

# Orexo AB (publ)

## – Interim report January-September 2008

Orexo AB, P.O. Box 303, SE-751 05 Uppsala, Sweden  
Tel: +46 18-780 88 00, Fax: +46 18-780 88 88, E-mail: [info@orexo.com](mailto:info@orexo.com)  
Internet: [www.orexo.com](http://www.orexo.com) Corp. reg. no. 556500-0600

Uppsala, November 10, 2008

## Orexo AB (publ) – Interim report January-September 2008

### Key events during the period

- Net revenues amounted to MSEK 141.2 (21.7)
- A loss of MSEK 88.6 (loss: 128.6) was reported after tax
- Earnings per share amounted to a loss of SEK 4.10 (loss: 9.24)
- Cash flow from operating activities was negative in an amount of MSEK 94.2 (neg. 131.8)
- The exclusive world rights to two Orexo pharmaceuticals, Sublinox™ (OX22) and OX-NLA, were licensed to Meda AB.
- Abstral®/Rapinyl was approved for registration in Europe by the EMEA's Committee for Medicinal Products for Human Use (CHMP).

### Third quarter of 2008

- Net revenue amounted to MSEK 61.0 (6.5). A profit of MSEK 1.9 (loss: 34.1) was reported for the third quarter, corresponding to earnings per share of SEK 0.09 (loss: 2.44)
- Cash flow from operating activities was negative in an amount of MSEK 51.3 (neg. 34.3)
- Abstral® was approved for marketing in the UK
- Orexo announced licensing agreements for Abstral®/Rapinyl with ProStrakan and changed partners in the US
- The registration application for Sublinox™ (OX22) was accepted after the first evaluation as complete for final evaluation by the Food and Drug Administration (FDA) in the US
- Orexo initiated a clinical Phase II program for OX914 – a new product candidate for treatment of inflammatory respiratory diseases
- Orexo and Boehringer Ingelheim extended their research agreement regarding OX-MPI

### Key events after the closing date

- On October 31, the rights for Rapinyl in North America were transferred from Orexo's previous partner Endo Pharmaceuticals to ProStrakan Ltd. In conjunction with the transfer, Orexo received MUSD 0.75 from Endo according to the previous agreement. Orexo also received MUSD 2.6 in compensation from Endo to finance the Phase III studies now in progress. In addition, ProStrakan will pay MUSD 2 to Orexo in conjunction with the takeover.

**Condensed statement of operations <sup>1</sup>**

MSEK	3 months 2008 July-Sept.	3 months 2007 July-Sept.	9 months 2008 Jan.-Sept.	9 months 2007 Jan.-Sept.	12 months 2007 Jan.-Dec.
Net revenues	61.0	6.5	141.2	21.7	76.8
Profit/loss after tax	1.9	-34.1	-88.6	-128.6	-172.6
Loss per share, before dilution (SEK)	0.09	-2.44	-4.10	-9.24	-11.42
Loss per share, after dilution (SEK) <sup>2</sup>	0.09	-2.44	-4.10	-9.24	-11.42

**Torbjörn Bjerke, President and CEO, comments:**

Orexo continued its strong development and we took further steps during the past quarter towards our goal of developing Orexo into a profitable pharmaceutical company. The most important events during the third quarter and until today were:

- Launch of Abstral® in Sweden and the start of sales.
- Approval of Abstral® for marketing in the UK. The decision was announced earlier than anticipated, and the launch of Abstral® in Europe's largest market can now take place toward the end of the year.
- We are satisfied that the transfer of the rights to Rapinyl in North America took place earlier than planned. We and our partner ProStrakan will now conclude the Phase III studies, which are expected to be completed in December. At the same time, we are preparing the submission of the registration application and marketing of Rapinyl in North America.

**Key events during the period****Abstral® approved for marketing in the UK**

The British authority MHRA (Medicines and Healthcare products Regulatory Agency) approved Abstral® (intended for breakthrough pain in cancer patients) for marketing in the UK. As a consequence of this approval, Orexo received a partial payment of MUSD 1.

The approval was granted earlier than expected, meaning that ProStrakan can conclude pricing negotiations and move up the launch in the UK to the end of 2008 with the result that sales of Abstral® can take place in the UK during all of 2009.

**Launch of Abstral® in Sweden**

Abstral® was launched in Sweden during the third quarter 2008. The product is sold through Orexo's joint venture with ProStrakan.

<sup>1)</sup> Refers to the Group unless otherwise stated. Figures in parentheses refer to the corresponding period of the preceding year.

<sup>2)</sup> Since a loss being reported, the same earnings are reported both after and before dilution.

**FDA began final evaluation of Sublinox™**

The registration application for Sublinox™ was accepted after the first evaluation as complete for a final evaluation by the Food and Drug Administration (FDA) in the US. Sublinox™ contains the well-known active substance zolpidem and is based on Orexo's proprietary technology to produce a tablet that quickly dissolves under the tongue.

Data on which the application was based includes a clinical study of patients with sleeping disorders that was completed in October 2007. The study showed that Sublinox™ induced sleep 30 percent faster after administration, compared with Ambien/Stilnoct. The study also showed that patients remain asleep throughout the night. The safety profile for Sublinox™ was comparable with Ambien/Stilnoct.

**Orexo signed license agreement with ProStrakan in North America**

In July, Endo Pharmaceuticals decided to return Rapinyl to Orexo as a result of a change in strategy by the company's new management. Prior to the return, Orexo had received a total of MUSD 26.9 in license revenues from Endo Pharmaceuticals. In addition, Endo had invested approximately MUSD 40 in development of Rapinyl.

