# Interim report January-June 2014

*Unless otherwise stated in this report, all data refers to the Group. Figures in parentheses relate to the corresponding period in 2013.*

## Positive results from clinical trials with Zubsolv®

**Second quarter 2014**

- Total net revenues amounted to MSEK 117.3 (69.0). Revenues from launched products, excluding one-off milestones, amounted to MSEK 115.6 (68.6). Revenue recognition approach for Zubsolv changed from the second quarter.
- Earnings after tax were MSEK -50.2 (-115.7).
- Earnings per share were SEK -1.58 (-4.00).
- Cash flow from operating activities amounted to MSEK -228.2 (84.4).
- Orexo completed issue and listing of a MSEK 500 unsecured bond.
- inVentiv Health selected as new partner for the commercialization of Zubsolv in the US.
- Positive results from two phase 3 clinical trials assessing Zubsolv for induction of buprenorphine maintenance therapy.
- Top-line data from a phase 3 clinical trial demonstrated that Zubsolv is as effective as Suboxone® film in the treatment of opioid dependence.
- Orexo commenced patent infringement litigation against Actavis.

**First half 2014**

- Total net revenues amounted to MSEK 219.1 (208.8). Revenues from launched products, excluding one-off milestones, amounted to MSEK 217.4 (140.7).
- Earnings after tax were MSEK -71.4 (-88.2).
- Earnings per share were SEK -2.24 (-3.05).
- Cash flow from operating activities amounted to MSEK -328.0 (79.4).
- Cash and cash equivalents amounted to MSEK 110.6 (300.7).
- Reimbursement agreement for Zubsolv signed with UnitedHealth Group and OptumRx.

| *MSEK* | **2014** | **2013** | **2014** | **2013** | **2013** |
|---|---|---|---|---|---|
| | **Apr-Jun** | **Apr-Jun** | **Jan-Jun** | **Jan-Jun** | **Jan-Dec** |
| Net revenues | 117.3 | 69.0 | 219.1 | 208.8 | 429.4 |
| Revenues from launched products | 115.6 | 68.6 | 217.4 | 205.0 | 421.6 |
| EBIT | -38.4 | -112.7 | -54.7 | -82.4 | -139.7 |
| EBITDA | -35.9 | -67.5 | -49.8 | -36.0 | -89.1 |
| Earnings after tax | -50.2 | -115.7 | -71.4 | -88.2 | -154.9 |
| Earnings per share, SEK | -1.58 | -4.00 | -2.24 | -3.05 | -5.16 |
| Cash flow from operating activities | -228.2 | 84.4 | -328.0 | 79.4 | -265.8 |
| Cash and cash equivalents | 110.6 | 300.7 | 110.6 | 300.7 | 105.6 |

**Teleconference**
CEO Nikolaj Sørensen and CFO Henrik Juuel will present the report at a teleconference today at 1:00pm CET. Presentation slides are available via the link and on the website.
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## CEO's comments

The second quarter of 2014 has been another eventful quarter for Orexo. In May, we issued a MSEK 500 non-secured corporate bond, fully subscribed a few days after the announcement, showing confidence from investors in our business. Later the same month, we announced a new commercialization partner, and finally in June, we finalized two clinical trials (ISTART and 007) with positive results, further enhancing our ability to differentiate Zubsolv from competitors. In parallel, Zubsolv® sales volume (tablets, demand) has grown by nearly 20% from the first quarter and Zubsolv has started to gain market share again.

The major achievement during the quarter was the finalization and positive outcome of two of our clinical trials with Zubsolv. Short term, the studies will provide convincing scientific evidence of the equivalent efficacy of Zubsolv, despite a 29% lower dose of buprenorphine, compared to the leading competitor in the market. This has been a concern raised by patients and prescribers during the launch phase. Long term, the positive results of the combined ISTART and 007 studies in the induction phase of treatment for opioid dependence, can provide Zubsolv with additional differentiation from generic alternatives. We plan to submit our application for an expansion of the Zubsolv label to include induction during the fourth quarter of 2014. The two clinical trials, are, to our knowledge, the largest ever made in this disease area and underscores the commitment that Orexo has to advance the quality of treatment of patients suffering from opioid dependence, based on science, research and development.

In May, we announced a new partnership with inVentiv Health for our commercial field activities. With the new partnership, we take the full leadership of the commercialization and all sales managers are employed by Orexo. The change will enhance our agility and decisiveness in our commercial efforts in the launch of Zubsolv. I am pleased to announce that all sales representatives selected by Orexo, who were offered a position, have decided to move to the new contract. This is an excellent evidence of the commitment to and belief in the opportunities for Zubsolv, from those who are meeting customers every day in the field.

We look forward to the second half of 2014, which will jump start with the implementation of the exclusive agreement with UnitedHealth Group on July 1, expected to provide an immediate positive impact on Zubsolv revenues. I personally spend a considerable amount of time in the US, meeting prescribers in their offices. The feedback I receive from prescribers who have made Zubsolv their preferred choice, makes me even more convinced of the market potential of Zubsolv and the value it can bring to patients with the advanced sublingual tablet formulation, offering patients a choice of treatment with a fast dissolve time, a pleasant menthol taste and with a 29% lower dose compared to the leading competitors.

Nikolaj Sørensen
President and CEO

# Operations

## Launched products

### Zubsolv® – treatment of opioid dependence

The market for buprenorphine/naloxone products continues to demonstrate the growth exhibited during the first quarter and has grown nearly 10% in total prescription volume YTD June 2014 vs the prior year. Significant inhibitors of additional growth are the limited number of physicians with a DATA 2000 waiver, allowing them to prescribe buprenorphine for opioid dependence, and the cap on the number of patients each DATA2000 waived physician can treat with buprenorphine for opioid dependence. The focus on solving the lack of access to opioid dependence treatment in the US has increased substantially. Recently, a U.S. Senate Forum held on June 18 concluded that the current cap in the number of patients each physician can treat should be increased or eliminated[1].

