Interim report January-September 2014

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

Zubsolv® evolution continues. 81 percent increase in Zubsolv tablets prescribed compared to previous quarter.

Third quarter 2014

- Total net revenues amounted to MSEK 130.7 (121.1). Revenues from launched products, excluding one-off milestones, amounted to MSEK 130.7 (70.3).
- Earnings after tax were MSEK -36.8 (-28.9).
- Earnings per share were SEK -1.13 (-0.94).
- Cash flow from operating activities amounted to MSEK -152.1 (-229.9).
- 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.
- Orexo completed its private placement of approx. MSEK 346.5, including all Orexo shares held in treasury by the company in addition to newly issued shares.

January-September 2014

- Total net revenues amounted to MSEK 349.8 (329.9). Revenues from launched products, excluding one-off milestones, amounted to MSEK 348.1 (211.0).
- Earnings after tax were MSEK -108.2 (-117.1).
- Earnings per share were SEK -3.37 (-3.97).
- Cash flow from operating activities amounted to MSEK -480.0 (-150.3).
- Cash and cash equivalents amounted to MSEK 299.2 (91.9).
- Reimbursement agreement for Zubsolv signed with UnitedHealth Group and OptumRx.
- Orexo completed issue and listing of a MSEK 500 unsecured bond.
- inVentiv Health selected as new partner for the commercialization of Zubsolv in the US.
- Positive results from two phase III clinical trials assessing Zubsolv for induction of buprenorphine maintenance therapy.
- Top-line data from a phase III clinical trial demonstrated that Zubsolv is as effective as Suboxone® film in the treatment of opioid dependence.
- Orexo commenced patent infringement litigation against Actavis.

After the period

- Orexo submitted application to FDA for expanded label for Zubsolv®.

MSEK	**2014**	**2013**	**2014**	**2013**	**2013**
	Jul-Sep	**Jul-Sep**	**Jan-Sep**	**Jan-Sep**	**Jan-Dec**
Net revenues	130.7	121.1	349.8	329.9	429.4
Revenues from launched products	130.7	116.8	348.1	321.8	421.6
EBIT	-29.3	-25.5	-84.0	-107.9	-139.7
EBITDA	-26.8	-24.0	-76.6	-60.0	-89.1
Earnings after tax	-36.8	-28.9	-108.2	-117.1	-154.9
Earnings per share, SEK	-1.13	-0.94	-3.37	-3.97	-5.16
Cash flow from operating activities	-152.1	-229.9	-480.0	-150.3	-265.8
Cash and cash equivalents	299.2	91.9	299.2	91.9	105.6

Teleconference
CEO Nikolaj Sørensen, CFO Henrik Juuel and Chief Medical Officer Michael Sumner will present the report at a teleconference today at 1:30pm CET (07:30am EDT)..
Presentation slides are available via the link and on the website.
Internet: http://financialhearings.nu/141022/orexo/
Telephone: +46 8 519 993 59 (SE), +44 203 194 05 53 (UK) or +1 855 269 26 07 (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

During the third quarter we have taken several important steps to improve the treatment of opioid dependence and to establish Zubsolv as a preferred choice. We finalized the detailed analysis of our clinical studies. Especially the ISTART study demonstrated interesting and positive data for Zubsolv, outlined in the Zubsolv section, which will become the foundation for our commercial efforts in the fourth quarter. Another important milestone has been the implementation of the agreement with United Health Group (UHG) where Zubsolv became the exclusive choice for patients in the highly controlled plans of UHG. The agreement with UHG has been followed by additional market access agreements, the most noteworthy being the agreement with the largest commercial prescription payer, the pharmacy benefit manager (PBM) Express Scripts (ESI) and a leading Managed Medicaid provider WellCare. ESI will place Zubsolv in a preferred position from January 2015 and WellCare will place Zubsolv in an exclusive position with implementation starting in November this year.

I am pleased to see that sales of Zubsolv continue to grow; in terms of tablets prescribed Zubsolv increased by more than 80 percent compared to the second quarter. The significant growth resulted in a market share (tablets prescribed) that increased to 4 percent in September compared to 2.3 percent in June. A lot of the growth came from our agreement with UHG, however we also experienced double digit growth in all other major books of business, and even within large commercial insurance companies where Zubsolv is not yet a preferred product, for instance within ESI, we saw double digit growth. This shows that Zubsolv is competitive and during the summer we have seen many of our sales districts exceeding 10 percent market share in the commercial prescription segment i.e. the market segment where we have comparable or better market access than our competitors.

A continuous clinical and pharmaceutical development of Zubsolv is the foundation for our strategy to ensure sustainable long term growth. A first step on the clinical development was taken when we filed an application to expand the Zubsolv label to include Induction of treatment. In addition, we are expecting approval of our higher strengths shortly. With a new label and new dosages, more patients can get the right dose by taking only one tablet and thus reduce the need to combine different dosages from the first day of treatment. We are working on several additional life cycle initiatives for Zubsolv, which can differentiate the product further from competing treatment alternatives.

