Interim report January-September 2015

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

Zubsolv® growth driven by patient and physician choice

Third quarter 2015

- Total net revenues amounted to MSEK 139.5 (130.7).
- Zubsolv net revenue amounted to MSEK 110.8 (68.4).
- Earnings after tax were MSEK -46.1 (-36.8).
- Earnings per share were SEK -1.33 (-1.13).
- Cash flow from operating activities amounted to MSEK -79.5 (-152.1).
- Zubsolv excluded from CVS Caremark preferred position in 2016 after closed tender process.
- New exclusive agreement with unnamed Pharmacy Benefit Manager in Managed Medicaid.
- FDA approved Zubsolv for induction treatment of opioid dependence.
- U.S. Department of Health and Human Services announced intention to expand patient access to treatment of opioid dependence.

January - September 2015

- Total net revenues amounted to MSEK 415.0 (349.8).
- Zubsolv net revenue amounted to MSEK 296.4 (148.5).
- Earnings after tax were MSEK -146.2 (-108.2).
- Earnings per share were SEK -4.24 (-3.37).
- Cash flow from operating activities amounted to MSEK -108.5 (-480.0).
- Cash and cash equivalents amounted to MSEK 201.2 (299.2).
- Orexo broadened Zubsolv product range by launching Zubsolv 8.6 mg/2.1 mg.
- Orexo announced newly listed granted US patent.
- Orexo commenced patent infringement litigation against Actavis concerning Abstral® in the US.
- New clinical data established Zubsolv as effective, well tolerated for maintenance treatment of opioid dependence and increases patients' work productivity.
- Orexo divested the subsidiary Kibion; short term negative net impact of MSEK -5.3 on EBIT.
- FDA approved the medium tablet strength, 2.9 mg/0.71 mg, of Zubsolv.
- Orexo settled patent infringement litigation against Mylan regarding Edluar®.

After the period: Nothing to report.

MSEK	**2015 Jul-Sep**	**2014 Jul-Sep**	**2015 Jan-Sep**	**2014 Jan-Sep**	**2014 Jan-Dec**
Net revenues	139.5	130.7	415.0	349.8	570.3
EBIT	-39.4	-29.3	-124.7	-84.0	-25.0
EBITDA	-33.9	-26.8	-113.1	-76.6	-12.5
Earnings after tax	-46.1	-36.8	-146.2	-108.2	-56.6
Earnings per share, SEK	-1.33	-1.13	-4.24	-3.37	-1,73
Cash flow from operating activities	-79.5	-152.1	-108.5	-480.0	-487.3
Cash and cash equivalents	201.2	299.2	201.2	299.2	284.5

Teleconference
CEO Nikolaj Sørensen and CFO Henrik Juuel will present the report at a teleconference today at 2:00pm CET. Presentation slides are available via the link and on the website.
Internet: http://financialhearings.nu/151022/orexo/
Telephone: + 46 856642693 (SE), + 44 2034281434 (UK) or +1 6465025118 (US).

For further information, please contact:
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CEO's comments

The third quarter has been eventful for Orexo. Overall the quarter has developed in a positive direction, even if the decision by the Pharmacy Benefit Manager (PBM) CVS Caremark in August to remove Zubsolv® from the preferred formulary was a short term setback. For the medium and long term, the most important and encouraging news for Zubsolv's growth potential was the announcement of plans by the US Government to expand access to treatment of opioid dependence in the US and the FDA approval of Zubsolv for use at initiation of treatment for opioid dependence (Induction) on August 11th.

We are encouraged by Zubsolv's positive growth in demand and market share during the third quarter. The demand for Zubsolv grew by 6 percent[1] and the market share increased by 0.3 percentage points to 6.2 percent. The main growth drivers were the profitable non-exclusive commercial and cash segments. These segments are associated with lower rebates, and in combination with growth and stable inventory levels at the wholesalers, net sales of Zubsolv grew by 22 percent compared to Q2.

Since the launch of Zubsolv, we have repeatedly highlighted the significant patient need for increased access to treatment. We therefore welcome the initiative from the United States Department of Health and Human Services' (HHS) Secretary Sylvia M. Burwell, to improve patient access to medication assisted treatment. The actual changes to the legislation are yet to be disclosed. We anticipate this increase in access to be ruled upon later this year or early next year. The ambition level indicates that the changes will have substantial positive impact on the access to treatment in the long term. To cite Secretary Burwell: "Despite the evidence supporting the clinical efficacy of MAT (Medical Assisted Treatment) for the treatment of opioid use disorders, it is highly underutilized". An expansion to MAT is anticipated to have positive effect on patient wellbeing, market dynamics and growth opportunities for Zubsolv long term.

