

## Orexo AB (publ.) – Interim Report January-March 2008

Orexo AB, P.O. Box 303, SE-751 05 Uppsala, Sweden

Tel: +46 (0) 18-780 88 00, Fax: +46 (0) 18-780 88 88, E-mail: <u>info@orexo.com</u>

Internet: www.orexo.com Corp. reg. no 556500-0600

This text is an unofficial 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.

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Uppsala, May 7, 2008

## Orexo AB (publ) – Interim Report January-March 2008

## Executing in line with the strategy to build a profitable company

## Period in brief

- Net revenues amounted to MSEK 24.0 (6.4)
- The loss after tax was MSEK 62.2 (loss: 37.9)
- Earnings per share amounted to a loss of SEK 2.88 (loss: 2.73)

## Key events first quarter of 2008

- Potential new mechanism for treatment of asthma and COPD published.
- Rapinyl<sup>™</sup>/Abstral approved for marketing in Sweden.
- OX-NLA nasal spray shows excellent local tolerance for patients with hay fever.
- Report result confirms clinical effect of OX17 for treatment of GERD.

## Key events after period end

- Orexo's Annual General Meeting held on April 3.
- Meda AB acquired the exclusive world rights to two of Orexo's patented drugs: Sublinox™
  (OX22) and OX-NLA.
- A Phase I study of OX19 confirms that Orexo's new nasal spray formulation for the administration of desmopressin, a peptide used for treatment of incontinence, shows significantly better uptake than nasal sprays currently on the market. Next step for Orexo is to seek partnership for further development of the product.

## Condensed statement of operations 1

MSEK	3 months 2008 Jan-Mar	3 months 2007 Jan-Mar	12 months 2007 Jan-Dec
Net revenues	24.0	6.4	76.8
Loss after tax	(62.2)	(37.9)	(172.6)
Earnings per share before dilution (SEK)	(2.88)	(2.73)	(11.42)
Earnings per share after dilution (SEK) <sup>2</sup>	(2.88)	(2.73)	(11.42)

<sup>1)</sup> Refers to the Group, which includes acquisition of Biolipox from November 23, 2007, unless stated otherwise in this report. Figures in parentheses are for the corresponding period of the preceding year.

 $<sup>^{2}</sup>$ ) Since earnings are negative, the same earnings per share are reported after dilution as before dilution.



## CEO's remarks

## Torbjörn Bjerke, President and CEO, comments:

"Our goal is to develop Orexo into a profitable pharmaceutical company. Therefore, it is pleasing to note that Orexo has taken major strides in this direction during the past quarter.

The agreement we signed with Meda is a distinct step closer to our goal and is added to the already successful cooperation we have with ProStrakan, Endo Pharmaceuticals, Kyowa Haako and Boehringer Ingelheim. It is satisfying that the agreement with Meda covers a product with its origin in Biolipox and a product with its roots in Orexo. This further strengthens my conviction about the benefit of the merger of the two companies last year.

During the period Rapinyl<sup>™</sup>/Abstral was approved for marketing in Sweden, which was an important success for us. We are now looking forward to an EMEA decision during the current half year to be able to launch the product in cooperation with ProStrakan during the third quarter of the year. The product will be marketed under the name Abstral.

We are continuing to work at a high pace to capitalize on our valuable portfolio of projects and to generate new commercial successes thereby creating long-term profitability and shareholder value."



## **KEY EVENTS FIRST QUARTER 2008**

#### Potential new mechanism for treatment of asthma and COPD

The discovery of the eoxins and their characteristics has paved the way for a new class of pharmaceuticals for treatment of asthma and COPD (Chronic Obstructive Pulmonary Disease). In January 2008 one of the world's most-renowned scientific journals, *Proceedings of the National Academy of Sciences of the United States (PNAS)*, published Orexo´s research on the initial discovery and biological functions of eoxins. The publication describes the scientific rationale behind Orexo´s drug development program on eoxin inhibitors for treatment of asthma and COPD.

A first candidate drug is currently undergoing pre-clinical safety studies to enable commencement of clinical phase I studies.

## Rapinyl<sup>™</sup>/Abstral approved for marketing in Sweden

The Swedish Medical Products Agency has taken the decision to issue a Marketing Authorization for Rapinyl™/Abstral in Sweden based on its assessment report made as reference member state for the EU regulatory procedure. Sweden is the reference member state for the ongoing application for approval of Rapinyl™/Abstral within the EU, in which an answer is expected during the current half year. If approval is denied, the rights to sell the product in Sweden cease. The product is expected to be launched in Sweden during the third quarter of 2008 through Orexo's and ProStrakan's joint-venture sales company. The product will be sold under the name Abstral.

## OX-NLA Nasal Spray shows excellent local tolerability in patients with rhinitis

Orexo has developed a unique and patented formulation of cetirizine and liposomes, OX-NLA Nasal Spray. A completed Phase II tolerability study with rhinitis patients shows that OX-NLA Nasal Spray is tolerated well with no local side effects such as stinging and pain in the nose. Earlier studies have shown that treatment with OX-NLA Nasal Spray gives a rapid onset relief and is as effective as cetirizine in tablets.

The conclusion of the study is that the liposomes in OX-NLA Nasal Spray are able to mask the irritating characteristics of cetirizine.

#### Confirmed clinical effect OX17 for treatment of reflux disease (GERD)

New clinical data from a Phase II study confirms that Orexo's product OX17 has a medical benefit for treatment of GERD. OX17 quickly and effectively inhibits gastric acid production, a prerequisite for effective symptom relief in GERD patients. The result demonstrates the clinical potential of OX17 and is an important step in the development of a commercial product.



