

# orexo

**“I am pleased to report a positive cash flow from operations for the first quarter of 2016.”**

Nikolaj Sørensen, President and CEO

### **About Orexo**

Orexo is a specialty pharmaceutical company commercializing its proprietary product Zubsolv® for treatment of opioid dependence in the US. Zubsolv is an advanced formulation of buprenorphine and naloxone using Orexo’s unique knowledge and expertise in sublingual drug delivery. R&D is focusing on reformulation of known substances to new improved products that meet great unmet medical needs by using its patented proprietary technologies. Orexo’s share is listed on Nasdaq Stockholm Mid Cap (STO:ORX) and is available as ADRs on OTCQX (ORXOY) in the US. Orexo’s global headquarters and R&D are based in Uppsala, Sweden. [www.orexo.com](http://www.orexo.com)

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## Future reporting dates

Interim Report, January – June 2016	July 12, 2016
Interim Report, January – September 2016	October 20, 2016
Full Year Report for the 2016 financial year	January 26, 2017

This Interim Report is covered in a conference call on the date of publication. Details on how to access the call is provided on page 1 and on Orexo's website.

Unless otherwise stated in this report, all data refers to the Group. Figures in parentheses relate to the corresponding period in 2015.

## Orexo reports positive cash flow for the quarter.

### First quarter 2016

- Total net revenues MSEK 151.0 (149.0).
- Zubsolv® net revenue MSEK 98.4 (94.5).
- Earnings after tax MSEK -34.5 (-15.5).
- Earnings per share SEK -1.0 (-0.45).
- Cash flow from operating activities MSEK 22.5 (6.5).
- Cash and cash equivalents MSEK 233.0 (289.3).
- AstraZeneca acquired all rights to Orexo's OX-CLI project for MUSD 5. The agreement also includes potential future royalties and milestone payments.

MSEK	2016 Jan-Mar	2015 Jan-Mar	2015 Jan-Dec
Net revenues	151.0	149.0	643.3
Revenues from launched products	110.2	149.0	643.3
EBIT	-26.2	-8.1	-169.0
EBITDA	-19.4	-5.1	-88.3
Earnings after tax	-34.5	-15.5	-198.0
Earnings per share, SEK	-1.0	-0.45	-5.74
Cash flow from operating activities	22.5	6.5	-102.2
Cash and cash equivalents	233.0	289.3	198.1

### Teleconference

CEO Nikolaj Sørensen and CFO Henrik Juuel will present the report at a teleconference on April 21, 2016 at 2:00 pm CET (08:00 am EDT). Presentation slides are available via the link and on the website.

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## CEO's comments

I am pleased to report a positive cash flow from operations, despite the CVS Caremark loss, for the first quarter of 2016. This even excludes the MUSD 5 from the agreement with AstraZeneca for OX-CLI which we will receive in the second quarter. I am also encouraged to see the amount of Zubsolv® in milligram prescribed increased by 7 percent in March compared with January. On an annual level our net sales for Zubsolv increased by 15 percent compared to first quarter last year when adjusted for inventory changes. The improvement in net sales is driven by a more favorable gross to net ratio, the price increase announced in January and the increase in the value per prescription due to higher average dosage strengths with the launch of three new dosages in 2015.

The highlight of the quarter has been the extensive work on a federal level in the US to improve access to treatment of opioid dependence, e.g. Zubsolv. During the quarter the Senate committee (HELP) responsible for improving treatment of opioid dependence proposed a legislation to increase the amount of patients each physician can treat from 100 to 500. Shortly thereafter the United States Department of Health and Human Services (HHS) proposed a new regulation increasing the number of patients from 100 to 200. Additionally, the House of Representatives is also in the process of proposing legislation to raise the cap potentially up to 450. All proposals are still being discussed, but it is clear that the question is no longer if improvements in patient access will happen, but how and when. This will have positive impact on our ability to continue growing the number of patients being treated, Zubsolv sales and market share. Our experience from the market tells us that Zubsolv is more successful capturing patients new to treatment, than converting existing patients from their current treatment. Thus, improvements in access to treatment will have positive effects on Zubsolv and Orexo.

We maintain a positive outlook for Orexo and Zubsolv in 2016 and beyond, reinforced by a positive sales trajectory excluding CVS Caremark, expected improvements in patient's access to treatment in the US and good progress in the contract negotiations with a partner for Zubsolv outside the US. These negotiations are expected to be finalized in the second quarter. However, we also recognize the need to show financial strength and improvements in profitability. We are constantly assessing the optimal allocation of our resources and expect lower operating expenses in 2016 than 2015 with the current market conditions. As soon as we know how the anticipated positive changes, on a US federal level, affect the market conditions, we will assess our level of investments to ensure we are well positioned to fully capture these opportunities.

