

orexo

**“I am encouraged by and enthusiastic about the opportunities for Orexo arising from the patient cap lift from 100 to 275 in the US.”**

Nikolaj Sørensen, CEO and President

**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.

For more information about Orexo please visit [www.orexo.com](http://www.orexo.com) or follow us on Twitter, [@orexoabpubl](https://twitter.com/orexoabpubl).

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## Future reporting dates

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 2 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.

## Positive cash flow and EBIT. Expansion of Zubsolv® to new markets and improved market access position in the US.

### Second quarter 2016

- Total net revenues MSEK 188.2 (126.5).
- Zubsolv net revenue MSEK 178.2 (91.1).
- Earnings after tax MSEK 5.0 (-84.6).
- Earnings per share SEK 0.14 (-2.46).
- Cash flow from operating activities MSEK 20.0 (-35.6).
- Cash and cash equivalents MSEK 252.9 (282.1).
- Zubsolv was selected by the State of Maryland as the exclusive preferred buprenorphine/naloxone agent for the FFS Medicaid Formulary effective July 1, 2016.
- A license agreement was signed with Mundipharma, which obtains ex-US global rights to Zubsolv. The upfront payment of MEUR 7 (MSEK 65.4) is fully included as revenue in the quarter. The agreement also includes potential future royalties and milestone payments.

### First half year 2016

- Total net revenues MSEK 339.2 (275.5).
- Zubsolv net revenue MSEK 276.6 (185.6).
- Earnings after tax MSEK -29.5 (-100.1).
- Earnings per share SEK -0.85 (-2.91).
- Cash flow from operating activities MSEK 42.5 (-29.0).
- AstraZeneca acquired all rights to Orexo's OX-CLI project for MUSD 5 (MSEK 40.8). The agreement also includes potential future royalties and milestone payments.

### Important event after the period

- The United States Department of Health and Human Services (HHS) announced an increase in the buprenorphine patient cap from 100 to 275.

MSEK	2016 Apr-Jun	2015 Apr-Jun	2016 Jan-Jun	2015 Jan-Jun	2015 Jan-Dec
Net revenues	188.2	126.5	339.2	275.5	643.3
EBIT	12.1	-77.3	-14.1	-85.4	-169.0
EBITDA	17.2	-74.2	-2.3	-79.3	-88.3
Earnings after tax	5.0	-84.6	-29.5	-100.1	-198.0
Earnings per share, SEK	0.14	-2.46	-0.85	-2.91	-5.74
Cash flow from operating activities	20.0	-35.6	42.5	-29.0	-102.2
Cash and cash equivalents	252.9	282.1	252.9	282.1	198.1

**Teleconference**

CEO Nikolaj Sørensen and CFO Henrik Juuel will present the report at a teleconference on July 12, 2016, at 2:00pm CET.

Presentation slides are available via the link and on the website.

Internet: <https://wonderland.videosync.fi/2016-07-12-orexo-q2report>

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## CEO's comments

During the quarter Orexo attained several important objectives and continues to build additional financial strength with a positive EBIT and for the second consecutive quarter a positive cash flow.

I am encouraged by and enthusiastic about the opportunities for Orexo arising from the announcement the increase in the number of patients each physician can treat for opioid dependence in the US from 100 to 275.<sup>1</sup> I am confident this market expansion will benefit Zubsolv® and Orexo.

In light of the expected growth in patient access treatment, I am pleased to announce that effective July 1<sup>st</sup> Zubsolv is the only preferred buprenorphine/naloxone product within the largest Fee For Service (FFS) Medicaid program in the US, the state of Maryland. The Maryland decision strengthens Orexo's and Zubsolv's position in the increasingly important public segment.

Prior to the implementation of the Maryland agreement and anticipated market growth following the cap lift, I was pleased to see our net sales of Zubsolv in the US grow during the quarter by nearly 15 percent compared to Q1, driven by a mix of increased demand, inventory and improved gross to net ratio.

Opioid dependence is a growing global epidemic and today 20 million people outside the US are estimated to suffer from the disease. I am looking forward to a successful partnership with Mundipharma to make Zubsolv available to patients across the world. For Orexo the priority has been to find a partner with an international organization covering all of the key markets for Zubsolv and with a strong track record of successful launch and commercialization of many products on a global scale. Besides creating value from the launch of Zubsolv outside the US, we are also expecting other scale effects which will positively contribute to the creation of value and support our progress towards sustainable profitability.

I am proud to see that we achieved a positive EBIT and cash flow in this quarter due to the closure of the Mundipharma agreement and a continued overall improved financial performance. In this quarter our expenses for the on-going patent litigation against Actavis in the US have increased, due to the completion of the trial in the district court of Delaware. We remain confident that the court will support our claims and the validity of our patents for Zubsolv, enabling us to fully capitalize on the opportunities materializing this quarter and early July.

