# Orexo AB (publ) Interim report, January–March 2005

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

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

Internet: www.orexo.com Corp. Reg. No. 556500-0600

# Orexo AB (publ) Interim report, January–March 2005

# Key events during the period

- Net sales amounted to MSEK 1.2 (1.1) 12
- Net loss after tax was MSEK 18.8 (loss: 8.9)
- Earnings per share amounted to a loss of SEK 509.90 (loss: 260.54)
- Efficacy study for OX 22 (pharmaceutical for the treatment of temporary sleep disturbances) was completed with positive results
- Increased investment in diagnostic pharmaceutical new subsidiary centered on Diabact<sup>®</sup> UBT currently under formation
- Continued organizational expansion new analytical laboratory was opened and additional expertise recruited
- Dr. Nils-Otto Ahnfelt was appointed Project Director

# Significant events after March 31

- Dr. Thomas Leoo was appointed new Medical Director
- Dr. Anders Pettersson former Medical Director and one of Orexo's founders will now head Orexo's innovation team, with responsibility for identifying and evaluating future product candidates.
- Lena Söderström assumed responsibility for the Orexo subsidiary Diabact UBT
- Orexo was nominated for the "2005 Export Award" for successful internationalization
- Professor John Sjögren was elected as a new Board member at the Orexo Annual General Meeting

Financial summary of the period	3 months	3 months <sup>2</sup>
• •	2005	2004
MSEK	Jan-March	Jan-March
Net sales	1.2	1.1
Profit/loss after tax	-18.8	-8.9
Earnings per share, SEK	-509.90	-260.54

Unless otherwise specified in this interim report, all statements refer to the Group. Figures in parentheses indicate the outcome for the corresponding period in the preceding 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.

Figures for 2004 have been restated in accordance with IFRS. For more information, see pages 15-21.

# 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

Orexo recruited additional expertise during the period (the number of employees increased from 26 to 32 during the reporting period) and the company's portfolio of development projects was expanded and further advanced. Concurrently, a new analytical laboratory was developed, 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<sup>®</sup> UBT. Diabact<sup>®</sup> 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.

Lena Söderström will be the operating manager of the subsidiary. She has vast experience from research as well as production and marketing. Most recently, she was employed at Fresenius Kabi AB. She assumed her new position on May 2.

#### Key events after March 31

#### 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.

#### Lena Söderström appointed manager of new Orexo subsidiary based on Diabact® UBT

During the period, it was decided that Orexo will establish a subsidiary based on its first commercialized product Diabact®UBT. On May 2, Lena Söderström assumed the position of operating manager of the new subsidiary.

#### Orexo nominated for "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 which 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. 86 companies were nominated and Orexo was one of six companies in final round.

#### Professor John Sjögren elected as 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, that is, how drug substances are absorbed and distributed in the body. He has particularly studied tablet formulation processes and technical properties of excipients as well as formulation principles and biopharmaceutic methodology for evaluation of tablet preparations.

# OX 22 – a full night's sleep without "hang-over" symptoms

Global sales of products to treat insomnia and sleep disorders were estimated at USD 2.4 billion in 2003. Orexo's product for the treatment of insomnia – OX 22 – offers patients a rapid and effective sleep aid without side-effects in the form of "hang-over" effects. With these competitive advantages, OX 22 is believed to have significant medical and commercial potential.

During the period, Orexo completed Phase I and Phase II studies with positive results. Efforts have been initiated to find commercialization partners for marketing and sales of the product in all markets.

OX 22 is based on Orexo's sublingual tablet technology, which is patented in the US, Japan and Australia, among other countries. Patent applications have also been submitted in all other major markets.

# **Operations**

#### Orexo in brief

Orexo is a product focused drug delivery company that develops proprietary pharmaceuticals to address areas of unmet therapeutic need. By exploiting its expertise in medicine and pharmaceutical development, Orexo develops novel pharmaceuticals based on well documented compounds and Orexos patented drug delivery technologies and its unique expertise in "dry formulations" (for example tablets).

