



## Full year report January-December 2014

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

### Zubsolv® continues to gain market share

#### Fourth quarter 2014

- Total net revenues amounted to MSEK 220.5 (99.5). Revenues from launched products, excluding one-off milestones, amounted to MSEK 162.0 (99.5).
- Earnings after tax were MSEK 51.6 (-37.8).
- Earnings per share were SEK 1.50 (-1.19).
- Cash flow from operating activities amounted to MSEK -7.3 (-115.5).
- Orexo submitted application to FDA for expanded label for Zubsolv®.
- FDA approved two higher dosage strengths of Zubsolv.
- Orexo received MGBP 5 milestone payment for Abstral® in Europe.

#### January-December 2014

- Total net revenues amounted to MSEK 570.3 (429.4). Revenues from launched products, excluding one-off milestones, amounted to MSEK 510.1 (310.8).
- Earnings after tax were MSEK -56.6 (-154.9).
- Earnings per share were SEK -1.73 (-5.16).
- Cash flow from operating activities amounted to MSEK -487.3 (-265.8).
- Completion of issue and listing of a MSEK 500 unsecured bond and private placement of approx. MSEK 346.5, including all Orexo shares held in treasury by the company in addition to newly issued shares.
- Cash and cash equivalents amounted to MSEK 284.5 (105.6).
- Exclusive reimbursement agreement for Zubsolv entered with UnitedHealth Group and WellCare.
- inVentiv Health selected as new commercial partner for Zubsolv in the US from July 1<sup>st</sup>.
- Positive results achieved from two phase 3 clinical trials assessing Zubsolv for induction of buprenorphine maintenance therapy and top-line data showing that Zubsolv is as effective as Suboxone® film in the treatment of opioid dependence.
- Orexo commenced patent infringement litigation against Actavis concerning Zubsolv.
- OX-MPI project was returned to Orexo.
- Orexo enhanced its commercial focus by placing all manufacturing of Zubsolv with partners in the US and streamlining operations in Uppsala.

MSEK	2014	2013	2014	2013
	Oct-Dec	Oct-Dec	Jan-Dec	Jan-Dec
Net revenues	220.5	99.5	570.3	429.4
Revenues from launched products	220.5	99.5	568.6	421.6
EBIT	59.0	-31.7	-25.0	-139.7
EBITDA	64.1	-29.0	-12.5	-89.1
Earnings after tax	51.6	-37.8	-56.6	-154.9
Earnings per share before dilution, SEK	1.50	-1.19	-1.73	-5.16
Cash flow from operating activities	-7.3	-115.5	-487.3	-265.8
Cash and cash equivalents	284.5	105.6	284.5	105.6

**Teleconference**

CEO Nikolaj Sørensen and CFO Henrik Juuel will present the report at a teleconference on January 29, 2014 at 2:00pm CET (08:00am EDT).

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

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## CEO's comments

It is with pride that I can report a long list of achievements for Orexo during 2014 accomplished by our colleagues in Sweden and the US. Orexo gained significantly more traction with Zubsolv in the US and we have successfully completed the first Zubsolv post-launch clinical trials and product developments. We have also strengthened the Swedish and the US organizations and we have created a stronger financial platform by raising nearly SEK 850 million in additional capital to support launch of Zubsolv and life cycle management activities.

The main focus during 2014 has been to continue the launch of Zubsolv in the US. We are proud to see that the brand has reached a market share of nearly 6 percent. Benchmarking the Zubsolv launch to other similar launches of new formulations of opioids, Zubsolv has been the strongest performing launch since 2011 and with significant margin outperformed the most recent launch in the Buprenorphine/Naloxone category. A key growth driver has been the continuing improvement in market access and by the third quarter we completed our objective of having equal or better access to the market than our leading branded competitor for more than 50 percent of the market. We have successfully closed exclusive contracts for patients within CVS/Caremark and United Health Group and in the fourth quarter with WellCare. These exclusive contracts have been important in gaining physicians' and patients' confidence in Zubsolv and we have seen many physicians increasing their brand preference for Zubsolv after initiating treatment with the product following an exclusive contract implementation. During 2014 we have made a large transition of the sales force, moving the field force to a new partner and employing all sales managers within Orexo. Clear benefits from this change in field force structure have materialized during the fourth quarter, where we have seen consistent improvements in field force productivity and we have seen the first sales districts exceeding 15 percent market share and several other now exceeding 10 percent.

To secure the long term growth of Zubsolv, we have continued with extensive investments in the product. During 2014 we completed two clinical trials and gained approval for two additional dosage strengths in December. The clinical trial comparing Zubsolv with our leading competitor, the ISTART study, was especially important. The study confirmed the patient preference for Zubsolv and that the two products have a similar clinical effect. This study has gained positive attention and improved the dialogue with physicians significantly. The results have enabled us to apply for an expanded label to include induction of treatment and we have received confirmation from the FDA that the expected approval date is during the third quarter of 2015.

