

Interim Report Q1 2018

# Zubsolv<sup>®</sup> US growth of 26 percent in local currency

## Q1 2018 highlights

- › Total net revenues of SEK 139.7 million, up 9.7 percent from Q1 previous year

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- › Zubsolv US net revenue of SEK 131.1 million, up 14.9 percent in SEK and 26.2 percent in local currency compared to the same period last year

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- › EBITDA of SEK -16.6 million, in line with guidance

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- › Cash flow from operating activities of SEK 106.0 million, building a cash balance of SEK 437.5 million

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- › Pipeline update, two more projects disclosed

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- › Earnings per share, before dilution SEK -0.75 (-1.00), earnings per share after dilution SEK -0.75 (-1.00)

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SEK million, if nothing else is mentioned	2018 Jan-Mar	2017 Jan-Mar	12 mth Apr 2017 - Mar 2018	12 mth Apr 2016 - Mar 2017
Net revenues	139.7	127.4	656.0	682.3
wherof Zubsolv <sup>®</sup> US net revenue	131.1	114.1	502.8	497.5
Cost of goods sold	-48.4	-46.2	-166.6	-163.3
Operating expenses	-113.1	-104.4	-430.6	-464.3
EBIT	-21.8	-23.2	58.8	54.7
EBIT margin, %	-15.6	-18.2	9.0	8.0
EBITDA	-16.6	-18.1	79.7	74.4
Earnings per share, before dilution, SEK	-0.75	-1.00	0.92	0.84
Earnings per share, after dilution, SEK	-0.75	-1.00	0.92	0.84
Cash flow from operating activities	106.0	28.2	224.4	150.9
Cash and cash equivalents	437.5	250.6	437.5	250.6

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

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## About Orexo

Orexo develops improved pharmaceuticals based on innovative drug delivery technologies. The focus is primarily on opioid dependence and pain but the aim is to address therapeutic areas where our competence and technologies can create value. The products are commercialized by Orexo in the US or via selected partners worldwide. The main market today is the American market for buprenorphine/naloxone products, where Orexo sells the product Zubsolv®. Total net sales for 2017 amounted to SEK 643.7 million and the number of employees at year-end was 90. Orexo is listed on the Nasdaq Stockholm Mid Cap (ORX) and is available as ADRs on OTCQX (ORXOY) in the US. The head office, where research and development is also performed, is situated in Uppsala, Sweden.



### For further information, please contact

Nikolaj Sørensen, CEO and President or Henrik Juuel, EVP and CFO  
Tel: +46 18 780 88 00. Email: [ir@orexo.com](mailto:ir@orexo.com)

### Presentation

At 3.00 pm CET, the same day as the announcement of the report, Orexo invites analysts, investors and media to attend an audiocast with a web presentation where Nikolaj Sørensen, CEO, and Henrik Juuel, CFO, will present the report. After the presentation a Q&A will be held. Questions can also be sent in advance to [ir@orexo.com](mailto: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-q1-2018>

Telephone: (SE) +46 856 642 664 (UK) +44 203 008 9802 (US) +1 855 753 2235.

The presentation material will be available on Orexo's website one hour prior to the audiocast.

### Financial calendar

Interim Report Q2 2018 - July 11, 2018 at 8.00 am CET

Interim Report Q3 2018 - October 25, 2018 at 8.00 am CET

### For more information about Orexo

Please visit, [www.orexo.com](http://www.orexo.com). You can also follow Orexo on Twitter, @orexoabpubl, LinkedIn and YouTube.

For more information about Zubsolv in the US, see the product and market websites [www.zubsolv.com](http://www.zubsolv.com) and [www.rise-us.com](http://www.rise-us.com).



# Promising start for 2018



"With confidence in our financial position we continue to invest in broadening our pipeline and to pursue new business development opportunities."

Photo: Mats Lundgren

As I have indicated previously, the improved US market access delivered strong growth and Zubsolv® broke its volume record and delivered a revenue growth of 26 percent in local currency. We also generated new early-stage projects leading to an update of our development pipeline. The financial position continued to improve, fueled by yet another strong cash-generating quarter.

Since we received confirmation of our improved market access position in the US from January 2018, I have had high expectations of Zubsolv sales growth in the first quarter of 2018. The main driver has been the new exclusive contracts implemented during the quarter. However, I am also encouraged by the growth seen in the competitive non-exclusive segments of the business. Our new preferred position with CVS Caremark has been a key contributor, despite the intense competition from other branded and generic products with similar preferred status. In the overall market, Zubsolv was the only branded product to gain market share in the quarter.

Building on the strong financial result in 2017, we continue to strengthen our financial position. I am pleased that our net cash improved by more than SEK 100 million during the quarter. The positive cash flow is explained by positive contributions from working capital. A key target for the company is to improve the profit contribution from our core business i.e. Zubsolv in the US. Adjusting for the expenses involved in setting up our new supply chain, which will generate an expected improvement in the cost of goods, and applying future expected cost of goods, we would have been profitable this quarter. Hence, I expect this investment to positively impact the profitability in the second half of 2018 and beyond, further reinforcing our expectations of a positive EBITDA for the full year. With confidence in our financial position we continue to invest in broadening our pipeline and to pursue new business development opportunities.

The focused work of developing and expanding our pipeline in recent years has started to show results. Based on positive in vitro data, we have decided to progress another early-stage project to the clinical stage. The new project is a naloxone rescue medication, with the aim of having superior attributes compared to products available today on the market or in development. Finally, we have also identified an opportunity to develop a new NSAID formulation which might have the potential to replace opioids for acute treatment of moderate to severe pain. These are early development programs and although there is need for more work, I am pleased that we now can report an expanded development pipeline.

Regarding OX382, where we aim to develop a swallowable formulation of buprenorphine, we conducted our first clinical trial in humans. We have just received the results and we will need to continue the pharmaceutical formulation work before we can progress this project further.

Due to the high activity in our pipeline and due to priority reasons we have decided to park the OX51 project. Hence it will not be disclosed in our pipeline overview after this report.