During the third quarter, we signed two framework agreements with PBMs, enabling an improved position in large public plans. These two agreements can potentially more than compensate for the market share loss from CVS Caremark during 2016. We announced one of these in August and the other one was signed later in the quarter. We continue to have a constructive dialog with several major payer organizations and expect further improvements in market access in the fourth quarter.

I am personally satisfied that we during the third quarter continued to improve our commercial position through the new approval of the induction label, increasing sales and market share, new market access agreements further supported by the future significant improvement in the market conditions with the anticipated changes in the legislation in the US. Our efforts to find a partner for Zubsolv outside the US and our exciting project OX-51 continue to progress well. We are confident that we will find partners for these two products further strengthening Orexo's long term growth opportunities.

Nikolaj Sørensen
President and CEO

[1] *All sales data is IMS weekly prescription data using four week rolling averages for market share and growth.*

Operations

Launched products

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 8.1 percent YTD compared to same period in 2014.

Year to date Zubsolv has grown by 151 percent in terms of number of prescriptions compared to the same period in 2014, and in the third quarter Zubsolv grew by 6 percent compared to the second quarter. The main growth driver is a continued increase in market share in the commercial and cash segments. Growth in these segments is the main focus of our sales and marketing teams, as these segments are more profitable and responsive to sales efforts. The less profitable public segment is primarily driven by market access and rebates. It is important to gain traction in the commercial and cash segments in order to improve the profitability of the business.

The demand and unmet need for the treatment of opioid dependence is significantly higher than the access available to treatment. Today, less than half of those diagnosed with opioid dependence receive treatment. The prevalence of opioid dependence could be up to 10 times larger than the number of patients receiving medical assisted treatment (MAT) today. In 2014 more than 10 million Americans used opioids for non-medical use and nearly 1 million used heroin according to the Department of Health and Human Services in the US (HHS).

On September 17, the Secretary of the HHS announced an initiative to significantly improve access to MAT. The details of the changes in legislation are yet to be disclosed, but we anticipate that the main elements will be an opportunity for more physicians to offer treatment, and opportunities for certain specific physician categories to treat more than the current limit of 100 patients. A change in the current patient limit is likely to have an immediate effect on the number of patients treated, although it is unlikely that the physicians will immediately maximize a potential new limit as the initiation of treatment is time consuming. The main benefit will be the long term incentive for more patients to have access to higher quality care as a larger number of physicians and addiction centers expand operations and invest in establishing the infrastructure required to receive and treat more opioid dependency.

The growth in the third quarter is a result of the increased investment in a larger field force and the improvement in the marketing message and dialog with the physicians, leveraging the award winning Out-The-Monster concept (www.outthemonster.com). We have significantly improved the frequency and consistency of the sales meetings with our most important prescribers and compared to the first half of 2015 we have grown our share with the highest prescribing physicians (top 20 in each district) to 8.7 percent at the end of Q3 from 7.2 percent in Q2.

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

Share of:			
Total market volume/value	42% / ~50%	18% / ~30%	39% / ~20%
Zubsolv market volume	62%	15%	22%

Source: IMS PA, Orexo estimates
December data: R4W WE 12/26/2014
September data: R4W WE 9/25/2015

Commercial (private insurance)
(42% of the total market, 62% of Zubsolv business in September)

In the commercial segment Zubsolv market share increased by 0.8 percentage points and prescriptions grew 6 percent during Q3 comparing June with September. The growth is driven by increased market share among high Zubsolv prescribers and is not related to changes in market access during the period.

To improve the gross to net sales ratio it is important for Zubsolv to gain market share within the commercial insurer and cash segments above that of the heavily discounted public payer contracts. With increased market share and growth in the commercial segment, the gross-to-net sales ratio has improved in the third quarter. The overall growth YTD of this segment was 6 percent, Zubsolv growth in this segment versus prior year was 125 percent and Zubsolv is accessible to more than 90 percent of the patients. The loss of the preferred position with CVS Caremark will impact this segment in 2016, and the access to Zubsolv will be reduced to around 82 percent of patients, provided the exclusion list is fully implemented. As previously communicated this could impact Orexo's current gross demand sales negatively by approximately 10-15% as from Q1 2016, however, several activities have been initiated to minimize this impact of the CVS Caremark decision, such as making new agreements with other payers and strengthen our market share with the majority of the overall CVS Caremark patients not covered by the exclusion list.