#### KEY EVENTS AFTER CLOSE OF THE PERIOD

## Orexo and Meda AB in potential billion SEK deal

Meda has acquired the exclusive worldwide commercialization rights from Orexo of two patented drugs: Sublinox<sup>TM</sup> (OX22) and OX-NLA.

Sublinox<sup>TM</sup> (OX22) (treatment of insomnia) contains the well-documented active substance zolpidem, one of the world's most used substances for treatment of this disorder. Sublinox<sup>TM</sup> (OX22) uses a unique and patented tablet formulation for fast and effective absorption. A recent phase III study confirmed that Sublinox<sup>TM</sup> (OX22) gives faster onset of action than other zolpidem tablet formulations. Regulatory submission to the Food and Drug Administration (FDA) in the United States is expected before the 3rd quarter 2008.

OX-NLA is a patented nasal spray formulation with the antihistamine substance cetirizine. The liposomes in OX-NLA give the product unique features. OX-NLA is being documented for the treatment of allergic and non-allergic rhinitis, one of Meda's major therapeutic areas. The product is entering phase III and Meda will fund continued development. Meda also has exclusive rights to combination products based on OX-NLA.

For exclusive worldwide rights for Sublinox<sup>™</sup> (OX22) and OX-NLA, Meda has paid MUSD 20. Meda has also agreed to the following one-time milestone payments for each product, when a yearly sales level is reached:

	Sublinox	<sup>CM</sup> (OX22)	OX-	NLA
At FDA approval	MUS	D 30	MUS	SD 15
Sales milestones	Sales > MUSD 150 > MUSD 200 > MUSD 400	Payment MUSD 20 MUSD 20 MUSD 20	Sales > MUSD 150 > MUSD 300	Payment MUSD 20 MUSD 20

Orexo will receive double-digit royalty on net sales.

## Orexo reports on first Phase I study for OX19

Orexo has developed a new nasal spray formulation for administration of pharmaceuticals, for which a clinical Phase 1 study shows significantly better uptake of desmopressin than nasal sprays currently on the market.

In the clinical study OX19-001, Orexo compared a new nasal powder spray with the current liquid dessmopressin nasal spray on healthy volunteers. The study showed with statistical significance that the uptake with the nasal powder spray was three times higher than for the liquid spray, with no delay in the time to reach maximum plasma concentration. The powder spray appeared to render less variation in the uptake of desmopressin.



Orexo's nasal powder platform potentially provides a means for increasing bioavailability with less variation for other peptides as well as small molecular pharmaceutical substances.

The study also included a sublingual tablet formulation. However, the bioavailability of desmopressin did not increase enough to reach the primary objective for the sublingual tablet formulation.

Orexo will seek a partner for the continued development of the nasal powder formulation of desmopressin.

## Orexo's Annual General Meeting on April 3

The Annual General Meeting resolved to re-elect Monica Caneman, Johan Christenson, Staffan Lindstrand and Kjell Strandberg, and to elect for the first time Ray Hill and Bengt Samuelsson, as members of the Board of Directors. 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 plan including the issuance of warrants and approval of disposal of the warrants under the employee stock option plan. The employee stock option plan consists of 470,000 employee stock options. Each employee stock option can be exercised to acquire one share in Orexo against payment of an exercise price determined as 110 per cent of the market value of the Orexo's share at the time of allotment.

The Meeting resolved to adopt a Board member shareholder plan including the issuance of 27,500 warrants and approval of disposal of the warrants issued under the Board member share plan. Board members participating in Orexo´s Board member shareholder plan will receive 50% of their Board fee and their fee for committee work, if any, in cash and will be allocated a number of Board shares, which value at the time of allotment shall correspond to 50% of the remuneration of the Board fee and fee for committee work, if any.



## **Operations**

#### Orexo in brief

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

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

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

## Orexo's product portfolio

## **Commercialized products**

**Diabact**<sup>®</sup> **UBT/Heliprobe**<sup>™</sup> **System**– Diabact<sup>®</sup> UBT s Orexo's first commercialized product. Like the Heliprobe<sup>™</sup> System, Diabact<sup>®</sup> UBT is a breath test used to diagnose the presence of *Helicobacter pylori*, the bacteria that cause gastric ulcers. Breath tests are recommended by expert groups for *Helicobacter pylori* in Europe as the primary choice and the most reliable non-invasive test to diagnose active infection. Its advantages include the fact that it prevents the patient having to undergo a gastroscopy examination, which many consider unpleasant. The societal benefits are, for example, that the examination is fast, easy and less expensive than gastroscopy.

Distribution and marketing agreements for Diabact® UBT have been signed for Austria, Finland, Germany, Hong Kong, Ireland, Serbia, Sweden and the UK. In Japan, a licensing agreement was signed with Kyowa Hakko Kogyo Co. Ltd. The Heliprobe™ System has distribution and marketing agreements in approximately twenty countries in the Middle East, Asia and Eastern Europe.

