Full year report January-December 2015

Unless otherwise stated in this report, all data refers to the Group. Figures in parentheses relate to the corresponding period in 2014.

2015 – a year of investments and growth. Zubsolv® revenue growth of 83 percent.

Fourth quarter 2015

- Total net revenues amounted to MSEK 228.3 (220.5).
- Zubsolv net revenue amounted to MSEK 120.3 (79.5).
- Earnings after tax were MSEK -51.8 (51.6).
- Earnings per share were SEK -1.50 (1.50).
- Cash flow from operating activities amounted to MSEK 6.3 (-7.3).
- Orexo received MGBP 5 milestone payment for Abstral® in Europe.
- Orexo recorded OX-MPI non-cash impairment charge of MSEK 62.
- Orexo announced new Abstral partner in the US.
- Orexo settled Abstral US patent litigation with Actavis.
- Orexo filed for FDA approval of new Zubsolv low dose.

January-December 2015

- Total net revenues amounted to MSEK 643.3 (570.3).
- Net revenues, adjusted [1)], were MSEK 586.3 (396.7), up by 47.8 percent.
- Zubsolv net revenue amounted to MSEK 416.7 (228.0).
- Earnings after tax were MSEK -198.0 (-56.6).
- Earnings per share were SEK -5.74 (-1.73).
- EBITDA, adjusted [1)], were MSEK -145.3 (-186.1), an improvement of MSEK 40.8.
- Cash flow from operating activities amounted to MSEK -102.2 (-487.3).
- Cash and cash equivalents amounted to MSEK 198.1 (284.5).
- Orexo broadened Zubsolv product range.
- FDA approved Zubsolv for induction treatment of opioid dependence.
- New clinical data established Zubsolv as effective, well tolerated for maintenance treatment of opioid dependence and increases patients' work productivity.
- Zubsolv excluded from CVS Caremark preferred position effective from January 1, 2016 after closed tender process.
- New exclusive agreement with unnamed Pharmacy Benefit Manager in Managed Medicaid.
- Orexo divested the subsidiary Kibion.
- Orexo settled patent infringement litigation against Mylan regarding Edluar®.

MSEK	**2015 Oct-Dec**	**2014 Oct-Dec**	**2015 Jan-Dec**	**2014 Jan-Dec**
Net revenues	228.3	220.5	643.3	570.3
Revenues from launched products	228.3	220.5	643.3	568.6
EBIT	-44.3	59.0	-169.0	-25.0
EBITDA	24.8	64.1	-88.3	-12.5
Earnings after tax	-51.8	51.6	-198.0	-56.6
Earnings per share before dilution, SEK	-1.50	1.50	-5.74	-1.73
Cash flow from operating activities	6.3	-7.3	-102.2	-487.3
Cash and cash equivalents	198.1	284.5	198.1	284.5

Key figures adjusted for non-cash fixed Abstral® royalty [1)]

MSEK	2015 Oct-Dec	2014 Oct-Dec	2015 Jan-Dec	2014 Jan-Dec
Net revenues, adjusted [1)]	228.3	186.0	586.3	396.7
EBITDA, adjusted [1)]	24.8	29.6	-145.3	-186.1

[1)] The non-cash fixed Abstral royalty represents an amortization of fixed and unconditional payments received in connection with the 2012 agreement with ProStrakan. This was fully recognized in the P&L by May 2015.

Teleconference
CEO Nikolaj Sørensen and CFO Henrik Juuel will present the report at a teleconference on January 28, 2016 at 2:00 p.m. CET (08:00 a.m. EDT).
Presentation slides are available via the link and on the website.
Internet: http://financialhearings.nu/160128/orexo/
Telephone: 46 8 566 42652 (SE), +44 203 426 2845 (UK) or +1 347 329 1282 (US).

For further information, please contact:
Nikolaj Sørensen, CEO or Henrik Juuel, EVP and CFO
Tel: +46 (0)18 780 88 00, E-mail: ir@orexo.com

CEO's comments

The United States consume 80 percent of the world's opioids, but only account for 4.6 percent of the world's population and the amount of opioid painkillers prescribed is enough to medicate every single adult in the country for one month. The consequences, when opioids are abused, on the society is severe and in 2014, 28,647 people died from drug overdose with opioids[1] in the US. This a tripling since year 2000 and has created an outcry in major media in the US e.g. the cover page of the first Newsweek® of 2016 read "Why Are White Americans Dying Younger?", with the answer being the prescription opioid epidemic.

Since the initiation of our commercial journey for Zubsolv®, we have highlighted the significant unmet need for opioid dependence treatment. More than 10 million Americans are using opioids for non-medical purposes and less than 1 million receiving any type of treatment today. The need for actions from the authorities in the United States is imminent and this was one of the first topics raised by President Obama in his final State of the Union speech. We know several concrete improvements are being evaluated, one being how to double the amount of prescribers in this disease space[2]. We have anticipated this type of change and it has been an integral part of our business plans since we decided to establish a commercial entity in the US. Two years into our commercial journey in the US, we finally see concrete steps in the right direction for the patients and for Orexo and this give me strong confidence in the journey have ahead of us.

