# Orexo AB (publ.) Year-end Report, January to December 2010

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Uppsala, February 16, 2011

# Orexo AB (publ) – Year-end Report, January – December 2010

- Abstral continues to grow strongly and is now also approved in the USA.
- OX-MPI has made significant progress towards clinical trials and has received its first milestone payment.
- The three new programs OX219, OX51 and OX27 announced in August 2010 have now all entered the clinical phase.

# Key events during the period

- The loss after tax for the year excluding exceptional items was MSEK –54.9 (-98.1). <sup>1)</sup> Including these items, the loss after tax for the year was MSEK -89.2 (-98.1).
- Royalty income from Abstral®, Orexo's leading sublingual fentanyl product for breakthrough pain in cancer patients, increased to MSEK 42.2 (16.2). Product sales amounted to MSEK 183.
- Orexo and its partner Boehringer Ingelheim reported a significant step forward in their cooperation aimed at development of drugs to treat pain and inflammation. The first milestone payment amounted to MSEK 57.6 and was paid in January 2011. Additional amounts will be payable when certain other milestones are achieved, as well as royalties on sales of commercial products.
- In June, Orexo signed a collaboration and licensing agreement for new drugs for respiratory diseases with Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica NV ("OMJ"). The agreement provides Orexo with research funding of up to MSEK 167 during the first three years, including an advance payment of MSEK 77.8. In addition, Orexo will be entitled to milestone payments of up to MSEK 4,390 if certain other stages are achieved, plus additional sales milestones and royalties in each program.
- Orexo reported positive Phase I clinical data for OX219, a new sublingual tablet formulation for the treatment of opioid dependence.
- Net revenues amounted to MSEK 210.5 (236.1).
- Cashflow from operating activities was MSEK -43.0 (-133.9).
- The loss after tax per share was SEK -3.81 (-4.32).
- Cash and cash equivalents amounted to MSEK 135.8 compared to MSEK 87.4 at the beginning of the period.
- Orexo financial and strategic position was strengthened earlier in the year when Novo Growth Equity invested in a convertible debt instrument.

# **Fourth Quarter**

- Net revenues amounted to MSEK 109.1 (27.9).
- Cashflow from operating activities was MSEK -29.2 (-16.2).
- Profit after tax for the quarter excluding exceptional items was MSEK 28.0 (-58.0), and including exceptional items the profit for the quarter after tax was MSEK 2.1 (-58.0).

- Earnings per share amounted to SEK 1.20 (-2.48) excluding exceptional items and SEK 0.09 (-2.48) including exceptional items.
- The exceptional items for the period were the costs in respect of recruitment costs of MSEK 1.8 and the write-down of the costs of the OX914 program of MSEK 24.1 in the fourth quarter.

#### KEY EVENTS AFTER THE PERIOD

• Abstral® (sublingual fentanyl) approved for sale by the FDA in the USA ProStrakan has indicated it plans to launch Abstral in the USA during the first quarter of 2011. Abstral is the first product approved in the USA under the FDA's risk evaluation and management system (REMS) for immediate release fentanyl products. The REMS program for Abstral allows prescription through outpatient pharmacies and hospitals.

# • Appointment of New CEO

Anders Lundström was appointed as the new CEO to drive Orexo's future commercial development. Anders' solid international background and strong commercial experience, is ideal for the company's increased focus on developing, marketing and sale of its own pharmaceutical products. Anders joins Orexo from Biogen Idec in the USA, one of the world's leading biotechnology companies.

# • Extraordinary General Meeting on February 16, 2011

On January 11, 2011, the company published notice of an extraordinary general meeting to be held on Wednesday, February 16, 2011, at 16:00 at the Summit Hitech building on Sveavägen 9-11 in Stockholm. This EGM has been convened to decide on the adoption of a performance-based incentive program for 2011/2021. For more detailed information on the proposed incentive program refer to the notice and the full proposal, which are available on the Orexo website, <a href="https://www.orexo.com">www.orexo.com</a>.

<sup>1)</sup> Unless otherwise stated in this report, all figures refer to the Orexo Group. Figures in brackets indicate the results for the corresponding period in 2009.

# **Operations**

"For the full year 2010, we saw strong sales of Abstral, providing an increase of approximately 320%. Sales of Edluar also grew, particularly in the fourth quarter.

