

Orexo AB (publ) – Interim Report, January-September 2005

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**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.**

Uppsala, October 11, 2005

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Key events during the period

- Net sales amounted to MSEK 59.0 (year-earlier period: 85.9) ^{1 2}
- After tax, a net loss of MSEK -7.9 was reported (27.4)
- Earnings per share amounted to a loss of SEK -211.70 (786.19)
- Rapinyl™ (OX 20) – Orexo received a milestone payment of MUSD 6.5 (approx. MSEK 50), following completion of clinical study
- New recruitment and reorganization implemented to facilitate continued expansion – Claes Wentzel appointed new Executive Vice President and CFO and Thomas Lundqvist, one of Orexo's founders, appointed new Executive Vice President and CSO.
- Extraordinary General Meeting was held at which Hans-Peter Hasler was appointed new Member of the Board

Third Quarter 2005

- Net sales amounted to MSEK 56.1 (72.1) ^{1 2}
- After tax, a net profit of MSEK 27.4 was reported (45.4)
- Earnings per share amounted to MSEK 723.15 (1,263.11)

Financial summary for the period

	3 months 2005 July-Sept	3 months 2004 July-Sept	9 months 2005 Jan-Sept	9 months 2004 Jan-Sept	12 months 2004 Jan-Dec
MSEK					
Net sales	56.1	72.1	59.0	85.9	86.7
Profit/loss after tax	27.4	45.4	-7.9	27.4	-16.8
Earnings per share, SEK	723.15	1 263.11	-211.70	786.19	-474.56

¹ Unless stated otherwise, this interim report refers to the Group. Figures within parentheses denote results for the corresponding period during the previous year. All share-related data refers to information prior to the split authorized by the Annual General Meeting on April 20 that is conditional on agreements between the principal owners. At the time of the presentation of this report, the conditions have not been fulfilled.

² Figures for 2004 have been restated in accordance with IFRS. For more information, see page 16

Orexo develops new, innovative drugs – faster and with lower development risk.

Period in brief

January

Continued growth – new, analytical laboratory opened and additional expertise recruited

As the company's portfolio of development projects expands and further advances, Orexo recruits additional expertise and adds new premises. In January, a new analytical laboratory was completed, in line with Orexo's ambition to reach long-term profitability through sound and balanced growth and to become a leading company in drug delivery.

Dr Nils-Otto Ahnfelt appointed Project Director

During the period, Dr. Nils-Otto Ahnfelt was recruited to the position of Project Director, with the task of driving development of the company's product portfolio on a project basis. Dr. Nils-Otto Ahnfelt has a Ph.D. from the Department of Analytical Pharmaceutical Chemistry at the University of Uppsala. He has more than 20 years of industry experience, mainly from Pharmacia, and joins Orexo from Doxa AB, where he was head of the company's R&D operations.

February

Efficacy study for OX 22 completed with positive results

During the period, Orexo completed an efficacy study for OX 22, with positive results. OX 22 is a pharmaceutical product for the treatment of temporary sleep disturbances, and is considered to have substantial medical and commercial potential.

The technology is patented in the US, Japan and Australia, among other countries. Patent applications have also been submitted in other major markets. Work has been initiated to find commercialization partners for marketing and selling the product in all main markets.

March

Increased investment in diagnostic pharmaceutical – new subsidiary centered on Diabact® UBT currently under formation

During the period, it was decided that Orexo will establish a subsidiary based on its first commercialized product Diabact® UBT. Diabact® UBT is a breath test used to detect the presence of the stomach-ulcer bacterium *Helicobacter pylori*.

Orexo has earlier signed distribution and marketing agreements for Diabact® UBT in Finland, Hong Kong, Ireland, the UK and Sweden. In the Japanese market, a license agreement has been signed with the Kyowa Hakko pharmaceuticals company.

April

Dr Thomas Leoo appointed new Medical Director

Dr. Thomas Leoo has been appointed the new Medical Director. He assumed his position on May 2 and succeeded Anders Pettersson.

Dr Anders Pettersson to head Orexo's innovation team

Dr. Anders Pettersson – former Medical Director and co-founder of Orexo – will head Orexo's innovation team, with responsibility for expansion of the product portfolio. Dr. Pettersson's main task will be to identify and evaluate the company's future product candidates.

*May***Lena Söderström appointed manager of Orexo's new subsidiary based on Diabact® UBT**

During the period Orexo decided to form a subsidiary based on its first commercialized product, Diabact® UBT. Lena Söderström assumed her new position as manager of the subsidiary on May 2.

Orexo nominated for the “2005 Export Award” for successful internationalization

Orexo was nominated for the “2005 Export Award”. The prize is awarded by the “Swedish Export Council” to companies that have shown strong growth in their exports or international sales in recent years with success in several markets, have developed a unique concept in their offering or marketing approach, and have positive sales growth with sustained profitability. Eighty-six firms were nominated and Orexo was one of six companies in the final round.

Professor John Sjögren elected new Board member at Orexo AGM

Professor John Sjögren was elected to the Board of Directors at Orexo's Annual General Meeting on April 20, 2005. Professor Sjögren has conducted internationally renowned research in the areas of pharmaceutical technology and biopharmaceutics (how drug substances are absorbed and distributed in the body). Between 1959 and 1994 he held a variety of management positions with responsibility for Astra Hässle's pharmaceutical research and between 1984 and 1998 he was a member of the company's management team.

