

# Interim report, January-March 2011

References made in this interim report relate to the Group unless otherwise stated. Figures in parentheses relate to the same period in the previous year.

#### For the period

- Abstral sales continued to develop well in Europe and the product has now been approved in the US and Canada.
- Anders Lundström appointed new CEO.
- Positive data from the first clinical trial in the OX51 project, for treatment of acute intensive pain episodes.
- Net revenues increased to MSEK 41.5 (36.4).
- Royalty revenues from Abstral in Europe amounted to MSEK 14.0 (8.5).
- The loss after tax was MSEK 39.2 (loss: 27.6).
- Cash flow from operating activities amounted to MSEK 16.3 (neg: 19.7).
- Loss per share amounted to SEK 1.67 (loss: 1.18).
- Cash and cash equivalents were MSEK 150.3 at the end of the period, compared with MSEK 135.8 at year-end.

#### After the close of the period

- Orexo announced that the Board of Directors has decided, subject to approval of an Extraordinary General Meeting, to implement a preferential rights issue. Please see separate press release.
- Abstral was launched in the US in April. Royalty revenues due to inventory build-up in the US
  are estimated at MSEK 18.3.
- Kyowa Hakko Kirin's acquisition of ProStrakan Group plc was approved in April.

# **Key figures**

MSEK	3 months	3 months	12 months
	2011	2010	2010
	Jan-March	Jan-March	Jan-Dec
Net revenue	41.5	36.4	210.5
Operating loss	-36.6	-26.7	-81.7
Net profit for the period	-39.2	-27.6	-89.2
Earnings/loss per share, SEK	-1.67	-1.18	-3.81
Cash flow from operating activities	16.3	-19.7	-43.0
Cash and cash equivalents	150.3	50.4	135.8

#### **Teleconference**

CEO Anders Lundström will present the report at a teleconference today at 11:30 am CET. Presentation slides are available via link and on the website.

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# CEO's comments

This has been an exciting period for Orexo. The most significant event in the first quarter was that Abstral®, our product for cancer breakthrough pain, was approved in the US, which is potentially its best market. Our partner ProStrakan launched Abstral in the US early in the second quarter, and our initial sales royalties are expected to slightly exceed MSEK 18.

Reaching new markets is crucial for our continued growth and -sales continue to rise in our existing markets in Europe. In the first quarter, our royalty revenues from this area rose 65 percent year-on-year, which means that Abstral now accounts for more than half of our total product revenues.

We also out-licensed Abstral in remaining major markets in Asia and Australia to Invida, a very strong regional partner. Invida will apply for approval in several potentially major markets, such as Australia, India, Indonesia, South Korea and Taiwan.

Abstral is not only a key product for us, but also for ProStrakan, our sales and marketing partner in North America and most of Europe. Now that our Japanese partner for Abstral, Kyowa Hakko Kirin, has acquired ProStrakan, we feel confident that by combining the knowledge, organization and resources of these two companies, Abstral is even better positioned for continued success.

In the future, we intend to build own success mainly on proprietary products, which is why Orexo adopted a new strategy in autumn 2010. As a result, we started three programs aimed at developing products that Orexo will sell through its own organization in the US or in Europe. The programs are based on our expertise in creating new and better therapies from existing pharmaceuticals. Our new programs have developed rapidly and this progress continued during the first quarter. In February, we had a successful meeting with the FDA concerning OX219, where our development plan was confirmed. An application for permission to start the next major study is now being prepared as part of this project.

Positive clinical data was reported for OX51, a new sublingual formulation of an existing treatment of acute intensive pain episodes, some of which are not treated optimally today. The next study in this program is planned to commence later this year.

In the third program OX27 for the treatment of breakthrough pain in cancer patients, all patients in the study have been recruited and we will present the results in the second quarter.

In order to drive all three development programs to a successful and fast product launch, we are now implementing a rights issue for shareholders and holders of the company's convertibles. In connection with this, Novo A/S may strengthen its ownership and Orexo will also gain strong new investors. The fact that major shareholders have such confidence in us is a sign of strength.

I would also like to mention our research collaborations that continue to develop according to plan. The OX17 program is progressing in collaboration with our partner Novartis. The partnership with Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica NV (OMJ) concerning Orexo's arachidonic acid programs, OX-CLI and OX-ESI, is also developing well. The drug candidate that Boehringer Ingelheim chose for the OX-MPI program is being prepared to enter the clinical phase.

To conclude, Orexo continues to deliver in line with its strategy to become a specialty pharma company.

