Interim Report Q2 2019

Improving all fundamentals

Q2 2019 highlights

- Total net revenues of SEK 201.2 million (199.7), up 0.8 percent and 19.1 percent when excluding ex-US milestone payment of SEK 30.8 million in Q2 2018
- Zubsolv® US net revenues of SEK 184.4 million (158.4), up 16.4 percent in SEK and 6.7 percent in local currency
- EBITDA of SEK 60.4 million (50.6), up 19.4 percent
- US EBIT of SEK 87.5 million (55.5), up 57.6 percent
- Cash flow from operating activities of SEK 46.1 million (39.0), building a cash balance of SEK 697.0 million (494.8)
- Net earnings of SEK 54.6 million (50.1), up 9.0 percent

Important events after the end of the period

- 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 will be prepaid in August 2019

16%
Zubsolv® US net revenues growth in SEK

SEK 55 m
Net earnings

SEK 697 m
Cash and cash equivalents

SEK m, unless otherwise stated	2019 Apr-Jun	2018 Apr-Jun	2019 Jan-Jun	2018 Jan-Jun	12 mth Jul 2018-Jun 2019	12 mth Jul 2017-Jun 2018
Net revenues	201.2	199.7	375.5	339.4	819.2	696.7
whereof Zubsolv® US net revenues	184.4	158.4	346.1	289.5	678.2	537.1
Cost of goods sold	-31.3	-37.6	-56.6	-86.0	-142.4	-168.4
Operating expenses	-117.1	-116.7	-265.1	-229.9	-550.8	-433.7
EBIT	52.8	45.4	53.8	23.5	126.0	94.5
EBIT margin, %	26.2	22.7	14.3	6.9	15.4	13.6
US EBIT	87.5	55.5	159.4	80.8	276.7	132.4
US EBIT margin, %	47.4	35.0	46.1	27.9	40.8	24.6
EBITDA	60.4	50.6	72.3	33.7	155.0	115.2
Earnings per share, before dilution, SEK	1.54	1.45	1.93	0.70	5.1	2.29
Earnings per share, after dilution, SEK	1.51	1.45	1.90	0.70	5.0	2.28
Cash flow from operating activities	46.1	39.0	97.1	144.9	193.3	214.6
Cash and cash equivalents	697.0	494.8	697.0	494.8	697.0	494.8

Unless otherwise stated in this report, all data refers to the Group, and numbers relate to the actual 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-q2-2019
Telephone: SE: +46 8 50 55 8350 UK: +44 33 33 00 9031 US: +1 83 35 26 8380
The presentation material will be available on Orexo´s website prior to the audiocast.

Financial calendar
Interim Report Q3 2019 - October 24 at 8:00 am CET
Full Year Report incl. Q4 2019 - January 30, 2020 at 8:00 am CET
Interim Report Q1 2020 - April 28 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 fundamentals fueling business development and pipeline progress

Following a strong first quarter, I am pleased to report that the second quarter has continued on the same positive trajectory. Zubsolv® remains the core driver of Orexo's strong financial performance and improved profitability. Zubsolv continues to demonstrate resilience to increased competition and with greater profit contribution from our US operations, we remain focused on expanding our pipeline and product portfolio with new assets.

Strengthened financial performance – EBITDA reached SEK 60.4 million
The second quarter of 2019 marks the first quarter in many years where our legal expenses are immaterial, and where the full impact of revenue growth and efficiency improvements are reflected in the financial health of the business. The second quarter has been the strongest financial period for the company to date, when excluding milestone payments. Isolating the financial performance of US operations, the EBIT margin reached 47 percent and contributed to our overall profitability with SEK 87.5 million (USD 9.2 million), a significant improvement of 58 percent in SEK from last year. With a cash position of SEK 697 million, our main focus is to expand our pipeline and to identify commercially attractive assets to drive future growth.

Business development gaining traction
Today, Orexo is in a strong position to engage in partnering and new business activities, thanks to our commercial platform in the US, a profitable business with strong patent protection for Zubsolv, and a solid cash position. We are actively engaged in new business and partnering discussions to ensure the longer-term growth of the business and we are an increasingly attractive partner in the opioid addiction market and its adjacents treatment areas. We are currently in negotiations for the rights to new and existing products. Assuming the negotiations materialize, we would expect to present our first agreement in the second half of 2019.

Development programs making good progress
Our three most advanced internal projects continue to progress as planned. The next significant milestone will be the phase I study of OX338, a sublingual formulation with ketorolac for the treatment of pain, planned for Q4 this year. For OX338, OX124 and OX125 we feel confident in the clinical development risk profile of these programs and continue to work towards realizing their commercial potential. From an external development perspective, we are also pleased to see our partner, Gesynta Pharma AB, progress OX-MPI (microvascular disease) into a phase I clinical trial.

Market Dynamics – Market access is key
The current trend in the addiction market is for payers to provide more product choice to patients. This would benefit Orexo in fast-growing public markets where Zubsolv currently has fewer reimbursement agreements. However, it also poses a risk in the form of greater competition when it comes to signing and keeping exclusive contracts for Zubsolv. We expect United Health Group will start reimbursing generic products later this year, but will also maintain Zubsolv in the current position as a preferred formula with unrestricted reimbursement. We have recently seen a similar change with Humana, where we lost some percentage points in market share, but our sales volumes have remained resilient and we have seen the Zubsolv demand increase by 3 percent since last quarter, despite increased generic competition. This demonstrates our competitive edge when patients and clinicians are aware of the benefits of Zubsolv over generic products.

