orexo

A specialty pharmaceutical company which has developed four products – from idea to patient

Interim Report Q2 2017

Summary

Unless otherwise stated in this report, all data refers to the Group. Numbers in parentheses relate to the corresponding period in 2016.

Financial overview Q2 2017

- Total net revenues SEK 159.1 million (188.2)
- Zubsolv® US net revenue SEK 124.1 million (112.8)
- EBIT SEK 9.8 million (12.1)
- EBITDA SEK 15.0 million (17.2)
- Earnings per share, before and after dilution, SEK 0.09/0.09 (0.14/0.14)
- Cash flow from operating activities SEK 48.7 million (20.0)
- Cash and cash equivalents SEK 294.3 million (252.9)
- Guidance of full year 2017 positive EBITDA is confirmed

Financial overview YTD 2017

- Total net revenues SEK 286.4 million (339.2)
- Zubsolv US net revenue SEK 238.2 million (211.2)
- EBIT SEK -13.6 million (-14.1)
- EBITDA SEK -3.2 million (-2.3)
- Earnings per share, before and after dilution, SEK -0.91/-0.91 (-0.85/-0.85)
- Cash flow from operating activities SEK 76.9 million (42.5)

Other highlights Q2 2017

- Orexo´s partner AstraZeneca advanced OX-CLI into clinical trials which triggered a milestone payment of USD 2.5 million
- Based on positive data a new project, OX382 - oral formulation, has been added to the pipeline

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Presentation

At 2 pm, the same day as the announcement of the report, Orexo invites analysts, investors and media to attend an audiocast with a web presentation where Nikolaj Sørensen, CEO, and Henrik Juuel, CFO, will present the report. After the presentation a Q&A will be held. Questions can also be sent in advance to ir@orexo.com, no later than 11.00 am CET. Please view the instructions below on how to participate. Internet: http://tv.streamfabriken.com/orexo-q2-2017. Telephone: (SE) +46 8 566 426 92, (UK) +44 20 300 89 807 or (US) +1 855 831 5945. The presentation material will be available on Orexo´s website one hour prior to the audiocast.

Financial calender

Interim Report Q3 2017 – October 19, 2017, 8.00 am CET

Contents

Continued strong financial performance

One of the important objectives for 2017 is to maintain company profitability and sustain our strong financial position, and I am pleased that the Q2 results demonstrate that we are progressing according to plan. In particular, our US business continues to improve, with Zubsolv® US showing a double digit growth (10 percent) in net sales from last year resulting in both positive profit and cash flow contributions in the second quarter on a Group level.

Another of my key objectives this year is to progress our pipeline. I am encouraged to see that during the second quarter our pipeline has made significant progress. The effort of developing the next generation of our drug delivery technologies has led to one specific project (OX382), an innovative oral formulation, progressing to late pre-clinical stage and is now ready for clinical phase I trial within the next 6 to 9 months. Furthermore, I am encouraged to see that the OX-CLI project, which is managed by our partner AstraZeneca, has progressed into clinical phase I. Our pipeline now has assets ranging from the exploratory phase to the registration phase consisting of six promising internal and partnered projects. The combined potential of these projects provides for new milestones and royalty streams as they evolve, in combination with future assets for our US organization to commercialize.

The US market for our lead product Zubsolv continues to show strong growth, but is also challenging with most of the growth coming from the public segment. Since Zubsolv currently has limited market access in the public segment in several of the growing geographies, it is a challenge to maintain overall market share. However, in the regions where Zubsolv has market access combined with field force coverage, Zubsolv continues to win market share and gain volume. In this market environment, I appreciate that we have managed to grow our net sales year over year and gain volume, although we need to and are focused on improving our ability to compete in the fast growing public segment.

The critical success factor to be able to compete in the public segment is price. Consequently, we have increased the investment in our market access efforts and adjusted our overall marketing mix to optimize the balance between growth and profitability. To improve profitability and competitiveness improved effectiveness of our supply chain has become a key success factor. I am very pleased with the progress we are making in our supply chain and we will be able to significantly reduce our cost of goods sold. We are still finalizing the details of our supply chain for 2018 and beyond, but applying the anticipated future manufacturing cost of Zubsolv to the 2016 result, would have more than doubled our net earnings.

Continuing to look forward I am confident that our efforts regarding market access will start to pay off. Most of the existing formulary positions have been confirmed for 2018, to date none have been removed and we have also gained new contracts effective from 2018. Additionally we are making good progress in current negotiations which can further improve our ability to capture the strong growth that characterizes our main market. The journey of developing a growing profitable pharmaceutical company has just begun, enabling a strong financial platform for continued investment in the evolution of Orexo. The strong financial performance, positive signs in market access for 2018 in the US and the pipeline progress in Q2 are important indications that we are heading in the right direction.

Nikolaj Sørensen
President and CEO

Orexo has guided positive EBITDA for the full year 2017, however negative for the first half year as Abstral® royalties are skewed towards second half year. For Q2 2017 EBITDA amounted to SEK 15.0 million (17.2) and for the first half year EBITDA amounted to SEK -3.2 million (-2.3), fully in line with previous guidance. Zubsolv® net revenue growth and strong cost containment continue to improve the underlying profitability of the company. Cash flow from operating activities was again positive resulting in a cash balance of SEK 294.3 million reducing the net debt to SEK 45.7 million and thereby further cementing the strong financial foundation for the company.