## Prioritized projects in which licensing agreements have been signed

Rapinyl<sup>™</sup>/Abstral – for the treatment of acute pain is in Phase III in the US and in the registration phase in Europe. Rapinyl<sup>™</sup>/Abstral was developed for the treatment of cancer-related breakthrough pain as its primary indication. Orexo's principal technology, the sublingual dosage method, whereby a fast-dissolving tablet is placed under the tongue, enables a quicker onset of action and more predictable effects – on-demand features. Licensing agreements for Rapinyl<sup>™</sup> /Abstral have been signed with Endo Pharmaceuticals for the North American market, ProStrakan Group plc for the European market and Kyowa Hakko Kogyo Ltd for the Japanese market. Distribution agreements for CIS (Russia and other former members of the Soviet Union), Bulgaria and Romania have been signed with Gedeon Richter Ltd and with Hospira in Asia Pacific markets including Australia and New Zealand.

In December 2005, Endo Pharmaceuticals launched Phase III studies on Rapinyl™/Abstral. Endo Pharmaceuticals announced positive results from an interim analysis of the Phase III studies in



December 2007. Rapinyl<sup>™</sup>/Abstral is undergoing registration in the European market. The registration process was transferred to EMEA's Committee for Medicinal Products for Human Use (CHMP), a decision regarding the registration approval is expected to be made in the first half of 2008. Rapinyl<sup>™</sup>/Abstral was approved during the first quarter of 2008 for marketing in Sweden.

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

**Sublinox**<sup>TM</sup> **(OX22)** – for the treatment of sleep disturbances, is in Phase III development. Sublinox<sup>TM</sup> (OX22) is based on Orexo's sublingual tablet technology. In 2006, the US insomnia market amounted to SEK 3.3 billion (according to IMS sales data).

A license agreement regarding Sublinox $^{TM}$  (OX22) was signed after the close of the period with Meda covering exclusive world rights.

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

A preparatory meeting was held with the FDA in January 2008 regarding the registration application for Sublinox<sup>TM</sup> (OX22) in the US. The meeting confirmed Orexo's registration strategy. Work with the registration application is under way and is expected to result in a submission during the second quarter of 2008. This is somewhat later than announced previously and is due to the administrative work being more extensive than previously anticipated.

**OX-NLA**—fast-acting effect for treatment of allergic and non-allergic rhinitis

A license agreement covering exclusive world-wide commercialization rights for OX-NLA was signed with Meda after the close of the period . In accordance with the agreement, Meda is responsible for the project's continued development including all related costs.

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

In a recently completed study of patients with rhinitis, OX-NLA nasal spray showed favorable



tolerance without local side effects , i.e. stinging and pain. The conclusion is that the liposomes in OX-NLA Nasal Spray appear to mask the irritating effects of cetirizine.

## Prioritized projects in which licensing agreement discussions have begun

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

The clinical trial program confirms that effective inhibition of acid secretion is rapidly achieved after taking the first dose. Effective acid inhibition can be maintained as long as the symptoms persist. This is a favorable and unique clinical profile for a drug intended for the treatment of GERD. The clinical results were presented at the "Digestive Disease Week" conference in Los Angeles, California, in the US on May 21, 2006. A pharmacological dynamic study has been concluded in patients with GERD and the clinical data confirms that OX17 has a competitive profile for treatment of GERD.

*OX914* – for the treatment of COPD and asthma. The aim of this project is to develop an orally active product that blocks the PDE4 enzyme existing in many pro-inflammatory cells. In clinical studies of various substances that inhibit PDE4, several companies have demonstrated positive treatment effect in COPD and asthma. However, no substance has reached the market, mainly due to side effects, primarily nausea. OX914 has shown favorable effects in preclinical models of COPD and asthma and clinical studies have not shown increased frequency of nausea compared with placebo.

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

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



## Other projects with future potential for further development

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

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

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

*OX30* – slow and controlled release of opioids for the treatment of chronic pain and with a potential to reduce the risk of abuse.

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



## The period in figures: January 1 - March 31, 2008

## Condensed consolidated statement of operations

	3 months	3 months 1	2 months
	2008	2007	2007
MSEK	Jan-Mar	Jan-Mar	Jan-Dec
Net revenues	24.0	6.4	76.8
Cost of goods sold	(3.9)	(2.7)	(14.4)
Gross profit	20.1	<b>3.</b> 7	62.4
Selling costs	(8.0)	(4.2)	(27.0)
General and administrative expenses	(15.3)	(10.8)	(58.9)
Research and development costs	(62.2)	(28.9)	(156.0)
Other operating income and expenses	0.9	0.0	(1.1)
Operating loss*	(64.5)	(40.2)	(180.6)
Net financial items	2.2	2.3	7.7
Loss after financial items	(62.3)	(37.9)	(172.8)
Tax	0.1	0.0	0.2
Net loss for the period	(62.2)	(37.9)	(172.6)

<sup>\*</sup> Includes costs for employee stock options of MSEK 2.4 for the period January-March 2008 (MSEK 1.5 January-March 2007).

#### **Revenues**

Net revenues

Net revenues for January-March 2008 amounted to MSEK 24.0 (6.4). The revenue increase is attributable mainly to revenue from the cooperation with Boehringer Ingelheim GmbH, Germany for OX-MPI.

The other item is reinvoiced costs to partners.

#### Net revenues were distributed as follows:

MSEK	Jan-Mar 2008	Jan-Mar 2007	Jan-Dec 2007
Diabact® UBT	1.3	0.7	5.2
Heliprobe™System	4.7	4.1	19.7
ProStrakan AB J/V 50%	2.1	-	2.7
License revenue Rapinyl™	-	-	34.0
/Abstral			
Other	15.9	1.6	15.2
Total	24.0	6.4	76.8

#### **Expenses and earnings**

Selling expenses

Consolidated selling expenses for the period January-March 2008 amounted to MSEK 8.0 (4.2).

