

References made in this interim report pertain to the Group unless otherwise stated. Figures in parentheses relate to the corresponding year-earlier period.

OREXO'S PROPRIETARY DEVELOPMENT PROGRAMS ADVANCE

For the period

- Net revenues totaled to MSEK 142.9 (101.4).
- Loss after tax was MSEK 121.0 (loss: 91.4).
- Cash flow from operating activities showed a loss of MSEK 70.3 (loss: 13.7).
- Loss per share was SEK 4.61 (loss: 3.90).
- Cash and cash equivalents at the end of the period totaled MSEK 294.3 compared with MSEK 135.8 at year end.
- Royalty revenues from Abstral® sales rose to MSEK 51.3 (30.3).
- Completion of a new share issue amounting to some MSEK 245 before transaction costs. ATP and Abingworth became new shareholders and Novo A/S is the largest shareholder.
- A Phase I study of OX219 for the treatment of opioid dependence showed positive results.
- Positive data from the first clinical study of OX27 for the treatment of breakthrough pain in cancer patients.
- The insomnia-treatment Sublinox (Edluar), licensed to Meda, was approved for sales in Canada.
- Wagner Analysen Technik GmbH in Germany was acquired through the subsidiary Kibion AB.
- The management group was strengthened by the recruitment of a new Chief Financial Officer and Chief Commercial Officer.

Following the period

- A Chief Scientific Officer was appointed.

Third quarter

- Net revenues totaled MSEK 46.2 (35.9).
- Cash flow from operating activities was a negative MSEK 39.1 (neg: 25.0).
- Loss after tax was MSEK 55.9 (loss: 28.5).
- Loss per share was SEK 1.87 (loss: 1.22).

Key figures

MSEK	3 months 2011 Jul-Sep	3 months 2010 Jul-Sep	9 months 2011 Jan-Sep	9 months 2010 Jan-Sep	12 months 2010 Jan-Dec
Net revenues	46.2	35.9	142.9	101.4	210.5
Operating loss	-61.3	-25.8	-121.5	-84.5	-81.7
Net loss for the period	-55.9	-28.5	-121.0	-91.4	-89.2
Earnings/loss per share, SEK	-1.87	-1.22	-4.61	-3.90	-3.81
Cash flow from operating activities	-39.1	-25.0	-70.3	-13.7	-43.0
Cash and cash equivalents	294.3	165.6	294.3	165.6	135.8

Teleconference

CEO Anders Lundström and CFO Carl-Johan Blomberg will present the report at a teleconference today at 10:00 a.m. CET.

Presentation slides are available by link and on the website. Internet: <http://livecast.se/stockontv/111109/orexo/>

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CEO's comments

"It is interesting to follow the strong sales growth of Abstral®. During the first nine months of the year, our royalty revenues from the pain product rose 69 percent to MSEK 51.3. The product continues to capture market shares in Europe and sales have increased by more than 60 percent year to date. In September, Abstral was launched in the Netherlands and it has also been approved for marketing in Russia, where our partner is preparing a launch in the coming year.

In the US, all fast-acting fentanyl products will be sold under REMS program from the end of the first quarter, 2012. Only then will Abstral compete on equal terms with other products, as it has so successfully done in Europe.

The development of our proprietary products is advancing at rapid pace. During the third quarter, we obtained positive results from a study of OX219 which is developed for the treatment of opioid dependence. The results have confirmed our commercial formulation and dose. Since our registration application may be based on data from an already approved drug, our clinical studies will not be as extensive. This is but one of the many advantages to our strategy of developing new patentable products based on existing successful therapies in clinical use.

Our two other proprietary programs are proceeding according to plan and during the fourth quarter, we are expecting data from our next study of OX27, which is being developed for breakthrough pain in cancer patients.

Orexo's new orientation towards becoming a specialty pharmaceutical company places new demands on our organization. The strengthening of the executive management is the next step in our strategy to create profitability focusing on our three proprietary programs. Consequently, during the third quarter, we recruited Peter Edman as Chief Scientific Officer and Nikolaj Sørensen as Chief Commercial Officer (CCO), both new key positions.

Peter Edman, with his solid scientific background and long experience from all the phases of drug development, is well-suited to shoulder the overall responsibility of Orexo's R&D. The position of CCO is also central, since Orexo's commercial operations will be expanded significantly.

Nikolaj Sørensen joins us from Pfizer, where he was responsible for the marketing and sales of a leading pain product in Europe and Canada. In addition, he has also been Managing Director for Pfizer in Sweden. To make the management team complete we also have a new highly-qualified CFO in place, Carl-Johan Blomberg, who is also responsible for Investor Relations and IT.

During the final quarter, we will continue the development of our proprietary development programs, both by clinical and commercial planning. Preparing a commercial launch is a substantial undertaking that spans several years and is established gradually, bringing Orexo closer to becoming a leading specialty pharmaceutical company, step-by-step."

Anders Lundström
President and CEO

Key events for the period

- **Positive data from OX219 study**

During the period, positive results were received from a Phase I study of OX219 for the treatment of opioid dependence. The study was designed to decide the commercial formulation and dose for the project. The selected formulation was based on Orexo's proprietary sublingual technology.

- **Positive clinical data for OX27**

In June, positive results were reported from the first pharmacokinetic study for the OX27 project, which is aimed at developing the treatment of breakthrough pain among cancer patients.

- **Sublinox (Edluar) approved in Canada**

In July, the insomnia-treatment Sublinox (Edluar) was approved for sale in Canada. Meda and its partner Valeant plan to launch the product during the fourth quarter of 2011. Orexo, which has developed the product, will have rights to sales royalties.

- **Acquisition of Wagner Analysen Technik GmbH (WAT)**

In July, the subsidiary Kibion AB acquired Wagner Analysen Technik GmbH (WAT), a leading manufacturer of IRIS instruments and substrates for diagnostic breath testing. The acquisition reinforces Kibion's operations and creates considerable opportunity for future growth, and consequently a unit with increased independence. The purchase consideration amounted to MEUR 1.2 and was financed entirely through a bank loan. A supplementary purchase consideration will be paid if a well-defined sales target is achieved. The acquisition is expected to contribute positively to Orexo's earnings within 12 months.