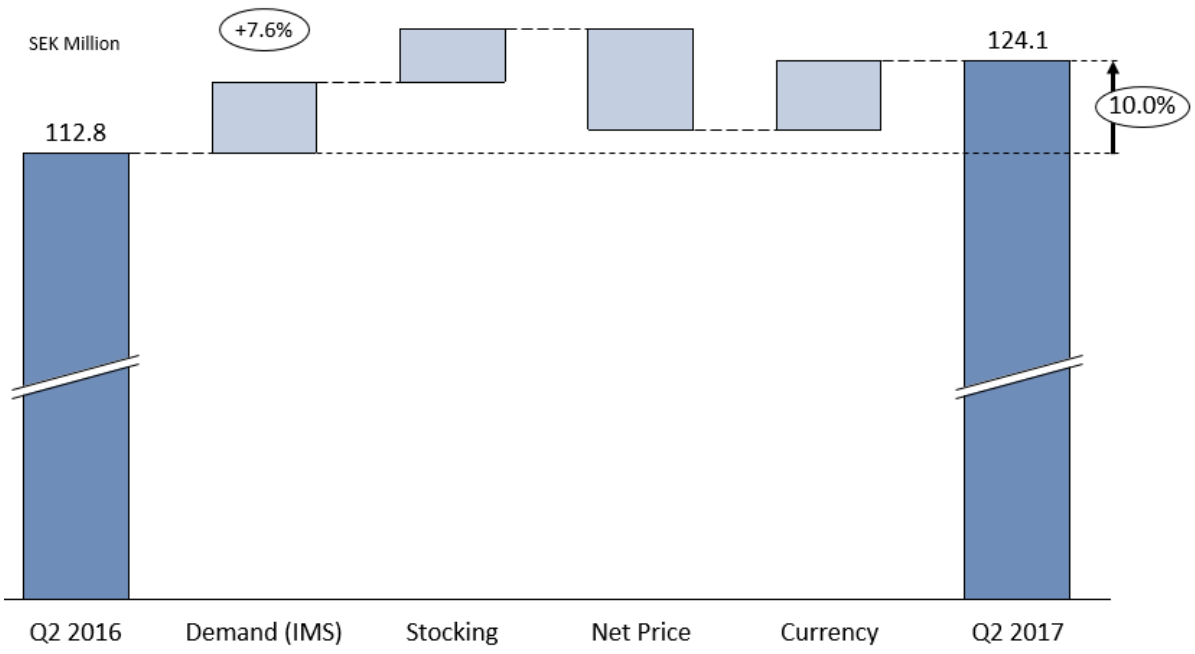
Revenues

Total revenues for Q2 2017 amounted to SEK 159.1 million (188.2) corresponding to a 15.5 percent decline over the previous year explained by higher milestone income in Q2 2016. Excluding milestone income net Edrevenue grew by 11.8 percent in the same period with Zubsolv US and Abstral being the growth drivers. For the period January to June, 2017, total revenue amounted to SEK 286.4 million (339.2). Higher milestone income in 2016 again explains the decline; excluding the milestone income net revenue grew by 13.6 percent.

Commercial products

Zubsolv US revenue amounted to SEK 124.1 million (112.8) in Q2 2017 corresponding to 10.0 percent growth over same period last year. This growth was driven by 7.6 percent growth in demand against a market that grew by 9.8 percent in the same period. Commercial and Cash segments together only grew by approximately 2 percent and the public segment, which Zubsolv US only has 27 percent access to, accounted for the rest of the total growth in the market. Wholesaler inventory levels had a positive impact on the growth between the two quarters. The average net tablet price was positively impacted by the 6 percent price increase from January 1, 2017, however more than off-set by higher gross-to-net deductions caused by continued high price pressure and a changed payer mix. Finally a stronger USD currency supported the growth measured in SEK.

Q2 Zubsolv US revenue growth by key drivers[1]



[1] Orexo analysis using IMS demand data

Abstral® revenues amounted to SEK 9.7 million (5.4) for Q2 2017. The growth was driven by the continued strong performance of Abstral in Europe. For the European region Orexo receives royalties for sales exceeding EUR 42.5 million and this happened earlier in Q2 this year.

Revenues from Edluar® amounted to SEK 3.4 million (4.5) for Q2 2017.

Partner projects
Q2 2017 included a milestone payment from AstraZeneca relating to the OX-CLI project amounting to SEK 21.8 million that was triggered by the project entering into clinical phase I trials.

Total net revenues were distributed as follows

MSEK	2017 Apr-Jun	2016 Apr-Jun	2017 Jan-Jun	2016 Jan-Jun	2016 Jan-Dec
Zubsolv® US	124.1	112.8	238.2	211.2	481.8
Zubsolv – Rest of the World	-	65.4	-	65.4	65.9
Zubsolv – total	**124.1**	**178.2**	**238.2**	**276.6**	**547.7**
Abstral royalties	9.7	5.4	18.4	13.6	100.4
Milestone payment Abstral	-	-	-	-	2.2
Abstral – total	**9.7**	**5.4**	**18.4**	**13.6**	**102.6**
Edluar royalties	3.4	4.5	8.0	8.1	14.8
OX-CLI	21.8	-	21.8	40.8	40.8
Total	**159.1**	**188.2**	**286.4**	**339.2**	**705.9**

Costs and earnings

Cost of goods sold
Cost of goods sold (COGS) amounted to SEK 35.8 million (33.9) for Q2 2017, all relating to Zubsolv US. The period January to March, 2017, was negatively impacted by items amounting to a total of approximately SEK 10 million. The main items were the cost of the previously announced de-blistering project and the expensing of indirect production cost due to low manufacturing volume during the period. Higher manufacturing volumes are expected for the second half of 2017 and this, in isolation, is expected to result in relatively lower COGS levels than seen in the first half of 2017.

Selling expenses
Selling expenses amounted to SEK 49.7 million (56.4) for Q2 2017. The lower level compared with the previous year reflects a continued highly targeted investment strategy focusing on geographies with good market access and potential for growth.

Administrative expenses
Administrative expenses for Q2 2017 amounted to SEK 22.4 million (62.7). Q2 2016, when the patent infringement litigation against Actavis was trialed at court, included very significant legal costs. Only minimal legal costs related to IP litigations were incurred in Q2 2017.

Research and development costs
In Q2 2017 research and development costs amounted to SEK 39.1 million (28.7). Higher costs for Q2 2017 reflect investments in the current pipeline of projects.

Costs for long-term incentive program
The Group's total costs for employee stock option programs during Q2 2017 amounted to SEK 1.3 million (1.6). For the period January to June 2017, the costs amounted to SEK 0.4 million (2.2).

Other income and expenses
Other income and expenses amounted to SEK -2.3 million (5.6) for Q2 2017. This primarily comprises of exchange-rate gains/losses derived from revaluations of balance sheet items in foreign currency.

Depreciation and amortization
Depreciation and amortization amounted to SEK 5.2 million (5.1) for Q2 2017.

Net financial items
Net financial items for Q2 2017 amounted to SEK -5.1 million (-5.5). All the net financial items are related to financing activities.

Tax
Total tax for Q2 2017 amounted to SEK 1.6 million (1.6).

Net earnings
Net earnings amounted to SEK 3.1 million (5.0) for Q2 2017.

Cash flow and financial position

At June 30, 2017, cash and cash equivalents amounted to SEK 294.3 million (252.9) and interest-bearing liabilities, to SEK 340.0 million (495.5). The bond loan was reclassified to current liabilities as it matures in May 2018. Orexo bonds bought back in the market have been netted out against liabilities on the balance sheet and are not included as cash equivalents.

Cash flow from operating activities was positive and amounted to SEK 48.7 million (20.0) for Q2 2017 largely driven by adjustments for non-cash items and mainly explained by changes in provisions relating to US payer rebates.

Seven consecutive quarters with positive cash flow from operating activities have now reduced the net debt to SEK 45.7 million. This brings Orexo in a strong financial position and in a good position to refinance the corporate bond in part or full and in due time.

