Q4 incl. Full Year Report 2019

Strong fundamentals in place to fuel strategy for future growth

Q4 2019 highlights

- Total net revenues of SEK 238.1 million (227.1), up 4.8 percent
- Zubsolv® US net revenues of SEK 190.5 million (166.7), up 14.3 percent in SEK and 7.5 percent in local currency
- Net earnings of SEK 38.9 million (51.6), down 24.6 percent
- EBITDA of SEK 85.8 million (42.8), up 100.5 percent. EBITDA ex Abstral® of SEK 39.6 million (-9.6).
- US EBIT of SEK 98.2 million (62.0), up 58,4 percent
- Cash flow from operating activities of SEK 60.2 million (71.7), building a cash balance of SEK 816.8 million (589.8)
- Acquired the exclusive US rights to commercialize vorvida®, a digital therapy for alcohol use disorder with scientifically proven efficacy
- Dennis Urbaniak was appointed as Executive Vice President Digital Therapeutics
- Announced a Capital Markets Day to be held in Stockholm, Sweden, on March 17, 2020
- Financial outlook provided for 2020, see page 11

Important events after the end of the period

- OX338 showed promising results from the human PK study, assessing novel ketorolac formulations for treatment of pain

14.3%
Zubsolv® US net revenue growth in Q4 (7.5% in USD)

100.5%
EBITDA growth in Q4

SEK 816.8 m
Cash and cash equivalents (SEK 60.2 m from operating activities in Q4)

SEK m, unless otherwise stated	2019 Oct-Dec	2018 Oct-Dec	2019 Jan-Dec	2018 Jan-Dec	Δ 2018-2019
Net revenues	238.1	227.1	844.8	783.1	8%
whereof Zubsolv® US net revenues	190.5	166.7	719.2	621.5	16%
Cost of goods sold	-23.0	-43.4	-105.6	-171.8	-39%
Operating expenses	-143.5	-146.1	-508.0	-515.6	-1%
EBIT	71.5	37.6	231.2	95.8	141%
EBIT margin, %	30.0	16.6	27.4	12.2	15.2 ppt
US EBIT	98.2	62.0	350.9	198.3	77%
US EBIT margin, %	51.6	37.2	48.8	31.9	16.9 ppt
EBITDA	85.8	42.8	272.1	116.6	133%
Earnings per share, before dilution, SEK	1.12	1.49	6.33	3.99	59%
Earnings per share, after dilution, SEK	1.10	1.47	6.20	3.93	58%
Cash flow from operating activities	60.2	71.7	290.9	242.0	20%
Cash and cash equivalents	816.8	589.8	816.8	589.8	38%

Unless otherwise stated in this report, all data refers to the Group, and numbers relate to the current quarter while numbers in parentheses relate to the corresponding period in 2018.

Content

About Orexo
Develops improved pharmaceuticals and digital therapeutics addressing unmet needs within the growing space of addiction. The products are commercialized by Orexo in the US or via partners worldwide. The main market today is the American market for buprenorphine/naloxone products, where Orexo commercialize its lead product Zubsolv® for treatment of opioid use disorder. Total net sales for 2019 amounted to SEK 844,8 million and the number of employees was 128. 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, Joseph DeFeo, EVP and CFO or Lena Wange, IR & Communications Manager
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 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-q4-2019
Telephone: SE +46 8 505 583 55 UK +44 3 333 009 031 US +1 6 467 224 957
The presentation material will be available on Orexo´s website prior to the audiocast.

Financial calendar
Annual General Meeting 2020 - April 16, 2020 at 4 pm CET
Annual Report 2019 - Week 13, 2020
Interim Report Q1 2020 - April 28, 2020 at 8.00 am CET
Interim Report Q2 2020 - July 16, 2020 at 8.00 am CET
Interim Report Q3 2020 - November 4, 2020 at 8.00 am CET
Q4 incl. Full Year Report 2020 - January 28, 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.

2019 – a record year further establishing a strong foundation for future growth

2019 delivered the strongest financial results for Orexo, with the fourth quarter being no exception. This was driven by a stellar performance from our teams in Sweden and the US, who oversaw additional strategic objectives for the year with the advancement of our pipeline and two partnership agreements for digital therapeutics; promising growth drivers for Orexo's future.

A strong year financially and operationally – SEK 272 m in EBITDA and SEK 817 m in cash

I am pleased to report a very strong financial performance both in the fourth quarter and for the full year. Despite increased competition from generics in the first half of 2019, we have managed to grow Zubsolv® sales on a full year basis, control our costs and we are proud to present an all-time-high financial result. The fourth quarter saw continued sales growth, above market average, of Zubsolv in the reimbursed open formulary businesses of the market fully compensating for the decline in the previously exclusive reimbursement contracts and cash segment. In the fourth quarter this decline has levelled off, and we are now entering a period where Zubsolv will be less dependent on individual exclusive contracts with insurance companies.

During 2019 we have been very active in assessing business development, M&A opportunities and progressing the R&D pipeline. Our strong financial position enables us to continue to pursue opportunities to acquire complementary products and companies, and to invest in our R&D pipeline.

R&D - our strategic investments for growth

As a result of our pipeline progression during 2019, we are now in a strong position to invest properly in our wholly-owned assets over the course of 2020. We intend to complete the development program for OX124, a naloxone rescue medication for opioid overdose, during 2020, with the potential for FDA approval in 2021. The naloxone rescue market is currently valued at USD 300 million, with strong double-digit growth, and OX124 could be a more effective product on the market with a unique nasal delivery system. We are also planning the first clinical trial for OX125 in H1 2020, addressing the same market, but with nalmefene as the active ingredient. We also completed the first clinical trial for OX338, a non-opioid painkiller, at the end of 2019, with promising clinical results, but with a need to continue to optimize the formulation to ensure we can obtain a unique product profile and strong IP protection.

Digital Therapeutics – new frontiers in patient care

I remain confident that digital therapeutics will become an integral part of the healthcare landscape and that addiction is one of the main areas most in need of innovative ways to deliver treatment. During the quarter we took significant steps forward in executing our strategy, we signed a second agreement with GAIA AG in Q4 2019, licensing the rights to vorvida®, a digital therapy for alcohol use disorder. This complemented the earlier partnership agreement with GAIA (in August 2019) to develop and commercialize OXD01, a digital therapy for the treatment of Opioid Use Disorder. We intend to develop OXD01 for a potential launch in the US in 2021, subject to regulatory approval, and plan to prepare vorvida® for launch in the US market in H2 2020, pending feedback from the FDA. vorvida® has already been launched in Europe and has generated impressive clinical evidence on the effect on alcoholism – which continues to be an area of high unmet medical need.

