retained earnings			23,193	23,193 467,822
Liabilities and equity  Share capital  Retained earnings  Equity total			23,193 292,948	23,193 467,822 <b>491,01</b> 5
Liabilities and equity  Share capital  Retained earnings  Equity total  Trade payables			23,193 292,948 <b>316,141</b>	23,193 467,822 <b>491,015</b> 9,831
Liabilities and equity  Share capital Retained earnings  Equity total  Trade payables Payables to subsidiary Prepayments from customers			23,193 292,948 <b>316,141</b> 13,376 0 2,329	23,193 467,822 <b>491,015</b> 9,831 1,421 5,072
Liabilities and equity  Share capital Retained earnings  Equity total  Trade payables Payables to subsidiary Prepayments from customers  Other liabilities			23,193 292,948 <b>316,141</b> 13,376 0 2,329 15,067	23,193 467,822 <b>491,015</b> 9,831 1,421 5,072
Liabilities and equity  Share capital Retained earnings  Equity total  Trade payables Payables to subsidiary Prepayments from customers  Other liabilities			23,193 292,948 <b>316,141</b> 13,376 0 2,329	23,193 467,822 <b>491,01</b> 5 9,831 1,421 5,072
Liabilities and equity  Share capital Retained earnings  Equity total  Trade payables Payables to subsidiary Prepayments from customers Other liabilities  Current liabilities			23,193 292,948 <b>316,141</b> 13,376 0 2,329 15,067	23,193 467,822 <b>491,015</b> 9,831 1,421 5,072 15,066 <b>31,38</b> 9
Total assets  Liabilities and equity  Share capital Retained earnings  Equity total  Trade payables Payables to subsidiary Prepayments from customers Other liabilities  Current liabilities  Total liabilities  Total equity and liabilities			23,193 292,948 <b>316,141</b> 13,376 0 2,329 15,067 <b>30,772</b>	23,193 467,822 491,015 9,831 1,421 5,072 15,065 31,389
Liabilities and equity  Share capital Retained earnings  Equity total  Trade payables Payables to subsidiary Prepayments from customers Other liabilities  Current liabilities  Total liabilities			23,193 292,948 <b>316,141</b> 13,376 0 2,329 15,067 <b>30,772</b>	23,193 467,822 <b>491,015</b> 9,831 1,421 5,072 15,066 <b>31,38</b> 9
Liabilities and equity  Share capital Retained earnings  Equity total  Trade payables Payables to subsidiary Prepayments from customers Other liabilities  Current liabilities  Total liabilities  Total equity and liabilities	1 Financial ar	nd operational risks	23,193 292,948 <b>316,141</b> 13,376 0 2,329 15,067 <b>30,772</b>	23,193 467,822 <b>491,015</b> 9,831 1,421 5,072 15,066 <b>31,38</b> 9
Liabilities and equity  Share capital Retained earnings  Equity total  Trade payables Payables to subsidiary Prepayments from customers Other liabilities  Current liabilities  Total liabilities  Total equity and liabilities  Material accounting policies	1 Financial ar 10 Related pa		23,193 292,948 <b>316,141</b> 13,376 0 2,329 15,067 <b>30,772</b> 30,772	23,193 467,822 <b>491,015</b> 9,831 1,421 5,072 15,066 <b>31,38</b> 9
Liabilities and equity  Share capital Retained earnings  Equity total  Trade payables Payables to subsidiary Prepayments from customers Other liabilities  Current liabilities  Total liabilities  Total equity and liabilities  Material accounting policies Treasury shares	10 Related par		23,193 292,948 316,141 13,376 0 2,329 15,067 30,772 30,772 346,913	23,193 467,822 <b>491,015</b> 9,831 1,421 5,072 15,066 <b>31,38</b> 9
Liabilities and equity  Share capital Retained earnings  Equity total  Trade payables Payables to subsidiary Prepayments from customers Other liabilities  Current liabilities	<ul><li>10 Related par</li><li>11 Basic and of</li></ul>	rties	23,193 292,948 316,141 13,376 0 2,329 15,067 30,772 30,772 346,913	23,193 467,822 <b>491,015</b> 9,831 1,421 5,072 15,066 <b>31,38</b> 9

Statement of changes in equity			
DKK '000	Share capital	Retained earnings	Total
Equity at January 1, 2012	23,193	418,204	441,397
Warrants compensation expenses	0	13,246	13,246
Comprehensive income for the year	0	36,372	36,372
Equity at December 31, 2012	23,193	467,822	491,015
Equity at January 1, 2013	23,193	467,822	491,015
Warrants compensation expenses	0	8,802	8,802
Comprehensive income for the year	0	-183,676	-183,676
Equity at December 31, 2013	23,193	292,948	316,141

Changes in share capital	
Share capital at December 31, 2008	17,682
Capital increase at November 23, 2010	4,337
Capital increase at December 9, 2010	852
Capital increase at December 12, 2011	322
Share capital at December 31, 2012	23,193
Share capital at December 31, 2013	23,193

The share capital consists of 23,193,047 ordinary shares of DKK 1 each. All shares have been fully paid.

Statement of cash flows			
DKK '000	Note	2013	2012
Net result for the year		-183,676	36,372
Adjustments	16	12,912	14,590
Change in working capital	17	-3,643	13,782
Cash flow from operating activitie	S		
before financing items		-174,407	64,744
Financial income received		4,870	3,979
Financial expenses paid		-81	-184
Cash flow from operating activitie	s	-169,618	68,539
Change in deposit		-17	-60
Purchase of property, plant and equip	ment	-4,569	-8,849
Purchase of securities	ment	-47,356	-97,480
Disposal of securities		148,750	119,837
Cash flow from investing activities	<u> </u>	96,808	13,448
<b>3</b>			
Cash flow from financing activities	5	0	0
Decrease / increase in cash and c	ash equivalents	-72,810	81,987
Cash and cash equivalents at January	<sup>,</sup> 1	358,847	278,265
Exchange rate adjustments		141	-1,405
Cash and cash equivalents at Dec	ember 31	286,178	358,847

#### Note 1 - Material accounting policies

The financial statements of Zealand Pharma A/S for 2013 has been prepared in accordance with International Financial Reporting Standards (IFRS) as adopted by the EU and in accordance with additional Danish disclosure requirements for annual reports of listed companies.

The amounts in the annual report are denominated in Danish kroner (DKK '000).

As at 1. January 2013 Zealand Pharma A/S merged with its subsidiary BetaCure Holding A/S, consequently consolidated financial statements are no longer presented.

### Changes to accounting policies, including presentation and implementation of accounting standards

Zealand Pharma A/S has implemented the accounting standards adopted by the IASB and the EU as well as related amendments and interpretations effective for the financial year 2013.

