Interim report January-September 2013

Unless otherwise stated in this report, all data refers to the Group. Figures in parentheses relate to the corresponding period in 2012.

Zubsolv® - successfully launched in the US on September 16

During the period

- Net revenues amounted to MSEK 329.9 (242.7).
- Revenues from launched products increased by 69 percent to MSEK 321.8 (190.1).
- Earnings after tax were MSEK -117.1 (-63.6). Earnings include impairment of MSEK 43.9 for OX-NLA during the second quarter. The project has been licensed to Meda since 2008.
- Earnings per share were SEK -3.97 (-2.14).
- Cash flow from operating activities amounted to MSEK -150.3 (105.5).
- Cash and cash equivalents amounted to MSEK 91.9 (306.2).
- Zubsolv was approved by the FDA and launched in the US on September 16.
- Three studies were initiated for Zubsolv regarding early and long-term effects and how well patients comply with treatment.
- Convertible bonds subscribed for by Novo A/S converted.
- OX51 phase II study for the prevention of pain in connection with surgical procedures completed.
- Sponsored Level 1 ADR program initiated in the US (symbol ORXOY on the OTC market).
- Abstral® approved in Japan.
- Henrik Juuel appointed new CFO.

Guidance

The previously communicated guidance for Q4 2013 remains unchanged. A positive EBIT for Q4 2013 is still expected.

MSEK	**2013 Jul-Sep**	**2012 Jul-Sep**	**2013 Jan-Sep**	**2012 Jan-Sep**	**2012 Jan-Dec**
Net revenues	121.1	76.1	329.9	242.7	326.3
Revenues from launched products	116.8	73.9	321.8	190.1	267.1
EBIT	-25.5	-29.2	-107.9	-57.7	-79.4
EBIDTA	-24.0	-27.7	-60.0	-52.5	-62.1
Earnings after tax	-28.9	-30.8	-117.1	-63.6	-85.9
Earnings per share	-0.94	-1.05	-3.97	-2.14	-2.92
Cash flow from operating activities	-229.9	-66.9	-150.3	105.5	28.7
Cash and cash equivalents	91.9	306.2	91.9	306.2	228.1

Teleconference

CEO Nikolaj Sørensen and CFO Henrik Juuel will present the report at a teleconference today at 2 p.m. CET. Presentation slides are available via the link and on the website.
Internet: http://financialhearings.nu/131023/orexo/
Telephone: SE: +46851999359, UK: +442076602077, US: +18557161598

For further information, please contact:
Nikolaj Sørensen, CEO, tel: +46 (0)703 50 78 88, e-mail: nikolaj.sorensen@orexo.com
Henrik Juuel, EVP and CFO, tel: +46 (0)722 20 94 77, e-mail: henrik.juuel@orexo.com

CEO's comments

In the half-year report, we communicated that we received the formal FDA approval for Zubsolv® in the US just a few days into the third quarter. Once approval had been secured, intense launch preparations were further accelerated, including setting up a U.S. subsidiary and creating awareness of Zubsolv with key customers. Comprehensive and extensive preparations and the recruiting of a highly competent and experienced team in the US enabled Zubsolv to be launched in September with reimbursement for more than 70% of current patients in the market. Moreover, approximately 11,000 pharmacies pre-ordered Zubsolv, for stocking purposes, ensuring a readiness to meet the demand for Zubsolv. It is a significant accomplishment for Orexo to have been able to set up an entire commercial organization and secure the supply of Zubsolv across the US in the course of just a few months. I am proud of my many colleagues who have worked intensely all summer to make this happen.

The foundation for the launch of Zubsolv has now been laid and we begin the exciting work of gaining market share and improving treatment of opioid dependence. The feedback from patients and prescribing physicians, that I have received, has been positive, even if many prescribing physicians first want to test the product on a few patients before they begin to use Zubsolv more widely. Many important prescribing physicians have already come back to us with promising feedback and I anticipate seeing rapidly increasing sales during the fourth quarter and accelerating during 2014.

A key factor for the continuing success of Zubsolv is to secure competitive reimbursement conditions. I see good progress in the on-going negotiations indicating significant improvement in reimbursement during Q1 2014 for both commercial and public plans. I am awaiting final outcome of pricing reviews scheduled by most payers during Q4 2014 and I expect to see the first significant improvements in reimbursement late this year. I see no signals of Zubsolv being without reimbursement for the major commercial and public plans and I expect restrictions in prescriptions to be limited to a few, primarily public plans. I am certain that many patients will shortly have access to Zubsolv with similar reimbursement to our competition.