The business has started positively in 2018 and we will continue to focus all our attention on improving business performance even further, which makes me excited about Orexo's future prospects.

Uppsala, Sweden, April 26, 2018

Nikolaj Sørensen  
President and CEO

# Financial information

## Revenues

Total revenues for the quarter amounted to SEK 139.7 million (127.4) corresponding to a 9.7 percent increase over the same period the previous year. The increase was driven by strong Zubsolv® growth reaching nearly 15 percent in SEK and 26 percent in local currency.

### Commercial products

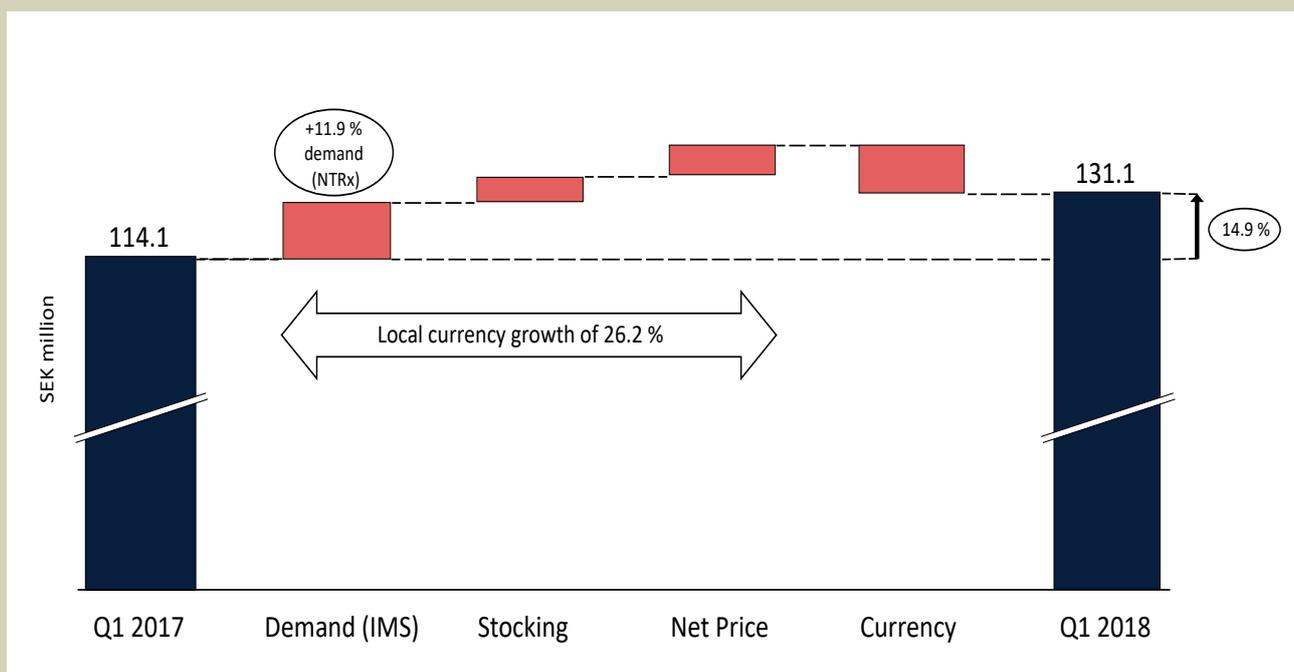
Zubsolv US revenues amounted to SEK 131.1 million (114.1) for the quarter, corresponding to 14.9 percent growth. In local currency (USD) the equivalent growth rate was 26.2 percent equal to sales of USD 16.1 million in Q1. The key growth factor was the increased demand driven by improved market access from January 1, 2018. The increased demand also drove increased wholesaler stocking, which contributed to the overall growth. A price increase of approximately 6 percent from January 1, 2018, contributed positively to the net price that was otherwise negatively impacted by higher rebates following the new exclusive agreements.

Abstral® revenues amounted to SEK 5.8 million (8.7) for the quarter. The lower level compared with previous year is mainly explained by true-up adjustments made to prior period estimates.

Revenues from Edluar® amounted to SEK 2.8 million (4.6) for the quarter and included a correction to prior periods reported by our partner Mylan.

The key growth factor was the increased demand driven by improved market access from January 1, 2018

ZUBSOLV® US NET REVENUE GROWTH BY KEY DRIVERS, Q1 2018 VERSUS Q1 2017<sup>1)</sup>



<sup>1)</sup> Orexo analysis using IMS demand data

### Development projects

There were no revenues from development projects during the quarter. The period April 2017 to March 2018, includes a milestone payment from AstraZeneca relating to the OX-CLI project of USD 2.5 million (SEK 21.8 million) that was triggered by the project entering clinical phase I trials. This project has now, as earlier communicated, been terminated by AstraZeneca and Orexo has decided not to take the project back. There are no financial implications of the termination. The period April 2016 to March 2017 includes an upfront payment of EUR 7 million (SEK 65.9 million) from Mundipharma who acquired the rights to Zubsolv outside the US.

### Costs and earnings

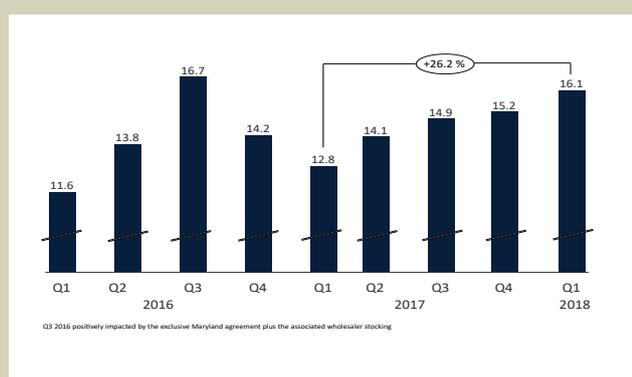
#### Cost of goods sold

Cost of goods sold (COGS) amounted to SEK 48.4 million (46.2) for the quarter and all relates to Zubsolv in the US market. Relatively expensive batches were sold during the quarter and caused a relatively low Zubsolv US gross margin. The manufacturing efficiency program aimed to reduce COGS is still expected to start having effect from second half year 2018.