We also appointed Dennis Urbaniak as Executive Vice President of Digital Therapeutics. Together with Dennis, we are finalizing our overarching digital business plan, and are excited to share more details at our upcoming Capital Markets Day in March 2020 in Stockholm, Sweden.

"Together with Dennis, we are finalizing our overarching digital business plan, and are excited to share more details at our upcoming Capital Markets Day in March 2020 in Stockholm, Sweden."

Summary and Outlook

With 2019 behind us, I want to express my appreciation to my entire team for their efforts in making 2019 a strong year, both financially and through pipeline progress. Our focus is now to leverage the results of 2019 to build an even more exciting future for Orexo. 2020 is set to be an important year of investment for the company, as we commit significant resources to the final development of OX124, and our two digital therapies, OXD01 and vorvida®. We are confident these investments can be financed by the profits generated by Zubsolv in the US and we are excited to develop these opportunities over the year, with the ultimate goal of strengthening Orexo's future position. My team and I are looking forward to a prosperous 2020 and thank all our investors and stakeholders for their confidence in Orexo.

Uppsala, Sweden, January 30, 2020

Nikolaj Sørensen
President and CEO

Financial information

Revenues

Total revenues amounted to SEK 238.1 million (227.1) for the quarter, corresponding to 4.8 percent increase. The increase was solely driven by the Zubsolv® US growth.

Total revenues amounted to SEK 844.8 million (783.1) for the full year, corresponding to 7.9 percent increase.

Zubsolv US revenues for the quarter amounted to SEK 190.5 million (166.7), corresponding to 14.3 percent growth in SEK. In local currency (USD) the equivalent growth rate was 7.5 percent, equal to sales of USD 19.8 million. Zubsolv US revenue for the full year amounted to SEK 719.2 million (621.5), an increase of 15.7 percent. In local currency (USD) the equivalent increase was 6.5 percent, equal to sales of USD 76.0 million.

Net revenues for the quarter were positively impacted by improved prices and by a one-time adjustment of SEK 10.6 million of rebates relating to prior periods. Wholesaler inventory levels were increased by SEK 13.2 million during the quarter.

Abstral® royalty amounted to SEK 46.2 million (52.4) for the quarter mainly explained by lower volumes in Europe and in the US. Abstral® royalty amounted to SEK 112.6 million (118.8) for the full year. Royalty for sales in Europe were received until December 31, 2019, when the European contract with Kyowa Kirin expired. During the period Orexo was informed by its partner in the US, Sentynl, that they will withdraw Abstral from sale and the last sale date was on October 31, 2019.

Royalty from Edluar® amounted to SEK 1.3 million (2.9) for the quarter and to SEK 11.6 million (6.6) for the full year.

Costs of goods sold

Cost of goods sold (COGS) amounted to SEK 23.0 million (43.4) for the quarter all related to Zubsolv US. For the full year COGS amounted to SEK 105.6 million (171.8) also related to Zubsolv US. This corresponds to an average COGS per tablet 40 percent lower than the average realized in 2017 and is above the full year target of 35 percent reduction in COGS.

Operating expenses

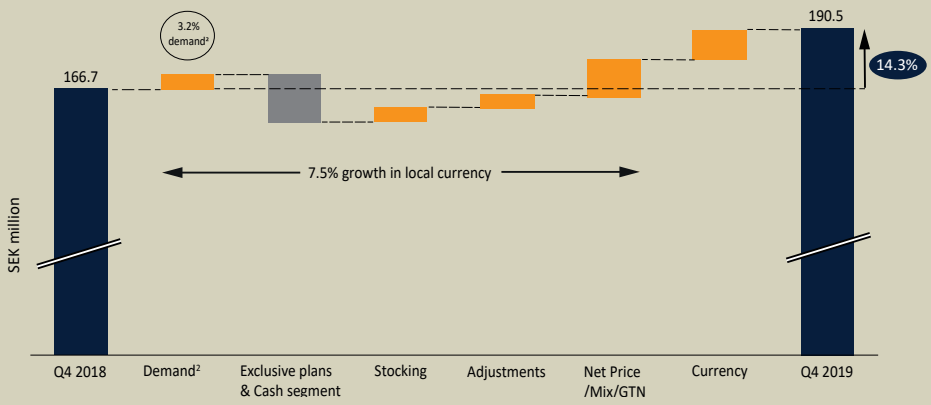
Selling expenses amounted to SEK 50.6 million (48.0) for the quarter. The increase over the same period last year is mainly explained by timing of activities. Selling expenses amounted to SEK 191.9 million (191.4) for the full year.

Administrative expenses amounted to SEK 26.9 million (54.7). The decrease versus prior year is explained by lower legal expenses. Legal expenses for IP litigations reached SEK 0.6 million (26.4) for the quarter. Administrative expenses amounted to SEK 139.6 million (166.7) for the full year. Orexo has together with its lawyers decided not to appeal the decision where the District Court in Delaware denied Orexo´s motion for a new trial. Actavis will not be able to claim Orexo for any compensation related to incurred legal costs.

Research and development costs amounted to SEK

COGS per tablet was 40 percent lower than the average realized in 2017

ZUBSOLV US NET REVENUES GROWTH BY KEY DRIVERS, Q4 2019 VERSUS Q4 2018[1]



[1] Orexo analysis using IMS demand data plus institutional sales
[2] Excluding exclusive plans (Wellcare, UHC and Human) and cash segment

58.6 million (47.0) for the quarter. The increase is mainly related to the development projects. Research and development costs amounted to SEK 181.3 million (166.8) for the full year.

Other operating income and expenses amounted to SEK -7.4 million (3.6) for the quarter mainly explained by exchange-rate losses derived from revaluations of parent company balance sheet items in foreign currency, predominantly cash in USD and to SEK 4.8 million (9.3) for the full year.

Operating profit

Orexo's profitability remained strong and EBITDA amounted to SEK 85.8 million (42.8) for the quarter due to growing contribution from the US commercial business supported by lower COGS and no spending on IP litigations. When excluding Abstral royalty, EBITDA amounted to SEK 39.6 million (-9.6) in Q4 2019.

EBITDA amounted to SEK 272.1 million (116.6) for the full year and when excluding Abstral royalty to SEK 159.5 million (-2.2).

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 with lower operational expenses. The US commercial business contributed with an EBIT improvement to SEK 98.2 million (62.0) for the quarter equal to an EBIT margin of 51.6 percent (37.2). In local currency EBIT amounted to USD 10.7 million (6.8) for Q4 2019.

The US commercial business contributed with an EBIT improvement of SEK 350.9 million (198.3) for the full year equal to an EBIT margin of 48.8 percent (31.9).

Net financial items and tax

Net financial items amounted to SEK -22.5 million (-0.3) for the quarter mainly explained by negative exchange rate impact on bank accounts in the US.

Net financial items amounted to SEK -3.3 million (-3.6) for the full year.