Orexo expanded its licensing agreement with the international specialty pharmaceuticals company ProStrakan Group plc to also include North America. ProStrakan, which was already Orexo's partner for sales and marketing of Abstral®/Rapinyl in Europe, will now also be responsible for sales and marketing of the product in the US. In Europe, the EMEA decided to recommend approval of Abstral® in June of this year.

ProStrakan has established offices with management and marketing in the US and is currently recruiting 67 sales representatives in partnership with NovaQuest (part of the Quintiles Group).

In conjunction with the transfer from Endo and in accordance with 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-level compensation, excluding the MUSD 2 received on the effective date of the agreement. In the earlier agreement with Endo, sales-level compensation could have reached a total of MUSD 39.2.

In conjunction with the signing of the agreement, the existing agreement pertaining to Europe was also amended. Milestone payments linked to approval in the five largest markets were reduced from MEUR 5 to MUSD 5, while sales-level compensation was increased from MEUR 10 to MEUR 19.9. At the same time royalty compensation was increased by 7-9 percentage units. Royalty compensation in North America was increased with a corresponding amount in relation to the previous agreement with Endo.

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

OX914 is a new 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 pathology 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 of this year. 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 and valued at MEUR 250, excluding royalties. With respect to the next milestone payment from the partnership with Boehringer Ingelheim, Orexo expects this to take place during the first half of 2009.

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 PGE<sub>2</sub>, 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 closing date**

On October 31, the North American rights for Rapinyl were transferred from Orexo's former partner Endo Pharmaceuticals to ProStrakan Ltd. In conjunction with the transfer, Orexo received MUS\$ 0.75 from Endo in accordance with the previous agreement. Orexo also received MUS\$ 2.6 in compensation from Endo to finance the Phase III studies now in progress. In addition, ProStrakan will pay Orexo MUS\$ 2 in conjunction with the transfer.

## Operations

### Orexo in brief

Orexo is a pharmaceutical company focusing on the development of new, patented drugs by combining well-documented substances with innovative technologies and developing new treatment forms for respiratory and inflammatory diseases.

Orexo has a broad and competitive product portfolio in the late development phase, with three products on the market, three products in clinical phases and one in the registration phase.

Orexo has licensed out the marketing rights for Abstral®/Rapinyl for the North American, European and Japanese markets, world rights for Sublinox™ (OX22) and OX-NLA, and is cooperating with Boehringer Ingelheim in the development of a new pharmaceuticals class for treatment of pain and inflammation. Orexo has also established a Nordic sales organization through a joint venture with ProStrakan.

### Orexo's product portfolio

#### Commercialized products

**Abstral®/Rapinyl** – for the treatment of acute pain is approved for sale 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 of effect and a predictable effect with "on-demand" features. License agreements for Abstral®/Rapinyl have been signed with ProStrakan Group Ltd. for the European and North American markets and with Kyowa Hakko 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 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 study were announced in December 2007. When the Phase III study comprising all 100 patients has been completed, a registration application will be submitted to the FDA in the US.

**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 10 to 15 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 licensed to the Japanese market.

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

### **Prioritized projects in which licensing 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 has been signed with Meda.

During October 2007, Orexo completed the Phase III program by conducting the effect, local tolerance and safety study trials among patients using Sublinox™ – for the treatment of temporary insomnia – with positive results. The efficacy trials confirmed that Sublinox™ renders a 30 percent faster onset of sleep, compared with Ambien™, in patients suffering from sleeping disorders. The study also showed that patients remain asleep throughout the night. The study strengthens existing documentation 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 pharmaceutical for pain, inflammation and fever with fewer side-effects than existing drugs such as the classic NSAID preparation (for example diclofenac) 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 nonallergic rhinitis.

A license agreement covering exclusive worldwide 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 treatment of allergic and nonallergic 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 good and fast-acting effects, making NLA suitable for on-demand treatment. Local treatment in the nose reduces the risk for systematic 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.

### **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 existing in many pro-inflammatory cells. In clinical



studies of various substances that inhibit PDE4, several companies have demonstrated positive treatment effect in COPD and asthma. However, no substance has reached the market, mainly due to side effects, primarily nausea. OX914 has shown favorable effects in preclinical models of COPD and asthma and clinical studies have not shown increased frequency of nausea compared with placebo. Orexo is initiating a clinical Phase II program for OX914 that is expected to be completed during the first half of 2009, after which discussions of licensing agreements will begin.

### **Prioritized projects for which licensing discussions have begun**

**OX17** – for the treatment of GERD (gastro esophageal 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 H<sub>2</sub>-receptor blocker and a proton pump inhibitor (PPI). To date, patents have been granted 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. The clinical results were presented at the “Digestive Disease Week” conference in Los Angeles, California, in the US on May 21, 2006. A pharmacological dynamic study has been concluded on patients suffering from GERD and the clinical data confirms that OX17 has a competitive profile for treatment of GERD. With regard to licensing discussions under way for OX17, these are ongoing with a number of companies, but to ensure the best agreement possible, it will not be possible to conclude an agreement before year-end.

**OX2477** – an entirely new class of agents with treatment potential for asthma and COPD. Orexo has discovered a new group of mediators, eoxines, that are formed primarily in cells in respiratory passages and have shown powerful pro-inflammatory effects. Accordingly, release of eoxines in the lungs could make an important contribution to the inflammatory process in COPD and asthma. The project aims to develop an entirely new class of pharmaceuticals against asthma, COPD and other inflammatory diseases.