Anders Lundström President and CEO

# Key events for the period

# Abstral® approved in the US and Canada

Abstral became the first product to be approved in the US according to the FDA's Risk Evaluation and Mitigation Strategy (REMS) for transmucosal fentanyl products. The US approval was followed by approval in Canada in February.

#### Anders Lundström appointed new CEO

Anders Lundström was appointed new CEO in January and was given the task to drive the company's commercial development. Anders joins Orexo from Biogen Idec in the US.

#### Positive clinical data for 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.

#### New partner in Asia and Pacific area for Abstral

In January, Orexo signed an exclusive licensing and distribution agreement with Invida Group for Abstral, entailing commercialization in 11 countries, including Australia and India.

#### A long-term incentive program adopted

The Extraordinary General Meeting on February 16, 2011 adopted a long-term incentive program for 2011/2021 for senior executives.

# Key events after the close of the period

#### Abstral launched and available in the US

In early April, Orexo's partner ProStrakan launched Abstral in the US. Royalty revenues due to inventory build-up in the US are estimated at MSEK 18.3.

#### Kyowa Hakko Kirin acquires ProStrakan

In February, Orexo's partner for Abstral in Japan, Kyowa Hakko Kirin, made an offer for the ProStrakan Group plc., which is Orexo's partner for Abstral in the US and Europe. The transaction was approved on April 21. Orexo's opinion is that we have a stronger partner for sales of Abstral as a result of this transaction.

#### Board structure decided by AGM

The Annual General Meeting on April 7, 2011 decided to re-elect Michael Shalmi, Staffan Lindstrand, Kjell Strandberg, Ray Hill and Bengt Samuelsson as members of the Board of Directors and Håkan Åström was re-elected as Chairman of the Board of Directors.

# Orexo announces preferential rights issue – see separate press release

Orexo announced that the Board of Directors had decided, subject to approval at an Extraordinary General Meeting, to implement a rights issue with preferential rights for existing shareholders and holders of the company's convertibles 2010/2015 – for more information, please see separate press release.

#### Robin Wright resigns as CFO

In April, Robin Wright announced that he would resign as CFO and leave the company at the end of April. The recruitment of a new CFO has commenced.

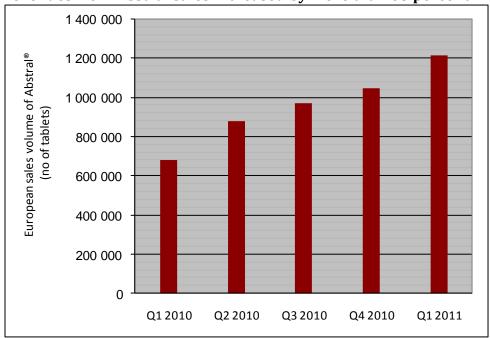
# Operations

# **Launched products**

Revenues from launched products rose 27 percent to MSEK 27.0 (21.3) during the first quarter of 2011.

Royalty revenues from Abstral® increased 65 percent to MSEK 14.0, compared with MSEK 8.5 for the corresponding period in the preceding year. Sales of the product rose 18 percent compared with the last quarter of 2010. This increase is mainly due to continued success in most European markets.





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

Royalty revenues from Edluar™ amounted to MSEK 0.7 for the period.

Sales for Diabact® UBT and Heliprobe® System amounted to MSEK 8.7 (9.9) for the period, which is weaker than expected. The main reason for the decline is that orders from a small number of large markets were postponed until the second quarter together with the negative exchange rate effect of MSEK 0.4.

Orexo's proportion of ProStrakan AB's sales rose 24 percent to MSEK 3.6 (2.9). Sales for Abstral through ProStrakan AB rose 53 percent to MSEK 2.6 (1.7).

#### **Collaborative projects**

Revenues from new and existing licensing agreements amounted to MSEK 7.4 (6.3) for the period. These comprise a recognized portion of the non-recurring upfront payment made by Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica NV (OMJ) and the upfront payment from the Invida Group Pte Limited of MSEK 0.9.

# **Proprietary development programs**

After a successful meeting with the US FDA in February, Orexo decided to continue developing the OX219 program. As part of this project, an application for permission to start the next major study is in preparation. The project is to compete in the market for opiate addiction, which is globally valued at

approximately USD 1.4 billion, predominantly in the US (app. USD 1 billion). The market is currently dominated by Suboxone (Reckitt Benckiser).

Positive clinical data were reported for OX51, a new sublingual formulation of an existing treatment of acute intensive pain episodes, some of which are not optimally treated today. The project has the potential to address a market with approximately 130 million pain episodes annually in the US and the EU.

The clinical study with OX27 for the treatment of breakthrough pain in cancer patients was completed and the results will be reported in the second quarter of 2011. The program relates to a fast-acting, sublingual formulation of an existing pharmaceutical that is designed for effective treatment of breakthrough pain episodes that can affect cancer patients.

