

# Orexo AB (publ.)

## – Interim report, January-September 2010

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Corp. Reg. No. 556500-0600

Uppsala, November 10, 2010

## Orexo AB (publ) – Interim report, January -September 2010

### **Abstral™ for treatment of breakthrough cancer pain continued to grow strongly**

#### **Key events during the period**

- Net revenues amounted to MSEK 101.4 (208.2).<sup>1)</sup>
- Cash flow from operating activities as a negative MSEK 13.7 (neg:117.7)
- Royalties from Abstral™, Orexo's leading sublingual fentanyl treatment for breakthrough cancer pain, increased to MSEK 30.3 (6.3)
- The loss after tax was MSEK 91.4 (loss: 40.1).
- The loss per share was SEK 3.90 (loss: 1.78).
- Cash and cash equivalents at the end of the period totaled MSEK 165.6 compared with MSEK 87.4 at the beginning of the period.
- A convertible loan in the amount of SEK 111,150,000 from Novo A/S was implemented.
- In June, Orexo entered into an alliance and license agreement regarding new pharmaceuticals for the treatment of respiratory diseases with Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica NV (collectively "OMJ"). The agreement provides Orexo with up to MUSD 21.5 (MSEK 167) in research financing for the first three years, including an upfront payment of MUSD 10 (MSEK 77.8) intended to cover all future development costs for Orexo. In addition, Orexo is to be entitled to full milestone payments of up to MUSD 564 (MSEK 4,390), plus further sales milestones and royalties for each program.
- Orexo signed a license and distribution agreement encompassing the approval, marketing and sales of Abstral™ in the Middle East and Africa with NewBridge Pharmaceuticals. The terms and conditions of the agreement cover an upfront payment and remuneration on achieving regulatory milestones and sales targets, as well as profit sharing.

#### **Third quarter**

- Net revenues amounted to MSEK 35.9 (63.7).<sup>1)</sup>
- Cash flow from operating activities was a negative MSEK 25.0 (neg: 43.2)
- The loss after tax was MSEK 28.5 (loss: 9.5).
- The loss per share was SEK 1.22 (loss: 0.41).

<sup>1)</sup> References made in this interim report are to the Group unless otherwise stated. Figures in parentheses relate to the year-earlier period.

## **KEY EVENTS DURING THE THIRD QUARTER OF 2010**

- In September, Orexo signed a license and distribution agreement encompassing the approval, marketing and sales of Abstral™ in the Middle East and Africa with NewBridge Pharmaceuticals. The terms and conditions of the agreement cover an upfront payment and remuneration on achieving regulatory milestones and sales targets, as well as profit sharing.
- The US Food and Drug Administration, FDA informed Orexo's partner ProStrakan Group plc (LSE:PSK) that the administration will not maintain its previously communicated decision deadline, or PDUFA date, for Abstral™ in early September. The FDA review is now in the final stage, and a decision is expected shortly.
- Orexo started work on its collaboration to find new pharmaceuticals for the treatment of respiratory diseases with Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica NV ("OMJ"). This work is eligible for up to MUSD 21.5 (MSEK 167) in research financing over the first three years.
- Following consultations with the Pharmaceuticals and Medical Devices Agency of Japan, Orexo's partner, Kyowa Hakko Kirin Co, Ltd decided to withdraw an application for the approval of KW-2246 (Orexo's sublingual fentanyl product Abstral®) in order to conduct further clinical trials.
- Orexo announced that its second-largest owner, Novo A/S, increased its shareholding in Orexo by acquiring 1,397,142 shares. Following the acquisition, Novo A/S's holding totals 3,893,184 shares, or about 16.7 percent of the total number of shares in the company. In addition, Novo A/S also holds a convertible loan in Orexo, which, if the loan were to be converted into shares, would correspond to a further 2,340,000 shares, or 9.1 percent of all shares. Accordingly, in the event of a full conversion, Novo A/S', shareholding in Orexo would be 24.2 percent.
- On August 20, Orexo launched the next step in its strategy to focus on deploying Orexo's well-established and proven reformulation technologies to develop new proprietary products targeted at the Specialty Pharmaceutical market. As part of this strategy, Orexo has initiated three new development programs aimed at marketing these products through an Orexo-owned marketing and sales organization, starting in one of the major markets, the EU or the USA.  
To optimize execution of this strategy, the company is seeking a Chief Executive Officer who has a broad international commercial experience. The search for a new Chief Executive Officer is in its late stage.
- In August, Orexo reported that it had appointed Robin Wright as its new EVP Head of Finance and Strategy.

## **KEY EVENTS AFTER THE PERIOD**

### **New President appointed for Kibion**

Petter Bäckgren was appointed the new President of the diagnostics subsidiary Kibion. Petter has solid sales, marketing and corporate management experience from the pharmaceuticals and diagnostics sector, both in the Nordic region and internationally.

## Operations

“During the third quarter, Abstral™ sales were 480% higher than in the same period last year. Sales of Edluar™, Orexo’s sublingual zolpidem treatment for insomnia, continue to grow more strongly from a low base, with new stock being ordered for the first time since launch and generating royalty income for Orexo.

The decision of the US Food & Drug Administration (“FDA”) was delayed beyond the expected Prescription Drug User Fee Act (“PDUFA”) date in early September. The FDA review is currently in the final stage, and a decision is expected shortly.

During the period, Orexo signed a new license and distribution agreement for Abstral™ in most of the Middle East and African countries. Terms were not disclosed. The agreement with NewBridge enables Abstral™ to be sold in even more geographic markets and marks another step in the company’s efforts to develop a global product. Our alliance with NewBridge will make Abstral™ available to thousands of additional physicians and assist them in the treatment of cancer patients suffering from severe pain.

In August, Orexo launched the next step in its strategy to focus its business model on deploying its well-established and proven reformulation technologies to develop new proprietary products targeted at the Specialty Pharmaceutical market. As part of this strategy, Orexo has initiated the first three proprietary development programs. The company intends to commercialize these products through an Orexo-owned marketing and sales organization, starting in one of the major markets EU or USA.

