Full year report January-December 2013

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

2013 – the year Zubsolv® was approved and successfully launched in the US

During the period

- Net revenues amounted to MSEK 429.4 (326.3).
- Revenues from launched products increased by 58 percent to MSEK 421.6 (267.1).
- Earnings after tax were MSEK -154.9 (-85.9). 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 -5.16 (-2.92).
- Cash flow from operating activities amounted to MSEK -265.8 (28.7).
- Cash and cash equivalents amounted to MSEK 105.6 (228.1).
- Orexo's commercial management structure was strengthened and a US commercial subsidiary, Orexo Inc., was established in New Jersey.
- Zubsolv was approved by the FDA for maintenance treatment of opioid dependence and was launched on the US market on September 16. The product has steady gained between 0.1% and 0.2% share points per week, and at the end of December Zubsolv had reached a 1.9% share of Total prescriptions.
- Orexo entered into a commercial partnership with Publicis Touchpoint Solutions for the launch of Zubsolv in the US.
- Three clinical Zubsolv studies were initiated with the aim to analyze early and long-term usage and how well patients comply with treatment.
- An OX51 phase II study for the prevention of pain in connection with surgical procedures was completed showing a significant dose response with no safety concerns for the dose range studied.
- Orexo sold the rights of Abstral® to Galena Biopharma, Inc. in the US and the product was re-launched in October. At the end of December Abstral had attained a market share of about 5 % in terms of prescriptions, the highest ever since Abstral was approved in US in 2011.
- Abstral® was approved in Japan in September and launched on the Japanese market in December by Kyowa Hakko Kirin.
- The convertible bond subscribed for by Novo A/S in 2010 was converted by Orexo.
- A sponsored Level 1 ADR program was initiated in the US (symbol ORXOY).
- Orexo entered into an agreement with Danske Bank for a credit facility of MSEK 200.

After the end of the year

- On January 2, 2014 Orexo was moved to the Mid Cap segment of NASDAQ OMX.
- In order to create more financial flexibility during the launch of Zubsolv, Orexo has increased its short term loan agreement with Danske Bank with an additional MSEK 70. This facility will be available during first half of 2014.

MSEK	**2013**	**2012**	**2013**	**2012**
	Oct-Dec	**Oct-Dec**	**Jan-Dec**	**Jan-Dec**
Net revenues	99.5	83.6	429.4	326.3
Revenues from launched products	99.5	77.0	421.6	267.1
EBIT	-31.7	-21.7	-139.7	-79.4
EBITDA	-29.0	-9.6	-89.1	-62.1
Earnings after tax	-37.8	-22.2	-154.9	-85.9
Earnings per share	-1.19	-0.77	-5.16	-2.92
Cash flow from operating activities	-115.5	-76.8	-265.8	28.7
Cash and cash equivalents	105.6	228.1	105.6	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.
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CEO's comments

It is a pleasure to report on the achievements for 2013, which has been a year of tremendous transformation. The major highlights we achieved include approval of Zubsolv for sale in the US, establishment of manufacturing and a commercial subsidiary in the US, and finally that we launched Zubsolv in the US market. Although we just have commenced the launch of Zubsolv, I am pleased with the continued positive sales development and our improving market access position. We have laid the foundation for a successful 2014 - and by further improving our contracts with private and public insurance providers the coming year will aid to secure a commercial success of Zubsolv.

The key factor for future success on the US market is to secure competitive market access for Zubsolv, i.e. contracts with private and public insurance providers to ensure access and preferential reimbursement. The first improvements came in November and December and I expect that Zubsolv will continue to improve the competitive position in the months to come. The implementation of the contract with CVS Caremark becomes effective as from January 1st this year and we have already achieved similar terms and conditions with Medimpact. This means that patients with restrictive insurance plans in these programs can only choose Zubsolv or generic products as of January 1, 2014. The effect of the improved reimbursements and the targeted sales efforts could already be seen at the end of December, and I am pleased to see gross sales increased by more than 60 percent during the first full week of January and the amount of tablets sold doubled during the first two weeks of January.

Another major factor that will determine the commercial success of Zubsolv is the product awareness amongst prescribers, our ability to sell Zubsolv to the doctors against the competing products, and our success in developing Zubsolv further through comprehensive investments into life cycle management activities. In order to take advantage of the improved market access, our commercialization partner Publicis Touchpoint Solutions will expand its sales organization at the end of January. This expanded organization will primarily concentrate on areas where there are a high percentage of patients with a favorable price coverage and reimbursement for Zubsolv.

