



Interim report, January-December 2012

Unless otherwise stated in this report, all data refers to the Group. Figures in parentheses relate to the corresponding period in 2011.

OREXO IS PREPARING ZUBSOLV™ FOR LAUNCH IN THE USA - DRUG APPLICATION ACCEPTED BY FDA WITH A JULY 6, 2013 TARGET APPROVAL DATE

During the year

- Net revenues amounted to MSEK 326.3 (199.6).
- Net revenues from launched products increased by 102 percent to MSEK 267.1 (132.4).
- Earnings after tax were MSEK -85.9 (-392.0).
- Earnings per share were SEK -2.92 (-14.43).
- Cash flow from operating activities amounted to MSEK 28.7 (-117.2).
- Cash and cash equivalents amounted to MSEK 228.1 (246.9).
- The licensing agreement with ProStrakan was renegotiated. ProStrakan/Kyowa Hakko Kirin retain the rights outside the USA and Orexo obtains the rights to Abstral in the USA and receives MSEK 610 in fixed royalties.
- In June Edluar®, for treatment of short-term insomnia, was approved in Europe.
- During the third quarter Orexo bought back company's own shares, in total amounting to MSEK 53.
- In October, Orexo engaged Guggenheim Securities as financial advisor to explore different commercial partnership solutions for Zubsolv and Abstral in USA.
- A dose-finding phase II study was initiated in October for OX51, for the prevention of procedure-induced pain.
- In November, Kyowa Hakko Kirin submitted a New Drug Application for KW-2246 (Abstral) in Japan.
- In September, a New Drug Application for Zubsolv was submitted to the FDA. The application was accepted for review by the FDA in November and the planned date for notification of approval is July 6, 2013.

After the end of the year

- Orexo entered into a research agreement with AstraZeneca for respiratory disease OX-CLI program.

MSEK	2012	2011	2012	2011
	Oct-Dec	Oct-Dec	Jan-Dec	Jan-Dec
Net revenues	83.6	56.7	326.3	199.6
Revenues from launched products	77.0	39.6	267.1	132.4
EBIT	-21.7	-270.0	-79.4	-391.5
EBITDA	-9.6	-35.5	-62.1	-112.4
Earnings after tax	-22.2	-271.0	-85.9	-392.0
Earnings per share	-0.77	-9.07	-2.92	-14.43
Cash flow	-76.8	-46.9	28.7	-117.2
Cash and cash equivalents	228.1	246.9	228.1	246.9
Equity/assets ratio %	40	57	40	57

Teleconference

CEO Anders Lundström and CFO Carl-Johan Blomberg will present the report at a teleconference today at 10:00 a.m. CET. Presentation slides are available via the link and on the website. Internet: <http://livecast.wehay.com/playontv/130131/orexo/>
Telephone: +44 (0) 20 3003 2666 - Standard International Access; 020 089 6377 - Stockholm Toll Free; 0808 109 0700 - UK Toll Free; 1 866 966 5335 - USA Toll Free)

CEO's comments

2012 was a successful year for Orexo. The most important event was the submission of the New Drug Application for Zubsolv™ (buprenorphine/naloxone) in the USA.

Zubsolv is a product for treatment of opioid dependence, a huge medical and societal problem in the USA. The current buprenorphine/naloxone market value is \$1.5 billion and growing steadily. Zubsolv can be the first new improved product in this market.

In November FDA accepted the application for further review and we anticipate notification of approval in July 2013. Based on this anticipation, we focus more or less the entire company resources towards a launch of Zubsolv in the US market in September 2013. This comprises scaling up the manufacturing capacity in Sweden and the USA, the completion of a Zubsolv preference study with convincing results compared to the market leader Suboxone® Film and the preparation of three new clinical studies, all of which will start in the first half of 2013, with the aim to differentiate Zubsolv from competitors and to expand the label.

We are also working on creating a stronger product line for Zubsolv by developing a new taste and an expanded dose range of the current Zubsolv formulation. Furthermore, we are evaluating different strategic and commercial options for a successful commercialization in the US and we expect to have this in place well ahead of the launch.

