Q4 incl. Full Year Report 2018

2018 was a pivotal year for Orexo

Q4 2018 highlights

- Total net revenues of SEK 227.1 million (191.0), up 18.9 percent from Q4 previous year
- Zubsolv® US net revenue of SEK 166.7 million (126.5), up 31.8 percent in SEK and 21.3 percent in local currency compared to the same period last year
- EBITDA of SEK 42.8 million (35.3), EBITDA excluding IP litigation costs of SEK 69.2 million (43.1)
- US EBIT of SEK 62.0 million (19.8)
- Cash flow from operating activities of SEK 71.7 million (-23.0), building a cash balance of SEK 589.8 million (327.9)
- Earnings per share, before dilution SEK 1.49 (0.77), earnings per share after dilution SEK 1.47 (0.77)
- The US field force, previously contracted, was internalized to further strengthen the commercial organization
- US Court of Appeals denied Actavis's petition for rehearing regarding validity of the Zubsolv patent ´330
- All rights to Zubsolv in all countries outside the US were regained from Mundipharma

Important events after the period

- Positive results from human PK study assessing Orexo's new intranasal naloxone formulations (OX124) for opioid overdose reversal
- The US District Court of Delaware issued a final, non-appealable judgement that Actavis's generic Zubsolv products infringe the US patent ´330, preventing Actavis from launching their infringing generics in the US until 2032
- The Board of Directors proposes that no dividend is paid for the financial year 2018

SEK million, unless otherwise stated	2018 Oct-Dec	2017 Oct-Dec	2018 Jan-Dec	2017 Jan-Dec	Δ 2017-2018
Net revenues	227.1	191.0	783.1	643.7	22%
whereof Zubsolv® US net revenue	166.7	126.5	621.5	485.8	28%
Cost of goods sold	-43.4	-50.3	-171.8	-164.4	4%
Operating expenses	-146.1	-110.6	-515.6	-421.9	22%
EBIT	37.6	30.1	95.8	57.4	67%
EBIT margin, %	16.6	15.8	12.2	8.9	3.3 ppt
US EBIT	62.0	19.8	198.3	73.7	169%
US EBIT margin, %	37.2	15.7	31.9	15.2	16.7 ppt
EBITDA	42.8	35.3	116.6	78.2	49%
Earnings per share, before dilution, SEK	1.49	0.77	3.99	0.67	496%
Earnings per share, after dilution, SEK	1.47	0.77	3.93	0.67	487%
Cash flow from operating activities	71.7	-23.0	242.0	146.6	65%
Cash and cash equivalents	589.8	327.9	589.8	327.9	80%

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

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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 2018 amounted to SEK 783.1 million and the number of employees at year-end was 129. 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
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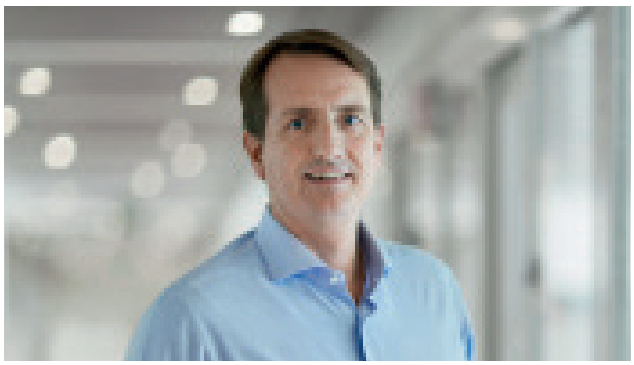
Presentation
At 2.00 pm CET, the same day as the announcement of the report, Orexo invites analysts, investors and media to attend an audiocast with a web presentation where Nikolaj Sørensen, CEO, and Joseph DeFeo, CFO, will present the report. After the presentation a Q&A will be held. Questions can 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-q4-2018
Telephone: SE: +46 8 50 558 354 UK: +44 33 33 009 267 US: +1 64 67 224 904
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, 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
Interim Report Q3 2019, October 24 at 8:00 am CET
Full Year Report - January 30, 2020 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.

Delivering on strategy to drive future growth



Overview - delivering our strategy
2018 was a pivotal year for Orexo, with a positive patent litigation outcome allowing us to focus on the future shape of the Company and our ambitious growth strategy for 2019 and beyond. I am proud of the progress the team has made against our strategic objectives, both operationally and financially. I believe 2019 will see further success as we look to expand our US commercial platform, drive sales of Zubsolv® and strengthen our pipeline further.

Operational - multiple highlights
Beyond the successful patent litigation outcome, two key operational highlights during 2018 were the efficiency improvements to the supply chain and the expansion of our pipeline programs. Improving manufacturing efficiency is an ongoing objective for the business, and I am pleased to see the progress we have made towards reducing manufacturing costs towards the goal of 35 percent cost reduction in the second half of 2019.
Our pipeline has also expanded from one project, OX382 (oral buprenorphine) to four projects under development, including OX124 (naloxone for opioid overdose treatment) which reported encouraging clinical data in early January 2019. The strength of this data supports the commercial potential of this program which we believe will address an unmet need provide an improved product for opioid overdose patients, compared to currently available options.

Financials – a record-breaking performance
Financially we passed the SEK 100 million EBITDA level with a full year EBITDA of SEK 116.6 million, an increase of nearly 50 percent over 2017. This growth was mainly due to greater sales of Zubsolv in the US, with an increase of 27.9 percent from 2017, in combination with the EBIT contribution from our US operations, which has more than doubled both in SEK and EBIT margin. Looking specifically at the fourth quarter, I am pleased to see the positive trend in the US continue, along with improving performance and margins reaching SEK 62.0 million in EBIT, and an EBIT margin of 37.2 percent.

Market dynamics - Orexo is well positioned
The US market for Zubsolv is becoming increasingly dynamic, which will present new opportunities for Orexo as we look to expand our commercial operations and attract new commercial stage products in the US as set out in our strategy. Alongside these opportunities, we expect to experience some pricing challenges from the potential launch of the generic Suboxone® Film. We have taken steps to address these headwinds in the form of competitive measures to ensure Zubsolv remains a commercially attractive and competitive product.

