# Orexo AB (publ)

# - Interim Report, January - June 2005

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

### Key events during the period

- Net sales amounted to MSEK 2.9 (13.8) 1 2
- Net loss after tax was MSEK -35.2 (loss: 18.0)
- Earnings per share amounted to a loss of SEK 953.45 (loss: 525.32)
- Dr. Thomas Leoo 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 Orexo subsidiary Diabact® UBT
- Orexo was nominated for the "2005 Export Award" for successful internationalization
- Professor John Sjögren elected new Board member at the Orexo Annual General Meeting
- Orexo AB sells the rights to its cell-penetrating peptide technology, CPP, for MSEK 9.5, resulting in a capital gain of MSEK 8.9

### Second Quarter 2005

- Net sales amounted to MSEK 1.7 (12.7) 1 2
- Net loss after tax was MSEK -16.4 (loss: -9.1)
- Earnings per share amounted to a loss of MSEK 443.55 (loss: 264.48)

### Significant events after June 30

• Subscription for 1 337 shares based on unit issue carried out during 2004, representing 100 percent of the total amount of warrants.

3 months	3 months	6 months	6 months	12 months
2005	2004	2005	2004	2004
April-June	April-June	JanJune	JanJune	JanDec.
1.7	12.7	2.9	13.8	86.7
-16.4	-9.1	-35.2	-18.0	-16.8
-443.55	-264.48	-953.45	-525.32	-474.56
	2005 April-June 2 1.7 -16.4	2005 2004 April-June April-June 1.7 12.7 -16.4 -9.1	2005 2004 2005 April-June April-June JanJune 1.7 12.7 2.9 -16.4 -9.1 -35.2	April-June April-June JanJune JanJune  1.7 12.7 2.9 13.8 -16.4 -9.1 -35.2 -18.0

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.

<sup>2</sup> 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

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® 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.

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.

#### 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

# Orexo was 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 6 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.

Stomach pain? Diabact® UBT makes it possible to diagnose the patient – fast and convenient, safely and accurately.

Dyspepsia – persistent problems or discomfort from the upper abdomen – is a global public health problem that in Sweden annually results in over a half million visits to the doctor. Even though the symptoms cause major discomfort for the patient – and by extension major costs for society – today there is no generally recognized diagnostic model.

Orexo's Diabact® UBT is a pharmaceutical designed to address the clinical need for a fast, convenient, non-invasive, accurate and cost effective test for the diagnosis of Helicobacter pylori infection. To increase its focus on Diabact® UBT, Orexo has formed a subsidiary based on the product to make it possible to achive its full market potential.

During the second quarter, Orexo substantially increased its marketing efforts in Finland and the UK, while preparing for continued expansion into other European and global markets. Lena Söderström was appointed Managing Director of the subsidiary and will head the business related to Diabact® UBT.

Diabact® UBT was launched in 2000 and is based on Orexo's patented tablet formulation model for rapidly disintegrating and fast dissolving tablets. Orexo has distribution and marketing agreements for Diabact® UBT in Finland, Hong Kong, Ireland, the UK, and Sweden. For the Japanese market, Orexo has signed a licensing agreement with Kyowa Hakko Kogyo Co Ltd.

### **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 36 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
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® 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.

 $Rapinyl^{TM}(OX\ 20)$  – for the treatment of acute pain. Rapinyl^M (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 RapinylM (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 - June 30, 2005

#### Condensed income statement

	3 months	3 months	6 months	6 months 1	2 months
	2005	2004	2005	2004	2004
MSEK	April-June	April-June	e JanJune	e JanJune	JanDec.
Net sales	1.7	<b>12.</b> 7	2.9	13.8	86.7
Gross profit/loss	0.8	12.2	1.4	12.8	84.8
Selling expenses	-0.6	-0.6	-0.6	-1.0	-1.8
Administrative expenses	-9.4	-8.2	-16.5	-11.1	-24.6
Research and development costs	-16.2	-11.3	-28.8	-17.6	-64.4
Other income and expenses	8.9	-0.0	8.8	-0.0	0.3
Operating profit/loss	-16.6	-7.9	-35.8	-16.9	-5.8
Net financial items	0.2	0.0	0.5	0.1	-9.8
Tax	0.0	-1.1	0.0	-1.1	-1.1
Profit/loss for the period	-16.4	-9.1	-35.2	-18.0	-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 2.9 (13.8) -79.0 percent

