

Interim report, January-September 2012

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

OREXO CLOSER TO LAUNCHING ZUBSOLV™ (OX219) – NEW TREATMENT OF OPIOID DEPENDENCE

During the interim period

- Net revenues amounted to MSEK 242.7 (142.9).
- Revenues from launched products increased by 105 percent to MSEK 190.1 (92.8).
- EBITDA amounted to MSEK -52.5 (-76.9).
- Earnings after tax were MSEK -63.6 (-121.0).
- Earnings per share were SEK -2.14 (-4.61).
- Cash flow from operating activities amounted to MSEK 105.5 (-70.3).
- Cash and cash equivalents amounted to MSEK 306.2 (294.3).
- Fixed royalty related to Abstral® according to the new agreement amounted to MSEK 59.4 (17.7) during third quarter.
- In September, an application for registration of Zubsolv (OX219) was submitted to the FDA five months earlier than planned.
- During the third quarter Orexo performed a buyback of the company's own shares, in total amounting to MSEK 53.

After the interim period

 In October Guggenheim Securities LLC was retained to explore strategic alternatives for commercialization in the US.

MSEK	2012	2011	2012	2011	2011
	July-Sept	July-Sept	Jan-Sept	Jan-Sept	Jan-Dec
Net revenues	76.1	46.2	242.7	142.9	199.6
Revenues from launched products	73.9	31.0	190.1	92.8	132.4
EBIT	-29.2	-61.3	-57.7	-121.5	-391.5
EBDITA	-27.7	-20.6	-52.5	-76.9	-112.4
Earnings after tax	-30.8	-55.8	-63.6	-121.0	-392.0
Earnings per share	-1.05	-1.87	-2.14	-4.61	-14.43
Cash flow	-66.9	-39.1	105.5	-70.3	-117.2
Cash and cash equivalents	306.2	294.4	306.2	294.4	246.9
Equity/assets ratio %	37	72	37	72	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/stockontv/121025/orexo/

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CEO's comments

During the third quarter we reached an important milestone when we submitted an application for the registration of Zubsolv™ (OX219) to the U.S. Food and Drug Administration, FDA. Zubsolv is a product for the treatment of opioid dependence. Thanks to a great effort by our co-workers, we managed to do this five months earlier than originally planned, which I am very impressed by.

There is a considerable market potential for Zubsolv in the USA, in a fast growing market. Zubsolv has several important patient friendly properties which make the tablet easy to use (such as rapid dissolution and smaller tablet size). We believe Zubsolv to be competitive product and anticipate that we can take considerable market shares and achieve sales of up to 500 million dollars a year. The launch of Zubsolv is planned for the third quarter of 2013. In order to strengthen Zubsolv's competitiveness, we have initiated a new development program to further differentiate our product from those of our competitors.

However, besides the very interesting prospects with Zubsolv, as previously announced we entered into a new agreement with ProStrakan regarding Abstral® during the second quarter. The agreement has strengthened Orexo financially and we will regain the Abstral product rights in the USA during the first quarter of 2013. Our future presence in the USA will thus be based on Orexo offering the market two attractive products – Zubsolv and Abstral. We have engaged Guggenheim Securities, LLC as a financial advisor to explore different strategic alternatives for commercialization in the USA. Based on the analysis, we will announce at the end of this year how our commercialization plan for the USA will be designed. As a consequence of this ongoing strategic review, the buyback of shares will not be restarted now.

Anders Lundström President and CEO

Operations

Development programs

Zubsolv[™] / OX219 – opioid dependence

During the third quarter Orexo submitted an application for the registration of Zubsolv, a tablet consisting of buprenorphine and naloxone, to the U.S. Food and Drug Administration, FDA. The application comprised a total of four clinical studies and a product stability program involving two production facilities. Submission of the application to the FDA was five months earlier than estimated. Orexo estimates that the launch of Zubsolv will take place during the third quarter of 2013 and Zubsolv is thus expected to be the first product to compete with Suboxone® in the US market for opioid dependence.

The market for the treatment of opioid dependence is large and growing in the USA. We estimate sales of Suboxone to reach USD 1.5 billion in 2012. Based on historical annual growth of about 15 percent, the market may be valued at just over 2 billion dollars in 2014. Underlying driving forces of market growth are an increased number of opioid dependent people, an increased percentage of people seeking and receiving help for their dependence, and price increases.

