Interim Report Q3 2018

# The win in the patent litigation strengthen Orexo's long term business opportunities

## Q3 2018 highlights

- Orexo wins appeal against Actavis on Zubsolv patent in the US, expiring in 2032
- Total net revenues of SEK 216.6 million (166.2), up 30.3 percent from Q3 previous year
- Zubsolv® US net revenue of SEK 165.4 million (121.1), up 36.6 percent in SEK and 24.3 percent in local currency compared to the same period last year
- EBITDA of SEK 39.8 million (46.1), EBITDA excluding IP litigation costs, of SEK 71.0 million (50.8)
- US EBIT of SEK 55.6 million (31.8)
- Cash flow from operating activities of SEK 24.5 million (92.3), building a cash balance of SEK 516.6 million (370.7)
- Earnings per share, before dilution SEK 1.80 (0.82), earnings per share after dilution SEK 1.77 (0.81)

## Important events after the period

- The contracted US field force is internalized to further strengthen the commercial organization
- Joseph DeFeo is appointed as new CFO from November 1, 2018
- A Capital Markets Day will be hosted in Stockholm, Sweden, on December 6, 2018

| SEK million, unless otherwise stated | 2018 Jul-Sep | 2017 Jul-Sep | 2018 Jan-Sep | 2017 Jan-Sep | 12 mth Oct 2017 - Sep 2018 | 12 mth Oct 2016 - Sep 2017 |
|---|---|---|---|---|---|---|
| Net revenues | 216.6 | 166.2 | 556.0 | 452.6 | 747.0 | 637.3 |
| whereof Zubsolv® US net revenue | 165.4 | 121.1 | 454.9 | 359.3 | 581.4 | 487.5 |
| Cost of goods sold | -42.4 | -32.1 | -128.4 | -114.1 | -178.7 | -159.0 |
| Operating expenses | -139.6 | -93.2 | -369.4 | -311.3 | -480.0 | -428.6 |
| EBIT | 34.6 | 40.9 | 58.2 | 27.2 | 88.2 | 49.8 |
| EBIT margin, % | 16.0 | 24.6 | 10.5 | 6.0 | 11.8 | 7.8 |
| US EBIT | 55.6 | 31.8 | 136.5 | 54.0 | 156.2 | 51.6 |
| US EBIT margin, % | 33.6 | 26.3 | 30.0 | 15.0 | 26.9 | 10.6 |
| EBITDA | 39.8 | 46.1 | 73.7 | 42.8 | 109.0 | 67.1 |
| Earnings per share, before dilution, SEK | 1.80 | 0.82 | 2.50 | -0.10 | 3.27 | 0.55 |
| Earnings per share, after dilution, SEK | 1.77 | 0.81 | 2.46 | -0.10 | 3.26 | 0.55 |
| Cash flow from operating activities | 24.5 | 92.3 | 170.4 | 169.6 | 147.4 | 241.0 |
| Cash and cash equivalents | 516.6 | 370.7 | 516.6 | 370.7 | 516.6 | 370.7 |

Unless otherwise stated in this report, all data refers to the Group. Numbers in parentheses relate to the corresponding period in 2017.

# Content



**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 products are commercialized by Orexo in the US or via selected partners worldwide. The main market today is the American market for buprenorphine/naloxone products, where Orexo sells the product Zubsolv®. Total net sales for 2017 amounted to SEK 643.7 million and the number of employees at year-end was 90. Orexo is listed on the Nasdaq Stockholm Mid Cap (ORX) and is available as ADRs on OTCQX (ORXOY) in the US. The head office, where research and development is also performed, is situated in Uppsala, Sweden.

**For further information, please contact**
Nikolaj Sørensen, CEO and President, Henrik Juuel, EVP and CFO or Joseph DeFeo, EVP and CFO from November 1, 2018. Tel: +46 18 780 88 00, +1 855 982 7658 Email: 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-q3-2018
Telephone: SE: +46 856 642 696 UK:+44 2030 089 808 US: +1 855 8315 946
The presentation material will be available on Orexo´s website one hour prior to the audiocast.

**Financial calendar**
Full Year Report - January 30, 2019 at 8.00 am CET
Publication of the Annual Report, March week 12, 2019
Interim Report Q1 2019, May 2, 2019 at 8.00 am CET
Interim Report Q2 2019, July 11, 2019 at 8.00 am CET

**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.

# Our focus is now on expansion of the business


Photo: Mats Lundgren

The third quarter has been another important milestone in Orexo's history as we have significantly strengthened the long-term business prospects of our company.

After 52 months of waiting we received the decision from the US Federal Court, reversing the decision by the District Court and validating our '330 patent. The '330 patent is one of three patents covering Zubsolv® until 2032 and with this confirmation of its validity in a precedential decision from the Federal Court in the US, we have significantly strengthened the patent protection around Zubsolv for another 13 years.

During the patent litigation Orexo has continued to evolve and reached several important milestones: we have delivered stable profitability since 2016, the company is net cash positive, and we have initiated three new innovative development projects.

The natural question now is what is next for Orexo. In our journey towards becoming a leading addiction company we will intensify the efforts to reach our objectives in three priority areas.

Firstly, we have an objective to maintain and improve profitability to enable increased investments in late stage R&D and business development. The main focus is on the Zubsolv business we control in the US and I am pleased to see that the twelve-month rolling EBIT margin of our Zubsolv US business has improved from 11 percent to 27 percent in one year and contributed with USD 18 million to Group EBIT during the last year. All other things equal and applying our guidance on cost of goods improvement to the current Zubsolv US business, we would reach an EBIT of USD 25 million for our Zubsolv business with current volumes and OPEX. Even when excluding all royalties and milestones from out-licensed products, Orexo is profitable with the contribution from Zubsolv in the US when excluding our current IP litigation costs. With continued strong development of Zubsolv in the US regarding both revenue and profitability we will be able to invest in the required clinical development of our own pipeline until approval and have the financial strength to compete for business development opportunities when they occur.

Secondly, with the strong foundation from our commercial operations in the US, we have intensified our R&D efforts. We currently have three on-going projects with a well-defined target profile that all address key unmet needs in areas that are complementary to our commercial infrastructure. We are currently testing which formulations will meet the desired profile. Formulations in all three projects will be tested in-vivo during the next six months with OX124 becoming the most advanced and entering a human clinical phase I trial in Q4, 2018. To further accelerate future development, we are upgrading our Uppsala site in Sweden to enable manufacturing of clinical trial material for phase I/II in-house.

Thirdly, the patent outcome enables us to intensify our business development and M&A efforts to broadening our late-stage and commercial product portfolio. With the continuously improving net-cash position, we are ready to invest when an opportunity emerges that complements Zubsolv and offers attractive synergies. With the improved confidence in Zubsolv's long-term prospects, we have internalized our complete field force. Based on previous feedback from potential partners, this will further enhance Orexo's attractiveness as a partner.

The financial results of the quarter continue on the positive trajectory from Q2. In particular the contribution from our US business has further improved, primarily explained by revenue growth of 24.3 percent in local currency. The most significant investment during the quarter is our legal case against Actavis for infringement of our '996 patent with their generic versions of Suboxone® and Subutex® tablets. The case will be associated with significant costs in the next quarters. We are confident we have a strong case and should be awarded damages for the infringement of our '996 patent.

