

## Interim Report January-December 2011

Unless otherwise stated in this report, all data refers to the group. Figures in parentheses are for the corresponding periods in 2010.

# POSITIVE DEVELOPMENT IN ABSTRAL® SALES AND OREXO'S PROPRIETARY PROGRAMS WHILE THE OX-CLI AND OX-ESI PROJECTS ARE ABORTED

#### **During the year**

- Net revenues amounted to 199.6 MSEK (210.5).
- The loss after tax was MSEK -392.0 (-89.2).
- Impairment of acquired development related to the OX-CLI and OX-ESI projects amounted to MSEK 233
- Operating income adjusted for impairment of acquired development amounted to MSEK -120.3 (-56.0).
- Cash flow from operating activities amounted to MSEK -117.2 (-43.0).
- The loss per share amounted to SEK -14.43 (-3.81).
- Cash and cash equivalents at the end of the year, amounted to MSEK 246.9 (MSEK 135.8).
- Royalty revenues from Abstral<sup>®</sup> sales increased to MSEK 70.5 (42.2).
- Abstral was approved and introduced in the US and Canada.
- A new share issue worth approximately MSEK 245, before transaction costs, was completed.
   ATP and Abingworth became new shareholders and Novo A/S became the largest shareholder.
- All three development programs, OX219, OX51 and OX27 advanced according to plan and positive results were reported from clinical studies.

#### After the period

Negotiations regarding the collaboration with Janssen Pharmaceuticals, Inc. on OX-CLI and OX-ESI ended, and hence Orexo aborts the project activities.

#### Fourth quarter

- Net revenues amounted to MSEK 56.7 (109.1).
- Cash flow from operating activities amounted to MSEK -46.9 (-29.2).
- The loss after tax was MSEK -271.0 (2.2).
- The loss per share amounted to SEK -9.07 (0.09).

## **Key figures**

MSEK	3 months 2011 Oct-Dec	3 months 2010 Oct-Dec	Full year 2011 Jan-Dec	Full year 2010 Jan-Dec
Net revenue	56.7	109.1	199.6	210.5
Operating loss	-269.9	2.8	-391.5	-81.7
Loss for the period	-271.0	2.2	-392.0	-89.2
Loss per share, SEK	-9.07	0.09	-14.43	-3.81
Cash flow from operating activities	-46.9	-29.2	-117.2	-43.0
Cash and cash equivalents	246.9	135.8	246.9	135.8

#### Conference call

## CEO comments

"The strong sales growth for Abstral® continued in the fourth quarter, which meant that the royalty revenue from this pain product increased by 67 per cent in 2011 to MSEK 70.5. We see continued growth in most markets in Europe and despite increased competition, Abstral succeeds in maintaining, and in many markets strengthening its market position in Europe.

In the U.S. the FDA decided in December to approve a common risk management system for all fast-acting fentanyl products. The new system will come into effect in March 2012, which means that Abstral, for the first time, will be able to compete on equal terms with other fast acting fentanyl products in the U.S. market.

It was obviously a disappointment to us that our collaboration on two projects in the arachidonic acid field with Janssen Pharmaceuticals, Inc. (formerly OMJ) has been ended. Unfortunately, we lack the funds to continue on our own to develop the OX-CLI and OX-ESI projects and have therefore decided to close them down.

In 2011 we announced positive results from a Phase I study with OX219, for the treatment of opioid dependence. The study results confirmed the final commercial formulation, and dose for the product. We are advancing the program and in the first half of 2012 pre-registration studies will be initiated.

We end 2011, showing that all three of our proprietary development programs are advancing towards the market according to plan. Most promising is the initiation of pre-registration studies for OX219 in the first quarter of 2012. Altogether, with the progress in our projects, a very good staff and a management team with the right skills, we are as planned, on our way to become a successful specialty pharma company."

Anders Lundström President and CEO

## Key events during the year

### Abstral® sales in Europe, U.S. and Canada

During the year, sales growth for Abstral in Europe was very strong and sales growth in the fourth quarter was approximately 60 percent, compared to the same period in the previous year. At the beginning of the year, Abstral became the first product to be approved in the U.S., under the FDA's individual risk management plan (REMS) for fast acting fentanyl products. In December, the FDA approved a new joint national risk management system, which in March 2012 will replace the individual REMS for these products. With this in effect, Abstral will be able to compete on equal terms with other products in its class in the U.S. market. In February, Abstral was approved in Canada, one of the world's ten largest pharmaceutical markets, and introduced in June by ProStrakan's partner Paladin Labs.

#### New share issue, stronger shareholder base

A new share issue worth approximately MSEK 245, before transaction costs, was conducted during the year. The new share issue secured financing for the late stage development of OX219, OX51 and OX27 towards launch. The institutional shareholder base was broadened by ATP and Abingworth becoming new shareholders. Novo A / S increased its holding and became the largest shareholder.

## Positive clinical data in all proprietary programs

**OX219** – In September, positive results were reported from a phase I study with OX219 for the treatment of opioid dependence. The purpose of the study was to develop the commercial formulation and dose for the program. The chosen formulation is based on Orexo's proprietary sublingual technology.

**OX51** – In March positive data was reported from the first clinical study in the OX51 project, which aims to develop a treatment for acute intensive pain episodes in relation to care-related, diagnostic or therapeutic procedures in patients who are not receiving sufficient pain relief.

**OX27** – In June positive results were reported from the first pharmacokinetic study in the OX27-project, for the treatment of breakthrough cancer pain. The study showed that the active pharmaceutical ingredient is both absorbed and eliminated quickly. Results from the second clinical study were reported in December and confirmed that OX27 has the potential to be dosed more flexibly than fentanyl-based products.