Summary and outlook
2019 is on track to be Orexo's strongest year to date, both financially and operationally. Zubsolv remains a key driver of growth for the business, while management intend to build on the progress made to ensure the longer-term health of the company. To this end we will continue to expand our pipeline and product portfolio to offer best in class treatment options where they are needed most.

Uppsala, Sweden, July 11, 2019

Nikolaj Sørensen
President and CEO

Financial information

Revenues

Total revenues amounted to SEK 201.2 million (199.7), corresponding to an 0.8 percent increase. When this is adjusted for the Zubsolv ex-US milestone of SEK 30.8 million in Q2 2018, revenues increased by 19.1 percent. The increase was primarily driven by the Zubsolv US growth.

Zubsolv US revenues amounted to SEK 184.4 million (158.4), corresponding to 16.4 percent growth in SEK. In local currency (USD) the equivalent growth rate was 6.7 percent, equal to sales of USD 19.5 million.
When comparing the development to Q2 2018, the growth is negatively impacted by the loss of the exclusive position at Wellcare Medicaid, although the change result in lower rebates offsetting most of the volume decline. Also in Q2 2018 the net sales benefitted from an adjustment from prior periods with SEK 12.2 million.
The main growth driver in local currency was the demand (NTRx) increase of 7.4 percent when excluding WellCare (1 percent increase including WellCare) and the 4 percent price increase from January 1, 2019. The demand was positively affected by increased market access from January 1, 2019, and volume growth on a majority of the other formularies.
Wholesaler inventory levels were increased by USD 0.5 million during the quarter. The SEK/USD exchange rate had a positive impact.

Abstral® royalties amounted to SEK 13.1 million (11.9). The increase was primarily driven by true-up adjustments made to prior period estimates. Royalties for sales in Europe will be received until December 31, 2019, when the European contract with Kyowa Kirin expires.

Royalties from Edluar® amounted to SEK 2.4 million (-1.4).

An OX-MPI milestone of SEK 1.3 million was earned during the quarter.

Costs of goods sold

Cost of goods sold (COGS) amounted to SEK 31.3 million (37.6) for the quarter all 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.

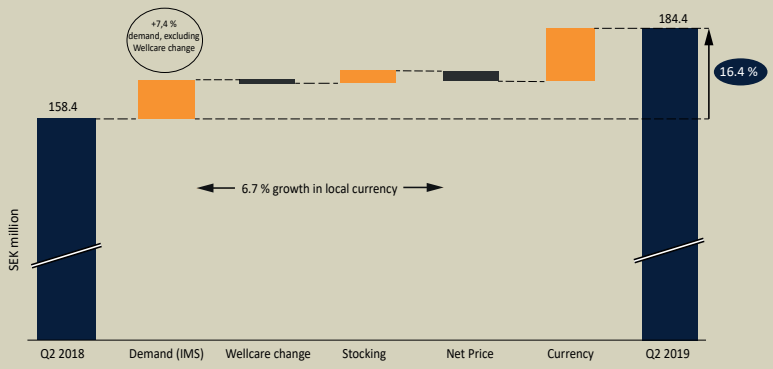
Operating expenses

Selling expenses amounted to SEK 49.0 million (48.6). The minor increase over the same period last year is mainly explained by stronger US currency and higher business development related costs, while savings from internalized sales force contributed positively.

Administrative expenses amounted to SEK 24.5 million (34.0). The decrease versus prior year is explained by lower legal expenses. Legal expenses for IP litigations reached SEK 3.1 million (17.0) for the quarter.

Research and development costs amounted to SEK 43.5 million (37.0). The increase is related to a higher activity level in the R&D pipeline.

ZUBSOLV US NET REVENUE GROWTH BY KEY DRIVERS, Q2 2019 VERSUS Q2 2018[1]



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

Other operating income and expenses amounted to SEK -0.1 million (2.9) mainly explained by exchange-rate losses derived from revaluations of parent company balance sheet items in foreign currency.

Operating profit

Orexo's profitability continued to improve and Orexo reports EBITDA in a quarter with SEK 60.4 million due to growing contribution from the US commercial business.

The EBIT contribution from US commercial business continues to grow, driven by Zubsolv® growth, COGS reductions and operational leverage in the US enabling revenue growth without any material increase in the operational expenses. The US commercial business contributed with an EBIT improvement to SEK 87.5 million (55.5) equal to an EBIT margin of 47.4 percent (35.0). In local currency EBIT amounted to USD 9.2 million (6.4) for Q2 2019.

The US commercial business contributed with an EBIT improvement to SEK 87.5 million (55.5)

Net financial items and tax

Net financial items amounted to SEK 5.7 million (4.0). These items are related to financing activities including interest income/expenses and exchange-rate gains/losses derived from foreign currency bank accounts.
For the quarter the bond loan related costs were more than completely offset by earned interest on bank accounts in the US and by a positive exchange rate impact.