- Amendment to IAS 1 The amendment implies requirements of presentation of elements in other comprehensive income which will be recycled to the income statement separate from elements which are not.
- IAS 32/IFRS 7 The amendment provides further guidance as regards offsetting and related disclosures.
- IFRS 13 General standard on fair value measurement.
- The annual improvements comprise:
- IAS 1, clarification of comparable disclosures when presenting statement of financial positions for three years
- IAS 16, spare parts and servicing equipment for land, buildings and equipment are to be classified as property, plant and equipment rather than inventory when they qualify as such.
- IAS 32, clarification of tax in the income statement and equity, respectively.
- IAS 34, segment disclosures in interim financial statements.

The implementation of standards, amendments and interpretations has not had any significant effect to Zealand Pharma A/S.

The accounting policies applied by Zealand Pharma A/S, remain unchanged compared to the previous year.

### Most recently adopted accounting standards (IFRS) and interpretations (IFRIC)

At the end of January 2014, IASB published the following new accounting standards and interpretations which are assessed to be relevant to Zealand Pharma A/S.

• IFRS 9 – The number of classification criteria is reduced to two; amortised cost or fair value.

The standards and interpretations published by the IASB which are presently considered as irrelevant to Zealand Pharma A/S comprise, IFRS 10, IFRS 11, IFRS 12, amendments to IAS 27 and IAS 28 and IFRIC 20. The mentioned standards and interpretations have been adopted by the EU, except for IFRS 9 and the annual minor improvements to applicable IFRSs.

Zealand Pharma A/S expects to implement the new standards and interpretations when the application becomes mandatory.

#### **Translation policies**

Transactions denominated in foreign currencies are translated at the exchange rates at the dates of transaction.

Exchange differences arising between the rate on the date of transaction and the rate on the payment day are recognized in the income statement as financial income or financial expenses.

Where foreign exchange exposures are considered cash flow hedges, value adjustments are recognized directly in equity.

Receivables, payables and other monetary items denominated in foreign currencies that have not been settled at the balance sheet date are translated by applying the exchange rates at the balance sheet date. Differences arising between the rate at balance sheet date and the rate at the date of the arising of the receivable or payable are recognized in the income statement under financial income and expenses.

Fixed assets purchased in foreign currencies are measured at the rate of the date of transaction.

#### The income statement

The income statement is classified by function.

#### Revenue

Revenue comprises royalties, milestone payments and other income from collaboration agreements. Revenue is recognized when it is probable that future economic benefits will flow to the company and these economic benefits can be measured reliably. Royalty income from licenses is based on third-party sales of licensed products and is recognized in accordance with contract terms when third-party results are available and are deemed to be reliable.

The income from agreements with multiple components and where the individual components cannot be separated is recognized over the period of the agreement. In addition, recognition requires that all material risks and benefits related to the ownership of the goods and services included in the transaction are transferred to the purchaser.

If all risks and benefits have not been transferred, the revenue is recognized as deferred income until all components in the transaction have been completed.

#### **Royalty expenses**

Royalty expenses comprise royalty paid to third parties on certain milestone payments and royalty income from collaboration agreements.

#### **Research and development expenses**

Research expenses comprise salaries, contributions to pension schemes and other expenses, including patent expenses, as well as depreciation and amortization attributable to the company's research activities. Research expenses are recognized in the income statement as incurred.

Development expenses comprise salaries, contributions to pension schemes and other expenses, including depreciation and amortization, attributable to the company's development activities.

Capitalization assumes that the development of the technology or the product in the company's opinion has been completed, that all necessary public registrations and marketing approvals have been received, and that expenses can be reliably measured. Furthermore, it has to be established that the technology or the product can be commercialized and that the future income from the product can cover, not only the production, selling and administrative expenses, but also development expenses.

Overhead expenses have been allocated to research and development based on the number of employees in research and development.

#### **Administrative expenses**

Administrative expenses include expenses for administrative personnel, expenses related to company premises, operating leases, investor relation, etc. Overhead expenses have been allocated to administration based on the number of employees in administration.

#### Other operating income

Other operating income includes income of a secondary nature, including grants related to research and development projects. It also includes funding received from Boehringer Ingelheim International GmbH related to their research collaboration with Zealand Pharma A/S and also development expenses for ZP2929 that are funded by Boehringer Ingelheim International GmbH.

#### **Public Grants**

Public grants are recognized when a final and firm right to the grant has been obtained. Public grants are included in other operating income as the grants are considered to be cost refunds. Grants related to investments are set off against the purchase price. Possible future conditional return obligations regarding the received grants will be disclosed in a note to the financial statements as a contingent liability.

#### **Net financials**

Financial income and financial expenses are recognized in the income statement with the amounts related to the financial year. Financial income and financial expenses include interest receivable and payable, as well as realized and unrealized exchange rate adjustments and realized and unrealized gains and losses on marketable securities (designated as fair value through the income statement).

#### Tax on results for the year

Tax on results for the year which comprises current tax and changes in deferred tax is recognized in the income statement with the portion of taxes related to the taxable income for the year whereas the portion attributable to entries on equity is recognized directly in equity.

#### **Segment reporting**

The company is managed by a management team reporting to the chief executive officer. No separate business areas or separate business units have been identified in connection with product candidates or geographical markets. As a consequence of this, no segment reporting is made concerning business areas or geographical areas.

#### Statement of financial position

#### Property, plant and equipment

Plant and machinery, other fixtures and fittings, tools and equipment and leasehold improvements are measured at cost less accumulated depreciation.

Cost comprises acquisition price and costs directly related to acquisition until the time when the company starts using the asset.

The basis for depreciation is cost less estimated residual value after the end of useful life. Assets are depreciated under the straight-line method over the expected useful lives of the assets. The depreciation periods are as follows:

- Leasehold improvements 5 years
- Plant and machinery 5 years
- Other fixtures and fittings, tools and equipment 3–5 years

Profits and losses arising from disposal of plant and equipment are stated as the difference between the selling price less the selling costs and the carrying amount of the asset at the time of the disposal. Profits and losses are recognized in the income statement under research and development expenses and administrative expenses.

#### Investments in subsidiaries

The parent company's shares in subsidiaries are measured at fair value

Fair value adjustments of subsidiaries are recognized in the income statement under "Financial income".

Investments in subsidiaries are measured in Statement of financial position under "Investments in subsidiaries".

#### Impairment of non-current assets

The carrying amount of intangible assets, property, plant and equipment as well as non-current asset investments is reviewed for impairment when events or changed conditions indicate that the carrying amount may not be recoverable. If there is such an indication, an impairment test is made. An impairment loss is recognized in the amount with which the carrying amount exceeds the recoverable amount of the asset, which is the higher of the net present value and the net selling price. In order to assess the impairment, the assets are grouped on the least identifiable group of assets that generates cash flows (cash flow generating units). Impairments are recognized in the income statement under the same items as the related depreciation and amortization.