Zubsolv sales volume, measured in number of prescription tablets, grew by 20% during the second quarter 2014 compared to the first quarter 2014 and the Zubsolv TRx market share has increased, especially during June, to 2.43% the last week of June compared to 2% entering the quarter. The competition is significant and there is inertia in the market slowing the switch to a new product. The 29% lower buprenorphine dose of Zubsolv creates anxiety among some patients about the equivalence of the treatment to their prior therapy. With the results from the two studies, the Induction, STabilization, Adherence and Retention Trial (ISTART, Study OX219-006) and Study OX219-007 (Induction), Orexo has now established strong scientific evidence of the equivalent effect of Zubsolv in both induction and in a head-to-head comparison with the leading competitor in maintenance treatment. In total, the two studies included 1,068 opioid dependent patients, of which the ISTART study accounted for 70% of the patients, making it the largest clinical trial conducted to date in this disease area. The data from the clinical trials, and short term especially the ISTART study, will be a significant contributor in the commercial messaging and aspiration to position Orexo and Zubsolv as leaders in advancing the treatment of opioid dependence.

The primary endpoint of the ISTART study was retention in treatment at Day 15 with Zubsolv and Suboxone film. The study showed that there was no difference in retention in treatment at Day 15 [Zubsolv arm: 83% (273/329); Suboxone film arm: 82.5% (269/326)]. As previously announced, an additional co-primary endpoint assessed Zubsolv as a treatment for induction of buprenorphine maintenance therapy compared to generic buprenorphine monotherapy. There was no difference in retention at Day 3 [Zubsolv arm: 93.3% (309/329); generic buprenorphine arm: 92.6% (302/326)] in the per protocol set. Similar improvements for both groups were observed in Clinical Opiate Withdrawal Scale (COWS), Subjective Opiate Withdrawal Scale (SOWS), and opioid cravings VAS total scores. Physicians and patients, using the Clinical Global Impression (CGI-I) and Patient Global Impression (PGI-I) Improvement scales, reported that both treatments resulted in an average score of “much improved” from baseline at study end.

Combined data from the ISTART and Study OX219-007, in 1,068 opioid dependent patients, showed that over 90% of patients treated with Zubsolv were retained in treatment at Day 3 using a 29% lower dose of buprenorphine[2]. The two studies had similar structure during the three-day induction phase to enable a combined analysis of the induction results. These results enable

[1] Source: http://www.levin.senate.gov/newsroom/press/release/at-forum-levin-and-hatch-hail-success-of-drug-to-combat-heroin/opioid-addiction-and-discuss-methods-to-expand-access/?section=alltypes

[2] Source: Detailed data is published in Orexo press release, June 23, 2014, available on www.orexo.com

Orexo to pursue a regulatory submission of an expanded label of Zubsolv to include initiation of treatment in the US. The submission of the application is planned for the fourth quarter of 2014.

The potential expansion of the label of Zubsolv to include induction can be an enabler for Orexo to encourage DATA 2000 waivered physicians with low or no prescription activity with buprenorphine/naloxone products today to initiate and expand prescribing of buprenorphine/naloxone products for opioid dependent patients post FDA approval. Orexo's market based survey among waivered physicians found that 62%[3] indicated a lack of training and education as the main barrier to initiating therapy for opioid dependent patients. The main difficulty was found to be the induction phase of the treatment and with an expanded label Orexo could take an active role in education and information about how to optimally initiate treatment with Zubsolv. Of the 25,388[4] DATA 2000 waivered prescribers, only about 5,800 frequently prescribe buprenorphine/naloxone products today. Increasing the share of active prescribers offers a significant growth opportunity for Zubsolv and improved access to treatment for patients.

In addition to the two finalized studies, all patients from these studies have been offered the chance to enter a six-month Zubsolv safety and efficacy study, expected to be finalized during the autumn with results available early 2015.

Improving Zubsolv's market access position continues to be a main focus for Orexo and as previously announced, Orexo reached an agreement with UnitedHealth Group (UHG) where Zubsolv was moved from non-covered to equal coverage at the beginning of April, and will progress to an exclusive position for patients in highly controlled commercial plans effective July 1. Some of the growth in Q2 comes from UHG, but primarily from new patients, as physicians manage some administrative hurdles of switching patients prior to July 1. UHG accounts for nearly 4% of the market and the majority of the patients are in the highly controlled plans covered by the exclusive agreement between UHG and Orexo. During the quarter Orexo has continued to improve Zubsolv's market access position with several regional plans (e.g. Excellus BcBS in NY and Harvard Pilgrim Medicare Part D in Massachusetts), and additional improvements are in the late stages of negotiation.

[3] Source: Orexo primary research (conducted via 9 telephone interviews and 81 Internet surveys covering a total of 90 Data 2000 Certified physicians that have treated no or a limited number of opioid dependent patients with Buprenorphine / Naloxone combination)

[4] Source: http://www.levin.senate.gov/newsroom/press/release/at-forum-sen-levin-hails-success-of-drug-to-combat-heroin/opioid-addiction-and-discusses-methods-to-expand-access/?section=alltypes

## Abstral® and Edluar®

Due to the early timing of the Q2 report, Orexo has not yet received final data for the second quarter sales for Abstral and Edluar from our partners and data included in this report is estimated based on the sales in Q1 and prognosis shared by our partners.

