

Zealand Pharma A/S announces Full Year results and publication of the Annual Report for 2013

- **Commercial launch of Lyxumia[®], the first peptide medicine from Zealand pipeline to reach the market, marks key transition to a sustainable revenue stream**
- **Important pipeline advances:**
 - **Start of the LixiLan Phase III clinical program by Sanofi for the fixed-ratio combination of Lyxumia[®] with Lantus[®]**
 - **Start and advance of Phase II Proof-of-Concept study with danegaptide**
 - **Supportive Phase IIa results on elsiglutide and advancement in clinical development by Helsinn**
- **Net result of DKK - 184 (EUR - 25) million in line with expectations**
- **End of year cash and securities of DKK 311 (EUR 42) million**
- **2014 Financial guidance:**
 - **Royalties on sales of Lyxumia[®]**
 - **Expected milestone payments of DKK 97 (EUR 13) million, of which DKK 82 (EUR 11) million has been received**
 - **Net operating expenses of DKK 200-210 (EUR 27-28) million**

Copenhagen, 20 March 2014 – Zealand Pharma A/S (“Zealand”) (NASDAQ OMX Copenhagen: ZEAL), announces financial results in line with guidance and important advances for the company’s portfolio of peptide based medicines, including the launch of Lyxumia[®], for the twelve month period from 1 January to 31 December 2013.

In a comment to this announcement, **David H. Solomon, President and CEO of Zealand, said:**

“2013 was a pivotal year for Zealand. Lyxumia[®], the first product from Zealand’s pipeline to be marketed, was launched by Sanofi in Europe, Japan and several overseas countries for the treatment of Type 2 diabetes. This event marks the key transition to a sustainable revenue stream for our company. We do see attractive sales potential for Lyxumia[®] based on the differentiating profile of this medicine coupled with Sanofi’s globally strong market position.

“With a solid cash balance, including milestone based revenue and a view to growing sales royalties, we feel confident about our financial position going forward. Still, we remain diligent in terms of our operational expenses, as we are setting the scene for accelerated growth of our pipeline and increased value creation.



“Sanofi’s start earlier this year of the LixiLan Phase III program with the fixed-ratio combination of Lyxumia[®] with Lantus[®] is another important element in building a strong foundation for our continued activities. The path forward to planned regulatory filings for this important new diabetes medicine in late 2015 has been set, supporting its potential to be the first GLP-1/basal insulin combination medicine to be launched in the US.

“For our proprietary pipeline, under the direction of our new CSO Torsten Hoffman, we have advanced danegaptide into Phase II clinical studies as a potential first-in-class medication to protect against tissue damage. Further, we have prioritized our preclinical portfolio to focus our resources on advancing the most promising peptide therapeutics towards the clinic. This has freed resources for enhanced innovation to leverage further on our expertise in peptides and provide novel medicines to best meet patients’ needs.”

Product and pipeline status with highlights for the fourth quarter of 2013 and the period thereafter

Lyxumia[®] (lixisenatide) (Type 2 diabetes) – Licensed to and marketed by Sanofi

- In March 2013, Lyxumia[®] was launched in the first European markets by Sanofi, who holds global development and commercial rights to the product under a license agreement with Zealand.
- Currently approved in more than 40 countries worldwide for the treatment of Type 2 diabetes, with subsequent commercial launches ongoing in Europe, Japan, Mexico and other overseas markets.
 - In Germany, price negotiations under the AMNOG reference pricing process have ended and based on the outcome, Sanofi has decided to withdraw Lyxumia[®] from the German market as of 1 April 2014. The arbitration process has begun and, in parallel, Sanofi is completing additional clinical studies to demonstrate the additional benefit of Lyxumia[®] to the Joint Evaluation Committee (G-BA) through an even larger evidence base.
- Zealand is entitled to royalties based on Sanofi’s global sales of Lyxumia[®]. In 2013, initial royalty revenue amounted to EUR 0.9 (DKK 6.6) million, and Sanofi continues the commercial roll-out of the product.
- In the US, submission for regulatory approval of lixisenatide is planned for 2015 after completion of the ongoing cardiovascular outcome study, ELIXA. The enrolment of 6,000 patients in ELIXA was completed in August 2013 and final study results are expected to be available in the first half of 2015.
- In December 2013, new clinical data presented at IDF showed support for the flexibility in timing of administration of once-daily Lyxumia[®]. The data showed similar glucose lowering effect with Lyxumia[®] whether administered before breakfast or before the main meal.

