

Orexo AB (publ)

– Interim report January-June 2008

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Uppsala, August 14, 2008

Orexo AB (publ) – Interim report January-June 2008

Key events during the period

- Net revenues amounted to MSEK 80.2 (15.2)
- A loss after tax of MSEK 90.5 (loss: 94.5) was reported
- Earnings per share amounted to a loss of SEK -4.19 (loss: 6.80)
- The exclusive world rights to two Orexo pharmaceuticals, Sublinox™ (OX22) and OX-NLA, were licensed to Meda AB.
- Rapinyl™/Abstral was approved for registration in Europe by the EMEA's Committee for Medicinal Products for Human Use (CHMP).
- Cash flow from continuing operations was MSEK -42,8 (-97,5)

Second quarter of 2008

- Net revenue amounted to MSEK 56.2 (8.8)
- The loss after tax was MSEK 28.3 (loss: 56.6)
- Earnings per share amounted to a loss of SEK 1.31 (loss: 4.06)
- Cash flow from continuing operations was MSEK 45,7 (-48,6)

Key events after the closing date

- After the initial evaluation, the registration application for Sublinox™ (OX22) was accepted as complete for final evaluation by the Food and Drug Administration (FDA) in the US.
- Orexo expanded the licensing agreement with ProStrakan for Rapinyl™/Abstral and changed partners in the US.

Condensed statement of operations ¹

MSEK	3 months 2008 April-June	3 months 2007 April-June	6 months 2008 Jan.-June	6 months 2007 Jan.-June	12 months 2007 Jan.-Dec.
Net revenues	56.2	8.8	80.2	15.2	76.8
Loss after tax	-28.3	-56.6	-90.5	-94.5	-172.6
Loss per share, before dilution (SEK)	-1.31	-4.06	-4.19	-6.80	-11.42
Loss per share, after dilution (SEK) ²	-1.31	-4.06	-4.19	-6.80	-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 company is growing at all levels, with successes for several of our products and new recruitment of key personnel.

During the period, Orexo received a positive opinion recommending approval from EMEA for Abstral in Europe. This was an important building block in our goal of becoming a profitable pharmaceuticals company. Sales of the product will begin in Sweden during August this year. I am convinced that Abstral will be an important therapy in the treatment of cancer patients suffering from breakthrough pain and look forward to further development of the product together with our business partner, ProStrakan Group.

We announced an expansion of our licensing agreement with ProStrakan regarding sales and marketing of Abstral also to the North American market. The new agreement also entails an increase in royalty levels by slightly more than 40 percent in both Europe and the US.

In summary, it was an eventful quarter with two very important events are the Approval for Rapinyl™/Abstral and the Agreement with Meda”.

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

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

Key events during the period

Orexo's Annual General Meeting on April 3 – two new Board members elected

The Annual General Meeting resolved to re-elect Monica Caneman, Johan Christenson, Staffan Lindstrand and Kjell Strandberg, and to elect new members Ray Hill and Bengt Samuelsson, as members of the Board of Directors. Håkan Åström was re-elected as Chairman of the Board of Directors until the close of the next Annual General Meeting.

The Meeting resolved to adopt a new employee stock option plan including the issuance of warrants and approval of disposal of the warrants under the employee stock option plan. The employee stock option plan consists of 470,000 employee stock options. Each employee stock option can be exercised to acquire one share in Orexo against payment of an exercise price determined as 110 percent of the market value of the Orexo share at the date of allotment.

The Meeting 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 director fee and any fee for committee work in cash and will be allocated a number of Board Member shares, whose value at the time of allotment shall correspond to 50% of the director fee and any fee for committee work. The right to acquire new shares under the Shareholder Plan is subject to the Board member continuing to serve as a Board member throughout all or part of the period in office.

Exclusive global rights to two Orexo drugs, Sublinox™ (OX22) and OX-NLA licensed to Meda AB

Sublinox™ (OX22) for temporary treatment of sleeping disorders contains the well-documented active substance zolpidem, one of the world's most-used drugs for treatment of sleeping disorders. Sublinox™ (OX22) uses a unique and patented sublingual tablet formulation that provides fast and reliable onset effect. A recently completed Phase III study confirmed that Sublinox™ (OX22) produces a more rapid effect than other zolpidem tablet formulations. The FDA application for Sublinox™ (OX22) was submitted during the second quarter of 2008.

OX-NLA is a nasal spray formulation containing the antihistamine substance cetirizine. The liposomes in OX-NLA give the product its unique characteristics. OX-NLA is documented for treatment of allergic and non-allergic rhinitis, one of Meda's principal treatment areas. The product is at the start of Phase III. Meda will take over and finance continued development. Meda has also acquired the exclusive rights for combination products based on OX-NLA.