The launch of Zubsolv two weeks before the end of the quarter naturally entails only a small effect on sales for the quarter, but I am following the development of sales in the US closely. The focus of the US team is to get the high-prescribing physicians to start prescribing Zubsolv, in anticipation of 2014 and for future growth of the product.

The first nine months of 2013 have been rewarding for the Orexo team as our hard work has begun to bear fruit. Our journey as a fully integrated specialty pharmaceutical company is now in full bloom, and I look forward to leading Orexo as a top tier organization improving treatment for millions of people suffering from opioid dependence.

Nikolaj Sørensen
President and CEO

Operations

Launched products

Zubsolv® – treatment of opioid dependence

Zubsolv was approved by the Food and Drug Administration (FDA) on July 3 for maintenance treatment of opioid dependence, as part of a complete treatment plan including counseling and psychosocial support. Zubsolv was launched into the U.S. market and made available in pharmacies for patients by September 16.

Zubsolv is entering a large and growing market for opioid dependence treatment. The current US market of products containing buprenorphine/naloxone amounts to approximately USD 1.7 billion in value, before rebates to payers, co-pay support and other discounts have been deducted. The market has continued to grow the last year by 20% in value and 13 % in volume. In March this year two generic copies entered the market for the old tablet formulation. The generics have replaced this old tablet formulation and have stabilized with just below 15% market share in volume. Today only 1 in 10 patients are treated with buprenorphine/naloxone combination products and the significant unmet patient need is likely to drive continued growth beyond USD 1.7 billion in the years to come.

Orexo has taken the decision to become a fully integrated specialty pharmaceutical company by establishing our own commercial operations in the United States to launch Zubsolv. To optimize fast and efficient access to health care providers treating opioid dependence Orexo signed a partnership with Publicis Touchpoint Solutions (PTS), who are responsible for the field force and field medical operations and execution. The partnership agreement is valid until 2016 with no extended obligations between Orexo and PTS. The partnership is based on a risk sharing arrangement in which PTS covers the expenses for field operations and recovers their investment as the Zubsolv franchise becomes profitable. This agreement provides Orexo limited financial exposure during the launch period, maintains possession of all rights to Zubsolv and secured access to a well-established infrastructure for field force operations. The partnership with PTS enabled Orexo to build a national field force in the US facilitating the launch of Zubsolv in September, 10 weeks post FDA approval.

To ensure a successful start for Zubsolv, it has been vital to ensure the product is available at wholesalers and in the pharmacies across the US from the first day of launch. We are satisfied to see wholesalers ordering Zubsolv worth more than MSEK 65 and around 11,000 pharmacies pre-ordered Zubsolv for launch. However, as this initial stocking is based on the guaranteed sales policies within the US pharma market enabling the wholesalers to return the product, Orexo has decided only to book the revenue which has been supported by actual patient prescriptions during the last two weeks of September sales, equal to MSEK 0.5.

A key objective is to ensure competitive reimbursement with the key U.S. payers. At launch, the reimbursement position of Zubsolv provided availability for more than 70% of the market. For most patients, at this time, the reimbursement is based on a “Tier 3” position, which require patients to a co-pay for Zubsolv of 50-75$. Our US organization continues to work intensively to secure profitable agreements with payers, with the objective of obtaining a status of parity with our competition. We will expect to see significant improvements in the reimbursement status of Zubsolv during the fourth quarter and into 2014. However, like all new products on the US market, Zubsolv is subject to reviews, processes and policies for individual commercial and public payers, with the consequence that some payers will take more time to consider and grant a

competitive position for Zubsolv. For especially the public payers (Medicaid and Medicare) accounting for about 30% of the market, Zubsolv is subject to a lengthy review time and the reimbursement will be limited during 2013. Today Zubsolv is reimbursed for about 1/3 of the current patients covered by these public plans. The negotiations are on-track to ensure improved reimbursement during Q1 2014 for most plans and we maintain the objective to gain at least similar reimbursement as our competitors for the majority of the plans within the first year from launch.

The efforts to ensure that the physicians are well-informed and educated to prescribe Zubsolv® are progressing as planned. A main focus has been to meet with the highest prescribing physicians to ensure that they will prescribe and evaluate Zubsolv in their patient population.