As recently communicated we will host a Capital Markets Day on December 6 in Stockholm. Together with my management team I am looking forward to sharing more insights into our plans moving forward, the market we operate in and more details about our exciting R&D portfolio.

Uppsala, Sweden, October 25, 2018

Nikolaj Sørensen
President and CEO

# Financial information

Orexo's profitability continue to improve driven by a strong and growing contribution from the US commercial business. When excluding the IP litigation[1], EBITDA was realized at SEK 71.0 million. An increase from SEK 50.8 million in the same period previous year.

The EBIT contribution from the US commercial business continues to grow, driven by Zubsolv growth, COGS reductions and the very scalable organization allowing growth at little additional operating expenses. For the quarter the US commercial business contributed with an EBIT of SEK 55.6 million (31.8) equal to an EBIT margin of 33.6 (26.3) percent.

## Revenues

Total revenues for the quarter amounted to SEK 216.6 million (166.2), corresponding to a 30.3 percent increase over the same period the previous year. The increase was driven by strong Zubsolv® growth, reaching 36.6 percent in SEK.

**Commercial products**
Zubsolv US revenues amounted to SEK 165.4 million (121.1) for the quarter, corresponding to 36.6 percent growth in SEK. In local currency (USD) the equivalent growth rate was 24.3 percent, equal to sales of USD 18.5 million.

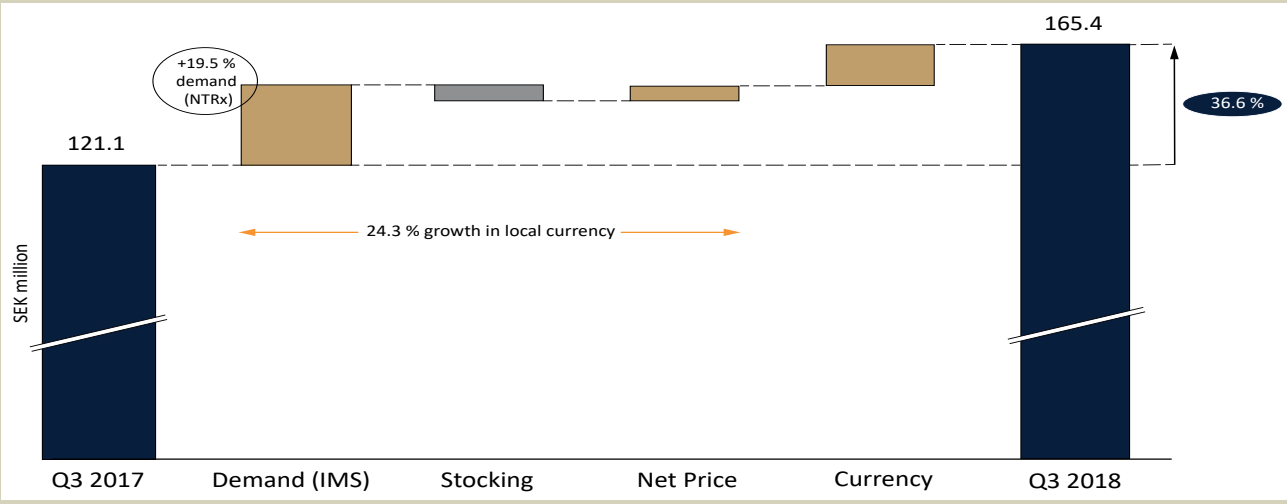
The key year over year growth factor was the 19.5 percent increase in demand (NTRx) driven by improved market access from January 1, 2018. Net prices were positively impacted by the 6 percent price increase from January 1, 2018, and by a USD 0.5 million adjustment of rebates relating to prior periods. Wholesaler inventory levels were reduced slightly during the quarter as a consequence of a stable sales development allowing optimization of inventory levels. The SEK/USD exchange rate had a positive impact on the year over year growth.

Abstral® revenues amounted to SEK 48.7 million (39.4) for the quarter. The growth was primarily driven by an appreciation of EUR vs SEK over the period and volume growth in the Rest of the World segment. Revenues from Edluar® amounted to SEK 2.3 million (5.7) for the quarter. Supply issues in the US market caused a temporary loss of business which is now gradually building up again.

Zubsolv, Rest of World, revenues amounted to SEK 0.2 million (0.0). Zubsolv was launched by our partner, Mundipharma, in Germany and Sweden during Q2, 2018, and is still in the early launch phase.

Zubsolv US revenues amounted to SEK 165.4 million (121.1) for the quarter, corresponding to 36.6 percent growth, in SEK

ZUBSOLV US NET REVENUE GROWTH BY KEY DRIVERS, Q3 2018 VERSUS Q3 2017[2]




[1] Mainly related to the patent infringement litigation against Actavis for their generic versions of Suboxone® and Subutex® tablets in the US
[2] Orexo analysis using IMS demand data plus institutional sales

**Development projects**
There were no revenues from development projects during the quarter. 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. This project has, as earlier communicated, been terminated by AstraZeneca and Orexo has decided not to take the project back. There are no financial implications of the termination.

## Costs and earnings

**Cost of goods sold**
Cost of goods sold (COGS) amounted to SEK 42.4 million (32.1) for the quarter and all relates to Zubsolv® in the US market. This corresponds to an average COGS per tablet 8 percent lower than the average realized in 2017. The ambition with the manufacturing efficiency program is to reduce the average cost per tablet by approximately 35 percent compared with the average 2017 level. This ambition level is expected to be realized in the second half of 2019. While the direction and the ambition level is clear, variations can still occur between individual quarters due to miscellaneous manufacturing variances.

This quarter COGS included additional costs of approximately SEK 1.5 million related to standard stability testing required to prolong and maintain product shelf-life.

**Selling expenses**
Selling expenses amounted to SEK 51.5 million (43.3). The increase over same period last year is explained by a small field force expansion to take advantage of the improved market access position, additional market research expenses and finally also a stronger US currency.

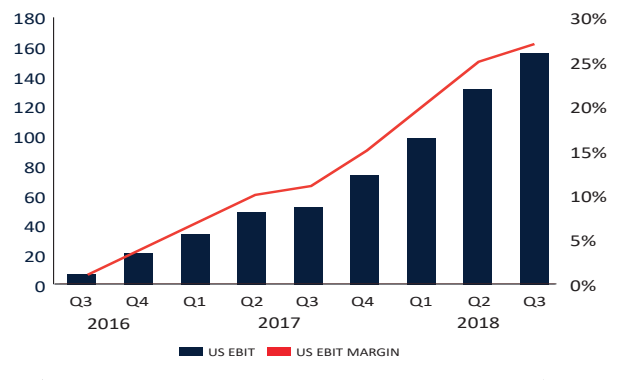
**Administrative expenses**
Administrative expenses for the quarter amounted to SEK 50.8 million (21.0). The significant increase versus prior year is explained by higher legal expenses related to the patent infringement litigation against Actavis for their generic versions of Suboxone® and Subutex® tablets in the US, see Note 3. Legal expenses for IP litigations reached SEK 31.2 million (4.7) for the quarter.

