



## Zealand Pharma A/S – Interim report for Q1 2014 (un-audited)

- *In January 2014, Zealand received a USD 15 million milestone payment from Sanofi relating to the start of Phase III trials with LixiLan, the fixed-ratio combination of Lyxumia<sup>®</sup> and Lantus<sup>®</sup>. First regulatory filing of LixiLan is expected as early as end 2015*
- *Lyxumia<sup>®</sup> royalty revenue to Zealand amounted to DKK 4/EUR 0.5 million in Q1 2014. Excluding Germany, royalties increased 49% compared to Q4 2013*
- *Continued Lyxumia<sup>®</sup> roll-out by Sanofi with additional launches expected in 2014. Resubmission of New Drug Application in the US is planned for 2015, after completion of the ELIXA cardiovascular outcome study*
- *Net results was a profit of DKK 29/EUR 4 million. End period cash and securities of DKK 350/EUR 47 million*

Copenhagen, 29 April 2014 – Zealand Pharma A/S (Zealand) (CVR no. 20 04 50 78) (NASDAQ OMX Copenhagen: ZEAL) announces its un-audited interim report for the period from 1 January – 31 March 2014, a quarter which saw important advances for the company's portfolio of peptide based medicines and a positive financial net result of DKK 29/EUR 4 million.

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

*“In the first quarter of 2014, Zealand’s financial position has been further strengthened and this is in parallel to important progress in our portfolio of novel peptide medicines. The initiation of the Phase III development program for the LixiLan combination of Lyxumia<sup>®</sup> with Lantus<sup>®</sup> demonstrates a clear path towards regulatory filing for this important diabetes product, expected as early as end 2015. We feel confident that Zealand has a strong basis to support our ongoing and planned pipeline activities.”*

### Financial highlights for the first quarter of 2014

*(Comparative figures for the same period 2013 are shown in brackets)*

- Revenue of DKK 85.0/EUR 11.4 million *(DKK 0.0/EUR 0.0 million)*.
- Net operating expenses of DKK 44.9/EUR 6.0 million *(DKK 57.9/EUR 7.8 million)*.
- Net result of DKK 28.8/EUR 3.9 million *(DKK -57.3/EUR -7.7 million)*.
- Earnings per share of DKK 1.27/EUR 0.17 *(DKK -2.53/EUR -0.34)*

- End of period cash and securities of DKK 349.6/EUR 46.9 million (DKK 441.3/EUR 59.2 million).

### **Product and pipeline highlights and status for Q1 2014 and the period thereafter**

#### *Lyxumia® (lixisenatide) – Type 2 diabetes (developed and marketed by Sanofi under a global license agreement)*

- Sales royalties to Zealand in Q1 2014 amounted to DKK 3.8/EUR 0.5 million. Royalties from sales of Lyxumia® outside Germany increased 49% compared to Q4 2013.
- Lyxumia® is now available in a number of countries, including the UK, Italy, Spain, Japan and Mexico, with additional launches expected in 2014. In Germany, Sanofi suspended distribution of Lyxumia® on April 1, 2014 given unsuccessful pricing negotiation with the National Association of Statutory Health Insurance Funds (SpiBu). An arbitration process is ongoing and, after the completion of this process, Sanofi will reassess the situation.
- In the US, Sanofi plans to resubmit a New Drug Application in 2015 after completion of the cardiovascular outcome trial ongoing in the US, named ELIXA

#### *Fixed-ratio combination of Lyxumia® (lixisenatide) and Lantus® (insulin glargine) (LixiLan) – Type 2 diabetes (In Phase III development under license agreement with Sanofi)*

- In January, Sanofi initiated the Phase III clinical development program for the fixed-ratio combination of Lyxumia® with Lantus®, a product that is administered as a single once-daily injection, well within its previous guidance of H1 2014.
- The milestone triggered a payment to Zealand of USD 15 million.
- Under the Phase III program, two trials are currently recruiting patients, investigating the effect of treatment with LixiLan, the fixed-ratio combination of Lyxumia® and Lantus® 1) in 1,125 people with Type 2 diabetes versus treatment with either Lyxumia® or Lantus® alone (LixiLan-O trial) and 2) on HbA1c levels in 700 people with Type 2 diabetes versus treatment with Lantus® alone (LixiLan-L trial).
- A New Drug Application (NDA) for the fixed-ratio combination of Lyxumia® and Lantus® could be submitted by Sanofi in the United States as early as the end of 2015, creating the potential for this product to be the first single injection combination of a GLP-1 receptor agonist and a basal insulin to be launched in the US.

