

Orexo AB (publ.) – Year-end Report January-December, 2008

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**This text is a translation of the Year-end Report prepared in Swedish.
In the event of any discrepancy between the English translation and the official
Swedish version, the Swedish version shall prevail.**

Uppsala, February 17, 2009

Orexo AB (publ) – Year-end Report January–December, 2008

The year in brief

- Net revenues increased to MSEK 233.3 (76.8)
- The loss after tax was MSEK 103.1 (loss: 172.6)
- Earnings per share amounted to a loss of SEK 4.77 (loss: 11.42)
- The exclusive global rights to two of Orexo's drugs – Sublinox™ and OX-NLA – were outlicensed to Meda AB.
- Abstral™ was approved for registration in Europe by the EMEA's Committee for Medicinal Products for Human Use (CHMP).
- Abstral™ was approved for marketing in Sweden, Germany and the UK.
- Orexo announced licensing agreements for Abstral™ with ProStrakan and changed its US partner, from Endo Pharmaceuticals to ProStrakan.
- The registration application for Sublinox™ was accepted by the US Food and Drug Administration (FDA) after an initial evaluation as complete for substantive review.
- Orexo initiated the clinical phase II program for OX914 – a new product candidate for the treatment of inflammatory respiratory diseases.
- Orexo and Boehringer Ingelheim extended their research collaboration for OX-MPI.

Fourth quarter, 2008

- Net revenues rose to MSEK 92.1 (55.1)
- The after-tax loss was MSEK 14.4 (loss: 44.0)
- Earnings per share amounted to a loss of SEK 0.67 (loss: 2.47)

Key events after the year-end

- Orexo signed an exclusive development agreement with a large healthcare company, providing for joint development of Orexo's OX17 program for gastroesophageal reflux disease (GERD).
- Orexo and the Chinese pharmaceutical company NovaMed Pharmaceuticals signed a distribution agreement that grants NovaMed exclusive rights to market and sell Abstral™, Orexo's product for the treatment of breakthrough cancer pain, in the People's Republic of China.

Condensed statement of operations ¹

MSEK	2008 3 months Oct-Dec	2007 3 months Oct-Dec	2008 12 months Jan-Dec	2007 12 months Jan-Dec
Net revenues	92.1	55.1	233.3	76.8
Loss after tax	-14.4	-44.0	-103.1	-172.6
Earnings per share, before dilution (SEK)	-0.67	-2.47	-4.77	-11.42
Earnings per share after dilution (SEK) ²	-0.67	-2.47	-4.77	-11.42

Torbjörn Bjerke, President and CEO, comments:

2008 was one of the most active and operationally successful years so far for Orexo. We have confirmed a strategic direction and are on our way to become a profitable pharmaceutical company. A number of factors contributed to Orexo's success, including the approval of Abstral™ in Europe, successful clinical trials, a major deal with Meda covering two of our products, and the change of partner for Rapinyl/Abstral™ in North America, with increased royalty rates.

The year 2009 may be an even more eventful year for Orexo since we, together with our partner Meda, expect a decision from the US Food and Drug Administration (FDA) in respect of Sublinox™ – designed to treat sleep disturbances. We will also submit a registration application for Rapinyl/Abstral™ to the FDA. We expect higher sales of Abstral™, as the product has now been launched in Sweden, Germany and the UK, with more territories expected in 2009. Also during the current year, the focus will be on identifying new business partners and strict cost control. Orexo has sufficient cash liquidity to permit it to continue pursuing operations on the basis of the same business model up to and including 2010 without additional financing.

¹) Refers to the Group, unless stated otherwise in this report. Figures in parentheses are for the corresponding period of the preceding year. Biolipox was consolidated in the Group as of November 23, 2007.

²) Since earnings are negative, the same earnings per share are reported after dilution as before dilution.

2008 in brief

The exclusive global rights to two of Orexo's drugs – Sublinox™ (OX22) and OX-NLA – were outlicensed to Meda AB.

Sublinox™ (OX22) (temporary treatment of insomnia) contains a well-documented active substance zolpidem, one of the world's most commonly used pharmaceuticals for the treatment of sleeping disturbances. Sublinox™ (OX22) uses a unique and patented tablet formulation for fast and reliable onset of action. An application to the FDA for Sublinox™ (OX22) was submitted during the second quarter of 2008.

OX-NLA is a nasal spray formulation containing the substance cetirizine (antihistamine). Liposomes in OX-NLA provide the product with unique features. OX-NLA has been documented for the treatment of allergic and non-allergic rhinitis – one of Meda's key therapy areas. The product is in the initial stages of Phase III. Meda will take over and finance its continuing development. Meda has also acquired the exclusive rights for further combination products based on OX-NLA.

Abstral™/Rapinyl approved for registration in Europe

Abstral™/Rapinyl – designed for the treatment of breakthrough pain resulting from cancer – has been approved for registration in Europe by the EMEA's Committee for Medical products for Human Use (CHMP).

Launch of Abstral™ in Sweden

Abstral™ was launched in Sweden during the third quarter of 2008. The product is sold through ProStrakan AB, which is Orexo's joint venture with ProStrakan Group plc.

Abstral™ approved for marketing in the UK and Germany.

Approval in these territories means that ProStrakan will launch Abstral™ in both countries in early 2009.

FDA commenced the final evaluation process for Sublinox™

The registration application for Sublinox™ was accepted by the Food and Drug Administration (FDA) in the U.S., as complete for substantive review after initial evaluation. Sublinox™ contains the well-known active substance zolpidem and is based on Orexo's sublingual technology, involving a rapidly-dissolving tablet placed under the tongue.

The data supporting the application include a clinical study involving patients with sleep disturbances, which was concluded in October 2007. The study showed that Sublinox™ induced sleep 30% earlier after dosage compared with Ambien/Stilnoct and that patients sleep through the night. The safety profile for Sublinox™ was comparable with that of Ambien/Stilnoct.

Orexo replaced its license partner for Abstral™/Rapinyl in North America with ProStrakan

In July, Endo Pharmaceuticals decided to return Rapinyl to Orexo, as a result of the change in Endo's corporate strategy set by the company's new executive management. Up to the return date, Orexo had received a total of MUSD 26.9 in license fees from Endo Pharmaceuticals. Of that, MUSD 0.75 in respect of the termination and MUSD 1.5 for Endo's prior commitment for the ongoing Phase III study was received on October 31.