We believe this proactive strategy, together with improved market access in both the Commercial and Public Segment, strengthens Orexo's position as a profitable specialty pharmaceutical company with commercial operations in the US in this increasingly competitive market.

Strategic objectives for growth
During our Capital Markets Day in December, our Chairman presented our main strategic objective moving forward, which is to "Broaden the commercial platform to leverage scale and expand sales". The main implications of this objective is to more proactively pursue business development and M&A opportunities. To achieve this the team at Orexo will continue to ensure the strong performance of our core business and strengthen our financial position to make us an attractive and trusted partner. Considering our strong financial position with close to SEK 590 million in cash and the flexibility we now have with the rights to Zubsolv outside of the US, we are well placed to pursue new strategic opportunities for further growth.

Summary and Outlook
2018 was a key year for Orexo. Winning the patent litigation for Zubsolv allowed us to secure the foundations for our US operations until 2032. The outlook for 2019 is encouraging; we expect profitability to continue to improve both from our US operations and on a corporate level, in line with our ambitious strategic goals to grow the business both organically and through acquisitions. Once again I would like to thank my colleagues in Sweden and the US for their contribution to the business during 2018 - the results we have accomplished together are all due to their hard work and perseverance. Building on a highly successful 2018, I and my team at Orexo look forward to expanding our commercial platform to leverage scale, increase profitability and ultimately provide innovative and affordable treatments to patients suffering from opioid use disorders.

Uppsala, Sweden, January 30, 2019

Nikolaj Sørensen
President and CEO

Financial information

Orexo's profitability continued 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 69.2 million for the fourth quarter and at SEK 199.4 million for the full year. An increase from SEK 43.1 million in the same quarter previous year and an increase from SEK 100.6 million in the previous year.

The EBIT contribution from the US commercial business continues to grow, driven by Zubsolv® growth, COGS reductions and operational leverage in the US enabling revenue growth without increasing the operational expenses. For the quarter the US commercial business contributed with a significant EBIT improvement to SEK 62.0 million (19.8) equal to an EBIT margin of 37.2 percent (15.7) and an EBIT for the full year of SEK 198.3 million (73.7) equal to an EBIT margin of 31.9 percent (15.2).

Revenues

Total revenues for the quarter amounted to SEK 227.1 million (191.0), corresponding to an 18.9 percent increase over the same period in the previous year. The increase was driven by strong Zubsolv US growth, reaching 31.8 percent in SEK.

For the full year 2018, total revenues amounted to SEK 783.1 million (643.7), corresponding to a 21.7 percent increase also driven by strong Zubsolv US revenue growth.

Commercial products
Zubsolv US revenues amounted to SEK 166.7 million (126.5) for the quarter, corresponding to 31.8 percent growth in SEK. In local currency (USD) the equivalent growth rate was 21.3 percent, equal to sales of USD 18.4 million for the fourth quarter.

The key year over year growth factor was the 22 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.

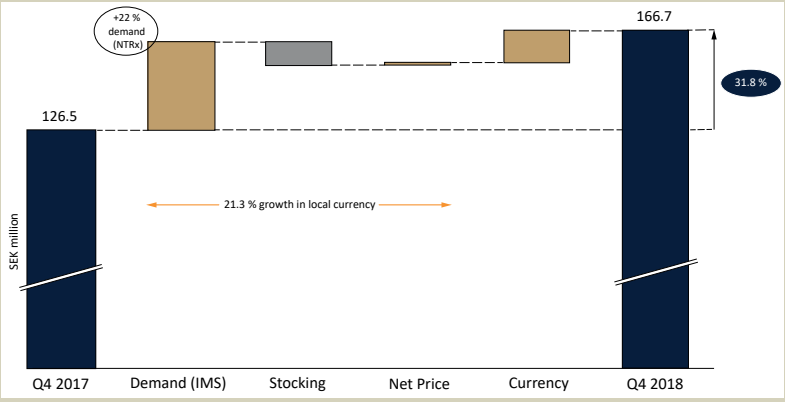
For the full year 2018, Zubsolv US revenue amounted to SEK 621.5 million (485.8) corresponding to 27.9 percent growth. In local currency the full year growth was 25.3 percent.

Abstral® revenues amounted to SEK 52.4 million (55.4) for the quarter. The decrease was primarily driven by lower sales in some areas of the EU and the US. For the full year Abstral revenues amounted to SEK 118.8 million (113.2), an increase of 4.9 percent over previous year.

Revenues from Edluar® amounted to SEK 2.9 million (3.6) for the quarter and for the full year to SEK 6.6 million (17.3). Supply issues in the US market caused a temporary loss of business which is now gradually building up again.

Zubsolv, ex US, revenues amounted to SEK 5.2 million (5.6) and for the full year to SEK 36.2 million (5.6) as the launch of Zubsolv in the EU triggered a milestone payment of EUR 3 million in June 2018. Mundipharma, Orexo's Zubsolv partner ex US, has decided for strategic reasons to exit the partnership as of April 13, 2019. This offers Orexo the opportunity to regain the rights and to choose the best route to maximize the potential for Zubsolv on markets outside the US.

ZUBSOLV US NET REVENUE GROWTH BY KEY DRIVERS, Q4 2018 VERSUS Q4 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 and during the full year. 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. 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 43.4 million (50.3) for the quarter of which SEK 38.0 million relates to Zubsolv® in the US market. This corresponds to an average COGS per tablet 21 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 SEK 5.4 million related to the last Zubsolv supplied to Mundipharma. These products were supplied at direct cost as per the agreement. COGS amounted to SEK 171.8 million (164.4) for the full year of which SEK 166.3 million relates to Zubsolv in the US market.