Orexo is dedicated to improving the treatment for patients suffering from opioid dependence. An example of this is demonstrated by the initiation of three clinical studies concurrent with the approval of Zubsolv. The aim of the current programs is to document the ability to use Zubsolv in initiation of treatment, document patients' adherence to treatment and to study preference of Zubsolv to our main competitor. The results from two of these studies is expected in first half 2014 with the remaining study to be reported in the second half of 2014. Additionally, Orexo is in the process of developing several new alternative formulations of Zubsolv including additional strengths and new flavors.

Based on the prevalence of opioid dependence in the US, market dynamics, and the significant unmet needs and a successful outcome of the clinical and life cycle programs, Orexo maintains its position that Zubsolv has the potential to exceed MUSD 500 in peak sales.

Abstral®

Abstral is a rapidly-disintegrating, sublingual (under the tongue) rapid acting formulation of fentanyl, a well-established opioid, and is indicated for the management of breakthrough pain. Abstral has been launched in Europe and the US and was approved in Japan in September.

In March, Orexo sold Abstral in the US to Galena Biopharma Inc. Orexo initially received USD 10 million and during the third quarter a further USD 5 million was earned as final payment pursuant to the agreement. Furthermore, low double digit royalties will be paid, and payments will be made when certain milestones based on predetermined sales levels are reached. This sale means that Orexo has secured net payments related to Abstral of more than SEK 700 million over the past fifteen months. To this should be added future milestone and royalty payments.

Galena's preparations for the re-launch of Abstral has been proceeding according to plan and the company has established a commercial organization, initiated manufacturing of the commercial product and secured broad access to Abstral for patients. The launch of Abstral in the US by Galena Biopharma Inc. was initiated early October. The market in the US has stabilized after several years of decline and amounted over the last 12 months to about USD 360 million (SEK 2.3 billion).

In Europe, Abstral is marketed by our partner ProStrakan Ltd. The product continues its positive development in this market and during the first three quarters of 2013 sales amounted to more than EUR 39 million (SEK 360 million), which corresponds to growth of 29%. The market share for Abstral in Europe amounts to 27%, which makes Abstral the leading fast-acting fentanyl product. At the present sales rate, Orexo will receive royalties for Abstral in Europe during Q4 2013, for sales exceeding EUR 42.5 million.

On September 20, Abstral® was approved by the Japanese authorities, where the product has been registered and will be sold by Kyowa Hakko Kirin Co., Ltd. The approval generated a milestone payment to Orexo in Q3. Kyowa Hakko Kirin is well established within the field of cancer pain and since 2010 has sold Fentos®Tape, a fentanyl plaster preparation. A launch in Japan is expected as soon as a price has been determined.

Orexo will also receive royalties for Abstral in the future from other markets where the product is approved. On August 21, Abstral was approved in Australia, but has not yet gained reimbursement. In the Middle East, Abstral has now been approved in the United Arab Emirates, Bahrain, Kuwait, Lebanon, Oman and Qatar.

We expect that Abstral will be launched shortly in further markets.

Edluar®

Sales of Edluar increased during the first half of the year by 65% in the US and Canada. The launch of Edluar has been initiated in Europe by our collaboration partner Meda AB and the product is now available in Germany, Sweden and Belgium. Edluar will be launched in more European countries during 2013 and 2014.

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 dose-finding study was completed in June 2013 on patients undergoing prostate biopsies. The primary aim of the study to demonstrate an anesthetic effect in connection with the procedure was achieved. The placebo-controlled study, in which three different sublingual doses of OX51 and placebo were studied, showed a statistically significant dose response with regard to maximum pain experienced during the procedure. Treatment with OX51 was safe and was well received in all dose groups, and no effect on local tolerability was observed in any dose group. Furthermore, OX51 did not display any sedative effect or drowsiness compared with placebo.

Through a dialogue with regulatory authorities, Orexo will create a development strategy for OX51.

Collaboration projects

OX-MPI – PGE2-inhibition (Prostaglandin E2)
The aim is to develop a completely new pharmaceutical class based on Orexo's prostaglandin research. The OX-MPI project is in a preclinical phase and evaluation of potential clinical strategies is ongoing. Boehringer Ingelheim has sole responsibility for all research and development and commercialization of future products. If the project is successful, Boehringer Ingelheim will make payments to Orexo as and when certain milestones are achieved. In addition to this, royalty is to be paid on future sales.

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.