*June***Orexo AB sells the rights to its cell-penetrating peptide technology, CPP, for MSEK 9.5**

Orexo's strategy is to regularly evaluate and analyze the company's products as well as its technologies. Orexo's business model is based on short development times and low development risk. The company believes that Orexo's cell-penetrating peptide-technology (CPP) is promising, but is still in the early research phase. Therefore the sale of this technology was a natural step for Orexo in this situation. The purchase price totaled MSEK 9.5 and resulted in a capital gain for Orexo of MSEK 8.9. Professor Ülo Langel and Dr. Mattias Hällbrink made the purchase through their company.

*September***New recruitment and reorganization implemented to facilitate continued expansion – Claes Wenthzel appointed as Executive Vice President and CFO and Thomas Lundqvist, one of Orexo's founders, appointed new Executive Vice President and CSO**

Orexo has appointed Claes Wenthzel new Executive Vice President and Chief Financial Officer (CFO), with overall responsibility for the company's financial and administrative functions. Among other positions, Claes Wenthzel has been Executive Vice President and CFO at Perbio Science, a biotech company formerly listed on the Stockholm Stock Exchange, and CFO at medical engineering company Louis Gibeck AB, also formerly listed on the Stockholm Stock Exchange. He assumed his new position on September 1, 2005.

In addition, Thomas Lundqvist, one of Orexo's founders, is taking up the position as Executive Vice President and CSO (Chief Scientific Officer), with overall responsibility for the company's scientific activities. At the same time, Nils-Otto Ahnfelt, previously Project Director, assumed the position of Research & Development Director.

Extraordinary General Meeting held – Hans-Peter Hasler appointed new member of the Board

Orexo held an Extraordinary General Meeting on September 16. The Meeting passed resolutions regarding the number of Board Members and the issue of employee stock options. In addition, Hans-Peter Hasler was elected to the Board.

Since 2003, Hans-Peter Hasler, who was born in 1956, has been Senior Vice President and head of the US biotechnology company BiogenIdec's international operations. Prior to that, he had many years of international experience from the pharmaceutical and biotechnology industry, including Senior Vice President and global manager of Wyeth-Ayerst Pharmaceuticals' strategic marketing, President of the Wyeth Group in Germany, Operational Manager of AHP/Wyeth in Switzerland, Operational Manager of AHP/Wyeth in Central and Eastern Europe and manager of Abbott AG's pharmaceutical division in Switzerland.

Rapinyl™ (OX 20) – Orexo received milestone payment of MUSD 6.5 (approx. MSEK 50), following completion of clinical phase II study

Orexo AB has fulfilled the requirements for qualification for the first milestone payment of MUSD 6.5 from Endo Pharmaceuticals Inc., following completion of a clinical study of Rapinyl™ (OX 20), Orexo's patented product for the treatment of acute pain in cancer patients. The two companies signed a licensing agreement in August 2004 that provides Endo Pharmaceuticals with the sole right to the development and marketing of Rapinyl™ (OX 20) in the North American market.

Effect when needed

Regurgitation of acid reflux and stomach pain are a few of the symptoms of Gastro Esophageal Reflux Prevention (GERD). This is a common ailment in the western world, which if left untreated, can lead to inflammation of the lower part of the esophagus and, in the worst-case scenario, to cancer.

GERD is usually caused by a rupture and transient relaxation of the “gate” or sphincter, which results in inadequate closure between the stomach and the esophagus. Acidity of the stomach irritates the unprotected mucous membrane in the esophagus, which leads to pain and discomfort. To date, GERD has been treated with either H2 receptor antagonists (histamine Type 2 receptor antagonists), where the benefit is that the effect is achieved quickly, although the long-term effect is less advantageous, or with PPI (proton pump inhibitors), which provides long-term inhibition of the development of acid but takes several days before the full effect is attained.

Orexo has combined these two well-documented principles in its OX 17 product candidate. This combination is aimed to result in an effective inhibition of the acid secretion from the first to the last dose of OX 17. The symptoms disappear quickly and a week of treatment could be sufficient for the patient to be relieved of the discomfort for a long period of time.

According to industry sources, the global market for H2 receptor antagonists and PPI during 2004 was worth USD 1.8 billion and USD 20.5 billion, respectively. The market for the treatment of stomach ulcers and GERD is expected to grow by 5.2% annually up to 2008.

A global patent for the product has been applied for, and the first country to grant a patent is New Zealand. Results from studies involving healthy volunteers confirm the pharmacological effects of OX 17 and its significant treatment potential. In August 2005, OX 17 entered Clinical Phase I/II studies.

Operations

Orexo in brief

Orexo is a product focused drug delivery company that develops new pharmaceuticals within areas subject to considerable clinical needs. By exploiting its expertise in medicine and pharmaceutical development, Orexo focuses on the further development of existing pharmaceutical substances. By combining well-documented compounds with Orexo's patented drug delivery technologies and its unique expertise in "dry formulations" (for example, tablets), new patented pharmaceuticals can be developed.

Orexo's drug development activities are commercially driven at all levels and to date, the company has elected to focus on tablet-based, fast-dissolving and oral transmucosal formulations for the treatment of acute conditions or symptoms such as acute pain and sleeping disorders where a fast and reproducible onset of action is desirable.

Orexo was founded in Uppsala in 1995 and has grown into an organization with 40 full-time employees, most of whom are active in research and development, clinical development and pharmaceutical registration. At present, the company has one product on the market, three under clinical development – of which one has been out-licensed in the US and Japan – and two projects in formulation development phase. Orexo has adopted an active intellectual property rights strategy and has built up an extensive patent portfolio to protect its products and technologies.