#### Financial assets

Financial assets include receivables, securities and cash. Financial assets can be divided into the following categories: loans and receivables, financial assets at fair value through the income statement, available-for-sale financial assets and held-to maturity investments. Financial assets are assigned to the different categories by management on initial recognition, depending on the purpose for which the investments were acquired. The designation of financial assets is re-evaluated at every reporting date at which a choice of classification or accounting treatment is available. All financial assets are recognized on their settlement date. All financial assets that are not classified as fair value through the income statement are initially recognized at fair value, plus transaction costs.

Trade receivables are provided against when objective evidence is received that the company will not be able to collect all amounts due to it in accordance with the original terms of the receivables. The amount of the write-down is determined as the difference between the assets' carrying amount and the present value of estimated future cash flows.

#### Leases

Lease agreements are classified as either financial or operating leases based on the criteria in IAS 17. Lease payments under operating leases and other rental agreements are recognized in the income statement over the term of the agreements. The company's total obligation related to operating leases and rental agreements is stated under contingent assets and liabilities etc.

#### Own shares

Purchase and sales prices as well as dividend from own shares are recognized directly under retained earnings under equity.

Capital reductions by cancellation of own shares reduce the share capital by an amount equaling the nominal values of the

Profit from sale of own shares, respectively issue of shares in connection with exercise of warrants is entered directly on equity.

#### Prepaid expenses

Prepaid expenses comprise incurred expenses related to the following financial year.

#### Tax payable and deferred tax

Current tax liabilities and current tax receivables are recognized in the statement of financial position as tax calculated on the taxable income for the year adjusted for tax on previous years' taxable income and taxes paid on account/prepaid. Deferred tax is measured according to statement of financial position liability method in respect of temporary differences between the carrying amount and the tax base of assets and liabilities. Deferred tax assets including the tax value of tax losses carry forward, are measured at the expected realizable value, either by elimination in tax on future earnings or by set-off against deferred tax liabilities within the same legal tax entity and jurisdiction.

Deferred tax is measured on the basis of the tax rules and tax rates in force at the balance sheet date when the deferred tax is expected to crystallize as current tax. Any changes in deferred tax as a consequence of amendments to tax rates are recognized in the income statement.

#### **Prepayments from customers**

Prepayments from customers comprise not yet consumed prepayments relating to the research collaboration with Boehringer Ingelheim International GmbH.

#### Other liabilities

Financial liabilities are recognized initially at fair value. In subsequent periods, financial liabilities are measured at amortized cost corresponding to the capitalized value using the effective interest method; consequently the difference between the proceeds and the nominal value is recognized in the income statement over the maturity period of the loan.



Other payables are measured at amortized cost corresponding to nominal value.

#### **Employee incentive programs (warrant programs)**

Share based incentive programs have been established, which have to be settled in cash or in the enterprise's equity instruments, and are offered to a number of employees and the Executive Management. Incentive programs were offered in 2005, 2007 and 2009-2013.

The value of services received as consideration for granted warrants is measured at the fair value of the warrant. The fair value is determined at the grant date and is recognized in the income statement as staff costs over the period in which the final right to the warrant is obtained. The contra entry to this is recognized under equity. In connection with the initial recognition of the warrants, an estimate is made of the number of warrants that the employees are expected to obtain rights to. Subsequently, an adjustment is made for changes in the estimate of the number of shares that the employees have obtained rights to so the total recognition is based on the actual number of shares that the employees have obtained rights to. The fair value of the granted options is estimated by application of the Black and Scholes pricing model.

#### **Statement of cash flows**

The statement of cash flows shows the cash flow for the year together with the cash and cash equivalents at the beginning and end of the year.

#### **Cash flow from operating activities**

Cash flow from operating activities is presented indirectly and is calculated as the net result adjusted for non-cash operating items, changes in the net working capital, financial and extraordinary items paid and income taxes paid.

#### **Cash flow from investment activities**

Cash flow from investment activities includes payments associated with the purchase and sale of fixed assets and investments.

#### **Cash flow from financing activities**

Cash flow from financing activities comprises new equity, loan financing and repayment of interest bearing debt.

#### Cash and cash equivalents

Cash and cash equivalents comprise cash and bank balances.

#### Accounting estimates and assessments

In the statement of the carrying amounts of certain assets and liabilities estimates are required on how future events will affect the carrying amounts of these assets and liabilities at the balance sheet date.

The used estimates are based on assumptions assessed reasonable by management, however, estimates are inherently uncertain and unpredictable. The assumptions can be incomplete or inaccurate and unexpected events or circumstances might occur. Furthermore, the company is subject to risks and uncertainties that might result in deviations in actual results compared to estimates.

#### Revenue

Evaluating the criteria for revenue recognition with respect to the company's research and development and collaboration agreements requires management's judgment to ensure that all criteria have been fulfilled prior to recognizing any amount of revenue. In particular, such judgments are made with respect to determination of the nature of transactions, whether simultaneous transactions shall be considered as one or more revenue-generating transactions, allocation of the contractual price (upfront and milestone payments subscribed in connection with a collaboration agreement) to several elements included in an agreement, and the determination of whether the significant risks and rewards have been transferred to the buyer. Collaboration agreements are reviewed carefully to understand the nature of risks and rewards of the arrangement. All the company's revenue-generating transactions, including those with Sanofi S.A., Helsinn Healthcare S.A., Boehringer Ingelheim International GmbH and Abbvie Inc. have been subject to such evaluation by management

#### **Employee incentive programs**

In accordance with IFRS 2 "Share-based Payment", the fair value of the warrants at grant date is recognized as an expense in the income statement over the vesting period, the period of delivery of work. Subsequently, the fair value is not re-measured. The fair value of each warrant granted during the year is calculated using the Black Scholes pricing model. This pricing model requires the input of subjective assumptions such as:

The expected stock price volatility, which is based upon the historical volatility of Zealand Pharma A/S's stock price;

The risk-free interest rate, which is determined as the interest rate on Danish government bonds (bullet issues) with a maturity of five years;

The expected life of warrants, which is based on vesting terms, expected rate of exercise and life terms in current warrant program.

These assumptions can vary over time and can change the fair value of future warrants granted.

#### **Deferred tax**

Zealand Pharma A/S recognizes deferred tax assets, including the tax base of tax loss carry-forwards, if management assesses that these tax assets can be offset against positive taxable income within a foreseeable future.

This judgment is made on an ongoing basis and is based on budgets and business plans for the coming years, including planned commercial initiatives. The creation and development of therapeutic products within the biotechnology and pharmaceutical industry is subject to considerable risks and uncertainties. Zealand Pharma A/S has so far reported significant losses, and as a consequence, has unused tax losses. Management has concluded, that deferred tax assets should not be recognized as of December 31, 2013, and a 100 % valuation allowance of the deferred tax asset is recognized in accordance with IAS 12, "Income Taxes." The tax assets are currently not deemed to meet the criteria for recognition as management is not able to provide any convincing positive evidence that deferred tax assets should be recognized.

