Orexo AB (publ.)
– Year-end Report January-December 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, February 17, 2010

Orexo AB (publ) –
Year-end Report January–December 2009

Key events during the year

- Net revenues totaled MSEK 236.1 (233.3).
- The loss after tax was MSEK 98.1 (loss: 103.1).
- The loss per share amounted to a loss of SEK 4.32 (loss: 4.77).
- Cash and cash equivalents at year-end totaled MSEK 87.4 (188.2).
- Abstral was launched in UK, Germany, France, Spain and Greece.
- In March, the FDA approved Orexo's product Edluar for the short-term treatment of insomnia. The approval resulted in Orexo receiving a milestone payment of MUSD 5 from Meda.
- In August, Orexo signed an exclusive license agreement with Novartis. The agreement covered OX17 program for the treatment of gastroesophageal reflux disease (GERD).
- In February, Orexo acquired the British drug delivery company PharmaKodex Ltd. The acquisition strengthens Orexo's strategy to develop drugs based on well-established, effective substances.

Fourth quarter

- Net revenues totaled MSEK 27.9 (92.1).
- The net loss after tax was MSEK 58.0 (loss: 14.4).
- The loss per share was SEK 2.48 (loss: 0.67).
- Orexo's partner, ProStrakan Group plc, announced that the registration application for Abstral in the US had been accepted for final review by FDA.
- Royalty revenues from Abstral in Europe rose to MSEK 9.9 compared to MSEK 3.3 in the third quarter.

Torbjörn Bjerke, President and CEO, comments:

Sales of Abstral continue to show robust growth, with royalty revenues rising sharply during the fourth quarter – up threefold from the preceding quarter. Our partner, ProStrakan, launched during 2009 Abstral in UK, Germany, France, Spain and Greece, and product launches in additional markets are imminent. Sales growth confirms that there is a substantial medical requirement in the case of cancer patients suffering from breakthrough pain.

During the third quarter, our partner ProStrakan filed a registration application for Abstral in the US. The FDA accepted the registration application as complete for evaluation during the fourth quarter and, if the approval process proceeds on schedule, the product may be launched in the US during the latter half of 2010.

Orexo's primary focus for 2010 is commercialization, sales and marketing as well as continuing cost control. Rising royalty revenues, combined with lower costs, mean that we are approaching our goal of being a pharmaceutical company with sustainable profitability. We expect our operation cost to be about MSEK 200-220.

Torbjörn Bjerke
President and CEO

KEY EVENTS DURING THE FOURTH QUARTER OF 2009

The FDA commences final review of the registration application for Abstral
Orexo's partner ProStrakan Group plc announced that the registration application (New Drug Application, NDA) for Abstral was accepted for final review by the US Food and Drug Administration (FDA).

Orexo and Hospira terminated the distribution agreement for Southeast Asia
Orexo and Hospira have terminated the distribution agreement that granted Hospira the rights to market Abstral in Southeast Asia. Orexo has commenced negotiations with other distributors covering the rights to Abstral in the region.

KEY EVENTS AFTER THE CLOSE OF THE PERIOD

Regulatory filing of Abstral in Canada was made by ProStrakan's partner Paladin Labs Inc. in February 2010. The submission was accepted for review by Health Canada, the Canadian Government Department with responsibility for public health.

The submission has been granted priority review status by Health Canada and review of the application is therefore expected to conclude in 180 days.

Operations

Orexo's product portfolio

Commercialized products

Abstral – for the treatment of breakthrough pain among cancer patients
Abstral is a drug that provides fast and effective treatment of breakthrough pain in cancer patients who already receives pain treatment by means of opioids. The drug 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 the body rapidly absorbs the active ingredient 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.

Edluar – for insomnia
Edluar is a drug 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 to treat insomnia. Edluar placed under the tongue where it rapidly dissolves and the active substance is absorbed through the mucous membrane. Meda, the international specialty pharmaceutical company, has acquired the global rights to Edluar.

Diabact UBT - diagnosis of Helicobacter pylori
Diabact UBT is a product 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, is painless and takes ten minutes to administer. The actual analysis is conducted at an external laboratory. Orexo's subsidiary, Kibion, markets the product.

Heliprobe System – diagnosis of Helicobacter pylori
Heliprobe System is a "doctor's office test" to identify 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. Orexo's subsidiary, Kibion markets the product.

Projects covered by licensing agreements

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, discomfort and pain. Current treatments either provide fast, short-term effects or slow, but sustained 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
During 2008 a Phase II study was completed that confirmed that OX17 rapidly and effectively reduces the formation of stomach acid and that acid curtailment continues effectively as long as treatment is required. This is an attractive and unique profile for drugs designed to treat gastroesophageal reflux disease.

In August 2009, Orexo signed an exclusive, global license agreement with a company in the Novartis group covering OX17 program. Pursuant to the agreement, Orexo will receive payments

when development milestones are reached and will also receive payments when sales-related targets are met. In addition, Orexo will receive royalties on Novartis' future sales of the product.