To ensure a solid financial foundation of Zubsolv and to advance our pipeline, we successfully completed a private share placement in September. Our major investments in inventory and clinical studies are behind us, we have streamlined the Swedish operations, and our US commercial operations are very close to break-even, we are now well positioned to expand our focus and will initiate the next steps in our development pipeline. Two immediate initiatives will be to decide the final development path and commercialization strategy for OX51 and for Zubsolv outside the US. For both initiatives we will assess the optimal timing of involving external partners from a value creation perspective. This will enable a continued management and R&D focus on the Zubsolv US launch and life cycle management.

Our main focus remains on the commercialization of Zubsolv. We will continue to expand our field force as market access improves and our expectations for the last quarter of 2014 are set high. We have accomplished a lot during the first three quarters of 2014, and we are fully committed to continue at a high pace to ensure that we gain additional market share, fully leveraging the clinical results from the ISTART study and improved market access.

Nikolaj Sørensen
President and CEO

Launched products

Zubsolv® – treatment of opioid dependence

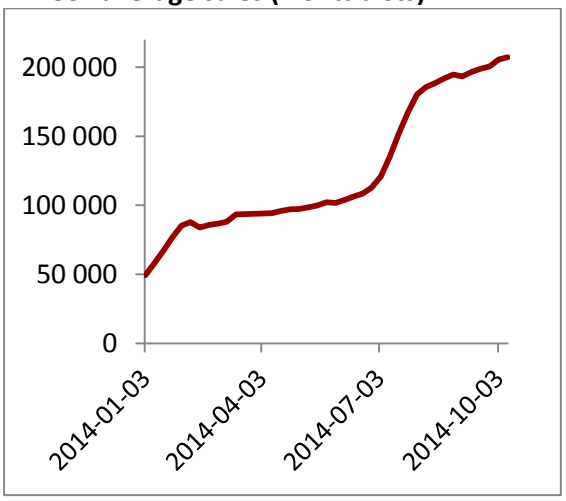
(buprenorphine/naloxone CIII sublingual tablet) for maintenance treatment of opioid dependence

Sales performance

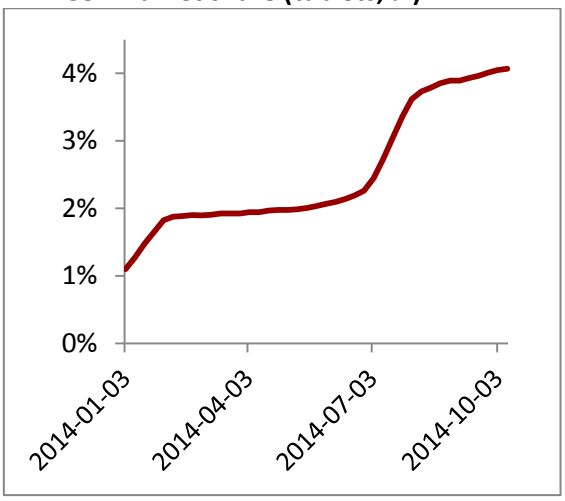
Zubsolv started the third quarter well by increasing the number of tablets prescribed by 64 percent in the first four full weeks of July compared to the last four weeks of June. Zubsolv has continued to outgrow the market during the quarter and in the last four full weeks (weeks 36-39) tablet sales increased by 15 percent compared to the first four full weeks of July. The market share in terms of number of tablets sold ended up at 4 percent in September compared to 2.3 percent in June.

The main driver of the increase has been the exclusive contract with UHG. However, Zubsolv has gained market share in all patient segments and the growth in August and September has been driven by patients with other insurance solutions. Many physicians starting to prescribe Zubsolv following the UHG agreement have broadened their prescription of Zubsolv to other patients, which was one of the objectives of the exclusive agreement.

4-week average sales (# of tablets)



4-week market share (tablets, %)



Note: Weekly script data is partly based on extrapolation and is associated with uncertainties
Source: Bloomberg, WK weekly data

Market access

Market access has continued to improve during the third quarter, with the largest and most important gain being the PBM ESI deciding to add Zubsolv to their preferred list as from January 1, 2015. ESI is the largest commercial prescription payer in the US, and until January 1, 2015, Zubsolv will be covered as non-preferred in a Tier 3 position. With the contract with ESI, Orexo has accomplished the aim of being covered in parity with or better than our leading branded competitor for the majority of the market. Furthermore, our agreement with CVS Caremark has been extended to 2015 as well.

During the quarter, Orexo has entered into agreements with several additional payers and improved the coverage in large states such as Michigan, Ohio, Texas and California. Additional agreements have been signed with the second and third largest managed Medicaid providers CareSource and WellCare. The WellCare agreement will be implemented starting November 1 and

is a fully exclusive contract for Zubsolv, which will be the only Bup/Nlx product available for patients insured through WellCare.

