Interim Report Q3 2019

Strong financials paving the way for broadening the business

Q3 2019 highlights

- Total net revenues of SEK 231.2 million (216.6), up 6.7 percent
- Zubsolv® US net revenues of SEK 182.7 million (165.4), up 10.4 percent in SEK and 3.0 percent in local currency
- EBITDA of SEK 114.1 million (39.8), up 186.7 percent. EBITDA ex Abstral® of SEK 71.7 million (-8.9).
- US EBIT of SEK 93.4 million (55.6), up 68.0 percent
- Cash flow from operating activities of SEK 135.7 million (24.5), building a cash balance of SEK 812.9 million (516.6)
- Net earnings of SEK 111.7 million (62.2), up 79.6 percent
- Signed license and supply agreement for Zubsolv in Australia and New Zealand with Mundipharma Pty Ltd.
- SEK 32.5 million (10 percent) of the total corporate bond loan was prepaid
- Signed partnership agreement with GAIA AG to develop a digital therapy for treatment of opioid dependence

>2x
Increase in EBITDA YTD

SEK 112 m
Net earnings

SEK 813 m
Cash and cash equivalents

SEK m, unless otherwise stated	2019 Jul-Sep	2018 Jul-Sep	2019 Jan-Sep	2018 Jan-Sep	12 mth Oct 2018-Sep 2019	12 mth Oct 2017-Sep 2018
Net revenues	231.2	216.6	606.7	556.0	833.9	747.0
whereof Zubsolv® US net revenues	182.7	165.4	528.8	454.9	695.4	581.4
Cost of goods sold	-25.9	-42.4	-82.5	-128.4	-125.9	-178.7
Operating expenses	-99.4	-139.6	-364.5	-369.4	-510.7	-480.0
EBIT	105.9	34.6	159.7	58.2	197.4	88.2
EBIT margin, %	45.8	16.0	26.3	10.5	23.7	11.8
US EBIT	93.4	55.6	252.7	136.4	314.5	156.2
US EBIT margin, %	51.1	33.6	47.8	30.0	45.2	26.9
EBITDA	114.1	39.8	186.3	73.7	229.3	109.0
Earnings per share, before dilution, SEK	3.22	1.80	5.21	2.50	6.66	3.27
Earnings per share, after dilution, SEK	3.16	1.77	5.10	2.46	6.54	3.26
Cash flow from operating activities	135.7	24.5	230.7	170.4	302.5	147.4
Cash and cash equivalents	812.9	516.6	812.9	516.6	812.9	516.6

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
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 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
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-q3-2019
Telephone: SE: +46 8 566 427 06 UK: +44 333 300 92 67 US: +1 833 5268 383
The presentation material will be available on Orexo´s website prior to the audiocast.

Financial calendar
Full Year Report incl. Q4 2019 - January 30, 2020 at 8:00 am CET
Annual General Meeting 2020 - April 16, 2020 at 4 pm CET
Interim Report Q1 2020 - April 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.

Strong financials driving continued focus on new product opportunities and pipeline progression

During the quarter we saw significant changes in the US market against which Zubsolv® continued to perform well and the company reported another strong financial performance. These results, along with our solid cash position, provide the necessary headroom to advance our promising pipeline of opioid focused products, whilst also embracing the trend towards the adoption of complementary digital therapeutics.

All-Time-High financial performance – EBITDA reached SEK 114 million

Following a very strong second quarter, I am pleased to report another period marked by strong financial results. Also when excluding the Abstral® royalty we show strong numbers, as EBITDA ex Abstral amounted to SEK 71.7 million (-8,9). This is driven by increased sales of Zubsolv in market segments with below average rebates. The results also reflect improved efficiency measures introduced at Orexo and some adjustment of lower returns and rebates relating to prior periods. The financial result has been achieved against some short-term headwinds with three payers removing exclusivity for Zubsolv and expanding reimbursement to include other products. For Zubsolv, the immediate impact is competition in the previously exclusive contracts, WellCare, Humana and United Health Group. Longer term, Zubsolv will benefit from more payers opening up for reimbursement of Zubsolv with lower rebates. I am encouraged to see continued double digit growth for Zubsolv in the plans not impacted by changes in market access and where the rebates are lower than the exclusive contracts.

Market Dynamics – increased funding of treatment will improve the business case

A topic that has attracted media attention is the ongoing lawsuits of manufacturers of opioid pain medication. Orexo is not implicated in any of these cases, but some of the damages from these lawsuits is expected to be used to improve the treatment for opioid addiction. In many states, patient advocacy groups have lobbied for universal access for all treatment options. This has resulted in legislative changes in some states to force publicly financed payers to reimburse all products, including Zubsolv. The increased funding of treatment will also encourage the introduction of new treatment options, which bodes well for Orexo's pipeline of opioid treatments, including our recent foray into digital therapeutics - increasingly seen as critical to successfully treating opioid addiction.

Digital Therapies – an exciting, growing market set to improve patient outcomes

The use of digital therapeutics is increasing with digital poised to play a key role in most, if not all, future interactions with health care providers. Based on our existing infrastructure and

our knowledge of the addiction market, Orexo is well positioned to become a leader in bringing new digital treatment solutions to the market. Our strategy is to focus on solutions with scientifically proven therapeutic effect which will benefit the healthcare system as a whole and more importantly patients. Our partnership with GAIA, announced in August, is a good example of this strategy in action. GAIA has collated evidence from more than 10,000 patients that supports the use of their digital Cognitive Behavioral Therapy in depression and alcohol addiction to improve treatment outcomes. While leveraging the synergies from our existing infrastructure in the US our strategy is to continue with our considered buy and build strategy and complement our existing offering with new digital therapeutics to bring comprehensive and effective treatment solutions to improve patient outcomes.