OX-NLA – for the treatment of 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 (hay fever) and non-allergic rhinitis. 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, confirming that OX-NLA is suitable for on-demand treatment. OX-NLA 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. Drugs commonly 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 that long-term use of these drugs raised the risk of cardiovascular side effects led to the withdrawal of several COX-2 inhibitors from the market in 2004. The remaining COX-2 inhibitors and prescription-only NSAIDs also carry warnings.

OX-MPI features 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 and, thus, curtail the formation of PGE2, leading in turn to reduced inflammation and a reduction in pain. Since the action mechanism 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 pharmaceuticals.

Projects in which cooperation and licensing discussions have been initiated

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. Completed Phase I studies to date have shown highly satisfactory safety and tolerance. An experimental Phase IIa study 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 from the study in respect of the treatment of COPD.

OX-AAF – for the treatment of inflammatory respiratory diseases
OX-AAF (arachidonic acid franchise) is the general term for the R&D projects aimed at developing a new generation of drugs for the treatment of asthma and COPD, and which are more effective than current treatments. The projects are based on Orexo's leading research in the arachidonic acid cascade and offer favorable potential to develop into a new drug for the treatment of 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 mechanism indicates 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 various series of molecules and has developed a proprietary portfolio of potential drug candidates. A number of these have shown favorable results in various pharmacological models. Work is continuing in a bid to optimize biological effects and other characteristics that are significant 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 healthy 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 of new anti-inflammatory drugs.

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

Project status
Orexo has developed several series of models and has configured a portfolio of potential drug candidates. Efforts are continuing to optimize the biological effects and other characteristics that are important for an effective and safe drug.

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™.

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.

OX19 – treatment of incontinence

OX19 is focused on developing more effective pharmaceutical forms of desmopressin for the treatment of 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. No activities are on going at the moment.

OX641
OX641 was obtained through the acquisition of PharmaKodex in February 2009 and it is aimed at developing a product that provides fast, lasting pain relief from migraine headaches. Orexo intends to license this project to a major pharmaceutical company.

Project status
Formulation phase. No project activities are ongoing at the moment.

The period in figures, January 1 – December 31, 2009

Condensed consolidated statement of operations

	3 months 2009 Oct-Dec	3 months 2008 Oct-Dec	12 months 2009 Jan-Dec	12 months 2008 Jan-Dec
MSEK				
Net revenues	**27.9**	**92.1**	**236.1**	**233.3**
Cost of goods sold	-6.3	-4.2	-23.6	-17.4
Gross profit	**21.6**	**87.9**	**212.5**	**215.9**
Selling expenses	-14.0	-13.5	-39.3	-38.8
Administrative expenses	-14.0	-16.9	-46.3	-55.3
Research and developments costs	-51.9	-75.6	-224.2	-238.1
Other operating income and costs	0.4	1.8	-1.8	3.8
Operating profit/loss*	**-57.9**	**-16.3**	**-99.1**	**-112.5**
Net financial items	-0.1	1.7	2.1	9.0
Profit/loss after financial items	**-58.0**	**-14.5**	**-96.9**	**-103.5**
Tax	-	0.1	-1.1	0.4
Net loss for the period	**-58.0**	**-14.4**	**-98.1**	**-103.1**

** Includes the costs of personnel stock options in the amount of MSEK 8.2 for the period January–December 2009 (MSEK 1.5 January-December 2008).*

Revenues

Net revenues

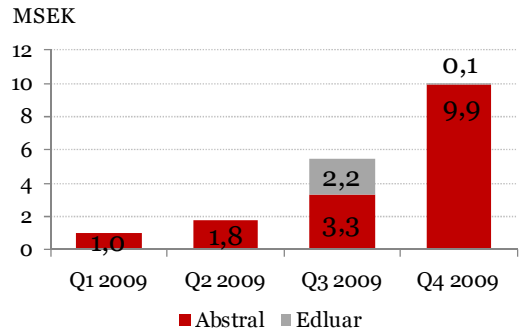
Consolidated net revenues for the period January-December 2009 totaled MSEK 236.1 (233.3). The rise in revenues for the period is primarily attributable to higher license revenues and rising royalties.

Sales of Abstral in Europe progressed sharply and exceeded expectations. Royalty revenues were MSEK 9.9 for the fourth quarter, compared with MSEK 3.3 during the third quarter, up 300 percent.

In August, Meda commenced the launch of Edluar in the US. Royalty revenues from Edluar totaled MSEK 2.3 for the year, of which the largest portion is attributable to stockpiling in connection with the launch during August 2009.

Net revenues during the period October-December 2009 were MSEK 27.9 (92.1). The change compared to 2008 relates to large one-time revenues during 2008 from outlicensing of Edluar to Meda and the change of partner in the USA from Endo Pharmaceuticals to ProStrakan. The R&D funding was also high during the fourth quarter 2008 which relates to the finalizing of the Phase III studies for Abstral in the US.

