orexo

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

Interim Report Q3 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 Q3 2017

- Total net revenues SEK 166.2 million (181.9)
- Zubsolv® US net revenue SEK 121.1 million (142.4)
- EBIT SEK 40.9 million (43.0)
- EBITDA SEK 46.1 million (50.9)
- Earnings per share, before and after dilution, SEK 0.82/0.81 (1.04/1.04)
- Cash flow from operating activities SEK 92.3 million (31.1)
- Cash and cash equivalents SEK 370.7 million (276.9)
- Guidance of full year 2017 positive EBITDA is confirmed

Financial overview YTD 2017

- Total net revenues SEK 452.6 million (521.2)
- Zubsolv US net revenue SEK 359.3 million (353.6)
- EBIT SEK 27.2 million (29.1)
- EBITDA SEK 42.8 million (48.8)
- Earnings per share, before and after dilution, SEK -0.10/-0.10 (0.19/0.19)
- Cash flow from operating activities SEK 169.6 million (84.8)

Other highlights Q3 2017

- Zubsolv gained preferred position on CVS Caremark 2018 formulary
- The Committee for Medicinal Products for Human Use, CHMP, announced a positive opinion for treatment of opioid dependence with Zubsolv in Europe
- An asset purchase agreement was signed with Gesynta Pharma AB for OX-MPI
- Pipeline updated
- Subject to market conditions, Orexo is contemplating issuing a new corporate bond during Q4 2017 at an aggregate amount of SEK 300 – 350 million. The proceeds of such bond issue would be used towards redeeming the existing outstanding bonds in full.

For further information, please contact

Nikolaj Sørensen, President and CEO
Tel +46 18 780 88 00
E-mail ir@orexo.com

Henrik Juuel, EVP and CFO
Tel +46 18 780 88 00
E-mail ir@orexo.com

Presentation

At 2.00 pm CET, 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: https://tv.streamfabriken.com/orexo-q3-2017. Telephone: (SE) +46 8 566 426 92, (UK) +44 203 008 98 07 or (US) +1 855 831 5945.
The presentation material will be available on Orexo´s website one hour prior to the audiocast.

Financial calendar

Year-End Report 2017 -	January 25, 2018 at 8.00 am CET
Publication of the Annual Report -	March week 12, 2018
Interim Report Q1 2018 -	April 26, 2018 at 8.00 am CET
Interim Report Q2 2018 -	July 11, 2018 at 8.00 am CET

Contents

CEO comments

Eventful quarter paving the way for the future

In Q3 we have met several of the objectives for 2017 and I am in particular proud of the accomplishments that will strengthen the foundation for Orexo in 2018 and beyond.

From a financial perspective we continue our track record of positive cash flow from operations and have now surpassed two years of unbroken positive quarterly cash flow. I am also pleased to announce we have reached positive EBITDA (and EBIT) year-to-date, which is one of the targets in our guidance for the full-year. The positive result is driven primarily by the continued positive profit contribution from our US business, strong Abstral® performance in Europe and continued firm cost management.

Market access is the main driver of market share and growth in the US market for Zubsolv® and has gained significant focus and priority in 2017. Looking forward to 2018, we managed to secure the best improvements in market access for Zubsolv since 2014 and overall our market access in 2018 will be the best ever for Zubsolv. In the commercial segment Zubsolv's formulary access beginning January 1 will be the best of any product in the buprenorphine/naloxone market, whether branded or generic. In the fast-growing public segment Zubsolv will have significant improvement in access, both in parity with competitors and some exclusive preferred positions within Medicare Part D. These improvements in market access are the result of our relentless efforts to make Zubsolv the most valuable choice from a medical and financial perspective for patients and payers in the US. These market access gains combined with our improvements in the supply chain will ensure affordable access to this life saving treatment for more patients, while Orexo maintains healthy gross margins.

While Zubsolv in the US remains our main focus, we are constantly working to strengthen and broaden our product offering and pipeline with new products and projects. The newest and most important near-term revenue generating project will be the launch of Zubsolv in Europe. With the positive opinion from the European committee, CHMP, in September, Zubsolv is well on track to receive approval later this year by the European Commission and for our partner Mundipharma to start launching Zubsolv during the first half of 2018. Upon launch, Zubsolv will be the first ever, fast-dissolving alternative to Suboxone® tablets in Europe.

Additionally, we have filed a patent application for our OX382 project in September and we are aiming to bring to market the first ever swallowable oral formulation of buprenorphine. A swallowable tablet is generally preferred by patients and physicians, due to the added convenience and in opioid dependence treatment it allows for improved efficiency in the multitude of clinics using supervised treatment settings. The next step will be a clinical phase I trial scheduled to start in Q1, 2018.

One of my overarching objectives has been to make Orexo profitable and with the current trajectory for 2017 we expect to present a positive net profit for the full year and we have reached a positive net cash position, thus eliminating any financing risk of the corporate bond issued in 2014. Both of these factors are testimony to our ability to drive effectiveness and apply strict cost controls while improving the foundations to grow our top line in the years to come. With the positive development in market access in the US, improved supply chain, approval of Zubsolv in Europe and updated pipeline I am confident we have paved the way for profitable growth in 2018 and beyond.

Nikolaj Sørensen
President and CEO

Financial information and business review

EBITDA for Q3 2017, amounted to SEK 46.1 million (50.9) and SEK 42.8 million (48.8) for the period January – September. This means that Orexo is well on track to deliver on the full year EBITDA guidance. An update and clarification of the full year guidance can be found in the Outlook 2017 section.

Cash flow from operating activities was again positive and increased the cash position to SEK 370.7 million, turning Orexo net cash positive. Subject to market conditions, Orexo is now planning to make an early redemption of the corporate bond during Q4 2017, and issue a new corporate bond with a total value of SEK 300 - 350 million.