Today more than 90 percent of Zubsolv sales come from commercial and cash patients. The rebate agreements with public payers exceed the rebates to commercial insurance providers due to the system in the US guaranteeing public payers the best price. Thus, a higher share of public payers will have a negative impact on the gross to net revenue ratio at Orexo. The expectation is that public contracts will have a positive effect on patients with other insurance solutions as market share is critical to gaining attention and agreements with commercial insurance companies. For non-exclusive contracts with commercial providers the rebate is significantly lower. With additional overall volume Orexo will have greater opportunities to negotiate agreements with lower rebates and the expectation is to see improvement in the gross to net revenue ratio long term, provided price competition remains at the current level.

Life cycle management (LCM)

During the third quarter Orexo took an important LCM step forward. We have finalized the analysis of the ISTART (OX219-006) study with positive results and after the end of the quarter we finalized the analysis of the Induction results of the ISTART (OX219-006) study and OX219-007 study and this has enabled Orexo to submit an application for an expanded label.

ISTART results

On June 23, Orexo announced the top-line data from a Phase III clinical trial demonstrating that Zubsolv is as effective as Suboxone® film in the treatment of opioid dependence. The results from a randomized, non-inferiority, multicenter, comparative trial (N=758) establish that, despite a 29 percent lower dose, Zubsolv provides equivalent efficacy compared to Suboxone film in patients who are opioid dependent. The Induction, STabilization, Adherence and Retention Trial (ISTART) sponsored by Orexo is the largest trial ever conducted with buprenorphine (N=758).

During the third quarter Orexo analyzed the detailed results of the study and the results clearly strengthen the position of Zubsolv. The detailed analysis focused on the switch phase of the study and included a preference test between the products. The previous data on preference is from a small study with healthy volunteers, while this study contains data from a large population of patients, where most have been using opioids for more than 10 years. In the ISTART study more than 70 percent preferred Zubsolv after being exposed to both products, primarily driven by better taste (77.5 percent preferred Zubsolv) followed by mouth feel and ease of use, both exceeding 70 percent preference for Zubsolv. As previously announced the clinical effect in terms of cravings and withdrawal symptoms is identical between the products and treatment-related adverse events were similar between the compared products.

At Day 15 of the study all patients were forced to switch and patients switching treatments at Day 15 had no significant difference in clinical response. Looking at the clinical effect at Day 22 of the study patients showed similar changes from baseline in Clinical Opiate Withdrawal Scale, COWS, Subjective Opiate Withdrawal Scale, SOWS and cravings total scores. During the last phase of the study also the retention of the patients who had shifted were studied and saw less withdrawal from treatment among patients who had shifted to Zubsolv compared to those who had shifted to Suboxone Film. 8.7 percent of patients who switched from Zubsolv to Suboxone and 6.1 percent of patients who switched from Suboxone to Zubsolv withdrew from treatment by Day 22.

Submission of application for expanded label to include initiation of treatment

On October 10, Orexo submitted an application to the FDA for an expanded label for Zubsolv to include initiation of treatment for opioid dependence. Orexo anticipates approval of the expanded label during the third quarter of 2015.

The application for initiation of treatment is supported by the data from the ISTART and OX219-007 studies. In the full dataset, Orexo found no difference when comparing ZUBSOLV and generic buprenorphine monotherapy, when used as treatment for the induction of buprenorphine maintenance therapy.

In a survey performed by Orexo of DATA2000 waivered physicians, who are less active in treating opioid dependent patients, initiation of treatment was cited by more than 40 percent of the respondents as the main challenge when treating patients for opioid dependence. 58 percent of the physicians said more education would be a main driver for increasing their use of buprenorphine-based treatment. An induction label would allow Orexo to customize the education to meet the specific needs of these physicians to increase their comfort in treating patients suffering from opioid dependence.

Patient assistance program

Today, Orexo has the most comprehensive patient assistance program for commercially insured and cash Bup/Nlx patients. The current patient assistance program includes co-pay assistance of a maximum of $2.5 per tablet and a possibility for patients to receive their first 30 tablets for free using two vouchers of 15 tablets each. With improving market access the utilization of the co-pay coupons has declined from 75-85 percent in Q2 to 55-65 percent of the prescriptions in Q3. When used, the average co-pay assistance is less than $2 per tablet on average and declining with improved market access. Less than 5 percent of tablet volume and less than 10 percent of prescriptions were associated with a free tablet voucher in Q3.

Patients suffering from opioid dependence are from all socio economic categories and some patients have a difficult financial position. As a commitment to the disease area and to take social responsibility for these patients, Orexo will implement an indigent patient assistance program to support these patients during the fourth quarter. Initially the program will cover a maximum of 1000 patients. This program will not be visible in the weekly sales statistics and the costs will be included under selling expenses.

Abstral® and Edluar®

Due to the timing of the Q3 report, Orexo has not yet received final data for the third quarter sales for Abstral and Edluar from our partners and data included in this report is partly estimated based on forecast and preliminary Q3 sales reports shared by our partners.

Abstral
Sale of Abstral in the EU continues to grow and the increase in Q2 was 23 percent compared to Q2 in 2013. Total sales in the EU for Q1 and Q2 exceeded MEUR 31. Orexo will receive royalties on sales exceeding MEUR 42.5 and estimated royalties are included in the results from September.