#### **Research and Development**

According to the IAS 38, "Intangible Assets," intangible assets arising from development projects should be recognized in the statement of financial position. The criteria that must be met for capitalization are that:

- the development project is clearly defined and identifiable and the attributable costs can be measured reliably during the development period;
- the technological feasibility, adequate resources to complete and a market for the product or an internal use of the product can be documented; and
- management has the intent to produce and market the product or to use it internally.

Such an intangible asset should be recognized if sufficient certainty can be documented that the future income from the development project will exceed the aggregate cost of production, development and the sale and administration of the product. A development project involves a single product candidate undergoing a high number of tests to illustrate its safety profile and the effect on human beings prior to obtaining the necessary final approval of the product from the appropriate authorities. The future economic benefits associated with the individual development projects are dependent on obtaining such approval. Considering the significant risk and duration of the development period related to the development of biological products, management has concluded that the future economic benefits associated with the individual projects cannot be estimated with sufficient certainty until the project has been finalized and the necessary regulatory final approval of the product has been obtained. Accordingly, Zealand Pharma A/S has not recognized such assets at this time and therefore all research and development costs are recognized in the income statement when incurred. The total research and development costs related to the continuing operations amounted to DKK 164 million in 2014 compared to DKK 183 million in 2013.



#### Note 2 - Revenue

In 2013, revenue is related to royalty from sales of Lyxumia® received from Sanofi S.A.

In 2012, revenue is related to milestones received from Sanofi S.A., Action Pharma A/S, Boehringer Ingelheim International GmbH and Helsinn Healthcare S.A.

#### **Note 3 – Royalty expenses**

In 2013, the royalty expenses are related to royalty from sales of Lyxumia® received from Sanofi S.A.

In 2012, the royalty expenses are related to the milestone payments received from Sanofi S.A., Helsinn Healthcare S.A. and Action Pharma A/S.



In 2013 and 2012, Zealand Pharma has, in addition to government grants, also received research funding from Boehringer Ingelheim International GmbH and Helsinn Healthcare S.A.

Note 5 – Financal income		
DKK '000	2013	2012
Interest income	3,044	5,627
Fair value adjustments, investments in subsidiaries	0	39
Exchange rate adjustments	141	0
Total financial income	3,185	5,666

Note 6 – Financial expenses		
DKK '000	2013	2012
Other interest expenses	81	225
Fair value securities	1,162	61
Exchange rate adjustments	0	1,405
Total financial expenses	1,243	1,691

Note 7 - Tax on ordinary activities		
DKK '000	2013	201
Net result for the year before tax	-183,676	36,37
Tax rate	-183,676 25 %	25 °
Expected tax expenses	-45,919	9,09
Adjustment for non-deductible expenses	-45,919 69	9,08
Reduction of corporate tax rate from 25 % to 22 %	23,616	
Adjustment merger with subsidiary	-9,071	
Change in tax assets (not recognized)	31,305	-9,15
Total tax on ordinary activities	0	0,10
Breakdown of unrecognized deferred tax assets:		
Breakdown of unrecognized deferred tax assets:  Tax losses carried forward (available indefinitely)	355,783	243,62
Tax losses carried forward (available indefinitely)	355,783 295,779	243,62 202,96
Tax losses carried forward (available indefinitely) Research and development expenses		202,96
-	295,779	
Tax losses carried forward (available indefinitely) Research and development expenses Rights Non-current assets	295,779 43,019	202,96 43,01 39,48
Tax losses carried forward (available indefinitely) Research and development expenses Rights Non-current assets Other	295,779 43,019 45,396	202,96 43,01 39,48 38,42
Tax losses carried forward (available indefinitely) Research and development expenses Rights Non-current assets Other	295,779 43,019 45,396 47,230	202,96 43,01 39,48 38,42
Tax losses carried forward (available indefinitely) Research and development expenses Rights	295,779 43,019 45,396 47,230 <b>787,207</b>	202,96 43,01 39,48 38,42 <b>567,5</b> 2
Tax losses carried forward (available indefinitely) Research and development expenses Rights Non-current assets Other Total temporary differences	295,779 43,019 45,396 47,230	202,96 43,01

#### Recognized deferred tax asset

As a consequence of tax losses from previous years, there are no actual or deferred taxes.

Deferred tax reductions (tax assets) has not been recognized in the statement of financial position due to uncertainty as to whether this can be utilized.

Note 8 – Property, plant and equipment	Plant and	Other fixtures	Leasehold improve-	Fixed assets under
DKK '000	machinery	and fittings	ments	construction
Cost at January 1, 2012	47,457	7,290	9,501	507
Additions	8,017	60	772	0
Transfers	198	236	73	-507
Cost at December 31, 2012	55,672	7,586	10,346	0
Depreciation at January 1, 2012	32,601	6,747	7,533	0
Depreciation for the year	4,335	267	717	0
Transfers	0	56	-56	0
Depreciation at December 31, 2012	36,936	7,070	8,194	0
Carrying amount at December 31, 2012	18,736	516	2,152	0
Depreciation for the financial year has been charged as:				
Research and development expenses	4,335	224	602	0
Administrative expenses	0	43	115	0
Total	4,335	267	717	0
Cost at January 1, 2013	55,672	7,586	10,346	0
Additions	2,135	254	0	2,180
Disposals	0	-639	0	0
Cost at December 31, 2013	57,807	7,201	10,346	2,180
Depreciation at January 1, 2013	36,936	7,070	8,194	0
Depreciation for the year	4,857	361	693	0
Reversel of impairment and depriciation on disposed assets	0	-639	0	0
Depreciation at December 31, 2013	41,793	6,792	8,887	0
Carrying amount at December 31, 2013	16,014	409	1,459	2,180
Demonstration for the fire social.				
Depreciation for the financial year has been charged as:	4.057	000	F01	
Research and development expenses	4,857	292	561	0
Administrative expenses	0	69	132	0

#### Note 9 - Other non current assets

Investments
DKK '000 Investments
in subsidiaries

Cost at January 1, 2012	116,0	080
Cost at December 31, 2012	116,0	
Revaluation at January 1, 2012	-114,6	623
Fair value adjustment		39
Revaluation at December 31, 2012	-114,5	584
Carrying amount at December 31, 2012	1,4	496
Cost at January 1, 2013	116,0	080
Merger	-116,0	080
Cost at December 31, 2013		0
Revaluation at January 1, 2013	-114,5	584
Merger	114,5	584
Revaluation at December 31, 2013		0
Carrying amount at December 31, 2013		0

#### Subsidiaries

BetaCure Holding A/S, Glostup, Denmark merged with Zealand Pharma A/S as at January 1 2013

#### Note 10 - Treasury shares

At the end of 2013, treasury shares amounted to 564,223 (564,223), equivalent to 2.4 % (2.4) of the share capital at December 31. The number of treasury shares corresponds to a market value of DKK 33,289,157 (47,394,732)) at December 31. The full number of treasury shares have been purchased for DKK 1.7 million.

