Interim Report Q2 2018

Zubsolv® continues its strong performance

Q2 2018 highlights

- Total net revenues of SEK 199.7 million (159.1), up 25.5 percent from Q2 previous year
- Zubsolv US net revenue of SEK 158.4 million (124.1), up 27.6 percent in SEK and 29.8 percent in local currency compared to the same period last year
- EBITDA of SEK 50.6 million (15.0)
- Cash flow from operating activities of SEK 39.0 million (49.0), building a cash balance of SEK 494.8 million (294.3)
- Launch of Zubsolv initiated in the EU, which triggered a milestone payment of EUR 3 million
- Earnings per share, before dilution SEK 1.45 (0.09), earnings per share after dilution SEK 1.45 (0.09)

SEK million, unless otherwise stated	2018 Apr-Jun	2017 Apr-Jun	2018 Jan-Jun	2017 Jan-Jun	12 mth Jul 2017 - Jun 2018	12 mth Jul 2016 - Jun 2017
Net revenues	199.7	159.1	339.4	286.4	696.7	653.2
whereof Zubsolv® US net revenue	158.4	124.1	289.5	238.2	537.1	508.8
Cost of goods sold	-37.6	-35.8	-86.0	-82.0	-168.4	-165.2
Operating expenses	-116.7	-113.5	-229.9	-218.0	-433.8	-435.8
EBIT	45.4	9.8	23.5	-13.6	94.5	52.2
EBIT margin, %	22.7	6.2	6.9	-4.7	13.6	8.0
EBITDA	50.6	15.0	33.8	-3.2	115.2	72.2
Earnings per share, before dilution, SEK	1.45	0.09	0.70	-0.91	2.29	0.78
Earnings per share, after dilution, SEK	1.45	0.09	0.70	-0.91	2.28	0.78
Cash flow from operating activities	39.0	49.0	144.9	76.9	214.6	190.6
Cash and cash equivalents	494.8	294.3	494.8	294.3	494.8	294.3

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

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 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.

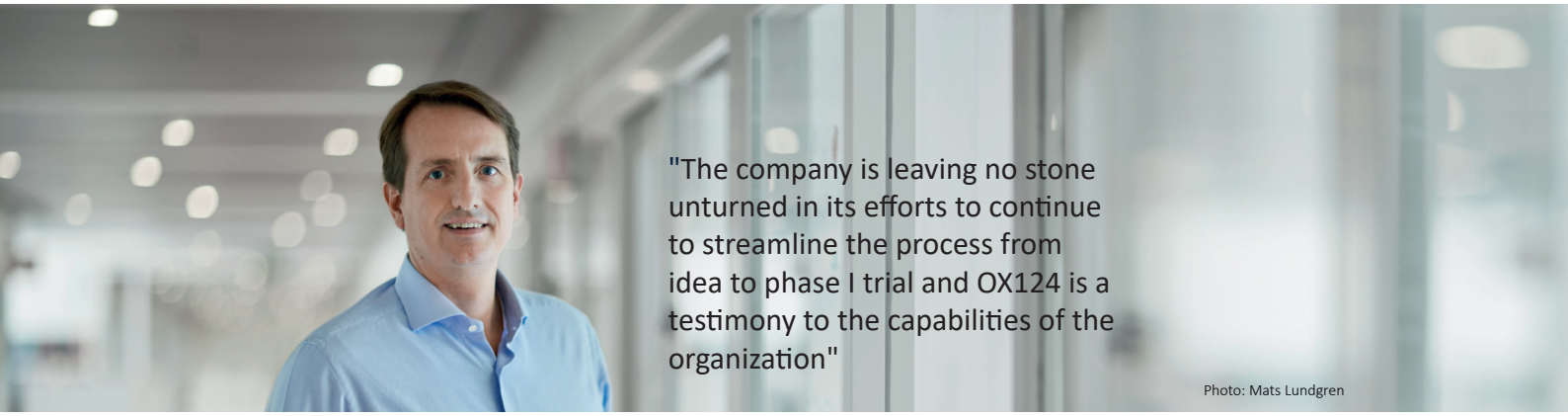
For further information, please contact
Nikolaj Sørensen, CEO and President or Henrik Juuel, EVP and CFO
Tel: +46 18 780 88 00. Email: ir@orexo.com

