



## DEAR READER

We are pleased to present the first Zealand Quarterly IR news letter, which we hope you will find useful.

This news letter highlights the main points of development for our company in 2013 to date. It also provides an update on the status and outlook for Lyxumia® (marketed by Sanofi for the treatment of Type 2 diabetes) as well as on our main pipeline assets, expected to drive mid- and long-term growth and value creation. Further, the news letter contains information on our recent and expected news flow, together with a schedule of upcoming Zealand IR events as well as noteworthy scientific and clinical events and presentations.

### DEVELOPMENT HIGHLIGHTS

In 2013, Zealand has met the most important milestone for a biotech company: the launch of its first discovered medicine, Lyxumia® (lixisenatide), which marks the outset for sustained sales based revenue. Under a global development and commercialization agreement with Sanofi, one of the world's leading diabetes companies, Lyxumia® is so far approved in Europe, Japan, Mexico, Australia and Brazil for the treatment of adult patients with Type 2 diabetes. Sanofi launched the product in the first countries in March/April and is continuing the roll-out gradually as national price and reimbursement negotiations are being settled.

Lyxumia® has a unique therapeutic profile which makes the product particularly well suited for use in combination with Lantus®, Sanofi's world-wide top-selling basal insulin. The ongoing country launches and sales ramp up of Lyxumia® are important processes for Zealand in realising the value of our agreement with Sanofi, which includes also Lixilan, a single-device Lantus®/Lyxumia® combination product, expected to enter Phase III studies in H1 2014. Royalty income from Lyxumia® sales are expected to increase in the coming years, and we have \$175m in remaining milestone payments under the agreement. We will update on the sales progress of Lyxumia® in parallel with Sanofi.

On 12 September 2013, it was announced that Sanofi had decided to voluntarily withdraw the New Drug Application (NDA) for lixisenatide in the U.S. The NDA included interim results from a large and very important Cardio-vascular Outcome Trial, ELIXA, and Sanofi's decision was a consequence of strong concerns that potential public disclosure of these results during the NDA review process would compromise the integrity of the entire ELIXA study as it is still ongoing. The withdrawal of the NDA is thus not related to any safety issues with lixisenatide or deficiencies in the NDA. Sanofi will re-submit the NDA in 2015 including full ELIXA results and have confirmed that the decision to postpone the U.S. NDA for lixisenatide has no consequences for the timing and start of Phase III studies with Lixilan.

Other important news in Q3 include:

- The signing of a new discovery and development partnership with Lilly, covering an exciting, novel approach in diabetes/obesity
- The appointment of Dr. Torsten Hoffmann as Zealand's new Chief Scientific Officer as of 1 October 2013. Torsten brings 16 years managerial and scientific experience from Roche and a strong dedication to focused innovation as one of the principal driving factors behind successful medicinal research and development

We look forward to keeping you updated on important news events going forward.

### EXPECTED UPCOMING NEWS EVENTS

#### Lyxumia® - (Sanofi)

- Updates on sales (quarterly)
- Results from Phase IV studies

#### Lantus®/Lyxumia® combination product - (Sanofi)

- Results from Phase IIb study of Fixed-Ratio combination (323 pts)
- Start of Phase III studies (exp. H1 2014)

#### ZP2929 - (Boehringer Ingelheim)

- Update on Phase I program and timelines (exp. Q1 2014)

#### Danegaptide

- Start of Phase IIa clinical Proof-of-Concept study (exp. Q4 2013)

#### Elsiglutide

- Start of Phase IIb study (exp. Q4 2013)

#### Other expected pipeline news

- ZP1480 (AbbVie) – Initiation of a second Phase IIb study
- Advance of new pre-clinical Zealand peptide drug candidates for addition to the pipeline

*In a comment for this news letter, DAVID SOLOMON, President and CEO of Zealand, said: "The development of our business in 2013 signals Zealand's unique position and strong outset for increased, future growth. Sanofi's recent decision to postpone filing of an NDA for lixisenatide in the US is a temporary, partial set-back in terms of revenue to Zealand, but a rational approach likely to add to the overall prospects for this medicine. We will continue to implement a careful balance between retaining a solid cash position and investments in pipeline advances and innovative peptide R&D. Importantly, we have Lyxumia®, our first peptide drug invention, on the market, commercialized by Sanofi as a novel diabetes medicine, which will ensure growing royalties to Zealand as it is being rolled-out. The development of our broad pipeline as well as our peptide research activities is now be led by Dr. Torsten Hoffmann, an experienced scientist and manager who shares our passion for innovation and peptide drug development as key value drivers. Our approach is already validated through several strong industry partnerships, most recently bolstered via our new agreement with Lilly, helping also to leverage Zealand's unique competences."*