Selling expenses include primarily costs for business development linked to outlicensing of Orexo's projects, Kibion AB and the joint-venture company ProStrakan AB. The increase in expenses is attributable mainly to the joint venture (ProStrakan AB) started in August 2007 and to some extent the effect of increased marketing efforts in the subsidiary Kibion AB.



#### Administrative expenses

Administrative expenses for the period January-March 2008 amounted to MSEK 15.3 (10.8). The increased costs are due partly to high costs of premises and IT after the move in summer 2007 and as an effect of the Biolipox acquisition.

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

The company's expenses in the first quarter for the employee stock option program amounted to MSEK 2.4 compared with MSEK 1.5 in the year-earlier period. MSEK 1.0 (0.6) of these expenses is attributable to administrative personnel, MSEK 1.3 (0.8) to R&D personnel and MSEK 0.1 (0.1) to sales personnel.

Program expenses refer to both the estimated cost of the value of the employees' service during the period, marked to market at the time of allotment and the portion of the estimated social security fees on the value appreciation during the period. The company will need to pay social security fees on the gain that may result from the exercise of the employee stock options, calculated as the difference between the strike price of the employee stock option and the market value of the shares.

The social security fees that may arise due to the employee stock option program have been largely hedged – financially and therefore in cash-flow terms – through the issue of warrants to one of Orexo's subsidiaries. This hedging does not qualify for hedge accounting according to IFRS.

#### Research and development expenses

Research and development expenses for the period January-March 2008 totaled MSEK 62.2 (28.9).

The increase in Research and development expenses compared with the year-earlier period is attributable to the acquisition of Biolipox in November 2007.

Research and development expenses include expenses for employees, employee stock options, premises, external costs for clinical trials, drug registration and laboratory services, as well as depreciation of equipment and amortization of acquired patents and other intangible assets. Orexo has no capitalized research and development costs. The company has several development projects in advanced phases, and/or in which discussions have been initiated regarding outlicensing. These including Rapinyl™/Abstral for the treatment of acute pain, OX-MPI for treatment of pain, inflammation and rheumatoid arthritis, Sublinox™ (OX22) for the treatment of insomnia, OX17 for GERD, OX-NLA for treatment of allergic and non-allergic rhinitis (hay fever), OX2477 that is an entirely new class of drugs to treat asthma and COPD and OX-CLI that is a new generation of pharmaceutical to treat asthma, COPD and rhinitis.

#### Other income and expenses

Other income and expenses for the period January-March 2008 totaled MSEK 0.9 (0.0).

#### Depreciation/amortization

Depreciation for the period January-March 2008 amounted to MSEK 2.9 (1.1).

## Tax

Tax assets (deferred tax) for the period January-March 2008 were MSEK 0.1 (0.0).

#### Net result

The operating loss for the period January-March 2008 amounted to MSEK 64.5 (loss: 40.2). The loss after net financial items totaled MSEK 62.3 (loss: 37.9), with the after-tax loss totaling MSEK 62.2 (loss: 37.9).



#### **Financial position**

Cash and cash equivalents at March 31, 2008 amounted to MSEK 201.6 (200.8) and current investments to MSEK o (76.4).

Cash flow from operating activities for the period January-March 2008 was a negative MSEK 88.5 (neg: 48.9). Cash flow after financing was negative at MSEK 90.0 (75.6).

Shareholders' equity at March 31, 2008 totaled MSEK 611.1 (287.7). The equity/assets ratio was 87 percent (87).

#### **Investments**

Gross investments in tangible fixed assets during the period January-March 2008 amounted to MSEK 1.2 (6.4).

#### **Parent Company**

The majority of the Group's business is carried out in the Parent Company, Orexo AB. Net revenues for the period January-March 2008 amounted to MSEK 8.1 (3.1), with the loss after financial items totaling MSEK 45.3 (loss: 38.1). Investments totaled MSEK 5.8 (6.4). Cash and cash equivalents in the Parent Company at March 31, 2008 amounted to MSEK 40.0 (198.6) and current investments to MSEK 0 (76.4).

#### Pledged assets and contingent liabilities

In the acquisition of Inflazyme a supplemental payment was agreed contingent on certain goals being met. Part of the supplemental payment was reported as long-term liabilities and MSEK 36.3 was recognized as contingent liabilities since the later is not assessed as a probable payment based on pharmaceutical development statistics. As cash-flow hedging for social fees pertaining to the employee stock options issued by Biolipox, warrants were issued to Pyrinox AB. Orexo is committed to cover any deficit greater that the cover provided by the warrants. In addition, the acquisition of Noster System AB involved an agreement on a supplemental purchase price of not more than MSEK 7.2, which would become payable if the growth of Heliprobe<sup>TM</sup> System achieves pre-determined sales targets through December 2009. The amount was reported under contingent liabilities, since Orexo has not assessed it as probable. Otherwise, no significant changes in contingent liabilities or pledged assets occurred during the period.