I am very pleased that we successfully renegotiated the Abstral® agreement with ProStrakan. The new agreement gives us fixed royalty revenues from Abstral sales outside the US of SEK 610 million plus the right to earn additional royalties when certain sales levels are reached. At the same time Orexo obtains the rights to Abstral in the USA as from July 2013. In parallel to the preparation of the Zubsolv launch we are also actively evaluating the best commercial solution for Abstral in the US, and we will have this in place before July 2013.

During 2012 we have strengthened Orexo's financial position and reduced cost levels. The success in these efforts has given us a good basis for generation of considerable revenues in the future. I look forward to developments during 2013 with confidence. With the current assumption of a regulatory approval of Zubsolv in July and subsequent launch in September 2013, we project that Orexo will turn profitable in late 2013 and cash flow positive in 2014.

Anders Lundström
President and CEO

Operations

Development programs

Zubsolv™ – opioid dependence

During 2012, a number of important studies were completed with positive results. A dose proportionality study documented the expected bioavailability of buprenorphine and naloxone with increasing doses of Zubsolv. In another study, Zubsolv was tested and compared with the market-leading product, Suboxone®, and the results displayed the same bioavailability for both products.

In September 2012, a New Drug Application was submitted in the USA to the U.S. Food and Drug Administration, FDA. This occurred several months earlier than estimated. Beside the positive results from the two studies previously mentioned, the time gained was due to the fact that it was possible to use the product stability data from our production site in Uppsala in the registration. In addition to the work at our production site in Uppsala, a production unit is being built up in the USA in collaboration with our CMO (Contract Manufacturing Organization).

In November, the FDA gave notification that the New Drug Application for Zubsolv had been accepted for review. The planned date for notification of approval is July 6, 2013. If this time schedule is followed, it is planned that the product will be launched in September 2013.

During the fourth quarter, a comparative acceptance study between Zubsolv and Suboxone® Film was carried out. The study showed that 9 out of 10 participants would choose Zubsolv rather than Suboxone Film for daily treatment.

In parallel with the New Drug Application in the USA, Orexo is working on further developing Zubsolv. Clinical studies will be initiated during the first half of 2013 in order to investigate whether it is possible to use Zubsolv upon initiation of treatment, how well patients comply with the Zubsolv treatment, and health economic aspects. The broad development program also includes, amongst other things, the development of new strengths and a new taste.

Orexo assesses that Zubsolv has great market potential due to its unique properties in a rapidly growing market with great medical needs. The company estimates that the product's market potential corresponds to annual sales of up to USD 500 million.

OX51 – procedure-induced pain

OX51 is a proprietary sublingual tablet formulation of alfentanil, the first oral alfentanil product for the prevention of acute intensive pain episodes in connection with diagnostic and therapeutic procedures. A clinical study was performed during the first half of 2012 where the results confirmed the choice of the final formulation for the coming phase II study. During autumn 2012, a dose-finding phase II study was initiated in patients undergoing prostate biopsies. It is estimated that the results from this European study, which comprises about 200 patients, will be available during the first half of 2013.

Approximately 130 million painful procedures are performed in the USA and Europe each year and the number is increasing. Today surgical procedures in hospitals are normally performed by giving the patient either a general or a local anaesthetic. OX51 offers effective relief from procedure-induced pain and reduces the need for giving patients a general anaesthetic.

OX27 – breakthrough pain in cancer patients

OX27 is designed to improve the treatment of breakthrough pain in cancer patients. The preparation is a fast-acting sublingual formulation of an existing pharmaceutical substance.

The OX27 project has been temporarily parked for priority reasons since spring 2012. The reason is that the company's resources have to a large extent been focused on Zubsolv™ and its further development.

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 collaboration with Boehringer Ingelheim, which was initiated in 2005, focuses on specific inhibition of the formation of prostaglandin E2 (PGE2) in different disease processes.

During 2012 a number of challenges regarding scaling up and formulation were solved. The project is proceeding in the preclinical phase with evaluation of potential clinical strategies.