## PRODUCTS AND PIPELINE

INDICATION	DISCOVERY/ PRECLINICAL	PHASE I	PHASE II	PHASE III	REGI- STRATION	MARKETED	PARTNER/ OWNERSHIP
Type 2 diabetes	Lyxumia® (Iixisenatide)						SANOFI
Type 2 diabetes	Lantus®/Iixisenatide combination product <sup>1)</sup>						
Diabetes/Obesity	ZP2929						Boehringer Ingelheim
Cardio-protection	Danegaptide						ZEAL &
Inflammatory Bowel Disease	ZP1848 <sup>2)</sup>						
Chemotherapy induced diarrhea	Elsiglutide						HELSINN
Acute Kidney Injury	ZP1480 (ABT-719)						abbvie
Cardio/Metabolic & Other indications							Lilly ZEAL &

1) Positive results from three clinical studies (~1,250 patients) evaluating the effect and safety of Lyxumia® and Lantus® given in combination as separate injections presented as part of the global GetGoal Phase III program for Iixisenatide, which forms the basis for the regulatory approvals and filings of Iixisenatide. Sanofi is preparing for additional Phase III studies of a Lantus®/Iixisenatide combination product, planned for start in H1 2014.

2) ZP1848 will be advanced into Phase II development only under a partnership.



## RECENT UPDATES AND STATUS OF PRODUCTS AND PIPELINE

### Marketed products:

#### Lyxumia® (Iixisenatide) – Type 2 diabetes (licensed to Sanofi) – Approved and marketed in Europe and Japan, US NDA exp 2015

- In February this year, Lyxumia® was approved in Europe and subsequent approvals have been received in Japan, Mexico, Brazil and Australia. Iixisenatide is under regulatory review in a number of other countries globally.
- In the U.S., an NDA is planned to be submitted in 2015, after completion of the ELIXA CV outcome study.
- Lyxumia® was launched by Sanofi in the first markets in March/April 2013, and roll-out of the product is on-going.
- Analyst consensus sales estimates for 2018: €604 million.

### Products in clinical development:

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

- Sanofi earlier this year completed a large Phase IIb study in 323 patients with Type 2 diabetes, having evaluated the efficacy and safety of a fixed-ratio Lantus®/Lyxumia® combination product. The results of the study are expected to be published in a medical journal in early 2014.
- Based on the results of the Phase IIb study, Sanofi earlier this year decided to advance the Lantus®/Lyxumia® combination product into Phase III development. Sanofi recently re-confirmed plans to start patient dosing in Phase III in H1 2014.

#### ZP2929 – Type 2 diabetes and/or obesity (partnered with Boehringer Ingelheim) – In Phase I

- Zealand and Boehringer Ingelheim continue to work closely together on the clinical Phase I development of ZP2929, which represents a novel therapeutic approach in diabetes and/or obesity. Current development activities include extended preclinical studies to fulfil FDA requirements for additional elucidation of this novel drug candidate's profile.
- Zealand expects to be able to give a further update on the expected timelines for the ZP2929 Phase I program in Q1 2014.

#### Danegaptide – Cardio-protection (Ischemic reperfusion injury) – In Phase II preparation

- Zealand's preparations for the start of a Phase IIa Proof-of-Concept study are progressing according to plan and the study is expected to start in Q4 2013.
- Danegaptide holds potential as a first in class drug candidate, representing a novel approach in cardio-pretecton.

#### Elsiglutide – Chemotherapy induced diarrhea (partnered with Helsinn) – In Phase IIb preparation

- In May 2013, based on supportive results from a Phase IIa study, our partner Helsinn decided to advance the development of elsiglutide into Phase IIb to further evaluate this promising peptide drug's potential in the prevention of Chemotherapy induced diarrhoea in colorectal cancer patients. The study is expected to commence in Q4 2013.
- Elsiglutide represents a potential first-in-class, once-daily subcutaneous treatment approach for this indication.