Nikolaj Sørensen  
CEO and President

<sup>1</sup> <https://www.whitehouse.gov/the-press-office/2016/07/06/fact-sheet-obama-administration-takes-more-actions-address-prescription>

# The interim period January-June in numbers

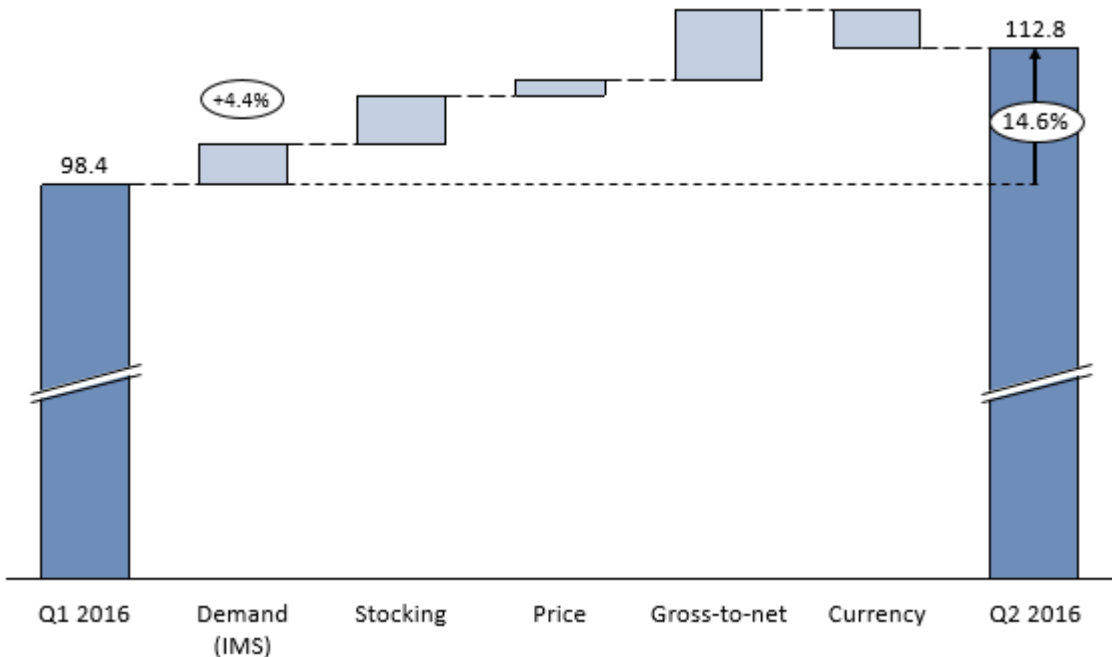
## Revenues

### Launched products

Global Zubsolv® Q2 revenue amounted to MSEK 178.2 (91.1) corresponding to a 96 percent growth over same period last year and a growth of 81 percent over previous quarter. The upfront milestone payment of MEUR 7, relating to the license agreement signed with Mundipharma, was an important driver of this growth.

Zubsolv revenue in the US market for Q2 amounted to MSEK 112.8 (91.1) corresponding to a growth of nearly 24 percent over same period last year, nearly 15 percent growth over previous quarter and nearly 18 percent in USD. Except for currency impact all the growth drivers contributed positively to the Zubsolv growth versus previous quarter. Demand increased by 4.4 percent driven by seasonality, general market growth and market share gain. Wholesaler stocking impact contributed slightly positive, the price increase implemented in Q1 2016 had a full quarter impact and finally gross-to-net ratio improved against Q1 2016. The gross-to-net ratio impact was partly caused by one-off adjustments of provisions from previous periods. The gross-to-net ratio is expected to be lower in the second half of the year due to this and as payer mix will change with the Maryland Medicaid agreement.

Q2 Zubsolv US revenue growth (MSEK) by key drivers<sup>1</sup>



<sup>1</sup>Orexo analysis using IMS demand data

Total Abstral® royalties and milestone payments amounted to MSEK 5.4 (27.8) for the period April-June 2016 and to MSEK 13.6 (69.6) for the period January-June 2016. The decrease compared to last year is explained by absence of the Abstral fixed royalty. This fixed royalty represented an amortization of the final fixed payment related to the 2012 agreement with ProStrakan and the fixed royalty was fully recognized in the P&L by May 2015.

Royalty revenues from Edluar® amounted to MSEK 4.5 (3.3) for the period April-June 2016 and MSEK 8.1 (7.5) for the period January-June 2016.

Due to divestment of Kibion in April 2015, there was no revenue for the period January –June 2016.

### 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). A license agreement was signed with Mundipharma in June, 2016, for ex-US global rights to Zubsolv® resulting in an upfront payment of MEUR 7 (MSEK 65.4). The agreement also includes potential future royalties and milestone payments.

### Total revenues

Total revenues during the period April-June 2016 amounted to MSEK 188.2 (126.5), an increase of 49 percent compared with the same period the previous year, driven by Zubsolv. For the period January-June 2016 total revenues amounted to MSEK 339.2 (275.5).