Boehringer Ingelheim has sole responsibility for all research and development and commercialization of future products. Boehringer Ingelheim makes payments to Orexo as and when certain milestones are achieved. In addition to this, royalty is to be paid on future sales.

OX17 – gastroesophageal reflux disease (GERD)

OX17 is being developed for the treatment of gastroesophageal reflux disease (GERD).

In August 2009, Orexo entered into a license agreement with Novartis in respect of OX17. Novartis is responsible for all development, production and marketing of future products. The project is in an early development stage.

OX-NLA - rhinitis (hay fever)

The aim of the OX-NLA project is to develop a fast-acting nasal spray based on the antihistamine cetirizine for the treatment of allergic and non-allergic rhinitis (hay fever).

Meda AB has a global license for OX-NLA and is responsible for the project's future development.

Product and project portfolio

	Product	Indication/Target	Rights	Preclinical	Ph.I	Ph.II	Ph.III	Market	Partner
Marketed products	ABSTRAL®	BREAKTHR. CANCER PAIN	-						
	EDLUAR™	INSOMNIA	GLOBAL						
	HELIPROBE®	<i>H.pylori</i> Dx	GLOBAL						
	DIABACT® UBT	<i>H.pylori</i> Dx	GLOBAL						
Internal Development	Zubsolv™	OPIOID DEPENDENCE	GLOBAL						
	OX51	PROCEDURE-INDUCED PAIN	GLOBAL						
	OX27	BREAKTHR. CANCER PAIN	GLOBAL						
Collaborations	OX-NLA	RHINITIS	GLOBAL						
	OX17	GERD	-						
	OX-MPI	PGE2 INHIBITION	-						

The interim period January-December in figures

Revenues

Launched products

Total revenues from Orexo's launched products increased during the period January-December 2012 by 102 percent, to MSEK 267.1 (132.4), compared with the same period the previous year. Royalty revenues from Abstral® amounted to MSEK 175.2 (70.5). During the period October to December the corresponding royalty revenues, in accordance with the new agreement with ProStrakan that is valid as of June 1, 2012), amounted to MSEK 59.5 (19.2) (see the interim report for the period January to June 2012. Kyowa Hakko Kirin submitted in November 2012 a New Drug Application for KW-2246 (Abstral) in Japan.

Royalty revenues from Edluar™ amounted to MSEK 6.3 (2.4) during the period. During the second quarter Edluar was approved in the EU and it is estimated that it will be launched there during 2013.

Kibion's sales during the period were MSEK 48.3 (43.9). The Middle East and the EU are Kibion's strongest markets.

Revenues related to development projects

The earlier portion, recognized as liability of the milestone payment from Janssen Pharmaceuticals Inc., has been recognized in its entirety during the year, as a result of the termination of the CLI project, as reported during the first quarter. Revenues related to development projects amounted in all to MSEK 36.7 (33.0).

Total revenues during the period amounted to MSEK 326.3 (199.6), an increase by 63 percent compared to 2011.

Net revenues were distributed as follows:

MSEK	Oct-Dec 2012	Oct-Dec 2011	Jan-Dec 2012	Jan-Dec 2011
Abstral royalties – old agreement*	-	19.2	36.8	70.5
Abstral royalties – new agreement**	59.5	-	138.4	-
Milestone payment Abstral	-	-	29.3	-
Edluar™ royalties	2.1	0.6	6.3	2.4
ProStrakan AB J/V 50%	-	3.4	8.0	15.6
Kibion (including WAT)	15.4	16.4	48.3	43.9
Total revenue from launched products	77.0	39.6	267.1	132.4
Partner-financed R&D costs	6.7	10.8	23.8	35.1
Licensing revenue for development projects	-	6.8	36.7	33.0
Other	-0.1	-0.5	-1.3	-0.9
Total	83.6	56.7	326.3	199.6

*Up to and including May 31, 2012.

**As from June 1, 2012.

Costs and earnings

Selling expenses

Selling expenses amounted to MSEK 62.0 (50.1) for the period January-December 2012 and MSEK 19.3 (15.8) for the period October-December 2012. Expenses relate primarily to marketing activities for the coming commercialization of Zubsolv™ and Abstral® in the USA and sales expenses in the subsidiary Kibion AB.