#### *Danegaptide – Ischemic reperfusion injuries (Zealand proprietary product – In Phase II development)*

- Novel Zealand proprietary peptide therapeutic, representing a first-in-class approach for the protection against ischemic reperfusion injuries, an area of high unmet medical need.

- Enrolment and treatment of patients is advancing well in the ongoing Phase II clinical Proof-of-Concept study evaluating the efficacy of danegaptide in the protection of cardiac damage from reperfusion injuries in patients following an acute myocardial infarction. The trial is planned to enroll 600 patients, and the first 100 patients have now been enrolled and treated, which is ahead of the expected time plan.

*Elsiglutide – Prevention of chemotherapy-induced diarrhea (In partnership with Helsinn – In Phase II development)*

- Elsiglutide represents a novel therapeutic approach, addressing a major unmet medical need in cancer therapy.
- Our partner Helsinn is preparing for the planned start of a Phase IIb trial in H2 2014 with results expected in 2015.

*Boehringer Ingelheim glucagon/GLP-1 collaboration and ZP2929 (In Phase I development – Type 2 diabetes and/or obesity)*

- In January 2014, Zealand and Boehringer Ingelheim announced a change to the development program that relates to their collaboration on novel dual-acting glucagon/GLP-1 receptor agonists. With financial terms unchanged, Boehringer Ingelheim is working to select a new lead candidate from among the compounds identified under the research part of the collaboration, which lapsed mid-2013.
- As part of the change, Zealand has taken control of the development of ZP2929 and the continued program is undergoing strategic review, including planned FDA interaction.

*Other preclinical activities are also progressing well*

These include the preclinical development of Zealand's novel glucagon analogue and the collaboration with Eli Lilly to design and develop novel therapeutic peptides for Type 2 diabetes and obesity.

**Financial outlook for 2014 unchanged**

Zealand maintains its financial outlook for 2014 as announced in the Full Year announcement and Annual Report for 2013 on 20 March 2014 (Company Announcement No.4/2014).

In 2014, the company expects to receive revenue from milestone payments and royalties on Lyxumia<sup>®</sup> sales.

Expected milestone payments amount to DKK 96 (EUR 13) million, including DKK 81 (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<sup>®</sup> sales in 2014.

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

**\* \* \***

**For further information, please contact:**

David Solomon, President and Chief Executive Officer  
Tel: +45 22 20 63 00

Hanne Leth Hillman, Vice President,  
Head of Investor Relations & Corporate Communications  
Tel: +45 50 60 36 89, 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 has leading expertise in the discovery, design and development of novel peptide medicines and a mature portfolio of therapeutic products, which are all based on internal inventions. The company's focus lies in the field of cardio-metabolic diseases, diabetes and obesity in particular, and its lead product is lixisenatide, a once-daily prandial GLP-1 agonist for the treatment of Type 2 diabetes, marketed as Lyxumia<sup>®</sup> under a license agreement with Sanofi. Lyxumia<sup>®</sup> is approved in several countries globally, including Europe and Japan. In the US, submission of an NDA is expected in 2015, after completion of a cardiovascular outcome study, ELIXA. A once-daily single injection combination of Lyxumia<sup>®</sup> and Lantus<sup>®</sup> (LixiLan) is in Phase III development with planned first regulatory filing in end 2015.

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: [www.zealandpharma.com](http://www.zealandpharma.com)

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## Key figures for the group

The Board of Directors and Executive Management have approved this interim report containing condensed financial information for the first three months of 2014 ending 31 March 2014. The report is prepared in accordance with IAS 34 as endorsed by the EU and the additional Danish disclosure requirements for listed companies. The accounting principles are unchanged in the three months of 2014 and reference is made to the Annual Report 2013 for a more detailed description of the accounting policies.

