orexo

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

Full Year Report incl. Q4 2017

Summary

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

Strengthened financial position and continued profitability

Financial overview Q4 2017

- Total net revenues SEK 191.0 million (184.7)
- Zubsolv® US net revenue SEK 126.5 million (128.2). In local currency a growth of 7.2 percent.
- EBIT SEK 30.1 million (33.2)
- EBITDA SEK 35.3 million (44.1)
- Earnings per share, before and after dilution, SEK 0.77/0.77 (0.97/0.96)
- Cash flow from operating activities SEK -23.0 million (71.4)
- Cash and cash equivalents SEK 327.9 million (282.4)

Financial overview Full Year 2017

- Total net revenues SEK 643.7 million (705.9)
- Zubsolv US net revenue SEK 485.8 million (481.8)
- EBIT SEK 57.4 million (51.7)
- EBITDA SEK 78.2 million (73.1)
- Earnings per share, before and after dilution, SEK 0.67/0.67 (0.84/0.84)
- Cash flow from operating activities SEK 146.6 million (156.2)
- Full year 2017 guidance confirmed

Other highlights Q4 2017

- Issue of new corporate bond amounting to a nominal value of SEK 325 million and redemption of 2014 corporate bond
- The European Commission approved Zubsolv for treatment of opioid dependence in Europe
- Improved market access position for Zubsolv US, as of January 1 and July 1, 2018. Mainly explained by exclusive contracts signed with Humana Medicare Part D, Humana Commercial, Envision Rx and a preferred position on CVS Caremark´s and Ohio FFS Medicaid´s formulary list.
- Astra Zeneca has decided to discontinue OX-CLI and Orexo will not reacquire the rights to the program
- The Board of Directors proposes that no dividend is paid for the financial year 2017

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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-q4-2017. Telephone: (SE) +46 8 566 42 662, (UK) +44 203 008 98 01 or (US) +1 855 753 2235.
The presentation material will be available on Orexo´s website one hour prior to the audiocast.

Financial calendar

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

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CEO comments

Entering an exciting 2018

The fourth quarter of 2017 developed as anticipated on all important parameters. I am proud to announce the second full year with a positive bottom line result and a slight increase in operating earnings compared to 2016, despite significantly lower milestone income during 2017.

We know the main driver of changes in volume and market share for Zubsolv® in the US is market access and to improve our market access position has been a key strategic focus for the company in 2017. We have worked closely with the managed care providers to prepare the implementation of the new agreements starting 2018 and to prepare the organization to fully leverage these opportunities in 2018. With the new improved market access position we have invested in additional field force in regions where market access provides growth opportunities in 2018.

In Q4, Zubsolv US net revenues grew 7.2 percent, in local currency, compared to the same quarter last year. I am pleased to report such an increase in the closing quarter of the year as we faced some negative developments related to United Health Group leaving the Health Exchanges early in the year, a large healthcare provider leaving WellCare and Maryland adding all products to their formulary list as from July 1.

We strive to expand our commercial platform in the US through business development or by developing our own proprietary products. To ensure we have the financial flexibility to capture opportunities when they emerge, we decided to issue a new corporate bond, even though we have a positive net cash position and expect to continue with a positive cash flow from operating activities on an annual basis in 2018 as well. With the financial position secured for the next four years, we will intensify our efforts in business development and further accelerate the development of our internal projects when feasible.

During the fourth quarter our internal pipeline progressed according to plan. The European Commission approved Zubsolv for treatment of opioid dependence in Europe, and our partner Mundipharma will commence launch of the product in Europe during the first half of 2018. For OX382, where we aim to be first-to-market, with a novel formulation of buprenorphine that enables oral administration, we initiated the clinical phase I trial, with trial results expected in Q2, 2018. We also continue the work to strengthen our pipeline with early stage projects that will fall into the addiction category and with the ambition to provide clear clinical differentiation versus currently available treatment alternatives. During the quarter, the OX-CLI program was discontinued by AstraZeneca, but the decision to discontinue the program has no financial impact on Orexo.

With the positive financial results, our improved market access and a final decision in the appeal process against Actavis upcoming, I am confident that we have paved the way for growth and an exciting 2018.