Orexo extended the licensing agreement with its partner, the international specialty pharma company ProStrakan Group plc so that its agreements with ProStrakan would also include North America. ProStrakan, which was already Orexo's partner for the sale and marketing of

Abstral™/Rapinyl in Europe, will now also assume responsibility for product sales and marketing in the U.S.

In connection with the transfer of the product from Endo – and pursuant to the new agreement for the North American market – Orexo received MUSD 2 from ProStrakan. Orexo may receive up to an additional MUSD 27 in application- and sales milestones, excluding the MUSD 2 it received upon signing of the agreement.

In conjunction with the signing of the agreement, the current agreement covering Europe was also amended. The milestone compensation linked to approval on the five largest markets was reduced from MEUR 5 to MUSD 5 and the sales level compensation in Europe was raised from MEUR 10 to MEUR 19.9. At the same time, royalty payments were increased by 7 to 9 percentage points. Royalty payments in North America were increased by a similar amount compared with the previous agreement with Endo.

Orexo initiated a clinical Phase II program for OX914 – a product candidate for treatment of inflammatory respiratory diseases

OX914 is a product candidate for treatment of inflammatory respiratory diseases.

OX914 acts by a mechanism called a PDE4 inhibition with an enhanced safety profile over other agents in this class. Orexo is developing OX914 for treatment of asthma, chronic obstructive pulmonary disease (COPD or smoker's disease) and rhinitis (hay fever).

A study has been initiated in which patients will be treated with OX914 using a clinical model for inflammatory respiratory diseases. Some 36 patients with seasonal allergic rhinitis will be treated with a placebo or OX914 in dosages of 15 or 50 mg for two weeks in a double-blind, three-way cross-over study. The effects on nasal symptoms and anti-inflammatory responses, as well as safety and tolerance will be documented.

The global market for respiratory products is about USD 17 billion.

Orexo and Boehringer Ingelheim extended research agreement

The existing three-year research partnership was extended by an additional 12 months as of November 2008. This research is being conducted within the framework of the global rights to develop and market a new and effective pharmaceutical for treatment of pain and inflammation.

The agreement comprises an extension of the original partnership that started in 2005 which has a potential value of MEUR 250, excluding royalties.

The objective of the partnership is to develop a pharmaceutical that selectively inhibits the prostaglandin enzyme (PG) E synthase (mPGES) to reduce the formation of PGE₂, a bodily substance that plays a central role in many inflammatory processes. Such a more selectively targeted active mechanism may result in drugs with fewer side effects than existing pain medications, such as the classic NSAID preparations.

Key events after the close of the period

Orexo signed an exclusive development agreement for its OX17 program

Orexo signed an exclusive development agreement with a large healthcare company, providing for joint development within Orexo's OX17 program for gastroesophageal reflux disease (GERD).

During this development work, Orexo will continue negotiations to enter into an appropriate global exclusive license agreement including the whole of Orexo's OX17 program and related intellectual property. This license agreement is anticipated during 2009. The financial terms were not disclosed.

Orexo signed an agreement for Abstral in China

Orexo and the Chinese pharmaceutical company NovaMed Pharmaceuticals have signed an exclusive licensing and distribution agreement that grants NovaMed rights to seek approval for Abstral, Orexo's product for treatment of breakthrough cancer pain, in the People's Republic of China, and if granted, to market and sell the product in that market.

The terms of the agreement include an upfront payment, regulatory milestones and sales milestones. The total value of the upfront payment and milestones is MUSD 4.75. In addition, Orexo will supply NovaMed with Abstral in China and will receive a margin on the sales of the product if approved. NovaMed will be responsible for managing the regulatory approval process including clinical studies, which is a standard requirement in China.

Orexo's product portfolio

Commercialized products

Abstral™/Rapinyl – for the treatment of acute pain is recommended for approval in Europe and is in clinical Phase III in the US. Abstral™/Rapinyl was developed for the treatment of cancer-related breakthrough pain as its primary indication. Orexo's principal technology, the sublingual dosage method whereby a fast-dissolving tablet is placed under the tongue, enables rapid onset and a predictable effect "on-demand". License agreements for Abstral™/Rapinyl have been signed with ProStrakan Group plc for the European and North American markets and with Kyowa Kirin for the Japanese market. Distribution agreements for the CIS (Russia and other countries in the former Soviet Union), Bulgaria and Romania have been signed with Gedeon Richter, with NovaMed for the Chinese market and with Hospira for Southeast Asia, including Australia and New Zealand.

In December 2005, Phase III studies began on Abstral™/Rapinyl in the US. Positive results from an interim analysis of the Phase III trials were announced in December 2007. Now, the inclusion of patients in the Phase III studies has been completed and ProStrakan plans to submit a registration application for Abstral™ to the FDA in the US during the course of 2009.

Abstral™ has already been launched in Sweden, UK, and Germany.

Diabact® UBT/Heliprobe™ System – Diabact® UBT is Orexo's first commercialized product. It is based on Orexo's patent-protected fast-dissolving tablet. The tablet contains bodily substances and is swallowed with water, meaning that no solution mixture needs to be prepared. A breath test is performed as early as ten minutes after administration. The result is more cost-

effective medical care, since time-consuming preparatory measures are eliminated. The sample is analyzed in a laboratory, and the result is available within two to three days.

The Heliprobe™ System breath test is also very user-friendly for both patients and medical personnel. The test result is available just 15 to 20 minutes after the patient has swallowed a urea capsule containing a mild radioactive dose, which makes immediate analysis possible.

Distribution and marketing agreements for Diabact® UBT have been signed for markets in the UK, Finland, Denmark, Hong Kong, Ireland, Germany, Austria, Serbia and Sweden. The technology is outlicensed in the Japanese market.

The Heliprobe™ System has been launched in more than 30 countries, including Eastern Europe, the Middle East and Asia. Thus, Orexo has access to well-established distribution and sales channels in a number of markets with substantial potential.

Prioritized projects for which agreements have been signed

Sublinox™ – for the treatment of sleeping disorders. Sublinox™ is based on Orexo's sublingual tablet technology. In 2006, the US insomnia market was worth USD 3.3 billion (according to IMS sales data).

A licensing agreement with exclusive world rights for Sublinox™ has been signed with Meda.

During October 2007, Orexo completed the clinical Phase III program for Sublinox™. The primary objectives of the trials in terms of effect, local tolerance and safety profile were attained. The efficacy trials confirmed that Sublinox™ renders a 30 percent faster onset of sleep, compared with Ambien™, in patients suffering from sleeping disorders. The phase III trials strengthen evidence that Sublinox™ is a safe and effective treatment for temporary insomnia.