ADR program

In September Orexo AB announced that a sponsored Level 1 ADR program had been launched in the US and that ADRs can now be traded via our depositary bank Citi under the symbol ORXOY. Pending a final standard approval by FINRA (US Financial Industry Regulator Authority) the ADR is also expected to become tradable on online trading platforms within two weeks from the date of this report. All company financial information and press releases will be mirrored for easy access on www.otcmarkets.com. An ADR is a security issued by a depositary bank and represents ownership of a company's underlying shares. ADR programs are created to make it easier for American investors to own shares in non-American companies and to be able to trade them in the same way as with American securities.

The interim period January-September in figures

Revenues

Launched products

Total revenues from Orexo's launched products increased during the period January-September 2013 by 69 percent, to MSEK 321.8 (190.1).

Sales of Zubsolv® to wholesalers in the US reached more than MSEK 65 in September, reflecting wholesalers' commitment to the product. A cautious and customary accounting approach for newly launched products was applied and only revenue corresponding to patient prescriptions was recognized in the quarter. This amounted to MSEK 0.5.

Revenues include one-time payments related to sales of rights of Abstral® in the US and approval of Abstral in Japan of MSEK 110.8. Sum of royalty revenues and one-time payments from Abstral amounted to MSEK 284.3 (145.0).

Royalty revenues from Edluar® amounted to MSEK 6.0 (4.2) during the period.

Kibion's sales during the period were MSEK 31.0 (32.9) MSEK. The decline in revenue is primarily explained by a temporary loss of reimbursement of Heliprobe in Turkey and import restrictions to Saudi Arabia.

Revenues related to development projects

Revenues related to development projects amounted in all to MSEK 7.8 (53.8) all related to Abstral approval in Japan. During the first quarter of 2012, MSEK 36.7, a portion previously recognized as deferred revenue, was taken up as revenue in connection with the discontinuation of the OX-CLI project with Janssen Pharmaceuticals, Inc.

Total revenues

Total revenues during the period amounted to MSEK 329.9 (242.7), an increase of 36 percent. During the period July-September net revenues were MSEK 121.1 (76.2).

Net revenues were distributed as follows:

MSEK	Jul-Sep 2013	Jul-Sep 2012	Jan-Sep 2013	Jan-Sep 2012	Jan-Dec 2012
Abstral royalties	55.8	59.4	173.5	115.7	175.2
Milestone payment Abstral	46.5	-	110.8	29.3	29.3
Edluar royalties	2.1	1.8	6.0	4.2	6.3
Zubsolv	0.5	-	0.5	-	-
ProStrakan AB joint venture 50 %	-	-	-	8.0	8.0
Kibion	11.9	12.7	31.0	32.9	48.3
Total revenue from launched products	***116.8***	***73.9***	***321.8***	***190.1***	***267.1***
Partner-financed R&D costs	4.0	3.7	6.2	17.1	23.8
Licensing revenue for development projects	-	-	1.6	36.7	36.7
Other	0.3	-1.4	0.3	-1.2	-1.3
Total	**121.1**	**76.2**	**329.9**	**242.7**	**326.3**

Costs and earnings

Selling expenses
Selling expenses amounted to MSEK 83.4 (42.7) for the period January-September 2013 and MSEK 42.9 (16.3) for the period July-September. The increase is driven by marketing activities for the coming commercialization of Zubsolv® in the US and the establishment of the US subsidiary. Costs related to the field force in the US are covered by Publicis Touchpoint Solutions in line with the agreement.

Administrative expenses
Administrative expenses for the period January-September 2013 amounted to MSEK 88.5 (63.4). Administrative expenses include expenses of a one-time nature related to sales of Abstral® in the US and development of the commercialization strategy in the US of MSEK 13.9. Other increases in expenses are attributable to the company's ongoing patent litigation regarding Edluar® in the US. Administrative expenses for the period July-September amounted to MSEK 28.8 (26.3).

Research and development costs
For the period January-September 2013, research and development costs amounted to MSEK 191.0 (166.2). The costs are for the most part attributable to activities related to clinical studies in the Zubsolv program and to preparations for and the starting up of production of Zubsolv. Research and development costs for the period July-September 2013 amounted to MSEK 62.3 (56.1). During the second quarter of 2013, two clinical studies have been capitalized amounting to MSEK 35.1, which means that the total research and development costs for the period January-September amount to MSEK 226.1 and for the period July-September MSEK 97.4.

Costs for long-term incentive program
The Group's total costs for employee stock options programs during the period January-September 2013 amounted to MSEK 18.7 (8.1). The increased costs are primarily provisions for social security fees due to the higher price of Orexo shares.