Revenues

Total revenues for Q3 2017 amounted to SEK 166.2 million (181.9) corresponding to an 8.7 percent lower level compared with the same period the previous year. Revenue for Q3 2016 included a significant one-time Zubsolv® US wholesaler inventory buy when the wholesalers reacted on the increased demand caused by the implementation of the exclusive agreement with the State of Maryland.

For the period January to September 2017, total revenues amounted to SEK 452.6 million (521.2). Higher milestone income in 2016 explains the decline. Excluding the milestone income net revenue grew by 3.9 percent.

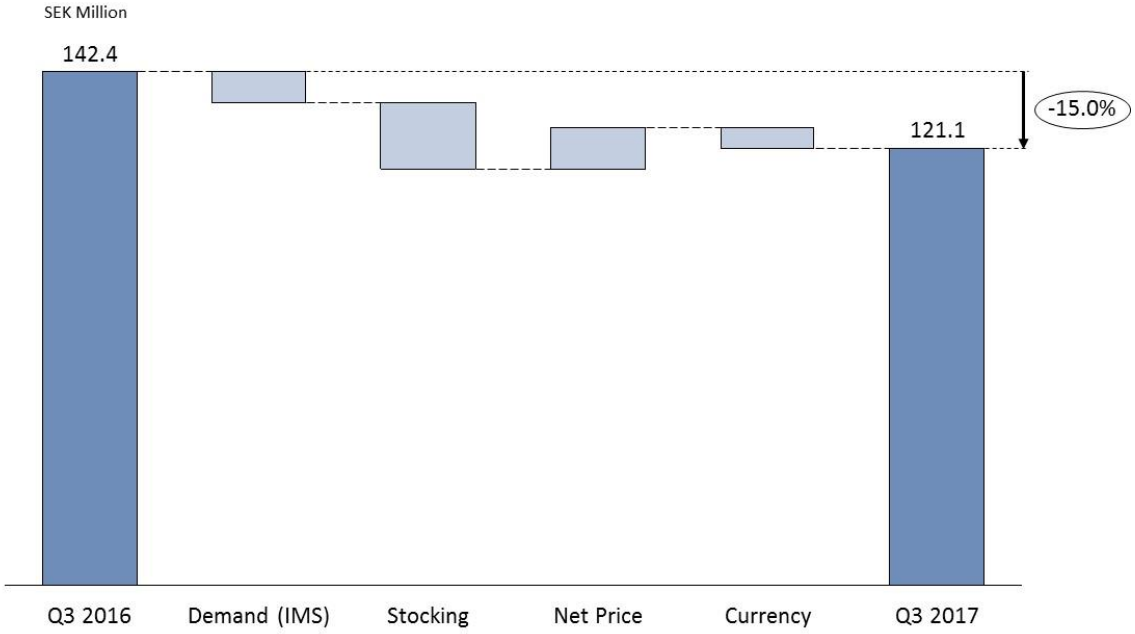
The movements of the USD versus SEK exchange-rate has impacted the Zubsolv US revenue measured in SEK negatively when comparing Q3 2017 against same period previous year, but even more when comparing against Q2 2017.

Commercial products

Zubsolv US revenue amounted to SEK 121.1 million (142.4) in Q3 2017, corresponding to a 15 percent decline from same period last year. From Q2, 2017, we have seen a small decline in SEK, but a positive development of 6 percent in local currency (USD).

The above mentioned one-time significant wholesaler buy explains the major part of the decline between Q3 2017 and same period prior year. The Q3 2017 demand, measured as sales out of pharmacies, declined by approximately 7 percent when comparing with same period the prior year. The lower demand was, however, more than compensated by a higher average net tablet price driven by the 6 percent price increase from January 1, 2017, and by lower average rebate levels.

Zubsolv® US net revenue growth by key drivers, Q3 2016 versus Q3 2017[1]



Abstral® revenues amounted to SEK 39.4 million (36.8) for Q3 2017. The growth was driven by continued strong performance of Abstral in Europe. For the European region Orexo receives royalties for sales exceeding EUR 42.5 million.

Revenues from Edluar® amounted to SEK 5.7 million (2.3) for Q3 2017. The increase was primarily related to a one-time adjustment of royalties from prior periods.

Development projects

The period January - September 2017, includes a milestone payment from AstraZeneca relating to the OX-CLI project of USD 2.5 million (SEK 21.8 million) that was triggered by the project entering clinical phase I trials. The same period the prior year included a USD 5 million (SEK 40.8 million) OX-CLI milestone payment from AstraZeneca when they acquired all rights to the project.

Total net revenues were distributed as follows

SEK million	2017 Jul-Sep	2016 Jul-Sep	2017 Jan-Sep	2016 Jan-Sep	2016 Jan-Dec
Zubsolv® US	121.1	142.4	359.3	353.6	481.8
Zubsolv – Rest of the World	-	0.4	-	65.9	65.9
Zubsolv – total	**121.1**	**142.8**	**359.3**	**419.5**	**547.7**
Abstral® royalties	39.4	36.8	57.8	50.4	100.4
Milestone payment Abstral	-	-	-	-	2.2
Abstral – total	**39.4**	**36.8**	**57.8**	**50.4**	**102.6**
Edluar royalties	5.7	2.3	13.7	10.5	14.8
OX-CLI	-	-	21.8	40.8	40.8
Total	**166.2**	**181.9**	**452.6**	**521.2**	**705.9**

[1] Orexo analysis using IMS demand data

Costs and earnings

Cost of goods sold
Cost of goods sold (COGS) amounted to SEK 32.1 million (38.3) for Q3 2017 and relates to Zubsolv® US in its entirety. A significant volume of products was manufactured during the quarter which resulted in a positive COGS variance. During quarters with a low level of manufacturing the amount of indirect production costs absorbed by manufactured volumes will be less than the actual indirect cost incurred and will create negative manufacturing variances. Net of accruals for obsolescence the positive variance for the quarter amounted to approximately SEK 5 million. In Q4 2017, relatively low volumes will be manufactured and a low negative variance can be expected.