A Phase I clinical study with OX219, directed towards treatment of opioid addiction, was initiated. OX219 is an improved version of the program originally acquired with the PharmaKodex transaction now using Orexo proprietary technologies. This product will compete in the opioid addiction market, which is today worth an estimated USD 1.4 billion globally, and is currently dominated by Suboxone®. Results from the initial study will be communicated during the fourth quarter.

The clinical trials for the next two proprietary programs, OX51 and OX27 will be performed by Q1, 2011.

Meda AB has informed Orexo that it will further develop the nasal cetirizine NLA product to complement Meda’s allergy product portfolio. The next stage of development of NLA is a clinical phase III program, for which the full cost will be carried by Meda AB.

As previously announced, the total cost base for 2010 is estimated at MSEK 200-220, excluding the new work on the OX-CLI and OX-ESI programs within the framework of the agreement with Ortho McNeil Janssen and Janssen Pharmaceutica for which research funding is received from the partner”, says Torbjörn Bjerke, President and CEO.

## The period in figures

### Condensed consolidated statement of operations

	<b>3 months</b>	<b>3 months</b>	<b>9 months</b>	<b>9 months</b>	<b>12 months</b>
	<b>2010</b>	<b>2009</b>	<b>2010</b>	<b>2009</b>	<b>2009</b>
	<b>July-Sept</b>	<b>July-Sept</b>	<b>Jan-Sept</b>	<b>Jan-Sept</b>	<b>Jan-Dec</b>
<b>MSEK</b>					
<b>Net revenues</b>	<b>35.9</b>	<b>63.7</b>	<b>101.4</b>	<b>208.2</b>	<b>236.1</b>
Cost of goods sold	-5.6	-5.2	-18.9	-17.3	-23.6
<b>Gross profit</b>	<b>30.3</b>	<b>58.5</b>	<b>82.5</b>	<b>190.9</b>	<b>212.5</b>
Selling expenses	-6.6	-6.5	-22.8	-25.3	-39.3
Administrative expenses	-17.4	-10.1	-36.7	-32.3	-46.3
Research and development costs	-33.0	-47.3	-111.1	-172.3	-224.2
Other operating income and expenses	0.9	-0.4	3.6	-2.1	-1.8
<b>Operating loss*</b>	<b>-25.8</b>	<b>-5.8</b>	<b>-84.5</b>	<b>-41.1</b>	<b>-99.1</b>
Net financial items	-2.7	-2.4	-6.9	2.2	2.1
<b>Loss after financial items</b>	<b>-28.5</b>	<b>-8.2</b>	<b>-91.4</b>	<b>-38.9</b>	<b>-96.9</b>
Tax	0.0	-1.4	0.0	-1.1	-1.1
<b>Net loss for the period</b>	<b>-28.5</b>	<b>-9.5</b>	<b>-91.4</b>	<b>-40.1</b>	<b>-98.1</b>

\* Includes the costs of employee stock options in the amount of MSEK 2.5 for the period January-September 2010 (MSEK 5.5 January-September 2009).

### Revenues

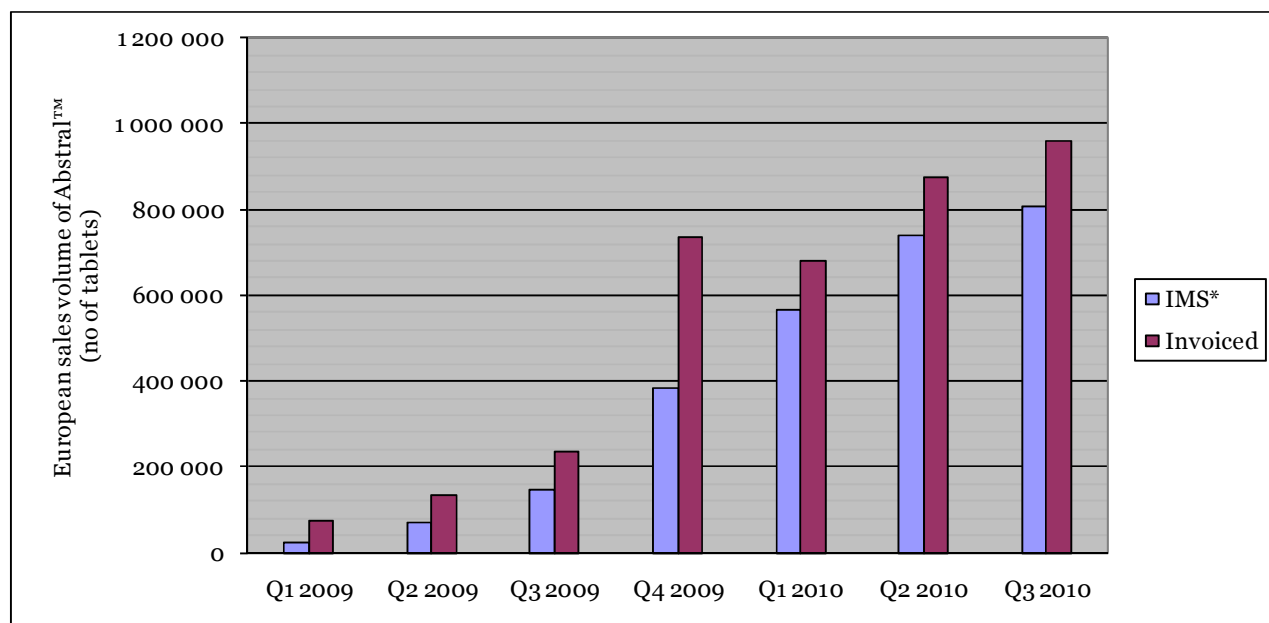
#### Net revenues

Consolidated net revenues for the period January-September 2010 amounted to MSEK 101.4 (208.2). Higher revenues in the year-earlier period derived primarily from the partnership with Meda and non-recurring compensation for the approval of Edluar™ in the USA in the first quarter of 2009.

