

# Interim report January-March 2014

Unless otherwise stated in this report, all data refers to the Group. Figures in parentheses relate to the corresponding period in 2013.

# Zubsolv®, now with broader market access

#### First quarter 2014

- Total net revenues amounted to MSEK 101.9 (139.8). Revenues from launched products, excluding one-off milestone, amounted to MSEK 101.9 (72.1).
- Earnings after tax were MSEK -21.1 (27.5).
- Earnings per share were SEK -0.66 (0.95).
- Cash flow from operating activities amounted to MSEK -99.7 (-5.0).
- Cash and cash equivalents amounted to MSEK 30.7 (218.9) before non-utilized credit facilities of MSEK 105.
- Reimbursement agreement for Zubsolv signed with UnitedHealth Group and OptumRx.

#### After the period

 Orexo has engaged Pareto Securities to investigate the market regarding issuance of a corporate bond. Proceeds would be used to finance the continued development and commercialization of Zubsolv and to reduce the existing bank debt.

MSEK	2014	2013	2013
	Jan-Mar	Jan-Mar	Jan-Dec
Net revenues	101.9	139.8	429.4
Revenues from launched products	101.9	136.4	421.6
EBIT	-16.2	30.2	-139.7
EBITDA	-13.7	31.5	-89.1
Earnings after tax	-21.1	27.5	-154.9
Earnings per share, SEK	-0.66	0.95	-5.16
Cash flow from operating activities	-99.7	-5.0	-265.8
Cash and cash equivalents	30.7	218.9	105.6

#### Teleconference

CEO Nikolaj Sørensen and CFO Henrik Juuel will present the report at a teleconference today on two occasions:

#### 9:00am CET

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### 2:00pm CET

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# CEO's comments

During the quarter, Orexo's focus has been to continue to improve the reimbursement status of Zubsolv. I am pleased to see that our dedication and efforts continue to pay off, with the announcement of an exclusive agreement with the largest insurance company in the USA, UnitedHealth Group. This agreement makes Zubsolv the only buprenorphine/naloxone product available to patients within UnitedHealth Group's highly controlled plans.

During the quarter, sales of Zubsolv doubled compared to the end of 2013, as a result of the brand exclusivity agreement with CVS Caremark and Medimpact. With this improved reimbursement, level we restricted the terms of the patient support program in order to increase the profitability of each prescription. As a result, the number of tablets per script nearly doubled within a few weeks, which temporarily slowed the growth of prescriptions week on week, but had a very positive impact on sales.

Improving reimbursement is currently the single most important commercial initiative to reach more patients. Zubsolv is clearly benefiting from being reimbursed in parity with or better than our competitors and we continue to work intensively to improve this position further. In addition to UnitedHealth Group, we have during the period either signed agreements or secured reimbursement improvements with several regional plans where Zubsolv has not previously been reimbursed. For example these plans cover patients located in the metro-Philadelphia area, Pittsburgh vicinity and across Ohio. The regional plans are, on a nationwide scale, smaller but they are critical to gain market leadership in high value concentrated U.S. geographies. The improvement of regional coverage will continue during the second quarter and I expect that this will start to have an effect on sales from late in the second quarter, in parallel with the agreement with UnitedHealth Group.

As a result of what we have learned during the initial launch period, the sales force has been restructured during the first quarter. We have increased the number of representatives in some areas with good market access, and replaced a part of the sales force with representatives having a higher competency and experience profile relative to the addiction specialty field. This restructuring has led to a typical disruption in sales force performance, but we have also experienced territories where sales representatives with a consistent visit frequency and selling approach in their calls clearly are achieving better results. Therefore, we are monitoring and working closely with our partner Publicis Touchpoint Solutions to improve the sales force performance and ability to impact prescriptions.

We continue to work hard to strengthen the differentiation of Zubsolv, and the three new clinical studies ongoing are expected to improve our dialogue with prescribers and increase confidence in Zubsolv and Orexo as the first results become available this summer. We are also working intensively to broaden our dosage range offerings.

Zubsolv is still in a launch mode and I expect the sales development to improve in a stepwise fashion as reimbursement improves and as the results of our clinical trials become available. We are well on track to reach our competitive reimbursement target level for Zubsolv. I am optimistic that this together with our highly dedicated US and SE organization, will enhance the conditions for strong sales growth in 2014.