Selling expenses
Selling expenses amounted to SEK 43.3 million (57.3) for Q3 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. The weakening of the USD versus SEK during the quarter had a positive impact on selling expenses as all expenses are in USD.

Administrative expenses
Administrative expenses for Q3 2017 amounted to SEK 21.0 million (33.3). The reduced level is primarily explained by less expenses related to the patent infringement litigation against Actavis. In Q4 a slight increase can be expected due to costs associated with the hearing in the Courts of Appeals on October 4.

Research and development costs
In Q3 2017 research and development costs amounted to SEK 29.0 million (24.1). During the quarter the pipeline of development projects mainly consumed internal resources and only little was spent on external activities. The redesign and implementation of a new supply chain is also consuming resources from the development organization.

Costs for long-term incentive program
The Group's total costs for employee stock option programs during Q3 2017 amounted to SEK 1.3 million (-1.7). For the period January to September 2017, the costs amounted to SEK 1.7 million (0.5).

Other income and expenses
Other income and expenses amounted to SEK 0.1 million (14.1) for Q3 2017. This comprises exchange-rate gains/losses derived from revaluations of operating receivables and payables in foreign currency and income/expenses from activities other than normal business operations. A minor impact from a one-time sale of buprenorphine back to the original supplier was included.

Depreciation and amortization
Depreciation and amortization amounted to SEK 5.2 million (7.9) for Q3 2017.

Net financial items
Net financial items for Q3 2017 amounted to SEK -11.3 million (-5.4). These items are related to financing activities including exchange-rate gains/losses derived from foreign currency bank accounts.

Tax
Total tax for Q3 2017 amounted to SEK 1.4 million (1.7).

Net earnings
Net earnings amounted to SEK 28.2 million (36.0) for Q3 2017.

Cash flow and financial position

At September 30 2017, cash and cash equivalents amounted to SEK 370.7 million (276.9) and interest-bearing liabilities to SEK 340.6 million (496.2).

The bond loan was reclassified to current liabilities in Q2 2017, 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 again positive and amounted to SEK 92.3 million (31.1) for Q3 2017 driven by strong operating earnings and a reduction in net working capital. Net working capital was primarily improved by continued inventory reductions and increased current liabilities. The inventory reductions was driven by a one-time sale of buprenorphine back to the original supplier amounting to SEK 21 million. The increase in current liabilities was mainly related to accruals for rebates to US payers (insurance companies and public payers).

Two years with constant positive quarterly cash flows from operating activities have finally turned Orexo into a net cash positive situation with a net debt of SEK -30.1 million. This brings Orexo in a strong financial position and in a good position to refinance the existing corporate bond. Subject to market conditions, Orexo is contemplating issuing a new corporate bond during Q4 2017 at an aggregate amount of SEK 300 – 350 million. The proceeds of such bond issue would be used towards redeeming the existing outstanding bonds in full and towards general corporate purposes.

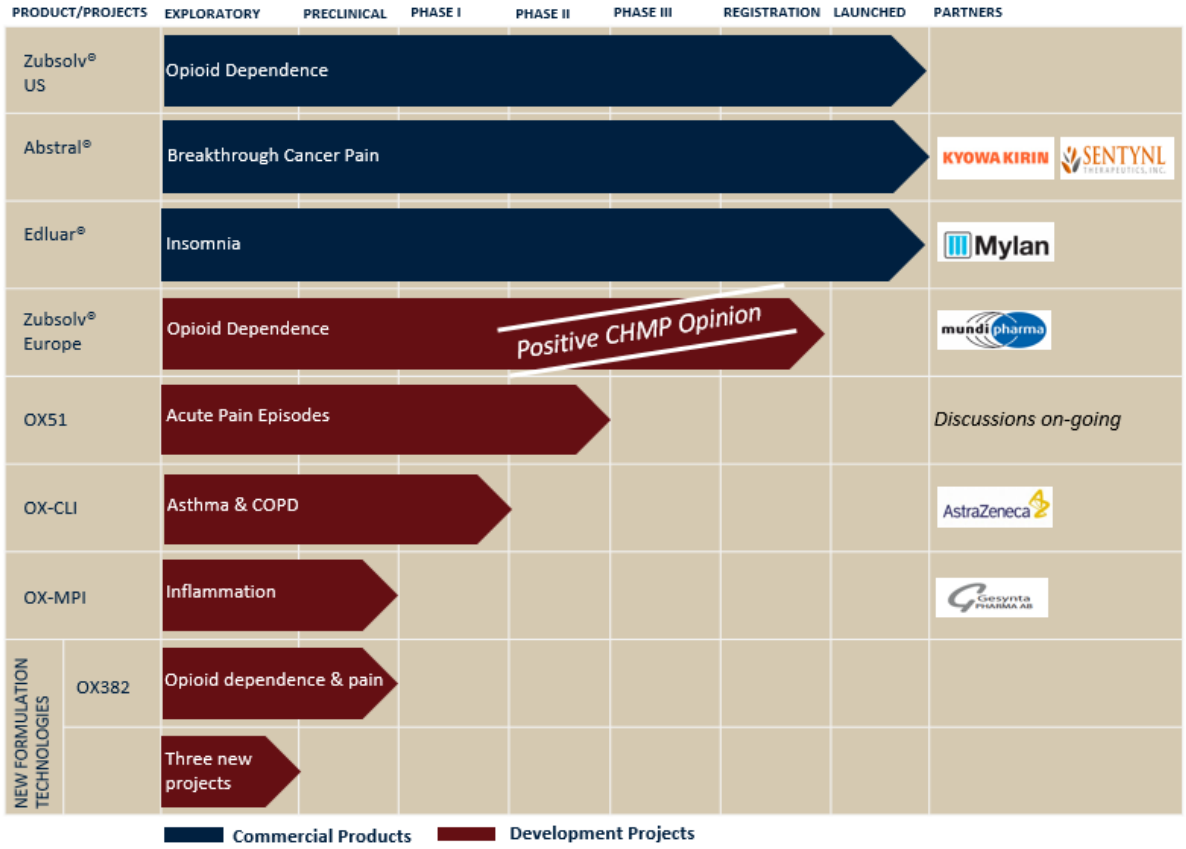
Shareholders' equity at September 30, 2017, was SEK 300.0 million (270.9). The equity/asset ratio was 29.0 percent (25.3).