## Recruitment of new President and strengthening of the management team

In addition to the recruitment of Anders Lundström as new President and CEO at the beginning of the year, the management team was also strengthened. During the year, Carl-Johan Blomberg was appointed new Chief Financial Officer, Nikolaj Sørensen was appointed Chief Commercial Officer, Marie Zachrisson was appointed HR Director and Peter Edman, Chief Scientific Officer.

#### Acquisition of Wagner Analysen Technik GmbH (WAT)

In July, the subsidiary Kibion AB acquired Wagner Analysen Technik GmbH (WAT), a leading manufacturer of IRIS instruments and substrates for diagnostic breath tests. The acquisition strengthens Kibion's operations and creates significant opportunities for future growth and thus a stronger self-contained business unit. The purchase price amounted to 1.2 MEUR and was financed entirely by bank loans. If well-defined sales targets are achieved, an additional purchase premium will be paid. The acquisition is expected to contribute positively to Orexo's earnings within 12 months.

## Sublinox (Edluar™) approved and launched in Canada

In July, the insomnia-treatment Sublinox (Edluar™) was approved for sale in Canada. Meda and its partner Valeant launched the product, in the fourth quarter of 2011. Orexo is entitled to royalties on sales.

## Key events after year-end

The collaboration with Janssen Pharmaceuticals, Inc. was terminated and OX-CLI/OX-ESI was closed down

Orexo AB and Janssen Pharmaceuticals, Inc. (formerly Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica NV) ("Janssen") have after a long period of negotiations agreed to terminate its collaboration and license agreement regarding OX-CLI and OX-ESI programs as well as a third Janssen program. Both parties regained all commercial rights to their respective research programs. Hence, Orexo will close down the projects and has fully written down the value of projects related to acquired research and development. The impairment, amounting to 232.5 million, is charged in 2011 and does not affect Orexo's liquid funds.

## Operations

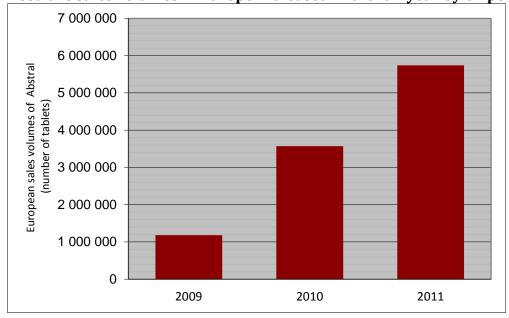
## Launched products

Revenues from product sales increased during the year by 38 percent to MSEK 132.4 (95.7). Royalty revenues from Abstral® increased during the year by 67 percent to MSEK 70.5 (42.2), compared to last year. Sales growth for Abstral in Europe remains strong, and in the fourth quarter, sales increased by 60 percent compared to the same quarter in the previous year. We see an increased competition from new fast-acting fentanyl products in several markets. Abstral has proven to be very competitive, and many cancer patients in Europe, who have breakthrough pain today, do not receive optimal pain management. With the launch of several new products, the awareness of existing treatment options increases and consequently so does the potential market for Abstral.

Abstral was introduced to the U.S. market during the year by Orexo's partner ProStrakan. In the U.S., the product can be sold only through pharmacies approved according to the FDA Risk Management System (REMS). REMS has been a major drawback for the new products in the market, since established products were given a deferment in the implementation of REMS until March 2012. In December, the U.S. Food and Drug Administration, FDA, approved a common risk management program for all fentanyl products. This significantly improves Abstral's potential in the U.S. market and gives the product a more balanced competitive situation. The new REMS will come into effect in March 2012.

In February, Abstral, in partnership with Gedeon Richter, was approved in Russia. In collaboration with NewBridge, the product was approved in Kuwait in August and in January 2012 in Lebanon. During the year Orexo also a signed a distribution agreement with NovaMed for Hong Kong, which is a small market, but strategically important for the launch in China. Traditionally, registration processes are faster in Hong Kong and the market is an important gateway into mainland China.

## Abstral's sales volumes in Europe increased in the full year by 61 per cent



The bars refer to invoiced sales from our partner ProStrakan Group plc to wholesalers.

Royalty income from Edluar™ in the year amounted to MSEK 2.4.

Kibion's sales during the fourth quarter of MSEK 16.4 (12.1) include MSEK 2.9 from Wagner Analysen Technik GmbH (WAT), which was acquired in the third quarter. Efforts to integrate WAT in Kibion AB have been a top priority during the latter part of 2011. Agreements for the sale of Diabact® UBT in

combination with the analytical instrument IRIS have been negotiated in some key markets and are expected to generate new sales as a direct synergistic effect of the acquisition from 2012 onwards.

Orexo's Nordic joint venture, ProStrakan AB, increased its total sales in the Nordic region during the year by of 38 percent. Orexo's reported share amounted to MSEK 15.6 (12.3). The sales of Abstral® through ProStrakan AB increased by 88 percent to MSEK 14.2 (7.6) in the same period.

## **Collaborative projects**

Revenues from new and existing licensing agreements during the year amounted to MSEK 33.0 (81.1). These consist primarily of the revenue-registered portion of the milestone payment received from the former collaboration partner Janssen Pharmaceuticals, Inc., formerly Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica NV ("Janssen").

Regarding the partner-funded R&D costs related to collaboration projects - see page 9.

# Orexo's proprietary development programs OX219

In the third quarter, positive results were reported in a phase I study with OX219, that is being developed to treat opioid dependence. The purpose of this study was to decide the final commercial formulation and dose for the product. The chosen formulation is based on Orexo's proprietary sublingual technology. Further development of the program is progressing and the next step is preregistration studies that will be initiated in the first half of 2012. The registration application is scheduled to be submitted in 2013. The global market for products for the treatment of opioid dependence currently amounts to 1.4 billion USD and is expected in 2019 to amount to 2.2 billion USD (Datamonitor, 2010).