#### Note 11 - Contingent assets

The company has an unrecognized deferred tax asset of DKK 173 million (142). See note 7.

Note 12 - Lease commitments		
DKK '000	2013	2012
Operating lease agreements:		
Within 1 year	4,247	3,801
2 to 5 years	1.377	841
More than 5 years	0	0
Total	5,624	4,642

Operating lease agreements include rental agreement of building, company cars and office equipment.

In 2013 DKK 7.2 million (7.1) was recognized in the income statement.

The leases are subject to terms of interminability of between 6 and 60 months.

Note 13 – Information on staff and remuneration		_
DKK '000	2013	2012
The total staff salaries can be specified as follows:		
Salaries	90,394	83,821
Pension schemes	6,588	
Other social security costs	9,777	
Total	106,759	96,839
The amount is charged as:		
Research and development expenses	85,379	
Administrative expenses	21,380	15,494
Total	106,759	96,839
Average number of employees	111	104

DKK '000	Base board fee	Warrant expenses	Other	Total
Remuneration 2012 included above to the:				
Board of Directors				
Daniel Ellens	350	1,838		2,188
Jørgen Lindegaard	400			400
Peter Benson	150			
Alain Munoz	150		714	864
Michael Owen	100			100
Florian Reinaud	150			
Jutta af Rosenborg	300			300
Hanne Heidenheim Bak <sup>1</sup>	100			100
Helle Størum <sup>1</sup>	150			
Christian Thorkildsen <sup>1</sup>	150			
Total	2,000	1,838	714	4,552
Remuneration 2013 included above to the:				
Board of Directors				
Daniel Ellens	400	1,532		1,932
Jørgen Lindegaard	350			350
Peter Benson	150			150
Alain Munoz	150		714	864
Michael Owen	150			150
Florian Reinaud	150			150
Jutta af Rosenborg	300			300
Hanne Heidenheim Bak <sup>1</sup>	150			150
Helle Størum <sup>1</sup>	150			150
Christian Thorkildsen <sup>1</sup>	150			150
Total	2,100	1,532	714	4,346

<sup>&</sup>lt;sup>1</sup> The table only includes remuneration related to board work for the Employee elected board members.

Note 13					Warrant	
	Base		Pension	Other	Warrant compens.	
DKK '000	salary	Bonus	contribution	benefits	expenses	Total
Remuneration 2012 included above to the:						
Executive management Directors						
David Solomon	3,366	400	0	240	2.158	6,163
Mats Blom	1,776	196	0	243	737	2,952
Christian Grøndahl	2,118	254	210	193	737	
John Hyttel	1,514	206	150	85	737	2,692
	8,774	1,056	360	761	4,369	15,318
Other members						
Arvind M. Hundal	1,271	152	126	93	737	2,380
Total	10,046	1,208	486	853	5,106	17,698
Remuneration 2013 included above to the:						
Executive management Directors						
David Solomon	4,195	255	167	240	0	4,857
Mats Blom	1,683	229	137	243	0	2,292
Christian Grøndahl 1	1,643	215	162	398	0	2,418
Other members	7,521	699	466	881	0	9,567
Arvind M. Hundal	1,314	190	130	93	0	1,727
Agneta Svendberg	1,100	160	110	151	1,708	3,229
Torsten Hoffmann	719	153	72	139	0	1,083
	3,133	503	312	383	1,708	6,039
Total	10,654	1,202	778	1,264	1,708	15,606

<sup>&</sup>lt;sup>1</sup> Christian Grøndahl is included for the period January 1 2013 – March 15 2013