Market for drug delivery

The science of drug delivery can be summarized as the process of ensuring that the active compound of a pharmaceutical product is optimally delivered to the site of action. The demand for drug delivery-products is increasing rapidly due to the fact that these new pharmaceuticals can for example offer shorter time to onset of effect or improved safety profiles.

Many pharmaceutical products on the market today have shortcomings – for example, they are slow-acting, have side effects, must be administered frequently or perhaps can only be injected. This is why demand for technologies that can make already existing products more efficient is increasing rapidly. In 2004, industry sources estimated that the value of the market for drug delivery products exceeded USD 66 billion and that it was expected to grow to more than USD 110 billion in 2007. About one out of five drugs of the 200 best-selling prescription pharmaceuticals in the US are based on drug delivery technologies.

Orexo's portfolio

Orexo's portfolio of approved pharmaceuticals, clinical development phase product candidates and projects in formulation development stages include:

PRODUCT / PRODUCT CANDIDATES	INDICATION / THERAPEUTIC AREA	FORMULATION DEVELOPMENT	CLINICAL PHASE	REG. FILED	MARKET
Diabact® UBT	Diagnostic of Helicobacter pylori-infection				
OX 20	Acute pain				
OX 22	Insomnia				
OX 17	GERD				
OX 19	Incontinence				
OX 40	Migraine				

Diabact® UBT – Orexo's first product and the product around which the company was founded – is a pharmaceutical used for diagnosis of *Helicobacter pylori* – that is, the stomach ulcer bacteria. The product is based on Orexo's fast-dissolving tablet technology. *Diabact® UBT* was launched in 2000 and is currently marketed in Finland, the UK, Germany, Ireland and Sweden. In Japan, the technology has been licensed to the Kyowa Hakko Kogyo pharmaceutical company.

Rapinyl™ (OX 20) – for the treatment of acute pain. *Rapinyl™ (OX 20)* was developed for the treatment of cancer-related breakthrough pain as its primary indication. Orexo's principal technology, the sublingual dosage, offers rapid and predictable onset of action. License agreements for *Rapinyl™ (OX 20)* have been signed with Endo Pharmaceuticals for the North American market and with Kyowa Hakko Kogyo for the Japanese market.

Orexo is considering establishing its own sales organization for *Rapinyl™ (OX 20)* in selected European markets including the Nordic region, independently or in combination with partnership agreements with selected pharmaceutical companies. However, Orexo continues simultaneously to evaluate the possibility of outlicensing of *Rapinyl™ (OX 20)* in these markets.

OX 22 – for the treatment of insomnia. *OX 22* is based on Orexo's sublingual tablet technology. One advantage over the currently available drugs for treating sleep disturbances include shorter time to onset of sleep. Phase I and II studies have been completed, with positive results confirming the product's medical potential for on demand medication of sleep disturbances.

OX 17 – for the treatment of GERD, gastro esophageal reflux disease, a disease that gives the patient recurrent heartburn. In *OX 17*, two marketed/well-known active substances have been combined so that the acid secretion is rapidly and effectively inhibited through two different mechanisms of action. *OX 17* was developed to offer fast and at the same time lasting relief from the symptoms of reflux disease. A patent for the product has been applied for globally and New Zealand became the first country to approve the patent. The results of a feasibility study involving healthy test subjects, confirm the product's pharmacological effects and significant medical potential.

OX 19 – for the treatment of urinary incontinence. In addition to the treatment of nocturia, *OX 19* also focuses on short-term on-demand treatment of urinary incontinence in women suffering from overactive bladder. *OX 19* is in the formulation phase.

OX 40 – for the acute treatment of moderate and severe migraine. *OX 40* is formulated to have a fast, predictable onset of effect, which is an essential characteristic of effective on-demand medication. The formulation of *OX 40* is ongoing.

The period in figures; January 1 – September 30, 2005

Condensed income statement

	3 months	3 months	9 months	9 months	12 months
	2005	2004	2005	2004	2004
MSEK	July-Sept	July-Sept	Jan-Sept	Jan-Sept	Jan-Dec
Net sales	56.1	72.1	59.0	85.9	86.7
Gross profit/loss	55.4	71.8	56.8	84.6	84.8
Selling expenses	-1.0	-0.4	-1.7	-1.4	-1.8
Administrative expenses	-9.2	-6.0	-25.7	-17.0	-24.6
Research and development costs	-18.8	-20.5	-47.6	-38.1	-64.4
Other income and expenses	0.9	0.3	0.8	0.3	0.3
Sale of subsidiary	0	0	8.9	0	0
Operating profit/loss	27.2	45.3	-8.5	28.4	-5.8
Net financial items	0.1	0.1	0.6	0.2	-9.8
Tax	0	0	0	-1.2	-1.2
Profit/loss for the period	27.4	45.4	-7.9	27.4	-16.8

As of January 1, 2005, the Group applies the International Financial Reporting Standards (IFRS), formerly known as the IAS, in accordance with EU regulations. The effects of the transition have been entered in the accounts through an adjustment of shareholders' equity for 2004. Comparable figures for 2004 have been restated; see page 16 ff.

Revenue

Net sales: MSEK 59.0 (85.9) –31.3 percent

Net sales for the January-September 2005 period totaled MSEK 59.0 (85.9). The sales was according to plan and is mainly attributable to one-off compensation of approximately MSEK 75 (MUSD 10.0) recorded during the first nine months 2004, compared with the milestone payment of approximately MSEK 50 (MUSD 6.5) recorded during the third quarter of 2005. The sales of Diabact® UBT increased to MSEK 3.6 (2.7).