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 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, no later than 11.00 am CET. Please view the instructions below on how to participate.
Internet: https://tv.streamfabriken.com/orexo-q2-2018
Telephone: SE: +46 856 642 664 UK: +44 203 0089 802 US: +1 855 7532 235
The presentation material will be available on Orexo´s website one hour prior to the audiocast.

Financial calendar
Interim Report Q3 2018 - October 25, 2018 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.
For more information about Zubsolv in the US, see the product and market websites www.zubsolv.com and www.rise-us.com.

Zubsolv® continues its strong performance



During Q2 Zubsolv continued its strong performance, building on the improved market access for 2018. The strong Zubsolv growth is the main driver behind the total revenue growth in SEK of 25 percent and an EBITDA of SEK 51 million. Q2, 2018 was one of the best quarters ever in Orexo's history in terms of these measures.

Zubsolv® grew more than 20 percent in prescribed tablets compared to Q2 2017 and Zubsolv sales are the most important driver of Orexo's profitability and growth. Profitability has also improved due to our work on reducing the cost of goods, which is starting to show some effects. Furthermore, the milestone payment of EUR 3 million following the launch of Zubsolv in Europe also contributed to a positive result. From a company perspective, I find it promising that we are able to be profitable even when excluding the milestone payment for Zubsolv Europe and any significant royalties from Abstral and Edluar. With continued improvements in the cost of goods expected in the second half of this year and royalties from Abstral in Europe, 2018 is on track to becoming a record year for Orexo in terms of profitability and sales.

We are intensifying our efforts to develop new products and during Q4 we will start a phase I trial for our OX124 naloxone rescue medication. Our aim is to develop a product with a unique product profile addressing some of the shortcomings of the market leader in the US today. The final timeline of development is dependent on the result of the phase I trial. From a corporate perspective, I am very proud that we are ready to test OX124 in humans about a year after the project was started in our development department. The company is leaving no stone unturned in its efforts to continue to streamline the process from idea to phase I trial and OX124 is a testimony to the capabilities of the organization.

During the quarter the market has been very dynamic with the launch of a new depot formulation of buprenorphine in the US and the approval of two generic versions of the market leader Suboxone Film.
The uptake of the depot formulation has been slow, which is in line with our expectations. With the current regulatory landscape and the complexity associated with prescribing a depot formulation, the impact on Zubsolv is most likely limited. With potential near-term generic competition for Suboxone Film, the market leader, the market landscape will change. However, we are already competing with several generics and while there eventually could be some additional price pressure from Suboxone Film, the market dynamic among actively promoted brands will change which can lead to opportunities, for Orexo and Zubsolv in the US.

While I am pleased with business performance in the quarter, I am disappointed that we have not yet received a decision in the litigation process against Actavis on one of the three Zubsolv US patents expiring in 2032. It is now more than nine months since the final hearing in the Court of Appeals and we had expected a decision by now. However we remain optimistic about a positive outcome and a resolution shortly, but are not able to provide more specific guidance.

Financial performance in Q2 has been strong and looking ahead to the second half I feel confident we will continue with strong performance for the rest of the year. This will further improve the foundation for future growth and enable us to continue the exciting journey towards becoming a leading addiction company.

Uppsala, Sweden, July 11, 2018

Nikolaj Sørensen
President and CEO

Financial information

Revenues

Total revenues for the quarter amounted to SEK 199.7 million (159.1), corresponding to a 25.5 percent increase over the same period the previous year. The increase was driven by strong Zubsolv® growth, reaching nearly 28 percent in SEK and 30 percent in local currency.