## PLANNED IR EVENTS

### Upcoming institutional investor and analyst events:

24 October 2013	Investor roadshow - Frankfurt
15 November 2013	Q3 2013 Conference Call
19 November 2013	Consilium Strategic Communications Annual Healthcare Conference in association with Covington & Burling LLP - London
20-21 November 2013	Jefferies 2013 Global Healthcare Conference: Presentation and investor meetings - London
28 November 2013	Redeye Investor Event: Presentation and investor meetings - Stockholm
29 November 2013	Bryan Garnier 1-on-1 Healthcare Investor Conference: Investor meetings, - Paris
2-3 December 2013	Investor roadshow - Boston and New York, US
13-16 January 2014	JP Morgan Healthcare Conference - San Francisco, US

### Upcoming retail investor events:

6 November 2013	Retail Investor meeting - at Zealand, Copenhagen
-----------------	--

### Upcoming scientific events:

10-14 November 2013	The American Association of Pharmaceutical Scientists (AAPS) Annual meeting, San Antonio, Texas
14-15 November 2013	The Danish Diabetes Academy's Diabetes and technology meeting, Copenhagen – Zealand presentation: "Can glucagon be produced in a soluble form"
2-6 December 2013	International Diabetes Forum's World Diabetes Congress, Melbourne

## RECENT IR EVENTS

In October, Zealand has hosted a group meeting at The French Society of Financial Analysts and held meetings with investors and financial journalists in Paris. In September, Zealand hosted both investor and analyst meetings in connection with the Annual EASD Diabetes conference in Barcelona and presented at the Bank of America Merrill Lynch Global Healthcare Conference in London, including individual meetings with institutional investors. In London, Zealand also held meetings with sell-side analysts. Late September, Zealand presented a retail investor forum in Malmö, Sweden. On a regular basis, Zealand hosts investor and analyst meetings at its company address.

## 2013 FINANCIAL CALENDAR (Zealand will announce its 2014 Financial Calendar later in 2013)

15 November 2013	Interim report for the nine months ended 30 September 2013
------------------	--

## FINANCIAL STATUS

Financial highlights for H1 2013 (Comparative figures for the same period 2012 in brackets. In 2012, Zealand received several event related milestone payments from its partners).

- Revenue of DKK 1.1/EUR 0.1 million (DKK 186.2/EUR 25.1 million)
- Net operating expenses of DKK 106.2/EUR 14.2 million (DKK 82.8/EUR 11.1 million)
- Net result of DKK -104.3/EUR -14.0 million (DKK 89.4/EUR 12.0 million)
- Earnings per share of DKK -4.61/EUR -0.62 (DKK 3.95/EUR 0.53)
- End of period cash and securities of DKK 403.6/EUR 54.2 million (DKK 525.0/EUR 70.7 million)

## RECENT SCIENTIFIC PUBLICATIONS AND PRESENTATIONS

### Lyxumia® (lixisenatide):

"Therapeutic efficacy of lixisenatide added to basal insulin is greater when FPG is well-controlled", J. Vidal et al. – Oral presentation, EASD 49<sup>th</sup> Annual meeting, 23-27 Sept 2013

"Efficacy of lixisenatide in patients with different levels of beta-cell function as assessed by C-peptide/glucose ratio", J.J. Meier – Poster, EASD 49<sup>th</sup> Annual meeting, 23-27 Sept 2013

"Pharmacodynamic characteristics of lixisenatide once daily versus liraglutide once daily in patients with type 2 diabetes insufficiently controlled on metformin", C Kapitzka et al., Diabetes Obes Metab. 2013 July; 15(7): 642–649

"Once-daily lixisenatide as add-on to basal insulin ± OADs in patients with Type 2 diabetes selectively reduces postprandial hyperglycemic daytime exposure", M. Riddle et al. – Poster, ADA 73<sup>rd</sup> Scientific sessions, 21-25 June 2013

"Expanding the basal-plus regimen: basal insulin + lixisenatide is more likely to achieve the composite outcome of HbA<sub>1c</sub> <7%, no documented symptomatic hypoglycemia and no weight gain compared with basal + prandial insulin", J. Rosenstock et al. – Poster, ADA 73<sup>rd</sup> Scientific Sessions, 21-25 June 2013

### Zealand publications:

ZP3022, a GLP-1-gastrin dual agonist: "β-cell mass expansion and survival", J. Skarbaliene et al. – Poster, EASD 49<sup>th</sup> Annual meeting, 23-27 Sept 2013