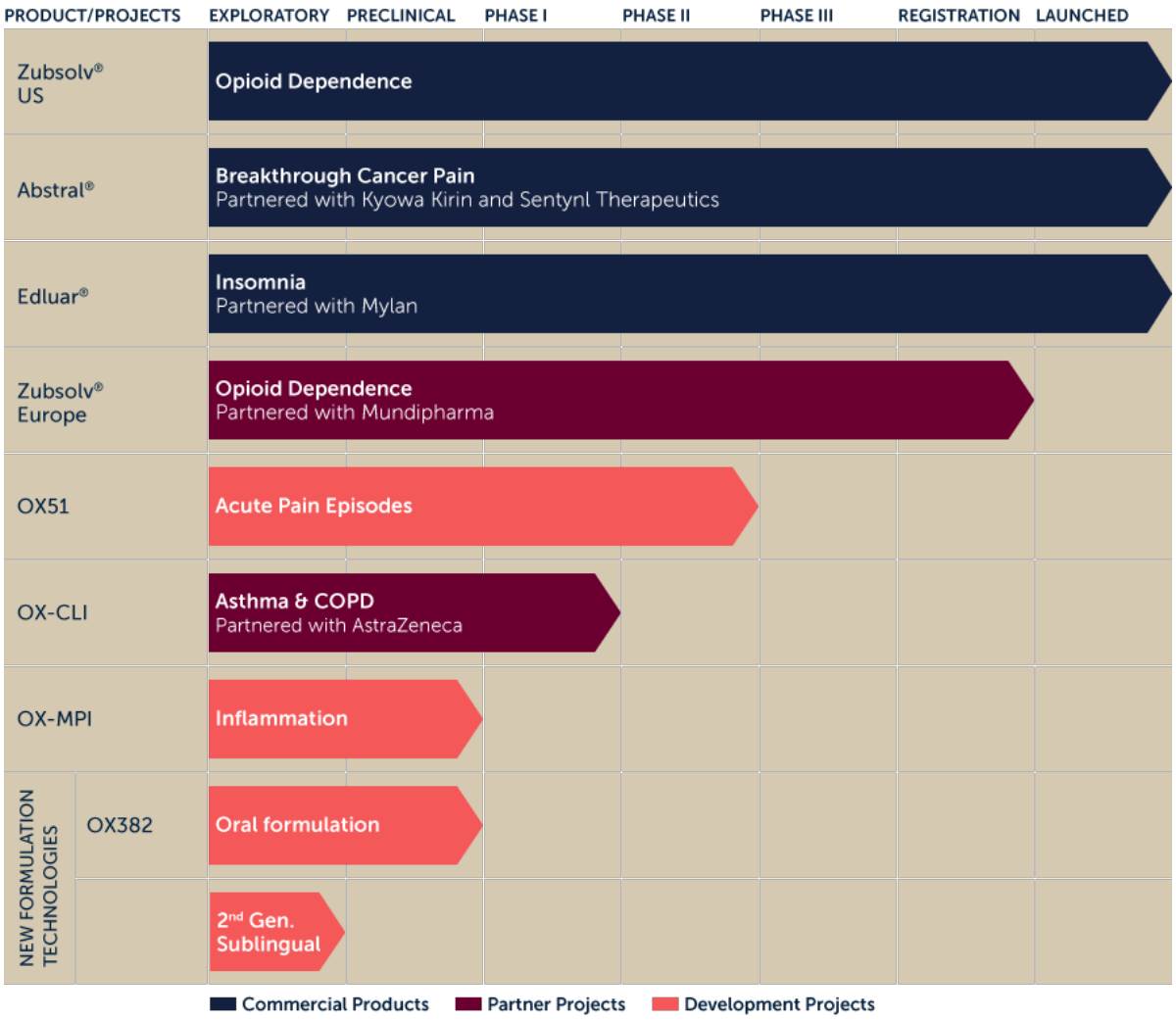
Shareholders' equity at June 30, 2017, was SEK 275.8 million (240.5). The equity/asset ratio was 28.3 (22.2) percent.

Investments in fixed assets

Gross investments in tangible and intangible fixed assets amounted to SEK 0.5 million (0.2) for Q2 2017.

Operations

Pipeline of products and projects



Commercial products

Zubsolv® US – opioid dependence
(buprenorphine/naloxone CIII sublingual tablet)

The second quarter of 2017 demonstrated total buprenorphine/naloxone market growth of 3.6 percent in volume compared to Q1 2017, and 9.8 percent compared to Q2 2016. The market forecast is continued expansion as more waivered providers expand their patient load by becoming waivered and as currently waivered prescribers expand their patient limits. To date, greater than 3,100 waivered physicians are eligible to increase their patient load to 275 while nurse practitioners and physicians assistants now total over 1,300 waivered to treat opioid dependency.

Zubsolv's Q2 2017 performance when compared to Q1 2017 shows an increase of 1.0 percent in tablets dispensed to patients through pharmacies and a 7.6 percent increase over Q2 2016. This increase in tablets dispensed was driven primarily by higher commercial prescription volumes from United Health Group. The main negative growth driver in Q2 2017 was the cash paying patients and the decision by CareSource (a large managed Medicaid plan, the change was highlighted in Orexo Q1 report) to stop reimbursement for all branded products in the category.

Among the payer segments, the public segment continues to be the fastest growing segment. The cash and commercial segments, however, grew at a greater rate than during the first quarter of 2017. Additionally, the cash and commercial segments are anticipated to increase with time as patient access to treatment capacity improves and as changes to US healthcare laws occur impacting patient flow by the various payer segments.

With the increased share of volume in the public segment and increased price pressure across all segments there has been a negative impact on the gross to net ratio for 2017. However, Zubsolv® prices were raised from January 1, which has compensated for a portion of the increased rebates.

Market access update

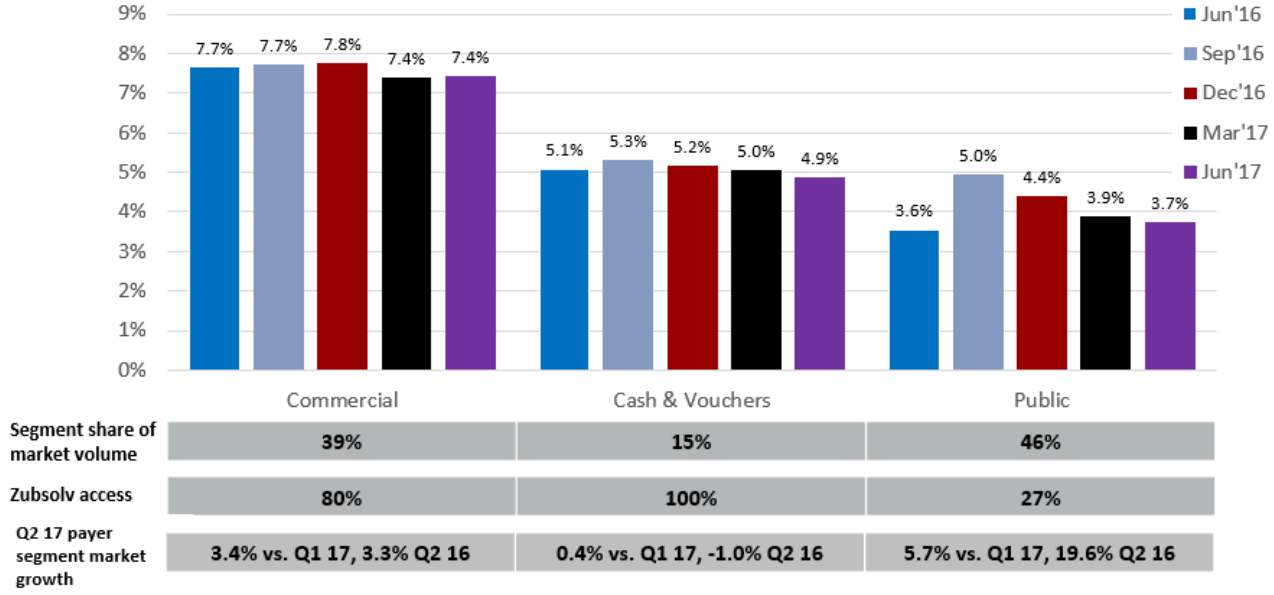
Market access remains a core driver of Zubsolv performance. Improvements in market access continue to materialize. Most of the existing formulary positions have been confirmed for 2018 and to date none have been removed and we have also gained new contracts effective from 2018. Within the commercial segment Blue Cross of Arizona has added Zubsolv as the only preferred branded product along with generics. We have also recently signed an exclusive contract with a regional pharmacy benefit management (PBM) company from January 1 2018. The effect of this will depend on the ability of the PBM to implement the formulary change with the clients (insurance companies).