As compensation for the exclusive global rights for Sublinox™ (OX22) and OX-NLA, Meda paid MUSD 20, of which the entire initial one-time payment was attributable to OX22. Meda will also make the following one-time compensation payments to Orexo in conjunction with the achievement of certain milestones in annual sales.

	Sublinox™ (OX22)		OX-NLA	
Upon registration approval by the FDA	MUSD 30		MUSD 15	
Milestones for annual sales	Sales	One-time payment	Sales	One-time payment
	> MUSD 150	MUSD 20	> MUSD 150	MUSD 20
	> MUSD 200	MUSD 20	> MUSD 300	MUSD 20
	> MUSD 400	MUSD 20		

Orexo will receive a double-digit royalty payment from Meda’s sales.

Abstral/Rapinyl™ approved for registration in Europe

Abstral/Rapinyl™, which is intended for treatment of breakthrough pain in cancer, has been approved for registration in Europe by the EMEA’s Committee for Medical products for Human Use (CHMP). Approval means that the product will be launched in Sweden during the third quarter and plans are also under way for launch in other European countries under the brand name Abstral toward the end of the year.

In conjunction with the approval, ProStrakan reached an agreement with the EMEA to provide EMEA with additional safety data from the ongoing clinical studies.

Key events after the closing date

FDA begins final evaluation of Sublinox™

After the initial evaluation, the registration application for Sublinox™ (OX22) was accepted as complete for final evaluation. Sublinox™ contains the well-known active substance zolpidem, is based on Orexo's sublingual tablet technology and is a tablet that quickly disintegrates under the tongue.

The data on which the application is based includes a clinical study of patients suffering from sleeping disorders completed in October 2007. The study showed that Sublinox™ induced sleep 30 percent faster, compared with Ambien/Stilnoct, and that patients slept the entire night. The safety profile for Sublinox™ was comparable to Ambien/Stilnoct.

Orexo signs license agreement with ProStrakan in North America

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

Endo will complete and finance the Phase III studies now in progress. When the agreement with Endo is terminated a fee of USD 750,000 is to be paid to Orexo. This is estimated to take place no later than January 30, 2009.

Orexo has consequently expanded the licensing agreement with ProStrakan Group plc, the international specialty pharmaceuticals company, to include North America as a new territory. ProStrakan, which was previously Orexo's partner for sales and marketing of Rapinyl™/Abstral in Europe, will now also be responsible for sales and marketing of Rapinyl™/Abstral in North America. Abstral was approved for marketing in Europe in June this year.

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

In respect of the transfer from Endo and the new agreement for the North American market, Orexo will receive MUSD 2 from ProStrakan. This is estimated to take place no later than January 30, 2009. In addition, Orexo may receive a further MUSD 27 in application and sales-level compensation and milestones, excluding the MUSD 2 received at effective date of the agreement. In the earlier agreement with Endo could the total amount in sales milestones be up to MUSD 39.2.

In conjunction with signing of the contract, the existing contract pertaining to Europe was also amended. The milestone compensation linked to approval in the five largest markets was reduced from MEUR 5 to MUSD 5, and sales-level compensation in Europe was increased from MEUR 10 to MEUR 19.9. At the same time, royalty payments were raised by 7 to 9 percentage points, corresponding to an increase of slightly more than 40 percent. The royalty compensation in North America was increased by a corresponding amount, in relation to the previous agreement with Endo.

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 of new treatment forms for respiratory and inflammatory diseases.

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

Orexo has licensed out the marketing rights to Rapinyl™/Abstral for the North American, European, Asian and Japanese markets, world rights for Sublinox™ (OX22) and OX-NLA, and is cooperating with Boehringer Ingelheim in the development of a new pharmaceutical drug 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

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 analysis 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 swallowing. 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 component, 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 in the Japanese market.

Since the Heliprobe™ System has been launched in more than 30 countries, including Eastern Europe, the Middle East and Asia, Kibion 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

Rapinyl™/Abstral – for the treatment of acute pain is approved for sale in Europe and is in Phase III in the US. Rapinyl™/Abstral 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 and predictable onset of drug effect with "on-demand" features. License agreements for Rapinyl™/Abstral have been signed with ProStrakan Group Ltd. for the European and North American markets and with Kyowa Hakko for the Japanese market. Distribution agreements for the CIS (Russia and other

countries in the former Soviet Union), Bulgaria and Rumania have been signed with Gedeon Richter and for Southeast Asia, including Australia and New Zealand with Hospira.

In December 2005, Phase III studies began in the USA on Rapinyl™/Abstral. Positive results from an interim analysis of the Phase III study were announced in December 2007. When all 100 patients Phase III studies have been completed, a registration application will be submitted to the FDA in the US. At present, it is expected that this will take place toward the end of this year.