The US market for Abstral, i.e. fentanyl-based products for breakthrough pain, continues to grow. Net sales of Abstral continue to increase and reached MUSD 2.3 in Q2. 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 continue with 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.

The launch of Abstral in Japan has been successful. The Japanese market for treatment of break through 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 total sales of Edluar, commercialized by Meda AB, continued to increase in the first half of 2014. Royalties have increased by over 50 percent in the first half of 2014 compared to the same period last year. The increase is mainly driven by the strong sales increase in Canada.

Kibion – diagnosis of Helicobacter Pylori
Kibion´s streamlined distributor network in the Middle East and Northern Africa, has led to fewer and larger distributors. The new distributor strategy is expected to improve the sustainability of the sales across the product line in the region. Our distributor partners have during the period focused on establishing market access in the Middle East region to more countries and with broader product line. Internally Kibion has taken an important step forward with an ISO 13485 certification of the subsidiary in Bremen, Wagner Analysen Technik GmbH. The certification will enable access to more markets of the IRIS® Brand. Kibion's sales during the period July-September 2014 were MSEK 11.8. Kibion is preparing to introduce an upgraded generation of IRIS device which will be launched during 2015 and expected to drive growth in sales of both IRIS and Diabact.

Development programs

OX51 – prevention of acute episodes of intense pain
OX51 is a new sublingual formulation containing alfentanil. The project has been developed to meet the rapidly growing demand for effective pain relief during short surgical and invasive procedures.
A placebo-controlled study in prostate biopsies was completed in June 2013. Three different sublingual doses of OX51 and placebo were studied, showing a statistically significant dose response with regard to maximum pain experienced during the procedure. Treatment with OX51 was safe and well tolerated in all dose groups. Furthermore, OX51 did not display any sedative effect or drowsiness compared with placebo.
We are currently assessing different alternatives to advance this program. The alternatives assessed include the possibility for Orexo to take the program into phase III alone or to find a partner to collaborate 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 to Orexo. The project aims to develop products based on specific inhibition of prostaglandin E2 (PGE2) in different disease conditions. Since 2005 Boehringer Ingelheim has been responsible for all research and development within the OX-MPI project.
The evaluation of the results from Boehringer Ingelheim is ongoing and when it is completed, Orexo will make a final decision on the potential to continue the project with a new external partner. 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
Orexo entered into a collaboration agreement with AstraZeneca in January 2013 regarding OX-CLI, a preclinical program for potential new treatment of respiratory tract diseases. Under the agreement AstraZeneca gains the rights to perform extensive preclinical research and evaluation of substances in Orexo's OX-CLI program. AstraZeneca also has an option to acquire all substances linked to the program. Transfer and a licensing agreement will then be agreed on by the parties, whereby Orexo will receive milestone payments during the development phase and royalty payments based on future revenues. AstraZeneca is responsible for all development costs for the project.

The interim period January-September in numbers

Revenues

Launched products

Total revenues from Orexo's launched products amounted to MSEK 130.7 (116.8) during the period July-September 2014, an increase of 12 percent compared with the same period the previous year. The same period the previous year included Abstral milestone payments amounting to MSEK 46.5. Excluding these, growth was 83 percent and driven by Zubsolv. For the period January-September 2014 revenues amounted to MSEK 349.8 (329.9), with Zubsolv revenue growth more than off-setting 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.

Zubsolv revenue for the third quarter of 2014 grew 44 percent over the second quarter of 2014 period. Demand volume in tablets increased by 81 percent quarter over quarter with the ex-factory volume increasing by 51 percent due to higher wholesaler inventory stocking, driven by increased demand, and the change of accounting approach in Q2. The 51 percent growth in ex-factory tablet sales translated into 44 percent net revenue growth due to a different payer split in Q3 with exclusive agreements representing more of the total revenue.

The increased demand for Zubsolv was driven by the United Health Group exclusive agreement that was effective from July 1, 2014. Zubsolv market share in tablets for the full period July-Sep 2014 was 3.8, up 2.1 percentage points versus the previous quarter and increasing from 2.3 percent the last month of the second quarter to 4.0 percent the last month of this quarter, according to WK weekly sales data.

Total Abstral royalties and milestone payments amounted to MSEK 47.5 (102.3) for the period July-September 2014 and to MSEK 157.8 (284.3) for the period January-September 2014. The decrease for the period July-September 2014 is explained by the milestone payments in 2013 and by the fixed and non-conditional element which is decreasing year by year. The underlying variable of royalty elements keep increasing as sales of Abstral increase. The period January-September 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.

The fixed and non-conditional Abstral royalties for the period July-September 2014 were MSEK 34.5 out of the total Abstral royalties of MSEK 47.5. 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. As these fixed payments have all been received the recognition in the P&L has no cash impact.

Royalty revenues from Edluar® amounted to MSEK 3.0 (2.1) for the period July-September 2014 and to MSEK 10.5 (6.0) for the period January-September 2014.

Kibion's sales for the period July-September 2014 were MSEK 11.8 (11.9) and for the period January-September 2014 MSEK 31.3 (31.0).