Nikolaj Sørensen  
President and CEO

# The period January-March in numbers

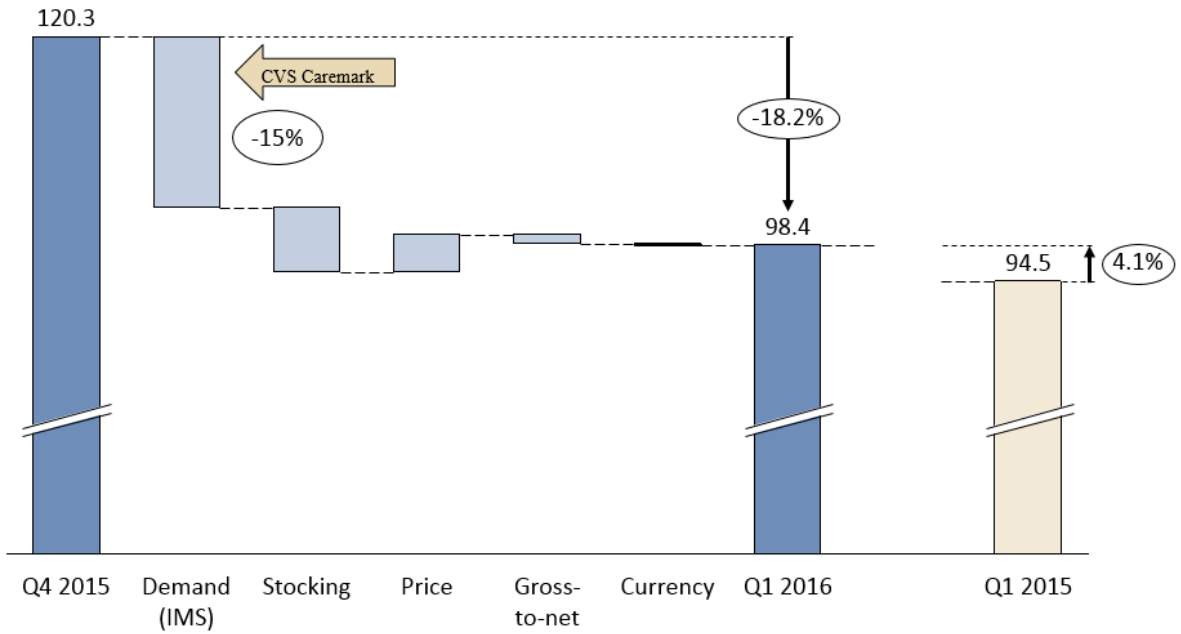
## Revenues

### Launched products

Total revenues from Orexo’s launched products amounted to MSEK 110.2 (149.0) during the period January-March 2016, a decrease of 26 percent compared with the same period the previous year. The decrease is explained by the Abstral® fixed royalty that was included for the last time in May, 2015, and revenue from the subsidiary Kibion that was divested in April, 2015. Excluding Abstral fixed royalty and Kibion revenue the growth was 4 percent driven by Zubsolv® sales.

In line with expectations and previous communication, Zubsolv demand declined by nearly 15 percent from the previous quarter. The decline was mainly driven by the CVS Caremark decision to exclude Zubsolv from a preferred position and excluded from the high controlled commercial plans and to a lesser extent by start-of-year movements of patients between public payer programs and market decline in Kentucky. Zubsolv net revenue was further negative impacted by a stocking effect when comparing against Q4, 2015. The negative stocking impact is explained by two factors; net revenue in Q4, 2015, included pipeline fill from the launch of two additional strengths of Zubsolv and the reduced demand in Q1, 2016, caused wholesalers to adjust their inventory holdings to the new demand level. The 5 percent price increase announced in January 2016, with effect from February 2016, had a positive impact of approximately MSEK 4 on net revenue for Q1, 2016. The gross-to-net ratio was slightly lower in Q1 compared with previous quarter due to change in payer split primarily driven by the lower revenue through CVS Caremark. The USD/SEK exchange rate had a marginal negative impact on Zubsolv net revenue for the quarter.

### Q1 Zubsolv revenue growth (MSEK) by key drivers



Source: Orexo analysis using IMS demand data

Total Abstral® royalties and milestone payments amounted to MSEK 8.2 (41.8). The decrease is explained by the Abstral fixed royalty that was included for the last time in May, 2015. This royalty represents an amortization of the final fixed and unconditional payments related to the 2012 agreement with ProStrakan.

Royalty revenues from Edluar® amounted to MSEK 3.6 (4.2) during the period.

### Revenues related to collaboration projects

In March, 2016, AstraZeneca decided to exercise an option under an existing agreement to acquire all rights to the OX-CLI project. This triggered a milestone payment of MUSD 5 (MSEK 40.8).

### Total revenues

Total revenues during the period amounted to MSEK 151.0 (149.0), an increase of 1.3 percent compared with the same period the previous year.

