# Orexo AB (publ.)
# – Interim report, January - June 2009

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

Uppsala, August 21, 2009

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## Key events during the period

- Net revenues amounted to MSEK 144.6 (80.2).
- The loss after tax was MSEK 30.5 (loss: 90.5).
- The loss per share was SEK 1.38 (loss: 4.19).
- Cash and cash equivalents at the end of the quarter amounted to MSEK 137.2 (247.1).
- The US Food and Drug Administration (FDA) approved Orexo's Edluar™ product for the short-term treatment of insomnia. The approval meant that Orexo received a milestone payment from Meda of MUSD 5.
- Orexo signed an exclusive development agreement with a large healthcare company. The agreement covers the development of Orexo's OX17 program for the treatment of gastroesophageal reflux disease (GERD).
- Orexo acquired the UK drug delivery company PharmaKodex Ltd. The acquisition strengthens Orexo's strategy of developing unique drugs based on well-established, effective substances.

## Second quarter

- Net revenues amounted to MSEK 29.6 (56.2).
- Loss after tax was MSEK 56.9 (loss: 28.3).
- The loss per share was SEK 2.53 (loss: 1.31).
- Orexo announced Abstral is ready for launch in France.
- Orexo's Annual General Meeting was held April 23.

## Key events after the end of the period

- Meda has initiated the launch of Orexo's product Edluar™ in the US market.
- ProStrakan has submitted a registration application for Abstral to the US Food and Drug Administration (FDA). Orexo receives an unpublished milestone payment.
- Orexo announced positive Phase III results for KW-2246 (Abstral™) in Japan and receives MUSD 2.
- As part of the established strategy to become a profitable pharmaceutical company and as a natural effect of the development of the product portfolio, costs will decrease. In addition, the management has decided to enhance the efficiency of research and development and relocate the operations conducted in Solna to Uppsala.
- The second installment for the acquisition of PharmaKodex was paid in the form of new issued Orexo shares. The installment was decided on August 21, 2009 and PharmaKodex's former shareholders received a total of 933,781 newly issued Orexo shares.

# Condensed statement of operations

| MSEK | 3 months 2009 Apr-June | 3 months 2008 Apr-June | 6 months 2009 Jan-June | 6 months 2008 Jan-June | 12 months 2008 Jan-Dec |
|---|---|---|---|---|---|
| **Net revenues** | **29.6** | **56.2** | **144.6** | **80.2** | **233.3** |
| **Loss after tax** | **-56.8** | **-28.3** | **-30.5** | **-90.5** | **-103.1** |
| **Earnings per share, before dilution (SEK)** | **-2.53** | **-1.31** | **-1.38** | **-4.19** | **-4.77** |
| **Earnings per share, after dilution (SEK)** | **-2.53** | **-1.31** | **-1.38** | **-4.19** | **-4.77** |

## CEO's COMMENTS:

This half year has been a period of significant progress for Orexo. We see good growth in our revenue stream and a significant reduction in loss on our way to profitability. Importantly, we received our second major market approval within 12 months, from the FDA in the US for Edluar with our partner Meda. Following its approval in the EU last year, we have seen the royalties from Abstral increase as our partner ProStrakan launched the product in additional countries such as the UK, Germany and France. We also obtained new distribution agreements for Abstral in China and Israel.

We gained new technologies and programs through the acquisition of PharmaKodex, which we are already using to create new products for ourselves and also for potential new big pharma partners. We continue to have a great focus on business development in order to close additional revenue-generating partnerships with excellent pharma partners. In this context, we have signed new formulation development and partnership option agreements that could enable us to add new revenue streams within the next few years. As a consequence of all this, I am confident that Orexo is on track to become a profitable company.

Earlier this week our partner Meda launched Edluar in the US which was earlier than anticipated. I am certain that Meda is well placed to sell Edluar in the US market. At Orexo, we are delighted that American patients suffering from insomnia can benefit from a valuable product developed by our R&D team.

The response to Abstral's launch from patients and doctors is highly favorable throughout Europe. Abstral is now on sale in the UK, Germany and Sweden, and during July, it was also launched in France – one of Europe's largest markets for pain-relieving drugs based on fentanyl. During August, ProStrakan submitted the registration application for Abstral in the US, as a result of which we received a milestone payment. If the FDA approves the file for review, Abstral may be approved for the US market in 2010. Importantly, we reported positive results for KW-2246 (Abstral) in Japan with our partner Kyowa Hakko Kirin. Kyowa will now prepare for the submission of a registration application in Japan, which marks another important step in the international development of Abstral. Another line of revenue for us is our subsidiary Kibion, which markets diagnostic products for Helicobacter Pylori and saw a robust trend during the first six months, with sales of MSEK 21.5, up 48 percent compared with the same period in the preceding year. We expect continuing good growth in Kibion, along with increasing earnings.

The trend for our product portfolio implies that the risks and costs will now become lower. This, together with other streamlining throughout the business, will result in staff reductions by approximately 25 people, mainly on the new chemical entity research side. Our research activities at the Karolinska Institute will be fully integrated into our headquarters site in Uppsala enabling a more effective and lean R&D organization. The above, combined with increased royalty revenues, mean that we are coming increasingly closer to our goal of being a sustainably profitable pharmaceutical company.

I look forward to an exciting autumn for Orexo.

Torbjörn Bjerke
President and CEO

## KEY EVENTS DURING THE SECOND QUARTER OF 2009

### Orexo announced Abstral is ready for launch in France

Price negotiations with the French authorities regarding Abstral™ were concluded earlier than expected and ProStrakan launched Abstral™ in the French market in July. Abstral™ is being marketed in France by ProStrakan's 17 strong sales force. France is considered an important market for Abstral, since it is one of the largest established markets for fentanyl in Europe.

### Orexo's 2009 Annual General Meeting held on April 23

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

The Meeting resolved to adopt a new employee stock option program and Board member shareholder program, see also Note 3.

The Annual General Meeting resolved to authorize the Board – for the purpose of allowing purchases of other companies, and products and the entering into of collaboration agreements as well as to fulfill obligations in agreements that the company has entered into, - to decide on the issuance of new shares but, however, such issuance may not entail that the company's registered share capital or number of shares in the company increases by more than a total of 15 percent, or leads to the company's share capital exceeding the maximum permissible share capital permitted at any time by the Articles of Association. Not more than one third of the authorization (i.e. an increase with 5 per cent) may be used to fulfil obligations in agreements that the company has entered into for payment by set off or in kind and not more than two thirds (i.e. an increase with 10 per cent) may be used for the purpose of allowing the company to purchase other companies and products and to enter into collaboration agreements.

## KEY EVENTS AFTER THE CLOSE OF THE PERIOD

### Orexo's product Edluar™ has been launched in the US by Meda

Meda has initiated the launch of the drug Edluar™ in the USA. The launch follows the US Food and Drug Administration's (FDA) approval in March this year of Edluar™ 5 mg and 10 mg sublingual tablets for the short-term treatment of insomnia characterized by difficulties with sleep initiation.

### Orexo announced positive Phase III results for KW-2246 (Abstral™) in Japan

Orexo's partner in Japan, Kyowa Hakko Kirin, obtained positive phase III results in Japan for KW-2246, which is approved for the treatment of breakthrough pain in cancer patients and marketed under the brand Abstral™ in Europe. Kyowa Hakko Kirin will now proceed with preparations for the submission of a registration application for KW-2246 in Japan for use in continuous pain management of acute cancer pain (breakthrough pain). Orexo receives a milestone payment of MUSD 2 in connection with the completed phase III study.

### Registration application submitted for Abstral™ in the US

ProStrakan Group plc, an international specialty pharma company, has submitted the New Drug Application (NDA) for Abstral™ (for the treatment of breakthrough cancer pain in opioid-tolerant patients) to the US Food and Drug Administration (FDA).

The filing of Abstral™ will generate a milestone payment to Orexo as part of the agreement with ProStrakan for North America that in total can give USD 27 million in certain regulatory and sales milestone payments. In addition, Orexo will receive royalties on product sales.