Administrative expenses

Administrative expenses for the period January-December 2012 amounted to MSEK 82.6 (49.6). The increase was mainly attributable to legal expenses related to the company's ongoing patent litigation regarding Edluar™ in the US. Expenses for the renegotiation of the Abstral agreement are also part of the increased costs. For the period October-December administrative expenses amounted to MSEK 19.2 (12.2).

Research and development costs

For the period January-December 2012, research and development costs amounted to MSEK 216.2 (194.4), of which MSEK 23.8 (35.1) has been covered by collaboration partners, primarily the former collaboration partner Janssen and Kyowa Hakko Kirin. The increase compared with the previous year is mainly attributable to activities related to clinical studies, primarily in the Zubsolv program. For the period October-December 2012, research and development costs amounted to MSEK 49.9 (56.9).

Other income and expenses

Other income and expenses amounted to MSEK -17.1 (-268.0) during the period January-December 2012 and to MSEK -9.5 (-231.6) during the period October-December 2012. Other expenses include expenses of MSEK 12.1 attributable to the workforce reduction that has been carried out and the write-down of previously acquired research and development, amounting to MSEK 10.2. As Zubsolv in its entirety is based on Orexo's own proprietary technology, the technology included in the acquisition of PharmaKodex has now been completely written off. The remainder of other income and expenses comprises exchange-rate gains/losses.

Depreciation and amortization

Depreciation and amortization amounted to MSEK 7.1 (7.8) for the period January-December and MSEK 1.9 (1.9) for the period October-December.

Net financial items

Net financial items for the period January-December amounted to MSEK -8.2 (-7.9). Net financial items include interest expenses of MSEK 12.0 for convertible debentures.

Earnings

Operating earnings for the period January-December were SEK -79.4 (-391.5).

Financial position

At December 31, 2012, cash and cash equivalents amounted to MSEK 228.1 (246.9) and interest-bearing liabilities to MSEK 120.6 (120.9). This includes a convertible bond amounting to MSEK 111, which has a conversion price of SEK 47.50, maturing on March 31, 2015.

Cash flow from operating activities for the period January-December 2012 was MSEK 28.7 (-117.2).

During the period April-June a sales milestone payment related to Abstral was received amounting to MEUR 3.3, as well as a payment of MGBP 22.5 in accordance with the new agreement with ProStrakan.

A resolution was adopted at an Extra Shareholder Meeting on July 13, 2012 to introduce a buy-back program of the company's own shares. A maximum of 10 percent of the shares outstanding can be bought back up until

the next Annual General Meeting. Up until December 31, 1,121,124 shares, corresponding to 3.7 percent of the number of shares outstanding, had been bought back for at a value of MSEK 53. No shares were bought back during the period October to December.

Shareholders' equity at December 31, 2012 was MSEK 191.2 (311.1). The equity/assets ratio was 40 (57) 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 10 percentage units.

Investments in fixed assets

Gross investments in tangible fixed assets amounted to MSEK 5.8 (4.7) for the period January-December and to MSEK 1.6 (0.1) for the period October-December.

Parent Company

Most of the Group's business is carried out in the Parent Company, Orexo AB. Net revenues for the period January-December 2012 amounted to MSEK 272.0 (140.8) and earnings after financial items were MSEK -157.1 (-443.8). Investments amounted to MSEK 5.8 (4.7). As of December 31, 2012, cash and cash equivalents in the Parent Company amounted to MSEK 216.6 (227.9). During the period, shares in subsidiaries decreased by MSEK 57.9. This decrease is attributable to the write-down of shares due to the write-down of the value of acquired technology and to the divestment of the Nordic sales company jointly owned with ProStrakan.

Future reporting dates

Annual General Meeting 2013	April 11, 2013, 5 pm
Interim report, January – March 2013	April 26, 2013
Interim report, January – June 2013	July 12, 2013
Interim report, January – September 2013	October 23, 2013
Year-end report for the 2013 financial year	January 30, 2014

Interim reports are covered in a conference call on the date of publication. Details on how to access the calls are provided in each report and on Orexo's website.