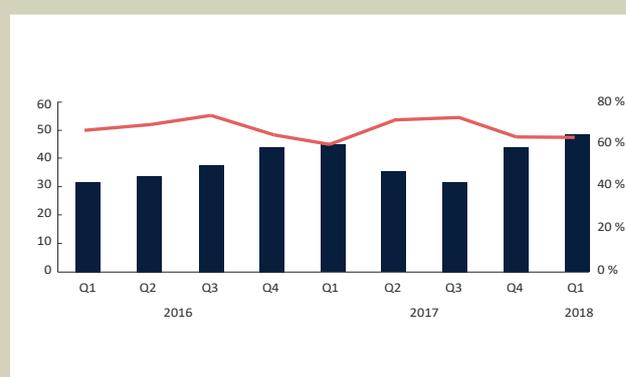
#### DISTRIBUTION OF TOTAL NET REVENUES

SEK million	2018 Jan-Mar	2017 Jan-Mar	12 mth Apr 2017 - Mar 2018	12 mth Apr 2016- Mar 2017
Zubsolv® US	131.1	114.1	502.8	497.5
Zubsolv – Rest of the World	—	—	5.6	65.9
<b>Zubsolv – total</b>	<b>131.1</b>	<b>114.1</b>	<b>508.4</b>	<b>563.4</b>
Abstral® royalties	5.8	8.7	110.3	100.9
Milestone payment Abstral	—	—	—	2.2
<b>Abstral – total</b>	<b>5.8</b>	<b>8.7</b>	<b>110.3</b>	<b>103.1</b>
Eduvar® royalties	2.8	4.6	15.5	15.8
OX-CLI	—	—	21.8	—
<b>Total</b>	<b>139.7</b>	<b>127.4</b>	<b>656.0</b>	<b>682.3</b>

ZUBSOLV US NET REVENUES, MUSD



COST OF GOODS SOLD, MSEK, & ZUBSOLV US GROSS PROFIT MARGIN, %



**Selling expenses**

Selling expenses amounted to SEK 43.3 million (48.3). A continued highly targeted investment strategy together with a lower SEK/USD exchange rate explains the lower expense level in 2018 compared with previous year.

**Administrative expenses**

Administrative expenses for the quarter amounted to SEK 27.2 million (26.3). Approximately SEK 8 million legal expenses related to IP litigations were included and this was slightly above last year's level.

**Research and development costs**

In Q1 2018, research and development costs amounted to SEK 45.3 million (30.3). Main projects consuming resources were the manufacturing efficiency program, OX382 and other early stage projects.

**Costs for long-term incentive program**

The Group's total costs for employee share-based payment programs during Q1 2018 amounted to SEK 1.1 million (-0.9).

**Other income and expenses**

Other operating income and expenses amounted to SEK 2.7 million (0.5) for Q1 2018. This comprises exchange-rate gains/losses derived from revaluations of operating receivables and payables in foreign currency and income/expenses from activities other than normal business operations.

**Depreciation and amortization**

Depreciation and amortization amounted to SEK 5.2 million (5.1) for the quarter.

**Net financial items**

Net financial items for the quarter amounted to SEK -3.0 million (-6.6). These items are related to financing activities including exchange-rate gains/losses derived from foreign currency bank accounts.

**Tax**

Total tax expenses for the quarter amounted to SEK -1.1 million (-4.8).

**Net earnings**

Net earnings amounted to SEK -25.9 million (-34.6) for the quarter.

**Cash flow and financial position**

At March 31 2018, cash and cash equivalents amounted to SEK 437.5 million (250.6) and interest bearing liabilities to SEK 319.5 million (339.4).

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 106.0 million (28.2) and was driven by increased provisions for US payer rebates, decreased inventory levels and decreased receivables. The increased provisions for US payer rebates was caused by the significant Zubsolv® US revenue growth with associated rebates being paid in future quarters.

Shareholders' equity at March 31, 2018, was SEK 305.4 million (273.3). The equity/asset ratio was 29.5 percent (29.2).

**Investments in fixed assets**

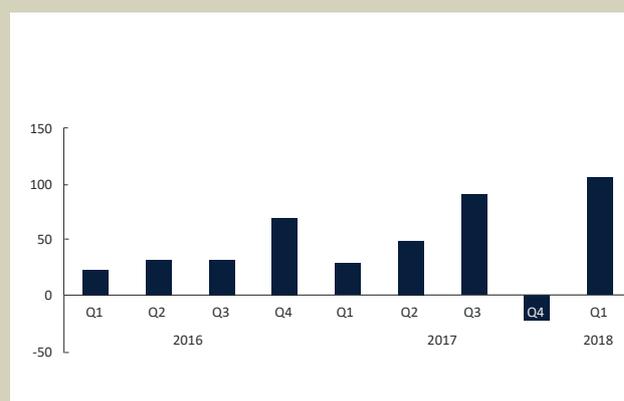
Gross investments in tangible and intangible fixed assets amounted to SEK 0.0 million (0.4) for Q1 2018.

## Cash flow from operating activities for the quarter amounted to SEK 106 million

EBITDA, MSEK



CASH FLOW FROM OPERATING ACTIVITIES, MSEK



# Operations

## Commercial products

PIPELINE OF COMMERCIAL PRODUCTS AND DEVELOPMENT PROJECTS



### Zubsolv® US – treatment of opioid dependence

The first quarter of 2018 demonstrated a buprenorphine/naloxone market growth of 2.7 percent in volume compared to Q4 2017, and 11.5 percent over Q1 2017. The market forecast is continued growth as more providers begin to take on a greater patient load by becoming waived and as currently waived prescribers expand their patient cap limits. Currently, greater than 4,000 waived physicians are eligible to increase their patient load up to 275, while nurse practitioners and physicians assistants now total over 5,500 waived to treat opioid dependency.