The filing of Abstral™ has yet to be validated by the FDA before being accepted for review, and therefore no PDUFA date has yet been assigned.

### Second installment in acquisition of PharmaKodex

Orexo acquired the UK drug delivery company PharmaKodex in February 2009 in return for payment to be issued in two installments. The first installment was paid on February 23, 2009 in the form of newly issued Orexo shares and a decision regarding the second installment was made by Orexo on August 21, 2009. As payment for the first installment, 843,992 new Orexo shares were issued to PharmaKodex's former shareholders. 933,781 new Orexo shares were issued as a supplementary consideration in accordance with the Board decision on August 21, 2009. Through the two installments, PharmaKodex is valued at approximately MGBP 6.5, taking into consideration the share price on each issue occasion.

### Cost reduction

As part of the established strategy to become a profitable pharmaceutical company and as a natural effect of the development of the product portfolio, costs will decrease. In addition, the management has decided to enhance the efficiency of research and development and relocate the operations conducted in Solna to Uppsala.

### Cost forecast for 2009 and 2010

As the product portfolio becomes increasingly mature, costs will decrease. Management's assessment is that the Group's overall operating expenses in the financial year 2009 will amount to MSEK 300- 320, which will then fall by approximately MSEK 100 in the 2010 financial year.

## Operations

### Orexo's product portfolio

#### Commercialized products

**Abstral™ – for the treatment of breakthrough cancer pain**
Abstral™ is a drug that provides fast and effective treatment of breakthrough pain in cancer patients who already are receiving opioids for the treatment of their pain. Abstral™ is based on Orexo's sublingual tablet technology and the analgesic, fentanyl.

Abstral™ is a fast-dissolving tablet that is placed under the tongue. The benefit is that its active ingredient, fentanyl, is rapidly absorbed by the body through the mucous membrane. The effect is thereby faster and more predictable than that of drugs that reach the bloodstream through the intestines. The tablet is also easy to use, store and handle.

*Sales*
ProStrakan Group plc has the sales rights for Europe and North America. In early 2009, ProStrakan launched Abstral™ in the UK and Germany. The product was launched in France in July 2009 and the launch in Spain is planned for the second half of 2009.

Orexo's and ProStrakan Group plc's joint sales company, ProStrakan AB, has the sales rights for the Nordic countries and is responsible for sales and marketing there. ProStrakan AB launched Abstral™ in Sweden in the third quarter of 2008.

In the US, a registration application was submitted to the US Food and Drug Administration (FDA) on August 5, 2009. Orexo's partner ProStrakan Group plc is responsible for the registration process in the US.

Kyowa Hakko Kirin has the rights for Japan, where a registration application is currently being prepared for the product. Distribution agreements for Russia and the CIS (the other countries in the former Soviet Union), Bulgaria and Rumania have been signed with Gedeon Richter. A distribution agreement has been signed with Hospira for the Southeast Asian market, including Australia and New Zealand. For the Chinese market, Orexo has signed a license- and distribution agreement with NovaMed, and for the Israeli market, Orexo has signed a distribution agreement with Neopharm.

**Edluar™ – for the short-term treatment of insomnia**
Edluar™ is an drug for insomnia, based on Orexo's sublingual tablet technology and the active substance zolpidem. Zolpidem is a well-documented substance that has been used for a long time in drugs against insomnia. The Edluar™ tablet is placed under the tongue where it rapidly dissolves and the active substance is absorbed through the mucous membrane. The international specialty pharmaceutical company Meda has acquired the global rights to Edluar™.

*Sales*
In March 2009, the US Food and Drug Administration (FDA) approved Edluar™ for the short-term treatment of insomnia, characterized by difficulties with sleep initiation, and the launch of the product has now been initiated in the USA.

**Diabact® UBT – diagnosis of Helicobacter pylori**
Diabact® UBT is used to diagnose the presence of Helicobacter pylori, the bacterium that causes gastric ulcers. The product is a breath test based on Orexo's patented tablet technology for rapidly dissolving tablets. The breath test has high reliability, painless administration, takes ten minutes to carry out and is then sent to a laboratory for analysis. The product is sold by Orexo's subsidiary Kibion.

**Heliprobe® System – diagnosis of Helicobacter pylori**
Heliprobe® System is a "doctor's office test" for the presence of the gastric ulcer bacterium, Helicobacter pylori. The product has a number of advantages, including high reliability, painless administration, a short test time and on-site results. The product is sold by Orexo's subsidiary Kibion.

## Project covered by licensing agreements

**OX-NLA – against rhinitis (hay fever)**
The purpose of OX-NLA is to develop a fast-acting nasal spray based on the antihistamine cetirizine for the treatment of allergic and non-allergic rhinitis (hay fever). Orexo has developed a new formulation of cetirizine that can be administered directly to the nose by means of a spray. This was difficult in the past, since the substance itself causes irritation and

stinging in the nasal mucous membrane. Administering the medication locally in the nose provides a faster effect on the allergic symptoms than if it is given in tablet form. The rapid effect also means that OX-NLA can be used safely and effectively for on-demand treatment.

*Project status*
Clinical Phase II studies of OX-NLA have shown satisfactory and fast-acting effects, which makes OX-NLA suitable for on-demand treatment. The nasal spray has favorable tolerance without causing local side effects in the form of stinging and pain. The international specialty pharmaceutical company Meda has acquired the global rights to OX-NLA and combination products based on it. Meda is responsible for the project's further development.

**OX-MPI – against pain and inflammation**
OX-MPI is aimed at developing an effective new drug for the treatment of inflammatory pain, such as from rheumatoid arthritis. Common drugs currently used to treat inflammatory pain are part of the group referred to as Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), such as Naproxen and Voltaren. Long-term use of NSAIDs can result in side effects such as stomach bleeding and high blood pressure. COX-2 inhibitors, which have a more specific mechanism, were developed to avoid NSAIDs' side effects and their use grew rapidly. The discovery of a risk of cardiovascular side effects led to several COX-2 inhibitors being withdrawn in 2004. The remaining COX-2 inhibitors and prescription-only NSAIDs also carry warnings.

OX-MPI is derived from an entirely new mechanism based on the identification of a specific enzyme – membrane-bound prostaglandin (PG) E synthase (mPGES). This enzyme is necessary for the production of PGE2, a substance produced by the body, which plays a pivotal role in many inflammatory processes. The goal for the OX-MPI project is to develop a drug that blocks the mPGES enzyme to curtail the formation of PGE2, leading in turn to reduced inflammation and a reduction in pain. Since the mechanism of action is more selective than NSAIDs and COX-2 inhibitors, OX-MPI offers the potential to be equally effective, but with fewer side effects.

*Project status*
An exclusive cooperation and license agreement for the development and commercialization of OX-MPI was signed in November 2005 with Boehringer Ingelheim GmbH. Since then, cooperation has proceeded around the development of selected $PGE_2$ inhibitors. Activities are in progress to optimize both the biological effect and other characteristics that are important for effective and safe drugs.

## Projects in which cooperation and licensing discussions have been initiated

**OX17 – against gastroesophageal reflux disease (GERD)**
OX17 is being developed for the treatment of gastroesophageal reflux disease (GERD). Patients suffering from GERD experience recurring heartburn, involving acidic regurgitation linked to stomachache, discomfort and pains. Current treatments either provide fast, short-term effects or slow, but lasting relief. By combining two well-known substances that inhibit acid secretion in the stomach but take different lengths of time to have an effect – an H2-receptor blocker and a proton-pump inhibitor (PPI) – OX17 provides both a rapid and sustained effect.

*Project status*
In 2008, a Phase II study was concluded that showed that OX17 quickly and effectively reduces the secretion of acid in the stomach and that this acid-inhibiting effect continues to last as long as the symptoms require treatment. This is an attractive and unique profile for a drug to treat GERD. In early 2009, Orexo signed an exclusive development agreement with a large healthcare company. Parallel with this development work, Orexo and its partner will continue negotiations to enter into an appropriate globally exclusive licensing agreement including Orexo's entire OX17 program and related intellectual property. This licensing agreement is expected to be signed in 2009.