Annual Report 2012

Orexo AB's Annual Report will be presented on the company's website by March 21, 2013.

Uppsala, January 31, 2013
Orexo AB (publ)

Anders Lundström
President and CEO

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Review report

Report of Review of Interim Financial Information

Introduction

We have reviewed this report for the period January 1 to December 31, 2012 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, January 31, 2013

PricewaterhouseCoopers AB

Lars Kylberg
Authorised Public Accountant

Consolidated statement of operations

MSEK	Notes	3 months 2012 Oct-Dec	3 months 2011 Oct-Dec	12 months 2012 Jan-Dec	12 months 2011 Jan-Dec
Net revenues		83.6	56.7	326.3	199.6
Cost of goods sold	2	-7.4	-10.2	-27.9	-29.0
Gross profit		76.2	46.5	298.4	170.6
Selling expenses	2	-19.3	-15.8	-62.0	-50.1
Administrative expenses	2	-19.2	-12.2	-82.6	-49.6
Research and development costs	2	-49.9	-56.9	-216.2	-194.4
Other operating income and expenses	2	-9.5	-231.6	-17.1	-268.0
Operating earnings		-21.7	-270.0	-79.4	-391.5
Financial items – net		-2.3	-1.4	-8.2	-7.9
Earnings before tax		-24.0	-271.4	-87.6	-399.4
Income tax		1.8	0.4	1.7	7.4
Net earnings for the period¹⁾		-22.2	-271.0	-85.9	-392.0

Consolidated statement of comprehensive income

MSEK	3 months 2012 Oct-Dec	3 months 2011 Oct-Dec	12 months 2012 Jan-Dec	12 months 2011 Jan-Dec
Earnings for the period	-22.2	-271.0	-85.9	-392.0
Other comprehensive income				
Cash flow hedge	3.6	-	14.4	-
Exchange-rate differences	-	-0.6	-0.6	-0.7
Other comprehensive earnings for the period, net after tax	3.6	-0.6	13.8	-0.7
Total comprehensive earnings for the period¹⁾	-18.6	-271.6	-72.1	-392.7
Earnings per share, before dilution, SEK	-0.77	-9.07	-2.92	-14.43
Earnings per share, after dilution, SEK	-0.77	-9.07	-2.92	-14.43

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	2012 Dec 31	2011 Dec 31
ASSETS			
Fixed assets			
Tangible fixed assets		35.1	39.2
Goodwill		25.8	33.5
Acquired research and development		106.2	116.6
Other intangible fixed assets		3.1	0.8
Financial assets		18.5	-
Total fixed assets		188.7	190.1
Current assets			
Inventories		28.3	26.7
Accounts receivable and other receivables		36.7	82.4
Cash and cash equivalents		228.1	246.9
Total current assets		293.1	356.0
Total assets		481.8	546.1
SHAREHOLDERS' EQUITY AND LIABILITIES			
	3		
Total shareholders' equity		191.2	311.1
Long-term liabilities			
Provisions		4.0	0.6
Long-term liabilities, non-interest bearing		4.1	4.2
Long-term liabilities, interest bearing		109.5	110.3
Deferred tax liability		4.1	1.8
Total long-term liabilities		121.7	116.9
Current liabilities			
Current liabilities, non-interest bearing		157.8	107.5
Current liabilities, interest bearing		11.1	10.6
Total current liabilities		168.9	118.1
Total liabilities		290.6	235.0
Total shareholders' equity and liabilities		481.8	546.1

Consolidated changes in shareholders' equity

MSEK	2012 Dec 31	2011 Dec 31
Opening balance, shareholders' equity	311.1	468.2
Total comprehensive earnings for the period	-72.1	-392.7
Employee stock options, vested amount	4.3	4.1
Buyback of shares	-53.0	-
New share issues	0.9	231.5
Closing balance, shareholders' equity	191.2	311.1