- **Completion of new share issue, strong shareholder base**

In July, Orexo announced a significant change of shareholders and a new number of shares as a result of the successfully completed new share issue of some MSEK 245.

The newcomer investors were Denmark's largest pension fund, Arbejdsmarkedets Tillægspension (ATP), and the specialized life-science investor, Abingworth. In addition, existing owner Novo A/S became the largest shareholder.

- **Orexo strengthens its commercial competences**

In September, Nikolaj Sørensen was appointed Chief Commercial Officer. Sørensen has extensive experience in the pharmaceutical industry and will be responsible for Orexo's commercial operations and the development of the company's commercial strategies.

- **New Chief Financial Officer recruited**

In September, Carl-Johan Blomberg was appointed the new CFO with responsibilities for the company's financial functions, IR and IT. Blomberg has a broad experience of many years in economic and financial functions related to a range of industries such as engineering, electronics and pharmaceuticals.

Key events following the close of the period

- **Chief Scientific Officer appointed**

Orexo appointed Peter Edman as Chief Scientific Officer. Edman brings with him many years of experience in all the phases of pharmaceutical development and a solid background in research. He was most recently at Sobi (Swedish Orphan Biovitrum) and will assume the position of CSO at Orexo on January 1, 2012.

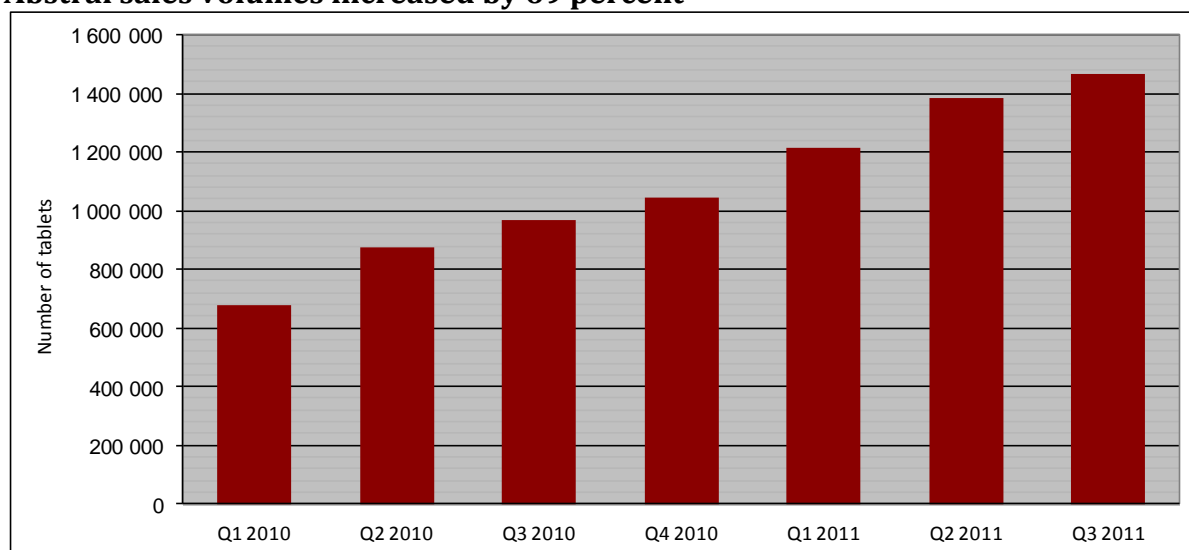
Operations

Products launched

Revenues from product sales rose 39 percent during the period January-September 2011 to MSEK 92.8 (67.0). Royalty revenues from Abstral® increased during the same period by 69 percent to MSEK 51.3 (30.3), compared with the year-earlier period. The sales growth for Abstral in Europe remained considerably strong and sales have increased by more than 60 percent during the January-September period. During the third quarter, sales in Europe increased 46 percent and consequently showed a similar pattern as the year-earlier period. The growth was strongest in Spain and France - the largest markets for fast-acting fentanyl products. In September, Abstral was launched in the Netherlands, Europe's seventh largest market for pharmaceuticals. During the period, Abstral, in partnership with Gedeon Richter, was approved in Russia and in partnership with NewBridge, was approved in Kuwait.

In April, Abstral was introduced in the US by Orexo's partner ProStrakan, which sells the product through pharmacies approved in accordance with the REMS (risk evaluation and mitigation strategy) system. Actiq and Fentora - the two market-leading products in the US—are not yet included in the REMS system, which means a significant competitive disadvantage for Abstral. Cephalon, which provides these products, has initiated the implementation of its own REMS system in October, which will be adopted during the first quarter of 2012. When a REMS system is adopted by all players in the market, they will compete on equal terms and; consequently, Abstral will be well-positioned.

Abstral sales volumes increased by 69 percent



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

Royalty revenues from Edluar™ amounted to MSEK 1.8 for the period.

During the third quarter, Kibion AB acquired Wagner Analysen Technik GmbH (WAT). Kibion's total third quarter sales of MSEK 8.2 (8.0) comprised those of WAT, which amounted to MSEK 1.7. During the quarter, Heliprobe® System was registered in Columbia, which is expected to lead to sales in 2012.

ProStrakan AB's sales rose by 41.9 percent during the period January-September 2011. Orexo's shares amounted to MSEK 12.2 (8.6). Sales of Abstral through ProStrakan AB rose 88.9 percent to MSEK 5.1 (2.7) during the same period.

Collaborative projects

Revenues from new and existing licensing agreements amounted to MSEK 26.2 (16.2) during the period January-September 2011. These comprise a recognized portion of the nonrecurring payment made by Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica NV (OMJ).

Refer to page 9 for information on partner-financed R&D costs in respect of collaborative projects.

Proprietary development programs

OX219

During the third quarter, positive results were received from a Phase I study of OX219 which is being developed for the treatment of opioid dependence. The study was designed to decide the commercial formulation and dose for OX219. Orexo complies with the 505 (b)(2) registration procedure, whereby the FDA's approval may be based on data from already approved drugs—in this case, the market-leading Suboxone®. This enables Orexo to obtain approval without costly clinical studies on effects and safety, and consequently creates a significantly faster route to market.