Cash (Cash & Vouchers) (patient)
(18% of the total market, 15% of Zubsolv business in September)

During the third quarter, Zubsolv completely recouped the loss of market share in this segment, experienced in the first half of 2015. The loss of market share was driven by increased competition and more specifically by improved co-pay and voucher offers from the branded competitors. Orexo has maintained its existing co-pay and voucher programs and therefore the market share gain can be fully attributed to improved commercial execution and performance. The overall decline YTD of this segment was -7 percent, and Zubsolv is accessible for 100 percent of the patients.

Public (Managed Medicaid, FFS Medicaid, Medicare)
(39% of the total market, 22% of Zubsolv® business in September)

The public market is different than 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. With four generics in the market, we have seen increased hesitance by some payers to give first line access to new branded competitors. During the 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 are progressing well. When accomplished, these new agreements may increase access to Zubsolv for patients in this segment in selected geographies, and potentially more than fully compensate for the loss of preferred position within the CVS Caremark's commercial plans.

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 in specific geographies. 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 YTD of this segment was 20 percent and Zubsolv is accessible for 41 percent of the patients today. The growth in this segment come from the cash paying patients and coverage expansion as a result of the Affordable Care Act legislation in the US.

Life cycle management
During the quarter, Zubsolv was approved for induction of treatment. This new indication is very important from a strategic perspective to leverage the opportunity arising when the market expands, following improved access to treatment. Orexo has found that the induction phase of treatment is one of the key inhibitors for new physicians to treat patients and expand their treatment services to more patients. The commercial launch of the new induction label will be coordinated with the launch of the two new dosages Zubsolv 2.9 mg/0.8 mg and 11.4 mg/2.9 mg buprenorphine/naloxone and will take place in the second half of October. The launch of the two new dosages in Q4, 2015, is expected to contribute 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.

The first patients in the new registry study REZOLV (Retrospective Evaluation of Zubsolv Outcomes – A Longitudinal View) entered the study in July. The study demonstrates Orexo's continued commitment to further improving clinical outcomes and education in the treatment of the opioid dependent patient. This retrospective look at 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. Significant interest has already been shown by numerous sites, and set up activities are at an advanced stage, with data expected in the middle of 2016.

Abstral® and Edluar®

Due to the timing of the Q3 report, Orexo has not yet received final data for third quarter sales of Abstral and Edluar. Data included in this report are based on Orexo's forecast and available Abstral and Edluar sales reports for the first six months of the year from our partners.

Abstral – breakthrough pain in cancer patients

Sales of Abstral in the EU continued to grow and amounted to MEUR 19 in Q2 2015, which is an increase of 21 percent compared to Q2 2014. Orexo receives royalties on sales exceeding MEUR 42.5. This trigger point was reached in Q3 and the revenue was accrued on the basis of the forecasts of Orexo and preliminary reports from the partner ProStrakan Group Plc.

The US market for Abstral, i.e. fentanyl-based products for breakthrough pain, continued to grow. Net sales grew to MUSD 3.4 in Q2 2015, which is all time high quarterly sales and corresponds to a 45 percent increase compared to Q2 2014. In February 2015, Orexo filed a patent infringement action against Actavis Laboratories FL, Inc.

Sales of Abstral in the RoW region (markets excluding EU and the US) have continued to display high growth, driven by sales in the Middle East, Korea and Israel. Total sales for the RoW reached MUSD 1.1 in Q2 2015, which is an increase of 438 percent compared with Q2 2014.

The launch of Abstral in Japan was successful. Due to the fact that the market for treatment of breakthrough cancer pain with rapid acting fentanyl is still in the early stages, our commercial partner Kyowa Hakko Kirin is focusing on growing the market.

Edluar – treatment of short-term insomnia

Sales of Edluar continued to grow and reached MUSD 3.3 in Q2 2015, which is an increase of 73 percent compared with Q2 2014. The global commercial partner for Edluar is Meda AB.

Kibion – test and analytical instruments for diagnosing 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 new sublingual formulation containing alfentanil. The project has been developed to meet the rapidly growing demand for effective pain relief during short surgical and diagnostic procedures.

A placebo-controlled dose-finding study in patients undergoing prostate biopsy was completed in 2013. The results supported a continuation of the development of OX-51 to the next phase in development towards a new product. Work is ongoing to scale-up the manufacturing process and prepare for initiation of a phase III clinical trial.

The commercial potential of OX-51 is estimated to be substantial and Orexo is presently in the process of identifying a partner for phase III and commercialization in various geographies. Discussions are ongoing with several companies.

Collaboration projects

OX-MPI – PGE2-inhibition (Prostaglandin E2)
In August 2014, Boehringer Ingelheim returned the OX-MPI project to Orexo.