Orexo is at present evaluating the most optimal commercialization strategy for Zubsolv. Sales and marketing of Zubsolv will be directed towards a well-defined group of prescribing physicians. Orexo intends to present its choice of US commercialization strategy at the end of the year.

Zubsolv is based on Orexo's patented sublingual (under the tongue) tablet technology. This enables patients to be offered a product that has a rapid dissolution time and a smaller tablet size than the current marketed tablet. Tests so far have demonstrated that Zubsolv is preferred over this tablet.

In parallel with the registration application in the USA, Orexo is working on further differentiation of Zubsolv vis-à-vis Suboxone. The objective is to further develop the product in a broad development program which contains, amongst other things, new strengths and tastes and new clinical documentation such as the possibility of using Zubsolv for the initiation of treatment for opioid dependence. A study to document patients' preference regarding Zubsolv compared to Suboxone film will be initiated shortly.

Orexo estimates that annual sales of Zubsolv can amount to 500 million dollars.

OX51 – acute intense pain in connection with procedures

OX51 is a proprietary sublingual tablet formulation of alfentanil, the first oral alfentanil product for the prevention of acute intense 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 final formulation for the coming phase II study. During the fourth quarter, we plan to initiate an international dose-finding study in patients undergoing prostate biopsy. The study will comprise approximately 200 patients and it is estimated that the results will be available during the first half of 2013. It is estimated that 130 million painful procedures of this type are performed in the USA and EU each year and the need for improved pain relief medication is increasing as the procedures are being performed to a greater extent within outpatient clinics.

OX27 - breakthrough pain in cancer patients

The aim of the project is to develop a product for the treatment of breakthrough pain in cancer patients. The project has been reprioritized during the quarter and product development has been temporarily stopped, and the resources thus made available have been reallocated to $\mathsf{Zubsolv}^\mathsf{TM}$ and its further development.

Collaboration projects

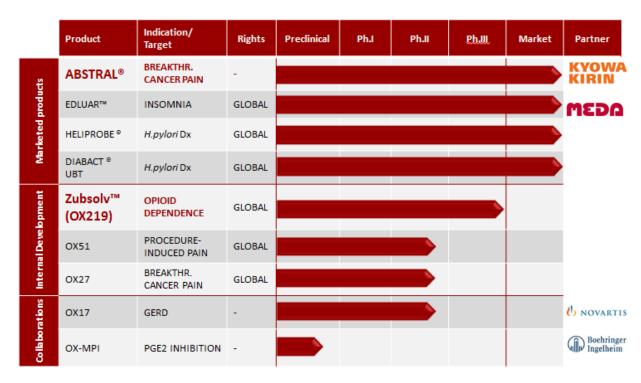
OX-MPI - PGE2 inhibition (Prostaglandin E2)

The collaboration with Boehringer Ingelheim was initiated in 2005 with focus on specific inhibition of the formation of PGE2 in different disease processes. Challenges regarding scaling up and formulation have been successfully solved and the project is proceeding in the preclinical phase with the evaluation of potential clinical strategies. Boehringer Ingelheim has sole responsibility for all research and development and commercialization of future products.

OX17 – gastroesophageal reflux disease (GERD)

The project, which is in an early developmental stage, has been licenced to Novartis. Novartis is responsible for all development, production and marketing of future products.

Product and project portfolio



The interim period January-September in figures

Revenues

Launched products

Total revenues from Orexo's launched products increased during the period January-September 2012 by 105 percent, to MSEK 190.1 (92.8), compared with the same period the previous year. Royalty revenues from Abstral® amounted to MSEK 145.0 (51.3). During the period July to September the corresponding royalty revenues, in accordance with the new agreement with ProStrakan, valid as of June 1, 2012 (see the interim report for the period January to June 2012), amounted to MSEK 59.4 (17.7).

Royalty revenues from Edluar™ amounted to MSEK 4.2 (1.8) during the period. During the second quarter Edluar was approved in the EU and is predicted to be launched during 2013.

Kibion's sales during the period were MSEK 32.9 (27.5). The Middle East and Europe are the strongest regions for Kibion. Political developments in the Middle East have entailed greater uncertainty with regard to Kibion's sales. In relation to our previous sales-forecast of MSEK 60 our assessment of total sales 2012 now is in the region of MSEK 50-55.

Revenues related to development projects

The earlier portion reported as liability of the milestone payment from Janssen has been recognized in its entirety during the period, 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 53.8 (50.5).

Total revenues during the period amounted to MSEK 242.7 (142.9), an increase of 70 percent.