Investments in fixed assets

Gross investments in tangible and intangible fixed assets amounted to SEK 0.5 million (1.0) for Q3 2017.

Operations

Pipeline of commercial products and development projects



Commercial products

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

The third quarter of 2017 demonstrated buprenorphine/naloxone market growth of 2.2 percent in volume compared to Q2 2017, and 10.7 percent compared to Q3 2016. The market forecast is continued expansion as more providers begin to take on a patient load by becoming waivered and as currently waivered prescribers expand their patient cap limits from 100 to 275 patients. To date, more than 3,500 waivered physicians are eligible to increase their patient load to 275, while nurse practitioners and physician's assistants now total over 2,800 waivered to treat opioid dependency.

Zubsolv's development in both volume and market share can primarily be explained by dynamics in market access. While the first half of 2017 outperformed the same period in 2016, Zubsolv volume and market share made a significant jump in July 2016 with an exclusive preferred position in Maryland. During the last year we have seen the Maryland share and volume contribution erode as Maryland had weak control of the prescriptions and allowed patients to move back to their previous medication. From July this year Maryland has added all products to the preferred Medicaid formulary and we have seen some additional erosion impacting both market share and volume. Zubsolv's Q3 2017 performance when compared to Q2 2017 shows a 1.1 percent decrease in tablets dispensed to patients through pharmacies and a 7.1 percent decrease versus the same quarter in 2016. The overall impact on net sales from the Maryland change in Q3 has been positive as the impact on volume is more than compensated by lower rebates.

The US payer market is made up of three distinct payer segments. Of these segments, two are managed segments which are the commercial (private insurance) and public (Managed Medicaid, FFS Medicaid and Medicare Part D). The cash segment is available for every patient to access directly.

To date, the public segment continues to be the fastest growing payer segment. During the quarter the commercial segment continued to grow while the cash segment declined. Zubsolv's market access in the growing public segment has resulted in more than 80 percent of the growth between Q3 2016 and Q3 2017 and has been with payers currently not recommending Zubsolv® and blocking access to Zubsolv for patients. Improving Zubsolv market access in the growth market is a key success factor to increase market share and volume growth.

Zubsolv Market Access Formulary Improvements in 2018

At an overall level Orexo has secured a series of market access improvements for Zubsolv scheduled for 2018, and assuming a continued growth pattern, Zubsolv will double access to the growing segment of the market, providing much more additional opportunity for Zubsolv to grow its volume.

Broken down by segment, Zubsolv will, in the commercial segment, be nearly universally reimbursed in a preferred position in 2018, primarily explained by the new preferred position within CVS Caremark and the fact that Zubsolv has not lost any preferred position from 2017. Also, Zubsolv will from January 1 be the exclusive preferred product for certain patient categories with two additional accounts in the commercial segment. In the public segment, Zubsolv will become preferred on two top 5 Medicare Part D, accounts of which one will make Zubsolv the exclusive preferred products. Within FFS Medicaid Zubsolv is becoming the preferred choice with one additional top 10 account and will be preferred with 6 of 10 top 10 FFS Medicaid providers from January 1, 2018.

Within the payer segments in which Orexo has secured market access improvements, the new accounts are growing market volume at a faster rate than the currently accessible market for Zubsolv. The accounts in the commercial segment to which Zubsolv has access today grew 5 percent between Q3 2016 and Q3 2017. In comparison the payers to which Zubsolv will gain access in 2018 grew 12 percent. In Medicare Part D, the other major segment where Zubsolv has 2018 improvements, the market growth rate for currently accessible accounts was 17 percent, while the growth rate for the new accounts from January 2018 was 22 percent.

The improvement in market access in 2018 is the best development in market access for Zubsolv since 2014. While some of the exclusive contracts will have an impact early in 2018, the main value is from the broader preferred status and Orexo's ability to compete in larger geographies for market share and volume in the growing segment of the market. The impact and value of the exclusive contract is highly dependent on the health plans ability and willingness to control the prescriptions and we have experienced wide variations in the final market share, ranging from United Health Group and WellCare with Zubsolv market share well above 75 percent to Maryland with less than 40 percent market share.

Paragraph IV litigations against Actavis regarding Zubsolv in the US

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. An oral session was held in the US Court of Appeals for the Federal Circuit on October 4 2017. Due to the current workload a decision from the Court could take up to 9 months, which is later than previously expected. Orexo has no influence on the timing of the decision and the decision can come earlier without prior notification to Orexo.

In addition, two new Zubsolv US patents, 9,259,421 and 9,439,900 (both expire September 2032), have been issued and listed in the Orange Book in 2016. Orexo has initiated a litigation process against Actavis for infringement of these two patents, but the litigation process is on hold awaiting the decision by the Court of Appeals for the Federal Circuit with regard to Orexo's US Patent No. 8,940,330.

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 the 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 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.