#### Significant risk and uncertainty factors

Uncertainty regarding success of development efforts

Orexo is a Group in the development stage with only two products on the market and a number of other product candidates in various development stages, of which some in late clinical development phase. Research and development of pharmaceuticals care characterized by significant operating risks,. Many factors affect the probability that a drug project will result in an approved pharmaceutical. For example, a potential drug candidate that demonstrated favorable effects in animal models may lack any significant effect in humans. Risks for side-effects can also complicate the drug project. However, the risk of not reaching the market diminishes after the project passes through the various phases in the development process. If the Group's clinical trials are not successful, Orexo would lack the possibility to outlicense 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 Orexo develops, 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 also be so in the future, for development, implementation of clinical trails, 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 manufacturing and storage of pharmaceuticals and biological products involve environmental risks and are subject to environmental legislation, which can delay or disrupt operations. Changes to the healthcare system can also impact Orexo's operations and profitability.

## Key personnel

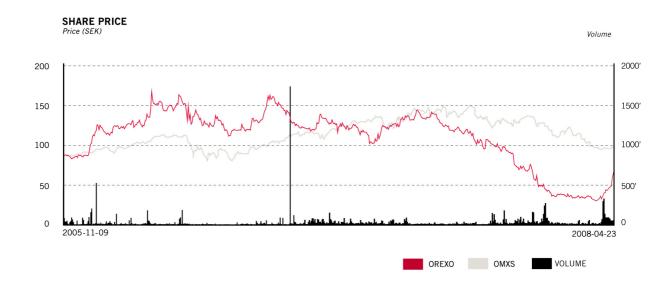
Orexo is dependent on its personnel and certain key individuals. In the event they should terminate their employment this could disrupt and delay development processes. To motivate and retain personnel and key persons, the company has an options program aimed at all employees, among other incentives.

#### Financial risk

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

#### Share and market value

Orexo's share was introduced on November 9, 2005 at a price of SEK 90 and was traded at SEK 51 on March 31, 2008. The company's market capitalization, based on the number of shares outstanding on March 31, 2008, amounted to SEK 1.1 billion.



#### Analysts who monitor Orexo

ABG Sundal Collier Alexander Lindström

D. Carnegie AB Kristofer Liljeberg-Svensson and Camilla Oxhamre

Handelsbanken Markets Erik Hultgård
Redeye Björn Andersson
Remium Securities Johan Isaksson

SEB Gustaf Vahlne and Lars Hevreng



# Future reporting dates Interim report, April-June

Interim report, April-June 2008	August 14
Interim report, July-September 2008	November 10
Year-end Report 2008	at latest February 28, 2009
Uppsala, May 7, 2008	

Orexo AB (publ)

Torbjörn Bjerke, President and CEO

For further information, please contact:

Torbjörn Bjerke, President and CEO, tel +46 (0)18-780 88 12, e-mail: <a href="mailto:torbjorn.bjerke@orexo.com">torbjörn.bjerke@orexo.com</a> Claes Wenthzel, Executive Vice President & CFO, tel +46 (0)18-780 88 44, e-mail: <a href="mailto:claes.wenthzel@orexo.com">claes.wenthzel@orexo.com</a>



#### **Review report**

We have reviewed the appended report for the period January 1 to March 31, 2008 for Orexo AB (publ). The company's management is responsible for the preparation and fair presentation of this interim report in accordance with the Annual Accounts Act and IAS 34. Our responsibility is to express an opinion on this interim report based on our review.

We conducted our review in accordance with the Standard on Review Engagements SÖG 2410, Review of Interim Financial Information Performed by the Independent Auditor of the Entity, issued by FAR. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review has a different purpose and is substantially less 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, May 7, 2008 Öhrlings PricewaterhouseCoopers

Leonard Daun Authorized Public Accountant



## CONSOLIDATED BALANCE SHEET

ASSETS         Fixed assets         Tangible fixed assets       56,527       11,969       57,790         Goodwill       16,030       8,988       16,030         Intangible fixed assets       377,213       1,714       377,335         Total fixed assets       449,770       22,671       451,155         Current assets       14,230       7,796       13,294         Accounts receivable and other receivables       34,842       23,275       42,261         Tax assets       3,060       1,525       3,565         Current investments       -       76,402       -         Cash and bank balances       201,597       200,830       291,598         Total current assets       253,729       309,828       350,718
Tangible fixed assets       56,527       11,969       57,790         Goodwill       16,030       8,988       16,030         Intangible fixed assets       377,213       1,714       377,335         Total fixed assets       449,770       22,671       451,155         Current assets         Inventories       14,230       7,796       13,294         Accounts receivable and other receivables       34,842       23,275       42,261         Tax assets       3,060       1,525       3,565         Current investments       -       76,402       -         Cash and bank balances       201,597       200,830       291,598
Goodwill       16,030       8,988       16,030         Intangible fixed assets       377,213       1,714       377,335         Total fixed assets       449,770       22,671       451,155         Current assets       14,230       7,796       13,294         Accounts receivable and other receivables       34,842       23,275       42,261         Tax assets       3,060       1,525       3,565         Current investments       -       76,402       -         Cash and bank balances       201,597       200,830       291,598
Intangible fixed assets       377,213       1,714       377,335         Total fixed assets       449,770       22,671       451,155         Current assets       14,230       7,796       13,294         Accounts receivable and other receivables       34,842       23,275       42,261         Tax assets       3,060       1,525       3,565         Current investments       -       76,402       -         Cash and bank balances       201,597       200,830       291,598
Current assets         449,770         22,671         451,155           Current assets         14,230         7,796         13,294           Accounts receivable and other receivables         34,842         23,275         42,261           Tax assets         3,060         1,525         3,565           Current investments         -         76,402         -           Cash and bank balances         201,597         200,830         291,598
Current assets         Inventories       14,230       7,796       13,294         Accounts receivable and other receivables       34,842       23,275       42,261         Tax assets       3,060       1,525       3,565         Current investments       -       76,402       -         Cash and bank balances       201,597       200,830       291,598
Inventories       14,230       7,796       13,294         Accounts receivable and other receivables       34,842       23,275       42,261         Tax assets       3,060       1,525       3,565         Current investments       -       76,402       -         Cash and bank balances       201,597       200,830       291,598
Accounts receivable and other receivables       34,842       23,275       42,261         Tax assets       3,060       1,525       3,565         Current investments       -       76,402       -         Cash and bank balances       201,597       200,830       291,598
Accounts receivable and other receivables       34,842       23,275       42,261         Tax assets       3,060       1,525       3,565         Current investments       -       76,402       -         Cash and bank balances       201,597       200,830       291,598
Current investments       - 76,402       -         Cash and bank balances       201,597       200,830       291,598
Cash and bank balances 201,597 200,830 291,598
, , , , , , , , , , , , , , , , , , , ,
Total current assets 253,729 309,828 350,718
Total assets 703,499 332,499 801,873
SHAREHOLDERS' EQUITY AND LIABILITIES 3
Share capital 8,647 5,555 8,647
Capital contributions 837,197 357,469 835,202
Accumulated losses (234,759) (75,369) (172,597)
Total shareholders' equity 611,085 287,655 671,252
Long-term liabilities
Provisions 329 4 750 162
Long-term liabilities 9 224 - 9 595
Deferred tax liability 762 337 877
Total long-term liabilities 10,315 5,087 10,634
Current liabilities
Current liabilities, non-interest-bearing 82,099 39,757 119,987
Total liabilities 92,414 44,844 130,621
Total shareholders' equity 703,499 332,499 801,873 and liabilities
<b>Pledged assets</b> 2,500 3,500 14,500
Contingent liabilities         43,550         7,250         43,550