Orexo's drug development activities are commercially driven and to date, the company has focused 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 32 employees representing pharmaceutical, clinical and regulatory expertise. 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 2003, according to estimates by industry sources, the value of the market for drug delivery products was close to USD 61 billion – up 15% over the preceding year. 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	RESEARCH/ FORMULATION DEVELOPMENT	CLINICAL PHASE	REGISTRATION FILED	MARKET INTRODUCTION
D. 1 0 1 1 D.	D				
Diabact® UBT	Diagnosis of Helicobacter pylori infection				
OX 20	Acute pain		:		
OX 22	Insomnia				
OX 17	GERD		:		
OX 19	Urinary incontinence				
OX 40	Migraine				

*Diabact*<sup>®</sup> *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<sup>®</sup> 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.

 $Rapinyl^{TM}$  (OX 20) – for the treatment of acute pain. Rapinyl<sup>TM</sup> (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<sup>TM</sup> (OX 20) have been signed with Endo Pharmaceuticals for the North American market and with Kyowa Hakko Kogyo for the Japanese market. Licensing negotiations for the rest of the world are ongoing.

*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/wellknown 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 diurnal 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 quarter in figures: January 1-March 31, 2005

#### Condensed income statement

	3 months	3 months	12 months
	2005	2004	2004
MSEK	Jan-March	Jan-March	Jan-Dec
Net sales	1.2	1.1	86.7
Gross profit/loss	0.6	0.6	84.8
Selling expenses	-0.1	-0.4	-1.8
Administrative expenses	-7.1	-2.9	-24.7
Research and development costs	-12.6	-6.3	-64.4
Other income and expenses	-0.0	0.0	0.3
Operating profit/loss	-19.2	-9.0	-5.8
Net financial items	0.3	0.0	-9.8
Tax	0.0	0.0	-1.2
Profit/loss for the period	-18.8	-9.0	-16.8

As of January 1, 2005, the Group applies International Financial Reporting Standards (IFRS), formerly 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 15-21.

#### Revenue

#### Net sales: MSEK 1.2 (1.1), +9.0%

Orexo's net sales were MSEK 1.2 for the first quarter of 2005, compared with MSEK 1.1 for the first quarter of 2004. This corresponds to an increase of 9.0%, attributable to increased sales of Diabact® UBT. The net sales figure for the full-year 2004 includes a total of MSEK 83.1 in license revenues booked during the second and third quarters of 2004.

#### **Expenses and earnings**

#### Gross profit: MSEK 0.6 (0.6), 0.0%

Gross profit amounted to MSEK 0.6 (49.3% of net sales) for the first quarter of 2005, compared with MSEK 0.6 (52.6% of net sales) for the first quarter of 2004. The cost of goods sold was MSEK 0.6 for the first quarter of 2005, compared with MSEK 0.5 in the first quarter of 2004, representing an increase of 20.0%.

#### Administrative expenses: MSEK 7.1 (2.9), +144.8%

Administrative expenses amounted to MSEK 7.1 for the first quarter of 2005, compared with MSEK 2.9 for the first quarter of 2004, corresponding to an increase of 144.8%. The increase was attributable to the company's continued development, entailing further expansion of Orexo's organization and infrastructure.

The company's expenses pertaining to the employee stock options program totaled MSEK 1.0, of which administrative expenses account for MSEK 0.8 and research and development costs for MSEK 0.2. The costs pertain to value growth during the period and to estimated social security charges on this value growth. The company is required to pay social security charges on the gain – calculated as the difference between the exercise price of the options and the market price of the share upon exercise of the options – that may arise when the options are exercised.

The social security charges that may arise as a result of the employee options program have been hedged –

financially and in cash-flow terms, but not in the accounts – through the issuance of warrants to one of Orexo's subsidiaries.