Our other key product, Abstral, continued to develop positively during 2013 in Europe and towards end of the year also in the US. The US partner for Abstral, Galena Biopharma Inc., has already demonstrated that they can drive market share growth, as Abstral reached about five percent share of total prescription in the beginning of 2014 – 7 months from the contract was signed. Abstral was also approved and launched in Japan by Kyowa Hakko Kirin during the year and we look forward to a similar success on this market.

In 2013 we decided to undertake significant investment in clinical trials and to establish manufacturing processes and substantial inventories of Zubsolv in relation to the launch. I am looking forward to a 2014 where we will leverage these investments to drive the success of Zubsolv. In the coming year we will have a high focus on driving sales of Zubsolv, complete the initiated life-cycle management initiatives, and secure optimal management of the working capital to develop a profitable Orexo. The united Swedish and US colleagues of Orexo are fully committed to secure the commercial success of Zubsolv.

Nikolaj Sørensen
President and CEO

Operations

Launched products

Zubsolv® (buprenorphine and naloxone) sublingual tablet (CIII)

Zubsolv was approved by the Food and Drug Administration (FDA) on July 3, 2013 and Zubsolv sublingual tablet is indicated for the maintenance treatment of opioid dependence, and should be used as part of a complete treatment plan including counseling and psychosocial support. Zubsolv was launched on the US market and made available in pharmacies on September 16, 2013.

The current market of products containing buprenorphine/naloxone (Bup/Nal) continues with double digit growth and amounts to approximately USD 1.9 billion in value, before rebates to payers, co-pay support and other discounts have been deducted. Zubsolv exited 2013 with close to 2% of total prescriptions market gaining market share every week since launch.

Today only a small percentage of opioid dependent patients are treated with Bup/Nal combination products, and the significant unmet medical need is likely to drive continued growth in the years to come. The inclusion of addiction treatment as an "essential benefit" under the Affordable Care Act, is likely to have a positive impact on the number of patients treated. Insurance companies are obliged to cover an essential health care benefit, and with a significant higher prevalence of addiction problems among the uninsured population, the Affordable Care Act can be expected to drive additional growth in patients treated.

Orexo AB has established a US commercial subsidiary, Orexo US, Inc., in Morristown, New Jersey to lead and execute the launch of Zubsolv. Orexo is responsible for the market access (price and reimbursement), marketing, medical operations and supply of Zubsolv. To optimize fast and efficient access to health care practitioners treating opioid dependence, Orexo signed a partnership agreement with Publicis Touchpoint Solutions (PTS) for the field force and field medical operations and execution, the partnership agreement will continue until December 31st – 2016. The partnership is based on a risk sharing arrangement in which PTS covers the expenses for field operations and recovers their investment when the Zubsolv franchise becomes profitable. This agreement limits Orexo's financial exposure during the launch period, still maintaining all rights to Zubsolv as well as a secured access to a well-established infrastructure for field force operations. During the launch period the size of the field force has been staffed with approximately 50 Health Care Liaisons, but it will be increased in locations with high frequency of patients with advantageous market access at the end of January 2014.

At launch, the reimbursement position provided an availability of Zubsolv to more than 70% of the market. For most patients the reimbursement was based on a "Tier 3" position in 2013, requiring a patient co-pay of 50-75 USD for a Zubsolv prescription. Our US organization has continued to focus their efforts on securing profitable and competitive agreements with payers, with the objective of obtaining parity status with our competition. The reimbursement position has improved during the fourth quarter with movement of Zubsolv to Tier 2 in several plans e.g. Medimpact and Blue Cross Blue Shield of Massachusetts, Optum Rx, University of Pittsburgh Medical Center health plan. We have gained parity reimbursement with our branded competitor in large state Medicaid programs like New York, New Jersey and Tennessee. More importantly, we have secured an even better position with several plans starting in January. Most noteworthy being that Zubsolv is the exclusive branded product with CVS Caremark and Medimpact effective January 1st, 2014 for patients with restricted insurance plans, i.e. plans where the insurance companies control the products prescribed. Negotiations continue with all payers 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.