#### **OX51**

Positive clinical data for OX51 was reported in the first quarter. This is a new sublingual formulation of an existing treatment for acute intensive pain episodes, associated with care-related, diagnostic or therapeutic procedures, in patients who currently are not receiving sufficient pain relief. OX51 should allow pain treatment in these procedures to become more efficient and the need for sedating patients should be reduced. The planning of the first patient study within the program was completed during the second half of 2011. The medical need is estimated at around 130 million pain episodes, annually in the U.S. and the EU.

### **OX27**

The program involves the development of a fast-acting sublingual formulation of an existing treatment, and is designed for optimal treatment of episodes of breakthrough pain, which commonly affect cancer patients. During the second quarter, positive results were reported from the first pharmacokinetic study in the OX27 project. The study showed that the active pharmaceutical ingredient is both absorbed and eliminated quickly, making it well suited for this kind of pain treatment. Results from the subsequent clinical study were obtained in the fourth quarter, confirming that OX27 has the potential to be dosed more flexibly than existing fentanyl-based products.

## The period in figures

## Consolidated income statement in brief

MSEK	3 months	3 months	12 months	12 months
	2011	2010	2011	2010
	Oct-Dec	Oct-Dec	Jan-Dec	Jan-Dec
		100.14	100.0	242 - 4
Net revenue	56.7	109.1*	199.6	210.5*
Cost of goods sold	-10.2	-7.4	-29.0	-26.3
Gross profit	46.5	101.7	170.6	184.2
Selling expenses	-15.8	-12.4	-50.1	-35.2
Administrative expenses	-12.2	-10.1	-49.6	-46.8
Research & development				
costs	-56.8	-51.7	-194.4	-161.1
Other operating income &				
expenses**	-231.6	-24.7	-268.0	-22.8
Operating loss	-269.9	2.8	-391.5	-81.7
Net financial items	-1.5	-0.6	-7.9	-7.5
Loss after financial items	-271.4	2.2	-399.4	-89.2
Tax	0.4	0.0	7.4	0.0
Net loss for the period	-271.0	2.2	-392.0	-89.2

<sup>\*</sup> Includes milestone payment from Boehringer Ingelheim of MSEK 56.3.

<sup>\*\*</sup> Includes the full year impairment of previously acquired technology of MSEK 271.2 (MSEK 25.8).

## **Revenues**

### Net revenues

Net revenues for January-December 2011 amounted to MSEK 199.6 (210.5). Compared to the previous year, net revenues are influenced by higher royalty revenues from Abstral®, and lower non-recurring licensing revenues from collaborative projects.

During the fourth quarter 2011 the net revenues amounted to MSEK 56.7 (109.1).

## Net revenues were distributed as follows

MSEK	Oct-Dec 2011	Oct-Dec 2010	Jan-Dec 2011	Jan-Dec 2010
Abstral royalties	19.2	11.9	70.5	42.2
Edluar™ royalties	0.6	0.8	2.4	1.3
ProStrakan AB J/V 50 %	3.4	3.7	15.6	12.3
Kibion	16.4	12.1	43.9	39.9
Total revenue from launched				
products	39.6	28.5	132.4	95.7
Partner-financed R&D costs Licensing revenue for development projects	10.8	15.9 64.9	35.1 33.0	33.8 81.1
Other	-0.5	-0.2	-0.9	-0.1
Total	56.7	109.1	199.6	210.5

## **Costs and earnings**

#### Sales expenses

Sales expenses amounted to MSEK 50.1 (35.2) in January–December 2011 and amounted to MSEK 15.8 (12.4) for the fourth quarter 2011. The increase is primarily attributable to costs for ongoing Phase IV studies for Abstral®, to be ended in March 2012, market support activities for Orexo's project portfolio, increased sales costs in the subsidiary Kibion AB and the joint-venture, ProStrakan AB, and costs for Kibion AB in connection with the acquisition of Wagner Analysen Technik GmbH.

#### Administrative expenses

Administrative expenses in January–December 2011 amounted to MSEK 49.6 (46.8). These include costs attributed to the recruitment of new senior executives, the implementation of a long term incentive program 2011/2021 and legal costs related to the company's patent portfolio. For the fourth quarter, administrative expenses amounted to MSEK 12.2 (10.2).

### Research & development costs

Research & development costs in January-December 2011 amounted to MSEK 194.4 (161.1), of which 27.8 MSEK (33.8) was covered by the former collaboration partner Janssen Pharmaceuticals, Inc., formerly Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica NV (OMJ). The increase is attributed to activities related to clinical studies in Orexo's proprietary programs. For the fourth quarter 2011 research and development costs amounted to MSEK 56.8 (51.7).

### Expenses for long-term incentive program

The Group's total expenses in 2011 for employee stock option plans amounted to MSEK 3.1, excluding costs of implementation, compared to MSEK 3.3 in the same period previous year.

#### Other income and expenses

Other income and expenses during 2011 amounted to MSEK -268.0 (-22.8). Included in other costs is the impairment of previously acquired research and development with a total of MSEK 271.2. Of this amount, MSEK 232.5 refers to the now terminated research collaboration with Janssen, while MSEK 38.7 refers to the choice of formulation made for Orexo's proprietary development project OX219, which is entirely attributable to PKX219 that was included in the acquisition of PharmaKodex. The rest of the other income and expenses consists of foreign exchange gains/losses. For the period October-December 2011 other income and expenses amounted to MSEK -231.6 (-24.7).

## Depreciation

Depreciation for the full-year 2011 amounted to MSEK 7.8 (9.6), and for the fourth quarter to MSEK 1.9 (3.7).

#### Net financial income

Net financial items for the full-year 2011 amounted to MSEK -7.9 (-7.5). Net interest income includes interest expenses of MSEK 11.8 for convertible debentures.

#### Income tax

The income tax for the full-year 2011 amounting to MSEK 7.4 (0.0) is entirely attributable to the reversal of deferred tax, related to impairment of acquired technology, relating to PKX219.