#### Research and development costs: MSEK 12.6 (6.3), +100.0%

Research and development costs were MSEK 12.6 for the first quarter of 2005, compared with MSEK 6.3 for the first quarter of 2004, corresponding to an increase of 100.0%. The increase was primarily attributable to the expansion of the product portfolio through the addition of product candidates that are in different development phases, clinical studies for Rapinyl<sup>TM</sup> (OX 20) and OX 22 Insomnia, as well as to the recruitment of additional key expertise. In addition, provisions attributable to the company's employee stock options program were made. See "Administrative expenses" above.

#### Operating loss: MSEK 19.2 (loss: 9.0), -113.4%

Orexo's operating loss was MSEK 19.2 for the first quarter of 2005, compared with a loss of MSEK 9.0 for the first quarter of 2004. The deterioration in earnings is attributable to higher research and development costs and also an increase in administrative expenses. See sections above.

#### **Financial position**

#### Total liquid funds at March 31: MSEK 60.9 (4.2), +1,334%

Consolidated liquid funds at March 31 amounted to MSEK 60.9 (4.2). Shareholders' equity was MSEK 57.2 (26.9) and the equity/assets ratio was 72.3% (79.5).

#### **Investments and depreciation**

#### Gross investments: MSEK 0.7 (0.0)

Gross investments in tangible assets amounted to MSEK 0.7 (0.0) for the first quarter of 2005. These investments consist primarily of investments in production and research equipment. Depreciation for the period amounted to MSEK 0.7 (1.4). The reduction in depreciation is mainly due to lower goodwill amortization. A writedown of consolidated goodwill was made in the annual accounts at December 31, 2004.

#### **Parent Company**

Most of Orexo's operations are conducted through the Parent Company, Orexo AB. Net sales for the first quarter of 2005 amounted to MSEK 1.2, compared with MSEK 1.1 for the first quarter of 2004. The loss after net financial items for the first quarter of 2005 amounted to MSEK 18.3, compared with a loss of MSEK 8.5 in the first quarter of 2004. Investments for the first quarter of 2005 were MSEK 0.7, compared with MSEK 0.0 for the first quarter of 2004. On Mach 31, 2005, liquid funds in Orexo AB amounted to MSEK 60.8, compared with MSEK 1.9 on March 31, 2004, corresponding to a change in liquid funds of MSEK 58.9.

#### Personnel

#### Personnel expenses: MSEK 8.0 (4.6), +6 new employees

Personnel expenses for the first quarter of 2005 totaled MSEK 8.0 (4.6). Six new employees were recruited during the first quarter of 2005. The average number of employees was 32 (20). All personnel are employed on a full-time basis.

#### Number of shares and warrants outstanding

The number of shares and warrants outstanding at March 31, 2005 is distributed as follows:

Number of shares 36,952
Number of options 5,302

Of which:

<ul><li>stock options</li></ul>	2,477
- transferred warrants	1,488
– warrants from unit issue	1,337

The number of shares and warrants outstanding remained unchanged during the first quarter of 2005.

Of the options issued by the Parent Company on March 31, 2005, 738 warrants were held by the Pharmacall AB subsidiary for future allocation and cash-flow hedge of social security fees. For further information about the Orexo employee stock option program, see Note 8 in the company's 2004 Annual Report.

#### Pledged assets and contingent liabilities

In March 2005, Orexo was informed that the National Tax Board is considering not granting the company a VAT deduction of approx. MSEK 2. The legal position on the matter is uncertain but the company assesses that it will not be charged more than MSEK 0.4 in VAT. Apart from this, no significant change in pledged assets and contingent liabilities occurred during the period.

This interim report is unaudited.