DKK thousand		2014	2013	2013
INCOME STATEMENT AND		1.1 - 31.3	1.1 - 31.3	1.1 - 31.12
COMPREHENSIVE INCOME	Note	Q1	Q1	Full year
Revenue		84,997	0	6,574
Royalty expenses		-11,474	0	-872
<b>Gross profit</b>		<b>73,523</b>	<b>0</b>	<b>5,702</b>
Research and development expenses		-36,926	-54,258	-164,467
Administrative expenses		-7,989	-7,053	-34,155
Other operating income		0	3,395	7,302
<b>Operating result</b>		<b>28,608</b>	<b>-57,916</b>	<b>-185,618</b>
Net financial items		242	589	1,942
<b>Net result for the period (after tax)</b>		<b>28,850</b>	<b>-57,327</b>	<b>-183,676</b>
<b>Comprehensive income for the period</b>		<b>28,850</b>	<b>-57,327</b>	<b>-183,676</b>
Earnings per share - basic (DKK)		1.27	-2.53	-8.10
Earnings per share - diluted (DKK)		1.27	-2.52	-8.10
<b>STATEMENT OF FINANCIAL POSITION</b>				
Cash and cash equivalents		349,648	363,343	286,178
Securities		0	77,955	24,383
<b>Total assets</b>		<b>381,662</b>	<b>470,961</b>	<b>346,913</b>
Share capital ('000 shares)		23,193	23,193	23,193
<b>Shareholder's equity</b>		<b>344,991</b>	<b>442,554</b>	<b>316,141</b>
Equity / assets ratio		0.90	0.94	0.91
<b>CASH FLOW</b>				
Depreciation		1,520	1,486	5,911
Change in working capital		9,562	1,023	-3,643
Purchase of property, plant and equipment		-1,683	-598	-4,569
Free cash flow	1	39,124	-44,306	-174,187
<b>OTHER</b>				
Share price (DKK)		69.00	81.50	59.00
Market capitalization (MDKK)		1,600,317	1,890,230	1,368,387
Equity per share (DKK)	2	15.25	19.56	13.97
Avg. number of employees (full-time equivalents)		90	109	111
Products on the marked		1	0	1
Compounds in clinical development (end period)		6	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



## Financial Review for the first quarter of 2014

*(Comparative figures for the same period 2013 are shown in brackets)*

### Income statement

The net result for the first three months of 2014 was a profit of DKK 28.8 million compared to a loss of DKK 57.3 million for the same period of 2013. The increase in net result is a consequence mainly of a milestone payment received by Zealand in Q1 2013 under the license agreements with Sanofi, while no milestone payments were received in Q1 2013. Further, net operating expenses were lower during the first three months of 2014 compared to the same period of 2013.

### Revenue

In January, Sanofi commenced the LixiLan Phase III clinical development program for the fixed-ratio single injection combination of Lyxumia<sup>®</sup> with Lantus, which triggered a milestone payment of DKK 81.2 million (USD 15 million) to Zealand. In addition Zealand received DKK 3.8 million in royalty revenue on Sanofi's sales of Lyxumia<sup>®</sup> in the first quarter of 2014.

### Royalty expenses

Royalty expenses for the period was DKK 11.5 million (0.0).

### Research and development expenses

Research and development expenses amounted to DKK 36.9 million (54.3) which was in line with expectations. The decrease of DKK 16.4 million compared to 2013 is due to non-recurring costs in 2013 for warrant programs and severance costs of DKK 12.1 million and other one-time costs of DKK 1.3 million. In addition other research and development costs are down DKK 2.1 million.

### Administrative expenses

Administrative expenses for the period amounted to DKK 8.0 million (7.1). The increase is related to an increase in consultancy costs and a change in the allocation of common costs.

### Other operating income

Other operating income for the period amounted to DKK 0.0 million (3.4). Other operating income has mainly consisted of funding of development costs for ZP2929 and research costs under the collaboration with Boehringer Ingelheim. As a consequence of an announced change in the development program, the continued development of ZP2929 is now under Zealand's control outside the collaboration, and therefore no other operating income was registered for the period.

### Operating result

The operating result for the period was a profit of DKK 28.6 million (-57.9).

### Net financial items

Net financial items consist of interest income, banking fees and regulations based on changes in exchange rates. Net financial items for the first three months of 2014 amounted to DKK 0.2 million (0.6).

**Result from ordinary activities before tax**

Result from ordinary activities before tax in the period came to DKK 28.8 million (-57.3).

**Tax on ordinary activities**

No tax on the result from ordinary activities has been recorded since Zealand offsets any tax through tax losses carried forward from previous years.

No deferred tax asset has been recognized in the statement of financial position due to uncertainty as to whether tax losses can be utilized.

**Net result**

Net result for the first three months of 2014 amounted to DKK 28.8 million (-57.3).