Abstral® - breakthrough cancer pain

Due to the timing of this Interim Report, Orexo has not yet received final data for Q3 sales of Abstral and Edluar® from our partners and hence the calculation of Q3 royalties is based on Orexo´s forecast and preliminary Q3 sales reports where available. For the same reason the Abstral and Edluar sections below primarily refer to the sales development in Q2 2017.

Sales of Abstral in the EU continue to grow and amounted to EUR 22 million in Q2 2017, which is an increase of 7 percent in Q2 2017 compared to Q2 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., was acquired by Zydus Cadila in January 2017. Net sales were 72 percent lower in Q2 2017 compared with the 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 2.5 million in Q2 2017, which is an increase of 5 percent compared with Q2 2016.

Sales of Abstral in Japan declined 7 percent during the second local commercial quarter, March 2017 to May 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, were 73 percent higher in Q2 2017 compared to Q2 2016 mainly driven by a onetime positive adjustment of net sales in the US. Total sales for Q2 2017 amounted to EUR 5.1 million (2.9).

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.

Development projects

Orexo's development efforts follow a three-pronged approach:

- Orexo has three internal development projects underway that are aimed at broadening our commercial platform and offering a comprehensive range of treatment options to opioid dependent patients. Once on the market, these products will be highly synergistic with Zubsolv® and Orexo's existing commercial footprint, unlocking commercial synergies and profit growth such as OX382. The most advanced of these projects is an innovative swallowable formulation of buprenorphine, which represents a first-to-market opportunity for Orexo and will have clear benefits over today's treatment options.

- For development assets that do not have a direct fit with our current commercial platform in the United States, such as Zubsolv outside the US, OX-CLI, OX-MPI and OX51, Orexo's strategy is to work with partners who have more insight into the respective disease space or geographies and more capacity to drive the development forward.

- Some of our development platforms can be used for a broad spectrum of possible pharmaceutical compounds. Orexo is constantly testing APIs for application in one of our platforms even if those fall

outside our direct commercial focus segments. In such cases, Orexo will perform the early stages of development and then find partners for these assets.

Zubsolv® Europe – opioid dependence

In Q3 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) issued a positive opinion for Zubsolv for use in the treatment of opioid dependence. The European Commission is now reviewing the CHMP opinion and a final decision is expected in Q4 2017.
Orexo has jointly worked with Mundipharma and its network of independent associated companies, who have acquired all rights to Zubsolv outside the United States, to complete the submission that was filed with the European Medicines Agency (EMA) in October 2016. The submission was based on data from a bioequivalence study, previous pharmacokinetic studies, and Orexo's extensive clinical program that includes data on more than 1,000 opioid dependent patients.

Depending on local reimbursement, a launch of Zubsolv in Europe is anticipated to be initiated in H1 2018. Orexo will receive a milestone payment pending achievement of an EU marketing authorization and commercialization of Zubsolv and are also entitled to receive up to low double-digit royalties on future net sales. Furthermore, Orexo will supply the product to Mundipharma and will be rewarded for future savings in the cost of goods.

With an estimated 1.3 million high-risk opioid users[2], opioid dependence is a serious health concern in Europe where heroin accounts for a majority of the opioid misuse. While opioid dependence in Europe has not reached the epidemic proportions seen in the United States, there are several alarming trends. The number of overdose-related deaths has increased for the third consecutive year[3] and synthetic opioids are a growing health threat.[4] Consequently, there are signs of expansion of the opioid market in Europe according to UNODC.[5]

OX382 – oral formulation of buprenorphine

Orexo is developing a swallowable formulation of buprenorphine (OX382). The aim is to be first-to-market in this new product class and to offer clear benefits over today's treatment options for certain patient categories and treatment settings.

For most treatments without need for immediate absorption of the active ingredient, a swallowable formulation is preferred and generally recognized as the standard formulation. Buprenorphine has poor and unreliable absorption in the gastrointestinal (GI) tract which has so far been the major hurdle to develop a swallowable formulation. Orexo has developed, and filed a patent application for an innovative technology that could address these hurdles and deliver buprenorphine in a controlled and reliable manor in the GI tract.

This new formulation is expected to have several convincing advantages over currently available buprenorphine formulations. Swallowable pharmaceuticals are generally preferred by patients over sublingual or buccal products as they do not have issues with bad taste or local irritation in the mouth. In addition, OX382 would offer specific benefits wherever patients receive their opioid dependence treatment under supervision of a health care professional or a pharmacist. Unlike today, there will be no need to wait for a sublingual or buccal formulation to dissolve in the mouth, allowing for much more efficient processes in the respective clinics. Supervised (opioid dependence) treatment is common in the US, e.g., for patients who receive treatment in methadone clinics, and is particularly common in Europe where about half of opioid dependent patients receive treatment in a monitored setting.

The new unique product could be used in both opioid dependence and pain treatment. The development program is approaching the first clinical study in humans (Phase I), which is expected to be completed in H1, 2018. With a positive result of the phase I study Orexo will outline the development plan and priority of potential indications, which will enable more firm guidance on the commercial potential and development risks.

[2] European Drug Report 2017
[3] European Drug Report 2017
[4] European Drug Report 2017
[5] World Drug Report 2017

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 with sales of products based on the OX-CLI program.

OX-MPI – inflammation

The lead candidate drug in the OX-MPI program, BI1029539, has been identified as a highly selective anti-inflammatory compound targeting microsomal prostaglandin E synthase (mPGES-1).
The OX-MPI program was acquired by Gesynta Pharma AB on September 29 2017. Gesynta Pharma AB is a recently formed research company located in Stockholm, Sweden, and among the founders are highly reputed executives from the biotech industry and experienced researchers at the Karolinska Institute within the field of arachidonic acid pathways and inflammatory diseases. At the time of the acquisition the project was in the preclinical phase and Gesynta Pharma AB will progress the candidate drug into proof-of-concept clinical trials.