**DISTRIBUTION OF TOTAL NET REVENUES**

| SEK million | 2018 Jul-Sep | 2017 Jul-Sep | 2018 Jan-Sep | 2017 Jan-Sep | 12 mth Oct 2017-Sep 2018 | 12 mth Oct 2016-Sep 2017 |
|---|---|---|---|---|---|---|
| Zubsolv® US | 165.4 | 121.1 | 454.9 | 359.3 | 581.4 | 487.5 |
| Zubsolv – Rest of the World | 0.2 | — | 31.0 | — | 36.6 | — |
| **Zubsolv – total** | **165.6** | **121.1** | **485.9** | **359.3** | **618.0** | **487.5** |
| Abstral® royalties | 48.7 | 39.4 | 66.4 | 57.8 | 121.8 | 110.0 |
| Edluar® royalties | 2.3 | 5.7 | 3.7 | 13.7 | 7.3 | 18.0 |
| OX-CLI | — | — | — | 21.8 | — | 21.8 |
| **Total** | **216.6** | **166.2** | **556.0** | **452.6** | **747.1** | **637.3** |

ZUBSOLV US NET REVENUES (LTM [1], SEK MILLION )


US EBIT AND US EBIT MARGIN (LTM [1], SEK MILLION)




[1] LTM, Last Twelve Months

**Research and development costs**
In Q3 2018, research and development costs amounted to SEK 37.5 million (29.0). The increase is explained by higher activity level and OX124 preparation for a clinical trial to be initiated in Q4.

**Costs for long-term incentive program**
The Group's total costs for employee share-based payment programs during Q3 2018 amounted to SEK 1.5 million (1.3). The amount realized was higher than previous quarters in 2018 due to a higher share price driving related provisions for social security costs.

**Other income and expenses**
Other operating income and expenses amounted to SEK 0.2 million (0.1) for Q3 2018.

**Depreciation and amortization**
Depreciation and amortization amounted to SEK 5.2 million (5.2) for the quarter.

**Net financial items**
Net financial items for the quarter amounted to SEK -4.2 million (-11.3). These items are related to financing activities including interest income/expenses and exchange-rate gains/losses derived from foreign currency bank accounts. For the quarter the exchange rate impact was limited as the SEK/USD rate at the end of Q3, 2018 was close to the rate at the end of the previous quarter.

**Tax**
Total tax expenses for the quarter amounted to SEK 31.8 million (-1.4). Tax for the quarter was positively impacted by a SEK 33.2 million adjustment of the parent company´s tax asset, driven by increased profitability, see Note 4.

**Net earnings**
Net earnings amounted to SEK 62.2 million (28.2) for the quarter.

## Cash flow and financial position

At September 30 2018, cash and cash equivalents amounted to SEK 516.6 million (370.7) and interest bearing liabilities to SEK 320.2 million (340.6), i.e. a positive net cash position of SEK 196.4 million. The strong cash position enables Orexo to continue to pursue its strategy to progress the development pipeline and to pursue business development opportunities with the target to add more commercial stage products to the US commercial infrastructure.

Cash flow from operating activities for the quarter amounted to SEK 24.5 million (92.3). The lower level compared with same period last year is explained by the timing of significant payments of payer rebates related to Zubsolv in the US and by a lower positive contribution from changes in working capital.

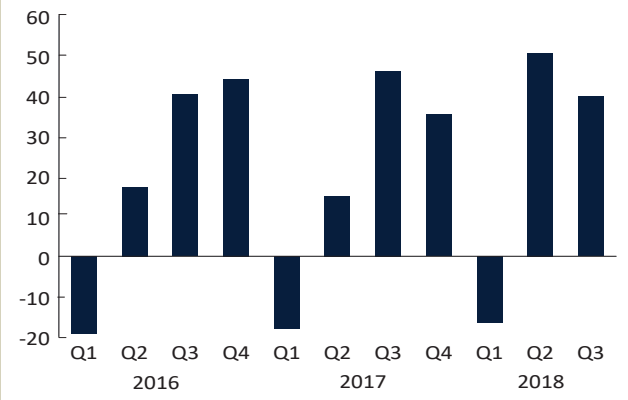
Shareholders' equity at September 30, 2018, was SEK 424.4 million (300.0). The equity/asset ratio was 35.1 percent (29.0).

## Investments in fixed assets

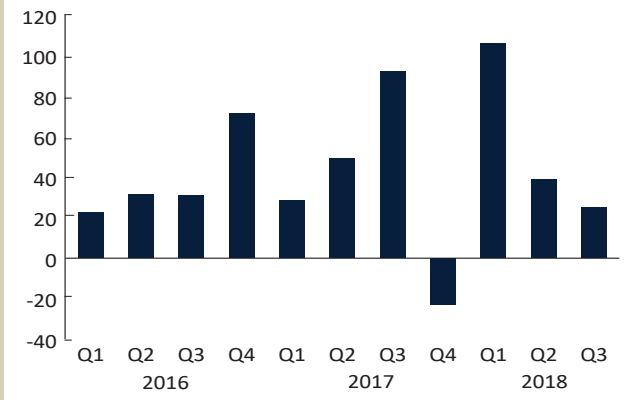
Gross investments in tangible and intangible fixed assets amounted to SEK 0.5 million (0.5) for Q3 2018.