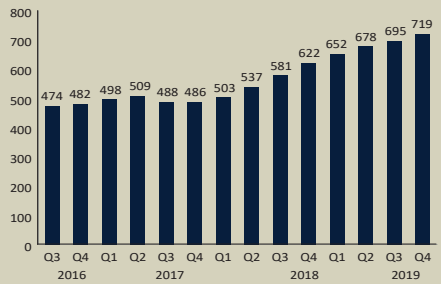
Total tax expenses amounted to SEK -10.1 million (14.3) for the quarter. Tax for the quarter was negatively impacted by decreased parent company tax asset of SEK -11.8 and positively impacted by a SEK 1.7 million

The US commercial business contributed with an EBIT improvement to SEK 98.2 million (62.0) for the quarter equal to an EBIT margin of 51.6 percent (37.2)

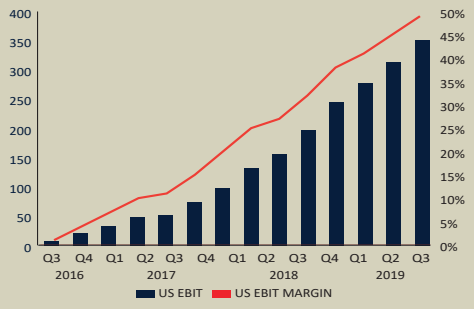
DISTRIBUTION OF TOTAL NET REVENUES

SEK m	2019 Oct-Dec	2018 Oct-Dec	2019 Jan-Dec	2018 Jan-Dec
Zubsolv® US	190.5	166.7	719.2	621.5
Zubsolv - ex US	0.0	5.2	0.1	36.2
Zubsolv – total	**190.5**	**171.9**	**719.3**	**657.8**
Abstral® royalties	46.2	52.4	112.6	118.8
Edluar® royalties	1.3	2.9	11.6	6.6
OX-MPI	0.0	-	1.4	-
Total	**238.1**	**227.1**	**844.8**	**783.1**

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



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



[1] LTM, Last Twelve Months

adjustment to deferred tax assets related to temporary differences while the parent company tax asset related to future deductibles for historical losses increased by SEK 18.2 million over the same period the previous year.

Total tax expenses amounted to SEK -8.8 million (45.7) for the full year and was negatively impacted by decreased parent company tax asset of SEK -11.8 while adjustment to deferred tax assets related to temporary differences had a positive impact of SEK 3.0. The parent company tax asset increased by SEK 53.3 million over the same period the previous year.

Orexo performs regular assessments of its deferred tax asset and makes adjustments according to the recognition requirements of IAS 12.

Net earnings

Net earnings for the quarter amounted to SEK 38.9 million (51.6) and for the full year to SEK 219.1 million (137.9).

IFRS 16 Leases had a negative impact on net earnings of SEK -0.3 million for the quarter and a negative impact of SEK -0.9 million for the full year.

Cash, cash flow and net cash/debt

As of December 31, 2019, cash and cash equivalents amounted to SEK 816.8 million (589.8) and interest bearing liabilities to SEK 289.6 million (320.6), i.e. a positive net cash position of SEK 527.2 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. Orexo will continue to keep the vast majority of the cash balance in USD as most business development opportunities are in the US.

Cash flow from operating activities for the quarter amounted to SEK 60.2 million (71.7) and for the full year to SEK 290.9 million (242.0).

Investments

Gross investments in tangible and intangible fixed assets amounted to SEK 21.4 million (1.4) for the quarter. Higher investment is mainly explained by payment of a non-refundable first milestone of SEK 15.8 million. Gross investments in tangible and intangible fixed assets amounted to SEK 35.9 million (3.6) for the full year.

Equity

Shareholders' equity at December 31, 2019, was SEK 706.4 million (476.1). The equity/asset ratio was 47.1 percent (37.0).

Parent company

Net revenues amounted to SEK 187.3 million (128.6) for the quarter of which SEK 139.8 million (68.2) was related to sales to Group companies. Net revenues amounted to SEK 534.0 million (407.6) for the full year of which SEK 408.5 million (246.0) was related to sales to Group companies.

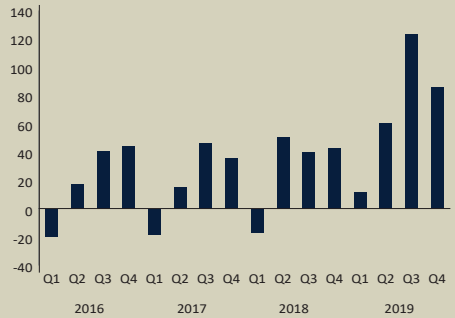
Earnings before tax were SEK 69.1 million (25.4) for the quarter and SEK 231.1 million (52.0) for the full year.

Investments for the quarter amounted to SEK 21.4 million (1.4) and for the full year to SEK 35.9 million (3.6).

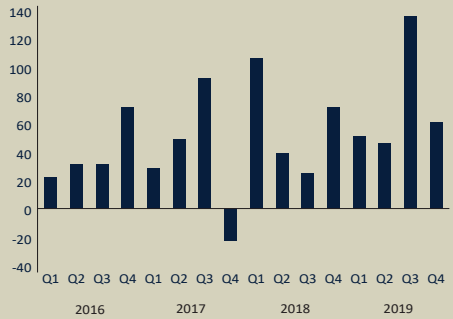
As of December 31, 2019, cash and cash equivalents in the parent company amounted to SEK 469.0 million (303.2).

Cash and cash equivalents amounted to SEK 816.8 million (589.8)