Under the terms of the agreement Orexo will receive a tiered double-digit share of the future revenues that Gesynta Pharma AB generates from the OX-MPI project.

OX51 – acute pain episodes

OX51 is a new sublingual tablet 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 potential partners are ongoing. The discussion has taken longer than anticipated and some critical areas remain to be agreed to finalize the negotiations of a co-development program.

New formulation technologies

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 can currently not be administered sublingually. The project is in the exploratory phase, and several active ingredients have been identified as promising candidates for this new technology.

In addition, Orexo has two non-disclosed projects, both of which will also fall into the addiction category and with the ambition to provide clear clinical differentiation versus currently available treatment alternatives. Orexo will disclose more details once the final feasibility tests are completed and have shown positive results.

Parent Company

Net revenues for Q3 2017 amounted to SEK 114.8 million (86.9). Earnings before tax were SEK 24.2 million (23.0). Investments amounted to SEK 0.5 million (0.3). As of September 30 2017, cash and cash equivalents in the Parent Company amounted to SEK 215.4 million (164.0).

Outlook 2017

The outlook for 2017 provided in the 2016 Full Year report and subsequently updated in Interim Reports has been updated based on the performance year-to-date, a depreciation of USD against SEK and current plans for the remaining part of the year.

For the period January – September 2017, Orexo delivered a positive EBITDA of SEK 42.8 million. EBITDA for Q4 2017, is also expected to be positive, however lower than the level reported in Q3 2017. In Q4 increased investments in the R&D pipeline and the supply chain project are expected, as well as a relatively higher Zubsolv® COGS level. Total OPEX, including the investments mentioned, for Q4 is expected to be approximately SEK 110 million.

The outlook is now based on September 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 an operational nature and Orexo is continuously exposed to risks in relation to the intellectual property rights and legal disputes as highlighted on page 8-9 and in Note 3.

Uppsala, Sweden, October 19, 2017

Orexo AB (publ.)

Nikolaj Sørensen
President and CEO

Review report

Orexo AB, corporate identity number 556500-0600

Introduction
We have reviewed the condensed interim report for Orexo AB as at September 30, 2017 and for the nine months period then ended. The Board of Directors and the Managing Director are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of review
We conducted our review in accordance with the International Standard on Review Engagements, ISRE 2410 *Review of Interim Financial Statements Performed by the Independent Auditor of the Entity*. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and other generally accepted auditing standards in Sweden. The procedures performed in a review do not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Conclusion
Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material respects, in accordance with IAS 34 and the Swedish Annual Accounts Act regarding the Group, and in accordance with the Swedish Annual Accounts Act regarding the Parent Company.

Stockholm 19 October 2017

Ernst & Young AB

Björn Ohlsson
Authorized Public Accountant

Consolidated statement of operations

SEK million	Notes	2017 Jul-Sep	2016 Jul-Sep	2017 Jan-Sep	2016 Jan-Sep	2016 Jan-Dec
Net revenues		166.2	181.9	452.6	521.2	705.9
Cost of goods sold		-32.1	-38.3	-114.1	-104.7	-149.6
Gross profit		**134.1**	**143.6**	**338.5**	**416.5**	**556.3**
Selling expenses		-43.3	-57.3	-141.3	-174.4	-240.6
Administrative expenses		-21.0	-33.3	-69.8	-131.2	-161.6
Research and development costs		-29.0	-24.1	-98.4	-97.8	-132.3
Other operating income and expenses		0.1	14.1	-1.8	16.0	29.9
Operating earnings		**40.9**	**43.0**	**27.2**	**29.1**	**51.7**
Net financial items		-11.3	-5.4	-23.0	-17.3	-16.1
Earnings before tax		**29.6**	**37.6**	**4.2**	**11.8**	**35.6**
Tax		-1.4	-1.7	-7.8	-5.3	-6.5
Net earnings for the period[1]		**28.2**	**36.0**	**-3.6**	**6.5**	**29.0**

Consolidated statement of comprehensive income

SEK million	2017 Jul-Sep	2016 Jul-Sep	2017 Jan-Sep	2016 Jan-Sep	2016 Jan-Dec
Earnings for the period	**28.2**	**36.0**	**-3.6**	**6.5**	**29.0**
Other comprehensive income					
Items that may subsequently be reversed to the statement of operations:					
Reclassification assets available for sale	-	-	-	-	-0.9
Exchange-rate differences	-5.3	-7.7	-8.4	-8.6	6.2
Other comprehensive earnings for the period, net after tax	**-5.3**	**-7.7**	**-8.4**	**-8.6**	**5.3**
Total comprehensive earnings for the period [1]	**22.9**	**28.3**	**-12.0**	**-2.1**	**34.3**
Earnings per share, before dilution, SEK	0.82	1.04	-0.10	0.19	0.84
Earnings per share, after dilution, SEK	0.81	1.04	-0.10	0.19	0.84

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

Consolidated balance sheet

SEK million	Notes	2017 Sep 30	2016 Sep 30 Restated	2016 Dec 31
ASSETS				
Fixed assets				
Tangible fixed assets		20.0	23.1	22.1
Intangible assets		125.4	138.8	138.2
Deferred tax assets		30.1	24.8	24.8
Other financial assets		7.0	7.5	7.9
Total fixed assets		**182.5**	**194.2**	**193.0**
Current assets				
Inventories		272.1	360.8	344.2
Accounts receivable and other receivables		208.0	240.7	199.2
Cash and cash equivalents		370.7	276.9	282.4
Total current assets		**850.8**	**878.4**	**825.8**
Total assets		**1,033.3**	**1,072.6**	**1,018.8**
SHAREHOLDERS' EQUITY AND LIABILITIES				
Total shareholders' equity		**300.0**	**270.9**	**310.3**
Long-term liabilities				
Provisions		3.4	2.4	1.2
Long-term liabilities, interest bearing		-	496.2	397.8
Total long-term liabilities		**3.4**	**498.6**	**399.0**
Current liabilities and provisions				
Provisions		207.2	170.9	163.9
Current liabilities, interest bearing		340.6	-	-
Current liabilities, non-interest bearing		182.2	132.2	145.6
Total current liabilities and provisions		**730.0**	**303.1**	**309.5**
Total liabilities		**733.4**	**801.7**	**708.5**
Total shareholders' equity and liabilities		**1,033.3**	**1,072.6**	**1,018.8**