At launch, 40% of physicians specializing in addiction treatment were aware of Zubsolv, which has increased to more than 90% in December. The increase in awareness was primarily driven by Health Care Liaison visits, and we see a clear correlation between doctors with frequent visits and the decision to prescribe Zubsolv, today close to 2000 doctors have prescribed Zubsolv. Thus, the expansion of the field force is important to continue gaining market share. In addition to visits by Health Care Liaisons, a key parameter for the physicians to start prescribing is that the product will be reimbursed. To ensure the patients access to Zubsolv will not be negatively affected by pricing and reimbursement issues, Orexo has, during the launch period, offered a generous patient support program (e.g. copay patient support cards, 15 tablet sample vouchers, limited 30-day free trial offer). This has been important to doctors to initiate prescriptions, but it has reduced the net sales for Orexo. Orexo will gradually make these programs more restrictive during 2014 as we secure reimbursement in parity with our competitors.

It has been vital to ensure that the product is available at wholesalers and in the pharmacies across the US from the first day of launch. We were satisfied to see that wholesalers have ordered Zubsolv worth more than MSEK 65 and approximately 11,000 pharmacies pre-ordered Zubsolv at launch. During the fourth quarter an additional 2,000 pharmacies stocked Zubsolv and more than 9,000 have re-ordered the product. This is a strong indicator of increased interest and demand for Zubsolv. Orexo has during the fourth quarter continued to build inventory of Zubsolv, especially the active ingredients (Buprenorphine and Naloxone) to ensure the ability to meet increased demand.

Orexo is dedicated to improving the treatment for patients suffering from opioid dependence. An example of this is the initiation of three new clinical studies concurrent with the approval of Zubsolv. The aims of the programs are to document the ability to use Zubsolv in initiation of treatment, document patients' adherence to treatment and to study preference of Zubsolv versus our main competitor. The results from two of these studies are expected in 1H'14 with the remaining study to be reported in the 2H'14. Additionally, Orexo is in the process of developing several new formulations including additional strengths and flavors, the launch of the broader product range will be based on regulatory approval by the FDA and timing from a commercial perspective. Orexo will continue to invest in clinical documentation of Zubsolv to gain further differentiation and to facilitate that an increased share of the untreated 4.5 million opioid dependent patient population gain access to treatment.

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 take 25-30% of the market value, which today equals USD 1,9 billion, before rebates and other deductions.

Abstral® - treatment of breakthrough cancer pain

Abstral has been launched in Europe, the US and Japan. In March, Orexo sold the rights of Abstral in the USA to Galena Biopharma, Inc. Initially Orexo received USD 10 million and during the third quarter of 2013 a further USD 5 million was paid in final payment pursuant to the agreement. Furthermore, low double digit royalties will be paid, and payments will also 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 MSEK 700 over the past 15 months. To this should be added future milestone and royalty payments.

Galena's re-launch of Abstral in the beginning of October 2013 proceeded according to plan and the company established commercial operations, initiated manufacturing of the product and secured subsidized prices for Abstral patients during the second and third quarters of 2013. The US market for fentanyl-based products for breakthrough pain has stabilized after declining for several years and amounted to approximately USD 360 million (SEK 2.3 billion) during the past twelve months. Since the re-launch in October, Abstral has attained a market share of about 5% in terms of the number of prescriptions, a significant improvement from the existing demand.

In Europe Abstral is marketed by ProStrakan Ltd. The product continues its positive development on this market, and during 2013 sales amounted to more than EUR 53 million (SEK 480 million), which corresponds to a growth of 29%. Abstral market share in Europe is about 27%, which makes Abstral the leading fast-acting fentanyl product on this market. Orexo will receive a 15 percent royalty on Abstral in Europe, 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 the third quarter. Kyowa Hakko Kirin is well established within the field of cancer pain and has since 2010 sold Fentos®Tape, a fentanyl plaster preparation. On November 10 the price for Abstral in Japan was set and Kyowa Hakko Kirin launched Abstral on December 12.

Orexo will also receive royalties on Abstral in the future from other markets where the product is approved. Abstral was approved in Australia on August 21, but has not yet been granted a subsidized price. In the Middle East Abstral has now been approved in the United Arab Emirates, Bahrain, Kuwait, Lebanon, Oman and Qatar. During 2014, we expect that Abstral will be launched in further markets.