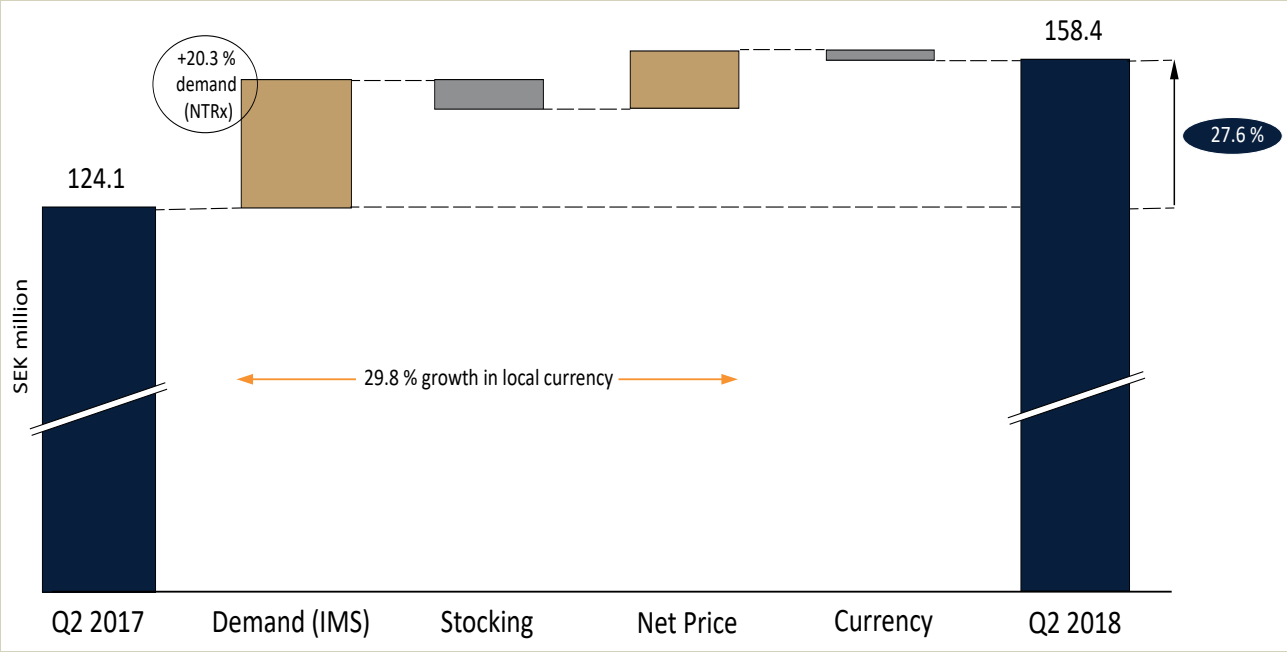
Commercial products
Zubsolv US revenues amounted to SEK 158.4 million (124.1) for the quarter, corresponding to 27.6 percent growth. In local currency (USD) the equivalent growth rate was 29.8 percent, equal to sales of USD 18.3 million in Q2. The key year over year growth factor was the 20.3 percent increase in demand (NTRx) driven by improved market access from January 1, 2018. Net prices were positively impacted by the 6 percent price increase from January 1, 2018, and by a USD 1.4 million adjustment of rebates relating to prior periods. Wholesaler inventory levels were reduced slightly during the quarter, which is typical following a quarter with rapid increase in demand. The USD/SEK rate had a minor negative impact on the year over year growth.

Abstral® revenues amounted to SEK 11.9 million (9.8) for the quarter.

Revenues from Edluar® amounted to SEK -1.4 million (3.4) for the quarter and included a correction of prior periods due to wrong numbers reported by Orexo´s partner Mylan.

The key year over year growth factor was the 20.3 percent increase in demand (NTRx) driven by improved market access from January 1, 2018

ZUBSOLV® US NET REVENUE GROWTH BY KEY DRIVERS, Q2 2018 VERSUS Q2 2017[1)]



[1)] Orexo analysis using IMS demand data

Development projects
There were no revenues from development projects during the quarter. Q2, 2017, includes a milestone payment from AstraZeneca relating to the OX-CLI project of USD 2.5 million (SEK 21.8 million) that was triggered by the project entering clinical phase I trials. This project has, as earlier communicated, been terminated by AstraZeneca and Orexo has decided not to take the project back. There are no financial implications of the termination.