Total tax expenses for the quarter amounted to SEK -3.9 million (0.7). Tax for the quarter was negatively impacted by a SEK 2.4 million adjustment to deferred tax assets related to temporary differences.

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

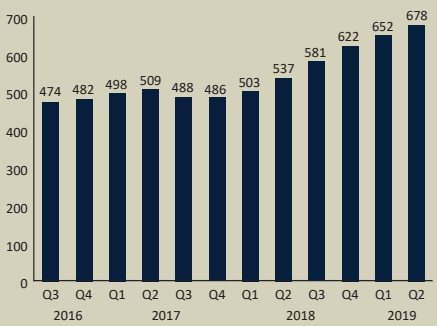
Net earnings

Net earnings amounted to SEK 54.6 million (50.1). IFRS 16 Leases had a negative impact of SEK -0.3 million on net earnings.

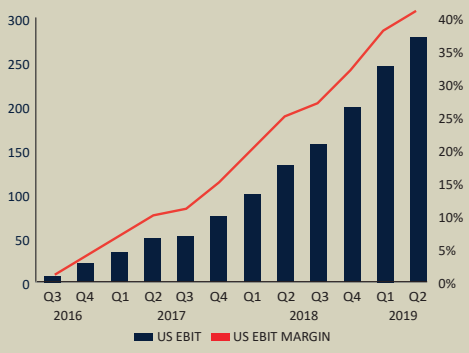
DISTRIBUTION OF TOTAL NET REVENUES

SEK million	2019 Apr-Jun	2018 Apr-Jun	2019 Jan-Jun	2018 Jan-Jun	12 mth Jul 2018-Jun 2019	12 mth Jul 2017-Jun 2018
Zubsolv® US	184.4	158.4	346.1	289.5	678.2	537.1
Zubsolv - ex US	-	30.8	-	30.8	5.4	36.4
Zubsolv – total	**184.4**	**189.2**	**346.1**	**320.3**	**683.6**	**573.5**
Abstral® royalties	13.1	11.9	24.0	17.7	125.1	112.5
Edluar® royalties	2.4	-1.4	4.2	1.4	9.4	10.7
OX-MPI	1.3	-	1.3	-	1.3	-
Total	**201.2**	**199.7**	**375.5**	**339.4**	**819.3**	**696.7**

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



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



[1] LTM, Last Twelve Months

Cash, cash flow and net cash/debt

At June 30, 2019, cash and cash equivalents amounted to SEK 697.0 million (494.8) and interest bearing liabilities to SEK 321.3 million (319.8), i.e. a positive net cash position of SEK 375.7 million. The strong cash position enables Orexo to continue to pursue its strategy to progress the development pipeline and to pursue business development opportunities with the target to add more commercial stage products to the US commercial infrastructure.

Cash flow from operating activities for the quarter amounted to SEK 46.1 million (39.0).

After the end of the period Orexo has communicated that according to the terms of the corporate bond loan Orexo will prepay part of the bond, due to the strong current and expected cash flow, in combination with a weak Swedish krona. The payment amounts to 10 percent of bond and will be paid in August 2019.

Investments

Gross investments in tangible and intangible fixed assets amounted to SEK 0.8 million (1.7).

Equity

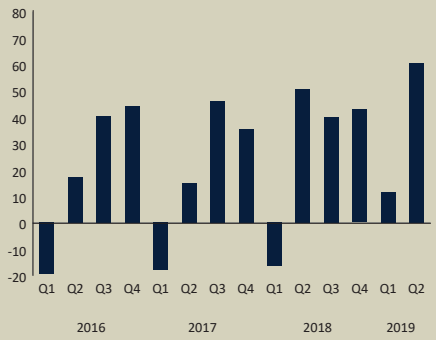
Shareholders' equity at June 30, 2019, was SEK 552.9 million (361.3). The equity/asset ratio was 38.4 percent (30.8).

Parent company

Net revenues amounted to SEK 101.2 million (89.3). Earnings before tax were SEK 41.6 million (25.5). Investments amounted to SEK 0.8 million (1.7). As of June 30, 2019, cash and cash equivalents in the parent company amounted to SEK 391.8 million (241.5).

Cash and cash equivalents amounted to SEK 697.0 million (494.8)