**Abstral**
Sales of Abstral in the EU continued with strong growth of 25% in the first quarter, and total sales in the EU for the quarter exceeded MEUR 15. With the current trend Orexo is likely to receive royalties on sales exceeding MEUR 42.5 from late Q3, and for the full fourth quarter of 2014 from our partner Prostrakan Group plc.

The US market for Abstral i.e. fentanyl based products for breakthrough pain, continues to grow. Net sales of Abstral increased by 65% in Q1 2014 vs Q4 in 2013, and reached MUSD 2.2. Orexo's partner in the US, Galena Biopharma Inc., has indicated full year sales in the range of MUSD 11-15 in 2014. Galena Biopharma has initiated a 1000 patient registry study (RELIEF) to evaluate patient experience with Abstral for breakthrough cancer pain assessing patient-reported data using quality-of-life and pain measurement tools.

The launch of Abstral in Japan has been successful. Abstral was second to launch, about 3 months post the launch of a competing rapid-acting fentanyl product. The Japanese market for treatment of break through cancer pain with rapid acting fentanyl is still in the early stages. Hence our commercial partner Kyowa Hakko Kirin is now focusing on growing the market.

**Edluar**
The total sales of Edluar, commercialized by Meda AB, continued to increase in 2013. Sales increased by 66 %, primarily from the strong sales increase in Canada and the launch in Europe. Sales in the US also showed strong growth.

## Kibion – diagnosis of Helicobacter Pylori

Kibion´s consolidation of markets in the Middle East and North Africa and committed investments from new distributors of the commercialization of Kibion´s products are progressing as planned. Product registrations for key markets in the Middle East Region are expected within the year. By securing product access in key markets through registrations, Kibion will be able to supply an increased number of patients in a region which has a high prevalence of Helicobacter pylori infection.
Kibion's sales for the period April-June 2014 were MSEK 12.1 (8.6) and for the period January-June 2014 MSEK 19.5 (19.1). Sales growth drivers for the period were key markets in the Middle East region, mainly consisting of increased sales of Heliprobe System®. Launch preparations in Latin America and to enter Colombia with Heliprobe System® are ongoing and sales start is expected during the year.

## Development programs

**OX51 – prevention of acute episodes of intense pain**
OX51 is a new sublingual formulation containing alfentanil. The project has been developed to meet the rapidly growing demand for effective pain relief during short surgical and invasive procedures.
A dose-finding study was completed in June 2013 on patients undergoing prostate biopsies. The primary aim of the study to demonstrate an anesthetic effect in connection with the procedure was achieved. The placebo-controlled study, in which three different sublingual doses of OX51 and placebo were studied, showed a statistically significant dose response with regard to maximum pain experienced during the procedure. Treatment with OX51 was safe and well tolerated in all dose groups. Furthermore, OX51 did not display any sedative effect or drowsiness compared with placebo.
Orexo has decided to wait with further development due to the current business focus and priority on the Zubsolv launch and its life cycle management.

## Collaboration projects

**OX-MPI – PGE2-inhibition (Prostaglandin E2)**
The aim is to develop a completely new pharmaceutical class based on Orexo's prostaglandin research. Boehringer Ingelheim and Orexo are currently evaluating the most feasible opportunities for PGE2-synthase inhibition. The evaluation will be completed during the third quarter. The compound is associated with an intangible asset originating from Orexo's acquisition of Biolipox in 2007.

**OX-CLI - respiratory tract diseases**
Orexo entered into a collaboration agreement with AstraZeneca in January 2013 regarding OX-CLI, a preclinical program for potential new treatment of respiratory tract diseases. Under the agreement AstraZeneca gains the rights to perform extensive preclinical research and evaluation of substances in Orexo's OX-CLI program. AstraZeneca also has an option to acquire all substances linked to the program. Transfer and a licensing agreement will then be agreed on by the parties, whereby Orexo will receive milestone payments during the development phase and royalty payments based on future revenues. AstraZeneca is responsible for all development costs for the project.

## The interim period January-June in figures

### Revenues

#### Launched products

Total revenues from Orexo's launched products amounted to MSEK 115.6 (68.6) during the period April-June 2014, an increase of 69 percent compared with the same period the previous year. The increase was driven by Zubsolv, which was not on the market the same period last year. For the period January-June 2014 revenues amounted to MSEK 217.4 (205.0), with Zubsolv revenue growth more than off-setting an Abstral milestone payment in the first quarter of 2013.

Orexo decided to change the revenue recognition approach for Zubsolv from the second quarter of 2014. Previously only revenues corresponding to patient prescriptions were recognized as there was very little experience of Zubsolv in the market and a steady wholesaler purchase pattern was not yet established. During the first six months of 2014 Orexo has seen wholesaler purchases stabilizing with weekly reordering and payments. The original pipeline fill supplied to wholesalers at launch has been consumed by now and wholesalers currently hold around two weeks of demand of inventory. The impact of the change in accounting approach was approximately MUSD 2 on net revenue in the second quarter. When converting invoiced sales to wholesaler's net revenue, Orexo is applying a conservative return provision policy with return rates significantly above experienced levels so far. This policy will be continuously updated based on return experience.

Total Abstral royalties and milestone payments amounted to MSEK 52.4 (57.9) for the period April-June 2014 and to MSEK 110.3 (182.0) for the period January-June 2014. The decrease for the period April-June 2014 is explained by the fixed and non-conditional element which is decreasing year by year whereas the underlying variable royalty element keeps increasing as sales of Abstral increase. The period January-June 2013 included a MUSD 10 upfront payment from Galena Biopharma, Inc, as part of the payment for acquiring the rights to Abstral in the US.