> "Our strategy is to focus on solutions with scientifically proven therapeutic effect which will benefit the healthcare system as a whole and more importantly patients."

Summary and Outlook

2019 is on track to deliver a very strong financial result enabling the company to execute on the overarching strategy to expand the commercial platform. Our next near term milestones will be the results from our ongoing OX338 study and possibly new business development agreements. Building on the financial success of Zubsolv, we have the resources to both continue broadening our pipeline and product portfolio and to build a presence in the increasingly important and complementary digital therapeutics market.

Uppsala, Sweden, October 24, 2019

Nikolaj Sørensen
President and CEO

Financial information

Revenues

Total revenues amounted to SEK 231.2 million (216.6) for the quarter, corresponding to 6.7 percent increase. The increase was primarily driven by the Zubsolv® US growth.

Total revenues amounted to SEK 606.7 million (556.0) for the first nine months, corresponding to 9.1 percent increase.

Zubsolv US revenues for the quarter amounted to SEK 182.7 million (165.4), corresponding to 10.4 percent growth in SEK. In local currency (USD) the equivalent growth rate was 3.0 percent, equal to sales of USD 19.1 million. Zubsolv US revenues for the first nine months amounted to SEK 528.7 million (454.9), an increase of 16.2 percent. In local currency (USD) the equivalent increase was 6.2 percent, equal to sales of USD 56.2 million.

Net revenues for the quarter were positively impacted by improved prices and by a total of SEK 14.2 million adjustment of lower returns and by one-time adjustment of rebates relating to prior periods completely offsetting the volume decline. Wholesaler inventory levels were decreased by SEK 7.6 million during the quarter.

Abstral® royalties amounted to SEK 42.4 million (48.7) for the quarter mainly explained by lower volumes in Europe and in the US. Abstral® royalties amounted to SEK 66.3 million (66.4) the first nine months. Royalties for sales in Europe will be received until December 31, 2019, when the European contract with Kyowa Kirin expires. After the period Orexo was informed by its partner in the US Sentynl that they will withdraw Abstral from sale and the last sale date is scheduled for October 31, 2019.

Royalties from Edluar® amounted to SEK 6.1 million (2.3) for the quarter and to SEK 10.2 million (3.7) for the first nine months.

An OX-MPI milestone of SEK 0.1 million was earned during the quarter.

Costs of goods sold

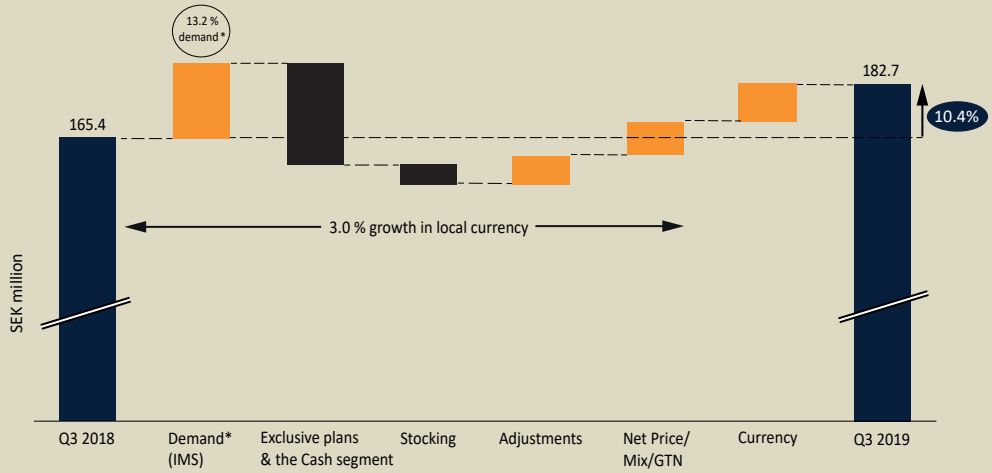
Cost of goods sold (COGS) amounted to SEK 25.9 million (42.4) for the quarter all related to Zubsolv in the US market. For the first nine months COGS amounted to SEK 82.5 million (128.4) also related to Zubsolv in the US market. This corresponds to an average COGS per tablet 37 percent lower than the average realized in 2017 and is in line with the full year target of 35 percent reduction in COGS.

COGS per tablet was 37 percent lower than the average realized in 2017 and is in line with the full year target of 35 percent reduction in COGS.

Operating expenses

Selling expenses amounted to SEK 45.0 million (51.5) for the quarter. The decrease over the same period last year is mainly explained by organizational efficiencies including

ZUBSOLV US NET REVENUE GROWTH BY KEY DRIVERS, Q3 2019 VERSUS Q3 2018[1]



[1] Orexo analysis using IMS demand data plus institutional sales

* Excluding the Cash segment and changes at WellCare, Humana and United Health Group

internalized sales force. Selling expenses amounted to SEK 141.3 million (143.4) for the first nine months.

Administrative expenses amounted to SEK 18.1 million (50.8). The decrease versus prior year is explained by lower legal expenses. Legal expenses for IP litigations reached SEK -3.0 million (31.2) for the quarter. Administrative expenses amounted to SEK 112.7 million (112.0) for the first nine months.

Research and development costs amounted to SEK 41.6 million (37.5) for the quarter. The increase is related to the manufacturing of OX338 tablets for the clinical trial initiated in October. Research and development costs amounted to SEK 122.7 million (119.8) for the first nine months.