# CONSOLIDATED STATEMENT OF OPERATIONS

	Notes	3 months 2008 Jan-Mar	3 months 2007 Jan-Mar	12 months 2007 Jan-Dec
Net revenues		23,995	6,402	76,757
Cost of goods sold	2	(3,896)	(2,681)	(14,384)
Gross profit		20,099	3,721	62,373
Selling expenses	2	(8,002)	(4,237)	(26,982)
General and administrative expenses	2	(15,301)	(10,813)	(58,932)
Research and development costs	2	(62,184)	(28,857)	(155,972)
Other operating income		873	2,839	9,958
Other operating expenses	2	-	(2,870)	(11,014)
Operating profit/loss		(64,515)	(40,217)	(180,569)
Earnings from financial investments				
Interest income		2,273	2,289	8,231
Interest expenses		(35)	(17)	(2)
Other financial expenses		-	-	(473)
Total earnings after financial items		(62,277)	(37,945)	(172,834)
Tax		115	20	237
Net loss for the period		(62,162)	(37,925)	(172,597)
Loss per share, before dilution, SEK		(2.88)	(2.73)	(11.42)
Earnings per share after dilution, SEK		(2.88)	(2.73)	(11.42)
Average number of shares, before dilution		21,617,395	13,886,625	15,108,176
Average number of shares, after dilution		22,749,675	14,201,401	16,183,863
Number of shares, before dilution		21,617,395	13,887,250	21,617,395
Number of shares, after dilution		22,749,675	14,202,026	22,693,082



## CONSOLIDATED CASH-FLOW STATEMENTS

	Notes	3 months 2008 Jan-Mar	3 months 2007 Jan-Mar	12 months 2007 Jan-Dec
Continuing operations				
Loss before interest expense and interest income		(64,515)	(40,217)	(180,569)
Interest income		2,273	2,289	8,231
Interest expenses		(35)	(17)	(23)
Other financial expenses		-	-	(473)
-				
	4	5,252	2,596	7,461
Adjustment for items not included in cash flow				
Cash flow from continuing operations before changes in working capital		(57,025)	(35,349)	(165,373)
Change in working capital				
Accounts receivable		(3,471)	4,705	2,537
Other current receivables		11,395	(8,695)	(18,266)
Inventories		(936)	1,438	(4,060)
Current liabilities		(38,284)	(10,953)	37,069
Provisions		167	(88)	(4,657)
Long-term liabilities		(371)	-	-
Cash flow from continuing operations		(88,525)	(48,942)	(152,750)
Investing activities				
Acquisition of machinery and equipment		(1,160)	(6,380)	(49,318)
Divestment of machinery and equipment		11	-	-
Acquisition of current investments		_	(20,276)	(19,762)
Divestment of current investments		-	-	75,888
Acquisition of subsidiaries		(327)	-	158,151
Cash flow after investments		(90,001)	(75,598)	12,209
Change in financing				
Proceeds from new share issue		-	20	2,981
Cash flow after financing activities		(90,001)	(75,578)	15,190
Cash flow for the year				
Cash and cash equivalents, at the beginning of period		291,598	276,408	276,408
Changes in cash and cash equivalents		(90,001)	(75,578)	15,190
Cash and cash equivalents, at the close of period		201,597	200,830	291,598