Net revenues were distributed as follows:

MSEK	Jul-Sep 2012	Jul-Sep 2011	Jan-Sep 2012	Jan-Sep 2011	Jan–Dec 2011
Abstral royalties – old agreement*	•	17.7	36.8	51.3	70.5
Abstral royalties – new agreement**	59.4	•	78.9	-	-
Milestone payment Abstral	-	•	29.3	-	-
Edluar royalties	1.8	0.5	4.2	1.8	2.4
ProStrakan AB J/V 50%	•	4.6	8.0	12.2	15.6
Kibion (including WAT)	12.7	8.2	32.9	27.5	43.9
Total revenue from launched					
products	73.9	31.0	190.1	92.8	132.4
Partner-financed R&D costs	3.7	7.7	17.1	24.3	35.1
Licensing revenue for development	-	7.9	36.7	26.2	33.0
projects					
Other	-1.4	-0.4	-1.2	-0.4	-0.9
Total	76.2	46.2	242.7	142.9	199.6

^{*}Up to and including May 31, 2012.

^{**}As from June 1, 2012.

Costs and earnings

Selling expenses

Selling expenses amounted to MSEK 42.7 (34.3) for the period January-September 2012 and to MSEK 16.3 (10.7) for the period July-September 2012. Expenses relate primarily to marketing activities for the coming commercialization of Zubsolv™ and Abstral® in the USA, sales expenses in the subsidiary Kibion AB and in the previous joint venture company ProStrakan AB.

Administrative expenses

Administrative expenses for the period January-September 2012 amounted to MSEK 63.4 (37.4). The increase was mainly attributable to legal expenses related to the company's ongoing patent litigation regarding Edluar™ in the US. The renegotiation of the Abstral agreement and the reclassification of expenses in the subsidiary Kibion are also part of the increased costs. For the period July-September administrative expenses amounted to MSEK 26.3 (11.5).

Research and development costs

For the period January-September 2012, research and development costs amounted to MSEK 166.2 (137.5), of which MSEK 17.1 (24.3) has been covered by collaboration partners, primarily the former collaboration partner Janssen. The increase compared with the corresponding period the previous year is mainly attributable to activities related to clinical studies, primarily in the Zubsolv program. For the period July-September 2012 research and development costs amounted to MSEK 56.1 (42.2).

Other income and expenses

Other income and expenses amounted to MSEK -7.6 (-36.4) during the period January-September 2012 and to MSEK 0.1 (-37.8) during the period July-September 2012. Other expenses include expenses of MSEK 11.2 attributable to the workforce reduction that has been carried out. The remainder of other income and expenses comprises exchange-rate gains/losses.

Depreciation and amortization

Depreciation and amortization amounted to MSEK 5.2 (5.9) for the period January-September and MSEK 1.5 (2.0) for the period July-September.

Net financial items

Net financial items for the period January-September amounted to MSEK -5.9 (-6.5). Net financial items include interest expenses of MSEK 9.0 for convertible debentures.

Earnings

Operating earnings for the period January-September were SEK -57.7 (-121.5).

Financial position

At September 30, 2012, cash and cash equivalents amounted to MSEK 306.2 (294.3) and interest bearing liabilities to MSEK 118.0 (118.8). 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-September 2012 was MSEK 105.5 (-70.3).

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

A resolution was adopted at the General Meeting of shareholders on July 13, 2012 to introduce a buyback 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 September 30, 1,121,124 shares, corresponding to 3.7 percent of the number of shares outstanding, had been bought back at a value of MSEK 53.

Shareholders' equity at September 30, 2012 was MSEK 208.4 (581.7). The equity/assets ratio was 37 (72) 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 14 percentage units.

Investments in fixed assets

Gross investments in tangible fixed assets amounted to MSEK 4.2 (4.7) for the period January-September and to MSEK 0.8 (1.1) for the period July-September.

Parent Company

Most of the Group's business is carried out in the Parent Company, Orexo AB. Net revenues for the period January-September 2012 amounted to MSEK 193.7 (86.1) and earnings after financial items were MSEK -110.2 (-162.0). Investments amounted to MSEK 4.2 (4.7). As of September 30, 2012, cash and cash equivalents in the Parent Company amounted to MSEK 294.0 (273.6).

Future reporting dates

Year-end report for the 2012 financial year	January 31, 2013
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.