Within the public segment effective July 1, 2017 the state of Wisconsin' public fee for service Medicaid program has added Zubsolv to its preferred formulary. Medicare Part D, ESI (PBM) has also added Zubsolv to the preferred formulary position effective January 1, 2018.

Maryland, FFS Medicaid, will be retaining Zubsolv in a preferred formulary position along with adding all products in the category. The anticipated impact to Zubsolv financially is minimal due to a significantly reduced rebate level, although we expect some negative effect on volume and market share starting July 1 2017.

The second and the third quarter is a very active time in the market access arena as ongoing negotiations are finalized with PBM's and insurers in all segments as planning for late 2017 and 2018 formulary changes are decided. We expect more announcements of the formularies for 2018 during the third quarter e.g. the largests PBMs, ESI and CVS Caremark.

Zubsolv US market share per type of payer segment, rolling 4 weeks, June 2016-June 2017[2]



	Commercial	Cash & Vouchers	Public
Segment share of market volume	39%	15%	46%
Zubsolv access	80%	100%	27%
Q2 17 payer segment market growth	3.4% vs. Q1 17, 3.3% Q2 16	0.4% vs. Q1 17, -1.0% Q2 16	5.7% vs. Q1 17, 19.6% Q2 16

[2] IMS has restated historical data. IMS XPO: Jun. 16 data: R4W WE 06/24/2016, Sept. 16 data: R4W WE 9/23/2016, Dec. 16 data: R4W WE 12/23/2016, Mar. 17 data: R4W WE 03/10/2017, Jun.17 data: R4W WE 06/23/2017

Commercial (private insurance)
(39% of the total market, 54.3% of Zubsolv® business in Q2)

In the commercial segment, Zubsolv's prescription volume increased 4.7 percent compared to Q1 2017 while market share remained stable at 7.4 percent. A core contributor of Zubsolv's volume increase was the resurgence in United Health Group's Zubsolv volume after the negative effects of Q1's drop due to the withdrawal from the Affordable Care Acts exchange plans. The entire buprenorphine/naloxone market commercial segment has grown 3.4 percent in volume compared to Q1 2017, and grew 3.3 percent compared to Q2 2016. Zubsolv had unrestricted access to 80 percent of the business in the commercial segment.

Cash (Cash & Vouchers)
(15% of the total market, 13.4% of Zubsolv business in Q2)

Zubsolv´s market share during the quarter has been relatively stable at 4.9 in Q2 2017 versus 5.0 percent in Q1 2017 in this segment. The cash market is the most sensitive market to price and discount programs and the dynamics within this segments has been impacted by recent more aggressive pricing of generic products.

The cash segment has grown 0.4 percent in volume during Q2 2017 compared to Q1 2017, and has declined by 1 percent compared to Q2 2016. Zubsolv has access to 100 percent of the business in the cash segment.

Public (Managed Medicaid, FFS Medicaid, Medicare Part D)
(46% of the total market, 32.3% of Zubsolv business in Q2)

The public market continues as the fastest growing segment in the buprenorphine/naloxone market driven by increased access to publicly financed insurances for opioid dependent patients. This segment has grown 5.7 percent in volume during Q2 compared to Q1 2017, and 19.6 percent compared to Q2 2016. During the quarter Zubsolv had access to 27 percent of the business in the public segment. Zubsolv market share during the quarter decreased slightly from 3.9 percent in Q1 2017 to 3.7 percent in Q2 2017 in this segment, mainly explained by the decline in CareSource.

Paragraph IV litigations against Actavis regarding Zubsolv in the US
No change since Q1 2017 Interim Report. See Note 3 for more information.

Patent infringement litigation against Actavis for their generic versions of Suboxone® and Subutex® tablets in the US
No change since Q1 2017 Interim Report. See Note 3 for more information.

Abstral® - breakthrough cancer pain

Due to the timing of this Interim Report, Orexo has not yet received final data for second quarter sales of Abstral and Edluar® from our partners and hence the calculation of Q2 royalties is based on Orexo´s forecast and preliminary Q2 sales reports where available. For the same reason the Abstral and Edluar sections below primarily refer to the sales development in Q1 2017.

Sales of Abstral in the EU continue to grow and amounted to EUR 23 million, which is an increase of 12 percent in Q1 2017 compared to Q1 2016. Orexo receives royalty on sales exceeding EUR 42.5 million, which in 2017 was achieved in June.

In the US market, Orexo's partner since November 2015, Sentynl Therapeutics Inc. continued with its relaunch of Abstral during the quarter. In Q1 2017, net sales were 18 percent lower than same period in 2016, a significant reduction, but a limited impact in absolute terms.

Sales of Abstral in the region RoW (markets excluding the EU and the US) have continued to grow. Total sales for the RoW reached USD 2.3 million in Q1 2017, which is an increase of 59 percent compared with Q1 2016.

Orexo's commercial partner in Japan, Kyowa Hakko Kirin, continued to focus on growing the Japanese market for Abstral®. Net sales grew 10 percent during the first local commercial quarter, December 2016 to February 2017, compared to the same period in 2016.

Edluar® - insomnia

Global sales of Edluar, commercialized by Mylan, which in 2016 acquired our former partner Meda AB, stayed flat between Q1 2017 and the same period of 2016. Total sales for Q1 2017 amounted to EUR 3.3 million (3.3).

Edluar is likely to face generic competition in the North American markets during 2017 which is expected to have negative impact on sales in 2017 and beyond.

Partner projects

Zubsolv® Europe – opioid dependence

In June, 2016, Mundipharma acquired the rights to Zubsolv outside the US (Rest of the World, RoW). The first important milestone in the collaboration was achieved in October, 2016, when a regulatory submission for Zubsolv RoW was filed with the European Medicines Agency (EMA). Approval of Zubsolv for the treatment of opioid dependence in Europe, is anticipated by the end of 2017 or early 2018. In parallel other markets are evaluated outside Europe and the US.