Costs and earnings

Cost of goods sold
Cost of goods sold (COGS) amounted to SEK 37.6 million (35.8) for the quarter and all relates to Zubsolv® in the US market. This corresponds to an average COGS per tablet approximately 25 percent lower than realized in Q1 2018. The lower average COGS per tablet is the first real visible results from the manufacturing efficiency program. Inventory levels have reached a level that enables manufacturing to demand at higher batch sizes and the more expensive products produced in the past have now all been sold. More savings are expected from December 2018 when tablet manufacturing will have been transferred to a new contract manufacturer (CMO).

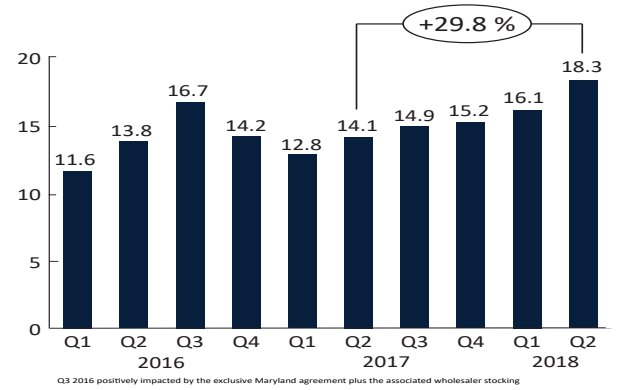
Selling expenses
Selling expenses amounted to SEK 48.6 million (49.7) and all relates to the US commercial organization. The scalable commercial infrastructure enables coping with the improved market access without incurring additional expenses.

Administrative expenses
Administrative expenses for the quarter amounted to SEK 34.0 million (22.4). The increase versus the prior year is explained by higher legal expenses related to the patent infringement litigation against Actavis for their generic versions of Suboxone® and Subutex® tablets in the US. Legal expenses for IP litigations reached SEK 17 million for the quarter.

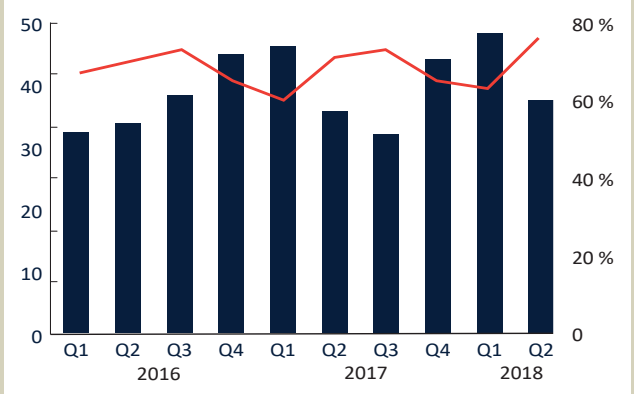
DISTRIBUTION OF TOTAL NET REVENUES

SEK million	2018 Apr-Jun	2017 Apr-Jun	2018 Jan-Jun	2017 Jan-Jun	12 mth Jul 2017-Jun 2018	12 mth Jul 2016-Jun 2017
Zubsolv® US	158.4	124.1	289.5	238.2	537.1	508.8
Zubsolv – Rest of the World	30.8	—	30.8	—	36.4	0.5
Zubsolv – total	**189.2**	**124.1**	**320.3**	**238.2**	**573.5**	**509.3**
Abstral® royalties	11.9	9.8	17.7	18.4	112.5	105.2
Milestone payment Abstral	—	—	—	—	—	2.2
Abstral – total	**11.9**	**9.8**	**17.7**	**18.4**	**112.5**	**107.4**
Edluar® royalties	-1.4	3.4	1.4	8.0	10.7	14.7
OX-CLI	—	21.8	—	21.8	—	21.8
Total	**199.7**	**159.1**	**339.4**	**286.4**	**696.7**	**653.2**

ZUBSOLV US NET REVENUES, MUSD



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



Research and development costs
In Q2 2018, research and development costs amounted to SEK 37.0 million (39.1). The main projects consuming resources were OX124, OX382, the manufacturing efficiency program and other early stage projects.