**OX-CLI** – a new generation of agents with treatment potential in asthma, COPD and rhinitis. Orexo is developing an orally administered, dual-acting drug with bronchodilating and anti-inflammatory effects. Studies in 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 – September 30, 2008

### Condensed consolidated statement of operations

	3 months 2008 July-Sept.	3 months 2007 July- Sept.	9 months 2008 Jan.- Sept.	9 months 2007 Jan.- Sept.	12 months 2007 Jan.-Dec.
<b>MSEK</b>					
<b>Net revenues</b>	<b>61.0</b>	<b>6.5</b>	<b>141.2</b>	<b>21.7</b>	<b>76.8</b>
Cost of goods sold	-4.3	-3.4	-13.2	-10.2	-14.4
<b>Gross profit</b>	<b>56.7</b>	<b>3.1</b>	<b>128.0</b>	<b>11.5</b>	<b>62.4</b>
Selling expenses	-6.7	-5.0	-25.3	-18.5	-27.0
Administrative expenses	-10.8	-13.8	-38.4	-36.8	-58.9
Research and development costs	-41.4	-20.2	-162.6	-90.7	-156.0
Other operating income and costs	1.5	0.1	2.1	0.0	-1.1
<b>Operating loss</b>	<b>-0.7</b>	<b>-35.8</b>	<b>-96.2</b>	<b>-134.5</b>	<b>-180.6</b>
Net financial items	2.5	1.6	7.3	5.8	7.7
<b>Profit/loss after financial items</b>	<b>1.8</b>	<b>-34.2</b>	<b>-88.9</b>	<b>-128.7</b>	<b>-172.8</b>
Tax	0.1	0.1	0.3	0.1	0.2
<b>Net profit/loss for the period</b>	<b>1.9</b>	<b>-34.1</b>	<b>-88.6</b>	<b>-128.6</b>	<b>-172.6</b>

### Revenue

#### Net revenue

Consolidated net revenue for the period January – September 2008 amounted to MSEK 141.2 (21.7). The sharp increase in the third quarter, compared with the preceding year, was primarily due to licensing revenues of MSEK 30 from Meda for licensing of Sublinox and MSEK 6 from ProStrakan Group Plc in conjunction with the approval of Abstral® in the UK but also revenues from the partnership with Boehringer Ingelheim GmbH relating to OX-MPI and compensation from Endo and from the joint-venture company ProStrakan AB.

Sales of Abstral® amounted to MSEK 1,1 during the period (whereof 50% is Orexo's share). The sales are related to inventory build-up at Apoteket, this inventory is estimated to cover 2008.

Net revenue was distributed as follows:

MSEK	Jan.-Sept. 2008	Jan.-Sept. 2007	Jan.-Dec. 2007
Diabact® UBT	4.1	3.7	5.2
Heliprobe™ System	17.2	14.6	19.7
ProStrakan AB J/V 50% (of which Abstral® 50%)	7.0 (0.6)	0.7	2.7
License revenue	65.3	0.0	34.0
Other	47.7	2.7	15.2
Total	141.2	21.7	76.8

During the period July – September 2008, net revenue amounted to MSEK 61.0 (6.5).

### Expenses and earnings

#### Selling expenses

Consolidated selling expenses amounted to MSEK 25.3 (18.5) for the period January – September 2008 and to MSEK 6.7 (5.0) for the period July – September 2008.

Selling expenses primarily include costs for business development linked to the licensing of Orexo's projects and costs in Kibion AB and the joint-venture company ProStrakan AB. The increase in selling expenses between the corresponding periods of 2007 and 2008 was primarily an effect of increased investment in business development mainly for licensing and higher costs in the joint venture ProStrakan AB.

#### *Administrative expenses*

Administrative expenses amounted to MSEK 38.4 (36.8) for the period January – September 2008 and to MSEK 10.8 (13.8) for the period July – September 2008.

The increase with respect to the year-earlier period was primarily due to the acquisition of Biolipox, but also due to the new premises in Uppsala following the move in summer 2007.

#### *Research and development costs*

Research and development costs amounted to MSEK 162.6 (90.7) for the period January–September 2008 and to MSEK 41.4 (20.2) for July – September 2008. Of the period's expenses, MSEK 15.7 was re-invoiced to partners and is included in net revenues, meaning that the period's net costs for research and development amounted to MSEK 25.7.

Research and development costs include costs 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. The company has several development projects in advanced phases and/or for which discussions on licensing have been initiated or concluded. These include Abstral®/Rapinyl for the treatment of acute pain, OX-MPI for treatment of pain, inflammation and rheumatism, Sublinox™ for the treatment of sleeping disorders, OX 17 for GERD, OX-NLA for treatment of allergic and nonallergic rhinitis (hay fever), OX2477, a completely new class of pharmaceuticals for asthma and COPD, and OX-CLI, a new generation of pharmaceuticals for the treatment of asthma, COPD and rhinitis.

#### *Expenses for the company's employee stock option plan*

For the period July – September 2008, the company's costs for the employee stock option plan totaled MSEK -2.6 (0.2). The reduction in costs during the quarter was due to the decline in the share price during the period, which resulted in reduced expenses, which are reported as a reduction in provisions for estimated social costs, and a change in the assessment of how great a proportion of the options that are expected to be earned, which resulted in a one-time effect during the quarter.

For the period January–September 2008, costs for the employee stock option plan amounted to MSEK 3.2 (3.3), of which MSEK 2.3 (1.2) was attributable to administrative employees, MSEK 1.1 (2.1) to research and development-related personnel and MSEK -0.2 (0.0) to sales-related personnel.

#### *Other income and costs*

Other income and costs, consisting primarily of exchange-rate gains and losses, amounted to income of MSEK 2.1 (0.0) for the period January – September 2008 and to income of MSEK 1.5 (0.1) for the period July – September 2008.