Royalty revenues from Edluar® amounted to MSEK 3.6 (2.1) for the period April-June 2014 and to MSEK 7.5 (3.9) for the period January-June 2014. Royalties for Abstral and Edluar for the period April-June 2014 are based on estimated sales of the products as final numbers were not available from our partners.
Kibion's sales for the period April-June 2014 were MSEK 12.1 (8.6) and for the period January-June 2014 MSEK 19.5 (19.1). Sales growth drivers for the period were key markets in the Middle East region, mainly consisting of increased sales of Heliprobe System®. Launch preparations in Latin America and to enter Colombia with Heliprobe System® are ongoing and sales start is expected during the year.

#### Revenues related to development projects

There were no revenues related to development projects during the period January-June 2014. During the first half of 2013, there were revenues related to approval of Abstral in Japan amounting to MSEK 3.8.

#### Other revenues

During the period April-June 2014, Orexo's subsidiary Biolipox received a minor milestone payment in the form of shares in the company Aquinox Pharmaceuticals.

## Total revenues

Total revenues during the period April-June 2014 amounted to MSEK 117.3 (69.0) MSEK, an increase of 70 percent compared with the same period the previous year, driven by Zubsolv. For the period January-June 2014 total revenues amounted to MSEK 219.1 (208.8).

## Total net revenues were distributed as follows:

| *MSEK* | Apr-Jun 2014 | Apr-Jun 2013 | Jan-Jun 2014 | Jan-Jun 2013 | Jan-Dec 2013 |
|---|---|---|---|---|---|
| Abstral royalties | 52.4 | 57.9 | 110.3 | 117.7 | 246.0 |
| Milestone payment Abstral | - | - | - | 64.3 | 110.8 |
| Edluar royalties | 3.6 | 2.1 | 7.5 | 3.9 | 8.7 |
| Zubsolv | 47.5 | - | 80.1 | - | 7.3 |
| Kibion | 12.1 | 8.6 | 19.5 | 19.1 | 48.8 |
| ***Total revenue from launched products*** | ***115.6*** | ***68.6*** | ***217.4*** | ***205.0*** | ***421.6*** |
| Partner-financed R&D costs | - | 0.4 | - | 2.2 | 6.2 |
| Licensing revenue for development projects | - | - | - | 1.6 | 1.6 |
| Other revenues | 1.7 | - | 1.7 | - | - |
| **Total** | **117.3** | **69.0** | **219.1** | **208.8** | **429.4** |

## Costs and earnings

In this section, all references to future cost and spend levels are subject to changes of plan and the occurrence of unforeseen events.

*Cost of goods sold*

The cost of goods sold amounted to MSEK 24.8 (7.1) for the period April-June 2014 and to MSEK 41.6 (14.0) for the period January-June 2014.

*Selling expenses*

Selling expenses amounted to MSEK 55.1 (21.6) for the period April-June 2014. The increase was primarily driven by the commercialization of Zubsolv® in the US. During the second quarter Orexo entered into a new collaboration agreement with inVentiv Health for the commercialization of Zubsolv in the US. This new partnership is effective from July 1 and the second quarter selling expenses include full field force cost for the second quarter to the previous partner plus limited transition cost. The second quarter selling expense level is expected to remain relatively unchanged in the period July-December 2014.
Selling expenses for the period January-June 2014 amounted to MSEK 84.6 (40.5).

*Administrative expenses*

Administrative expenses for the period April-June 2014 amounted to MSEK 27.7 (25.0). Quarterly administrative expenses for the period July-December 2014 are expected to be slightly higher than for the period April- June 2014 due to an expected increase in legal expenses. For the period January-June 2014 the administrative expenses amounted to MSEK 52.5 (59.6).

*Research and development costs*

For the period April-June 2014, research and development costs amounted to MSEK 50.5 (82.1). The costs are attributable to clinical studies and other life cycle management activities in the Zubsolv program. During the second quarter of 2014, clinical studies were capitalized in the amount of MSEK 23.2, which means that the total research and development spend for the period April-June 2014 amounted to MSEK 73.3.

The quarterly research and development costs for the period July-December 2014 are expected to stay approximately at the same level as for the period April-June 2014. However the total spend will decrease significantly as capitalization of trial spend will be reduced with the finalization of the ISTART and 007 trials. For the period January-June 2014 R&D costs amounted to MSEK 98.3 (128.7) and the R&D spend amounted to MSEK 160.3.

*Costs for long-term incentive program*

The Group's total costs for employee stock option programs during the period April-June 2014 amounted to MSEK -1.3 (1.7). The negative costs are due to reduced provisions for social security fees due to the development of the Orexo share price during the period. For the period January-June 2014 the costs amounted to MSEK -7.0 (4.3).

*Other income and expenses*

Other income and expenses amounted to MSEK 2.4 (-45.9) during the period April-June 2014 and to MSEK 3.2 (-48.4) for the period January-June 2014. Other income and expenses primarily comprised exchange-rate gains/losses. The period April-June 2013 included an impairment charge of MSEK 43.9 related to the OX-NLA project

*Depreciation and amortization*

Depreciation and amortization amounted to MSEK 2.5 (1.2) for the period April-June 2014 and to MSEK 4.9 (2.5) for the period January-June.

*Net financial items*
Net financial items for the period April-June 2014 amounted to MSEK -9.8 (-3.0) and include a non-recurring and non-cash exchange rate impact of MSEK -4.4 related to an older receivable purchase agreement that was finally settled during the period. For the period January-June 2014 net financial items amounted to MSEK -13.7 (-5.8).

*Earnings*
Operating earnings amounted to MSEK -38.4 (-112.7) for the period April-June 2014 and to MSEK -54.7 (-82.4) for the period January-June 2014.