The selected formulation is based on Orexo's proprietary sublingual technology. The objective with OX219 is to create a new, patented drug for the treatment of opioid dependence. Orexo performs the clinical development of the product in the US, which is also the primary market for Suboxone, the current market-leading pharmaceutical preparation for the treatment of opioid dependence. The current global market for treatments of opiate dependence amounts to USD 1.4 billion and is estimated to reach USD 2.2 billion by 2019 (Datamonitor, 2010).

OX51

Positive clinical data was reported in March for OX51. This is a new sublingual formulation of an existing treatment for acute intensive pain episodes in conjunction with care-related, diagnostic or therapeutic procedures for patients who currently do not receive sufficient pain relief. The planning of the first patient study in the program will be completed during the second half of the year.

The project has the potential to address a market with an estimated 130 million pain episodes annually in the US and EU. A significant portion of such pain episodes is currently treated through the anesthetization of patients, which requires considerable healthcare resources. By managing these pain episodes more efficiently with OX51 and thereby reducing the need for anesthetization, a major potential market is created for the product.

OX27

The program involves a fast-acting sublingual formulation for an existing drug and is designed for optimal treatment of breakthrough pain episodes than can affect cancer patients. In June, positive results were reported from the initial pharmacokinetic study for the OX27 project. It indicated the ability of the active pharmaceutical ingredient to both be absorbed and eliminated quickly, which makes the product well-suited to such pain treatments. The subsequent clinical study was initiated in June and the results are expected during the fourth quarter of 2011.

The period in figures

Condensed consolidated income statement

MSEK	3 months 2011 Jul-Sep	3 months 2010 Jul-Sep	9 months 2011 Jan-Sep	9 months 2010 Jan-Sep	12 months 2010 Jan-Dec
Net revenues	46.2	35.9	142.9	101.4	210.5
Cost of goods sold	-5.5	-5.6	-18.8	-18.9	-26.3
Gross profit	40.8	30.3	124.1	82.5	184.2
Selling expenses	-10.7	-6.6	-34.3	-22.8	-35.2
Administrative expenses	-11.5	-17.4	-37.4	-36.7	-46.8
Research and development costs	-42.2	-31.3	-137.5	-109.4	-161.1
Other operating income and expenses*	-37.8	-0.8	-36.4	1.9	-22.8
Operating loss	-61.3	-25.8	-121.5	-84.5	-81.7
Net financial items	-1.5	-2.7	-6.5	-6.9	-7.5
Loss after financial items	-62.8	-28.5	-128.0	-91.4	-89.2
Tax	7.0	0.0	7.0	0.0	0.0
Net loss for the period	-55.9	-28.5	-121.0	-91.4	-89.2

* Includes a MSEK 38.7 (MSEK 1.7) impairment loss on previously acquired technology.

Revenues

Net revenues

Net revenues for January-September 2011 totaled MSEK 142.9 (101.4). The increase was primarily attributable to higher royalty revenues from Abstral® and higher licensing revenues from joint ventures.

During the period July-September 2011, net revenues totaled MSEK 46.2 (35.9).

Net revenues were distributed as follows:

<i>MSEK</i>	Jul-Sep 2011	Jul-Sep 2010	Jan-Sep 2011	Jan-Sep 2010	Jan-Dec 2010
Abstral royalties	17.7	10.8	51.3	30.3	42.2
Edluar royalties	0.5	0.4	1.8	0.4	1.3
ProStrakan AB J/V 50 %	4.6	2.7	12.2	8.6	12.3
Kibion	8.2	8.0	27.5	27.7	39.9
<i>Total revenues from products launched</i>	31.0	21.9	92.8	67.0	95.7
Partner-financed R&D costs	7.7	6.0	24.3	17.9	33.8
License revenues for development projects	7.9	7.8	26.2	16.2	81.1
Other	-0.4	0.0	-0.4	0.1	-0.1
Total	46.2	35.9	142.9	101.4	210.5

Expenses and earnings

Selling expenses

Selling expenses during January-September 2011 totaled MSEK 34.3 (22.8) and amounted to MSEK 10.7 (6.6) for the period July–September 2011. The increase was due mainly to higher costs for ongoing Phase IV studies for Abstral, market-support activities for Orexo's project portfolio and higher selling expenses in the subsidiary Kibion AB and in the joint venture, ProStrakan AB, as well as the costs in Kibion in conjunction with the acquisition of Wagner Analysen Technik GmbH.

Administrative expenses

Administrative expenses for January-September 2011 totaled MSEK 37.4 (36.7). These expenses were attributable to such costs as the recruitment of new senior executives, implementation of long-term incentive programs for the period 2011/2021 and legal costs relating to the company's patent portfolio. A Paragraph IV process is ongoing in the US, with the patent for Edluar being challenged. For the period of July–September, administrative expenses totaled MSEK 11.5 (17.4).

Research and development costs

Research and development costs for January-September 2011 totaled MSEK 137.5 (109.4), of which MSEK 24.3 (17.9) was covered by the business partners, Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica NV (OMJ). The increase pertained primarily to activities relating to Phase I studies for proprietary programs. For the period of July–September 2011, research-and-development costs amounted to MSEK 42.2 (31.3).

Expenses for the long-term incentive program

The Group's expenses for its employee stock options program for the period January-September 2011 totaled MSEK 2.2, excluding implementation costs, compared with MSEK 2.5 for the corresponding year-earlier period.

Other revenues and expenses

Other revenues and expenses amounted to an expense of MSEK 36.4 (revenue: 1.9) MSEK for the period January-September 2011. Other revenues and expenses comprise a MSEK 38.7 impairment loss on previously acquired technology based on the choice of formulation for the proprietary development project, OX219. The project is entirely attributable to PKX219, which was included in the acquisition of PharmaKodex. Other revenues and expenses consist primarily of exchange rate gains/losses. For the period July-September 2011, other revenues and expenses amounted to an expense of MSEK 37.8 (expense: 0.8).