For the period July-September 2010, consolidated net revenues totaled MSEK 35.9 (63.7). This difference was mainly due to the higher level of license deal milestone revenue including country launches and US filing of Abstral™ in the same period for 2009, but royalty revenue continued to increase.

During the second quarter, Orexo entered into an alliance and license agreement with Ortho-McNeil-Janssen Pharmaceuticals Inc. which will initially extend over a three-year period. The non-recurring upfront of MUSD 10 (MSEK 77.8) received on signing of the agreement will be distributed on a straight line basis over the three-year period. In addition, Orexo will receive and recognize funding for the research alliance on a continuous basis over the agreement period.

**Royalty revenues from marketed products, excluding license revenues, increased by more than 400 per cent compared with the same period of 2009**



*IMS refers to IMS audited sales data, which are statistical estimates of actual in-market sales of the product to pharmacies and hospitals. Invoiced refers to sales invoiced by ProStrakan Group plc to wholesalers.*

Royalty revenues from Abstral™ during the January-September period amounted to MSEK 30.3, compared with MSEK 6.3 in the year-earlier period. Royalty revenues for the period July-September 2010 totaled MSEK 10.8 (3.3), an increase of 227%.

Kibion AB's sales amounted to MSEK 27.7 (30.4), with the difference due to the significant weakening of the Euro in 2010 compared with the same period in 2009.

ProStrakan AB's sales rose to MSEK 17.2 (16.2), of which 50 percent was recognized in Orexo's sales. Abstral's sales through ProStrakan AB grew to MSEK 2.7 (1.3).

License revenues amounted to MSEK 16.2 (119.3) and pertained to the approval of Abstral™ in Italy and Moldova, an upfront payment concerning the signing of an agreement with NewBridge Pharmaceuticals and the portion of the nonrecurring compensation received by Ortho-McNeil-Janssen Pharmaceuticals Inc. that was recognized as revenue. License revenues from the year-earlier period primarily pertained to out-licensing of the insomnia drug Edluar™ to Meda and compensation for the approval of Edluar™ in the USA.

Royalty revenues from Edluar™ resumed in the period, once the initial launch stock was exhausted by orders from pharmacies and wholesalers. Edluar™ royalties for the period were MSEK 0.4, compared with nil last quarter, and sales of Edluar™ were again up more than 45% on the previous quarter at just under MUS\$ 1.5.

In September Edict Pharmaceuticals filed a "Paragraph IV-Certification" in the US claiming that their sublingual dosage form containing zolpidem can be marketed without infringing Orexo's patent protecting Edluar™. Orexo has filed a lawsuit claiming patent infringement and intends to defend the IP-protection for Edluar™.

**Net sales were distributed as follows:**

<i>MSEK</i>	July-Sept 2010	July-Sept 2009	Jan-Sept 2010	Jan-Sept 2009	Jan-Dec 2009
Abstral™ - royalty	10.8	3.3	30.3	6.3	16.2
Edluar™ - royalty	0.4	2.2	0.4	2.2	2.3
ProStrakan AB J/V 50%	2.7	2.6	8.6	8.1	10.8
Kibion AB	8.0	8.9	27.7	30.4	40.7
<b>Total revenue from launched products</b>	<b>21.9</b>	<b>17.0</b>	<b>67.0</b>	<b>47.0</b>	<b>70.0</b>
Partner funded R&D costs	6.0	16.6	17.9	41.8	46.4
License revenues	7.8	30.1	16.2	119.3	119.5
Other	0.0	0.0	0.1	0.0	0.2
<b>Total</b>	<b>35.9</b>	<b>63.7</b>	<b>101.4</b>	<b>208.2</b>	<b>236.1</b>

**Expenses and earnings***Selling expenses*

Selling expenses for the period January-September 2010 amounted to MSEK 22.8 (25.3) and for the period July-September 2010 to MSEK 6.6 (6.5).

Selling expenses included business development expenses relating to the out-licensing of Orexo's projects, phase IV studies, and operations in Kibion AB and the joint venture company ProStrakan AB.

*Administrative expenses*

Administrative expenses for the period January-June 2010 amounted to MSEK 36.7 (32.3). Higher expenses were related to the provision of costs related to severance pay for the CEO and CFO. For the July-September 2010 period, administrative expenses amounted to MSEK 17.4 (10.1).

*Research and development costs*

Research and development costs for the period January-September 2010 amounted to MSEK 111.1 (172.3). MSEK 17.9 (41.8) of these costs was funded by partners during the period. Research and development costs for the period July-September 2010 amounted to MSEK 33.0 (47.3).

The lower costs were primarily related to the development of our product portfolio, which thus required less external research activities, but also to the cost cuts that were implemented in 2009 and that achieved full effect as of January 1, 2010.

*Expenses for the company's employee stock options program*

The company's expenses for the employee stock options program for the period January-September 2010 totaled MSEK 2.5, compared with MSEK 5.5 for the year-earlier period.

*Other revenues and expenses*

For the period January-September 2010, other revenues and expenses, primarily consisting of exchange-rate gains/losses, amounted to revenue of MSEK 3.6 (loss: 2.1) and for the period July-September 2010 to revenue of MSEK 0.9 (loss: 0.4).

*Depreciation/amortization*

Depreciation/amortization for the period January-September 2010 amounted to MSEK 5.9 (6.6) and for the period July-September 2010 to MSEK 1.9 (1.9).

### *Net financial items*

Net financial items for the period January-September 2010 totaled an expense of MSEK 6.9 (income: 2.2). Net financial items included interest expenses of MSEK 5.8 related to the convertible loan, and unrealized exchange-rate and other credit expenses. Net financial items for the year-earlier period included income of MSEK 3.9 that was attributable to second installment payment received in conjunction with the acquisition of PharmaKodex entailing that this be categorized as an embedded derivative, resulting in a positive earnings effect from a declining stock market price.

### *Earnings*

The operating loss for the period January-September 2010 was MSEK 84.5 (loss: 41.1). The loss after net financial items was MSEK 91.4 (loss: 38.9) and the loss after tax was MSEK 91.4 (loss: 40.1).