Revenues related to development projects

There were no revenues related to development projects during the period January-September 2014. During January-September 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 July-September 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 July-September 2014 amounted to MSEK 130.7 (121.1) MSEK, an increase of 8 percent compared with the same period the previous year, driven by Zubsolv. For the period January-September 2014 total revenues amounted to MSEK 349.8 (329.9).

Total net revenues were distributed as follows:

MSEK	Jul-Sep 2014	Jul-Sep 2013	Jan-Sep 2014	Jan-Sep 2013	Jan-Dec 2013
Abstral royalties	47.5	55.8	157.8	173.5	246.0
Milestone payment Abstral	-	46.5	-	110.8	110.8
Edluar royalties	3.0	2.1	10.5	6.0	8.7
Zubsolv	68.4	0.5	148.5	0.5	7.3
Kibion	11.8	11.9	31.3	31.0	48.8
Total revenue from launched products	***130.7***	***116.8***	***348.1***	***321.8***	***421.6***
Partner-financed R&D costs	-	4.0	-	6.2	6.2
Licensing revenue for development projects	-	-	-	1.6	1.6
Other revenues	-	0.3	1.7	0.3	-
Total	**130.7**	**121.1**	**349.8**	**329.9**	**429.4**

Costs and earnings

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

Cost of goods sold

The cost of goods sold amounted to MSEK 30.4 (11.9) for the period July-September 2014 and to MSEK 72.0 (25.8) for the period January-September 2014.

Selling expenses

Selling expenses amounted to MSEK 53.6 (42.9) for the period July-September 2014. The increase was driven by the commercialization of Zubsolv® in the US. The period July-September 2014 includes full costs related to the field force in accordance with the agreement with inVentiv Health for the commercialization of Zubsolv in the US. The fourth quarter of 2014 selling expense level is expected to be higher than the third quarter of 2014 level due to a higher activity level and increased investments in commercialization of Zubsolv. Selling expenses for the period January-September 2014 amounted to MSEK 138.2 (83.4).

Administrative expenses
Administrative expenses for the period July-September 2014 amounted to MSEK 29.0 (28.8). Quarterly administrative expenses for the period October-December 2014 are expected to be slightly higher than for the period July-September 2014 due to an expected increase in legal expenses. For the period January-September 2014 administrative expenses amounted to MSEK 81.5 (88.5).

Research and development costs
For the period July-September 2014, research and development costs amounted to MSEK 51.9 (62.3). The costs are attributable to clinical studies and other life cycle management activities in the Zubsolv program. During the third quarter of 2014, no R&D spend was capitalized.
The quarterly research and development costs for the period October-December 2014 are expected to be slightly higher than the level realized for the period July-September 2014.
For the period January-September 2014 R&D costs amounted to MSEK 150.2 (191.0) and the R&D spend amounted to MSEK 210.5, including MSEK 60.3 of capitalized R&D spend.

Costs for long-term incentive program
The Group's total costs for employee stock option programs during the period July-September 2014 amounted to MSEK 6.7 (14.4). For the period January-September 2014 the costs amounted to MSEK -0.3 (18.7). The negative 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 4.9 (-0.7) during the period July-September 2014 and to MSEK 8.1 (-49.2) for the period January-September 2014. Other income and expenses primarily comprised exchange-rate gains/losses. Other expenses for the period July-September 2014 include expenses of MSEK 1.1 attributable to the announced restructuring of the Uppsala organization. An additional MSEK 6 restructuring cost is expected in the fourth quarter. The period January-September 2013 included an impairment charge of MSEK 43.9 related to the OX-NLA project.

Depreciation and amortization
Depreciation and amortization amounted to MSEK 2.5 (1.5) for the period July-September 2014 and to MSEK 7.4 (4.0) for the period January-September 2014.

Net financial items
Net financial items for the period July-September 2014 amounted to MSEK -7.8 (-3.4) and include costs for the corporate bond amounting to MSEK 6.8. For the period January-September 2014 net financial items amounted to MSEK -21.5 (-9.1).

Earnings
Operating earnings amounted to MSEK -29.3 (-25.5) for the period July-September 2014 and to MSEK -84.0 (-107.9) for the period January-September 2014.

Cash-flow and financial position

At September 30, 2014, cash and cash equivalents amounted to MSEK 299.2 (91.9) and interest-bearing liabilities to MSEK 496.1 (56.8). No bank debt existed at the end of the period.

Cash flow from operating activities amounted to MSEK -152.1 (-229.9) for the period July-September 2014 and to MSEK -480.0 (-150.3) for the period January-September 2014. Cash flow from financing activities amounted to MSEK 338.5 (59.6) for the period July-September 2014 and includes the proceeds from the private placement of shares.

Cash flow before financing activities for the period January-September 2014 was MSEK -543.7. This amount was impacted by the Zubsolv inventory build and the capitalized R&D spends enabling filing to the FDA of an expanded

label to include induction treatment. With the inventory build and the induction studies now being completed and the cash-flow from operating activities improving, the cash-flow burn will improve going forward.