#### **Earnings**

Operating loss for the full-year 2011 amounted to MSEK -391.5 (-81.7).

## **Financial position**

Cash and cash equivalents amounted per December 31, 2011 to MSEK 246.9 (135.8).

Cash flow from operating activities in 2011 amounted to MSEK -117.2 (-43.0). The cash flow has been affected positively by the milestone payment from Boehringer Ingelheim, amounting to MSEK 56.3, which was recognized as revenue in 2010 but paid in 2011

The new share issue completed in the third quarter, contributed MSEK 231.2 in total after transaction expenses.

Shareholder's equity per December 31, 2011 amounted to MSEK 311.1 (468.2). The equity ratio was 57 (66) percent.

#### **Investments**

Gross investments in tangible assets in 2011 amounted to MSEK 4.7 (3.4) and for the fourth quarter 2011 MSEK 0.0 (1.1).

#### **Seasonal Variations**

Orexo's operations are not subject to seasonal variations. However, pharmaceutical sales in new markets are influenced by stock-building, especially in a launch phase.

## **The Parent Company**

Most of the Group's operations are conducted in the parent company Orexo AB. Net sales for the full-year 2011 amounted to 140.8 (113.0) MSEK and profit after financial items was MSEK -443.8 (-118.6). Investments amounted to 4.7 (3.4) MSEK. Liquid assets in the parent company at December 31, 2011 were MSEK 227.9 (101.4). During the period, shares in subsidiaries decreased by MSEK 374.6. This decrease is in part attributable to the impairment of shares due to the impairment of acquired technology and in part attributable to the reduction of Biolipox AB's reserve fund, which has been returned to the parent company.

### **Significant Risks and Uncertainties**

Significant risks and uncertainties are included in the Annual Report for 2010. Since the annual report was issued, no significant changes have occurred other than as described below.

#### Financial Risks

The completed rights issue offering during the period has decreased Orexo's financial risk.

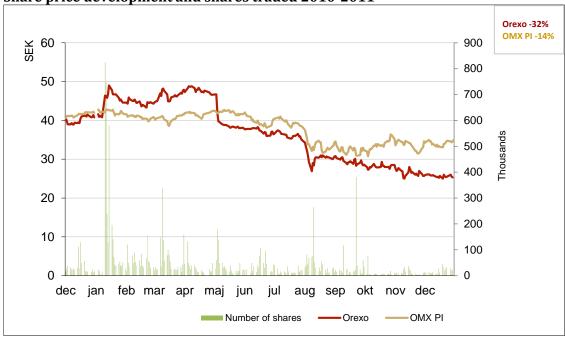
#### Dividend

The Board does not intend to propose a dividend for the financial year 2011.

#### **Share and Market Value**

Orexo's shares were listed on December 31, 2011 to SEK 27.7. The company's market value based on the number of outstanding shares on December 31, 2011 amounted to MSEK 827.





## **Analysts monitoring Orexo**

ABG Sundal Collier Erik Hultgård
Carnegie Camilla Oxhamre

Nordea Olle Sjölin
Pharmium Securities Frédéric Gomez

Redeye Klas Palin and Peter Östling

Rodman & Renshaw Michael Higgins SEB Enskilda Lars Hevreng

**Future reporting dates** 

Annual General Meeting 2012	April 11, 2012, 16.00
Interim report, January-March 2012	April 27, 2012
Interim report, January-June 2012	July 12, 2012
Interim report, January-September 2012	October 25, 2012
Year-end report for 2012	January 31, 2013

Interim reports will be covered in a conference call on the date of publication. Details on the calls will be given in each report.

### **Annual General Meeting 2012**

Orexo AB's Annual General Meeting will be held on Wednesday, April 11, 2012 at 16:00 at Orexo AB, Virdings allé 32A in Uppsala. Notice will be published no later than March 8, 2012.

#### **Annual Report 2011**

Orexo AB's Annual Report will be presented on the company's website by March 21, 2012 and sent to shareholders upon request.

Uppsala January 31, 2012 Orexo AB (publ)

Anders Lundström
President and Chief Executive Officer

For further information, please contact:

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#### **About Orexo**

Orexo has four launched products, several development collaborations with partners, and three proprietary development projects. Orexo's launched drugs are Abstral ® for breakthrough cancer pain, which is sold by Kyowa Hakko Kirin/ProStrakan Group plc in Europe and the U.S., the sleeping pill Edluar ™, sold by Meda in the U.S., and two products, Diabact® UBT / Heliprobe ® System, for diagnosis of Helicobacter pylori, which are marketed through the subsidiary Kibion AB.

### Goals, mission and strategy

Orexo's goal is to build a portfolio of proprietary products, which will be marketed and sold by a proprietary organization in Europe or the U.S. Orexo will become a fully integrated, profitable specialty pharmaceutical company.

In their proprietary development projects, all in clinical stage, Orexo is focusing on pain relief and opioid dependence. The company combines well-known substances with innovative drug delivery technologies to create new, patented drugs that provide improved or new treatments. The development of these drugs is often conducted with less risk and in less time compared with projects using than new drug molecules. Orexo has development collaborations in this area as well.

Existing partnerships are important strategic assets, both financially and in terms of expertise. These aim to develop new drugs to treat diseases such as inflammatory pain and gastro esophageal reflux disease (GERD).

## Orexo product and project portfolio

Product/Project	Indication
Abstral	Breakthrough cancer pain
Edluar™	Insomnia
Diabact® UBT	Breath Test, Helicobacter pylori
Heliprobe® System	Test, Helicobacter pylori
OX17	GERD (gastro esophageal reflux disease)
OX27	Breakthrough cancer pain
OX51	Acute intensive pain episodes
OX219	Opioid dependence
OX-NLA	Rhinitis
OX-MPI	Inflammatory pain

## Auditor's report

We have reviewed this report for Orexo AB (publ) for the period January 1 to December 31, 2011. It is the board and the CEO who are responsible for the preparation and presentation of this interim financial information in accordance with IAS 34 and the Annual Accounts Act. Our responsibility is to express a conclusion on this interim financial information based on our review.