Depreciation/amortization

Depreciation/amortization amounted to MSEK 5.9 (5.9) for the period January-September 2011 and to MSEK 2.0 (1.9) for July–September 2011.

Net financial items

Net financial items for the period January-September 2011 amounted to an expense of MSEK 6.5 (expense: 6.9). Net financial items primarily comprise interest expenses of MSEK 8.8 in respect of the convertible loan.

Income tax

The income tax amounted to MSEK 7.0 (0.0) for the period January-September 2011 and is entirely attributable to the recovery of deferred tax related to the impairment of acquired technology.

Earnings

The operating loss for the period January-September 2011 totaled MSEK 121.5 (loss: 84.5).

Financial position

As of September 30, 2011, cash and cash equivalents totaled MSEK 294.3 (165.6).

Cash flow from operating activities for the period January-September 2011 was a negative MSEK 70.3 (13.7). Cash flow for the period was positively affected by a nonrecurring payment of MSEK 56.3 from Boehringer Ingelheim, where revenue was recognized in 2010 but paid in 2011.

The new share issue completed during the third quarter has provided a total of MSEK 231.2 after issue costs.

Shareholders' equity as of September 30, 2011 amounted to MSEK 581.7 (466.2). The equity ratio was 72 (66) percent.

Investments

Gross investments in tangible fixed assets amounted to MSEK 4.7 (2.3) for the period January-September 2011 and MSEK 1.1 (0.2) for the period July-September 2011.

Seasonal variations

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

Parent Company

Most of the Group's business is carried out in the Parent Company, Orexo AB. Net revenue for the period January-September 2011 totaled MSEK 86.1 (61.5), and the loss after financial items was MSEK 162.0 (loss: 97.8). Investments totaled MSEK 4.7 (2.3). As of September 30, 2011, cash and cash equivalents in the Parent Company amounted to MSEK 273.6 (130.5).

During the period, shares of the subsidiary were reduced by MSEK 118.7. The reduction is partly attributable to the write-down of acquired technology and partly to the reduction of Biolipox AB's statutory reserve, which was repaid to the Parent Company.

Significant risks and uncertainties

Significant risks and uncertainties are disclosed in the 2010 Annual Report. Apart from the following, no significant changes in terms of business risks and uncertainties have occurred since the publication of Annual Report.

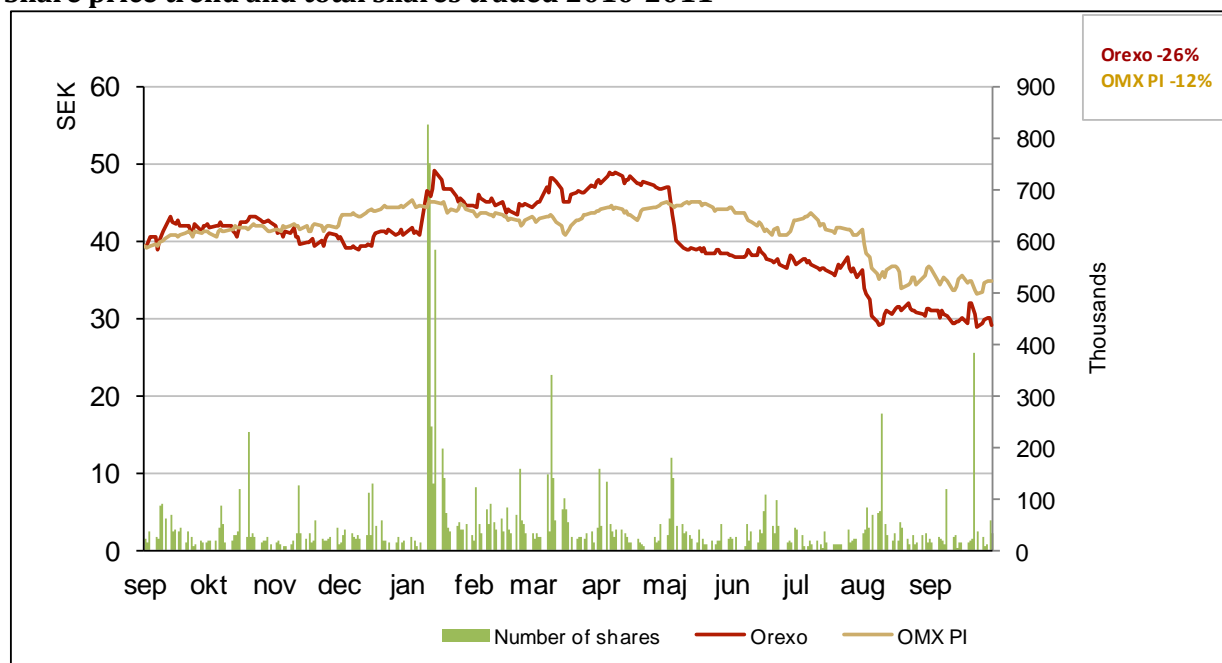
Financial risks

The successful completion of the rights issue during the period has reduced Orexo's financial risks.

Share and market value

Orexo's share traded at SEK 28.60 on September 30, 2011. The company's market capitalization, based on the number of shares outstanding on September 30, 2011, was MSEK 854.

Share price trend and total shares traded 2010-2011



Analysts covering Orexo

ABG Sundal Collier	Erik Hultgård
Carnegie	Camilla Oxhamre
Nordea	Olle Sjölin
Pharmium Securities	Frédéric Gomez
Redeye	Klas Palin and Peter Östling
Rodman & Renshaw	Michael Higgins
SEB Enskilda	Lars Hevren

Future reporting dates

Year-end report for fiscal year 2011	January 31, 2012
Annual General Meeting 2012	April 11, 2012, at 4:00 p.m.
Interim report January–March 2012	April 27, 2012
Interim report January–June 2012	July 12, 2012
Interim report January–September 2012	October 25, 2012
Year-end report for fiscal year 2012	January 31, 2013

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

Uppsala, November 9, 2011
Orexo AB (publ)

Anders Lundström
President and Chief Executive Officer

For further information, please contact:

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About Orexo

Orexo has four products on the market, several significant partnerships and three proprietary development projects. Orexo's launched pharmaceuticals are Abstral™, 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 tablet Edluar™ which is sold by Meda in the US, and two products, Diabact® UBT/Heliprobe® System, for diagnosing the gastric ulcer bacterium, *Helicobacter pylori*, through its subsidiary Kibion.