Other operating income and expenses amounted to SEK 5.3 million (0.2) for the quarter and to SEK 12.3 million (5.8) for the first nine months mainly explained by exchange-rate gains derived from revaluations of parent company balance sheet items in foreign currency, predominantly cash in USD.

Operating profit

Orexo's profitability continued to improve and Orexo reports All-Time-High EBITDA in a quarter with SEK 114.1 million (39.8) due to growing contribution from the US commercial business supported by lower COGS and no spending on IP litigations.

EBITDA amounted to SEK 186.3 million (73.7) for the first nine months.

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 93.4 million (55.6) for the quarter equal to an EBIT margin of 51.1 percent (33.6). In local currency EBIT amounted to USD 9.7 million (6.2) for Q3 2019.

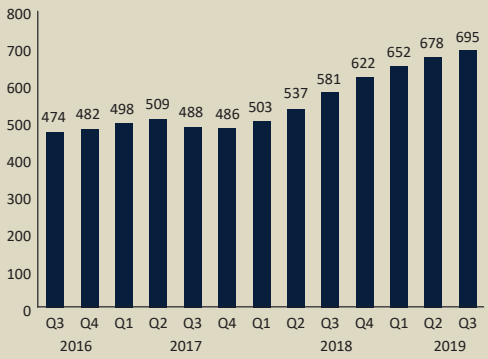
The US commercial business contributed with an EBIT improvement of SEK 252.7 million (136.4) for the first nine months equal to an EBIT margin of 47.8 percent (30.0).

The US commercial business contributed with an EBIT improvement to SEK 93.4 million (55.6).

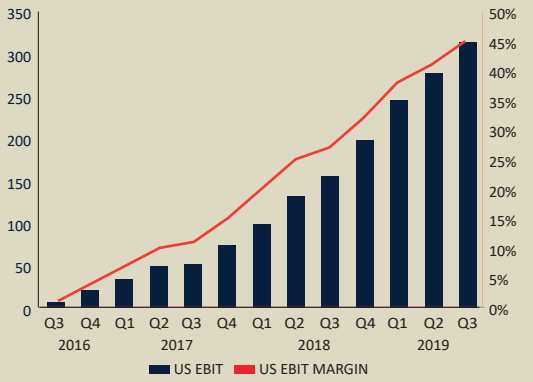
DISTRIBUTION OF TOTAL NET REVENUES

SEK m	2019 Jul-Sep	2018 Jul-Sep	2019 Jan-Sep	2018 Jan-Sep	12 mth Oct 2018-Sep 2019	12 mth Oct 2017-Sep 2018
Zubsolv® US	182.7	165.4	528.7	454.9	695.4	581.4
Zubsolv - ex US	0.0	0.2	0.1	31.0	5.3	36.6
Zubsolv – total	**182.7**	**165.6**	**528.8**	**485.9**	**700.7**	**618.0**
Abstral® royalties	42.4	48.7	66.3	66.4	118.7	121.8
Edluar® royalties	6.1	2.3	10.2	3.7	13.1	7.3
OX-MPI	0.1	-	1.4	-	1.4	-
Total	**231.2**	**216.6**	**606.7**	**556.0**	**833.9**	**747.1**

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



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



[1] LTM, Last Twelve Months

Net financial items and tax

Net financial items amounted to SEK 8.7 million (-4.2) for the quarter. These items are related to financing activities including interest income/expenses and exchange-rate gains/losses derived from foreign currency bank accounts, predominantly in USD. For the quarter the bond loan related costs were more than completely offset by earned interest on bank accounts in the US and by a positive exchange rate impact.

Net financial items amounted to SEK 19.2 million (-3.2) for the first nine months.

Total tax expenses amounted to SEK -3.0 million (31.8) for the quarter. Tax for the quarter was negatively impacted by a SEK -1.9 million adjustment to deferred tax assets related to temporary differences while the parent company tax asset increased by SEK 33.2 million over the same period the previous year.

Total tax expenses amounted to SEK 1.3 million (31.4) for the first nine months and was positively impacted by a SEK 5.0 million adjustment to deferred tax assets related to temporary differences while the parent company tax asset increased by SEK 35.1 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 111.7 million (62.2) and for the first nine months to SEK 180.3 million (86.4).

IFRS 16 Leases had a negative impact on net earnings of SEK -0.2 million for the quarter and a negative impact of SEK -0.8 million for the first nine months.

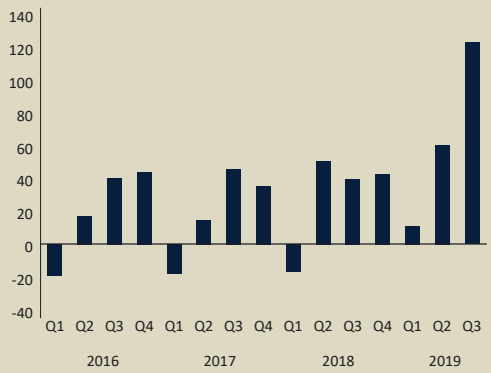
Cash, cash flow and net cash/debt

As of September 30, 2019, cash and cash equivalents amounted to SEK 812.9 million (516.6) and interest bearing liabilities to SEK 289.2 million (320.2), i.e. a positive net cash position of SEK 523.7 million. During the quarter 10 percent of the bond was prepaid. 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. We continue to keep the vast majority of our cash balance in USD as most business development opportunities are in the US.