### Total net revenues were distributed as follows

MSEK	Apr-Jun 2016	Apr-Jun 2015	Jan-Jun 2016	Jan-Jun 2015	Jan-Dec 2015
Zubsolv® US	112.8	91.1	211.2	185.6	416.7
Zubsolv Non US Upfront payment	65.4	-	65.4	-	-
<b>Zubsolv – total</b>	<b>178.2</b>	<b>91.1</b>	<b>276.6</b>	<b>185.6</b>	<b>416.7</b>
Abstral® royalties	5.4	5.3	13.6	12.2	77.2
Fixed royalty Abstral <sup>1</sup>	-	22.5	-	57.0	57.0
Milestone payment Abstral	-	-	-	0.4	66.0
<b>Abstral – total</b>	<b>5.4</b>	<b>27.8</b>	<b>13.6</b>	<b>69.6</b>	<b>200.2</b>
Edluar® royalties	4.5	3.3	8.1	7.5	13.6
Kibion	-	4.3	-	12.8	12.8
Other revenues	-	-	40.8	-	-
<b>Total</b>	<b>188.2</b>	<b>126.5</b>	<b>339.2</b>	<b>275.5</b>	<b>643.3</b>

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

### Costs and earnings

#### Cost of goods sold

The cost of goods sold amounted to MSEK 33.9 (36.4) for the period April-June 2016 and MSEK 66.4 (69.1) for the period January-June 2016, and all relates to Zubsolv.

#### Selling expenses

Selling expenses amounted to MSEK 56.4 (81.7) for the period April-June 2016. Slightly below the level guided previously. Q2 selling expenses decreased by 8 percent over Q1 driven by the full quarter impact of the optimization of the field force for Zubsolv in the US that was initiated late Q4, 2015. Selling expenses for the period January-June 2016 amounted to MSEK 117.1 (154.8). For the period July-December 2016 a similar expense level is expected.

#### *Administrative expenses*

Administrative expenses for the period April-June 2016 amounted to MSEK 62.7 (33.1), significantly higher than the level previously guided. This extraordinary high level of expenses in Q2 is explained by significant costs incurred in relation to the patent infringement case against Actavis. For the period January-June 2016 the administrative expenses amounted to MSEK 97.8 (64.8). The expense level in H2, 2016 is expected to amount to approximately MSEK 80, but this is dependent on progress in and development of legal disputes.

#### *Research and development costs*

For the period April-June 2016, research and development costs amounted to MSEK 28.7 (38.1), lower than previously guided due to the license agreement signed with Mundipharma. Under the signed license agreement Mundipharma will cover cost previously incurred by Orexo for the preparation of Zubsolv® for markets outside of the US. For the period January-June 2016, R&D costs amounted to MSEK 73.7 (73.2). The expense level for H2 is expected to amount to approximately MSEK 80.

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

The Group's total costs for employee stock option programs during the period April-June 2016 amounted to MSEK 1.6 (-8.4). For the period January-June 2016, the costs amounted to MSEK 2.2 (-9.3).

#### *Other income and expenses*

Other income and expenses amounted to MSEK 5.6 (-14.5) during the period April-June 2016 and for the period January-June 2016 it amounted to MSEK 1.8 (1.0). This is primarily comprised of exchange-rate gains/losses derived from revaluations of balance sheet items due to a higher SEK/USD rate versus end of Q4, 2015.

#### *Depreciation and amortization*

Depreciation and amortization amounted to MSEK 5.0 (3.1) for the period April-June 2016 and to MSEK 11.8 (6.1) for the period January-June.

#### *Net financial items*

Net financial items for the period April-June 2016 amounted to MSEK -5.5 (-5.7). All the net financial items are related to financing activities. For the period January-June 2016 net financial items amounted to MSEK -11.8 (-11.3).

#### *Earnings*

Net earnings amounted to MSEK 5.0 (-84.6) for the period April-June 2016 and to MSEK -29.5 (-100.1) for the period January-June 2016.

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

At June 30, 2016, cash and cash equivalents amounted to MSEK 252.9 (282.1) and interest-bearing liabilities to MSEK 495.5 (493.1).

Cash flow from operating activities was positive and amounted to MSEK 20 (-35.6) for the period April-June 2016 driven by a positive contribution from both operating earnings and working capital. Net working capital was primarily reduced by increased payables more than compensating for increased receivables. The MEUR 7 Zubsolv ex-US milestone payment is included as a receivable on the balance sheet on June 30, 2016. Cash flow from operating activities for the period January-June was positive and amounted to MSEK 42.5 (-29.0).



The financial position is considered adequate for Orexo to pursue the current strategy.

Shareholders' equity at June 30, 2016 was MSEK 240.5 (369.0). The equity/assets ratio was 22 (31) percent.

**Investments in fixed assets**

Gross investments in tangible and intangible fixed assets amounted to MSEK 0.2 (1.2) for the period April-June 2016. For the period January-June 2016, gross investments amounted to MSEK 0.3 (2.2).