## Positive net cash position of SEK 196.4 million

EBITDA, SEK MILLION

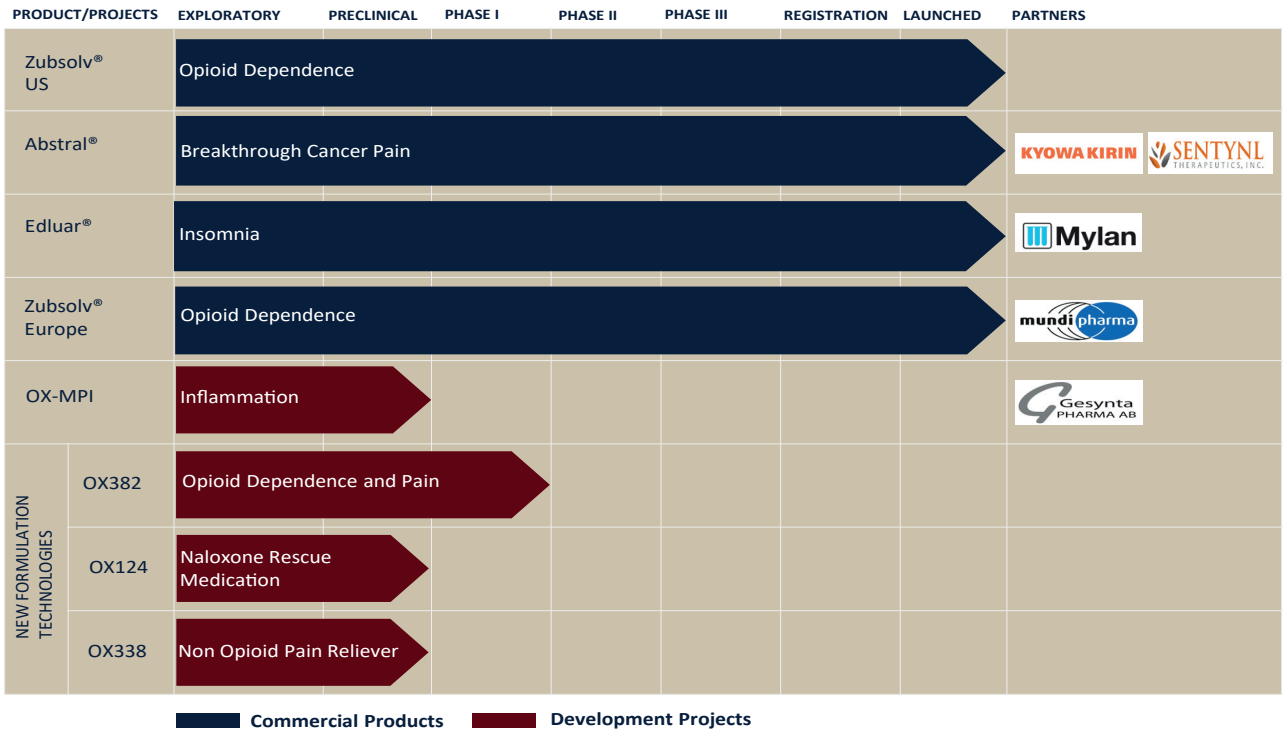



CASH FLOW FROM OPERATING ACTIVITIES, SEK MILLION



# Operations

PIPELINE OF COMMERCIAL PRODUCTS AND DEVELOPMENT PROJECTS




## Commercial products

### Zubsolv® US – opioid dependence

The third quarter of 2018 demonstrated a buprenorphine/naloxone market declining slightly by 0.3 percent in volume compared to Q2 2018, and a strong 12.2 percent growth over Q3 2017. During the quarter Dr. Reddy Laboratories launched, at risk, a generic version of the film formulation. A preliminary injunction was immediately filed and upheld, limiting further sales of the generic film formulation. However, the initial shipments were enough to erode a peak of 5.3 percent share from Suboxone® Film.

The market forecast is for continued growth, as the epidemic continues to escalate and as more providers begin to treat opioid dependence and also take on a greater patient load. Currently, greater than 4,300 waivered physicians can increase their patient load up to 275, while nurse practitioners and physicians assistants now total over 8,200 waivered to treat opioid dependency, compared to just 3,800 this quarter last year. Nurse Practitioners and Physicians Assistants first became eligible to receive a waiver to treat opioid dependency after passing of the CARA legislation. A federal bill currently awaiting final approval is expected to further expand the number of providers offering treatment.

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

The market forecast is for continued growth, as the epidemic continues to escalate and as more providers begin to treat opioid dependence and also take on a greater patient load

Zubsolv significantly outpaced prior year Q3 volumes with 19.8 percent growth. Compared to Q2, Zubsolv Q3 volume slightly declined by -1.6 percent, while net sales had a small positive development of 1.2 percent. Looking at Zubsolv volume on a rolling 4 week span, Zubsolv hit an all-time high for the period ending on August 31.

Zubsolv weekly average share in Q3 was 5.55 percent which was down slightly from the 5.62 percent in Q2.

Commencing in 2018, Zubsolv has the best commercial access of any buprenorphine/naloxone product marketed. In the commercial segment, Zubsolv is nearly universally reimbursed. On the competitive formularies where Zubsolv competes with generic tablets and other buprenorphine/naloxone brands Zubsolv has fought to capture 6 percent growth, from Q2 2018, in Caremark Commercial. Humana Commercial, where Zubsolv became the exclusive product at the start of year continues to grow in volume, achieving 8 percent volume growth in Q3 over Q2. In the public segment, Zubsolv is the exclusive product on the Humana Medicare Part D plan and is growing volumes during the quarter with this formulary position as well. The impact and value of the exclusive contracts are highly dependent on the health plans' ability to control the prescription.

Market access has been a continual key growth driver for Zubsolv and the objective remains to improve the access position for Zubsolv with a focus on the growing Public segment. For 2019, we are proud to announce that we to date have maintained the market access position from 2018 and are optimistic of further improvement in the public segment. We are waiting for final confirmation from some large states of the 2019 formulary which we expect will improve Zubsolv's market access in the fast growing public segment.

On the competitive formularies where Zubsolv competes with generic tablets and other buprenorphine/naloxone brands Zubsolv has fought to capture 6 percent growth, from Q2 2018, in Caremark Commercial

**Paragraph IV litigations against Actavis regarding Zubsolv in the US**
See Note 3.

**Patent infringement litigation against Actavis for their generic versions of Suboxone® and Subutex® tablets in the US**
See Note 3.

## Zubsolv Europe – opioid dependence

In Q2, 2018, Zubsolv was launched in the EU by Orexo´s partner Mundipharma, who owns the commercial rights to Zubsolv outside the US and is fully responsible for the commercialization of Zubsolv. The first launch markets were Germany and Sweden where Mundipharma has obtained reimbursement. Launch timings in other major European markets are subject to local reimbursement decisions, which remain ongoing. The development of sales will depend on the ability to navigate multiple market factors including local reimbursement decisions, evolving market dynamics, as well as providers' willingness to prescribe Zubsolv.

The early launch in Germany and Sweden has been below expectations. Efforts to broaden the prescriber base in Germany are being implemented and progress is being made to increase regional formulary access in Sweden.

Zubsolv is the first buprenorphine/naloxone sublingual tablet for the treatment of opioid dependence in Europe to be made available in up to six different strengths. This allows more individualized, flexible dosing and potentially fewer tablets compared with existing buprenorphine/naloxone therapies.

## Abstral® - breakthrough cancer pain

Due to the timing of this 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 2018.

Sales of Abstral in the EU amounted to EUR 21.9 million in Q2 2018, which is 1 percent lower compared with the same period in 2017. For the EU market Orexo receives royalty on sales exceeding EUR 42.5 million, which in 2018 was achieved in June.

In the US market net sales were 39 percent higher in Q2 2018 compared with the same period in 2017.
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 3.9 million in Q2 2018, which is an increase of 48 percent compared with Q2 2017.

Sales of Abstral in Japan decreased 7 percent during the second local commercial quarter, March 2018 to May 2018, compared to the same period in 2017.

## Edluar® - insomnia

Global sales of Edluar were 69 percent lower in Q2 2018 compared to Q2 2017 explained by a temporary loss of business in US market due to supply issues which have now been resolved. Total sales for Q2 2018 amounted to EUR 1.1 million (5.1).

## 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.

Changes during the quarter:
The formulation development has continued based on the insights gained from the result in the first clinical study performed in the previous quarter and formulation optimization has allowed for advancement into in-vivo pharmacokinetic studies starting in Q4 2018.

**OX124 - naloxone rescue medication**
OX124 is based on a novel and unique technology developed to provide a rapidly acting naloxone rescue medication with a differentiated profile compared to currently marketed products and other products under development. The project supports Orexo´s ambition to take a broader responsibility within the addiction space.

Changes during the quarter:
The development proceeds according to plan and advances into human phase 1 studies during Q4 2018.

OX124 - The development proceeds according to plan and advances into human phase 1 studies during Q4 2018

**OX338 - new NSAID formulation**
The aim is to develop a new NSAID formulation which could replace opioids for the acute treatment of moderate to severe pain and thus remove the risk to develop an addiction. The project supports Orexo´s ambition to take a broader responsibility within the addiction space.