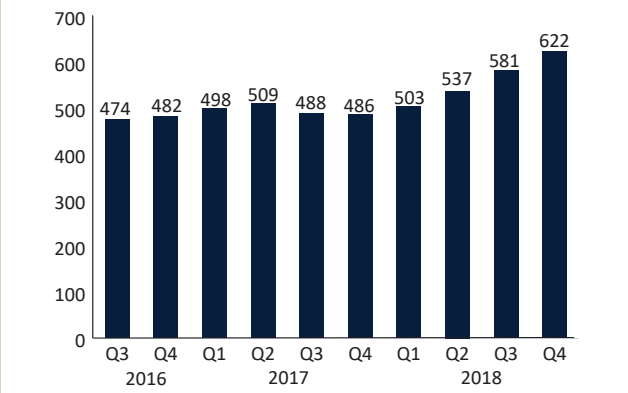
Selling expenses
Selling expenses amounted to SEK 48.0 million (49.2). The decrease over same period last year is explained by timing of additional market research expenses. For the full year 2018, selling expenses amounted to SEK 191.4 million (190.5).

Administrative expenses
Administrative expenses for the quarter amounted to SEK 54.7 million (26.3) and for the full year to SEK 166.7 million (96.1). 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 26.4 million (7.8) for the quarter and for the full year SEK 82.8 million (22.4).

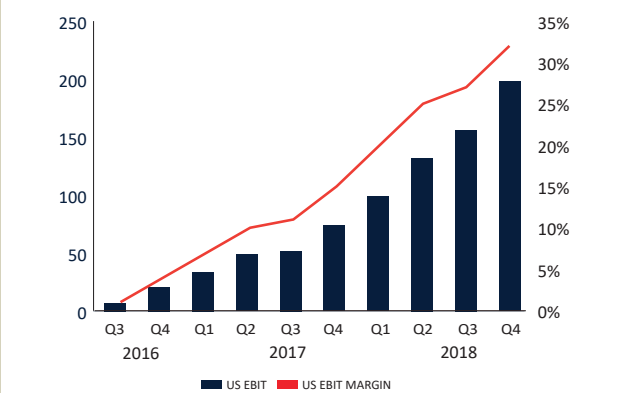
DISTRIBUTION OF TOTAL NET REVENUES

SEK million	2018 Oct-Dec	2017 Oct-Dec	2018 Jan-Dec	2017 Jan-Dec
Zubsolv® US	166.7	126.5	621.5	485.8
Zubsolv – ex US	5.2	5.6	36.2	5.6
Zubsolv – total	**171.9**	**132.1**	**657.8**	**491.4**
Abstral® royalties	52.4	55.4	118.8	113.2
Edluar® royalties	2.9	3.6	6.6	17.3
OX-CLI	—	—	—	21.8
Total	**227.1**	**191.0**	**783.1**	**643.7**

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 Q4 2018, research and development costs amounted to SEK 47.0 million (35.8) and for the full year to SEK 166.8 million (134.2). The increase is explained by higher activity level, including the human PK study for OX124 and by the manufacturing efficiency program.

Costs for long-term incentive program
The Group's total costs for employee share-based payment programs during Q4 2018 amounted to SEK -1.0 million (1.6). The negative cost for the quarter is explained by reversals of prior period costs due to vesting conditions related to employment not met. For the full year 2018, the costs amounted to SEK 1.4 million (3.0).

Other income and expenses
Other operating income and expenses amounted to SEK 3.6 million (0.7) for Q4 2018. The increase is mainly explained by an insurance reimbursement for legal costs. For the full year 2018 other operating income and expenses amounted to SEK 9.3 million (-1.1). The increase is largerly part explained by exchange-rate gains derived from revaluations of parent company balance sheet items in foreign currency and to a lesser part by an insurance reimbursement for legal costs.

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

Net financial items
Net financial items for the quarter amounted to SEK -0.3 million (-4.7) and to SEK -3.6 million (-27.7) for the full year. 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 bond loan related costs were almost completely offset by earned interest on bank accounts in the US and by a positive exchange rate impact as the SEK/USD rate at the end of Q4, 2018 was slightly higher than the rate at the end of the previous quarter and at the previous year end.

Tax
Total tax expenses for the quarter amounted to SEK 14.3 million (1.3) and to SEK 45.7 million (-6.5) for the full year. Tax for the quarter was positively impacted by a SEK 18.2 million and the full year was positively impacted by a SEK 53.3 million due to adjustments of the parent company´s deferred tax asset, driven by increased profitability, see Note 4.

Net earnings
Net earnings amounted to SEK 51.6 million (26.7) for the quarter and to SEK 137.9 million (23.2) for the full year.

Cash flow and financial position

At December 31 2018, cash and cash equivalents amounted to SEK 589.8 million (327.9) and interest bearing liabilities to SEK 320.6 million (319.1), i.e. a positive net cash position of SEK 269.2 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 71.7 million (-23.0). The higher level compared with same period last year is explained by higher operating earnings and by a positive contribution from changes in working capital.

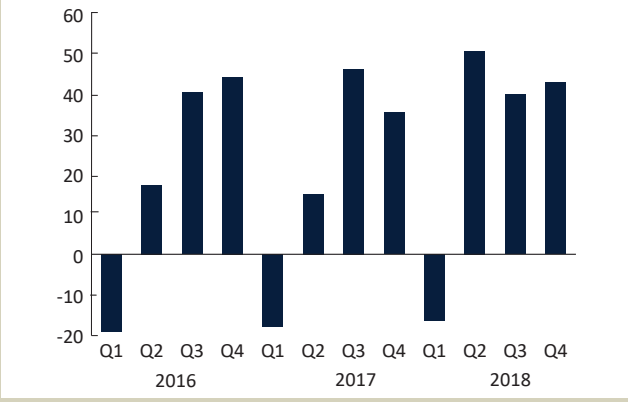
Shareholders' equity at December 31, 2018, was SEK 476.1 million (329.1). The equity/asset ratio was 37.0 percent (32.8).

The Board of Directors proposes that no dividend is paid for the financial year 2018.