**Equity**

Equity stood at DKK 345.0 million (442.6) at the end of the period, corresponding to an equity ratio of 90 % (94).

**Capital expenditure**

Investments in new laboratory equipment for the period amounted to DKK 1.7 million (0.6).

**Cash flow**

Cash flow from operating activities amounted to DKK 40.8 million (-43.7), and cash flow from investing activities to DKK 22.6 million (47.9) of which DKK 24.4 million (48.5) relates to sale of securities. The total cash flow for the first three months of 2014 amounted to DKK 63.4 million (4.2).

**Cash and cash equivalents**

As of 31 March 2014, Zealand had cash and cash equivalents including securities of DKK 349.6 million (441.3).

**Financial outlook for 2014**

Zealand maintains its financial outlook for 2014 as announced in the Full Year announcement and Annual Report for 2013 on 20 March 2014 (Company Announcement No.4/2014).

In 2014, the company expects to receive revenue from milestone payments and royalties on Lyxumia<sup>®</sup> sales.

Expected milestone payments amount to DKK 96 (EUR 13) million, including DKK 81 (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<sup>®</sup> sales in 2014.

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





### **Risk factors**

This interim report contains forward-looking statements, including forecasts of future expenses as well as expected business related events. Such statements are subject to risks and uncertainties as various factors, some of which are beyond the control of Zealand, may cause actual results and performance to differ materially from the forecasts made in this interim report. Without being exhaustive, such factors include e.g. general economic and business conditions, including legal issues, scientific and clinical results, fluctuations in currencies etc. A more extensive description of risk factors can be found in the 2013 Annual Report under the section Risk management and internal control.



## Management's Statements on the Interim Report

The Board of Directors and the Executive Management have today considered and adopted the interim report of Zealand Pharma A/S for the period 1 January – 31 March 2014. The interim report has not been audited or reviewed by the company's auditor.

The report is prepared in accordance with IAS 34 as endorsed by the EU and the additional Danish disclosure requirements for listed companies. The accounting principles are unchanged in the first three months of 2014 and reference is made to the Annual Report 2013 for a more detailed description of the accounting policies.

In our opinion, the interim report gives a true and fair view of the Group's assets, equity and liabilities and financial position at 31 March 2014 and of the results of the Group's operations and the Group's cash flows for the period 1 January – 31 March 2014.

Moreover, in our opinion, the Management's Review gives a true and fair view of the development in the company's operations and financial conditions, of the net result for the period and the financial position while also describing the most significant risks and uncertainty factors that may affect the Group.

*Copenhagen, 29 April 2014*

## Executive Management

David H. Solomon	Mats Blom
President and CEO	Senior Vice President and CFO

## Board of Directors

Daniël J. Ellens Chairman	Jørgen Lindegaard Vice chairman	Peter Benson
Alain Munoz	Florian Reinaud	Jutta af Rosenborg
Michael Owen	Christian Thorkildsen	Helle Størum
Hanne Heidenheim Bak		