On January 10, 2011 Abstral was approved by the FDA for sale in the United States. As a result of the approval and the new distribution agreements signed with Newbridge for the Middle East and Africa and Invida for the remaining key markets in Asia and Australia, Abstral is now a global product.

In August Orexo launched their new strategy "Orexo 2015". It is based on developing and commercializing products in-house in the future. In the first program, OX-219 (for the treatment of opioid dependence) has already completed a positive Phase I trial. Clinical phase I trials have been initiated in the other two new programs, OX27 and OX51.

Orexo's arachidonic acid research made significant progress during the year. The company entered an alliance and license agreement with Ortho-McNeil-Janssen Pharmaceuticals and Janssen Pharmaceutica on its program OX-CLI for the treatment of respiratory diseases. Orexo also achieved its first milestone for OX-MPI in the research collaboration with Boehringer Ingelheim, "says Anders Lundström, President and CEO.

# The period in figures

## **Summary of Consolidated Income Statement**

	3 months 2010 Oct-Dec	3 months 2009 Oct-Dec	12 months 2010 Jan-Dec	12 months 2009 Jan-Dec
MSEK				
Net revenue	109.1	27.9	210.5	236.1
Costs of goods sold	-7.4	-6.3	-26.3	-23.6
Gross Profit	101.7	21.6	184.2	212.5
Selling expenses	-12.4	-14.0	-35.2	-39.3
Administrative expenses	-10.1	-14.0	-46.8	-46.3
Research & development	-75.8	-51.9	-186.9	-224.2
costs				
Other operating income &	-0.6	0.4	3.0	-1.8
expenses				
Operating profit*	2.8	-57.9	-81.7	-99.1
Net financial items	-0.6	-0.1	-7.5	2.1
Profit after financial	2,2	-58,o	-89.2	-96.9
items				
Tax	_	-	-	-1.1
Net Profit for the	2,2	-58.o	-89.2	-98.1
period				

<sup>\*</sup> includes the costs of employee stock options in the amount of MSEK 3.3 for the period January to December 2010 (MSEK 8.2 January to December 2009).

#### **Revenues**

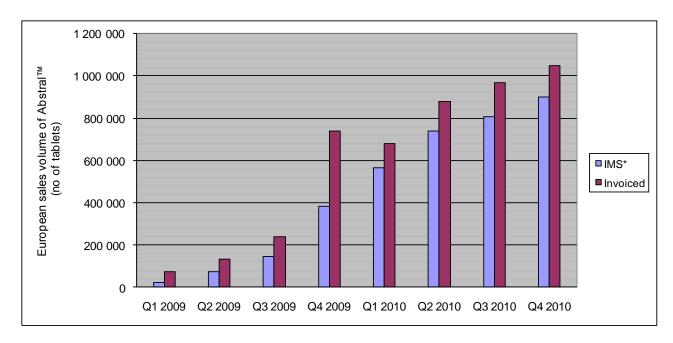
Net revenue

Net sales for January-December 2010 amounted to MSEK 210.5 (236.1). The decrease is attributable to lower licensing revenues and transfers of costs and related research funding from the partner, but these are partially offset by sharply higher royalty revenues.

During the period October-December 2010, net revenues were MSEK 109.1 (27.9). The higher net revenue for the quarter is primarily attributable to the first milestone payment of MSEK 57.6 from the agreement with Boehringer Ingelheim.

During the second quarter Orexo began its collaboration and license agreement with Ortho-McNeil-Janssen Pharmaceuticals Inc. The agreement runs initially for three years. The initial payment of MSEK 77.8 which was received when the contract was made, is accounted for evenly over the three year period. In addition, Orexo has begun receiving reimbursement payments of collaborative research costs from this period onward.

# Revenues from Abstral sales increased by over 320 percent compared with the same period in 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 year January – December 2010 amounted to MSEK 42.2, compared with MSEK 16.2 for 2009. Royalty revenues for the period October - December 2010 amounted to MSEK 11.9 (9.9).

Sales for Kibion during the year January — December 2010 amounted to MSEK 39.9 (40.7) after a strong recovery in the fourth quarter. Volume growth in the number of urea breath tests was around 10%. The small decrease in sales should be read in the context of a marked weakening of the euro in 2010 (responsible for around MSEK -1.7 m).