During 2014, we have strengthened our financial position considerably and with this strong financial position, we will continue to invest in the development of the Zubsolv franchise. During 2015 we will seek approval for one additional dosage strength and plan to initiate at least one new clinical trial. 2015 is also a year where the work to enable the launch of Zubsolv outside the US will intensify. Together with colleagues at Orexo in Sweden and the US we are looking forward to 2015 with great confidence. Our top priority remains securing the commercial success of Zubsolv, but we are also excited about starting to take the next steps in the life cycle of Zubsolv, progressing the development of OX51 and evaluating new development projects.

Nikolaj Sørensen  
President and CEO

# Operations

## Launched products

### Zubsolv® – treatment of opioid dependence

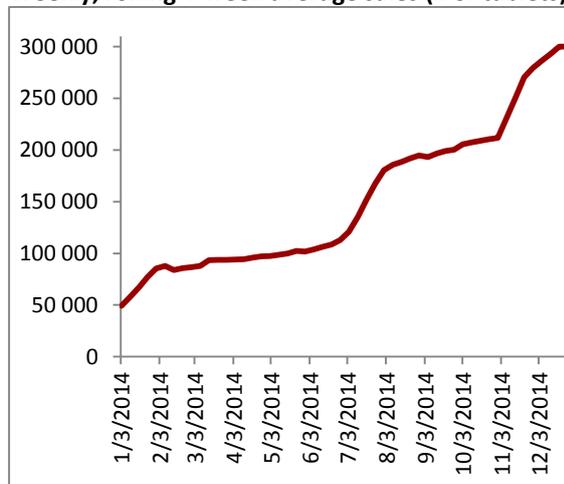
(buprenorphine/naloxone CIII sublingual tablet) for maintenance treatment of opioid dependence

#### Sales performance

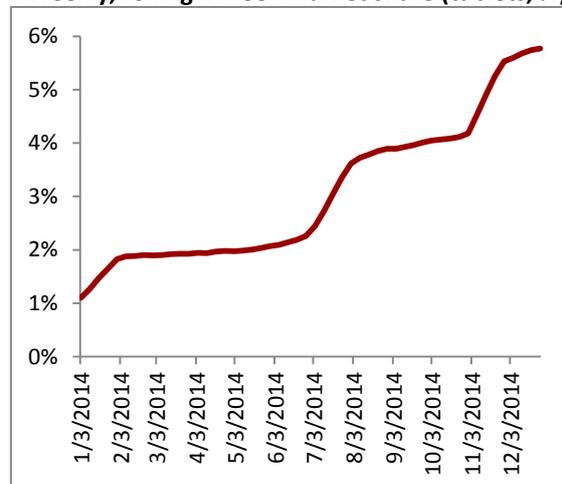
The fourth quarter demonstrated strong tablet growth of 41 percent vs the third quarter (IMS data). Zubsolv grew steadily through October and implementation of the WellCare exclusive contract effective November 1<sup>st</sup> accelerated the positive trend. When excluding the effect of the WellCare contract Zubsolv grew with 19 percent and significantly outgrew the market (3 percent) across all books of business during the quarter. Zubsolv's sales force productivity metrics have improved significantly post the inVentiv transition. Sales Force execution and Zubsolv messages are being delivered with better precision and this has strengthened confidence with our customer base. The confidence is strengthened by the new marketing message based on the iSTART clinical data, which demonstrates similar clinical efficacy of Zubsolv vs. Suboxone Film coupled with a 70 percent patient preference, as objectively measured by the iSTART study which had 758 patients participating. The trial data reinforces directly the message we have been communicating since launch.

During the fourth quarter the payer mix of Zubsolv spread more broadly across multiple payer segments primarily due to the market access improvements secured in the public sector with the majority of the shift coming from the implementation of the WellCare exclusive agreement. For the fourth quarter the commercial and cash segment now represents 73 percent of the payer mix versus 90 percent as reported in the third quarter report, and the Medicaid segment now accounts for 23 percent of Zubsolv turnover. As a reminder from the Q3 report, the commercial and cash segment rebate levels are lower than those associated with public payers (Medicaid & Medicare). However the expectation and experience of the public payers is that they have a positive effect on patients with other insurances and those paying cash. The growth of prescriptions to patients with commercial insurance not offering Zubsolv exclusively was 33 percent and prescriptions to the cash paying patients grew 26 percent. This will have a positive impact on the net sales of Zubsolv long term.