**Operations**

*Launched products*

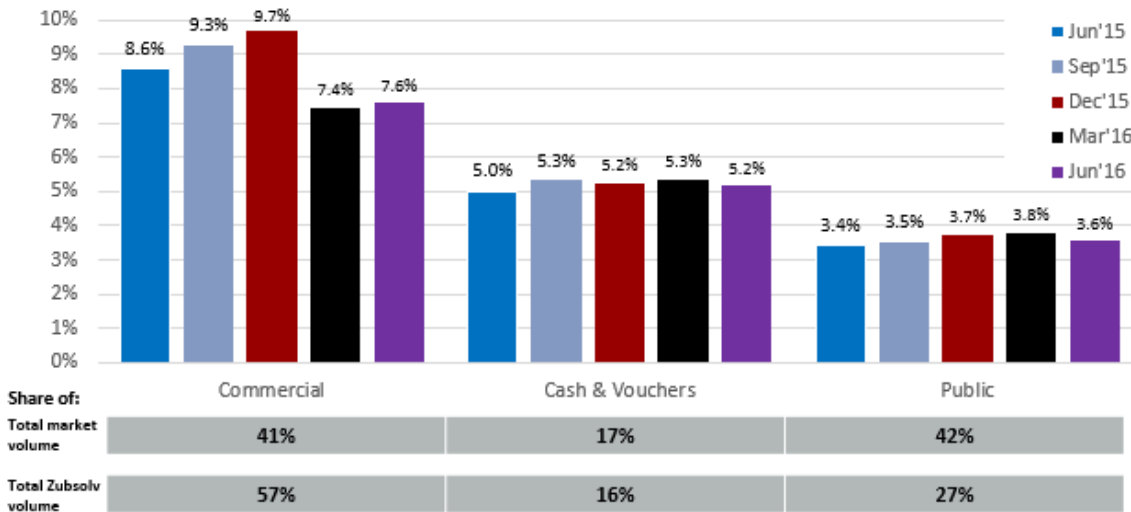
**Zubsolv® in the US market – treatment of opioid dependence**  
(buprenorphine/naloxone CIII sublingual tablet)

Overall the total market has increased 3.3 percent in volume compared to Q1 2016, and is up 7.3 percent compared to Q2 2015. While this high single digit growth versus the same period last year is expected to continue based on current market dynamics a catalyst to greater market growth rates and increased new patient flow is the announcement of an increase in the buprenorphine patient cap from 100 to 275.

Zubsolv performance when compared to Q1 2016 demonstrated a growth of nearly 4.4 percent in tablets dispensed to patients. The payer market for Zubsolv is made up of three distinct payer segments. Of these segments, two are managed segments which are the commercial (private insurance) and public (Managed Medicaid, FFS Medicaid and Medicare Part D). The cash segment is available for patients to directly access.

Within the payer segments by far the fastest growing is the public segment while the growth within the cash and commercial markets has stagnated. Based on these trends and the longer formulary review times associated with the public market, Orexo has been increasing efforts in the public segment to capitalize on these trends. While the rebates associated with preferred formulary positions in the public segment are higher than commercial segments the overall investments required are more modest versus the cash segment and the unrestricted access positions in the commercial segment.

**Zubsolv market share per type of payer segment, rolling 4 weeks, June 2015-June 2016<sup>1</sup>**



<sup>1</sup> IMS PA. Mar'15 data: R4W WE 3/27/2015; Jun'15 data: R4W WE 6/26/2015; Sept'15 data: R4W WE 9/25/2015; Dec'15 data: R4W WE 12/25/2015; Mar'16 data: R4W WE 03/25/2016; Jun'16 data: R4W WE 06/17/2016

### Commercial (private insurance)

(41% of the total market, 57% of Zubsolv® business in June)

In the commercial segment, Zubsolv's market share increased by 0.2 percentage points and prescriptions increased 2 percent compared to Q1 2016. This increase is driven by continued commercial efforts plus a regional plan, CDPHP, placing Zubsolv in an exclusive position effective March 1<sup>st</sup>.

The CVS Caremark loss year to date has stabilized and Zubsolv has maintained about 20 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 grown 4 percent in volume compared to Q1 2016, and 1 percent compared to Q2 2015. Zubsolv has unrestricted access to 81 percent of the business in the commercial segment.

### Cash (Cash & Vouchers, the patient pays)

(17% of the total market, 16% of Zubsolv business in June)

Zubsolv's market share has declined slightly from 5.3 percent to 5.2 percent in Q2 2016 in this segment. The dynamics contributing to the Q2 2016 share loss in this segment are related to two key factors. The first factor is that in January when Caremark switched formulary status a cohort of Zubsolv patients paid cash for a short period of time before being transitioned. The second dynamic is the regional use of generic discount cards resulting in a price level below Zubsolv in some regions. During the quarter this dynamic was confined to a small number of states that implemented restrictions on physician payments for services. The cash segment has decreased 2 percent in volume during Q2 compared to Q1 2016, but has grown 3 percent compared to Q2 2015. Zubsolv has access to 100 percent of the business in the cash segment.

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

(42% of the total market, 27% of Zubsolv business in June)

The public market continued with the fastest growth in the disease area driven by increased access to publicly financed insurances for opioid dependent patients. This segment has grown 6 percent in volume during Q2 compared to Q1, 2016, and 17 percent compared to Q2, 2015. During the quarter Zubsolv had access to 39 percent of the business in the public segment. The market share of Zubsolv decreased slightly in this segment by 0.2 percentage points from Q1 2016. For the quarter this was mainly attributed to volume losses at Wellcare and growth in areas where Zubsolv® is not reimbursed today.