Besides creating value from the launch of Zubsolv in the rest of the world, we are also expecting other scale effects, e.g. through increased production volumes, which overtime could further improve Orexo´s gross margin.

Pending future market authorization approvals and achievement of various commercial milestones Orexo is entitled to further milestone payments along with up to low double digit royalties on future net sales.

OX-CLI – asthma and COPD

OX-CLI is a Leukotriene (LT) C4 Synthase inhibitor program. The OX-CLI compounds, based on a new chemical entity (NCE), could enable the development of a completely novel personalized treatment for respiratory disorders such as asthma and COPD.

OX-CLI is developed by Orexo´s partner AstraZeneca. In Q2 2017 the project advanced into clinical phase 1 studies which triggered a milestone payment of USD 2.5 million. AstraZeneca will continue the drug development without any further involvement of Orexo.

Future milestone payments can be expected if OX-CLI meets defined development and commercial objectives. In addition to the milestones, Orexo will receive a tiered single digit royalty on future net-revenue associated to sales of products based on the OX-CLI program.

Development projects

OX51 – acute pain episodes

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 diagnostic procedures.

A placebo-controlled dose-finding study in patients undergoing prostate biopsy was completed in 2013. The results supported a continuation of the development of OX51 to the next phase in development towards a new product.

To be able to take the project into phase III discussions with partners are ongoing.

OX-MPI – inflammation

PGE2-inhibition-treatment of inflammatory related pain. The aim with this project is to develop a completely new class of products based on Orexo's prostaglandin research (selective inhibition of prostaglandin E2 synthase).

Discussions with an external partner for OX-MPI is ongoing.

New formulation technologies

OX382 – oral formulation

Many active ingredients face major challenges when administered by the oral route. For example, incomplete dissolution in the GI-tract, poor intestinal absorption and extensive metabolism may all limit bioavailability. Consequently, many drugs are not effective when administered orally. Orexo is currently developing a new formulation technology that might overcome these issues, enabling oral administration of drugs for which this route is not feasible today. The project is in the exploratory phase, and several active substances have been identified as promising candidates for this technology. We obtained promising data with the first active substance from animal studies in rats and will proceed into clinical phase I trial within the next 6 to 9 months with the results expected first half of 2018.

2nd generation sublingual formulation technology

Orexo is currently developing its second-generation sublingual formulation technology. The aim is to perfect the Sublingual delivery of drugs, thereby unlocking new active ingredients that are currently not possible to administer sublingually. The project is in the exploratory phase, and several active ingredients have been identified as promising candidates for this technology.

Parent Company

Net revenues for Q2 2017 amounted to SEK 113.7 million (167.5). Earnings before tax were SEK 6.2 million (17.2). Investments amounted to SEK 0.5 million (0.2). As of June 30, 2017, cash and cash equivalents in the Parent Company amounted to SEK 145.4 million (146.5).

Outlook 2017

The outlook for 2017 provided in the 2016 Full Year report has been updated with regards to the expected full year OPEX level. The rest of the outlook remains unchanged with the caution that Zubsolv® market share might be difficult to grow if the market growth continue to favor the public segments where Zubsolv has a low level of access.

Orexo expects to deliver a positive EBITDA for the full year 2017.

Zubsolv in the US will contribute with continued year over year net revenue growth, driven by market growth and market share gains. No further milestone payments from license partners are expected in 2017.

Full year OPEX is expected to be approximately SEK 475 million (was previously in the range of SEK 500 million to SEK 510 million).

The outlook is based on January 2017 exchange rates.

Forward looking statements

This report includes forward-looking statements. Actual results may differ from those stated. Internal and external factors may affect Orexo's results.

Risks and uncertainty factors

Significant risks and uncertainties are presented in the Annual Report for 2016. The continued commercialization of Zubsolv® entails risk exposure of operational nature and Orexo is continuously exposed to risks in relation to the intellectual property rights and legal disputes as highlighted in Note 3.

Assurance by the Board of Directors

The Board of Directors and the CEO 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.

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

Uppsala, Sweden, July 11, 2017

Orexo AB (publ.)

Martin Nicklasson Chairman of the Board	Raymond Hill Board member	Staffan Lindstrand Board member
Kristina Schauman Board member	Michael Shalmi Board member	David Colpman Board member
Kirsten Detrick Board member	Nikolaj Sørensen President and CEO	

Consolidated statement of operations

MSEK	Notes 1	2017 Apr-Jun	2016 Apr-Jun	2017 Jan-Jun	2016 Jan-Jun	2016 Jan-Dec
Net revenues		159.1	188.2	286.4	339.2	705.9
Cost of goods sold		-35.8	-33.9	-82.0	-66.4	-149.6
Gross profit		**123.3**	**154.3**	**204.4**	**272.8**	**556.3**
Selling expenses		-49.7	-56.4	-97.9	-117.1	-240.6
Administrative expenses		-22.4	-62.7	-48.8	-97.8	-161.6
Research and development costs		-39.1	-28.7	-69.4	-73.7	-132.3
Other operating income and expenses		-2.3	5.6	-1.9	1.8	29.9
Operating earnings		**9.8**	**12.1**	**-13.6**	**-14.1**	**51.7**
Net financial items		-5.1	-5.5	-11.7	-11.8	-16.1
Earnings before tax		**4.7**	**6.6**	**-25.2**	**-25.9**	**35.6**
Tax		-1.6	-1.6	-6.4	-3.6	-6.5
Net earnings for the period[1]		**3.1**	**5.0**	**-31.6**	**-29.5**	**29.0**

Consolidated statement of comprehensive income

MSEK	2017 Apr-Jun	2016 Apr-Jun	2017 Jan-Jun	2016 Jan-Jun	2016 Jan-Dec
Earnings for the period	3.1	**5.0**	**-31.6**	**-29.5**	**29.0**
Other comprehensive income					
Items that may subsequently be reversed to the statement of operations:					
Change in fair value assets available for sale	-	-	-	-	-
Reclassification assets available for sale	-	-	-	-	-0.9
Cash flow hedge	-	-	-	-	-
Exchange-rate differences	-1.9	-1.7	**-3.3**	-0.9	6.2
Other comprehensive earnings for the period, net after tax	**-1.9**	**-1.7**	**-3.3**	**-0.9**	**5.3**
Total comprehensive earnings for the period [1]	**1.2**	**3.3**	**-34,9**	**-30.4**	**34.3**
Earnings per share, before dilution, SEK	0.09	0.14	-0.91	-0.85	0.84
Earnings per share, after dilution, SEK	0.09	0.14	-0.91	-0.85	0.84

[1] All equity and earnings for the respective period are attributable to the Parent Company's shareholders