Nikolaj Sørensen President and CEO

# Operations

# **Launched products**

# Zubsolv® - treatment of opioid dependence

The market for Zubsolv (buprenorphine/naloxone) continued to grow throughout the first quarter by 10% in volume (prescriptions). The changes in insurance coverage due to the Affordable Care Act are expected to have a positive impact on market volumes, when more patients have access to insurance coverage. Also, large opioid addiction clinics are being established in several areas, which is likely to improve the professionalism of the opioid addiction treatment, as the current prescribers and physicians come with a wide disparity of backgrounds and mostly operate out of small independent clinics. This change is also likely to improve patient access to treatment and support long-term growth in opioid dependence treatment.

Zubsolv tablet sales grew in the first quarter by 145% compared to the last quarter of 2013. A main driver of the growth was the agreement with CVS Caremark, which increased the share of patients with commercial insurance. An important factor in driving profitability has been to increase the number of tablets per prescription and Orexo decided to restrict the co-pay support program at the end of 2013 to facilitate larger prescriptions. The number of tablets per script has increased from about 16 at the end of 2013 to more than 27 during the first quarter of 2014, driving sales both in terms of dollars and the number of tablets sold. Both grew 22% comparing the first four full weeks of the quarter with the last four weeks in 2013. In comparison, prescriptions grew by 7% in the same period.

A focus for the quarter was to continue to improve the market access position. Orexo reached an agreement with UnitedHealth Group and Zubsolv was moved from non-covered to Tier 2 coverage at the beginning of April and will progress to Tier 1 for patients in highly controlled plans on July 1. Additionally, as of July 1, in these highly controlled plans Zubsolv will be the only buprenorphine/naloxone product covered for these patients. UnitedHealth Group was the last holdout of the leading commercial health plans to start reimbursing Zubsolv. A similar agreement has been reached with Keystone First, a managed Medicaid health plan in the metropolitan Philadelphia area, and their patients will be moved to Zubsolv over the coming months, as their prior authorization for receiving treatment is renewed. Progress to gain parity reimbursement is proceeding according to plan. Several additional regional public plans in Texas, Massachusetts, Pennsylvania and Ohio have also provided Zubsolv improved reimbursement during the quarter. Another positive development for improved access occurred with a recent legislative change in West Virginia, where Zubsolv will be allowed to be dispensed from June 5. Currently, only the competing Film formulation has been allowed at the retail pharmacies, since the Film was the only product in a unit dose child resistant package prior to Zubsolv approval.

During the period, the life cycle program continued to progress according to plan and the last patients were recruited in two of the three ongoing clinical trials. We expect to report the outcomes of these studies during the summer. These studies are expected to enable a stronger differentiation of Zubsolv and if positive will be the first patient studies completed with Zubsolv, which will significantly enhance our message and position with both payers and prescribers.

#### Abstral<sup>®</sup>

In Europe, sales continued to develop positively in the first quarter, with strong growth compared to the first quarter of 2013. In particular, Spain continues to develop positively and reached high sales levels. If the current trend continues, Orexo is likely to receive royalties on sales exceeding MEUR 42.5 from late Q3 and for the full fourth quarter of 2014.

The US market for fentanyl based products for breakthrough pain has increased to approximately MUSD 400. Net sales of Abstral have gone off with a successful launch in the US. Sales reached MUSD 1.3 in the fourth quarter compared to total net sales of MUSD 2.7 for the entire 2013. The publicly available data for Abstral indicate continued strong development during Q1, but Orexo has not yet received final sales data for the first quarter from the commercial partner in the USA, Galena Biopharma Inc. During the first quarter, Galena Biopharma has increased the forecast for the year to MUSD 11-15 from MUSD 8-12, confirming positive development.

The launch of Abstral in Japan has been successful. Abstral was the second to launch about 3 months after the competing rapid-acting fentanyl products and since launch, Abstral has penetrated the market steadily. The Japanese rapid acting fentanyl market is still underdeveloped, hence our commercial partner Kyowa Hakko Kirin is now focusing on growing the market.

#### **Edluar®**

Royalty from Edluar recognized in the period amounted to MSEK 4, of which MSEK 1 relates to a positive adjustment of the royalty estimate included in the Q4 2013 report and the remaining MSEK 3 is the estimated royalty for Q1 2014. With the final 2013 numbers available, Edluar delivered solid sales growth of 66% in 2013 versus previous years.