Uppsala, October 25, 2012 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 September 30, 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, October 25, 2012

PricewaterhouseCoopers AB

Lars Kylberg Authorised Public Accountant

Consolidated statement of operations

MSEK	Notes	3 months 2012	3 months 2011	9 months 2012	9 months 2011	12 months 2011
		Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Dec
Net revenues		76.1	46.2	242.7	142.9	199.6
Cost of goods sold	2	-6.7	-5.5	-20.5	-18.8	-29.0
Gross profit		69.4	40.7	222.2	124.1	170.6
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Selling expenses	2	-16.3	-10.7	-42.7	-34.3	-50.1
Administrative expenses	2	-26.3	-11.4	-63.4	-37.4	-49.6
Research and development costs	2	-56.1	-42.1	-166.2	-137.5	-194.4
Other operating income and expenses	2	0.1	-37.8	-7.6	-36.4	-268.0
Operating earnings		-29.2	-61.3	-57.7	-121.5	-391.5
Financial items – net		-1.5	-1.5	-5.9	-6.5	-7.9
Earnings before tax		-30.7	-62.8	-63.6	-128.0	-399.4
Income tax		-0.1	7.0	0.0	7.0	7.4
Net earnings for the period ¹⁾		-30.8	-55.8	-63.6	-121.0	-392.0

Consolidated statement of comprehensive income

MSEK	3 months 2012 Jul-Sep	3 months 2011 Jul-Sep	9 months 2012 Jan-Sep	9 months 2011 Jan-Sep	12 months 2011 Jan-Dec
Earnings for the period	-30.8	-55.8	-63.6	-121.0	-392.0
Other comprehensive income					
Cash flow hedge Exchange-rate differences Other comprehensive earnings for the period, net after tax	7.8 -0.8 7.0	1.7 1.7	10.8 -0.6 10.2	-	-0.7 - 0.7
Total comprehensive earnings for the period ¹⁾	-23.8	-54.1	-53.4	-121.0	-392.7
Earnings per share, before dilution, SEK	-1.05	-1.87	-2.14	-4.61	-14.43
Earnings per share, after dilution, SEK	-1.05	-1.87	-2.14	-4.61	-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 Sep 30	2011 Sep 30	2011 Dec 31
ASSETS				
Fixed assets				
Tangible fixed assets		36.2	40.6	39.2
Goodwill Acquired research and development		25.5 116.5	33.8 349.1	33.5 116.6
Acquired research and development Other intangible fixed assets		2.8	0.9	0.8
Financial assets		14.7	-	-
Total fixed assets		195.7	424.4	190.1
Current assets				
Inventories		26.9	18.3	26.7
Accounts receivable and other receivables		35.7	76.3	82.4
Cash and cash equivalents		306.2	294.4	246.9
Total current assets		368.8	389.0	356.0
Total assets		564.5	813.4	546.1
SHAREHOLDERS' EQUITY AND LIABILITIES	3			
Total shareholders' equity		208.4	581.7	311.1
Long-term liabilities				
Provisions		3.7	5.0	0.6
Long-term liabilities, non-interest bearing		4.0	-	4.2
Long-term liabilities, interest bearing		106.9	107.5	110.3
Deferred tax liability		5.6	1.8	1.8
Total long-term liabilities		120.2	114.3	116.9
Current liabilities				
Current liabilities, non-interest bearing		224.8	106.1	107.5
Current liabilities, interest bearing		11.1	11.3	10.6
Total current liabilities		235.9	117.4	118.1
Total liabilities		356.1	231.7	235.0
Total shareholders' equity and liabilities		564.5	813.4	546.1
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Consolidated changes in shareho	nuers equity			
MSEK		2012	2011	2011
		Sep 30	Sep 30	Dec 31
Opening balance, shareholders' equity		311.1	468.2	468.2
Total comprehensive earnings for the period		-53.4	-121.0	-392.7
Employee stock options, vested amount		3.5	3.1	4.1
Buyback of shares		-53.0	-	-
New share issues		0.2	231.4	231.5
Closing balance, shareholders' equity		208.4	581.7	311.1