OX-MPI – Selective prostaglandin E2 inhibitor for pain, inflammation and rheumatism. The project is aimed at developing a new, effective drug for pain, inflammation and fever with fewer side-effects than existing drugs such as the classic NSAID preparation (Diclofenac for example) and the more recently developed COX-2 inhibitors (for example, Vioxx and Celebrex). The mechanism is based on the discovery of a specific enzyme, prostaglandin (PG) E2 synthase (mPGES), a bodily substance that plays a central role in many inflammatory processes. The project has been conducted since 2005 with Boehringer Ingelheim GmbH, Germany, which has acquired the global sales rights. Orexo retained co-promotion rights to markets in the Nordic countries and the Baltic States.

OX-NLA – fast-acting effect for treatment of allergic and non-allergic rhinitis. A license agreement covering exclusive global commercialization rights for OX-NLA has been signed with Meda. Under the agreement, Meda is responsible for the project's continued development, including all related costs.

OX-NLA Nasal Spray for the treatment of allergic and non-allergic rhinitis contains the active component cetirizine. Orexo has developed a unique formulation that reduces cetirizine's local irritating properties. Clinical Phase II studies have shown both favorable and fast-acting effects, making NLA suitable for on-demand treatment. Local treatment in the nose reduces the risk for systemic side effects, such as drowsiness.

In a recently completed study of patients with rhinitis, OX-NLA nasal spray showed favorable tolerance without local side effects in the form of stinging and pain. The conclusion is that the liposomes in OX-NLA Nasal Spray appear to mask the irritating effects of cetirizine.

OX17 – for the treatment of GERD (gastroesophageal reflux disease), a disorder that gives the patient recurrent heartburn, involving acidic regurgitation linked to stomach ache, discomfort and sharp pains in the esophagus. OX17 is a patent-pending fixed combination of two well-established active substances that each inhibits acid secretion in the stomach: an H₂-receptor blocker and a proton pump inhibitor (PPI). To date, patents have been secured in Europe, China, Australia and New Zealand.

The clinical trial program confirms that effective inhibition of acid secretion is rapidly achieved after taking the first dose. Effective acid inhibition can be maintained as long as the symptoms persist. This is a favorable and unique clinical profile for a drug intended for the treatment of GERD. A pharmacodynamic study has been concluded on patients suffering from GERD and the clinical data confirm that OX17 has a competitive profile for the treatment of GERD.

In February 2009, Orexo signed an exclusive development agreement with a large healthcare company. During this development work, Orexo will continue negotiations to enter into an appropriate global exclusive license agreement including the whole of Orexo's Ox17 program and related intellectual property. This license agreement is anticipated during 2009.

Other prioritized projects

OX914 – for the treatment of COPD and asthma. The aim of this project is to develop an orally active product that blocks the PDE4 enzyme present in many pro-inflammatory cells. In clinical trials of various substances that inhibit PDE4, several companies have demonstrated positive treatment effects for COPD and asthma. However, no substance has reached the market, mainly due to side effects, primarily nausea. OX914 has demonstrated favorable effects in preclinical models of COPD and asthma and clinical studies have not shown increased frequency of nausea compared with placebo. Orexo has initiated a clinical Phase II program for OX914, which is expected to be complete during the first half of 2009.

Prioritized projects for which licensing discussions have begun

OX2477 – an entirely new class of agents with treatment potential for asthma and COPD. Orexo has identified a new group of mediators – eoxins – that are formed primarily in cells in respiratory passages and have shown powerful pro-inflammatory effects. Accordingly, eoxin release in the lungs could play a significant role in the inflammatory process involved in COPD and asthma. The project aims to develop an entirely new class of pharmaceuticals to curtail asthma, COPD and other inflammatory diseases.

OX-CLI – a new generation of agents with treatment potential for asthma, COPD and rhinitis. Orexo is developing an orally administered, dual-acting drug with bronchodilating and anti-inflammatory effects. Studies using animals that lack the target protein have shown significantly reduced inflammatory responses in various asthma and COPD models. Orexo has identified molecules that show favorable effects in different pharmacological models. A patent portfolio with potential candidate drugs has been prepared.

The period in figures, January 1 – December 31, 2008

Condensed consolidated statement of operations

MSEK	2008	2007	2008	2007
	3 months Oct-Dec	3 months Oct-Dec	12 months Jan-Dec	12 months Jan-Dec
Net revenues	92.1	55.1	233.3	76.8
Cost of goods sold	-4.2	-4.2	-17.4	-14.4
Gross profit	87.9	50.9	215.9	62.4
Selling expenses	-13.5	-8.5	-38.8	-27.0
Administrative expenses	-16.9	-22.1	-55.3	-58.9
Research and development costs	-75.6	-65.3	-238.1	-156.0
Other operating income and costs	1.8	-1.0	3.8	-1.1
Operating loss	-16.3	-46.1	-112.5	-180.6
Net financial items	1.7	2.0	9.0	7.8
Profit/loss after financial items	-14.5	-44.1	-103.5	-172.8
Tax	0.1	0.1	0.4	0.2
Net profit/loss for the period	-14.4	-44.0	-103.1	-172.6

Revenues

Net revenues

Consolidated net revenues for the period January-December 2008 amounted to MSEK 233.3 (76.8). The sharp rise for the period compared with a year earlier is related to revenue from Meda of MSEK 88.6 for the outlicensing of Sublinox™, plus revenue of MSEK 13 from ProStrakan Ltd in connection with the approval of Abstral™ in the UK and Germany, along with revenues from ProStrakan Ltd of MSEK 15.5 in conjunction with the takeover of the rights for Rapinyl in North America. Moreover, revenue from cooperation with Boehringer Ingelheim GmbH in respect of the OX-MPI project and the invoicing of research and development costs, as well revenue as from the joint venture company, ProStrakan AB, contributed to the increase.

Sales of Abstral™ totaled MSEK 1.4 during the period (of which 50% is Orexo's share).

During the period October-December 2008, net revenues were MSEK 92.1 (55.1).