Consolidated balance sheet

MSEK	Notes 1	2017 Jun 30	2016 Jun 30 Restated	2016 Dec 31
ASSETS				
Fixed assets				
Tangible fixed assets		20.8	22.9	22.1
Intangible assets		129.8	144.2	138.2
Deferred tax assets		20.6	24.8	24.8
Other financial assets		-	1.2	-
Total fixed assets		**171.2**	**193.1**	**185.1**
Current assets				
Inventories		292.9	379.5	344.2
Accounts receivable and other receivables		217.8	260.1	207.1
Cash and cash equivalents		294.3	252.9	282.4
Total current assets		**805.0**	**892.5**	**833.7**
Total assets		**976.2**	**1,085.5**	**1,018.8**
SHAREHOLDERS' EQUITY AND LIABILITIES				
Total shareholders' equity		**275.8**	**240.5**	**310.3**
Long-term liabilities				
Provisions		0.6	2.3	1.3
Long-term liabilities, interest bearing		-	495.5	397.8
Total long-term liabilities		**0.6**	**497.8**	**399.0**
Current liabilities and provisions				
Current liabilities interest bearing		340.0	-	-
Provisions, current liabilities, non-interest bearing		359.8	347.2	309.5
Total current liabilities and provisions		**669.8**	**347.2**	**309.5**
Total liabilities		**700.4**	**845.0**	**708.5**
Total shareholders' equity and liabilities		**976.2**	**1,085.5**	**1,018.8**

Consolidated changes in shareholders' equity

MSEK	2017 Jun 30	2016 Jun 30	2016 Dec 31
Opening balance, shareholders' equity	**310.3**	**266.4**	**270.1**
Total comprehensive earnings for the period	-34.9	-30.4	34.3
Employee stock options, vested amount	0.4	4.5	3.7
Buy back of shares	-	-	-0.1
New share issue	-	-	2.3
Closing balance, shareholders' equity	**275.8**	**240.5**	**310.3**

Consolidated cash flow statements

MSEK	Notes 1	2017 Apr-Jun	2016 Apr-Jun Restated	2017 Jan-Jun	2016 Jan-Jun Restated	2016 Jan-Dec
Operating earnings		9.6	12.1	-13.6	-14.1	51.7
Financial income and expenses		-5.3	-7.1	-22.3	-15.4	-28.3
Adjustment for non-cash items	2	42.8	30.0	62.9	14.0	44.1
Cash flow from operating activities before changes in working capital		**47.1**	**35.0**	**27.0**	**-15.5**	**67.5**
Changes in working capital		**1.7**	**-15.0**	**49.9**	**58.0**	**88.7**
Cash flow from operating activities		**48.7**	**20.0**	**76.9**	**42.5**	**156.2**
Acquisition of tangible and intangible fixed assets		-0.5	-0.2	-0.8	-0.3	-1.4
Disposal of fixed assets		-	-	-	-	1.8
Sale of subsidiary		-	-	-	11.0	5.0
Cash flow from investing activities		**-0.5**	**-0.2**	**-0.8**	**10.8**	**5.4**
New share issue		-	-	-	-	2.2
Change in loans		-	-	-59.0	-	-92.8
Cash from financing activities		**0.0**	**0.0**	**-59.0**	**0.0**	**-90.6**
Cash flow for the period		**48.2**	**19.8**	**17.2**	**53.3**	**71.0**
Cash and cash equivalents at the beginning of the period		**250.6**	**233.0**	**282.4**	**198.1**	**198.1**
Exchange-rate differences in cash and cash equivalents		-4.6	0.1	-5.4	1.5	13.3
Changes in cash and cash equivalents		48.2	19.8	17.2	53.3	71.0
Cash and cash equivalents at the end of the period		**294.3**	**252.9**	**294.3**	**252.9**	**282.4**

Key Figures[1]

Orexo makes use of the key figures below and believe they are useful for readers of the financial reports as a complement to other performance measures when assessing implementation of strategic investments and the Group's ability to meet financial objectives and commitments.

	2017 Apr-Jun	2016 Apr-Jun Restated	2017 Jan-Jun	2016 Jan-Jun Restated	2016 Jan-Dec
EBIT margin, %	6.2	6.4	-4.7	-4.2	7.0
Return on shareholder equity, %	1.1	2.1	-10.8	-11.6	10.0
Net debt, MSEK	45.7	242.6	45.7	242.6	115.4
Debt/equity ratio, %	123.3	206.0	123.3	206.0	128.2
Equity/assets ratio, %	28.3	22.2	28.3	22.2	30.5
Number of shares, before dilution	34,539,585	34,583,763	34,539,585	34,583,763	34,477,423
Number of shares, after dilution	34,551,912	34,688,754	34,539,585	34,688,754	34,574,412
Earnings per share, before dilution, SEK	0.09	0.14	-0.91	-0.85	0.84
Earnings per share, after dilution, SEK	0.09	0.14	-0.91	-0.85	0.84
Number of employees at the end of the period	98	99	98	99	102
Shareholders' equity, MSEK	275.8	240.5	275.7	240.5	310.3
Capital employed, MSEK	615.8	736.0	615.8	736.0	708.1
Working capital, MSEK	105.2	545.3	105.2	545.3	524.2

[1] Definitions and reconciliations of key figures are presented on page 20 of this report

Parent Company statement of operations

MSEK	Notes	2017 Apr-Jun	2016 Apr-Jun	2017 Jan-Jun	2016 Jan-Jun	2016 Jan-Dec
Net revenues		113.7	167.5	236.0	220.1	379.3
Cost of goods sold		-36.5	-52.6	-96.3	-54.6	-83.6
Gross profit		**77.2**	**114.9**	**139.7**	**165.5**	**295.7**
Selling expenses		-16.9	-18.4	-41.9	-57.7	-105.7
Administrative expenses		-16.5	-55.2	-35.2	-83.6	-129.1
Research and development costs		-30.2	-21.8	-53.9	-98.6	-141.8
Other operating income and expenses		-2.4	2.4	-2.0	-1.7	24.3
Operating earnings		**11.2**	**22.0**	**6.8**	**-76.0**	**-56.6**
Interest income and expenses		-3.5	-4.2	-8.3	-8.4	-16.2
Exchange rate adjustment		-	-	-1.3	-	-32.1
Other financial expenses		-1.5	-0.6	-2.6	-0.7	9.3
Net financial items		**-5.0**	**-4.8**	**-12.2**	**-9.1**	**-39.1**
Earnings before tax		**6.2**	**17.2**	**-5.4**	**-85.1**	**-95.7**
Tax		-	-	-	-	-
Earnings for the period		**6.2**	**17.2**	**-5.4**	**-85.1**	**-95.7**

Parent company statement of comprehensive income

MSEK	2017 Apr-Jun	2016 Apr-Jun	2017 Jan-Jun	2016 Jan-Jun	2016 Jan-Dec
Earnings for the period	**6.2**	**17.2**	**-5.4**	**-85.1**	**-95.7**
Other comprehensive income	**-**	**-**	**-**	-	-
Total comprehensive earnings for the period[1]	**6.2**	**17.2**	**-5.4**	**-85.1**	**-95.7**

[1] All equity and earnings for the respective period are attributable to the Parent Company's shareholders

Parent Company balance sheet

MSEK	Notes	2017 Jun 30	2016 Jun 30	2016 Dec 31
ASSETS				
Fixed assets				
Tangible and intangible fixed assets		150.3	169.9	159.8
Shares in subsidiaries		149.3	148.0	149.7
Total fixed assets		**299.6**	**317.9**	**309.5**
Current assets				
Inventories		210.7	258.4	269.6
Accounts receivable and other receivables		156,0	295.2	76.8
Cash and bank balances		145,4	146.5	211.7
Total current assets		**512,1**	**700.2**	**558.1**
Total assets		**811,7**	**1,018.1**	**867.5**
SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES				
Shareholders' equity		**258.6**	**270.3**	**263.5**
Long-term liabilities		**0.6**	**497.8**	**399.0**
Current liabilities		**552,5**	**250.0**	**205.0**
Total liabilities		**553,1**	**747.8**	**604.1**
Total shareholders' equity and liabilities		**811,7**	**1,018.1**	**867.6**

Notes

1. Accounting policies

This 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 2016 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 2017

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

Restatements

The company refers to the annual report 2016 Note 38 for more information on adjusted financial statements.