Weekly, rolling 4-week average sales (# of tablets)



Weekly, rolling 4-week market share (tablets, %)



Note: Weekly script data is based on extrapolation and is associated with uncertainties in the launch phase of new pharmaceuticals  
Source: Wolters Kluwer weekly data

## **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 2014.

### **Abstral**

Sales of Abstral in the EU continue to grow and the increase in Q3 was 26 percent compared to Q3 in 2013. Total sales in the EU for Q1-Q3 amounted to MEUR 49. Orexo receives royalties on sales exceeding MEUR 42.5 and estimated royalties were included in the results from September. The annual sales of Abstral in the EU exceeded MEUR 60.0 during 2014 and in December triggered a milestone payment of MGBP 5 from the commercial partner in Europe, ProStrakan Group plc.

The US market for Abstral, i.e. fentanyl-based products for breakthrough pain, continues to grow. Net sales of Abstral reached MUSD 1.6 in Q3. Orexo's partner in the US, Galena Biopharma Inc., has indicated full year sales in the range of MUSD 8-10 in 2014. Galena Biopharma is continuing with a patient registry study (RELIEF) to evaluate patient experience with Abstral for breakthrough cancer pain, assessing patient-reported data using quality-of-life and pain measurement tools. This data will become important for the future commercial success of Abstral. Orexo has announced that a paragraph IV patent certification notice has been received from Actavis Laboratories FL, Inc. Together with Galena Biopharma, Orexo is investigating the details of the notice before deciding upon the response.

The launch of Abstral in Japan has been successful. The Japanese market for treatment of breakthrough cancer pain with rapid-acting fentanyl is still in the early stages. Hence, our commercial partner Kyowa Hakko Kirin continues to focus on growing the market.

### **Edluar**

The global sales of Edluar, commercialized by Meda AB, have continued to increase during Q1-Q3 2014. Royalties for the fourth quarter 2014 were negatively impacted by a retroactive adjustment made together with Orexo's partner Meda AB and resulted in a net royalty of only MSEK 0.2 recognized for the quarter.

## **Kibion – diagnosis of Helicobacter Pylori**

The new distribution strategy for Kibion, with a more streamlined network of distributors, especially in the Middle East region, generated strong sales performance contributing to all time high sales for the period October-December 2014 with MSEK 19.9 (17.7) and for the period January-December 2014 MSEK 51.2 (48.8). Kibion delivered a positive profit contribution to Orexo of MSEK 3.5 for 2014, which is the strongest result for Kibion ever. The positive profit development can be attributed to a significant focus on profitable growth and streamlining of the operations. Development activities on the new IRIS system have been successfully completed enabling market introduction during first quarter 2015. The new IRIS system is expected to generate increased system sales as well as increased Diabact UBT sales.

## **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 invasive procedures.

A placebo-controlled dose-finding study in prostate biopsies was completed in June 2013. The results supported a continuation of the development of OX51 to the next phase in development towards a new product.

We are currently assessing different alternatives to advance this program. The alternatives assessed include the possibility of Orexo taking the program into phase III alone or finding a partner to collaborate with for selected geographies in phase III and commercialization.

## **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.

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 process to identify a new external partner for OX-MPI has been initiated.

The OX-MPI project is associated with an intangible fixed asset of MSEK 62 from the acquisition of Biolipox and this asset will be impaired if a final decision is taken to discontinue the project.

### **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. Under the agreement AstraZeneca gains the rights to perform extensive preclinical research and evaluation of substances in Orexo's OX-CLI program. AstraZeneca also has an option to acquire all substances linked to the program. Transfer and a licensing agreement will then be agreed on by the parties, whereby Orexo will receive milestone payments during the development phase and royalty payments based on future revenues. AstraZeneca is responsible for all development costs for the project.

## The period January-December in numbers

### Revenues

#### Launched products

Total revenues from Orexo's launched products amounted to MSEK 220.5 (99.5) during the period October-December 2014, an increase of 122 percent compared with the same period the previous year. The period October-December 2014 included an Abstral® milestone payment amounting to MSEK 58.5. Excluding this, growth was 63 percent and driven by Zubsolv. For the period January-December 2014 revenues from launched products amounted to MSEK 568.6 (421.6), with Zubsolv revenue growth more than off-setting higher Abstral milestone payments in 2013.

Since the Q2 2014 report Orexo has recognized Zubsolv revenue based on wholesaler invoicing. Zubsolv revenue in the Orexo P&L is the net revenue derived from gross revenue invoiced to wholesalers less rebates to payers, vouchers and copay cards to patients, wholesaler fees and provisions for potential and actual product returns. On a full year basis, the revenue impact of the change in accounting approach was immaterial as sales to wholesalers followed the patient demand rather closely.

The increased demand for Zubsolv was to a large extent driven by the WellCare exclusive agreement that was effective from November 1, 2014, but also supported by continued growth in the non-exclusive segment. Zubsolv average market share in tablets for the four weeks of December ended at 5.8 percent, up 1.8 percentage points from September, according to Wolters Kluwer weekly sales data.