Objective, business concept and strategy

Orexo's objective is to build a portfolio of proprietary products, which are to be marketed and sold through the company's own organization in Europe or in the US. The objective is that Orexo will become a profitable and fully integrated specialist pharmaceutical company.

In its proprietary development projects and throughout all clinical phases, Orexo focuses not only on pain relief and anti-inflammatory pharmaceuticals, but also on the treatment of 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 at lower risk and in shorter time spans than new drug molecules. Orexo also has partnerships in this area.

Existing partnerships are key strategic assets, from both a financial and competence perspective. Three of the out-licensed projects are based on Orexo's knowledge in the arachidonic acid cascade. The aim is to develop completely new drugs 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).

Orexo product and project portfolio

Product/project	Indication
Abstral®	Breakthrough pain in cancer patients
Edluar™	Sleeping disorders
Diabact® UBT	Exhalation test, <i>Helicobacter pylori</i>
Heliprobe® System	Test, <i>Helicobacter pylori</i>
OX17	GERD (gastroesophageal reflux)
OX27	Breakthrough pain in cancer patients
OX51	Acute intense pain episodes
OX219	Opioid dependence
OX-NLA	Rhinitis
OX-MPI	Inflammatory pain
OX-CLI	Asthma/COPD

Review report

We have reviewed the appended report for the period January 1 to September 30, 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. 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 9, 2011

PricewaterhouseCoopers AB

Leonard Daun
Authorized Public Accountant

Consolidated statement of operations

KSEK	Notes	3 months 2011 Jul-Sep	3 months 2010 Jul-Sep	9 months 2011 Jan-Sep	9 months 2010 Jan-Sep	12 months 2010 Jan-Dec
Net revenues		46,225	35,854	142,888	101,362	210,499
Costs of goods sold	2	-5,475	-5,577	-18,810	-18,858	-26,321
Gross profit		40,750	30,277	124,078	82,504	184,178
Selling expenses	2	-10,698	-6,607	-34,294	-22,824	-35,223
Administrative expenses	2	-11,434	-17,394	-37,369	-36,667	-46,819
Research and development costs	2	-42,151	-31,268	-137,533	109,438	-161,120
Other operating income		2,213	2,521	5,606	6,445	7,746
Other operating expenses	2	-40,020	-3,339	-42,016	-4,535	-30,535
Operating loss		-61,340	-25,810	-121,528	-84,515	-81,773
Financial income		1,805	200	2,755	264	1,456
Financial expense		-3,274	-2,902	-9,216	-7,139	-8,942
Financial items, net		-1,469	-2,702	-6,461	-6,875	-7,486
Pre-tax loss		-62,809	-28,512	-127,989	-91,390	-89,259
Income tax		6,935	9	6,967	14	13
Net loss for the period		-55,874	-28,503	-121,022	-91,376	-89,246
Loss for the period attributable to:						
Parent Company shareholders		-55,874	-28,503	-121,022	-91,376	-89,246
Non-controlling interests		-	-	-	-	-
Loss per share, attributable to Parent Company shareholders during the period (SEK per share):						
Loss per share, before dilution, SEK		-1.87	-1.22	-4.61	-3.90	-3.81
Loss per share, after dilution, SEK		-1.87	-1.22	-4.61	-3.90	-3.81

Consolidated statement of comprehensive income

KSEK	3 months 2011 Jul-Sep	3 months 2010 Jul-Sep	9 months 2011 Jan-Sep	9 months 2010 Jan-Sep	12 months 2010 Jan-Dec
Net loss for the period	-55,874	-28,503	-121,022	-91,376	-89,246
Other comprehensive income					
Exchange-rate differences	1,760	-2,465	-34	-2,972	-3,524
Other comprehensive income/loss for the period, net after tax	1,760	-2,465	-34	-2,972	-3,524
Total comprehensive income/loss for the period	-54,114	-30,968	-121,056	-94,348	-92,770
Total comprehensive income/loss attributable to:					
Parent Company shareholders	-54,114	-30,968	-121,056	-94,348	-92,770

CHANGES IN CONSOLIDATED SHAREHOLDERS' EQUITY

Attributable to Parent Company shareholders ¹⁾

KSEK	Share capital	Other contributed capital	Accumulated loss	Translation differences	Total	Total share- holders' equity
Opening balance, January 1, 2010	9,360	1,094,453	-549,907	-5,245	548,661	548,661
Total comprehensive income/loss for the period	-	-	-91,376	-2,972	-94,348	-94,348
Employee stock options, vested amount	-	1,823	-	-	1,823	1,823
Debenture loan – equity portion	-	10,005	-	-	10,005	10,005
New share issues	1	43	-	-	44	44
Closing balance, September 30, 2010	9,361	1,106,324	-641,283	-8,217	466,185	466,185
Opening balance, January 1, 2011	9,361	1,106,798	-639,153	-8,769	468,237	468,237
Total comprehensive income for the period	-	-	-121,022	-34	-121,056	-121,056
Employee stock options, vested amount	-	3,124	-	-	3,124	3,124
New share issues	2,579	228,820	-	-	231,399	231,399
Closing balance, September 30, 2011	11,940	1,338,742	-760,175	-8,803	581,704	581,704

¹⁾ There are no non-controlling interests.