In a market facing dramatic changes, being at the forefront in terms of scientific documentation and developing a product range, providing the optimal convenience and flexibility for patients and physicians are important competitive differentiators. Thus, I am happy to report our registry study REZOLV is about to finalize the patient recruitment with more than 1,000 patients enrolled by the end of 2015. Also our product development has progressed and we launched two new tablet strengths in the fourth quarter. However, when I met physicians during the launch of these new tablets, they inquired about a tablet with lower strength to improve their ability to tapering down with Zubsolv. Thus, I am pleased to report that we have filed for approval a new lower dosage in Q4, 2015 and we anticipate FDA approval in Q4, 2016.

While we continue to invest in the growth of Zubsolv, we also continuously assess where and how to optimize the use of our resources. As a reaction to the change in market access from January 1, 2016 we have made an adjustment in the sales force in selected geographies. This will increase efficiency and enable a focus where our presence has the highest return on investment potential. One such region is the State of New York where we won an exclusive regional contract to be implemented in March 2016. We will ensure we have sufficient resources in this region to optimize the value of this contract. Another important driver of the profitability of our commercial investments, is the price and I am pleased to report we have been able to increase the price of Zubsolv in January 2016.

Our efforts to find a partner for Zubsolv outside the US and for our project OX-51 continue to progress well. We expect to finalize the full license agreement for Zubsolv outside the US in the first half of 2016. Like we have seen with Abstral® in Europe, the right partner for Zubsolv will further strengthening Orexo's long term growth opportunities.

Nikolaj Sørensen
President and CEO

[1] http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm?s_cid=mm6450a3_w
[2] Huffington Post, Oct 21, 2015.

Operations

Zubsolv® – treatment of opioid dependence

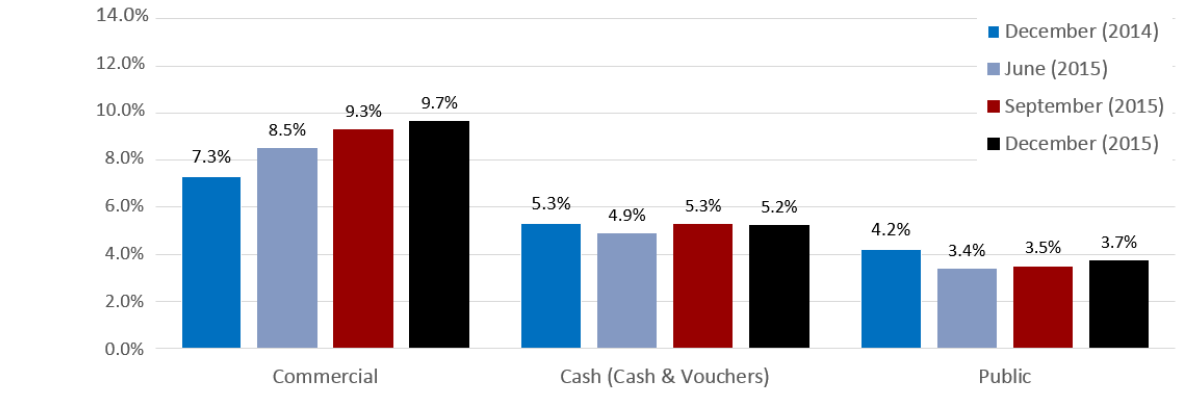
(buprenorphine/naloxone CIII sublingual tablet) for treatment of opioid dependence.

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 has grown 7.8 percent in 2015 compared to 2014.

Zubsolv has grown by 102.8 percent in terms of number of tablets dispensed to patients compared to 2014, and in the fourth quarter Zubsolv demand grew by 5.9 percent compared to the third quarter. The main driver of Zubsolv growth is a continued increase in market share in the commercial segment. Growth in the relatively open commercial segment (i.e. all products are reimbursed and accessible for patients) is the main focus of our sales and marketing teams. This segment is more profitable and responsive to sales efforts compared to the highly controlled public segment. During the year our competitors have become more aggressive in their rebating resulting in less attractiveness of exclusive contracts. The long term sustainability of Zubsolv sales is dependent on the ability to win market share in payer categories with limited rebates. During 2015, Zubsolv captured 2.4 percent market share from competitors in the commercial segment, reaching a total of 9.7 percent, without major exclusive contracts to facilitate the growth. Orexo Inc. has recently made a price adjustment of 5 percent to reflect inflation. This is the first price adjustment since the launch of Zubsolv in 2013 and follows a similar price increase made by our largest competitor.

The Zubsolv growth in the fourth quarter is a result of the increased investment in field force, the improvements made to Zubsolv's selling message, and improving the quality of the dialogue with physicians. This improved dialogue includes leveraging the multiple award winning Out-The-Monster campaign (www.outthemonster.com). However, we constantly monitor the performance and profitability of each sales territory along with the growth required to reach a positive profit contribution. As a result of this monitoring, along with the loss of the CVS Caremark contract effective January 1, 2016, we have reduced the field force in selected geographies

Zubsolv Market Share per Type of Payer (rolling 4 weeks)



Share of:			
Total market volume	42%	18%	40%
Zubsolv market volume/tablets	63%	14%	23%

Source: IMS PA
Dec'14 data: R4W WE 12/26/2014, Jun'15 data: R4W WE 5/22/2015, Sept'15 data: R4W WE 9/25/2015, Dec'15 data: R4W WE 12/25/2015

Commercial (private insurance)
(42% of the total market, 63% of Zubsolv® business in December)

In the commercial segment, Zubsolv's market share increased by 0.4 percentage points and prescriptions grew 6 percent during Q4 compared to the rolling 4 weeks of September. This growth is explained by market share capture across many accounts, and not related to changes in Zubsolv's market access position in the commercial segment during the period.