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

Zubsolv has outpaced market growth in Q1 2018 both over Q4 2017 and Q1 in prior year. Quarter over quarter Zubsolv grew 12.4 percent, while the market grew only

2.7 percent and Zubsolv was the only branded product in the category that grew its market share during this period. Comparing against Q1 2017 Zubsolv grew 11.9 percent while the market grew 11.5 percent.

Zubsolv's weekly volume attained multiple all-time highs for Q1 2018. When measuring volume within a rolling 4 week span, Zubsolv hit all-time highs for six consecutive weeks. Zubsolv share ended the quarter with 5.7 percent on a four week basis, an increase with 0.6 percentage points from December. This success is attributable to Zubsolv growth across payer segments and across formulary positions. Quarter over quarter Zubsolv grew 23.2 percent in Public, 8.9 percent in Commercial, and 1.2 percent in Cash.

### Zubsolv was the only branded product in the category that grew its market share during this period

As reported previously, Orexo secured multiple market access improvements for Zubsolv® that commenced this quarter, providing much more additional opportunity for Zubsolv to continue to grow volume. The improvement in market access for 2018 is the best development in market access for Zubsolv since 2014.

In the commercial segment, Zubsolv is now nearly universally reimbursed, primarily explained by the new preferred position within CVS Caremark. In addition, effective January 1, 2018, Zubsolv became the exclusive preferred product with Envision Rx and Humana in the commercial segment. In recent weeks Zubsolv achieved expected volumes on both payers, with a 70 percent market share in Envision Rx, a much faster market share climb than we first saw with UHG Commercial. In the public segment, Zubsolv became the exclusive product on the Humana Medicare Part D plan and is growing volumes during the quarter with this formulary position as well. The impact and value of the exclusive contracts are highly dependent on the health plans' ability and willingness to control the prescriptions; we have experienced wide variations in the final market share after exclusivity implementation is complete, from United Health Group and WellCare with Zubsolv market share well above 75 percent, to Maryland with less than 40 percent market share.

While the Humana Medicare Part D and Envision commercial exclusive contracts are having an impact, the main value is from the broader preferred status, including Caremark commercial, and Orexo's ability to compete in larger geographies for market share and volume in the growing public segment of the market. Within the competitive business segments where Zubsolv and at least one other competitor is available, the brand has made gains across the board in Cash, Commercial, and Public. More Zubsolv sales territories are growing quarter over quarter in the competitive business segments now than in the past four quarters. While these business segments have seen growth, Commercial has for Zubsolv been the core driver of the volume gains quarter over quarter. Meanwhile, the market has declined in Commercial volume quarter over quarter. Zubsolv's new Commercial formulary position with CVS Caremark has led to a surge in new Zubsolv prescriptions with the plan which is accountable for large part of Zubsolv's commercial gains.

Market access has been a key growth driver for Zubsolv and the objective remains to improve the access position for Zubsolv with a focus on the growing Public segment. The next major improvement was expected to be the previously announced change in Ohio from July 1, 2018, when the state FFS Medicaid was expected to take control of all state funded Medicaid pharmaceutical benefits, the final decision on this change has now been postponed to 2019.

#### **Paragraph IV litigations against Actavis regarding Zubsolv in the US**

See Note 3 on page 17.

#### **Patent infringement litigation against Actavis for their generic versions of Suboxone® and Subutex® tablets in the US**

See Note 3 on page 17.

#### **Zubsolv Europe – opioid dependence**

In Q4 2017, Zubsolv received authorization by the European Commission for treatment of opioid dependence in Europe. Zubsolv is the first buprenorphine/naloxone drug to be approved in Europe with six different dosages. This allows individually tailored dosages, with potentially fewer tablets compared with existing substitute therapies. Orexo's partner Mundipharma, who own the commercial rights to Zubsolv outside the US, has planned to initiate launch in the first half of 2018 and the development of sales will depend on the re-imburement outcome in individual markets.

#### **Abstral® - breakthrough cancer pain**

Due to the timing of this report, Orexo has not yet received final data for Q1 sales of Abstral and Edluar® from our partners and hence the calculation of Q1 royalties is based on Orexo's forecast and preliminary Q1 sales reports where available. For the same reason, the Abstral and Edluar sections below primarily refer to the sales development in Q4 2017.

Sales of Abstral in the EU amounted to EUR 22 million in Q4 2017, which is on the same level with sales in Q4 2016. For the EU market Orexo receives royalty on sales exceeding EUR 42.5 million, which in 2017 happened in June.

In the US market, Orexo's partner since November 2015, Sentyln Therapeutics Inc., was acquired by Zydus Cadila in January 2017. Net sales were 19 percent higher in Q4 2017 compared with the same period in 2016.

Sales of Abstral in the region RoW (markets excluding the EU, the US and Japan) have continued to grow. Total sales for the RoW reached USD 4.2 million in Q4 2017, which is an increase of 38 percent compared with Q4 2016.

Sales of Abstral in Japan decreased 10 percent during the fourth local commercial quarter, September 2017 to November 2017, compared to the same period in 2016.

## Edluar® - insomnia

Global sales of Edluar, commercialized by Mylan, were 54 percent lower in Q4 2017 compared to Q4 2016 mainly driven by a onetime negative adjustment of net sales in the US. Total sales for Q4 2017 amounted to EUR 2.1 million (4.6).

## Development projects

### OX382 – oral formulation of buprenorphine

Orexo is developing a swallowable formulation of buprenorphine (OX382). The aim is to be first-to-market in this new product class and to offer clear benefits over today's treatment options for certain patient categories and treatment settings.

Changes during the quarter:

Based on results from the first clinical study, formulation development will continue before progressing the project further. It is a challenge to obtain the desired properties from a swallowable buprenorphine formulation. But we have gained significant insights from the first trial which will guide us in the continued efforts to develop the product.

### OX124 - naloxone rescue medication

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

Changes during the quarter:

Pre-clinical proof of concept has been established which supports advancement into clinical stage development.

### OX338 - new NSAID formulation

The aim is to develop a new NSAID formulation which could replace opioids for the acute treatment of moderate to severe pain and with a view to removing the risk to develop an addiction. The project supports Orexo's ambition to take a broader responsibility within the addiction space.