Consolidated balance sheet

KSEK	Notes	2011 Sep 30	2010 Sep 30	2010 Dec 31
ASSETS				
Fixed assets				
Tangible fixed assets		40,592	42,602	41,666
Goodwill	7	33,806	17,800	17,679
Acquired research and development		349,111	423,332	388,487
Other intangible fixed assets		895	1,420	1,251
Total fixed assets		424,404	484,154	449,083
Current assets				
Inventories		18,319	9,577	7,965
Accounts receivable and other receivables		76,297	48,870	119,845
Cash and cash equivalents		294,340	165,645	135,798
Total current assets		388,956	224,092	236,608
Total assets		813,360	708,246	712,691
SHAREHOLDERS' EQUITY AND LIABILITIES				
	3			
Share capital		11,940	9,361	9,361
Other capital contributions		1,338,742	1,106,324	1,106,798
Accumulated losses		-760,175	-641,283	-639,153
Translation differences		-8,803	-8,217	-8,769
Total shareholders' equity		581,704	466,185	468,237
Long-term liabilities				
Provisions		4,974	10,798	1,112
Long-term liabilities, interest-bearing		107,510	91,510	94,421
Deferred tax liability		1,806	9,036	8,911
Total long-term liabilities		114,290	111,344	104,444
Current liabilities				
Current liabilities, non-interest-bearing*		106,052	121,238	130,531
Current liabilities, interest-bearing		11,314	9,479	9,479
Total liabilities		231,656	242,061	244,454
Total shareholders' equity and liabilities		813,360	708,246	712,691

* Including advance payment of MSEK 43.2 from the OX-CLI cooperation.

Consolidated cash-flow statements

KSEK	Note	2011 Jul-Sep	2010 Jul-Sep	2011 Jan-Sep	2010 Jan-Sep	2010 Jan-Dec
Operating activities						
Operating loss before interest expense and interest income		-61,340	-25,810	-121,528	-84,515	-81,773
Interest income		1,805	200	2,755	264	550
Interest expense		-2,305	-2,902	-6,928	-6,030	-8,942
Other financial expenses		-138	-	-138	-1,109	906
Adjustment for non-cash items	4	40,722	7,156	44,664	9,890	39,825
Cash flow from operating activities before changes in working capital		-21,256	-21,356	-81,175	-81,500	-49,434
Changes in working capital						
Accounts receivable		-5,847	6,461	50,752	2,760	-67,453
Other current receivables		4,393	19,446	831	9,037	8,275
Inventories		-5,877	-2,050	-9,777	-1,137	475
Current liabilities		-14,708	-25,284	-33,816	58,191	65,751
Provisions		4	-1,288	-503	-316	299
Long-term provisions		4,216	-881	3,400	-755	-880
Cash flow from operating activities		-39,075	-24,952	-70,288	-13,720	-42,967
Investing activities						
Acquisition of machinery and equipment		-1,050	-170	-4,680	-2,286	-3,438
Acquisition of subsidiaries		-10,298	-	-10,298	-	-
Cash flow after investments		-50,423	-25,122	-85,266	-16,006	-46,405
Change in financing						
New issue		102,041	44	244,808	44	44
Issue expenses		-11,334	-	-12,798	-	-
Proceeds from the issue of convertible debentures		-	-	-	111,150	111,150
Amortization of loans		-	-	-	-16,000	-16,000
Loans raised		11,743	-	11,743	-	-
Cash flow after financing		52,027	-25,078	158,487	79,188	48,789
Cash flow for the year						
Cash and cash equivalents at the beginning of the period		242,497	190,853	135,798	87,414	87,414
Exchange-rate differences in cash and cash equivalents		-184	-130	55	-957	-405
Changes in cash and cash equivalents		52,027	-25,078	158,487	79,188	48,789
Cash and cash equivalents at the end of the period		294,340	165,645	294,340	165,645	135,798

Key figures

	3 months 2011 Jul-Sep	3 months 2010 Jul-Sep	9 months 2011 Jan-Sep	9 months 2010 Jan-Sep	12 months 2010 Jan-Dec
Operating margin, %	-133	-72	-85	-83	-39
Profit margin, %	-136	-80	-90	-90	-42
Return on total capital, %	-7	-4	-16	-12	-12
Return on equity, %	-9	-6	-24	-18	-18
Return on capital employed, %	-8	-5	-19	-15	-14
Debt/equity ratio, %	20	22	20	22	22
Equity/assets ratio, %	72	66	72	66	66
Current ratio, %	331	171	331	171	188
Acid ratio, %	316	164	316	164	183
Average number of shares, before dilution	29,850,940	23,403,752	26,269,419	23,402,085	23,402,502
Average number of shares, after dilution	32,380,626	25,942,413	28,818,593	25,353,390	25,500,884
Number of shares, after full dilution	33,647,834	26,610,080	33,647,834	26,610,080	26,609,081
Number of shares, before dilution	29,850,940	23,403,752	29,850,940	23,403,752	23,403,752
Number of shares, after dilution	32,373,345	25,945,232	32,373,345	25,945,232	25,943,070
Loss per share, before dilution, SEK	-1.87	-1.22	-4.61	-3.90	-3.81
Loss per share, after dilution, SEK	-1.87	-1.22	-4.61	-3.90	-3.81
Shareholders' equity per share, before dilution, SEK	19.49	19.92	19.49	19.92	20.01
Shareholders' equity per share, after dilution, SEK	17.97	17.97	17.97	17.97	18.05
Number of employees at the end of the period	108	106	108	106	105
Average number of employees	108	105	106	105	105
Shareholders' equity, KSEK	581,704	466,185	581,704	466,185	468,237
Capital employed, KSEK	699,591	567,174	699,591	567,174	572,137

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

Share-related key figures have been calculated retroactively based on the so-called bond issue element in the implemented preferential issue in June 2011.