**OX914 – to treat COPD and asthma**
OX914 is being developed for the treatment of inflammatory diseases such as COPD (smoker's disease) and asthma. The anti-inflammatory effect is gained by blocking the PDE4 enzyme. Clinical studies with substances that block PDE4 have shown positive treatment effects but also some side effects, mainly nausea. To date, OX914 has not shown a higher frequency of nausea among patients treated with active substances compared with placebo.

*Project status*
OX914 has shown favorable effects in preclinical models of COPD and asthma. Phase I studies to date have shown highly satisfactory safety and tolerance. An experimental Phase IIa study in Rhinitis has shown that oral treatment with OX914 shows no statistically significant reduction in patient symptoms of nasal irritation with allergens (such as pollen) compared with placebo. However, no conclusions can be drawn about the effectiveness in treating COPD.

**OX-AAF – for the treatment of inflammatory respiratory diseases**
OX-AAF (arachidonic acid franchise) is the general term for the Orexo research projects aimed at developing a new generation of drugs for the treatment of asthma and COPD that are more effective than current treatments. The project is based on Orexo's leading expertise in the arachidonic acid cascade and its importance in these diseases.

*OX-CLI*
The objective of the OX-CLI project is to develop an oral, non-steroid-based, anti-inflammatory and bronchodilatory drug for the treatment of all stages of asthma and COPD. The target protein in the OX-CLI project has a central role in the inflammatory process. Studies in animals that lack the target protein have shown significantly reduced inflammatory responses in various disease models for asthma and COPD. The action mechanisms indicate that a better effect could be attained with OX-CLI than with current oral-based treatments using leukotriene inhibitors such as montelukast (Singulair®).

*Project status*
Orexo has identified several series of molecules and established a patent portfolio with potential drug candidates. A number of these have shown favorable effects in various pharmacological models. Work is continuing to optimize biological effects and other characteristics that are important for an effective and safe drug.

*OX2477*
OX2477 is aimed at developing a drug that inhibits the 15-lipoxygenase enzyme (15-LO). This enzyme appears to have a key role in the inflammatory process and is present in larger quantities in lung tissue among smokers and patients with bronchitis or asthma than among non-smokers. Orexo has identified a new group of pro-inflammatory mediators – eoxins – that are formed via 15-LO, which further strengthens interest in this enzyme as a target protein for the development new anti-inflammatory drugs.

The objective of the OX2477 project is to develop an oral, non-steroid-based, anti-inflammatory drug that has the potential to replace or reduce the use of inhaled steroids to deal with asthma or COPD.

*Project status*
Orexo has developed several series of molecules and established a patent portfolio with potential drug candidates. These are being evaluated in terms of their biological effect and other properties that are important for an effective and safe drug.

**OX19 – treatment of incontinence**
OX19 is focused on developing more effective pharmaceutical forms of desmopressin to more effectively treat incontinence. In addition to the treatment of nocturia, the product is also being developed for the short-term, on-demand treatment of urinary incontinence in women suffering from an overactive bladder.

*Project status*
Orexo has developed a nasal powder formulation for administering desmopressin. Data from a Phase I study confirm that this offers significantly better uptake than nasal sprays currently on the market. The next step is to seek partnership for further development of the product.

**OX641**
OX641 was obtained through the acquisition of PharmaKodex in February 2009. The project aims to develop a product that provides fast, lasting pain relief for migraine headaches. Orexo intends to license out this project to a major pharmaceutical company.

*Project status*
Formulation phase.

**OX-PKX**
OX-PKX is a designation for the development and outlicensing of the drug delivery technologies that were included in the acquisition of PharmaKodex. The purpose is to develop proprietary products and also to offer major pharmaceutical companies innovative drug delivery technologies to improve and upgrade their products. The technologies are: I) Xerosol II) Taste Transformation and III) Pandermal.

*Project status*
Formulation phase.

## Other projects

**OX219**
OX219 is being developed to create a drug to combat opioid dependency – such as heroin addiction – and which is fast acting and easy to use. Buprenorphine and naloxone – the active substances in OX219 – have favorable effects on opioid addiction that have been documented within the framework of medical, social and psychological treatment. Buprenorphine, a partial opioid agonist, offers a limited “high” and dampens the withdrawal symptoms and desire for narcotics. Naloxone counteracts the “high” that arises in connection with intravenous injection of buprenorphine. This means that the risk of abuse is reduced and thus also illegal dealing. By using the Xerosol technique, Orexo expects to create a drug that tastes better, acts faster and is easier to take than the market-leading Suboxone™. Orexo plans to conduct clinical studies during 2009.

*Project status*
Ready for clinical studies.

**OX30 – treatment of chronic pain**
OX30 is being developed to create long-acting pain relief medication with little risk of abuse. The active substance is an opioid with a slow release controlled from an oral pharmaceutical. The active substance is incorporated in a ceramic material, thus making it difficult to extract the opioid, as well as rendering the drug less prone to abuse.

*Project status*
Pre-project phase.

# The period in figures: January 1 – June 30, 2009

**Condensed consolidated statement of operations**

| | 3 months 2009 Apr-June | 3 months 2008 Apr-June | 6 months 2009 Jan-June | 6 months 2008 Jan-June | 12 months 2008 Jan-Dec |
|---|---|---|---|---|---|
| **MSEK** | | | | | |
| **Net revenues** | **29.6** | **56.2** | **144.6** | **80.2** | **233.3** |
| Cost of goods sold | -6.5 | -5.0 | -12.2 | -8.9 | -17.4 |
| **Gross profit** | **23.1** | **51.2** | **132.4** | **71.3** | **215.9** |
| | | | | | |
| Selling expenses | -9.5 | -10.6 | -18.8 | -18.6 | -38.8 |
| Administrative expenses | -11.3 | -12.4 | -22.1 | -27.7 | -55.3 |
| Research and development expenses | -58.9 | -59.1 | -125.0 | -121.2 | -238.1 |
| Other operating income and expenses | 1.1 | -0.2 | -1.7 | 0.6 | 3.8 |
| **Operating loss*** | **-55.4** | **-31.0** | **-35.3** | **-95.5** | **-112.5** |
| | | | | | |
| Net financial items | -1.5 | 2.6 | 4.6 | 4.8 | 9.0 |
| **Loss after financial items** | **-56.9** | **-28.4** | **-30.7** | **-90.7** | **-103.5** |
| | | | | | |
| Tax | 0.1 | 0.1 | 0.2 | 0.2 | 0.4 |
| **Net profit/loss for the period** | **-56.8** | **-28.3** | **-30.5** | **-90.5** | **-103.1** |

** Includes costs of employee stock options in the amount of MSEK 3.7 for the period January-June 2009 (MSEK 5.8 for January-June 2008).*

**Revenues**

*Net revenues*

Net revenues for January-June 2009 totaled MSEK 144.6 (80.2). The increase in revenues is primarily related to revenues in connection with cooperation with Meda and the approval of Edluar in the US and Abstral™ in Spain and France.

Sales of Abstral in Europe have developed strongly and better than expected. Royalty revenues amounted to MSEK 1.7 in the second quarter, compared with the first quarter, when royalties were MSEK 1.3. The first quarter's royalty income was positively impacted by stock-building prior to the launch in the UK and Germany.

Net revenues during the period April-June 2009 totaled MSEK 29.6 (56.2). The decrease compared with previous year relates to income from outlicensing of Edluar to Meda in April 2008.