ZP-GA-1, liquid formulation glucagon: "A novel glucagon analogue, ZP-GA-1, displays increased chemical and physical stability in liquid formulation", D. Riber et al – Poster, ADA 73<sup>rd</sup> Scientific Sessions, 21- 25 June 2013

## ZEALAND SHARE PRICE PERFORMANCE



## NEWS ANNOUNCEMENTS IN Q3 2013

- 26 Sept New preclinical data on novel Zealand GLP-1-gastrin dual agonist presented at EASD
- 24 Sept Lyxumia data presented at EASD support know complementary effects in combination with basal insulin
- 12 Sept Decision by Sanofi to withdraw the NDA for lixisenatide in the US and resubmit with full ELIXA data
- 3 Sept Appointment of Dr. Torsten Hoffmann as new CSO
- 29 Aug New peptide drug research and development collaboration with Lilly
- 29 Aug H1 2013 Interim report
- 1 Aug Update from Sanofi on commercial roll-out of Lyxumia®

## ANALYSTS COVERING ZEALAND

- Bryan Garnier - Eric le Berrigaud (Buy, DKK 90)
- Danske Markets - Thomas Bowers (Buy, DKK 85)
- Handelsbanken - Peter Sehested
- Jefferies - Peter Welford (Buy, DKK115)
- Nordea - Michael Novod (Sell, DKK 60)
- Oddo - Sébastien Malafosse (Reduce, DKK 84)

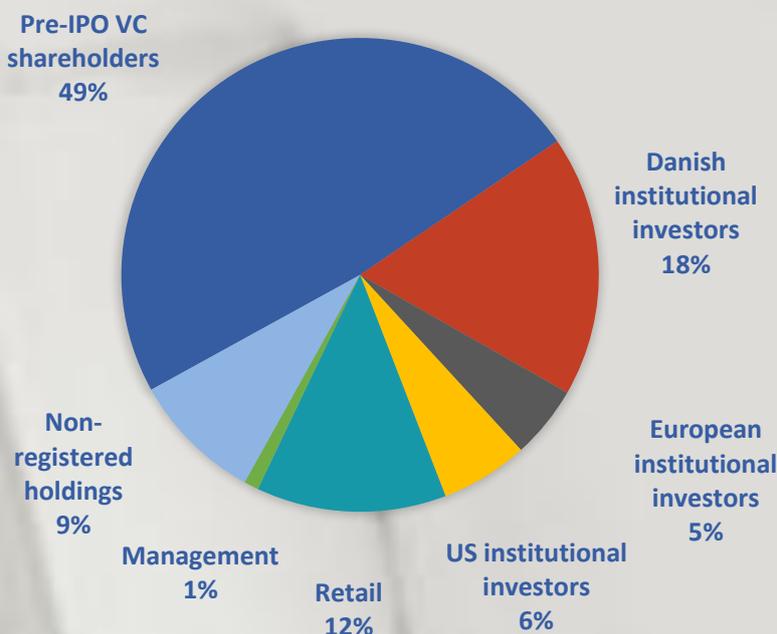
## SELECT ANALYSTS COVERING SANOFI with comments and price forecasts on Lyxumia® and the Lixilan single combination:

- BarCap - Michael Leuchten & team
- Bank of America Merrill Lynch - Graham Parry & team
- Berenberg - Alistair Campbell & team
- Citi Bank - Andrew Baum & team
- Credit Suisse - Luisa Hector & team
- Leerink Swann - Seamus Fernandez & team
- Societe Generale - Steve McGarry & team

## MANAGEMENT

- David H. Solomon**  
President and Chief Executive Officer
- Mats Blom**  
Senior Vice President and Chief Financial Officer
- Torsten Hoffmann**  
Executive Vice President and Chief Scientific Officer
- Arvind Hundal**  
Senior Vice President and Chief Business Officer
- Agneta Svedberg**  
Senior Vice President and Chief Operating Officer

## ZEALAND SHAREHOLDER STRUCTURE



## INVESTOR AND MEDIA RELATIONS

**Hanne Leth Hillman**  
Vice President and Head of IR & Corporate Communications  
E-mail: [hlh@zealandpharma.com](mailto:hlh@zealandpharma.com)  
Tel: +45 5060 3689

### ADDRESS

Zealand Pharma  
Smedeland 36  
2600 Glostrup (Copenhagen) , DENMARK  
Tel: +45 8877 3600