Consolidated cash-flow statements

MSEK	Notes	2012 Oct-Dec	2011 Oct-Dec	2012 Jan-Dec	2011 Jan-Dec
Operating activities		-21.7	-270.0	-79.4	-391.5
Financial income and expenses		-1.5	-0.7	-5.1	-5.0
Adjustment for non-cash items	4	12.4	234.7	23.5	279.3
Cash flow from operating activities before changes in working capital		-10.8	-36.0	-61.0	-117.2
Changes in working capital		-66.0	-10.9	89.7	0.0
Cash flow from operating activities		-76.8	-46.9	28.7	-117.2
Acquisition of machinery and equipment		-1.6	-0.1	-5.8	-4.7
Sale of machinery and equipment		0.1	-	0.6	-
Acquisition of subsidiaries		-	-	-	-10.3
Sale JV		-	-	12.1	-
Cash flow from investing activities		-1.5	-0.1	6.9	-15.0
New share issue		0.6	-	0.8	232.0
Amortization of loans		-0.6	-	-2.3	11.7
Buyback of shares		-	-	-53.0	-
Cash flow from financing activities		-	-	-54.5	243.7
Cash flow for the period		-78.3	-47.0	-18.9	111.5
Cash and cash equivalents at the beginning of the period		306.2	294.3	246.9	135.8
Exchange-rate difference in cash and cash equivalents		0.2	-0.4	0.1	-0.4
Changes in cash and cash equivalents		-78.3	-47.0	-18.9	111.5
Cash and cash equivalents at the end of the period		228.1	246.9	228.1	246.9

Key figures

	3 months 2012 Oct-Dec	3 months 2011 Oct-Dec	12 months 2012 Jan-Dec	12 months 2011 Jan-Dec
Operating margin, %	-26	-476	-24	-196
Profit margin, %	-29	-478	-27	-200
Return on total capital, %	-4	-36	-14	-53
Return on equity, %	-11	-54	-33	-78
Return on capital employed, %	-7	-43	-20	-63
Debt/equity ratio, %	63	39	63	39
Equity/assets ratio, %	40	57	40	57
Current ratio, %	174	301	174	301
Acid ratio, %	157	279	157	279
Average number of shares, before dilution	28,815,734	29,860,643	29,448,932	27,167,225
Average number of shares, after dilution	31,640,371	32,369,137	32,100,967	29,706,229
Number of shares, before dilution	28,825,208	29,865,495	28,825,208	29,865,495
Number of shares, after dilution	31,645,177	32,370,704	31,645,177	32,370,704
Earnings per share, before dilution, SEK	-0.77	-9.07	-2.92	-14.43
Earnings per share, after dilution, SEK	-0.77	-9.07	-2.92	-14.43
Shareholders' equity per share, before dilution, SEK	6.63	10.42	6.63	10.42
Shareholders' equity per share, after dilution, SEK	6.04	9.61	6.04	9.61
Number of employees at the end of the period	92	118	92	118
Shareholders' equity, KSEK	191,194	311,101	191,194	311,101
Capital employed, KSEK	397,174	611,329	397,174	611,329

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

Parent Company statement of operations

MSEK	Notes	3 months 2012 Oct-Dec	3 months 2011 Oct-Dec	12 months 2012 Jan-Dec	12 months 2011 Jan-Dec
Net revenues		78.3	54.6	272.0	140.8
Cost of goods sold		-	-	-	-
Gross profit		78.3	54.6	272.0	140.8
Selling expenses		-16.9	-6.6	-46.8	-22.7
Administrative expenses		-17.9	-19.2	-114.2	-76.3
Research and development costs		-48.6	-53.7	-206.7	-182.5
Other operating income and expenses		-9.9	0.8	-19.3	-36.7
Operating earnings		-15.0	-24.1	-115.0	-177.4
Interest income and expenses		-2.5	-1.8	-9.1	-10.5
Impairment of shares in subsidiaries		-29.4	-255.9	-29.1	-255.9
Sales JV		-	-	-3.9	-
Financial items - net		-31.9	-257.7	-42.1	-266.4
Earnings before tax		-46.9	-281.8	-157.1	-443.8
Tax		-	-	-	-
Earnings for the period		-46.9	-281.8	-157.1	-443.8