Shareholders' equity at September 30, 2014 was MSEK 399.2 (191.7). The equity/assets ratio was 34 (30) percent. The royalty payment in accordance with the Abstral agreement, which has been received but not yet recognized as revenue, has affected the equity/assets ratio negatively by approximately 3 percentage points.

During the period July-September 2014, Orexo completed a private placement of 2,493,046 Orexo shares. The placement included all Orexo shares held in treasury by the company in addition to newly issued shares. The price of SEK 139 per share was determined through a book-building procedure, resulting in total cash proceeds of approximately MSEK 346.5 before transaction costs. Following the private placement of shares, completed in September 2014, and based on existing plans and forecasts, Orexo see no need for additional financing.

Investments in fixed assets

Gross investments in tangible and intangible fixed assets amounted to MSEK -0.9 (37.0) for the period July-September 2014. For the period January-September 2014 gross investments amounted to MSEK 63.9 (46.0). The increase in investments comes mainly from the capitalization of selected clinical trials in the amount of MSEK 60.3.

Parent Company

Net revenues for the period January-September 2014 amounted to MSEK 255.7 (408.8). Earnings after financial items were MSEK -99.4 (25.7). Investments amounted to MSEK 63.4 (10.2). As of September 30, 2014, cash and cash equivalents in the Parent Company amounted to MSEK 257.2 (73.6).

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

Year-end report for the 2014 financial year	January 29, 2015
Publication of the Annual Report	Week 13, 2015
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
Year-end 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.

Uppsala, October 22, 2014
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 September 30 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, October 22, 2014
PricewaterhouseCoopers AB

Lars Kylberg
Authorised Public Accountant

Mikael Winkvist
Authorised Public Accountant

Consolidated statement of operations

MSEK	Notes	2014 Jul-Sep	2013 Jul-Sep	2014 Jan-Sep	2013 Jan-Sep	2013 Jan-Dec
Net revenues		130.7	121.1	349.8	329.9	429.4
Cost of goods sold	2	-30.4	-11.9	-72.0	-25.8	-29.3
Gross profit		**100.3**	**109.3**	**277.8**	**304.1**	**400.1**
Selling expenses	2	-53.6	-42.9	-138.2	-83.4	-125.1
Administrative expenses	2	-29.0	-28.8	-81.5	-88.5	-126.4
Research and development costs	2	-51.9	-62.3	-150.2	-191.0	-238.2
Other operating income and expenses	2	4.9	-0.7	8.1	-49.2	-50.1
Operating earnings		**-29.3**	**-25.5**	**-84.0**	**-107.9**	**-139.7**
Net financial items		-7.8	-3.4	-21.5	-9.1	-13.7
Earnings before tax		**-37.1**	**-28.9**	**-105.5**	**-117.1**	**-153.4**
Tax		0.3	-	-2.7	-	-1.5
Net earnings for the period[1)]		**-36.8**	**-28.9**	**-108.2**	**-117.1**	**-154.9**

Consolidated statement of comprehensive income

MSEK	2014 Jul-Sep	2013 Jul-Sep	2014 Jan-Sep	2013 Jan-Sep	2013 Jan-Dec
Earnings for the period	**-36.8**	**-28.9**	**-108.2**	**-117.1**	**-154.9**
Other comprehensive income					
Items that may subsequently be reversed to the statement of operations:					
Cash flow hedge	1.4	-0.9	-4.3	-6.8	-8.7
Exchange-rate differences	2.0	-1.5	0.9	-0.2	-1.9
Other comprehensive earnings for the period, net after tax	**3.4**	**-2.4**	**-3.4**	**-7.0**	**-10.6**
Total comprehensive earnings for the period [1)]	**-33.4**	**-31.3**	**-111.6**	**124.1**	**-165.5**
Earnings per share, before dilution, SEK	-1.13	-0.94	-3.37	-3.97	-5.16
Earnings per share, after dilution, SEK	-1.13	-0.94	-3.37	-3.97	-5.16

[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	2014 Sep 30	2013 Sep 30	2013 Dec 31
ASSETS				
Fixed assets				
Tangible fixed assets		30.2	32.8	33.3
Goodwill		26.8	25.9	26.4
Acquired research and development		62.3	62.3	62.3
Other intangible fixed assets		165.5	47.6	106.0
Financial assets		1.0	9.7	-
Total fixed assets		**285.8**	**178.3**	**228.0**
Current assets				
Inventories		473.5	229.0	383.4
Accounts receivable and other receivables		113.1	144.0	55.2
Cash and cash equivalents		299.2	91.9	105.6
Total current assets		**885.8**	**464.9**	**544.3**
Total assets		**1 171.6**	**643.2**	**772.3**
SHAREHOLDERS' EQUITY AND LIABILITIES				
Total shareholders' equity	3	**399.2**	**191.7**	**161.5**
Long-term liabilities				
Provisions		8.4	7.2	9.6
Long-term liabilities, non-interest bearing		-	4.1	-
Long-term liabilities, interest bearing		493.7	4.5	104.1
Deferred tax liability		-	2.1	-
Total long-term liabilities		**502.1**	**18.0**	**113.7**
Current liabilities				
Current liabilities, non-interest bearing		267.9	381.2	360.1
Current liabilities, interest bearing		2.4	52.3	137.0
Total current liabilities		**270.3**	**433.5**	**497.1**
Total liabilities		**772.4**	**451.5**	**610.8**
Total shareholders' equity and liabilities		**1 171.6**	**643.2**	**772.3**