Effective July 1, 2016 Zubsolv is the exclusive preferred product on the State of Maryland fee for service formulary which is the largest fee for service Medicaid state in the US. This decision taken by the state was made based on Zubsolv's product characteristics, the clinical dataset, a competitive rebate and a unique and diverse number of stakeholders. Other products will remain accessible for patients, but require a prior authorization process for each prescription. The total gross value of all prescriptions in Maryland is today MUSD 25 on an annual basis equal to about 1.3 percentage points overall market share. Based on experience we do not anticipate to take all of the Maryland business and among other things the firmness of the prior authorization process will decide the final market share. The agreement is associated with a high rebate and will have negative impact on the overall gross-to-net ratio of the company, but positive EBIT contribution as the cost of implementation is limited for Orexo.

### The REZOLV study

The REZOLV study was designed to expand our understanding of those factors that impact the success of Zubsolv treatment for opioid addiction. Using a retrospective design for a real-world perspective, we

collected data on the clinical practice and the individual healthcare providers, the quality and quantity of clinical support, the patient's medical and addiction history, and a range of psychosocial factors. We examined the effect of these characteristics on outcomes during the first month of treatment. The study included more than 1,000 patients treated at 95 clinical sites throughout the US. Final study results will be available in August 2016.

### ***Abstral® and Edluar®***

Due to the early timing of the Q2 report, Orexo has not yet received final data for second quarter sales of Abstral and Edluar. Data included in this report are based on Orexo's forecast and available sales reports for Q1 from our partners.

#### Abstral – for rapid relief from breakthrough pain in cancer patients

Sales of Abstral in the EU continue to grow and amounted to MEUR 20, which is an increase of 15 percent in Q1 2016 compared to Q1 2015. Orexo receives royalty on sales exceeding MEUR 42.5, which is expected to happen in early or mid Q3.

In the US market, Orexo's new partner since November 2015, Sentyln Therapeutics Inc. continued with its relaunch of Abstral during the quarter. In Q1 2016, and still in launch face, net sales decreased with 36 percent compared to same period in 2015.

Sales of Abstral in the region RoW (markets excluding EU and the US) have continued to grow in Israel and Korea while a first time sales were recorded in Australia. Total sales for the RoW reached MUSD 1.4 in Q1 2016, which is an increase of 118 percent compared with Q1 2015.

Orexo's commercial partner in Japan, Kyowa Hakko Kirin, continued to focus on growing the Japanese market for Abstral. Net sales grew by a double digit figure during the two first months of Q1, 2016, over the same period in 2015.

#### Edluar- for treatment of short-term insomnia

Global sales of Edluar, commercialized by Meda AB, decreased by 3 percent in Q1 2016 compared to Q1 2015. Total sales for the quarter amounted to MEUR 3.3 (3.4).

### ***Development programs***

#### OX51 – prevention of acute episodes of 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 diagnostic procedures.

A placebo-controlled dose-finding study in patients undergoing prostate biopsy was completed in 2013. The results supported a continuation of the development of OX51 to the next phase in development towards a new product. During the second quarter 2016, work has continued to optimize and scale-up the manufacturing process in preparation of a phase III clinical trial.

The commercial potential of OX51 is estimated to be substantial and Orexo is presently in the process of identifying the optimal partner for phase III and commercialization in various geographies. Discussions are ongoing with several companies.

#### 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 projects***

#### OX-CLI - respiratory tract diseases

The OX-CLI project is a leukotriene C4 synthase inhibitor program. 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 had established a collaboration with Orexo for OX-CLI in 2013 and has been responsible for all research and development activities and investments since 2013. As the program has advanced into pre-clinical development with an identified development compound (candidate drug), AstraZeneca has chosen to exercise their option to acquire all rights to the OX-CLI project. In accordance with the option agreement, Orexo earned a milestone payment of MUSD 5 during Q1, 2016, for the rights to OX-CLI.

After the acquisition of the rights to OX-CLI, AstraZeneca will continue the drug development without further involvement of Orexo. 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.

### ***Un-disclosed projects***

Un-disclosed projects includes ideas and concepts. When commercial evaluation of market potential have been completed and patent applications filed more information about these projects will be communicated. At the present stage these projects have a limited impact on costs.

### **Parent Company**

Net revenues for the period January-June 2016 amounted to MSEK 220.1 (208.8). Earnings after financial items were MSEK -85.0 (-78.5). Investments amounted to MSEK 0.3 (2.2). As of June 30, 2016, cash and cash equivalents in the Parent Company amounted to MSEK 146.5 (174.2).

### **Risks and uncertainty factors**

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

### **Assurance by the Board of Directors**

The Board of Directors and the CEO give their assurance that the interim report provides a fair and accurate view of the Company's and the Group's operations, financial position and earnings and describes the significant risks and uncertainties facing the company and the companies included in the Group.

The company's auditors have not reviewed this interim report.

Uppsala, Sweden, July 12, 2016

Orexo AB (publ.)