Changes during the quarter:

A decision was taken to add this project to the development pipeline.

### OX-MPI – inflammation

The lead candidate drug in the OX-MPI program, BI1029539, has been identified as a highly selective anti-inflammatory compound targeting microsomal prostaglandin E synthase (mPGES-1). The project is developed by Orexo's partner Gesynta Pharma AB which owns the rights to the project.

Changes during the quarter:

Gesynta Pharma AB secured SEK 22 million in funding for completion of the pre-clinical development.

### OX51 – acute pain episodes

OX51 is a new sublingual tablet formulation containing alfentanil. The project has been developed to meet the rapidly growing demand for effective pain relief during short surgical and diagnostic procedures. The project has successfully passed phase II clinical trial and is available for potential partners, but so far the right match has not been identified.

Changes during the quarter:

Orexo has decided to minimize internal resources on this project as it falls outside the commercial focus of the company. Consequently, the project has been removed from the pipeline overview.

**OX124 and OX338 supports Orexo's ambition to take a broader responsibility within the addiction space**

## Parent Company

Net revenues for Q1 2018 amounted to SEK 58.5 million (122.4). Earnings before tax were SEK -27.0 million (-11.6). Investments amounted to SEK 0.0 million (0.4). As of March 31 2018, cash and cash equivalents in the Parent Company amounted to SEK 236.7 million (160.8).

During Q1 2017 two batches of Zubsolv® 5.7 mg were returned from Orexo Inc. to Orexo AB and 35 batches were sold back to Orexo Inc., these transactions had a positive net impact on the parent company revenue and net earnings.

## Important events after the period

At the Annual General Meeting held on April 12, 2018, the AGM resolved on re-electing Martin Nicklasson as Chairman of the Board of Directors. All other Board members were also re-elected except Michael Shalmi, Novo Holdings A/S, who was not up for re-election. The AGM resolved on replacing Shalmi with Henrik Kjaer Hansen, also from Novo Holdings A/S.

## Outlook 2018

The first quarter 2018 results are in line with guidance provided previously and the guidance remains unchanged. For convenience the 2018 guidance provided in connection with the Q4 2017 report is repeated below.

For 2018 Orexo expects to continue to deliver positive EBITDA on a full year basis, primarily driven by Zubsolv US revenue growth and continued focus on cost control. The impact from new Zubsolv US market access agreements will ramp up during the year and a negative EBITDA is expected for Q1 2018.

With the improved market access situation for Zubsolv US, Orexo expects to gain volume and market share during 2018. Total milestone payment level in 2018 is expected to be slightly above the 2017 level.

Manufacturing efficiency programs aimed to reduce COGS is expected to have affect from second half-year 2018.

Full year OPEX is expected to be approximately SEK 500 million. The increase over 2017 is driven by expansion of US commercial footprint and progression of development projects. Only a limited amount has been included for the Actavis litigation for Zubsolv, assuming a positive outcome.

The outlook is based on current exchange rates (January 2018).

## Forward looking statements

This report includes forward-looking statements. Actual results may differ from those stated. Internal and external factors may affect Orexo's results.

## Risks and uncertainty factors

Significant risks and uncertainties are presented in the Annual Report for 2017. The continued commercialization of Zubsolv entails risk exposure of an operational nature and Orexo is continuously exposed to risks in relation to development projects and the intellectual property rights and legal disputes as highlighted in Note 3.

Uppsala, Sweden, 26 April, 2018

Orexo AB (publ)

Nikolaj Sørensen  
President and CEO

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

# Financial Reports and Notes

## CONSOLIDATED STATEMENT OF OPERATIONS

SEK million	Notes	2018 Jan-Mar	2017 Jan-Mar	2017 Jan-Dec
Net revenues	5	139.7	127.4	643.7
Cost of goods sold		-48.4	-46.2	-164.4
<b>Gross profit</b>		<b>91.3</b>	<b>81.2</b>	<b>479.3</b>
Selling expenses		-43.3	-48.3	-190.5
Administrative expenses		-27.2	-26.3	-96.1
Research and development expenses		-45.3	-30.3	-134.2
Other operating income and expenses		2.7	0.5	-1.1
<b>Operating earnings</b>		<b>-21.8</b>	<b>-23.2</b>	<b>57.4</b>
Net financial items		-3.0	-6.6	-27.7
<b>Earnings before tax</b>		<b>-24.8</b>	<b>-29.8</b>	<b>29.7</b>
Tax		-1.1	-4.8	-6.5
<b>Net earnings for the period<sup>1</sup></b>		<b>-25.9</b>	<b>-34.6</b>	<b>23.2</b>

## CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

SEK million	2018 Jan-Mar	2017 Jan-Mar	2017 Jan-Dec
<b>Earnings for the period</b>	<b>-25.9</b>	<b>-34.6</b>	<b>23.2</b>
<b>Other comprehensive income</b>			
<b>Items that may subsequently be reversed to the statement of operations:</b>			
Exchange-rate differences	1.2	-1.4	-7.5
<b>Other comprehensive earnings for the period, net after tax</b>	<b>1.2</b>	<b>-1.4</b>	<b>-7.5</b>
<b>Total comprehensive earnings for the period<sup>1</sup></b>	<b>-24.7</b>	<b>-36.0</b>	<b>15.7</b>
Earnings per share, before dilution, SEK	-0.75	-1.00	0.67
Earnings per share, after dilution, SEK	-0.75	-1.00	0.67

<sup>1</sup> All equity and earnings for the respective period are attributable to the Parent Company's shareholders