Nikolaj Sørensen
President and CEO

EBITDA for the quarter amounted to SEK 35.3 million (44.1) and SEK 78.2 million (73.1) for the full year 2017. Financial results for the full year 2017 were in line with guidance provided in connection with the Q3 2017 Interim Report.

During the quarter Orexo refinanced its corporate bond by issuing a new bond with a nominal value of SEK 325 million and redeeming the 2014 corporate bond. At December 31, 2017, after the refinancing, Cash and Cash equivalents amounted to SEK 327.9 million leaving Orexo in a net cash positive situation.

Revenues

Total revenues for the quarter amounted to SEK 191.0 million (184.7) corresponding to a 3.4 percent increase over the same period the previous year. The increase was primarily explained by higher Abstral® revenue and supply of Zubsolv® to Mundipharma for their launch in 2018. The supply to Mundipharma was done at cost.

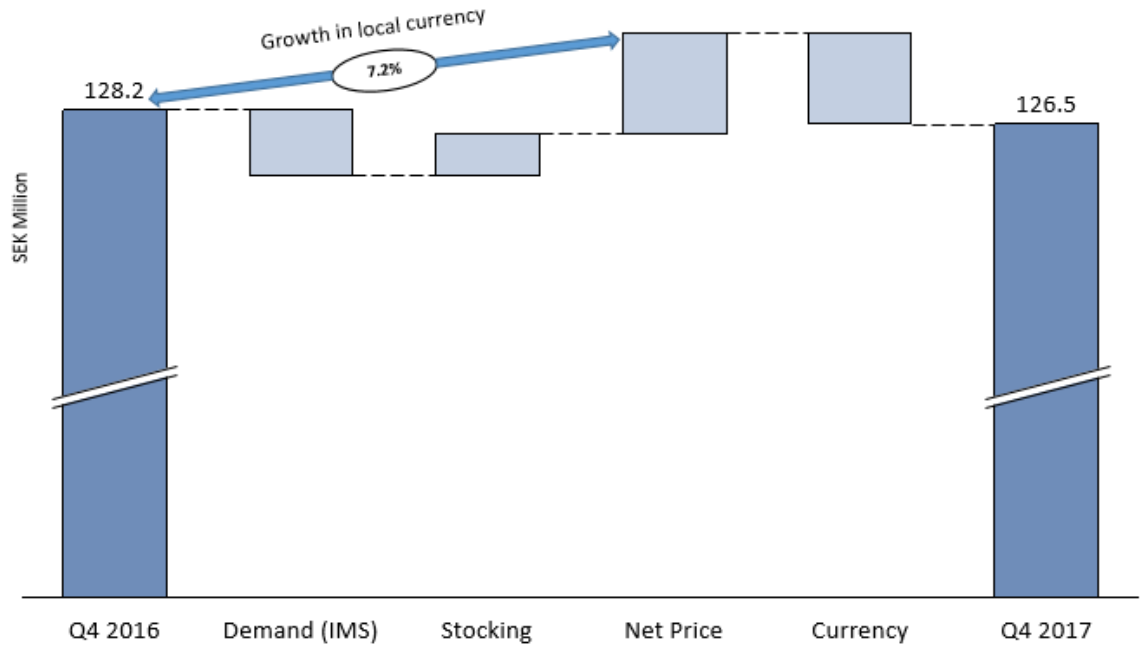
For the full year 2017, total revenues amounted to SEK 643.7 million (705.9). Lower milestone revenue in 2017 explains the decline. Excluding the milestone income net revenue grew by 4.2 percent, driven by Zubsolv US and Abstral.

Commercial products

Zubsolv US revenue amounted to SEK 126.5 million (128.2) for the quarter. In local currency Zubsolv US grew by 7.2 percent, however due to lower SEK/USD rate, the revenue measured in SEK declined year over year with 1.3 percent for the quarter.

The growth in local currency was driven by a lower volume demand that was more than off-set by better net prices and supported by additional wholesaler stocking in Q4 2017 in anticipation of the improved market access situation for Zubsolv US from January 1, 2018.

Zubsolv® US net revenue growth by key drivers, Q4 2016 versus Q4 2017[1]



[1] Orexo analysis using IMS demand data

For the full year 2017 Zubsolv® US revenue amounted to SEK 485.8 million (481.8) corresponding to 0.8 percent growth. In local currency the full year growth was 0.8 percent as well.