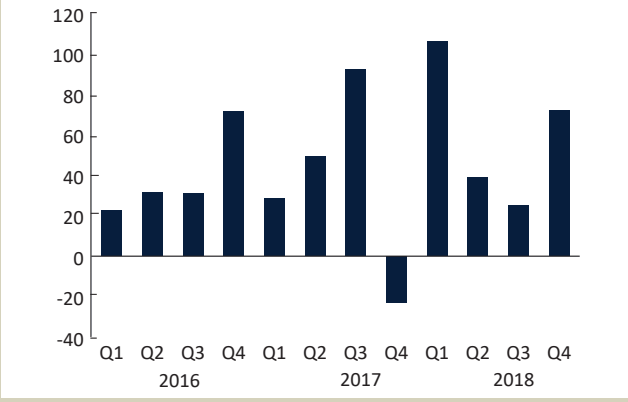
Investments in fixed assets

Gross investments in tangible and intangible fixed assets amounted to SEK 1.4 million (0.8) for Q4 2018 and SEK 3.6 million (1.6) for the full year.

EBITDA, SEK MILLION

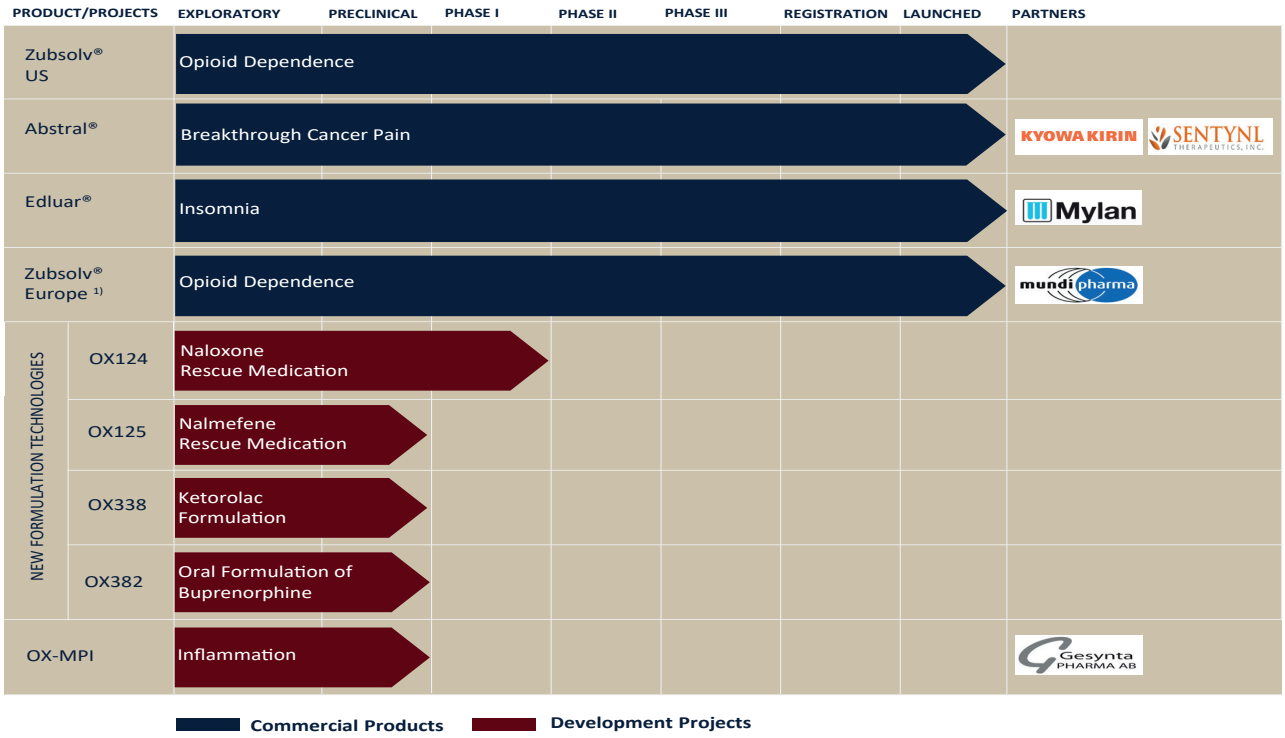


CASH FLOW FROM OPERATING ACTIVITIES, SEK MILLION



Operations

PIPELINE OF COMMERCIAL PRODUCTS AND DEVELOPMENT PROJECTS



Commercial products

Zubsolv® US – opioid dependence

The fourth quarter of 2018 demonstrated an expanding buprenorphine/naloxone market, with 4.2 percent growth in volume compared to Q3 2018, and a strong 14.1 percent growth over Q4 2017. The market forecast is for continued growth, as the epidemic continues to escalate and as more providers begin to treat opioid addiction and also take on an increasing patient load. Dr Reddy Laboratories´generic version of the film formulation which was approved by FDA and temporary launched at risk, has not yet been reintroduced to the market due to ongoing litigations.

Currently, greater than 4,400 waivered physicians are certified to increase their patient load up to 275. Over 2,300 physicians became newly waivered to accept their first opioid dependence patients this quarter which is the highest number ever recorded. Nurse practitioners and physicians assistants now total over 9,600 waivered to treat opioid dependency, compared to just 5,200 this quarter last year.

While the number of prescribers is growing the market remains highly concentrated with 6,000 prescribers accounting for 80 percent of all prescriptions written.

A federal bill has been approved in Q4 2018 to expand the waiver eligibility to additional types of midlevel practitioners, and the application process is now in development.

Over 2,300 physicians became newly waivered to accept their first opioid dependence patients this quarter which is the highest number ever recorded

[1] Following a portfolio organization at Mundipharma Orexo will regain the ex-US rights as of April 13, 2019

In Q4, 2018, Zubsolv® significantly outpaced the prior year's Q4 volume with 22 percent growth. Compared to Q3 2018, Zubsolv Q4 volume grew by 1.5 percent. Q4 2018 is Zubsolv's largest ever volume quarter, and volume is continuing to grow, hitting all-time highs in the latest non-holiday week of 12/21/2018 on both a single week (407k tablets) and rolling 4 week span basis (1.6 million tablets).