Royalty revenues, 2009



Net revenues were distributed as follows:

MSEK	3 months 2009 Oct-Dec	3 months 2008 Oct-Dec	12 months 2009 Jan-Dec	12 months 2008 Jan-Dec
License royalties	0.2	57.9	119.5	123.1
Abstral – royalty	9.9	-	16.2	0.1
Edluar – royalty	0.1	-	2.3	-
Reinvoicing of R&D costs	4.7	24.2	46.4	71.8
Diabact® UBT	3.6	2.5	7.9	6.6
Heliprobe® System	6.7	4.8	32.8	22.0
ProStrakan AB J/V 50%	2.7	2.7	10.8	9.7
Other			0,2	
Total	**27.9**	**92.1**	**236.1**	**233.3**

Expenses and earnings

Selling expenses

Selling expenses for the year totaled MSEK 39.3 (38.8), with the period October-December 2009 accounting for MSEK 14.0 (13.5). Selling expenses include business development expenses relating to the licensing out of Orexo's projects and operating costs for Kibion AB and the joint venture company ProStrakan AB.

Administrative expenses

Administrative expenses in 2009 totaled MSEK 46.3 (55.3), down 16 percent. The decrease was due primarily to efficiency-enhancement programs. Administrative expenses for the period October-December 2009 were MSEK 14.0 (16.9).

Expenses for the company's employee stock options program

The company's expenses for the employee stock options program for the full year totaled MSEK 8.2 (1.5). Of this total, MSEK 4.0 (1.1) is attributable to administrative personnel; MSEK 3.4 (0.5) to R&D personnel; and MSEK 0.8 (-0.1) to sales personnel. For the October-December period, the company's expenses for the stock options program were MSEK 2.7 (-1.7).

Research and development costs

Research and development costs for the full year totaled MSEK 224.2 (238.1). MSEK 13, 8 is additional cost in 2009 relating to the acquisition of PharmaKodex. Cost for asset impairment totaled MSEK 2, 0 (0). MSEK 46.4 (71.8) of costs was reinvoiced. For the period October-December, R&D costs totaled MSEK 51.9 (75.6). The fall in costs in the fourth quarter compared with the year-earlier period is because of to the high costs for the completion of Abstral's clinical Phase III studies in the US 2008. R&D costs will go down significantly during 2010 as Orexo will have full effect from the reduction of employees and the move of laboratories from Solna to Uppsala and less external costs in the development projects.

Depreciation/amortization
Depreciation for the full year was MSEK 10.5 (10.7), with MSEK 1.9 (2.6) for the period October-December 2009.

Net financial items
Net financial items for the period January-December 2009 totaled MSEK 2.1 (9.0), with a shortfall of MSEK 0.1 (1.7) for the period October-December. Net financial items include revenue of MSEK 4.1, attributable to the fact that the second installment payment in conjunction with the acquisition of PharmaKodex entailed that this be categorized as an embedded derivative, which is valued at its market value via the statement of operations, resulting in a positive earnings effect of a declining stock market price and an estimated interest expense of MSEK 2.3 due to the present value of this second installment payment.

Tax
The tax cost for the full year was MSEK 1.1 (-0.4), of which MSEK 1.4 pertained to non-Swedish tax-at-source for installment payments received pursuant to the license agreement for Abstral in Japan. Otherwise, tax pertains to deferred tax.

Earnings
The operating loss for the year totaled MSEK 99.1 (loss: 112.5). The loss for the year after financial items was MSEK 96.9 (loss: 103.5), with the loss after tax amounting to MSEK 98.1 (loss: 103.1). Earnings were charged with restructuring costs of MSEK 6.6 relating to the acquisition of PharmaKodex Ltd.

The operating loss for the period October-December was MSEK 57.9 (loss: 16.3). The loss for the period after financial items totaled MSEK 58.0 (loss: 14.5), with the loss after tax amounting to MSEK 58.0 (loss: 14.4).

Financial position
Group cash and cash equivalents at December 31, 2009 amounted to MSEK 87.4 (188.2). During 2009 a loan of 16 MSEK from Nordea has increased the cash position.

Cash flow from operating activities for the full year resulted in a shortfall of MSEK 133.9 (neg: 101.5). Cash flow after financing resulted in a deficit of MSEK 96.3 (neg: 103.4).

Cash flow from operating activities for the period October-December 2009 amounted to a shortfall of MSEK 16.2 (neg: 7.3). Cash flow after financing resulted in a deficit of MSEK 16.9 (neg: 7.4).

Shareholders' equity at December 31, 2009 amounted to MSEK 548.7 (569.8). The equity/assets ratio was 85 percent (81).

Investments
Gross investments in tangible fixed assets during the year totaled MSEK 3.2 (1.7), with the period October-December 2009 accounting for MSEK 1.5 (0.2). Refer to Note 6 as regards the investment in PharmaKodex Ltd.