Other income and expenses
Other income and expenses amounted to MSEK -49.2 (-7.6) during the period January-September 2013. Other expenses include expenses of MSEK 7.3 attributable to the change in the workforce and impairment carried out during the second quarter of previously acquired research and development regarding OX-NLA which has been licensed to Meda AB, of MSEK 43.9. The remainder of other income and expenses comprises primarily exchange-rate gains/losses.

Depreciation
Depreciation and amortization amounted to MSEK 4.0 (5.2) for the period January-September 2013 and MSEK 1.5 (1.5) for the period July-September 2013.

Net financial items
Net financial items for the period January-September 2013 amounted to MSEK -9.1 (-5.9). Net financial items include interest expenses of MSEK 9.6 for convertible debentures.

Earnings
Operating earnings amounted to MSEK -107.9 (-57.7) for the period January-September 2013 and to MSEK -25.5 (-29.2) MSEK for the period July-September.

Financial position

At September 30, 2013, cash and cash equivalents amounted to MSEK 91.9 (306.2) and interest-bearing liabilities to MSEK 56.8 (118.0). Interest-bearing liabilities at September 30, 2012 included a convertible

bond amounting to MSEK 111, with a conversion price of SEK 47.50. This convertible bond was converted in August 2013.

An overdraft facility amounting to MSEK 50 was opened with Nordea during the third quarter.

Cash flow from operating activities for the period January-September 2013 was MSEK -150.3 (105.5). During the period January-September 2013, inventories of Zubsolv® increased by MSEK 182.0.
Accounts receivables increased from MSEK 35.7 to MSEK 161.6, driven by sales of Zubsolv to wholesalers in the US and the increase in revenue from Abstral®.

Shareholders' equity at September 30, 2013 was MSEK 191.7 (208.4). The equity/assets ratio was 30 (37) 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 23 percentage points. As this is recognized, the equity/assets will increase by approximately 10 percentage units per quarter until end of May 2014.

The valuation of derivatives intended to hedge coming cash flows has been done at current market prices.

With the cash position, available facilities and the value of own shares and significant assets on the balance sheet in the shape of receivables and inventories, Orexo is in a financially sound position to pursue the commercial opportunity with Zubsolv in the US.

Investments in fixed assets

Gross investments in tangible and intangible fixed assets amounted to MSEK 46.0 (4.2) for the period January-September 2013 and MSEK 37.0 (0.8) for the period July-September 2013. The increase in investments comes from the capitalization of two clinical studies during the third quarter amounting to MSEK 35.1 and also an investment in production equipment for the production of Zubsolv.

Parent Company

Net revenues for the period January-September 2013 amounted to MSEK 408.8 (193.7). Most of the increase is attributable to internal sales of Zubsolv to Orexo Inc. Earnings after financial items were MSEK 25.7 (-110.2). Investments amounted to MSEK 10.2 (4.2). As of September 30, 2013, cash and cash equivalents in the Parent Company amounted to MSEK 73.6 (294.0).

Future reporting dates

Year-end report for the 2013 financial year	January 30, 2014
Publication of the annual report	Week 13, 2014
Annual General Meeting 2014	April 15, 2014, 4 pm
Interim report, January – March 2014	April 25, 2014
Interim report, January – June 2014	July 11, 2014
Interim report, January – September 2014	October 22, 2014
Year-end report for the 2014 financial year	January 29, 2015

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.

Review report

Report of Review of Interim Financial Information

Introduction
We have reviewed this report for the period January 1 to September 30, 2013 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 Swedish Standard on Review Engagements SÖG 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 23, 2013