We have conducted our review in accordance with International Standard on Review Engagements 2410: Review of Interim Financial Information 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 procedures and completing other review procedures. A review has a different focus and is substantially smaller in scope than an audit conducted in accordance with Standards on Auditing in Sweden RS and auditing practices. The procedures performed in a review do not enable us to obtain an assurance that we are aware of all significant matters that might be identified in an audit. The conclusion based on a review does not give the same assurance as a conclusion based on an audit.

Based on our review, nothing has come to our attention that causes us to believe that the accompanying interim report has not been complied for the Group in accordance with the Annual Accounts Act and IAS 34 and for the Parent Company in accordance with the Annual Accounts Act.

Uppsala, January 31, 2012

PricewaterhouseCoopers AB

Leonard Daun
Authorized Public Accountant

## Consolidated statement of operations

KSEK	Notes	3 months 2011 Oct-Dec	3 months 2010 Oct-Dec	12 months 2011 Jan-Dec	12 months 2010 Jan-Dec
Net revenues		56 726	109 137	199 614	210 499
Cost of goods sold	2	-10 187	-7 463	-28 997	-26 321
Gross profit		46 539	101 674	170 617	184 178
Selling expenses	2	-15 812	-12 399	-50 106	-35 223
Administrative expenses	2	-12 192	-10 152	-49 561	-46 819
Research & development costs	2	-56 878	-51 682	-194 411	-161 120
Other operating income		3 075	1 301	8 681	7 746
Other operating expenses	2	-234 707	-26 000	-276 723	-30 535
Operating profit		-269 975	2 742	-391 503	-81 773
Financial income		1 645	1 192	4 400	1 456
Financial expense		-3 101	-1 803	-12 317	-8 942
Financial items – net		-1 456	-611	-7 917	-7 486
Pre-tax profit		-271 431	2 131	-399 420	-89 259
Income tax		444	-1	7 411	13
Net Profit for the period		-270 987	2 130	-392 009	-89 246
Profit for the period attributable to Parent Company shareholders Minority interests		-270 987	2 130	-392 009	-89 246
Profit per share, attributable to Parent Company shareholders		-	-	-	-
during the period					
Profit per share, before dilution		-9.07	0,09	-14.43	-3,81
Profit per share, after dilution		-9.07	0,08	-14.43	-3,81

## Consolidated statement of comprehensive income

KSEK	3 months 2011 Oct-Dec	3 months 2010 Oct-Dec	12 months 2011 Jan-Dec	12 months 2010 Jan-Dec
Profit for the period	-270 987	2 130	-392 009	-89 246
Other comprehensive income				
Exchange-rate differences Other comprehensive income for the	-637	-552	-671	-3 524
period, net after tax	-637	-552	-671	-3 524
Total comprehensive income for the period	-271 624	1 578	-392 680	-92 770
Total comprehensive income attributable to				
Parent Company shareholders	-271 624	1 578	-392 680	-92 770

## CHANGES IN CONSOLIDATED SHAREHOLDERS' EQUITY

Attributable to the Parent Company shareholders 1)

KSEK	Share Capital	Other Capital Contributed	Accumulated loss	Translation differences	Total	Total shareholders' equity
Opening balance at January 1, 2011	9 360	1 094 453	-549 907	-5 245	548 661	548 661
Total comprehensive income	-	-	-89 246	-3 524	-92 770	-92 770
Employee stock options, vested amount	-	2 297	-	-	2 297	2 297
Convertible bonds - equity component	-	10 005	-	-	10 005	10 005
New share issues	1	43	-	-	44	44
Closing balance at December 31, 2010	9 361	1 106 798	-639 153	-8 769	468 237	468 237
Opening balance at January 1, 2011	9 361	1 106 798	-639 153	-8 769	468 237	468 237
Total comprehensive income	-	-	-392 009	-671	-392 680	-392 680
Employee stock options, vested amount	-	4 139	-	-	4 139	4 139
New share issues	2 585	228 820	-	-	231 405	231 405
Closing balance at December 21, 2011	11 946	1 339 757	-1 031 162	-9 440	311 101	311 101

<sup>&</sup>lt;sup>1)</sup> There are no minority interests.

## Consolidated balance sheet

KSEK	Notes	2011 31 Dec	2010 31 Dec
ASSETS			
Fixed assets			
Tangible fixed assets		39 241	41 666
Goodwill	7	33 448	17 679
Acquired R&D		116 610	388 487
Other intangible fixed assets		809	1 251
Total fixed assets		190 108	449 083
Current assets			
Inventories		26 689	7 965
Accounts receivables and other receivables		82 445	119 845
Cash and cash equivalents		246 859	135 798
Total current assets		355 993	236 608
Total assets		546 101	712 691
SHAREHOLDERS' EQUITY & LIABILITIES	3		
Share capital		11 946	9 361
Capital contributions		1 339 757	1 106 798
Accumulated losses		-1 031 162	-639 153
Translation differences		-9 440	-8 769
Total shareholders' equity		311 101	468 237
Long-term liabilities			
Provisions		565	1 112
Long-term liabilities, non-interest-bearing		4 218	-
Long-term liabilities, interest-bearing		110 295	94 421
Deferred tax liability		1 807	8 911
Total long-term liabilities		116 885	104 444
Current liabilities			
Current liabilities, non-interest-bearing		107 477	130 531
Current liabilities, interest-bearing		10 638	9 479
Total liabilities		235 000	244 454
Total shareholders' equity and liabilities		546 101	712 691