For the period July-September 2010, the operating loss totaled MSEK 25.8 (loss: 5.8). The loss after net financial items amounted to MSEK 28.5 (loss: 8.2) and the loss after tax to MSEK 28.5 (loss: 9.5).

### **Financial position**

At September 30, 2010, cash and cash equivalents amounted to MSEK 165.6 (107.1), while the corresponding figure at June 30, 2010 was MSEK 190.9.

The convertible bond issue, which took place on April 7, has been recognized in the form of a liability share and an equity share, based on the fair value of the liability share. The division into these two components was based on market interest rates of 10.5 percent. Related transaction expenses were allocated proportionally to both of these components in relation to how the issue proceeds were distributed. The convertible bond has a conversion rate of SEK 47.50, entailing a premium of about 25 percent compared with the closing price on March 12, 2010 of SEK 37.90, and is connected to an option that entitles Orexo AB to convert the loan when the share price exceeds the conversion price by 50 percent during a certain period. The convertible bond bears an annual rate of interest of 8 percent. If the loan is not converted to shares, it shall be repaid no later than March 31, 2015.

Cash flow from operating activities for the period January-September 2010 was a negative MSEK 13.7 (neg: 117.7). Cash flow after financing was MSEK 79.7 (neg: 79.4).

Cash flow from operating activities for the period July-September 2010 was a negative MSEK 25.0 (neg: 43.2). Cash flow after financing was a negative MSEK 24.6 (neg: 28.7).

At September 30, 2010, shareholders' equity totaled MSEK 466.2 (601.4). The equity/assets ratio was 66 percent (88).

Current financing is sufficient to pursue all projects described below through clinical phase I, and also to advance at least one of these projects to the approval stage without the need for further milestone payments from out-licensed research and development projects. Consequently, the Board believes that the company's current financial position is sufficient for continued operations.

### **Investments**

Gross investments in tangible fixed assets during the period January-September 2010 amounted to MSEK 2.3 (1.7) and for the period July-September 2010 to MSEK 0.2 (0.6).



## **Product portfolio**

### *Three new development programs*

A clinical phase I study for OX219 has commenced. An additional two new development programs, OX51 and OX27, which focus on various pain indications, have been initiated and clinical studies will begin in Q4 2010 and Q1 2011, respectively. Further information is presented in a separate press release - visit [www.orexo.com](http://www.orexo.com).

## **Parent Company**

Most of the Group's business is carried out in the Parent Company, Orexo AB. Net revenues for the period January-September 2010 totaled MSEK 61.5 (159.2), with the loss after financial items amounting to MSEK 97.8 (loss: 25.1). Investments amounted to MSEK 2.3 (1.7). Cash and cash equivalents in the Parent Company at September 30, 2010 totaled MSEK 130.5 (13.5), with current investments amounting to MSEK 0.0 (0.0).

## **Significant risks and uncertainties**

Significant risks and uncertainties are detailed in the 2009 Annual Report. Since the Annual Report was published, significant changes occurred as described below.

### *Financial risks*

As a result of the implementation of the issue of convertibles, which generated proceeds of MSEK 111 before expenses, and revenues in conjunction with the out-licensing of the OX-CLI and OX-ESI projects to Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica NV (collectively "OMJ"), Orexo's financial risks have decreased significantly.

## **Share and market value**

Orexo's share traded at SEK 42.20 at September 30, 2010. The company's market capitalization, based on the number of shares outstanding on September 30, 2010, amounted to MSEK 987.6.

## **Future reporting dates**

Year-end report for 2010 _____	February 16, 2011
Annual General Meeting 2011 _____	April 7, 2011
Interim report, January-March 2011 _____	May 4, 2011
Interim report, January-June 2011 _____	August 10, 2011
Interim report, January-September 2011 _____	November 9, 2011

Uppsala, November 10, 2010

Orexo AB (publ)

Torbjörn Bjerke  
President and CEO

*For further information, please contact:*

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Robin Wright, EVP Head of Finance, Phone: +44 7720 30 00 25, e-mail: [robin.wright@orexo.com](mailto:robin.wright@orexo.com)

**Analysts monitoring Orexo**

ABG Sundal Collier	Erik Hultgård
Carnegie	Camilla Oxhamre
Handelsbanken Markets	<i>New analyst being appointed</i>
Nordea	Patrik Ling
Pharmium Securities	Frédéric Gomez
Redeye	Klas Palin and Björn Fahlén
Rodman & Renshaw	Michael Higgins
SEB Enskilda	Gustaf Vahlne

## **Review report**

We have reviewed the appended report for the period January 1 to September 30, 2010 for Orexo AB (publ). The Board of Directors is responsible for the preparation and fair presentation of this interim report in accordance with the Annual Accounts Act and IAS 34. Our responsibility is to express an opinion on this interim report based on our review.

We conducted our review in accordance with the Standard on Review Engagements SÖG 2410, Review of Interim Financial Information Performed by the Independent Auditor of the Entity, as issued by FAR. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review has a different direction and is substantially more restricted in scope than an audit conducted in accordance with Standards on Auditing in Sweden RS and other generally accepted auditing practices. The procedures performed in a review do not enable us to obtain a level of assurance that would make us aware of all significant matters that might be identified in an audit. Therefore, the conclusion expressed based on a review does not give the same level of assurance as a conclusion expressed based on an audit.