Orexo has evaluated all data on the selected development compound from Boehringer Ingelheim and still sees value in the project. Currently, Orexo is actively seeking a new external partner. The OX-MPI project is associated with an intangible fixed asset of MSEK 62 and this asset may be impaired if a final decision is taken to discontinue the project.

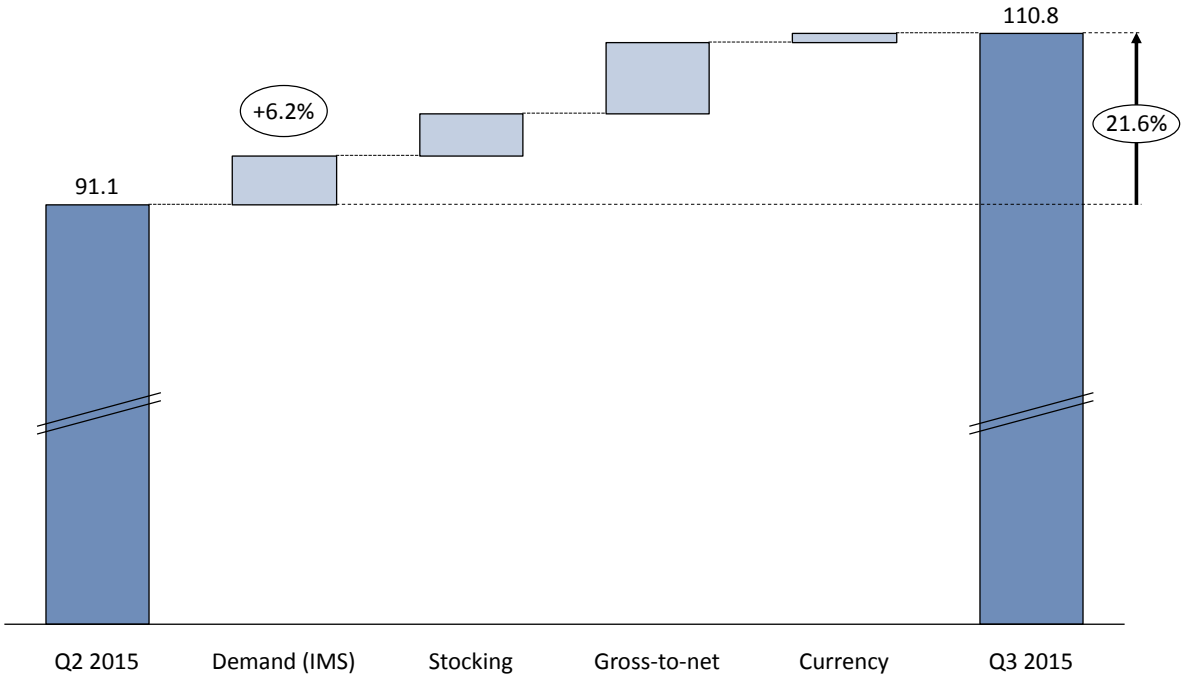
OX-CLI – respiratory tract diseases
In January 2013, Orexo entered into a collaboration agreement with AstraZeneca regarding OX-CLI, a preclinical program for potential new treatment of respiratory tract diseases. AstraZeneca is responsible for all development costs for the project.

The interim period January-September in figures

Revenues

The Zubsolv® Q3 revenue amounted to MSEK 110.8 (68.4) corresponding to a 62% growth over same period last year. Compared with Q2, 2015, Zubsolv revenue grew by 21.6%. This growth was supported by increased demand, stable wholesaler inventory levels, improved gross-to-net ratio and to a limited extent also the USD/SEK exchange rate. Demand contributed with 6.2 percent growth, driven by market share gains in the non-exclusive commercial segment and by the general market growth. A stable wholesaler inventory level contributed positively in this analysis as Q2, 2015, was negatively impacted by launch and pipeline fill of 8.6 mg in Q1, 2015. The gross-to-net ratio developed positively during Q3, 2015, driven by market share gains in the non-exclusive and relatively more profitable segment of the market and by one-off adjustments of rebate accruals from prior periods.

Q3 Zubsolv growth by key drivers [1)]



1) Analysis based on IMS demand volume growth. Stocking is calculated as a residual and sanity checked with wholesaler data. Gross-to-net and currency components are actuals.