ProStrakan AB's sales have increased to MSEK 24.5 (21.6), of the reported 50% of Orexo turnover. Abstral sales through ProStrakan AB increased to MSEK 12.3 (10.8).

Revenue from new and existing license deals amounted to MSEK 81.1 (119.5). Revenues mainly comprise the milestone payment from Boehringer Ingelheim of MSEK 57.6 and the accounting release during the year of the upfront payment received from Ortho-McNeil-Janssen Pharmaceuticals, Inc. Last year's license revenue consisted primarily of milestones from the out-licensing of the insomnia therapy Edluar  $^{\text{TM}}$  to Meda AB and consideration for approval of Edluar  $^{\text{TM}}$  in the United States.

Royalty revenues for Edluar for the period January-December amounted to MSEK 1.3.

#### Net revenues were distributed as follows:

MSEK	Oct-Dec	Oct-Dec	Jan-Dec	Jan-Dec
	2010	2009	2010	2009
Abstral® - royalty	11.9	9.9	42.2	16.2
Edluar™ - royalty	0.8	0.1	1.3	2.3
ProStrakan AB J/V 50 %	3.7	2.7	12.3	10.8
Kibion AB	12.1	10.3	39.9	40.7
Total revenue from launched	28.5	23.0	<b>95</b> ·7	70.0
products				
Partner-funded R&D costs	15.9	4.7	33.8	46.4
License revenues	64.9	0.2	81.1	119.5
Other	-0.2	_	-0.1	0.2
Total	109.1	27.9	210.5	236.1

### **Expenses and earnings**

#### Selling expenses

Selling expenses for the period January-December 2010 amounted to MSEK 35.2 (39.3) and for the period October-December 2010 to MSEK 12.4 (14.0). The selling expenses include the costs of business development associated with licensing of Orexo projects, the costs of Phase IV trials, selling activity in Kibion AB and the joint venture company ProStrakan AB.

#### Administrative expenses

Administrative expenses for the period January-December 2010 amounted to MSEK 46.8(46.3). These costs include provision for costs related to replacement of the CEO and CFO. For the period from October-December 2010 administrative expenses amounted to MSEK 10.2 (14.0).

### Research and development costs

Research and development costs for the period January-December 2010 amounted to MSEK 186.9 (224.2). MSEK 33.8 (46.4) of this cost is covered by Orexo's collaboration partners, and such reimbursements are included in net revenues. The lower costs are primarily related to the development of our proprietary product portfolio and therefore lower external research activities, but also to the cost reductions made in 2009 which have now been given full effect from January 1, 2010.

For the period October-December 2010, research and development costs amounted to MSEK 75.8 (51.9). During this period an impairment write-down of MSEK 24.1 for the OX914 project were charged to research and development costs.

#### Exceptional costs

The exceptional items for the period were the costs in respect of the replacement and recruitment of the new CEO and CFO of MSEK 8.4 in the third quarter, the recruitment costs of MSEK 1.8 and the write-down of the costs of the OX914 program of MSEK 24.1 in the fourth quarter.

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

The company's costs for the employee stock option plan for the period January-December 2010 amounted to MSEK 3.3, compared with a cost of MSEK 8.2 during the same period last year.

### Other income and expenses

Other income and expenses, primarily consisting of exchange rate gains and losses, for the period January-December 2010 amounted to MSEK 3.0 (-1.8) and for the period October - December 2010 to MSEK -0.6 (0.4).

The total operating costs for Orexo in 2010 were just under MSEK 220 as indicated early in the year. This does not include additional research and development expenses in the collaboration with OMJ to the extent that these are covered by research funding from OMJ, the impairment write-down of OX914 or the costs of placement of the convertible loan with Novo A/S.

#### **Depreciation**

Depreciation for the period January-December 2010 amounted to MSEK 9.6 (10.5), and for the period October-December 2010 to MSEK 3.7 (1.9).

#### Net financial income

Net financial income for the period January-December 2010 amounted to MSEK -7.5 (2.1). Net interest income included interest expense of MSEK 8.7 in respect of the convertible debentures held by Novo A/S. The financial items also include reported unrealized foreign exchange losses and other credit charges.