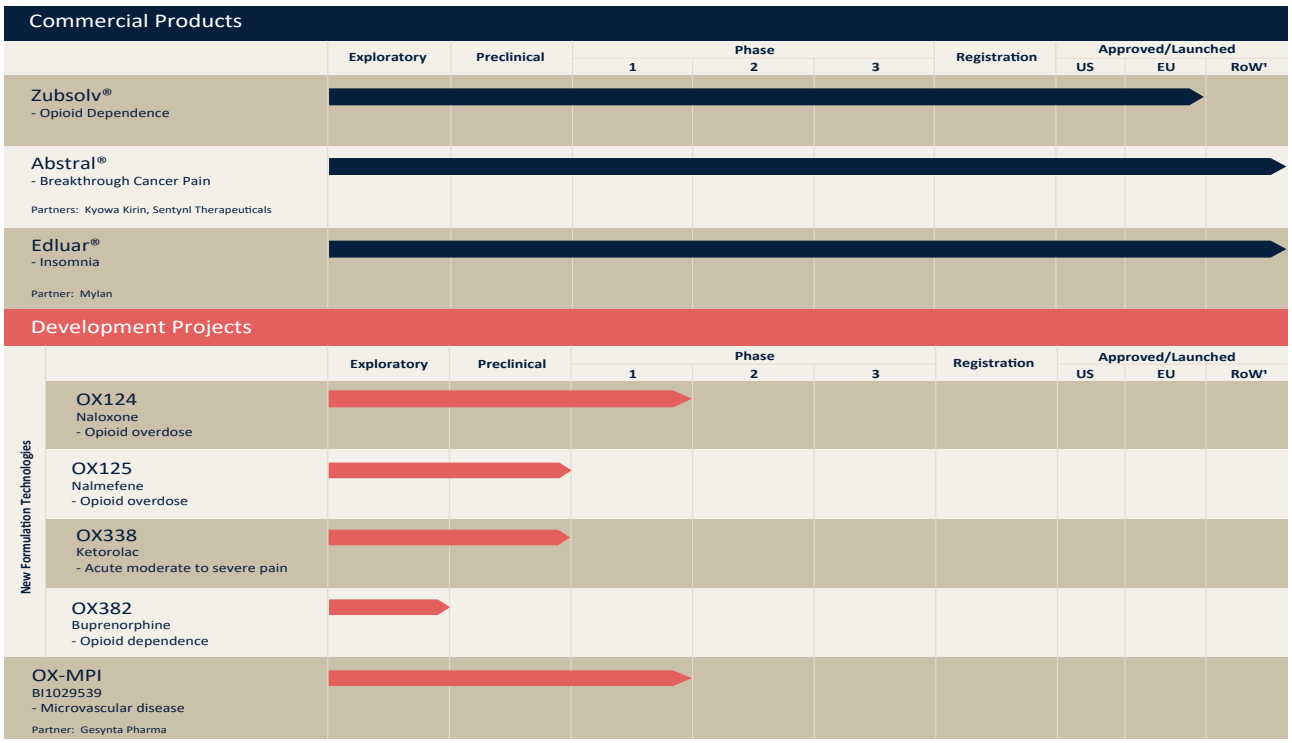
EBITDA, SEK m



CASH FLOW FROM OPERATING ACTIVITIES, SEK m

Operations

PIPELINE OF COMMERCIAL PRODUCTS AND DEVELOPMENT PROJECTS



Commercial products

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

The market demonstrated strong growth of 13 percent in volume compared to Q218, and 7 percent growth over Q119. 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. Five generic versions of buprenorphine/naloxone film have entered the market since February 22, 2019, including an authorized generic from Indivior through Sandoz AG. While the launch of these generics has had a large impact on Suboxone Film market share it has had a limited impact on Zubsolv´s volume to-date demand.

Over 3,400 physicians became newly waivered to accept their first opioid dependence patients this quarter which is the highest number ever recorded. Nurse practitioners and physicians assistants now total over 13,000 waivered to treat opioid dependency, compared to just 6,700 this quarter last year.

New federal legislation will expand the practitioners who can become certified prescribers, which is expected to continue to improve patient access to treatment and expand the market for Zubsolv.

In Q219, Zubsolv volume grew 3 percent over Q119. Zubsolv volume grew 1 percent versus Q218 due to the loss of exclusive access in highly rebated WellCare Medicaid in November 2018. However, as the rebate has been lowered, Zubsolv´s profitability per prescription has increased. Excluding WellCare volume decline, Zubsolv volume grew 7 percent over Q218.

The market forecast is continued volume growth, as the 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

Zubsolv® maintained its best-in-class coverage in the commercial segment at 96 percent coverage and increased generic competition has not had any impact on the access to Zubsolv. The current trend is to provide access to more treatment options for patients and we do expect the generic products can be made accessible with payers where Zubsolv has exclusive access today e.g. United Health Group.

Zubsolv´s Commercial volume grew 5 percent in Q219 compared to Q119, and grew 7 percent compared to Q218. Within Caremark Commercial, Zubsolv grew 8 percent over Q119 and 24 percent over Q218. Zubsolv also grew within Express Scripts Commercial, 5 percent over Q119 and 11 percent over Q218. Both are large, competitive formularies where Zubsolv competes with other buprenorphine/naloxone products.

In the public segment, Zubsolv maintained 38 percent access. Zubsolv has gained access in two additional state Medicaid programs, and Washington DC (as of April 1) and Missouri (as of August 1). Last quarter, Zubsolv gained access in the state Medicaid programs of Ohio, Texas, Florida and Alabama. Within those states, Zubsolv has grown volume 66 percent in Q219 versus Q119, with 78 percent growth in Florida, 73 percent growth in Ohio, 48 percent growth in Alabama, and 26 percent growth in Texas. Zubsolv continues to grow in states where it has had long time access as well, with 16 percent growth versus Q119 in Michigan Medicaid, Zubsolv's second largest Medicaid volume state.