During the quarter we have continuously worked to improve the market access position in this segment, given the higher profitability, and Zubsolv's ability to gain market share among these patients. With the exception of the Pharmacy Benefit Manager (PBM), CVS Caremark, we have during the quarter secured that the market access position of 2015 will remain in 2016.

As previously communicated, the loss of CVS Caremark could impact Orexo's current total gross demand sales negatively by approximately 10-15 percent starting in Q1 of 2016. During the fourth quarter several activities have been initiated to minimize this impact. We expect the impact to have full effect by the end of the first quarter.

The overall growth in 2015 of this segment was 5 percent, and Zubsolv has access to 88 percent of the patients.

Cash (Cash & Vouchers) (patient)
(18% of the total market, 14% of Zubsolv business in December)

During the entire 2015, Zubsolv has, with some minor fluctuations, maintained its market share of about 5.2-5.3 percent.

This segment showed an overall decline of 5 percent in 2015, and Zubsolv has access to 100 percent of the patients.

Public (Managed Medicaid, FFS Medicaid, Medicare)
(40% of the total market, 23% of Zubsolv business in December)

The public market is different from the commercial and cash markets, as access to the market is tightly controlled by the payers that are contracted to manage the public funds available to pay for prescriptions. Most payers have policies encouraging generic alternatives as a first choice, if they exist in the product category. The competition for contracts in this segment has increased during the year and we have seen some increase in the rebates required to gain exclusive contracts. As Orexo secures a more sustainable business, our focus has increasingly been to improve access and reimbursement for Zubsolv in this segment. We have during 2015 and in the fourth quarter improved access in several states (Illinois, Nevada, Oklahoma) as well as with important regional payers (CDPHP, Virginia Premier).

During the third quarter, Orexo entered into two agreements with PBMs in the public sector, enabling a preferred position with the insurance companies using the services of these PBMs. The negotiations with several insurance companies under the umbrella of these PBMs have progressed and we have secured an exclusive position with one regional insurance company (CDPHP) and these contracts have enabled Orexo to maintain and gain a reimbursement in parity with our main competitor with several important payers in 2016.

Although they are usually a smaller part of the overall market, the public payers are often leaders in their local markets and drive prescribing selection of medicines in certain geographies. Thus, it is important for Zubsolv to gain access to the patients with public insurance to gain traction. The rebate levels in the public market are higher than in the commercial market, as all companies are

required by law to provide at least the same rebate ("best price") as is offered to the commercial insurance companies.

The overall growth in 2015 of this segment was 18 percent and Zubsolv® has access to 38 percent of the patients.

Life cycle management
During the quarter we launched the new induction label in coordination with the launch of the two new dosages of Zubsolv 2.9 mg/0.8 mg and 11.4 mg/2.9 mg buprenorphine/naloxone. The launch of the two new dosages in Q4, 2015, contributed with approximately MSEK 6 in net revenue due to the pipeline fill. This stocking effect may, however, have a negative impact in Q1, 2016, as the inventory level is normalized. During the quarter we have made an application for one additional dosage strength which, if approved, will be the lowest single dosage strength available in the market. Many physicians require lower dosages to enable adjustment of the dose to the right level for the individual patient

We included more than 1,000 patients in the registry study REZOLV (Retrospective Evaluation of Zubsolv® Outcomes – A Longitudinal View) by the end of December 2015 and expect to finalize the recruitment in early January which is in alignment to our internal plan. This retrospective study on the use of Zubsolv in a real world setting aims to fill a significant gap in the knowledge base of how to best treat opioid dependency through examining and characterizing the impact of treatment and psychosocial factors on treatment outcomes. Factors such as patient and prescriber characteristics, care settings, patient agreements and behavioral therapies will be studied. At the same time, this study is an evidence of Orexo's continued commitment to further improve clinical outcomes and education of all stakeholders in the treatment of the opioid dependent patient. The first data is expected in the middle of 2016.

Abstral® and Edluar®
Due to the timing of the Q4 report, Orexo has not yet received final data for the fourth quarter sales for Abstral and Edluar from our partners and calculation of royalties for Q4 is based on Orexo forecast and preliminary Q4 sales reports shared by our partners. As final sales numbers are not available, the Abstral and Edluar sections below primarily refer to the sales development in Q3 of 2015.

Abstral
Sales of Abstral in the EU continued to grow and the increase in Q3 was 12 percent compared to Q3 in 2014. Total sales in the EU for Q1-Q3 amounted to MEUR 57. Orexo receives royalties on sales exceeding MEUR 42.5 and estimated royalties were included in the results from August. The annual sales of Abstral in the EU exceeded MEUR 67.5 during 2015 and in December triggered a milestone payment of MGBP 5 from the commercial partner in Europe, ProStrakan Group plc.