The OX17 program is progressing in collaboration with partner Novartis. The partnership with OMJ concerning Orexo's arachidonic acid programs, OX-CLI and OX-ESI, is also developing well. The drug candidate that Boehringer Ingelheim selected in the OX-MPI program is being prepared for entry into the clinical phase.

# The period in figures

# **Summary of Consolidated Income Statement**

MSEK	3 months	3 months	12 months
	2011	2010	2010
	Jan-March	Jan-March	Jan-Dec
Net revenue	41.5	36.4	210.5
Costs of goods sold	-6.5	-6.4	-26.3
Gross profit	35.0	30.0	184.2
Selling expenses	-12.2	-7.4	-35.2
Administrative expenses	-12.2	-8.8	-46.8
Research and development costs	-47.4	-41.9	-186.9
Other operating income and expenses	0.2	1.3	3.0
Operating loss*	-36.6	-26.7	-81.7
Net financial items	-2.6	-0.9	-7.5
Loss after financial items	-39.2	-27.6	-89.2
Tax	0.0	0.0	0.0
Net loss for the period	-39.2	-27.6	-89.2

<sup>\*</sup> Includes the costs of employee stock options in the amount of MSEK 1.4 for the period January-March 2011 (MSEK 1.7 January to March 2010).

## Revenues

## Net revenue

Net revenues for January-March 2011 amounted to MSEK 41.5 (36.4). The increase was primarily due to higher royalty revenues from Abstral $^{\circ}$  and Edluar $^{\circ}$ .

# Net revenues were distributed as follows:

MSEK	Jan-March	Jan-March	Jan-Dec
	2011	2010	2010
Abstral - royalty	14.0	8.5	42.2
Edluar - royalty	0.7	-	1.3
ProStrakan AB J/V 50%	3.6	2.9	12.3
Diabact® UBT / Heliprobe® System	8.7	9.9	39.9
Total revenues from launched products	27.0	21.3	95.7
Partner-funded R&D costs	7.2	8.8	33.8
License revenues	7.4	6.3	81.1
Other	-0.1	-	-0.1
Total	41.5	36.4	210.5

## **Expenses and earnings**

#### Selling expenses

Selling expenses for the period January-March 2011 amounted to MSEK 12.2 (7.4). Selling expenses include business development expenses relating to the out-licensing of Orexo's projects, phase IV studies, operations in the subsidiary Kibion AB and joint venture company ProStrakan AB. Higher expenses were mainly due to the increased costs of the ongoing phase IV studies for Abstral, market-related activities for Orexo's project portfolio and increased selling expenses in Kibion AB and ProStrakan AB.

#### Administrative expenses

Administrative expenses for the period January-March 2011 amounted to MSEK 12.2 (8.8). The higher expenses were mainly due to the recruitment of a new CEO and for the implementation of a long-term incentive program 2011/2021 for senior executives.

#### Research and development costs

Research and development costs for the period January-March 2011 amounted to MSEK 47.4 (41.9), of which MSEK 7.2 (8.8) is covered by Orexo's partners, Novartis, Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica NV (OMJ). The higher costs were primarily due to activities in phase I studies relating to Orexo's proprietary programs.

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

The company's expenses for the employee stock options program for the first quarter totaled MSEK 1.4, excluding implementation costs, compared with MSEK 1.7 for the year-earlier period.

#### Other revenues and expenses

Other revenue and expenses for the period January-March 2011 comprise mainly exchange rate profits/ losses and totaled an expense of MSEK 0.2 (revenue: 1.3).

#### Depreciation/amortization

Depreciation/amortization for the period January-March 2011 amounted to MSEK 1.9 (2.0).

#### Net financial items

Net financial items for the period January-March 2011 totaled expenses of MSEK 2.6 (expense: 0.9). Net financial items include interest expenses of MSEK 2.9 relating to the convertible loan.

#### **Earnings**

Orexo posted an operating loss for the period January-March 2011 of MSEK 36.6 (loss: 26.7).

#### **Financial position**

Group cash and cash equivalents at March 31, 2011 amounted to MSEK 150.3 (50.4).

Cash flow from operating activities for the period January-March 2011 amounted to an inflow of MSEK 16.3 (outflow: 19.7).

Shareholders' equity at March 31, 2011 totaled MSEK 427.8 (519.2). The equity/assets ratio was 64 (87) percent.

Current financing is sufficient to pursue all projects in Orexo's development portfolio through clinical phase I, and also to take at least one of these projects through to approval, without further milestone payments from outlicensed research and development projects.