Over Q119 Zubsolv grew 3 percent in the overall public segment and declined 2 percent versus Q218. Excluding Wellcare, Zubsolv would have grown 6 percent in the segment versus Q119 and 19 percent versus Q218. Starting in Q2, generic film has access to the highly rebated Humana Medicare Part D where Zubsolv has been an exclusive product, creating an opportunity for higher profitability due to lower rebates and to date the volume impact on Zubsolv has been insignificant from the increased competition.

Initial additional states have indicated Zubsolv is likely to become accessible in 2020, but have not yet finalized the formulary for next year, with the exception of Colorado Medicaid which has confirmed Zubsolv access in 2020.

Zubsolv in geographies outside the United States – opioid dependence

Orexo is in advanced negotiations with potential new partners who are interested in commercializing Zubsolv in the EU, after the termination of the agreement with Mundipharma for the ex-US rights. In parallel, Orexo has been working intensively to establish a streamlined supply chain outside the US as low cost of goods will be essential in response to the price pressure characterizing the EU market.

After the end of the period 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 the first half of 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]

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 optimization of the new nasal formulation has continued and the preparations for the pivotal pharmacokinetic bridging study in 2020 are on-going.

After the end of the period 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.

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 last quarter from the human pharmacokinetic study for OX124 the formulation development for OX125 has accelerated and preparations for conducting the first human pharmacokinetic study in 2020 are on-going.

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:
Formulation development has continued and preparations to conduct the first human pharmacokinetic study in the second half of 2019 are on-going.

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 last quarter did not support progressing the current formulation into clinical phase. Options for continued development, assessing other formulation options, are on-going.

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 project is progressing according to plan and preparations were made to initiate phase 1 clinical trials that was initiated in beginning of July 2019. Assuming further successful development phase II clinical trials are planned to be conduced next year.

Other information

Outlook 2019

• For 2019 Orexo expects to improve the positive EBITDA on a full year basis
• Orexo believes that the overall volume of Zubsolv® sales in the US in 2019 will increase, despite increased competition from Suboxone® Film generics. However we do expect that a launch of corresponding generics will increase market risk and uncertainty but also offer opportunities.
• 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 (June 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, July 11, 2019
Orexo AB (publ.)

Nikolaj Sørensen
President and CEO

Assurance by the Board of Directors

The Board of Directors and the CEO give their assurance that the six-month report provides a fair and accurate view of the Company´s and the Group´s operations, financial positions and earnings and describes the significant risk and uncertainties facing the company and the companies included in the group.

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

Uppsala, Sweden, July 11, 2019
Orexo AB (publ)

Martin Nicklasson Chairman of the Board	Henrik Kjaer Hansen Board member	Staffan Lindstrand Board member
Kristina Schauman Board member	Kirsten Detrick Board member	David Coplman Board member
Mary-Pat Christie Board member	Fred Wilkinson Board member	Nikolaj Sørensen President & CEO

Financial reports, notes and key figures

CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS

SEK million	Notes	2019 Apr-Jun	2018 Apr-Jun	2019 Jan-Jun	2018 Jan-Jun	2018 Jan-Dec
Net revenues	6	201.2	199.7	375.5	339.4	783.1
Cost of goods sold		-31.3	-37.6	-56.6	-86.0	-171.8
Gross profit		**169.9**	**162.1**	**318.9**	**253.4**	**611.4**
Selling expenses		-49.0	-48.6	-96.3	-92.0	-191.4
Administrative expenses		-24.5	-34.0	-94.6	-61.2	-166.7
Research and development expenses		-43.5	-37.0	-81.2	-82.4	-166.8
Other operating income and expenses		-0.1	2.9	6.9	5.7	9.3
Operating earnings		**52.8**	**45.4**	**53.8**	**23.5**	**95.8**
Net financial items		5.7	4.0	10.5	1.0	-3.6
Earnings before tax		**58.5**	**49.4**	**64.3**	**24.5**	**92.2**
Tax	4	-3.9	0.7	4.3	-0.4	45.7
Net earnings for the period[1]		**54.6**	**50.1**	**68.6**	**24.1**	**137.9**