#### **Earnings**

The operating loss for January-December 2010 amounted to MSEK -81.8 (-99.1). The loss after financial items was MSEK -89.3 (-96.9) and loss after taxes was MSEK -89.2 (-98.1).

For the period October-December 2010, operating profit amounted to MSEK 2.8 (-57.9). Profit after financial items was MSEK 2.2 (-58.0) and profit after tax was MSEK 2.2 (-58.0).

# **Financial Position**

Cash and cash equivalents at 31 December 2010 were MSEK 135.8 (87.4). The milestone payment from Boehringer Ingelheim of MSEK 57.6 was paid only in January 2011 and has therefore not affected cash flow in 2010.

The convertible bond issue which took place on April 7 has been reported as a liability and an equity-related component based on the fair value of the liability. The division between these two components has been made based on an estimated market interest rate which is 10.5%. Attributable transaction costs are allocated proportionally on these two components relative to how the proceeds are distributed. The convertible bonds have a conversion price of SEK 47.50 per share representing a premium of approximately 25% over the closing price on March 12, 2010 of SEK 37.90 per share, and are associated with an option that gives Orexo the right to convert the loan when the stock price exceeds the conversion price by 50% in a given period. The convertible loan carries an actual annual interest rate of 8%. In the event the loan is not convertible into shares, it will be repayable by March 31, 2015.

Cash flow from operations for the period January-December 2010 amounted to SEK -43.0 (-133.9). Cash flow after financing amounted to MSEK 48.8 (-95.7).

Cash flow from operations for the period October-December 2010 amounted to MSEK -29.2 (-16.2) and cash flow after financing was MSEK -30.4 (-16.9).

Shareholders' equity at December 31, 2010 amounted to MSEK 468.2 (548.7). The equity ratio was 66 (85) percent.

Current funding is sufficient to run all the 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.

#### **Investments**

Gross investment in fixed assets for the period January-December 2010 was MSEK 3.4 (2.6) and for the period October-December 2010 MSEK 1.1 (1.5).

#### **Product Portfolio**

*Three new development programs* 

A phase I clinical study for OX219 was successful and continued development of the program will be determined following a meeting with the U.S. Food and Drug Administration, FDA in the first quarter of 2011. OX219 is a revised version of the program that originally was acquired through the acquisition of PharmaKodex. The product will compete in the market for treatment of opioid dependence. This market is estimated to represent a value of about \$1.4 billion globally. It is currently dominated by Suboxone® (Reckitt Benckiser plc). The successful outcome of this program is an important step in building Orexo's own product portfolio.

Clinical trials have begun for the two other development programs announced in 2010, OX51 and OX27. Both programs are designed for various pain indications and study results will be reported in the second quarter of 2011. Additional information on the results from the OX219-study is presented in a separate press release available on www.orexo.com.

#### **Parent Company**

Most of the Group's operations are conducted in the parent company Orexo. Net sales for the period January-December 2010 amounted to MSEK 113.0 (208.2) and the loss after financial items was MSEK - 118.6 (-41.3). Investments amounted to MSEK 3.4 (3.2). Cash in the parent company at 31 December 2010 amounted to MSEK 101.4 (12.8) and short-term investments amounted to MSEK 0.0 (0.0).

#### Significant risks and uncertainties

Significant risks and uncertainties are detailed in the Annual Report for 2009. Since the annual report was issued, significant changes have occurred as described below.

### Financial Risks

Through the issue of convertible debt, which raised MSEK 111 before expenses, revenue related to the outlicensing of the project OX-CLI to Ortho-McNeil-Janssen Pharmaceuticals, Inc. and milestone payments from Boehringer Ingelheim for projects MPI, Orexo's financial risks have declined significantly.

#### **Dividend**

The Board does not intend to propose a dividend for the financial year 2010.

## **Equity and market**

Orexo shares were traded on February 14, 2011 at SEK 44.90 per share. The company's market value based on the number of outstanding shares at February 14, 2011 amounted to MSEK 1,027.