Net revenues were distributed as follows:

MSEK	Oct-Dec 2008	Oct-Dec 2007	Jan-Dec 2008	Jan-Dec 2007
Diabact® UBT	2.5	1.5	6.6	5.2
Heliprobe™ System	4.8	5.1	22.0	19.7
ProStrakan AB J/V 50%	2.7	2.0	9.7	2.7
License revenue	57.9	34.0	123.2	34.0
Forwarded invoicing of R & D costs	24.2	12.5	71.8	15.2
Total	92.1	55.1	233.3	76.8

Expenses and earnings

Costs for the entire year totalled MSEK 332.2 (241.9), with the increase from the preceding year relating to the acquisition of Biolipox AB which was completed in the fourth quarter of 2007.

Costs for the period October – December totalled MSEK 106, of which MSEK 24.2 were re-invoiced to partners and suppliers. In addition, MSEK 18 represents provisions for costs connected with registration at the FDA for Rapinyl; these costs will not be invoiced on to our partner ProStrakan. With a reduction of costs in the fourth quarter by the aforementioned amounts, the consolidated operating costs totalled MSEK 63.8 for the period October – December 2008.

The pro forma statement of operations presented below is for Orexo AB, including Biolipox AB, and shows the trend in 2008 compared with 2007. It is important to note that research and development costs in the amount of MSEK 71.8 were re-invoiced in 2008. This means that ongoing costs for research and development will continue to decline in 2009. The table below excludes the 50% jointly owned company, ProStrakan AB, as well as costs related to employee stock options.

CONSOLIDATED STATEMENT OF OPERATIONS – PRO FORMA 2007 – 2008 (Excluding ProStrakan AB and costs of employee stock options)

	Pro forma 2007 Jan-Dec	Pro forma 2008 Jan-Dec	Percentage change
Net revenues	103.1	223.6	117%
Cost of goods sold	-13.7	-15.1	10%
Gross profit	89.4	208.5	133%
Selling expenses	-23.6	-30.2	28%
Administrative expenses	-84.3	-52.8	-37%
Research and development costs	-255.5	-237.6	-7%
Other operating income	0.6	3.8	533%
Operating loss	-273.4	-109.6	+60%

Selling expenses

Selling expenses for the year totalled MSEK 38.8 (27.0), with the period October-December of 2008 accounting for MSEK 13.5 (8.5).

Selling expenses primarily include expenses associated with business development linked to the outlicensing of Orexo's projects, as well as expenses incurred in Kibion AB and the joint venture company ProStrakan AB. The increase in selling expenses between the corresponding periods in 2007 and 2008 are related to the increased focus on business development, notably for outlicensing, and a greater commitment to the joint venture company, ProStrakan AB.

Administrative expenses

Administrative expenses for 2008 totalled MSEK 55.3 (58.9). For the period October-December 2008, administrative expenses totalled MSEK 16.9 (22.1).

Research and development costs

Research and development costs for 2008 totalled MSEK 238.1 (156,0), with the period October-December 2008 accounting for MSEK 75.6 (65.3). For 2008 as a whole, MSEK 71.8 was re-invoiced, with the period October – December 2008 accounting for MSEK 24.2.

Research and development expenses include expenses for employees, employee stock options, premises, external costs for clinical trials, drug registration and laboratory services, as well as depreciation of equipment and amortization of acquired patents and other intangible assets. Orexo has no capitalized research and development costs.

Expenses for the company's employee stock options program

Overall, the company incurred expenses for its employee stock option program in the amount of MSEK -1.7 (-1.9) for the period October-December 2008. The factor underlying the cost reduction for the quarter was the fall in stock price during the period, resulting in reduced costs, as reflected in a decrease in provisions for estimated social security fees.

For 2008 as a whole, expenses for the employee stock option program totalled MSEK 1.5 (1.4), of which MSEK 1.1 (-0.2) is attributable to administrative personnel, MSEK 0.5 (1.6) to research and development-related personnel and MSEK -0.1 (0.0) to sales-related personnel.

Depreciation/amortization

Depreciation for the period January-December 2008 totalled MSEK 10.7 (5.9).

Tax

Tax assets (deferred tax) for the period January-December 2008 totalled MSEK 0.4 (0.2).

Net result

The operating loss for the year totalled MSEK 112.5 (loss: 180.6). The loss after financial items amounted to MSEK 103.5 (loss: 172.8), with the loss after tax amounting to MSEK 103.1 (loss: 172.6).

The operating loss for the period October-December 2008 was MSEK 16.3 (loss: 46.1). The loss for the period after financial items and tax totalled MSEK 14.4 (loss: 44.0).

Financial position

Group cash and cash equivalents plus current investments amounted to MSEK 188.2 (291.6) at December 31, 2008.

Cash flow from operating activities for 2008 resulted in a deficit of MSEK 101.5 (deficit: 152.8). Cash flow after financing amounted to a deficit of MSEK 103.4 (15.2). Cash flow from operating activities for the period October-December resulted in a deficit of MSEK 7.3 (deficit: 21.0). Cash flow after financing resulted in a deficit of MSEK 7.4 (149.1).

Shareholders' equity at December 31, 2008 totalled MSEK 569.8 (671.3). The equity/assets ratio was 81 percent (84).

Investments

Gross investments in tangible fixed assets during the year totalled MSEK 1.7 (49.3), with the period October-December 2008 accounting for MSEK 0.2 (7.6). The decline compared with corresponding periods in 2007 is attributable to the renovation of new premises conducted in 2007.

Parent Company

Most of the Group's business is carried out in the Parent Company, Orexo AB. Net revenues in 2008 totalled MSEK 207.8 (48.4), with the loss after financial items totalling MSEK 54.8 (loss: 159.9). Investments totalled MSEK 1.7 (49.3). Cash and cash equivalents in the Parent Company at December 31, 2008 amounted to MSEK 29.6 (109.5).

Pledged assets and contingent liabilities

In the acquisition of Inflazyme, a supplemental payment was agreed contingent on certain goals being met. Part of the supplemental payment was reported as long-term liabilities and MSEK 34.9 was reported as contingent liabilities since the latter is not assessed as a probable payment based on pharmaceutical development statistics. The supplemental payment was adjusted for changes in exchange rates during the year. As cash-flow hedging for social fees pertaining to the employee stock options issued by Biolipox, warrants were issued to Pyrinox AB. Orexo is committed to cover any deficit greater than the cover provided by the warrants. In addition, the acquisition of Noster System AB involved an agreement on a supplemental purchase price of not more than MSEK 7.2, which would become payable if the growth of Heliprobe™ System achieves pre-determined sales targets by year-end 2009. The amount is reported under contingent liabilities, since Orexo does not deem it as likely. The previous pledged assets related to currency futures and chattel mortgages were terminated and reversed.