#### *Depreciation/amortization*

Depreciation/amortization amounted to MSEK 8.1 (3.5) for the period January–September 2008 and to MSEK 2.6 (1.4) for the period July – September 2008. The increase was primarily due to investments during 2007 in new office premises and the acquisition of Biolipox AB.

#### *Tax*

Tax expenses during January–September 2008 amounted to MSEK 0.3 (0.1).

#### *Net loss*

The operating loss for the period January – September 2008 amounted to MSEK 96.2 (loss: 134.5). The loss after net financial items was MSEK 89.0 (loss: 128.7), and the loss after tax was MSEK 88.6 (128.6). Between comparable periods, revenue increased strongly, mainly due to the license revenue from Meda that was received during 2008. At the same time, Orexo continued expanding its business, including the acquisition of Biolipox, which resulted in increased operating expenses.

The operating loss for the period July - September was MSEK 0.7 (loss: 35.8). Profit after financial items amounted to MSEK 1.8 (loss: 34.2), and profit after tax was MSEK 1.9 (loss: 34.1).

### **Financial position**

The Group's cash and cash equivalents amounted to MSEK 195.7 (142.5) at September 30, 2008 and short-term investments amounted to MSEK 0 (10.0).

Cash flow from operating activities for the period January–September 2008 was a negative MSEK 94.2 (neg: 131.8). Cash flow after financing was a negative MSEK 95.9 (neg: 133.9).

Cash flow from operating activities for the period July–September 2008 was a negative MSEK 51.3 (neg: 34.3). Cash flow after financing was a negative MSEK 51.5 (neg: 45.2).

Shareholders' equity on September 30, 2008 amounted to MSEK 585.6 (202.6). The equity/assets ratio was 83 percent (79).

### **Investments**

Gross investments in tangible fixed assets amounted to MSEK 1.5 (41.7) for the period January–September 2008 and to MSEK 0.2 (22.7) for the period July - September 2008. The decline from the year-earlier period was primarily attributable to remodeling of new premises during 2007.

### **Parent Company**

The majority of the Group's business is carried out in the parent company, Orexo AB. Net revenues for the period January–September 2008 amounted to MSEK 90.4 (5.9) and the loss after net financial items was MSEK 77.7 (loss: 129.3). Investments amounted to MSEK 1.5 (41.7). The Parent Company's cash and cash equivalents and current investments totaled MSEK 36.7 (140.3).

### **Assets pledged and contingent liabilities**

The agreement reached in conjunction with the acquisition of Inflazyme included a supplementary purchase consideration conditional upon achievement of certain targets. Portions of this supplementary purchase price are recognized as long-term liabilities, and MSEK 36.3 is carried as a contingent liability, since it is not considered probable that payment will be required based on pharmaceutical trend statistics. As a cash-flow hedge for social security fees relating to employee stock options issued by Biolipox, stock options were issued to Pyrinox AB. Orexo has undertaken to cover any deficit in addition to the amount covered by the employee stock options. Furthermore, in conjunction with the acquisition of Noster System AB, Orexo agreed to pay a supplementary purchase consideration of not more than MSEK 7.2, which would become payable if the growth of Heliprobe™ System achieves pre-determined sales targets up to December 31, 2009. The amount was reported under contingent liabilities. Otherwise, no significant changes in contingent liabilities or pledged assets occurred during the period.

### **Significant risks and uncertainties**

#### *Uncertainty regarding success of development efforts*

Orexo is a Group in the development stage with only three products on the market and a number of other product candidates in various development stages, of which some in the late clinical development phase. 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 the 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 would lack the possibility 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 can delay or disrupt operations. Changes to the healthcare system can also impact Orexo's operations and profitability.

#### *Key personnel*

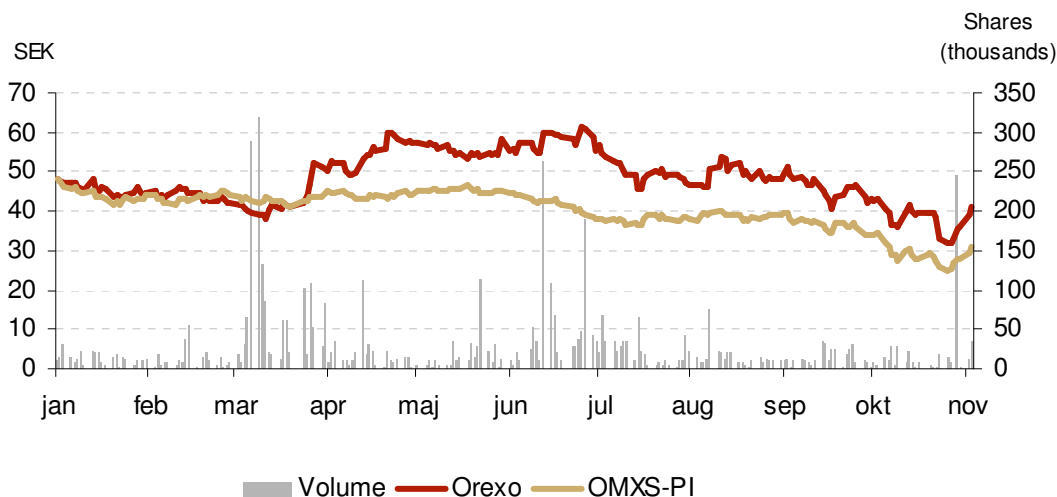
Orexo is dependent on its personnel and certain key individuals. In the event they should terminate their employment this could disrupt and delay development processes. To motivate and retain personnel and key individuals, the company offers such incentives as an options program aimed at all employees.