### Total net revenues were distributed as follows:

MSEK	2016 Jan-Mar	2015 Jan-Mar	2015 Jan-Dec
Abstral royalties	8.2	6.9	77.2
Abstral fixed royalty <sup>1)</sup>	-	34.5	57.0
Milestone payment Abstral	-	0.4	66.0
<b>Abstral – Total</b>	<b>8.2</b>	<b>41.8</b>	<b>200.2</b>
Edluar royalties	3.6	4.2	13.6
Zubsolv®	98.4	94.5	416.7
Kibion	-	8.5	12.8
<b>Total revenue from launched products</b>	<b>110.2</b>	<b>149.0</b>	<b>643.3</b>
Other revenues	40.8	-	-
<b>Total</b>	<b>151.0</b>	<b>149.0</b>	<b>643.3</b>

<sup>1)</sup> For more details, see Revenues – Launched products

### Costs and earnings

#### Cost of goods sold

Cost of goods sold amounted to MSEK 32.5 (32.7) for the period January-March 2016 and all relates to Zubsolv.

#### Selling expenses

Selling expenses amounted to MSEK 60.8 (73.1) for the period January-March 2016. The lower spend level reflects the resizing of the field force conducted in Q4, 2015, and lower marketing costs and to a lesser extent the divestment of Kibion. For Q2, 2016, a similar spend level is expected.

#### Administrative expenses

Administrative expenses for the period January-March 2016 amounted to MSEK 35.1 (31.7). Included are significant costs related to maintenance and protection of IP rights. For Q2, 2016, a spend level of MSEK 35 – 40 is expected, however this is highly dependent on the development of ongoing IP litigations.

#### *Research and development costs*

For the period January-March, 2016, research and development costs amounted to MSEK 45.0 (35.1). For Q2, 2016, a spend level of approximately MSEK 40 is expected.

#### *Costs for long-term incentive program*

The Group's total costs for employee stock option programs during the period January-March, 2016, amounted to MSEK 0.6 (-0.9).

#### *Other income and expenses*

Other income and expenses amounted to MSEK -3.8 (15.5) for the period January-March 2016 and primarily comprised exchange-rate gains/losses derived from revaluations of balance sheet items. The effect for the period January-March, 2016, is primarily a result of a lower SEK/USD rate versus end of Q4, 2015.

#### *Depreciation*

Depreciation and amortization amounted to MSEK 6.8 (3.0) for the period January-March, 2016.

#### *Net financial items*

Net financial items for the period January-March, 2016, amounted to MSEK -6.4 (-5.6). All the net financial items are related to financing activities.

#### *Earnings*

Operating earnings amounted to MSEK -34.5 (-15.5) for the period January-March, 2016.

### **Cash flow and financial position**

At March 31, 2016, cash and cash equivalents amounted to MSEK 233.0 (289.3) and interest-bearing liabilities to MSEK 494.9 (496.1).

Cash flow from operating activities for the period January-March 2016 was positive by MSEK 22.5 (6.5) primarily driven by a positive contribution from changes in working capital. Changes in working capital was mainly driven by increases in accounts payable and continued reduction in inventory levels. A deferred non-conditional payment of MSEK 11 from the divestment of the subsidiary Kibion was received during the period and reduced a corresponding receivable on the balance sheet. The OX-CLI milestone of MUS\$ 5 that was earned in Q1, 2016, has been included as a receivable on the balance sheet and will be paid during Q2, 2016.

Orexo considers its financial position adequate for the current strategy.

Shareholders' equity at March 31, 2016, was MSEK 233.6 (440.4). The equity/assets ratio was 23 (36) percent.

### **Investments in fixed assets**

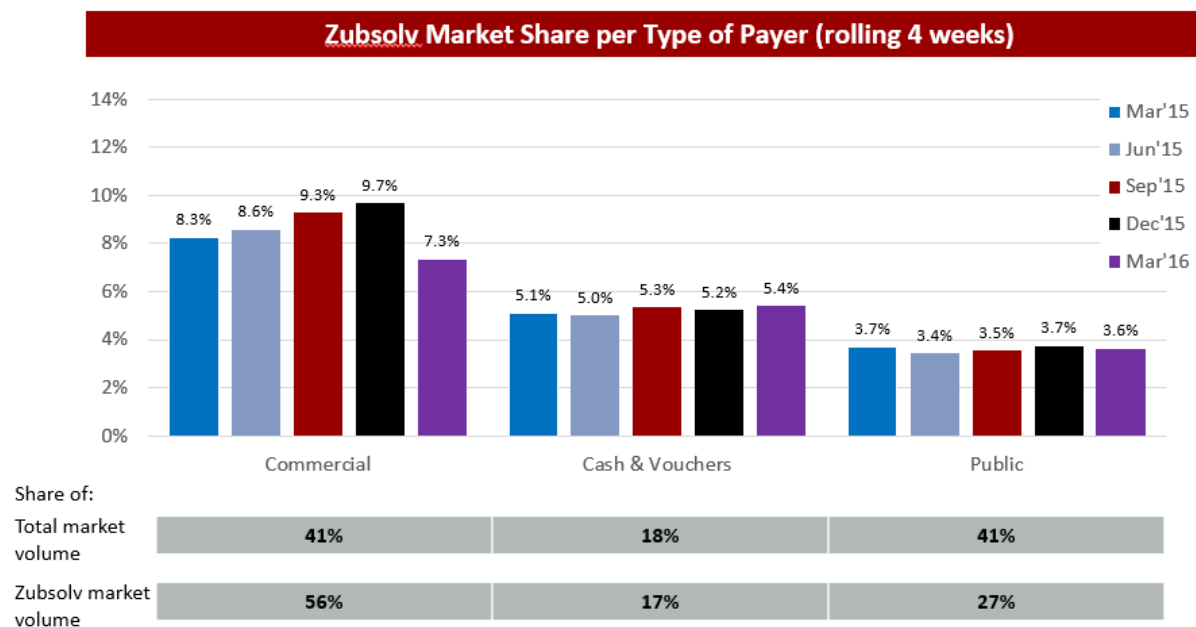
Gross investments in tangible and intangible fixed assets amounted to MSEK 0.1 (1.0) for the period January-March, 2016.