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

Uppsala, November 10, 2010  
PricewaterhouseCoopers AB

Leonard Daun  
Authorized Public Accountant

**CONSOLIDATED STATEMENT  
OF OPERATIONS**

	Notes	3 months 2010 Jul-Sept	3 months 2009 Jul-Sept	9 months 2010 Jan-Sept	9 months 2009 Jan-Sept	12 months 2009 Jan-Dec
Net revenues		35,854	63,676	101,362	208,247	236,104
Cost of goods sold	2	-5,577	-5,149	-18,858	-17,351	-23,650
<b>Gross profit</b>		<b>30,277</b>	<b>58,527</b>	<b>82,504</b>	<b>190,896</b>	<b>212,454</b>
Selling expenses	2	-6,607	-6,458	-22,824	-25,277	-39,261
Administrative expenses	2	-17,394	-10,131	-36,667	-32,261	-46,308
Research and development costs	2	-32,919	-47,310	-111,089	-172,303	-224,216
Other operating income		2,521	1,456	6,445	6,501	8,239
Other operating expenses	2	-1,688	-1,893	-2,884	-8,681	-9,991
<b>Operating loss</b>		<b>-25,810</b>	<b>-5,809</b>	<b>-84,515</b>	<b>-41,125</b>	<b>-99,083</b>
Financial income		200	195	264	4,823	4,868
Financial expense		-2,902	-2,564	-7,139	-2,606	-2,726
<b>Financial items – net</b>		<b>-2,702</b>	<b>-2,369</b>	<b>-6,875</b>	<b>2,217</b>	<b>2,142</b>
<b>Pre-tax loss</b>		<b>-28,512</b>	<b>-8,178</b>	<b>-91,390</b>	<b>-38,908</b>	<b>-96,941</b>
Income tax		9	-1,358	14	-1,143	-1,138
<b>Net loss for the period</b>		<b>-28,503</b>	<b>-9,536</b>	<b>-91,376</b>	<b>-40,051</b>	<b>-98,079</b>
<b>Loss for the period attributable to:</b>						
Parent Company shareholders		-28,503	-9,536	-91,376	-40,051	-98,079
Minority interests		-	-	-	-	-
<b>Loss per share attributable to Parent Company shareholders during the period</b>						
<b>(SEK per share):</b>						
Loss per share, before dilution, SEK		-1.22	-0.41	-3.90	-1.78	-4.32
Loss per share, after dilution, SEK		-1.22	-0.41	-3.90	-1.78	-4.32

**CONSOLIDATED STATEMENT OF  
COMPREHENSIVE INCOME**

	3 months 2010 July-Sept	3 months 2009 July-Sept	9 months 2010 Jan-Sept	9 months 2009 Jan-Sept	12 months 2009 Jan-Dec
<b>Loss for the period</b>	<b>-28,503</b>	<b>-9,536</b>	<b>-91,376</b>	<b>-40,051</b>	<b>-98,079</b>
<b>Other comprehensive income</b>					
Hedging of net investments	-	2,111	-	2,329	2,329
Exchange-rate differences	-2,465	-6,949	-2,972	-9,539	-7,574
<b>Other comprehensive income for the period, net after tax</b>	<b>-2,465</b>	<b>-4,838</b>	<b>-2,972</b>	<b>-7,210</b>	<b>-5,245</b>
<b>Total comprehensive income for the period</b>	<b>-30,968</b>	<b>-14,374</b>	<b>-94,348</b>	<b>-47,261</b>	<b>-103,324</b>
<b>Total comprehensive income attributable to:</b>					
Parent Company shareholders	-30,968	-14,374	-94,348	-47,261	-103,324

**CHANGES IN CONSOLIDATED SHAREHOLDERS' EQUITY**

**Attributable to the Parent Company's shareholders <sup>1)</sup>**

	Share capital	Other capital contributed	Accumulated loss	Translation differences	Total	Total shareholders' equity
<b>Opening balance, January 1, 2009</b>	<b>8,647</b>	<b>1,012,964</b>	<b>-451,828</b>	<b>-</b>	<b>569,783</b>	<b>569,783</b>
Total comprehensive income for the period	-	-	-40,051	-7,210	-47,261	-47,261
Employee stock options, vested amount	-	4,394	-	-	4,394	4,394
New share issues	713	73,733	-	-	74,446	74,446
<b>Closing balance, September 30, 2009</b>	<b>9,360</b>	<b>1,091,091</b>	<b>-491,879</b>	<b>-7,210</b>	<b>601,362</b>	<b>601,362</b>
<b>Opening balance, January 1, 2010</b>	<b>9,360</b>	<b>1,094,453</b>	<b>-549,907</b>	<b>-5,245</b>	<b>548,661</b>	<b>548,661</b>
Total comprehensive income for the period	-	-	-91,376	-2,972	-94,348	-94,348
Employee stock options, vested amount	-	1,823	-	-	1,823	1,823
Convertible bond – equity share	-	10,005	-	-	10,005	10,005
New share issues	1	43	-	-	44	44
<b>Closing balance, September 30, 2010</b>	<b>9,361</b>	<b>1,106,324</b>	<b>-641,283</b>	<b>-8,217</b>	<b>466,185</b>	<b>466,185</b>

1) There are no minority interests

## CONSOLIDATED BALANCE SHEET

	Notes	2010 30 Sep	2009 30 Sep	2009 31 Dec
<b>Assets</b>				
<b>Fixed assets</b>				
Tangible fixed assets		42,602	46,219	45,814
Goodwill		17,800	16,030	17,987
Acquired R&D		422,332	424,836	427,030
Other intangible fixed assets		1,420	2,117	1,982
<b>Total fixed assets</b>		<b>484,154</b>	<b>489,202</b>	<b>492,813</b>
<b>Current assets</b>				
Inventories		9,577	9,172	8,440
Accounts receivable and other receivables		40,887	74,231	59,622
Tax receivables		7,983	3,487	1,045
Cash and cash equivalents		165,645	107,061	87,414
<b>Total current assets</b>		<b>224,092</b>	<b>193,951</b>	<b>156,521</b>
<b>Total assets</b>		<b>708,246</b>	<b>683,153</b>	<b>649,334</b>
<b>SHAREHOLDERS' EQUITY &amp; LIABILITIES</b>				
	3			
Share capital		9,361	9,360	9,360
Capital contributions		1,106,324	1,091,091	1,094,453
Accumulated losses		-641,283	-491,879	-549,907
Translation difference		-8,217	, -7,210	-5,245
<b>Total shareholders' equity</b>		<b>466,185</b>	<b>601,362</b>	<b>548,661</b>
<b>Long-term liabilities</b>				
Provisions		10,798	1,337	11,114
Long-term liabilities, interest-bearing		91,510	16,000	12,800
Long-term liabilities, non-interest-bearing		-	9,805	-
Deferred tax liability		9,036	9,449	9,791
<b>Total long-term liabilities</b>		<b>111,344</b>	<b>36,591</b>	<b>33,705</b>
<b>Current liabilities</b>				
Current liabilities, non-interest-bearing*		121,238	45,200	63,768
Current liabilities, interest-bearing		9,479	-	3,200
<b>Total liabilities</b>		<b>242,061</b>	<b>81,791</b>	<b>100,673</b>
<b>Total shareholders' equity and liabilities</b>		<b>708,246</b>	<b>683,153</b>	<b>649,334</b>