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

SEK million	2019 Apr-Jun	2018 Apr-Jun	2019 Jan-Jun	2018 Jan-Jun	2018 Jan-Dec
Earnings for the period	**54.6**	**50.1**	**68.6**	**24.1**	**137.9**
Other comprehensive income					
Items that may subsequently be reversed to the statement of operations:					
Exchange-rate differences	0.5	5.3	3.7	6.5	7.0
Other comprehensive earnings for the period, net after tax	**0.5**	**5.3**	**3.7**	**6.5**	**7.0**
Total comprehensive earnings for the period[1]	**55.1**	**55.4**	**72.3**	**30.6**	**144.9**
Earnings per share, before dilution, SEK	1.54	1.45	1.93	0.70	3.99
Earnings per share, after dilution, SEK	1.51	1.45	1.90	0.70	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 Jun 30	2018 Jun 30	2018 Dec 31
ASSETS			
Fixed assets			
Tangible fixed assets	19.4	20.3	20.0
Intangible fixed assets	95.5	112.1	103.9
Right-of-use assets	65.5	—	—
Deferred tax assets	110.2	35.5	92.8
Other financial assets	10.8	7.8	10.4
Total fixed assets	**301.4**	**175.7**	**227.2**
Current assets			
Inventories	150.6	194.2	173.6
Accounts receivable and other receivables	291.1	308.8	296.1
Cash and cash equivalents	697.0	494.8	589.8
Total current assets	**1,138.7**	**997.8**	**1,059.5**
Total assets	**1,440.1**	**1,173.5**	**1,286.7**
SHAREHOLDERS' EQUITY AND LIABILITIES			
Total shareholders' equity	**552.9**	**361.3**	**476.1**
Long-term liabilities			
Provisions	7.8	3.9	6.5
Long-term liabilities, interest bearing	321.3	319.8	320.6
Lease liabilities, long-term	42.0	—	—
Total long-term liabilities	**371.2**	**323.7**	**327.1**
Current liabilities and provisions			
Provisions	298.4	307.9	265.8
Current liabilities, non-interest bearing	196.9	180.6	217.6
Lease liabilities, current	20.8	—	—
Total current liabilities and provisions	**516.0**	**488.5**	**483.4**
Total liabilities	**887.2**	**812.2**	**810.5**
Total shareholders' equity and liabilities	**1,440.1**	**1,173.5**	**1,286.7**

CONSOLIDATED CHANGES IN SHAREHOLDERS' EQUITY

SEK million	2019 Jun 30	2018 Jun 30	2018 Dec 31
Opening balance, shareholders' equity	**476.1**	**329.1**	**329.1**
Total comprehensive earnings for the period	72.3	30.6	144.9
Share-based payments	4.4	1.5	2.1
Buy back of shares	—	—	—
New share issue	0.0	0.1	0.1
Closing balance, shareholders' equity	**552.9**	**361.3**	**476.1**

CONDENSED CONSOLIDATED CASH FLOW STATEMENTS

SEK million		2019 Apr-Jun	2018 Apr-Jun	2019 Jan-Jun	2018 Jan-Jun	2018 Jan-Dec
Operating earnings		52.7	45.4	53.8	23.5	95.8
Interest received		2.6	—	4.7	—	3.1
Interest paid		-3.6	-6.0	-7.4	-13.1	-14.8
Income taxes paid		-9.2	—	-9.2	—	-18.1
Adjustment for non-cash items	2	21.2	30.0	44.1	90.7	61.9
Cash flow from operating activities before changes in working capital		**63.8**	**69.4**	**86.1**	**101.1**	**127.9**
Changes in working capital		**-17.6**	**-30.4**	**11.0**	**43.8**	**114.1**
Cash flow from operating activities		**46.1**	**39.0**	**97.1**	**144.9**	**242.0**
Acquisition of tangible and intangible fixed assets		-0.8	-1.7	-0.8	-1.7	-3.6
Acquisition of financial assets		—	—	—	—	-2.5
Cash flow from investing activities		**-0.8**	**-1.7**	**-0.8**	**-1.7**	**-6.2**
New share issue		0.0	0.1	0.0	0.1	0.1
Buy back shares		0.0	—	0.0	—	-0.1
Repayment of loans		-3.8	0.4	-14.5	0.8	—
Cash from financing activities		**-3.8**	**0.5**	**-14.5**	**0.9**	**0.0**
Cash flow for the period		**41.6**	**37.8**	**81.7**	**144.1**	**235.8**
Cash and cash equivalents at the beginning of the period		**647.4**	**437.5**	**589.8**	**327.9**	**327.9**
Exchange-rate differences in cash and cash equivalents		8.1	19.5	25.5	22.8	26.1
Changes in cash and cash equivalents		49.7	57.3	107.2	166.9	261.9
Cash and cash equivalents at the end of the period		**697.0**	**494.8**	**697.0**	**494.8**	**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 Apr-Jun	2018 Apr-Jun	2019 Jan-Jun	2018 Jan-Jun	2018 Jan-Dec
EBIT margin, %	26.2	22.7	14.3	6.9	12.2
Return on shareholder equity, %	10.4	15.0	13.3	7.0	34.3
Net debt, SEK million	-375.7	-175.0	-375.7	-175.0	-269.2
Debt/equity ratio, %	58.1	88.5	58.1	88.5	67.3
Equity/assets ratio, %	38.4	30.8	38.4	30.8	37.0
Number of shares, before dilution	35,498,310	34,560,456	35,498,310	34,560,456	34,560,456
Number of shares, after dilution	36,153,872	34,619,261	36,153,872	34,619,261	35,095,980
Earnings per share, before dilution, SEK	1.54	1.45	1.93	0.70	3.99
Earnings per share, after dilution, SEK	1.51	1.45	1.90	0.70	3.93
Number of employees at the end of the period	130	89	130	89	129
Shareholders' equity, SEK million	552.9	361.3	552.9	361.3	476.1
Capital employed, SEK million	874.3	681.1	874.3	681.1	796.7
Working capital, SEK million	-74.4	14.5	-74.4	14.5	-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 Apr-Jun	2018 Apr-Jun	2019 Jan-Jun	2018 Jan-Jun	2018 Jan-Dec
Net revenues		101.2	89.3	218.0	147.9	407.6
Cost of goods sold		-23.0	-24.9	-50.3	-50.7	-116.2
Gross profit		**78.2**	**64.4**	**167.7**	**97.2**	**291.4**
Selling expenses		-2.1	11.0	-5.0	10.3	-10.3
Administrative expenses		-16.4	-27.2	-78.9	-46.9	-135.2
Research and development costs		-36.1	-29.5	-66.5	-68.5	-138.3
Other operating income and expenses		13.5	2.9	35.6	5.7	50.6
Operating earnings		**37.0**	**21.6**	**52.8**	**-2.2**	**58.1**
Interest income and expenses		-2.9	-3.7	-6.3	-7.3	-14.4
Other financial income and expenses		7.5	7.5	14.7	8.3	8.2
Net financial items		**4.6**	**3.9**	**8.4**	**1.0**	**-6.1**
Earnings before tax		**41.6**	**25.5**	**61.2**	**-1.2**	**52.0**
Tax	4	0.0	1.9	0.0	1.9	53.3
Earnings for the period		**41.6**	**27.4**	**61.2**	**0.7**	**105.3**