Net revenues were distributed as follows:

| *MSEK* | Jan-June 2009 | Jan-June 2008 | Jan-Dec 2008 |
|---|---|---|---|
| Diabact® UBT | 3.1 | 2.6 | 6.6 |
| Heliprobe® System | 18.4 | 11.7 | 22.0 |
| ProStrakan AB J/V 50% | 5.5 | 4.4 | 9.7 |
| License revenues | 89.3 | 29.5 | 123.1 |
| Royalties | 3.0 | - | 0.1 |
| Re-invoicing, R & D expenses | 25.3 | 32.0 | 71.8 |
| **Total** | **144.6** | **80.2** | **233.3** |

**Expenses and earnings**

*Selling expenses*

Selling expenses for the period January-June 2009 amounted to MSEK 18.8 (18.6), and to MSEK 9.5 (10.6) for the period April-June 2009. Selling expenses include expenses for business development arising from the outlicensing of Orexo's project, Kibion AB, and the joint-venture company ProStrakan AB.

*Administrative expenses*

Administrative expenses for the period January-June 2009 totaled MSEK 22.1 (27.7), which was a decrease of 20 percent. The decrease was primarily attributable to efficiency improvements. For the period April-June 2009, administrative expenses were MSEK 11,3 (12,4).

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

The company's expenses for the employee stock option program in the period January-June 2009 totaled MSEK 3.7, compared with MSEK 5.8 in the year-earlier period. MSEK 1.4 (2.8) of these expenses is attributable to administrative personnel, MSEK 1.7 (2.7) to R&D personnel and MSEK 0.6 (0.3) to sales personnel. For the period April-June, the company's expenses for the options program were MSEK 2.6 (3.4).

Program expenses pertain both to estimated costs for the value of employee vesting during the period, marked to market at the time of allotment, as well as the estimated payroll overhead on the changes in value of the vested portion during the period. The company will need to pay payroll overheads on any gain that arises in conjunction with the exercise of employee stock options, calculated as the difference between the strike price of the stock option and the market value of the share.

The payroll overhead that could arise as a result of the employee stock option program has been hedged financially – and, thus, largely for cash flow purposes – through the issue of warrants to one of Orexo's subsidiaries. This hedging does not qualify for hedge accounting in accordance with IFRS.

*Research and development expenses*

Research and development expenses for the period January-June 2009 totaled MSEK 125.0 (121.2), of which MSEK 25.3 (32.0) was re-invoiced to partners during the period. For the period April-June, research and development expenses were MSEK 58.9 (59.1).

The rise in research and development expenses compared with the same period a year earlier is attributable to PharmaKodex in the amount of MSEK 7.9 (0) and costs linked to registration applications for Abstral™/Rapinyl in the US, which amounted to approximately MSEK 21 (0), while asset impairment costs totaled MSEK 2 (0).

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 a number of development projects that have made considerable progress in their development phases and/or for which discussions concerning outlicensing have commenced.

*Other operating income and expenses*

Other operating income and expenses for the period January-June 2009 amounted to an expense of MSEK 1.7 (income: 0.6), with income of MSEK 1.1 (expense: 0.2) for the period April-June 2009.

*Depreciation/amortization*
Depreciation/amortization for the period January-June 2009 totaled MSEK 6.7 (5,5), with MSEK 2.3 (2.6) for April-June 2009.

*Net financial items*
Net financial items for the period January-June 2009 totaled MSEK 4.6 (4.8). These include income of MSEK 3.9 because the content of the agreement covering the second installment payment for the acquisition of PharmaKodex is such that this is classified as an imbedded derivative, which is valued at fair value over the income statement, which results in a positive effect on earnings from a declining share price.

*Tax*
Tax income (deferred tax) for the period January-June 2009 amounted to MSEK 0.2 (0.2).

*Net profit/loss*
The net loss for the period January-June 2009 was MSEK 35.3 (loss: 95.5). The net loss for the period after financial items was MSEK 30.7 (loss: 90.7), while the loss after tax was MSEK 30.5 (loss: 90.5). Earnings were charged with restructuring costs of MSEK 6.6 relating to the acquisition of PharmaKodex Ltd.

The operating loss for the period April-June was MSEK 55.4 (loss: 31.0). The loss for the period after financial items was MSEK 56.9 (loss: 28.4), while the loss after tax totaled MSEK 56.8 (loss: 28.3).

**Financial position**
Group cash and cash equivalents amounted to MSEK 137.2 (247.1) at June 30, 2009.

Cash flow from operating activities for the period January-June 2009 amounted to a negative MSEK 74.4 (neg: 42.8). Cash flow after financing amounted to a negative MSEK 50.7 (neg: 44.5).

Cash flow from operating activities for the period April-June 2009 amounted to a negative MSEK 11.8 (pos: 45.7). Cash flow after financing amounted to a negative MSEK 12.7 (pos: 45.5).

Shareholders' equity at June 30, 2009 totaled MSEK 581.6 (585.1). The equity/assets ratio was 84 percent (77).

**Investments**
Gross investments in tangible fixed assets totaled MSEK 1.1 (1.3) for the period January -June 2009 and MSEK 0.9 (0.1) for the period April-June 2009. Refer to Note 6 regarding the investment in PharmaKodex Ltd.

**Parent Company**
Most the Group's business is carried out in the Parent Company, Orexo AB. Net revenues for the period January-June 2009 totaled MSEK 110.1 (46.2), with the loss after financial items totaling MSEK 24.9 (loss: 76.1). Investments totaled MSEK 1.1 (5.9). Cash and cash equivalents in the Parent Company at June 30, 2009 amounted to MSEK 9.4 (83.1), while current investments were MSEK 0.0 (0.0).

**Pledged assets and contingent liabilities**
In the acquisition of Inflazyme in November 2007, a supplemental payment was agreed contingent on certain goals being met. Part of the supplemental payment was reported as long-term liabilities and MSEK 36.9 has been reported as contingent liabilities since the latter is not assessed as a probable payment based on pharmaceutical development statistics. The supplemental payment was adjusted for changes in exchange rates during the year. As cash-flow hedging for payroll overhead pertaining to the employee stock options issued by Biolipox, warrants were issued to Pyrinox AB. Orexo is committed to cover any deficit greater than the cover provided by the warrants during the duration, up to and including 31 December 2016.

Orexo's acquisition of Noster System AB 2006 involved an agreement on a supplemental purchase price of not more than MSEK 7.2, which would become payable if the growth of Heliprobe™ System achieves pre-determined sales targets by year-end 2009. The amount is reported under contingent liabilities, since Orexo does not deem it likely. The previous pledged assets related to currency futures and chattel mortgages were terminated and reversed.

Orexo acquired the UK drug delivery company PharmaKodex in February 2009 in return for payment to be issued in two installments. The first installment was paid on February 23, 2009 in the form of new issued Orexo shares. A decision regarding the second installment was made by Orexo on August 21, 2009. As payment for the first installment, 843,992 new Orexo shares were issued to PharmaKodex's former shareholders. A total of 933,781 new Orexo shares were issued as a supplementary consideration in August 2009. The transaction also involves additional conditional payments based on revenues from licenses for PharmaKodex' current program and technologies, as well as being based on payments for certain milestones, and which are not reported as a liability.

**Significant risks and uncertainties**
Significant risks and uncertainties are in essentially the same for the parent company and group, more detailed information about the financial risks are found in Orexo's annual report for 2008.

*Uncertainty regarding success of development programs*
Orexo is a Group in the development stage with four products on the market and a number of other product candidates in various development stages, with some in the late clinical development phase. The research and development of pharmaceuticals are characterized by significant operating risks, however the pharmaceutical industry is only to a limited extent affected by cyclical fluctuations. Several factors affect the probability that a drug project will result in an approved drug. 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 drug projects. However, the risk of not reaching the market diminishes as the project passes through the various phases in the development process. If the Group's clinical trials are not successful, Orexo may lack the potential to license out or commercialize new products.

*Competing operations*
Orexo's competitors are large pharmaceutical and biotech companies with substantial financial resources and which conduct research in the same areas as Orexo. There is a risk that these competitors develop a pharmaceutical that is better than those developed by Orexo, or that they reach the market faster, whereby the future value of the Group's products will be less 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 drugs and biological products involve environmental risks and are subject to environmental legislation, which may delay or disrupt operations. Changes to the healthcare system can also impact on Orexo's operations and profitability.