EBITDA, SEK m

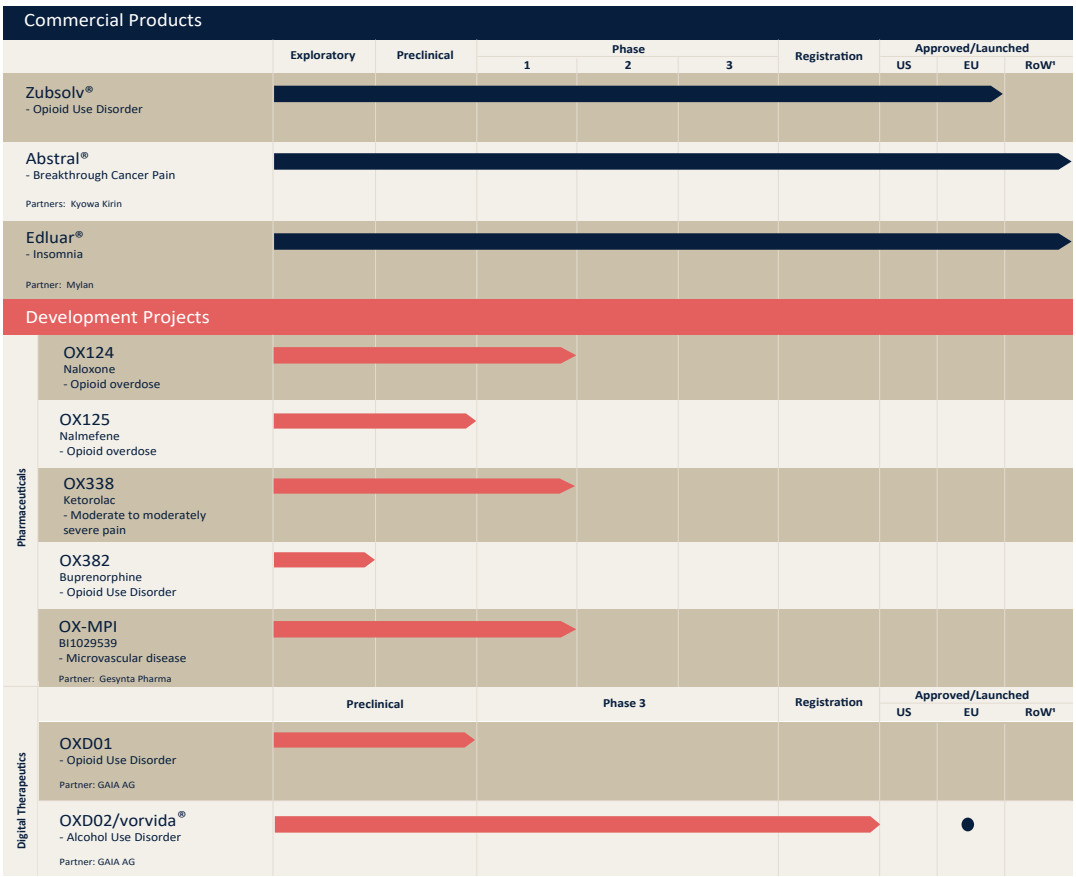


CASH FLOW FROM OPERATING ACTIVITIES, SEK m



Operations

PIPELINE OF COMMERCIAL PRODUCTS AND DEVELOPMENT PROJECTS



Commercial products

Zubsolv® US – treatment of Opioid Use Disorder

Quarter 4 2019's strong financial performance, despite a slight decline in Zubsolv volumes, demonstrates Orexo's multidisciplinary management of the US business focusing on collaboration across multiple fields, such as market access, trade distribution, supply, commercial operations and finance has enabled improved financial performance quarter over quarter.

In Q419, Zubsolv net revenues have grown 4 percent over Q319 and 8 percent over Q418 in USD, despite the decline in unit volume of 3 percent versus Q319 and 9 percent versus Q418.

Zubsolv's net revenues increase over Q418 is explained by an increased gross to net, improved prices, effective management of inventory to lower returns and some one-time rebate adjustments. Zubsolv's net revenues increase over Q319 is driven by Zubsolv's 4 percent unit growth in the open market (see below) and some inventory build, with offset from losses in formerly exclusive high rebate plans. Zubsolv open formulary business sales have grown 17 percent over Q418 and continue on their growth trajectory, driven by gains in Caremark Commercial. The decline in volume is primarily due to a formulary change in three specific payers (Humana, United Healthcare Group, and WellCare) coupled with continued decline in Zubsolv cash volume. The impact of the formulary changes had decreased

Zubsolv open formulary business sales have grown 17 percent over Q418 and continue on their growth trajectory

[1] Rest of the World, excluding US and Europe

● vorvida® has been launched in Germany and Switzerland by GAIA

during Q4 as Humana reversed its decline trend and grew in December, while United Health Group had stabilized for a number of weeks in December.

The market demonstrated strong growth of 15 percent in unit volume compared to Q418, and 4 percent growth over Q319. The market forecast is continued volume growth, as the opioid epidemic continues to escalate and as more providers begin to treat opioid addiction and take on an increasing patient load.

Relative to market unit volume growth, market prescription volume (total prescriptions) has grown less equating to only 9 percent compared to Q418. The reason for this change is solely within the cash segment of the market as prescription volume has not kept pace with unit volume growth. Cash paying patients historically took home half the quantity of buprenorphine/naloxone units per prescription, as compared to insured patients. The decreasing costs of generics have resulted in an increase in the cash segment's units per prescription and thereby reducing the need for multiple prescriptions. The impact being cash units increasing and cash prescriptions actually decreasing compared to Q418. Analyzing market dynamics excluding the cash segment demonstrates retail market prescription growth and unit growth are within 1 percent of each other, at 14 and 15 percent, respectively.

Over 2,900 physicians became newly waivered to accept their first opioid dependence patients this quarter. Nurse practitioners and physicians assistants now total 17,000 waivered to treat opioid dependency, compared to just 9,600 this quarter last year. For the first time, nurse practitioners and physicians assistants are now eligible to increase their limit to 275 patients, and 430 have done so this quarter. Federal legislation along with increasing pressure on healthcare providers to become medication assisted treatment waivered is expected to continue to grow the provider base with the expectation of improved patient access to treatment and expanding the market for Zubsolv®.

In Q419, Zubsolv's open formulary business grew by 4 percent over Q319 and 17 percent over Q418. The growth over Q418 is being driven by strong growth in every insured market segment; open Commercial grew 14 percent, open Medicaid grew 21 percent, and open Medicare D grew 13 percent. Zubsolv grew over Q319 in every segment as well. Zubsolv's open formulary business is total business where Zubsolv is reimbursed and competes with other products in the market both brand and/or generics. Open formulary business excludes recent formulary changes, the cash segment, and Zubsolv's few remaining exclusive access payers.

Zubsolv maintained its best-in-class coverage in the commercial segment at 97 percent, and has begun 2020 at 98 percent coverage with the addition of Florida Blue Cross Blue Shield. The strength of commercial access had also improved in Q419 as Zubsolv became the only branded product on Caremark and Aetna's Commercial formularies. On Caremark's national formulary, which makes up the majority of Caremark's market volume, Zubsolv grew by 34 percent over Q319 and 53 percent over Q418.

Within Medicaid, Zubsolv continues to grow in the states it gained access to in 2019; Ohio, Texas, Florida and Alabama. Within those states, Zubsolv has grown Medicaid volume 12 percent in Q419 over Q319, and 4x the volume in Q418. Zubsolv coverage in the public segment had decreased slightly in Q419 due to Pennsylvania Medicaid payers starting to follow the generic tablet only fee for service formulary.