The net sales of Abstral in the US market continued to grow and reached MUSD 2.2 in Q3 which is 16 percent higher than during the same quarter in 2014. In October Orexo entered into a settlement and license agreement with Actavis Laboratories FL, Inc. and settled the patent litigation. The license agreement allows Actavis to enter the market in June 2018, or earlier under certain conditions, whereas Orexo's patents listed in FDA's Orange Book for Abstral expire in September 2019. Galena Biopharma Inc. divested its Abstral business with unchanged Orexo terms to the privately held company Sentynl Therapeutics Inc. in November.

Orexo's commercial partner Kyowa Hakko Kirin continued to focus on growing the Japanese market for treatment of break through cancer pain with rapid-acting fentanyl, Abstral.

Edluar®
The global sales of Edluar, commercialized by Meda AB, have continued to grow during Q1-Q3 2015 and the increase for the period was 37 percent and for the Q3 44 percent compared to the same time in 2014.

Kibion – diagnosis of the gastric ulcer bacterium *Helicobacter pylori*
The subsidiary Kibion AB was divested on April 30, 2015.

Development programs

OX-51 – prevention of acute episodes of pain
OX-51 is a novel sublingual formulation containing alfentanil. The product has been developed to meet the rapidly growing demand for effective pain relief during short surgical and diagnostic procedures. The quick onset and offset, short duration, minimum of sedation and drowsiness, and convenient administration make OX-51 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 the development of OX-51 to the next phase in development towards a new product. In 2015, Orexo worked to scale-up the manufacturing process in preparation for a phase 3 clinical trial to be conducted by a future partner. The commercial potential of OX-51 is estimated to be substantial and Orexo aims to identify a partner for phase 3 and commercialization in various geographies. At the end of 2015, discussions were ongoing with several companies.

Collaboration projects

OX-MPI – PGE2-inhibition (Prostaglandin E2)
In August 2014, Orexo's partner Boehringer Ingelheim decided to return the OX-MPI project (selective inhibition of prostaglandin E2 synthase) to Orexo. Since 2005 Boehringer Ingelheim had been responsible for all research and development within the OX-MPI project. Orexo still considers OX-MPI an attractive asset and has since the return of the project been working to identify a new partner. Orexo will continue the dialogue with potential partners, however as part of the annual impairment assessment process it was decided to fully write down the value of the asset with the consequence that a non-cash charge of MSEK 62 was recorded in the fourth quarter 2015.

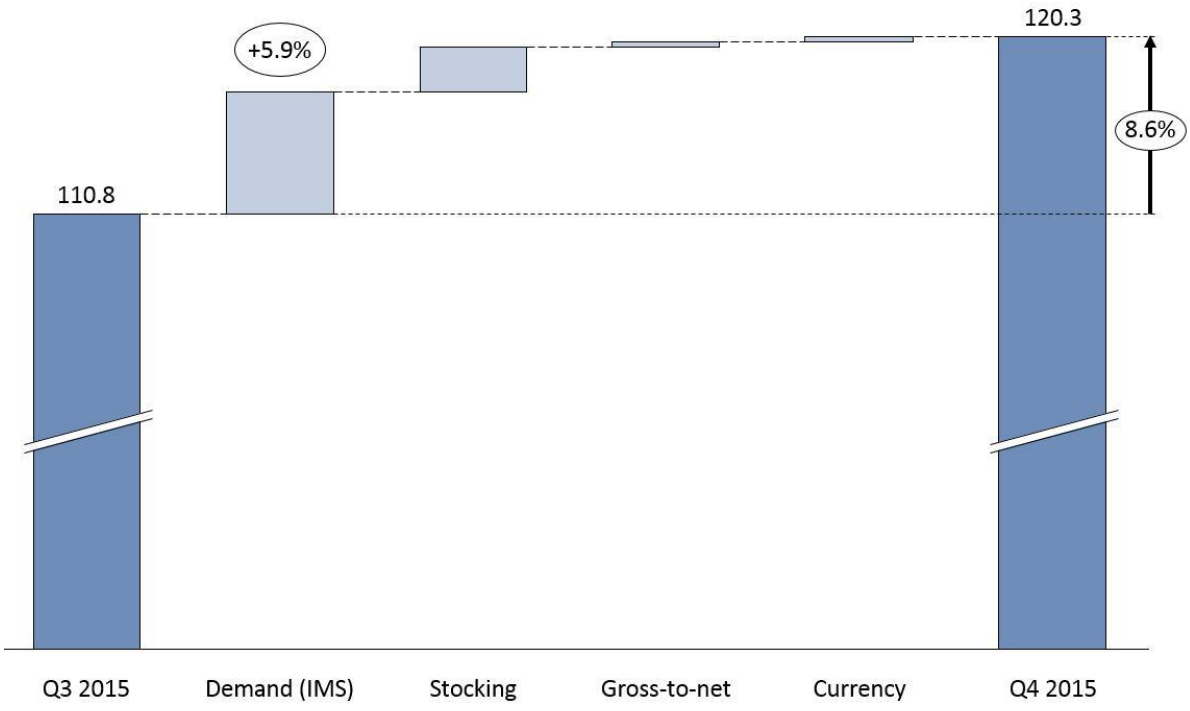
OX-CLI – respiratory tract diseases
In January 2013, Orexo entered into a collaboration agreement with AstraZeneca regarding OX-CLI, a preclinical program for potential new treatment of respiratory tract diseases. AstraZeneca is responsible for all development costs for the project.