#### **Analysts monitoring Orexo**

ABG Sundal Collier Erik Hultgård
Carnegie Camilla Oxhamre

Handelsbanken Markets New analyst being appointed

Nordea Patrik Ling Pharmium Securities Frédéric Gomez

Redeye Klas Palin and Peter Östling

Rodman & Renshaw Michael Higgins SEB Enskilda Gustaf Vahlne

#### **Future reporting dates**

Extraordinary General Meeting	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

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

# **Extraordinary General Meeting 2011**

An Extraordinary General Meeting for Orexo will be held on Wednesday, February 16, 2011, at 4:00pm at Summit Hitech building on Sveavägen 9-11 in Stockholm.

Notice of this meeting was published on January 11, 2011.

## **Annual General Meeting 2011**

The Annual General Meeting for Orexo AB will be held on April 7, 2011 at 3.00pm at the IVA Conference Centre, Grev Turegatan 16, in Stockholm.

Notice of the meeting will be published not later than March 10, 2011.

# **Annual Report 2010**

Orexo AB's annual report and financial statements will presented on the company website no later than March 17, 2011, and can be sent to shareholders upon request.

Uppsala, February 16, 2011

Orexo AB (publ)

Anders Lundström President and Chief Executive Officer

For further information, please contact:

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#### **AUDITORS 'REPORT**

We have reviewed the attached report for the period January 1 to December 31, 2010 for Orexo AB (publ).. Orexo's management is responsible for the preparation and presentation of this interim report in accordance with the Annual Accounts Act and IAS 34. Our responsibility is to express a conclusion on this interim financial information based on our review.

We 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, issued by FAR. 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 compiled 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, February 16, 2011 PricewaterhouseCoopers AB

Leonard Daun Authorised Public Accountant

# CONSOLIDATED STATEMENT OF OPERATIONS

KSEK		3 months	3 months	12 months	12 months	
	Notes	2010	2009	2010	2009	
		Oct-Dec	Oct-Dec	Jan-Dec	Jan-Dec	
Not revenues		100 105	05 955	010 400	006 104	
Net revenues	•	109,137	27,857	210,499	236,104	
Cost of goods sold	2	-7,463	-6,299	-26,321	-23,650	
Gross profit		101,674	21,558	184,178	212,454	
Selling expenses	2	-12,399	-13,984	-35,223	-39,261	
Administrative expenses	2	-10,152	-14,047	-46,819	-46,308	
Research & development costs	2	-75,825	-51,913	-186,914	-224,216	
Other operating income		1,301	1,738	7,746	8,239	
Other operating expenses	2	-1,857	-1,310	-4,741	-9,991	
Operating profit		2,742	-57,958	-81,773	-99,083	
Financial income		1,192	45	1,456	4,868	
Financial expense		-1,803	-120	-8,942	-2,726	
Financial items - net		-1,003 - <b>611</b>		-7,4 <b>86</b>	2,142	
rmanciai items - net		-011	<b>-75</b>	-/,400	2,142	
Pre-tax profit		2,131	-58,033	-89,259	-96,941	
Income tax		-1	5	13	-1,138	
Net Profit for the period		2,130	-58,028	-89,246	-98,079	
Profit for the period attributable to:						
Parent Company shareholders Minority interests		2,130	-58,028 -	-89,246 -	-98,079 -	
Profit for the period attributable to Parent Company shareholders during the period during the period (SEK per share):						
Profit per share, before dilution		0.09	-2.48	-3.81	-4.32	

# CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

KSEK	3 months	3 months	12 months	12 months
	2010	2009	2010	2009
	Oct-Dec	Oct-Dec	Jan-Dec	Jan-Dec
Profit for the period	2,130	-58,028	-89,246	-98,079
Other comprehensive income				
Hedging of net investments	-	-	-	2,329
Exchange-rate differences	-552	1,957	-3,524	-7,574
Other comprehensive income for the	-552	1,957	-3,524	-5,245
period, after tax				
Total comprehensive income for the period	1,578	-56,071	-92,770	-103,324
Total comprehensive income attributable to:				
Parent company shareholders	1,578	-56,071	-92,770	-103,324