PricewaterhouseCoopers AB

Lars Kylberg
Authorised Public Accountant

Mikael Winkvist
Authorised Public Accountant

Consolidated statement of operations

MSEK	Notes	3 months 2013 Jul-Sep	3 months 2012 Jul-Sep	9 months 2013 Jan-Sep	9 months 2012 Jan-Sep	12 months 2012 Jan-Dec
Net revenues		121.1	76.1	329.9	242.7	326.3
Cost of goods sold	2	-11.9	-6.7	-25.8	-20.5	-27.9
Gross profit		**109.3**	**69.4**	**304.1**	**222.2**	**298.4**
Selling expenses	2	-42.9	-16.3	-83.4	-42.7	-62.0
Administrative expenses	2	-28.8	-26.3	-88.5	-63.4	-82.6
Research and development costs	2	-62.3	-56.1	-191.0	-166.2	-216.2
Other operating income and expenses	2	-0.7	0.1	-49.2	-7.6	-17.1
Operating earnings		**-25.5**	**-29.2**	**-107.9**	**-57.7**	**-79.4**
Financial items – net		-3.4	-1.5	-9.1	-5.9	-8.2
Earnings before tax		**-28.9**	**-30.7**	**-117.1**	**-63.6**	**-87.6**
Income tax		-	-0.1	-	0.0	1.7
Net earnings for the period[1)]		**-28,9**	**-30.8**	**-117.1**	**-63.6**	**-85.9**

Consolidated statement of comprehensive income

MSEK	3 months 2013 Jul-Sep	3 months 2012 Jul-Sep	9 months 2013 Jan-Sep	9 months 2012 Jan-Sep	12 months 2012 Jan-Dec
Earnings for the period	**-28.9**	**-30.8**	**-117.1**	**-63.6**	**-85.9**
Other comprehensive income					
Items that may subsequently be reversed to the statement of operations:					
Cash flow hedge	-0.9	7.8	-6.8	10.8	14.4
Exchange-rate differences	-1.5	-0.8	-0.2	-0.6	-0.6
Other comprehensive earnings for the period, net after tax	**-2.4**	**7.0**	**-7.0**	**10.2**	**13.8**
Total comprehensive earnings for the period [1)]	**-31.3**	**-23.8**	**-124.1**	**-53.4**	**-72.1**
Earnings per share, before dilution, SEK	-0.94	-1.05	-3.97	-2.14	-2.92
Earnings per share, after dilution, SEK	-0.94	-1.05	-3.97	-2.14	-2.92

[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	2013 Sep 30	2012 Sep 30	2012 Dec 31
ASSETS				
Fixed assets				
Tangible fixed assets		32.8	36.2	35.1
Goodwill		25.9	25.5	25.8
Acquired research and development		62.3	116.5	106.2
Other intangible fixed assets		47.6	2.8	3.1
Financial assets		9.7	14.7	18.5
Total fixed assets		**178.3**	**195.7**	**188.7**
Current assets				
Inventories		229.0	26.9	28.3
Accounts receivable and other receivables		144.0	35.7	36.7
Cash and cash equivalents		91.9	306.2	228.1
Total current assets		**464.9**	**368.8**	**293.1**
Total assets		**643.2**	**564.5**	**481.8**
SHAREHOLDERS' EQUITY AND LIABILITIES				
Total shareholders' equity	3	**191.7**	**208.4**	**191.2**
Long-term liabilities				
Provisions		7.2	3.7	4.0
Long-term liabilities, non-interest bearing		4.1	4.0	4.1
Long-term liabilities, interest bearing		4.5	106.9	109.5
Deferred tax liability		2.1	5.6	4.1
Total long-term liabilities		**18.0**	**120.2**	**121.7**
Current liabilities				
Current liabilities, non-interest bearing		381.2	224.8	157.8
Current liabilities, interest bearing		52,3	11.1	11.1
Total current liabilities		**433.5**	**235.9**	**168.9**
Total liabilities		**451.5**	**356.1**	**290.6**
Total shareholders' equity and liabilities		**643.2**	**564.5**	**481.8**

Consolidated changes in shareholders' equity

MSEK	2013 Sep 30	2012 Sep 30	2012 31 dec
Opening balance, shareholders' equity	**191.2**	**311.1**	**311.1**
Total comprehensive earnings for the period	-124.1	-53.4	-72.1
Employee stock options, vested amount	1.2	3.5	4.3
Buyback of shares	-	-53.0	-53.0
New share issues	10.6	0.2	0.9
Redemption of convertible bonds	112.8	-	-
Closing balance, shareholders' equity	**191.7**	**208.4**	**191.2**