Consolidated changes in shareholders' equity

SEK million	2017 Sep 30	2016 Sep 30	2016 Dec 31
Opening balance, shareholders' equity	**310.3**	**270.1**	**270.1**
Total comprehensive earnings for the period	-12.0	-2.1	34.3
Employee stock options, vested amount	1.7	0.8	3.7
Buy back of shares	-	-	-0.1
New share issue	-	2.1	2.3
Closing balance, shareholders' equity	**300.0**	**270.9**	**310.3**

Consolidated cash flow statements

SEK million	Notes 1	2017 Jul-Sep	2016 Jul-Sep Restated	2017 Jan-Sep	2016 Jan-Sep Restated	2016 Jan-Dec
Operating earnings		40.9	43.0	27.2	29.1	51.7
Financial income and expenses		-14.3	-7.1	-32.8	-22.5	-28.3
Adjustment for non-cash items	2	11.1	11.3	88.9	52.6	44.1
Cash flow from operating activities before changes in working capital		**37.7**	**47.2**	**83.3**	**59.2**	**67.5**
Changes in working capital		**54.6**	**-16.1**	**86.3**	**25.6**	**88.7**
Cash flow from operating activities		**92.3**	**31.1**	**169.6**	**84.8**	**156.2**
Acquisition of tangible and intangible fixed assets		-0.5	-1.0	-0.8	-1.2	-1.4
Disposal of fixed assets		-	-	-	-	1.9
Sale of subsidiary		-	-	-	-	5.0
Cash flow from investing activities		**-0.5**	**-1.0**	**-0.8**	**-1.2**	**5.5**
New share issue		-	2.1	-	2.1	2.2
Change in loans		-	-	-59.0	-	-92.8
Cash from financing activities		**0.0**	**2.1**	**-59.0**	**2.1**	**-90.6**
Cash flow for the period		**91.8**	**32.2**	**109.8**	**85.7**	**71.1**
Cash and cash equivalents at the beginning of the period		**294.3**	**252.9**	**282.4**	**198.1**	**198.1**
Exchange-rate differences in cash and cash equivalents		-15.4	-8.2	-21.5	-6.9	13.2
Changes in cash and cash equivalents		91.8	32.2	109.8	85.7	71.1
Cash and cash equivalents at the end of the period		**370.7**	**276.9**	**370.7**	**276.9**	**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 Jul-Sep	2016 Jul-Sep Restated	2017 Jan-Sep	2016 Jan-Sep Restated	2016 Jan-Dec
EBIT margin, %	24.6	23.6	6.0	5.6	7.0
Return on shareholder equity, %	10.0	14.0	-1.0	2.0	10.0
Net debt, SEK million	-30.1	219.3	-30.1	219.3	115.4
Debt/equity ratio, %	113.5	183.2	113.5	183.2	128.2
Equity/assets ratio, %	29.0	25.3	29.0	25.3	30.5
Number of shares, before dilution	34,539,585	34,531,107	34,539,585	34,531,107	34,477,423
Number of shares, after dilution	34,667,421	34,588,455	34,539,585	34,588,455	34,574,412
Earnings per share, before dilution, SEK	0.82	1.04	-0.10	0.19	0.84
Earnings per share, after dilution, SEK	0.81	1.04	-0.10	0.19	0.84
Number of employees at the end of the period	92	102	92	102	102
Shareholders' equity, SEK million	300.0	270.9	300.0	270.9	310.3
Capital employed, SEK million	640.6	767.1	640.6	767.1	708.1
Working capital, SEK million	120.8	575.3	120.8	575.3	516.3

[1] Definitions and reconciliations of key figures are presented on page 21 of this report

Parent Company statement of operations

SEK million	Notes	2017 Jul-Sep	2016 Jul-Sep	2017 Jan-Sep	2016 Jan-Sep	2016 Jan-Dec
Net revenues		114.8	86.9	350.8	307.0	379.3
Cost of goods sold		-38.0	-11.5	-134.2	-66.1	-83.6
Gross profit		**76.8**	**75.4**	**216.6**	**240.9**	**295.7**
Selling expenses		-4.6	-17.2	-46.6	-74.9	-105.8
Administrative expenses		-13.7	-24.0	-48.9	-107.6	-129.1
Research and development costs		-23.1	-16.4	-76.9	-115.0	-141.8
Other operating income and expenses		0.1	9.7	-1.8	8.1	24.3
Operating earnings		**35.5**	**27.5**	**42.4**	**-48.5**	**-56.7**
Interest income and expenses		-2.7	-3.9	-11.0	-12.3	-16.2
Exchange rate adjustment		-	-	-1.3	-	-32.1
Other financial expenses		-8.6	-0.6	-11.2	-1.3	9.3
Net financial items		**-11.3**	**-4.5**	**-23.5**	**-13.6**	**-39.1**
Earnings before tax		**24.2**	**23.0**	**18.9**	**-62.1**	**-95.8**
Tax		-	-	-	-0.1	-
Earnings for the period		**24.2**	**23.0**	**18.9**	**-62.2**	**-95.8**

