

## Zealand Pharma A/S announces Full Year results and Annual Report for 2012

– *First Zealand invented medicine, Lyxumia<sup>®</sup> for Type 2 diabetes now approved in Europe and under regulatory review globally*

– *Revenues of DKK 224 (EUR 30) million and net results of DKK 36 (EUR 5) million for 2012 were the best ever in the history of Zealand*

Copenhagen, 14 March 2013 – Zealand Pharma A/S (“Zealand”) (NASDAQ OMX Copenhagen: ZEAL), a Danish biotechnology company dedicated to the discovery and development of novel peptide drugs, reports an increase in revenue and other operating income, a positive net result, an improved cash position and important progress with its drug development pipeline and business activities for the twelve month period from 1 January to 31 December 2012. The results are in line with the company’s financial outlook for the year.

### Financial highlights for 2012

- Revenue of DKK 223.6 (EUR 30.0) million (2011: DKK 142.3 (EUR 19.1) million).
- Royalty expenses of DKK 15.9 (EUR 2.1) million (2011: DKK 0.1 (EUR 0) million).
- Net operating expenses of DKK 175.2 (EUR 23.5) million (2011: DKK 133.4 (EUR 17.9) million).
- Net result of DKK 36.4 (EUR 4.9) million (2011: 13.4 (EUR 1.8) million).
- Cash and securities amounted to DKK 485.9 (EUR 65.2) million as at 31 December 2012 (2011: DKK 427.7 (EUR 57.4) million).

### Key financial highlights in Q4 2012

- Revenue in Q4 2012 amounted to DKK 0.0 million (Q4 2011: DKK 22.3 million). Revenue for the period last year was related to milestone payments from Zealand’s partner Helsinn Healthcare.
- Net operating expenses increased to DKK 55.0 million (Q4 2011: DKK 42.6 million) reflecting a higher activity level within R&D and increased costs for salaries and incentive programs.
- Net result for Q4 amounted to DKK -52.5 million (Q4 2011: DKK -19.2 million).

### Pipeline highlights for 2012

*Lyxumia<sup>®</sup> (lixisenatide) - Type 2 diabetes*

- Following completion of the global pivotal GetGoal clinical program, a milestone payment of DKK112.5 (USD 20) million was received from Sanofi.
- The efficacy and safety of lixisenatide on top of basal insulin were supported by substantial data from the GetGoal Duo 1 and GetGoal-L studies presented by Sanofi at the American Diabetes Association's (ADA's) 72<sup>nd</sup> Annual Scientific Sessions and later at the 48<sup>th</sup> European Association for



- the Study of Diabetes (EASD) Annual Meeting.
- Lixisenatide was submitted for approval by Sanofi in Japan.

#### **In Q4 2012:**

- Lixisenatide received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) under the European Medicines Agency recommending the approval of the product in Europe under the name of Lyxumia<sup>®</sup>, as the first once-daily prandial GLP-1 agonist for the treatment of adults with Type 2 diabetes in combination with basal insulin, including Lantus<sup>®</sup> (insulin glargine), the world's most prescribed basal insulin, and/or oral anti-diabetic medicines.

#### *ZP2929 - Type 2 diabetes and/or obesity*

- Under the agreement with Boehringer Ingelheim, Zealand advanced ZP2929, a dual acting glucagon/GLP-1 agonist, into clinical development with the start of a Phase I study in the United States under an Investigational New Drug application with the Food and Drug Administration (FDA).

#### *Elsiglutide - Chemotherapy induced diarrhea*

- Partner Helsinn initiated a Phase IIa study to evaluate the safety and efficacy of the GLP-2 peptide agonist elsiglutide for the prevention of diarrhea in patients with colorectal cancer treated with chemotherapy.

#### *ZP1480 (ABT-719) - Acute kidney injury*

- A new license agreement was signed with AbbVie (formerly Abbott) on ZP1480 (referred to by AbbVie as ABT-719) and Zealand received a USD 11 (DKK 66) million milestone payment.

#### *ZP3022 - Diabetes*

- New preclinical data were presented at ADA and EASD on ZP3022, a novel GLP-1-gastrin dual peptide agonist, showing a significant improvement in glycemic control and an increase in pancreatic beta-cell mass.