Net sales for the period between January and June 2005 totaled MSEK 2.9 (13.8). The reduction in sales is according to plan and is mainly attributable to license revenues of MSEK 11.6 booked during the second quarter of 2004. Most of the remaining sales and cost of goods sold are attributable to the sale of Diabact® UBT.

Net sales for the period between April and June 2005 totaled MSEK 1.7 (12.7).

#### **Expenses and earnings**

Selling expenses: MSEK 0.6 (1.0) -36.0 percent

Most of the selling expenses are attributable to the sale of Diabact® UBT. Selling expenses between January and June 2005 amounted to MSEK 0.6, which was 36.0 percent lower than the corresponding period last year.

Selling expenses for the period between April and June 2005 were MSEK 0.6 (0.6).

Administrative expenses: MSEK 16.5 (11.1) +49.2 percent

Administrative expenses between January and June 2005 were MSEK 16.5 (11.1), an increase of 49.2 percent. The increase was attributable to the continued development of the company along with the continued expansion of Orexo's organization and infrastructure.

Expenses for the company's employee stock option program totaled MSEK 2.5, attributable to administrative expenses of MSEK 1.7 and research and development costs of MSEK 0.8. These expenses refer both to the increase in value earned during the period and social security costs calculated based on this increase in value. The company will need to pay social security fees on

the gain—calculated as the difference between the redemption 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 accrue as a result of the employee options program have been hedged in terms of cash flow through the issuance of warrants to one of Orexo's subsidiaries.

Administrative expenses between April and June 2005 totaled MSEK 9.4 (8.2).

Research and development costs: MSEK 28.8 (17.6) +63.6 percent

Research and development costs between January and June 2005 were MSEK 28.8 (17.6), an increase of 63.6 percent. The increase was mainly attributable to an expanded product portfolio with drug candidates in various clinical phases, recruitment of additional employees to be able to handle even more development projects, as well as provisions to cover the social security fees attributable to the employee stock option programs for people within R&D, described under "Administrative expenses" above.

Research and development costs between April and June 2005 were MSEK 16.2 (11.3).

#### Depreciation and amortization

Depreciation between January and June 2005 amounted to MSEK 1.4 (1.4).

#### Sale of subsidiary

The operating loss includes a capital gain of MSEK 8.9 that occurred with 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 June 2005 amounted to MSEK 0.0 (1.1).

#### Loss

Operating loss between January and June 2005 amounted to MSEK 35.8 (loss: 16.9). Net loss for the period after financial items totaled MSEK 35.2 (loss: 16.9) and loss after tax was MSEK 35.2 (loss: 18.0).

Operating loss for the period between April and June 2005 amounted to MSEK 16.6 (loss: 7.9). Net loss for the period after financial items totaled MSEK 16.4 (loss: 7.9) and loss after tax was MSEK 16.4 (loss: -9.1).

#### **Financial position**

The Group's liquid assets as at June 30, 2005, totaled MSEK 53.5 (2.2). Equity amounted to MSEK 41.9 (18.1). The equity/assets ratio was 58.3 percent (54.9).

#### Investments

Gross investments in tangible assets between January and June 2005 amounted to MSEK 1.5 (0.9) 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 2.9 (13.8) and net loss after financial items was MSEK 35.2 (loss: 16.0). Investments amounted to MSEK 1.5 (0.9). The company's liquid funds totaled MSEK 53.5 (1.0).

#### **Personnel**

Personnel expenses for the period amounted to MSEK 20.3 (16.9). Thirteen people were hired during the period. The average number of employees was 30 (22). All personnel were employed on a full-time basis.