To pursue all three proprietary development programs through to launch, Orexo is now implementing a preferential rights issue. With regard to existing liquidity, Orexo deems that the working capital after the rights issue will be sufficient to meet working capital needs for at least the next 12 months.

#### **Investments**

Gross investments in tangible fixed assets for the period January-March 2011 totaled MSEK 1.9 (1.3).

#### **Seasonal variations**

Orexo's operations are not affected by seasonal variations. However, sales of pharmaceutical in new markets can be affected by inventory build-ups, particularly in the launching phase.

#### **Parent Company**

Most of the Group's business is carried out in the Parent Company, Orexo AB. Net revenues for the period January-March 2011 totaled MSEK 22.6 (24.7), with the loss after financial items amounting to MSEK 49.2 (loss: 24.3). Investments totaled MSEK 1.9 (1.3). Cash and cash equivalents in the Parent Company at March 31, 2011 totaled MSEK 48.4 (15.1), with current investments amounting to MSEK 0.0 (0.0).

# Significant risks and uncertainties

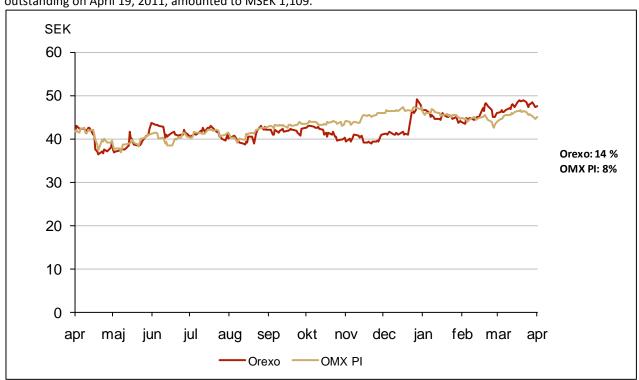
Significant risks and uncertainties are disclosed in the Annual Report 2010. Since the Annual Report was issued, no significant changes to the business risks and uncertainties have occurred.

#### Financial risks

Due to a milestone payment from Boehringer Ingelheim in relation to the OX-MPI project that was recognized as income in December 2010, Orexo's financial risks have been reduced slightly.

#### Share and market value

Orexo's share traded at SEK 47.40 on April 19, 2011. The company's market value, based on the number of shares outstanding on April 19, 2011, amounted to MSEK 1,109.



# **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**

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.

Uppsala, May 4, 2011

Orexo AB (publ)

Anders Lundström

**President and Chief Executive Officer** 

For further information, please contact:

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#### Orexo in brief

Orexo is a pharmaceutical company with focus on the therapeutic areas of pain and inflammation. Orexo has four products on the market, several significant partnerships and three proprietary development projects. Orexo's launched pharmaceuticals are Abstral<sup>™</sup>, for the treatment of breakthrough pain in cancer patients which is sold by Kyowa Hakko Kirin/ ProStrakan Group plc. in Europe and the US, insomnia treatment tablet Edluar<sup>™</sup> which is sold by Meda in the US, and two products Diabact<sup>®</sup> UBT / Heliprobe<sup>®</sup> System for diagnosing the gastric ulcer bacterium, Helicobacter pylori, through its subsidiary Kibion.

#### Objective, business concept and strategy

Revenues from launched pharmaceuticals and partnerships are enabling Orexo to build a portfolio of proprietary products, which are to be marketed and sold through its own organization in Europe or in the US. The objective is that Orexo will become a fully integrated specialist pharmaceutical company.

Existing partnerships are key strategic assets, from both a financial and competence perspective. Three of the out-licensed projects build on Orexo's knowledge in the arachidonic acid cascade. The aim is to develop completely new pharmaceuticals for the treatment of major diseases, including inflammatory pain and respiratory diseases such as asthma and COPD. Orexo's partners in this area are Boehringer Ingelheim, Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica NV (OMJ).

Within its three proprietary development projects, each of which is in the clinical phase, Orexo focuses on pain relief and anti-inflammatory pharmaceuticals with one program in opioid dependence. The company combines well-known substances with innovative drug-delivery technologies to create new patented pharmaceuticals that provide improved or new treatments. These pharmaceuticals can often be developed with lower risk and in shorter time spans than new drug molecules. Orexo also has partnerships in this area.

#### Business model

Orexo's business model is to create profitability through sales of launched products, through its own infrastructure or through partners, and through partnership and licensing agreements. Since 2010, Orexo has also focused on building a portfolio of proprietary pharmaceuticals that will be sold through its own organization in the EU or the US.