Sublinox™ (OX22) – for the treatment of sleeping disorders. Sublinox™ (OX22) is based on Orexo's sublingual tablet technology. In 2006, the US insomnia market was worth MUSD 3.3 billion (according to IMS sales data).

After the close of the period, a license agreement regarding Sublinox™ (OX22) was signed with Meda covering exclusive world rights.

During October, Orexo completed the Phase III program by conducting the effect, local tolerance and safety study trials among patients using Sublinox™ (OX22) – for the treatment of temporary insomnia – with positive results. The efficacy trials confirmed that Sublinox™ (OX22) renders a 30 percent faster onset of sleep compared with Ambien™, in patients suffering from sleeping disorders. The study also showed that more patients remain asleep throughout the night. The study strengthens existing documentation that Sublinox™ (OX22) is a safe and effective treatment for temporary insomnia.

OX-MPI – Selective prostaglandin E2 synthesis inhibitors 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 is partnered 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 was signed with Meda during the quarter. 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 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 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.

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 H₂-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.

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.

OX2477 – Is a part of an entirely new class of agents with treatment potential for asthma and COPD. Orexo has discovered a new group of mediators, eoxins, that are formed primarily in cells in respiratory passages and have shown powerful pro-inflammatory effects. Accordingly, release of eoxins 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.

Other projects with potential for further development

OX-LSAID – for the treatment of moderate to severe asthma. The LSAID-program contains non-steroidal anti-inflammatory substances that have shown favorable effects in preclinical asthma models. Clinical studies have shown effects on certain parameters in patients with asthma.

OX19 – for the treatment of daytime and nocturnal urinary incontinence (nocturia). In addition to the treatment of nocturia, OX19 also focuses on the short-term, on-demand treatment of urinary incontinence in women suffering from an overactive bladder. A pharmacological study in healthy persons has been concluded. Orexo will seek partners for continued development of the nasal powder preparation of desmopressin.

OX40 – for the acute treatment of moderate and severe migraine. The plan for the project is to develop a candidate drug with a fast and predictable onset of effect, an essential characteristic for effective on-demand medication.

OX23 – for the treatment of acute pain. Based on Orexo's sublingual technology – the sublingual dosage form allowing a rapid dissolution of a tablet placed under the tongue resulting in a prompt onset of effect and predictable effects – typical “on-demand” properties.

The period in figures, January 1 – June 30, 2008

Condensed consolidated statement of operations

MSEK	3 months	3 months	6 months	6 months	12 months
	2008	2007	2008	2007	2007
	April-June	April- June	Jan.- June	Jan.- June	Jan.-Dec.
Net revenue	56.2	8.8	80.2	15.2	76.8
Cost of goods sold	-5.0	-4.1	-8.9	-6.8	-14.4
Gross profit	51.2	4.7	71.3	8.4	62.4
Sales costs	-10.6	-9.3	-18.6	-13.5	-27.0
Administrative expenses	-12.4	-12.1	-27.7	-22.9	-58.9
Research and development costs	-59.1	-41.6	-121.2	-70.4	-156.0
Other operating income and expenses	-0.2	-0.2	0.6	-0.2	-1.1
Operating loss	-31.0	-58.5	-95.5	-98.6	-180.6
Net financial items	2.6	1.9	4.8	4.1	7.7
Loss after financial items	-28.4	-56.6	-90.7	-94.5	-172.8
Tax	0.1	0.0	0.2	0.0	0.2
Net loss for the period	-28.3	-56.6	-90.5	-94.5	-172.6

Revenue

Net revenue

Consolidated net revenue for the period January – June 2008 amounted to MSEK 80.2 (15.2). The sharp increase compared with the preceding year was primarily due to licensing revenues from Meda, from which Orexo received MSEK 118 (MUSD 20) in one-time compensation. These revenues will be booked linearly up until FDA approval has been gained (12 months). MSEK 29.5 was recognized up until June 30, 2008. However, revenues from the partnership with Boehringer Ingelheim GmbH relating to OX-MPI and from the joint venture company ProStrakan also contributed to net revenue.

Net revenue was distributed as follows:

MSEK	Jan.-June 2008	Jan.-June 2007	Jan.-Dec. 2007
Diabact® UBT	2.6	3.0	5.2
Heliprobe™ System	11.7	9.7	19.7
ProStrakan AB J/V 50%	4.4	-	2.7
License revenue	29.5	-	34.0
Other	32.0	2.5	15.2
Total	80.2	15.2	76.8

During the period April – June 2008, net revenue amounted to MSEK 56.2 (8.8).