#### Number of shares and warrants outstanding

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

	Opening balance	Resigned	Additional	Closing balance
Number of shares Number of options	36,952 5,302	J		36,952 5,302
Of which:				
<ul> <li>stock options</li> </ul>	2,477	-126	44	2,395
- warrants	1,488		82	1,570
<ul> <li>warrants from unit i</li> </ul>	ssue 1,337			1,337

Of the above warrants issued by the Parent Company, as at June 30, 2005, the subsidiary Pharmacall AB held 744 warrants for future allocation and cash-flow hedge of social security fees. For more information about the Orexo employee stock option program, please see note 8 in the company's 2004 Annual Report.

During the period, 126 employee stock options were returned due people who left the company. 44 employee stock options from 2003 years employee stock option programme were allocated to people hired during the period. The allocation regards the category "other personnel". Moreover, allocation of 42 stock options not yet completed has been carried out during the period.

#### Pledged assets and contingent liabilities

During the period the Swedish Tax Agency allowed Orexo a previously considered VAT deduction of about MSEK 2.0. The sale of CPP rights reduced contingent liabilities by MSEK 1.5. Apart from this, no significant change in pledged assets and contingent liabilities occurred during the period.

#### **Balance sheet**

KSEK	June 30,	June 30,	Dec. 31,
	2005	2004	2004
Assets			
Fixed assets			
Intangible fixed assets	3,538	5,525	4,529
Goodwill	o	13,237	О
Tangible fixed assets	2,687	2,516	2,277
Financial fixed assets	2,405	2,405	2,405
Total fixed assets	8,630	23,683	9,211
Current assets			
Inventories	2,524	2,248	1,419
Current receivables	7,153	4,824	6 805
Cash and bank balances	53,539	2,216	84,240
Total current assets	63,216	9,288	92,464
Total assets	71,846	32,971	101,675
Shareholders' equity and liabilities			
Shareholders' equity			
Share capital	3,695	3,428	3,695
Restricted equity	73,365	61,360	94,418
Accumulated losses	-35,198	-46,681	-23,019
Total shareholders' equity Note	41,862	18,107	75,094
Liabilities			
Current liabilities, interest-free	29,984	14,864	26,581
Total liabilities	29,984	14,864	26,581
Total shareholders' equity and liabilities	71,846	32,971	101,675
Pledged assets	2,500	2,500	2,500
Contingent liabilities	50	1,550	1,550

#### Income Statement

	4/1-6/30	4/1-6/30	1/1-6/30	1/1-6/30	1/1-12/31
KSEK	2005	2004	2005	2004	2004
		2004	_000	_007	
Net sales	1,696	12,730	2,926	13,833	86,715
Cost of goods sold	-918	-530	-1,542	-1,053	-1,930
Gross profit	778	12,200	1,384	12,780	84,785
_					
Selling expenses	-565	-603	-656	-1,021	-1,839
Administrative expenses	-9,450	-8,184	-16,516	-11,071	-24,638
Research and development costs	-16,185	-11,328	-28,813	-17,626	-64,398
Other operating revenues	44	10	62	68	672
Other operating expenses	-92	-23	-116	-40	-368
Capital gain from sale of subsidiary	8,865	О	8,865	0	0
Operating loss	-16,605	-7,928	-35,790	-16,910	-5,786
Profit from financial investments					
Interest income	219	28	562	70	695
Interest expense	-4	-10	-4	-11	-79
Other financial expense	0	0	0	0	-10,455
Total profit from financial	215	18	558	59	-9,839
investments					
Tax	0	-1, 156	0	-1, 156	-1,156
Net loss for period	-16,390	-9,066	-35,232	-18,007	-16,781
Province and how before that or OPV		261.40	000 40		
Earnings per share, before dilution, SEK	-443.55	-264.48	-953.45	-525.32	-474.56
Earnings per share, after dilution, SEK  Average number of shares, before dilution	-443.55	-264.48	-953.45	-525.32	-474.56
Average number of shares, perore dilution  Average number of shares, after dilution	36,952	34,278	36,952	34,278	35,361
Number of shares, before dilution	39,490	35,442	39,492	35,476	37,906
Number of shares, after dilution	36,952	34,278	36,952	34,278	36,952
Number of shares, after dilution	39,489	35,353	39,489	35,353	39,497
	4/1-6/30	4/1-6/30	1/1-6/30	1/1-6/30	1/1-12/31
*)	2005	2004	2005	2004	2004
Costs distributed by type of cost (SEK 000s)		2004	2000	_004	
Raw materials and supplies	1,409	1,906	2,650	2,355	2,897
Other external costs	12,760	5,542	23,211	9,653	39,080
Personnel costs	12,319	12,536	20,328	17,428	35,160
Depreciation and write-downs	722	684	1,454	1,375	16,036
Total	27,210	20,668	47,643	30,811	
		_5,555	1/,5~70	00,011	93,173