#### Kibion - diagnosis of Helicobacter Pylori

During 2013, Kibion streamlined its operations by restructuring the distributor network in the Middle East and Northern Africa leading to fewer and larger distributors. They have committed additional investments to the commercialization of Kibion's products. Kibion sales during the period were MSEK 7.4 (10.5). The decline was primarily caused by temporary market access restrictions in a few key markets.

#### **Development programs**

### OX51 – prevention of acute episodes of intense pain

OX51 is a new sublingual formulation containing alfentanil. The project has been developed to meet the rapidly growing demand for effective pain relief during short surgical and invasive procedures.

A dose-finding study was completed in June 2013 on patients undergoing prostate biopsies. The primary aim of the study to demonstrate an anesthetic effect in connection with the procedure was achieved. The placebo-controlled study, in which three different sublingual doses of OX51 and placebo were studied, showed a statistically significant dose response with regard to maximum pain experienced during the procedure. Treatment with OX51 was safe and well tolerated in all dose groups. Furthermore, OX51 did not display any sedative effect or drowsiness compared with placebo.

Orexo has decided to wait further development due to the complete business focus and priority on the Zubsolv launch and its life cycle management.

# **Collaboration projects**

### OX-MPI – PGE2-inhibition (Prostaglandin E2)

The aim is to develop a completely new pharmaceutical class based on Orexo's prostaglandin research. The OX-MPI project is in a preclinical phase and evaluation of potential clinical strategies is ongoing. Boehringer Ingelheim has sole responsibility for all research and development and commercialization of future products. If the project is successful, Boehringer Ingelheim will make payments to Orexo as and when certain milestones are achieved. In addition to this, royalty is to be paid on future sales.

### **OX-CLI - respiratory tract diseases**

Orexo entered into a collaboration agreement with AstraZeneca in January 2013 regarding OX-CLI, a preclinical program for potential new treatment of respiratory tract diseases. Under the agreement AstraZeneca gains the rights to perform extensive preclinical research and evaluation of substances in Orexo's OX-CLI program. AstraZeneca also has an option to acquire all substances linked to the program. Transfer and a licensing agreement will then be agreed on by the parties, whereby Orexo will receive milestone payments during the development phase and royalty payments based on future revenues. AstraZeneca is responsible for all development costs for the project.

# The interim period January-March in figures

#### Revenues

#### **Launched products**

Total revenues from Orexo's launched products amounted to MSEK 101.9 (136.4) during the period January-March 2014. The first quarter of 2013 included revenues of MSEK 64.3 related to the milestone payment from Abstral® in the US. Excluding the one-off milestone, revenues from launched products increased by 41 percent in the first quarter compared to the same quarter last year (MSEK 101.9 versus MSEK 72.1).

For Zubsolv, a cautious and customary accounting approach for newly launched products in the US was applied and only revenues corresponding to patient prescriptions were recognized in the quarter. This amounted to MSEK 32.6.

Royalty revenues from Edluar® amounted to MSEK 4.0 (1.8) during the period. MSEK 1 of these relates to a positive adjustment of the royalty estimate included in the Q4 2013 report and the remaining MSEK 3 is the estimated royalty for Q1 2014.

Kibion's sales during the period were MSEK 7.4 (10.5). The decline in revenue is primarily explained by temporary market access restrictions on key markets, which is expected to be solved within the coming quarter, as well as by a decrease in reimbursement for breath tests in Turkey.

# Revenues related to development projects

There were no revenues related to development projects during the period January-March 2014. During the first quarter of 2013, there were revenues related to approval of Abstral in Japan amounting to MSEK 3.4.

#### **Total revenues**

Total revenues during the period amounted to MSEK 101.9 (139.8), a decrease of 27 percent. Excluding the MSEK 64.3 one-off milestone payment from Abstral in Q1 2013 the increase in total revenues was 35%.

#### Total net revenues were distributed as follows:

MSEK	Jan-Mar	Jan-Mar	Jan-Dec
	2014	2013	2013
Abstral royalties	57.9	59.8	246.0
Milestone payment Abstral	-	64.3	110.8
Edluar royalties	4.0	1.8	8.7
Zubsolv	32.6	-	7.3
Kibion	7.4	10.5	48.8
Total revenue from launched products	101.9	136.4	421.6
Partner-financed R&D costs	-	1.8	6.2
Licensing revenue for development projects	-	1.6	1.6
Total	101.9	139.8	429.4

#### Costs and earnings

#### Cost of goods sold

Cost of goods sold amounted to MSEK 16.8 (6.9) for the period January-March 2014.