Martin Nicklasson  
Chairman of the Board

Raymond Hill  
Board member

Staffan Lindstrand  
Board member

Kristina Schauman  
Board member

Michael Shalmi  
Board member

David Colpman  
Board member

Kirsten Detrick  
Board member

Nikolaj Sørensen  
CEO and President

## Financial Reports and key figures

### Consolidated statement of operations

MSEK	Notes	2016 Apr-Jun	2015 Apr-Jun	2016 Jan-Jun	2015 Jan-Jun	2015 Jan-Dec
Net revenues		188.2	126.5	339.2	275.5	643.3
Cost of goods sold	2	-33.9	-36.4	-66.4	-69.1	-136.1
<b>Gross profit</b>		<b>154.3</b>	<b>90.1</b>	<b>272.8</b>	<b>206.4</b>	<b>507.2</b>
Selling expenses	2	-56.4	-81.7	-117.1	-154.8	-297.5
Administrative expenses	2	-62.7	-33.1	-97.8	-64.8	-141.5
Research and development costs	2	-28.7	-38.1	-73.7	-73.2	-172.6
Other operating income and expenses	2	5.6	-14.5	1.8	1.0	-64.6
<b>Operating earnings</b>		<b>12.1</b>	<b>-77.3</b>	<b>-14.1</b>	<b>-85.4</b>	<b>-169.0</b>
Net financial items		-5.5	-5.7	-11.8	-11.3	-22.1
<b>Earnings before tax</b>		<b>6.6</b>	<b>-83.0</b>	<b>-25.9</b>	<b>-96.7</b>	<b>-191.1</b>
Tax		-1.6	-1.6	-3.6	-3.4	-6.9
<b>Net earnings for the period<sup>1)</sup></b>		<b>5.0</b>	<b>-84.6</b>	<b>-29.5</b>	<b>-100.1</b>	<b>-198.0</b>

### Consolidated statement of comprehensive income

MSEK	2016 Apr-Jun	2015 Apr-Jun	2016 Jan-Jun	2015 Jan-Jun	2015 Jan-Dec
<b>Earnings for the period</b>	<b>5.0</b>	<b>-84.6</b>	<b>-29.5</b>	<b>-100.1</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	2.8
Exchange-rate differences	-1.7	7.3	-0.9	4.1	-4.3
<b>Other comprehensive earnings for the period, net after tax</b>	<b>-1.7</b>	<b>8.7</b>	<b>-0.9</b>	<b>6.9</b>	<b>-1.5</b>
<b>Total comprehensive earnings for the period<sup>1)</sup></b>	<b>3.3</b>	<b>-75.9</b>	<b>-30.4</b>	<b>-93.2</b>	<b>-199.5</b>
Earnings per share, before dilution, SEK	0.14	-2.46	-0.85	-2.91	-5.74
Earnings per share, after dilution, SEK	0.14	-2.46	-0.85	-2.91	-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 June 30	2015 June 30	2015 Dec 31
<b>ASSETS</b>				
<b>Fixed assets</b>				
Tangible fixed assets		22.9	26.6	24.7
Goodwill		-	-	-
Acquired research and development		-	62.3	-
Other intangible fixed assets		147.8	168.1	159.1
Financial assets		1.2	1.3	2.1
<b>Total fixed assets</b>		<b>171.9</b>	<b>258.3</b>	<b>185.9</b>
<b>Current assets</b>				
Inventories		379.5	447.8	398.9
Accounts receivable and other receivables		281.3	194.5	233.4
Cash and cash equivalents		252.9	282.1	198.1
<b>Total current assets</b>		<b>913.7</b>	<b>924.4</b>	<b>830.4</b>
<b>Total assets</b>		<b>1,085.5</b>	<b>1,182.7</b>	<b>1,016.3</b>
<b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>				
<b>Total shareholders' equity</b>	3	<b>240.5</b>	<b>369.0</b>	<b>266.4</b>
<b>Long-term liabilities</b>				
Provisions		2.3	6.9	3.9
Long-term liabilities, interest bearing		495.5	493.1	494.4
<b>Total long-term liabilities</b>		<b>497.8</b>	<b>500.0</b>	<b>498.3</b>
<b>Current liabilities</b>				
Current liabilities, non-interest bearing		347.2	313.7	251.6
Current liabilities, interest bearing		-	-	-
<b>Total current liabilities</b>		<b>347.2</b>	<b>313.7</b>	<b>251.6</b>
<b>Total liabilities</b>		<b>845.0</b>	<b>813.7</b>	<b>749.9</b>
<b>Total shareholders' equity and liabilities</b>		<b>1,085.5</b>	<b>1,182.7</b>	<b>1,016.3</b>
<b>Pledged assets</b>		<b>-</b>	<b>100.0</b>	<b>100.0</b>

## Consolidated changes in shareholders' equity

MSEK	2016 June 30	2015 June 30	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	-30.4	-93.2	-199.5
Employee stock options, vested amount	4.5	3.3	7.1
New share issue		3.9	3.8
<b>Closing balance, shareholders' equity</b>	<b>240.5</b>	<b>369.0</b>	<b>266.4</b>