#### **Events after the end of the financial year**

- Lyxumia<sup>®</sup> (lixisenatide) received a Marketing Authorization by the European Commission, granting approval to this first Zealand invented medicine in 27 EU member countries as well as Norway, Iceland and Liechtenstein. The product has received approval also in Mexico.
- The FDA accepted for review the New Drug Application (NDA) filed by Sanofi in December 2012 for lixisenatide in the US.
- Sanofi had the first commercial sales of Lyxumia<sup>®</sup> in the United Kingdom, the first European country to make this medicine available for patients.
- Owing to a technical issue encountered during the last development steps (industrialization, validation, usability and manufacturing) of the Lantus<sup>®</sup>/lixisenatide Fix-Flex single combination product (allowing for flexible dosing of Lantus<sup>®</sup> combined with a fixed lixisenatide dose), Sanofi announced that timelines for start of Phase III studies with the combination product are currently being reassessed.
- In parallel, the enrolment of 323 patients in a Phase IIb study to evaluate also a Lantus<sup>®</sup>/lixisenatide Fixed-Ratio single combination product was completed.
- Zealand announced the decision to advance danegaptide into a single-site clinical efficacy promising study with expected start in Q4 2013 to further profile this peptide drug as a novel therapeutic approach in cardio-protection.
- Agneta Svedberg was named as the successor to former Senior Vice President and Chief Operating Officer, John Hyttel, who retired after 14 years with the company.



**David H. Solomon, President and CEO of Zealand, commented:**

*“2012 was a decisive year for Zealand, culminating in November with the positive CHMP recommendation for approval of Lyxumia® in Europe. This was followed in February this year by the formal Marketing Authorization for the drug, recently resulting in first sales of this Zealand discovered medicine to benefit patients. We were profitable in 2012 based on milestone payments from our partners, and we ended the year with a solid financial position. With the prospects in 2013 of further commercial roll-out of Lyxumia®, Zealand is now on a path to sustained revenues.*

*“Elsewhere in the portfolio we also saw encouraging advances for both our partnered and proprietary clinical drug candidates. Peptide innovation, partnerships and commercialization form the cornerstones of Zealand’s future success. They will be our continued focus in 2013 as we work to achieve our objectives of providing benefits to patients and returns to our shareholders as a sustainable, next-generation biotech company.”*

**Financial outlook for 2013**

In 2013, Zealand expects revenue from royalties on first sales of Lyxumia® (lixisenatide) and potential success based milestone payments from its collaboration partners. As Sanofi has given no guidance on the expected sales of Lyxumia® and as the timing of milestone based payments is largely outside Zealand’s control, no revenue guidance is provided at this point in time.

Net operating expenses in 2013 are expected at a range of DKK 210-240 (EUR 28-32) million. This represents an expected increase of DKK 35-65 (EUR 5-9) million compared to 2012, which is mainly attributable to intensified clinical research activities.

**The Annual Report 2012**

This full year results announcement should be read in conjunction with Zealand’s Annual Report 2012, issued together with the release. From today, an electronic copy of the Annual Report 2012 can be found on and downloaded also from the company’s website under the Investor section.

Printed versions of Zealand’s Annual Report 2012 will be distributed in mid-April and will be available from Zealand upon request.

**Conference call**

Zealand will host a conference call today, Thursday, 14 March at 14:00 CET/ 9:00 EST. David H. Solomon, President & Chief Executive Officer, Mats Blom, Chief Financial Officer and Hanne Leth Hillman, Vice President of IR and Corporate Communication, will host the call to present the Full Year results and Annual Report for 2012, followed by a Q&A session.

The conference call will be conducted in English and the dial-in numbers are:

DK toll free (Denmark based participants only) 8088 8649  
DK standard access +45 3272 9273  
International, incl. UK +44 (0) 20 3003 2666  
US +1 866 966 5335

A live broadcast of the conference call including a slide presentation will be screened at the following link:

<http://livecast.wehay.com/playontv/130314/zealandpharma/>

Participants are recommended to register approximately 10 minutes ahead of the presentation.