Significant risks and uncertainties*Uncertainty regarding success of development efforts*

Orexo is a Group in the development stage with three products on the market and a number of other product candidates in various development stages, with some in the late clinical development phase. The research and development of pharmaceuticals are characterized by significant operating risks. Many factors affect the probability that a drug project will result in an approved pharmaceutical. For example, a potential drug candidate that demonstrated favorable effects in animal models may lack any significant effect on humans. Risks for side-effects can also complicate a drug project. However, the risk of not reaching the market diminishes as the project passes through the various phases in the development process. If the Group's clinical trials are not successful, Orexo may lack the potential to license out or commercialize new products.

Competing operations

Orexo's competitors are large pharmaceutical and biotech companies with substantial financial resources and which conduct research in the same areas as Orexo. There is a risk that these competitors develop a pharmaceutical that is better than those developed by Orexo, or that they reach the market faster, whereby the future value of the Group's products will be lower than originally expected.

Partners and the authorities

Orexo is dependent on partners – and is expected to remain so in the future – for development, implementation of clinical trials, approval from regulatory authorities regarding manufacturing, marketing and sales of the Group's product candidates. Orexo's and its partners' facilities and processes require the approval of the regulatory authorities and the manufacture and storage of pharmaceuticals and biological products involve environmental risks and are subject to environmental legislation, which may delay or disrupt operations. Changes to the healthcare system can also impact on Orexo's operations and profitability.

Key personnel

Orexo is dependent on its personnel and certain key individuals. In the event they terminate their employment, this could disrupt and delay development processes. To motivate and retain personnel and key individuals, the company offers such incentives as an options program aimed at all employees.

Financial risk

Orexo’s operations entail exposure to risks due to changes in interest rates, exchange rates, and credit and counterparty risks as well as liquidity and financing risks. Orexo has developed guidelines and policies to effectively manage and limit these risks.

Orexo plans to reduce its operating costs during 2009 and the Board concludes that current financing, even without additional licensing agreements, is sufficient to pursue operations without additional financing in 2009. The assessment is that Orexo has the necessary funding also for 2010 given the current business model and the potential for cost cutting.

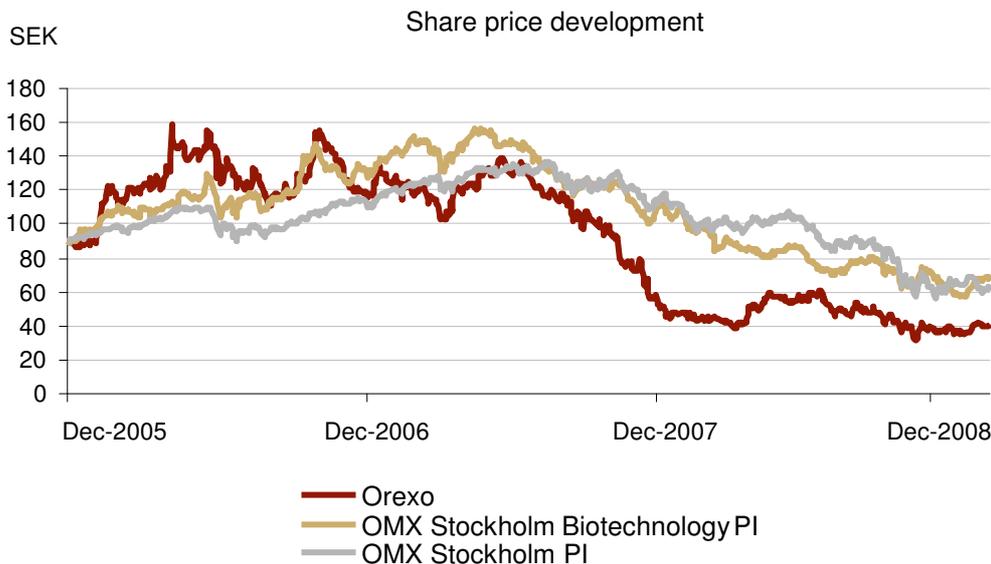
Group cash and cash equivalents amounted to MSEK 188 at December 31, 2008.

Dividend

The Board does not intend to propose a dividend for the 2008 fiscal year.

Share and market value

Orexo’s share traded at SEK 36.30 on December 30, 2008. The company’s market capitalization, based on the number of shares outstanding on December 31, 2008, amounted to MSEK 785. At December 31, 2007, the company’s market value amounted to MSEK 1,016.



Analysts monitoring Orexo:

ABG Sundal Collier	Alexander Lindström
Carnegie	Camilla Oxhamre
Handelsbanken Markets	Erik Hultgård
Nordea	Patrik Ling
Remium	Johan Isaksson
Redeye	Björn Andersson
SEB Enskilda	Gustaf Vahlne

Future information dates:

Annual General Meeting, 2009	April 23, 2009
Interim report, January - March 2009	May 6, 2009
Interim report, January - June 2009	August 21, 2009
Interim report, January - September 2009	November 10, 2009

Annual General Meeting, 2009

The Annual General Meeting will be held in Stockholm, Thursday, April 23, 2009 at 5:00 p.m. at Summit, Grev Turegatan 30. Notice of the Meeting will be released not later than March 26, 2009.

Annual Report

Orexo AB's Annual Report will be presented on the company's website not later than April 9, 2009 and will be sent to the shareholders who so request.

Uppsala February 17, 2009

Orexo AB (publ)

Torbjörn Bjerke, President and CEO

For further information, please contact:

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Review report

We have reviewed the appended report for the period January 1 to December 31, 2008. The Board of Directors is responsible for the preparation and fair presentation of this interim report in accordance with the Annual Accounts Act. 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, 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 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, February 17, 2009
PricewaterhouseCoopers