Zubsolv business in the three specific formulary change payers (Humana, United Healthcare Group, and WellCare), the cash segment, and the few remaining exclusive plans, as a group declined 10 percent versus Q319 and 26 percent versus Q418. Zubsolv previously had exclusive access on these three payer formularies, which are United Health Group (Commercial), where generic film and tablets were added to formulary, Humana (Medicare D & Commercial), where generic film was added. It is important to note that at United Commercial and Humana Medicare Part D and Commercial, Zubsolv's position on these formularies is not disadvantaged to these generic competitors. At WellCare (Medicaid), where Zubsolv was moved in November 2018 to a restricted position only generic tablets are now on formulary i.e. Zubsolv is reimbursed, but at a disadvantageous position to generic tablets.

Orexo continues to strive for commercial and operational excellence. Zubsolv net revenues growth combined with a disciplined approach to financial management is highlighted by market access and trade providing lower returns and better margins.

The market forecast is continued volume growth, as the opioid epidemic continues to escalate and as more providers begin to treat opioid addiction and take on an increasing patient load

Zubsolv in geographies outside the US – treatment of Opioid Use Disorder

In Q3 2019, a license and supply agreement for Australia and New Zealand was signed with Mundipharma Pty Ltd., who supported Orexo in obtaining marketing authorization in Australia. Subject to price and reimbursement decisions in Australia, the launch is planned to take place in 2020. Orexo will receive royalties on future net sales. In Australia, an estimated 735,000 people used opioids for non-medical purposes in 2016-2017,[1] and more than 50,000 people received pharmacotherapy treatment for opioid dependence in 2018.[2] The number of opioid-induced deaths among Australians aged 15-64 years amounted to 1,045 in 2016.[3]

Orexo has continued to work intensively to establish a streamlined supply chain outside the US as low cost of goods will be essential in response to the increasing price pressure from generics characterizing the EU market. The ability to close collaborations with new potential partners will be dependent on the outcome of pricing discussion which are ongoing with authorities in multiple European countries.

Development projects

OX124 - opioid overdose rescue drug containing naloxone
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:
In consultation with FDA, the work to prepare for the pivotal pharmacokinetic bridging study in H2 2020 is ongoing with an ambition to get approval during 2021.

OX125 - opioid overdose rescue drug containing nalmefene
OX125 is based on a novel and unique technology developed to provide a rapidly acting nalmefene rescue medication with the aim of providing differentiated profile compared to currently marketed products and other products under development.

Like naloxone, nalmefene is a full opioid receptor antagonist which reverses the effects of opioid agonists, while having a significantly longer half-life than naloxone.

Changes during the quarter:
Continued preparations for the first human pharmacokinetic study in the first half of 2020 are ongoing.

OX338 - acute moderate to moderately severe pain
OX338 is based on a new sublingual tablet formulation of ketorolac for treatment of moderate to moderately 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 first human pharmacokinetic study was performed. The study results, recieved in beginning of 2020, showed promising results, but with a need to further optimize the formulation in order to obtain a unique product profile and IP protection.

OX382 – Opioid Use Disorder (OUD)
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 formulation offers several advantages over currently available administrations routes for certain patient groups and treatment settings.

Changes during the quarter:
Results from the in-vivo animal Proof of Concept study conducted during Q1 2019 did not support progressing the current formulation into clinical phase. Options for continued development, assessing other formulation options, are ongoing.

OX-MPI – Microvascular diseases
Cardiovascular morbidity and mortality are common in chronic inflammatory diseases due to vascular inflammation and endothelial dysfunction. The lead candidate drug, BI1029539, has been identified as a highly selective anti-inflammatory compound targeting microsomal prostaglandin E synthase (mPGES-1).

OX124 - in consultation with FDA, the work to prepare for the pivotal pharmacokinetic bridging study in H2 2020 is ongoing

[1] Opioid harm in Australia and comparisons between Australia and Canada. Australian Government, Australian Institute of Health and Welfare.
[2] National Opioid Pharmacotherapy Statistics Annual Data collection (NOPSAD) 2018, AIHW.
[3] Opioid-, amphetamine-, and cocaine-induced deaths in Australia: August 2018. National Drug and Alcohol Research Centre.

Selective deletion of mPGES-1 activity leads to anti-inflammatory, vasodilatory and platelet inhibitory effects.

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

Changes during the quarter:
The first clinical trial, phase 1, initiated in Q3 2019 is ongoing and the results are expected in the first half of 2020. Assuming further successful development, phase II clinical trials are planned to be conducted later in 2020.

OXD01 - Opioid Use Disorder (OUD)
In Q3 2019 Orexo signed an agreement with GAIA AG, a global leader in digital therapeutics, for the development of a digital therapy for treatment of OUD. The access to and quality of counselling and psychosocial support, which is required in a complete treatment plan in the US, remains one of the main barriers to successful treatment of OUD. Orexo believes that a fully-automated digital therapy can become a valuable addition to existing treatment plans, which will improve patients' access to treatment and overall treatment outcomes.

OXD01 will be developed based on GAIA's proprietary artificial intelligence (AI) system broca®, which has been the backbone of more than 70 products and been tested on more than 10,000 patients during clinical trials to date. It engages users in highly individualized, simulated 1:1 interactions, guiding patient´s step-by-step towards specific goals and therapeutic targets. This individualization makes GAIA's products unique and has proven to have a significant positive impact on patients' treatment outcomes during both multiple clinical trials and actual treatment in various healthcare settings and indications around the world. The broca® platform has the flexibility to run the highly individualized products on nearly all web compatible devices.

Orexo holds the exclusive global rights to OXD01.

Changes during the quarter:
A joint team bringing together GAIA's development expertise with Orexo´s deep expertise within OUD, has been established. GAIA initiated the technical development of the new DTx.

OXD01 is expected to get filed with FDA in 2021.

OXD02/vorvida® - Alcohol Use Disorder (AUD)
OXD02/vorvida® is a fully automated digital therapy developed by Orexo´s partner GAIA and is based on its proprietary artificial intelligence (AI)-expert system, broca®. Vorvida® is scientifically proven to reduce troublesome drinking patterns in adults with AUD. In a randomized controlled trial involving 608 adults with problematic alcohol intake, researchers found that participants in the intervention group with vorvida® significantly reduced their daily alcohol consumption over three and six months, with significant effect sizes.[1] Additionally, in comparison to the control group, vorvida® users reported fewer days of binge drinking and drunkenness while stating high acceptance and utility rates of vorvida® at the same time.

AUD is a major health crisis affecting approximately 14.5 million people in the United States.[2] Each year, more than 88,000 people die from alcohol-related causes,[3] making it the third leading preventable cause of death in the country. Alcohol misuse costs the United States about USD 249 billion per year.[4]

Changes during the quarter:
The exclusive US commercial rights for vorvida® were acquired from GAIA. To take OXD02/vorvida® to the US market, which is expected in H2 2020, Orexo and GAIA are evaluating the most effective regulatory pathway and will seek collaborative discussions with FDA.