Net sales for the July-September 2005 period totaled MSEK 56.1 (72.1). The license-based payments mentioned above were recorded during the third quarter of both 2005 and 2004.

Expenses and earnings

Selling expenses: MSEK 1.7 (1.4) +23.3 percent

Most of the selling expenses are attributable to the sale of Diabact® UBT. Selling expenses between January and September 2005 amounted to MSEK 1.7, which was 23.3 percent higher than the corresponding period of the preceding year.

Selling expenses for the July-September 2005 period amounted to MSEK 1.0 (0.4).

Administrative expenses: MSEK 25.7 (17.0) +51.1 percent

Administrative expenses between January and September 2005 amounted to MSEK 25.7 (17.0), an increase of 51.1 percent. The increase was attributable to the continued development of the company combined with the continued expansion of Orexo's organization and infrastructure.

Of the company's costs of MSEK 3.5 for the employee stock option program, MSEK 2.1 was attributable to administrative expenses and MSEK 1.4 to research and development costs. These expenses refer both to the increase in value earned during the period and social security costs calculated on the basis of this increase in value. The company will have to pay social security fees on the gain—calculated as the difference between the exercise price of the employee options and the

market value of the share at the time the employee option is exercised—that may arise in conjunction with the exercising of the employee options.

The social security fees that may occur as a result of the employee options program have been hedged in terms of cash flow, but not in the accounts, through the issuance of warrants to one of Orexo's subsidiaries.

Administrative expenses between July and September 2005 totaled MSEK 9.2 (6.0).

Research and development costs: MSEK 47.6 (38.1) +24.9 percent

Research and development costs between January and September 2005 amounted to MSEK 47.6 (38.1), an increase of 24.9 percent. Research and development costs include a royalty remuneration of MSEK 5.1 for the period, which was attributable to OX 20 (Rapinyl™). The royalty remuneration was made due to the recorded milestone payment during the third quarter of 2005. Orexo's total royalty costs attributable to OX 20 (Rapinyl™) cannot exceed MSEK 30.0, of which MSEK 15.1 has been recorded, including the remuneration of MSEK 5.1 mentioned above.

Research and development costs comprise costs for employees, premises, external costs for clinical testing, pharmaceutical registration and laboratory services, as well as depreciation of equipment, goodwill, acquired patents and other intangible assets. Orexo has no capitalized costs for research and development. Orexo's management assesses that research and development costs will continue to be a major cost item in the future. In relation to the total operating expenses, research and development costs could decline, however, when Orexo's current and future products are commercialized, which would increase other cost items, such as production, marketing and selling costs for Orexo products.

Research and development costs between July and September 2005 amounted to MSEK 18.8 (20.5).

Depreciation and amortization

Depreciation between January and September 2005 amounted to MSEK 2.2 (2.1).

Sale of subsidiary

The operating loss includes a capital gain of MSEK 8.9 that occurred on Orexo's sale of the CPP rights. The transaction was carried out through the sale of a wholly owned subsidiary.

Tax

Tax expenses between January and September 2005 amounted to MSEK 0.0 (1.2). The tax for the first nine months of 2004 was attributable to foreign withholding tax for milestone payments received in accordance with the license agreement for Rapinyl™ (OX 20) entered into with Kyowa Hakko of Japan, which could not be offset against Swedish income tax.

Net result

The operating loss for the January and September 2005 period amounted to MSEK 8.5 (profit: 28.4). The net loss for the period after financial items totaled MSEK 7.9 (profit: 28.5) and the loss after tax amounted to MSEK 7.9 (profit: 27.4).

The operating profit for the July and September 2005 period amounted to MSEK 27.2 (45.3). The profit for the period after financial items totaled MSEK 27.4 (45.4) and period after tax amounted to MSEK 27.4 (45.4).

Financial position

The Group's liquid assets as at September 30, 2005 totaled MSEK 28.6. Cash flow during the nine-month period was a negative MSEK 55.7. The milestone payment of approximately MSEK 50 included under net sales will not have a positive impact on cash flow until the fourth quarter of 2005.

Equity amounted to MSEK 68.5 (116.4). The equity/assets ratio was 70.2 percent (81.5).

Investments

Gross investments in tangible assets between January and September 2005 amounted to MSEK 1.9 (1.0) and mainly consist of investments in production and research equipment.

Parent company

The majority of the Group's business is carried out in the parent company Orexo AB. Net sales amounted to MSEK 59.1 (85.9) and net loss after financial items was MSEK 7.3 (profit: 29.6). Investments amounted to MSEK 1.9 (1.0). The company's liquid funds totaled MSEK 26.5 (110.5).

Personnel

Personnel expenses for the period amounted to MSEK 29.7 (25.2). Seventeen employees were hired during the period. The average number of employees was 35 (21). All personnel were employed on a full-time basis.

Number of shares and warrants outstanding

The number of shares and warrants outstanding as at September 30, 2005 are distributed as follows:

	Opening balance	Resigned	Additional	Closing balance
Number of shares	36 952		1 337 ¹	38 289
Number of options	5 237	-1 463	1 451	5 225
Of which:				
- stock options	1 753	-126	1 036	2 663
- warrants held by subsidiaries for cash flow hedging of social security fees:	724		333	1 057
- warrants	1 423		82	1 505
- warrants from unit issue	1 337	-1 337		0

During the report period, 200 stock options were allotted to senior executives. In addition, a total of 92 stock options were allotted to two newly appointed Board members based on a proposal from certain shareholders. The exercise price for these total of 292 stock options is SEK 13 408 per share and the last day to exercise these stock options is December 31, 2015. The stock options vest in three equal installments on each of the first three anniversaries of December 31, 2005. The market value per option is estimated, using the Black & Scholes model, at the time of issue to be SEK 8 570 per stock option.