Leonard Daun
Authorized Public Accountant

CONSOLIDATED BALANCE SHEET

SEK 000s	Notes	2008 Dec 31	2007 Dec 31
ASSETS			
Fixed assets			
Tangible fixed assets		50,317	57,790
Goodwill		16,030	16,030
Other intangible fixed assets		375,941	377,335
Total fixed assets		442,288	451,155
Current assets			
Inventories		13,982	13,294
Accounts receivable		57,535	45,826
Cash and bank balances		188,220	291,598
Total current assets		259,737	350,718
Total assets		702,025	801,873
SHAREHOLDERS' EQUITY AND LIABILITIES			
	3		
Share capital		8,647	8,647
Capital contributions		1,012,964	1,011,380
Accumulated losses		-451,828	-348,775
Total shareholders' equity		569,783	671,252
Long-term liabilities			
Provisions		490	162
Long-term liabilities		9,510	9,595
Deferred tax liability		415	877
Total long-term liabilities		10,415	10,634
Current liabilities			
Current liabilities, non-interest-bearing		121,827	119,987
Total liabilities		132,242	130,621
Total shareholders' equity and liabilities		702,025	801,873
Pledged assets		-	14,500
Contingent liabilities		42,120	43,550

CONSOLIDATED STATEMENT OF OPERATIONS

SEK 000s	Notes	3 months 2008 Oct-Dec	3 months 2007 Oct-Dec	12 months 2008 Jan-Dec	12 months 2007 Jan-Dec
Net revenues		92,135	55,079	233,346	76,757
Cost of goods sold	2	-4,204	-4,195	-17,446	-14,384
Gross profit		87,931	50,884	215,900	62,373
Selling expenses	2	-13,549	-8,469	-38,818	-26,982
Administrative expenses	2	-16,865	-22,148	-55,294	-58,932
Research and development costs	2	-75,552	-65,320	-238,125	-155,972
Other operating income		3,205	183	7,451	9,958
Other operating expenses	2	-1,442	-1,199	-3,611	-11,014
Operating loss		-16,272	-46,069	-112,497	-180,569
Earnings from financial investments					
Interest income		1,819	2,433	9,268	8,231
Interest expenses		-76	-1	-266	-23
Other financial expenses		0	-473	0	-473
Profit/loss after financial items		-14,529	-44,110	-103,495	-172,834
Tax		96	114	441	237
Net profit/loss for the period		-14,433	-43,996	-103,054	-172,597
Loss per share, before dilution, SEK		-0.67	-2.47	-4.77	-11.42
Loss per share, after dilution, SEK		-0.67	-2.47	-4.77	-11.42
Average number of shares, before dilution		21,617,395	17,783,010	21,617,395	15,108,176
Average number of shares, after dilution		22,684,988	18,858,697	22,689,035	16,183,863
Number of shares, before dilution		21,617,395	21,617,395	21,617,395	21,617,395
Number of shares, after dilution		22,684,988	22,693,082	22,684,988	22,693,082

**CONSOLIDATED
CASH-FLOW STATEMENTS**

SEK 000s

		3	3	12	12
	Notes	months	months	months	months
		2008	2007	2008	2007
		Oct-Dec	Oct-Dec	Jan-Dec	Jan-Dec
Continuing operations					
Loss before interest expense and interest income		-16,272	-46,069	-112,497	-180,569
Interest income		-76	-1	-266	-23
Interest expenses		1,819	2,433	9,268	8,231
Other financial expenses		-	-473	-	-473
Adjustment for items not included in cash flow	4	868	694	12,254	7,461
Cash flow from continuing operations before changes in working capital		-13,661	-43,416	-91,241	-165,373
Change in working capital					
Accounts receivable		-3,378	-444	-19,172	2,537
Other current receivables		306	-7,896	7,463	-18,266
Inventories		-1,210	-2,366	-688	-4,060
Current liabilities		10,237	34,903	1,894	37,069
Provisions		-36	-1,746	328	-4,657
Long-term liabilities		410	-	-85	-
Cash flow from continuing operations		-7,332	-20,965	-101,501	-152,750
Investing activities					
Acquisition of machinery and equipment		-220	-7,569	-1,671	-49,318
Divestment of machinery and equipment		110	-	121	-
Change in current investments		-	9,951	-	56,126
Acquisition of subsidiaries		-	167,396	-327	158,151
Cash flow after investments		-7,442	148,813	-103,378	12,209
Change in financing					
Proceeds from new share issue		-	255	-	2,981
Cash flow after financing activities		-7,442	149,068	-103,378	15,190
Cash flow for the year					
Cash and cash equivalents, beginning of period		195,662	142,530	291,598	276,408
Changes in cash and cash equivalents		-7,442	149,068	-103,378	15,190
Cash and cash equivalents, at close of period		188,220	291,598	188,220	291,598

KEY FIGURES

	3 months 2008 Oct-Dec	3 months 2007 Oct-Dec	12 months 2008 Jan-Dec	12 months 2007 Jan-Dec
Operating margin, %	-18	-84	-48	-235
Profit margin, %	-16	-80	-44	-225
Return on total capital, %	-2	-8	-14	-45
Return on equity, %	-3	-10	-17	-53
Return on capital employed, %	-3	-10	-17	-53
Debt/equity ratio, multiple	0	0	0	0
Equity/assets ratio, %	82	84	82	84
Current ratio, %	213	292	213	292
Acid ratio, %	202	281	202	281
Average number of shares, before dilution	21,617,395	17,783,010	21,617,395	15,108,176
Average number of shares, after dilution	22,684,988	18,858,697	22,689,035	16,183,863
Number of shares, after full dilution	23,300,567	23,010,220	23,300,567	23,010,220
Number of shares, before dilution	21,617,395	21,617,395	21,617,395	21,617,395
Number of shares, after dilution	22,684,988	22,693,082	22,684,988	22,693,082
Earnings per share before dilution. SEK	-0.67	-2.47	-4.77	-11.42
Earnings per share after dilution. SEK	-0.67	-2.47	-4.77	-11.42
Shareholders' equity per share before dilution. SEK	26.36	31.05	26.36	31.05
Shareholders' equity per share after dilution. SEK	25.12	29.58	25.12	29.58
Number of employees at close of period	128	129	128	129
Average number of employees	128	102	123	80
Shareholders' equity	569,783	671,252	569,783	671,252
Capital employed	569,783	671,252	569,783	671,252

DEFINITIONS

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

Profit margin: Profit/loss after financial items as a percentage of net revenues.

Return on total capital: Operating profit/loss plus financial income as a percentage of average balance sheet total.

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

Return on capital employed: Operating profit/loss plus financial income as a percentage of average capital employed.

Capital employed: Interest-bearing liabilities and shareholders' equity.

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

Equity/assets ratio: Shareholders' equity in relation to total assets.

Current ratio: Current assets as a percentage of current liabilities.

Acid ratio: Current assets excluding inventories as a percentage of current liabilities.

Number of shares after full dilution: Total number of shares plus the maximum number of shares that can be subscribed for through options outstanding.