Zubsolv Rest of World revenue for the quarter included supply of Zubsolv to Mundipharma for their European launch. The products were supplied at direct cost as per the agreement.

Abstral® revenues amounted to SEK 55.4 million (52.2) for the quarter. The 6.1 percent growth was driven by continued strong performance of Abstral in Europe. For the full year Abstral revenue amounted to SEK 113.2 million (102.6), an increase of 10.3 percent over previous year.

Revenues from Edluar® amounted to SEK 3.6 million (4.3) for the quarter and for the full year to SEK 17.3 million (14.8).

Development projects

For the quarter no revenue was earned from development projects. The full year 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. This project has now been terminated by AstraZeneca and Orexo has decided not to take the project back. There are no financial implications of the termination. Full year 2016 also includes an upfront payment of EUR 7 million (SEK 65.9 million) from Mundipharma who acquired the rights to Zubsolv globally outside the US.

Total net revenues were distributed as follows

SEK million	2017 Oct-Dec	2016 Oct-Dec	2017 Jan-Dec	2016 Jan-Dec
Zubsolv® US	126.5	128.2	485.8	481.8
Zubsolv – Rest of the World	5.6	-	5.6	65.9
Zubsolv – total	**132.1**	**128.2**	**491.4**	**547.7**
Abstral® royalties	55.4	52.2	113.2	100.4
Milestone payment Abstral	-	-	-	2.2
Abstral – total	**55.4**	**52.2**	**113.2**	**102.6**
Edluar® royalties	3.6	4.3	17.3	14.8
OX-CLI	-	-	21.8	40.8
Total	**191.0**	**184.7**	**643.7**	**705.9**

Costs and earnings

Cost of goods sold

Cost of goods sold (COGS) amounted to SEK 50.3 million (34.2) for the quarter and to SEK 164.4 million (149.6) for the full year. COGS for the quarter includes COGS of approximately SEK 6 million related to Zubsolv supplied to Mundipharma for their European launch. These products were supplied at direct cost as per the agreement. The Q4 2016 COGS included a SEK 10.7 million positive impact of a restatement of the 2016 inventory opening balance.

Selling expenses

Selling expenses amounted to SEK 49.2 million (66.2) for the quarter with the lower level compared with the previous year reflecting a continued targeted investment strategy. The Q4 2017 level, however, was 13 percent higher than Q3 2017 level due to investments to prepare for the improved market access from January 1, 2018 and increased activities in business development. For the full year 2017, selling expenses amounted to SEK 190.5 million (240.6).

Administrative expenses
Administrative expenses for the quarter amounted to SEK 26.3 million (30.4) and for the full year to SEK 96.1 million (161.6). Lower legal expenses relating to patent infringement litigations explains the significant reduction in full year administrative expenses. Total patent infringement related legal expenses included for the full year 2017 were approximately SEK 22 million (78).

Research and development costs
In Q4 2017, research and development costs amounted to SEK 35.8 million (34.5). Main projects consuming resources were OX382, patent work on early stage projects and the supply chain optimization project. For the full year 2017, the costs amounted to SEK 134.2 million (132.3). The clinical program for OX382 has started in Q1 2018 and will have a small impact on R&D expenses in the first half-year, 2018.

Costs for long-term incentive program
The Group's total costs for employee share-based payment programs during Q4 2017 amounted to SEK 1.5 million (2.9). For the full year 2017, the costs amounted to SEK 3.0 million (3.7).

Other income and expenses
Other income and expenses amounted to SEK 0.7 million (13.8) for Q4 2017 and to SEK -1.1 million (29.9) for the full year. 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.

Depreciation and amortization
Depreciation and amortization amounted to SEK 5.2 million (10.9) for quarter and to SEK 20.8 million (21.4) for the full year.

Net financial items
Net financial items for the quarter amounted to SEK -4.7 million (1.2) and to SEK -27.7 million (-16.1) for the full year. These items are related to financing activities including exchange-rate gains/losses derived from foreign currency bank accounts.

Tax
Total tax expenses for the quarter amounted to SEK -1.3 million (1.1) and SEK 6.5 million (6.5) for the full year. The Q4 number includes a revaluation of a US deferred tax asset that was revalued based on the recent US tax bill with a reduced corporate tax rate. The lower US tax rate will benefit Orexo going forward, but short term it reduced the value of a deferred tax asset. The Q4 number further includes an Orexo AB tax asset created on the basis of being a profitable entity.