#### *Financial risk*

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

#### **Share**

Orexo's share was introduced on November 9, 2005 at a price of SEK 90 and was traded at SEK 42 on September 30, 2008. The company's market capitalization, based on the number of shares outstanding on September 30, 2008, was SEK 0.9 billion.



#### **Analysts who monitor Orexo**

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

**Future reporting dates**

Year-end Report 2008	February 17, 2009
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**

Orexo's Annual General Meeting will be held on April 23, 2009 in Stockholm.

Uppsala, November 10, 2008

Orexo AB (publ)

Torbjörn Bjerke  
President and CEO

*For further information, please contact*

Torbjörn Bjerke, President and CEO, tel: +46 18 780 88 12, e-mail: [torbjorn.bjerke@orexo.com](mailto:torbjorn.bjerke@orexo.com)

Claes Wenthzel, Vice President and CFO, tel: +46 18 780 88 44, e-mail: [claes.wenthzel@orexo.com](mailto:claes.wenthzel@orexo.com).

**Review report**

We have reviewed the appended interim report for the period January 1 to September 30, 2008 for Orexo AB (publ). The company's management 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, issued by FAR. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review has a different purpose and is substantially more limited 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 IAS 34 and the Annual Accounts Act for the Group and in accordance with the Annual Accounts Act for the Parent Company.

Uppsala, November 10, 2008  
PricewaterhouseCoopers AB

Leonard Daun  
Authorized Public Accountant

# **CONSOLIDATED BALANCE SHEET**

(SEK 000s)

	Notes	Sept. 30, 2008	Sept. 30, 2007	Dec. 31, 2007
<b>ASSETS</b>				
<b>Fixed assets</b>				
Tangible fixed assets		52,435	45,386	57,790
Goodwill		16,032	16,013	16,030
Other intangible assets		376,317	4,012	377,335
<b>Total fixed assets</b>		<b>444,784</b>	<b>65,411</b>	<b>451,155</b>
<b>Current assets</b>				
Inventories		12,772	10,928	13,294
Accounts receivable and other receivables		50,519	26,190	42,261
Tax receivables		3,944	2,204	3,565
Short-term investments		-	9,951	-
Cash and bank balances		195,662	142,530	291,598
<b>Total current assets</b>		<b>262,897</b>	<b>191,803</b>	<b>350,718</b>
<b>Total assets</b>		<b>707,681</b>	<b>257,214</b>	<b>801,873</b>
<b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>				
	3			
Share capital		8,647	5,584	8,647
Capital contributions		838,216	363,014	835,202
Accumulated losses		-261,218	-166,045	-172,597
<b>Total shareholders' equity</b>		<b>585,645</b>	<b>202,553</b>	<b>671,252</b>
<b>Long-term liabilities</b>				
Provisions		526	1,908	162
Long-term liabilities		9,100	-	9,595
Deferred tax liability		531	992	877
<b>Total long-term liabilities</b>		<b>10,157</b>	<b>2,900</b>	<b>10,634</b>
Current liabilities, non-interest-bearing		111,879	51,761	119,987
<b>Total liabilities</b>		<b>122,036</b>	<b>54,661</b>	<b>130,621</b>
<b>Total shareholders' equity and liabilities</b>		<b>707,681</b>	<b>257,214</b>	<b>801,873</b>
<b>Pledged assets</b>				
Pledged assets		2,500	2,500	14,500
<b>Contingent liabilities</b>		<b>43,550</b>	<b>7,250</b>	<b>43,550</b>



# **CONSOLIDATED STATEMENT OF OPERATIONS**

(SEK 000s)

	Notes	3 months 2008 July-Sept.	3 months 2007 July-Sept.	9 months 2008 Jan.- Sept.	9 months 2007 Jan.- Sept.	12 months 2007 Jan.- Dec.
Net sales		60,970	6,470	141,211	21,678	76,757
Cost of goods sold	2	-4,339	-3,378	-13,242	-10,189	-14,384
<b>Gross profit</b>		<b>56,631</b>	<b>3,092</b>	<b>127,969</b>	<b>11,489</b>	<b>62,373</b>
Selling expenses	2	-6,685	-5,019	-25,269	-18,513	-26,982
Administrative expenses	2	-10,751	-13,801	-38,429	-36,784	-58,932
Research and development costs	2	-41,325	-20,211	-162,573	-90,652	-155,972
Other operating income		1,627	179	4,246	9,775	9,958
Other operating costs	2	-181	-58	-2,169	-9,815	-11,014
<b>Operating loss</b>		<b>-684</b>	<b>-35,818</b>	<b>-96,225</b>	<b>-134,500</b>	<b>-180,569</b>
<b>Earnings from financial</b>						
<b>Investments</b>						
Interest income		2,468	1,663	7,449	5,798	8,231
Interest expenses		-15	-4	-190	-22	-23
Other financial items		0	0	0	0	-473
<b>Result after financial items</b>		<b>1,769</b>	<b>-34,159</b>	<b>-88,966</b>	<b>-128,724</b>	<b>-172,834</b>
Tax		115	83	345	123	237
<b>Net profit/loss for the period</b>		<b>1,884</b>	<b>-34,076</b>	<b>-88,621</b>	<b>-128,601</b>	<b>-172,597</b>
Profit/loss per share, before dilution, SEK		0.09	-2.44	-4.10	-9.24	-11.42
Earnings per share, after dilution, SEK		0.09	-2.44	-4.10	-9.24	-11.42
Average number of shares, before dilution		21,617,395	13,955,864	21,617,395	13,923,550	15,108,176
Average number of shares, after dilution		22,700,914	14,146,271	22,700,914	14,113,957	16,183,863
Number of shares, before dilution		21,617,395	13,961,250	21,617,395	13,961,250	21,617,395
Number of shares, after dilution		22,700,914	14,151,657	22,700,914	14,151,657	22,693,082