Total Abstral® royalties and milestone payments amounted to MSEK 25.4 (47.5) for the quarter and to MSEK 95.0 (157.8) for the period January-September 2015. The decrease is explained by the lower Abstral fixed royalty. This royalty represents an amortization of the final fixed and unconditional payment related to the 2012 agreement with ProStrakan. The fixed royalty was fully recognized in the P&L in May 2015. Excluding the fixed royalty and milestones total Abstral royalties grew by 117 percent during the period January-September 2015 compared with previous year.

Royalty revenues from Edluar® amounted to MSEK 3.3 (3.0) for the quarter and to MSEK 10.8 (10.5) for the period January-September 2015.

Total revenues

Total revenues during Q3 amounted to MSEK 139.5 (130.7), an increase of 7 percent compared with the same period the previous year, driven by Zubsolv®. For the period January-September 2015 total revenues amounted to MSEK 415.0 (349.8) a growth of 18.6 percent compared with same period the previous year.

Total net revenues were distributed as follows:

MSEK	Jul-Sep 2015	Jul-Sep 2014	Jan-Sep 2015	Jan-Sep 2014	Jan-Dec 2014
Abstral® royalties	25.4	13.0	37.6	17.3	46.6
Fixed royalty Abstral	-	34.5	57.0	140.5	173.6
Milestone payment Abstral	-	-	0.4	-	58.5
Abstral – total	***25.4***	***47.5***	***95.0***	***157.8***	***278.7***
Edluar® royalties	3.3	3.0	10.8	10.5	10.7
Zubsolv	110.8	68.4	296.4	148.5	228.0
Kibion	-	11.8	12.8	31.3	51.2
Other	-	-	-	1.7	1.7
Total	***139.5***	***130.7***	***415.0***	***349.8***	***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 34.8 (30.4) for the period July-September 2015 and to MSEK 103.8 (72.0) for the period January-September 2015. Cost of goods sold for the period July-September 2015 all relates to Zubsolv.

Selling expenses

Selling expenses amounted to MSEK 70.8 (53.6) for the period July-September 2015.
Selling expenses for the period January-September 2015 amounted to MSEK 225.5 (138.2). The increase over previous year is explained by no selling costs included for Q1, 2014, field force expansion commenced in Q2, 2015, and finally an increased USD/SEK exchange rate. The Q4 expense level is expected to stay approximately the same as in Q3.

Administrative expenses

Administrative expenses for the period July-September 2015 amounted to MSEK 34.8 (29.0). For the period January-September 2015, the administrative expenses amounted to MSEK 99.6 (81.5) and approximately half of these expenses are directly related to protection of IP rights. The expense level in Q4, 2015, is expected to be around the same level as in Q3.

Research and development costs

For the period July-September 2015, research and development costs amounted to MSEK 43.3 (51.9). This corresponds to 14% growth over Q2, 2015, and is primarily explained by the REZOLV study (Zubsolv registry study) in the US. The period July-September includes MSEK 2.6 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-September 2015, R&D costs amounted to MSEK 116.6 (150.2). The research and development costs for the period July-September 2015 were below anticipated level primarily due to timing of the REZOLV study. For the full year 2015, R&D costs are expected to end around MSEK 185 and none of this will be capitalized.

Costs for long-term incentive program
The Group's total costs for employee stock option programs during the period July-September 2015 amounted to MSEK -2.9 (6.7) due to reversed provisions for social security fees due to the development of the Orexo share price during the period. For the period January-September 2015, the costs amounted to MSEK -12.2 (-0.3).

Other income and expenses
Other income and expenses amounted to MSEK 4.8 (4.9) during the period July-September 2015.
For the period January-September 2015, other income and expenses amounted to MSEK 5.8 (8.1). Except for the loss on divestment of Kibion amounting to MSEK 5.3 in Q2, other income and expenses primarily comprised exchange-rate gains/losses from revaluation of balance sheet items in foreign currency.

Depreciation and amortization
Depreciation and amortization amounted to MSEK 5.5 (2.5) for the period July-September 2015 and the increase is primarily is due to commencement of amortization of clinical trials following the approval of the induction label. Depreciation and amortization for the period January-September 2015 amounted to MSEK 11.6 (7.4).

Net financial items
Net financial items for the period July-September 2015 amounted to MSEK -4.7 (-7.8). All the net financial items are related to financing activities.
For the period January-September 2015, net financial items amounted to MSEK -16.0 (-21.5).

Earnings
Operating earnings amounted to MSEK -39.4 (-29.3) for the period July-September 2015 and to MSEK -124.7 (-84.0) for the period January-September 2015.

Cash-flow and financial position

At September 30, 2015, cash and cash equivalents amounted to MSEK 201.2 (299.2) and interest-bearing liabilities to MSEK 493.7 (496.1).