Parent Company
Most of the Group's business is carried out in the Parent Company, Orexo AB. Net revenues in 2009 totaled MSEK 208.2 (207.8), with the loss after financial items amounting to MSEK 41.8 (loss: 54.8). Investments totaled MSEK 3.2 (1.7). Cash and cash equivalents in the Parent Company at December 31, 2009 totaled MSEK 12.8 (29.6), with current investment amounting to 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. MSEK 10.3 of the supplemental payment is reported as a provision and MSEK 37.8 was reported as a contingent liability, since the latter is not assessed as a probable payment based on pharmaceutical development statistics. The supplemental payment was adjusted for changes in exchange rates during the year. As cash-flow hedging for social security fees pertaining to the employee stock options issued by Biolipox, warrants were issued to Pyrinox AB. Orexo has pledged to handle any deficits exceeding the cover provided by the warrants during their lifetime through December 31, 2016.

In the acquisition of Noster System AB in 2006, Orexo agreed on a supplemental purchase price of not more than MSEK 7.2, which will become payable if the growth of Heliprobe™ System achieves pre-determined sales targets by year-end 2009. The supplemental purchase price is estimated to be MSEK 1.8–2.0 and will be paid out during the first quarter of 2010. The calculated supplemental purchase price is now booked as a debt and the contingent liability has been moved.

Orexo acquired the British drug company PharmaKodex in February 2009. This corporate acquisition also includes conditional payments based on revenues from licenses for the current PharmaKodex' program and technologies, as well as being based on payments for certain milestones and which are not reported as a liability.

Orexo has a loan of MSEK 16 from the Swedish bank, Nordea, the collateral for which consists of chattel mortgages in an equivalent amount.

Significant risks and uncertainties

Significant risks and uncertainty factors are essentially the same for the Parent Company and the Group. More detailed information on financial risk is available in Orexo's annual report for 2008.

Uncertainty regarding the success of development efforts

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. Several factors affect the probability that a drug project will result in an approved pharmaceutical. For example, a potential drug candidate that demonstrated favorable effects in animal models may lack any significant effect on humans. Risks for side-effects can also complicate a drug project. However, the risk of not reaching the market diminishes as the project passes through the various phases in the development process. If the Group's clinical trials are not successful, Orexo may lack the potential to license out or commercialize new products.

Competing operations

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

Partners and the authorities

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

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

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

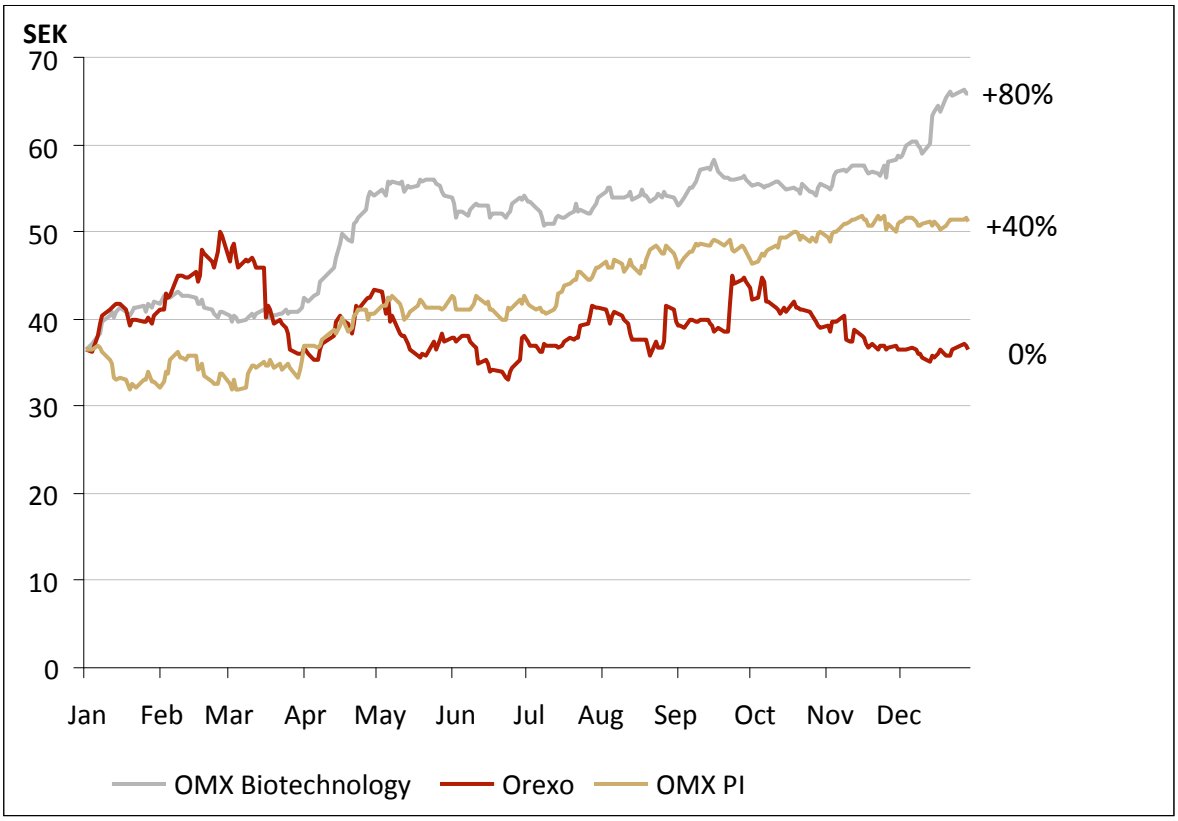
Given the lower cost base 2010 and increased credit facilities of MSEK 19 that was received in February 2010, the Board estimates that current financing is sufficient to pursue the operations.