## Consolidated cashflow statements

KSEK	Notes				
		2011	2010	2011	2010
		Oct-Dec	Oct-Dec	Jan-Dec	Jan-Dec
Operations Operating income before interest					
expense and interest income		-269 975	2 742	-391 503	-81 773
Interest received		1 645	286	4 400	550
Interest paid		-2 369	-2 912	-9 297	-8 942
Other financial expenses		_	2 015	-138	906
Adjustment for non-cash items	4	2 183	29 935	46 847	39 825
Cash flow from operations before					
changes in working capital		-234 690	32 066	-279 354	-49 434
Changes in working capital					
Accounts receivable		-8 054	-70 213	42 698	-67 453
Other current receivables		1 906	-762	2 737	8 275
Inventories		-8 370	1 612	-18 147	475
Current liabilities		846	7 560	-32 970	65 751
Provisions		-44	615	-547	299
Long-term provisions		2 785	-125	6 185	-880
Cashflow from operations		-46 940	-29 247	-117 228	-42 967
Investing activities					
Acquisition of machinery and equipment		-56	-1 152	-4 736	-3 438
Acquisition of subsidiaries		-	-	-10 298	-
Cashflow after investments		-46 996	-30 399	-132 262	-46 405
Change in financing					
New share issues		6	-	244 814	44
Share issues expense Proceeds from issue of convertible bonds		-	-	-12 798	-
		-	-	-	111 150
Amortization of loans		-	-	-	-16 000
Loans received		-	-	11 743	-
Cashflow after financing		-46 990	-30 399	111 497	48 789
Cashflow for the year					
Cash and cash equivalents, beginning of the year		294 340	165 645	135 798	87 414
Funkanan naka diffananan in asah and					
Exchange rate differences in cash and		401	rra	126	405
cash equivalents Changes in cash and cash equivalents		-491 -46 990	552 -30 399	-436 111 497	-405 48 789
Changes in cash and cash equivalents		-40 330	-30 333	111 47/	40 / 03
Cash and cash equivalents, close of					
period		246 859	135 798	246 859	135 798

## Key figures

	3 months 2011 Oct-Dec	3 months 2010 Oct-Dec	12 months 2011 Jan-Dec	12 months 2010 Jan-Dec
Operating margin, %	-476	3	-196	-39
Profit margin, %	-478	2	-200	-42
Return on total capital, %	-36	1	-53	-12
Return on equity, %	-54	0	-78	-18
Return on capital employed, %	-43	0	-63	-14
Debt/equity ratio, %	39	22	39	22
Equity/assets ratio, %	57	66	57	66
Current ratio, %	301	188	301	188
Acid ratio, %	279	183	279	183
Average number of shares, before dilution	29 860 643	23 403 752	27 167 225	23 402 502
Average number of shares, after dilution	32 369 137	25 943 366	29 706 229	25 500 884
Number of shares, after full dilution	33 817 759	26 609 081	33 817 759	26 609 081
Number of share, before dilution	29 865 495	23 403 752	29 865 495	23 403 752
Number of share, after dilution	32 370 704	25 943 070	32 370 704	25 943 070
Earnings/loss per share, before dilution,				
SEK	-9.07	0,09	-14.43	-3.81
Earnings/loss per share, after dilution, SEK	-9.07	0,08	-14.43	-3.81
Shareholders' equity per share, before				
dilution, SEK	10.42	20.01	10.42	20.01
Shareholders' equity per share, after				
dilution, SEK	9.61	18.05	9.61	18.05
Number of employees at end of period	113	105	113	105
Average number of employees	112	106	107	105
Shareholder's equity, KSEK	311 101	468 237	311 101	468 237
Capital employed, KSEK	611 329	572 137	611 329	572 137

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

## Parent company statement of operations

KSEK	Notes	3 months 2011 Oct-Dec	3 months 2010 Oct-Dec	12 months 2011 Jan-Dec	12 months 2010 Jan-Dec
Net revenues Cost of goods sold Gross profit		54 647 - <b>54 647</b>	51 443 - <b>51 443</b>	140 772 - <b>140 772</b>	112 951 - <b>112 951</b>
Selling expenses Administrative expenses Research & Development costs Other operating income Other operating expenses Operating profit		-6 578 -19 196 -53 745 1 215 -368 -24 025	-5 146 -16 701 -46 344 922 -2 078 -17 904	-22 739 -76 291 -182 478 3 519 -40 185 -177 402	-16 533 -61 605 -145 395 4 136 -2 998 -109 444
Earnings from financial investments					
Financial income Financial expense Other financial expense  Loss after financial items		1 616 -3 417 -255 944 -281 770	282 -3 236 - - -20 858	3 758 -14 181 -255 944 -443 769	506 -9 399 -295 -118 632
Tax  Loss for the period		-281 770	- -20 858	- -443 769	-118 632

## Parent company balance sheet

KSEK		2011	2010
	Notes	31-Dec	31-Dec
ASSETS			
Fixed assets		20.000	44 566
Tangible fixed assets Intangible fixed assets		39 060 72	41 566
Shares in subsidiaries/joint ventures		230 089	218 604 763
Total fixed assets		269 221	646 547
Total fixed assets		203 221	040 347
Current assets			
Inventories		15 555	2 529
Accounts receivable and other receivables		120 838	133 986
Cash and bank balances		227 850	101 400
Total current assets		364 243	237 915
Total assets		633 464	884 462
			001.102
SHAREHOLDERS' EQUITY, PROVITIONS & LIABILITIES	-		
LIABILITIES	5		
Restricted equity		302 697	300 112
Non-restricted equity		29 603	240 414
Total shareholders' equity		332 300	540 526
Long-term liabilities			
Provisions		565	1 135
Borrowings		99 839	94 421
Total long-term liabilities		100 404	95 556
Current liabilities, non-interest-bearing		191 868	238 901
Current liabilities, interest-bearing		8 892	9 479
Total current liabilities		200 760	248 380
Total can circ maximizes		200 700	0 000
Total liabilities		301 164	343 936
Total shough aldows a suite 119 1999			
Total shareholders' equity and liabilities		622.464	004.463
		633 464	884 462
Pledged assets		44 000	44 000
_		<del>-</del>	
Contingent liabilities		-	6 050

## Notes

## 1. Accounting policies

- This interim report was prepared pursuant to IAS 34. Orexo applies IFRS as approved by the EU.
- The accounting principles stated below are identical to those applied in the preparation of the 2010 Annual Report.
- The Parent Company's financial statements were prepared in accordance with RFR 2.2 (Swedish Financial Accounting Standards Council's recommendation) and Chapter 9 of the Swedish Annual Accounts Act.
- The classification of impairment of acquired research and development has changed since previous reports. Impairment charges are now recognized as other costs instead of as previously as research and development costs. Comparative figures have been restated under the new classification. The changes for the group is for the year 2010 MSEK 25.8.