Edluar® - treatment of insomnia

As of this report, Orexo has not received the full year sales numbers from Meda AB, the commercial partner for Edluar. However, during the first three quarters of 2013 sales of Edluar amounted to USD 8.2 million, in the US, Canada and the EU combined. This is an increase of 60% compared with the same period previous year. The launch of Edluar has been initiated in Europe and the product is now available in Germany, Italy, Sweden and Belgium. Edluar is expected to be launched in more European countries during 2014.

Kibion – diagnosis of Helicobacter Pylori

Kibion, a subsidiary of Orexo, is the world-leading supplier of simple and reliable breath tests for diagnosis of the stomach ulcer bacterium *Helicobacter pylori*. During 2013, sales of Kibion's products, Diabact®, Heliprobe® and IRIS®, were equal to those in 2012. The sales development was negatively impacted by a temporary loss of reimbursement in Turkey and import limitations in Saudi Arabia. During 2013, Kibion streamlined its operations through restructuring the distributor network in the Middle East and Northern Africa leading to fewer and larger distributors, who have committed additional investments to the commercialization of Kibion's products. The restructuring has also enabled more efficient operations across Kibion, with improved profit contribution to Orexo overall.

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 in patients undergoing prostate biopsies. The primary aim of the study was to demonstrate an anaesthetic effect in connection with the procedure. The placebo-controlled study, in which three different sublingual doses of OX51 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, OX 51 did not display any sedative effect or drowsiness compared with placebo.

The next phase in the development of OX51 is dependent on the outcome of the dialogue with regulatory authorities.

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 preclinical phase and evaluation of potential clinical strategies is ongoing. Boehringer Ingelheim has the sole responsibility for all research and development and commercialization of future products. If the project is successful, Boehringer Ingelheim will make payments to Orexo if and when certain milestones are achieved. In addition to this, royalty is to be paid on future sales. Boehringer Ingelheim is responsible for all development costs for 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 gained the rights to perform extensive preclinical research and evaluation of compounds in Orexo's OX-CLI program. AstraZeneca has an option to acquire all compounds linked to the program, 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 2013 Orexo AB launched a sponsored Level 1 ADR program in the US and trade in ADRs begun via OTCQX International, which is a segment of the OTCQX market in the US (www.otcmarkets.com), under the symbol ORXOY. 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 US investors to own non-US companies and to be able to trade them in the same way as with US securities.

The period January-December

Revenues

Launched products

Total revenues increased during the period January-December 2013 by 58 percent, to MSEK 421.6 (267.1).

Sales of Zubsolv to wholesalers in the USA were approximately MSEK 70 in 2013. A customary practice in the industry regarding newly launched products and where there is no reliable historical data, is to recognize only revenue corresponding to patient prescriptions. This amounted to MSEK 7.3 in net sales. The net sales were negatively impacted by short term promotional launch campaigns to enable patients to test the product. The scope of these campaigns will be reduced from January 1st, 2014, increasing the net value per prescription.

Total revenues include one-time payments of MSEK 110.8 related to sale of the rights to Abstral® in the USA and approval of Abstral in Japan.
Revenues from Abstral, including royalties and one-time payments, amounted to MSEK 356.8 (204.5).

Royalty revenues from Edluar™ amounted to MSEK 8.7 (6.3) during the period January-December 2013.

Kibion's sales during the period were MSEK 48.8 (48.3). The development in sales during 2013 was affected negatively by a temporary loss of reimbursement of Heliprobe in Turkey and import limitations in Saudi Arabia.

Revenues related to development projects

Revenues related to development projects amounted to MSEK 7.8 (60.5). These revenues derived in their entirety from the approval of Abstral 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 429.4 (326.3), an increase of 32 percent. During the period October-December net revenues were MSEK 99.5 (83.6).

Net revenues were distributed as follows:

MSEK	Oct-Dec 2013	Oct-Dec 2012	Jan-Dec 2013	Jan-Dec 2012
Abstral royalties	72.4	59.5	246.0	175.2
Milestone payment Abstral	-	-	110.8	29.3
Edluar royalties	2.6	2.1	8.7	6.3
Zubsolv	6.8	-	7.3	-
ProStrakan AB joint venture 50 %	-	-	-	8.0
Kibion	17.7	15.4	48.8	48.3
Total revenue from launched products	***99.5***	***77.0***	***421.6***	***267.1***
Partner-financed R&D costs	-	6.7	6.2	23.8
Licensing revenue for development projects	-	-	1.6	36.7
Other	-	-0.1	-	-1.3
Total	**99.5**	**83.6**	**429.4**	**326.3**

Costs and earnings

Cost of goods sold
Cost of goods sold amounted to MSEK 29.3 (27.9) for the period January-December 2013. The period October-December 2013 was positively impacted by Zubsolv inventory adjustments with a value of approximately MSEK 6.