Lyxumia[®]/Lantus[®] fixed-ratio combination (Type 2 diabetes) – In Phase III development under license agreement with Sanofi

- In February, Sanofi announced the initiation of the LixiLan Phase III development program with the fixed-ratio single daily injection combination of Lyxumia[®] with Lantus[®]. Lantus[®] is the most prescribed basal insulin world-wide with a market share of close to 80%.
- The Phase III program is expected to complete in the second half of 2015, and regulatory submissions could begin at the end of 2015. This timing leaves the attractive potential for the Lantus[®]/Lyxumia[®] combination 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.



Danegaptide (Ischemic reperfusion injury) – In Phase II development

- Danegaptide is a Zealand-invented peptide with cell-protective properties. In preclinical studies, this peptide has shown potential pointing towards its use as the first medicinal therapy to protect against tissue damage from ischemic reperfusion injuries.
- In September 2013, Zealand initiated a Phase II Clinical Proof-of-Concept study to evaluate the effect of danegaptide in the protection of cardiac tissue against reperfusion injury in patients with acute myocardial infarction.
- The study is being conducted in collaboration with one of the world's leading cardiac centres, located in Copenhagen. The enrolment of up to 600 patients is progressing according to plan. Study results are expected in the second half of 2015.

Elsiglutide (Chemotherapy induced diarrhea) – In Phase II development under partnership with Helsinn

- Based on supportive results from a Phase IIa study, Helsinn continues preparations for the advancement of elsiglutide into a Phase IIb clinical dose finding study to further evaluate the potential of this promising peptide drug in the prevention of chemotherapy induced diarrhea in colorectal cancer patients.
- The Phase IIb study is expected to commence in the second half of 2014 with planned completion in 2015.

ZP2929 (Type 2 diabetes and/or obesity) – In Phase I development

- In February 2014, Zealand and Boehringer Ingelheim announced a change to the collaboration on novel dual-acting glucagon/GLP-1 agonists to treat Type 2 diabetes and/or obesity with the selection of a new lead compound to replace ZP2929.
- ZP2929 is now under Zealand's full control, and the continued development program is undergoing strategic review. The program is conducted under an IND with the FDA, and as a next step Zealand will interact with the FDA and present its preferred strategy for the continued Phase I development and design, including results from additional preclinical studies.

Selected preclinical programs

- At the American Diabetes Association's meeting in 2013, Zealand presented the first data on a novel glucagon analogue, suitable for liquid formulation, showing superior physico-chemical properties over native glucagon, while retaining similar efficacy. The attractive properties of this glucagon analogue create the potential for its use in a easy-to-use rescue pen for improved treatment of severe hypoglycemia in diabetes. Zealand is preparing for the advancement of this peptide therapeutic into clinical development.
- The collaboration between Zealand and Boehringer Ingelheim continues towards the selection of a new lead candidate from the portfolio of novel glucagon/GLP-1 dual agonists and compound designs invented under the two-year research part of the collaboration, including compounds designed for once-weekly dosing.



Financial highlights for 2013

- Revenue of DKK 6.6 (EUR 0.9) million (2012: DKK 223.6 (EUR 30.0) million). Revenue in 2013 stems from initial Lyxumia® sales royalties, whereas revenue in 2012 was based on milestone payments, which type of revenue varies greatly from year to year.
- Royalty expenses of DKK -0.9 (EUR 0.1) million (2012: DKK -15.9 (EUR 2.1) million).
- Net operating expenses of DKK 191.3 (EUR 25.7) million (2012: DKK 175.2 (EUR 23.5) million).
- Net result of DKK -183.7 (EUR 24.6) million (2012: DKK 36.4 (EUR 4.9) million).
- Cash and securities amounted to DKK 310.6 (EUR 41.6) million on 31 December 2013 (2012: DKK 485.9 (EUR 65.1) million).

Key financial highlights in Q4 2013

- Revenue of DKK 3.2 (EUR 0.4) million (Q4 2012: DKK 0 (EUR 0) million). Revenue for the period was related to royalties from Zealand's partner Sanofi.
- Net operating expenses of DKK 48.2 (EUR 6.5) million (Q4 2012: DKK 55.0 (EUR 7.4) million) The decrease is a result of reduced use of R&D consultants and lower personnel costs.
- Net result of DKK -44.8 (EUR -6.0) million (Q4 2012: DKK -52.5 (EUR -7.0) million).

Financial guidance for 2014

In 2014, Zealand will receive 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 the 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® sales in 2014.

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

The Annual Report 2013

This full year result announcement should be read in conjunction with Zealand's Annual Report 2013, published today. A PDF-version of the Annual Report 2013 is attached to this announcement and can be accessed and downloaded also from Zealand's corporate website www.zealandpharma.com.