Cash flow from operating activities amounted to MSEK -79.5 (-152.1) for the period July-September 2015 driven by a negative contribution from operating earnings and a negative contribution from an increase in net working capital. Net working capital was primarily increased by reduction in payables as significant Zubsolv® rebates were due during the quarter and by Abstral® receivables increasing with increased revenue. Continued lower inventories had a positive impact on net working capital. Cash flow from operating activities for the period January-September amounted to MSEK -108.5 (-480.0).

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 September 30, 2015 was MSEK 325.2 (399.2). The equity/assets ratio was 29 (34) percent.

Investments in fixed assets

Gross investments in tangible and intangible fixed assets amounted to MSEK 0.9 (-0.9) for the period July-September 2015. For the period January-September 2015, gross investments amounted to MSEK 3.1 (63.9).

Parent Company

Net revenues for the period January-September 2015 amounted to MSEK 293.7 (255.7). Earnings after financial items were MSEK -131.2 (-99.4). Investments amounted to MSEK 3.1 (63.4). As of September 30, 2015, cash and cash equivalents in the Parent Company amounted to MSEK 104.1 (257.2).

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

Year-end report for the 2015 financial year	January 28, 2016
Publication of the Annual Report	Week 12, 2016
Annual General Meeting 2016	April 15, 2016, 4 pm CET
Interim report, January-March 2016	April 21, 2016
Interim report, January-June 2016	July 12 2016
Interim report, January-September 2016	October 20, 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, www.orexo.com.

Uppsala, October 22, 2015
Orexo AB (publ)

Nikolaj Sørensen
President and CEO

Report of Review of Interim Financial Information

Introduction

We have reviewed the condensed interim financial information (interim report) of Orexo AB as of September 30, 2015 and the nine-month period then ended. The board of directors and the CEO are responsible for the preparation and presentation of the interim financial information 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, 2015

PricewaterhouseCoopers

Lars Kylberg
Authorized Public Accountant

Mikael Winkvist
Authorized Public Accountant

Consolidated statement of operations

MSEK	Notes	2015 Jul-Sep	2014 Jul-Sep	2015 Jan-Sep	2014 Jan-Sep	2014 Jan-Dec
Net revenues		139.5	130.7	415.0	349.8	570.3
Cost of goods sold	2	-34.8	-30.4	-103.8	-72.0	-107.4
Gross profit		**104.7**	**100.3**	**311.2**	**277.8**	**462.9**
Selling expenses	2	-70.8	-53.6	-225.5	-138.2	-193.6
Administrative expenses	2	-34.8	-29.0	-99.6	-81.5	-113.0
Research and development costs	2	-43.3	-51.9	-116.6	-150.2	-197.8
Other operating income and expenses	2	4.8	4.9	5.8	8.1	16.5
Operating earnings		**-39.4**	**-29.3**	**-124.7**	**-84.0**	**-25.0**
Net financial items		-4.7	-7.8	-16.0	-21.5	-27.6
Earnings before tax		**-44.1**	**-37.1**	**-140.8**	**-105.5**	**-52.6**
Tax		-2.0	0.3	-5.4	-2.7	-4.0
Net earnings for the period[1)]		**-46.1**	**-36.8**	**-146.2**	**-108.2**	**-56.6**

Consolidated statement of comprehensive income

MSEK	2015 Jul-Sep	2014 Jul-Sep	2015 Jan-Sep	2014 Jan-Sep	2014 Jan-Dec
Earnings for the period	**-46.1**	**-36.8**	**-146.2**	**-108.2**	**-56.6**
Other comprehensive income					
Items that may subsequently be reversed to the statement of operations:					
Cash flow hedge	0.0	1.4	2.8	-4.3	-2.8
Exchange-rate differences	0.1	2.0	4.2	0.9	-0.3
Other comprehensive earnings for the period, net after tax	**0.1**	**3.4**	**7.0**	**-3.4**	**-3.1**
Total comprehensive earnings for the period [1)]	**-46.0**	**-33.4**	**-139.2**	**-111.6**	**-59.7**
Earnings per share, before dilution, SEK	-1.33	-1.13	-4.24	-3.37	-1.73
Earnings per share, after dilution, SEK	-1.33	-1.13	-4.24	-3.37	-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 Sep 30	2014 Sep 30	2014 Dec 31
ASSETS				
Fixed assets				
Tangible fixed assets		25.6	30.2	29.1
Goodwill		-	26.8	27.4
Acquired research and development		62.3	62.3	62.3
Other intangible fixed assets		164.0	165.5	169.5
Financial assets		2.3	1.0	1.2
Total fixed assets		**254.2**	**285.8**	**289.5**
Current assets				
Inventories		430.0	473.5	478.1
Accounts receivable and other receivables		224.6	113.1	173.8
Cash and cash equivalents		201.2	299.2	284.5
Total current assets		**855.8**	**885.8**	**936.4**
Total assets		**1 110.0**	**1 171.6**	**1 225.9**
SHAREHOLDERS' EQUITY AND LIABILITIES				
Total shareholders' equity	3	**325.2**	**399.2**	**455.0**
Long-term liabilities				
Provisions		3.9	8.4	9.0
Long-term liabilities, non-interest bearing		-	-	-
Long-term liabilities, interest bearing		493.7	493.7	493.8
Deferred tax liability		-	-	-
Total long-term liabilities		**497.6**	**502.1**	**502.8**
Current liabilities				
Current liabilities, non-interest bearing		287.2	267.9	265.6
Current liabilities, interest bearing		-	2.4	2.5
Total current liabilities		**287.2**	**270.3**	**268.1**
Total liabilities		**784.8**	**772.4**	**770.9**
Total shareholders' equity and liabilities		**1 110.0**	**1 171.6**	**1 225.9**