The strong increase of 41 percent in Zubsolv tablet demand (IMS) translated into a 30 percent increase in ex-factory<sup>1</sup> tablet sales due to higher wholesaler inventory growth in the third quarter compared with the fourth quarter. Net revenue of Zubsolv grew by 16.2 percent in Q4 vs Q3, supported by stronger USD vs SEK especially later in the fourth quarter. Net revenue in Q4 was negatively impacted by the payer composition further skewed towards exclusive agreements with the implementation of the WellCare deal. Continued growth in the non-exclusive segment will improve net revenue relative to gross revenue.

Total Abstral royalties and milestone payments amounted to MSEK 120.9 (72.4) for the period October-December 2014 and to MSEK 278.7 (356.8) for the period January-December 2014. The increase for the period October-December 2014 is explained by the milestone payment in the period and growth in sales in both the US and EU. The milestone payment was earned when annual sales of Abstral in Europe passed MEUR 60. The period January-December 2013 included a one-time payment related to sales of Abstral in the US and approval of Abstral in Japan amounting to MSEK 110.8. In 2015 Orexo expects to receive royalties for Abstral in Europe from the third quarter, when sales of Abstral is expected to exceed the MEUR 42.5 annual threshold for royalty payments from Europe.

The fixed and un-conditional Abstral royalties for the period October-December 2014 were MSEK 34.5, out of the total Abstral royalties of MSEK 62.4. This part represents an amortization of the final fixed and unconditional payment related to the 2012 agreement with ProStrakan. The fixed payment amounts will be fully recognized in the P&L by May 2015 and will in 2015 amount to MSEK 34.5 in Q1 and MSEK 23.0 in Q2. As these fixed payments have all been received the recognition in the P&L has no cash impact.

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<sup>1</sup> Ex-factory sales: Gross value of tablets sold and invoiced to wholesalers, i.e. before rebates to payers and other deductions.

Royalty revenues from Edluar® amounted to MSEK 0.2 (2.6) for the period October-December 2014 and to MSEK 10.7 (8.7) for the period January-December 2014.

The period October – December 2014 was negatively impacted by royalty corrections made together with our partner, amounting to approx. MSEK 2 related to previous periods.

Kibion's sales for the period October-December 2014 were MSEK 19.9 (17.7) and for the period January-December 2014 MSEK 51.2 (48.8), corresponding to 5 percent growth for the full year.

### Revenues related to development projects

There were no revenues related to development projects during the period January-December 2014. During January-December 2013, there were revenues related to approval of Abstral in Japan amounting to MSEK 7.8.

### Other revenues

No other revenues were recognized during the period October-December 2014. During the period April-June 2014, Orexo's subsidiary Biolipox received a minor milestone payment in the form of shares in the company Aquinox Pharmaceuticals.

### Total revenues

Total revenues during the period October-December 2014 amounted to MSEK 220.5 (99.5), an increase of 121 percent compared with the same period the previous year, driven by Zubsolv and Abstral. For the period January-December 2014 total revenues amounted to MSEK 570.3 (429.4), an increase of 33 percent and driven by Zubsolv that more than compensated for lower Abstral net revenue.

### Total net revenues were distributed as follows:

MSEK	Oct-Dec 2014	Oct-Dec 2013	Jan-Dec 2014	Jan-Dec 2013
Abstral royalties	27.9	16.8	46.6	17.7
Abstral fixed royalty <sup>*)</sup>	34.5	55.6	173.6	228.3
Milestone payment Abstral	58.5	-	58.5	110.8
<b>Abstral – Total</b>	<b>120.9</b>	<b>72.4</b>	<b>278.7</b>	<b>356.8</b>
Edluar royalties	0.2	2.6	10.7	8.7
Zubsolv	79.5	6.8	228.0	7.3
Kibion	19.9	17.7	51.2	48.8
<b>Total revenue from launched products</b>	<b>220.5</b>	<b>99.5</b>	<b>568.6</b>	<b>421.6</b>
Partner-financed R&D costs	-	-	-	6.2
Licensing revenue for development projects	-	-	-	1.6
Other revenues	-	-	1.7	-
<b>Total</b>	<b>220.5</b>	<b>99.5</b>	<b>570.3</b>	<b>429.4</b>

<sup>\*)</sup> For more details, see Revenues – Launched products on page 9.

### Costs and earnings

#### Cost of goods sold

The cost of goods sold amounted to MSEK 35.4 (3.5) for the period October-December 2014 and to MSEK 107.4 (29.3) for the period January-December 2014.