2. Cash flow

Adjustment for non-cash items

MSEK	2017 Apr-Jun	2016 Apr-Jun	2017 Jan-Jun	2016 Jan-Jun	2016 Jan-Dec
Depreciation/amortization and impairment	4.6	5.0	10.0	11.8	25.0
Gain/loss on disposal	-	-	-	-	-5.0
Change in provisions	41.7	-7.2	72.5	23.4	42.0
Change in fair value of financial instruments	-	-	-	-	0.2
Share based payments	1.1	-0.6	0.3	-	3.7
Exchange rate income and expenses	-4.6	-	-20.0	-	-21.8
Total	**42.8**	**-2.8**	**62.9**	**35.2**	**44.1**

3. Legal disputes

Paragraph IV litigations against Actavis regarding Zubsolv in the US

In May 2014, Actavis notified Orexo that it had filed an ANDA for generic Zubsolv 1.4 and 5.7 mg products in the US alleging that Orexo's patents were invalid and not infringed. In June 2014, Orexo initiated the litigation process against Actavis. The decision in this litigation process, involving Orexo's US patents 8,454,996 and 8,940,330, was issued on November 15, 2016, by the United States District Court for the District of Delaware. The District Court held that Orexo's '996 patent is valid and infringed by Actavis's generic Zubsolv 1.4 and 5.7 mg products. The District Court also held that Orexo's '330 patent is invalid. The '996 and '330 patents expire in September 2019 and September 2032, respectively. On December 7, 2016, Orexo appealed the District Court's decision relating to the validity of the '330 patent to the Court of Appeals for the Federal Circuit. Actavis did not appeal the District Court's decision relating to the validity and infringement of the '996 patent, securing Zubsolv exclusivity on the US market until at least September 24, 2019. Generally, the Federal Circuit takes about one year from the District Court decision to render a ruling on the appeal.

During the litigation process, Orexo has received approval of several new strengths of Zubsolv (2.9, 8.6 and 11.4 mg), and Actavis has filed new ANDAs for these new strengths. Consequently, Orexo has initiated separate litigation processes for these new strengths. These lawsuits are based on the same patents as the initial process and the decision of the first litigation process may influence and control the decision in the litigation processes regarding the new strengths.
In addition, two new Zubsolv patents, US patents 9,259,421 and 9,439,900, have been issued and listed in the Orange Book with the FDA, after the initiation of the first litigation process. Both of these patents are related to the '330 patent and expire in September 2032. Orexo has initiated new litigation processes against Actavis involving all strengths (except the recently approved 0.7 mg strength) on the '421 and '900 patents.

Patent infringement litigation against Actavis for their generic versions of Suboxone® and Subutex® tablets in the US

In March 2017 Orexo filed a patent infringement action in United States District Court for the District of Delaware against Actavis Elizabeth LLC, Actavis Pharma, Inc., and their parent company Teva (collectively "Actavis"). Orexo alleges that Actavis's generic versions of Suboxone and Subutex tablets infringe Orexo's US Patent No. 8,454,996 (the '996 patent). Actavis's generic version of Suboxone was approved by the FDA in February 2013 and their generic version of Subutex in February 2015. Orexo is seeking compensation for damages caused by Actavis's infringement of the '996 patent since approval of these two products.

4. Important events after the period

No material events occurred after the period.

Definitions and reconciliations of key figures

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

Margins	**Definition/calculation**	**Purpose**
Gross margin	Gross profit divided by net revenues	Gross Margin is used to measure the relative direct profitability from sold products
Operating margin (EBIT margin)	Operating earnings as a percentage of net revenues	Operating profit margin is used for measuring the operational profitability
Return	**Definition/calculation**	**Purpose**
Return on equity	Net earnings for the period as a percentage of average shareholders' equity	Return on equity is used to measure profit generation, given the resources attributable to the owners of the Parent Company
Capital structure	**Definition/calculation**	**Purpose**
Net Debt	Current and long-term interest-bearing liabilities including pension liabilities, less cash and cash equivalents	The net debt is used as an indication of the ability to pay off all debts if these became due simultaneously on the day of calculation, using only available cash and cash equivalents
Debt/equity ratio	Total liabilities divided by shareholders' equity	The debt/equity ratio measures how much debt a company is using to finance its assets relative to the amount of value represented in shareholder's equity.
Equity/assets ratio	Shareholders' equity as a percentage of total assets	This ratio is an indicator of the company's leverage used to finance the firm
Working capital	Current assets less current liabilities	Working capital is used to measure the company's ability, besides cash and cash equivalents, to meet current operational obligations
Capital employed	Interest-bearing liabilities and shareholders' equity	Capital employed measures the amount of capital used and serves as input for the return on capital employed
Gross investments	Value of investment before amortization	Gross investments is a measure of the company's investments in tangible and intangible fixed assets
Data per share	**Definition/calculation**	**Purpose**
Number of shares after dilution	Shares at the end of the period adjusted for the dilutive effect of potential shares	Is used to calculate earnings per share after dilution
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	The earnings per share before dilution measures the amount of net profit that is available for payment to its shareholders per share before dilution
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	The earnings per share after dilution measures the amount of net profit that is available for payment to its shareholders per share after dilution
Other definitions	**Definition/calculation**	**Purpose**
Gross Revenues	Grand total of all invoiced sales transactions reported in a period, without any deductions	Reflects the company's invoiced revenues without any deductions
Net Revenues	Gross Revenues less deductions for sales rebates, sales allowances, distribution, sales returns and other relevant deductions	Reflects the company's invoiced revenues after deductions
Gross to net ratio	Net Revenues divided by Gross Revenues	Reflects a relative portion of net revenue as percentage of gross revenue
Operating expenses	An expense incurred in daily operating activities. Expense related to financing is not considered part of daily operating activities.	Operating expenses reflect costs for selling, administration, research and development, depreciation and other operating income and operating expenses
EBIT	Earnings before net financial items and tax, the same as Operating earnings	This measure enables the profitability to be compared across locations where corporate taxes differ and irrespective the financing structure of the company
EBITDA	Earnings before interest, taxes, depreciation and amortization. EBIT plus depreciation	Profit measure which is more closely correlated with cash flow as non-cash items like Depreciation and Amortization are excluded