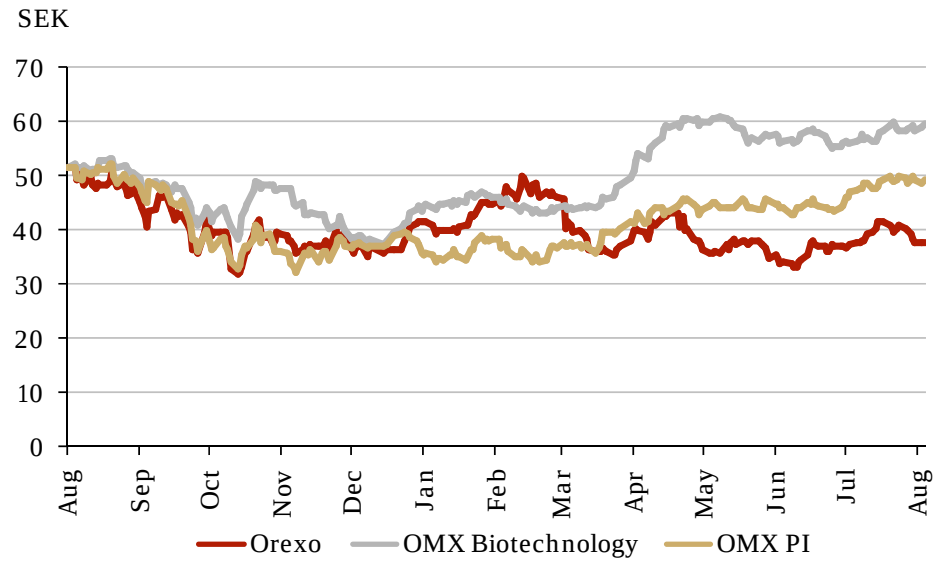
*Key personnel*
Orexo is dependent on its personnel and certain key individuals. In the event they terminate their employment, this could disrupt and delay development processes. To motivate and retain personnel and key individuals, the company offers such incentives as an options program.

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

With Orexo's program to reduce its operating costs it is the Board's assessment that current financing is sufficient to pursue operations, even without income from additional outlicensing agreements.

**Orexo share and market capitalization**
The Orexo share was quoted on June 30, 2009 at SEK 37.8. The company's market capitalization, which is based on the number of shares outstanding on June 30, 2009, totaled MSEK 849.3.

**Share price trend during last twelve months (august 2008 – august 2009)**



*Analysts monitoring Orexo:*

| | |
|---|---|
| ABG Sundal Collier | Alexander Lindström |
| Carnegie | Camilla Oxhamre |
| Handelsbanken Markets | Erik Hultgård |
| Nordea | Patrik Ling |
| Redeye | Björn Fahlén and Klas Palin |
| SEB Enskilda | Gustaf Vahlne |

**Future reporting dates:**

Interim report, January-September 2009 November 10
Year-end report, January-December, 2009 February 17, 2010

**Statement of assurance by the Board of Directors**

The Board of Directors and President hereby affirm that the six-month interim report provides an accurate overview of the operations of the Company and Group, as well as their financial position and earnings, and describes significant risks and uncertainties faced by the company and the companies included in the Group.

Uppsala, August 21, 2009

Orexo AB (publ)

| | | |
|---|---|---|
| Håkan Åström<br>Board Chairman | Monica Caneman<br>Board member | Johan Christenson<br>Board member |
| Raymond Hill<br>Board member | Staffan Lindstrand<br>Board member | Bengt Samuelsson<br>Board member |
| Kjell Strandberg<br>Board member | Peter Lindborg<br>Board member | Torbjörn Bjerke<br>President and CEO |

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Johan Andersson, Investor Relations Manager, tel: +46 702 10 04 51, e-mail: johan.andersson@orexo.com

**Review report**

We have reviewed the appended report for the period January 1 to June 30, 2009 for Orexo AB (publ). Company 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 takes a different direction and is substantially more restricted in scope than an audit conducted in accordance with Standards on Auditing in Sweden (RS) and other generally accepted auditing practices. The procedures performed in a review do not enable us to obtain a level of assurance that would make us aware of all significant matters that might be identified in an audit. Therefore, the conclusion expressed based on a review does not give the same level of assurance as a conclusion expressed based on an audit.

Based on our review, nothing has come to our attention that causes us to believe that the appended interim report has not in all significant respects been compiled in accordance with the Annual Accounts Act and IAS 34 and for the Parent Company in accordance with the Annual Accounts Act.

Uppsala, August 21, 2009
PricewaterhouseCoopers AB

Leonard Daun
Authorized Public Accountant

## CONSOLIDATED STATEMENT OF OPERATIONS

| | Notes | 3 months 2009 Apr-June | 3 months 2008 Apr-June | 6 months 2009 Jan-June | 6 months 2008 Jan-June | 12 months 2008 Jan-Dec |
|---|---|---|---|---|---|---|
| Net revenues | | 29,623 | 56,246 | 144,571 | 80,241 | 233,346 |
| Cost of goods sold | 2 | -6,521 | -5,007 | -12,202 | -8,903 | -17,446 |
| **Gross profit** | | **23,102** | **51,239** | **132,369** | **71,338** | **215,900** |
| Selling expenses | 2 | -9,469 | -10,582 | -18,819 | -18,584 | -38,818 |
| Administrative expenses | 2 | -11,286 | -12,377 | -22,130 | -27,678 | -55,294 |
| Research and development expenses | 2 | -58,874 | -59,064 | -124,993 | -121,248 | -238,125 |
| Other operating income | | 2,394 | 1,746 | 5,045 | 2,619 | 7,451 |
| Other operating expenses | 2 | -1,268 | -1,988 | -6,788 | -1,988 | -3,611 |
| **Operating result** | | **-55,401** | **-31,026** | **-35,316** | **-95,541** | **-112,497** |
| Financial income | | 169 | 2,708 | 703 | 4,981 | 9,268 |
| Financial expenses | | -36 | -140 | -42 | -175 | -266 |
| Other financial items | | -1,682 | - | 3,925 | - | - |
| **Financial items – net** | | **-1,549** | **2,568** | **4,586** | **4,806** | **9,002** |
| **Loss before tax** | | **-56,950** | **-28,458** | **-30,730** | **-90,735** | **-103,495** |
| Tax | | 115 | 115 | 215 | 230 | 441 |
| **Net loss for the period** | | **-56,835** | **-28,343** | **-30,515** | **-90,505** | **-103,054** |
| **Net loss for the period attributable to:** | | | | | | |
| Parent Company's shareholders | | -56,835 | -28,343 | -30,515 | -90,505 | -103,054 |
| Minority interests | | - | - | - | - | - |
| **Earnings/loss per share, based on net profit attributable to the Parent Company's shareholders during the period (SEK/share):** | | | | | | |
| Earnings per share, before dilution, SEK | | -2.53 | -1.31 | -1.38 | -4.19 | -4.77 |
| Earnings per share, after dilution, SEK | | -2.53 | -1.31 | -1.38 | -4.19 | -4.77 |

## *CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME*

| | 3 months 2009 Apr-June | 3 months 2008 Apr-June | 6 months 2009 Jan-June | 6 months 2008 Jan-June | 12 months 2008 Jan-Dec |
|---|---|---|---|---|---|
| **Net loss for the period** | **-56,835** | **-28,343** | **-30,515** | **-90,505** | **-103,054** |
| **Other comprehensive income** | | | | | |
| Hedging of net investments | -2,980 | - | -128 | - | - |
| Exchange-rate differences | 5,655 | - | -261 | - | - |
| **Other comprehensive income for the period, net after tax** | **2,675** | **-** | **-3,89** | **-** | **-** |
| **Total comprehensive income for period** | **-54,160** | **-28,343** | **-30,904** | **-90,505** | **-103,054** |
| **Total comprehensive income attributable to:** | | | | | |
| Parent Company's shareholders | -54,160 | -28,343 | -30,904 | -90,505 | -103,054 |