In 2018, Zubsolv had the best commercial access of any buprenorphine/naloxone products in the commercial segment. Starting in 2019 Zubsolv has secured coverage with Blue Cross North Carolina, expanding its best-in-class coverage and reaching a record high 97 percent commercial coverage access. Within Caremark Commercial, a competitive formulary where Zubsolv competes with generic tablets and other buprenorphine/naloxone brands, Zubsolv has captured 7 percent growth over Q3 and gained share. Humana Commercial, where Zubsolv became the exclusive product at the start of year continues to grow in volume, achieving 5 percent volume growth in Q4 over Q3.

In the public segment, Zubsolv is the exclusive product on the Humana Medicare Part D plan and has grown 10 percent in tablet volume over Q3. In November, Zubsolv lost exclusive access to Wellcare Medicaid and versus Q3 2018 has lost 18 percent of tablet volume in the payer. However, we maintain reimbursement in WellCare, but at a less preferred position after generics. The loss of Wellcare, will result in minimal impact to Zubsolv profitability since it was an exclusive agreement in the highly rebated Managed Medicaid segment. Despite the loss of Wellcare exclusive in November, Zubsolv grew tablet volume by 3 percent in the public segment. 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.

2019 starts with new competitive access for Zubsolv in Medicaid within a multitude of states, when totaled, are worth an estimated USD 140 million in total market volume, resulting in the overall access increase from 32 to 38 percent in the Public segment. These include the largest total market volume Medicaid state, Ohio, as well as Alabama which are effective January 1, Texas effective January 21 and shortly, Florida, and Washington DC access follows.

Paragraph IV litigations against Actavis regarding Zubsolv in the US
This patent litigation case was fully judged in Orexo´s favour and was closed after the period, as the US District Court of Delaware in January 10 issued as expected the final, non-appealable judgement that Actavis's generic Zubsolv products infringe Orexo's US patent No. 8,940,330. For detailed information, 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

Orexo´s partner Mundipharma, who owns the commercial rights to Zubsolv outside the US, has for strategic reasons determined to exit the partnership during the quarter, enabling Orexo to regain the ex-US rights on April 13, 2019.

This offers Orexo the opportunity to choose the best route to maximize the potential of Zubsolv ex US, and to ensure that more patients have access to the treatment. Orexo is in active discussions with several companies who are interested in becoming Orexo's partner for all or selected markets outside the US.

Both Mundipharma and Orexo are committed to cooperate closely to ensure a smooth transition.

Zubsolv was approved in Europe in 2017 and launched by Mundipharma in Germany and Sweden in Q2, 2018. Pricing and reimbursement processes are ongoing in all other major European markets. Furthermore, Zubsolv has been submitted for approval in Australia.

Orexo has now the opportunity to choose the best route to maximize the potential of Zubsolv ex-US, and to ensure that more patients have access to the treatment

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 2018.

Sales of Abstral in the EU amounted to EUR 23.7 million in Q3 2018, which is 1 percent lower compared with the same period in 2017. This is mainly explained by lower sales in the CEE region while Benelux, Spain and Italy continued to grow. 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 62 percent lower in Q3 2018 compared with the same period in 2017.

Sales of Abstral in the region RoW (markets excluding the EU, the US and Japan) were 2 percent lower compared with the same period in 2017. Total sales for the RoW reached USD 3.2 million in Q3 2018.

Sales of Abstral in Japan decreased 36 percent during the third local commercial quarter, June 2018 to August 2018, compared to the same period in 2017.

In September 2019, the patents for Abstral in the EU will expire. As the EU contract with Kyowa Kirin runs until December 31, 2019, Orexo expects that royalty for the EU will decrease slightly during the year compared to 2018, but will cease for 2020. EU´s share of Abstral's total royalty amounts to approximately 80 percent.

Edluar - insomnia

Global sales of Edluar were 22 percent lower in Q3 2018 compared to Q3 2017 explained by a temporary loss of business in US market due to supply issues which have now been resolved. Total sales for Q3 2018 amounted to EUR 2.4 million (3.1).

Development projects

OX124 - naloxone rescue medication
OX124 is based on a novel and unique technology developed to provide a rapidly acting naloxone rescue medication with the aim to provide differentiated profile compared to currently marketed products and other products under development.

Naloxone is a full opioid receptor antagonist which reverses the effects of opioid agonists, including the life threatening respiratory depressant effects occurring in an opioid overdose.

Changes during the quarter:
A human pharmacokinetic (PK) study, OX124-001, was initiated in 20 healthy volunteers, assessing Orexo's novel naloxone nasal spray formulations intended for opioid overdose reversal.

The study was a cross-over, comparative, bioavailability study comparing four development formulations of OX124 to Narcan® Nasal Spray 4mg, the current market-leading naloxone rescue medication in the US.

Positive results were delivered in beginning of 2019 and showed that all formulations of OX124 were well tolerated and displayed substantially higher plasma concentrations of naloxone, sustained duration of elevated plasma concentrations, and equivalent or superior onset time when compared to Narcan®.

The next step for the project is to continue to further optimize the formulation and prepare for a pivotal pharmacokinetic bridging study in 2020 in consultation with FDA.

OX125 - nalmefene rescue medication
OX125 is based on a novel and unique technology developed to provide a rapidly acting nalmefene rescue medication with the aim to provide differentiated profile compared to currently marketed products and other products under development. Nalmefene is a full opioid receptor antagonist which reverses the effects of opioid agonists, including the life threatening respiratory depressant effects occurring in an opioid overdose.

Changes during the quarter:
Following the very positive results for the OX124 human PK-study a decisions was made to accelerate the development of the project.

OX338 - ketorolac formulation
OX338 is based on a new sublingual tablet formulation of Ketorolac for acute treatment of moderate to severe pain. Ketorolac is a potent NSAID with analgesic effect comparable to many opioids used for short term pain management and can thus replace opioids for many procedures and indications reducing overall opioid consumption.

Changes during the quarter:
The formulation development continued and an in-vivo animal PK study was initiated. After the period, postive study results were recieved from the in-vivo study supporting advancement into PK studies, expected to be initiated during 2019.