Expenses and earnings

Selling expenses

Consolidated selling expenses amounted to MSEK 18.6 (13.5) for the period January – June 2008 and to MSEK 10.6 (9.3) for the period April - June 2008.

Selling expenses primarily include costs for business development linked to the licensing-out 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 increased cost for business development mainly outlicensing and costs in the joint venture (ProStrakan AB).

Administrative expenses

Administrative expenses amounted to MSEK 27.7 (22.9) for the period January – June 2008 and to MSEK 12.4 (12.1) for the period April-June 2008.

The increase with respect to the corresponding period for 2007 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 expenses

Research and development expenses amounted to MSEK 121.2 (70.4) for the period January–June 2008 and to MSEK 59.1 (41.6) for April–June 2008.

The increase in research and development expenses compared with the corresponding period for 2007 was attributable to the acquisition of Biolipox AB in November 2007.

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. The company has several development projects in advanced phases, including Rapinyl™/Abstral for the treatment of acute pain, OX-MPI for treatment of pain, inflammation and rheumatism, Sublinox™ (OX22) for the treatment of sleeping disorders, OX17 for GERD, OX-NLA for treatment of allergic and non-allergic 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 April-June 2008, the company's costs for the employee stock option plan totaled MSEK 3.4 (2.0). The higher costs during the quarter were due to an increase in the number of outstanding options resulting from the acquisition of Biolipox in November 2007, allotments in February 2008 according to the stock option plan resolved by the 2007 Annual General Meeting, the Board Member share ownership plan approved by the 2008 Annual General Meeting and amounts vested by employees during this and previous stock option plans during the period. The increase in share price during the period also resulted in increased costs being recognized as a provision for calculated social security fees.

For the period January-June 2008, costs for the employee stock option plan amounted to MSEK 5.8 (3.5), of which MSEK 2.8 (1.3) was attributable to administrative employees, MSEK 2.7 (1.9) to research and development-related personnel and MSEK 0.3 (0.3) to sales-related personnel.

Other income and expenses

Other income and expenses, consisting primarily of exchange-rate gains and losses, amounted to income of MSEK 0.6 (expense: 0.2) for the period January – June 2008 and to an expense of MSEK 0.2 (expense: 0.2) for the period April-June 2008.

Depreciation/amortization

Depreciation/amortization amounted to MSEK 5.5 (2.1) for the period January–June 2008 and to MSEK 2.6 (1.0) for the period April–June 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–June 2008 amounted to MSEK 0.2 (0.0).

Net loss

The operating loss for the period January – June 2008 amounted to MSEK 95.5 (loss: 98.6). The loss after net financial items was MSEK 90.7 (94.5), and the loss after tax was MSEK 90.5 (94.5). 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 April – June was MSEK 31.0 (loss: 58.5). The loss after financial items was MSEK 28.4 (loss: 56.6), and the loss after tax was MSEK 28.3 (loss: 56.6).

Financial position

The Group's cash and cash equivalents amounted to MSEK 247.1 (187.8) at June 30, 2007 and short-term investments amounted to MSEK 0 (30.9).

Cash flow from operating activities for the period January–June 2008 was a negative MSEK 42.8 (neg: 97.5). Cash flow after financing was a negative amount of MSEK 44.5 (neg. 88.6).

Cash flow from operating activities for the period April–June 2008 was a negative MSEK 45.7 (neg. 48.6). Cash flow after financing was a negative amount of MSEK 45.5 (neg. 13.1).

Shareholders' equity on June 30, 2008 amounted to MSEK 585.1 (235.3). The equity/assets ratio was 77 percent (80 percent).

Investments

Gross investments in tangible fixed assets amounted to MSEK 1.3 (19.1) for the period January–June 2008 and to MSEK 0.1 (12.7) for the period April–June 2007. The decline from the corresponding period was primarily attributable to remodeling of new premises and investments in production and research equipment 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–June 2008 amounted to MSEK 46.2 (5.5) and the loss after net financial items was MSEK 76.1 (loss: 95.8). Investments amounted to MSEK 5.9 (19.1). The Parent Company's cash and cash equivalents and current investments totaled MSEK 83.1 (217.2).