Changes during the quarter:
Formulation development continues and an in-vivo pharmacokinetic study will be initiated during Q4 2018.

**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 project is developed by Orexo´s partner Gesynta Pharma AB who owns the rights to the project.

Changes during the quarter:
Progressing according to plan.

## Parent Company

Net revenues for Q3 2018 amounted to SEK 131.1 million (114.8). Earnings before tax were SEK 27.9 million (24.2). Investments amounted to SEK 0.5 million (0.5). As of September 30, 2018, cash and cash equivalents in the Parent Company amounted to SEK 259.6 million (215.4).

The tax asset was increased by SEK 33.2 million reflecting an updated assessment and recent announced changes in the Swedish corporate tax rate.

## Important events after the period

The contracted US field force internalizes to further strengthen the commercial organization.

Joseph DeFeo is appointed as new CFO from November 1, 2018.

A Capital Market Day will be hosted in Stockholm, Sweden, on December 6, 2018.

## Outlook 2018

The January-September, 2018, results are in line with guidance provided previously and the full year outlook for 2018 is unchanged from previous guidance.

Orexo expects to deliver positive EBITDA again in Q4 of 2018 driven by a continued strong Zubsolv® US contribution, Abstral® EU royalties and a reduced Zubsolv COGS level. Full year OPEX is still expected to amount to approximately SEK 500 million, including SEK 20 million for legal expenses related to IP litigation in Q4, 2018.

This outlook is based on current exchange rates (October 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 2017. 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 in Note 3.

Uppsala, Sweden, October 25, 2018
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, 2018 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, Sweden, October 25, 2018
Ernst & Young AB

Björn Ohlsson
Authorized Public Accountant

# Financial Reports and Notes

## CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS

| SEK million | Notes | 2018 Jul-Sep | 2017 Jul-Sep | 2018 Jan-Sep | 2017 Jan-Sep | 2017 Jan-Dec |
|---|---|---|---|---|---|---|
| Net revenues | 6 | 216.6 | 166.2 | 556.0 | 452.6 | 643.7 |
| Cost of goods sold | | -42.4 | -32.1 | -128.4 | -114.1 | -164.4 |
| **Gross profit** | | **174.2** | **134.1** | **427.6** | **338.5** | **479.3** |
| Selling expenses | | -51.5 | -43.3 | -143.4 | -141.3 | -190.5 |
| Administrative expenses | | -50.8 | -21.0 | -112.0 | -69.8 | -96.1 |
| Research and development expenses | | -37.5 | -29.0 | -119.8 | -98.4 | -134.2 |
| Other operating income and expenses | | 0.2 | 0.1 | 5.8 | -1.8 | -1.1 |
| **Operating earnings** | | **34.6** | **40.9** | **58.2** | **27.2** | **57.4** |
| Net financial items | | -4.2 | -11.3 | -3.2 | -23.0 | -27.7 |
| **Earnings before tax** | | **30.4** | **29.6** | **55.0** | **4.2** | **29.7** |
| Tax | 4 | 31.8 | -1.4 | 31.4 | -7.8 | -6.5 |
| **Net earnings for the period**[1] | | **62.2** | **28.2** | **86.4** | **-3.6** | **23.2** |

## CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

| SEK million | 2018 Jul-Sep | 2017 Jul-Sep | 2018 Jan-Sep | 2017 Jan-Sep | 2017 Jan-Dec |
|---|---|---|---|---|---|
| **Earnings for the period** | **62.2** | **28.2** | **86.4** | **-3.6** | **23.2** |
| **Other comprehensive income** | | | | | |
| **Items that may subsequently be reversed to the statement of operations:** | | | | | |
| Exchange-rate differences | -0.7 | -5.3 | 5.9 | -8.4 | -7.5 |
| **Other comprehensive earnings for the period, net after tax** | **-0.7** | **-5.3** | **5.9** | **-8.4** | **-7.5** |
| **Total comprehensive earnings for the period**[1] | **61.5** | **22.9** | **92.3** | **-12.0** | **15.7** |
| Earnings per share, before dilution, SEK | 1.80 | 0.82 | 2.50 | -0.10 | 0.67 |
| Earnings per share, after dilution, SEK | 1.77 | 0.81 | 2.46 | -0.10 | 0.67 |

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

## CONDENSED CONSOLIDATED BALANCE SHEET

| SEK million | 2018 Sep 30 | 2017 Sep 30 | 2017 Dec 31 |
|---|---|---|---|
| **ASSETS** | | | |
| **Fixed assets** | | | |
| Tangible fixed assets | 19.5 | 20.0 | 20.1 |
| Intangible fixed assets | 108.3 | 125.4 | 121.0 |
| Deferred tax assets | 78.4 | 30.1 | 28.3 |
| Other financial assets | 7.7 | 7.0 | 7.1 |
| **Total fixed assets** | **213.9** | **182.5** | **176.5** |
| **Current assets** | | | |
| Inventories | 180.5 | 272.1 | 250.2 |
| Accounts receivable and other receivables | 297.3 | 208.0 | 249.3 |
| Cash and cash equivalents | 516.6 | 370.7 | 327.9 |
| **Total current assets** | **994.4** | **850.8** | **827.4** |
| **Total assets** | **1,208.3** | **1,033.3** | **1,003.9** |
| **SHAREHOLDERS' EQUITY AND LIABILITIES** | | | |
| **Total shareholders' equity** | **424.4** | **300.0** | **329.1** |
| **Long-term liabilities** | | | |
| Provisions | 6.6 | 3.4 | 5.8 |
| Long-term liabilities, interest bearing | 320.2 | — | 319.1 |
| **Total long-term liabilities** | **326.8** | **3.4** | **324.9** |
| **Current liabilities and provisions** | | | |
| Provisions | 266.0 | 207.2 | 200.9 |
| Current liabilities, interest bearing | — | 340.6 | — |
| Current liabilities, non-interest bearing | 191.1 | 182.2 | 149.0 |
| **Total current liabilities and provisions** | **457.1** | **730.0** | **349.9** |
| **Total liabilities** | **783.9** | **733.4** | **674.8** |
| **Total shareholders' equity and liabilities** | **1,208.3** | **1,033.3** | **1,003.9** |

## CONSOLIDATED CHANGES IN SHAREHOLDERS' EQUITY

| SEK million | 2018 Sep 30 | 2017 Sep 30 | 2017 Dec 31 |
|---|---|---|---|
| **Opening balance, shareholders' equity** | **329.1** | **310.3** | **310.3** |
| Total comprehensive earnings for the period | 92.3 | -12.0 | 15.7 |
| Employee stock options, vested amount | 3.0 | 1.7 | 3.0 |
| Buy back of shares | -0.1 | — | — |
| New share issue | 0.1 | — | 0.1 |
| **Closing balance, shareholders' equity** | **424.4** | **300.0** | **329.1** |