PARENT COMPANY STATEMENT OF COMPREHENSIVE INCOME

SEK million	2019 Apr-Jun	2018 Apr-Jun	2019 Jan-Jun	2018 Jan-Jun	2018 Jan-Dec
Earnings for the period	**41.6**	**27.4**	**61.2**	**0.7**	**105.3**
Other comprehensive income	—	—	—	—	—
Total comprehensive earnings for the period	**41.6**	**27.4**	**61.2**	**0.7**	**105.3**

CONDENSED PARENT COMPANY BALANCE SHEET

SEK million	2019 Jun 30	2018 Jun 30	2018 Dec 31
ASSETS			
Fixed assets			
Intangible fixed assets	95.5	112.1	103.9
Tangible fixed assets	19.4	29.7	20.0
Deferred tax assets	60.9	—	60.9
Shares in subsidiaries	153.4	151.0	152.3
Total fixed assets	**329.2**	**292.8**	**337.1**
Current assets			
Inventories	133.7	158.7	155.3
Accounts receivable and other receivables	135.3	133.6	166.8
Cash and bank balances	391.8	241.5	303.2
Total current assets	**660.8**	**533.8**	**625.3**
Total assets	**990.0**	**826.6**	**962.4**
SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES			
Shareholders' equity	**482.7**	**311.8**	**416.9**
Long-term liabilities			
Other provisions	5.5	3.5	4.9
Bond loan	321.3	319.8	320.6
Total long-term liabilities	**326.8**	**323.3**	**325.5**
Current liabilities			
Accounts payable	12.1	16.7	19.6
Other liabilities	7.0	11.2	25.3
Liabilities to Group companies	137.6	140.3	143.2
Accrued expenses and deferred income	23.8	23.3	32.0
Total current liabilities	**180.5**	**191.5**	**220.1**
Total liabilities	**507.3**	**514.8**	**545.6**
Total shareholders' equity and liabilities	**990.0**	**826.6**	**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.

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 divide up the cost into 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 Q2 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**

SEK million	2019 Apr-Jun	2019 Jan-Jun
Net revenues	—	—
Cost of goods sold	—	—
Gross profit	**0.0**	**0.0**
Selling expenses	0.1	0.1
Administrative expenses	0.1	0.2
Research and development expenses	0.2	0.5
Other operating income and expenses	—	—
Operating earnings	**0.4**	**0.8**
Net financial items	-0.7	-1.5
Earnings before tax	**-0.3**	**-0.7**
Tax	0.1	0.1
Net earnings for the period	**-0.3**	**-0.6**

2. Cash flow

ADJUSTMENT FOR NON-CASH ITEMS

SEK million	2019 Apr-Jun	2018 Apr-Jun	2019 Jan-Jun	2018 Jan-Jun	2018 Jan-Dec
Depreciation/amortization and impairment	7.6	5.2	18.5	10.3	20.8
Change in provisions	12.1	27.5	24.6	84.7	45.6
Share based payments	1.3	0.4	4.4	1.5	2.1
Exchange rate income and expenses	0.1	-3.1	-3.4	-5.8	-6.5
Total	**21.2**	**30.0**	**44.1**	**90.7**	**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. During the quarter 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 June 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

- 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 will be prepaid in August 2019

8. Revenue from contracts with customers

SEK million			2019 Apr-Jun		
Type of revenue	**Zubsolv®**	**Abstral®**	**Edluar®**	**OX-MPI**	**Total**
Sales, products	184.4	—	—	—	**184.4**
Royalties	—	13.1	2.4	—	**15.5**
Milestones	—	—	—	1.3	**1.3**
Total revenue from contracts with customers	**184.4**	**13.1**	**2.4**	**1.3**	**201.2**
Geographical markets	**Zubsolv**	**Abstral**	**Edluar**	**OX-MPI**	**Total**
US	184.4	1.0	1.2	—	**186.6**
EU	—	4.5	0.3	1.3	**6.0**
Rest of the world	—	7.6	1.0	—	**8.6**
Total revenue from contracts with customers	**184.4**	**13.1**	**2.4**	**1.3**	**201.2**