To take OXD02/vorvida® to the US market, which is expected in H2 2020, Orexo and GAIA are evaluating the most effective regulatory pathway

[1]Jördis M. Zill, Eva Christalle, Björn Meyer, Martin Härter, and Jörg Dirmaier The Effectiveness of an Internet Intervention Aimed at Reducing Alcohol Consumption in Adults: Results of a Randomized Controlled Trial (Vorvida) Dtsch Arztebl Int 2019; 116: 127–33. DOI: 10.3238/arztebl.2019.0127
[2]Centers for Disease Control and Prevention (CDC). Alcohol and Public Health: Alcohol-Related Disease Impact (ARDI). Average for United States 2006-2010 Alcohol-Attributable Deaths Due to Excessive Alcohol Use. https://go.usa.gov/xKBjQ.
[3]Sacks, J.J.; Gonzales, K.R.; Bouchery, E.E.; Tomedi, L.E.; and Brewer, R.D. 2010 National and state costs of excessive alcohol consumption. American Journal of Preventive Medicine49(5):e73–e79, 2015.
[4]Substance Abuse and Mental Health Services Administration (SAMHSA). Results from the 2017 National Survey on Drug Use and Health: Detailed Tables. Table 5.5A—Alcohol Use Disorder in Past Year Among Persons Aged 12 or Older, by Age Group and Demographic Characteristics: Numbers in Thousands, 2016 and 2017. https://www.samhsa.gov/data/sites/default/files/cbhsq-reports/NSDUHDetailedTabs2017/NSDUHDetailedTabs2017.htm.

Other information

Financial outlook 2019 - outcome

• 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
Outcome: +133 percent
• Orexo believes the overall net sales of Zubsolv® in the US will increase in local currency, despite increased competition from Suboxone® Film generics
Outcome: +8 percent
• 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
Outcome: +40 percent
• 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.
Outcome: SEK 508 million
• 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.
Outcome: OX338 advanced in phase 1 trial
• The first new partnerships for Zubsolv outside the US is expected to be initiated in 2019
Outcome: Initiated partnership with Mundipharma Pty. for Australia and New Zeeland

Financial outlook 2020

• The buprenorphine/naloxone market will continue to show a double-digit growth
• Net sales of Zubsolv in the US is expected to be in line with 2019. The open businesses will grow, while the previously highly rebated exclusive segments, including cash, will decrease.
• Due to increased R&D investments OPEX will reach a level of SEK 550-600 million
• Due to a decrease in the Abstral® royalty of approximately SEK 85 million, as an effect of expiration of IP protection in the US and the EU, and increased investments in R&D, EBITDA will decrease
• US EBIT margin from Zubsolv US will be in the range of 45-50 percent
• The outlook is based on exchange/rates in December 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.

Dividend

The Board of Directors proposes that no dividend is paid for the financial year 2019.

Risks and uncertainty factors

Significant risks and uncertainties are presented in the Annual Report for 2018. 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.

Uppsala, Sweden, January 30, 2020
Orexo AB (publ.)

Nikolaj Sørensen
President and CEO

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

Financial reports, notes and key figures

CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS

SEK million	Notes	2019 Oct-Dec	2018 Oct-Dec	2019 Jan-Dec	2018 Jan-Dec
Net revenues	6	238.1	227.1	844.8	783.1
Cost of goods sold		-23.0	-43.4	-105.6	-171.8
Gross profit		**215.0**	**183.7**	**739.2**	**611.4**
Selling expenses		-50.6	-48.0	-191.9	-191.4
Administrative expenses		-26.9	-54.7	-139.6	-166.7
Research and development expenses		-58.6	-47.0	-181.3	-166.8
Other operating income and expenses		-7.4	3.6	4.8	9.3
Operating earnings		**71.5**	**37.6**	**231.2**	**95.8**
Net financial items		-22.5	-0.3	-3.3	-3.6
Earnings before tax		**49.0**	**37.3**	**227.9**	**92.2**
Tax	4	-10.1	14.3	-8.8	45.7
Net earnings for the period[1]		**38.9**	**51.6**	**219.1**	**137.9**
Earnings per share, before dilution, SEK		1.12	1.49	6.33	3.99
Earnings per share, after dilution, SEK		1.10	1.47	6.20	3.93

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

SEK million	2019 Oct-Dec	2018 Oct-Dec	2019 Jan-Dec	2018 Jan-Dec
Earnings for the period	**38.9**	**51.6**	**219.1**	**137.9**
Other comprehensive income				
Items that may subsequently be reversed to the statement of operations:				
Exchange-rate differences	-6.3	1.1	3.4	7.0
Other comprehensive earnings for the period, net after tax	**-6.3**	**1.1**	**3.4**	**7.0**
Total comprehensive earnings for the period[1]	**32.6**	**52.7**	**222.5**	**144.9**

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

CONDENSED CONSOLIDATED BALANCE SHEET

SEK million	2019 Dec 31	2018 Dec 31
ASSETS		
Fixed assets		
Tangible fixed assets	22.0	20.0
Intangible fixed assets	113.9	103.9
Right-of-use assets	57.0	—
Deferred tax assets	85.5	92.8
Other financial assets	1.4	10.4
Total fixed assets	**279.9**	**227.2**
Current assets		
Inventories	131.8	173.6
Accounts receivable and other receivables	272.6	296.1
Cash and cash equivalents	816.8	589.8
Total current assets	**1,221.2**	**1,059.5**
Total assets	**1,501.1**	**1,286.7**
SHAREHOLDERS' EQUITY AND LIABILITIES		
Total shareholders' equity	**706.4**	**476.1**
Long-term liabilities		
Provisions	10.7	6.5
Long-term liabilities, interest bearing	289.6	320.6
Lease liabilities, long-term	33.3	—
Total long-term liabilities	**333.6**	**327.1**
Current liabilities and provisions		
Provisions	269.3	265.8
Current liabilities, non-interest bearing	170.5	217.6
Lease liabilities, current	21.4	—
Total current liabilities and provisions	**461.1**	**483.4**
Total liabilities	**794.7**	**810.5**
Total shareholders' equity and liabilities	**1,501.1**	**1,286.7**

CONSOLIDATED CHANGES IN SHAREHOLDERS' EQUITY

SEK million	2019 Dec 31	2018 Dec 31
Opening balance, shareholders' equity	**476.1**	**329.1**
Total comprehensive earnings for the period	222.5	144.9
Share-based payments	5.8	2.1
Buy back of shares	—	—
New share issue	2.0	0.1
Closing balance, shareholders' equity	**706.4**	**476.1**