OX382 – oral formulation of buprenorphine
OX382 is being developed as an oral, swallowable formulation containing buprenorphine and naloxone for the treatment of opioid dependence. Buprenorphine is a partial opioid receptor agonist used in medically assisted treatment of opioid dependence to alleviate symptoms of withdrawal and naloxone, an opioid receptor antagonist, is part of the formulation as an abuse deterrent. A swallowable formulations offer several advantages over currently available administrations routes for certain patient groups and treatment settings.

Changes during the quarter:
The formulation development continued based on the insights gained from the result in the first clinical study performed in the beginning of 2018. Proof-of-Concept in-vivo animal study will be initiated in the beginning of 2019 and the study results are expected in H1 2019.

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 own the rights to the project.

Changes during the quarter:
Progressing according to plan.

Parent Company

Net revenues for Q4 2018 amounted to SEK 128.6 million (127.0). Earnings before tax were SEK 25.4 million (16.2). Investments amounted to SEK 1.4 million (0.8). As of December 31, 2018, cash and cash equivalents in the Parent Company amounted to SEK 303.2 million (215.1).

The deferred tax asset was increased by SEK 18.2 million reflecting an updated assessment and an increased profitability in addition recent announced changes in the Swedish corporate tax rate, had an impact on the full year.

Important events after the period

Positive results from human PK study assessing Orexo's new intranasal naloxone formulations for opioid overdose reversal.

The US District Court of Delaware issued a final, non-appealable judgement that Actavis's generic Zubsolv® products infringe the US patent ´330, preventing Actavis from launching their infringing generics in the US until 2032.

Outlook 2019

• For 2019 Orexo expects to improve the positive EBITDA on a full year basis and on a quarterly basis the development will follow the same pattern as previous year
• Orexo believes that the overall volume of Zubsolv sales in the US in 2019 will increase, despite increased competition from a potential launch of Suboxone® Film generics. However we do expect that a launch of corresponding generics will increase market risk and uncertainity but will also offer opportunities.
• The manufacturing efficiency program aimed to reduce the average Cost of Goods Sold (COGS) per tablet by 35 percent in H2, 2019 compared to 2017
• Full year OPEX is expected to stay at the same level as 2018 with approximately SEK 500 million. The final outcome is dependent on the cost of the IP litigation against Actavis for their generic versions of Suboxone and Subutex® and possible appeals after the court hearing in the District Court in March.
• Additional investments may be needed if development programs reach clinical stage faster than anticipated. Orexo expects to advance at least one additional development program to phase I trial during 2019.
• The first new partnerships for Zubsolv outside the US is expected to be initated in 2019
• The outlook is based on current exchange rates (January 2019)

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, January 30, 2019
Orexo AB (publ.)

Nikolaj Sørensen
President and CEO

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

Financial Reports and Notes

CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS

SEK million	Notes	2018 Oct-Dec	2017 Oct-Dec	2018 Jan-Dec	2017 Jan-Dec
Net revenues	6	227.1	191.0	783.1	643.7
Cost of goods sold		-43.4	-50.3	-171.8	-164.4
Gross profit		**183.7**	**140.7**	**611.4**	**479.3**
Selling expenses		-48.0	-49.2	-191.4	-190.5
Administrative expenses		-54.7	-26.3	-166.7	-96.1
Research and development expenses		-47.0	-35.8	-166.8	-134.2
Other operating income and expenses		3.6	0.7	9.3	-1.1
Operating earnings		**37.6**	**30.1**	**95.8**	**57.4**
Net financial items		-0.3	-4.7	-3.6	-27.7
Earnings before tax		**37.3**	**25.4**	**92.2**	**29.7**
Tax	4	14.3	1.3	45.7	-6.5
Net earnings for the period[1]		**51.6**	**26.7**	**137.9**	**23.2**

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

SEK million	2018 Oct-Dec	2017 Oct-Dec	2018 Jan-Dec	2017 Jan-Dec
Earnings for the period	**51.6**	**26.7**	**137.9**	**23.2**
Other comprehensive income				
Items that may subsequently be reversed to the statement of operations:				
Exchange-rate differences	1.1	1.0	7.0	-7.5
Other comprehensive earnings for the period, net after tax	**1.1**	**1.0**	**7.0**	**-7.5**
Total comprehensive earnings for the period[1]	**52.7**	**27.7**	**144.9**	**15.7**
Earnings per share, before dilution, SEK	1.49	0.77	3.99	0.67
Earnings per share, after dilution, SEK	1.47	0.77	3.93	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 Dec 31	2017 Dec 31
ASSETS		
Fixed assets		
Tangible fixed assets	20.0	20.1
Intangible fixed assets	103.9	121.0
Deferred tax assets	92.8	28.3
Other financial assets	10.4	7.1
Total fixed assets	**227.2**	**176.5**
Current assets		
Inventories	173.6	250.2
Accounts receivable and other receivables	296.1	249.3
Cash and cash equivalents	589.8	327.9
Total current assets	**1,059.5**	**827.4**
Total assets	**1,286.7**	**1,003.9**
SHAREHOLDERS' EQUITY AND LIABILITIES		
Total shareholders' equity	**476.1**	**329.1**
Long-term liabilities		
Provisions	6.5	5.8
Long-term liabilities, interest bearing	320.6	319.1
Total long-term liabilities	**327.1**	**324.9**
Current liabilities and provisions		
Provisions	265.8	200.9
Current liabilities, non-interest bearing	217.6	149.0
Total current liabilities and provisions	**483.4**	**349.9**
Total liabilities	**810.5**	**674.8**
Total shareholders' equity and liabilities	**1,286.7**	**1,003.9**

CONSOLIDATED CHANGES IN SHAREHOLDERS' EQUITY

SEK million	2018 Dec 31	2017 Dec 31
Opening balance, shareholders' equity	**329.1**	**310.3**
Total comprehensive earnings for the period	144.9	15.7
Share-based payments	2.1	3.0
Buy back of shares	—	—
New share issue	0.1	0.1
Closing balance, shareholders' equity	**476.1**	**329.1**