\* includes the unrecognized portion of the OX-CLI deal upfront funding of MSEK 69.3

**CONSOLIDATED CASH-  
FLOW STATEMENTS**

	Notes	3 months 2010 July-Sept	3 months 2009 July-Sept	9 months 2010 Jan-Sept	9 months 2009 Jan-Sept	12 months 2009 Jan-Dec
<b>Operations</b>						
Operating loss before interest expense and interest income		-25,810	-5,809	-84,515	-41,125	-99,083
Interest income		200	11	264	714	759
Interest expense		-2,902	-235	-6,030	-277	-397
Tax paid		-	-1,389	-	-1,389	-1,389
Other financial expenses		-	-	-1,109	-	-
Adjustment for non-cash items	4	7,156	3,672	9,890	14,108	20,834
<b>Cash flow from operations before changes in working capital</b>		<b>-21,356</b>	<b>-3,750</b>	<b>-81,500</b>	<b>-27,969</b>	<b>-79,276</b>
<b>Changes in working capital</b>						
Accounts receivable		6,461	-22,813	2,760	-16,966	-2,963
Other current receivables		19,446	-6,209	9,037	3,095	6,143
Inventories		-2,050	-988	-1,137	4,810	5,542
Current liabilities		-25,284	-9,882	58,191	-81,791	-64,487
Provisions		-1,288	655	-316	847	1,114
Long-term provisions		-881	-248	-755	295	-
<b>Cash flow from operations</b>		<b>-24,952</b>	<b>-43,235</b>	<b>-13,720</b>	<b>-117,679</b>	<b>-133,927</b>
<b>Investing activities</b>						
Acquisition of machinery and equipment		-170	-636	-2,286	-1,688	-2,588
Divestment of machinery and equipment		-	-	-	2	2
Acquisition of subsidiaries		-	-	-	24,695	24,695
<b>Cash flow after investments</b>		<b>-25,122</b>	<b>-43,871</b>	<b>-16,006</b>	<b>-94,670</b>	<b>-111,818</b>
<b>Change in financing</b>						
New share issue		44	-800	44	-710	90
Proceeds from issue of convertible bond		-	-	111,150	-	-
Loans raised		-	16,000	-	16,000	16,000
Amortization of loans		-	-	-16,000	-	-
<b>Cash flow from financing activities</b>		<b>-25,078</b>	<b>-28,671</b>	<b>79,188</b>	<b>-79,380</b>	<b>-95,728</b>

	Notes	<b>3 months 2010 July-Sept</b>	<b>3 months 2009 July-Sept</b>	<b>9 months 2010 Jan-Sept</b>	<b>9 months 2009 Jan-Sept</b>	<b>12 months 2009 Jan-Dec</b>
<b>Cash flow for the year</b>						
Cash and cash equivalents, beginning of period		190,853	137,178	87,414	188,220	188,220
Exchange-rate differences in cash and cash equivalents		-130	-1,446	-957	-1,779	-5,078
Changes in cash and cash equivalents		-25,078	-28,671	79,188	-79,380	-95,728
<b>Cash and cash equivalents, close of period</b>		<b>165,645</b>	<b>107,061</b>	<b>165,645</b>	<b>107,061</b>	<b>87,414</b>



## KEY FIGURES

	3 months 2010 July-Sept	3 months 2009 July-Sept	9 months 2010 Jan-Sept	9 months 2009 Jan-Sept	12 months 2009 Jan-Dec
Operating margin, %	-72	-9	-83	-20	-42
Profit margin, %	-80	-9	-90	-18	-41
	-4	0	-12	-5	-14
Return on total capital, %					
Return on equity, %	-6	-1	-18	-6	-17
Return on capital employed, %	-5	0	-15	-7	-16
Debt/equity ratio, multiple	22	0	22	0	0
Equity/assets ratio, %	66	88	66	88	85
Current ratio, %	171	429	171	429	234
Acid ratio, %	164	409	164	409	221
Average number of shares, before dilution	23,403,752	22,778,731	23,402,085	22,485,961	22,714,784
Average number of shares, after dilution	25,942,413	23,881,183,	25,353,390	23,588,413	23,801,489
Number of shares, after full dilution	26,610,080	25,361,950	26,610,080	25,361,950	25,326,775
Number of shares, before dilution	23,403,752	23,401,252	23,403,752	23,401,252	23,401,252
Number of shares, after dilution	25,945,232	24,503,704	25,945,232	24,503,704	24,487,957
Earnings/loss per share, before dilution, SEK	-1.22	-0.41	-3.90	-1.78	-4.32
Earnings/loss per share, after dilution, SEK	-1.22	-0.41	-3.90	-1.78	-4.32
Shareholders' equity per share before dilution, SEK	19,92	25.70	19,92	25.70	23.45
Shareholders' equity per share after dilution, SEK	17,97	24.54	17,97	24.54	22.41
Number of employees at close of period	106	126	106	126	108
Average number of employees	105	126	105	126	124
Shareholders' equity	466,185	601,362	466,185	601,362	548,661
Capital employed	567,174	617,362	567,174	617,362	564,661