Uppsala, May 18, 2005

Orexo AB (publ)

Zsolt Lavotha, President and CEO

#### **Balance sheet**

Amounts in SEK 000s	Mar 31, 2005	Mar 31, 2004*	Dec 31, 2004*
Assets			
Fixed assets			
Intangible fixed assets	4,031	6,022	4,529
Goodwill	0	13,238	0
Tangible fixed assets	2,736	1,805	2,277
Financial fixed assets	2,405	2,405	2,405
Total fixed assets	9,172	23,470	9,211
Current assets			
Inventories	1,933	1,940	1,419
Current receivables	7,087	0	6,805
Cash and bank balances	60,890	4,246	84,240
Total current assets	69,910	10,326	92,464
Total assets	79,082	33,796	101,675
Shareholders' equity and liabilities			
Shareholders' equity			
Share capital	3,695	3,428	3,695
Restricted equity	95,347	38,358	94,418
Accumulated losses	-41,861	-14,911	-23,019
Total shareholders' equity Note 1	57,181	26,875	75,094
Liabilities			
Current liabilities, interest-free	21,901	6,921	26,581
Total liabilities	21,901	6,921	26,581
Total shareholders' equity and liabilities	79,082	33,796	101,675
Pledged assets	2,500	2,500	2,500
Contingent liabilities	1,550	1,550	1,550

<sup>\*</sup> Restated in accordance with IFRS

#### Income Statement

	Jan 1-Mar 31	Jan 1-Mar 31	Jan 1-Dec 31
SEK 000s	2005	2004*	2004*
Net sales	1,230	1,103	86,715
Cost of goods sold	-624	-523	-1,930
Gross profit	606	580	84,785
Selling expenses	-91	-418	-1,839
Administrative expenses	-7,066	-2,887	-24,638
Research and development costs	-12,628	-6,298	-64,398
Other operating revenue	18	58	672
Other operating expenses	-24	-17	-368
Operating loss	-19,185	-8,982	-5,786
Profit from financial investments			
Interest income	343	42	695
Interest expense	0	-1	-79
Other financial expense	0	0	-10,455
Total profit from financial investments	343	41	-9,839
Total profit from imancial investments	343	71	-7,037
Tax	0	0	-1,156
Net loss for the period	-18,842	-8,941	-16,781
Earnings per share, before dilution, SEK	-509.90	-260.54	-474.56
Earnings per share, after dilution, SEK	-509.90	-260.54	-474.56
Average number of shares, before dilution	36,952	34,278	35,361
Average number of shares, after dilution	39,492	35,479	37,906
Number of shares, before dilution	36,952	34,278	36,952
Number of shares, after dilution	39,492	35,479	39,497
Depreciation	732	684	5,635

<sup>\*</sup> Restated in accordance with IFRS

#### Cash-flow statement

	Jan 1-Mar 31	Jan 1-Mar 31	Jan 1-Dec 31
SEK 000s	2005	2004*	2004*
Operating activities			
Operating profit/loss before interest expense and interest income	-19,185	-8,982	-5,786
Interest expense	0	-1	-79
Interest income	342	42	695
Other financial expense	0	0	-10,455
Tax paid	0	0	-1,156
Adjustment for items not included in cash flow	1,738**	895**	18,879**
Cash flow from operating activities before changes	-17,105	-8,046	2,098
in working capital			
Changes in working capital	124	(10	210
Accounts receivable	164	-619	-319
Other current receivables	-444	338	-2,629
Inventories	-514	-583	-62
Current liabilities	-4,758	-2,368	16,818
Cash flow from operating activities	-22,657	-11,278	15,906
To a local			
Investing activities	600	_	
Acquisition of machinery and equipment	-693	-7	-1,120
Liquid funds from the acquisition of subsidiaries	0	0	0
Cash flow after investing activities	-23,350	-11,285	14,786
Changes in financing			
New share issue	0	49	53,972
Cash flow after financing activities	-23,350	-11,236	68,758
Cash now after infancing activities	-23,330	-11,230	00,730
Cash flow for the period			
Liquid funds at beginning of period	84,240	15,482	15,482
Change in liquid funds	-23,350	-11,236	68,758
Liquid funds at end of period	60,890	4,246	84,240
Changes in consolidated shareholders' equity			
Opening shareholders' equity as per the Balance Sheet	75,094	35,575	35,575
Net loss for the year	-18,842	-8,941	-16,781
New share issue		49	53,757
Option program	929	192	2,543
Amount at close of period	57,181	26,875	75,094
* D I HING			
* Restated in accordance with IFRS			
** Calculation of adjustments for items not included in cash flow			
Depreciation / write-down	732	684	16,036
Scrapping	0	0	20
Estimated costs, employee option program	1,006		2,823
Total	1,738		18,879
<del></del>	1,700	0,5	10,077