Consolidated changes in shareholders' equity

MSEK	2015 Sep 30	2014 Sep 30	2014 Dec 31
Opening balance, shareholders' equity	**455.0**	**161.5**	**161.5**
Total comprehensive earnings for the period	-139.2	-111.6	-59.7
Employee stock options, vested amount	5.5	8.9	11.5
Buy back of shares	0.1	-	-
New share issues	3.8	188.4	189.7
Sales of treasury shares	-	152.0	152.0
Closing balance, shareholders' equity	**325.2**	**399.2**	**455.0**

Consolidated cash-flow statements

MSEK	Notes	2015 Jul-Sep	2014 Jul-Sep	2015 Jan-Sep	2014 Jan-Sep	2014 Jan-Dec
Operating earnings		-39.3	-29.3	-124.7	-84.0	-25.0
Financial income and expenses		-6.8	-7.5	-21.5	-24.2	-31.6
Adjustment for non-cash items	4	2.6	10.9	7.5	9.2	21.0
Cash flow from operating activities before changes in working capital		**-43.5**	**-25.9**	**-138.7**	**-99.0**	**-35.6**
Changes in working capital		**-36.0**	**-126.2**	**30.2**	**-381.0**	**-451.7**
Cash flow from operating activities		**-79.5**	**-152.1**	**-108.5**	**-480.0**	**-487.3**
Acquisition of tangible and intangible fixed assets		-0.9	0.9	-3.1	-63.9	-71.7
Sale of subsidiary		-	0.2	21.8	0.2	-
Cash flow from investing activities		**-0.9**	**1.1**	**18.7**	**-63.7**	**-71.7**
New share issue		-	187.1	3.8	188.4	189.7
Sales of treasury shares		-	152.0	-	152.0	152.0
Buy back of shares		-	-	0.1	-	-
Change in loans		-	-0.6	-1.2	398.1	397.7
Cash flow from financing activities		**-**	**338.5**	**2.7**	**738.5**	**739.4**
Cash flow for the period		**-80.4**	**187.5**	**-87.1**	**194.8**	**180.4**
Cash and cash equivalents at the beginning of the period		**282.1**	**110.6**	**284.5**	**105.6**	**105.6**
Exchange-rate differences in cash and cash equivalents		-0.5	1.1	3.8	-1.2	-1.5
Changes in cash and cash equivalents		-80.4	187.5	-87.1	194.8	180.4
Cash and cash equivalents at the end of the period		**201.2**	**299.2**	**201.2**	**299.2**	**284.5**

Key figures

	2015 Jul-Sep	2014 Jul-Sep	2015 Jan-Sep	2014 Jan-Sep	2014 Jan-Dec
Operating margin, %	-28	-22	-30	-24	-4
Return on equity, %	-13	-24	-37	-75	-27
Net debt, MSEK	-292	-197	-292	-197	-212
Debt/equity ratio, %	152	124	152	124	109
Equity/assets ratio, %	29	34	29	34	37
Number of shares, before dilution	34,580,810	34,325,155	34,580,810	34,325,155	34,345,697
Number of shares, after dilution	34,830,244	35,247,419	34,830,244	35,247,419	35,306,976
Earnings per share, before dilution, SEK	-1.33	-1.13	-4.24	-3.37	-1.73
Earnings per share, after dilution, SEK	-1.33	-1.13	-4.24	-3.37	-1.73
Number of employees at the end of the period	94	113	94	113	90
Shareholders' equity, KSEK	325,178	399,195	325,178	399,195	455,023
Capital employed, KSEK	818,905	895,268	818,905	895,268	951,259