Consolidated cash-flow statements

MSEK	Notes	2012 Jul-Sep	2011 Jul-Sep	2012 Jan-Sep	2011 Jan-Sep	2011 Jan-Dec
Operating activities		-29.2	-61.3	-57.7	-121.5	-391.5
Financial income and expenses		-0.7	-0.6	-3.6	-4.4	-5.0
Adjustment for non-cash items	4	5.2	40.7	11.1	44.7	279.3
, agustinent for non easi items	•	3.2	10.7		1117	273.3
Cash flow from operating activities before						
changes in working capital		-24.7	-21.2	-50.2	-81.2	-117.2
Changes in working capital		-42.2	-17.9	155.7	10.9	0.0
Cash flow from operating activities		-66.9	-39.1	105.5	-70.3	-117.2
Acquisition of machinery and equipment		-0.8	-1.0	-4.2	-4.7	-4.7
Sale of machinery and equipment		0.4	-	0.5	-	-
Acquisition of subsidiaries		-	-10.3	-	-10.3	-10.3
Sales JV		_	-	12.1	-	-
Cash flow from investing activities		-0.4	-11.3	8.4	-15.0	-15.0
New share issue		0.2	90.7	0.2	232.0	232.0
Amortization of loans		-0.6	11.7	-1.7	11.7	11.7
Buyback of shares		-53.0	-	-53.0	-	-
Cash flow from financing activities		-53.4	102.4	-54.5	243.7	243.7
Cash flow for the period		-120.7	52.0	59.4	158.4	111.5
Cash and cash equivalents at the beginning of the period		426.1	242.5	246.9	135.8	135.8
Exchange-rate difference in cash and cash						
equivalents		0.8	-0.2	-0.1	0.1	-0.4
Changes in cash and cash equivalents		-120.7	52.0	59.4	158.4	111.5
Cash and cash equivalents at the end of						
the period		306.2	294.3	306.2	294.3	246.9

Key ratios

J	3 months 2012 Jul-Sep	3 months 2011 Jul-Sep	9 months 2012 Jan-Sep	9 months 2011 Jan-Sep	12 months 2011 Jan-Dec
Operating margin, %	-38	-133	-23	-85	-196
Profit margin, %	-40	-136	-26	-90	-200
Return on total capital, %	-5	-7	-10	-16	-53
Return on equity, %	-11	-9	-23	-24	-78
Return on capital employed, %	-7	-8	-14	-19	-63
Debt/equity ratio, %	57	20	57	20	39
Equity/assets ratio, %	37	72	37	72	57
Current ratio, %	156	331	156	331	301
Acid ratio, %	145	316	145	316	279
Average number of shares, before dilution	29,226, 005	29,850,940	29,659, 998	26,269,419	27,167, 225
Average number of shares, after dilution	31,991, 090	32,380,626	32,254, 498	28,818,593	29,706, 229
Number of shares, before dilution	28,801, 119	29,850,940	28,801, 119	29,850,940	29,865, 495
Number of shares, after dilution	31,666, 198	32,373,345	31,666, 198	32,373,345	32,370, 704
Earnings per share, before dilution, SEK	-1.05	-1.87	-2.14	-4.61	-14.43
Earnings per share, after dilution, SEK	-1.05	-1.87	-2.14	-4.61	-14.43
Shareholders' equity per share, before					
dilution, SEK	7.23	19.49	7.23	19.49	10.42
Shareholders' equity per share, after					
dilution, SEK	6.58	17.97	6.58	17.97	9.61
Number of employees at the end of the					
period	96	108	96	108	118
Shareholders' equity, KSEK	208,358	581,704	208,358	581,704	311,101
Capital employed, KSEK	326,373	699,591	326,373	699,591	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 Jul-Sep	3 months 2011 Jul-Sep	9 months 2012 Jan-Sep	9 months 2011 Jan-Sep	12 months 2011 Jan-Dec
Net revenues		65.7	28.3	193.7	86.1	140.8
Cost of goods sold		-	-	-	-	-
Gross profit		65.7	28.3	193.7	86.1	140.8
Selling expenses		-13.4	-4.6	-29.9	-16.2	-22.7
Administrative expenses		-25.2	-18.0	-96.3	-57.1	-76.3
Research and development costs		-54.5	-39.3	-158.1	-128.7	-182.5
Other operating income and expenses		-0.7	-38.7	-9.5	-37.5	-36.7
Operating earnings		-28.1	-72.3	-100.1	-153.4	-177.4
Interest income and expenses		-1.7	-2.0	-6.5	-8.6	-10.5
Impairment of shares in subsidiaries		0.3	-	0.3	-	-255.9
Sales JV		-	-	-3.9	-	-
Financial items - net		-1.4	-2.0	-10.1	-8.6	-266.4
Earnings before tax		-29.5	-74.3	-110.2	-162.0	-443.8
Tax		-	-	-	-	-
Earnings for the period		-29.5	-74.3	-110.2	-162.0	-443.8