## Operations

### Launched products

#### Zubsolv® – treatment of opioid dependence (buprenorphine/naloxone CIII sublingual tablet)

The market for Zubsolv consists of three distinct payer segments; commercial (private insurance), cash (patient) and public (Managed Medicaid, FFS Medicaid and Medicare Part D). Overall the total market demonstrated nearly 9 percent volume growth in Q1, 2016, compared to Q1, 2015 and similar to previous years a slight decline compared to the fourth quarter. While this high single digit growth is expected to continue a significant catalyst to additional growth appears to be coming to fruition from legislative changes in the US allowing increased access to treatment of opioid addiction.



Source: IMS PA. Mar'15 data: R4W WE 3/27/2015, Jun'15 data: R4W WE 6/26/2015, Sep'15 data: R4W WE 9/25/2015, Dec'15 data: R4W WE 12/25/2015, Mar'16 data: R4W WE 03/18/2016

#### Commercial (private insurance) (41% of the total market, 56% of Zubsolv business in March)

In the commercial segment, Zubsolv's market share decreased by 2.4 percentage points and prescriptions decreased 21 percent during Q1 compared Q4, 2015. This decline is solely due to the loss of the exclusive brand position with CVS Caremark. Excluding CVS Caremark Zubsolv market share increased with 0.3 percentage points compared with Q4, 2015, driven by the continued commercial efforts.

Apart from CVS Caremark the market access position in this segment is maintained from Q4, 2015. As previously announced a small regional plan, CDPHP, has placed Zubsolv in an exclusive position from March 1, but had marginal impact on the overall sales and market share. We have maintained 20-25 percent of the CVS Caremark volume in the quarter with a positive impact on the overall gross to net rebate in this segment.



The commercial segment has declined 1 percent during Q1 compared to Q4, 2015, and was flat compared to Q1, 2015. Zubsolv® has unrestricted access to 79 percent of the business in the commercial segment.

Cash (Cash & Vouchers) (patient)

(18% of the total market, 17% of Zubsolv business in March)

Zubsolv market share has increased slightly to 5.4 percent in this segment. The sales in this segment increased in the early part of the quarter probably boosted by some CVS Caremark patients paying cash for Zubsolv and an increased competitiveness of Orexo's offering to cash paying patients. The cash segment remains financially attractive and Orexo continues to evolve the offering and services to cash patients, e.g. through rebated home delivery.

The cash segment has declined 4 percent in volume compared to Q4, 2015, but has grown nearly 10 percent compared to Q1, 2015. Zubsolv has access to 100 percent of the patients.

Public (Managed Medicaid, FFS Medicaid, Medicare Part D)

(41% of the total market, 27% of Zubsolv business in March)

The public market continued with the fastest growth in the disease area driven by increased access to publicly financed insurances for opioid dependent patients. The market share of Zubsolv declined slightly with 0.1 percent point driven solely by a decline in overall volume in Kentucky where Zubsolv has a significant market share due to the WellCare contract. The loss in Kentucky and within WellCare was partly compensated by increased sales to other Medicaid providers where Zubsolv received improved reimbursement status from January 1 and an exclusive position with CDPHP in NY State from March 1, 2016, where most patients have converted to Zubsolv during March.

This segment has grown 2 percent in volume in Q1, 2016, compared to Q4, 2015, and 18 percent compared to Q1, 2015. Zubsolv has access to 39 percent of the patients.

**Abstral® and Edluar®**

Due to the timing of the Q1 report, Orexo has not yet received final data for first quarter sales for Abstral and Edluar from our partners and calculation of royalties for Q1 is based on Orexo's forecast and on available sales reports shared by our partners. As final sales figures are not available, the Abstral and Edluar sections below primarily refer to the development of sales in Q4, 2015.

Abstral

Sales of Abstral in Europe continued to grow and Q4, 2015, showed a 16 percent increase over Q4, 2014. Total sales in Europe for 2015 amounted to MEUR 77.8. Orexo receives royalties on sales exceeding MEUR 42.5 on a calendar year and expects the 2016 sales in Europe to exceed this threshold in Q3, 2016.

The US market for Abstral, i.e. fentanyl-based products for breakthrough pain, also continued to grow in 2015. Net sales of Abstral reached MUSD 2.4 in Q4, 2015, and full-year sales reached MUSD 10.7 (9.3) in 2015. Galena Biopharma Inc. divested its US Abstral business with unchanged Orexo terms to the privately held company Sentyln Therapeutics Inc. in November, 2015.