Consolidated changes in shareholders' equity

MSEK	2014 Sep 30	2013 Sep 30	2013 Dec 31
Opening balance, shareholders' equity	**161.5**	**191.2**	**191.2**
Total comprehensive earnings for the period	-111.6	-124.1	-165.5
Employee stock options, vested amount	8.9	1.2	3.5
Buyback of shares	-	-	-
New share issues	188.4	10.6	19.4
Sales of treasury shares	152.0	-	-
Conversion of convertible bonds	-	112.8	112.9
Closing balance, shareholders' equity	**399.2**	**191.7**	**161.5**

Consolidated cash-flow statements

MSEK	Notes	2014 Jul-Sep	2013 Jul-Sep	2014 Jan-Sep	2013 Jan-Sep	2013 Jan-Dec
Operating earnings		-29.3	-25.5	-84.0	-107.9	-139.7
Financial income and expenses		-7.5	-1.6	-24.2	-5.5	-11.6
Adjustment for non-cash items	4	10.9	13.9	9.2	63.0	86.9
Cash flow from operating activities before changes in working capital		**-25.9**	**-13.2**	**-99.0**	**-50.4**	**-64.4**
Changes in working capital		**-126.2**	**-216.7**	**-381.0**	**-99.9**	**-201.4**
Cash flow from operating activities		**-152.1**	**-229.9**	**-480.0**	**-150.3**	**-265.8**
Acquisition of tangible and intangible fixed assets		0.9	-37.0	-63.9	-46.0	-107.5
Sale of machinery and equipment		0.2	-	0.2	-	-
Cash flow from investing activities		**1.1**	**-37.0**	**-63.7**	**-46.0**	**-107.5**
New share issue		187.1	8.4	188.4	10.6	19.4
Sales of treasury shares		152.0	-	152.0	-	-
Change in loans		-0.6	51.2	398.1	50.0	234.2
Cash flow from financing activities		**338.5**	**59.6**	**738.5**	**60.6**	**253.6**
Cash flow for the period		**187.5**	**-207.3**	**194.8**	**-135.7**	**-119.7**
Cash and cash equivalents at the beginning of the period		**110.6**	**300.7**	**105.6**	**228.1**	**228.1**
Exchange-rate differences in cash and cash equivalents		1.1	-1.5	-1.2	-0.5	-2.8
Changes in cash and cash equivalents		187.5	-207.3	194.8	-135.7	-119.7
Cash and cash equivalents at the end of the period		**299.2**	**91.9**	**299.2**	**91.9**	**105.6**

Key figures

	2014 Jul-Sep	2013 Jul-Sep	2014 Jan-Sep	2013 Jan-Sep	2013 Jan-Dec
Operating margin, %	-22	-21	-24	-33	-32
Return on equity, %	-24	-19	-75	-59	-88
Net debt, MSEK	-197	-35	-197	-35	-135
Debt/equity ratio, %	124	30	124	30	154
Equity/assets ratio, %	34	30	34	30	21
Number of shares, before dilution	34,325,155	31,553,317	34,325,155	31,553,317	31,790,784
Number of shares, after dilution	35,247,419	32,853,008	35,247,419	32,853,008	32,976,554
Earnings per share, before dilution, SEK	-1.13	-0.94	-3.37	-3.97	-5.16
Earnings per share, after dilution, SEK	-1.13	-0.94	-3.37	-3.97	-5.16
Number of employees at the end of the period	113	104	113	104	108
Shareholders' equity, KSEK	399,195	191,747	399,195	191,747	161,459
Capital employed, KSEK	895,268	248,534	895,268	248,534	402,533

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

Parent Company statement of operations

MSEK	Notes	2014 Jul-Sep	2013 Jul-Sep	2014 Jan-Sep	2013 Jan-Sep	2013 Jan-Dec
Net revenues		119.7	219.0	255.7	408.8	452.3
Cost of goods sold		-36.6	-59.1	-56.4	-62.5	-91.4
Gross profit		**83.1**	**159.9**	**199.3**	**346.3**	**360.9**
Selling expenses		-38.6	-4.0	-106.0	-36.5	-45.1
Administrative expenses		-20.2	-22.0	-55.8	-81.4	-110.0
Research and development costs		-42.8	-60.2	-125.7	-186.4	-228.3
Other operating income and expenses		5.5	-0.8	8.9	-4.6	-5.4
Operating earnings		**-13.0**	**72.9**	**-79.3**	**37.4**	**-27.9**
Interest income and expenses		-6.0	-3.5	-12.7	-9.5	-10.1
Impairment of shares in subsidiaries		-	-	-	-2.2	-2.2
Other financial expenses		-1.1	-	-7.4	-	-4.1
Net financial items		**-7.1**	**-3.5**	**-20.1**	**-11.7**	**-16.4**
Earnings before tax		**-20.1**	**69.4**	**-99.4**	**25.7**	**-44.3**
Tax		-0.1	-	-0.1	-	-1.5
Earnings for the period		**-20.2**	**69.4**	**-99.5**	**25.7**	**-45.8**