Earnings after financial items	Operating earnings (EBIT) plus financial income less financial expense	Earnings after financial items reflects earnings after, any results from participations in Group and associated companies, results from securities and receivables that fall within the type of fixed assets as well as interest expenses and interest income

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

EBITDA MSEK	**2017 Apr-Jun**	**2016 Apr-Jun**	**2017 Jan-Jun**	**2016 Jan-Jun**	**2016 Jan-Dec**
EBIT	9.8	12.1	-13.6	-14.1	51.7
Depreciation and amortization	5.2	5.1	10.4	11.8	21.4
EBITDA	**15.0**	**17.2**	**-3.2**	**-2.3**	**73.1**

Return on shareholders' equity	**2017 Apr-Jun**	**2016 Apr-Jun Restated**	**2017 Jan-Jun**	**2016 Jan-Jun**	**2016 Jan-Dec**
Shareholders' equity beginning balance	273.3	233.6	273.3	270.1	270.1
Shareholders' equity ending balance	275.8	240.5	310.3	240.5	310.3
Average shareholders' equity	274.6	237.1	291.8	255.3	290.2
Net earnings	3.1	5.0	-31.6	-29.5	29.0
Return on shareholders' equity %	**1.1**	**2.1**	**-10.8**	**-11.6**	**10.0**

Operating expenses MSEK	**2017 Apr-Jun**	**2016 Apr-Jun**	**2017 Jan-Jun**	**2016 Jan-Jun**	**2016 Jan-Dec**
Selling expenses	-49.7	-56.4	-97.9	-117.1	-240.6
Administrative expenses	-22.4	-62.7	-48.8	-97.8	-161.6
Research and development costs	-39.1	-28.7	-69.4	-73.7	-132.3
Other operating income and expenses	-2.3	5.6	-1.9	1.8	29.9
Operating expenses	**-113.5**	**-142.2**	**-218.0**	**-286.8**	**-504.6**

Gross investments MSEK	**2017 Apr-Jun**	**2016 Apr-Jun**	**2017 Jan-Jun**	**2016 Jan-Jun**	**2016 Jan-Dec**
Investments in tangible fixed assets	0.4	0.0	0.6	0.1	1.1
Investments in intangible fixed assets	0.1	0.2	0.1	0.2	0.3
Gross investments	**0.5**	**0.2**	**0.7**	**0.3**	**1.4**

Glossary

Alfentanil
A potent synthetic opioid analgesic drug, used for anaesthesia in surgery

American Depositary Receipt (ADR)
An instrument that is issued by a depositary bank that represents ownership of a company's underlying shares. ADR programs are created to facilitate US investors to hold shares in non-US companies and trade them in the same way as US securities.

Anaesthesia
Procedure for lowering a patient's consciousness to enable a Medical procedure to proceed without pain for the patient

ANDA
An Abbreviated New Drug Application (ANDA) is an application for a US generic drug approval for an existing licensed medication or approved drug

Breakthrough pain
A short, intensive period of pain that occurs in addition to chronic levels of long-term pain even though these are treated by regular painkillers

Buprenorphine
A potent opioid partial agonist first used as a pain-relieving substance,but now most commonly used to help patients withdraw from more addictive opioid drugs such as morphine

CARA
The Comprehensive Addiction and Recovery Act (CARA) became law in the US in July 2016. CARA authorizes a series of grants aimed at among other things developing treatment programs which further expands buprenorphine prescribing rights to nurse practitioners and physician assistants

Cash & vouchers segment
One of the three distinct payer segments in the market for treatment of opioid dependence. In this segment, the patient is paying for the prescriptions out of pocket

CLI
Cysteinyl Leukotriene Inhibitor

Clinical studies/Clinical trials
Studies of the safety and efficacy of a drug in human beings

Commercial segment
One of the three distinct payer segments in the market for treatment of opioid dependence. The commercial segment is funded by private insurances or employers

Drug delivery
The process through which a pharmaceutical may be introduced to the patient that enables the active compound to function as intended

EMA
The European Medicine Agency

FDA
The US Food and Drug Administration

Fentanyl
An opioid with a similar effect on human patients as morphine. Used mainly within anasthesia and analgesia

GMP
Good Manufacturing Practice

HHS
The US Department of Health and Human Services

IP
Intellectual Properties

Naloxone
An opioid inverse agonist used to counter the effects of opioids

NCE
New Chemical Entity

Opioids
Collective term for compounds that act via opioid receptors on nerve cells, mainly in the central nervous system

PBM (Pharmacy Benefit Manager)
Responsible for management of costs associated with prescription pharmaceuticals and recommendations on behalf of insurance companies and employers in the US

PGE
Prostaglandin (PG) E2 – biologically active mediator derived from arachidonic acid and involved in inflammatory conditions

Phase I studies
Studies mainly of the safety of a drug. Performed on healthy human volunteers

Phase II studies
Studies of the safety and efficacy of a drug in appropriate doses. Performed on a limited number of patients

Phase III studies
Studies of the safety and efficacy of a drug in a clinical setting. Performed on a large number of patients

Preclinical development/Preclinical studies
Studies of the safety and efficacy of a drug prior to evaluation in humans. Can be performed on animals and in various cell systems

Public segment
One of three distinct payer segments in the market for treatment of opioid dependence. The public segment covers state and federal funded reimbursement programs i.e. Managed Medicaid, FFS Medicaid, Medicare Part D

REZOLV
The REZOLV (Retrospective Evaluation of Zubsolv® Outcomes – A Longitudinal View) study is a medical record review conducted to examine and characterize the impact of treatment and psychosocial factors on the early outcomes of patients who utilized Zubsolv therapy for opioid dependence. The data was collected from 1,080 patients being treated by 134 physicians across 87 US treatment sites of which 80 were private practices and 7 were institutional sites.

Sublingual
Under the tongue

Zolpidem
A pharmaceutical substance used to treat temporary or short-term insomnia

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www.orexo.com

About Orexo
Orexo develops improved pharmaceuticals based on innovative drug delivery technologies. The focus is primarily on opioid dependence and pain but it is also our aim to address other therapeutic areas where our competence and technologies can create value. The products are commercialized by Orexo in the US or via selected partners worldwide. The main market today is the American market for the treatment of opioid dependence, where Orexo sells the product Zubsolv®. Total net sales for 2016 amounted to SEK 705.9 million and the number of employees was 102. Orexo is listed on the Nasdaq Stockholm Mid Cap (ORX) index and is available as ADRs on OTCQX (ORXOY) in the US. The head office, where also research and development is performed, is situated in Uppsala, Sweden.

For more information about Orexo, please visit www.orexo.com. You can also follow Orexo on Twitter, @orexoabpubl, LinkedIn and YouTube. For more information about Zubsolv in the US, see the product and market websites www.zubsolv.com and www.rise-us.com.