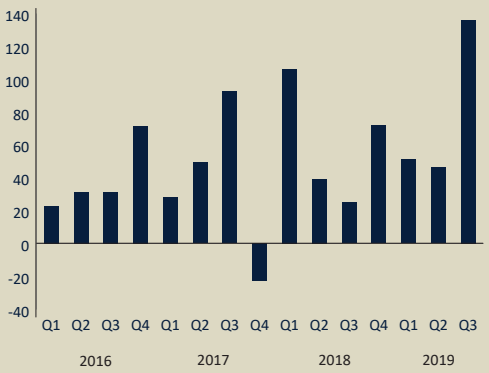
Cash flow from operating activities for the quarter amounted to SEK 135.7 million (24.5) and for the first nine months to SEK 230.7 million (170.4).

As of September 30, 2019, cash and cash equivalents amounted to SEK 812.9 million (516.6).

EBITDA, SEK m



CASH FLOW FROM OPERATING ACTIVITIES, SEK m



Investments

Gross investments in tangible and intangible fixed assets amounted to SEK 13.7 million (0.5) for the quarter. Higher investment is explained by payment of a non-refundable initial milestone of SEK 10.8 million. Gross investments in tangible and intangible fixed assets amounted to SEK 14.5 million (2.2) for the first nine months.

Equity

Shareholders' equity at September 30, 2019, was SEK 671.7 million (424.4). The equity/asset ratio was 43.5 percent (35.1).

Parent company

Net revenues amounted to SEK 128.6 million (131.1) for the quarter of which SEK 80.2 million (80.0) was related to sales to Group companies. Net revenues amounted to SEK 346.7 million (279.0) for the first nine months of which SEK 268.4 million (177.8) was related to sales to Group companies

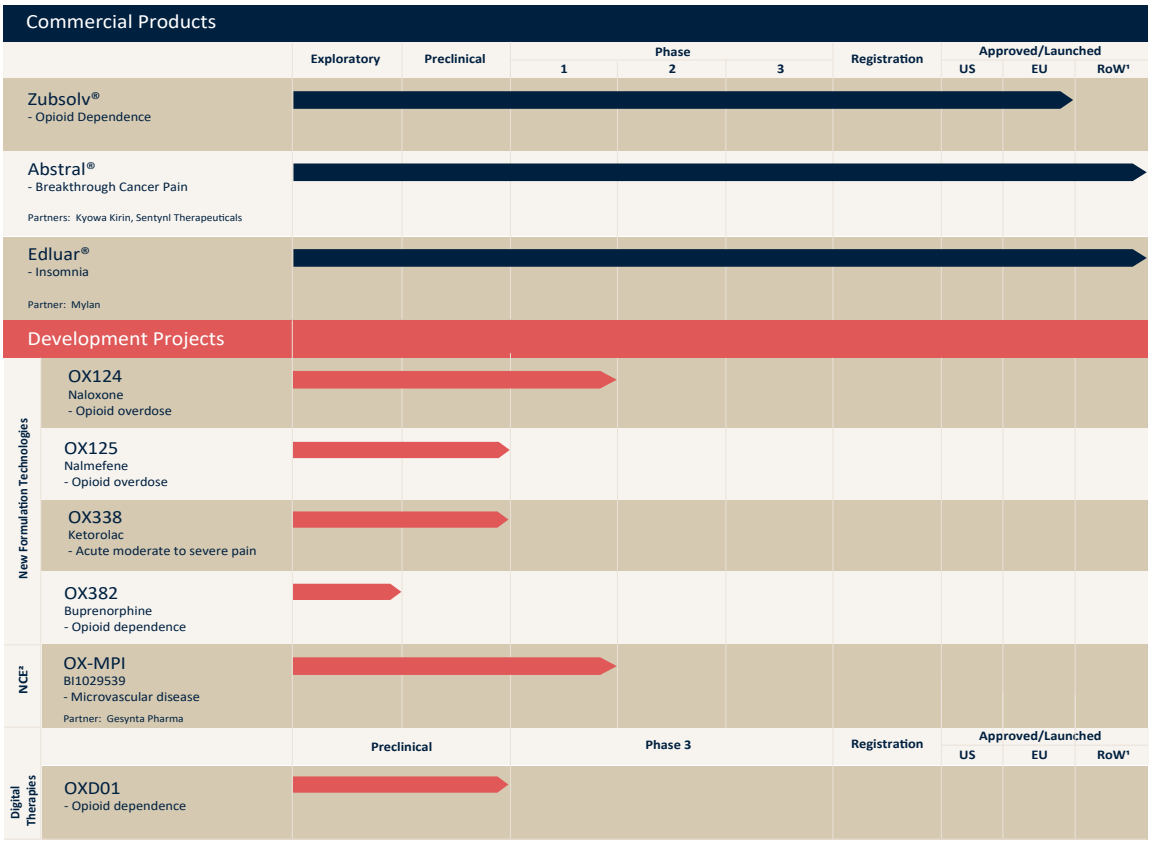
Earnings before tax were SEK 100.8 million (27.9) for the quarter and SEK 162.0 million (26.7) for the first nine months.

Investments for the quarter amounted to SEK 13.7 million (0.5) and for the first nine months to SEK 14.5 million (2.2).

As of September 30, 2019, cash and cash equivalents in the parent company amounted to SEK 411.2 million (259.6).