### New and amended accounting policies as of 2011

• No new or revised International Reporting Standards have come into effect that are expected to have any significant impact on the Group.

#### 2. Costs distributed by type of cost

	2011 Oct-Dec	2010 Oct-Dec	2011 Jan-Dec	2010 Jan-Dec
Raw materials and supplies	16 085	9 562	43 116	35 306
Other external costs	44 638	43 177	160 005	114 821
Personnel costs	34 601	28 697	117 605	116 126
Depreciation and impairment	234 451	26 260	279 072	33 764
TOTAL	329 775	107 696	599 798	300 017

Research and development costs encompass costs for personnel, premises, external costs for clinical studies, drug registration, and laboratory services, as well as depreciation of equipment, acquired patents and other intangible assets. All development costs recognized in the balance sheet pertain to assets that have arisen through acquisitions.

## 3. Shareholders' equity

## Shares outstanding

The number of shares outstanding as at December 31, 2011, was 29 865 495, all of which were common shares. All shares carry entitlement to one vote each.

Number of shares outstanding at January 1, 2011	23 403 752
Subscription for shares through the use of stock options	23 555
New share issue	6 438 188
Number of shares outstanding at December 31, 2011	29 865 495

#### **Options**

At December 31, 2011, a total of 2 299 538 options were outstanding that carry rights to new subscription of 2 180 422 shares in Orexo and to be exchanged for 119 116 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 year 2011 distributed by category.

Employee-related options	Opening Jan 1, 2011	Change	Closing Dec 31, 2011
Of which:  Decided and allocated employee stock options	837 148		837 148
Expired	637 146	-227 801	-227 801
Exercised		-42 988	-42 998
Allotted		975 000	975 000
Total			1 541 359
Decided and allotted Boards options	60 920	14 641	75 561
Exercised		-14 555	-14 555
Total			61 006
Decided and allotted warrants	10 000		10 000
Total			10 000
Decided but not allotted employee stock options			
Opening balance, as approved by the 2009 AGM	470 000	-470 000	-
Approved by the extra GM 2011		565 000	565 000
Total			565 000
Warrants held by subsidiaries as cash flow hedging for social security fees	139 873	-17 700	122 173
Total			122 173
Total options outstanding	1 517 941	781 597	2 299 538

During the year 2011, a total of 57 543 employee stock options from Orexo's options program were exercised, of which 28 540 were exercised during the fourth quarter.

#### Allotment

In 2011, Orexo has introduced a performance based, long-term incentive program, which before exercising includes performance that provides subscription rights for a total of 1 540 000 shares in Orexo. The right to acquire new shares through the exercise of performance shares requires each employee to meet certain vesting conditions.

Of the total number of performance shares allotted 50 percent are earned based on time and internal business objectives ("time-based performance shares") and 50 per cent based on share price development and the relative share performance ("share price-based performance shares"). Of these performance shares 500,000 have been allotted free of charge to the CEO in March 2011, and 245,000 performance shares have

been allotted free of charge to the rest of the rest of management in April 2011 and 230,000 performance shares have been allotted to executive officers in October 2011. Of these performance shares 487,500 are time-based and 487,500 share price-based. The subscription price for the performance shares allotted in March was set at 44.40 SEK, the subscription price for the performance shares awarded in April was set at 47.80 SEK and the subscription price for the performance shares awarded in October was set at 29 SEK. The final exercise date for the options is December 31, 2021.

For the time-based portion of the shares the market value is calculated using the Black-Scholes method and for the share price-based portion the Monte Carlo method is applied. The market value of the options that were allotted in March is 20.25 SEK for the time-based portion and 13.37 SEK for the share price-based portion. For the options that were allotted in April, the market value is 19.19 SEK for the time-based portion and 12.41 SEK for the share price-based portion, and for the options that were allotted in October the market value is 8.23 SEK for the time-based portion and 6.15 SEK for the share price-based portion.

#### Allotment of Board member options in May, 2011

In May 2011, a total of 14 641 Board members options were allotted that provide entitlement to subscribe for a total of 14 641 shares in Orexo. These Board member options have been allotted free of charge to the Board members elected at the 2011 AGM. Vesting of Board member options takes the form of 25 percent after the date of publication of Orexo's interim report for the first quarter and 25 percent after the publication of the interim reports for quarter's two to four during the mandate period for the 2011 financial year. The final exercise date for Board member options is December 31, 2018 and the strike price is 0.40 SEK per share. The market value, calculated using Black & Scholes method, was 43.70 SEK on the allotment date.