Net earnings
Net earnings amounted to SEK 26.7 million (33.3) for the quarter and to SEK 23.2 million (29.0) for the full year.

Cash flow and financial position

At December 31 2017, cash and cash equivalents amounted to SEK 327.9 million (282.4) and interest-bearing liabilities to SEK 319.1 million (397.8).

During the quarter, Orexo refinanced the corporate bond maturing in May 2018 by issuing a new SEK 325 million corporate bond and redeeming the old bond. This refinancing secures a strong financial position going forward with a cash position exceeding total interest bearing debt by SEK 8.8 million (-115.4).

Cash flow from operating activities for the quarter amounted to SEK -23.0 million (71.4) and was mainly caused by increased receivables and decreased current liabilities. Current liabilities decreased as significant payer rebates were due for payment in the US and increased receivables due to increased wholesaler purchases during December in anticipation of increased demand in Q1 2018.

Cash flow from financing activities for the quarter amounted to SEK -26.4 million (-92.7) and is explained by the reduction in interest bearing debt following the refinancing process.

Shareholders' equity at December 31, 2017, was SEK 329.1 million (310.3). The equity/asset ratio was 32.8 percent (30.0).

The Board of Directors proposes that no dividend is paid for the financial year 2017.

Investments in fixed assets

Gross investments in tangible and intangible fixed assets amounted to SEK 0.8 million (0.1) for Q4 and SEK 1.6 million (1.3) for the full year 2017.

Operations

Pipeline of commercial products and development projects

Commercial products

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

The fourth quarter of 2017 demonstrated a buprenorphine/naloxone market growth of 2.5 percent in volume compared to Q3 2017, and 11.3 percent over Q4 2016. The market forecast is continued growth as more providers begin to take on a greater patient load by becoming waivered and as currently waivered prescribers expand their patient cap limits. Currently, greater than 3,700 waivered physicians are eligible to increase their patient load up to 275, while nurse practitioners and physicians assistants now total over 3,800 waivered to treat opioid dependency.

Zubsolv's development in both volume and market share can primarily be explained by dynamics in market access. Zubsolv grew 2 percent in the profitable Commercial segment over Q3, and 6 percent in Medicare Part D. This momentum is expected to continue to grow in 2018 with the new Commercial and Medicare Part D market access wins. In Medicaid, during 2017 the Maryland FFS share and volume contribution eroded as Maryland had weak formulary controls of the prescriptions and allowed patients to move back to their previous medication. From July 1, 2017, Maryland added all buprenorphine products to the preferred Medicaid formulary and we have seen additional erosion through Q4 impacting both market share and volume. The overall impact on Net Sales from the Maryland change has been positive as the impact on volume is more than compensated by lower rebates. Overall, Zubsolv's Q4 2017 performance when compared to Q3 2017 shows a 0.2 percent decrease in tablets dispensed to patients through pharmacies and a 6.3 percent decrease versus the same quarter in 2016.

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 directly access.

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 80 percent of the growth between Q4 2016 and Q4 2017 being with payers that did not allow their patient access to Zubsolv®. Improving Zubsolv market access in the growth markets is a key success factor to increase market share and volume growth.

2018 Zubsolv Market Access Formulary Improvements

Orexo has secured a series of market access improvements for Zubsolv commencing in 2018, and assuming that payer growth rates remain constant, Zubsolv will almost double the access to the growing segments of the market, providing much more additional opportunity for Zubsolv to grow volume.

In the commercial segment, Zubsolv will be nearly universally reimbursed in 2018, primarily explained by the new preferred position within CVS Caremark and Zubsolv not losing any preferred position from 2017. In addition, effective January 1, Zubsolv will be the exclusive preferred product with Envision Rx and Humana in the commercial segment. In the public segment, Zubsolv will become the exclusive product on the Humana Medicare Part D plan. In addition, starting July 1, 2018, Zubsolv will be a preferred agent on all Ohio state Medicaid formularies, which is the largest Medicaid state in the US. With these improvements within FFS Medicaid, Zubsolv will be preferred with 6 of the top 10 health plans from January 1, 2018.