Parent Company statement of operations

KSEK		3 months	3 months	9 months	9 months	12 months
		2011	2010	2011	2010	2010
	Notes	Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Dec
Net revenues		28,310	21,637	86,125	61,508	112,951
Cost of goods sold		-	-	-	-	-
Gross profit		28,310	21,637	86,125	61,508	112,951
Selling expenses		-4,564	-1,480	-16,161	-11,387	-16,533
Administrative expenses		-18,060	-24,003	-57,095	-44,904	-61,605
Research and development costs		-39,277	-30,527	-128,733	-97,400	-145,395
Other operating income		618	888	2,304	3,214	4,136
Other operating expenses		-39,300	-2,021	-39,817	-2,571	-2,998
Operating loss		-72,273	-35,506	-153,377	-91,540	-109,444
Earnings from financial investments						
Interest income		1,675	192	2,142	224	506
Interest expense		-3,659	-2,983	-10,764	-6,163	-9,399
Other financial costs		-	-	-	-295	-295
Loss after financial items		-74,257	-38,297	-161,999	-97,774	-118,632
Tax		-	-	-	-	-
Loss for the period		-74,257	-38,297	-161,999	-97,774	-118,632

Parent Company balance sheet

KSEK	Notes	2011 Sep 30	2010 Sep 30	2010 Dec 31
ASSETS				
Fixed assets				
Tangible fixed assets		40,367	42,465	41,566
Intangible fixed assets		108	254	218
Shares in subsidiaries/joint ventures		486,033	604,763	604,763
Total fixed assets		526,508	647,482	646,547
Current assets				
Inventories		6,912	2,734	2,529
Accounts receivable and other receivables		101,316	113,162	133,986
Cash and bank balances		273,590	130,525	101,400
Total current assets		381,818	246,421	237,915
Total assets		908,326	893,903	884,462
SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES				
	5			
Restricted equity		302,691	300,112	300,112
Non-restricted equity		310,359	260,878	240,414
Total shareholders' equity		613,050	560,990	540,526
Long-term liabilities				
Provisions		609	929	1,135
Loans		96,884	91,510	94,421
Total long-term liabilities		97,493	92,439	95,556
Current liabilities, non-interest-bearing		188,891	230,995	238,901
Current liabilities, interest-bearing		8,892	9,479	9,479
Total current liabilities		197,783	240,474	248,380
Total liabilities		295,276	332,913	343,936
Total shareholders' equity and liabilities		908,326	893,903	884,462
Pledged assets		44,000	16,000	44,000
Contingent liabilities		13,111	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, (Swedish Financial Accounting Standards Council's recommendation) and Chapter 9 of the Swedish Annual Accounts Act.
- The classification of impairment losses for acquired research and development has been amended since earlier reports. Such impairment is now recognized under Other Costs instead of Research and Development Costs as in previous reports. Comparative historical figures have been restated in accordance with the new classification. Changes for the Group were MSEK 1.6 for the period January-September 2010 and MSEK 25.8 for the period January-September 2010.

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	2011	2010	2010
	Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Dec
Raw materials and supplies	7,779	8,570	27,031	25,744	35,306
Other external costs	34,644	21,531	115,367	71,644	114,821
Personnel costs	26,662	30,534	83,004	87,429	116,126
Depreciation/amortization and impairment	40,693	3,548	44,621	7,504	33,764
TOTAL	109,778	64,183	270,023	192,321	300,017

Research and development costs encompass costs for personnel, 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 as of September 30, 2011 was 29,850,940, all of which were common shares. All shares carry entitlement to one vote each.

Number of shares outstanding at January 1, 2011	23,403,752
Subscription of shares through exercise of employee stock options	9,000
New issue	6,438,188
Number of shares outstanding at September 30, 2011	29,850,940

Options

As of September 30, 2011, a total of 2,399,234 options were outstanding that carry rights to new subscription of 2,255,052 shares in Orexo and the exchanged of 144,182 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 to September 30, 2011, distributed by category.

Employee-related options	Opening Jan 1, 2011	Change	Closing Sep 30, 2011
Of which:			
Decided and allocated employee stock options	837,148		837,148
Expired		-163,145	-163,145
Exercised		-29,003	-29,003
Allotted		745,000	745,000
<i>Total</i>			1,390,000
Decided and allotted Board options	60,920	14,641	75,561
<i>Total</i>			75,561
Decided and allotted warrants	10,000		10,000
<i>Total</i>			10,000
Decided but not allotted employee stock options			
Opening balance, as approved by the 2009 AGM	470,000	-470,000	-
Resolved at the Extraordinary General Meeting in 2011		795,000	795,000
<i>Total</i>			795,000
Warrants held by subsidiaries as cash-flow hedging for social security fees	139,873	-11,200	128,673
<i>Total</i>			128,673
Total options to employees	1,517,941	881,293	2,399,234

During the January-September 2011 period, a total of 29,003 employee stock options from Orexo's options program were exercised, of which 15,361 were exercised during the period July-September.

Allotment in March and April

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 were allotted free of charge to the President on March 7, 2011 and 245,000 performance shares were allotted free of charge to senior executives on April 26. Of these

performance shares, 372,500 are time-based and 372,500 are share-price based performance shares. The exercise price for the performance shares that were allotted on March 7 has been set at SEK 44.40 and the exercise price for the performance shares that were allotted on April 26 has been set at SEK 47.80. The final date for exercising the options is December 31, 2021.

For the time-based portion of the shares, the market capitalization is calculated according to the Black & Scholes method and for the share-price based portion, the Monte Carlo method is used. The market capitalization of the options allotted on March 7 is SEK 20.25 for the time-based portion and SEK 13.37 for the share-price based portion. For the options allotted on April 26, the market capitalization is SEK 19.19 for the time-based portion and SEK 12.41 for the share-price based portion.

Allotment of Board options in May 2011

In May 2011, 14,641 Board options were allotted, which carry the entitlement to subscription of a total of 14,641 shares in Orexo. These Board shares were allotted free of charge to Board members elected at the 2011 AGM. The Board shares will be allotted in a proportion of 25 percent the day after Orexo publishes its interim report for the first quarter and 25 percent after the publishing the interims for quarters two and four during the mandate period for the 2011 fiscal year. Board members' entitlement to redemption will come into effect two years after the 2011 AGM. The final date for exercising Board shares is December 31, 2018 and the share price is SEK 0.40 per share. The market capitalization, which is calculated according to the Black & Scholes method, was SEK 43.70 on the allotment date.