## Consolidated cash flow statements

MSEK	Notes	2016 Apr-Jun	2015 Apr-Jun	2016 Jan-Jun	2015 Jan-Jun	2015 Jan-Dec
Operating earnings		12.1	-77.3	-14.1	-85.4	-169.0
Financial income and expenses		-7.1	-7.0	-15.4	-14.7	-29.0
Adjustment for non-cash items	4	6.6	2.8	14.0	4.9	78.6
<b>Cash flow from operating activities before changes in working capital</b>		<b>11.6</b>	<b>-81.5</b>	<b>-15.5</b>	<b>-95.2</b>	<b>-119.4</b>
<b>Changes in working capital</b>		<b>8.4</b>	<b>45.9</b>	<b>58.0</b>	<b>66.2</b>	<b>17.2</b>
<b>Cash flow from operating activities</b>		<b>20.0</b>	<b>-35.6</b>	<b>42.5</b>	<b>-29.0</b>	<b>-102.2</b>
Acquisition of tangible and intangible fixed assets		-0.2	-1.2	-0.3	-2.2	-4.1
Sale of subsidiary		-	21.8	11.0	21.8	21.8
<b>Cash flow from investing activities</b>		<b>-0.2</b>	<b>20.6</b>	<b>10.8</b>	<b>19.6</b>	<b>17.7</b>
New share issue		-	3.2	-	3.9	3.8
Change in loans		-	-0.6	-	-1.3	-1.2
<b>Cash flow from financing activities</b>		<b>-</b>	<b>2.6</b>	<b>-</b>	<b>2.6</b>	<b>-2.6</b>
<b>Cash flow for the period</b>		<b>19.8</b>	<b>-12.4</b>	<b>53.3</b>	<b>-6.8</b>	<b>-81.9</b>
<b>Cash and cash equivalents at the beginning of the period</b>		<b>233.0</b>	<b>289.3</b>	<b>198.1</b>	<b>284.5</b>	<b>284.5</b>
Exchange-rate differences in cash and cash equivalents		0.1	5.2	1.5	4.4	-4.5
Changes in cash and cash equivalents		19.9	-12.4	53.3	-6.8	-81.9
<b>Cash and cash equivalents at the end of the period</b>		<b>252.9</b>	<b>282.1</b>	<b>252.9</b>	<b>282.1</b>	<b>198.1</b>



## Key figures<sup>1</sup>

	<b>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>	<b>2015</b>
	<b>Apr-Jun</b>	<b>Apr-Jun</b>	<b>Jan-Jun</b>	<b>Jan-Jun</b>	<b>Jan-Dec</b>
Operating margin, %	6	-61	-4	-31	-26
Return on shareholder equity, %	2	-21	-13	-24	-53
Net debt, MSEK	-243	-211	-243	-211	-296.3
Debt/equity ratio, %	206	134	206	134	186
Equity/assets ratio, %	22	31	22	31	26
Number of shares, before dilution	34 583 763	34,445,810	34 583 763	34,445,810	34,580,810
Number of shares, after dilution	34 688 754	34,820,507	34 688 754	34,820,507	34,873,345
Earnings per share, before dilution, SEK	0.14	-2.46	-0.85	-2.91	-5,74
Earnings per share, after dilution, SEK	0.14	-2.46	-0.85	-2.91	-5.74
Number of employees at the end of the period	99	101	99	101	90
Shareholders' equity, KSEK	240,544	369,064	240,544	369,064	266,459
Capital employed, KSEK	736,092	862,184	736,092	862,184	760,793

<sup>1</sup> Definitions of key figures are presented on the final page of this report.

## Parent Company statement of operations

MSEK	Notes	2016	2015	2016	2015	2015
		Apr-Jun	Apr-Jun	Jan-Jun	Jan-Jun	Jan-Dec
Net revenues		167.5	86.3	220.1	208.8	518.9
Cost of goods sold		-52.6	-33.1	-54.6	-72.1	-155.9
<b>Gross profit</b>		<b>114.9</b>	<b>53.2</b>	<b>165.5</b>	<b>136.7</b>	<b>363.0</b>
Selling expenses		-18.4	-65.7	-57.7	-123.6	-226.9
Administrative expenses		-55.2	-24.9	-83.6	-46.3	-108.1
Research and development costs		-21.8	-29.9	-98.6	-55.5	-122.9
Other operating income and expenses		2.5	3.0	-1.6	21.1	5.0
<b>Operating earnings</b>		<b>22.1</b>	<b>-64.3</b>	<b>-75.9</b>	<b>-67.6</b>	<b>-89.9</b>
Interest income and expenses		-4.2	-4.9	-8.4	-9.7	-18.7
Impairment of shares in subsidiaries		-	-	-	-	-63.8
Sales of subsidiary		-	-	-	-	13.1
Other financial expenses		-0.6	-0.6	-0.7	-1.2	-2.5
<b>Net financial items</b>		<b>-4.8</b>	<b>-5.5</b>	<b>-9.1</b>	<b>-10.9</b>	<b>-71.9</b>
<b>Earnings before tax</b>		<b>17.3</b>	<b>-69.8</b>	<b>-85.0</b>	<b>-78.5</b>	<b>-161.8</b>
Tax		-0.1	-0.4	-0.1	-0.5	-0.5
<b>Earnings for the period</b>		<b>17.2</b>	<b>-70.2</b>	<b>-85.1</b>	<b>-79.0</b>	<b>-162.3</b>