Selling expenses
Selling expenses amounted to MSEK 125.1 (62.0) for the period January-December 2013 and MSEK 41.7 (19.3) for the period October-December. The increased expenses are due to marketing activities related to Zubsolv® in the USA and to the building up of the US subsidiary. Costs related to the field force in the USA are covered by Publicis Touchpoint Solutions in line with the agreement.

Administrative expenses
Administrative expenses for the period January-December 2013 amounted to MSEK 126.4 (82.6). Administrative expenses include expenses of a one-time nature related to sales of Abstral® in the USA and to development of the commercialization strategy in the USA 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 October-December amounted to MSEK 37.9 (19.2).

Research and development costs
For the period January-December 2013, research and development costs amounted to MSEK 238.2 (216.2). The costs are for the most part attributable to activities related to clinical studies on Zubsolv and to preparations of and production of Zubsolv. Research and development costs for the period October-December 2013 amounted to MSEK 47.2 (49.9). During the second half of 2013 three clinical studies were capitalized at an amount of MSEK 91.5, which means that the total research costs and development expenditure for the period January-December amounted to MSEK 329.7 and for the period October-December MSEK 103.6.

Costs for long-term incentive program
The Group's total costs for employee stock option programs during the period January-December 2013 amounted to MSEK 40.0 (9.3). The increased costs are primarily due to provisions for social security fees due to the higher price of Orexo shares. The table below illustrates where the cost has been included in the Operating Costs.

MSEK	*Oct-Dec 2013*	*Oct-Dec 2012*	*Jan-Dec 2013*	*Jan-Dec 2012*
Administrative expenses	*12.5*	*0.6*	*17.8*	*5.3*
Research and development costs	*2.8*	*0.4*	*12.6*	*2.9*
Selling expenses	*6.0*	*0.2*	*9.6*	*1.1*
Total costs	***21.3***	***1.2***	***40.0***	***9.3***

Other income and expenses
Other income and expenses amounted to MSEK -50.1 (-17.1) during the period January-December 2013. Other expenses include expenses of MSEK 9.1 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 and amortization
Depreciation and amortization amounted to MSEK 6.7 (7.1) for the period January-December 2013 and MSEK 2.7 (1.9) for the period October-December 2013.

Net financial items
Net financial items for the period January-December 2013 amounted to MSEK -13.7 (-8.2). Net financial items include interest expenses of MSEK 9.6 for convertible bonds and expenses related to financing amounting to MSEK 3.

Earnings
Operating earnings amounted to MSEK -139.7 (-79.4) for the period January-December 2013 and to MSEK -31.7 (-21.7) for the period October-December.

Financial position

On December 31, 2013, cash and cash equivalents amounted to MSEK 105.6 (228.1) and interest-bearing liabilities to MSEK 241.1 (120.6). Interest-bearing liabilities on December 31, 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.

A revolving credit facility amounting to MSEK 200 was signed with Danske Bank during the fourth quarter. MSEK 100 of this facility was drawn down during the fourth quarter of 2013.

Furthermore a fixed and unconditional royalty payment of MGBP 12.5 to be received in June 2014 was discounted and cashed in during the fourth quarter. The fixed royalty amount relates to the restructuring of the Abstral® agreement with ProStrakan announced in June 2012. The amount is included in interest-bearing liabilities.

Cash flow from operating activities for the period January-December 2013 was MSEK -265.8 (28.7). During the period January-December 2013, the Zubsolv® inventory increased by MSEK 358 in value.

Shareholders' equity on December 31, 2013 was MSEK 161.5 (191.2). The equity/assets ratio was 21 (40) 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 12 percentage units.

These cash and cash equivalents, available credit facilities and the value of Orexo's own shares, as well as substantial assets on the balance sheet in the form of accounts receivables and inventories, provide Orexo with a good financial position to carry out the commercialization of Zubsolv in the US.