The period January-December in figures

Revenues

The Zubsolv® Q4 revenue amounted to MSEK 120.3 (79.5) corresponding to a 51 percent growth over same period last year. Compared with Q3, 2015, Zubsolv revenue grew by 8.6 percent. This growth was supported by a 5.9 percent increased demand and moderately increased wholesaler inventory levels caused by the launch of 2.9 mg and 11.4 mg dosages. The gross-to-net ratio remained unchanged from the Q3 level and so did the average USD/SEK exchange rate. The increased demand was driven by continued market share gains in the non-exclusive commercial segment and by the general market growth.

Q4 Zubsolv revenue growth (MSEK) by key drivers [1)]



1) Orexo analysis using IMS demand data.

Total Abstral® royalties and milestone payments amounted to MSEK 105.1 (120.9) for the quarter and to MSEK 200.2 (278.7) for the period January-December 2015. The decrease is explained by the lower Abstral fixed royalty. The fixed royalty represents an amortization of the final fixed and unconditional payment related to the 2012 agreement with ProStrakan and was fully recognized in the P&L in May 2015. The period October-December 2015 includes a milestone of MGBP 5 earned as part of the European Abstral agreement with ProStrakan Group Plc and triggered by annual European Abstral sales exceeding MEUR 67.5. Excluding the fixed royalty and milestones total Abstral royalties grew by 66 percent during the period January-December 2015 compared with previous year.

Royalty revenues from Edluar® amounted to MSEK 2.9 (0.2) for the quarter and to MSEK 13.6 (10.7) for the period January-December 2015. The period October-December 2014 was negatively

impacted by royalty corrections made together with our partner, amounting to approximately MSEK 2 related to previous periods.

Total revenues

Total revenues during the period October-December 2015 amounted to MSEK 228.3 (220.5). For the period January-December 2015 total revenues amounted to MSEK 643.3 (570.3), a growth of 13 percent compared with same period previous year, driven by Zubsolv® and Abstral® variable royalties.

Total net revenues were distributed as follows:

MSEK	**2015 Oct-Dec**	**2014 Oct-Dec**	**2015 Jan-Dec**	**2014 Jan-Dec**
Abstral royalties	39.5	27.9	77.2	46.6
Abstral fixed royalty	-	34.5	57.0	173.6
Milestone payment Abstral	65.6	58.5	66.0	58.5
Abstral – Total	***105.1***	***120.9***	***200.2***	***278.7***
Edluar® royalties	2.9	0.2	13.6	10.7
Zubsolv	120.3	79.5	416.7	228.0
Kibion	-	19.9	12.8	51.2
Total revenue from launched products	***228.3***	***220.5***	***643.3***	***568.6***
Other revenues	-	-	-	1.7
Total	**228.3**	**220.5**	**643.3**	**570.3**

Costs and earnings

In this section, all references to future cost and spend levels are subject to changes of plan, the occurrence of unforeseen events and changes in exchange rates versus Swedish Kronor.

Cost of goods sold

The cost of goods sold amounted to MSEK 32.3 (35.4) for the period October-December 2015 and to MSEK 136.1 (107.4) for the period January-December 2015. Cost of goods sold for the period October-December all relates to Zubsolv.

Selling expenses

Selling expenses amounted to MSEK 72.0 (55.4) for the period October-December 2015; in line with previous guidance. For the period January-December 2015 selling expenses amounted to MSEK 297.5 (193.6). The increase over previous year is explained by no field force costs included for Q1 2014, field force expansion commenced in Q2 2015, and finally an increased USD/SEK exchange rate. Quarterly selling expenses for the first half year 2016 is expected to be at a slightly lower level than in Q4, 2015, due to the reduction of field force, effective January 1, 2016.

Administrative expenses

Administrative expenses for the period October-December 2015 amounted to MSEK 41.8 (31.5); higher than previously guided due to expenses to protect IP rights. For the period January-December 2015 administrative expenses amounted to MSEK 141.5 (113.0), and approximately half of these expenses are directly related to protection of IP rights. Quarterly administrative expenses for the first half year 2016 is expected to be at the same level as in Q4, 2015, however this is highly dependent on the development of ongoing litigations, which was the largest single administrative expense category in 2015.

Research and development costs

For the period October-December 2015, research and development costs amounted to MSEK 56.0 (47.6). The period October-December includes MSEK 3.8 amortization of the intangible asset relating to the

Zubsolv® induction label. Since the approval of the indication, the amortization of the asset has commenced. For the period January-December 2015, R&D costs amounted to MSEK 172.6 (197.8); lower than previously guided due to timing of individual projects. R&D costs for the first half year 2016 are expected to be approximately MSEK 100.

Costs for long-term incentive program
The Group's total costs for employee stock option programs during the period October-December 2015 amounted to MSEK 2.0 (6.0). For the period January-December 2015 the costs amounted to MSEK -10.2 (5.7). The decreased costs are due to reduced provisions for social security fees due to the development of the Orexo share price during the period.