#### Selling expenses

Selling expenses amounted to MSEK 29.4 (18.9) for the period January-March 2014. The increase is driven by the commercialization of Zubsolv in the US. Costs related to the field force in the US are covered by Publicis Touchpoint Solutions in line with the agreement.

#### Administrative expenses

Administrative expenses for the period January-March 2014 amounted to MSEK 24.8 (34.6). The lower costs are primarily explained by non-recurring expenses regarding sales of Abstral® in the US during the period January-March 2013.

#### Research and development costs

For the period January-March 2014, research and development costs amounted to MSEK 47.9 (46.6). The costs are mostly attributable to activities related to clinical studies in the Zubsolv® program. During the first quarter of 2014, clinical studies were capitalized amounting to MSEK 38.7, which means that the total research and development spend for the period January-March amounted to MSEK 86.6.

#### Costs for long-term incentive program

The Group's total costs for employee stock options programs during the period January-March 2014 amounted to MSEK -5.7 (2.6). The negative costs are due to reduced provisions for social security fees due to the Orexo share price development.

# Other income and expenses

Other income and expenses amounted to MSEK 0.8 (-2.5) during the period January-March 2014. Other income and expenses primarily comprised exchange-rate gains/losses.

#### Depreciation

Depreciation and amortization amounted to MSEK 2.5 (1.3) for the period January-March 2014.

#### Net financial items

Net financial items for the period January-March 2014 amounted to MSEK -3.9 (-2.7). Net financial items include expenses related to financing activities amounting to MSEK 1.9.

#### **Earnings**

Operating earnings amounted to MSEK -21.1 (27.5) for the period January-March 2014.

# Cash-flow and financial position

At March 31, 2014, cash and cash equivalents amounted to MSEK 30.7 (218.9) and interest-bearing liabilities to MSEK 306.2 (113.9).

A non-utilized credit facility of MSEK 105 is available with Danske Bank.

Cash flow from operating activities for the period January-March 2014 was MSEK -99.7 (-5.0).

Shareholders' equity at March 31, 2014, was MSEK 144.0 (236.9). The equity/assets ratio was 19 (47) percent. The royalty payment in accordance with the Abstral agreement, which has been received but not

yet recognized as revenue, has affected the equity/assets ratio negatively by approximately 5 percentage points.

With the cash position, available facilities, the value of the company's own shares and significant assets on the balance sheet such as receivables and inventories, Orexo is in a financially sound position to pursue the commercial opportunity with Zubsolv in the US. In order to take advantage of currently attractive financial markets, Orexo has engaged Pareto Securities to investigate the market regarding issuance of a corporate bond. The proceeds would be used to reduce the existing bank debt and to finance the continued development and commercialization of Zubsolv.

#### **Investments in fixed assets**

Gross investments in tangible and intangible fixed assets amounted to MSEK 40.6 (5.1) for the period January-March, 2014. The increase in investments comes from the capitalization of clinical studies during the first quarter amounting to MSEK 38.7.

### **Parent Company**

Net revenues for the period January-March 2014 amounted to MSEK 62.9 (129.4). Earnings after financial items were MSEK -24.3 (27.7). Investments amounted to MSEK 1.7 (5.1). As of March 31, 2014, cash and cash equivalents in the Parent Company amounted to MSEK 7.9 (200.5).

#### Risks and uncertainty factors

Significant risks and uncertainties are presented in the Annual Report for 2013. The overall risk has decreased since the approval of Zubsolv in July 2013. However, the launch of Zubsolv in the US will entail risk exposure of a more operational nature.

# **Future reporting dates**

Interim report, January – June 2014	July 11, 2014
Interim report, January – September 2014	October 22, 2014
Year-end report for the 2014 financial year	January 29, 2015

Interim reports are covered in a conference call on the date of publication. Details on how to access the calls are provided in each report and on Orexo's website.