The Board of Directors proposes that no dividend is paid for the financial year 2013.

Investments in fixed assets

Gross investments in tangible and intangible fixed assets amounted to MSEK 107.5 (5.8) for the period January-December 2013 and MSEK 61.5 (1.6) for the period October-December 2013. The increase in investments comes from the capitalization of three clinical studies during the second half of the year amounting to MSEK 91.5 and also an investment in production equipment for the production of Zubsolv.

Parent Company

Net revenues for the period January-December 2013 amounted to MSEK 452.3 (272.0). Most of the increase is attributable to internal sales of Zubsolv to Orexo Inc. Earnings after financial items were

MSEK -44.3 (-157.1). Investments in tangible assets amounted to MSEK 13.8 (5.8). As of December 31, 2013, cash and cash equivalents in the Parent Company amounted to MSEK 48.7 (216.6).

Future reporting dates

Annual General Meeting 2014	April 15 2014, 4pm
Interim report, January – March 2014	April 25, 2014
Interim report, January – June 2014	July 11, 2014
Interim report, January – September 2014	October 22, 2014
Full year report for the 2014 financial year	January 29, 2015

Financial 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 website.

Annual Report 2013

Orexo AB's Annual Report is to be published on the company website no later than March 25, 2014.

Uppsala, January 30, 2014
Orexo AB (publ)

Nikolaj Sørensen
President and CEO

Review report

Report of Review of Financial Information

Introduction
We have reviewed this report for the period January 1 to December 31, 2013 for Orexo AB (publ). The board of directors and the CEO are responsible for the preparation and presentation of this financial report in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this financial 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 financial report is not prepared, in all material respects, in accordance with IAS 34 and the Swedish Annual Accounts Act, regarding the Group, and with the Swedish Annual Accounts Act, regarding the Parent Company.

Uppsala, January 30, 2014

PricewaterhouseCoopers AB

Lars Kylberg
Authorised Public Accountant

Mikael Winkvist
Authorised Public Accountant

Consolidated statement of operations

MSEK	Notes	Oct-Dec 2013	Oct-Dec 2012	Jan-Dec 2013	Jan-Dec 2012
Net revenues		99.5	83.6	429.4	326.3
Cost of goods sold	2	-3.5	-7.4	-29.3	-27.9
Gross profit		**96.0**	**76.2**	**400.1**	**298.4**
Selling expenses	2	-41.7	-19.3	-125.1	-62.0
Administrative expenses	2	-37.9	-19.2	-126.4	-82.6
Research and development costs	2	-47.2	-49.9	-238.2	-216.2
Other operating income and expenses	2	-0.9	-9.5	-50.1	-17.1
Operating earnings		**-31.7**	**-21.7**	**-139.7**	**-79.4**
Financial items – net		-4.6	-2.3	-13.7	-8.2
Earnings before tax		**-36.3**	**-24.0**	**-153.4**	**-87.6**
Income tax		-1.5	1.8	-1.5	1.7
Net earnings for the period[1)]		**-37.8**	**-22.2**	**-154.9**	**-85.9**

Consolidated statement of comprehensive income

MSEK	Oct-Dec 2013	Oct-Dec 2012	Jan-Dec 2013	Jan-Dec 2012
Earnings for the period	**-37.8**	**-22.2**	**-154.9**	**-85.9**
Other comprehensive income				
Items that may subsequently be reversed to the statement of operations:				
Cash flow hedge	1.1	3.6	-8.7	14.4
Exchange-rate differences	-1.7	-	-1.9	-0.6
Other comprehensive earnings for the period, net after tax	**-0.6**	**3.6**	**-10.6**	**13.8**
Total comprehensive earnings for the period [1)]	**-38.4**	**-18.6**	**-165.5**	**-72.1**
Earnings per share, before dilution, SEK	-1.19	-0.77	-5.16	-2.92
Earnings per share, after dilution, SEK	-1.19	-0.77	-5.16	-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 Dec 31	2012 Dec 31
ASSETS			
Fixed assets			
Tangible fixed assets		33.3	35.1
Goodwill		26.4	25.8
Acquired research and development		62.3	106.2
Other intangible fixed assets		106.0	3.1
Financial assets		-	18.5
Total fixed assets		**228.0**	**188.7**
Current assets			
Inventories		383.4	28.3
Accounts receivable and other receivables		55.2	36.7
Cash and cash equivalents		105.6	228.1
Total current assets		**544.3**	**293.1**
Total assets		**772.3**	**481.8**
SHAREHOLDERS' EQUITY AND LIABILITIES			
Total shareholders' equity	3	**161.5**	**191.2**
Long-term liabilities			
Provisions		9.6	4.0
Long-term liabilities, non-interest bearing		-	4.1
Long-term liabilities, interest bearing		4.1	109.5
Deferred tax liability		-	4.1
Total long-term liabilities		**13.7**	**121.7**
Current liabilities			
Current liabilities, non-interest bearing		360.1	157.8
Current liabilities, interest bearing		237,0	11.1
Total current liabilities		**597,1**	**168.9**
Total liabilities		**610,8**	**290.6**
Total shareholders' equity and liabilities		**772.3**	**481.8**