## CHANGES IN CONSOLIDATED SHAREHOLDERS' EQUITY

### Attributable to the Parent Company's shareholders

| | Share capital | Other contributed capital | Accumulated loss | Translation differences | Total | Total shareholders' equity 1) |
|---|---|---|---|---|---|---|
| Opening balance, January 1, 2008 | 8,647 | 1,011,380 | -348,775 | - | 671,252 | 671,252 |
| Total comprehensive income for the period | - | - | -90,505 | - | -90,505 | -90,505 |
| Employee stock options, vested value for employees | - | 4,377 | - | - | 4,377 | 4,337 |
| **Closing balance, June 30, 2008** | **8,647** | **1,015,757** | **-439,280** | **-** | **585,124** | **585,124** |
| Opening balance, January 1, 2009 | 8,647 | 1,012,964 | -451,828 | - | 569,783 | 569,783 |
| Total comprehensive income for the period | - | - | -30,643 | -261 | -30,904 | -30,904 |
| Employee stock options, vested value for employees | - | 3,359 | - | - | 3,359 | 3,359 |
| New share issue | 340 | 38,996 | - | - | 39,336 | 39,336 |
| **Closing balance, June 30, 2009** | **8,987** | **1,055,319** | **-482,471** | **-261** | **581,574** | **581,574** |

1) *There are no minority interests*

## *CONSOLIDATED BALANCE SHEET*

| | Notes | 2009 June 30 | 2008 June 30 | 2008 Dec 31 |
|---|---|---|---|---|
| **ASSETS** | | | | |
| **Non-curent assets** | | | | |
| Tangible non-current assets | | 47,988 | 54,466 | 50,317 |
| Goodwill | | 16,030 | 16,030 | 16,030 |
| Acquired research and development | | 432,175 | 373,908 | 373,908 |
| Other intangible non-current assets | | 2,559 | 2,856 | 2,033 |
| **Total non-current assets** | | **498,752** | **447,260** | **442,288** |
| **Current assets** | | | | |
| Inventories | | 8,184 | 14,452 | 13,982 |
| Accounts receivable and other receivables | | 49,868 | 47,407 | 53,313 |
| Tax receivables | | 2,753 | 3,773 | 4,222 |
| Cash and cash equivalents | | 137,178 | 247,134 | 188,220 |
| **Total current assets** | | **197,983** | **312,766** | **259,737** |
| **Total assets** | | **696,735** | **760,026** | **702,025** |
| **SHAREHOLDERS' EQUITY AND LIABILITIES** | 3 | | | |
| Share capital | | 8,987 | 8,647 | 8,647 |
| Other contributed capital | | 1,055,319 | 1,015,757 | 1,012,964 |
| Accumulated losses | | -482,471 | -439,280 | -451,828 |
| Translation differences | | -261 | - | - |
| **Total shareholders' equity** | | **581,574** | **585,124** | **569,783** |
| **Long-term liabilities** | | | | |
| Provisions | | 682 | 1,074 | 490 |
| Long-term liabilities | | 10,053 | 9,100 | 9,510 |
| Deferred tax liability | | 10,750 | 647 | 415 |
| **Total long-term liabilities** | | **21,485** | **10,821** | **10,415** |
| **Current liabilities** | | | | |
| Current liabilities, non-interest-bearing | | 93,676 | 164,081 | 121,827 |
| **Total liabilities** | | **115,161** | **174,902** | **132,242** |
| **Total shareholders' equity and liabilities** | | **696,735** | **760,026** | **702,025** |
| **Pledged assets** | | - | 2,500 | - |
| **Contingent liabilities** | | 44,110 | 43,550 | 42,120 |

## *CONSOLIDATED CASH-FLOW STATEMENT*

| | Notes | 3 months 2009 Apr-June | 3 months 2008 Apr-June | 6 months 2009 Jan-June | 6 months 2008 Jan-June | 12 months 2008 Jan-Dec |
|---|---|---|---|---|---|---|
| **Operations** | | | | | | |
| Loss before interest expense and interest income | | -55,401 | -31,026 | -35,316 | -95,541 | -112,497 |
| Interest income | | 169 | 2,708 | 703 | 4,981 | 9,268 |
| Interest expenses | | -36 | -140 | -42 | -175 | -266 |
| Adjustment for items not included in cash flow | 4 | 245 | 6,103 | 14,233 | 11,355 | 12,265 |
| **Cash flow from operations before changes in working capital** | | **-55,023** | **-22,355** | **-20,422** | **-79,380** | **-91,230** |
| **Changes in working capital** | | | | | | |
| Accounts receivable | | 59,489 | -6,482 | 5,847 | -9,953 | -19,172 |
| Other current receivables | | -1,755 | -6,796 | 5,379 | 4,599 | 7,463 |
| Inventories | | 6,661 | -222 | 5,798 | -1,158 | -688 |
| Current liabilities | | -21,625 | 80,910 | -71,781 | 42,626 | 1,894 |
| Provisions | | 134 | 745 | 192 | 912 | 328 |
| Long-term liabilities | | 306 | -124 | 543 | -495 | -85 |
| **Cash flow from operations** | | **-11,813** | **45,676** | **-74,444** | **-42,849** | **-101,490** |
| **Investing activities** | | | | | | |
| Acquisition of machinery and equipment | | -931 | -139 | -1,052 | -1,299 | -1,671 |
| Divestment of machinery and equipment | | 2 | - | 2 | 11 | 110 |
| Acquisition of subsidiaries | | - | - | 24,695 | -327 | -327 |
| **Cash flow after investments** | | **-12,742** | **45,537** | **-50,799** | **-44,464** | **-103,378** |
| **Change in financing** | | | | | | |
| Proceeds from new share issue | | 15 | 0 | 90 | 0 | - |
| **Cash flow after financing activities** | | **-12,727** | **45,537** | **-50,709** | **-44,464** | **-103,378** |
| **Cash flow for the year** | | | | | | |
| Cash and cash equivalents, beginning of period | | 148,187 | 201,597 | 188,220 | 291,598 | 291,598 |
| Exchange-rate differences in cash and cash equivalents | | 1,718 | - | -333 | - | - |
| Changes in cash and cash equivalents | | -12,727 | 45,537 | -50,709 | -44,464 | -103,378 |
| **Cash and cash equivalents, at close of period** | | **137,178** | **247,134** | **137,178** | **247,134** | **188,220** |

## *KEY FIGURES*

| | 3 months 2009 Apr-June | 3 months 2008 Apr-June | 6 months 2009 Jan-June | 6 months 2008 Jan-June | 12 months 2008 Jan-Dec |
|---|---|---|---|---|---|
| Operating margin, % | -187 | -55 | -24 | -119 | -48 |
| Profit margin, % | -192 | -51 | -21 | -113 | -44 |
| Return on total capital, % | -8 | -4 | -4 | -12 | -14 |
| Return on shareholders' equity, % | -9 | -5 | -5 | -14 | -17 |
| Return on capital employed, % | -9 | -5 | -6 | -14 | -17 |
| Debt/equity ratio, multiple | 0 | 0 | 0 | 0 | 0 |
| Equity/assets ratio, % | 84 | 77 | 84 | 77 | 82 |
| Current ratio, % | 211 | 191 | 211 | 191 | 213 |
| Acid ratio, % | 203 | 182 | 203 | 182 | 202 |
| Average number of shares, before dilution | 22,467,248 | 21,617,395 | 22,183,945 | 21,617,395 | 21,617,395 |
| Average number of shares, after dilution | 23,556,612 | 22,797,594 | 23,273,309 | 22,823,435 | 22,689,035 |
| Number of shares, after full dilution | 24,484,169 | 23,398,558 | 24,484,169 | 23,398,558 | 23,300,567 |
| Number of shares, before dilution | 22,467,471 | 21,617,395 | 22,467,471 | 21,617,395 | 21,617,395 |
| Number of shares, after dilution | 23,556,835 | 22,823,435 | 23,556,835 | 22,823,435 | 22,684,988 |
| Loss per share, before dilution, SEK | -2.53 | -1.31 | -1.38 | -4.19 | -4.77 |
| Loss per share, after dilution, SEK | -2.53 | -1.31 | -1.38 | -4.19 | -4.77 |
| Shareholders' equity per share, before dilution, SEK | 25.89 | 27.07 | 25.89 | 27.07 | 26.36 |
| Shareholders' equity per share, after dilution, SEK | 24.69 | 25.64 | 24.69 | 25.64 | 25.12 |
| Number of employees at close of period | 128 | 120 | 128 | 120 | 128 |
| Average number of employees | 128 | 125 | 126 | 125 | 123 |
| Shareholders' equity | 581,574 | 585,124 | 581,574 | 585,124 | 569,783 |
| Capital employed | 581,574 | 585,124 | 581,574 | 585,124 | 569,783 |