Orexo's commercial partner Kyowa Hakko Kirin continued to focus on growing the Japanese market for Abstral. Net sales grew by a low double digit figure in Q4, 2015, over the same period in 2014.

## Edluar®

Global sales of Edluar, commercialized by Meda AB, have continued to grow and the increase in Q4, 2015, was 19 percent compared to Q4, 2014. Total sales for 2015 amounted to MEUR 14.2 (10.9).

## *Development programs*

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

OX51 is a novel sublingual formulation comprising alfentanil. The project has been developed to meet the rapidly growing demand for effective pain relief during short-term painful procedures. The quick onset and offset, short duration, minimum of sedation and drowsiness, and convenient administration make OX51 suitable for prevention of pain for a multitude of surgical and diagnostic procedures.

A placebo-controlled dose-finding study in patients undergoing prostate biopsy was completed in 2013. The results supported a continuation of OX51 to the next phase in development towards a new product. During the first quarter 2016, Orexo continued the work to scale-up the manufacturing process in preparation for a phase 3 clinical trial to be conducted by a future partner. Orexo aims to identify a partner for phase 3 and commercialization in various geographies.

### **OX-MPI – PGE2-inhibition-treatment of inflammatory pain**

The aim with this project is to develop a completely new class of products based on Orexo's prostaglandin research (selective inhibition of prostaglandin E2 synthase). Since 2005 Boehringer Ingelheim had been responsible for all research and development within the OX-MPI project. In August 2014, Boehringer Ingelheim, decided to return the project, including all immaterial property rights and results, to Orexo. The evaluation of the results from Boehringer Ingelheim has been completed, and Orexo still sees potential in the project due to a unique target, an identified development compound and several granted patents. The work to identify an external partner for OX-MPI is ongoing.

## *Collaboration project*

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

During the first quarter of 2016 AstraZeneca acquired all rights to the leukotriene C4 synthase inhibitor program (OX-CLI project). The OX-CLI compounds, based on a new chemical entity (NCE), could enable to develop a completely new personalized treatment for respiratory diseases as asthma and COPD.

AstraZeneca established a collaboration with Orexo for OX-CLI in 2013 and maintained an option to acquire all rights in the program. As the program has advanced into pre-clinical development with an identified development compound (candidate drug), AstraZeneca has chosen to exercise this option. AstraZeneca has been responsible for all research and development activities and investments since 2013. After the acquisition of the rights to OX-CLI, AstraZeneca will continue the drug development without further involvement of Orexo.

In accordance with the option agreement from 2013, Orexo earned a milestone payment of MUSD 5 during Q1, 2016, for the rights to OX-CLI. Future milestone payments can be expected if OX-CLI meets defined development and commercial objectives. In addition to the milestones Orexo will receive a tiered single digit royalty on future net-revenue associated to sales of products based on the OX-CLI program.

### **Important event after the reported period**

Kirsten Detrick was elected as a new board member at the AGM on April 15, 2016.

### **Parent Company**

Net revenues for the period January-March 2016 amounted to MSEK 52.6 (122.5). Earnings after financial items were MSEK -102.3 (-8.7). Investments amounted to MSEK 0.1 (1.0). As of March 31, 2016, cash and cash equivalents in the Parent Company amounted to MSEK 163.3 (205.9).

### **Risks and uncertainty factors**

Significant risks and uncertainties are presented in the Annual Report for 2015. The continued commercialization of Zubsolv® entails risk exposure of operational nature and Orexo is continuously exposed to risks in relations to the intellectual property rights and legal disputes as highlighted in Note 6.

The company's auditors have not reviewed this Interim Report.

Uppsala, Sweden, April 21, 2016

Orexo AB (publ)

Nikolaj Sørensen  
President and CEO

## Financial Reports and key figures

### Consolidated statement of operations

MSEK	Notes	2016 Jan-Mar	2015 Jan-Mar	2015 Jan-Dec
Net revenues		151.0	149.0	643.3
Cost of goods sold	2	-32.5	-32.7	-136.1
<b>Gross profit</b>		<b>118.5</b>	<b>116.3</b>	<b>507.2</b>
Selling expenses	2	-60.8	-73.1	-297.5
Administrative expenses	2	-35.1	-31.7	-141.5
Research and development costs	2	-45.0	-35.1	-172.6
Other operating income and expenses	2	-3.8	15.5	-64.6
<b>Operating earnings</b>		<b>-26.2</b>	<b>-8.1</b>	<b>-169.0</b>
Net financial items		-6.4	-5.6	-22.1
<b>Earnings before tax</b>		<b>-32.6</b>	<b>-13.7</b>	<b>-191.1</b>
Tax		-1.9	-1.8	-6.9
<b>Net earnings for the period<sup>1)</sup></b>		<b>-34.5</b>	<b>-15.5</b>	<b>-198.0</b>