# **CONSOLIDATED CASH- FLOW STATEMENTS**

(SEK 000s)

	Notes	3 months 2008 July-Sept.	3 months 2007 July-Sept.	9 months 2008 Jan.-Sept.	9 months 2007 Jan.-Sept.	12 months 2007 Jan.-Dec.
<b>Continuing operations</b>						
Loss before interest income and interest expense		-684	-35,818	-96,225	-134,500	-180,569
Interest income		2,468	1,663	7,449	5,798	8,231
Interest expenses		-15	-4	-190	-22	-23
Other financial expenses						-473
Adjustment for items not included in cash flow	4	31	1,178	11,386	6,767	7,461
<b>Cash flow from operations before changes in working capital</b>		<b>1,800</b>	<b>-32,981</b>	<b>-77,580</b>	<b>-121,957</b>	<b>-165,373</b>
<b>Change in working capital</b>						
Accounts receivable		-5,841	3,916	-15,794	2,981	2,537
Other current receivables		2,558	-556	7,157	-10,370	-18,266
Inventories		1,680	-491	522	-1,694	-4,060
Current liabilities		-50,969	-853	-8,343	2,166	37,069
Provisions		-548	-3,318	364	-2,911	-4,657
Long-term liabilities		-	-	-495	-	-
<b>Cash flow from continuing operations</b>		<b>-51,320</b>	<b>-34,283</b>	<b>-94,169</b>	<b>-131,785</b>	<b>-152,750</b>
<b>Investing activities</b>						
Acquisition of machinery and equipment		-152	-22,698	-1,451	-41,749	-49,318
Divestment of machinery and equipment		-	-	11	-	-
Acquisition of current investments		-	20,978	-	46,175	-19,762
Divestment of current investments		-	-	-	-	75,888
Acquisition of shares in subsidiaries		-	-9,245	-327	-9,245	158,151
<b>Cash flow after investments</b>		<b>-51,472</b>	<b>-45,248</b>	<b>-95,936</b>	<b>-136,604</b>	<b>12,209</b>
<b>Change in financing</b>						
Proceeds from new share issue		-	-	-	2,726	2,981
<b>Cash flow after financing activities</b>		<b>-51,472</b>	<b>-45,248</b>	<b>-95,936</b>	<b>-133,878</b>	<b>15,190</b>
<b>Cash flow for the period</b>						
Cash and cash equivalents at the beginning of period		<b>247,134</b>	<b>187,778</b>	<b>291,598</b>	<b>276,408</b>	<b>276,408</b>
Change in cash and cash equivalents		-51,472	-45,248	-95,936	-133,878	15,190
<b>Cash and cash equivalents at end of period</b>		<b>195,662</b>	<b>142,530</b>	<b>195,662</b>	<b>142,530</b>	<b>291,598</b>

## KEY FIGURES

(SEK 000s)

	3 months July-Sept. 2008	3 months July-Sept. 2007	9 months Jan.-Sept. 2008	9 months Jan.-Sept. 2007	12 months Jan.-Dec. 2007
Operating margin, %	-1	-554	-68	-620	-235
Profit margin, %	3	-528	-63	-594	-225
Return on total capital, %	0	-12	-12	-41	-45
Return on shareholders' equity, %	0	-16	-14	-49	-53
Return on capital employed, %	0	-16	-14	-49	-53
Debt/equity ratio, multiple	0	0	0	0	0
Equity/assets ratio, %	83	79	83	79	84
Current ratio, %	235	371	235	371	292
Acid ratio, %	224	349	224	349	281
Average number of shares, before dilution	21,617,395	13,955,864	21,617,395	13,923,550	15,108,176
Average number of shares, after dilution	22,700,914	14,146,271	22,700,914	14,113,957	16,183,863
Number of shares after full dilution	23,349,608	14,896,025	23,349,608	14,896,025	23,010,220
Number of shares, before dilution	21,617,395	13,961,250	21,617,395	13,961,250	21,617,395
Number of shares, after dilution	22,700,914	14,151,657	22,700,914	14,151,657	22,693,082
Profit/loss per share, before dilution, SEK	0.09	-2.44	-4.10	-9.24	-11.42
Profit/loss per share, after dilution, SEK	0.09	-2.44	-4.10	-9.24	-11.42
Shareholders' equity per share, before dilution, SEK	27.09	14.51	27.09	14.51	31.05
Shareholders' equity per share, after dilution, SEK	25.80	14.31	25.80	14.31	29.58
Number of employees at the end of the period	124	74	124	74	129
Average number of employees	121	72	121	68	80
Shareholders' equity	585,645	202,553	585,645	202,553	671,252
Capital employed	585,634	202,553	585,645	202,553	671,252

## Definitions

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

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

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

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

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

**Capital employed:** Average of 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 through options outstanding.

**Number of shares, after dilution:** Calculation of the dilution from options issued by the company through 2005 was carried out in accordance with IAS 33.