Operations

PIPELINE OF COMMERCIAL PRODUCTS AND DEVELOPMENT PROJECTS



Commercial products

Zubsolv® US – treatment of opioid dependence

(buprenorphine/naloxone CIII sublingual tablet)

Quarter 3 2019's strong financial performance, despite a slight decline in Zubsolv volumes, demonstrates Orexo's management of the US business from our on-going multidisciplinary management style incorporating constant collaboration across market access, trade distribution, supply, commercial operations and finance has enabled improved financial performance quarter over quarter. In Q319, Zubsolv net sales have grown 3 percent over Q318 in USD, despite the decline in unit volume of 5 percent versus Q219 and 4 percent versus Q318. Zubsolv's net sales increase is explained by improved prices, effective management of inventory to lower returns and some one-time rebate adjustments. The decline in volume is due to a formulary change in three specific payers coupled with continued decline in Zubsolv cash volume. However, Zubsolv has grown in the open market (see below), but not with sufficient momentum during the quarter to compensate for the decline in volume within these three specific payers and the cash market.

The market demonstrated strong growth of 14 percent in unit volume compared to Q318, and 3 percent growth over Q219. 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.

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.

[1] Rest of the World, excluding US and Europe
[2] New Chemical Entity

Relative to market unit volume growth, market prescription volume (total prescriptions) has grown less equating to only 8 percent compared to Q318. 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 Q318.

Analyzing market dynamics excluding the cash segment demonstrates retail market prescription growth and unit growth are within 1 percent of each other, at 13 and 14 percent, respectively.

Over 3,200 physicians became newly waivered to accept their first opioid dependence patients this quarter. Nurse practitioners and physicians assistants now total 15,000 waivered to treat opioid dependency, compared to just 8,100 this quarter last year. 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 Q319, Zubsolv's open business volume was stable versus Q219 and grew 16 percent over Q318. The growth over Q318 is being driven by strong growth in every market segment; open Commercial grew 16 percent, open Medicaid grew 20 percent, and open Medicare D grew 14 percent. Zubsolv's open business is total business where Zubsolv is reimbursed and competes with other products in the market both brand and/or generics, open business excludes recent formulary changes, the cash segment, and Zubsolv's remaining exclusive access payers.

Zubsolv increased its best-in-class coverage in the commercial segment to 97 percent, which includes Zubsolv being the only branded product on Caremark and Aetna's Commercial formularies beginning in Q419.

Zubsolv increased its coverage in the public segment to 39 percent coverage. Within Medicaid, Zubsolv continues to grow in the states it gained access this year; Ohio, Texas, Florida and Alabama. Within those states, Zubsolv has grown Medicaid volume 8 percent in Q319 over Q219.

Zubsolv business in the three specific formulary change payers, the cash segment, and the remaining exclusive plans, as a group declined 9 percent versus Q219 and 18 percent versus Q318. 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 sales growth combined with a disciplined approach to financial management is highlighted by market access and trade providing lower returns and better margins. This has resulted in Orexo having the opportunity to lower the returns reserve.

Collectively, Zubsolv's rates have improved with regard to recent formulary changes. Improving our access despite recent market dynamics is a strong indicator of Orexo's distinction in market access. Orexo continues to position itself for greater access in the public setting.

Zubsolv in geographies outside the US – opioid dependence

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. The launch is planned to take place in 2020 and 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 recently launched generics characterizing the EU market. The ability to initiate collaborations with new potential partners will be dependent on the outcome of pricing discussion which are ongoing with authorities in multiple European countries.

A license and supply agreement for Australia and New Zealand was signed with Mundipharma Pty Ltd.

[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.

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 2020 is ongoing.

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.

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 positive results received in the beginning of the year from the human pharmacokinetic study for OX124, the formulation development for OX125 has continued and preparations for conducting the first human pharmacokinetic study in 2020 are ongoing.

OX338 - acute moderate to severe pain

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:
Clinical trial material was successfully manufactured in our GMP-upgraded laboratories in Uppsala, Sweden, and the first human pharmacokinetic study was initiated according to plan shortly after the end of the period. The study will be finalized in Q4 and we anticipate to communicate the results early in 2020.

OX382 – opioid dependence

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 the first quarter 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).

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 trials, phase 1, were initiated and assuming further successful development phase II clinical trials are planned to be conducted in 2020.

OXD01 - opioid dependence

Together with GAIA AG, a global leader in digital therapeutics, a digital therapy (DTx) for treatment of opioid dependence is being developed. The access to and quality of counselling and psychosocial support, which is required in a complete treatment plan in the US, remain one of the main barriers to successful treatment of opioid dependence. Orexo believes that a fully-automated

OX338 – the first human pharmacokinetic study was initiated according to plan shortly after the end of the period.

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 technology platform 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. Based on an artificial intelligence (AI)-expert system, broca® engages users in highly individualized, simulated 1:1 interactions, guiding patients 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. GAIA's broca® platform has the flexibility to run the highly individualized products on nearly all web compatible devices, including virtual reality applications.

Orexo holds the exclusive global rights to OXD01 and the DTx is expected to get filed with FDA in 2021 and the launch estimates to take place in the US in 2022.

Changes during the quarter:
Since the agreement was signed in August 2019, a co-development team has been established to provide GAIA with Orexo´s comprehensive expertise within opioid use disorder, to prepare for the development of the DTx.

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.

Other information

Outlook 2019

- For 2019 Orexo expects to improve the positive EBITDA on a full year basis
- Orexo believes the overall net sales of Zubsolv® in the US will increase in local currency, despite increased competition from Suboxone Film generics
- The manufacturing efficiency program aimed to reduce the average Cost of Goods Sold (COGS) per tablet by 35 percent in 2019 compared to 2017 (~30 percent compared to 2018)
- Full year OPEX is expected to stay at the same level as 2018 with approximately SEK 500 million
- The outlook is based on current exchange rates (September 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 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, October 24, 2019
Orexo AB (publ.)