## Cash-flow and financial position

At June 30, 2014, cash and cash equivalents amounted to MSEK 110.6 (300.7) and interest-bearing liabilities to MSEK 496.0 (116.9).

Cash flow from operating activities amounted to MSEK -228.2 (84.4) for the period April-June 2014 and to MSEK -328.0 (79.4) for the period January-June 2014. Cash flow from financing activities amounted to MSEK 334.5 (-0.4) for the period April–June 2014 and includes the proceeds from the MSEK 500 bond issue and repayment of bank facilities amounting to MSEK 165.

Shareholders' equity at June 30, 2014 was MSEK 90.5 (102.5). The equity/assets ratio was 10 (17) percent. The royalty payment in accordance with the Abstral agreement, which has been received but not yet recognized as revenue, has affected the equity/assets ratio negatively by approximately 14 percentage points.

During the period April-June 2014, Orexo issued a 4-year MSEK 500 unsecured bond. The bond loan will run with a variable interest rate of Stibor 3m + 4.00% and will have a total framework amount of SEK 1 billion. The bond is listed on NASDAQ OMX Stockholm. Proceeds were used to eliminate existing bank loans during the period and the remaining proceeds will be used to fund the continued Zubsolv commercialization.

Orexo owns 1,121,124 own shares, bought back in 2012.

## Investments in fixed assets

Gross investments in tangible and intangible fixed assets amounted to MSEK 25.0 (3.9) for the period April-June 2014. The increase in investments comes mainly from the capitalization of selected clinical trials during the period in the amount of MSEK 23.2. For the period January-June 2014 gross investments amounted to MSEK 65.5 (9.0).

## Parent Company

Net revenues for the period January-June 2014 amounted to MSEK 136.0 (189.8). Earnings after financial items were MSEK -79.3 (-43.7). Investments amounted to MSEK 65.2 (8.5). As of June 30, 2014, cash and cash equivalents in the Parent Company amounted to MSEK 80.3 (252.2).

## Risks and uncertainty factors

Significant risks and uncertainties are presented in the Annual Report for 2013. The overall risk has decreased since the approval of Zubsolv. However, the launch of Zubsolv in the US will entail risk exposure of a more operational nature.

## Future reporting dates

| | |
|---|---|
| Interim report, January – September 2014 | October 22, |
| Year-end report for the 2014 financial year | January 29, |

Interim reports are covered in a conference call on the date of publication. Details on how to access the calls are provided in each report and on Orexo's website.

The company's auditors have not reviewed this interim report.

# Assurance by the Board of Directors

The Board of Directors and the President give their assurance that the six-month report provides a fair and accurate view of the Company's and the Group's operations, financial position and earnings and describes the significant risks and uncertainties facing the company and the companies included in the Group.

Uppsala, July 11, 2014

Orexo AB (publ)

| | | |
|---|---|---|
| Martin Nicklasson<br>Chairman of the Board | Raymond Hill<br>Board member | Staffan Lindstrand<br>Board member |
| Kristina Schauman<br>Board member | Michael Shalmi<br>Board member | |

Nikolaj Sørensen
President and CEO

## Consolidated statement of operations

| MSEK | Notes | 2014 Apr-Jun | 2013 Apr-Jun | 2014 Jan-Jun | 2013 Jan-Jun | 2013 Jan-Dec |
|---|---|---|---|---|---|---|
| Net revenues | | 117.3 | 69.0 | 219.1 | 208.8 | 429.4 |
| Cost of goods sold | 2 | -24.8 | -7.1 | -41.6 | -14.0 | -29.3 |
| **Gross profit** | | **92.5** | **61.9** | **177.6** | **194.8** | **400.1** |
| Selling expenses | 2 | -55.1 | -21.6 | -84.6 | -40.5 | -125.1 |
| Administrative expenses | 2 | -27.7 | -25.0 | -52.5 | -59.6 | -126.4 |
| Research and development costs | 2 | -50.5 | -82.1 | -98.3 | -128.7 | -238.2 |
| Other operating income and expenses | 2 | 2.4 | -45.9 | 3.2 | -48.4 | -50.1 |
| **Operating earnings** | | **-38.4** | **-112.7** | **-54.7** | **-82.4** | **-139.7** |
| Net financial items | | -9.8 | -3.0 | -13.7 | -5.8 | -13.7 |
| **Earnings before tax** | | **-48.2** | **-115.7** | **-68.4** | **-88.2** | **-153.4** |
| Tax | | -2.0 | - | -3.0 | - | -1.5 |
| **Net earnings for the period**[1)] | | **-50.2** | **-115.7** | **-71.4** | **-88.2** | **-154.9** |

## Consolidated statement of comprehensive income

| MSEK | 2014 Apr-Jun | 2013 Apr-Jun | 2014 Jan-Apr | 2013 Jan-Apr | 2013 Jan-Dec |
|---|---|---|---|---|---|
| **Earnings for the period** | **-50.2** | **-115.7** | **-71.4** | **-88.2** | **-154.9** |
| **Other comprehensive income** | | | | | |
| *Items that may subsequently be reversed to the statement of operations:* | | | | | |
| Cash flow hedge | -5.7 | -22.2 | -5.7 | -5.9 | -8.7 |
| Exchange-rate differences | -1.2 | 2.2 | -1.1 | 1.3 | -1.9 |
| **Other comprehensive earnings for the period, net after tax** | **-6.9** | **-20.0** | **-6.8** | **-4.6** | **-10.6** |
| **Total comprehensive earnings for the period** [1)] | **-57.1** | **-135.7** | **-78.2** | **-92.8** | **-165.5** |
| Earnings per share, before dilution, SEK | -1.58 | -3.05 | -2.24 | -4.00 | -5.16 |
| Earnings per share, after dilution, SEK | -1.58 | -3.05 | -2.24 | -4.00 | -5.16 |