CONDENSED CONSOLIDATED CASH FLOW STATEMENTS

SEK million	Notes	2019 Oct-Dec	2018 Oct-Dec	2019 Jan-Dec	2018 Jan-Dec
Operating earnings		71.5	37.6	231.2	95.8
Interest received		2.7	3.1	9.9	3.1
Interest paid		-6.6	-4.9	-17.7	-14.8
Income taxes paid		-3.2	-2.2	-12.2	-18.1
Adjustment for non-cash items	2	26.4	0.8	41.3	61.9
Cash flow from operating activities before changes in working capital		**90.7**	**34.4**	**252.5**	**127.9**
Changes in working capital		**-30.6**	**37.3**	**38.4**	**114.1**
Cash flow from operating activities		**60.2**	**71.7**	**290.9**	**242.0**
Acquisition of tangible and intangible fixed assets		-21.4	-1.4	-35.9	-3.6
Acquisition of financial assets		—	-2.5	—	-2.5
Diposal of financial assets		10.4	—	9.5	—
Cash flow from investing activities		**-11.0**	**-3.9**	**-26.3**	**-6.2**
New share issue		—	—	2.0	0.1
Buy back shares		—	—	—	-0.1
Repayment of loans		-4.3	—	-55.8	—
Cash from financing activities		**-4.3**	**0.0**	**-53.7**	**0.0**
Cash flow for the period		**44.8**	**67.8**	**210.8**	**235.8**
Cash and cash equivalents at the beginning of the period		**812.9**	**516.6**	**589.8**	**327.9**
Exchange-rate differences in cash and cash equivalents		-40.9	5.4	16.1	26.1
Changes in cash and cash equivalents		3.9	73.2	227.0	261.9
Cash and cash equivalents at the end of the period		**816.8**	**589.8**	**816.8**	**589.8**

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.

	2019 Oct-Dec	2018 Oct-Dec	2019 Jan-Dec	2018 Jan-Dec
EBIT margin, %	30.0	16.6	27.4	12.2
Return on shareholder equity, %	5.6	11.5	37.1	34.3
Net debt, SEK million	-527.2	-269.2	-527.2	-269.2
Debt/equity ratio, %	41.0	67.3	41.0	67.3
Equity/assets ratio, %	47.1	37.0	47.1	37.0
Number of shares, before dilution		34,560,456		34,560,456
Number of shares, after dilution		35,095,980		35,095,980
Earnings per share, before dilution, SEK	1.12	1.49	6.33	3.99
Earnings per share, after dilution, SEK	1.10	1.47	6.20	3.93
Number of employees at the end of the period	128	129	128	129
Shareholders' equity, SEK million	706.4	476.1	706.4	476.1
Capital employed, SEK million	996.0	796.7	996.0	796.7
Working capital, SEK million	-56.7	-13.8	-56.7	-13.8

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

CONDENSED PARENT COMPANY STATEMENT OF OPERATIONS

SEK million	Notes	2019 Oct-Dec	2018 Oct-Dec	2019 Jan-Dec	2018 Jan-Dec
Net revenues		187.3	128.6	534.0	407.6
Cost of goods sold		-31.0	-29.7	-98.6	-116.2
Gross profit		**156.3**	**98.9**	**435.3**	**291.4**
Selling expenses		-1.2	—	-6.6	-10.3
Administrative expenses		-16.2	-45.8	-105.6	-135.2
Research and development costs		-50.7	-39.7	-152.3	-138.3
Other operating income and expenses		3.9	13.7	67.2	50.6
Operating earnings		**92.1**	**27.1**	**238.0**	**58.1**
Interest income and expenses		-1.9	-3.3	-10.9	-14.4
Other financial income and expenses		-21.1	1.6	4.0	8.2
Net financial items		**-23.0**	**-1.7**	**-6.9**	**-6.1**
Earnings before tax		**69.1**	**25.4**	**231.1**	**52.0**
Tax	4	-11.8	18.2	-11.8	53.3
Earnings for the period		**57.3**	**43.7**	**219.3**	**105.3**

PARENT COMPANY STATEMENT OF COMPREHENSIVE INCOME

SEK million	2019 Oct-Dec	2018 Oct-Dec	2019 Jan-Dec	2018 Jan-Dec
Earnings for the period	**57.3**	**43.7**	**219.3**	**105.3**
Other comprehensive income	—	—	—	—
Total comprehensive earnings for the period	**57.3**	**43.7**	**219.3**	**105.3**

CONDENSED PARENT COMPANY BALANCE SHEET

SEK million	2019 Dec 31	2018 Dec 31
ASSETS		
Fixed assets		
Intangible fixed assets	113.9	103.9
Tangible fixed assets	22.0	20.0
Deferred tax assets	49.0	60.9
Shares in subsidiaries	155.6	152.3
Total fixed assets	**340.6**	**337.1**
Current assets		
Inventories	113.4	155.3
Accounts receivable and other receivables	214.1	166.8
Cash and bank balances	469.0	303.2
Total current assets	**796.5**	**625.3**
Total assets	**1,137.1**	**962.4**
SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES		
Shareholders' equity	**644.0**	**416.9**
Long-term liabilities		
Other provisions	8.2	4.9
Bond loan	289.6	320.6
Total long-term liabilities	**297.8**	**325.5**
Current liabilities		
Accounts payable	22.8	19.6
Other liabilities	6.0	25.3
Liabilities to Group companies	144.7	143.2
Accrued expenses and deferred income	21.8	32.0
Total current liabilities	**195.3**	**220.1**
Total liabilities	**493.1**	**545.6**
Total shareholders' equity and liabilities	**1,137.1**	**962.4**

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 2018 Annual Report with exception for new and updated standards and interpretations described below.

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 2019
IFRS 16 Leases has replaced IAS 17. According to the new standard, most leased assets must be recognized in the balance sheet and the lessee shall report leasing costs as interest payments and depreciation of the asset. The standard is applied by the Group as from January 1, 2019. The Parent Company applies the exception rule in RFR 2. Orexo applied 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 was that a lease asset (right-of-use assets) and a lease liability were added, each at SEK 71.4 million. The P&L effect for Q4 2019 amounted to SEK -0.3 million.The difference between the opening balance sheet value of lease liabilities and the remaining operating lease payments under IAS 17, as disclosed in the 2018 annual report, is principally due to discounting of future lease payments.