	Drogram	Drogram	Drogram	Drogram	Drogram	Dragram	
	Program of 2010 02/nov/10	Program of 2010	Program of 2010	Program of 2010	Program of 2010	Program of 2010	
DKK '000	02/1109/10	10/feb/11	17/nov/11	10/feb/12	19/nov/12	08/feb/13	То
Outstanding warrants							
Number of warrants							
Outstanding as per January 1, 2012	595,406	440,500	227,085	0	0	0	1,262,9
Granted during the year	0	0	0	240,250	214,883	0	455,13
Forfeited during the year	0	-2,500	0	0	0	0	-2,5
Exercised during the year	0	0	0	0	0	0	
Expired during the year	0	0	0	0	0	0	
Outstanding as per December 31, 2012	595,406	438,000	227,085	240,250	214,883	0	1,715,62
Specified as follows:							
Board of directors	134,024	61,500	0	30,750	0	0	226,2
Executive management	406,582	0	183,864	0	183,864	0	774,3
Other employees	54,800	376,500	43,221	209,500	31,019	0	715,0
Total	595,406	438,000	227,085	240,250	214,883	0	1,715,6
Outstanding as per January 1, 2013	595,406	438,000	227,085	240,250	214,883	0	
Outstanding as per January 1, 2013 Granted during the year				240,250 0 -8,750	214,883 0 0	0 389,762 -22,500	389,70
Outstanding as per January 1, 2013 Granted during the year Forfeited during the year Exercised during the year	595,406 0	438,000 0	227,085 0	0	0	389,762	389,70
Outstanding as per January 1, 2013 Granted during the year Forfeited during the year Exercised during the year	595,406 0 0	438,000 0 -15,000	227,085 0 0	-8,750	0	389,762 -22,500	389,7
Outstanding as per January 1, 2013 Granted during the year Forfeited during the year Exercised during the year Expired during the year	595,406 0 0	438,000 0 -15,000	227,085 0 0	-8,750 0	0 0	389,762 -22,500 0	389,70 -46,2
Outstanding as per January 1, 2013 Granted during the year Forfeited during the year Exercised during the year Expired during the year Outstanding as per December 31, 2013	595,406 0 0 0	438,000 0 -15,000 0	227,085 0 0 0	0 -8,750 0 0	0 0 0 0	389,762 -22,500 0 0	389,70 -46,2
Outstanding as per January 1, 2013 Granted during the year Forfeited during the year Exercised during the year Expired during the year Outstanding as per December 31, 2013 Specified as follows:	595,406 0 0 0 0 595,406	438,000 0 -15,000 0 0 <b>423,000</b>	227,085 0 0 0 0 227,085	0 -8,750 0 0 <b>231,500</b>	0 0 0 0 <b>214,883</b>	389,762 -22,500 0 0 367,262	389,70 -46,25 2,059,15
Outstanding as per January 1, 2013 Granted during the year Forfeited during the year Exercised during the year Expired during the year Outstanding as per December 31, 2013 Specified as follows: Board of directors	595,406 0 0 0 0 595,406	438,000 0 -15,000 0 423,000	227,085 0 0 0 0 227,085	0 -8,750 0 0 <b>231,500</b>	0 0 0 0 <b>214,883</b>	389,762 -22,500 0 0 <b>367,262</b>	389,70 -46,29 2,059,13
Outstanding as per January 1, 2013 Granted during the year Forfeited during the year Exercised during the year Expired during the year Outstanding as per December 31, 2013  Specified as follows: Board of directors Executive management	595,406 0 0 0 0 <b>595,406</b> 134,024 327,358	438,000 0 -15,000 0 423,000	227,085 0 0 0 0 <b>227,085</b>	0 -8,750 0 0 <b>231,500</b> 0	0 0 0 <b>214,883</b> 0 152,845	389,762 -22,500 0 0 <b>367,262</b> 0 67,012	389,70 -46,29 2,059,19 134,09 712,20
Outstanding as per January 1, 2013 Granted during the year Forfeited during the year Exercised during the year Expired during the year Outstanding as per December 31, 2013  Specified as follows: Board of directors Executive management Other employees	595,406 0 0 0 0 595,406	438,000 0 -15,000 0 423,000	227,085 0 0 0 0 227,085	0 -8,750 0 0 <b>231,500</b>	0 0 0 0 <b>214,883</b>	389,762 -22,500 0 0 <b>367,262</b>	389,70 -46,29 2,059,19 134,09 712,20 1,212,88
Outstanding as per January 1, 2013 Granted during the year Forfeited during the year Exercised during the year Expired during the year Outstanding as per December 31, 2013  Specified as follows: Board of directors Executive management Other employees Total	595,406 0 0 0 0 595,406 134,024 327,358 134,024	438,000 0 -15,000 0 0 <b>423,000</b>	227,085 0 0 0 227,085 0 165,047 62,038	0 -8,750 0 0 <b>231,500</b> 0 0 231,500	0 0 0 214,883 0 152,845 62,038	389,762 -22,500 0 0 <b>367,262</b> 0 67,012 300,250	389,70 -46,29 2,059,19 134,09 712,20 1,212,88
Outstanding as per January 1, 2013 Granted during the year Forfeited during the year Exercised during the year Expired during the year Outstanding as per December 31, 2013  Specified as follows: Board of directors Executive management Other employees Total  Exercise period	595,406 0 0 0 0 <b>595,406</b> 134,024 327,358 134,024 <b>595,406</b>	438,000 0 -15,000 0 0 <b>423,000</b> 423,000 423,000	227,085 0 0 0 227,085 0 165,047 62,038 227,085	0 -8,750 0 0 <b>231,500</b> 0 0 231,500 <b>231,500</b>	0 0 0 214,883 0 152,845 62,038 214,883	389,762 -22,500 0 0 367,262 0 67,012 300,250 367,262	389,70 -46,29 2,059,19 134,09 712,20 1,212,88
Outstanding as per January 1, 2013 Granted during the year Forfeited during the year Exercised during the year Expired during the year Outstanding as per December 31, 2013  Specified as follows: Board of directors Executive management Other employees Total  Exercise period From	595,406 0 0 0 595,406 134,024 327,358 134,024 595,406	438,000 0 -15,000 0 423,000 423,000 423,000	227,085 0 0 0 227,085 0 165,047 62,038 227,085	0 -8,750 0 0 <b>231,500</b> 0 231,500 <b>231,500</b>	0 0 0 214,883 0 152,845 62,038 214,883	389,762 -22,500 0 0 367,262 0 67,012 300,250 367,262	389,70 -46,29 2,059,13 134,03 712,20 1,212,88
Outstanding as per January 1, 2013 Granted during the year Forfeited during the year Exercised during the year Expired during the year Outstanding as per December 31, 2013  Specified as follows: Board of directors Executive management Other employees Total  Exercise period From	595,406 0 0 0 0 <b>595,406</b> 134,024 327,358 134,024 <b>595,406</b>	438,000 0 -15,000 0 0 <b>423,000</b> 423,000 423,000	227,085 0 0 0 227,085 0 165,047 62,038 227,085	0 -8,750 0 0 <b>231,500</b> 0 0 231,500 <b>231,500</b>	0 0 0 214,883 0 152,845 62,038 214,883	389,762 -22,500 0 0 367,262 0 67,012 300,250 367,262	389,70 -46,29 2,059,13 134,03 712,20 1,212,88
Outstanding as per January 1, 2013 Granted during the year Forfeited during the year Exercised during the year Expired during the year Outstanding as per December 31, 2013  Specified as follows: Board of directors Executive management Other employees Total  Exercise period From until  Black & Scholes parameters	595,406 0 0 0 595,406 134,024 327,358 134,024 595,406 3/Nov/13	438,000 0 -15,000 0 423,000 423,000 423,000 10/Feb/14 10/Feb/16	227,085 0 0 0 227,085 0 165,047 62,038 227,085 17/Nov/14	0 -8,750 0 0 <b>231,500</b> 0 231,500 <b>231,500</b> 10/Feb/15 10/Feb/17	0 0 0 214,883 0 152,845 62,038 214,883 19/Nov/15 19/Nov/17	389,762 -22,500 0 0 <b>367,262</b> 0 67,012 300,250 <b>367,262</b> 10/Feb/16 10/Feb/18	389,70 -46,29 2,059,19 134,09 712,20 1,212,88
Outstanding as per January 1, 2013 Granted during the year Forfeited during the year Exercised during the year Expired during the year Outstanding as per December 31, 2013  Specified as follows: Board of directors Executive management Other employees Total  Exercise period From until  Black & Scholes parameters Term (months)	595,406 0 0 0 595,406 134,024 327,358 134,024 595,406 3/Nov/13	438,000 0 -15,000 0 0 423,000 423,000 423,000 10/Feb/14 10/Feb/16	227,085 0 0 0 227,085 0 165,047 62,038 227,085 17/Nov/14 17/Nov/16	0 -8,750 0 0 <b>231,500</b> 0 231,500 <b>231,500</b> 10/Feb/15 10/Feb/17	0 0 0 214,883 0 152,845 62,038 214,883 19/Nov/15 19/Nov/17	389,762 -22,500 0 0 <b>367,262</b> 0 67,012 300,250 <b>367,262</b> 10/Feb/16 10/Feb/18	389,70 -46,29 2,059,13 134,03 712,20 1,212,88
Outstanding as per January 1, 2013 Granted during the year Forfeited during the year Exercised during the year Expired during the year Outstanding as per December 31, 2013  Specified as follows: Board of directors Executive management Other employees Total  Exercise period From until  Black & Scholes parameters Term (months) Volatility *	595,406 0 0 0 595,406 134,024 327,358 134,024 595,406 3/Nov/13 3/Nov/15	438,000 0 -15,000 0 0 423,000 423,000 10/Feb/14 10/Feb/16	227,085 0 0 0 227,085 0 165,047 62,038 227,085 17/Nov/14 17/Nov/16	0 -8,750 0 0 <b>231,500</b> 0 231,500 <b>231,500</b> 10/Feb/15 10/Feb/17	0 0 0 214,883 0 152,845 62,038 214,883 19/Nov/15 19/Nov/17	389,762 -22,500 0 0 367,262 0 67,012 300,250 367,262 10/Feb/16 10/Feb/18	389,70 -46,29 2,059,13 134,03 712,20 1,212,88
Outstanding as per January 1, 2013 Granted during the year Forfeited during the year Exercised during the year Expired during the year  Outstanding as per December 31, 2013  Specified as follows: Board of directors Executive management Other employees  Total  Exercise period From until  Black & Scholes parameters Term (months) Volatility * Share price	595,406 0 0 0 595,406 134,024 327,358 134,024 595,406 3/Nov/13 3/Nov/15	438,000 0 -15,000 0 423,000 423,000 423,000 10/Feb/14 10/Feb/16	227,085 0 0 0 227,085 0 165,047 62,038 227,085 17/Nov/14 17/Nov/16 60 34 % 45.70	0 -8,750 0 0 0 231,500 231,500 10/Feb/15 10/Feb/17 60 44 % 70.0	0 0 0 214,883 0 152,845 62,038 214,883 19/Nov/15 19/Nov/17	389,762 -22,500 0 0 <b>367,262</b> 0 67,012 300,250 <b>367,262</b> 10/Feb/16 10/Feb/18	389,70 -46,29 2,059,13 134,03 712,20 1,212,88
Outstanding as per January 1, 2013 Granted during the year Forfeited during the year Exercised during the year Expired during the year Outstanding as per December 31, 2013  Specified as follows: Board of directors Executive management Other employees Total  Exercise period From until  Black & Scholes parameters Term (months) Volatility * Share price Exercise price DKK	595,406 0 0 0 595,406 134,024 327,358 134,024 595,406 3/Nov/13 3/Nov/15	438,000 0 -15,000 0 0 423,000 423,000 10/Feb/14 10/Feb/16	227,085 0 0 0 227,085 0 165,047 62,038 227,085 17/Nov/14 17/Nov/16	0 -8,750 0 0 <b>231,500</b> 0 231,500 <b>231,500</b> 10/Feb/15 10/Feb/17	0 0 0 214,883 0 152,845 62,038 214,883 19/Nov/15 19/Nov/17	389,762 -22,500 0 0 367,262 0 67,012 300,250 367,262 10/Feb/16 10/Feb/18	389,70 -46,29 2,059,13 134,03 712,20 1,212,88
Outstanding as per January 1, 2013 Granted during the year Forfeited during the year Exercised during the year Expired during the year  Outstanding as per December 31, 2013  Specified as follows: Board of directors Executive management Other employees  Total  Exercise period From until  Black & Scholes parameters Term (months) Volatility * Share price	595,406 0 0 0 595,406 134,024 327,358 134,024 595,406 3/Nov/13 3/Nov/15	438,000 0 -15,000 0 0 423,000 423,000 10/Feb/14 10/Feb/16 60 33 % 70.0 77.0	227,085 0 0 0 227,085 0 165,047 62,038 227,085 17/Nov/14 17/Nov/16 60 34 % 45.70 50.27	0 -8,750 0 0 0 231,500 231,500 10/Feb/15 10/Feb/17 60 44 % 70.0	0 0 0 214,883 0 152,845 62,038 214,883 19/Nov/15 19/Nov/17	389,762 -22,500 0 0 367,262 0 67,012 300,250 367,262 10/Feb/16 10/Feb/18	1,715,62 389,70 -46,25 2,059,13 134,02 712,20 1,212,85 2,059,13