#### Key data

	Mar 2005	Mar 2004*	Jan-Dec 2004*
Operating margin %	-1,559.8	-814.3	-6.6
Profit margin, %	-1,531.9	-810.6	-18.2
Return on total capital, %	-21.2	-22.8	-6.7
Return on equity, %	-28.2	-28.6	-30.3
Return on capital employed, %	-28.2	-28.6	-9.2
Debt/equity ratio, multiple	0	0	0
Equity/assets ratio, %	72.3	79.5	73.9
Current ratio, %	319.2	149.2	347.9
Quick ratio, %	310.4	121.2	342.5
Number of shares at end of period	36,952	34,278	36,952
Shareholders' equity per share, SEK	1,547.44	784.03	2,032.20
Number of employees	32	20	23
Number of outstanding warrants	3,965	2,643	3,965

#### **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 income as a percentage of the average total assets.

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

Adjusted shareholders' equity: Average shareholders' equity, including untaxed reserves, with deductions for deferred tax liability.

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

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

 $\textbf{Debt/equity ratio:} \ Interest-bearing \ liabilities \ divided \ by \ shareholders' \ equity.$ 

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

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

Quick 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 end of the period.

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

<sup>\*</sup> Restated in accordance with IFRS

# New accounting principles as of January 1, 2005

As of January 1, 2005, the company compiles its consolidated financial statements in accordance with IFRS. The interim report for the first quarter of 2005 is the first financial report submitted by the company 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.

IFRS 1 specifies 11 specific cases in which companies are entitled to apply exemptions from complete retroactive application, because IASB has estimated that the usefulness of retroactive application does not match the cost of application in these cases. Orexo intends to utilize the following four exemptions, while the other exemptions are not considered to apply to Orexo.

- 1. Business Combinations; Orexo will apply the exemption that entails that IFRS 3, Business Combinations, need not be applied for acquisitions completed before January 1, 2004 (CePeP AB).
- 2. Acquisition value of tangible fixed assets; Orexo has elected to report tangible fixed assets at historical acquisition cost, less accumulated depreciation.
- 3. 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.
- 4. IAS 39 "Financial Instruments: Recognition and Measurement" is applied as of January 1, 2005. Supported by IFRS 1, the company has elected not to recalculate comparative figures for financial instruments for 2004 in accordance with the principles of IAS 39. A reclassification and revaluation of the assets and liabilities that are to be reported in accordance with IAS 39 was implemented on January 1, 2005. Accordingly, financial instruments are reported in the comparative figures for 2004, based on the previously applied accounting principles. Orexo has not noted any differences between the reported value in accordance with IAS 39 and the previously reported value.

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 following effects are preliminary and could be changed, because certain IAS/IFRS standards are still be 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.

This interim report has been compiled in accordance with IAS 34, Interim Financial Reporting.

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 and calculation methods 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