Consolidated cash-flow statements

MSEK	Notes	3 months 2013 Jul-Sep	3 months 2012 Jul-Sep	9 months 2013 Jan-Sep	9 months 2012 Jan-Sep	12 months 2012 Jan-Dec
Operating earnings		-25.7	-29.2	-107.9	-57.7	-79.4
Financial income and expenses		-1.4	-0.7	-5.5	-3.6	-5.1
Adjustment for non-cash items	4	13.9	5.2	63.0	11.1	23.5
Cash flow from operating activities before changes in working capital		**-13.2**	**-24.7**	**-50.4**	**-50.2**	**-61.0**
Changes in working capital		**-216.7**	**-42.2**	**-99.9**	**155.7**	**89.7**
Cash flow from operating activities		**-229.9**	**-66.9**	**-150.3**	**105.5**	**28.7**
Acquisition of tangible and intangible fixed assets		-37.0	-0.8	-46.0	-4.2	-5.8
Sale of machinery and equipment		-	0.4	-	0.5	0.6
Sale joint venture		-	-	-	12.1	12.1
Cash flow from investing activities		**-37.0**	**-0.4**	**-46.0**	**8.4**	**6.9**
New share issue		8.4	0.2	10.6	0.2	0.8
Amortization of loans		51.2	-0.6	50.0	-1.7	-2.3
Buyback of shares		-	-53.0	-	-53.0	-53.0
Cash flow from financing activities		**59.6**	**-53.4**	**60.6**	**-54.5**	**-54.5**
Cash flow for the period		**-207.3**	**-120.7**	**-135.7**	**59.4**	**-18.9**
Cash and cash equivalents at the beginning of the period		**300.7**	**426.1**	**228.1**	**246.9**	**246.9**
Exchange-rate differences in cash and cash equivalents		-1.5	0.8	-0.5	-0.1	0.1
Changes in cash and cash equivalents		-207.3	-120.7	-135.7	59.4	-18.9
Cash and cash equivalents at the end of the period		**91.9**	**306.2**	**91.9**	**306.2**	**228.1**

Key figures

	3 months 2013 Jul-Sep	3 months 2012 Jul-Sep	9 months 2013 Jan-Sep	9 months 2012 Jan-Sep	12 months 2012 Jan-Dec
Operating margin, %	-21	-38	-33	-23	-24
Return on equity, %	-19	-11	-59	-23	-33
Net debt, MSEK	-35	-188	-35	-188	-107.5
Debt/equity ratio, %	30	57	30	57	63
Equity/assets ratio, %	30	37	30	37	40
Number of shares, before dilution	31,553,317	28,801,119	31,553,317	28,801,119	28,825,208
Number of shares, after dilution	32,853,008	31,666,198	32,853,008	31,666,198	31,645,177
Earnings per share, before dilution, SEK	-0.94	-1.05	-3.97	-2.14	-2.92
Earnings per share, after dilution, SEK	-0.94	-1.05	-3.97	-2.14	-2.92
Number of employees at the end of the period	104	96	104	96	92
Shareholders' equity, KSEK	191,747	208,358	191,747	208,358	191,194
Capital employed, KSEK	248,534	326,373	248,534	326,373	397,174

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

Parent Company statement of operations

MSEK	Notes	3 months 2013 Jul-Sep	3 months 2012 Jul-Sep	9 months 2013 Jan-Sep	9 months 2012 Jan-Sep	12 months 2012 Jan-Dec
Net revenues		219.0	65.7	408.8	193.7	272.0
Cost of goods sold		-59.1	-	-62.5	-	-
Gross profit		**159.9**	**65.7**	**346.3**	**193.7**	**272.0**
Selling expenses		-4.0	-13.4	-36.5	-29.9	-46.8
Administrative expenses		-22.0	-25.2	-81.4	-96.3	-114.2
Research and development costs		-60.2	-54.5	-186.4	-158.1	-206.7
Other operating income and expenses		-0.8	-0.7	-4.6	-9.5	-19.3
Operating earnings		**72.9**	**-28.1**	**37.4**	**-100.1**	**-115.0**
Interest income and expenses		-3.5	-1.7	-9.5	-6.5	-9.1
Impairment of shares in subsidiaries		-	0.3	-2.2	0.3	-29.1
Sales joint venture		-	-	-	-3.9	-3.9
Financial items - net		**-3.5**	**-1.4**	**-11.7**	**-10.1**	**-42.1**
Earnings before tax		**69.4**	**-29.5**	**25.7**	**-110.2**	**-157.1**
Tax		-	-	-	-	-
Earnings for the period		**69.4**	**-29.5**	**25.7**	**-110.2**	**-157.1**