## CONDENSED CONSOLIDATED CASH FLOW STATEMENTS

| SEK million | Notes | 2018 Jul-Sep | 2017 Jul-Sep | 2018 Jan-Sep | 2017 Jan-sep | 2017 Jan-Dec |
|---|---|---|---|---|---|---|
| Operating earnings | | 34.6 | 40.9 | 58.2 | 27.2 | 57.4 |
| Interest received | | — | 0.1 | — | 0.2 | 0.2 |
| Interest paid | | -2.5 | -2.8 | -9.8 | -14.1 | -15.6 |
| Income taxes paid | | -11.0 | -11.6 | -16.0 | -18.9 | -19.6 |
| Adjustment for non-cash items | 2 | -29.6 | 11.1 | 61.1 | 88.9 | 87.9 |
| **Cash flow from operating activities before changes in working capital** | | **-8.5** | **37.7** | **93.6** | **83.3** | **110.3** |
| **Changes in working capital** | | **33.0** | **54.6** | **76.8** | **86.3** | **36.3** |
| **Cash flow from operating activities** | | **24.5** | **92.3** | **170.4** | **169.6** | **146.6** |
| Acquisition of tangible and intangible fixed assets | | -0.5 | -0.5 | -2.2 | -0.8 | -1.6 |
| **Cash flow from investing activities** | | **-0.5** | **-0.5** | **-2.2** | **-0.8** | **-1.6** |
| New share issue | | — | — | 0.1 | — | 0.1 |
| Buy back shares | | -0.1 | — | -0.1 | — | — |
| Change in loans | | — | — | — | -59.0 | -85.5 |
| **Cash from financing activities** | | **-0.1** | **0.0** | **0.0** | **-59.0** | **-85.4** |
| **Cash flow for the period** | | **23.9** | **91.8** | **168.2** | **109.8** | **59.6** |
| **Cash and cash equivalents at the beginning of the period** | | **494.8** | **294.3** | **327.9** | **282.4** | **282.4** |
| Exchange-rate differences in cash and cash equivalents | | -2.1 | -15.4 | 20.5 | -21.5 | -14.1 |
| Changes in cash and cash equivalents | | 21.8 | 76.4 | 188.7 | 88.3 | 45.5 |
| **Cash and cash equivalents at the end of the period** | | **516.6** | **370.7** | **516.6** | **370.7** | **327.9** |

### 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.

| | 2018 Jul-Sep | 2017 Jul-Sep | 2018 Jan-Sep | 2017 Jan-Sep | 2017 Jan-Dec |
|---|---|---|---|---|---|
| EBIT margin, % | 16.0 | 24.6 | 10.5 | 6.0 | 8.9 |
| Return on shareholder equity, % | 15.8 | 9.8 | 22.9 | -1.2 | 7.3 |
| Net debt, SEK million | -196.4 | -30.1 | -196.4 | -30.1 | -8.8 |
| Debt/equity ratio, % | 75.4 | 113.5 | 75.4 | 113.5 | 97.0 |
| Equity/assets ratio, % | 35.1 | 29.0 | 35.1 | 29.0 | 32.8 |
| Number of shares, before dilution | 34,581,327 | 34,539,585 | 34,581,327 | 34,539,585 | 34,561,142 |
| Number of shares, after dilution | 35,162,920 | 34,667,421 | 35,162,920 | 34,539,585 | 34,671,706 |
| Earnings per share, before dilution, SEK | 1.80 | 0.82 | 2.50 | -0.10 | 0.67 |
| Earnings per share, after dilution, SEK | 1.77 | 0.81 | 2.46 | -0.10 | 0.67 |
| Number of employees at the end of the period | 102 | 92 | 102 | 92 | 90 |
| Shareholders' equity, SEK million | 424.4 | 300.0 | 424.4 | 300.0 | 329.1 |
| Capital employed, SEK million | 744.6 | 640.6 | 744.6 | 640.6 | 648.2 |
| Working capital, SEK million | 20.7 | 90.7 | 20.7 | 90.7 | 149.6 |

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

## CONDENSED PARENT COMPANY STATEMENT OF OPERATIONS

| SEK million | Notes | 2018 Jul-Sep | 2017 Jul-Sep | 2018 Jan-Sep | 2017 Jan-Sep | 2017 Jan-Dec |
|---|---|---|---|---|---|---|
| Net revenues | | 131.1 | 114.8 | 279.0 | 350.8 | 477.8 |
| Cost of goods sold | | -35.8 | -38.0 | -86.5 | -134.2 | -167.4 |
| **Gross profit** | | **95.3** | **76.8** | **192.5** | **216.6** | **310.4** |
| Selling expenses | | -20.6 | -4.6 | -10.3 | -46.6 | -73.3 |
| Administrative expenses | | -42.5 | -13.7 | -89.4 | -48.9 | -67.3 |
| Research and development costs | | -30.1 | -23.1 | -98.6 | -76.9 | -105.3 |
| Other operating income and expenses | | 31.2 | 0.1 | 36.9 | -1.8 | -1.2 |
| **Operating earnings** | | **33.3** | **35.5** | **31.1** | **42.4** | **63.3** |
| Interest income and expenses | | -3.7 | -2.7 | -11.1 | -11.0 | -14.6 |
| Exchange rate adjustment | | — | — | — | -1.3 | -1.3 |
| Other financial income and expenses | | -1.7 | -8.6 | 6.6 | -11.2 | -12.3 |
| **Net financial items** | | **-5.4** | **-11.3** | **-4.4** | **-23.5** | **-28.2** |
| **Earnings before tax** | | **27.9** | **24.2** | **26.7** | **18.9** | **35.1** |
| Tax | 4 | 33.2 | — | 35.1 | — | 7.6 |
| **Earnings for the period** | | **61.2** | **24.2** | **61.8** | **18.9** | **42.7** |

## PARENT COMPANY STATEMENT OF COMPREHENSIVE INCOME

| SEK million | 2018 Jul-Sep | 2017 Jul-Sep | 2018 Jan-Sep | 2017 Jan-Sep | 2017 Jan-Dec |
|---|---|---|---|---|---|
| **Earnings for the period** | **61.2** | **24.2** | **61.8** | **18.9** | **42.7** |
| **Other comprehensive income** | — | — | — | — | — |
| **Total comprehensive earnings for the period** | **61.2** | **24.2** | **61.8** | **18.9** | **42.7** |

## CONDENSED PARENT COMPANY BALANCE SHEET

| SEK million | 2018 Sep 30 | 2017 Sep 30 | 2017 Dec 31 |
|---|---|---|---|
| **ASSETS** | | | |
| **Fixed assets** | | | |
| Intangible fixed assets | 108.3 | 125.4 | 121.0 |
| Tangible fixed assets | 19.5 | 19.8 | 19.9 |
| Deferred tax asset | 42.6 | — | 7.5 |
| Shares in subsidiaries | 151.8 | 149.8 | 150.6 |
| **Total fixed assets** | **322.2** | **295.0** | **299.0** |
| | | | |
| **Current assets** | | | |
| Inventories | 150.5 | 193.2 | 186.3 |
| Accounts receivable and other receivables | 161.5 | 148.0 | 158.4 |
| Cash and bank balances | 259.6 | 215.4 | 215.1 |
| **Total current assets** | **571.6** | **556.6** | **559.8** |
| | | | |
| **Total assets** | **893.8** | **851.6** | **858.8** |
| | | | |
| **SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES** | | | |
| | | | |
| **Shareholders' equity** | **374.2** | **284.1** | **309.4** |
| | | | |
| **Long-term liabilities** | | | |
| Other provisions | 5.1 | 3.4 | 4.9 |
| Bond loan | 320.2 | — | 319.1 |
| **Total long-term liabilities** | **325.3** | **3.4** | **324.0** |
| | | | |
| **Current liabilities** | | | |
| Accounts payable | 11.5 | 16.9 | 28.9 |
| Bond loan | — | 340.6 | — |
| Other liabilities | 11.5 | 33.0 | 6.6 |
| Liabilities to Group companies | 134.8 | 148.0 | 169.1 |
| Accrued expenses and deferred income | 36.5 | 25.6 | 20.8 |
| **Total current liabilities** | **194.3** | **564.1** | **225.4** |
| | | | |
| **Total liabilities** | **519.6** | **567.5** | **549.4** |
| | | | |
| **Total shareholders' equity and liabilities** | **893.8** | **851.6** | **858.8** |

# 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 2017 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 2018**
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 applies 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 no material changes other than additional disclosure requirements, see Note 5.