Number of shares after dilution: Calculation of the dilution from options issued by the company up to 2005 has been carried out in accordance with IAS 33.

Earnings per share before dilution: Profit/loss divided by average number of shares outstanding before dilution.

Earnings per share after dilution: Profit/loss divided by average number of shares outstanding after dilution.

Shareholders' equity per shares before dilution: Shareholders' equity divided by the number of shares before dilution at the close of the period.

Shareholders' equity per share after dilution: Shareholders' equity divided by the number of shares after dilution at the close of the period.

PARENT COMPANY BALANCE SHEET

SEK 000s	Notes	2008 Dec 31	2007 Dec 31
ASSETS			
Fixed assets			
Tangible fixed assets		49,985	50,903
Intangible fixed assets		509	566
Shares in subsidiaries /joint ventures		524,169	523,842
Total fixed assets		574,663	575,311
Current assets			
Inventories		5,233	4,362
Accounts receivable		63,812	40
Current receivables		41,969	53,030
Current investments		-	-
Cash and bank balances		29,608	109,511
Total current assets		140,622	166,943
Total assets		715,285	742,254
SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES			
	6		
Share capital		8,647	8,647
Restricted equity		290,750	290,750
Non-restricted equity		309,797	366,535
Total shareholders' equity		609,194	665,932
Long-term liabilities			
Provisions		490	162
Total long-term liabilities		490	162
Current liabilities, non-interest-bearing		105,601	76,160
Total liabilities		106,091	76,322
Total shareholders' equity and liabilities		715,285	742,254
Pledged assets		-	2,500
Contingent liabilities		11,050	11,050

PARENT COMPANY STATEMENT OF OPERATIONS

SEK 000s		3 months 2008 Oct-Dec	3 months 2007 Oct-Dec	12 months 2008 Jan-Dec	12 months 2007 Jan-Dec
	Notes				
Net revenues		117,349	42,506	207,757	48,389
Cost of goods sold	5	-	-	-	-2,409
Gross profit		117,349	42,506	207,757	45,980
Selling expenses	5	-8,044	-3,365	-19,041	-15,408
Administrative expenses	5	-16,799	-18,187	-52,085	-54,327
Research and development costs	5	-71,346	-52,114	-197,689	-143,225
Other operating income		1,901	71	4,514	9,674
Other operating expenses	5	-604	-777	-1,779	-10,413
Operating profit/loss		22,457	-31,866	-58,323	-167,719
Earnings from financial investments					
Interest income		532	1,228	3,733	7,832
Interest expenses		-72	-1	-215	-11
Profit/loss after financial items		22,917	-30,639	-54,805	-159,898
Net profit/loss for the period		22,917	-30,639	-54,805	-159,898

Notes

1. Accounting principles

This Year-End Report was prepared pursuant to IAS 34, Interim Financial Reporting, which complies with the requirements of the Swedish Financial Accounting Standards Council's recommendation RFR 1.1, Interim Financial Reporting for Groups. As of 2005, Orexo applies IFRS as approved by the EU. The accounting principles and calculation methods comply with those applied in preparing the 2007 Annual Report.

Since the interim report of 31 March 2008, the classification between selling costs and administrative expenses has been changed. Business development is now classified as a selling expense and not as an administrative expense. Historical figures were recalculated according to the new classification. With effect from the fourth quarter, an adjustment has been made in the consolidated financial statements in the form of a reclassification among "Other capital contributions" and "Accumulated loss". The adjustments have also led to a recalculation of the comparative data. Total shareholders' equity remains unchanged. The change for 2007 is that MSEK 176.2 has been transferred to the "Accumulated loss", which subsequently amounts to MSEK 348.8

The Parent Company's accounting was prepared in accordance with RFR 2.1.

The amounts below are in SEK 000s, unless otherwise indicated.

2. Costs distributed by type of cost

	2008	2007	2008	2007
	Oct-Dec	Oct-Dec	Jan-Dec	Jan-Dec
Raw materials and supplies	8,228	13,326	32,444	26,835
Other external costs	63,257	51,181	181,642	132,307
Personnel costs	37,528	34,456	128,475	92,967
Depreciation and impairment	2,600	2,368	10,734	5,875
Re-invoicing of rebuilding costs	-	-	-	9,300
TOTAL	111,613	101,331	353,295	267,284

3. Shareholders' equity

Changes in Group equity

	2008	2007	2008	2007
	Oct-Dec	Oct-Dec	Jan-Dec	Jan-Dec
Shareholders' equity brought forward, according to balance sheet	585,645	202,553	671,252	324,350
Profit/loss for the period	-14,433	-43,996	-103,054	-172,597
Subscription of shares through the exercise of warrants	-	255	-	2,981
New share issues	-	438,775	-	438,775
New issue of stock options	-	52,875	-	52,875
Employee stock options, value of employees' service	-1,429	1,911	1,585	5,989
Acquired value of employee stock options	-	18,879	-	18,879
Amount at close of period	569,783	671,252	569,783	671,252

Shares outstanding

The number of shares outstanding at December 31, 2008, was 21,617,395 all of which were common shares. All shares carry entitlement to one vote each.

Outstanding shares at January 1, 2008	21,617,395
Share subscription through exercise of employee stock options	
Share subscription through exercise of warrants	
New issue of shares in conjunction with the acquisition of Biolipox AB	
Number of shares outstanding at December 31, 2008	21,617,395

Options

At December 31, there was a total of 2,577,897 options outstanding that carry rights corresponding to 2,112,672 shares in Orexo and the exercise of 465 225 options for shares in Orexo³. Each option written by Biolipox AB provides entitlement for exchange for one share in Orexo AB, and a corresponding number of shares is held by the independent company Pyrinox AB.

The list below shows the change in the number of options during the period January 1, 2008 to December 31, 2008 distributed among each category.

Under the period October - December 2008, 8,489 of Biolipox' employee stock options were exercised, entailing that the holders exchanged their options for 8,489 Orexo shares, which were held by the independent company, Pyrinox AB. However, such exercise does not require Orexo to issue more shares. During under the period January-December, Pyrinox sold 5,000 warrants to hedge cash flow-related social security fees. During the period October – December, 19,889 options were cancelled. These were related to unearned options for employees who had terminated their employment and, thus, could not exercise them.