 $<sup>^{\</sup>star}$  The volatility rate used is based on the actual volatility in the Zealand Pharma share price.



#### Warrants

Warrants may be exercised in the periods mentioned above, four times a year during a 4-week period starting from the time of the publication of Zealand Pharma's annual report or quarterly or semi-annual reports.

#### The 2010 Employee incentive program

The program was established in 2010 for the Board of Directors, Executive Management, employees and consultants of Zealand Pharma.

The Board of Directors is authorized to issue up to 2,750,000 warrants.

By December 31, 2013 2,059,136 warrants have been granted.

#### Effect on income statement

In 2013 the fair value of warrants recognized in the income statement amounts to DKK 8.8 million (13.2) of which DKK 1.5 million (1.8) relates to the Board of Directors and DKK 1.7 million (5.1) relates to the Executive Management.

DKK '000	2013	2012
The amount is charged as:  Research and development expenses	2 966	0.040
Administrative expenses  Total	3,866 4,936 <b>8,802</b>	8,848 4,397 <b>13,245</b>

#### **Note 14 – Financial and operational risks**

The goal of Zealand Pharma A/S's financial policy is to create a set of general guidelines for the financial risk management in order to reduce the company's sensitivity towards fluctuations in exchange rates, interest rates, credit rating and liquidity.

Zealand Pharma A/S's financial policy has been endorsed by Zealand's audit committee and ultimately approved by Zealand Pharma A/S's Board of Directors.

Zealand Pharma A/S is a biopharmaceutical company with limited revenues consisting of royalties, up-front payments and milestones received as part of Zealand Pharma A/S's partnering activities. Zealand Pharma A/S receives milestone payments from its current partners in USD and EUR.

Mainly exposed to research and development expenditures as well as a significant cash position, Zealand Pharma A/S is exposed to various financial risks, which among other relate to foreign exchange rate risk, interest risk, credit risk and liquidity risk.

#### Exchange rate risk

Zealand Pharma A/S does not engage in any exchange rate risk.

Most of Zealand Pharma A/S's financial transactions are made in DKK, USD and EUR.

The EUR/DKK exchange rate has politically been fixed within very narrow limits and Zealand Pharma A/S has evaluated that there are no transaction exposure or exchange rate risk regarding transactions in EUR.

Zealand Pharma A/S's milestone payments have been agreed in foreign currency, USD and EUR. However, as milestone payments are speculative the payments are not included in the basic exchange risk evaluation.

However, as Zealand Pharma A/S conduct toxicology studies and clinical trials in the US, Zealand Pharma A/S will be exposed to the exchange rate fluctuation and risks associated with transactions in USD. Zealand Pharma A/S's policy has up until now been to manage the transaction and translation risk associated with the USD passively, placing the revenues received from milestone payments in USD on an USD account for future payment of Zealand Pharma A/S's expenses denominated in USD, covering payments for the next 12 – 24 months, hereby matching Zealand Pharma A/S's assets with its liabilities.