### Consolidated statement of comprehensive income

MSEK	2016 Jan-Mar	2015 Jan-Mar	2015 Jan-Dec
<b>Earnings for the period</b>	<b>-34.5</b>	<b>-15.5</b>	<b>-198.0</b>
<b>Other comprehensive income</b>			
<i>Items that may subsequently be reversed to the statement of operations:</i>			
Cash flow hedge	-	1.4	2.8
Exchange-rate differences	0.8	-3.2	-4.3
<b>Other comprehensive earnings for the period, net after tax</b>	<b>0.8</b>	<b>-1.8</b>	<b>-1.5</b>
<b>Total comprehensive earnings for the period<sup>1)</sup></b>	<b>-33.7</b>	<b>-17.3</b>	<b>-199.5</b>
Earnings per share, before dilution, SEK	-1.0	-0.45	-5.74
Earnings per share, after dilution, SEK	-1.0	-0.45	-5.74

<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	2016 Mar 31	2015 Mar 31	2015 Dec 31
<b>ASSETS</b>				
<b>Fixed assets</b>				
Tangible fixed assets		23.7	28.2	24.7
Goodwill		-	27.0	-
Acquired research and development		-	62.3	-
Other intangible fixed assets		153.4	168.9	159.1
Financial assets		1.4	1.4	2.1
<b>Total fixed assets</b>		<b>178.5</b>	<b>287.8</b>	<b>185.9</b>
<b>Current assets</b>				
Inventories		382.5	480.1	398.9
Accounts receivable and other receivables		229.2	183.2	233.4
Cash and cash equivalents		233.0	289.3	198.1
<b>Total current assets</b>		<b>844.7</b>	<b>952.6</b>	<b>830.4</b>
<b>Total assets</b>		<b>1,023.2</b>	<b>1,240.4</b>	<b>1,016.3</b>
<b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>				
<b>Total shareholders' equity</b>	3	<b>233.6</b>	<b>440.4</b>	<b>266.4</b>
<b>Long-term liabilities</b>				
Provisions		2.6	8.9	3.9
Long-term liabilities, interest bearing		494.9	493.7	494.4
<b>Total long-term liabilities</b>		<b>497.5</b>	<b>502.6</b>	<b>498.3</b>
<b>Current liabilities</b>				
Current liabilities, non-interest bearing		292.1	295.0	251.6
Current liabilities, interest bearing		-	2.4	-
<b>Total current liabilities</b>		<b>292.1</b>	<b>297.4</b>	<b>251.6</b>
<b>Total liabilities</b>		<b>789.6</b>	<b>800.0</b>	<b>749.9</b>
<b>Total shareholders' equity and liabilities</b>		<b>1,023.2</b>	<b>1,240.4</b>	<b>1,016.3</b>

## Consolidated changes in shareholders' equity

MSEK	2016 Mar 31	2015 Mar 31	2015 Dec 31
<b>Opening balance, shareholders' equity</b>	<b>266.4</b>	<b>455.0</b>	<b>455.0</b>
Total comprehensive earnings for the period	-33.7	-17.3	-199.5
Employee stock options, vested amount	0.9	2.0	7.1
New share issues	-	0.7	3.8
<b>Closing balance, shareholders' equity</b>	<b>233.6</b>	<b>440.4</b>	<b>266.4</b>

## Consolidated cash flow statements

MSEK	Notes	2016 Jan-Mar	2015 Jan-Mar	2015 Jan-Dec
Operating earnings		-26.2	-8.1	-169.0
Financial income and expenses		-8.3	-7.7	-29.0
Adjustment for non-cash items	4	7.4	2.1	78.6
<b>Cash flow from operating activities before changes in working capital</b>		<b>-27.1</b>	<b>-13.7</b>	<b>-119.4</b>
<b>Changes in working capital</b>		<b>49.6</b>	<b>20.2</b>	<b>17.2</b>
<b>Cash flow from operating activities</b>		<b>22.5</b>	<b>6.5</b>	<b>-102.2</b>
Acquisition of tangible and intangible fixed assets		-0.1	-1.0	-4.1
Sales of subsidiary		11.0	-	21.8
<b>Cash flow from investing activities</b>		<b>10.9</b>	<b>-1.0</b>	<b>17.7</b>
New share issue		-	0.7	3.8
Change in loans		-	-0.6	-1.2
<b>Cash flow from financing activities</b>		<b>-</b>	<b>0.1</b>	<b>2.6</b>
<b>Cash flow for the period</b>		<b>33.4</b>	<b>5.6</b>	<b>-81.9</b>
<b>Cash and cash equivalents at the beginning of the period</b>		<b>198.1</b>	<b>284.5</b>	<b>284.5</b>
Exchange-rate differences in cash and cash equivalents		1.5	-0.8	-4.5
Changes in cash and cash equivalents		33.4	5.6	-81.9
<b>Cash and cash equivalents at the end of the period</b>		<b>233.0</b>	<b>289.3</b>	<b>198.1</b>