Nikolaj Sørensen
President and CEO

Review report

Orexo AB, corporate identity number 556500-0600

Introduction

We have reviewed the condensed interim report for Orexo AB as at September 30, 2018 and for the nine months period then ended. The Board of Directors and the Managing Director are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of review

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

Conclusion

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

Uppsala, Sweden, October 24, 2019
Ernst & Young AB

Björn Ohlsson
Authorized Public Accountant

Financial reports, notes and key figures

CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS

SEK million	Notes	2019 Jul-Sep	2018 Jul-Sep	2019 Jan-Sep	2018 Jan-Sep	2018 Jan-Dec
Net revenues	6	231.2	216.6	606.7	556.0	783.1
Cost of goods sold		-25.9	-42.4	-82.5	-128.4	-171.8
Gross profit		**205.3**	**174.2**	**524.2**	**427.6**	**611.4**
Selling expenses		-45.0	-51.5	-141.3	-143.4	-191.4
Administrative expenses		-18.1	-50.8	-112.7	-112.0	-166.7
Research and development expenses		-41.6	-37.5	-122.7	-119.8	-166.8
Other operating income and expenses		5.3	0.2	12.3	5.8	9.3
Operating earnings		**105.9**	**34.6**	**159.7**	**58.2**	**95.8**
Net financial items		8.7	-4.2	19.2	-3.2	-3.6
Earnings before tax		**114.6**	**30.4**	**178.9**	**55.0**	**92.2**
Tax	4	-3.0	31.8	1.3	31.4	45.7
Net earnings for the period[1]		**111.7**	**62.2**	**180.3**	**86.4**	**137.9**

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

SEK million	2019 Jul-Sep	2018 Jul-Sep	2019 Jan-Sep	2018 Jan-Sep	2018 Jan-Dec
Earnings for the period	**111.7**	**62.2**	**180.3**	**86.4**	**137.9**
Other comprehensive income	—	—	—	—	—
Items that may subsequently be reversed to the statement of operations:					
Exchange-rate differences	5.9	-0.7	9.6	5.9	7.0
Other comprehensive earnings for the period, net after tax	**5.9**	**-0.7**	**9.6**	**5.9**	**7.0**
Total comprehensive earnings for the period [1]	**117.6**	**61.5**	**189.9**	**92.3**	**144.9**
Earnings per share, before dilution, SEK	3.22	1.80	5.21	2.50	3.99
Earnings per share, after dilution, SEK	3.16	1.77	5.10	2.46	3.93

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

CONDENSED CONSOLIDATED BALANCE SHEET

SEK million	2019 Sep 30	2018 Sep 30	2018 Dec 31
ASSETS			
Fixed assets			
Tangible fixed assets	21.8	19.5	20.0
Intangible fixed assets	101.9	108.3	103.9
Right-of-use assets	62.2	—	—
Deferred tax assets	110.8	78.4	92.8
Other financial assets	12.3	7.7	10.4
Total fixed assets	**309.0**	**213.8**	**227.2**
Current assets			
Inventories	137.0	180.5	173.6
Accounts receivable and other receivables	286.4	297.3	296.1
Cash and cash equivalents	812.9	516.6	589.8
Total current assets	**1,236.4**	**994.4**	**1,059.5**
Total assets	**1,545.3**	**1,208.3**	**1,286.7**
SHAREHOLDERS' EQUITY AND LIABILITIES			
Total shareholders' equity	**671.7**	**424.4**	**476.1**
Long-term liabilities			
Provisions	8.3	6.6	6.5
Long-term liabilities, interest bearing	289.2	320.2	320.6
Lease liabilities, long-term	38.2	—	—
Total long-term liabilities	**335.7**	**326.8**	**327.1**
Current liabilities and provisions			
Provisions	281.9	266.0	265.8
Current liabilities, non-interest bearing	234.5	191.1	217.6
Lease liabilities, current	21.6	—	—
Total current liabilities and provisions	**537.9**	**457.1**	**483.4**
Total liabilities	**873.6**	**783.9**	**810.5**
Total shareholders' equity and liabilities	**1,545.3**	**1,208.3**	**1,286.7**

CONSOLIDATED CHANGES IN SHAREHOLDERS' EQUITY

SEK million	2019 Sep 30	2018 Sep 30	2018 Dec 31
Opening balance, shareholders' equity	**476.1**	**329.1**	**329.1**
Total comprehensive earnings for the period	189.9	92.3	144.9
Share-based payments	3.6	3.0	2.1
Buy back of shares	—	-0.1	—
New share issue	2.0	0.1	0.1
Closing balance, shareholders' equity	**671.7**	**424.4**	**476.1**