## CONSOLIDATED BALANCE SHEET

SEK million	2018 Mar 31	2017 Mar 31	2017 Dec 31
<b>ASSETS</b>			
<b>Fixed assets</b>			
Tangible fixed assets	19.4	21.5	20.1
Intangible fixed assets	116.6	133.9	121.0
Deferred tax assets	31.3	21.1	28.3
Other financial assets	7.3	—	7.1
<b>Total fixed assets</b>	<b>174.6</b>	<b>176.5</b>	<b>176.5</b>
<b>Current assets</b>			
Inventories	206.1	316.8	250.2
Accounts receivable and other receivables	217.2	192.2	249.3
Cash and cash equivalents	437.5	250.6	327.9
<b>Total current assets</b>	<b>860.8</b>	<b>759.6</b>	<b>827.4</b>
<b>Total assets</b>	<b>1,035.4</b>	<b>936.1</b>	<b>1,003.9</b>
<b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>			
<b>Total shareholders' equity</b>	<b>305.4</b>	<b>273.3</b>	<b>329.1</b>
<b>Long-term liabilities</b>			
Provisions	5.7	0.8	5.8
Long-term liabilities, interest bearing	319.5	339.4	319.1
<b>Total long-term liabilities</b>	<b>325.2</b>	<b>340.2</b>	<b>324.9</b>
<b>Current liabilities and provisions</b>			
Provisions	261.6	188.4	200.9
Current liabilities, non-interest bearing	143.2	134.3	149.0
<b>Total current liabilities and provisions</b>	<b>404.8</b>	<b>322.7</b>	<b>349.9</b>
<b>Total liabilities</b>	<b>730.0</b>	<b>662.9</b>	<b>674.8</b>
<b>Total shareholders' equity and liabilities</b>	<b>1,035.4</b>	<b>936.1</b>	<b>1,003.9</b>

## CONSOLIDATED CHANGES IN SHAREHOLDERS' EQUITY

SEK million	2018 Mar 31	2017 Mar 31	2017 Dec 31
<b>Opening balance, shareholders' equity</b>	<b>329.1</b>	<b>310.3</b>	<b>310.3</b>
Total comprehensive earnings for the period	-24.7	-36.0	15.7
Employee stock options, vested amount	1.1	-1.0	3.0
Buy back of shares	—	—	—
New share issue	—	—	0.1
<b>Closing balance, shareholders' equity</b>	<b>305.4</b>	<b>273.3</b>	<b>329.1</b>

## CONSOLIDATED CASH FLOW STATEMENTS

SEK million	Notes	2018 Jan-Mar	2017 Jan-Mar	2017 Jan-Dec
Operating earnings		-21.8	-23.2	57.4
Interest received		—	3.1	0.2
Interest paid		-7.1	-20.0	-37.4
Adjustment for non-cash items	2	60.7	20.1	87.9
<b>Cash flow from operating activities before changes in working capital</b>		<b>31.8</b>	<b>-20.0</b>	<b>108.1</b>
<b>Changes in working capital</b>		<b>74.2</b>	<b>48.2</b>	<b>38.5</b>
<b>Cash flow from operating activities</b>		<b>106.0</b>	<b>28.2</b>	<b>146.6</b>
Acquisition of tangible and intangible fixed assets		—	-0.3	-1.6
<b>Cash flow from investing activities</b>		<b>0.0</b>	<b>-0.3</b>	<b>-1.6</b>
New share issue		—	—	0.1
Change in loans		0.3	-59.0	-85.5
<b>Cash from financing activities</b>		<b>0.3</b>	<b>-59.0</b>	<b>-85.4</b>
<b>Cash flow for the period</b>		<b>106.3</b>	<b>-31.1</b>	<b>59.6</b>
<b>Cash and cash equivalents at the beginning of the period</b>		<b>327.9</b>	<b>282.4</b>	<b>282.4</b>
Exchange-rate differences in cash and cash equivalents		3.3	-0.7	-14.1
Changes in cash and cash equivalents		109.6	-31.1	59.6
<b>Cash and cash equivalents at the end of the period</b>		<b>437.5</b>	<b>250.6</b>	<b>327.9</b>

Key Figures<sup>1</sup>

Orexo makes use of the key figures below and believe they are useful for readers of the financial reports as a complement to other performance measures when assessing implementation of strategic investments and the Group's ability to meet financial objectives and commitments.

	2018 Jan-Mar	2017 Jan-Mar	2017 Jan-Dec
EBIT margin, %	-15.6	-18.2	8.9
Return on shareholder equity, %	-8.2	-11.9	7.3
Net debt, SEK million	-118.0	88.8	-8.8
Debt/equity ratio, %	104.6	124.2	97.0
Equity/assets ratio, %	29.5	29.2	32.8
Number of shares, before dilution	34,581,327	34,539,585	34,561,142
Number of shares, after dilution	34,687,494	34,539,585	34,671,706
Earnings per share, before dilution, SEK	-0.75	-1.00	0.67
Earnings per share, after dilution, SEK	-0.75	-1.00	0.67
Number of employees at the end of the period	88	102	90
Shareholders' equity, SEK million	305.4	273.3	329.1
Capital employed, SEK million	624.9	612.7	648.1
Working capital, SEK million	456.0	436.9	477.5

<sup>1</sup> Definitions and reconciliations of key figures are presented on page 19 of this report

## PARENT COMPANY STATEMENT OF OPERATIONS

SEK million	2018 Jan-Mar	2017 Jan-Mar	2017 Jan-Dec
Net revenues	58.5	122.4	477.8
Cost of goods sold	-25.8	-59.8	-167.4
<b>Gross profit</b>	<b>32.7</b>	<b>62.6</b>	<b>310.4</b>
Selling expenses	-0.8	-25.1	-73.3
Administrative expenses	-19.7	-18.7	-67.3
Research and development costs	-39.0	-23.7	-105.3
Other operating income and expenses	2.8	0.4	-1.2
<b>Operating earnings</b>	<b>-24.0</b>	<b>-4.5</b>	<b>63.3</b>
Interest income and expenses	-3.7	-4.8	-14.6
Exchange rate adjustment	—	-1.3	-1.3
Other financial expenses	0.7	-1.0	-12.3
<b>Net financial items</b>	<b>-3.0</b>	<b>-7.1</b>	<b>-28.2</b>
<b>Earnings before tax</b>	<b>-27.0</b>	<b>-11.6</b>	<b>35.1</b>
Tax	—	—	7.6
<b>Earnings for the period</b>	<b>-27.0</b>	<b>-11.6</b>	<b>42.7</b>