## Key figures

	<b>2016</b>	<b>2015</b>	<b>2015</b>
	<b>Jan-Mar</b>	<b>Jan-Mar</b>	<b>Jan-Dec</b>
Operating margin, %	-17	-5	-26
Return on equity, %	-14	-3	-53
Net debt, MSEK	-262.0	-206.8	-296.3
Debt/equity ratio, %	211.9	112.6	186
Equity/assets ratio, %	23	36	26
Number of shares, before dilution	34,583,763	34,358,897	34,580,810
Number of shares, after dilution	34,837,180	35,225,649	34,873,345
Earnings per share, before dilution, SEK	-1.00	-0.45	-5.74
Earnings per share, after dilution, SEK	-1.00	-0.45	-5.74
Number of employees at the end of the period	93	102	90
Shareholders' equity, KSEK	233,622	440,444	266,459
Capital employed, KSEK	728,563	936,579	760,793

*Definitions of key figures and a glossary are presented on page 18.*

## Parent Company statement of operations

MSEK	Notes	2016 Jan-Mar	2015 Jan-Mar	2015 Jan-Dec
Net revenues		52.6	122.5	518.9
Cost of goods sold		-2.0	-39.0	-155.9
<b>Gross profit</b>		<b>50.6</b>	<b>83.5</b>	<b>363.0</b>
Selling expenses		-39.3	-57.9	-226.9
Administrative expenses		-28.4	-21.4	-108.1
Research and development costs		-76.8	-25.6	-122.9
Other operating income and expenses		-4.1	18.1	5.0
<b>Operating earnings</b>		<b>-98.0</b>	<b>-3.3</b>	<b>-89.9</b>
Interest income and expenses		-4.3	0.3	-18.7
Impairment of shares in subsidiaries		-	-	-63.8
Sales of subsidiary		-	-	13.1
Other financial income and expenses		-	-5.7	-2.5
<b>Net financial items</b>		<b>-4.3</b>	<b>-5.4</b>	<b>-71.9</b>
<b>Earnings before tax</b>		<b>-102.3</b>	<b>-8.7</b>	<b>-161.8</b>
Tax		-	-0.1	-0.5
<b>Earnings for the period</b>		<b>-102.3</b>	<b>-8.8</b>	<b>-162.3</b>

## Parent Company balance sheet

MSEK	Notes	2016 Mar 31	2015 Mar 31	2015 Dec 31
<b>ASSETS</b>				
<b>Fixed assets</b>				
Tangible and intangible fixed assets		176.3	195.2	182.9
Shares in subsidiaries		148.7	209.9	148.5
<b>Total fixed assets</b>		<b>325.0</b>	<b>405.1</b>	<b>331.4</b>
<b>Current assets</b>				
Inventories		291.9	358.5	276.8
Accounts receivable and other receivables		203.8	243.0	320.7
Cash and bank balances		163.3	205.9	114.0
<b>Total current assets</b>		<b>659.0</b>	<b>807.4</b>	<b>711.5</b>
<b>Total assets</b>		<b>984.0</b>	<b>1,212.5</b>	<b>1,042.9</b>
<b>SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES</b>				
Shareholders' equity		251.8	498.5	353.4
Long-term liabilities		497.6	501.4	498.2
Current liabilities		234.6	212.6	191.3
<b>Total liabilities</b>		<b>732.2</b>	<b>714.0</b>	<b>689.5</b>
<b>Total shareholders' equity and liabilities</b>		<b>984.0</b>	<b>1,212.5</b>	<b>1,042.9</b>
Pledged assets		100.0	100.0	100.0



## 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 those applied in the preparation of the 2015 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 2016

- 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	2016 Jan-Mar	2015 Jan-Mar	2015 Jan-Dec
Raw materials and supplies	25.8	28.4	120.2
Other external costs	114.4	107.7	499.3
Personnel costs	39.3	38.4	146.6
Depreciation/amortization and impairment	6.8	3.0	80.7
<b>Total</b>	<b>186.3</b>	<b>177.5</b>	<b>846.8</b>

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, 2016, was 34,583,763, of which 34,448,763 were common shares and 135,000 were C shares. All common shares carry one voting right and the C shares 1/10 of a voting each.

Number of shares outstanding at January 1, 2016	34,580,810
Subscription for shares through exercise of employee stock options	2,953
Shares outstanding at March 31, 2016	34,583,763

### Options

As of March 31, 2016, a total of 1,824,758 options were outstanding that carry rights to new subscription of 1,715,521 shares in Orexo and the exchange of 109,237 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.

<b>Options to employees and Board members</b>	<b>Opening, Jan 1, 2016</b>	<b>Change</b>	<b>Closing, Mar 31, 2016</b>
Of which:			
Approved and allotted employee stock options	1,666,773		1,666,773
Exercised		-	-
Allotted		-	-
Expired		-70,207	-70,207
Approved and allotted Board options	192,319		192,319
Expired		-	-
Employee stock options approved by AGM, unallotted <sup>1)</sup>	497,417	-	497,417
Warrants held by subsidiaries as cash-flow hedging for social security fees	35,873	-	35,873
<b>Total number of options outstanding</b>	<b>2,392,382</b>	<b>-70,207</b>	<b>2,322,175</b>

<sup>1)</sup> All 497,417 unallotted options will be cancelled due to new LTI program implemented during 2015.