Cash F	low Sta	atement
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Cash Flow Statement					
	4/1-6/30	4/1-6/30	1/1-6/30	1/1-6/30	1/1-12/31
Amounts in KSEK	2005	2004	2005	2004	2004
On smating a satissition					
Operating activities	46.60=	<b>=</b> 000	a= =aa	16.010	06
Op. res. before interest expense and interest income	-16,605	-7,928	-35,790	-16,910	-5,786
Interest expense	-4	-10	<b>-4</b>	-11	-79
Interest income	220	28	562	70	695
Other financial expenses	0	0	0	0	-10,455
Tax paid	0	-1,156	0	-1,156	-1,156
Adjustment for items not included in cash flow**	-6,504	902	-4,766	1,797	18,879
Cash flow from operating activities	-22,893	-8,164	-39,998	-16,210	2,098
before change in working capital					
Changes in working capital					
Accounts receivables	-179	79	-15	-540	-319
Other current receivables	111	-764	-333	-426	-2 629
Inventories	-591	-308	-1 105	-891	-62
Current liabilities	7,635	7,925	2,877	5,557	16,818
Cash flow from operating activities	-15,917	-1,232	-38,574	-12,510	15,906
Investing activities					
Sale of subsidiary	9,405	0	9,405	0	0
Acquisition of machinery and equipment	-839	-905	-1 532	-912	-1 120
Cash flow after investments	-7,351	-2,137	-30,701	-13,422	14,786
Changes in financing					
New share issue	0	107	0	156	53 972
Cash flow after financing activities	-7,351	-2,030	-30,701	-13,266	68,758
Cash flow for the period	( - 0		0	0 -	0-
Liquid funds at beginning of period	60,890	4,246	84,240	15,482	15,482
Change in liquid funds	-7 <u>35</u> 1	-2 030	-30 701	-13 266	68 758
Liquid funds at end of period	53,539	2,216	53,539	2,216	84,240
**Adjustment for items not included in cash flo	W				
Depreciation and writedowns	722	692	1,454	1,376	16,036
Scrapping	O	0	0	0	20
Estimated costs, employee option program	1,526	210	2,532	421	2,823
Capital gain from sale of subsidiary	-8,865	0	-8,865	0	0
Other	113	0	113	0	0
Total	-6,504	902	-4,766	1,797	18,879
	70 - 1	<i>)</i>	• / / - =	,,,,,	,-,,

### Changes in consolidated shareholders' equity

	4/1-6/30	4/1-6/30	1/1-6/30	1/1-6/30	1/1-12/31
Amounts in SEK 000s	2005	2004	2005	2004	2004
Opening shareholders' equity as per the balance sheet	57,181	26,875	75,094	35,575	35,575
Net loss for the year	-16,390	-9,066	-35,232	-18,007	-16,781
New share issue	0	107	0	156	53 757
Option program	1,071	191	2,000	383	2,543
Amount at close of period	41,862	18,107	41,862	18,107	75,094