IFRS 9 financial instruments covers the recognition and valuation of financial assets and liabilities and replaces IAS 39 financial instruments: recognition and measurement.
The Group applies the new standard in its entirety as of January 1, 2018 and it has made an assessment of IFRS 9 and its effects on company's financial statements, which shows no material impact on the Group's and on the Parent Company's results and financial position.

IFRS 16 Leases will replace IAS 17. According to the new standard, most leased assets must be recognized in the balance sheet and the lessee shall divide up the cost into interest payments and depreciation of the asset. The standard will be applied by the Group and the Parent Company as from January 1, 2019. Orexo's preliminary assessment is that most of the leasing agreements that are recognized as operational leasing agreements will be recognized in the balance sheet. This will also mean that the cost of these will be recognized, divided up into interest payments and depreciation.

## 2. Cash flow

**ADJUSTMENT FOR NON-CASH ITEMS**

| SEK million | 2018 Jul-Sep | 2017 Jul-Sep | 2018 Jan-Sep | 2017 Jan-Sep | 2017 Jan-Dec |
|---|---|---|---|---|---|
| Depreciation/amortization and impairment | 5.2 | 5.2 | 15.5 | 15.6 | 20.8 |
| Change in provisions | -35.9 | 1.5 | 48.9 | 67.0 | 59.9 |
| Share based payments | 1.5 | 1.3 | 3.0 | 1.7 | 3.0 |
| Exchange rate income and expenses | -0.4 | 3.1 | -6.3 | 4.6 | 4.2 |
| **Total** | **-29.6** | **11.1** | **61.1** | **88.9** | **87.9** |

## 3. Legal disputes

**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.

On September 10, 2018, the US Court of Appeals for the Federal Circuit found Zubsolv US patent ´330 to be valid, and reversed the invalidity decision previously rendered by the District Court of Delaware in November 2016. The '330 patent and two new Zubsolv US patents, 9,259,421 and 9,439,900, listed in the Orange Book in 2016, are protecting Zubsolv in the US until 2032.

Orexo will request the District Court of Delaware to issue a judgment that Actavis's generic Zubsolv products infringe the '330 patent, and will not be FDA approved until 2032.

**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. The trial is scheduled for March, 2019.

## 4. Deferred tax

New Swedish corporate tax rates have been announced with 21.4 percent from January 1, 2019, and 20.6 percent from January 1, 2021. In line with IFRS which on this area is based on a principle that changes in tax rates should be incorporated into the accounting for the relevant tax positions immediately upon enactment, the company has performed a tax analysis. The tax-loss carry-forward in the Group amounts to SEK 1,441 million as of September 30 2018 and refers to the Swedish companies. Of these, SEK 42.6 million has been capitalized as per September 30, 2018. There is no time limit for when the remaining loss carryforwards can be utilized. The rest of the tax effect of the Group's temporary differences are related to non-deductible current provisions for sales rebates, sales allowances, distribution, sales returns and other relevant deductions in the company's US operations.

## 5. Financial instruments

The Group's financial instruments consists of current receivables, non-current receivables, cash and cash equivalents, current non-interest bearing liabilities, current interest-bearing liabilities and long-term interest-bearing liabilities. The financial instruments held by the group are recognized at amortized cost using the effective interest method. The group does not hold any financial instruments which are reported at fair value. The fair value of financial instruments held at the balance sheet date is significantly the same as the book value.

## 6. Related parties

There were no significant related parties transactions during the period.

## 7. Important events after the period

The contracted US field force internalized to further strengthen the commercial organization.

Joseph DeFeo is appointed as new CFO from November 1, 2018.

A Capital Market Day will be hosted in Stockholm, Sweden, on December 6, 2018.

## 8. Revenue from contracts with customers

| SEK million | 2018 Jul-Sep | | | | |
|---|---|---|---|---|---|
| **Type of revenue** | **Zubsolv®** | **Abstral®** | **Edluar®** | **OX-CLI** | **Total** |
| Sales, products | 165.4 | — | — | — | **165.4** |
| Royalties | 0.2 | 48.7 | 2.3 | — | **51.2** |
| Milestones | — | — | — | — | **0.0** |
| **Total revenue from contracts with customers** | **165.6** | **48.7** | **2.3** | **0.0** | **216.6** |
| | | | | | |
| **Geographical markets** | **Zubsolv** | **Abstral** | **Edluar** | **OX-CLI** | **Total** |
| US | 165.4 | 1.4 | 0.9 | — | **167.7** |
| EU | 0.2 | 40.0 | 0.3 | — | **40.5** |
| Rest of the world | — | 7.2 | 1.2 | — | **8.4** |
| **Total revenue from contracts with customers** | **165.6** | **48.6** | **2.4** | **0.0** | **216.6** |

| SEK million | 2017 Jul-Sep | | | | |
|---|---|---|---|---|---|
| **Type of revenue** | **Zubsolv** | **Abstral** | **Edluar** | **OX-CLI** | **Total** |
| Sales, products | 121.1 | — | — | — | **121.1** |
| Royalties | — | 39.4 | 5.7 | — | **45.1** |
| Milestones | — | — | — | — | **0.0** |
| **Total revenue from contracts with customers** | **121.1** | **39.4** | **5.7** | **0.0** | **166.2** |
| | | | | | |
| **Geographical markets** | **Zubsolv** | **Abstral** | **Edluar** | **OX-CLI** | **Total** |
| US | 121.1 | 0.4 | 3.9 | — | **125.4** |
| EU | — | 35.7 | 0.2 | — | **35.9** |
| Rest of the world | — | 3.3 | 1.6 | — | **4.9** |
| **Total revenue from contracts with customers** | **121.1** | **39.4** | **5.7** | **0.0** | **166.2** |

| SEK million | 2018 Jan-Sep | | | | |
|---|---|---|---|---|---|
| **Type of revenue** | **Zubsolv** | **Abstral** | **Edluar** | **OX-CLI** | **Total** |
| Sales, products | 454.9 | — | — | — | **454.9** |
| Royalties | 0.2 | 66.4 | 3.7 | — | **70.3** |
| Milestones | 30.8 | — | — | — | **30.8** |
| **Total revenue from contracts with customers** | **485.9** | **66.4** | **3.7** | **0.0** | **556.0** |
| | | | | | |
| **Geographical markets** | **Zubsolv** | **Abstral** | **Edluar** | **OX-CLI** | **Total** |
| US | 454.9 | 4.2 | -0.5 | — | **458.6** |
| EU | 31.0 | 43.9 | 1.0 | — | **75.9** |
| Rest of the world | — | 18.3 | 3.2 | — | **21.5** |
| **Total revenue from contracts with customers** | **485.9** | **66.4** | **3.7** | **0.0** | **556.0** |