[1)] *All equity and earnings for the respective period are attributable to the Parent Company's shareholders. There are no non-controlling interests.*

## Consolidated balance sheet

| MSEK | Notes | 2014 June 30 | 2013 June 30 | 2013 Dec 31 |
|---|---|---|---|---|
| **ASSETS** | | | | |
| **Fixed assets** | | | | |
| Tangible fixed assets | | 31.3 | 33.3 | 33.3 |
| Goodwill | | 26.7 | 26.1 | 26.4 |
| Acquired research and development | | 62.3 | 62.3 | 62.4 |
| Other intangible fixed assets | | 167.8 | 11.4 | 106.0 |
| Financial assets | | 1.2 | 10.9 | - |
| **Total fixed assets** | | **289.3** | **144.0** | **228.0** |
| **Current assets** | | | | |
| Inventories | | 435.1 | 116.1 | 383.4 |
| Accounts receivable and other receivables | | 80.1 | 30.9 | 55.2 |
| Cash and cash equivalents | | 110.6 | 300.7 | 105.6 |
| **Total current assets** | | **625.8** | **447.7** | **544.3** |
| **Total assets** | | **915.1** | **591.7** | **772.3** |
| **SHAREHOLDERS' EQUITY AND LIABILITIES** | | | | |
| **Total shareholders' equity** | 3 | **90.5** | **102.5** | **161.5** |
| **Long-term liabilities** | | | | |
| Provisions | | 9.4 | 5.9 | 9.6 |
| Long-term liabilities, non-interest bearing | | - | 4.2 | - |
| Long-term liabilities, interest bearing | | 493.6 | 105.7 | 104.1 |
| Deferred tax liability | | 0.5 | 2.4 | - |
| **Total long-term liabilities** | | **503.5** | **118.2** | **113.7** |
| **Current liabilities** | | | | |
| Current liabilities, non-interest bearing | | 318.7 | 359.8 | 360.1 |
| Current liabilities, interest bearing | | 2.4 | 11.2 | 137.0 |
| **Total current liabilities** | | **321.1** | **371.0** | **497.1** |
| **Total liabilities** | | **824.6** | **489.2** | **610.8** |
| **Total shareholders' equity and liabilities** | | **915.1** | **591.7** | **772.3** |

## Consolidated changes in shareholders' equity

| MSEK | 2014 June 30 | 2013 June 30 | 2013 Dec 31 |
|---|---|---|---|
| **Opening balance, shareholders' equity** | **161.5** | **191.2** | **191.2** |
| Total comprehensive earnings for the period | -78.2 | -92.8 | -165.5 |
| Employee stock options, vested amount | 5.9 | 1.9 | 3.5 |
| Buyback of shares | - | - | - |
| New share issues | 1.3 | 2.2 | 19.4 |
| Conversion of convertible bonds | - | - | 112.9 |
| **Closing balance, shareholders' equity** | **90.5** | **102.5** | **161.5** |

# Consolidated cash-flow statements

| MSEK | Notes | 2014 Apr-Jun | 2013 Apr-Jun | 2014 Jan-Jun | 2013 Jan-Jun | 2013 Jan-Dec |
|---|---|---|---|---|---|---|
| Operating earnings | | -38.4 | -112.7 | -54.7 | -82.4 | -139.7 |
| Financial income and expenses | | -12.5 | -2.2 | -16.6 | -4.2 | -11.6 |
| Adjustment for non-cash items | 4 | 1.5 | 46.0 | -1.7 | 49.1 | 86.9 |
| **Cash flow from operating activities before changes in working capital** | | **-49.4** | **-68.9** | **-73.0** | **-37.5** | **-64.4** |
| **Changes in working capital** | | **-178.8** | **153.3** | **-255.0** | **116.9** | **-201.4** |
| **Cash flow from operating activities** | | **-228.2** | **84.4** | **-328.0** | **79.4** | **-265.8** |
| Acquisition of tangible and intangible fixed assets | | -25.0 | -3.9 | -65.5 | -9.0 | -107.5 |
| Sale of machinery and equipment | | - | - | - | 0.1 | - |
| **Cash flow from investing activities** | | **-25.0** | **-3.9** | **-65.5** | **-8.9** | **-107.5** |
| New share issue | | 0.1 | 0.1 | 1.3 | 2.2 | 19.4 |
| Change in loans | | 334.4 | -0.5 | 398.8 | -1.1 | 234.2 |
| **Cash flow from financing activities** | | **334.5** | **-0.4** | **400.1** | **1.1** | **253.6** |
| **Cash flow for the period** | | **81.3** | **80.1** | **6.6** | **71.6** | **-119.7** |
| **Cash and cash equivalents at the beginning of the period** | | **30.7** | **218.9** | **105.6** | **228.1** | **228.1** |
| Exchange-rate differences in cash and cash equivalents | | -1.4 | 1.7 | -1.6 | 1.0 | -2.8 |
| Changes in cash and cash equivalents | | 81.3 | 80.1 | 6.6 | 71.6 | -119.7 |
| **Cash and cash equivalents at the end of the period** | | **110.6** | **300.7** | **110.6** | **300.7** | **105.6** |