## DEFINITIONS

Refer to the Annual Report for 2009

## PARENT COMPANY STATEMENT OF OPERATIONS

KSEK		3 months 2010	3 months 2009	9 months 2010	9 months 2009	12 months 2009
	Notes	July-Sept	July-Sept	Jan-Sept	Jan-Sept	Jan-Dec
Net revenues		21,637	49,052	61,508	159,165	208,183
Cost of goods sold		-	-	-	-	-
<b>Gross profit</b>		<b>21,637</b>	<b>49,052</b>	<b>61,508</b>	<b>159,165</b>	<b>208,183</b>
Selling expenses		-1,480	-2,985	-11,387	-10,486	-16,588
Administrative expenses		-24,003	-9,871	-44,904	-28,575	-42,260
Research & development expenses		-32,178	-40,039	-99,051	-146,230	-192,463
Other operating income		888	298	3,214	2,567	3,574
Other operating expenses		-370	-721	-920	-5,660	-6,203
<b>Operating loss</b>		<b>-35,506</b>	<b>-4,266</b>	<b>-91,540</b>	<b>-29,219</b>	<b>-45,757</b>
<b>Earnings from financial investments</b>						
Interest income		192	6,449	224	,6,661	230
Interest expenses		-2,983	-2,435	-6,163	-2,589	-2,543
Other financial income		-	-	-	-	6,269
Other financial expenses		-	-	-295	-	-
<b>Loss after financial items</b>		<b>-38,297</b>	<b>-252</b>	<b>-97,774</b>	<b>-25,147</b>	<b>-41,801</b>
Tax		-	-1,389	-	-1,389	-1,390
<b>Loss for the period</b>		<b>-38,297</b>	<b>-1,641</b>	<b>-97,774</b>	<b>-26,536</b>	<b>-43,191</b>

## PARENT COMPANY BALANCE SHEET

KSEK	Notes	2010 30-Sep	2009 30-Sep	2009 31-Dec
<b>ASSETS</b>				
<b>Fixed assets</b>				
Tangible fixed assets		42,465	45,877	45,523
Intangible fixed assets		254	400	363
Shares in subsidiaries/joint ventures		604,763	606,414	606,414
<b>Total fixed assets</b>		<b>647,482</b>	<b>652,691</b>	<b>652,300</b>
<b>Current assets</b>				
Inventories		2,734	1,519	1,385
Accounts receivable and other receivables		108,625	41,316	76,729
Tax receivables		4,537	2,679	728
Cash and bank balances		130,525	13,472	12,790
<b>Total current assets</b>		<b>246,421</b>	<b>58,986</b>	<b>91,632</b>
<b>Total assets</b>		<b>893,903</b>	<b>711,677</b>	<b>743,932</b>
<b>SHAREHOLDERS' EQUITY, PROVISIONS &amp; LIABILITIES</b>				
	5			
Restricted equity		300,112	300,111	300,111
Non-restricted equity		260,878	360,588	347,029
<b>Total shareholders' equity</b>		<b>560,990</b>	<b>660,699</b>	<b>647,140</b>
<b>Long-term liabilities</b>				
Provisions		929	1,337	813
Borrowings		91,510	16,000	12,800
<b>Total long-term liabilities</b>		<b>92,439</b>	<b>17,337</b>	<b>13,613</b>
Current liabilities, non-interest-bearing		230,995	33,641	79,979
Current liabilities, interest-bearing		9,479	-	3,200
<b>Total liabilities</b>		<b>240,474</b>	<b>50,978</b>	<b>83,179</b>
<b>Total shareholders' equity and liabilities</b>		<b>893,903</b>	<b>711,677</b>	<b>743,932</b>
<b>Pledged assets</b>		<b>16,000</b>	<b>16,000</b>	<b>16,000</b>
<b>Contingent liabilities</b>		<b>6,050</b>	<b>11,050</b>	<b>6,050</b>

## 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 2009 Annual Report.

During the period, Orexo issued a convertible bond. This compound financial instrument is initially recognized in the following manner: the liability share is measured at fair value and the equity share as the difference between the fair value of the entire convertible bond less the portion recognized as a liability. Transaction expenses have been allocated to the liability share and equity share in proportion to the value initially recognized.

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.

### **New and amended accounting policies as of 2010**

No new or revised IFRS have come into effect that are expected to have any significant impact on the Group.

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

	<b>2010</b>	<b>2009</b>	<b>2010</b>	<b>2009</b>	<b>2009</b>
	<b>July-Sept</b>	<b>July-Sept</b>	<b>Jan-Sept</b>	<b>Jan-Sept</b>	<b>Jan-Dec</b>
Raw materials and supplies	8,570	9,560	25,744	32,681	41,503
Other external costs	21,531	35,902	71,644	120,338	162,469
Personnel costs	30,534	23,621	87,429	94,278	128,619
Depreciation and impairment	3,548	1,857	7,504	8,574	10,838
<b>TOTAL</b>	<b>64,183</b>	<b>70,940</b>	<b>192,321</b>	<b>255,871</b>	<b>343,429</b>

Research and development costs encompass costs for personnel, employee stock options, premises, external costs for clinical trials, pharmaceutical registration and laboratory services, the depreciation/amortization of equipment, and the acquisition of 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 at September 30, 2010, was 23,403,752, all of which were common shares. All shares carry entitlement to one vote each.

#### **Options**

At September 30, a total of 1,531,801 options were outstanding that carry rights to new subscription of 1,339,486 shares in Orexo and to be exchanged for 192,315 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 January 1, 2010 to September 30, 2010 distributed by category.