Parent Company balance sheet

MSEK	Notes	2013 Sep 30	2012 Sep 30	2012 Dec 31
ASSETS				
Fixed assets				
Tangible and intangible fixed assets		79.3	38.1	38.0
Shares in subsidiaries/joint ventures		202.2	211.8	172.2
Total fixed assets		**281.5**	**249.9**	**210.2**
Current assets				
Inventories		182.3	15.0	18.5
Accounts receivable and other receivables		207.7	47.2	55.6
Cash and bank balances		73.6	294.0	216.6
Total current assets		**463.6**	**356.2**	**290.7**
Total assets		**745.1**	**606.1**	**500.9**
SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES				
Shareholders' equity		**277.7**	**172.7**	**127.3**
Long-term liabilities		**7.2**	**104.0**	**107.3**
Current liabilities		**460.2**	**329.4**	**266.3**
Total liabilities		**467.4**	**433.4**	**373.6**
Total shareholders' equity and liabilities		**745.1**	**606.1**	**500.9**
Pledged assets		**50.0**	**44.0**	**44.0**
Contingent liabilities		**11.1**	**10.4**	**8.4**

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 identical to those applied in the preparation of the 2012 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 2013

- 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	3 months 2013 Jul-Sep	3 months 2012 Jul-Sep	9 months 2013 Jan-Sep	9 months 2012 Jan-Sep	12 months 2012 Jan-Dec
Raw materials and supplies	9.6	7.4	23.1	27.3	37.4
Other external costs	95.5	68.7	267.9	165.0	221.3
Personnel costs	43.2	31.5	107.3	109.8	138.1
Depreciation/amortization and impairment	1.5	1.5	47.9	5.2	17.3
Total	**149.8**	**109.1**	**446.2**	**307.3**	**414.1**

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, 2013 was 32,674,441, all of which were common shares. All shares carry entitlement to one vote each.

Number of shares outstanding at January 1, 2013	29,946,332
Conversion of convertible bonds	2,460,526
Subscription for shares through exercise of employee stock options	267,583
Shares outstanding at September 30, 2013	32,674,441

1,121,124 shares were bought back during 2012. These are included in the total number of shares outstanding and are owned by Orexo.

Options

As of September 30, 2013, a total of 2,981,846 options were outstanding that carry rights to new subscription of 2,940,855 shares in Orexo and the exchange of 40,991 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, 2013**	**Change**	**Closing, Sep 30, 2013**
Of which:			
Approved and allotted employee stock options	1,500,469		
Exercised		-230,434	
Allotted		820,000	
Expired		-316,667	1,773,368
Approved and allotted Board options	288,085		
Allotted		200,000	
Expired		-272,397	215, 688
Approved and allotted warrants	10,000		
Exercised		-10,000	
Employee stock options approved by AGM, unallotted	380,000	496,667	876,667
Warrants held by subsidiaries as cash-flow hedging for social security fees	117,373	-1,250	116,123
Total number of options outstanding	**2 295,927**	**685,919**	**2,981,846**

During the period January-September, a total of 238,999 employee stock options from Orexo's options program were exercised.

Convertible bond

The outstanding convertible bond amounting to MSEK 111 was converted during the period, which means that the number of shares outstanding has increased by 2,460,526.

Number of shares after full dilution

Shares outstanding at September 30, 2013	32,674,441 [1)]
Employee stock options allotted	1,989,056
Employee stock options not yet allotted	876,667 [2)]
Warrants for cash-flow hedging for social security fees	116,123
	35,656,287

[1)] *Including 1,121,124 repurchased shares, owned by Orexo.*

[2)] *Can be allotted during the current year.*

4. Cash flow

Adjustment for non-cash items

MSEK	3 months 2013 Jul-Sep	3 months 2012 Jul-Sep	9 months 2013 Jan-Sep	9 months 2012 Jan-Sep	12 months 2012 Jan-Dec
Depreciation/amortization and impairment	1.5	1.5	47.9	5.2	17.3
Estimated costs for employee stock options program	14.4	4.5	18.7	8.1	9.3
Financial expenses, convertible bond	-2.0	-0.8	-3.6	-2.3	-3.1
Total	**13.9**	**5.2**	**63.0**	**11.0**	**23.5**

5. Pledged assets and contingent liabilities

As the Inflazyme project has been discontinued, the entire supplementary purchase consideration of MSEK 42.7 is recognized as 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.

6. Significant risks and uncertainties

Significant risks and uncertainties are presented in the Annual Report for 2012. The financial risk has decreased since the beginning of the year through the sale of Abstral® in the US. The approval of Zubsolv has further decreased the risk. However, the launch of Zubsolv in the US will entail risk exposure of an operational nature.

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 23, 2013, at 8:00 a.m. 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.