CONDENSED CONSOLIDATED CASH FLOW STATEMENTS

SEK million	Notes	2018 Oct-Dec	2017 Oct-Dec	2018 Jan-Dec	2017 Jan-Dec
Operating earnings		37.6	30.1	95.8	57.4
Interest received		0.5	0.1	0.5	0.2
Interest paid		-4,9	-3.7	-14.8	-15.6
Income taxes paid		-2.2	-0.7	-18.1	-19.6
Adjustment for non-cash items	2	0.8	-1.0	61.9	87.9
Cash flow from operating activities before changes in working capital		**31.8**	**24.8**	**125.3**	**110.3**
Changes in working capital		**39.9**	**-47.8**	**116.7**	**36.3**
Cash flow from operating activities		**71.7**	**-23.0**	**242.0**	**146.6**
Acquisition of tangible and intangible fixed assets		-1.4	-0.8	-3.6	-1.6
Acquisition of financial assets		-2.5	—	-2.5	—
Cash flow from investing activities		**-3.9**	**-0.8**	**-6.2**	**-1.6**
New share issue		—	0.1	0.1	0.1
Buy back shares		—	—	-0.1	—
Change in loans		—	-26.5	—	-85.5
Cash from financing activities		**0,0**	**-26.4**	**0.0**	**-85.4**
Cash flow for the period		**67.8**	**-50.2**	**235.8**	**59.6**
Cash and cash equivalents at the beginning of the period		**516.6**	**370.7**	**327.9**	**282.4**
Exchange-rate differences in cash and cash equivalents		5.4	7.4	26.1	-14.1
Changes in cash and cash equivalents		73.2	-42.8	261.9	45.5
Cash and cash equivalents at the end of the period		**589.8**	**327.9**	**589.8**	**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 Oct-Dec	2017 Oct-Dec	2018 Jan-Dec	2017 Jan-Dec
EBIT margin, %	16.6	15.8	12.2	8.9
Return on shareholder equity, %	11.5	8.5	34.3	7.3
Net debt, SEK million	-269.2	-8.8	-269.2	-8.8
Debt/equity ratio, %	67.3	97.0	67.3	97.0
Equity/assets ratio, %	37.0	32.8	37.0	32.8
Number of shares, before dilution	34,560,456	34,542,368	34,560,456	34,540,271
Number of shares, after dilution	35,095,980	34,652,931	35,095,980	34,650,835
Earnings per share, before dilution, SEK	1.49	0.77	3.99	0.67
Earnings per share, after dilution, SEK	1.47	0.77	3.93	0.67
Number of employees at the end of the period	129	90	129	90
Shareholders' equity, SEK million	476.1	329.1	476.1	329.1
Capital employed, SEK million	796.7	648.2	796.7	648.2
Working capital, SEK million	-13.8	149.6	-13.8	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 Oct-Dec	2017 Oct-Dec	2018 Jan-Dec	2017 Jan-Dec
Net revenues		128.6	127.0	407.6	477.8
Cost of goods sold		-29.7	-33.2	-116.2	-167.4
Gross profit		**98.9**	**93.8**	**291.4**	**310.4**
Selling expenses		—	-26.7	-10.3	-73.3
Administrative expenses		-45.8	-18.4	-135.2	-67.3
Research and development costs		-39.7	-28.4	-138.3	-105.3
Other operating income and expenses		13.7	0.6	50.6	-1.2
Operating earnings		**27.1**	**20.9**	**58.1**	**63.3**
Interest income and expenses		-3.3	-3.6	-14.4	-14.6
Exchange rate adjustment		—	—	—	-1.3
Other financial income and expenses		1.6	-1.1	8.2	-12.3
Net financial items		**-1.7**	**-4.7**	**-6.1**	**-28.2**
Earnings before tax		**25.4**	**16.2**	**52.0**	**35.1**
Tax	4	18.2	7.6	53.3	7.6
Earnings for the period		**43.7**	**23.8**	**105.3**	**42.7**

PARENT COMPANY STATEMENT OF COMPREHENSIVE INCOME

SEK million	2018 Oct-Dec	2017 Oct-Dec	2018 Jan-Dec	2017 Jan-Dec
Earnings for the period	**43.7**	**23.8**	**105.3**	**42.7**
Other comprehensive income	—	—	—	—
Total comprehensive earnings for the period	**43.7**	**23.8**	**105.3**	**42.7**

CONDENSED PARENT COMPANY BALANCE SHEET

SEK million	2018 Dec 31	2017 Dec 31
ASSETS		
Fixed assets		
Intangible fixed assets	103.9	121.0
Tangible fixed assets	20.0	19.9
Deferred tax asset	60.9	7.5
Shares in subsidiaries	152.3	150.6
Total fixed assets	**337.1**	**299.0**
Current assets		
Inventories	155.3	186.3
Accounts receivable and other receivables	166.8	158.4
Cash and bank balances	303.2	215.1
Total current assets	**625.3**	**559.8**
Total assets	**962.4**	**858.8**
SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES		
Shareholders' equity	**416.9**	**309.4**
Long-term liabilities		
Other provisions	4.9	4.9
Bond loan	320.6	319.1
Total long-term liabilities	**325.5**	**324.0**
Current liabilities		
Accounts payable	19.6	28.9
Other liabilities	25.3	6.6
Liabilities to Group companies	143.2	169.1
Accrued expenses and deferred income	32.0	20.8
Total current liabilities	**220.1**	**225.4**
Total liabilities	**545.6**	**549.4**
Total shareholders' equity and liabilities	**962.4**	**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 applies the simplified transition method and the main impact on Orexo's accounts arise from the reporting of lease contract for premises. The opening effect on the consolidated balance sheet as of January 1, 2019 is that a lease asset (right-of-use asset) and a lease liability are added, each at SEK 61.9 million.