An additional 44 stock options were allotted to newly employed personnel within the "Other employees" category under earlier stock option programs. During the period, 126 stock options were returned by employees who had left the company. In addition, 42 stock options were allotted to two consultants.

In September 2005, Orexo introduced a new stock option program, according to which the Board of Directors is entitled to allot a total of 700 options, which are part of the above summary. At September 30, none of these options had been allotted. During the period, 1 337 shares have been subscribed from stock options issued in the so called "unit issue" carried out during 2004.

For further information about Orexo's stock option programmed, see Note 8 in the company's annual report for 2004.

Pledged assets and contingent liabilities

No significant change in pledged assets and contingent liabilities occurred during the period.

- 1) Refer to the so called “unit issue” described under note 8 in the company’s annual report 2004. Through this “unit issue”, Orexo received KSEK 134.

Balance sheet

Amounts in SEK 000s	2005-09-30	2004-09-30	2004-12-31
Assets			
<i>Fixed assets</i>			
Intangible fixed assets	3 045	5 027	4 529
Goodwill	0	13 237	0
Tangible fixed assets	2 843	2 409	2 277
Financial fixed assets	2 405	2 405	2 405
<i>Total fixed assets</i>	8 293	23 078	9 211
<i>Current assets</i>			
Inventories	2 337	2 070	1 419
Current receivables	58 412	6 332	6 805
Cash and bank balances	28 559	111 235	84 240
<i>Total current assets</i>	89 308	119 637	92 464
Total assets	97 601	142 715	101 675
Shareholders' equity and liabilities			
<i>Shareholders' equity</i>			
Share capital	3 829	3 695	3 695
Restricted equity	72 062	109 717	94 418
Accumulated losses	-7 371	2 938	-23 019
<i>Total shareholders' equity</i>	68 520	116 350	75 094
Liabilities			
Current liabilities, interest-free	29 081	26 365	26 581
<i>Total liabilities</i>	29 081	26 365	26 581
Total shareholders' equity and liabilities	97 601	142 715	101 675
Pledged assets	2 500	2 500	2 500
Contingent liabilities	50	1 550	1 550

Income statement

	1/7-30/9 2005	1/7-30/9 2004	1/1-30/9 2005	1/1-30/9 2004	1/1-31/12 2004
Amounts in SEK 000s					
Net sales	56 072	72 098	58 998	85 931	86 715
Cost of goods sold	-618	-258	-2 160	-1 311	-1 930
Gross profit	55 454	71 840	56 838	84 620	84 785
Selling expenses	-1 040	-354	-1 696	-1 375	-1 839
Administrative expenses	-9 213	-5 951	-25 729	-17 022	-24 638
Research and development costs	-18 821	-20 521	-47 634	-38 147	-64 398
Other operating revenues	909	552	971	620	672
Other operating expenses	-43	-294	-159	-334	-368
Gain on sale of subsidiary	0	0	8 865	0	0
Operating profit/loss	27 246	45 272	-8 544	28 362	-5 786
Results from financial investments					
Interest received	122	186	684	256	695
Interest paid	-2	-68	-6	-79	-79
Other financial expenses		0		0	-10 455
Total result from financial investments	120	118	678	177	-9 839
Tax on profit for the period	0	0	0	-1 156	-1 156
Profit/loss for the period	27 366	45 390	-7 866	27 383	-16 781
Earnings per share, before dilution, SEK	723.15	1263.11	-211.70	786.19	-474.56
Earnings per share, after dilution, SEK	665.27	1179.48	-211.70	732.60	-474.56
Average number of shares, before dilution	37 843	35 935	37 249	34 830	35 361
Average number of shares, after dilution	41 135	38 483	37 249	37 378	35 361
Number of shares, before dilution	38 289	36 952	38 289	36 952	36 952
Number of shares, after dilution	41 581	39 500	38 289	39 500	36 952

Expenses distributed by cost item

	1/7-30/9 2005	1/7-30/9 2004	1/1-30/9 2005	1/1-30/9 2004	1/1-31/12 2004
Amounts in SEK 000s					
Raw materials and consumables	1 250	-388	3 900	1 967	2 897
Other external costs	18 440	19 301	41 651	28 954	39 080
Personnel costs	9 336	7 752	29 664	25 180	35 160
Depreciation/amortization and write-downs	709	713	2 163	2 088	16 036
Total	29 735	27 378	77 378	58 189	93 173