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 is 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 two products on the market and a number of other product candidates in various development stages, of which some are in late-stage clinical development. 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 lose the possibility to license out or commercialize those programs as 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

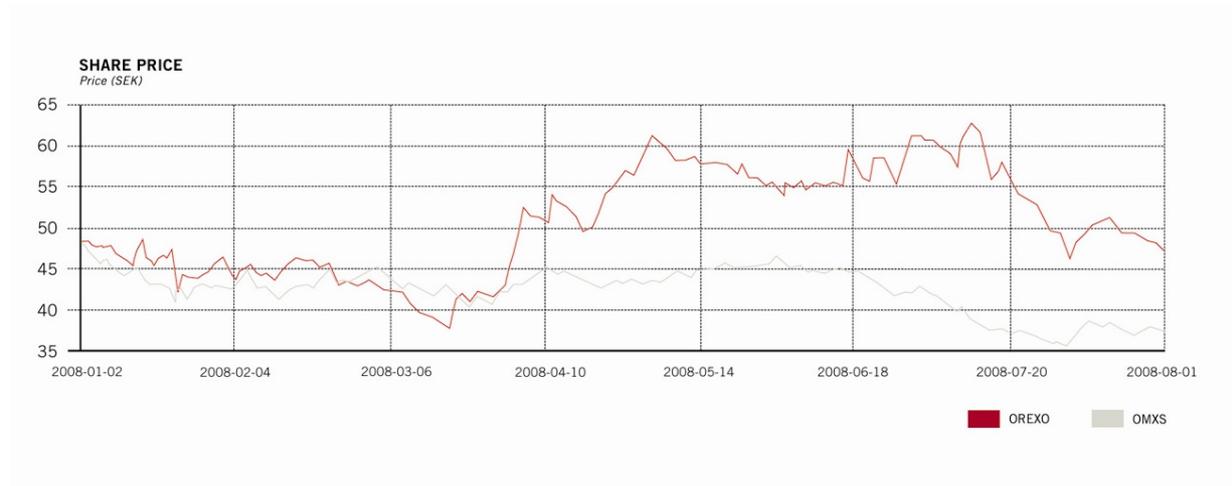
Orexo is dependent on its personnel and certain key individuals. In the event they should terminate their employment this could disrupt and delay development processes. To motivate and retain personnel and key individuals, the company offers such incentives as an options program aimed at all employees.

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 manage and limit these risks effectively.

Share

Orexo's share was introduced on November 9, 2005 at a price of SEK 90 and was traded at SEK 59 on June 30, 2008. The company's market capitalization, based on the number of shares outstanding on June 30, 2008, was SEK 1.3 billion.



Analysts who monitor Orexo

ABG Sundal Collier	Alexander Lindström and Jenni Ruottinen
Carnegie AB	Camilla Oxhamre
Handelsbanken Markets	Erik Hultgård
Redeye	Björn Andersson
SEB	Gustaf Vahlne and Lars Hevrenng

Future reporting dates

Interim Report, January-September 2008 _____ November 10
 Year-end Report 2008 _____ not later than February 28, 2009

Board of Directors' certification

The Board of Directors and the President certify that this interim report presents a fair overview of the operations, financial position and earnings of the company and the Group and that it describes any significant risks and uncertainties facing the company and the companies included in the Group.

Uppsala, August 14, 2008

Orexo AB (publ)

Håkan Åström
Chairman of the Board

Monica Caneman
Board member

Johan Christenson
Board member

Raymond Hill
Board member

Staffan Lindstrand
Board member

Bengt Samuelsson
Board member

Kjell Strandberg
Board member

Torbjörn Bjerke
President and CEO

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Review report

We have reviewed the appended report for the period January 1 to June 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, August 14, 2008
PricewaterhouseCoopers

Leonard Daun
Authorized Public Accountant

CONSOLIDATED BALANCE SHEET

(SEK 000s)

	Notes	June 30, 2008	June 30, 2007	Dec. 31, 2007
ASSETS				
Fixed assets				
Tangible fixed assets		54,466	23,696	57,790
Goodwill		16,030	8,988	16,030
Intangible fixed assets		376,764	1,629	377,335
Total fixed assets		447,260	34,313	451,155
Current assets				
Inventories		14,452	10,437	13,294
Accounts receivable and other receivables		47,407	29,706	42,261
Tax receivables		3,773	1,853	3,565
Short-term investments		0	30,929	-
Cash and bank balances		247,134	187,778	291,598
Total current assets		312,766	260,703	350,718
Total assets		760,026	295,016	801,873
SHAREHOLDERS' EQUITY AND LIABILITIES				
	3			
Share capital		8,647	5,584	8,647
Capital contributions		839,579	361,640	835,202
Accumulated losses		-263,102	-131,967	-172,597
Total shareholders' equity		585,124	235,257	671,252
Long-term liabilities				
Provisions		1,074	5,226	162
Long-term liabilities		9,100	-	9,595
Deferred tax liability		647	317	877
Total long-term liabilities		10,821	5,543	10,634
Current liabilities, non-interest-bearing		164,081	54,216	119,987
Total liabilities		174,902	59,759	130,621
Total shareholders' equity and liabilities		760,026	295,016	801,873
Pledged assets		2,500	2,500	14,500
Contingent liabilities		43,550	7,250	43,550