## Parent Company balance sheet

MSEK	Notes	2016 Jun 30	2015 Jun 30	2015 Dec 31
<b>ASSETS</b>				
<b>Fixed assets</b>				
Tangible and intangible fixed assets		169.9	193.5	182.9
Shares in subsidiaries		148.0	210.1	148.5
<b>Total fixed assets</b>		<b>317.9</b>	<b>403.6</b>	<b>331.4</b>
<b>Current assets</b>				
Inventories		258.4	336.4	276.8
Accounts receivable and other receivables		295.2	221.0	320.7
Cash and bank balances		146.5	174.2	114.0
<b>Total current assets</b>		<b>700.2</b>	<b>731.6</b>	<b>711.5</b>
<b>Total assets</b>		<b>1,018.1</b>	<b>1,135.2</b>	<b>1,042.9</b>
<b>SHAREHOLDERS' EQUITY. PROVISIONS AND LIABILITIES</b>				
<b>Shareholders' equity</b>		<b>270.3</b>	<b>432.8</b>	<b>353.4</b>
<b>Long-term liabilities</b>		<b>497.8</b>	<b>500.0</b>	<b>498.2</b>
				<b>191.3</b>
<b>Current liabilities</b>		<b>250.0</b>	<b>202.4</b>	
<b>Total liabilities</b>		<b>747.8</b>	<b>702.4</b>	<b>689.5</b>
<b>Total shareholders' equity and liabilities</b>		<b>1,018.1</b>	<b>1,135.2</b>	<b>1,042.9</b>
<b>Pledged assets</b>		<b>-</b>	<b>100.0</b>	<b>100.0</b>

## Parent company statement of comprehensive income

MSEK	2016 Apr-Jun	2015 Apr-Jun	2016 Jan-Jun	2015 Jan-Jun	2015 Jan-Dec
Earnings for the period	17.2	-70.2	-85.1	-79.0	-162.3
Other comprehensive income					
<i>Items that may subsequently be reversed to the statement of operations:</i>					
Cash flow hedge	-	-	-	-	-
Exchange-rate differences	-	-	-	-	-
<b>Other comprehensive earnings for the period, net after tax</b>	-	-	-	-	-
<b>Total comprehensive earnings for the period<sup>1</sup></b>	<b>17.2</b>	<b>-70.2</b>	<b>-85.1</b>	<b>-79.0</b>	<b>-162.3</b>

<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.

## 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 Apr-Jun	2015 Apr-Jun	2016 Jan-Jun	2015 Jan-Jun	2015 Jan-Dec
Raw materials and supplies	24.1	30.8	49.9	59.2	120.2
Other external costs	123.4	136.8	237.8	244.5	499.3
Personnel costs	37.6	33.0	76.9	71.4	146.6
Depreciation/amortization and impairment	5.0	3.1	11.8	6.1	80.7
<b>Total</b>	<b>190.1</b>	<b>203.7</b>	<b>376.4</b>	<b>381.2</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 June 30, 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 June 30, 2016	34,583,763

#### Options

As of June 30, 2016, a total of 2,284,493 options were outstanding that carry rights to new subscription of 1,715,521 shares in Orexo and the exchange of 71,555 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, June 30, 2016</b>
Of which:			
Approved and allotted employee stock options	1,666,773		1,666,773
Exercised		-	-
Allotted		-	-
Expired		-107,889	-107,889
Approved and allotted Board options	192,319		192,319
Expired		-	-
Employee stock options approved by AGM, unallotted	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>-107,889</b>	<b>2,284,493</b>

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

#### Number of shares after full dilution

Shares outstanding at June 30, 2015	34,583,763
Employee stock options allotted	1,715,521
	<hr/>
	36,299,284

#### 4. Cash flow

##### Adjustment for non-cash items

MSEK	2016 Apr-Jun	2015 Apr-Jun	2016 Jan-Jun	2015 Jan-Jun	2015 Jan-Dec
Depreciation/amortization and impairment	5.0	3.1	11.8	6.1	80.7
Estimated costs for employee stock options program	1.6	-8.4	2.2	-9.3	-10.2
Cash flow hedge	-	2.8	-	2.8	2.8
Sales of subsidiary	-	5.3	-	5.3	5.3
<b>Total</b>	<b>6.6</b>	<b>2.8</b>	<b>14.0</b>	<b>4.9</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. In June, 2016, the case was trialed at court in the US state of Delaware. The 30 month stay period ends in November, 2016.

## 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.
Zubsolv net revenue	Revenue net of discounts and returns.
Revenue from launched products	Revenue from products licensed to Orexo’s partners including Zubsolv US revenue.
EBIT	Operating profit before net financial items and tax.
EBITDA	Earnings before interest, taxes, depreciation and amortization. EBIT plus depreciation.
Gross to net ratio	Net Sales divided by Gross Sales
Operating expenses	A non-capital expense incurred in daily operating activities.
Net financial items	Financial revenue minus financial cost.
Net earnings	Operating Earnings plus Net Financial Items plus tax.
Gross investments	Value of an investment before depreciation
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.

## 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.  
OREXO INTERIM REPORT, JANUARY – JUNE 2016

**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:** This is information is information that Orexo AB (publ.) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 8.00 am CET on July 12, 2016.