4. Cash flow

Adjustment for non-cash items

KSEK	2011 Jul-Sep	2010 Jul-Sep	2011 Jan-Sep	2010 Jan-Sep	2010 Jan-Dec
Depreciation/amortization and impairment	40,693	3,548	44,621	7,504	33,764
Estimated costs for employee stock options program	760	698	2,193	2,544	3,309
Financial expenses, convertible bond	-731	2,910	-2,150	-158	2,752
Total	40,722	7,156	44,664	9,890	39,825

5. Shareholders' equity

Change in the Parent Company's shareholders' equity

KSEK	2011 Jul-Sep	2010 Jul-Sep	2011 Jan-Sep	2010 Jan-Sep	2010 Jan-Dec
Opening shareholders' equity, balance sheet	686,319	598,732	540,526	647,140	647,140
Net loss for the period	-74,257	-38,297	-161,999	-97,774	-118,632
Subscription of shares through the exercise of warrants	-	44	157	44	44
Employee stock options, vested value for employees	1,343	511	3,124	1,575	1,969
Convertible bond – equity share	-	-	-	10,005	10,005
New issue	-355	-	231,242	-	-
Closing amount	613,050	560,990	613,050	560,990	540,526

6. Pledged assets and contingent liabilities

During 2010, the Inflazyme project was discontinued, which entailed recognition of the entire supplementary purchase consideration of MSEK 44.6 as a contingent liability.

As cash-flow hedging for social security fees pertaining to the employee stock options issued by Biolipox, warrants were issued to Pyrinox AB. Orexo has pledged to handle any deficits exceeding the cover provided by the warrants during their lifetime through December 31, 2016.

Orexo acquired the UK drug company PharmaKodex in February 2009. This acquisition includes conditional payments based on license revenues from the current PharmaKodex program and technologies, as well as on payments for certain milestones that are not recognized as a liability.

Kibion acquired the German company Wagner Analysen Technik GmbH on August 1, 2011. The acquisition comprises a supplementary purchase consideration based on sales revenues.

Orexo has an overdraft facility of MSEK 35 from Nordea entailing chattel mortgages of MSEK 44 and pledging of all the shares of the subsidiary Kibion AB.

7. Acquisition of Wagner Analysen Technik GmbH

On August 1, Orexo AB achieved controlling influence and thereby the control of the acquired German company Wagner Analysen Technik GmbH (WAT). The company was acquired by Orexo's subsidiary Kibion AB and consolidated in the Orexo Group on the same day. The acquisition of WAT provides increased opportunities for Kibion to increase sales of existing products, and a broader platform for the development and commercialization of new breath tests.

The acquired company contributed net revenues of MSEK 1.7 and net losses of MSEK 0.2 for the period of August 1 to September 30, 2011. If the acquisition had taken place on January 1, 2011, the Group's net revenue would have been raised by MSEK 2.6 and the period's net income lowered by MSEK 3.5.

The acquisition was financed by means of a bank loan.

The acquisition also comprises an additional conditional payment, which is based on sales revenues. Kibion has made provision for a liability corresponding to the estimated amount of the payment. However, there is a ceiling on the amount of the supplementary purchase consideration.

The Acquisition value amounted to MSEK 15.8.

Acquired net assets and goodwill (MSEK):

Purchase consideration	10.4
Supplementary purchase consideration	4.3
Total purchase consideration	14.7
Fair value of acquired net assets	-1.1
Goodwill	15.8

The assets and liabilities included are as follows (MSEK):

	Fair value	Acquired carrying amount
Tangible assets	0.1	0.1
Inventories	0.6	0.6
Current receivables	8.0	8.0
Cash and cash equivalents	0.2	0.2
Current liabilities	-10.0	-10.0
Acquired net assets	-1.1	-1.1

Glossary

Arachidonic Acid

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

Drug delivery

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

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.

Fentanyl

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

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.

Helicobacter pylori

A bacterium that infects the mucous membrane of the stomach.

Clinical studies/clinical testing

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

COPD

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

Opioid analgesics

Pain-alleviating opioid.

Preclinical development/preclinical studies

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

Sublingual

Under the tongue.

Transmucosal

Administered above the mucous membrane.

Definitions of key figures

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

Number of shares after full dilution	Total number of shares plus the maximum number of shares that can be subscribed through options outstanding.
Number of shares after dilution	Calculation of dilution from options issued by the company up to and including 2005, carried out in accordance with IAS 33.
Return on total capital	Operating profit/loss plus financial revenues as a percentage of average total assets.
Return on shareholders' equity	Profit/loss for the period divided by average shareholders' equity.
Return on capital employed	Operating profit/loss plus financial revenues as a percentage of average capital employed.
Current ratio	Current assets as a percentage of current liabilities.
Gross margin	Gross profit divided by net revenues.
Shareholders' equity per share, before dilution	Shareholders' equity divided by the number of shares outstanding before dilution at the end of the period.
Shareholders' equity per share, after dilution	Shareholders' equity divided by the number of shares outstanding after dilution at the end of the period.
Average number of employees	Average number of full-year employees for the period.
Acid test ratio	Current assets excluding inventories as a percentage of current liabilities.
Capital turnover rate	Net revenues divided by average operating capital.
Net debt	Current and long-term interest-bearing liabilities including pension liabilities, less cash and cash equivalents.
Operating capital	Total assets less interest-free liabilities and provisions less cash and cash equivalents.
Earnings per share, before dilution	Profit/loss for the period after tax divided by the average number of shares outstanding before dilution during the period.
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.
Annual return on shareholders' equity	Profit/loss for the year divided by the average shareholders' equity.
Interest-coverage ratio	Profit/loss after net financial items plus interest expenses and similar items, divided by expenses and similar items.
Working capital, net	Interest-free current assets less interest-free current liabilities.
Working capital, net/net revenues	Average working capital, net, divided by net revenues.
Operating margin	Operating profit/loss as a percentage of net revenues.
Debt/equity ratio	Interest-bearing liabilities divided by shareholders' equity.
Equity/assets ratio	Shareholders' equity as a percentage of total assets.
Capital employed	Interest-bearing liabilities and shareholders' equity.
Profit margin	Profit/loss after net financial items.

Note

Orexo AB publ discloses the information provided herein pursuant to the Securities Markets Act. The information was provided for public release on November 9, 2011, at 8:00 a.m. This report has been prepared in both Swedish and English. In the event of any discrepancy in the content of the two versions, the Swedish version shall prevail.