CONSOLIDATED STATEMENT OF OPERATIONS

(SEK 000s)

	Notes	3 months 2008 April-June	3 months 2007 April-June	6 months 2008 Jan.-June	6 months 2007 Jan.-June	12 months 2007 Jan.-Dec.
Net revenue		56,246	8,806	80,241	15,208	76,757
Cost of goods sold	2	-5,007	-4,130	-8,903	-6,811	-14,384
Gross profit		51,239	4,676	71,338	8,397	62,373
Selling expenses	2	-10,582	-9,257	-18,584	-13,494	-26,982
Administrative expenses	2	-12,377	-12,170	-27,678	-22,983	-58,932
Research and development costs	2	-59,064	-41,584	-121,248	-70,441	-155,972
Other operating income		1,746	6,757	2,619	9,596	9,958
Other operating expenses	2	-1,988	-6,887	-1,988	-9,757	-11,014
Operating loss		-31,026	-58,465	-95,541	-98,682	-180,569
Earnings from financial investments						
Interest income		2,708	1,846	4,981	4,135	8,231
Interest expenses		-140	-1	-175	-18	-23
Other financial expenses		0	0	0	0	-473
Total loss from financial investments		-28,458	-56,620	-90,735	-94,565	-172,834
Tax		115	20	230	40	237
Net loss for the period		-28,343	-56,600	-90,505	-94,525	-172,597
Loss per share, before dilution, SEK		-1.31	-4.06	-4.19	-6.80	-11.42
Earnings per share, after dilution, SEK		-1.31	-4.06	-4.19	-6.80	-11.42
Average number of shares, before dilution		21,617,395	13,928,161	21,617,395	13,907,393	15,108,176
Average number of shares, after dilution		22,797,594	14,187,810	22,823,435	14,167,042	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		22,823,435	14,220,899	22,823,435	14,220,899	22,693,082

CONSOLIDATED CASH-FLOW STATEMENTS

(SEK 000s)

	Notes	3 months 2008 April-June	3 months 2007 April-June	6 months 2008 Jan.-June	6 months 2007 Jan.-June	12 months 2007 Jan.-Dec.
Continuing operations						
Loss before interest income and interest expense		-31,026	-58,465	-95,541	-98,682	-180,569
Interest income		2,708	1,846	4,981	4,135	8,231
Interest expenses		-140	-1	-175	-18	-23
Other financial expenses						-473
Adjustment for items not included in cash flow	4	6,103	2,993	11,355	5,589	7,461
Cash flow from operations before changes in working capital		-22,355	-53,627	-79,380	-88,976	-165,373
Change in working capital						
Accounts receivable		-6,482	-5,640	-9,953	-935	2,537
Other current receivables		-6,796	-1,119	4,599	-9,814	-18,266
Inventories		-222	-2,641	-1,158	-1,203	-4,060
Current liabilities		80,910	13,972	42,626	3,019	37,069
Provisions		745	495	912	407	-4,657
Long-term liabilities		-124	-	-495	-	-
Cash flow from continuing operations		45,676	-48,560	-42,849	-97,502	-152,750
Investing activities						
Acquisition of machinery & equipment		-139	-12,671	-1,299	-19,051	-49,318
Divestment of machinery & equipment		-	-	11	-	-
Acquisition of current investments		-	-	-	-19,762	-19,762
Divestment of current investments		-	45,473	-	44,959	75,888
Acquisition of shares in subsidiaries		-	-	-327	-	158,151
Cash flow after investments		45,537	-15,758	-44,464	-91,356	12,209
Change in financing						
Proceeds from new share issue		0	2,706	0	2,726	2,981
Cash flow after financing activities		45,537	-13,052	-44,464	-88,630	15,190
Cash flow for the period						
Cash and cash equivalents at the beginning of period		201,597	200,830	291,598	276,408	276,408
Change in cash and cash equivalents		45,537	-13,052	-44,464	-88,630	15,190
Cash & cash equivalents at end of period		247,134	187,778	247,134	187,778	291,598

KEY FIGURES
(SEK 000s)