Within the payer segments in which Orexo has secured market access improvements, these plans are growing market volume at a faster rate than the current set of plans reimbursing for Zubsolv. The payers on which Zubsolv has access on currently in commercial grew 5 percent between Q4 2016 and Q4 2017. The commercial payers on which Zubsolv will gain access in 2018 grew 11 percent over the same time frame. In Medicare Part D, the other major segment where Zubsolv has 2018 improvements at the start of year, the growth rate for currently accessible payers was only 1 percent, while the growth rate for those 2018 improvements was 24 percent. In Managed Medicaid, where access will increase midyear, the growth rate for currently accessible payers was only 2 percent, while the growth rate for those midyear improvements was 5 percent.

The improvement in market access in 2018 is the best development in market access for Zubsolv since 2014. While the Humana Medicare Part D and Envision commercial exclusive contracts will have an impact early in 2018, the main value is from the broader preferred status, including Caremark commercial, and Orexo's ability to compete in larger geographies for market share and volume in the growing public segment of the market. The impact and value of the exclusive contracts are highly dependent on the health plans' ability and willingness to control the prescriptions; we have experienced wide variations in the final market share, 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 in the worst case take up to 9 months from the date of the oral session. 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.

Zubsolv® Europe – opioid dependence

In the quarter, Zubsolv received authorization by the European Commission for treatment of opioid dependence in Europe. The approval means that a new novel treatment will be available on the European market. Depending on local reimbursement, a launch of Zubsolv in Europe is anticipated to be initiated in H1 2018. In parallel with the launching of Zubsolv in Europe, Mundipharma is evaluating other markets.

Orexo will receive a milestone payment pending 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 at current cost 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]

Abstral® - breakthrough cancer pain

Due to the timing of this report, Orexo has not yet received final data for Q4 sales of Abstral and Edluar® from our partners and hence the calculation of Q4 royalties is based on Orexo´s forecast and preliminary Q4 sales reports where available. For the same reason, the Abstral and Edluar sections below primarily refer to the sales development in Q3 2017.

Sales of Abstral in the EU continue to grow and amounted to EUR 24 million in Q3 2017, which is an increase of 10 percent compared to Q3 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 1 percent lower in Q3 2017 compared with the same period in 2016.

Sales of Abstral in the region RoW (markets excluding the EU, the US and Japan) have continued to grow. Total sales for the RoW reached USD 3.3 million in Q3 2017, which is an increase of 41 percent compared with Q3 2016.

Sales of Abstral in Japan grew 10 percent during the third local commercial quarter, June 2017 to August 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 18 percent lower in Q3 2017 compared to Q3 2016. Total sales for Q3 2017 amounted to EUR 3.1 million (3.8).

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

Development projects

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 in phase I (first clinical study in humans) with results expected in Q2, 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.

OX-CLI – asthma and COPD

OX-CLI is a Leukotriene (LT) C4 Synthase inhibitor program directed to the development of a novel treatment of respiratory disorders such as asthma and COPD. AstraZeneca acquired the program from Orexo in March 2016, and has since been fully responsible for its development. In June 2017, the program advanced into clinical phase 1 with compound AZD9898. In the study, AZD9898 was well tolerated in all doses explored but did not show required effect. As a consequence, AstraZeneca has decided to discontinue all research and development activities in respect of the program. Orexo will not reacquire or continue 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. Orexo has decided to discontinue the dialog with the potential partner for OX51 due to disagreement of the key terms reducing the financial attractiveness of a potential agreement. Orexo will have a meeting with FDA during Q1 to assess the required development program and continue the search for a development partner.

Parent Company

Net revenues for Q4 2017 amounted to SEK 127.0 million (72.3). Earnings before tax were SEK 16.2 million (-33.5). Investments amounted to SEK 0.8 million (0.1). As of December 31 2017, cash and cash equivalents in the Parent Company amounted to SEK 215.1 million (211.7). Sellback of de-blistered Zubsolv® tablets to Orexo US Inc. during the first half of the year had a positive impact on the full year net revenue and operating earnings.

Outlook 2018

For 2018 Orexo expects to continue to deliver positive EBITDA on a full year basis, primarily driven by Zubsolv US revenue growth and continued focus on cost control. The impact from new Zubsolv US market access agreements will ramp up during the year and a negative EBITDA is expected for Q1 2018.