SEK million			2018 Apr-Jun		
Type of revenue	**Zubsolv**	**Abstral**	**Edluar**	**OX-MPI**	**Total**
Sales, products	158.4	—	—	—	**158.4**
Royalties	—	11.9	-1.4	—	**10.5**
Milestones	30.8	—	—	—	**30.8**
Total revenue from contracts with customers	**189.2**	**11.9**	**-1.4**	**0.0**	**199.7**
Geographical markets	**Zubsolv**	**Abstral**	**Edluar**	**OX-MPI**	**Total**
US	158.4	1.3	-2.0	—	**157.6**
EU	30.8	5.1	0.3	—	**36.2**
Rest of the world	—	5.5	0.3	—	**5.8**
Total revenue from contracts with customers	**189.2**	**11.9**	**-1.4**	**0.0**	199.7

SEK million			2019 Jan-Jun		
Type of revenue	**Zubsolv**	**Abstral**	**Edluar**	**OX-MPI**	**Total**
Sales, products	346.1	—	—	—	**346.1**
Royalties	—	24.0	4.2	—	**28.1**
Milestones	—	—	—	1.3	**1.3**
Total revenue from contracts with customers	**346.1**	**24.0**	**4.2**	**1.3**	**375.5**
Geographical markets	**Zubsolv**	**Abstral**	**Edluar**	**OX-MPI**	**Total**
US	346.1	2.3	1.6	—	**349.8**
EU	—	10.4	0.8	1.3	**12.5**
Rest of the world	—	11.3	1.8	—	**13.1**
Total revenue from contracts with customers	**346.1**	**24.0**	**4.2**	**1.3**	**375.5**

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

SEK million	2018 Jan-Jun				
Type of revenue	**Zubsolv®**	**Abstral®**	**Edluar®**	**OX-MPI**	**Total**
Sales, products	289.5	—	—	—	**289.5**
Royalties	—	17.7	1.4	—	**19.1**
Milestones	30.8	—	—	—	**30.8**
Total revenue from contracts with customers	**320.3**	**17.7**	**1.4**	**0.0**	**339.4**
Geographical markets	**Zubsolv**	**Abstral**	**Edluar**	**OX-MPI**	**Total**
US	289.5	2.8	-1.3	—	**291.0**
EU	30.8	3.9	0.7	—	**35.4**
Rest of the world	—	11.0	2.0	—	**13.0**
Total revenue from contracts with customers	**320.3**	**17.7**	**1.4**	**0.0**	**339.4**

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 Apr-Jun	2018 Apr-Jun	2019 Jan-Jun	2018 Jan-Jun	2018 Jan-Dec
EBIT	52.8	45.4	53.8	23.5	95.8
Depreciation and amortization	7.6	5.2	18.5	10.3	20.8
EBITDA	**60.4**	**50.6**	**72.3**	**33.7**	**116.6**
IP litigation costs	3.1	17.0	51.8	25.2	82.8
EBITDA excluding IP litigation costs	**63.5**	**67.6**	**124.1**	**58.9**	**199.4**

RETURN ON SHAREHOLDERS' EQUITY	2019 Apr-Jun	2018 Apr-Jun	2019 Jan-Jun	2018 Jan-Jun	2018 Jan-Dec
Shareholders' equity beginning balance	496.6	305.4	476.1	329.1	329.1
Shareholders' equity ending balance	552.9	361.3	552.9	361.3	476.1
Average shareholders' equity	524.8	333.3	514.5	345.2	402.6
Net earnings	54.6	50.1	68.6	24.1	137.9
Return on shareholders' equity %	**10.4**	**15.0**	**13.3**	**7.0**	**34.3**

OPERATING EXPENSES SEK million	2019 Apr-Jun	2018 Apr-Jun	2019 Jan-Jun	2018 Jan-Jun	2018 Jan-Dec
Selling expenses	-49.0	-48.6	-96.3	-92.0	-191.4
Administrative expenses	-24.5	-34.0	-94.6	-61.2	-166.7
Research and development costs	-43.5	-37.0	-81.2	-82.4	-166.8
Other operating income and expenses	-0.1	2.9	6.9	5.7	9.3
Operating expenses	**-117.1**	**-116.7**	**-265.1**	**-229.9**	**-515.6**

GROSS INVESTMENTS SEK million	2019 Apr-Jun	2018 Apr-Jun	2019 Jan-Jun	2018 Jan-Jun	2018 Jan-Dec
Investments in tangible fixed assets	0.7	1.7	0.7	1.7	2.9
Investments in intangible fixed assets	0.1	0.0	0.1	0.0	0.7
Gross investments	**0.8**	**1.7**	**0.8**	**1.7**	**3.6**

US EBIT SEK million and EBIT margin %	2019 Apr-Jun	2018 Apr-Jun	2019 Jan-Jun	2018 Jan-Jun	2018 Jan-Dec
Consolidated operating earnings	52.8	45.4	53.8	23.5	95.8
Non US related items impacting operating earnings	-34.7	-10.1	-105.6	-57.3	-102.5
US EBIT	**87.5**	**55.5**	**159.4**	**80.8**	**198.3**
US EBIT margin %	**47.4**	**35.0**	**46.1**	**27.9**	**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