#### Interest rate risk:

Zealand Pharma A/S has the policy to avoid any financial instrument which exposes the company to any unwanted financial risk. Zealand Pharma A/S does not speculate in the underlying trends in the basic economy.

Zealand Pharma A/S invests its free cash in fixed rate, time defined bank deposits.

#### Credit risks

Zealand Pharma is exposed to credit risks in respect of receivables and bank balances. The maximum credit risk corresponds to the carrying amount.

Zealand Pharma A/S invest in AA+ (Standard&Poors) rated RealKredit bonds with < 24 months maturity.

Cash is not deemed to be subject to any credit risks, as the counterparts are banks with investment grade ratings. (i.e BBB- or higher by Standard&Poors).

#### Cash management

The purpose of Zealand Pharma A/S's cash management is to ensure that the company at all times has sufficient and flexible financial resources at its disposal.

Zealand Pharma A/S's short-term liquidity situation is matched with Zealand Pharma A/S's quarterly budget revisions to balance the demand for liquidity and maximize Zealand Pharma A/S's interest income by matching Zealand Pharma A/S's free cash in fixed rate, time defined bank deposits with Zealand Pharma A/S's expected future cash burn.

#### Capital structure

It is Zealand Pharma A/S's aim to have an adequate capital structure in relation to the underlying operating results and R&D projects, so that it is always possible to provide sufficient capital to support operations and its long term growth targets.

The Board of Directors finds that the current capital and share structure is appropriate to the shareholders and to the company.

	2013	2013	2012	2012
	Fluctuation	Effect	Fluctuation	<b>2012</b> Effect
HCD	. / 10.0/	0.100	. / 10 0/	00.570
USD	+/- 10 %	2.196	+/- 10 %	20.578
Interest rate	+/- 1 % basis point	3.918	+/- 1 % basis point	4.917

The table shows the effect on the profit/loss and equity of probable changes in the financial variables on the statement of financial position. A breakdown the aggregate liquidity risk on financial assets and liabilities is given below:



<sup>\*</sup> All cash flows are non-discounted and include all liabilities under contracts entered into, including, among other things, future interest payments on loans.

See the cash flow statement for a specification of capital resources as of December 31, 2013 and 2012.

#### Fair value measurement of financial instruments

Financial instruments carried at fair value can be divided into three levels:

- Level 1 Quoted prices (unadjusted) in active markets for identical assets or liabilities.
- Level 2 Inputs other than quoted prices included within level 1 that are observable for the assets or liability, either directly (i.e. as prices or indirectly (i.e. derived from prices).
- Level 3 Inputs for the asset or liability that are not based on observable market data.

DKK '000	Carrying amount	Level 1	Level 2	Level 3
2012				
Investment in subsidiaries	1,496	0	0	1,496
Securities	126,940	126,940	0	0
Total financial assets	128,436	126,940	0	1,496
2013				
Securities	24,383	24,383	0	0
Total financial assets	24,383	24,383	0	0

Movement during the year in level 3		
DKK '000	2013	2012
Non-listed shares		
Carrying amount at January 1	0	1,457
Gains/losses recognized in the income statement	0	39
Carrying amount at December 31	0	1,496

Investments in subsidiaries are measured at fair value. Since the subsidiary's assets and liabilities all are measured at fair value equity of the subsidiary is considered equal to fair value.

#### Note 15 – Related parties

Zealand Pharma A/S has no related parties with controlling interest.

Zealand Pharma A/S's related parties comprise of the companies' Board of Directors and Executive Management.

#### Transactions with related parties

Compensation to the Board of Directors and Executive Management is described in note 13. Further, the following transactions with related parties were conducted during the year: Board of Directors: Consultancy fee amounted to DKK 0.7 million (0.7); Employees: royalty payment to the SIP-inventor amounted to DKK 0.03 million (1.1).

<sup>\*\*</sup> The fair value of financial liabilities is determined as the discounted cash flows based on the market rates and credit conditions at the balance sheet date.

#### Ownership

The following shareholders are registered in Zealand Pharma's register of shareholders as being the owners of minimum 5 % of the voting rights or minimum 5 % of the share capital (1 share equals 1 vote):

Sunstone BI Funds and Life Science Ventures Fund Copenhagen, Denmark	25.7 %
LD Pension (Lønmodtagernes Dyrtidsfond) Copenhagen, Denmark	11.3 %
Innovation Capital Paris, France	11.0 %
LSP Amsterdam, The Netherlands	5.5 %
A/S Dansk Erhvervsinvestering Copenhagen, Denmark	5.2 %





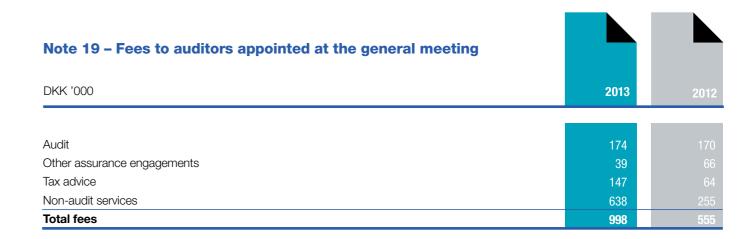
Note 18 - Basic and diluted earnings per share		
DKK '000	2013	201
Net result for the year  Adjusted net profit/loss accruing to the company's ordinary shares	-183,676 -183,676	36,372 36,372
Average number of ordinary shares	23,193,047	23,193,047
Average number of treasury shares  Adjusted average number of ordinary shares outstanding	-564,223 <b>22,628,824</b>	-564,223 <b>22,628,82</b> 4
Basic earnings per share	-8.10	1.61
Diluted earnings per share	-8.10	1.60

#### Basic earnings per share

Basic earnings per share is calculated as the net result for the period that accrue to the company's ordinary shares divided by the weighted average number of ordinary shares outstanding.

#### Diluted earnings per share

Diluted earnings per share is calculated as the net result for the period that accrue to the company's ordinary shares divided by the weighted average number of ordinary shares outstanding adjusted by the assumed dilutive effect of instruments in the form of convertible debt instruments and granted warrants outstanding that can be converted into ordinary shares.



# Company information and credits

#### Zealand Pharma A/S

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#### **Established**

1 April 1997

#### Registered office

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#### **Auditors**

PricewaterhouseCoopers Danmark Incorporated State Authorized Public Accountants Strandvejen 44 DK-2900 Hellerup

#### Design

Mervyn Kurlansky Trine Bjerre, Designvaerk

#### Illustrations

pp 22, 24, 32 - 35 Majbrit Linnebjerg

#### **Printing**

Dystan

#### Cover image

Based on a GIP-1 agonist peptide, from which lixisenatide is derived.