With the improved market access situation for Zubsolv US, Orexo expects to gain volume and market share during 2018. Total milestone payment level in 2018 is expected to be slightly above the 2017 level.

Manufacturing efficiency programs aimed to reduce COGS is expected to have affect from second half-year 2018.

Full year OPEX is expected to be approximately SEK 500 million. The increase over 2017 is driven by expansion of US commercial footprint and progression of development projects. Only a limited amount has been included for the Actavis litigation for Zubsolv, assuming a positive outcome.

The outlook is based on current exchange rates (January 2018).

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 development projects and the intellectual property rights and legal disputes as highlighted on page 8-9 and in Note 3.

Uppsala, Sweden, January 25, 2018

Orexo AB (publ.)

Nikolaj Sørensen
President and CEO

This report has not been reviewed by the company's auditors.

Consolidated statement of operations

SEK million	Notes	2017 Oct-Dec	2016 Oct-Dec	2017 Jan-Dec	2016 Jan-Dec
Net revenues		191.0	184.7	643.7	705.9
Cost of goods sold		-50.3	-34.2	-164.4	-149.6
Gross profit		**140.7**	**150.5**	**479.3**	**556.3**
Selling expenses		-49.2	-66.2	-190.5	-240.6
Administrative expenses		-26.3	-30.4	-96.1	-161.6
Research and development expenses		-35.8	-34.5	-134.2	-132.3
Other operating income and expenses		0.7	13.8	-1.1	29.9
Operating earnings		**30.1**	**33.2**	**57.4**	**51.7**
Net financial items		-4.7	1.2	-27.7	-16.1
Earnings before tax		**25.4**	**34.4**	**29.7**	**35.6**
Tax		1.3	-1.1	-6.5	-6.5
Net earnings for the period[1]		**26.7**	**33.3**	**23.2**	**29.0**

Consolidated statement of comprehensive income

SEK million	2017 Oct-Dec	2016 Oct-Dec	2017 Jan-Dec	2016 Jan-Dec
Earnings for the period	**26.7**	**33.3**	**23.2**	**29.0**
Other comprehensive income				
Items that may subsequently be reversed to the statement of operations:				
Reclassification assets available for sale	-	-0.9	-	-0.9
Exchange-rate differences	1.0	4.1	-7.5	6.2
Other comprehensive earnings for the period, net after tax	**1.0**	**3.2**	**-7.5**	**5.3**
Total comprehensive earnings for the period [1]	**27.7**	**36.5**	**15.7**	**34.3**
Earnings per share, before dilution, SEK	0.77	0.97	0.67	0.84
Earnings per share, after dilution, SEK	0.77	0.96	0.67	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 Dec 31	2016 Dec 31
ASSETS			
Fixed assets			
Tangible fixed assets		20.1	22.1
Intangible assets		121.0	138.2
Deferred tax assets		28.3	24.8
Other financial assets		7.1	7.9
Total fixed assets		**176.5**	**193.0**
Current assets			
Inventories		250.2	344.2
Accounts receivable and other receivables		249.3	199.2
Cash and cash equivalents		327.9	282.4
Total current assets		**827.4**	**825.8**
Total assets		**1,003.9**	**1,018.8**
SHAREHOLDERS' EQUITY AND LIABILITIES			
Total shareholders' equity		**329.1**	**310.3**
Long-term liabilities			
Provisions		5.8	1.2
Long-term liabilities, interest bearing		319,1	397.8
Total long-term liabilities		**324.9**	**399.0**
Current liabilities and provisions			
Provisions		200,9	163.9
Current liabilities, non-interest bearing		149.0	145.6
Total current liabilities and provisions		**349.9**	**309.5**
Total liabilities		**674.8**	**708.5**
Total shareholders' equity and liabilities		**1,003.9**	**1,018.8**

Consolidated changes in shareholders' equity

SEK million	2017 Dec 31	2016 Dec 31
Opening balance, shareholders' equity	**310.3**	**270.1**
Total comprehensive earnings for the period	15.7	34.3
Employee stock options, vested amount	3.0	3.7
Buy back of shares	-	-0.1
New share issue	0.1	2.3
Closing balance, shareholders' equity	**329.1**	**310.3**