Group cash and cash equivalents amounted to MSEK 87.4 at December 31, 2009.

Dividend
The Board does not intend to propose a dividend for the 2009 fiscal year.

Share and market value
Orexo's share traded at SEK 36.60 at December 31, 2009. The company's market capitalization, based on the number of shares outstanding on December 31, 2009, amounted to MSEK 856.5. At December 31, 2008, the company's market capitalization was MSEK 785.

Share price development 2009



Analysts monitoring Orexo:

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

Future reporting dates:

Annual General Meeting 2010	April 21, 2010
Interim Report, January — March 2010	May 5, 2010
Interim Report, January — June 2010	August 20, 2010
Interim Report, January — September 2010	November 10, 2010

Annual General Meeting, 2010
The Annual General Meeting of Orexo AB will be held on Wednesday April 21, 2010 at 3:00pm at the IVA Conference Center, Grev Turegatan 16, in Stockholm.

The notification of the meeting will be announced no later than March 24, 2010.

Annual Report
Orexo AB's Annual Report will be presented on the company's website no later than April 7, 2010 and will be sent to the shareholders who so request.

Uppsala, February 17, 2010
Orexo AB (publ)
Torbjörn Bjerke, President and CEO

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Claes Wenthzel, Executive Vice-President & CFO, Phone: +46 708 62 01 22, e-mail: claes.wenthzel@orexo.com

Review report

We have reviewed the appended report for the period January 1 to December 31, 2009 for Orexo AB (publ). The Board of Directors is responsible for the preparation and fair presentation of this interim report in accordance with the Annual Accounts Act and IAS 34. Our responsibility is to express an opinion on this interim report based on our review.

We conducted our review in accordance with the Standard on Review Engagements SÖG 2410, Review of Interim Financial Information Performed by the Independent Auditor of the Entity, as issued by FAR. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially more restricted in scope than an audit conducted in accordance with Standards on Auditing in Sweden RS and other generally accepted auditing practices. The procedures performed in a review do not enable us to obtain a level of assurance that would make us aware of all significant matters that might be identified in an audit. Therefore, the conclusion expressed based on a review does not give the same level of assurance as a conclusion expressed based on an audit.

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

Uppsala, February 17, 2010
Öhrlings PricewaterhouseCoopers

Leonard Daun
Authorized Public Accountant

CONSOLIDATED STATEMENT OF OPERATIONS

	Notes	3 months 2009 Oct-Dec	3 months 2008 Oct-Dec	12 months 2009 Jan-Dec	12 months 2008 Jan-Dec
Net revenues		27 857	92 135	236 104	233 346
Cost of goods sold	2	-6 299	-4 204	-23 650	-17 446
Gross profit		**21 558**	**87 931**	**212 454**	**215 900**
Selling expenses	2	-13 984	-13 549	-39 261	-38 818
Administrative expenses	2	-14 047	-16 865	-46 308	-55 294
Research and development costs	2	-51 913	-75 552	-224 216	-238 125
Other operating income		1 738	3 205	8 239	7 451
Other operating expenses	2	-1 310	-1 442	-9 991	-3 611
Operating loss		**-57 958**	**-16 272**	**-99 083**	**-112 497**
Financial income		45	1 819	4 868	9 268
Financial expense		-120	-76	-2 726	-266
Financial items – net		**-75**	**1 743**	**2 142**	**9 002**
Pre-tax loss		**-58 033**	**-14 529**	**-96 941**	**-103 495**
Income tax		5	96	-1 138	441
Net loss for the period		**-58 028**	**-14 433**	**-98 079**	**-103 054**

Loss for the period attributable to:				
Parent company shareholders	-58 028	-14 433	-98 079	-103 054
Minority interests	-	-	-	-

Loss per share, attributable to Parent Company shareholders during the period (SEK per share**):**				
Loss per share, before dilution, SEK	2.48	0.67	4.32	4.77
Loss per share, after dilution, SEK	2.48	0.67	4.32	4.77