#### Selling expenses

Selling expenses amounted to MSEK 55.4 (41.7) for the period October-December 2014. The increase was driven by the commercialization of Zubsolv® in the US. The full cost of the US field force was only included from Q2 2014. Selling expenses for the period January-December 2014 amounted to MSEK 193.6 (125.1), in line with previous guidance.

#### *Administrative expenses*

Administrative expenses for the period October-December 2014 amounted to MSEK 31.5 (37.9). For the period January-December 2014 administrative expenses amounted to MSEK 113.0 (126.4), in line with previous guidance.

#### *Research and development costs*

For the period October-December 2014, research and development costs amounted to MSEK 47.6 (47.2). The costs are attributable to clinical studies and other life cycle management activities in the Zubsoolv<sup>®</sup> program.

For the period January-December 2014, R&D costs amounted to MSEK 197.8 (238.2) and the R&D spend amounted to MSEK 259.0, including MSEK 61.2 of capitalized R&D spend. The R&D costs for the period October-December were below the level previously guided due to phasing of the R&D projects.

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

The Group's total costs for employee stock option programs during the period October-December 2014 amounted to MSEK 6.0 (21.3). For the period January-December 2014 the costs amounted to MSEK 5.7 (40.0). 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 8.4 (-0.9) during the period October-December 2014 and to MSEK 16.5 (-50.1) for the period January-December 2014. Other income and expenses primarily comprised exchange-rate gains/losses. Other expenses for the period October-December 2014 include MSEK 3.6 attributable to the announced restructuring of the Uppsala organization. For the period January-December 2014 a total of MSEK 4.7 in restructuring costs has been included. Another MSEK 1.1 restructuring cost is included under Research and development costs. The period January-December 2013 included an impairment charge of MSEK 43.9 related to the OX-NLA project.

#### *Depreciation and amortization*

Depreciation and amortization amounted to MSEK 5.1 (2.7) for the period October-December 2014 and to MSEK 12.5 (6.7) for the period January-December 2014.

#### *Net financial items*

Net financial items for the period October-December 2014 amounted to MSEK -6.1 (-4.6) and include costs for the corporate bond amounting to MSEK 6.2. For the period January-December 2014 net financial items amounted to MSEK -27.6 (-13.7).

#### *Earnings*

Operating earnings amounted to MSEK 59.0 (-31.7) for the period October-December 2014 and to MSEK -25.0 (-139.7) for the period January-December 2014.

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

At December 31, 2014, cash and cash equivalents amounted to MSEK 284.5 (105.6) and interest-bearing liabilities to MSEK 496.3 (241.1).

Cash flow from operating activities amounted to MSEK -7.3 (-115.5) for the period October-December 2014 and to MSEK -487.3 (-265.8) for the period January-December 2014. Cash flow from operating activities includes the payment of the MGBP 5 Abstral milestone earned and communicated in December 2014. Despite receiving the MGBP 5 milestone payment in December, the cash flow from operating activities is still below the EBIT for the quarter primarily as the fixed Abstral royalty has no cash impact and as Accounts receivable increase following

increased Zubsolv and Abstral revenue. Cash flow from financing activities amounted to MSEK 0.9 (192.9) for the period October-December 2014.

Cash flow before financing activities for the period January-December 2014 was MSEK -559.0. This amount was impacted by the significant Zubsolv inventory build, the major Zubsolv clinical trials and the expansion of the commercial presence in the US. With the majority of the inventory build and the major studies now completed cash flow from operating activities has already improved significantly.

Shareholders' equity at December 31, 2014 was MSEK 455.0 (161.5). The equity/assets ratio was 37 (21) percent.

During 2014, Orexo completed two major financing activities. A MSEK 500 four year unsecured corporate bond was issued in May and then a private placement of 2,493,046 Orexo shares, including all Orexo shares held in treasury by the company in addition to newly issued shares, was completed in August. The private placement resulted in total cash proceeds of approximately MSEK 346.5 before transaction costs.

The Board of Directors proposes that no dividend is paid for the financial year 2014.

### **Investments in fixed assets**

Gross investments in tangible and intangible fixed assets amounted to MSEK 7.8 (61.5) for the period October-December 2014. For the period January-December 2014 gross investments amounted to MSEK 71.7 (107.5). The investments mainly comprise capitalization of selected clinical trials in the amount of MSEK 61.2.

### **Parent Company**

Net revenues for the period January-December 2014 amounted to MSEK 398.5 (452.3), where of related party transactions amounted to MSEK 109.0 (79.1). Earnings after financial items were MSEK -65.4 (-44.3). Investments amounted to MSEK 71.3 (13.8). As of December 31, 2014, cash and cash equivalents in the Parent Company amounted to MSEK 247.2 (48.7).