ADJUSTMENT FOR IFRS 16

SEK million	2018-12-31	Effect of transition to IFRS 16	2019-01-01
ASSETS			
Right-of-use assets	—	74.1	74.1
Accrued income and prepaid expenses	25.7	-2.7	23.0
Total	**25.7**	**71.4**	**97.1**
SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES			
Lease liabilities, long-term	—	52.0	52.0
Lease liabilities, current	—	19.4	19.4
Total	**0.0**	**71.4**	**71.4**

EFFECTS OF IFRS 16

SEK million	2019 Oct-Dec	2019 Jan-Dec
Net revenues	—	—
Cost of goods sold	—	—
Gross profit	**0.0**	**0.0**
Selling expenses	0.1	0.3
Administrative expenses	0.1	0.4
Research and development expenses	0.2	1.0
Other operating income and expenses	—	—
Operating earnings	**0.4**	**1.6**
Net financial items	-0.7	-2.8
Earnings before tax	**-0.3**	**-1.2**
Tax	0.0	0.3
Net earnings for the period	**-0.3**	**-0.9**

2. Cash flow

ADJUSTMENT FOR NON-CASH ITEMS

SEK million	2019 Oct-Dec	2018 Oct-Dec	2019 Jan-Dec	2018 Jan-Dec
Depreciation/amortization and impairment	14.3	5.2	41.0	20.8
Change in provisions	3.9	-3.3	-2.7	45.6
Share based payments	2.2	-0.3	5.8	2.1
Exchange rate income and expenses	6.0	-0.8	-2.7	-6.5
Total	**26.4**	**0.8**	**41.3**	**61.9**

3. Legal disputes

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 was seeking compensation for damages caused by Actavis's infringement of the '996 patent since the year of approval of these two products. On March 29 the District Court of Delaware declared that Actavis does not infringe the ´996 patent with their generic versions of Suboxone and Subutex. In Q2 2019 Orexo filed a motion for a new trial in the District Court of Delaware. On December 11 the District Court denied Orexo´s motion for a new trial. Orexo is disappointed with the decision, but as it doesn´t have any impact on Orexo´s business, the company has together with its lawyers decided not to appeal. Actavis will not be able to claim Orexo for any compensation related to incurred legal costs.

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 1,180 million as of December 31 2019 and refers to the Swedish companies. Deferred tax assets of SEK 49.0 million for tax-loss carry-forwards have been capitalized as per December 31, 2019, 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

› OX338 showed promising results fom the human PK study, assessing novel ketorolac formulations for treatment of pain

8. Revenue from contracts with customers

SEK million			2019 Oct-Dec		
Type of revenue	**Zubsolv®**	**Abstral®**	**Edluar®**	**OX-MPI**	**Total**
Sales, products	190.5	—	—	—	**190.5**
Royalties	—	46.2	1.3	—	**47.5**
Milestones	—	—	—	0.0	**0.0**
Total revenue from contracts with customers	**190.5**	**46.2**	**1.3**	**0.0**	**238.1**
Geographical markets	**Zubsolv**	**Abstral**	**Edluar**	**OX-MPI**	**Total**
US	190.5	0.3	0.1	—	**190.9**
EU	—	41.6	0.6	0.0	**42.2**
Rest of the world	—	4.4	0.6	—	**4.9**
Total revenue from contracts with customers	**190.5**	**46.2**	**1.3**	**0.0**	**238.1**

SEK million			2018 Oct-Dec		
Type of revenue	**Zubsolv**	**Abstral**	**Edluar**	**OX-MPI**	**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-MPI**	**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			2019 Jan-Dec		
Type of revenue	**Zubsolv**	**Abstral**	**Edluar**	**OX-MPI**	**Total**
Sales, products	719.2	—	—	—	**719.2**
Royalties	0.1	112.6	11.6	—	**124.2**
Milestones	—	—	—	1.4	**1.4**
Total revenue from contracts with customers	**719.3**	**112.6**	**11.6**	**1.4**	**844.8**
Geographical markets	**Zubsolv**	**Abstral**	**Edluar**	**OX-MPI**	**Total**
US	719.2	2.2	4.4	—	**725.8**
EU	0.1	87.3	2.2	1.4	**91.0**
Rest of the world	—	23.1	4.9	—	**28.0**
Total revenue from contracts with customers	**719.3**	**112.6**	**11.6**	**1.4**	**844.8**

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

SEK million	2018 Jan-Dec				
Type of revenue	**Zubsolv**	**Abstral**	**Edluar**	**OX-MPI**	**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-MPI**	**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**

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	2019 Oct-Dec	2018 Oct-Dec	2019 Jan-Dec	2018 Jan-Dec
EBIT	71.5	37.6	231.2	95.8
Depreciation and amortization	14.3	5.2	40.9	20.8
EBITDA	**85.8**	**42.8**	**272.1**	**116.6**
IP litigation costs	0.6	26,4	49.4	82.8
EBITDA excluding IP litigation costs	**86.4**	**69,2**	**321.5**	**199.4**

RETURN ON SHAREHOLDERS' EQUITY	2019 Oct-Dec	2018 Oct-Dec	2019 Jan-Dec	2018 Jan-Dec
Shareholders' equity beginning balance	671.7	424.4	476.1	329.1
Shareholders' equity ending balance	706.4	476.1	706.4	476.1
Average shareholders' equity	689.1	450.3	591.3	402.6
Net earnings	38.9	51.6	219.1	137.9
Return on shareholders' equity %	**5.6**	**11.5**	**37.1**	**34.3**

OPERATING EXPENSES SEK million	2019 Oct-Dec	2018 Oct-Dec	2019 Jan-Dec	2018 Jan-Dec
Selling expenses	-50.6	-48.0	-191.9	-191.4
Administrative expenses	-26.9	-54.7	-139.6	-166.7
Research and development costs	-58.6	-47.0	-181.3	-166.8
Other operating income and expenses	-7.4	3.6	4.8	9.3
Operating expenses	**-143.5**	**-146.1**	**-508.0**	**-515.6**

GROSS INVESTMENTS SEK million	2019 Oct-Dec	2018 Oct-Dec	2019 Jan-Dec	2018 Jan-Dec
Investments in tangible fixed assets	5.1	1.3	8.8	2.9
Investments in intangible fixed assets	16.3	0.1	27.0	0.7
Gross investments	**21.4**	**1.4**	**35.9**	**3.6**

US EBIT SEK million and EBIT margin %	2019 Oct-Dec	2018 Oct-Dec	2019 Jan-Dec	2018 Jan-Dec
Consolidated operating earnings	71.5	37.6	231.2	95.8
Non US related items impacting operating earnings	-26.7	-24.1	-119.7	-102.5
US EBIT	**98.2**	**62.0**	**350.9**	**198.3**
US EBIT margin %	**51.6**	**37.2**	**48.8**	**31.9**

Glossary

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
Artificial intelligence
Artificial intelligence (AI) is the simulation of human intelligence processes by machines, especially computer systems
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
Broca®
GAIA's proprietary intelligence system, based on artificial intelligence, underpins the development of digital therapies targeting multiple therapy areas
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
Cash 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
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
Digital therapeutics (DTx)
Digital therapeutics, a subset of digital health, are evidence-based therapeutic interventions driven by high quality software programs to prevent, manage, or treat a medical disorder or disease
Digital health
Digital health is the convergence of digital technologies with health and healthcare to enhance the efficiency of healthcare delivery and make medicine more personalized and precise
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
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 antagonist 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