Key data	4/1-6/30	4/1-6/30	1/1-6/30	1/1-6/30	1/1-12/31
	2005	2004	2005	2004	2004
Operating margin, %	-979.1	-62.3	-1 223.2	-122.2	-6.6
Profit margin, %	-966.4	-62.1	-1 204.1	-121.8	-18.2
Return on total capital, %	-20.9	-21.2	-40.9	-43.4	-6.7
Return on equity, %	-33.1	-33.1	-60.4	-60.9	-30.3
Return on capital employed, %	-33.1	-28.9	-60.4	-57.0	-9.2
Debt/equity ratio, multiple	0	0	0	0	0
Equity/assets ratio, %	58.3	54.9	58.3	54.9	73.9
Current ratio, %	210.8	62.5	210.8	62.5	347.9
Quick ratio, %	202.4	47.4	202.4	47.4	342.5
Number of shares at end of period	36,952	34,278	36,952	34,278	36,952
Shareholders' equity per share, SEK	1 132.88	528.24	1 132.88	528.24	2 032.20
Number of employees	36	22	36	23	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.

As of January 1, 2005 Orexo prepares its consolidated accounts in compliance with International Financial Reporting Standards (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.

IFRS 1 gives companies the possibility to apply exceptions from complete retroactive application in eleven specific situations where IASB has determined that the benefit of retroactive application does not correspond to its cost. Orexo intends to use the following four exemptions; the other exemptions are not considered to apply to Orexo.

- 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 (Cepep AB) completed before January 1, 2004
- 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. Orexo has decided to apply IAS 39 beginning on January 1, 2005. The transition to IAS 39 "Financial instruments: Recognition and measurement" as of January 1, 2005, had no effect on the Group's earnings or financial position.

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

		Jan. 1, 2004 (transition date)			June 30, 2004			Dec. 31, 2004		
SEK 000s	Not	Swedish	Effect of transition to IFRS	IFRS	Swedish accounting	Effect of transition to IFRS	IFRS	Swedish accounting	Effect of transition to IFRS	IFRS
		rules			rules			rules		
ASSETS Fixed assets										
Intangible fixed assets		6,520		6,520	5,525		5,525	4,529		4,529
Goodwill		13,238		13,238	11,819	1,418	13,237	О		0
Tangible fixed assets		1,984		1,984	2,516		2,516	2,277		2,277
Financial fixed assets		2,405		2,405	2,405		2,405	2,405		2,405
		24,147		24,147	22,265	1,418	23,683	9,211		9,211
Current assets										
Inventories		1,357		1,357	2,248		2,248	1,419		1,419
Current receivables	a	4,166	-307	3,859	5,017	-193	4,824	11,147	-4,342	6,805
Cash and bank balances		15,482		15,482	2,216		2,216	84,240		84,240
		21,005	-307	20,698	9 481	-193	9,288	96,806	-4,342	92,464
Total assets		45,152	-307	44,845	31,746	1,225	32,971	106,017	-4,342	101,675
SHAREHOLDERS' EQUITY										
Equity and reserves attributable to Parent Company's shareholders										
Share capital		3,428		3,428	3,428		3,428	3,695		3,695
Restricted reserves	a	60,063	383	60,446	60,594	766	61,360	97,233	-2,815	94,418
Accumulated loss	a	-27,609	-690	-28,299	-47,140	459	-46,681	-21,492	-1,527	-23,019
Total shareholders' equity		35,882	-307	35,575	16,882	1,225	18,107	79,436	-4,342	75,094
LIABILITIES Current liabilities										
Current liabilities, interest-free		9,270		9,270	14,864		14,864	26,581		26,581
Total liabilities		9,270		9,270	14,864		14,864	26,581		26,581
Total shareholders' equity and liability	ties	45,152	-307	44,845	31,746	1,225	32,971	106,017	-4,342	101,675

	Not	Jan. 1, 2004	June 30, 2004	Dec. 31, 2004
Shareholders' equity according to previously applied principles		35,882	16,882	79,436
Share-based payment	a	-307	-193	-4,342
Goodwill not amortized after	b		1,418	
the transition date	b	_	1,410	
Tax effects of above		-	-	-
Total adjustment of shareholders' equity		-307	1,225	-4,342
Shareholders' equity according to IFRS		35,575	18,107	75,094