### **Risks and uncertainty factors**

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

### **Future reporting dates**

Annual General Meeting 2015	April 15, 2015, 4 pm
Interim report, January – March 2015	April 23, 2015
Interim report, January – June 2015	July 10, 2015
Interim report, January – September 2015	October 22, 2015
Full year report for the 2015 financial year	January 28, 2016

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 2014**

Orexo AB's Annual Report is to be published on the company website no later than March 25, 2015.

Uppsala, January 29, 2015  
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 2014 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 29, 2015  
PricewaterhouseCoopers AB

Lars Kylberg  
Authorised Public Accountant

Mikael Winkvist  
Authorised Public Accountant

## Consolidated statement of operations

MSEK	Notes	2014 Oct-Dec	2013 Oct-Dec	2014 Jan-Dec	2013 Jan-Dec
Net revenues		220.5	99.5	570.3	429.4
Cost of goods sold	2	-35.4	-3.5	-107.4	-29.3
<b>Gross profit</b>		<b>185.1</b>	<b>96.0</b>	<b>462.9</b>	<b>400.1</b>
Selling expenses	2	-55.4	-41.7	-193.6	-125.1
Administrative expenses	2	-31.5	-37.9	-113.0	-126.4
Research and development costs	2	-47.6	-47.2	-197.8	-238.2
Other operating income and expenses	2	8.4	-0.9	16.5	-50.1
<b>Operating earnings</b>		<b>59.0</b>	<b>-31.7</b>	<b>-25.0</b>	<b>-139.7</b>
Net financial items		-6.1	-4.6	-27.6	-13.7
<b>Earnings before tax</b>		<b>52.9</b>	<b>-36.3</b>	<b>-52.6</b>	<b>-153.4</b>
Tax		-1.3	-1.5	-4.0	-1.5
<b>Net earnings for the period<sup>1)</sup></b>		<b>51.6</b>	<b>-37.8</b>	<b>-56.6</b>	<b>-154.9</b>

## Consolidated statement of comprehensive income

MSEK	2014 Oct-Dec	2013 Oct-Dec	2014 Jan-Dec	2013 Jan-Dec
<b>Earnings for the period</b>	<b>51.6</b>	<b>-37.8</b>	<b>-56.6</b>	<b>-154.9</b>
<b>Other comprehensive income</b>				
<i>Items that may subsequently be reversed to the statement of operations:</i>				
Cash flow hedge	1.5	1.1	-2.8	-8.7
Exchange-rate differences	-1.2	-1.7	-0.3	-1.9
<b>Other comprehensive earnings for the period, net after tax</b>	<b>0.3</b>	<b>-0.6</b>	<b>-3.1</b>	<b>-10.6</b>
<b>Total comprehensive earnings for the period<sup>1)</sup></b>	<b>51.9</b>	<b>-38.4</b>	<b>-59.7</b>	<b>-165.5</b>
Earnings per share, before dilution, SEK	1.50	-1.19	-1.73	-5.16
Earnings per share, after dilution, SEK	1.46	-1.19	-1.73	-5.16

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

## Consolidated balance sheet

MSEK	Notes	2014 Dec 31	2013 Dec 31
<b>ASSETS</b>			
<b>Fixed assets</b>			
Tangible fixed assets		29.1	33.3
Goodwill		27.4	26.4
Acquired research and development		62.3	62.3
Other intangible fixed assets		169.5	106.0
Financial assets		1.2	-
<b>Total fixed assets</b>		<b>289.5</b>	<b>228.0</b>
<b>Current assets</b>			
Inventories		478.1	383.4
Accounts receivable and other receivables		173.8	55.2
Cash and cash equivalents		284.5	105.6
<b>Total current assets</b>		<b>936.4</b>	<b>544.3</b>
<b>Total assets</b>		<b>1,225.9</b>	<b>772.3</b>
<b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>			
<b>Total shareholders' equity</b>	3	<b>455.0</b>	<b>161.5</b>
<b>Long-term liabilities</b>			
Provisions		9.0	9.6
Long-term liabilities, interest bearing		493.8	104.1
<b>Total long-term liabilities</b>		<b>502.8</b>	<b>113.7</b>
<b>Current liabilities</b>			
Current liabilities, non-interest bearing		265.6	360.1
Current liabilities, interest bearing		2.5	137.0
<b>Total current liabilities</b>		<b>268.1</b>	<b>497.1</b>
<b>Total liabilities</b>		<b>770.9</b>	<b>610.8</b>
<b>Total shareholders' equity and liabilities</b>		<b>1,225.9</b>	<b>772.3</b>

## Consolidated changes in shareholders' equity

MSEK	2014 Dec 31	2013 Dec 31
<b>Opening balance, shareholders' equity</b>	<b>161.5</b>	<b>191.2</b>
Total comprehensive earnings for the period	-59.7	-165.5
Employee stock options, vested amount	11.5	3.5
New share issues	189.7	19.4
Sales of treasury shares	152.0	-
Conversion of convertible bonds	-	112.9
<b>Closing balance, shareholders' equity</b>	<b>455.0</b>	<b>161.5</b>