#### **KEY FIGURES**

	3 months 2008 Jan-Mar	3 months 2007 Jan-Mar	12 months 2007 Jan-Dec
Operating margin, %	(269)	(628)	(235)
Profit margin, %	(260)	(593)	(225)
Return on total capital, %	(8)	(10)	(45)
Return on equity, %	(10)	(12)	(53)
Return on capital employed, %	(10)	(12)	(53)
Debt/equity ratio, multiple	0	0	O
Equity/assets ratio, %	87	87	84
Current ratio, %	309	789	292
Acid ratio, %	292	769	281
Average number of shares, before dilution	21,617,395	13,886,625	15,108,176
Average number of shares, after dilution	22,749,675	14,201,401	16,183,863
Number of shares, after full dilution	23,382,170	14,562,050	23,010,220
Number of shares, before dilution	21,617,395	13,887,250	21,617,395
Number of shares, after dilution	22,749,675	14,202,026	22,693,082
Loss per share before dilution, SEK	(2.88)	(2.73)	(11.42)
Earnings per share after dilution, SEK	(2.88)	(2.73)	(11.42)
Shareholders' equity, before dilution, SEK	28.27	20.71	31.05
Shareholders' equity per share, after dilution, SEK	26.86	20.25	29.58
Number of employees at close of period	120	67	129
Average number of employees	124	66	80
Shareholders' equity	611,085	287,655	671,252
Capital employed	611,085	287,655	671,252

#### **DEFINITIONS**

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

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

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

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

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

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

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

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

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

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

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

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

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

**Earnings per share after dilution**: Profit/loss divided by average number of shares outstanding after dilution. **Shareholders' equity per shares before dilution**: Shareholders' equity divided by the number of shares before dilution at the close of the period.

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



## PARENT COMPANY BALANCE SHEET

SEK ooos	Notes	2008 March 31	2007 March 31	2007 Dec 31
ASSETS				
Fixed assets Tangible fixed assets		55.000	11,896	<b>5</b> 0,000
Intangible fixed assets Shares in subsidiaries/Joint		55,032 534	447	50,903 566
Ventures  Total fixed assets		524,169 <b>579,735</b>	100 <b>12,443</b>	523,842 <b>575,311</b>
Total fixed assets		3/9,/33		3/3,311
Current assets Inventories		5,980	1,550	4,362
Accounts and other receivables		50,886	42,840	4,302 51,987
Current receivables		1,473	1,443	1,083
Current investments		-,1/0	76,402	-,5
Cash and bank balances		39,999	198,565	109,511
Total current assets		98,338	320,800	166,943
Total assets		678,073	333,243	742,254
SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES	6			
Restricted equity		299,398	296,306	299,398
Non-restricted equity		322,345	(4,502)	366,534
Total shareholders' equity		621,743	291,804	665,932
Long-term liabilities				
Provisions		329	4,750	163
Total long-term liabilities		329	4,750	163
Current liabilities, non-interest- bearing		55,672	36,689	76,159
Total liabilities		56,330	41,439	76,322
Total shareholders' equity and liabilities		678,073	333,243	742,254
Pledged assets		2,500	3,500	2,500
Contingent liabilities		11,050	11,050	11,050



## PARENT COMPANY STATEMENT OF OPERATIONS

SEK ooos		3 months 2008	3 months	12 months 2007
	Notes	Jan-Mar	Jan-Mar	Jan-Dec
Net revenues		8,052	3,062	48,389
Cost of goods sold	5	_	(1,065)	(2,409)
Gross profit			1,997	45,980
Selling expenses General and administrative	5	(2,679)	(2,745)	(15,408)
expenses	5	(12,441)	(10,493)	(54,327)
Research and development costs	5	(39,394)	(29,070)	(143,225)
Other operating income		286	2,729	9,674
Other operating expenses	5	-	(2,774)	(10,413)
Operating profit/loss		(46,176)	(40,356)	(167,719)
Earnings from financial				
investments Interest income		928	0.500	7 900
Interest income Interest expenses		928 (17)	2,530 (6)	7,832 (11)
Total earnings after financial		(1/)	(0)	(11)
items		(45,265)	(37,832)	(159,898)
Net profit/loss for the period		(45,265)	(37,832)	(159,898)



#### **Notes**

#### 1. Accounting principles

This Year-End Report was prepared pursuant to IAS 34, Interim Financial Reporting, which complies with the requirements of the Swedish Financial Accounting Standards Council's recommendation RR 31, Interim Financial Reporting for Groups. As of 2005, Orexo applies IFRS as approved by the EU. The accounting principles and calculation methods comply with those applied in preparing the 2007 Annual Report.

The classification between selling expenses and administrative expenses is changed in this interim report. Business development is now classified as selling expenses and not as administrative expenses. Historical comparable figures are adjusted to reflect the new classification.

The Parent Company's accounting was prepared in accordance with RR32.

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

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

## 2. Group costs distributed by type of cost

	2008	2007	2007
	<b>Jan-Mars</b>	<b>Jan-Mars</b>	Jan-Dec
Raw materials and supplies	7,719	6,196	26,835
Other external costs	47,083	20,881	132,307
Personnel costs	31,722	18,448	92,967
Depreciation and impairment	2,859	1,063	5,875
Re-invoicing, rebuilding materials	-	2,870	9,300
TOTAL	89,383	49,458	267,284

#### 3. Shareholders' equity

# Changes in consolidated shareholders' equity

	2008	2007 Jan-	2007
والمسال والماسية والمسال والمس	Jan-Mars	Mars	Jan-Dec
Shareholders' equity brought forward	671,252	324,350	324,350
Loss for the period	(62,162)	(37,925)	(172,597)
Subscription for shares through the exercise			
of warrants	-	20	2,981
New issue of shares	-	-	438,775
New issue of warrants	-	-	52,875
Employee stock options, value of employees'			
service	1,995	1,210	5,989
Acquired value employee stock options	-	-	18,879
Amount at close of period	611,085	287,655	671,252



#### Share outstanding

The number of shares outstanding at March 31, 2008 amounted to 21,617,395, of which all were common shares. All shares carry entitlement to one vote each. There has been no change in the number of shares outstanding during the year.