#### Orexo products and projects

Product/project	Indication
Abstral®	Breakthrough cancer pain
Edluar™	Insomnia
Diabact® UBT	Breath test, Helicobacter pylori
Heliprobe® System	Test, Helicobacter pylori
OX17	GERD (gastroesophageal reflux)
OX27	Breakthrough cancer pain
OX51	Acute intensive pain episodes
OX219	Opioid dependence
OX-NLA	Rhinitis
OX-MPI	Inflammatory pain
OX-CLI	Asthma/KOL

# Review report

We have reviewed the appended report for the period January 1 to March 31, 2011 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 year-end 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, May 4, 2011 PricewaterhouseCoopers AB

Leonard Daun
Authorized Public Accountant

# Consolidated statement of operations

KSEK		3 months	3 months	12 months
	Notes	2011	2010	2010
		Jan–March	Jan–March	Jan–Dec
Net revenues		41,461	36,437	210,499
Cost of goods sold	2	-6,451	-6,400	-26,321
Gross profit		35,010	30,037	184,178
Selling expenses	2	-12,235	-7,439	-35,223
Administrative expenses	2	-12,233	-8,785	-46,819
Research and development costs	2	-47,419	-41,840	-186,914
Other operating income		1,763	2,048	7,746
Other operating expenses	2	-1,487	-709	-4,741
Operating loss		-36,601	-26,688	-81,773
Financial income		530	22	1,456
Financial expense		-3,081	-904	-8,942
Financial items – net		-2,551	-882	-7,486
Pre-tax loss		-39,152	-27,570	-89,259
Income tax		-9	5	13
Net loss for the period		-39,161	-27,565	-89,246
Loss for the period attributable to:				
Parent company shareholders		-39,161	-27,565	-89,246
Minority interests		-	-	-
Loss per share, attributable to Parent Company				
shareholders during the period (SEK per share):				
Loss per chare before dilution SEV		-1.67	-1.18	-3.81
Loss per share, before dilution, SEK Loss per share, after dilution, SEK		-1.67 -1.67	-1.18 -1.18	-3.81 -3.81
LOSS per Share, arter unution, SEN		-1.07	-1.10	-3.01

# Consolidated statement of comprehensive income

KSEK	3 months	3 months	12 months
	2011	2010	2010
	Jan-March	Jan–March	Jan–Dec
Net loss for the period	-39,161	-27,565	-89,246
Other comprehensive income			
Hedging of net investments			
Exchange-rate differences	-1,658	-2,559	-3,524
Other comprehensive income for the period, net after tax	-1,658	-2,559	-3,524
Total comprehensive income for the period	-40,819	-30,124	-92,770
Total comprehensive income attributable to:			
Parent Company's shareholders	-40,819	-30,124	-92,770

# **CHANGES IN CONSOLIDATED SHAREHOLDERS' EQUITY**

Attributable to the Parent Company's shareholders 1)

KSEK	Share capital	Other contribu- ted capital	Accumula- ted loss	Translation differences	Total	Total shareholders' equity
Opening balance, January 1, 2010	9,360	1,094,453	-549,907	-5,245	548,661	548,661
Total comprehensive income for the period	-	-	-27,565	-2,559	-30,124	-30,124
Employee stock options, vested amount	-	689	-	-	689	689
Closing balance, March 31, 2010	9,360	1,095,142	-577,472	-7,804	519,226	519,226
Opening balance, January 1, 2011	9,361	1,106,798	-639,153	-8,769	468,237	468,237
Total comprehensive income for the period	-	-	-39,161	-1,658	-40,819	-40,819
Employee stock options, vested amount		394	-	-	394	394
New issues	1	6	-	-	7	7
Closing balance, March 31, 2011	9,362	1,107,198	-678,314	-10,427	427,819	427,819

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

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KSEK	2011	2010	2010
ACCETC	Notes March 31	March 31	Dec. 31
ASSETS			
Fixed assets			
Tangible fixed assets	41,750	45,345	41,666
Goodwill	17,681	17,987	17,679
Acquired R&D	386,741	424,516	388,487
Other intangible fixed assets	1,065	1,769	1,251
Total fixed assets	447,237	489,617	449,083
Command assets			
Current assets	12.400	0.701	7.065
Inventories Accounts receivable and other	12,409	8,781	7,965
receivables	54,179	49,034	119,845
Tax receivables	150,320	50,432	135,798
Total current assets	216,908	108,247	236,608
Total cultent assets	210,508	100,247	230,008
Total assets	664,145	597,864	712,691
SHAREHOLDERS' EQUITY AND	3		
LIABILITIES			
Share capital	9,362	9,360	9,361
Capital contributions	1,107,198	1,095,142	1,106,798
Reserves	-678,314	-577,472	-639,153
Accumulated losses	-10,427	-7,804	-8,769
Total shareholders' equity	427,819	519,226	468,237
Long-term liabilities			
Provisions	1,143	12,187	1,112
Long-term liabilities, interest-bearing	90,975	-	94,421
Deferred tax liability	8,581	9,334	8,911
Total long-term liabilities	100,699	21,521	104,444
Current liabilities			
Current liabilities, non-interest-			
bearing*	126,735	57,117	130,531
Current liabilities, interest-bearing	8,892	-	9,479
	-,		5,115
Total liabilities	236,326	78,638	244,454
Total shareholders' equity	664,145	597,864	712,691
and liabilities			