CONDENSED CONSOLIDATED CASH FLOW STATEMENTS

SEK million	Notes	2019 Jul-Sep	2018 Jul-Sep	2019 Jan-Sep	2018 Jan-Sep	2018 Jan-Dec
Operating earnings		105.9	34.6	159.7	58.2	95.8
Interest received		2.5	0.0	7.2	0.0	3.1
Interest paid		-3.7	-2.5	-11.1	-9.8	-14.8
Income taxes paid		0.1	-11.0	-9.1	-16.0	-18.1
Adjustment for non-cash items	2	-29.1	-29.6	15.0	61.1	61.9
Cash flow from operating activities before changes in working capital		**75.7**	**-8.5**	**161.7**	**93.6**	**127.9**
Changes in working capital		**60.0**	**33.0**	**69.0**	**76.8**	**114.1**
Cash flow from operating activities		**135.7**	**24.5**	**230.7**	**170.4**	**242.0**
Acquisition of tangible and intangible fixed assets		-13.7	-0.5	-14.5	-2.2	-3.6
Acquisition of financial assets		-0.8	—	-0.8	—	-2.5
Cash flow from investing activities		**-14.5**	**-0.5**	**-15.3**	**-2.2**	**-6.2**
New share issue		0.0	0.0	2.0	0.1	0.1
Buy back shares		0.0	-0.1	0.0	-0.1	-0.1
Repayment of loans		-36.9	0.0	-51.4	0.0	—
Cash from financing activities		**-36.9**	**-0.1**	**-49.4**	**0.0**	**0.0**
Cash flow for the period		**84.3**	**23.9**	**166.0**	**168.2**	**235.8**
Cash and cash equivalents at the beginning of the period		**697.0**	**494.8**	**589.8**	**327.9**	**327.9**
Exchange-rate differences in cash and cash equivalents		31.6	-2.1	57.1	20.5	26.1
Changes in cash and cash equivalents		115.9	21.8	223.1	188.7	261.9
Cash and cash equivalents at the end of the period		**812.9**	**516.6**	**812.9**	**516.6**	**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 Jul-Sep	2018 Jul-Sep	2019 Jan-Sep	2018 Jan-Sep	2018 Jan-Dec
EBIT margin, %	45.8	16.0	26.3	10.5	12.2
Return on shareholder equity, %	18.2	15.8	31.4	22.9	34.3
Net debt, SEK million	-523.7	-196.4	-523.7	-196.4	-269.2
Debt/equity ratio, %	43.1	75.5	43.1	75.5	67.3
Equity/assets ratio, %	43.5	35.1	43.5	35.1	37.0
Number of shares, before dilution	34,710,639	34,581,327	34,603,847	34,581,327	34,560,456
Number of shares, after dilution	35,370,992	35,162,920	35,322,129	35,162,920	35,095,980
Earnings per share, before dilution, SEK	3.22	1.80	5.21	2.50	3.99
Earnings per share, after dilution, SEK	3.16	1.77	5.10	2.46	3.93
Number of employees at the end of the period	130	102	130	102	129
Shareholders' equity, SEK million	671.7	424.4	671.7	424.4	476.1
Capital employed, SEK million	960.9	744.6	960.9	744.6	796.7
Working capital, SEK million	-114.5	20.7	-114.5	20.7	-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 Jul-Sep	2018 Jul-Sep	2019 Jan-Sep	2018 Jan-Sep	2018 Jan-Dec
Net revenues		128.6	131.1	346.7	279.0	407.6
Cost of goods sold		-17.3	-35.8	-67.6	-86.5	-116.2
Gross profit		**111.3**	**95.3**	**279.0**	**192.5**	**291.4**
Selling expenses		-0.4	-20.6	-5.4	-10.3	-10.3
Administrative expenses		-10.5	-42.5	-89.4	-89.4	-135.2
Research and development costs		-35.0	-30.1	-101.5	-98.6	-138.3
Other operating income and expenses		27.7	31.2	63.3	36.9	50.6
Operating earnings		**93.1**	**33.3**	**145.9**	**31.1**	**58.1**
Interest income and expenses		-2.7	-3.7	-9.0	-11.1	-14.4
Other financial income and expenses		10.4	-1.7	25.1	6.6	8.2
Net financial items		**7.7**	**-5.4**	**16.1**	**-4.4**	**-6.1**
Earnings before tax		**100.8**	**27.9**	**162.0**	**26.7**	**52.0**
Tax	4	0.0	33.2	0.0	35.1	53.3
Earnings for the period		**100.8**	**61.2**	**162.0**	**61.8**	**105.3**

PARENT COMPANY STATEMENT OF COMPREHENSIVE INCOME

SEK million	2019 Jul-Sep	2018 Jul-Sep	2019 Jan-Sep	2018 Jan-Sep	2018 Jan-Dec
Earnings for the period	**100.8**	**61.2**	**162.0**	**61.8**	**105.3**
Other comprehensive income	—	—	—	—	—
Total comprehensive earnings for the period	**100.8**	**61.2**	**162.0**	**61.8**	**105.3**

CONDENSED PARENT COMPANY BALANCE SHEET

SEK million	2019 Sep 30	2018 Sep 30	2018 Dec 31
ASSETS			
Fixed assets			
Intangible fixed assets	101.9	108.3	103.9
Tangible fixed assets	21.8	19.5	20.0
Deferred tax assets	60.9	42.6	60.9
Shares in subsidiaries	154.3	151.8	152.3
Total fixed assets	**338.8**	**322.2**	**337.1**
Current assets			
Inventories	124.1	150.5	155.3
Accounts receivable and other receivables	192.0	161.5	166.8
Cash and bank balances	411.2	259.6	303.2
Total current assets	**727.3**	**571.6**	**625.3**
Total assets	**1,066.1**	**893.8**	**962.4**
SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES			
Shareholders' equity	**584.6**	**374.2**	**416.9**
Long-term liabilities			
Other provisions	6.6	5.1	4.9
Bond loan	289.2	320.2	320.6
Total long-term liabilities	**295.8**	**325.3**	**325.5**
Current liabilities			
Accounts payable	14.4	11.5	19.6
Other liabilities	8.2	11.5	25.3
Liabilities to Group companies	145.1	134.8	143.2
Accrued expenses and deferred income	18.1	36.5	32.0
Total current liabilities	**185.7**	**194.3**	**220.1**
Total liabilities	**481.5**	**519.6**	**545.6**
Total shareholders' equity and liabilities	**1,066.1**	**893.8**	**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 Q3 2019 amounted to SEK -0.2 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 Jul-Sep	2019 Jan-Sep
Net revenues	—	—
Cost of goods sold	—	—
Gross profit	**0.0**	**0.0**
Selling expenses	0.1	0.2
Administrative expenses	0.1	0.3
Research and development expenses	0.2	0.7
Other operating income and expenses	—	—
Operating earnings	**0.4**	**1.2**
Net financial items	-0.7	-2.2
Earnings before tax	**-0.3**	**-1.0**
Tax	0.1	0.2
Net earnings for the period	**-0.2**	**-0.8**