# 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 1 January, 2010	8,647	1,012,964	-451,828	-	569,783	569,783
Total comprehensive income	-	-	-98,079	-5,245	-193,324	-103,324
Employee stock options, vested amount	-	7,756	-	-	7,756	7,756
New share issues	713	73,733	-	-	74,446	74,446
Closing balance at 31 December 2009	9,360	1,094,453	-549,907	-5,245	548,661	548,661
Opening balance at 1 January, 2010	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 - shareholder's equity	-	10,005	-	-	10,005	10,005
New share issues	1	43	-	-	44	44
Closing balance at 31 December 2009	9,361	1,106,798	-639,153	-8,769	468,237	468,237

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

# CONSOLIDATED BALANCE

SHEET

KSEK		2010	2009
	Notes	31 Dec	31 Dec
Assets			
Fixed assets			0
Tangible fixed assets		41,666	45,814
Goodwill		17,679	17,987
Acquired R&D	3	388,487	427,030
Other intangible fixed assets		1,251	1,982
Total fixed assets		449,083	492,813
Current assets			
Inventories		7,965	8,440
Accounts receivables and other receivables		119,845	60,667
Cash and cash equivalents		135,798	87,414
Total current assets		263,608	156,521
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Total assets		712,691	649,334
SHAREHOLDERS' EQUITY &	4		
LIABILITIES	•		
Share capital		9,361	9,360
Capital contributions		1,106,798	1,094,453
Accumulated losses		-639,153	-549,907
Translation differences		-8,769	-5,245
Total shareholders equity		468,237	548,661
Long-term liabilities			
Provisions		1,112	11,114
Long-term liabilities, interest-bearing		94,421	12,800
Deferred tax liability		8,911	9,791
Total long-term liabilities		104,444	33,705
Current liabilities			
Current liabilities, interest-bearing		130,531	63,768
Current liabilities, non-interest-bearing		9,479	3,200
Carrent natimities, non-interest-bearing		<b>∀</b> ,4/∀	3,200
Total liabilities		244,454	100,673
Total shareholders' equity		712,691	649,334
and liabilities			

<sup>\*</sup> Includes the unrecognized portion of the OX-CLI deal upfront funding of MSEK 62.6.

# CONSOLIDATED CASHFLOW STATEMENTS

KSEK	Notes	3 months	3 months 2009	12 months 2010	12 months 2009
	Notes	Oct-Dec	Oct-Dec	Jan-Dec	Jan-Dec
Operations		ou bu	oet bee	oun Dec	oun Dec
Operating loss before interest		2,742	-57,958	-81,773	-99,083
expense and interest income					
Interest received		286	45	550	<i>7</i> 59
Interest paid		-2,912	-120	-8,942	-397
Tax paid		-	-	-	-1,389
Other financial expenses		2,015	-	906	-
Adjustment for non-cash items	5	29,935	6,726	39,825	20,834
Cashflow from operations before changes in working		32,066	-51,307	-49,434	-79,276
capital					
Changes in working capital					
Accounts receivable		-70,213	14,003	-67,453	-2,963
Other current receivables		-762	3,048	8,275	6,143
Inventories		1,612	732	475	5,542
Current liabilities		7,560	17,304	65,751	-64,487
Provisions		615	267	299 -880	1,114
Long-term provisions		-125	-295	-000	-
Cash flow from operations		-29,247	-16,248	-42,967	-133,927
Investing activities					
Acquisition of machinery and equipment		-1,152	-1,467	-3,438	-2,588
Divestment of machinery and		-	-	-	2
equipment Acquisition of subsidiaries		_	_	_	24,695
Cashflow after investments		-30,399	-17,715	-46,405	-111,818
Change in financing					
New share issues		-	800	44	90
Proceeds from issue of convertible		-	-	111,150	-
bonds					
Loans received		-	-	-	16,000
Amortization of loans		-	-	-16,000	-
Cashflow after financing		-30,399	-16,915	48,789	-95,728

KSEK	3 months		3 months	12 months	12 months
	Notes	2010	2009	2010	2009
		Oct-Dec	Oct-Dec	Jan-Dec	<b>Jan-Dec</b>
Cashflow for the year					
Cash and cash equivalents,		165,645	107,061	87,414	188,220
beginning of period					
Exchange rate differences in cash		552	-2,732	-405	-5,078
and cash equivalents					
Changes in cash and cash		-30,399	-16,915	48,789	-95,728
equivalents					
Cash and cash equivalents, close of period		135,798	87,414	135,798	87,414