## Consolidated cash-flow statements

MSEK	Notes	2014 Oct-Dec	2013 Oct-Dec	2014 Jan-Dec	2013 Jan-Dec
Operating earnings		59.0	-31.8	-25.0	-139.7
Financial income and expenses		-7.4	-6.2	-31.6	-11.6
Adjustment for non-cash items	4	11.8	24.0	21.0	86.9
<b>Cash flow from operating activities before changes in working capital</b>		<b>63.4</b>	<b>-14.0</b>	<b>-35.6</b>	<b>-64.4</b>
<b>Changes in working capital</b>		<b>-70.7</b>	<b>-101.5</b>	<b>-451.7</b>	<b>-201.4</b>
<b>Cash flow from operating activities</b>		<b>-7.3</b>	<b>-115.5</b>	<b>-487.3</b>	<b>-265.8</b>
Acquisition of tangible and intangible fixed assets		-7.8	-61.5	-71.7	-107.5
Sale of machinery and equipment		-0.2	-	-	-
<b>Cash flow from investing activities</b>		<b>-8.0</b>	<b>-61.5</b>	<b>-71.7</b>	<b>-107.5</b>
New share issue		1.3	8.8	189.7	19.4
Sales of treasury shares		-	-	152.0	-
Change in loans		-0.4	184.1	397.7	234.2
<b>Cash flow from financing activities</b>		<b>0.9</b>	<b>192.9</b>	<b>739.4</b>	<b>253.6</b>
<b>Cash flow for the period</b>		<b>-14.4</b>	<b>15.9</b>	<b>180.4</b>	<b>-119.7</b>
<b>Cash and cash equivalents at the beginning of the period</b>		<b>299.2</b>	<b>91.9</b>	<b>105.6</b>	<b>228.1</b>
Exchange-rate differences in cash and cash equivalents		-0.3	-2.2	-1.5	-2.8
Changes in cash and cash equivalents		-14.4	15.9	180.4	-119.7
<b>Cash and cash equivalents at the end of the period</b>		<b>284.5</b>	<b>105.6</b>	<b>284.5</b>	<b>105.6</b>

## Key figures

	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
	<b>Oct-Dec</b>	<b>Oct-Dec</b>	<b>Jan-Dec</b>	<b>Jan-Dec</b>
Operating margin, %	27	-31	-4	-32
Return on equity, %	13	-22	-27	-88
Net debt, MSEK	-211.8	-135.4	-211.8	-135.4
Debt/equity ratio, %	109	154	109	154
Equity/assets ratio, %	37	21	37	21
Number of shares, before dilution	34,345,697	31,790,784	34,345,697	31,790,784
Number of shares, after dilution	35,306,976	32,976,554	35,306,976	32,976,554
Earnings per share, before dilution, SEK	1.50	-1.19	-1.73	-5.16
Earnings per share, after dilution, SEK	1.46	-1.19	-1.73	-5.16
Number of employees at the end of the period	90	108	90	108
Shareholders' equity, KSEK	455,023	161,459	455,023	161,459
Capital employed, KSEK	951,259	402,533	951,259	402,533

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

## Parent Company statement of operations

MSEK	Notes	2014	2013	2014	2013
		Oct-Dec	Oct-Dec	Jan-Dec	Jan-Dec
Net revenues		142.8	43.5	398.5	452.3
Cost of goods sold		-7.8	-28.9	-64.2	-91.4
<b>Gross profit</b>		<b>135.0</b>	<b>14.6</b>	<b>334.3</b>	<b>360.9</b>
Selling expenses		-51.5	-8.6	-157.5	-45.1
Administrative expenses		-18.8	-28.6	-74.6	-110.0
Research and development costs		-35.0	-41.9	-160.7	-228.3
Other operating income and expenses		10.1	-0.8	19.0	-5.4
<b>Operating earnings</b>		<b>39.8</b>	<b>-65.3</b>	<b>-39.5</b>	<b>-27.9</b>
Interest income and expenses		-5.2	-0.6	-17.9	-10.1
Impairment of shares in subsidiaries		-	-	-	-2.2
Other financial expenses		-0.6	-4.1	-8.0	-4.1
<b>Net financial items</b>		<b>-5.8</b>	<b>-4.7</b>	<b>-25.9</b>	<b>-16.4</b>
<b>Earnings before tax</b>		<b>34.0</b>	<b>-70.0</b>	<b>-65.4</b>	<b>-44.3</b>
Tax		-0.4	-1.5	-0.5	-1.5
<b>Earnings for the period</b>		<b>33.6</b>	<b>-71.5</b>	<b>-65.9</b>	<b>-45.8</b>