Other income and expenses
Other income and expenses amounted to MSEK -70.5 (8.4) during the period October-December 2015. The increase is mainly related to write down of the OX-MPI asset amounting to MSEK 62.3. Other than the write down, other income and expenses primarily comprised exchange-rate gains/losses from revaluation of balance sheet items in foreign currency. For the period January-December 2015, other income and expenses amounted to MSEK -64.6 (16.5).

Depreciation
Depreciation and amortization amounted to MSEK 6.8 (5.1) for the period October-December 2015 and to MSEK 18.4 (12.5) for the period January-December 2015. The increase is primarily is due to commencement of amortization of clinical trials following the approval of the Zubsolv induction label.

Net financial items
Net financial items for the period October-December 2015 amounted to MSEK -6.0 (-6.1) and for the period January-December 2015 net financial items amounted to MSEK -22.1 (-27.6). All the net financial items are related to financing activities.

Earnings
Operating earnings amounted to MSEK -44.3 (59.0) for the period October-December 2015 and to MSEK -169.0 (-25.0) the period January-December 2015.

Cash-flow and financial position

At December 31, 2015, cash and cash equivalents amounted to MSEK 198.1 (284.5) and interest-bearing liabilities to MSEK 494.4 (496.3).

Cash flow from operating activities amounted to MSEK 6.3 (-7.3) for the period October-December 2015 driven by a positive contribution from operating activities off-set by an increase in net working capital. Net working capital was primarily increased by a reduction in payables as significant Zubsolv rebates were due at the end of the quarter and this more than off-set the positive contribution from lowered inventory levels. Cash flow from operating activities for the period January-December amounted to MSEK -102.2 (-487.3).

Considering current cash position, significant Zubsolv inventory level, partnering projects (OX-51 and Zubsolv outside of US) and the existing Zubsolv, Abstral® and Edluar® business, the financial position is considered adequate for Orexo to pursue the current strategy.

Shareholders' equity at December 31, 2015 was MSEK 266.4 (455.0). The equity/assets ratio was 26 (37) percent.

The Board of Directors proposes that no dividend is paid for the financial year 2015.

Investments in fixed assets

Gross investments in tangible and intangible fixed assets amounted to MSEK 1.1 (7.8) for the period October-December 2015. For the period January-December 2015 gross investments amounted to MSEK 4.1 (71.7).

Parent Company

Net revenues for the period January-December 2015 amounted to MSEK 518.9 (398.5), where of related party transactions amounted to MSEK 305.0 (109.0). Earnings after financial items were MSEK -161.8 (-65.4). During the fourth quarter 2015, a write down of shares for the subsidiary Biolipox AB was recorded amounting to MSEK 63.8 MSEK related to the write down of the OX-MPI asset.
Investments amounted to MSEK 4.1 (71.3). As of December 31, 2015, cash and cash equivalents in the Parent Company amounted to MSEK 114.0 (247.2).

Risks and uncertainty factors

Significant risks and uncertainties are presented in the Annual Report for 2014. The overall risk has decreased since the approval of Zubsolv®. However, the launch of Zubsolv in the US will entail risk exposure of a more operational nature.

Future reporting dates

Annual General Meeting 2016	April 15, 2016, 4 p.m.
Interim report, January – March 2016	April 21, 2016
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

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.

Annual Report 2015

Orexo AB's Annual Report is to be published on the company website no later than March 24, 2016.

Uppsala, January 28, 2016
Orexo AB (publ)

Nikolaj Sørensen
President and CEO

Review report

Report of Review of Interim Financial Information

Introduction
We have reviewed this report for the period January 1 to December 31 2015 for Orexo AB (publ). The board of directors and the CEO are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of Review
We conducted our review in accordance with the International Standard on Review Engagements ISRE 2410, Review of Interim Report Performed by the Independent Auditor of the Entity. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing, ISA, and other generally accepted auditing standards in Sweden. The procedures performed in a review do not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Conclusion
Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material respects, in accordance with IAS 34 and the Swedish Annual Accounts Act, regarding the Group, and with the Swedish Annual Accounts Act, regarding the Parent Company.

Uppsala, January 28, 2016
PricewaterhouseCoopers AB

Lars Kylberg
Authorised Public Accountant

Mikael Winkvist
Authorised Public Accountant

Consolidated statement of operations

MSEK	Notes	2015 Oct-Dec	2014 Oct-Dec	2015 Jan-Dec	2014 Jan-Dec
Net revenues		228.3	220.5	643.3	570.3
Cost of goods sold	2	-32.3	-35.4	-136.1	-107.4
Gross profit		**196.0**	**185.1**	**507.2**	**462.9**
Selling expenses	2	-72.0	-55.4	-297.5	-193.6
Administrative expenses	2	-41.8	-31.5	-141.5	-113.0
Research and development costs	2	-56.0	-47.6	-172.6	-197.8
Other operating income and expenses	2	-70.5	8.4	-64.6	16,5
Operating earnings		**-44.3**	**59.0**	**-169.0**	**-25.0**
Net financial items		-6.0	-6.1	-22.1	-27.6
Earnings before tax		**-50.3**	**52.9**	**-191.1**	**-52.6**
Tax		-1.5	-1.3	-6.9	-4.0
Net earnings for the period[1)]		**-51.8**	**51.6**	**-198.0**	**-56.6**