Uppsala, April 25, 2014

Orexo AB (publ)

Nikolaj Sørensen President and CEO

# Consolidated statement of operations

MSEK				
	Notes	2014	2013	2013
		Jan-Mar	Jan-Mar	Jan-Dec
National		101.0	120.0	420.4
Net revenues		101.9	139.8	429.4
Cost of goods sold	2	-16.8	-6.9	-29.3
Gross profit		85.1	132.9	400.1
Selling expenses	2	-29.4	-18.9	-125.1
Administrative expenses	2	-24.8	-34.6	-126.4
Research and development costs	2	-47.9	-46.6	-238.2
Other operating income and				
expenses	2	0.8	-2.5	-50.1
Operating earnings		-16.2	30.2	-139.7
Net financial items		-3.9	-2.7	-13.7
Earnings before tax		-20.1	27.5	-153.4
Tax		-1.0	_	-1.5
Tun		-1.0		-1.5
Net earnings for the period 1)		-21.1	27.5	-154.9

# Consolidated statement of comprehensive income

MSEK	2014	2013	2013
	Jan-Mar	Jan-Mar	Jan-Dec
Earnings for the period	-21.1	27.5	-154.9
Other comprehensive income			
Items that may subsequently be reversed to the statement of operations:			
Cash flow hedge	-	16.3	-8.7
Exchange-rate differences  Other comprehensive earnings for the period,	0.1	-0.9	-1.9
net after tax	0.1	15.4	-10.6
Total comprehensive earnings for the period $^{1)}$	-21.0	42.9	-165.5
Earnings per share, before		1	
dilution, SEK	-0.66	0.95	-5.16
Earnings per share, after			
dilution, SEK	-0.66	0.86	-5.16

<sup>&</sup>lt;sup>1)</sup> All equity and earnings for the respective period are attributable to the Parent Company's shareholders. There are no non-controlling interests.

# Consolidated balance sheet

MSEK	Notes	2014 Mar 31	2013 Mar 31	2013 Dec 31
ASSETS				
Fixed assets				
Tangible fixed assets		32.3	33.5	33.3
Goodwill		26.4	25.3	26.4
Acquired research and development		62.3	106.2	62.4
Other intangible fixed assets		144.8	8.7	106.0
Financial assets		205.0	39.4	220.0
Total fixed assets		265.8	213.1	228.0
Current assets				
Inventories		393.2	41.6	383.4
Accounts receivable and other receivables		54.4	29.1	55.2
Cash and cash equivalents		30.7	218.9	105.6
Total current assets		478.3	289.6	544.3
Total assets		744.1	502.8	772.3
SHAREHOLDERS' EQUITY AND LIABILITIES				
Total shareholders' equity	3	144.0	236.9	161.5
Long-term liabilities				
Provisions		7.4	5.7	9.6
Long-term liabilities, non-interest bearing		-	3.9	-
Long-term liabilities, interest bearing		103.5	102.9	104.1
Deferred tax liability		-	8.7	-
Total long-term liabilities		110.9	121.2	113.7
Current liabilities				
Current liabilities, non-interest bearing		286.5	133.6	360.1
Current liabilities, interest bearing		202.7	11.1	137.0
Total current liabilities		489.2	144.7	497.1
Total liabilities		600.1	265.9	610.8
Total shareholders' equity and liabilities		744.1	502.8	772.3
Consolidated changes in shareh	olders' equity			
MSEK		2014	2013	2013
		Mar 31	Mar 31	31 dec
Opening balance, shareholders' equity		161.5	191.2	191.2
Total comprehensive earnings for the period		-21.0	42.9	-165.5
Employee stock options, vested amount		2.3	0.7	3.5
Buyback of shares		-	-	-
New share issues		1.2	2.1	19.4
Conversion of convertible bonds		-	-	112.9
Closing balance, shareholders' equity		144.0	236.9	161.5

# Consolidated cash-flow statements

MSEK	Notes	2014 Jan-Mar	2013 Jan-Mar	2013 Jan-Dec
Operating earnings		-16.2	30.2	-139.7
Financial income and expenses		-4.2	-1.9	-11.6
Adjustment for non-cash items	4	-3.2	3.1	86.9
Cash flow from operating activities before changes in				
working capital		-23.6	31.4	-64.4
Changes in working capital		-76.1	-36.4	-201.4
Cash flow from operating activities		-99.7	-5.0	-265.8
Acquisition of tangible and intangible fixed assets Sale of machinery and		-40.6	-5.1	-107.5
equipment  Cash flow from investing		-	0.1	-
activities		-40.6	-5.0	-107.5
New share issue		1.2	2.1	19.4
Change in loans		64.4	-0.6	234.2
Cash flow from financing activities		65.6	1.5	253.6
Cash flow for the period		-74.7	-8.5	-119.7
Cash and cash equivalents at				
the beginning of the period		105.6	228.1	228.1
Exchange-rate differences in				
cash and cash equivalents Changes in cash and cash		-0.2	-0.7	-2.8
equivalents		-74.7	-8.5	-119.7
Cash and cash equivalents at				
the end of the period		30.7	218.9	105.6