	Opening Jan 1, 2010	Change	Closing Sept 30, 2010
<b>Employee-related options</b>			
<i>Of which:</i>			
Decided and allocated employee stock options	876,316		876,316
Expired		-,153,250	-153,250
Exercised		-2,500	-2,500
<i>Total</i>			<b>720,566</b>
Decided and allotted Board options	35,207		35,207
Allotted		25,713	25,713
<i>Total</i>			<b>60,920</b>
Decided and allotted warrants	10,000		10,000
<i>Total</i>			<b>10,000</b>
Decided but not allotted employee stock options 2009			
Opening balance, as approved by the 2009 AGM	470,000		470,000
<i>Total</i>			<b>470,000</b>
Warrants held by subsidiaries as cash-flow hedging for social security fees	78,000		78,000
<i>Total</i>			<b>78,000</b>
<b>Total options to employees</b>	<b>1,469,523</b>	<b>-130,037</b>	<b>1,339,486</b>
Employee stock options utilized from Biolipox AB (no dilution effect, included in newly issued shares in conjunction with acquisition of Biolipox)			
	196,107		130,192
Expired		-9,454	-9,454
Exercised		-56,461	-56,461
Warrants utilized from Biolipox AB for cash-flow hedging of social security fees (no dilution effect)	80,323	-18,200	62,123
<b>Total options from Biolipox</b>	<b>276,430</b>	<b>-84,115</b>	<b>192,315</b>
<b>Total options to employees</b>	<b>1,745,953</b>	<b>-214,152</b>	<b>1,531,801</b>
<b>Other options</b>			
Warrants related to supplemental payment in conjunction with acquisition of Biolipox AB	926,000	-926,000	-
<b>Total options outstanding</b>	<b>2,671,953</b>	<b>-1,140,152</b>	<b>1,531,801</b>

<sup>1</sup> All information regarding options issued by Orexo AB has been restated to take into account the 1:250 share split conducted in November 2005. The 2005 Annual Report states that older option certificates provide entitlement to subscribe for 250 shares after the split. The reported data regarding options issued by Orexo AB refer to the number of shares to which each option provides entitlement to subscribe for shares following the share split. All data regarding options issued by Biolipox AB are restated using a factor of 0.45854, which corresponds to the computed value of the options related to the share price for the Orexo share on the acquisition date. The reported data regarding the options issued by Biolipox refer to the number of shares for which each option may be exchanged after recalculation.

During the period January-September 2010, a total of 2,500 employee stock options from Orexo's options program were exercised, all during the period July-September. During the period January- September 2010, 56,461 of Biolipox' employee stock options were exercised, entailing that holders exercised their options in exchange for 56,461 shares held by the independent company Pyrinox AB. Of these employee stock options, none were exercised in the period July-September 2010. Exercise did not entail the issue of any new shares by Orexo.

On January 1, 2010, the 926,000 warrants pertaining to the additional purchase consideration for the Biolipox acquisition expired. They could have been exercised had certain events occurred before December 31, 2009, but since these events never occurred, the warrants expired.

Costs for the program pertain to the expected cost of the value of employee earnings during the period, as measured at market value on the date of distribution, and to the portion of estimated social security expenses related to the increase in value that was vested during the period. The company will have to pay social security expenses on gains that may arise in connection with the exercise of employee stock options, calculated as the difference between the redemption price of the employee stock options and the market value of the share. All things being equal, this means that a rise in the share price during the quarter increases the costs of the estimated social security fees.

The social security fees that could arise due to the employee stock option have been hedged financially and thus also in terms of cash flow through the issuance of warrants to a subsidiary of Orexo. This hedging does not qualify for hedge accounting in accordance with IFRS.

#### *Allotment of Board member options in May 2010*

In May 2010, a total of 25,713 Board member options were allotted that provide entitlement to subscribe for a total of 25,713 shares in Orexo. These Board member options have been allotted free of charge to the Board members elected at the 2010 AGM. Vesting of the Board member options takes the form of 25 percent after the date for the publication of Orexo's interim report for the first quarter and 25 percent after the publication of the interim reports for quarters two to four during the mandate period for the 2010 financial year. The right of Board members to request exercise arises two years after the 2010 AGM. The final exercise date for Board member options is December 31, 2017 and the strike price is SEK 0.40 per share. The market value, calculated using the Black & Scholes method, was SEK 37.86 on the allotment date.

#### **4. Cash flow**

##### **Adjustment for non-cash items**

	<b>2010</b>	<b>2009</b>	<b>2010</b>	<b>2009</b>	<b>2009</b>
	<b>July-Sept</b>	<b>July-Sept</b>	<b>Jan-Sept</b>	<b>Jan-Sept</b>	<b>Jan-Dec</b>
Depreciation/amortization and impairment	3,548	1,857	7,504	8,574	10,503
Estimated costs for employee stock options program	698	1,815	2,544	5,534	8,203
Other		-	-	-	2,128
Financial expenses, convertible bond	2,910	-	-158	-	-
<b>Total</b>	<b>7,156</b>	<b>3,672</b>	<b>9,890</b>	<b>14,108</b>	<b>20,834</b>

## 5. Shareholders' equity

### Change in the Parent Company's shareholders' equity

	2010 July-Sept	2009 July-Sept	2010 Jan-Sept	2009 Jan-Sept	2009 Jan-Dec
Opening shareholders' equity, balance sheet	598,732	626,462	647 140	609 194	609 194
Net loss for the period	-38,297	-1,641	-97,774	-26,536	-43,191
Subscription for shares through the exercise of warrants	44	-	44	90	-
New share issues	-	35,110	-	74,356	90
New warrant issues	-	-	-	-	74,356
Employee stock options, vested value for employees	511	768	1,575	3,595	6,691
Convertible bond – equity share	-	-	10,005	-	-
<b>Closing amount</b>	<b>560,990</b>	<b>660,699</b>	<b>560,990</b>	<b>660,699</b>	<b>647,140</b>

## 6. Pledged assets and contingent liabilities

In the acquisition of Inflazyme in November 2007, a supplemental payment was agreed contingent on certain goals being met. MSEK 9.9 of the supplemental payment was recognized as a provision and MSEK 34.3 was recognized as a contingent liability, since the latter is not assessed as a probable payment based on pharmaceutical development statistics. The supplemental payment was adjusted for changes in exchange rates during the year. 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 British drug company PharmaKodex in February 2009. This corporate acquisition includes conditional payments based on license revenues from the current PharmaKodex program and technologies, as well as on payments for certain milestones that are not recognized as a liability.

The overdraft facility of MSEK 35 that was secured from Nordea during the period led to a rise in non-property mortgages to MSEK 44 and pledging of all shares of Kibion AB.

### Note

Orexo AB publ. discloses the information provided herein pursuant to the Securities Markets Act. The information was provided for public release on November 10, 2010, at 8:00 a.m. CET. 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 take precedence.