Consolidated statement of comprehensive income

MSEK	2015 Oct-Dec	2014 Oct-Dec	2015 Jan-Dec	2014 Jan-Dec
Earnings for the period	**-51.8**	**51.6**	**-198.0**	**-56.6**
Other comprehensive income				
Items that may subsequently be reversed to the statement of operations:				
Cash flow hedge	-	1.5	2.8	-2.8
Exchange-rate differences	-8.5	-1.2	-4.3	-0.3
Other comprehensive earnings for the period, net after tax	**-8.5**	**0.3**	**-1.5**	**-3.1**
Total comprehensive earnings for the period [1)]	**-60.3**	**51.9**	**-199.5**	**-59.7**
Earnings per share, before dilution, SEK	-1.50	1.50	-5.74	-1.73
Earnings per share, after dilution, SEK	-1.50	1.46	-5.74	-1.73

[1)] 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	2015 Dec 31	2014 Dec 31
ASSETS			
Fixed assets			
Tangible fixed assets		24.7	29.1
Goodwill		-	27.4
Acquired research and development		-	62.3
Other intangible fixed assets		159.1	169.5
Financial assets		2.1	1.2
Total fixed assets		**185.9**	**289.5**
Current assets			
Inventories		398.9	478.1
Accounts receivable and other receivables		233.4	173.8
Cash and cash equivalents		198.1	284.5
Total current assets		**830.4**	**936.4**
Total assets		**1,016.3**	**1,225.9**
SHAREHOLDERS' EQUITY AND LIABILITIES			
Total shareholders' equity	3	**266.4**	**455.0**
Long-term liabilities			
Provisions		3.9	9.0
Long-term liabilities, interest bearing		494.4	493.8
Total long-term liabilities		**498.3**	**502.8**
Current liabilities			
Current liabilities, non-interest bearing		251.6	265.6
Current liabilities, interest bearing		-	2.5
Total current liabilities		**251.6**	**268.1**
Total liabilities		**749.9**	**770.9**
Total shareholders' equity and liabilities		**1,016.3**	**1,225.9**

Consolidated changes in shareholders' equity

MSEK	2015 Dec 31	2014 Dec 31
Opening balance, shareholders' equity	**455.0**	**161.5**
Total comprehensive earnings for the period	-199.5	-59.7
Employee stock options, vested amount	7.1	11.5
New share issues	3.8	189.7
Sales of treasury shares	-	152.0
Closing balance, shareholders' equity	**266.4**	**455.0**

Consolidated cash-flow statements

MSEK	Notes	2015 Oct-Dec	2014 Oct-Dec	2015 Jan-Dec	2014 Jan-Dec
Operating earnings		-44.3	59.0	-169.0	-25.0
Financial income and expenses		-7.5	-7.4	-29.0	-31.6
Adjustment for non-cash items	4	71.1	11.8	78.6	21.0
Cash flow from operating activities before changes in working capital		**19.3**	**63.4**	**-119.4**	**-35.6**
Changes in working capital		**-13.0**	**-70.7**	**17.2**	**-451.7**
Cash flow from operating activities		**6.3**	**-7.3**	**-102.2**	**-487.3**
Acquisition of tangible and intangible fixed assets		-1.1	-7.8	-4.1	-71.7
Sales of machinery and equipment		-	-0.2	-	-
Sales of subsidiary		**-**		21.8	
Cash flow from investing activities		**-1.1**	**-8.0**	**17.7**	**-71.7**
New share issue		-	1.3	3.8	189.7
Sales of treasury shares		-	-	-	152.0
Change in loans		-	-0.4	-1.2	397.7
Cash flow from financing activities		**-**	**0.9**	**2.6**	**739.4**
Cash flow for the period		**5.2**	**-14.4**	**-81.9**	**180.4**
Cash and cash equivalents at the beginning of the period		**201.2**	**299.2**	**284.5**	**105.6**
Exchange-rate differences in cash and cash equivalents		-8.3	-0.3	-4.5	-1.5
Changes in cash and cash equivalents		5.2	-14.4	-81.9	180.4
Cash and cash equivalents at the end of the period		**198.1**	**284.5**	**198.1**	**284.5**

Key figures

	2015 Oct-Dec	2014 Oct-Dec	2015 Jan-Dec	2014 Jan-Dec
Operating margin, %	-19	27	-26	-4
Return on equity, %	-17	13	-53	-27
Net debt, MSEK	-296.3	-211.8	-296.3	-211.8
Debt/equity ratio, %	186	109	186	109
Equity/assets ratio, %	26	37	26	37
Number of shares, before dilution	34,580,810	34,345,697	34,580,810	34,345,697
Number of shares, after dilution	34,873,345	35,306,976	34,873,345	35,306,976
Earnings per share, before dilution, SEK	-1.50	1.50	-5,74	-1.73
Earnings per share, after dilution, SEK	-1.50	1.46	-5.74	-1.73
Number of employees at the end of the period	90	90	90	90
Shareholders' equity, KSEK	266,459	455,023	266,459	455,023
Capital employed, KSEK	760,793	951,259	760,793	951,259