Consolidated cash flow statements

SEK million	Notes 1	2017 Oct-Dec	2016 Oct-Dec	2017 Jan-Dec	2016 Jan-Dec
Operating earnings		30.1	33.2	57.4	51.7
Financial income		0.1	0.6	0.2	0.6
Financial expenses		-4.4	-6.4	-37.4	-28.9
Adjustment for non-cash items	2	-1.0	-8.5	87.9	44.1
Cash flow from operating activities before changes in working capital		**24.8**	**18.9**	**108.1**	**67.5**
Changes in working capital		**-47.8**	**52.5**	**38.5**	**88.7**
Cash flow from operating activities		**-23.0**	**71.4**	**146.6**	**156.2**
Acquisition of tangible and intangible fixed assets		-0.8	-0.2	-1.6	-1.4
Disposal of fixed assets		-	1.9	-	1.9
Sale of subsidiary		-	5.0	-	5.0
Cash flow from investing activities		**-0.8**	**6.7**	**-1.6**	**5.5**
New share issue		0.1	0.1	0.1	2.2
Change in loans		-26.5	-92.8	-85.5	-92.8
Cash from financing activities		**-26.4**	**-92.7**	**-85.4**	**-90.6**
Cash flow for the period		**-50.2**	**-14.6**	**59.6**	**71.1**
Cash and cash equivalents at the beginning of the period		**370.7**	**276.9**	**282.4**	**198.1**
Exchange-rate differences in cash and cash equivalents		7.4	20.1	-14.1	13.2
Changes in cash and cash equivalents		-50.2	-14.6	59.6	71.1
Cash and cash equivalents at the end of the period		**327.9**	**282.4**	**327.9**	**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 Oct-Dec	2016 Oct-Dec	2017 Jan-Dec	2016 Jan-Dec
EBIT margin, %	15.8	18.0	8.9	7.0
Return on shareholder equity, %	8.0	11.0	7.0	10.0
Net debt, SEK million	-8.8	115.4	-8.8	115.4
Debt/equity ratio, %	97.0	128.2	97.0	128.2
Equity/assets ratio, %	32.8	30.0	32.8	30.0
Number of shares, before dilution	34,563,239	34,536,746	34,561,142	34,477,423
Number of shares, after dilution	34,673,802	34,579,512	34,671,706	34,574,337
Earnings per share, before dilution, SEK	0.77	0.97	0.67	0.84
Earnings per share, after dilution, SEK	0.77	0.96	0.67	0.84
Number of employees at the end of the period	90	102	90	102
Shareholders' equity, SEK million	329.1	310.3	329.1	310.3
Capital employed, SEK million	648.2	708.0	648.2	708.0
Working capital, SEK million	477.5	524.2	477.5	524.2

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

Parent Company statement of operations

SEK million	Notes	2017 Oct-Dec	2016 Oct-Dec	2017 Jan-Dec	2016 Jan-Dec
Net revenues		127.0	72.3	477.8	379.3
Cost of goods sold		-33.2	-17.5	-167.4	-83.6
Gross profit		**93.8**	**54.8**	**310.4**	**295.7**
Selling expenses		-26.7	-30.8	-73.3	-105.7
Administrative expenses		-18.4	-21.5	-67.3	-129.1
Research and development costs		-28.4	-26.8	-105.3	-141.8
Other operating income and expenses		0.6	16.3	-1.2	24.3
Operating earnings		**20.9**	**-8.0**	**63.3**	**-56.6**
Interest income and expenses		-3.6	-3.9	-14.6	-16.2
Exchange rate adjustment		-	-32.1	-1.3	-32.1
Other financial expenses		-1.1	10.5	-12.3	9.3
Net financial items		**-4.7**	**-25.5**	**-28.2**	**-39.1**
Earnings before tax		**16.2**	**-33.5**	**35.1**	**-95.7**
Tax		7.6	-	7.6	-
Earnings for the period		**23.8**	**-33.5**	**42.7**	**-95.7**

Parent company statement of comprehensive income

SEK million	2017 Oct-Dec	2016 Oct-Dec	2017 Jan-Dec	2016 Jan-Dec
Earnings for the period	**23.8**	**-33.5**	**42.7**	**-95.7**
Other comprehensive income	**-**	**-**	**-**	-
Total comprehensive earnings for the period	**23.8**	**-33.5**	**42.7**	**-95.7**