**DEFINITIONS**

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

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

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

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

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

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

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

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

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

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

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

**Number of shares after dilution:** Calculation of the dilution from options issued by the company up to 2005 pursuant to IAS 33.

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

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

**Shareholders' equity per 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 STATEMENT OF OPERATIONS

| SEK 000s | Notes | 3 months 2009 Apr-June | 3 months 2008 Apr-June | 6 months 2009 Jan-June | 6 months 2008 Jan-June | 12 months 2008 Jan-Dec |
|---|---|---|---|---|---|---|
| Net revenues | | 11,615 | 38,164 | 110,113 | 46,216 | 207,757 |
| Cost of goods sold | | - | - | - | - | - |
| **Gross profit** | | **11,615** | **38,164** | **110,113** | **46,216** | **207,757** |
| Selling expenses | | -3,817 | -5,510 | -7,501 | -8,189 | -19,041 |
| Administrative expenses | | -10,524 | -12,673 | -18,704 | -25,114 | -52,085 |
| Research and development expenses | | -51,784 | -52,154 | -106,191 | -91,548 | -197,689 |
| Other operating income | | 449 | 1,188 | 2,269 | 1,474 | 4,514 |
| Other operating expenses | | -246 | -1,138 | -4,939 | -1,138 | -1,779 |
| **Operating loss** | | **-54,307** | **-32,123** | **-24,953** | **-78,299** | **-58,323** |
| **Earnings from financial Investments** | | | | | | |
| Interest income | | 50 | 1,375 | 212 | 2,303 | 3,733 |
| Interest expenses | | -24 | -121 | -26 | -138 | -215 |
| Other financial expenses | | -2,980 | - | -128 | - | - |
| **Loss after financial items** | | **-57,261** | **-30,869** | **-24,895** | **-76,134** | **-54,805** |
| **Net loss for the period** | | **-57,261** | **-30,869** | **-24,895** | **-76,134** | **-54,805** |

## PARENT COMPANY BALANCE SHEET

| SEK 000s | Notes | 2009 June 30 | 2008 June 30 | 2008 Dec 31 |
|---|---|---|---|---|
| **ASSETS** | | | | |
| **Non-current assets** | | | | |
| Tangible non-current assets | | 47,553 | 53,358 | 49,985 |
| Intangible non-current assets | | 436 | 501 | 509 |
| Shares in subsidiaries/joint ventures | | 606,441 | 524,169 | 524,169 |
| **Total non-current assets** | | **654,430** | **578,028** | **574,663** |
| **Current assets** | | | | |
| Inventories | | 1,519 | 6,079 | 5,233 |
| Accounts receivable and other receivables | | 38,267 | 61,423 | 103,245 |
| Tax receivables | | 2,206 | 1,828 | 2,536 |
| Cash and bank balances | | 9,403 | 83,067 | 29,608 |
| **Total current assets** | | **51,395** | **152,397** | **140,622** |
| **Total assets** | | **705,825** | **730,425** | **715,285** |
| **SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES** | 5 | | | |
| Restricted equity | | 299,738 | 299,398 | 299,397 |
| Non-restricted equity | | 326,724 | 292,968 | 309,797 |
| **Total shareholders' equity** | | **626,462** | **592,366** | **609,194** |
| **Long-term liabilities** | | | | |
| Provisions | | 682 | 1,074 | 490 |
| **Total long-term liabilities** | | **682** | **1,074** | **490** |
| Current liabilities, non-interest-bearing | | 78,681 | 136,985 | 105,601 |
| **Total liabilities** | | **79,363** | **138,059** | **106,091** |
| **Total shareholders' equity and Liabilities** | | **705,825** | **730,425** | **715,285** |
| **Pledged assets** | | - | 2,500 | - |
| **Contingent liabilities** | | 11,050 | 11,050 | 11,050 |

## Notes

### *1. Accounting principles*

This interim report was prepared pursuant to IAS 34. Orexo applies IFRS as approved by the EU.

The Parent Company's accounting was prepared in line with RFR 2.2.

Apart from the exceptions stated below, the accounting principles applied in this interim report are described in greater detail in the notes to the 2008 annual report.

**New accounting principles in 2009**

Effective January 1, 2009, Orexo applies IFRS 8. The new standard requires that segment information be presented from the perspective of the executive management, which means that it is presented in the manner used in internal reporting. Since this is done at the Group level, Orexo's accounting will continue to be based on a single segment.

The amended IAS 1, Presentation of Financial Statements, is applied as of January 1, 2009. The amendment has affected Orexo's annual accounting retrospectively as of December 31, 2007. Among other implications, the amendment means that revenue and costs previously recognized directly against shareholders' equity is now recognized in a separate report directly after the statement of operations. Another change is that new designations may be used for the financial reports. However, this change is not mandatory and Orexo has elected to retain the current designations.

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

### *2. Costs distributed by type of cost*

| | 2009 Apr-June | 2008 Apr-June | 2009 Jan-June | 2008 Jan-June | 2008 Jan-Dec |
|---|---|---|---|---|---|
| Raw materials and supplies | 13,666 | 8,001 | 23,121 | 15,720 | 32,244 |
| Other external costs | 37,899 | 40,990 | 84,436 | 88,073 | 181,642 |
| Personnel costs | 33,550 | 37,388 | 70,657 | 69,110 | 128,475 |
| Depreciation and impairment | 2,303 | 2,638 | 6,717 | 5,497 | 10,734 |
| **TOTAL** | **87,418** | **89,017** | **184,931** | **178,400** | **353,295** |

### *3. Shareholders' equity*

***Shares outstanding***

The number of shares outstanding at June 30, 2009, was 22,467,471, all of which were common shares. All shares carry entitlement to one vote each.

During the period January-June, the number of shares outstanding increased by a total of 850,076 shares, whereof 843,992 shares through a non-cash issue at a price of SEK 46.50 per share and 6,084 shares through the exercise of employee stock options.

***Options***

At June 30, there was a total of 2,836,200 options outstanding that carry rights corresponding to 2,486,688 shares in Orexo and the exercise of 349,512 options for shares in Orexo[1]. Each option written by Biolipox AB provides entitlement for exchange for one share in Orexo AB, and a corresponding number of shares are held by the independent company Pyrinox AB.