## PARENT COMPANY STATEMENT OF COMPREHENSIVE INCOME

SEK million	2018 Jan-Mar	2017 Jan-Mar	2017 Jan-Dec
<b>Earnings for the period</b>	<b>-27.0</b>	<b>-11.6</b>	<b>42.7</b>
<b>Other comprehensive income</b>	<b>—</b>	<b>—</b>	<b>—</b>
<b>Total comprehensive earnings for the period</b>	<b>-27.0</b>	<b>-11.6</b>	<b>42.7</b>

## PARENT COMPANY BALANCE SHEET

SEK million	2018 Mar 31	2017 Mar 31	2017 Dec 31
<b>ASSETS</b>			
<b>Fixed assets</b>			
Intangible fixed assets	116.6	133.9	121.0
Tangible fixed assets	26.8	21.1	27.4
Shares in subsidiaries	151.1	148.6	150.6
<b>Total fixed assets</b>	<b>294.5</b>	<b>303.6</b>	<b>299.0</b>
<b>Current assets</b>			
Inventories	164.0	231.4	186.3
Accounts receivable and other receivables	97.4	143.0	158.4
Cash and bank balances	236.7	160.8	215.1
<b>Total current assets</b>	<b>498.1</b>	<b>535.2</b>	<b>559.8</b>
<b>Total assets</b>	<b>792.6</b>	<b>838.8</b>	<b>858.8</b>
<b>SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES</b>			
<b>Shareholders' equity</b>	<b>283.6</b>	<b>251.3</b>	<b>309.4</b>
<b>Long-term liabilities</b>			
Other provisions	4.6	0.7	4.9
Bond loan	319.5	339.4	319.1
<b>Total long-term liabilities</b>	<b>324.1</b>	<b>340.1</b>	<b>324.0</b>
<b>Current liabilities</b>			
Accounts payable	12.2	11.8	28.9
Other liabilities	7.6	13.0	6.6
Liabilities to Group companies	145.7	197.0	169.1
Accrued expenses and deferred income	19.4	25.6	20.8
<b>Total current liabilities</b>	<b>184.9</b>	<b>247.4</b>	<b>225.4</b>
<b>Total liabilities</b>	<b>509.0</b>	<b>587.5</b>	<b>549.4</b>
<b>Total shareholders' equity and liabilities</b>	<b>792.6</b>	<b>838.8</b>	<b>858.8</b>

# Notes

## 1. Accounting policies

This report was prepared pursuant to IAS 34. Orexo applies IFRS as approved by the EU.

The accounting policies stated below are in line with those applied in the preparation of the 2017 Annual Report.

The Parent Company's financial statements were prepared in accordance with RFR 2 (Swedish Financial Reporting Board's recommendation) and Chapter 9 of the Swedish Annual Accounts Act.

### **New and amended accounting policies as of 2018**

IFRS 15 revenue from contracts with customers replaces all previously issued standards and interpretations that deal with revenues in a coherent model of revenue recognition. The Group applies the new standard in its entirety as of January 1, 2018, and it has made an assessment of IFRS 15 and its effects on company's financial statements, which shows no material changes other than additional disclosure requirements, see Note 5.

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

## 2. Cash flow

### ADJUSTMENT FOR NON-CASH ITEMS

SEK million	2018 Jan-Mar	2017 Jan-Mar	2017 Jan-Dec
Depreciation/amortization and impairment	5.2	5.4	20.8
Gain/loss on disposal	—	—	—
Change in provisions	57.1	30.8	59.9
Change in fair value of financial instruments	—	—	—
Share based payments	1.0	-0.8	3.3
Exchange rate income and expenses	-2.6	-15.3	3.9
<b>Total</b>	<b>60.7</b>	<b>20.1</b>	<b>87.9</b>

## 3. Legal disputes

### Paragraph IV litigations against Actavis regarding Zubsolv® in the US

On December 7 2016, Orexo appealed the District Court's decision relating to the validity of the '330 patent to the Court of Appeals for the Federal Circuit. Actavis did not appeal the District Court's decision relating to the validity and infringement of the '996 patent, securing Zubsolv exclusivity on the US market until at least September 24, 2019. An oral session was held in the US Court of Appeals for the Federal Circuit on October 4, 2017. Due to the current workload a decision from the Court could in the worst case take up to 9 months from the date of the oral session. Orexo has no influence on the timing of the decision and the decision can come earlier without prior notification to Orexo.

In addition, two new Zubsolv US patents, 9,259,421 and 9,439,900 (both expire September 2032), have been issued and listed in the Orange Book in 2016. Orexo has initiated a litigation process against Actavis for infringement of these two patents, but the litigation process is on hold awaiting the decision by the Court of Appeals for the Federal Circuit with regard to Orexo's US Patent No. 8,940,330.

### Patent infringement litigation against Actavis for their generic versions of Suboxone® and Subutex® tablets in the US

In March 2017, Orexo filed a patent infringement action in the United States District Court for the District of Delaware against Actavis Elizabeth LLC, Actavis Pharma, Inc., and their parent company Teva (collectively "Actavis"). Orexo alleges that Actavis's generic versions of Suboxone and Subutex tablets infringe Orexo's US Patent 8,454,996 (the '996 patent). Actavis's generic version of Suboxone was approved by the FDA in February 2013 and their generic version of Subutex in February 2015. Orexo is seeking compensation for damages caused by Actavis's infringement of the '996 patent since approval of these two products.

## 4. Important events after the period

At the Annual General Meeting held in April 12, 2018, the AGM resolved on re-electing Martin Nicklasson as Chairman of the Board of Directors. All other Board members were also re-elected except Michael Shalmi, Novo Holdings A/S, who was not up for re-election. The AGM resolved on replacing Shalmi with Henrik Kjaer Hansen, also from Novo Holdings A/S.