# **Key Figures**

	3 months 2010 Oct-Dec	3 months 2009 Oct-Dec	12 months 2010 Jan-Dec	12 months 2009 Jan-Dec
Operating margin %	3	-207	-39	-42
Profit margin %	2	-207	-42	-41
Return on total capital, %	1	-9	-12	-14
Return on equity, %	0	-10	-18	-17
Return on capital employed, %	0	-10	-14	-16
Debt/equity ratio, multiple	22	0		0
Equity/assets ratio, %	66	85	66	85
Current ratio, %	188	234	188	234
Acid ratio, %	183	221	183	221
Average number of shares, before dilution	23,403,752	23,401,252	23,402,502	22,714,784
Average number of shares, after dilution	25,943,366	23,487,957	25,500,884	23,801,489
Number of shares, after full dilution	26,609,081	25,328,048	26,609,081	25,326,775
Number of shares, before dilution	23,403, 752	23,401,252	23,403,752	23,401,252
Number of shares, after dilution	25,943,070	24,487,957	25,943,070	24,487,957
Earnings/loss per share, before dilution, SEK	0.09	-2.48	-3.81	-4.32
Earnings/loss per share, after dilution, SEK	0.08	-2.48	-3.81	-4.32
Shareholders' equity per share, before dilution, SEK	20.01	23.45	20.01	23.45
Shareholders' equity per share, after dilution, SEK	18.05	22.41	18.05	22.41
Number of employees at end of period	105	108	105	108
Average number of employees	106	119	105	124
Shareholders' equity	468,237	548,661	468,237	548,661
Capital employed	572,137	564,661	572,137	564,661

# **DEFINITIONS**

Please refer to the Annual Report for 2009

# PARENT COMPANY STATEMENT OF OPERATIONS

KSEK	Notes	3 months 2010 Oct-Dec	3 months 2009 Oct-Dec	12 months 2010 Jan-Dec	12 months 2009 Jan-Dec
Net revenues Cost of goods sold Gross profit		51,443 - <b>51,443</b>	49,018 - <b>49,018</b>	112,951 - <b>112,951</b>	208,183 - <b>208,183</b>
Selling expenses Administrative expenses Research & development costs Other operating income Other operating expenses Operating profit		-5,146 -16,701 -47,995 922 -427 <b>-17,904</b>	-6,102 -13,685 -46,233 1,007 -543 -16,538	-16,533 -61,605 -147,046 4,136 -1,347 -109,444	-16,588 -42,260 -192,463 3,574 -6,203 <b>-45,75</b> 7
Earnings from financial investments Financial income Financial expense Other financial income Other financial expense Loss after financial items Tax		282 -3,236 - - - <b>20,858</b>	7 -123 - - -16,654	506 -9,399 - -295 <b>-118,632</b>	230 -2,543 6,269 - -41,801
Loss for the period		-20,858	-16,655	-118,632	-43,191

# PARENT COMPANY BALANCE SHEET

KSEK	Notes	2010 31-dec	2009 31-dec
ASSETS			
Fixed assets		((	
Tangible fixed assets Intangible fixed assets		41,566 218	45,523 363
Shares in subsidiaries/joint ventures		604,763	606,414
Total fixed assets		646,547	652,300
Current assets			
Inventories		2,529	1,385
Accounts receivable and other receivables		133,986	77,457
Cash and bank balances		101,400	12,790
Total current assets		237,915	91,632
Total assets		884,462	743,932
SHAREHOLDERS' EQUITY, PROVISIONS & LIABILITIES	6		
Restricted equity		300,112	300,111
Non-restricted equity		240,414	347,029
Total shareholders' equity		540,526	647,140
Long-term liabilities			
Provisions		1,135	813
Borrowings		94,421	12,800
Total long-term liabilities		95,556	13,613
Current liabilities, interest-bearing		238,901	79,979
Current liabilities, non-interest-bearing		9,479	3,200
Total liabilities		343,936	83,179
Total shareholders' equity and liabilities		884,462	743,932
Pledged assets		44,000	16,000
Contingent liabilities		6,050	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 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 International Financial Reporting Standards have come into effect that are expected to have any significant impact on the Group.