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

		April 1, 20	04 – June 30,	2004	Jan. 1, 2004– June 30 2004			2004		
		Swedish	Effect of		Swedish	Effect of		Swedish	Effect of	
SEK ooos	acco	ounting	transition	IFRS	accounting	transition	IFRS	accounting	transition	IFRS
SER GOOS		rules	to IFRS	11165	rules	to IFRS	TI KO	rules	to IFRS	II NO
Net sales		12,730		12,730	13,833		13,833	86,715		86,715
Cost of goods sold		-530		-530	-1,053		-1,053	-1,930		-1,930
Gross profit		12,200		12,200	12,780		12,780	84,785		84,785
Selling expenses	a	-593	-10	-603	-1,001	-20	-1,021	-1,803	-36	-1,839
Administrative expenses	a	-8,132	-52	-8,184	-10,967	-104	-11,071	-24,224	-414	-24,638
Research and development costs	a	-11,965	637	-11,328	-18,899	1,273	-17,626	-64,011	-387	-64,398
Other operating income		10		10	68		68	672		672
Other operating expenses		-23		-23	-40		-40	-368		-368
Operating profit/loss		-8,503	575	-7,928	-18,059	1,149	-16,910	-4,949	-837	-5,786
Interest income		28		28	70		70	695		695
Interest expense		-10		-10	-11		-11	-79		-79
Other financial expenses		0		0				-10,455		-10,455
Loss after financial items		-8,485	575	-7,910	-18,000	1,149	-16,851	-14,788	-837	-15,625
Tax on net loss for the year		-1,156		-1,156	-1,156		-1,156	-1,156		-1,156
Net loss for the year		-9,641	575	-9,066	-19,156	1,149	-18,007	-15,944	-837	-16,781
Earnings per share attributable to Parent Company's shareholders during the period (SEK)										
Parent Company's shareholders during the period (SEK)		091.05		064.49	FF0 94		505.00	450 90		474.76
Parent Company's shareholders during the period (SEK)  - before dilution	c	-281.25		-264.48	-558.84 9 94		-525.32	-450.89 450.89		-474.56
Parent Company's shareholders during the period (SEK)		-281.25 -281.25		-264.48 -264.48	-558.84 -558.84		-525,32 -525,32	-450.89 -450.89		-474.56 -474.56
Parent Company's shareholders during the period (SEK)  - before dilution  - after dilution	c c		Loss before taxes			Loss before taxes		-450.89	Loss before taxes	
Parent Company's shareholders during the period (SEK)  - before dilution	c c	-281.25		-264.48 Net loss	-558.84		-525.32 Net loss	-450.89		-474.56 Net loss for
Parent Company's shareholders during the period (SEK)  - before dilution  - after dilution  Results according to previously apploies	c c	-281.25  Operating-Profit/loss	taxes	-264.48  Net loss for the year	-558.84 Operating- Profit/loss	taxes	-525.32 Net loss For the year	-450.89  Operating-	taxes	-474.56  Net loss for the year
Parent Company's shareholders during the period (SEK)  - before dilution  - after dilution  Results according to previously apploice principles	c c	-281.25  Operating-Profit/loss -8,503	-8,485	Net loss for the year	Operating- Profit/loss	-18,000	-525.32 Net loss For the year	-450.89  Operating- Loss -4,949	-14,788	-474.56  Net loss for the year -15,944

#### a) Share-based payment

-7,928

-7,910

Result according to IFRS

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.

-16,910

-16,851

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 SEK 6,489,000.

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

-15,625

-16,781

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. 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.

#### 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 is 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. 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 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 -16,781 dilution (SEK 000s)

Average number of shares before dilution	35,361
Adjustment for warrants	2,545
Average number of shares after dilution	37,906

According to Swedish accounting rules, a company that calculates earnings per share after dilution after having issued warrants must 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. As in the past, the company has elected to calculate the dilution effect based on the present value of the subscription payment.

#### 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 six-month interim report in accordance with the recommendations issued by the Swedish Institute of Authorised 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.

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Upcoming report dates	
Interim Report July-September 2005	October 11, 2005
Year-end Report for fiscal year 2005	no later than February 28, 2006