<sup>\*</sup> Include advance payment of MSEK 56.2 from the OX-CLI cooperation.

# Consolidated cash-flow statements

KSEK		3 months	3 months	12 months
	Notes	2011	2010	2010
		Jan-March	Jan-March	Jan-Dec
Operations				
Operating loss before interest		-36,601	-26,688	-81,773
expense and interest income				
Interest income		530	22	550
Interest expense		-2,393	-198	-8,942
Other financial expenses		-	-706	906
Adjustment for non-cash items	4	2,643	3,632	39,825
Cash flow from operations before changes		-35,821	-23,938	-49,434
Change in working capital				
Accounts receivable		66,675	4,260	-67,453
Other current receivables		-1,099	7,373	8,275
Inventories		-4,444	-341	475
Current liabilities		-5,375	-7,644	65,751
Provisions		31	1,073	299
Long-term liabilities		-3,776	-457	-880
Cash flow from operations		16,281	-19,674	-42,967
Investing activities				
Acquisition of machinery and		-1,873	-1,331	-3,438
equipment  Cash flow after investments		14,408	-21,005	-46,405
Cash now after investments		14,406	-21,003	-40,403
Change in financing				
New share issue		7	-	44
Proceeds from the issue of		-	-	111,150
convertible debentures				
Amortization of loans		-	-12,800	-16,000
Cash flow after financing activities		14,415	-33,805	48,789

KSEK		3 months	3 months	12 months
	Notes	2011	2010	2010
		Jan-March	Jan-March	Jan-Dec
Cash flow for the year				
Cash and cash equivalents, beginning of period		135,798	87,414	87,414
Exchange-rate differences in cash and cash		107	-3,177	-405
equivalents				
Changes in cash and cash equivalents		14,415	-33,805	48,789
Cash and cash equivalents, close of period		150,320	50,432	135,798

# Key figures

	3 months	3 months	12 months
	2011	2010	2010
	Jan-March	Jan-March	Jan-Dec
Operating margin, %	-88	-73	-39
Profit margin, %	-94	-76	-42
Return on total capital, %	-5	-4	-12
Return on equity, %	-9	-5	-18
Return on capital employed, %	-6	-5	-14
Debt/equity ratio, multiple	23	0	22
Equity/assets ratio, %	64	87	66
Current ratio, %	160	189	188
Acid ratio, %	151	174	183
Average number of shares, before dilution	23,404,002	23,401,252	23,402,502
Average number of shares, after dilution	25,969,453	23,584,321	25,500,884
Number of shares, after full dilution	27,102,005	24,392,275	26,609,081
Number of shares, before dilution	23,404,502	23,401,252	23,403,752
Number of shares, after dilution	26,007,052	23,584,321	25,943,070
Earnings/loss per share, before dilution, SEK	-1.67	-1.18	-3.81
Earnings/loss per share, after dilution, SEK	-1.67	-1.18	-3.81
Shareholders' equity per share before	18.28	22.19	20.01
dilution, SEK			
Shareholders' equity per share after	16.47	22.02	18.05
dilution, SEK			
Number of employees at close of period	106	103	105
Average number of employees	105	104	105
Shareholders' equity	427,819	519,226	468,237
Capital employed	527,686	519,226	572,137

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

# Parent company statement of operations

KSEK	3 mon 20 Notes Jan–Ma	2010	12 months 2010 Jan-Dec
Net revenues	22,5	24,672	112,951
Cost of goods sold		-	-
Gross profit	22,5	24,672	112,951
C. III	6.5		46 522
Selling expenses	-6,5	•	-16,533
Administrative expenses	-18,6	•	-61,605
Research & development costs	-43,7	•	-147,046
Other operating income		981	4,136
Other operating expenses		-287	-1,347
Operating loss	-45,8	-23,808	-109,444
Earnings from financial			
investments			
Financial income		9	506
Financial expense	-3,6		-9,399
Other financial income		295	-295
Loss after financial items	-49,2	-24,291	-118,632
Тах		-	-
Loss for the period	-49,2	-24,291	-118,632