	3 months April-June 2008	3 months April-June 2007	6 months Jan.-June 2008	6 months Jan.-June 2007	12 months Jan.-Dec. 2007
Operating margin, %	-55	-664	-119	-649	-235
Profit margin, %	-51	-643	-113	-622	-225
Return on total capital, %	-4	-18	-12	-28	-45
Return on shareholders' equity, %	-5	-21	-14	-33	-53
Return on capital employed, %	-5	-21	-14	-33	-53
Debt/equity ratio, multiple	0	0	0	0	0
Equity/assets ratio, %	77	80	77	80	84
Current ratio, %	191	481	191	481	292
Acid ratio, %	182	462	182	462	281
Average number of shares, before dilution	21,617,395	13,928,161	21,617,395	13,907,393	15,108,176
Average number of shares, after dilution	22,797,594	14,132,683	22,823,435	14,167,042	16,183,863
Number of shares after full dilution	23,398,558	14,896,025	23,398,558	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	22,823,435	14,220,899	22,823,435	14,220,899	22,693,082
Loss per share, before dilution, SEK	-1.31	-4.06	-4.19	-6.80	-11.42
Loss per share, after dilution, SEK	-1.31	-4.06	-4.19	-6.80	-11.42
Shareholders' equity per share, before dilution, SEK	27.07	16.85	27.07	16.85	31.05
Shareholders' equity per share, after dilution, SEK	25.64	16.54	25.64	16.54	29.58
Number of employees at the end of the period	120	71	120	71	129
Average number of employees	125	69	125	68	80
Shareholders' equity	585,124	235,257	585,124	235,257	671,252
Capital employed	585,124	235,257	585,124	235,257	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.

PARENT COMPANY'S BALANCE SHEET

(SEK 000s)

	Notes	June 30 2008	June 30 2007	Dec. 31 2007
ASSETS				
Fixed assets				
Tangible fixed assets		53,358	23,629	50,903
Financial fixed assets		501	436	566
Shares in subsidiaries/Joint ventures		524,169	100	523,842
Total fixed assets		578,028	24,165	575,311
Current assets				
Inventories		6,079	2,575	4,362
Accounts receivable and other receivables		61,423	48,010	51,987
Tax receivables		1,828	1,753	1,083
Current investments		0	211,085	-
Cash and bank balances		83,067	6,105	109,511
Total current assets		152,397	269,528	166,943
Total assets		730,425	293,693	742,254
SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES				
	6			
Restricted equity		299,398	364,402	299,398
Non-restricted equity		292,968	-126,346	366,534
Total shareholders' equity		592,366	238,056	665,932
Long-term liabilities				
Provisions		1,074	5,226	163
Total long-term liabilities		1,074	5,226	163
Current liabilities, non-interest-bearing		136,985	50,411	76,159
Total liabilities		138,059	55,637	76,322
Total shareholders' equity, provisions and liabilities		730,425	293,693	742,254
Pledged assets		2,500	2,500	2,500
Contingent liabilities		11,050	11,050	11,050

PARENT COMPANY'S STATEMENT OF OPERATIONS

(SEK 000s)

	Notes	3 months April-June 2008	3 months April-June 2007	6 months Jan.-June 2008	6 months Jan.-June 2007	12 months Jan.-Dec. 2007
Net Revenue		38,164	2,447	46,216	5,509	48,389
Cost of goods sold	5	0	-1,281	0	-2,346	-2,409
Gross profit		38,164	1,166	46,216	3,163	45,980
Selling expenses	5	-5,510	-7,633	-8,189	-10,378	-15,408
Administrative expenses		-12,673	-12,195	-25,114	-22,688	-54,327
Research and development costs		-52,154	-41,370	-91,548	-70,440	-143,225
Other operating income		1,188	6,766	1,474	9,495	9,674
Other operating expenses	5	-1,138	-6,804	-1,138	-9,578	-10,413
Operating loss		-32,123	-60,070	-78,299	-100,426	-167,719
Earnings from financial investments						
Interest income		1,375	2,122	2,303	4,652	7,832
Interest expense		-121	-	-138	-6	-11
Total loss from financial investments		-30,869	-57,948	-76,134	-95,780	-159,898
Net loss for the period		-30,869	-57,948	-76,134	-95,780	-159,898

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.

In this interim report, 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.

In other respects, the accounting principles applied in this interim report are described in greater detail in the notes to the 2007 Annual Report.

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

2. Costs distributed by type of cost

	April-June 2008	April-June 2007	Jan.-June 2008	Jan.-June 2007	Jan.-Dec. 2007
Raw materials and supplies	8,001	3,502	15,720	9,698	26,835
Other external costs	40,990	41,342	88,073	62,421	132,307
Personnel costs	37,388	21,526	69,110	39,974	92,967
Depreciation and impairment	2,638	1,030	5,497	2,093	5,875
Re-invoicing of rebuilding costs		6,628		9,300	9,300
TOTAL	89,017	74,028	178,400	123,486	267,284

3. Shareholders' equity

Changes in Group equity

	April-June 2008	April-June 2007	Jan.-June 2008	Jan.-June 2007	Jan.-Dec. 2007
Shareholders' equity brought forward according to balance sheet	611,085	287,655	671,252	324,350	324,350
Loss for the period	-28,343	-56,600	-90,505	-94,525	-172,597
Subscription of shares through the exercise of warrants		2,706		2,726	2,981
New share issues		-		-	438,775
New share of employee stock options		-		-	52,875
Employee stock options, value of employees' service	2,382	1,494	4,377	2,704	5,989
Acquired value of employee stock options		-		-	18,879
Amount at close of period	585,124	235,255	585,124	235,255	671,252

Shares outstanding

The number of shares outstanding at June 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 June 30, there were 2,750,625 options outstanding carrying subscription rights corresponding to 2,251,163 shares in Orexo and exchange of 499,462 options to shares in Orexo³. 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–June 2008 period.