Consolidated changes in shareholders' equity

MSEK	2013 31 dec	2012 31 dec
Opening balance, shareholders' equity	**191.2**	**311.1**
Total comprehensive earnings for the period	-165.5	-72.1
Employee stock options, vested amount	3.5	4.3
Buyback of shares	-	-53.0
New share issues	19.4	0.9
Conversion of convertible bonds	112.9	-
Closing balance shareholders' equity	**161.5**	**191.2**

Consolidated cash-flow statements

MSEK	Notes	Oct-Dec 2013	Oct-Dec 2012	Jan-Dec 2013	Jan-Dec 2012
Operating earnings		-31.8	-21.7	-139.7	-79.4
Financial income and expenses		-6.2	-1.5	-11.6	-5.1
Adjustment for non-cash items	4	24.0	12.4	86.9	23.5
Cash flow from operating activities before changes in working capital		**-14.0**	**-10.8**	**-64.4**	**-61.0**
Changes in working capital		**-101.5**	**-66.0**	**-201.4**	**89.7**
Cash flow from operating activities		**-115.5**	**-76.8**	**-265.8**	**28.7**
Acquisition of tangible and intangible assets		-61.5	-1.6	-107.5	-5.8
Sale of machinery and equipment		-	0.1	-	0.6
Sale joint venture		-	-	-	12.1
Cash flow from investing activities		**-61.5**	**-1.5**	**-107.5**	**6.9**
New share issue		8.8	0.6	19.4	0.8
Change in loans		184.1	-0.6	234.2	-2.3
Buyback of shares		-	-	-	-53.0
Cash flow from financing activities		**192.9**	**-**	**253.6**	**-54.5**
Cash flow for the period		**15.9**	**-78.3**	**-119.7**	**-18.9**
Cash and cash equivalents at the beginning of the period		**91.9**	**306.2**	**228.1**	**246.9**
Exchange-rate differences in cash and cash equivalents		-2.2	0.2	-2.8	0.1
Changes in cash and cash equivalents		15.9	-78.3	-119.7	-18.9
Cash and cash equivalents at the end of the period		**105.6**	**228.1**	**105.6**	**228.1**

Key figures

	Oct-Dec 2013	Oct-Dec 2012	Jan-Dec 2013	Jan-Dec 2012
Operating margin, %	-31	-26	-32	-24
Return on equity, %	-22	-11	-88	-33
Net debt, MSEK	-135.4	-107.5	-135.4	-107.5
Debt/equity ratio, %	154	63	154	63
Equity/assets ratio, %	21	40	21	40
Number of shares, before dilution	31,790,784	28,825,208	31,790,784	28,825,208
Number of shares, after dilution	32,976,554	31,645,177	32,976,554	31,645,177
Earnings per share, before dilution, SEK	-1.19	-0.77	-5.16	-2.92
Earnings per share, after dilution, SEK	-1.19	-0.77	-5.16	-2.92
Number of employees at the end of the period	108	92	108	92
Shareholders' equity, KSEK	161,459	191,194	161,459	191,194
Capital employed, KSEK	402,533	397,174	402,533	397,174