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

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

**Shareholders' equity per share, 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'S BALANCE  
SHEET**

(SEK 000s)

	Notes	Sept. 30 2008	Sept. 30 2007	Dec. 31 2007
<b>ASSETS</b>				
<b>Fixed assets</b>				
Tangible fixed assets		51,712	45,250	50,903
Intangible fixed assets		468	413	566
Shares in subsidiaries/Joint ventures		524,169	18,379	523,842
<b>Total fixed assets</b>		<b>576,349</b>	<b>64,042</b>	<b>575,311</b>
<b>Current assets</b>				
Inventories		4,253	2,145	4,362
Accounts receivable and other receivables		62,207	45,656	51,987
Tax receivables		2,182	2,062	1,083
Current investments		-	9,951	-
Cash and bank balances		36,701	130,322	109,511
<b>Total current assets</b>		<b>105,343</b>	<b>190,136</b>	<b>166,943</b>
<b>Total assets</b>		<b>681,692</b>	<b>254,178</b>	<b>742,254</b>
<b>SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES</b>				
	6			
Restricted equity		299,398	365,775	299,398
Non-restricted equity		289,222	-159,824	366,534
<b>Total shareholders' equity</b>		<b>588,620</b>	<b>205,951</b>	<b>665,932</b>
<b>Long-term liabilities</b>				
Provisions		526	1,908	163
<b>Total long-term liabilities</b>		<b>526</b>	<b>1,908</b>	<b>163</b>
Current liabilities, non-interest-bearing		92,546	46,319	76,159
<b>Total liabilities</b>		<b>93,072</b>	<b>48,227</b>	<b>76,322</b>
<b>Total shareholders' equity, provisions and liabilities</b>		<b>681,692</b>	<b>254,178</b>	<b>742,254</b>
<b>Pledged assets</b>		<b>2,500</b>	<b>2,500</b>	<b>2,500</b>
<b>Contingent liabilities</b>		<b>11,050</b>	<b>11,050</b>	<b>11,050</b>

# **PARENT COMPANY'S STATEMENT OF OPERATIONS**

(SEK 000s)

	Notes	3 months July-Sept. 2008	3 months July- Sept. 2007	9 months Jan.- Sept. 2008	9 months Jan.- Sept. 2007	12 months Jan.- Dec. 2007
Net sales		44,192	374	90,408	5,883	48,389
Cost of goods sold	5	-	-63	-	-2,409	-2,409
<b>Gross profit</b>		<b>44,192</b>	<b>311</b>	<b>90,408</b>	<b>3,474</b>	<b>45,980</b>
Selling expenses	5	-2,808	-1,665	-10,997	-12,043	-15,408
Administrative expenses		-10,172	-13,452	-35,286	-36,140	-54,327
Research and development costs		-34,795	-20,671	-126,343	-91,111	-143,225
Other operating income		1,139	108	2,613	9,603	9,674
Other operating costs	5	-37	-58	-1,175	-9,636	-10,413
<b>Operating loss</b>		<b>-2,481</b>	<b>-35,427</b>	<b>-80,780</b>	<b>-135,853</b>	<b>-167,719</b>
<b>Earnings from financial Investments</b>						
Interest income		898	1,952	3,201	6,604	7,832
Interest expenses		-5	-4	-143	-10	-11
<b>Total loss after financial investments</b>		<b>-1,588</b>	<b>-33,479</b>	<b>-77,722</b>	<b>-129,259</b>	<b>-159,898</b>
<b>Net loss for the period</b>		<b>-1,588</b>	<b>-33,479</b>	<b>-77,722</b>	<b>-129,259</b>	<b>-159,898</b>

## Notes

### 1. Accounting principles

This interim report was prepared in accordance with IAS 34, Interim Financial Reporting, which complies with the requirements stipulated in the Swedish Financial Accounting Standards Council's recommendation RFR 1.1, Interim Financial Reporting for Groups. As of 2005, Orexo has applied 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 31 March 2008, the classification between selling costs and administrative expenses was 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.

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

The amounts below are in SEK thousands, unless otherwise indicated.

### 2. Costs distributed by type of cost

	<b>July-Sept. 2008</b>	<b>July-Sept. 2007</b>	<b>Jan.-Sept. 2008</b>	<b>Jan.-Sept. 2007</b>	<b>Jan.-Dec. 2007</b>
Raw materials and supplies	8,496	3,811	24,216	13,509	26,835
Other external costs	30,312	18,705	118,385	81,126	132,307
Personnel costs	21,837	18,537	90,947	58,511	92,967
Depreciation and impairment	2,637	1,414	8,134	3,507	5,875
Reinvoicing of rebuilding costs	-	-	-	9,300	9,300
<b>TOTAL</b>	<b>63,282</b>	<b>42,467</b>	<b>241,682</b>	<b>165,953</b>	<b>267,284</b>

### 3. Shareholders' equity

#### Changes in Group equity

	<b>July-Sept. 2008</b>	<b>July-Sept. 2007</b>	<b>Jan.-Sept. 2008</b>	<b>Jan.-Sept. 2007</b>	<b>Jan.-Dec. 2007</b>
Shareholders' equity brought forward according to balance sheet	<b>585,124</b>	<b>235,255</b>	<b>671,252</b>	<b>324,350</b>	<b>324,350</b>
Profit/loss for the period	1,884	-34,076	-88,621	-128,601	-172,597
Subscription of shares through the exercise of warrants	-	-	-	2,726	2,981
New share issues	-	-	-	-	438,775
New share of employee stock options	-	-	-	-	52,875
Employee stock options, value of employees' service	-1,363	1,374	3,014	4,078	5,989
Acquired value of employee stock options	-	-	-	-	18,879
<b>Amount at close of period</b>	<b>585,645</b>	<b>202,553</b>	<b>585,645</b>	<b>202,553</b>	<b>671,252</b>

**Shares outstanding**

The number of shares outstanding at September 30, 2008, was 21,617,395, all of which were common shares. All shares carry entitlement to one vote each. No increase in the number of shares outstanding occurred during the period.