Parent Company balance sheet

MSEK	Notes	2012 Sep 30	2011 Sep 30	2011 Dec 31
ASSETS				
Fixed assets				
Tangible and intangible fixed assets		38.1	40.5	39.1
Shares in subsidiaries/joint		30.1	40.5	33.1
ventures		211.8	486.0	230.1
Total fixed assets		249.9	526.5	269.2
Current assets				
Inventories Accounts receivable and other		15.0	6.9	15.6
receivables		47.2	101.3	120.8
Cash and bank balances		294.0	273.6	227.9
Total current assets		356.2	381.8	364.3
Total assets		606.1	908.3	633.5
SHAREHOLDERS' EQUITY; PROVISIONS AND LIABILITIES				
Shareholders' equity		172.7	613.0	332.3
Long-term liabilities		104.0	97.5	100.4
Current liabilities		329.4	197.8	200.8
Total liabilities		433.4	295.3	301.2
Total shareholders' equity and liabilities		606.1	908.3	633.5

Pledged assets		44.0	44.0	44.0
Contingent liabilities	5	10.4	13.1	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 Jul-Sep	2011 Jul-Sep	2012 Jan-Sep	2011 Jan-Sep	2011 Jan-Dec
Raw materials and supplies	7.4	7.8	27.3	27.0	43.1
Other external costs	68.7	34.7	165.0	115.4	160.0
Personnel costs	31.5	26.6	109.8	83.0	117.6
Depreciation/amortization and impairment	1.5	40.7	5.2	44.6	279.1
Total	109.1	109.8	307.3	270.0	599.8

Research and development costs encompass costs for personnel, premises, external costs for clinical trials, product 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 September 30, 2012 was 29,922,243, 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	56,748
Shares outstanding at September 30, 2012	29,922,243

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

Options

As of September 30, 2012, a total of 2,282,600 options were outstanding that carry rights to new subscription of 2,273,497 shares in Orexo and the exchange of 9,103 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, Sept 30, 2012
Of which:			
Approved and allocated employee stock options	1,541,359		
Expired		-154,864	-154,864
Exercised		-92,776	-92,776
Allotted		235,000	235,000
Total			1,528,719
Approved and allotted Board options	61,006		61,006
Exercised		-34, 498	-34,498
Allotted		270, 000	270,000
Total			296,508
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	330,000
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	-16,938	2,282,600

During the period January-September, a total of 56,748 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 fulfils 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 36.30. The final date for exercising the options is December 31, 2017.

Convertible bond

The outstanding convertible bond of MSEK 111, expiring in March 2015, will increase the number of outstanding shares by 2 340 000 if converted.

Number of shares fully diluted	
Shares outstanding at September 30, 2012	29,922,243 ¹⁾
Stock options allocated	1,835,227
Stock options not yet allocated	330,000 ²⁾
Warrants as hedge for cash-flow of social costs	117,373
Convertible bond (if converted)	2,340,000
	34,544,843

¹⁾ Including 1,121,124 shares bought back and held by Orexo

4. Cash flow

Adjustment for non-cash items

MSEK	2012	2011	2012	2011	2011
	Jul-Sep	Jul-	Jan-	Jan-Sep	Jan-Dec
		Sep	Sep		
Depreciation/amortization and impairment	1.5	40.7	5.2	44.6	279.0
Estimated costs for employee stock options program	4.5	0.7	8.1	2.2	3.1
Financial expenses, convertible bond	-0.8	-0.7	-2.3	-2.1	-2.9
Bad debt losses	-	-	-	-	0.1
Total	5.2	40.7	11.0	44.7	279.3

5. Pledged assets and contingent liabilities

During 2010, the Inflazyme project was discontinued, which entailed recognition of the entire supplementary purchase consideration of MSEK 44.8 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 Pyrinox AB. Orexo has pledged to handle any deficits exceeding the cover provided by the warrants during their lifetime through December 31, 2016.

²⁾ Expiring December 31, 2013, if not allocated.

Orexo acquired the UK drug company PharmaKodex in February 2009. This acquisition includes conditional payments based on license revenues from the current PharmaKodex program and technologies, as well as on payments for certain milestones. These are not recognized as a liability since it is not probable that any payment will be made.

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.

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 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, Shareholders' equity divided by the number of shares outstanding before dilution at

before dilution the end of the period.

Shareholders' equity per share, Shareholders' equity divided by the number of shares outstanding after dilution at

after dilution 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.

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 October 25, 2012, 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.