Printed versions of Zealand's Annual Report 2013 will be available from the beginning of April and can be provided by Zealand upon request (info@zealandpharma.com or investors@zealandpharma.com). The full report is only available in English version, but a printed version of a Corporate Story in Danish will be available before the Annual General Assembly on 29 April 2014.



Conference call

Zealand will host a conference call today, at 3 pm CET/ 10 am EST to present the Full Year 2013 results announcement and the Annual Report, which will be followed by a Q&A session. The call will be hosted by David Solomon, President and CEO, Mats Blom, CFO, and Hanne Leth Hillman, Vice President for Investor Relations and Corporate Communications.

The call will be conducted in English and the dial-in details to access the call are as follows:

DK: +45 32 72 80 18

US: (FreeCall dial-in) +1 866 682 8490

UK and international: +44 (0) 1452 555131

A live audio cast of the call including an accompanying slide presentation will be available via the following link: <http://www.media-server.com/m/p/nvqt76ii>

The audiocast can also be accessed from the investor section of Zealand's website (zealandpharma.com) and participants are advised to register approximately 10 minutes before the call starts. An on-demand version of the audiocast will also be available on the website following the call.

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About Zealand

Zealand Pharma A/S (NASDAQ OMX Copenhagen: ZEAL) ("Zealand") 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 cardio-metabolic diseases, diabetes and obesity in particular, and its lead drug invention is lixisenatide, a once-daily prandial GLP-1 agonist, which is licensed to Sanofi for the treatment of Type 2 diabetes. Lixisenatide (marketed by Sanofi as Lyxumia®) is approved in several countries globally, including Europe and Japan. In the U.S., an NDA is planned to be submitted in 2015, after completion of the ELIXA Cardiovascular outcome study. In February 2014, Sanofi started the pivotal Phase 3 clinical program for the Lantus®/Lyxumia® combination product (LixiLan).

Zealand has a partnering strategy for the development and commercialization of its products and, in addition to the license agreement with Sanofi in Type 2 diabetes, the company has partnerships with Boehringer Ingelheim in diabetes/obesity, Lilly in diabetes and obesity, Helsinn Healthcare in chemotherapy induced diarrhea and AbbVie in acute kidney injury.

For further information: zealandpharma.com

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Key figures

DKK thousand		2013	2012	2013	2012
		1.10 -	1.10 -	1.1 - 31.12	1.1 -
		31.12	31.12	31.12	31.12
INCOME STATEMENT AND COMPREHENSIVE INCOME	Note	Q4	Q4	Full year	Full year
Revenue		3.176	0	6.574	223.565
Royalty expenses		-417	-372	-872	-15.933
Gross profit		2.759	-372	5.702	207.632
Research and development expenses		-38.281	-51.188	-164.467	-182.759
Administrative expenses		-10.661	-10.432	-34.155	-27.611
Other operating income		790	6.632	7.302	35.135
Operating result		-45.393	-55.360	-185.618	32.397
Net financial items		618	2.896	1.942	3.975
Net result for the period (after tax)		-44.775	-52.464	-183.676	36.372
Comprehensive income for the period		-44.775	-52.464	-183.676	36.372
Earnings per share - basic (DKK)		-1,96	-2,32	-8,10	1,61
Earnings per share - diluted (DKK)		-1,97	-2,30	-8,10	1,60
				2013	2012
STATEMENT OF FINANCIAL POSITION				31-dec	31 Dec
Cash and cash equivalents				286.178	358.922
Securities				24.383	126.940
Total assets				346.913	522.404
Share capital ('000 shares)				23.193	23.193
Shareholder's equity				316.141	491.015
Equity / assets ratio				0,91	0,94
		2013	2012	2013	2012
		1.10 -	1.10 -	1.1 - 31.12	1.1 -
		31.12	31.12	31.12	31.12
CASH FLOW		Q4	Q4	Full year	Full year
Depreciation		1.731	1.514	5.911	5.319
Change in working capital		-12.958	38.324	-3.643	13.782
Purchase of property, plant and equipment		-114	-4.359	-4.569	-8.849
Free cash flow	1	-45.288	-10.983	-174.187	59.688
				2013	2012
OTHER				31-dec	31 Dec
Share price (DKK)				59,00	84,00
Market capitalization (MDKK)				1.368.387	1.948.216
Equity per share (DKK)	2			13,97	21,70
Avg. number of employees (full-time equivalents)				111	104
Compounds in clinical development (end period)				6	7
Products on the marked				1	0

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