Parent Company balance sheet

MSEK	Notes	2012 Dec 31	2011 Dec 31
ASSETS			
Fixed assets			
Tangible and intangible fixed assets		38.0	39.1
Shares in subsidiaries/joint ventures		172.2	230.1
Total fixed assets		210.2	269.2
Current assets			
Inventories		18.5	15.6
Accounts receivable and other receivables		55.6	120.8
Cash and bank balances		216.6	227.9
Total current assets		290.7	364.3
Total assets		500.9	633.5
SHAREHOLDERS' EQUITY; PROVISIONS AND LIABILITIES			
Shareholders' equity		127.3	332.3
Long-term liabilities		107.3	100.4
Current liabilities		266.3	200.8
Total liabilities		373.6	301.2
Total shareholders' equity and liabilities		500.9	633.5
Pledged assets		44.0	44.0
Contingent liabilities		8.4	11.3

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 2011 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 2012

- 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

	2012 Oct-Dec	2011 Oct-Dec	2012 Jan-Dec	2011 Jan-Dec
Raw materials and supplies	10.0	16.1	37.4	43.1
Other external costs	56.4	44.6	221.3	160.0
Personnel costs	28.3	34.6	138.1	117.6
Depreciation/amortization and impairment	12.1	234.5	17.3	279.1
Total	106.8	329.8	414.1	599.8

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. All development costs recognized in the balance sheet pertain to assets that were acquired through business combinations.

3. Shareholders' equity

Shares outstanding

The number of shares outstanding as of December 31, 2012 was 29,946,332, all of which were common shares. All shares carry entitlement to one vote each.

Number of shares outstanding at January 1, 2012	29,865,495
Subscription for shares through exercise of employee stock options	80,837
Shares outstanding at December 31, 2012	29,946,332

11,250 employee stock options, which were exercised during the period, have not yet been registered as shares.

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

Options

As of December 31, 2012, a total of 2,245,927 options were outstanding that carry rights to new subscription of 2,241,624 shares in Orexo and the exchange of 4,303 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, 2012	Change	Closing, Dec 31, 2012
Of which:			
Approved and allotted employee stock options	1,541,359		
Expired		-156,864	-156,864
Exercised		-119,026	-119,026
Allotted		235,000	235,000
Total			1,500,469
Approved and allotted Board options	61,006		61,006
Exercised		-42,921	-42,921
Allotted		270,000	270,000
Total			288,085
Approved and allotted warrants	10,000		10,000
Total			10,000
Approved but not yet allotted employee stock options			
Opening balance as approved by the 2011 AGM	565,000	-235,000	-235,000
Total			330,000
Warrants held by subsidiaries as cash-flow hedging for social security fees	122,173	-4,800	117,373
Total			117,373
Total number of options outstanding	2,299,538	-53,611	2,245,927

During the period January-December, a total of 161,947 employee stock options from Orexo's options program were exercised.

Allotment in performance-based, long-term incentive program

During 2011, Orexo introduced a performance-based, long-term incentive program that prior to exercise comprises performance shares that provide entitlement to subscription for a total of 1,540,000 Orexo shares. A condition for entitlement to acquire new shares through the exercise of performance shares is that each employee fulfills certain vesting conditions. Of the total number of performance shares allotted, 50 percent are vested on the basis of time and internal operational goals ("time-based performance shares") and 50 percent are based on the share-price trend and the relative share performance ("share-price based performance shares").

Of these performance shares, 165,000 were allotted free of charge in February 2012 and 70,000 performance shares were allotted free of charge in March. Of these performance shares, 117,500 are time-based and 117,500 are share-price based performance shares. The exercise price for the performance shares that were allotted in February was set at SEK 25.60 and the exercise price for the performance shares that were allotted in March was set at SEK 26.40. The final date for exercising the options is December 31, 2021.