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

Parent Company statement of operations

MSEK	Notes	2015 Jul-Sep	2014 Jul-Sep	2015 Jan-Sep	2014 Jan-Sep	2014 Jan-Dec
Net revenues		84.9	119.7	293.7	255.7	398.5
Cost of goods sold		-29.6	-36.6	-101.7	-56.4	-64.2
Gross profit		**55.3**	**83.1**	**192.0**	**199.3**	**334.3**
Selling expenses		-46.7	-38.6	-170.3	-106.0	-157.5
Administrative expenses		-28.3	-20.2	-74.6	-55.8	-74.6
Research and development costs		-33.4	-42.8	-88.9	-125.7	-160.7
Other operating income and expenses		4.9	5.5	26.0	8.9	19.0
Operating earnings		**-48.2**	**-13.0**	**-115.8**	**-79.3**	**-39.5**
Interest income and expenses		-3.9	-6.0	-13.6	-12.7	-17.9
Other financial expenses		-0.6	-1.1	-1.8	-7.4	-8.0
Net financial items		**-4.5**	**-7.1**	**-15.4**	**-20.1**	**-25.9**
Earnings before tax		**-52.7**	**-20.1**	**-131.2**	**-99.4**	**-65.4**
Tax		-	-0.1	-0.5	-0.1	-0.5
Earnings for the period		**-52.7**	**-20.2**	**-131.7**	**-99.5**	**-65.9**

Parent Company balance sheet

MSEK	Notes	2015 Sep 30	2014 Sep 30	2014 Dec 31
ASSETS				
Fixed assets				
Tangible and intangible fixed assets		188.5	193.7	196.6
Shares in subsidiaries		211.5	202.2	208.8
Total fixed assets		**400.0**	**395.9**	**405.4**
Current assets				
Inventories		317.9	362.8	378.4
Accounts receivable and other receivables		244.9	243.1	232.7
Cash and bank balances		104.1	257.2	247.2
Total current assets		**666.9**	**863.1**	**858.3**
Total assets		**1 066.9**	**1 259.0**	**1 263.7**
SHAREHOLDERS' EQUITY. PROVISIONS AND LIABILITIES				
Shareholders' equity		**382.2**	**467.3**	**504.7**
Long-term liabilities		**497.6**	**499.7**	**500.9**
Current liabilities		**187.1**	**292.0**	**258.1**
Total liabilities		**684.7**	**791.7**	**759.0**
Total shareholders' equity and liabilities		**1 066.9**	**1 259.0**	**1 263.7**
Pledged assets		**100.0**	**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 Jul-Sep	2014 Jul-Sep	2015 Jan-Sep	2014 Jan-Sep	2014 Jan-Dec
Raw materials and supplies	32.5	26.3	91.7	61.5	91.8
Other external costs	118.0	99.3	362.5	279.7	375.2
Personnel costs	34.1	44.9	105.5	108.3	154.4
Depreciation/amortization and impairment	5.5	2.5	11.6	7.4	12.5
Total	**190.1**	**173.0**	**571.3**	**456.9**	**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 September 30, 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 ordinary 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 September 30, 2015	34,580,810

Options

As of September 30, 2015, a total of 1,962,719 options were outstanding that carry rights to new subscription of 1,834,153 shares in Orexo and the exchange of 128,566 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, Sep 30, 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		-147,422	-147,422
Approved and allotted Board options	199,022		199,022
Expired		-3,750	-3,750
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		36,473
Total number of options outstanding	**2,584,017**	**-621,298**	**1,962,719**

During the period January-September 2015, a total of 100,113 employee stock options from Orexo's options program were exercised.

Number of shares after full dilution

Shares outstanding at September 30, 2015	34,580,810
Employee stock options allotted	1,834,153
	36,414,963

4. Cash flow

Adjustment for non-cash items

MSEK	**2015 Jul-Sep**	**2014 Jul-Sep**	**2015 Jan-Sep**	**2014 Jan-Sep**	**2014 Jan-Dec**
Depreciation/amortization and impairment	5.5	2.8	11.6	8.1	12.5
Estimated costs for employee stock options program	-2.9	6.7	-12.2	-0.3	5.7
Cash flow hedge	-	1.4	2.8	1.4	2.8
Sales of subsidiary	-	-	5.3	-	-
Total	**2.6**	**10.9**	**7.5**	**9.2**	**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.

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, 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.