**Options**

At September 30, there were 2,614,816 options outstanding carrying subscription rights corresponding to 2,121,213 shares in Orexo and the exchange of 493,603 options for shares in Orexo<sup>3</sup>. Each option issued by Biolipox AB carries the right of exchange for one share in Orexo AB, and the corresponding number of shares is held by the independent company Pyrinox AB.

The following table shows changes in the number of options in each category during the January–September 2008 period.

	Opening Jan. 1, 2008	-	+	Closing Sept. 30, 2008
<b>Stock options targeted to employees</b>				
Of which:				
Decided and allotted employee stock options	373,525	-89,450	412,500	696,575
Decided and allotted Board member stock options	-	-	16,388	16,388
Decided and allotted subscription warrants	15,250	-	-	15,250
Decided but not yet allotted employee stock options 2008	372,000	-372,000	389,000	389,000
Subscription warrants held by subsidiaries for cash-flow hedging of social security fees	78,000	-	-	78,000
<b>Total decided stock options</b>	<b>838,775</b>	<b>-461,450</b>	<b>817,888</b>	<b>1,195,213</b>
Employee stock options taken over from Biolipox AB (not resulting in dilution and included in newly issued shares in conjunction with the acquisition of Biolipox)	399,167	-35,938	-	363,229
Subscription warrants taken over from Biolipox AB for cash-flow hedging of social security fees (not resulting in dilution)	135,374	-5,000	-	130,374
<b>Total stock options from Biolipox</b>	<b>534,541</b>	<b>-40,938</b>	<b>-</b>	<b>493,603</b>
<b>Total stock options targeted to employees</b>	<b>1,373,316</b>	<b>-502,388</b>	<b>817,888</b>	<b>1,688,816</b>
<b>Other options</b>				
Subscription warrants constituting supplementary purchase consideration for the acquisition of Biolipox AB	926,000	-	-	926,000
<b>Total outstanding stock options</b>	<b>2,299,316</b>	<b>-502,388</b>	<b>817,888</b>	<b>2,614,816</b>

During the period July–September 2008, 859 Biolipox employee stock options were exercised in which the holders exchanged their options for 859 Orexo shares held by the independent company Pyrinox AB. Consequently, exercise did not result in Orexo issuing additional shares. During the period January–September, Pyrinox sold 5,000 warrants for cash flow hedging of social security costs.

<sup>3)</sup> All data is adjusted for the 1:250 share split carried out 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*

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:

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

The exercise price was SEK 44 per share and the term 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 plan 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 plan including the issuance of subscription warrants and approval of disposition of subscription warrants within the framework of the employee stock option plan. The employee stock option plan 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 established 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 plan. Full exercise of the warrants will result in a dilution of about 2.0% of the share capital and votes in Orexo. Of these employee stock options, 40,500 were allotted without charge to employees during the July – September 2008 period. 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 maturity period extends up until 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 Plan 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 Plan 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 July – September period, the Board of Directors resolved to cancel option certificates with entitlement to subscription for 89,450 shares. The cancelled options relate to earned options for employees who have terminated their employment and therefore will not be able to exercise them.

#### 4. Consolidated cash flow

##### Adjustment for items not included in cash flow

	July-Sept. 2008	July-Sept. 2007	Jan.-Sept. 2008	Jan.-Sept. 2007	Jan.-Dec. 2007
Depreciation/amortization and impairments	2,637	1,414	8,134	3,507	5,875
Calculated costs for employee stock option program	-2,596	-228	3,249	3,266	1,381
Other	-10	-8	3	-6	205
<b>Total</b>	<b>31</b>	<b>1,178</b>	<b>11,386</b>	<b>6,767</b>	<b>7,461</b>

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

	July-Sept. 2008	July-Sept. 2007	Jan.-Sept. 2008	Jan.-Sept. 2007	Jan.-Dec. 2007
Raw materials and supplies	4,420	494	8,113	5,727	9,162
Other external costs	22,450	17,594	84,909	79,600	125,146
Personnel costs	19,112	16,714	75,429	53,671	77,603
Depreciation and impairment	1,830	1,107	5,350	3,041	4,571
Reinvoicing of rebuilding costs	-	-	-	9,300	9,300
<b>TOTAL</b>	<b>47,812</b>	<b>35,909</b>	<b>173,801</b>	<b>151,339</b>	<b>225,782</b>

#### 6. Shareholders' equity

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

	July-Sept. 2008	July-Sept. 2007	Jan.-Sept. 2008	Jan.-Sept. 2007	Jan.-Dec. 2007
Shareholders' equity brought forward according to balance sheet	<b>592,366</b>	<b>238,056</b>	<b>665,932</b>	<b>328,406</b>	<b>328,406</b>
Loss for the period	-1,588	-33,479	-77,722	-129,259	-159,898
Subscription of shares through the exercise of warrants	-	-	-	2,726	2,981
New share issues	-	-	-	4,078	438,776
New issue of subscription warrants	-	-	-	-	52,875
Employee stock options, value of employees' service	-2,158	1,374	410	-	5,392
Group contributions	-	-	-	-	-2,600
<b>Amount at the close of the period</b>	<b>588,620</b>	<b>205,951</b>	<b>588,620</b>	<b>205,951</b>	<b>665,932</b>

#### 7. Events after the close of the period

See page 2.

##### Note

Orexo AB Publ. discloses the information provided herein pursuant to the Securities Markets Act. The information was provided for public release on November 10, 2008 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.