# 2. Costs distributed by type of cost

KSEK	2010	2009	2010	2009
	Oct-Dec	Oct-Dec	Jan-Dec	Jan-Dec
Raw materials and supplies	9,562	8,822	35,306	41,503
Other external costs	43,177	42,466	114,821	162,469
Personnel costs	28,697	34,341	116,126	128,619
Depreciation and impairment	26,260	1,929	33, 764	10,838
TOTAL	107,696	87,558	300,017	343,429

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. Acquired research and development

In the fourth quarter it was necessary to write down the value of the OX914 project, which has added MSEK 24.1 to the operating cost.

Opening balance 1 January 2010	427,030
Impairment	-25,794
Revaluation additional consideration	-9,100
Translation differences	-3,649
Closing balance 31 December 2010	388,487

# 4. Shareholders' equity

# Shares outstanding

The number of shares outstanding at December 31, 2010, was 23,403,752, all of which were common shares. All shares carry entitlement to one vote each.

# **Options**

At December 31, 2010, a total of 1,517,941 options were outstanding that carry rights to new subscription of 1,338,486 shares in Orexo and to be exchanged for 179,455 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 December 31, 2010 distributed by category.

	Opening Jan 1, 2010	Change	Closing Sept 30, 2010
Employee-related options			2010
Of which: Decided and allocated employee stock options Expired Exercised Total	876,316	-154,250 -2,500	876,316 -154,250 -2,500 <b>719,566</b>
Decided and allotted Board options	35,207		35,207
Allotted		25,713	25,713
Total			60,920
Decided and allotted warrants	10,000		10,000
Total			10,000
Decided but not allotted employee stock options 2009			
Opening balance, as approved by the 2009 AGM	470,000		470,000
Total			470,000
Warrants held by subsidiaries as cash-flow hedging for social security fees	78,000		78,000
Total			78,000
Total options to employees	1,469,523	-131,037	1,338,486
Employee stock options utilized from Biolipox AB (no dilution effect, included in newly issued shares in conjunction with acquisition of Biolipox) Expired Exercised	196,107	-9,454 -69,071	196,107 -9,454 -69,071
Warrants utilized from Biolipox AB for cash-flow hedging of social security fees (no dilution effect)	80,323	-18,450	61,873
Total options from Biolipox	276,430	-96,975	179,455
Total options to employees	1,745,953	-228,012	1,517,941
Other options			
Warrants related to supplemental payment in conjunction with acquisition of Biolipox AB	926,000	-926,000	-
Total options outstanding	2,671,953	-1,154,012	1,517,941

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 October - December. During the period January- December 2010, 69,071 of Biolipox' employee stock options were exercised, entailing that holders exercised their options in exchange for 69,071 shares held by the independent company Pyrinox AB. Of these employee stock options, 12,610 were exercised in the period October - December 2010. This 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.

#### 5. Cashflow

### Adjustment for non-cash items

KSEK	2010 Oct-Dec	2009 Oct-Dec	2010 Jan-Dec	2009 Jan-Dec
Depreciation/amortization and impairment	26,260	1,929	33,764	10,503
Estimated costs for employee stock options program	765	2,669	3,309	8,203
Other		2,128		2,128
Financial expenses, convertible bond	2,910	-	2,752	-
Total	29,935	6,726	39,825	20,834

### 6. Shareholders' Equity

# Change in the Parent Company's shareholders' equity

KSEK	2010 Oct-Dec	2009 Oct-Dec	2010 Jan-Dec	2009 Jan-Dec
Opening shareholders' equity, balance sheet	560,990	660,699	647,140	609,194
Net loss for the period Subscription for shares through the exercise of warrants	-20,858 -	-16,655 -	-118,632 44	-43,191 -
New share issues	-	-	-	90
New warrant issues	-	-	-	74,356
Employee stock options, vested value for employees	394	3,096	1,969	6,691
Convertible bond – equity share	-	-	10,005	-
Closing amount				
	540,526	647,140	540,526	647,140

#### 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. This supplemental payment was recognized partly as a provision and as a contingent liability, since the latter is not assessed as a probable payment based on pharmaceutical development statistics. During the quarter, the Inflazyme project was closed and the supplemental payment was entirely reclassified as a contingent liability of MSEK 45.7.

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 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 chattel 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 February 16, 2011, 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.