Parent Company balance sheet

SEK million	Notes	2017 Dec 31	2016 Dec 31
ASSETS			
Fixed assets			
Tangible and intangible fixed assets		148.4	159.8
Shares in subsidiaries		150.6	149.7
Total fixed assets		**299.0**	**309.5**
Current assets			
Inventories		186.3	269.6
Accounts receivable and other receivables		158.4	76.8
Cash and bank balances		215.1	211.7
Total current assets		**559.8**	**558.1**
Total assets		**858.8**	**867.6**
SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES			
Shareholders' equity		**309.4**	**263.5**
Long-term liabilities		**324.0**	**399.1**
Current liabilities		**225.4**	**205.0**
Total liabilities		**549.4**	**604.1**
Total shareholders' equity and liabilities		**858.8**	**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 1, 2018, and it has made an 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.

IFRS 9 financial instruments covers the recognition of financial assets and liabilities and replaces of IAS 39 financial instruments: recognition and measurement. The Group will apply the new standard in its entirety as of January 1st 2018 and it has made a preliminary assessment of IFRS 9 and its effects on company's financial statements, which shows that no material impact on the Group's and on the Parent Company's results and financial position. Furthermore no significant changes are expected in the presentation of the note of Financial instruments.

2. Cash flow

Adjustment for non-cash items

SEK million	2017 Oct-Dec	2016 Oct-Dec	2017 Jan-Dec	2016 Jan-Dec
Depreciation/amortization and impairment	5.1	5.3	20.8	25.0
Gain/loss on disposal	-	-5.0	-	-5.0
Change in provisions	-7.1	2.3	59.9	42.0
Change in fair value of financial instruments	-	-0.3	-	0.2
Share based payments	1.6	2.9	3.3	3.7
Exchange rate income and expenses	-0.6	-13.7	3.9	-21.8
Total	**-1.0**	**-8.5**	**87.9**	**44.1**

3. Legal disputes

Paragraph IV litigations against Actavis regarding Zubsolv® in the US
For an update please see the Operation section, Commercial products, page 8

Patent infringement litigation against Actavis for their generic versions of Suboxone® and Subutex® tablets in the US
For an update please see the Operation section, Commercial products, page 9

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 Oct-Dec	2016 Oct-Dec	2017 Jan-Dec	2016 Jan-Dec
EBIT	30.1	33.2	57.4	51.7
Depreciation and amortization	5.2	10.9	20.8	21.4
EBITDA	**35.3**	**44.1**	**78.2**	**73.1**

Return on shareholders' equity	2017 Oct-Dec	2016 Oct-Dec Restated	2017 Jan-Dec	2016 Jan-Dec
Shareholders' equity beginning balance	300.0	270.9	310.3	270.1
Shareholders' equity ending balance	329.1	310.3	329.1	310.3
Average shareholders' equity	314.6	290.6	319.7	290.2
Net earnings	26.7	33.3	23.2	29.0
Return on shareholders' equity %	**8.0**	**11.0**	**7.0**	**10.0**

Operating expenses SEK million	2017 Oct-Dec	2016 Oct-Dec	2017 Jan-Dec	2016 Jan-Dec
Selling expenses	-49.2	-66.2	-190.5	-240.6
Administrative expenses	-26.3	-30.4	-96.1	-161.6
Research and development costs	-35.8	-34.5	-134.2	-132.3
Other operating income and expenses	0.7	13.8	-1.1	29.9
Operating expenses	**-110.6**	**-117.3**	**-421.9**	**-504.6**

Gross investments SEK million	2017 Oct-Dec	2016 Oct-Dec	2017 Jan-Dec	2016 Jan-Dec
Investments in tangible fixed assets	0.8	0.0	1.1	1.0
Investments in intangible fixed assets	0.0	0.1	0.5	0.3
Gross investments	**0.8**	**0.1**	**1.6**	**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

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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 the aim is to address therapeutic areas where our competence and technologies can create value. The main market today is the US market for the treatment of opioid dependence where the product Zubsolv® is commercialized by Orexo. Other products are commercialized by license partners, including Zubsolv in markets outside of the US. Total net sales for 2017 amounted to SEK 643.7 million and the number of employees was approximately 100. 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 located 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.