## Parent Company balance sheet

MSEK	Notes	2014 Dec 31	2013 Dec 31
<b>ASSETS</b>			
<b>Fixed assets</b>			
Tangible and intangible fixed assets		196.6	137.4
Shares in subsidiaries		208.8	202.2
<b>Total fixed assets</b>		<b>405.4</b>	<b>339.6</b>
<b>Current assets</b>			
Inventories		378.4	303.3
Accounts receivable and other receivables		232.7	179.5
Cash and bank balances		247.2	48.7
<b>Total current assets</b>		<b>858.3</b>	<b>531.5</b>
<b>Total assets</b>		<b>1,263.7</b>	<b>871.1</b>
<b>SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES</b>			
<b>Shareholders' equity</b>		<b>504.7</b>	<b>217.4</b>
<b>Long-term liabilities</b>		<b>500.9</b>	<b>109.7</b>
<b>Current liabilities</b>		<b>258.1</b>	<b>544.0</b>
<b>Total liabilities</b>		<b>759.0</b>	<b>653.7</b>
<b>Total shareholders' equity and liabilities</b>		<b>1,263.7</b>	<b>871.1</b>
<b>Pledged assets</b>		<b>100.0</b>	<b>232.2</b>
<b>Contingent liabilities</b>		<b>-</b>	<b>-</b>

## 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 2013 Annual Report.
- The Parent Company's financial statements were prepared in accordance with RFR 2 (Swedish Financial Reporting Board's recommendation) and Chapter 9 of the Swedish Annual Accounts Act.

### New and amended accounting policies as of 2014

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

### 2. Costs distributed by type of cost

MSEK	2014	2013	2014	2013
	Oct-Dec	Oct-Dec	Jan-Dec	Jan-Dec
Raw materials and supplies	30.3	11.2	91.8	21.8
Other external costs	95.5	67.4	375.2	347.8
Personnel costs	46.1	59.7	154.4	167.0
Depreciation/amortization and impairment	5.1	2.2	12.5	50.1
<b>Total</b>	<b>177.0</b>	<b>140.5</b>	<b>633.9</b>	<b>586.7</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 December 31, 2014 was 34,345,697, all of which were common shares. All shares carry entitlement to one vote each.

Number of shares outstanding at January 1, 2014	32,911,908
Subscription for shares through exercise of employee stock options	61,867
New share issue	1,371,922
Shares outstanding at December 31, 2014	34,345,697

#### Options

As of December 31, 2014, a total of 2,584,017 options were outstanding that carry rights to new subscription of 2,546,855 shares in Orexo and the exchange of 37,162 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, 2014</b>	<b>Change</b>	<b>Closing, December 31, 2014</b>
Of which:			
Approved and allotted employee stock options	1,579,557		1,579,557
Exercised		-60,702	-60,702
Allotted		449,500	449,500
Expired		-117,250	-117,250
Approved and allotted Board options	215,688		215,688
Expired		-16,666	-16,666
Employee stock options approved by AGM, unallotted	829,667	-332,250	497,417
Warrants held by subsidiaries as cash-flow hedging for social security fees	38,123	-1,650	36,473
<b>Total number of options outstanding</b>	<b>2,663,035</b>	<b>-79,018</b>	<b>2,584,017</b>

During the period January-December 2014, a total of 59,702 employee stock options from Orexo's options program were exercised.

*Number of shares after full dilution*

Shares outstanding at December 31, 2014	34,345,697
Employee stock options allotted	2,050,127
Employee stock options not yet allotted	497,417 <sup>1)</sup>
Warrants for cash-flow hedging for social security fees	36,473
	36,929,714

<sup>1)</sup> Can be allotted during the current year.

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

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

<b>MSEK</b>	<b>2014 Oct-Dec</b>	<b>2013 Oct-Dec</b>	<b>2014 Jan-Dec</b>	<b>2013 Jan-Dec</b>
Depreciation/amortization and impairment	4.4	2.7	12.5	50.5
Estimated costs for employee stock options program	6.0	21.3	5.7	40.0
Financial expenses, convertible bond	1.4	-	2.8	-3.6
<b>Total</b>	<b>11.8</b>	<b>24.0</b>	<b>21.0</b>	<b>86.9</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.

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

Operations in PharmaKodex have been closed down. The acquired technology was written down in its entirety during 2011 and 2012. PharmaKodex's previous owners claim Orexo is using the PharmaKodex technology in the development of Zubsolv and initiated a legal process against Orexo in the UK. Orexo will vigorously dispute these unsubstantiated claims, as Zubsolv is developed without any use of technologies acquired from PharmaKodex. The maximum possible claims amount to MUSD 15.

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## 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 29, 2015, at 8:00am 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.