# Key figures

	2014 Jan-Mar	2013 Jan-Mar	2013 Jan-Dec
Operating margin, %	-16	22	-32
Return on equity, %	-15	14	-88
Net debt, MSEK	275.5	-104.9	-135.4
Debt/equity ratio, %	212.6	48	154
Equity/assets ratio, %	19	47	21
Number of shares, before dilution	31,817,609	28,881,458	31,790,784
Number of shares, after dilution	32,769,541	31,792,173	32,976,554
Earnings per share, before dilution, SEK	-0.66	0.95	-5.16
Earnings per share, after dilution, SEK	-0.66	0.86	-5.16
Number of employees at the end of the period	106	90	108
Shareholders' equity, KSEK	143,961	236,893	161,459
Capital employed, KSEK	450,169	350,829	402,533

Definitions of key figures are presented on the final page of this report.

# Parent Company statement of operations

MSEK	Notes	2014 Jan-Mar	2013 Jan-Mar	2013 Jan-Dec
Net revenues		62.9	129.4	452.3
Cost of goods sold		-4.3	-1.7	-91.4
Gross profit		58.6	127.7	360.9
Selling expenses		-23.5	-14.9	-45.1
Administrative expenses		-16.4	-33.6	-110.0
Research and development costs Other operating income and		-40.3	-45.0	-228.3
expenses		1.1	-2.3	-5.4
Operating earnings		-20.5	31.9	-27.9
Interest income and expenses		-1.9	-2.9	-10.1
Impairment of shares in subsidiaries		-	-1.3	-2.2
Other financial expenses		-1.9	-	-4.1
Net financial items		-3.8	-4.2	-16.4
Earnings before tax		-24.3	27,7	-44.3
Tax		-	-	-1.5
Earnings for the period		-24.3	27.7	-45.8

# Parent Company balance sheet

MSEK	Notes	2014 Mar 31	2013 Mar 31	2013 Dec 31
ASSETS		11101 01	11101 51	20001
Fixed assets				
Tangible and intangible fixed assets Shares in subsidiaries		175.0 202.2	42.1 170.8	137.4 202.2
Total fixed assets		377.2	212.9	339.6
Current assets				
Inventories		308.5	31.0	303.3
Accounts receivable and other receivables  Cash and bank balances		165.5 7.9	56.3 200.5	179.5 48.7
Total current assets		481.9	287.8	531.5
Total assets		859.1	500.7	871.1
SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES				
Shareholders' equity		196.6	157.9	217.4
Long-term liabilities		107.4	103.1	109.7
Current liabilities		555.1	239.7	544.0
Total liabilities		662.5	342.8	653.7
Total shareholders' equity and liabilities		859.1	500.7	871.1
Pledged assets		232.2	43.1	232.2
Contingent liabilities		-	11.2	-

### Notes

#### 1. Accounting policies

- This interim report was prepared pursuant to IAS 34. Orexo applies IFRS as approved by the EU.
- The accounting policies stated below are in line with to those applied in the preparation of the 2013 Annual Report.
- The Parent Company's financial statements were prepared in accordance with RFR 2 (Swedish Financial Reporting Board's recommendation) and Chapter 9 of the Swedish Annual Accounts Act.

# New and amended accounting policies as of 2014

• No new or amended International Financial Reporting Standards have come into effect that have any significant impact on the Group.

#### 2. Costs distributed by type of cost

MSEK	2014 Jan-Mar	2013 Jan-Mar	2013 Jan-Dec
Raw materials and supplies	13.9	7.0	21.8
Other external costs	73.8	71.4	347.8
Personnel costs	30.1	32.4	167.0
Depreciation/amortization and	2.5	1.3	50.1
impairment			
Total	120.3	112.1	586.7

Research and development costs encompass costs for personnel, premises, external costs for clinical trials, pharmaceutical registration and laboratory services, and the depreciation/amortization of equipment, acquired patents and other intangible assets.

# 3. Shareholders' equity

# Shares outstanding

The number of shares outstanding as of March 31, 2014 was 32,938,733, all of which were common shares. All shares carry entitlement to one vote each.