Parent Company balance sheet

MSEK	Notes	2014 Sep 30	2013 Sep 30	2013 Dec 31
ASSETS				
Fixed assets				
Tangible and intangible fixed assets		193.7	79.3	137.4
Shares in subsidiaries		202.2	202.2	202.2
Total fixed assets		**395.9**	**281.5**	**339.6**
Current assets				
Inventories		362.8	182.3	303.3
Accounts receivable and other receivables		243.1	207.7	179.5
Cash and bank balances		257.2	73.6	48.7
Total current assets		**863.1**	**463.6**	**531.5**
Total assets		**1 259.0**	**745.1**	**871.1**
SHAREHOLDERS' EQUITY. PROVISIONS AND LIABILITIES				
Shareholders' equity		**467.3**	**277.7**	**217.4**
Long-term liabilities		**499.7**	**7.2**	**109.7**
Current liabilities		**292.0**	**460.2**	**544.0**
Total liabilities		**791.7**	**467.4**	**653.7**
Total shareholders' equity and liabilities		**1 259.0**	**745.1**	**871.1**
Pledged assets		**100.0**	**50.0**	**232.2**
Contingent liabilities		**-**	**11.1**	**-**

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 Jul-Sep	2013 Jul-Sep	2014 Jan-Sep	2013 Jan-Sep	2013 Jan-Dec
Raw materials and supplies	26.3	9.6	61.5	23.1	21.8
Other external costs	99.3	95.5	279.7	267.9	347.8
Personnel costs	44.9	43.2	108.3	107.3	167.0
Depreciation/amortization and impairment	2.5	1.5	7.4	47.9	50.1
Total	**173.0**	**149.8**	**456.9**	**446.2**	**586.7**

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

3. Shareholders' equity

Shares outstanding
The number of shares outstanding as of September 30, 2014 was 34,325,155, 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	41,325
New share issue	1,371,922
Shares outstanding at September 30, 2014	34,325,155

Options
As of September 30, 2014, a total of 2,607,127 options were outstanding that carry rights to new subscription of 2,567,397 shares in Orexo and the exchange of 39,730 options for shares in Orexo. Each option issued by Biolipox AB provides entitlement to the exchange of one share in Orexo AB, and a corresponding number of shares are held by the independent company Pyrinox AB.

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

Options to employees and Board members	Opening, Jan 1, 2014	Change	Closing, September 30, 2014
Of which:			
Approved and allotted employee stock options	1,579,557		1,579,557
Exercised		-39,242	-39,242
Allotted		349,500	349,500
Expired		-92,250	-92,250
Approved and allotted Board options	215,688		215,688
Expired		-16,666	-16,666
Employee stock options approved by AGM, unallotted	829,667	-257,250	572,417
Warrants held by subsidiaries as cash-flow hedging for social security fees	38,123	-	38,123
Total number of options outstanding	**2,663,035**	**-55,908**	**2,607,127**

During the period January-September 2014, a total of 38,325 employee stock options from Orexo's options program were exercised.

Number of shares after full dilution		
Shares outstanding at September 30, 2014	34,325,155	
Employee stock options allotted	1,996,587	
Employee stock options not yet allotted	572,417	1)
Warrants for cash-flow hedging for social security fees	38,123	
	36,932,282	

1) *Can be allotted during the current year.*

4. Cash flow

Adjustment for non-cash items

MSEK	2014 Jul-Sep	2013 Jul-Sep	2014 Jan-Sep	2013 Jan-Sep	2013 Jan-Dec
Depreciation/amortization and impairment	2.8	1.5	8.1	47.9	50.5
Estimated costs for employee stock options program	6.7	14.4	-0.3	18.7	40.0
Financial expenses, convertible bond	-	-2.0	-	-3.6	-3.6
Cash flow hedge	1.4	-	1.4	-	-
Total	**10.9**	**13.9**	**9.2**	**63.0**	**86.9**

5. Pledged assets and contingent liabilities

As the Inflazyme project has been discontinued, the entire supplementary purchase consideration of MSEK 43.5 was previously recognized as a contingent liability. Current assessment is that there is no longer a contingent liability.

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

Orexo acquired the UK drug company PharmaKodex in February 2009. This acquisition included conditional payments based on Orexo's possible use of the PharmaKodex technology in product development. As this has not been the case, these are not recognized as a liability.
Operations in PharmaKodex have been closed down. The acquired technology was written down in its entirety during 2011 and 2012. PharmaKodex's previous owners now 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.

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 October 22, 2014, at 8:00 am 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.