Allotment in Board shareholder program

As a result of the successful acquisition of the American rights for Abstral and the continued development program process for Zubsolv, Orexo has created the foundation for establishing a successful commercial presence in the USA. In order to succeed in this work in the best possible way, it is considered necessary to tie the members of the Board closer to the company. In order to compensate, remunerate and motivate the members of the Board to assist through the extra work that this work for change involves, it has been decided to adopt the Board shareholder program 2012/2017.

In August 270,000 Board options were allotted free of charge. These have only been allotted to independent members of the Board. A condition for entitlement to acquire new shares through the exercise of performance shares is that certain vesting conditions are fulfilled. The exercise price for these has been set at SEK 36.3. The final date for exercising the options is December 31, 2017.

Convertible bond

The outstanding convertible bond amounting to MSEK 111 matures on March 31, 2015. If converted, this would increase the number of shares outstanding by 2,340,000.

Number of shares after full dilution

Shares outstanding at December 31, 2012	29,946,332 ¹⁾
Shares not yet registered	11,250
Employee stock options allotted	1,798,554
Employee stock options not yet allotted	330,000 ²⁾
Warrants for cash-flow hedging for social security fees	117,373
Convertible bond (upon conversion)	2,340,000
	34,543,509

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

²⁾ Expire on December 31, 2013, if not allotted.

4. Cash flow

Adjustment for non-cash items

MSEK	2012	2011	2012	2011
	Oct-Dec	Oct-Dec	Jan-Dec	Jan-Dec
Depreciation/amortization and impairment	12.1	234.4	17.3	279.0
Estimated costs for employee stock options program	1.2	0.9	9.3	3.1
Financial expenses, convertible bond	-0.8	-0.7	-3.1	-2.9
Bad debt losses	-	0.1	-	0.1
Total	12.5	234.7	23.5	279.3

5. Pledged assets and contingent liabilities

As the Inflazyme project was discontinued, the entire supplementary purchase consideration of MSEK 44.0 is recognized as a contingent liability.

As cash-flow hedging for social security fees pertaining to the employee stock options issued by Biolipox, warrants were issued to Pynox AB. 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.

6. Significant risks and uncertainties

Significant risks and uncertainties are presented in the Annual Report for 2011. The financial risk has decreased though the agreement with ProStrakan with regard to Abstral. No other significant changes have occurred since the Annual Report was submitted. The planned launch of Zubsolv in the USA during 2013 will entail risk exposure of an operational nature. Work on identifying and managing these risks is ongoing.

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 total capital	Operating earnings plus financial revenues as a percentage of average total assets.
Return on shareholders' equity	Net earnings for the period as a percentage of average shareholders' equity.
Return on capital employed	Operating earnings plus financial revenues as a percentage of average capital employed.
Current ratio	Current assets as a percentage of current liabilities.
Gross margin	Gross profit divided by net revenues.
EBITDA	Earnings before interest, taxes, depreciation, and amortization.
Shareholders' equity per share, before dilution	Shareholders' equity divided by the number of shares outstanding before dilution at the end of the period.
Shareholders' equity per share, after dilution	Shareholders' equity divided by the number of shares outstanding after dilution at the end of the period.
Average number of employees	Average number of full-year employees for the period.
Acid test ratio	Current assets excluding inventories as a percentage of current liabilities.
Capital turnover rate	Net revenues divided by average operating capital.
Net debt	Current and long-term interest-bearing liabilities including pension liabilities, less cash and cash equivalents.
Operating capital	Total assets less interest-free liabilities and provisions 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.
Annual return on shareholders' equity	Net earnings for the year divided by average shareholders' equity.
Interest-coverage ratio	Net earnings after net financial items plus interest expenses and similar items, divided by expenses and similar items.
Working capital, net	Interest-free current assets less interest-free current liabilities.
Working capital, net/net revenues	Average working capital, net, divided by net revenues.
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.
Profit margin	Net earnings after net financial items as a percentage of net revenues.

Please note

Orexo AB publ discloses the information provided herein pursuant to the Securities Markets Act. The information was provided for public release on January 31, 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.