		2014	2013	2013
<b>INCOME STATEMENT (DKK '000)</b>	<b>Note</b>	<b>Q1</b>	<b>Q1</b>	<b>Full year</b>
Revenue		84,997	0	6,574
Royalty expenses		-11,474	0	-872
<b>Gross profit</b>		<b>73,523</b>	<b>0</b>	<b>5,702</b>
Research and development expenses		-36,926	-54,258	-164,467
Administrative expenses		-7,989	-7,053	-34,155
Other operating income		0	3,395	7,302
<b>Operating result</b>		<b>28,608</b>	<b>-57,916</b>	<b>-185,618</b>
Financial income		255	1,054	3,185
Financial expenses		-13	-465	-1,243
<b>Result from ordinary activities before tax</b>		<b>28,850</b>	<b>-57,327</b>	<b>-183,676</b>
Tax on ordinary activities		0	0	0
<b>Net result for the period</b>		<b>28,850</b>	<b>-57,327</b>	<b>-183,676</b>
<b>Comprehensive income for the period</b>		<b>28,850</b>	<b>-57,327</b>	<b>-183,676</b>
Earnings per share - basic (DKK)		1.13	-2.53	-8.10
Earnings per share - diluted (DKK)		1.13	-2.52	-8.10
		<b>2014</b>	<b>2013</b>	<b>2013</b>
				<b>31</b>
<b>STATEMENT OF FINANCIAL POSITION (DKK '000)</b>	<b>Note</b>	<b>31 March</b>	<b>31 March</b>	<b>December</b>
<b>ASSETS</b>				
Plant and machinery		18,411	17,907	16,014
Other fixtures and fittings, tools and equipment		370	636	409
Leasehold improvements		1,444	1,973	1,459
Fixed assets under construction		0	0	2,180
Deposits		2,645	2,553	2,570
<b>Noncurrent assets total</b>		<b>22,870</b>	<b>23,069</b>	<b>22,632</b>
Trade receivables		11	11	11
Prepaid expenses		3,576	5,085	3,642
Other receivables		5,557	1,498	10,067
Securities		0	77,955	24,383
Cash and cash equivalents		349,648	363,343	286,178
<b>Current assets total</b>		<b>358,792</b>	<b>447,892</b>	<b>324,281</b>
<b>Total assets</b>		<b>381,662</b>	<b>470,961</b>	<b>346,913</b>
<b>LIABILITIES AND EQUITY</b>				
Share capital		23,193	23,193	23,193
Retained earnings		321,798	419,361	292,948
<b>Equity total</b>		<b>344,991</b>	<b>442,554</b>	<b>316,141</b>
Trade payables		8,276	7,696	13,376
Prepayment from customers		2,672	3,510	2,329
Other liabilities		25,723	17,201	15,067
<b>Current liabilities</b>		<b>36,671</b>	<b>28,407</b>	<b>30,772</b>
<b>Total liabilities</b>		<b>36,671</b>	<b>28,407</b>	<b>30,772</b>
<b>Total equity and liability</b>		<b>381,662</b>	<b>470,961</b>	<b>346,913</b>



	2014 Q1	2013 Q1	2013 Full Year
<b>STATEMENT OF CASH FLOWS (DKK '000)</b>			
Net result for the period	28,850	-57,327	-183,676
Adjustments	1,316	9,764	12,912
Change in working capital	9,562	1,023	-3,643
<b>Cash flow from operating activities before financing items</b>	<b>39,728</b>	<b>-46,540</b>	<b>-174,407</b>
Financial income received	1,092	2,855	4,870
Financial expenses paid	-13	-23	-81
<b>Cash flow from operating activities</b>	<b>40,807</b>	<b>-43,708</b>	<b>-169,618</b>
Change in deposit	-75	0	-17
Purchase of property, plant and equipment	-1,683	-598	-4,569
Purchase of securities	0	-41,704	-47,356
Disposal of securities	24,383	90,246	148,750
<b>Cash flow from investing activities</b>	<b>22,625</b>	<b>47,944</b>	<b>96,808</b>
<b>Cash flow from financing activities</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>Decrease / increase in cash and cash equivalents</b>	<b>63,432</b>	<b>4,236</b>	<b>-72,810</b>
Cash and cash equivalents at beginning of period	286,178	358,847	358,847
Exchange rate adjustments	38	260	141
<b>Cash and cash equivalents at end of period</b>	<b>349,648</b>	<b>363,343</b>	<b>286,178</b>

Note:

Exchange rate adjustments for Q1 and Full Year 2013 include DKK 75t relating to the subsidiary Betacure, merged into Zealand Pharma A/S as of 1 January 2013

	Share capital	Retained earnings	Total
<b>STATEMENT OF CHANGES IN EQUITY (DKK '000)</b>			
<b>Equity at 1 January 2014</b>	<b>23,193</b>	<b>292,948</b>	<b>316,141</b>
Comprehensive income for the period	0	28,850	28,850
<b>Equity at 31 March 2014</b>	<b>23,193</b>	<b>321,798</b>	<b>344,991</b>
<b>Equity at 1 January 2013</b>	<b>23,193</b>	<b>467,822</b>	<b>491,015</b>
Warrants compensation expenses	0	8,866	8,866
Comprehensive income for the period	0	-57,327	-57,327
<b>Equity at 31 March 2013</b>	<b>23,193</b>	<b>419,361</b>	<b>442,554</b>
<b>Changes in share capital</b>			
<b>Share capital at 31 December 2006</b>			<b>17,682</b>
Capital increase at 23 November 2010			4,337
Capital increase at 9 December 2010			852
Capital increase at 12 December 2011			322
<b>Share capital at 31 December 2013</b>			<b>23,193</b>
<b>Share capital at 31 March 2014</b>			<b>23,193</b>