During the period January-March 2016, no employee stock options from Orexo's options program were exercised.

### Number of shares after full dilution

Shares outstanding at March 31, 2016	34,583,763
Employee/Board stock options allotted	1,715,521
	<hr/>
	36,299,284

#### **4. Cash flow**

##### **Adjustment for non-cash items**

<b>MSEK</b>	<b>2016 Jan-Mar</b>	<b>2015 Jan-Mar</b>	<b>2015 Jan-Dec</b>
Depreciation/amortization and impairment	6.8	3.0	80.7
Estimated costs for employee stock options program	0.6	-0.9	-10.2
Cash flow hedge	-	-	2.8
Sales of subsidiary	-	-	5.3
<b>Total</b>	<b>7.4</b>	<b>2.1</b>	<b>78.6</b>

#### **5. Pledged assets and contingent liabilities**

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.

#### **6. Legal disputes**

On June 27, 2014 Orexo AB announced that it had filed a patent infringement action in United States against Actavis Elizabeth LLC and its parent company Actavis, Inc.

The lawsuit was filed in response to an Abbreviated New Drug Application (“ANDA”) filed by Actavis. In its application, Actavis seeks to market and sell generic versions of Orexo’s patented ZUBSOLV® (buprenorphine and naloxone) products in the US prior to the expiration of Orexo’s US Patents.

Because Orexo AB timely initiated a lawsuit against Actavis, the FDA is statutorily precluded from approving Actavis’ ANDA for 30 months, or until a district court decision finding the patents invalid or not infringed, whichever occurs earlier. The 30 month stay period ends in November, 2016. The process is still ongoing.

## Definitions of key figures

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

<b>Number of shares after dilution</b>	Shares at the end of the period adjusted for the dilutive effect of potential shares.
<b>Return on shareholders' equity</b>	Net earnings for the period as a percentage of average shareholders' equity.
<b>Net debt</b>	Current and long-term interest-bearing liabilities including pension liabilities, less cash and cash equivalents.
<b>Earnings per share, before dilution</b>	Net earnings for the period after tax divided by the average number of shares outstanding before dilution during the period.
<b>Earnings per share, after dilution</b>	Net earnings for the period after tax divided by the average number of shares outstanding after dilution during the period.
<b>Operating margin</b>	Operating earnings as a percentage of net revenues.
<b>Debt/equity ratio</b>	Interest-bearing liabilities divided by shareholders' equity.
<b>Equity/assets ratio</b>	Shareholders' equity as a percentage of total assets.
<b>Capital employed</b>	Interest-bearing liabilities and shareholders' equity.

## Glossary

### **Alfentanil**

A potent synthetic opioid analgesic drug, used for anaesthesia in surgery.

### **Anaesthesia**

Procedure for lowering a patient's consciousness to enable a medical procedure to proceed without pain for the patient.

### **Breakthrough pain**

A short, intensive period of pain that occurs in addition to chronic levels of long-term pain even though these are treated by regular painkillers.

### **Buprenorphine**

A potent opioid partial agonist first used as a pain-relieving substance, but now most commonly used to help patients withdraw from more addictive opioid drugs such as morphine.

### **Cash & vouchers market**

One of the three distinct payer segments in the US Zubsolv market. In this segment, the patient is paying for the prescriptions out of pocket.

### **CLI**

Cysteinyl Leukotriene Inhibitor.

### **Clinical studies/Clinical trials**

Studies of the safety and efficacy of a drug in human beings.

### **Commercial market**

One of the three distinct payer segments in the US Zubsolv market. The commercial market is funded by private insurances or employers.

### **Drug delivery**

The process through which a pharmaceutical may be introduced to the patient that enables the active compound to function as intended.

### **Fentanyl**

An opioid with a similar effect on human patients to morphine. Used mainly within anesthesia and analgesia.

**Naloxone**

An opioid inverse agonist used to counter the effects of opioids.

**Opioids**

Collective term for compounds that act via opioid receptors on nerve cells, mainly in the central nervous system.

**PBM (Pharmacy Benefit Manager)**

Responsible for management of costs associated with prescription pharmaceuticals and recommendations on behalf of insurance companies and employers in the US.

**PGE**

Prostaglandin (PG) E2 – biologically active mediator acting upon arachidonic acid locally in inflammatory conditions.

**Phase I studies**

Studies mainly of the safety of a drug. Performed on healthy human volunteers.

**Phase II studies**

Studies of the safety and efficacy of a drug and appropriate doses. Performed on a limited number of patients.

**Phase III studies**

Studies of the safety and efficacy of a drug in a clinical situation. Performed on a large number of patients.

**Preclinical development/Preclinical studies**

Studies of the safety and efficacy of a drug prior to evaluation in humans. Can be performed on animals and in various cell systems.

**Public Market**

One of three distinct payer segments in the US Zubsolv® market. The public market covers state and federal funded reimbursement programs i.e. Managed Medicaid, FFS Medicaid, Medicare Part D.

**Sublingual**

Under the tongue.

**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 21, 2016, at 8:00 a.m. CET. 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.