# 4. Cashflow Adjustment for non-cash items

KSEK	2011 Oct-Dec	2010 Oct-Dec	2011 Jan-Dec	2010 Jan-Dec
Depreciation and impairment	234 451	26 260	279 072	33 764
Estimated costs for employee stock options				
program	918	765	3 111	3 309
Financial expenses, convertible bond	-732	2 910	-2 882	2 752
Customer losses	53	-	53	-
Total	234 690	29 935	279 354	39 825

### 5. Shareholders' equity

# Change in the Parent Company's shareholders' equity

KSEK	2011 Oct-Dec	2010 Oct-Dec	2011 Jan-Dec	2010 Jan-Dec
Opening shareholders' equity, balance sheet	613 050	560 990	540 526	647 140
Net loss for the period Subscription for shares through the	-281 770	-20 858	-443 769	-118 632
exercise of warrants Employee stock options, vested value for	5	-	162	44
employees Convertible bond –	1 015	394	4 139	1 969
Equity share New share issue	-	-	- 231 242	10 005
Closing amount	332 300	540 526	332 300	540 526

## 6. Pledged assets and contingent liabilities

In 2010 the Inflazyme project was closed and the supplemental payment was entirely reclassified as a contingent liability of MSEK 45.5.

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.

Orexo acquired the British 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 payments for certain milestones that are not recognized as a liability.

Orexo has an overdraft facility of MSEK 35 secured from Nordea, which resulted in chattel mortgages of MSEK 44 and pledging of all shares in the subsidiary Kibion AB.

### 7. Acquisition of Wagner Analysen Technik GmbH

On August 1, Orexo AB reached controlling interest, and therefore control of the acquired German company Wagner Analysen Technik GmbH (WAT). The company was acquired by Orexo AB's subsidiary Kibion AB and was consolidated into Orexo group from the same day. The acquisition of WAT provides increased opportunities for Kibion to increase sales of existing products, and provides a broader platform for the development and commercialization of new breath testing.

The acquired company contributed net sales of MSEK 4.3 and a net profit of MSEK -0.2 for the period August 1-December 31, 2011. If the acquisition had occurred on January 1 2011, the consolidated net sales would have been MSEK 2.6 higher and net incomes for the period MSEK -3.5 less.

The acquisition was financed through bank loans.

The acquisition also includes additional contingent payments based on sales revenue.

A liability corresponding to the calculated fall out has been reserved in Kibion. There is however a ceiling on how much the additional purchase price can be.

The cost of acquisition is MSEK 14.3.

Acquired net assets and goodwill (MSEK):

Purchase price	10.0
Additional contingent payments	4.3
Total purchase price	14.3
Real value for acquired net assets	-1.7
Goodwill	16.0

#### Assets and liabilities included (MSEK):

	Real value	Acquired book
		value
Tangible assets	0.1	0.1
Inventories	0.6	0.6
Current receivables	7.2	7.2
Cash and cash equivalents	0.2	0.2
Current liabilities	-9.8	-9.8
Acquired net assets	-1.7	-1.7

## **Glossary**

#### Arachidonic acid

A natural substance, which, through transformation to prostaglandins, leukotrienes and eoxins, regulates a number of inflammatory processes in the body.

#### Breakthrough pain

A short, intensive period of pain that occurs in addition to chronic levels of long-term pain even though these are treated by regular painkillers.

#### Clinical studies/Clinical trials

Studies of the safety and efficacy of a drug in human beings.

#### COPD

Chronic Obstructive Pulmonary Disease, also known as "smoker's disease".

#### **Drug delivery**

The process through which a pharmaceutical may be introduced to the patient that enables the active compound to function as intended.

#### Fentanyl

An opioid with similar effect on human patients to morphine. Used mainly within anesthesia and analgesia.

#### Helicobacter pylori

A bacterium that can infect the mucous membrane lining of the stomach.

### Opioid analgesic

Pain relieving compound derived from synthetic or natural opium or morphine.

### Phase I studies

Studies mainly of the safety of a drug. Performed on healthy human volunteers.

#### **Phase II studies**

Studies of the safety and efficacy of a drug and appropriate doses. Performed on a limited number of patients.

#### **Phase III studies**

Studies of the safety and efficacy of a drug in a clinical situation. Performed on a large number of patients.

#### Preclinical development/Preclinical studies

Studies of the safety and efficacy of a drug prior to evaluation in humans. Can be performed on animals or in various cell systems.

#### Sublingual

Under the tongue.

#### Transmucosal

Administration of a drug through the mucosa.

## **Definition of key figures**

Key figures and certain other operational information and information per share have been defined as follows:

Number of shares after full dilution

Total number of shares plus the maximum number of shares that can be subscribed

through options outstanding.

Number of shares after dilution Calculation of dilution from options issued by the company until 2005 has been

made in accordance with IAS 33.

Return on total capital Operating profit/loss plus financial revenues as a percentage of average total

assets.

Return on shareholders' equity Profit/loss for the period as a percentage of average shareholders' equity.

Return on employed capital Operating profit/loss plus financial revenues as a percentage of average total

capital employed.

Current ration Current assets as a percentage of current liabilities.

Gross margin Gross profit divided by net revenues.

Shareholders' equity per share,

before dilution

Shareholders' equity divided by total number of shares before dilution at end of the

period.

Shareholders' equity per share,

after dilution

Shareholders' equity divided by total number of shares 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 interest-bearing liabilities Current and long-term interest-bearing liabilities, including pension liabilities,

minus cash and cash equivalents.

Operating capital Total assets, less interest-free liabilities and provisions less cash and cash

equivalents.

Earnings per share, before dilution

Profit/loss for the period divided by the average number of outstanding shares

before dilution.

Earnings per share, after dilution Profit/loss for the period divided by the average number of outstanding shares

after dilution.

Return on equity Profit/loss for the year divided by average shareholders' equity.

Interest coverage ratio Profit/loss after financial items plus interest expenses and similar items, divided by

interest expenses and similar items.

Working capital, net Interest-free current assets minus interest-free current liabilities.

Working capital, net/net revenue Average working capital, net, divided by net revenues.

Operating margin Operating profit/loss 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 Profit after financial items expressed as a percentage of net revenue.

#### 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, 2012, at 8:30 a.m. CET. This report has been prepared in both Swedish and English. In the event of any discrepancy in the content between the two versions, the Swedish version shall take precedence.