	_	Jan 1, 2004		De	ec 31, 2004	2004	
	_	(trans	sitional date)				
SEK 000s	Note	Swedish	Effect of	IFRS	Swedish	Effect of	IFRS
		accounting	transition		accounting	transition	
	_	rules	to IFRS		rules	to IFRS	
ASSETS							
Fixed assets							
Intangible fixed assets		6,520		6,520	4,529		4,529
Goodwill		13,238		13,238	0		0
Tangible fixed assets		1,984		1,984	2,277		2,277
Financial fixed assets	-	2,405		2,405	2,405		2,405
	=	24,147		24,147	9,211		9,211
Current assets							
Inventories		1,357		1,357	1,419		1,419
Current receivables	a	4,166	-307	3,859	11,147	-4,342	6,805
Cash and bank balances	=	15,482		15,482	84,240		84,240
	_	21,005	-307	20,698	96,806	-4,342	92,464
Total assets	-	45,152	-307	44,845	106,017	-4,342	101,675
SHAREHOLDERS' EQUITY							
Equity and reserves attributable to							
Parent Company shareholders							
Share capital		3,428		3,428	3,695		3,695
Restricted reserves	a	60,063	383	60,446	97,233	-2 815	94,418
Accumulated loss	a	-27,609	-690	-28,299	-21,492	-1 527	-23,019
Total shareholders' equity	_	35,882	-307	35,575	79,436	-4 342	75,094
LIABILITIES							
Current liabilities	_						
Current liabilities, interest-free		9,270		9,270	26,581		26,581
Total liabilities	=	9,270		9,270	26,581		26,581
Total shareholders' equity and	_	45,152	-307	44,845	106,017	- 4 342	101,675
liabilities					•		•
	-	<u> </u>					

	_	March 31, 2004		
SEK 000s	Note	Swedish accounting rules	Effect of transition to IFRS	IFRS
ASSETS	_			_
Fixed assets				
Intangible fixed assets		6,022		6,022
Goodwill	b	12,529	709	13,238
Tangible fixed assets		1,805		1,805
Financial fixed assets	_	2,405		2,405
	_	22,761	709	23,470
Current assets				
Inventories		1,940		1,940
Current receivables	a	4,390	-250	4,140
Cash and bank balances	=	4,246		4,246
	_	10,576	-250	10,326
Total assets	-	33,337	459	33,796
SHAREHOLDERS' EQUITY				
Equity and reserves attributable to				
Parent Company shareholders				
Share capital		3,428		3,428
Restricted reserves	a	37,783	575	38,358
Loss brought forward	a,b	-14,795	-116	-14,911
Total shareholders' equity	_	26,416	459	26,875
LIABILITIES	_			
Current liabilities				
Current liabilities, interest-free	_	6,921		6,921
Total liabilities	_	6,921		6,921
Total shareholders' equity and		33,337	459	33,796
liabilities	_			

	Note	Jan 1, 2004	Dec 31, 2004	March 31, 2004
Shareholders' equity according to		35,882	79,436	26,416
previously applied principles				
Share-based payment	a	-307	-4,342	-250
Goodwill not amortized after the transition	b	-	-	709
date				
Tax effects of above		-	-	
Total adjustment of shareholders' equity		-307	-4,342	-459
Shareholders' equity according to IFRS		35,575	75,094	26,875

## Preliminary effect of the application of IFRS on the consolidated income statement for 2004

#### 2004

G777 000	-			
SEK 000s	Note	Swedish accounting	Effect of transition to	IFRS
	<u>-</u>	rules	IFRS	
Net sales		86,715		86,715
Cost of sold goods	-	-1,930		-1,930
Gross profit		84,785		84,785
Selling expenses	a	-1,803	-36	-1,839
Administrative expenses	a	-24,224	-414	-24,638
Research and development costs	a	-64,011	-387	-64,398
Other operating income		672		672
Other operating expenses	_	-368		-368
Operating profit/loss		-4,949	-837	-5,786
Interest income		695		695
Interest expense		-79		-79
Other financial expenses	_	-10,455		-10,455
Loss after financial items		-14,788	-837	-15,625
Tax on net loss for the year	· <del>-</del>	-1,156		-1,156
Net loss for the year	_	-15,944	-837	-16,781

## Earnings per share attributable to Parent Company shareholders during the year (expressed in SEK)

- before dilution	c	-450.89	-474.56
- after dilution	c	-450.89	-474.56

	_	Operating loss	Loss before taxes	Net loss for the year
Results according to previously applied principles		-4,949	-14,788	-15,944
Share-based payment	a _	-837	-837	-837
Total adjustment of result		-837	-837	-837
Result according to IFRS		-5,786	-15,625	-16,781