Cash-flow statement

Amounts in SEK 000s	1/7-30/9 2005	1/7-30/9 2004	1/1-30/9 2005	1/1-30/9 2004	1/1-31/12 2004
<i>Continuing operations</i>					
Operating profit/loss before interest paid and interest received	27 246	45 272	-8 544	28 362	-5 786
Interest paid	-2	-68	-6	-79	-79
Interest received	122	186	684	256	695
Other financial costs	0	0	0	0	-10 455
Taxes paid	0	0	0	-1 156	-1 156
Adjustment for items not included in cash flow**	2 312	1 786	-2 454	3 583	18 879
Cash flow from continuing operations before changes in working capital	29 678	47 176	-10 320	30 966	2 098
<i>Change in working capital</i>					
Accounts receivable	-51 442	266	-51 457	-274	-319
Other current receivables	183	-1 773	-150	-2 199	-2 629
Inventories	187	178	-918	-713	-62
Current liabilities	-1 271	11 289	1 606	16 846	16 818
Cash flow from continuing operations	-22 665	57 136	-61 239	44 626	15 906
<i>Investing activities</i>					
Proceeds from sales of subsidiary	0	0	9 405	0	0
Acquisition of plant and equipment	-373	-108	-1 905	-1 020	-1 120
Cash flow after investments	-23 038	57 028	-53 739	43 606	14 786
<i>Change in financing</i>					
New share issue	-1 942	51 991	-1 942	52 147	53 972
Cash flow after financing	-24 980	109 019	-55 681	95 753	68 758
<i>Cash flow for the period</i>					
Liquid assets, opening balance	53 539	2 216	84 240	15 482	15 482
Change in liquid assets	-24 980	109 019	-55 681	95 753	68 758
Liquid assets at close of period	28 559	111 235	28 559	111 235	84 240

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

Amounts in SEK 000s	1/7-30/9 2005	1/7-30/9 2004	1/1-30/9 2005	1/1-30/9 2004	1/1-31/12 2004
Depreciation/amortization and write-downs	710	712	2 164	2 088	16 036
Disposals	0	0	0	0	20
Estimated costs of employee stock option program	1 602	1 074	4 134	1 495	2 823
Other	0	0	113	0	0
Gain on sale of subsidiary	0	0	-8 865	0	0
Total	2 312	1 786	-2 454	3 583	18 879

Changes in consolidated shareholders' equity

Amounts in SEK 000s	1/7-30/9 2005	1/7-30/9 2004	1/1-30/9 2005	1/1-30/9 2004	1/1-31/12 2004
Equity opening balance, according to balance sheet	41 862	18 107	75 094	35 575	35 575
Profit/loss for the period	27 366	45 390	-7 866	27 383	-16 781
Issue of units	134	0	134	0	0
Warrants issued	0	0	0	1 586	1 586
New share issue	0	52 439	0	52 439	52 439
Expenditures as part of current issue	-2 076	-448	-2 076	-1 878	0
Employee stock options, value of earned portion	1 234	862	3 234	1 245	2 275
Amount at close of period	68 520	116 350	68 520	116 350	75 094

Key figures	1/7-30/9	1/7-30/9	1/1-30/9	1/1-30/9	1/1-31/12
	2005	2004	2005	2004	2004
Operating margin, %	48.6	62.8	-14.5	33.0	-6.6
Profit margin, %	48.8	63.0	-13.3	33.2	-18.2
Return on total capital, %	38.4	50.3	-9.6	44.3	-6.7
Return on shareholders' equity, %	61.9	67.1	-14.5	54.0	-30.3
Return on capital employed, %	61.9	67.2	-14.5	56.5	-9.2
Debt/equity ratio, multiple	0	0	0	0	0
Equity/assets ratio, %	70.2	81.5	70.2	81.5	73.9
Current ratio, %	307.1	453.8	307.1	453.8	347.9
Acid test ratio, %	299.1	445.9	299.1	445.9	342.5
Number of shares at end of period	38 289	36 952	38 289	36 952	36 952
Shareholders' equity per share, SEK	1 789.55	3 148.68	1 789.55	3 148.68	2 032.20
Number of employees	40	24	40	24	23

Definitions

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

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

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

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

Adjusted shareholders' equity: Average shareholders' equity including untaxed reserves less deferred tax liability.

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

Capital employed: Average of interest-bearing liabilities and adjusted shareholders' equity.

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

Equity/assets ratio: Shareholders' equity in relation to the balance-sheet total.

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

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

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

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

Accounting principles

This interim report is prepared in accordance with IAS 34 Interim Financial Reporting, which complies with the requirements stipulated in the Swedish Financial Accounting Standards Council's recommendation RR 31, Interim Financial Reporting for Groups. The accounting principles have been amended in relation to the most recent annual report, due to the transition to IFRS. The effects of the transition to IFRS and the new accounting principles are described below.

As of January 1, 2005, Orexo started to compile its consolidated accounts in compliance with IFRS. The interim report for the first quarter of 2005 was the first one issued in accordance with IFRS. Up to 2004, the company applied the Swedish Financial Accounting Standards Council's recommendations and statements. The transition to IFRS is reported in accordance with IFRS 1, "First-time Adoption of International Financial Reporting Standards," which means that the date of transition is January 1, 2004.

IFRS 1 prescribes that the comparative year, 2004, also be reported in accordance with IFRS. Financial information concerning fiscal years prior to 2004 is not recalculated. According to the main rule, all applicable IFRS and IAS standards that have become effective and have been approved by the EU at December 31, 2005 must be applied retroactively. However, IFRS 1 contains a few exceptions from the main rule, which the companies may choose to apply.

Orexo intends to use the three exemptions described below; the other exemptions are not considered to apply to Orexo.

1. Company acquisitions and mergers: Orexo has elected to apply the exception that means that IFRS 3, Business Combinations, does not need to be applied on acquisitions completed before January 1, 2004. This affects Orexo's acquisition of Cepep AB in 2003.
2. Share-based Payment: Orexo has elected not to apply IFRS 2, and the associated recalculation requirement, for option programs under which allotment occurred prior to November 7, 2002.
3. IAS 39 "Financial instruments: Recognition and measurement." Orexo has applied IAS 39 since January 1, 2005. As permitted by IFRS 1, the company has decided not to recalculate in accordance with IAS 39 comparative figures for 2004 pertaining to financial instruments. A reclassification and revaluation of the assets and liabilities that are to be reported in accordance with IAS 39 was conducted on January 1, 2005. Accordingly, financial instruments are reported in the comparative figures for 2004 in accordance with the previously applied accounting principles. Orexo has concluded that there are no differences between the figures reported in accordance with IAS 39 and the previous accounting principles.