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

Parent Company statement of operations

MSEK	Notes	Oct-Dec 2013	Oct-Dec 2012	Jan-Dec 2013	Jan-Dec 2012
Net revenues		43.5	78.3	452.3	272.0
Cost of goods sold		-28.9	-	-91.4	-
Gross profit		**14.6**	**78.3**	**360.9**	**272.0**
Selling expenses		-8.6	-16.9	-45.1	-46.8
Administrative expenses		-28.6	-17.9	-110.0	-114.2
Research and development costs		-41.9	-48.6	-228.3	-206.7
Other operating income and expenses		-0.8	-9.9	-5.4	-19.3
Operating earnings		**-65.3**	**-15.0**	**-27.9**	**-115.0**
Interest income and expenses		-0.6	-2.5	-10.1	-9.1
Impairment of shares in subsidiaries		-	-29.4	-2.2	-29.1
Sales joint venture		-	-	-	-3.9
Other financial expenses		-4.1	-	-4.1	-
Financial items - net		**-4.7**	**-31.9**	**-16.4**	**-42.1**
Earnings before tax		**-70.0**	**-46.9**	**-44.3**	**-157.1**
Tax		-1.5	-	-1.5	-
Earnings for the period		**-71.5**	**-46.9**	**-45.8**	**-157.1**

Parent Company balance sheet

MSEK	Notes	2013 Dec 31	2012 Dec 31
ASSETS			
Fixed assets			
Tangible and intangible fixed assets		137.4	38.0
Shares in subsidiaries/joint ventures		202.2	172.2
Total fixed assets		**339.6**	**210.2**
Current assets			
Inventories		303.3	18.5
Accounts receivable and other receivables		179.5	55.6
Cash and bank balances		48.7	216.6
Total current assets		**531.5**	**290.7**
Total assets		**871.1**	**500.9**
SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES			
Shareholders' equity		**217.4**	**127.3**
Long-term liabilities		**9.7**	**107.3**
Current liabilities		**644.0**	**266.3**
Total liabilities		**653.7**	**373.6**
Total shareholders' equity and liabilities		**871.1**	**500.9**
Pledged assets		**232.2**	**44.0**
Contingent liabilities		**-**	**8.4**

Notes

1. Accounting policies

- This financial 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	Oct-Dec 2013	Oct-Dec 2012	Jan-Dec 2013	Jan-Dec 2012
Raw materials and supplies	11.2	10.0	21.8	37.4
Other external costs	67.4	56.4	347.8	221.3
Personnel costs	59.7	28.3	167.0	138.1
Depreciation/amortization and impairment	2.2	12.1	50.1	17.3
Total	**140.5**	**106.8**	**586.7**	**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 December 31, 2013 was 32,911,908, 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	505,050
Shares outstanding at December 31, 2013	32,911,908

During the period 3,000 employee stock options were exercised. These have not yet been registered as shares.

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 December 31, 2013, a total of 2,663,035 options were outstanding that carry rights to new subscription of 2,660,511 shares in Orexo and the exchange of 2,524 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, Dec 31, 2013**
Of which:			
Approved and allotted employee stock options	1,500,469		
Exercised		-471,245	
Allotted		905,000	
Expired		-354,667	1,579,557
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	449,667	829,667
Warrants held by subsidiaries as cash-flow hedging for social security fees	117,373	-79,250	38,123
Total number of options outstanding	**2,295,927**	**367,108**	**2,663,035**

During the period January-December, a total of 469,466 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 December 31, 2013	32,911,908 [1)]
Shares not yet registered	3,000
Employee stock options allotted	1,795,245
Employee stock options not yet allotted	829,667 [2)]
Warrants for cash-flow hedging for social security fees	38,123
	35,577,943

[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	Oct-Dec 2013	Oct-Dec 2012	Jan-Dec 2013	Jan-Dec 2012
Depreciation/amortization and impairment	2.7	12.1	50.5	17.3
Estimated costs for employee stock options program	21.3	1.2	40.0	9.3
Financial expenses, convertible bond	-	-0.8	-3.6	-3.1
Total	**24.0**	**12.5**	**86.9**	**23.5**

5. Pledged assets and contingent liabilities

As the Inflazyme project has been discontinued, the entire supplementary purchase consideration of MSEK 40.8 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.

Under the purchasing agreement, the former owner of Wagner Analysen Technik GmbH is entitled to an annual supplementary purchase consideration based on a predetermined development of sales. In Orexo's assessment, these sales objectives will not be achieved, and this is therefore no longer recognized as a liability.

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 USA. The approval of Zubsolv has further decreased the risk. However, the launch of Zubsolv in the USA 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 January 30, 2014, 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.