## Key figures

| | 2014 Apr-Jun | 2013 Apr-Jun | 2014 Jan-Jun | 2013 Jan-Jun | 2013 Jan-Dec |
|---|---|---|---|---|---|
| Operating margin, % | -33 | -163 | -25 | -39 | -32 |
| Return on equity, % | -42 | -62 | -55 | -47 | -88 |
| Net debt, MSEK | -385 | -184 | -385 | -184 | -135 |
| Debt/equity ratio, % | 548 | 114 | 548 | 114 | 154 |
| Equity/assets ratio, % | 10 | 17 | 10 | 17 | 21 |
| Number of shares, before dilution | 31,823,859 | 28,891,208 | 31,823,859 | 28,891,208 | 31,790,784 |
| Number of shares, after dilution | 32,671,750 | 31,878,141 | 32,671,750 | 31,878,141 | 32,976,554 |
| Earnings per share, before dilution, SEK | -1.58 | -4.00 | -2.24 | -3.05 | -5.16 |
| Earnings per share, after dilution, SEK | -1.58 | -4.00 | -2.24 | -3.05 | -5.16 |
| Number of employees at the end of the period | 112 | 93 | 112 | 93 | 108 |
| Shareholders' equity, KSEK | 90,543 | 102,507 | 90,543 | 102,507 | 161,459 |
| Capital employed, KSEK | 586,070 | 219,338 | 586,070 | 219,338 | 402,533 |

*Definitions of key figures are presented on the final page of this report.*

## Parent Company statement of operations

| MSEK | Notes | 2014 Apr-Jun | 2013 Apr-Jun | 2014 Jan-Jun | 2013 Jan-Jun | 2013 Jan-Dec |
|---|---|---|---|---|---|---|
| Net revenues | | 73.1 | 60.4 | 136.0 | 189.8 | 452.3 |
| Cost of goods sold | | -15.5 | -1.7 | -19.8 | -3.4 | -91.4 |
| **Gross profit** | | **57.6** | **58.7** | **116.2** | **186.4** | **360.9** |
| Selling expenses | | -43.9 | -17.6 | -67.4 | -32.5 | -45.1 |
| Administrative expenses | | -19.2 | -25.8 | -35.6 | -59.4 | -110.0 |
| Research and development costs | | -42.6 | -81.2 | -82.9 | -126.2 | -228.3 |
| Other operating income and expenses | | 2.3 | -1.5 | 3.4 | -3.8 | -5.4 |
| **Operating earnings** | | **-45.8** | **-67.4** | **-66.3** | **-35.5** | **-27.9** |
| Interest income and expenses | | -4.8 | -3.1 | -6.7 | -6.0 | -10.1 |
| Impairment of shares in subsidiaries | | - | -0.9 | - | -2.2 | -2.2 |
| Other financial expenses | | -4.4 | - | -6.3 | - | -4.1 |
| **Net financial items** | | **-9.2** | **-4.0** | **-13.0** | **-8.2** | **-16.4** |
| **Earnings before tax** | | **-55.0** | **-71.4** | **-79.3** | **-43.7** | **-44.3** |
| Tax | | - | - | - | - | -1.5 |
| **Earnings for the period** | | **-55.0** | **-71.4** | **-79.3** | **-43.7** | **-45.8** |

## Parent Company balance sheet

| MSEK | Notes | 2014 Jun 30 | 2013 Jun 30 | 2013 Dec 31 |
|---|---|---|---|---|
| **ASSETS** | | | | |
| **Fixed assets** | | | | |
| Tangible and intangible fixed assets | | 196.9 | 43.9 | 137.4 |
| Shares in subsidiaries | | 202.2 | 202.2 | 202.2 |
| **Total fixed assets** | | **399.1** | **246.1** | **339.6** |
| **Current assets** | | | | |
| Inventories | | 348.7 | 103.8 | 303.3 |
| Accounts receivable and other receivables | | 179.9 | 48.1 | 179.5 |
| Cash and bank balances | | 80.3 | 252.2 | 48.7 |
| **Total current assets** | | **260.2** | **404.1** | **531.5** |
| **Total assets** | | **1 008.0** | **650.2** | **871.1** |
| **SHAREHOLDERS' EQUITY. PROVISIONS AND LIABILITIES** | | | | |
| **Shareholders' equity** | | **145.2** | **87.7** | **217.4** |
| **Long-term liabilities** | | **500.1** | **106.4** | **109.7** |
| **Current liabilities** | | **362.7** | **456.1** | **544.0** |
| **Total liabilities** | | **862.8** | **562.5** | **653.7** |
| **Total shareholders' equity and liabilities** | | **1 008.0** | **650.2** | **871.1** |
| **Pledged assets** | | **100.0** | **43.1** | **232.2** |
| **Contingent liabilities** | | **-** | **10.6** | **-** |

# Notes

## *1. Accounting policies*

- This interim report was prepared pursuant to IAS 34. Orexo applies IFRS as approved by the EU.
- The accounting policies stated below are in line with those applied in the preparation of the 2013 Annual Report.
- The Parent Company's financial statements were prepared in accordance with RFR 2 (Swedish Financial Reporting Board's recommendation) and Chapter 9 of the Swedish Annual Accounts Act.

### New and amended accounting policies as of 2014

- No new or amended International Financial Reporting Standards have come into effect that have any significant impact on the Group.

## *2. Costs distributed by type of cost*

| MSEK | 2014 Apr-Jun | 2013 Apr-Jun | 2014 Jan-Jun | 2013 Jan-Jun | 2013 Jan-Dec |
|---|---|---|---|---|---|
| Raw materials and supplies | 21.3 | 6.5 | 35.3 | 13.5 | 21.8 |
| Other external costs | 106.6 | 100.9 | 180.4 | 172.4 | 347.8 |
| Personnel costs | 33.3 | 31.8 | 63.4 | 64.2 | 167.0 |
| Depreciation/amortization and impairment | 2.5 | 45.2 | 4.9 | 46.4 | 50.1 |
| **Total** | **163.7** | **184.4** | **284.0** | **296.5** | **586.7** |

Research and development costs encompass costs for personnel, premises, external costs for clinical trials, pharmaceutical registration and laboratory services, and the depreciation/amortization of equipment, acquired patents and other intangible assets.