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

	3 months 2009 Oct-Dec	3 months 2008 Oct-Dec	12 months 2009 Jan-Dec	12 months 2008 Jan-Dec
Net profit/loss for the period	**-58 028**	**-14 433**	**-98 079**	**-103 054**
Other comprehensive income				
Hedging of net investments	-	-	2 329	-
Exchange-rate differences	1 957	-	-7 574	-
Other comprehensive income for the period, net after tax	**1 957**	**-**	**-5 245**	**-**
Total comprehensive income for the period	**-56 071**	**-14 433**	**-103 324**	**-103 054**
Total comprehensive income attributable to:				
Parent Company's shareholders	-56 071	-103 054	-103 324	-103 054

CHANGES IN CONSOLIDATED SHAREHOLDERS' EQUITY
Attributable to the Parent Company's shareholders

	Share capital	Other contri-buted capital	Accumu-lated 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	-	-	-103 053	-	-103 053	-103 053
Employee stock options, vested amount	-	1 584	-	-	1 584	1 584
Closing value December 31, 2008	**8 647**	**1 012 964**	**-451 828**	**-**	**569 783**	**569 783**
Opening balance, January 1, 2009	8 647	1 012 964	-451 828	-	569 783	569 783
Total comprehensive income for the period	-	-	-98 079	-5 245	-103 324	-103 324
Employee stock options, vested amount	-	7 756	-	-	7 756	7 756
New share issues	713	73 733	-	-	74 446	74 446
Closing balance, December 31, 2009	**9 360**	**1 094 453**	**-549 907**	**-5 245**	**548 661**	**548 661**

1) *There are no minority interests*

CONSOLIDATED BALANCE SHEET

	Notes	2009 Dec. 31	2008 Dec. 31
ASSETS			
Fixed assets			
Tangible fixed assets		45 814	50 317
Goodwill		17 987	16 030
Acquired R&D	6	427 030	373 908
Other intangible fixed assets		1 982	2 033
Total fixed assets		**492 813**	**442 288**
Current assets			
Inventories		8 440	13 982
Accounts receivable and other receivables		59 622	53 313
Tax receivables		1 045	4 222
Cash and cash equivalents		87 414	188 220
Total current assets		**156 521**	**259 737**
Total assets		**649 334**	**702 025**
SHAREHOLDERS' EQUITY AND LIABILITIES	3		
Share capital		9 360	8 647
Capital contributions		1 094 453	1 012 964
Accumulated losses		-549 907	-451 828
Translation differences		-5 245	-
Total shareholders' equity		**548 661**	**569 783**
Long-term liabilities			
Provisions		11 114	10 000
Long-term liabilities, interest-bearing		12 800	-
Deferred tax liability		9 791	415
Total long-term liabilities		**33 705**	**10 415**
Current liabilities			
Current liabilities, non-interest-bearing		63 768	121 827
Current liabilities, interest-bearing		3 200	-
Total liabilities		**100 673**	**132 242**
Total shareholders' equity and liabilities		**649 334**	**702 025**
Pledged assets		16 000	-
Contingent liabilities		37 821	42 120

CONSOLIDATED CASH-FLOW STATEMENTS

	Notes	3 months 2009 Oct-Dec	3 months 2008 Oct-Dec	12 months 2009 Jan-Dec	12 months 2008 Jan-Dec
Operations					
Profit/loss before interest expense and interest income		-57 958	-16 272	-99 083	-112 497
Interest income		45	1 819	759	9 268
Interest expense		-120	-76	-397	-266
Tax paid		-	-	-1 389	-
Adjustment for items not included in cash flow	4	6 726	868	20 834	12 265
Cash flow from operations before changes in working capital		**-51 307**	**-13 661**	**-79 276**	**-91 230**
Change in working capital					
Accounts receivable		14 003	-3 378	-2 963	-19 172
Other current receivables		3 048	306	6 143	7 463
Inventories		732	-1 210	5 542	-688
Current liabilities		17 304	10 237	-64 487	1 894
Provisions		267	-36	1 114	328
Long-term liabilities		-295	410	-	-85
Cash flow from operations		**-16 248**	**-7 332**	**-133 927**	**-101 490**
Investing activities					
Acquisition of machinery and equipment		-1 467	-220	-3 155	-1 671
Divestment of machinery and equipment		-	110	2	110
Acquisition of subsidiaries		-	-	24 695	-327
Cash flow after investments		**-17 715**	**-7 442**	**-112 385**	**-103 378**
Change in financing					
New share issue		800	-	90	-
Loans raised		-	-	16 000	-
Cash flow after financing activities		**-16 915**	**-7 442**	**-96 295**	**-103 378**
Cash flow for the year					
Cash and cash equivalents, beginning of period		107 061	195 662	188 220	291 598
Exchange rate differences in cash and cash equivalents		-2 732	-	-4 511	-
Changes in cash and cash equivalents		-16 915	-7 442	-96 295	-103 378
Cash and cash equivalents, at close of period		**87 414**	**188 220**	**87 414**	**188 220**