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

Parent Company statement of operations

MSEK	Notes	2015 Oct-Dec	2014 Oct-Dec	2015 Jan-Dec	2014 Jan-Dec
Net revenues		225.2	142.8	518.9	398.5
Cost of goods sold		-54.2	-7.8	-155.9	-64.2
Gross profit		**171.0**	**135.0**	**363.0**	**334.3**
Selling expenses		-56.6	-51.5	-226.9	-157.5
Administrative expenses		-33.5	-18.8	-108.1	-74.6
Research and development costs		-34.0	-35.0	-122.9	-160.7
Other operating income and expenses		-7.9	10.1	5.0	19.0
Operating earnings		**39.0**	**39.8**	**-89.9**	**-39.5**
Interest income and expenses		-5.1	-5.2	-18.7	-17.9
Impairment of shares in subsidiaries		-63.8	-	-63.8	-
Sales of subsidiary		-	-	13.1	-
Other financial expenses		-0.7	-0.6	-2.5	-8.0
Net financial items		**-69.6**	**-5.8**	**-71.9**	**-25.9**
Earnings before tax		**-30.6**	**34.0**	**-161.8**	**-65.4**
Tax		-	-0.4	-0.5	-0.5
Earnings for the period		**-30.6**	**33.6**	**-162.3**	**-65.9**

Parent Company balance sheet

MSEK	Notes	2015 Dec 31	2014 Dec 31
ASSETS			
Fixed assets			
Tangible and intangible fixed assets		182.9	196.6
Shares in subsidiaries		148.5	208.8
Total fixed assets		**331.4**	**405.4**
Current assets			
Inventories		276.8	378.4
Accounts receivable and other receivables		320.7	232.7
Cash and bank balances		114.0	247.2
Total current assets		**711.5**	**858.3**
Total assets		**1,042.9**	**1,263.7**
SHAREHOLDERS' EQUITY. PROVISIONS AND LIABILITIES			
Shareholders' equity		**353.4**	**504.7**
Long-term liabilities		**498.2**	**500.9**
Current liabilities		**191.3**	**258.1**
Total liabilities		**689.5**	**759.0**
Total shareholders' equity and liabilities		**1,042.9**	**1,263.7**
Pledged assets		**100.0**	**100.0**
Contingent liabilities		**-**	**-**

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 2014 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 2015

- 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	2015 Oct-Dec	2014 Oct-Dec	2015 Jan-Dec	2014 Jan-Dec
Raw materials and supplies	28.5	30.3	120.2	91.8
Other external costs	136.8	95.5	499.3	375.2
Personnel costs	41.1	46.1	146.6	154.4
Depreciation/amortization and impairment	69.1	5.1	80.7	12.5
Total	**275.5**	**177.0**	**846.8**	**633.9**

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 December 31, 2015 was 34,580,810. All ordinary shares carry entitlement to one vote each. Class C shares carry entitlement to 1/10 vote each.

Number of shares outstanding at January 1, 2015	34,345,697
Class C shares	135,000
Subscription for shares through exercise of employee stock options	100,113
Shares outstanding as of December 31, 2015	34,580,810

During the period 2,953 board stock options were exercised. These have not yet been registered as shares.

Options

As of December 31, 2015, a total of 1,894,965 options were outstanding that carry rights to new subscription of 1,777,728 shares in Orexo and the exchange of 117,237 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.

Options to employees and Board members	**Opening, Jan 1, 2015**	**Change**	**Closing, Dec 31, 2015**
Of which:			
Approved and allotted employee stock options	1,851,105		1,851,105
Exercised		-100,113	-100,113
Allotted		127,404	127,404
Expired		-211,623	-211,623
Approved and allotted board stock options	199,022		199,022
Expired		-3,750	-3,750
Exercised		-2,953	-2,953
Employee stock options approved by AGM, unallotted*	497,417	-	497 417
Warrants held by subsidiaries as cash-flow hedging for social security fees	36,473	-600	35,873
Total number of options outstanding	**2,584,017**	**-689,052**	**1,894,965**

*All 497,417 unalloted options will be cancelled due to new LTI program implemented during 2015.

During the period January-December 2015, a total of 103,066 employee/board stock options from Orexo's options program were exercised.

Number of shares after full dilution

Shares outstanding at December 31, 2015	34,580,810
Employee/board stock options allotted	1,777,728
Shares not registered	2,953
	36,361,491

4. Cash flow

Adjustment for non-cash items

MSEK	**2015 Oct-Dec**	**2014 Oct-Dec**	**2015 Jan-Dec**	**2014 Jan-Dec**
Depreciation/amortization and impairment	69.1	4.4	80.7	12.5
Estimated costs for employee stock options program	2.0	6.0	-10.2	5.7
Cash flow hedge	-	1.4	2.8	2.8
Sales of subsidiary	-	-	5.3	-
Total	**71.1**	**11.8**	**78.6**	**21.0**

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 U.S. prior to the expiration of Orexo's U.S. 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 began as of the date Orexo AB received the Notice Letter from Actavis that notified Orexo of the ANDA filing. The process is still ongoing.

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 January 28, 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.