Number of shares outstanding at January 1, 2014	32,911,908
Subscription for shares through exercise of employee stock options	-26,825
Shares outstanding at March 31, 2014	32,938,733

During the period 1,750 employee stock options were exercised. These have not yet been registered as shares.

1,121,124 shares were bought back during 2012. These are included in the total number of shares outstanding and are owned by Orexo.

#### **Options**

As of March 31, 2014, a total of 2,528,127 options were outstanding that carry rights to new subscription of 2,526,520 shares in Orexo and the exchange of 1,607 options for shares in Orexo. Each option issued by Biolipox AB provides entitlement to the exchange of one share in Orexo AB, and a corresponding number of shares are held by the independent company Pyrinox AB.

The list below shows the change in the number of options during the period distributed by category.

Options to employees and Board members	Opening, Jan 1, 2014	Change	Closing, Mar 31, 2014
Of which:			
Approved and allotted employee stock options	1,579,557		1,579,557
Exercised		-25,992	-25,992
Allotted		304,500	304,500
Expired		-92,250	-92,250
Approved and allotted Board options	215,688		215,688
Allotted		-	-
Expired Employee stock options approved by AGM,		-16,666	-16,666
unallotted	829,667	-304,500	525,167
Warrants held by subsidiaries as cash-flow hedging for social security fees	38,123	-	38,123
Total number of options outstanding	2,663,035	-134,908	2,528,127

During the period January-March, a total of 25,075 employee stock options from Orexo's options program were exercised.

Number of shares after full dilution	
Shares outstanding at March 31, 2014	32,938,733 <sup>1)</sup>
Shares not registered	1,750
Employee stock options allotted	1,964,837
Employee stock options not yet allotted	525,167 <sup>2)</sup>
Warrants for cash-flow hedging for social security fees	38,123
	35,468,610

<sup>&</sup>lt;sup>1)</sup> Including 1,121,124 repurchased shares, owned by Orexo.

<sup>&</sup>lt;sup>2)</sup> Can be allotted during the current year.

# 4. Cash flow

# Adjustment for non-cash items

MSEK	2014 Jan-Mar	2013 Jan-Mar	2013 Jan-Dec
Depreciation/amortization and impairment Estimated costs for employee stock	2.5	1.3	50.5
options program	-5.7	2.6	40.0
Financial expenses, convertible bond	-	-0.8	-3.6
Total	-3.2	3.1	86.9

# 5. Pledged assets and contingent liabilities

As the Inflazyme project has been discontinued, the entire supplementary purchase consideration of MSEK 39.4 is recognized as a contingent liability.

Warrants were issued to Pyrinox AB as cash-flow hedging for social security fees pertaining to the employee stock options issued by Biolipox. Orexo has pledged to handle any deficits exceeding the cover provided by the warrants during their lifetime through December 31, 2016.

Orexo acquired the UK drug company PharmaKodex in February 2009. This acquisition included conditional payments based on Orexo's possible use of the PharmaKodex technology in product development. As this has not been the case, these are not recognized as a liability.

Operations in PharmaKodex have been closed down. The acquired technology was written down in its entirety during 2011 and 2012.

Orexo has collateral with Danske Bank comprising chattel mortgages of MSEK 200.

# **Definitions of key figures**

Key figures and certain other operating information per share are defined as follows:

Number of shares after dilution Shares at the end of the period adjusted for the dilutive effect of potential shares.

Return on shareholders'

equity Net earnings for the period as a percentage of average shareholders' equity.

Net debt Current and long-term interest-bearing liabilities including pension liabilities, less cash and

cash equivalents.

Earnings per share, before

dilution

Net earnings for the period after tax divided by the average number of shares outstanding

before dilution during the period.

Earnings per share, after

dilution

Net earnings for the period after tax divided by the average number of shares outstanding

after dilution during the period.

Operating margin Operating earnings as a percentage of net revenues.

Debt/equity ratio Interest-bearing liabilities divided by shareholders' equity.

Equity/assets ratio Shareholders' equity as a percentage of total assets.

Capital employed Interest-bearing liabilities and shareholders' equity.

#### Please note

Orexo AB publ discloses the information provided herein pursuant to the Financial Instruments Trading Act and/or the Securities Market Act. The information was provided for public release on April 25, 2014, at 8:00 a.m. This report has been prepared in both Swedish and English. In the event of any discrepancy in the content of the two versions, the Swedish version shall prevail.