## Preliminary effect of the application of IFRS on the consolidated income statement for Q1 2004

Jan 1, 2004 – Dec 31, 2004

SEK 000s	Note	Swedish accounting	Effect of transition to	IFRS
	_	rules	IFRS	
Net sales		1,103		1,103
Cost of sold goods	_	-523		-523
Gross profit		580		580
Selling expenses	a	-408	-10	-418
Administrative expenses	a	-2,835	-52	-2,887
Research and development costs	a	-6,934	636	-6,298
Other operating revenues		58		58
Other operating expenses	_	-17		-17
Operating profit/loss		-9,556	574	-8,982
Interest income		42		42
Interest expense	-	-1		-1
Loss after financial items	<u>-</u>	-9,515	574	-8,941
Tax on net loss for the year	_	0		0
Net loss for the year		-9,515	574	-8,941

## Earnings per share attributable to Parent Company shareholders during the year (expressed in SEK)

- before dilution	c	-277.58	-260.54
- after dilution	c	-277.58	-260.54

	_	Operating loss	Loss before taxes	Net loss for the year
		-9,556	-9,515	-9,515
Results according to previously applied				
principles				
Share-based payment	a	-135	-135	-135
Goodwill	b _	709	709	709
Total adjustment of result		574	574	574
Result according to IFRS		-8,982	-8,941	-8,941

#### 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 issued to its employees, free of charge, employee stock options during the period 2002-2004. 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 amounted to SEK 6,489,000. The employee stock options were previously reported in accordance with 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 SEK 690,000, and an increase in restricted reserves by SEK 383,000. The transition also meant that the remaining previously reported restricted reserves and prepaid personnel costs were reduced by SEK 307,000. The reported result after tax for 2004 was reduced by SEK 837,000, of which selling expenses accounted for 36,000, administrative expenses for 414,000 and research and development costs for 387,000. In accordance with the Swedish accounting rules, share-based payment according to this type of employee stock options plan were not reported as a cost in the income statement, other than at the real value on the date of issue.

#### 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 impairment test conducted on December 31, 2004 showed a need for impairment. The impairment was attributable to goodwill from the acquisition of the subsidiary CePeP AB. Because this company 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 impairment requirement. During the first to third quarters of 2004, the goodwill related to CePeP AB was amortized according to plan. 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. In this calculation, probability factors for project phases and a discounting factor of 15% were used. 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

A company that calculates earnings per share after dilution after having issued warrants must, in accordance with Swedish accounting rules, calculate the dilution effect on the basis of the present value of the subscription payment. IFRS (IAS 33) does not specify whether or not the subscription payment is to be calculated at present value. The company, as in the past, has elected to calculate the dilution effect on the basis of the present value of the subscription payment.

#### d) Classification of preferred share capital

The company has preference shares outstanding. Based on IFRS 32, all of the preference shares issued by Orexo constitute shareholders' equity.

#### Costs distributed by type of cost (SEK 00s)

	March 31, 2005	March 31, 2004	
Raw materials and supplies	1,242	449	
Other external costs	10,449	4,157	
Personnel costs	8,010	4,852	
Depreciation	732	685	
Total	20,433	10,143	

#### Forthcoming reporting occasions

Interim report April-June 2005	August 17, 2005
Interim report July-September 2005	October 24, 2005
Year-end report for 2005 fiscal year_	no later than February 28, 2006

#### For further information, please contact:

Zsolt Lavotha, President and CEO, Tel: +46-18-780 88 00, e-mail: zsolt.lavotha@orexo.se

Erik Bergman, CFO, Tel: +46-18-780 88 00, e-mail: <a href="mailto:erik.bergman@orexo.se">erik.bergman@orexo.se</a>

Johan Tamsen, Investor Relations, Tel: +46-733 – 25 40 10, e-mail: johan.tamsen@orexo.se