	Opening 1/1 2008	-	+	Closing 31/12 2008
Personnel-related options				
Of which:				
Decided and allotted employee stock options	373,525	-134,950	412,500	651,075
Decided and allotted employee Board options	-	-	12,847	12,847
Decided and allotted warrants	15,250	-	-	15,250
Decided but not allotted employee stock options, 2008	372,000	-372,000	429,500	429,500
Warrants held by subsidiary for cash-flow hedging of social security fees	78,000	-	-	78,000
Total decided options	838,775	-506,950	854,847	1,186,672
Employee stock options taken over from Biolipox AB (no dilution effect, included in newly issued shares in conjunction with acquisition of Biolipox)	399,167	-64,316	-	334,851
Warrants taken over from Biolipox AB subsidiary for cash-flow hedging of social security fees (no dilution effect)	135,374	-5,000	-	130,374
Total options from Biolipox	534,541	-69,316	-	465,225
Total options to employees	1,373,316	-576,266	854,847	1,651,897
Other options				
Warrants related to supplemental payment in conjunction with acquisition of Biolipox AB	926,000	-	-	926,000
Total options outstanding	2,299,316	-576,266	854,847	2,577,897

³⁾ All data regarding options written by Orexo AB is adjusted for the 1:250 share split in November 2005. As shown in the 2005 Annual Report, each old option carries rights to subscribe for 250 shares after the split. Reported figures regarding options issued by Orexo AB pertain to the number of shares for which each option entitles the holder to subscribe after the split. All figures relating to options issued by Biolipox AB were translated using a factor of 0.45854, which corresponded to the estimated value of the options in relation to the Orexo share price on the acquisition date. Reported figures regarding options issued by Biolipox relate to the number of shares for which each option may be exchanged after translation.

Allotment in February 2008

During February 2008, new employee stock options were allotted entitling the holders to subscribe for 372,000 new shares. The distribution among employees is as follows:

- CEO: 50,000 shares
- Other senior executives: 85,000 shares
- Other employees: 237,000 shares

The exercise price was SEK 44 per share and the lifetime of the options extends through December 31, 2017. One third of the total employee options are vested on each of the three annual dates immediately following February 21, 2008. The market value, as calculated using the Black & Scholes method, amounted to SEK 11.50 per option at the date of allotment.

New program decided at the Annual General Meeting

At Orexo's Annual General Meeting on April 3, 2008, it was resolved to adopt a new employee stock option program, which included the issuance of subscription warrants and approval of the utilization of subscription warrants within the framework of the employee stock option program. The employee stock option program consists of 470,000 employee stock options. Each employee stock option may be exercised to acquire one share in Orexo in exchange for payment of an exercise price set as 110 percent of the market value of the Orexo share on the date of allotment. A total of 470,000 subscription warrants were issued to the wholly owned subsidiary Pharmacall AB as a hedge for the program. Full exercise of the warrants will result in a dilution of about 2% of the share capital and votes in Orexo. Of these employee stock options, 40,500 were allotted without charge to employees of December 31, 2008. The distribution among employees was as follows:

- Other senior executives: 30,000 options
- Other employees: 10,500 options

The subscription price for the options is SEK 56 per share, and the option lifetime extends up to December 31, 2018. The market value, as calculated by the Black & Scholes method, amounted to SEK 15.38 per option on the allotment date.

The Meeting also resolved to adopt a Board Member Shareholder Plan including the issuance of 27,500 warrants and approval of disposal of the warrants issued under the Board Member Shareholder Plan. Board members participating in Orexo's Board Member Shareholder Program will receive 50% of their Board fee and any fee for committee work in cash and will be allotted a number of Board Member shares, whose value at the time of allotment shall correspond to 50% of the Board fee and any fee for committee work. The right to acquire new shares by using the Board shares is contingent on whether the Board member remains a Board member during the whole or only part of his/her period of office. Each Board Member share can be exercised to acquire one share in Orexo against payment of an exercise price determined as the par value of the Orexo share. During May 2008, 16,388 options were allotted from the Board Member Shareholder Program to Board members, and the options may be exercised up until December 31, 2015. Entitlement is earned with one fourth after the publication of Orexo's first quarter report and with one fourth following the publication of the interim reports for each of the quarters two to four during the term of office for the fiscal year in which the option holder was elected or re-elected. The market value, as calculated by the Black & Scholes method, amounted to SEK 55.15 per option on the allotment date.

During the January-December period, the Board of Directors resolved to cancel option certificates with entitlement to subscription for 134,950 shares. The cancelled options relate to earned options for employees who have terminated their employment and are therefore will unable to exercise them.

4. Consolidated cash flow

Adjustment for items not included in cash flow

	2008	2007	2008	2007
	Oct-Dec	Oct-Dec	Jan-Dec	Jan-Dec
Depreciation/amortization and impairments	2,600	2,368	10,734	5,875
Calculated costs for employee stock option program	-1,718	-1,885	1,531	1,381
Other	-14	211	-11	205
Total	868	694	12,254	7,461

5. The Parent Company's costs distributed by type of cost

	2008	2007	2008	2007
	Oct-Dec	Oct-Dec	Jan-Dec	Jan-Dec
Raw materials and supplies	3,671	3,435	11,784	9,162
Other external costs	57,233	45,546	142,142	125,146
Personnel costs	34,093	23,932	109,522	77,603
Depreciation and impairment	1,797	1,530	7,147	4,571
Invoicing of rebuilding costs	-	-	-	9,300
TOTAL	96,794	74,443	270,595	225,782

6. Shareholders' equity

Changes in the Parent Company's shareholders' equity

	2008	2007	2008	2007
	Oct-Dec	Oct-Dec	Jan-Dec	Jan-Dec
Shareholders' equity brought forward according to balance sheet	588,620	205,951	665,932	328,406
Net profit/loss for the period	22,917	-30,639	-54,805	-159,898
Disposal of hedge options	-	-	-	-
Subscription of shares through the exercise of warrants	-	255	-	2,981
New share issues	-	438,776	-	438,776
New issue of subscription warrants	-	52,875	-	52,875
Employee stock options, value of employees' service	-1,343	1,314	-933	5,392
Group contribution	-1,000	-2,600	-1,000	-2,600
Amount at the close of the period	609,194	665,932	609,194	665,932

Note

Orexo AB Publ. discloses the information provided herein pursuant to the Securities Markets Act. The information was provided for public release on February 17, 2009 at 08:00 a.m. CET. This report has been prepared in both Swedish and English. In case of variation in the content of the two versions, the Swedish version shall take precedence.