## *3. Shareholders' equity*

*Shares outstanding*
The number of shares outstanding as of June 30, 2014 was 32,944,983, all of which were common shares. All shares carry entitlement to one vote each.

| | |
|---|---|
| Number of shares outstanding at January 1, 2014 | 32,911,908 |
| Subscription for shares through exercise of employee stock options | 33,075 |
| Shares outstanding at June 30, 2014 | 32,944,983 |

1,121,124 shares were bought back during 2012. These are included in the total number of shares outstanding and are owned by Orexo.

*Options*
As of June 30, 2014, a total of 2,523,127 options were outstanding that carry rights to new subscription of 2,521,520 shares in Orexo and the exchange of 1,607 options for shares in Orexo. Each option issued by

Biolipox AB provides entitlement to the exchange of one share in Orexo AB, and a corresponding number of shares are held by the independent company Pyrinox AB.

**The list below shows the change in the number of options during the period distributed by category.**

| Options to employees and Board members | Opening, Jan 1, 2014 | Change | Closing, June 30, 2014 |
|---|---|---|---|
| Of which: | | | |
| Approved and allotted employee stock options | 1,579,557 | | 1,579,557 |
| Exercised | | -30,992 | -30,992 |
| Allotted | | 304,500 | 304,500 |
| Expired | | -92,250 | -92,250 |
| Approved and allotted Board options | 215,688 | | 215,688 |
| Expired | | -16,666 | -16,666 |
| Employee stock options approved by AGM, unallotted | 829,667 | -304,500 | 525,167 |
| Warrants held by subsidiaries as cash-flow hedging for social security fees | 38,123 | - | 38,123 |
| **Total number of options outstanding** | **2,663,035** | **-139,908** | **2,523,127** |

During the period January-June 2014, a total of 30,075 employee stock options from Orexo's options program were exercised.

| *Number of shares after full dilution* | | |
|---|---|---|
| Shares outstanding at June 30, 2014 | 32,944,983 | 1) |
| Employee stock options allotted | 1,959,837 | |
| Employee stock options not yet allotted | 525,167 | 2) |
| Warrants for cash-flow hedging for social security fees | 38,123 | |
| | 35,468,110 | |

*1) Including 1,121,124 repurchased shares, owned by Orexo.*

*2) Can be allotted during the current year.*

### *4. Cash flow*

**Adjustment for non-cash items**

| MSEK | 2014 Apr-Jun | 2013 Apr-Jun | 2014 Jan-Jun | 2013 Jan-Jun | 2013 Jan-Dec |
|---|---|---|---|---|---|
| Depreciation/amortization and impairment | 2.9 | 45.1 | 5.3 | 46.4 | 50.5 |
| Estimated costs for employee stock options program | -1.4 | 1.7 | -7.0 | 4.3 | 40.0 |
| Financial expenses, convertible bond | - | -0.8 | - | -1.6 | -3.6 |
| **Total** | **1.5** | **46.0** | **-1.7** | **49.1** | **86.9** |

### *5. Pledged assets and contingent liabilities*

As the Inflazyme project has been discontinued, the entire supplementary purchase consideration of MSEK 42.0 was previously recognized as a contingent liability. Current assessment is that there is no longer a contingent liability.

Warrants were issued to Pyrinox AB as cash-flow hedging for social security fees pertaining to the employee stock options issued by Biolipox. Orexo has pledged to handle any deficits exceeding the cover provided by the warrants during their lifetime through December 31, 2016.

Orexo acquired the UK drug company PharmaKodex in February 2009. This acquisition included conditional payments based on Orexo's possible use of the PharmaKodex technology in product development. As this has not been the case, these are not recognized as a liability.
Operations in PharmaKodex have been closed down. The acquired technology was written down in its entirety during 2011 and 2012. PharmaKodex previous owners now claim Orexo is using the PharmaKodex technology in the development of Zubsolv and initiated a legal process against Orexo in the UK. Orexo will vigorously dispute these unsubstantiated claims, as Zubsolv is developed without any use of technologies acquired from PharmaKodex. The maximum possible claims amount to MUSD 15.

Collateral with Danske Bank was reduced during the second quarter from MSEK 200 to MSEK 100 comprising chattel mortgages.

## Definitions of key figures

Key figures and certain other operating information per share are defined as follows:

| | |
|---|---|
| Number of shares after dilution | Shares at the end of the period adjusted for the dilutive effect of potential shares. |
| Return on shareholders' equity | Net earnings for the period as a percentage of average shareholders' equity. |
| Net debt | Current and long-term interest-bearing liabilities including pension liabilities, less cash and cash equivalents. |
| Earnings per share, before dilution | Net earnings for the period after tax divided by the average number of shares outstanding before dilution during the period. |
| Earnings per share, after dilution | Net earnings for the period after tax divided by the average number of shares outstanding after dilution during the period. |
| Operating margin | Operating earnings as a percentage of net revenues. |
| Debt/equity ratio | Interest-bearing liabilities divided by shareholders' equity. |
| Equity/assets ratio | Shareholders' equity as a percentage of total assets. |
| Capital employed | Interest-bearing liabilities and shareholders' equity. |

**Please note**
Orexo AB publ discloses the information provided herein pursuant to the Financial Instruments Trading Act and/or the Securities Market Act. The information was provided for public release on July 11, 2014, at 8:00 a.m. This report has been prepared in both Swedish and English. In the event of any discrepancy in the content of the two versions, the Swedish version shall prevail.