Parent company balance sheet				
KSEK	Notes	2011 March 31	2010 March 31	2010 Dec. 31
ASSETS				
Fixed assets				
Tangible fixed assets		41,686	45,112	41,566
Intangible fixed assets		181	327	218
Shares in subsidiaries/joint ventures		604,763	606,414	604,763
Total fixed assets		646,630	651,853	646,547
Current assets				
Inventories		5,923	1,651	2,529
Accounts receivable and other receivables		102,951	34,433	133,986
Cash and bank balances		48,406	15,098	101,400
Total current assets		157,280	51,182	237,915
Total assets		803,910	703,035	884,462
SHAREHOLDERS' EQUITY, PROVISIONS & AND LIABILITIES	5			
Restricted equity		300,113	300,111	300,112
Non-restricted equity		191,590	323,344	240,414
Total shareholders' equity		491,703	623,455	540,526
Long-term liabilities				
Provisions		1,165	1,475	1,135
Borrowings		90,975	-	94,421
Total long-term liabilities		92,140	1,475	95,556
Current liabilities, non-interest-bearing		121,786	78,105	238,901
Current liabilities, interest-bearing		8,892	-	9,479
Total current liabilities		130,678	78,105	248,380
Total liabilities		222,818	79,580	343,936
Total shareholders' equity and liabilities		803,910	703,035	884,462
Pledged assets		44,000	44,000	44,000
Contingent liabilities		1,000	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 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.

#### New and amended accounting policies as of 2011

• No new or amended 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

	2011	2010	2010
	Jan-Mar	Jan-Mar	Jan-Dec
Raw materials and supplies	8,781	8,611	35,306
Other external costs	41,881	27,275	114,821
Personnel costs	27,219	27,336	116,126
Depreciation and impairment	1,945	1,950	33,764
TOTAL	79,826	65,172	300,017

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

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.

The number of shares outstanding increased through the exercise of employee stock options; see table below. At March 31, 2011, these shares had not been registered at Euroclear.

Number of shares outstanding at January 1, 2011	23,403,752
Subscription of shares through exercise of employee stock options	750
Number of shares outstanding at March 31, 2011	23,404,502

#### **Options**

At March 31, 2011, a total of 3,040,759 options were outstanding that carry rights to new subscription of 2,870,661 shares in Orexo and to be exchanged for 170,098 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, 2011 through March 31, 2011 distributed by category.

Employee-related options	Opening Jan 1, 2011	Change	Closing, Mar 31, 2011
Of which:	710 566		710 566
Decided and allocated employee stock options	719,566	- 7,075	719,566 -7,075
Expired  Exercised		- 7,075 -750	-7,075 -750
Allotted		500,000	500,000
Total		300,000	1,211,741
rotar			
Decided and allotted Board options	60,920		60,920
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
Decided at EGM in 2011		1,040,000	1,040,000
Total			1,510,000
Warrants held by subsidiaries as cash-flow hedging	70.000		70,000
for social security fees	78,000		78,000
Total			78,000
Total options to employees	1,338,486	1,532,175	2,870,661
Employee stock options utilized from Biolipox AB (no dilution effect, included in newly issued shares in conjunction with acquisition	117,582		117,582
of Biolipox) Expired	117,562	-3,267	-3,267
Exercised		-1,890	-1,890
		,	,
Warrants utilized from Biolipox AB for cash-flow hedging of social security fees (no dilution effect)	61,873	-4,200	57,673
Total options from Biolipox	179,455	-9,357	170,098
Total options to employees	1,517,941	1,522,818	3,040,759

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-March 2011, a total of 750 employee stock options from Orexo's options program were exercised. During the period January-March 2011, a total of 1,890 of Biolipox' employee stock options were exercised, entailing that holders exercised their options in exchange for 1,890 shares held by the independent company Pyrinox AB. This exercise did not entail the issue of any new shares by Orexo.

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 in March

During 2011, Orexo introduced a performance-based, long-term incentive program that prior to exercise comprises performance shares that provide entitlement to subscription of a total of 1,540,000 Orexo shares. A condition for entitlement to acquire new shares through the exercise of performance shares is that each employee fulfills certain vesting conditions. Of the total number of performance shares allotted, 50 percent are vested on the basis of time and internal operational goals ("time-based performance shares") and 50 percent is based on the share-price trend and the relative share performance ("share-price based performance shares"). Of these performance shares, 500,000 performance shares, of which 250,000 are time-based and 250,000 share-price based performance shares, were allotted free of charge to the President on March 7, 2011. The subscription price for the performance shares providing entitlement to subscription of 500,000 shares and that were allotted in March 2011 has been set at SEK 44.4. The final date for exercising the option is December 31, 2021.