The changes in accounting principles that this transition requires and the transitional effects on the consolidated income statement and balance sheet are presented below. The sections below also describe the exemptions from full retroactive application that the company chose to apply. The following effects are preliminary and could be changed, because certain IAS/IFRS standards are still being reviewed and additional IFRIC statements may be expected during 2005. In addition, it is possible that standards that become effective on January 1, 2006 could have retroactive effects.

The Parent Company's accounts have been prepared in accordance with RR32. Compared with the most recent annual report, this has resulted in changed accounting principles because the Parent Company has found support in IFRS 2 for the reporting of incentive programs. The effects on the Parent Company's income statement and financial position are the same as the effects on the consolidated financial statements, because all employees are active in the Parent Company.

In other respects, the accounting principles used in this interim report are described in greater detail in the notes to the 2004 Annual Report.

Preliminary effect of the application of IFRS on the consolidated balance sheet

SEK 000s	Note	Jan. 1, 2004 (transition date)			Sep. 30, 2004			Dec. 31, 2004		
		Swedish	Effect of transition to IFRS	IFRS	Swedish	Effect of transition to IFRS	IFRS	Swedish	Effect of transition to IFRS	IFRS
		GAAP			GAAP			GAAP		
ASSETS										
Fixed assets										
Intangible fixed assets		6 520		6 520	5 027		5 027	4 529		4 529
Goodwill	b	13 238		13 238	11 110	2 127	13 237	0		0
Tangible fixed assets		1 984		1 984	2 409		2 409	2 277		2 277
Financial fixed assets		2 405		2 405	2 405		2 405	2 405		2 405
		24 147		24 147	20 951	2 127	23 078	9 211		9 211
Current assets										
Inventories		1 357		1 357	2 070		2 070	1 419		1 419
Current receivables	a	4 166	-307	3 859	11 625	-5 293	6 332	11 147	-4 342	6 805
Cash and bank balances		15 482		15 482	111 235		111 235	84 240		84 240
		21 005	-307	20 698	124 930	-5 293	119 637	96 806	-4 342	92 464
Total assets		45 152	-307	44 845	145 881	-3 166	142 715	106 017	-4 342	101 675
SHAREHOLDERS' EQUITY										
Equity and reserves attributable to Parent Company's shareholders										
Share capital		3 428		3 428	3 695		3 695	3 695		3 695
Restricted reserves	a	60 063	383	60 446	95 354	-4 113	91 241	97 233	-2 815	94 418
Accumulated losses	a	-27 609	-690	-28 299	20 467	947	21 414	-21 492	-1 527	-23 019
Total shareholders' equity		35 882	-307	35 575	119 516	-3 166	116 350	79 436	-4 342	75 094
Liabilities										
Current liabilities										
Current liabilities, interest-free		9 270		9 270	26 365		26 365	26 581		26 581
Total liabilities		9 270		9 270	26 365		26 365	26 581		26 581
Total shareholders' equity and liabilities		45 152	-307	44 845	145 881	-3 166	142 715	106 017	-4 342	101 675

Shareholders' equity according to previously applied principles

Share-based payment

Goodwill not amortized after
the transition date

Tax effects of above

Total adjustment of shareholders' equity

Shareholders' equity according to IFRS

Note	Jan. 1, 2004	Sept 30, 2004	Dec. 31, 2004
	35 882	119 516	79 436
a	-307	-5 293	-4 342
b	-	2 127	-
	-	-	-
	-307	-3 166	-4 342
	35 575	116 350	75 094

Preliminary effect of the application of IFRS on the consolidated income statement

SEK 000s	Note	2004-07-01 – 2004-09-30			2004-01-01 – 2004-09-30			2004		
		Swedish GAAP	Effect of transition to IFRS	IFRS	Swedish GAAP	Effect of transition to IFRS	IFRS	Swedish GAAP	Effect of transition to IFRS	IFRS
Net sales		72 098		72 098	85 931		85 931	86 715		86 715
Cost of goods sold		-258		-258	-1 311		-1 311	-1 930		-1 930
Gross profit		71 840		71 840	84 620		84 620	84 785		84 785
Selling expenses	a	-343	-11	-354	-1 344	-31	-1 375	-1 803	-36	-1 839
Administrative expenses	a	-5 849	-102	-5 951	-16 816	-206	-17 022	-24 224	-414	-24 638
Research and development costs	a, b	-21 122	601	-20 521	-40 021	1 874	-38 147	-64 011	-387	-64 398
Other operating revenues		552		552	620		620	672		672
Other operating expenses		-294		-294	-334		-334	-368		-368
Operating profit/loss		44 784	488	45 272	26 725	1 637	28 362	-4 949	-837	-5 786
Interest received		186		186	256		256	695		695
Interest expenses		-68		-68	-79		-79	-79		-79
Other financial expenses		0		0	0		0	-10 455		-10 455
Profit/loss after financial items		44 902	488	45 390	26 902	1 637	28 539	-14 788	-837	-15 625
Tax on net loss for the period		0		0	-1 156		-1 156	-1 156		-1 156
Profit/loss for the period		44 902	488	45 390	25 746	1 637	27 383	-15 944	-837	-16 781
Earnings per share attributable to Parent Company's shareholders during the period (SEK)										
- before dilution	c	1249.53		1263.11	739.20		786.19	-450.89		-474.56
- after dilution	c	1166.80		1179.48	688.81		732.60	-450.89		-474.56
Results according to previously applied principles										
Share-based payments	a	-221	-221	-221	-490	-490	-490	-837	-837	-837
Goodwill write-downs	b	709	709	709	2 127	2 127	2 127			
Total adjustment of result		488	488	488	1 637	1 637	1 637	-837	-837	-837
Result according to IFRS		45 272	45 390	45 390	28 362	28 539	27 383	-5 786	-15 625	-16 781