## 5. Revenue from contracts with customers

SEK million	2018 Jan-Mar				
Type of revenue	Zubsolv®	Abstral®	Edluar®	OX-CLI	Total
Sales, products	131.1	-	-	-	131.1
Royalties	-	5.8	2.8	-	8.6
Milestones	-	-	-	-	0.0
<b>Total revenue from contracts with customers</b>	<b>131.1</b>	<b>5.8</b>	<b>2.8</b>	<b>0.0</b>	<b>139.7</b>
Geographical markets	Zubsolv	Abstral	Edluar	OX-CLI	Total
US	131.1	1.5	0.7	-	133.3
EU	-	-1.2	0.4	-	-0.8
Rest of the world	-	5.5	1.7	-	7.2
<b>Total revenue from contracts with customers</b>	<b>131.1</b>	<b>5.8</b>	<b>2.8</b>	<b>0.0</b>	<b>139.7</b>
SEK million	2017 Jan-Mar				
Type of revenue	Zubsolv	Abstral	Edluar	OX-CLI	Total
Sales, products	114.1	-	-	-	114.1
Royalties	-	8.7	4.6	-	13.2
Milestones	-	-	-	-	0.0
<b>Total revenue from contracts with customers</b>	<b>114.1</b>	<b>8.7</b>	<b>4.6</b>	<b>0.0</b>	<b>127.4</b>
Geographical markets	Zubsolv	Abstral	Edluar	OX-CLI	Total
US	114.1	2.3	2.5	-	118.9
EU	-	0.7	0.1	-	0.8
Rest of the world	-	5.7	2.0	-	7.7
<b>Total revenue from contracts with customers</b>	<b>114.1</b>	<b>8.7</b>	<b>4.6</b>	<b>0.0</b>	<b>127.4</b>
SEK million	2017 Jan-Dec				
Type of revenue	Zubsolv	Abstral	Edluar	OX-CLI	Total
Sales, products	491.4	-	-	-	491.4
Royalties	-	113.2	17.3	-	130.5
Milestones	-	-	-	21.8	21.8
<b>Total revenue from contracts with customers</b>	<b>491.4</b>	<b>113.2</b>	<b>17.3</b>	<b>21.8</b>	<b>643.7</b>
Geographical markets	Zubsolv	Abstral	Edluar	OX-CLI	Total
US	485.8	5.1	10.3	-	501.1
EU	5.6	88.6	0.8	21.8	116.8
Rest of the world	-	19.5	6.3	-	25.8
<b>Total revenue from contracts with customers</b>	<b>491.4</b>	<b>113.2</b>	<b>17.3</b>	<b>21.8</b>	<b>643.7</b>

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

# Definitions and reconciliations of key figures

## Key figures and certain other operating information per share are defined as follows

Margins	Definition/calculation	Purpose
Gross margin	Gross profit divided by net revenues	Gross Margin is used to measure the relative direct profitability from sold products
Operating margin (EBIT margin)	Operating earnings as a percentage of net revenues	Operating profit margin is used for measuring the operational profitability
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	Total 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 less current liabilities	Working capital is used to measure the company's ability, besides cash and cash equivalents, 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
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 PER SHARE ARE RECONCILED AS FOLLOWS

<b>EBITDA SEK million</b>	<b>2018 Jan-Mar</b>	<b>2017 Jan-Mar</b>	<b>2017 Jan-Dec</b>
EBIT	-21.8	-23.2	57.4
Depreciation and amortization	5.2	5.1	20.8
<b>EBITDA</b>	<b>-16.6</b>	<b>-18.1</b>	<b>78.2</b>
<b>RETURN ON SHAREHOLDERS' EQUITY</b>			
	<b>2018 Jan-Mar</b>	<b>2017 Jan-Mar</b>	<b>2017 Jan-Dec</b>
Shareholders' equity beginning balance	329.1	310.3	310.3
Shareholders' equity ending balance	305.4	273.3	329.1
Average shareholders' equity	317.3	291.8	319.7
Net earnings	-25.9	-34.6	23.2
<b>Return on shareholders' equity %</b>	<b>-8.2</b>	<b>-11.9</b>	<b>7.3</b>
<b>OPERATING EXPENSES SEK million</b>			
	<b>2018 Jan-Mar</b>	<b>2017 Jan-Mar</b>	<b>2017 Jan-Dec</b>
Selling expenses	-43.3	-48.3	-190.5
Administrative expenses	-27.2	-26.3	-96.1
Research and development costs	-45.3	-30.3	-134.2
Other operating income and expenses	2.7	0.5	-1.1
<b>Operating expenses</b>	<b>-113.1</b>	<b>-104.4</b>	<b>-421.9</b>
<b>GROSS INVESTMENTS SEK million</b>			
	<b>2018 Jan-Mar</b>	<b>2017 Jan-Mar</b>	<b>2017 Jan-Dec</b>
Investments in tangible fixed assets	—	0.3	1.1
Investments in intangible fixed assets	—	0.1	0.5
<b>Gross investments</b>	<b>0.0</b>	<b>0.4</b>	<b>163</b>

# 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 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 market for treatment of opioid dependence. The commercial segment is funded by private insurances or employers

## **Drug delivery**

The process through which a pharmaceutical may be introduced to the patient that enables the active compound to function as intended

## **EMA**

The European Medicine Agency

## **FDA**

The US Food and Drug Administration

## **Fentanyl**

An opioid with a similar effect on human patients as morphine. Used mainly within anesthesia and analgesia

## **GMP**

Good Manufacturing Practice

## **HHS**

The US Department of Health and Human Services

## **In Vitro studies**

In an in vitro study; living matter is examined outside of its natural context e.g. in a test-tube

## **IP**

Intellectual Properties

## **Naloxone**

An opioid inverse agonist used to counter the effects of opioids

## **NSAID**

Non-steroid anti-inflammatory drugs which are active against pain, inflammation and fever

## **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 market for treatment of opioid dependence. The public segment covers state and federal funded reimbursement programs i.e. Managed Medicaid, FFS Medicaid, Medicare Part D

## **Reimbursement**

Contribution from the state or insurance company in order to reduce the price of drugs / treatment for the patient

## **Sublingual**

Under the tongue

## **Zolpidem**

A pharmaceutical substance used to treat temporary or short-term insomnia

This information is information that Orexo AB (publ.) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 8.00 am CET on April 26, 2018.