## **Options**

At March 31 there were a total of 2,299,316 options outstanding carry rights corresponding to 1,764,775 shares in Orexo and exercise of 534,541 options for shares in Orexo<sup>3</sup>. Each option issued by Biolipox AB carries the right to exchange for one share in Orexo AB and the corresponding number of shares is received by the independent company Pyrinox AB.

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

	Opening 1/1 2008	-	+	Closing 31/3 2008
Personnel-related options	,			
Of which:				
Decided and allotted employee stock options	373,525	-	372,000	745,525
Decided and allotted warrants	15,250	-	-	15,250
Decided but not allotted employee stock options 2005, 2006 and 2007	372,000	(372,000)	-	o
Warrants held by subsidiary for cash-flow hedging of social security fees	78,000	-	-	78,000
Total decided options	838,775	(372,000)	372,000	838,775
Employee stock options taken over from Biolipox AB (no dilution effect, included in newly issued shares in conjunction with acquisition of Biolipox)	408,436	-	-	408,436
Warrants taken over from Biolipox AB subsidiary for cash-flow hedging of social security fees (no dilution effect)	126,105	-	-	126,105
Total options from Biolipox	534,541	-	-	534,541
Total options to employees	1,373,316	(372,000)	372,000	1,373,316
Other options Warrants related to supplemental payment in acquisition of Biolipox AB Total options outstanding	926,000 <b>2,299,316</b>	- (372,000)	372,000	926,000 <b>2,299,316</b>

During January-March 2008, no employee stock options or warrants were exercised.

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<sup>&</sup>lt;sup>3</sup> All data is adjusted for the 1:250 share split carried out in November 2005. As shown in the 2005 Annual Report, each old option carries rights to subscribe for 250 shares after the split. The above information pertains in all respects to the number of shares for which each option provides subscription entitlement. All of the details pertaining to options issued by Biolipox AB are recalculated by a factor of 0.45854, corresponding to the estimated value of the options related to the price of the Orexo share on date of acquisition. The figures reported for the options issued by Biolipox AB pertain to the number of shares to which each option can be exchanged following recalculation.



#### Allotment in February

During February 2008, new employee stock options were allotted, which in total carry entitlement to subscribe for 372,000 new shares. Distribution among senior executives and employees was:

- President: 50,000 shares

Other senior executives: 85,000 sharesOther employees: 237,000 shares

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

#### New program decided at the Annual General Meeting

At Orexo's Annual General Meeting on April 3, 2008, it was resolved to adopt a new employee stock option plan including the issuance of subscription warrants and approval of disposition of subscription warrants within the framework of the employee stock option plan. The employee stock option plan consists of 470,000 employee stock options. Each employee stock option may be exercised to acquire one share in Orexo in exchange for payment of an exercise price established as 110 percent of the market value of the Orexo share on the date of allotment. A total of 470,000 subscription warrants were issued to the wholly owned subsidiary Pharmacall AB as a hedge for the program. Full exercise of the warrants will result in a dilution of about 2.0% of the share capital and votes in Orexo.

The Meeting resolved to adopt a Board member shareholder plan including the issuance of 27,500 warrants and approval of disposal of the warrants issued under the Board member share plan. Board members participating in Orexo´s Board member shareholder plan will receive 50% of their Board fee and their fee for committee work, if any, in cash and will be allocated a number of Board shares, which value at the time of allotment shall correspond to 50% of the remuneration of the Board fee and fee for committee work, if any. The right to acquire new shares by using the Board shares is contingent on whether the Board member remains as a Board member during the whole or only part of the mandate. Each Board member share can be exercised to acquire one share in Orexo against payment of an exercise price determined as the par value of the Orexo share.

#### 4. Cash flow

## Adjustment for items not included in cash flow

	2008 Jan-Mar	2007 Jan-Mar	2007 Jan-Dec
Depreciation/amortization and impairment Calculated costs for employee stock	2,859	1,063	5,875
option program	2,391	1,507	1,381
Miscellaneous	2	26	205
Total	5,252	2,596	7,461



## 5. Parent Company's costs distributed by type.

	2008 Jan-Mar	2007 Jan-Mar	2007 Jan-Dec
Raw materials and consumables	1,128	4,728	9,162
Other external expenses	30,850	20,539	125,146
Personnel costs	20,859	17,024	77,603
Depreciation/amortization and			
impairment	1,677	986	4,571
Re-invoicing, rebuilding materials.	-	2,870	9,300
TOTAL	54,514	46,147	225,782

## 6. Shareholders' equity

# Changes in the Parent Company's shareholders' equity

	2008 Jan-Mar	2007 Jan-Mar	2007 Jan-Dec
Shareholders' equity brought forward, according to the balance sheet	665,932	328,406	328,406
Profit/loss for the period Share subscription through exercise of	(45,265)	(37,832)	(159,898)
warrants	-	20	2,981
New issue of shares	-	-	438,776
New issue of warrants Employee stock options, value of	-	-	52,875
employees' services	1,076	1,210	5,392
Group contribution received	-	-	(2,600)
Amount at close of period	621,743	291,804	665,932