	Opening Jan. 1, 2008	-	+	Closing June 30, 2008
Stock options targeted to employees				
Of which:				
Decided and allotted employee stock options	373,525	-	372,000	745,525
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	470,000	470,000
Subscription warrants held by subsidiaries for cash-flow hedging of social security fees	78,000	-	-	78,000
Total decided stock options	838,775	-372,000	858,388	1,325,163
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	-35,079	-	364,088
Subscription warrants taken over from Biolipox AB for cash-flow hedging of social security fees (not resulting in dilution)	135,374	-	-	135,374
Total stock options from Biolipox	534,541	-35,079	-	499,462
Total stock options targeted to employees	1,373,316	-407,079	858,388	1,824,625
Other options				
Subscription warrants constituting supplementary purchase consideration for the acquisition of Biolipox AB	926,000	-	-	926,000
Total outstanding stock options	2,299,316	-372,000	858,388	2,750,625

During the period April – June 2008, 35,079 Biolipox employee stock options were exercised, resulting in the holders exchanging their options for 35,079 shares, which were held by the independent company Pyrinox AB. The exercise of options thus did not result in Orexo issuing additional shares.

³) 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. The above information pertains in all respects to the number of shares for which each option provides subscription entitlement. All of the details pertaining to options issued by Biolipox AB are recalculated by a factor of 0.45854, corresponding to the estimated value of the options related to the price of the Orexo share on date of acquisition. The figures reported for the options issued by Biolipox AB pertain to the number of shares to which each option can be exchanged following recalculation.

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. None of these options have yet been allocated.

The Meeting 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 under the board member share plan were allocated to the board members and the options can be exercised up until and including 31 December 2015. One fourth of the options are vested following the publication of Orexo's interim report for the first quarter and one fourth following the publications of the interim reports for the second until the fourth quarter, respectively, during the mandate period for the financial year when the option holder is elected or re-elected. The market value, calculated in accordance with Black & Scholes valuation method, was SEK 55.15 per option at the time of allocation.

4. Consolidated cash flow

Adjustment for items not included in cash flow

	April-June 2008	April-June 2007	Jan.-June 2008	Jan.-June 2007	Jan.-Dec. 2007
Depreciation/amortization and impairments	2,638	1,030	5,497	2,093	5,875
Calculated costs for employee stock option program	3,454	1,987	5,845	3,494	1,381
Other	11	-24	13	2	205
Total	6,103	2,993	11,355	5,589	7,461

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

	April-June 2008	April-June 2007	Jan.-June 2008	Jan.-June 2007	Jan.-Dec. 2007
Raw materials and supplies	2,565	505	3,693	5,233	9,162
Other external costs	31,609	41,515	62,459	62,006	125,146
Personnel costs	35,458	19,933	56,317	36,957	77,603
Depreciation and impairment	1,843	948	3,520	1,934	4,571
Reinvoicing of rebuilding costs		6,628		9,300	9,300
TOTAL	71,475	69,529	125,989	115,430	225,782

6. Shareholders' equity

Changes in the Parent Company's shareholders' equity

	April-June 2008	April-June 2007	Jan.-June 2008	Jan.-June 2007	Jan.-Dec. 2007
Shareholders' equity brought forward according to balance sheet	621,743	291,804	665,932	328,406	328,406
Loss for the period	-30,869	-57,948	-76,134	-95,780	-159,898
Subscription of shares through the exercise of warrants		2,706		2,726	2,981
New share issues		-		2,704	438,776
New issue of subscription warrants		-		-	52,875
Employee stock options, value of employees' service	1,492	1,494	2,568	-	5,392
Group contributions	-	-	-	-	-2,600
Amount at the close of the period	592,366	238,056	592,366	238,056	665,932

7. Events after the close of the period

In July, Endo Pharmaceuticals decided to return Rapinyl™/Abstral to Orexo as a consequence of an extensive change in the company's strategy implemented by its new management. This created an opportunity for Orexo to extend the licensing agreement with the international specialty pharmaceuticals company ProStrakan Group plc to include the North America in addition to the EU. At the same time, Orexo's royalty fees in Europe and the North America were increased. For more detailed information, see page 6.