2. Cash flow

ADJUSTMENT FOR NON-CASH ITEMS

SEK million	2019 Jul-Sep	2018 Jul-Sep	2019 Jan-Sep	2018 Jan-Sep	2018 Jan-Dec
Depreciation/amortization and impairment	8.2	5.2	26.7	15.5	20.8
Change in provisions	-31.1	-35.9	-6.6	48.9	45.6
Share based payments	-0.8	1.5	3.6	3.0	2.1
Exchange rate income and expenses	-5.3	-0.4	-8.7	-6.3	-6.5
Total	**-29.1**	**-29.6**	**15.0**	**61.1**	**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.

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 September 30, 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

No important events after the period

8. Revenue from contracts with customers

SEK million			2019 Jul-Sep		
Type of revenue	**Zubsolv®**	**Abstral®**	**Edluar®**	**OX-MPI**	**Total**
Sales, products	182.7	—	—	—	**182.7**
Royalties	0.0	42.4	6.1	—	**48.5**
Milestones	—	—	—	0.1	**0.1**
Total revenue from contracts with customers	**182.7**	**42.4**	**6.1**	**0.1**	**231.2**
Geographical markets	**Zubsolv**	**Abstral**	**Edluar**	**OX-MPI**	**Total**
US	182.7	-0.3	2.7	—	**185.0**
EU	0.0	35.3	0.8	0.1	**36.2**
Rest of the world	—	7.4	2.6	—	**10.0**
Total revenue from contracts with customers	**182.7**	**42.4**	**6.1**	**0.1**	**231.2**

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

SEK million			2019 Jan-Sep		
Type of revenue	**Zubsolv**	**Abstral**	**Edluar**	**OX-MPI**	**Total**
Sales, products	528.7	—	—	—	**528.7**
Royalties	0.1	66.3	10.2	—	**76.7**
Milestones	—	—	—	1.4	**1.4**
Total revenue from contracts with customers	**528.8**	**66.3**	**10.2**	**1.4**	**606.7**
Geographical markets	**Zubsolv**	**Abstral**	**Edluar**	**OX-MPI**	**Total**
US	528.7	1.9	4.3	—	**534.9**
EU	0.1	45.7	1.6	1.4	**48.8**
Rest of the world	—	18.7	4.4	—	**23.1**
Total revenue from contracts with customers	**528.8**	**66.3**	**10.2**	**1.4**	**606.7**

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

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

SEK million	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 Jul-Sep	2018 Jul-Sep	2019 Jan-Sep	2018 Jan-Sep	2018 Jan-Dec
EBIT	105.9	34.6	159.7	58.2	95.8
Depreciation and amortization	8.2	5.2	26.6	15.5	20.8
EBITDA	**114.1**	**39.8**	**186.3**	**73.7**	**116.6**
IP litigation costs	-3.0	31.2	48.8	56.4	82.8
EBITDA excluding IP litigation costs	**111.0**	**71.0**	**235.2**	**130.1**	**199.4**

RETURN ON SHAREHOLDERS' EQUITY	2019 Jul-Sep	2018 Jul-Sep	2019 Jan-Sep	2018 Jan-Sep	2018 Jan-Dec
Shareholders' equity beginning balance	552.9	361.3	476.1	329.1	329.1
Shareholders' equity ending balance	671.7	424.4	671.7	424.4	476.1
Average shareholders' equity	612.3	392.8	573.9	376.7	402.6
Net earnings	111.7	62.2	180.3	86.4	137.9
Return on shareholders' equity %	**18.2**	**15.8**	**31.4**	**22.9**	**34.3**

OPERATING EXPENSES SEK million	2019 Jul-Sep	2018 Jul-Sep	2019 Jan-Sep	2018 Jan-Sep	2018 Jan-Dec
Selling expenses	-45.0	-51.5	-141.3	-143.4	-191.4
Administrative expenses	-18.1	-50.8	-112.7	-112.0	-166.7
Research and development costs	-41.6	-37.5	-122.7	-119.8	-166.8
Other operating income and expenses	5.3	0.2	12.3	5.8	9.3
Operating expenses	**-99.4**	**-139.6**	**-364.5**	**-369.4**	**-515.6**

GROSS INVESTMENTS SEK million	2019 Jul-Sep	2018 Jul-Sep	2019 Jan-Sep	2018 Jan-Sep	2018 Jan-Dec
Investments in tangible fixed assets	3.0	0.0	3.8	1.6	2.9
Investments in intangible fixed assets	10.7	0.5	10.7	0.6	0.7
Gross investments	**13.7**	**0.5**	**14.5**	**2.2**	**3.6**

US EBIT SEK million and EBIT margin %	2019 Jul-Sep	2018 Jul-Sep	2019 Jan-Sep	2018 Jan-Sep	2018 Jan-Dec
Consolidated operating earnings	105.9	34.6	159.7	58.2	95.8
Non US related items impacting operating earnings	12.5	-21.0	-93.0	-78.2	-102.5
US EBIT	**93.4**	**55.6**	**252.7**	**136.4**	**198.3**
US EBIT margin %	**51.1**	**33.6**	**47.8**	**30.0**	**31.9**

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 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