a) Share-based payment

IFRS 2 "Share-based Payment" addresses share-based payment and, for accounting purposes, divides such payment into two main categories: payment made in the form of equity instruments and payment made in cash.

With respect to payment made in the form of equity instruments, the recommendation is to be applied for equity instruments allotted after November 7, 2002, and which were not earned (vested) before January 1, 2005. For these programs, the fair value of the benefit accrued over the period of earnings is to be expensed.

The company has issued its employees stock options between 2002 and 2004, free of charge. Of these employee stock options, one third of the allotment was earned (vested) on each of the first three anniversaries following their distribution, assuming that the holder was still an Orexo employee on this date. The fair value on issue of these programs totaled MSEK 6.5.

The employee stock options were previously reported in accordance with the real value method. They were reported as assets and they increased restricted reserves at the start of the programs and were then expensed over the vesting period, which means that the value of the reported asset was reduced as the options were earned. The effect on shareholders' equity in connection with the transition to IFRS on January 1, 2004 amounted to a reduction of the accumulated loss by KSEK 690, and an increase in restricted reserves by KSEK 383. The transition also meant that the remaining previously reported restricted reserves and prepaid personnel costs were reduced by KSEK 307. The reported

result after tax for 2004 was reduced by KSEK 837, of which selling expenses accounted for KSEK 36, administrative expenses for KSEK 414 and research and development costs for KSEK 387.

According to the Swedish accounting rules, share-based payment according to this type of employee stock options plan was not reported as a cost in the income statement, other than at the real value on the date of issue. The adjustments are due in their entirety to the fact that in the past Orexo reported the cost of the stock option programmed based on fair value at issue of the options, while in accordance with IFRS Orexo values this cost on the basis of the market value of these options at issue (calculated in accordance with, for example, the Black & Scholes model). According to both the previous principles and IFRS, this cost is accrued over the time for the earning of these options.

b) Goodwill and other intangible assets

IFRS 3 "Business Combinations" requires that goodwill and other intangible assets with an indefinite useful life no longer be amortized but instead be subject to impairment testing, firstly in connection with the transition to IFRS on January 1, 2004 and, secondly, annually or more often if there are any indications of a decline in value. Such an asset is to be impaired if the reported value exceeds the recoverable value. The company conducted impairment tests at January 1, 2004, and at December 31, 2004.

The recoverable value is the same as the value in use. In the impairment test conducted on January 1, 2004, the value in use was calculated in accordance with the cash flow method based on anticipated future revenues and costs for technology during the period 2002 to 2004, which was the anticipated life of the patents. In the calculation, the company has used a probability factor for project phases and a discount rate of 10%.

The impairment test conducted on December 31, 2004 showed a need for impairment. The impairment is attributable to goodwill from the acquisition of the subsidiary CePeP AB. Because Orexo has decided to focus on other technologies, this technology is not expected to generate economic benefits in the foreseeable future. This strategic change was implemented during the fourth quarter and resulted in the reporting of the impairment. During the first to third quarters of 2004, depreciation according to plan was implemented in accordance with the previously applied accounting principles.

The recoverable value is equal to the value in use, which is calculated in accordance with the cash-flow method, based on anticipated future revenues and costs. We used probability factors for project phases and a discounting factor of 15% in this calculation. The result of this test showed that Orexo could report an impairment pertaining to the goodwill attributable to CePeP AB. The impairment has been charged against the income statement item, research and development.

In accordance with Swedish accounting principles, all intangible assets, including goodwill, are amortized over an estimated period in use. This change does not affect shareholders' equity on the date of transition, because goodwill amortization prior to January 1, 2004 is not to be reversed. Due to the impairment posted on December 31, 2004, there is no amortization to be reversed for 2004 either, although there was amortization during the first to third quarters of 2004, which is being reversed.

C) Earnings per share in accordance with IFRS for fiscal year 2004

Result used for calculating earnings per share before and after dilution (SEK 000s)	-16 781
Average number of shares before dilution	35 361
Adjustment for warrants	2 545
Average number of shares after dilution	37 906

D) Classification of preferred share capital

Orexo has preference shares outstanding. Based on IAS 32, all of these shares constitute shareholders' equity.

Audit Report

We have reviewed this interim report in accordance with the recommendations issued by the Swedish Institute of Authorized Public Accountants (FAR). A review is considerably limited in comparison with an audit. We have found nothing to indicate that the Interim Report does not fulfill the requirements of the Swedish Annual Accounts Act.

Uppsala, October 11, 2005

Öhrlings PricewaterhouseCoopers AB

Leonard Daun
Authorized public accountant

Uppsala, October 11, 2005

Orexo AB (publ)

Zsolt Lavotha, President and CEO

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Upcoming report dates

Year-end Report for fiscal year 2005; not later than February 28, 2006