#### New program resolved by the Annual General Meeting

The Annual General Meeting also resolved to adopt a new Board of Directors' shareholder program comprising the issuance of not more than 24,000 warrants and approval of control over the warrants within the framework of ramen the Board of Directors' shareholder program. Members of the Board who participate in Orexo's Board of Directors' shareholder program will receive 50 percent of their director fee and any fee for committee work in cash and will be allotted Board of Directors' shares up to a total that on the allotment date corresponds to a value of 50 percent of the director fee and any fee for committee work. A condition for entitlement to acquire new shares under the Board of Directors' shareholder program is that the Member of the Board remains on the Board of Directors throughout his or her elected period in office. It will be possible to exercise each Board of Directors' share for the acquisition of one Orexo share in return for payment of a redemption amount set at the quotient value of the Orexo share.

#### 4. Cash flow

#### Adjustment for non-cash items

KSEK	2011	2010	2010
	Jan-Mar	Jan-Mar	Jan-Dec
Depreciation/amortization and impairment	1,945	1,950	33,764
Estimated costs for employee stock options	1,386	1,682	3,309
program			
Financial expenses, convertible bond	-688	-	2,752
Total	2,643	3,632	39,825

## 5. Shareholders' Equity

# Change in the Parent Company's shareholders' equity

KSEK	2011 Jan-Mar	2010 Jan-Mar	2010 Jan-Dec
Opening shareholders' equity, balance sheet	540,526	647,140	647,140
Net loss for the period Subscription for shares through the exercise of warrants	-49,225 7	-24,291 -	-118,632 44
Employee stock options, vested value for employees	395	606	1,969
Convertible bond – equity share	-	-	10,005
Closing amount	491,703	623,455	540,526

# 6. Pledged assets and contingent liabilities

During 2010, the Inflazyme project was discontinued, which entailed that the entire supplementary purchase consideration is recognized as a contingent liability of MSEK 43.9.

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.

### **Glossary**

#### **Arachidonic Acid**

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

#### Breakthrough pain

Short-lived and intense pain that occurs in addition to the otherwise well-controlled, long-term pain that is treated with opioid analgesics.

#### **Clinical studies**

Studies of a drug's effect and safety in humans.

#### COPD

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

#### **Drug delivery**

The process through which a pharmaceutical receives the composition and form that enables the active compound to function in an optimal way.

#### **Fentanyl**

An opioid with similar effects on living organisms as morphine but with less hypnotic activity. Used mainly within anesthesia and analgesia.

#### Helicobacter pylori

A bacterium that infects the mucous membrane of the stomach.

#### **Opioid analgesics**

Pain-killing opioids.

#### **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 dosages. Performed on a limited number of patients.

#### **Phase III studies**

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

#### Preclinical development/preclinical studies

Studies of a drug's effect and safety before being evaluated in humans. Can be performed on animals or in various cell systems.

#### Sublingual

Beneath the tongue.

#### Transmucosal

Administered through, or across, a mucous membrane.

# **Definitions of key figures**

Key figures and certain other operating information per share are defined as follows:

Acid test ratio, % Current assets excluding inventories as a percentage of current liabilities.

Average number of employees Average number of full-year employees for the period.

Capital turnover rate Net revenues divided by average operating capital.

Capital employed Interest-bearing liabilities and shareholders' equity.

Current ratio Current assets as a percentage of current liabilities.

Debt/equity ratio Interest-bearing liabilities divided by shareholders' equity.

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

after dilution during the period.

Earnings per share before dilution

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

before dilution during the period.

Equity/assets ratio Shareholders' equity as a percentage of total assets.

Gross margin Gross profit divided by net revenues.

Interest coverage ratio

Profit/loss after net financial items plus interest expenses and similar items, divided by

expenses and similar items.

Net interest-bearing liabilities

Current and long-term interest-bearing liabilities including pension liabilities, less cash

and cash equivalents.

Number of shares after dilution Calculation of dilution from options issued by the company up to and including 2005,

carried out in accordance with IAS 33.

Number of shares after full dilution Total number of shares plus the maximum number of shares that can be subscribed

through options outstanding.

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

Operating margin Operating profit/loss as a percentage of net revenues.

Profit margin Profit/loss after net financial items.

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

employed.

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

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

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

after dilution end of the period.

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

before dilution end of the period.

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

#### Note

Orexo AB publ. discloses the information provided herein pursuant to the Securities Markets Act. The information was provided for public release on May 4, 2011, at 7:15 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.