###



**For further information, please contact:**

**Zealand Pharma A/S**

David H. Solomon, President and Chief Executive Officer

Tel: +45 2220 6300

Hanne Leth Hillman, Vice President and Head of IR & Corporate Communication

Tel: +45 5060 3689, email: [hlh@zealandpharma.com](mailto:hlh@zealandpharma.com)

**About Zealand**

Zealand Pharma A/S ("Zealand") (NASDAQ OMX Copenhagen: ZEAL) is a biotechnology company based in Copenhagen, Denmark. Zealand specializes in the discovery, optimization and development of novel peptide drugs and has a broad and mature pipeline of drug candidates identified through its own drug discovery activities. The company's focus lies in the field of diabetes/metabolic diseases, and its lead drug invention is lixisenatide, a once-daily GLP-1 agonist, which is licensed to Sanofi for the treatment of Type 2 diabetes. Lixisenatide is approved in Europe (February 2013) under the name of Lyxumia®, and under regulatory review in a large number of other countries globally, including in the US (NDA filed in Dec 2012) and Japan (NDA filed in June 2013).

Zealand has a partnering strategy for the development and commercialization of its products and in addition to the collaboration with Sanofi in Type 2 diabetes, the company has partnerships with Boehringer Ingelheim in diabetes/obesity, Helsinn Healthcare in chemotherapy induced diarrhea and AbbVie in acute kidney injury. For further information: [www.zealandpharma.com](http://www.zealandpharma.com)



## Key figures for the group

DKK thousand	Note	2012 1.10 - 31.12	2011 1.10 - 31.12	2012 1.1 - 31.12	2011 1.1 - 31.12
		Q4	Q4	Full year	Full year
<b>INCOME STATEMENT AND COMPREHENSIVE INCOME</b>					
Revenue		0	22,316	223,565	142,284
Royalty expenses		-372	-112	-15,933	-112
<b>Gross profit</b>		<b>-372</b>	<b>22,204</b>	<b>207,632</b>	<b>142,172</b>
Research and development expenses		-51,188	-37,894	-182,759	-126,938
Administrative expenses		-10,432	-9,578	-27,611	-34,905
Other operating income		6,632	4,848	35,135	28,435
<b>Operating result</b>		<b>-55,360</b>	<b>-20,420</b>	<b>32,397</b>	<b>8,764</b>
Net financial items		2,896	1,255	3,975	4,613
<b>Net result for the period</b>		<b>-52,464</b>	<b>-19,165</b>	<b>36,372</b>	<b>13,377</b>
<b>Comprehensive income for the period</b>		<b>-52,464</b>	<b>-19,165</b>	<b>36,372</b>	<b>13,377</b>
Earnings per share - basic (DKK)		-2.32	-0.86	1.61	0.60
Earnings per share - diluted (DKK)		-2.30	-0.86	1.60	0.60
				<b>2012</b>	<b>2011</b>
<b>BALANCE SHEET</b>				<b>31 Dec</b>	<b>31 Dec</b>
Cash and cash equivalents				358,922	278,342
Securities				126,940	149,358
Total assets				520,983	469,481
Share capital ('000 shares)				23,193	23,193
Shareholder's equity				491,015	441,397
Equity / assets ratio				0.94	0.94
				<b>2012</b>	<b>2011</b>
				<b>1.10 - 31.12</b>	<b>1.10 - 31.12</b>
<b>CASH FLOW</b>				<b>Full year</b>	<b>Full year</b>
Depreciation		1,514	1,173	5,319	4,129
Change in working capital		38,324	-8,828	13,782	-30,943
Investments in fixed assets		-4,359	-1,304	-8,849	-11,475
Free cash flow	1	-10,983	-22,720	59,688	-12,637
				<b>2012</b>	<b>2011</b>
<b>OTHER</b>				<b>31 Dec</b>	<b>31 Dec</b>
Share price DKK				84.00	57.00
Market capitalization MDKK				1,948,216	1,322,004
Equity per share DKK	2			21.70	19.51
Average number of employees (full-time equivalents)				104	91
Compounds in clinical development (end period)				7	6

Notes:

(1) Free cash flow is calculated as cash flow from operating activities less purchase of property, plant and equipment

(2) Equity per share is calculated as shareholders equity divided by total number of shares less treasury shares