Parent company statement of comprehensive income

SEK million	2017 Jul-Sep	2016 Jul-Sep	2017 Jan-Sep	2016 Jan-Sep	2016 Jan-Dec
Earnings for the period	**24.2**	**23.0**	**18.9**	**-62.2**	**-95.8**
Other comprehensive income	**-**	**-**	**-**	-	-
Total comprehensive earnings for the period	**24.2**	**23.0**	**18.9**	**-62.2**	**-95.8**

Parent Company balance sheet

SEK million	Notes	2017 Sep 30	2016 Sep 30	2016 Dec 31
ASSETS				
Fixed assets				
Tangible and intangible fixed assets		145.2	165.0	159.8
Shares in subsidiaries		149.8	148.7	149.7
Total fixed assets		**295.0**	**313.7**	**309.5**
Current assets				
Inventories		193.2	271.6	269.6
Accounts receivable and other receivables		148.0	237.0	76.8
Cash and bank balances		215.4	164.0	211.7
Total current assets		**556.6**	**672.6**	**558.1**
Total assets		**851.6**	**986.3**	**867.6**
SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES				
Shareholders' equity		**284.1**	**295.6**	**263.5**
Long-term liabilities		**3.4**	**498.5**	**399.1**
Current liabilities		**564.1**	**192.2**	**205.0**
Total liabilities		**567.5**	**690.7**	**604.1**
Total shareholders' equity and liabilities		**851.6**	**986.3**	**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.

IFRS 15 revenue from contracts with customers replaces all previously issued standards and interpretations that deal with revenues in a coherent model of revenue recognition. The Group will apply the new standard in its entirety as of January 1st 2018 and it has made a preliminary assessment of IFRS 15 and its effects on company's financial statements, which shows that no material change are expected other than additional disclosure requirements.

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

SEK million	2017 Jul-Sep	2016 Jul-Sep	2017 Jan-Sep	2016 Jan-Sep	2016 Jan-Dec
Depreciation/amortization and impairment	5.6	7.9	15.7	19.7	25.0
Gain/loss on disposal	-	-	-	-	-5.0
Change in provisions	1.5	14.5	67.0	39.7	42.0
Change in fair value of financial instruments	-	-1.7	-	0.5	0.2
Share based payments	1.3	0.3	1.7	0.8	3.7
Exchange rate income and expenses	2.7	-9.7	4.5	-8.1	-21.8
Total	**11.1**	**11.3**	**88.9**	**52.6**	**44.1**

3. Legal disputes

Paragraph IV litigations against Actavis regarding Zubsolv® in the US
On June 27, 2014 Orexo AB announced that it had filed a patent infringement action in United States against Actavis Elizabeth LLC and its parent company Actavis, Inc. The lawsuit was filed in response to an Abbreviated New Drug Application ("ANDA") filed by Actavis. In its application, Actavis seeks to market and sell generic versions of Orexo's patented Zubsolv (buprenorphine and naloxone) products in the US prior to the expiration of Orexo's US patents. The decision in this litigation process was issued on November 15, 2016, by the United States District Court for the District of Delaware. The District Court held that Orexo's 8,454,996 patent is valid and infringed by Actavis's and that 8,940,330 patent is invalid. 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. An oral session was held in the US Court of Appeals for the Federal Circuit on October 4, 2017. Due to current workload a decision from the court could take up to 9 months, which is later than previously expected. Orexo has no influence on the timing of the decision and the decision can come earlier without prior notification to Orexo.

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. 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 to report under this section.

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 SEK million	2017 Jul-Sep	2016 Jul-Sep	2017 Jan-Sep	2016 Jan-Sep	2016 Jan-Dec
EBIT	40.9	43.0	27.2	29.1	51.7
Depreciation and amortization	5.2	7.9	15.6	19.7	21.4
EBITDA	**46.1**	**50.9**	**42.8**	**48.8**	**73.1**

Return on shareholders' equity	2017 Jul-Sep	2016 Jul-Sep Restated	2017 Jan-Sep	2016 Jan-Sep	2016 Jan-Dec
Shareholders' equity beginning balance	275.8	240.5	310.3	270.1	270.1
Shareholders' equity ending balance	300.0	270.9	300.0	270.9	310.3
Average shareholders' equity	287.9	255.7	305.2	268.7	288.4
Net earnings	28.2	36.0	-3.6	6.5	29.0
Return on shareholders' equity %	**10.0**	**14.0**	**-1.0**	**2.0**	**10.0**

Operating expenses SEK million	2017 Jul-Sep	2016 Jul-Sep	2017 Jan-Sep	2016 Jan-Sep	2016 Jan-Dec
Selling expenses	-43.3	-57.3	-141.3	-174.4	-240.6
Administrative expenses	-21.0	-33.3	-69.8	-131.2	-161.6
Research and development costs	-29.0	-24.1	-98.4	-97.8	-132.3
Other operating income and expenses	0.1	14.1	-1.8	16.0	29.9
Operating expenses	**-93.2**	**-100.6**	**-311.3**	**-387.4**	**-504.6**

Gross investments SEK million	2017 Jul-Sep	2016 Jul-Sep	2017 Jan-Sep	2016 Jan-Sep	2016 Jan-Dec
Investments in tangible fixed assets	0.2	1.0	0.3	1.0	1.0
Investments in intangible fixed assets	0.3	-	0.5	0.2	0.3
Gross investments	**0.5**	**1.0**	**0.8**	**1.2**	**1.3**

Glossary

Alfentanil
A potent synthetic opioid analgesic drug, used for anesthesia 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.

Anesthesia
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

CHMP
The Committee for Medicinal Products for Human Use

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 anesthesia 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

Reimbursement
Contribution from the state or insurance company in order to reduce the price of drugs / treatment for the patient

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

UNODC
United Nations of Drugs and Crime

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

This information is information that Orexo AB (publ.) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 8.00 am CET on October 19, 2017.

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.