| SEK million | 2017 Jan-Sep | | | | |
|---|---|---|---|---|---|
| **Type of revenue** | **Zubsolv®** | **Abstral®** | **Edluar®** | **OX-CLI** | **Total** |
| Sales, products | 359.3 | — | — | — | **359.3** |
| Royalties | — | 57.8 | 13.7 | — | **71.5** |
| Milestones | — | — | — | 21.8 | **21.8** |
| **Total revenue from contracts with customers** | **359.3** | **57.8** | **13.7** | **21.8** | **452.6** |
| | | | | | |
| **Geographical markets** | **Zubsolv** | **Abstral** | **Edluar** | **OX-CLI** | **Total** |
| US | 359.3 | 3.8 | 8.6 | — | **371.7** |
| EU | — | 40.2 | 0.5 | 21.8 | **62.5** |
| Rest of the world | — | 13.8 | 4.6 | — | **18.4** |
| **Total revenue from contracts with customers** | **359.3** | **57.8** | **13.7** | **21.8** | **452.6** |

| SEK million | 2017 Jan-Dec | | | | |
|---|---|---|---|---|---|
| **Type of revenue** | **Zubsolv** | **Abstral** | **Edluar** | **OX-CLI** | **Total** |
| Sales, products | 491.4 | — | — | — | **491.4** |
| Royalties | — | 113.2 | 17.3 | — | **130.5** |
| Milestones | — | — | — | 21.8 | **21.8** |
| **Total revenue from contracts with customers** | **491.4** | **113.2** | **17.3** | **21.8** | **643.7** |
| | | | | | |
| **Geographical markets** | **Zubsolv** | **Abstral** | **Edluar** | **OX-CLI** | **Total** |
| US | 485.8 | 5.1 | 10.2 | — | **501.1** |
| EU | 5.6 | 88.6 | 0.8 | 21.8 | **116.8** |
| Rest of the world | — | 19.5 | 6.3 | — | **25.8** |
| **Total revenue from contracts with customers** | **491.4** | **113.2** | **17.3** | **21.8** | **643.7** |

Geographical distribution of royalties and milestones are based on the counterparts registered office.

# 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 |
| US EBIT margin | US EBIT (SEK) as a percentage of US net revenues (SEK) | US EBIT 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 | Interest bearing 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 excluding cash and cash equivalents less current liabilities excluding interest bearing liabilities | Working capital is used to measure the company's ability, besides cash and cash equivalents and interest bearing liabilities, 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 |
| US EBIT (SEK) | US net revenues (SEK) less consolidated US cost of goods sold (SEK) less US operating expenses (SEK) | Profit measure which illustrates direct contribution (SEK) from US business |
| 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 ARE RECONCILED AS FOLLOWS

| EBITDA SEK million | 2018 Jul-Sep | 2017 Jul-Sep | 2018 Jan-Sep | 2017 Jan-Sep | 2017 Jan-Dec |
|---|---|---|---|---|---|
| EBIT | 34.6 | 40.9 | 58.2 | 27.2 | 57.4 |
| Depreciation and amortization | 5.2 | 5.2 | 15.5 | 15.6 | 20.8 |
| **EBITDA** | **39.8** | **46.1** | **73.7** | **42.8** | **78.2** |

| RETURN ON SHAREHOLDERS' EQUITY | 2018 Jul-Sep | 2017 Jul-Sep | 2018 Jan-Sep | 2017 Jan-Sep | 2017 Jan-Dec |
|---|---|---|---|---|---|
| Shareholders' equity beginning balance | 361.3 | 275.8 | 329.1 | 310.3 | 310.3 |
| Shareholders' equity ending balance | 424.4 | 300.0 | 424.4 | 300.0 | 329.1 |
| Average shareholders' equity | 392.8 | 287.9 | 376.7 | 305.2 | 319.7 |
| Net earnings | 62.2 | 28.2 | 86.4 | -3.6 | 23.2 |
| **Return on shareholders' equity %** | **15.8** | **9.8** | **22.9** | **-1.2** | **7.3** |

| OPERATING EXPENSES SEK million | 2018 Jul-Sep | 2017 Jul-Sep | 2018 Jan-Sep | 2017 Jan-Sep | 2017 Jan-Dec |
|---|---|---|---|---|---|
| Selling expenses | -51.5 | -43.3 | -143.4 | -141.3 | -190.5 |
| Administrative expenses | -50.8 | -21.0 | -112.0 | -69.8 | -96.1 |
| Research and development costs | -37.5 | -29.0 | -119.8 | -98.4 | -134.2 |
| Other operating income and expenses | 0.2 | 0.1 | 5.8 | -1.8 | -1.1 |
| **Operating expenses** | **-139.6** | **-93.2** | **-369.4** | **-311.3** | **-421.9** |

| GROSS INVESTMENTS SEK million | 2018 Jul-Sep | 2017 Jul-Sep | 2018 Jan-Sep | 2017 Jan-Sep | 2017 Jan-Dec |
|---|---|---|---|---|---|
| Investments in tangible fixed assets | - | 0.2 | 1.6 | 0.3 | 1.1 |
| Investments in intangible fixed assets | 0.5 | 0.3 | 0.6 | 0.5 | 0.5 |
| **Gross investments** | **0.5** | **0.5** | **2.2** | **0.8** | **1.6** |

| US EBIT SEK million and EBIT margin % | 2018 Jul-Sep | 2017 Jul-Sep | 2018 Jan-Sep | 2017 Jan-Sep | 2017 Jan-Dec |
|---|---|---|---|---|---|
| Consolidated operating earnings | 34.6 | 40.9 | 58.2 | 27.2 | 57.4 |
| Non US related items impacting operating earnings | -21.0 | 9.1 | -78.3 | -26.8 | -16.3 |
| **US EBIT** | **55.6** | **31.8** | **136.5** | **54.0** | **73.7** |
| **US EBIT margin %** | **33.6** | **26.3** | **30.0** | **15.0** | **15.2** |

# 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.
**ANDA**
An Abbreviated New Drug Application (ANDA) is an application for a US generic drug approval for an existing licensed medication or approved drug
**Anesthesia**
Procedure for lowering a patient's consciousness to enable a Medical procedure to proceed without pain for the patient
**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 US 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 US 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
**In Vitro studies**
In an in vitro study; living matter is examined outside of its natural context e.g. in a test-tube
**IP**
Intellectual Properties
**Naloxone**
An opioid inverse agonist used to counter the effects of opioids
**LTM**
Last Twelve Months
**NSAID**
Non-steroid anti-inflammatory drugs which are active against pain, inflammation and fever
**NTRx**
Tablets per prescription divided by 30
**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
**Proof of Concept studies**
A Proof of Concept study is performed to get a first indication of an idea's practical feasibility
**Public segment**
One of three distinct payer segments in the US 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
**Sublingual**
Under the tongue
**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 25, 2018.