2. Cash flow

ADJUSTMENT FOR NON-CASH ITEMS

SEK million	2018 Oct-Dec	2017 Oct-Dec	2018 Jan-Dec	2017 Jan-Dec
Depreciation/amortization and impairment	5.2	5.2	20.8	20.8
Change in provisions	-3.3	-7.1	45.6	59.9
Share based payments	-0.3	1.6	2.1	3.0
Exchange rate income and expenses	-0.8	-0.7	-6.5	4.2
Total	**0.8**	**-1.0**	**61.9**	**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 same Court also denied Actavis's petition for rehearing regarding validity of the Zubsolv® patent .

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 then requested the US District Court of Delaware to issue a judgment that Actavis's generic Zubsolv products infringe the '330 patent, and will not be approved by FDA until September 2032. Such a judgement was issued by the Court after the period, on January 10, 2019.

The infringement judgement implicates that Orexo has fully won this patent litigation case which is now declared closed.

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 the year of approval of these two products. The trial is scheduled for March 25-29, 2019.

A court decision will follow closely after, with the possibility to appeal from both sides.

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 1,414 million as of December 31 2018 and refers to the Swedish companies. Deferred tax assets of SEK 60.9 million for tax-loss carry-forwards have been capitalized as per December 31, 2018, for the part of these tax-loss carry-forwards which the company has assessed as fulfilling the recognition requirements of IAS 12. 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

Positive results from human PK study assessing Orexo's new intranasal naloxone formulations (OX124) for opioid overdose reversal.

The US District Court of Delaware issued a final, non-appealable judgement that Actavis's generic Zubsolv products infringe the US patent ´330, preventing Actavis from launching their infringing generics in the US until 2032.

8. Revenue from contracts with customers

SEK million	2018 Oct-Dec				
Type of revenue	**Zubsolv®**	**Abstral®**	**Edluar®**	**OX-CLI**	**Total**
Sales, products	172.0	—	—	—	**172.0**
Royalties	-0.1	52.4	2.9	—	**55.1**
Milestones	—	—	—	—	**0.0**
Total revenue from contracts with customers	**171.9**	**52.4**	**2.9**	**0.0**	**227.1**
Geographical markets	**Zubsolv**	**Abstral**	**Edluar**	**OX-CLI**	**Total**
US	166.7	0.6	1.2	—	**168.4**
EU	5.2	46.2	0.2	—	**51.6**
Rest of the world	—	5.6	1.5	—	**7.1**
Total revenue from contracts with customers	**171.9**	**52.4**	**2.9**	**0.0**	**227.1**

SEK million	2017 Oct-Dec				
Type of revenue	**Zubsolv**	**Abstral**	**Edluar**	**OX-CLI**	**Total**
Sales, products	132.1	—	—	—	**132.1**
Royalties	—	55.4	3.6	—	**59.0**
Milestones	—	—	—	—	**0.0**
Total revenue from contracts with customers	**132.1**	**55.4**	**3.6**	**0.0**	**191.0**
Geographical markets	**Zubsolv**	**Abstral**	**Edluar**	**OX-CLI**	**Total**
US	126.5	1.3	1.7	—	**129.4**
EU	5.6	48.4	0.3	—	**54.3**
Rest of the world	—	5.7	1.6	—	**7.3**
Total revenue from contracts with customers	**132.1**	**55.4**	**3.6**	**0.0**	**191.0**

SEK million	2018 Jan-Dec				
Type of revenue	**Zubsolv**	**Abstral**	**Edluar**	**OX-CLI**	**Total**
Sales, products	626.9	—	—	—	**626.9**
Royalties	0.1	118.8	6.6	—	**125.4**
Milestones	30.8	—	—	—	**30.8**
Total revenue from contracts with customers	**657.8**	**118.8**	**6.6**	0.0	**783.1**
Geographical markets	**Zubsolv**	**Abstral**	**Edluar**	**OX-CLI**	**Total**
US	621.5	4.8	0.7	—	**627.0**
EU	36.2	90.1	1.2	—	**127.5**
Rest of the world	—	24.0	4.7	—	**28.6**
Total revenue from contracts with customers	**657.8**	**118.8**	**6.6**	**0.0**	**783.1**

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 Oct-Dec	2017 Oct-Dec	2018 Jan-Dec	2017 Jan-Dec
EBIT	37.6	30.1	95.8	57.4
Depreciation and amortization	5.2	5.2	20.8	20.8
EBITDA	**42.8**	**35.3**	**116.6**	**78.2**

RETURN ON SHAREHOLDERS' EQUITY	2018 Oct-Dec	2017 Oct-Dec	2018 Jan-Dec	2017 Jan-Dec
Shareholders' equity beginning balance	424.4	300.0	329.1	310.3
Shareholders' equity ending balance	476.1	329.1	476.1	329.1
Average shareholders' equity	450.3	314.6	402.6	319.7
Net earnings	51.6	26.7	137.9	23.2
Return on shareholders' equity %	**11.5**	**8.5**	**34.3**	**7.3**

OPERATING EXPENSES SEK million	2018 Oct-Dec	2017 Oct-Dec	2018 Jan-Dec	2017 Jan-Dec
Selling expenses	-48.0	-49.2	-191.4	-190.5
Administrative expenses	-54.7	-26.3	-166.7	-96.1
Research and development costs	-47.0	-35.8	-166.8	-134.2
Other operating income and expenses	3.6	0.7	9.3	-1.1
Operating expenses	**-146.1**	**-110.6**	**-515.6**	**-421.9**

GROSS INVESTMENTS SEK million	2018 Oct-Dec	2017 Oct-Dec	2018 Jan-Dec	2017 Jan-Dec
Investments in tangible fixed assets	1.3	0.8	2.9	1.1
Investments in intangible fixed assets	0.1	0.0	0.7	0.5
Gross investments	**1.4**	**0.8**	**3.6**	**1.6**

US EBIT SEK million and EBIT margin %	2018 Oct-Dec	2017 Oct-Dec	2018 Jan-Dec	2017 Jan-Dec
Consolidated operating earnings	37.6	30.1	95.8	57.4
Non US related items impacting operating earnings	-24.4	10.3	-102.5	-16.3
US EBIT	**62.0**	**19.8**	**198.3**	**73.7**
US EBIT margin %	**37.2**	**15.7**	**31.9**	**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