The list below shows the change in the number of options during the period January 1, 2009 to June 30, 2009 distributed among each category.

| | Opening Jan 1, 2009 | Change | Closing June 30, 2009 |
|---|---|---|---|
| **Employee stock options** | | | |
| Of which: | | | |
| Decided and allotted employee stock options | 651,075 | | 651,075 |
| Allotted in February 2009(i) | | 329,500 | 329,500 |
| Exercised | | -6,084 | -6,084 |
| Expired | | -7,000 | -7,000 |
| **Total** | | | **967,491** |
| Decided and allotted Board member options | 12,845 | | 12,845 |
| Allotted in May 2009 (ii) | | 22,362 | 22,362 |
| **Total** | | | **35,207** |
| Decided and allotted warrants | 15,250 | | 15,250 |
| Expired | | -5,250 | -5,250 |
| **Total** | | | **10,000** |
| Decided but not allotted employee stock options | | | |
| Opening balance, approved by the 2008 AGM | 429,500 | | 429,500 |
| Less allotment in February 2009(1) | | -329,500 | -329,500 |
| Less options returned | | -100,000 | -100,000 |
| Approved by the 2009 AGM | | 470,000 | 470,000 |
| **Total** | | | **470,000** |
| Warrants held by subsidiary for cash-flow hedging of payroll overhead | 78,000 | | 78,000 |
| **Total** | | | **78,000** |
| **Total options to employees** | **1,186,670** | **374,018** | **1,560,698** |

[1] All information regarding options issued by Orexo AB has been restated to take into account the 1:250 share split conducted in November 2005. The 2005 Annual Report states that older option certificates provide entitlement to subscribe for 250 shares after the split. The reported data regarding options issued by Orexo AB refer to the number of shares to which each option provides entitlement to subscribe for shares following the share split. All data regarding options issued by Biolipox AB are restated using a factor of 0.45854, which corresponds to the computed value of the options related to the share price for the Orexo share on the acquisition date. The reported data regarding the options issued by Biolipox refer to the number of shares for which each option may be exchanged after recalculation.

| | | | |
|---|---|---|---|
| Employee stock utilized from Biolipox AB (no dilution effect, included in newly issued shares in conjunction with acquisition of Biolipox) | 334,851 | -88,903 | 245,948 |
| Warrants utilized from Biolipox AB subsidiary for cash-flow hedging of social security fees (no dilution effect) | 130,374 | -26,810 | 103,564 |
| **Total options from Biolipox** | **465,225** | **-** | **349,512** |
| **Total options to employees** | **1,651,895** | **258,305** | **1,910,210** |
| **Other options** | | | |
| Warrants related to supplemental payment in conjunction with acquisition of Biolipox AB | 926,000 | - | 926,000 |
| **Total options outstanding** | **2,577,895** | **258,305** | **2,836,210** |

During the period January-June 2009, 6,084 stock employee options from Orexo's employee stock options were exercised. During the period January-June 2009, 88,903 of Biolipox' employee stock options were also exercised, entailing that holders exchanged their options for 88,903 shares held by the independent company Pyrinox AB. Exercise did not entail any new share issues by Orexo.

*i) Allotment in February after return of 100,000 employee stock options in April 2009.*

In February 2009, new options were allotted to personnel. The distribution among executives following the return of 100,000 options in April 2009 was as follows:

- CEO: 30,000 shares
- Other senior executives: 120,000 shares
- Other employees: 179,500 shares

The strike price is SEK 51 per share and the options may be exercised through December 31, 2018. Vesting takes the form of one third of the total number allotted options on each of the three anniversary dates immediately after February 25, 2009. The market value, calculated according to the Black & Scholes method, was SEK 11.99 per option on the allotment date.

*ii) Allotment of Board member options in May 2009*

In May 2009, a total of 22,362 Board member options were allotted that provide entitlement to subscribe for a total of 22,362 shares in Orexo. These Board member options have been allotted free of charge to the Board members elected at the 2009 AGM. Vesting of the Board member options takes the form of 25 percent after the date for the publication of Orexo's interim report for the first quarter and 25 percent after the publication of the interim reports for quarters two to four during the mandate period for the 2009 financial year. The right of Board members to request exercise arises two years after the 2009 AGM. The final exercise date for Board member options is December 31, 2016 and the strike price is SEK 0.40 per share. The market value, calculated using the Black & Scholes method, was SEK 36.82 on the allotment date.

*AGM approved new program*
Orexo's AGM held on April 23, 2009 approved a new employee stock options program comprising the issuance of warrants as well as the approval of the disposal of warrants within the framework of employee stock options. Employee stock options comprise 470,000 employee stock options. Each employee stock option may be used to acquire one share in Orexo in return for payment of a strike price set at 110 percent of the market value of the Orexo share on the allotment date. Full exercise of the new options would lead to a dilution of approximately 2 percent of the share capital and voting rights in Orexo.

The AGM also approved a Board member shareholder program comprising the issuance of 31,350 warrants and the approval of the disposal of the warrants within the framework of the Board shareholder program. Board members who participate in Orexo's Board member shareholder program receive 50 percent of their Board fees and any fees for committee in cash and are allotted Board member shares in an amount that, on the allotment date, is equal in value to 50 percent of the Board fee and any fees for committee work. Entitlement to acquire shares pursuant to the Board member stock program is contingent on the Board member remaining on the Board for all or part of the mandate period. Each Board-program share may be used to acquire one share in Orexo in return for payment of a strike price set in relation to the par value of the Orexo share.

### *4. Cash flow*

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

| | **2009 Apr-June** | **2008 Apr-June** | **2009 Jan-June** | **2008 Jan-June** | **2008 Jan-Dec** |
|---|---|---|---|---|---|
| Depreciation/amortization and impairment | 2,303 | 2,638 | 6,717 | 5,497 | 10,734 |
| Estimated costs for employee stock options | 2,590 | 3,454 | 3,719 | 5,845 | 1,531 |
| Exchange-rate differences | 14 | - | - | - | - |
| Hedging of net investments | -2,980 | - | -128 | - | - |
| Unrealized change of value in derivatives | -1,682 | - | 3,925 | - | - |
| Other | - | 11 | - | 13 | - |
| **Total** | **245** | **6,103** | **14,233** | **11,355** | **12,265** |

### *5. Shareholders' equity*

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

| | **2009 Apr-June** | **2008 Apr-June** | **2009 Jan-June** | **2008 Jan-June** | **2008 Jan-Dec** |
|---|---|---|---|---|---|
| Opening shareholders' equity, according to the balance sheet | **681,720** | **621,743** | **609,194** | **665,932** | **665,932** |
| Net profit/loss for the period | -57,261 | -30,869 | -24,895 | -76,134 | -54,805 |

| | | | | | |
|---|---|---|---|---|---|
| Subscription for shares through the exercise of warrants | 15 | - | 90 | - | - |
| New share issues | - | - | 39,246 | - | - |
| New warrant issues | - | - | - | - | - |
| Employee stock options, vested value for employees | 1,988 | 1,492 | 2,827 | 2,568 | 933 |
| Group contribution | - | - | - | - | 1,000 |
| **Closing amount** | **626,462** | **592,366** | **626,462** | **592,366** | **609,194** |

### *6. Acquisition of PharmaKodex*

On February 24, Orexo AB attained decisive influence and thus control of the UK company PharmaKodex. The company was consolidated in the Orexo Group as of the same date.

Orexo acquired the company in return for payment to be issued in two installments. The first installment was paid on February 23, 2009 in the form of newly issued Orexo shares and a decision regarding the second installment was made by Orexo on August 21, 2009. As payment for the first installment, 843,992 new Orexo shares were issued to PharmaKodex's former shareholders. A total of 933,781 new Orexo shares were issued as a supplementary consideration in accordance with the Board decision on August 21, 2009. Through the two installments, PharmaKodex is valued at approximately MGBP 6.5, taking into consideration the share price on each issue occasion. The transaction also involves additional conditional payments based on revenues from licenses for PharmaKodex's current program and technologies, as well as being based on payments for certain milestones.

### *7. Events after the end of the period*

- The second installment for the acquisition of PharmaKodex was paid in the form of newly issued Orexo shares. A decision regarding the installment was made on August 21, 2009 and PharmaKodex's former shareholders received a total of 933,781 newly issued Orexo shares.

- Further information on events after the end of the period are shown on pages 5-6.

**Note**
Orexo AB publ. discloses the information provided herein pursuant to the Securities Markets Act. The information was provided for public release on August 21, 2009 at 08:45 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.