KEY FIGURES

	3 months 2009 Oct-Dec	3 months 2008 Oct-Dec	12 months 2009 Jan-Dec	12 months 2008 Jan-Dec
Operating margin, %	-207	-18	-42	-48
Profit margin, %	-207	-16	-41	-44
Return on total capital, %	-9	-2	-14	-14
Return on equity, %	-10	-3	-17	-17
Return on capital employed, %	-10	-3	-16	-17
Debt/equity ratio, multiple	0	0	0	0
Equity/assets ratio, %	85	82	85	82
Current ratio, %	234	213	234	213
Acid ratio, %	221	202	221	202
Average number of shares, before dilution	23 401 252	21 617 395	22 714 784	21 617 395
Average number of shares, after dilution	24 487 957	22 684 988	23 801 489	22 689 035
Number of shares, after full dilution	25 328 048	23 300 567	25 326 775	23 300 567
Number of shares, before dilution	23 401 252	21 617 395	23 401 252	21 617 395
Number of shares, after dilution	24 487 957	22 684 988	24 487 957	22 684 988
Loss per share, before dilution, SEK	2.48	0.67	4.32	4.77
Loss per share, after dilution, SEK	2.48	0.67	4.32	4.77
Shareholders' equity per share before dilution SEK	23.45	26.36	23.45	26.36
Shareholders' equity per share after dilution SEK	22.41	25.12	22.41	25.12
Number of employees at close of period	108	128	108	128
Average number of employees	119	128	124	123
Shareholders' equity	548 661	569 783	548 661	569 783
Capital employed	564 661	569 783	564 661	569 783

DEFINITIONS
Refer to the annual report for 2008

PARENT COMPANY BALANCE SHEET

SEK 000s	Notes	3 months 2009 Oct-Dec	3 months 2008 Oct-Dec	12 months 2009 Jan-Dec	12 months 2008 Jan-Dec
Net revenues		49 018	117 349	208 183	207 757
Cost of goods sold		-	-	-	-
Gross profit		**49 018**	**117 349**	**208 183**	**207 757**
Selling expenses		-6 102	-8 044	-16 588	-19 041
Administrative expenses		-13 685	-16 799	-42 260	-52 085
Research and development expenses		-46 233	-71 346	-192 463	-197 689
Other operating income		1 007	1 901	3 574	4 514
Other operating expenses		-543	-604	-6 203	-1 779
Operating profit/loss		**-16 538**	**22 457**	**-45 757**	**-58 323**
Earnings from financial investments					
Financial income		7	532	6 668	3 733
Financial expense		-123	-72	-2 712	-215
Profit/loss after financial items		**-16 654**	**22 917**	**-41 801**	**-54 805**
Tax		-1	-	-1 390	-
Net profit/loss for the period		**-16 655**	**22 917**	**-43 191**	**-54 805**

PARENT COMPANY BALANCE SHEET

SEK ooos	Notes	2009 Dec 31	2008 Dec 31
ASSETS			
Fixed assets			
Tangible fixed assets		45 523	49 985
Intangible fixed assets		363	509
Shares in subsidiaries/joint ventures		606 414	524 169
Total fixed assets		**652 300**	**574 663**
Current assets			
Inventories		1 385	5 233
Accounts receivable and other receivables		49 324	103 245
Tax receivables		728	2 536
Cash and bank balances		12 790	29 608
Total current assets		**64 227**	**140 622**
Total assets		**716 527**	**715 285**
SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES	5		
Restricted equity		300 111	299 397
Non-restricted equity		347 029	309 797
Total shareholders' equity		**647 140**	**609 194**
Long-term liabilities			
Provisions		813	490
Borrowings		12 800	-
Total long-term liabilities		**13 613**	**490**
Current liabilities, non-interest-bearing		52 574	105 601
Current liabilities, interest-bearing		3 200	-
Total liabilities		**55 774**	**106 091**
Total shareholders' equity and Liabilities		**716 527**	**715 285**
Pledged assets		16 000	-
Contingent liabilities		6 050	11 050

Notes

1. Accounting principles

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

The Parent Company's financial statements were prepared in accordance with RFR 2.2 (Swedish Financial Accounting Standards Council's recommendation).

With exception of that stated below, the accounting principles applied in this year-end report are described in detail in the Notes to the 2008 Annual Report.

New accounting principles for 2009

Effective January 1, 2009, Orexo applies Orexo IFRS 8. The new standard requires that segment information is presented from the perspective of executive management, which entails that it is presented in the manner used in internal reporting, and, since this monitoring is done at the consolidated level, Orexo's accounting will continue to apply to a single segment.

The amended IAS 1, Presentation of Financial Statements, is applied with effect from January 1, 2009. The change affects Orexo's annual financial statements retroactively from December 31, 2007. Among other things, the change means that revenues and expenses that were previously charged directly to shareholders' equity are now presented in a separate report immediately after the statement of operations. Another change is that new terminology in financial reports may be used. However, this change is not mandatory and Orexo has elected to use the terminology used heretofore.

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

2. Costs distributed by type of cost

	2009 Oct-Dec	**2008 Oct-Dec**	**2009 Jan-Dec**	**2008 Jan-Dec**
Raw materials and supplies	8 822	8 228	41 503	32 444
Other external costs	42 466	63 257	162 804	181 642
Personnel costs	34 341	37 528	128 619	128 475
Depreciation and impairment	1 929	2 600	10 503	10 734
TOTAL	**87 558**	**111 613**	**343 429**	**353 295**

3. Shareholders' equity

Shares outstanding

The number of shares outstanding at December 31, 2009, was 23,401,252, all of which were common shares. All shares carry entitlement to one vote each.

During the period, January–December, the number of outstanding shares increased by a total of 1,783,857 shares, of which 1,777,773 shares derived from non-cash issues, with 843,992 shares at a price of SEK 46.50 each and 933,781 shares at a price of SEK 42 each, and 6,084 shares through the exercise of employee stock options.

Options

At December 31, there were a total of 2,671,953 options outstanding that carry rights to new subscription of 2, 395,523 shares in Orexo and the exchange for 276,430 options for shares in Orexo[1]. Each option issued by Biolipox AB provides entitlement for exchange for one share in Orexo AB, and a corresponding number of shares is held by the independent company Pyrinox AB.

The list below shows the change in the number of options during the period January 1, 2009 to December 31, 2009 distributed among each category.

	Opening 1/1 2009	**Change**	**Closing 31/12 2009**
Employee-related options			
Of which:			
Decided and allotted employee stock options	651 075		651 075
Allotted, February 2009 (i)		329 500	329 500
Exercised		-6 084	-6 084
Expired		-98 175	-98 175
Total			**876 316**
Decided and allotted Board 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, as approved by the 2008 AGM	429 500		429 500
Less: allotment in February 2009(i)		-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 subsidiaries as cash-flow hedging for social security fees	78 000		78 000
Total			**78 000**
Total options to employees	**1 186 670**	**282 853**	**1 469 523**
Employee stock options utilized from Biolipox AB (no dilution effect, included in newly issued shares in conjunction with acquisition	334 851	-138 744	196 107

[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.

of Biolipox)

Warrants utilized from Biolipox AB for cash-flow hedging of social security fees (no dilution effect)	130 374	-50 051	80 323
Total options from Biolipox	**465 225**	**-188 795**	**276 430**
Total options to employees	**1 651 895**	**94 058**	**1 745 953**
Other options			
Warrants related to supplemental payment in conjunction with acquisition of Biolipox AB	926 000	-	926 000
Total options outstanding	**2 577 895**	**94 058**	**2 671 953**

During the period of January-December 2009, 6,084 employee stock options from Orexo's options program were utilized. Also, during the period January-December 2009, 138,744 of Biolipox' employee stock options were exercised, entailing that holders exercised their options in exchange for 138,744 shares held by the independent company Pyrinox AB. Exercise did not entail any new share issues by Orexo.

The 926,000 warrants under the headline "Other options" in the table above are for the potential additional payments for Biolipox. Those could have been used if certain milestones happened before December 31, 2009. These milestones did not occur, why the warrants will mature January 1, 2010.

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 of 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.

New program approved at AGM
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 work 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 Oct-Dec	**2008 Oct-Dec**	**2009 Jan-Dec**	**2008 Jan-Dec**
Depreciation/amortization and impairment	1 929	2 600	10 503	10 734
Estimated costs for employee stock options	2 669	-1 718	8 203	1 531
Other	2 128	-14	2 128	-
Total	**6 726**	**868**	**20 834**	**12 265**

5. Shareholders' equity

Changes in the Parent Company's shareholders' equity

	2009 Oct-Dec	**2008 Oct-Dec**	**2009 Jan-Dec**	**2008 Jan-Dec**
Opening shareholders' equity, balance sheet	**660 699**	**588 620**	**609 194**	**665 932**
Net profit/loss for the period	-16 655	22 917	-43 191	-54 805
Subscription for shares through the exercise of warrants	-	-	-	-
New share issues	-	-	90	-
New warrant issues	-	-	74 356	-
Employee stock options, vested value for employees	3 096	-1 343	6 691	-933
Group contribution	-	-1 000	-	-1 000
Closing amount	**647 140**	**609 194**	**647 140**	**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 GBP 6.5 million, 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.

The preliminary acquired balance sheet has been adjusted with MSEK 0, 9.

7. Events after the end of the period

- Information regarding events after the end of the period is presented shown on page 4.

Note
Orexo AB publ. discloses the information provided herein pursuant to the Securities Markets Act. The information was provided for public release on February 17, 2010, at 8:00 a.m. CET. This report has been prepared in both Swedish and English. In the event of any discrepancy in the content of the two versions, the Swedish version shall take precedence.