Costs for long-term incentive program
The Group's total costs for employee share-based payment programs during Q2 2018 amounted to SEK 0.4 million (1.3).

Other income and expenses
Other operating income and expenses amounted to SEK 2.9 million (-2.3) for Q2 2018. The higher SEK/USD FX rate in the quarter compared with Q1, 2018, created a net gain from operating receivables and payables in USD.

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

Net financial items
Net financial items for the quarter amounted to SEK 4.0 million (-5.1). These items are related to financing activities including exchange-rate gains/losses derived from foreign currency bank accounts. For the quarter gains on parent company deposits in USD denominated accounts more than off-set interest expenses from the bond loan.

Tax
Total tax expenses for the quarter amounted to SEK -0.7 million (1.6). Tax for the quarter was positively impacted by a SEK 1.9 million adjustment of the parent company´s tax asset, see Note 4.

Net earnings
Net earnings amounted to SEK 50.1 million (3.1) for the quarter.

Cash flow and financial position

At June 30 2018, cash and cash equivalents amounted to SEK 494.8 million (294.3) and interest bearing liabilities to SEK 319.8 million (340.0), i.e. a positive net cash position of SEK 175 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, before changes in working capital, for the quarter amounted to SEK 69.4 million (47.3) and was driven by a positive contribution from operating earnings and increased provisions for US payer rebates. Changes in working capital contributed negatively with increased receivables partly off-set by increased payables and continued lower inventory levels. The EUR 3 million milestone payment from Mundipharma earned during Q2 2018 will be paid to Orexo in July 2018 and was recognized as a receivable on June 30, 2018.

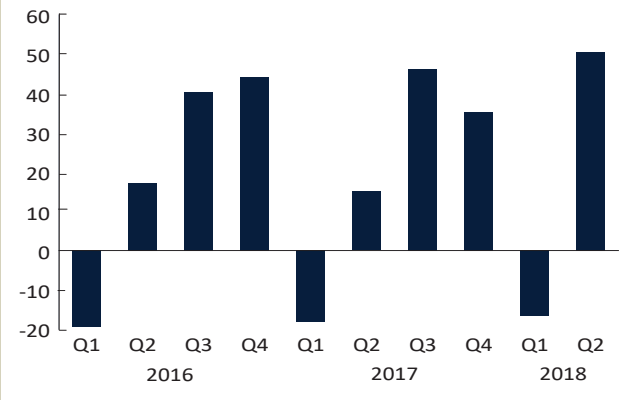
Shareholders' equity at June 30, 2018, was SEK 361.3 million (275.8). The equity/asset ratio was 30.8 percent (28.3).

Investments in fixed assets

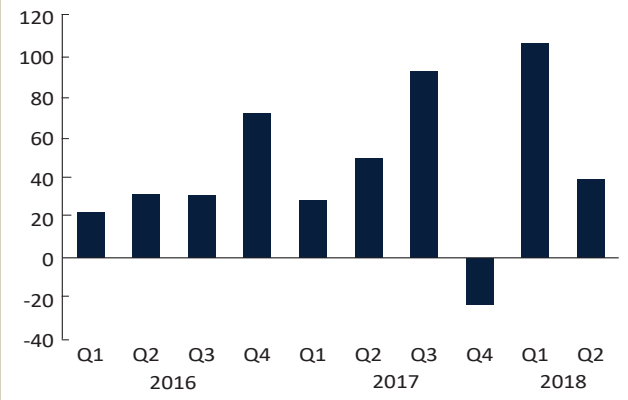
Gross investments in tangible and intangible fixed assets amounted to SEK 1.7 million (0.5) for Q2 2018.

Positive net cash position of SEK 175 million

EBITDA, MSEK



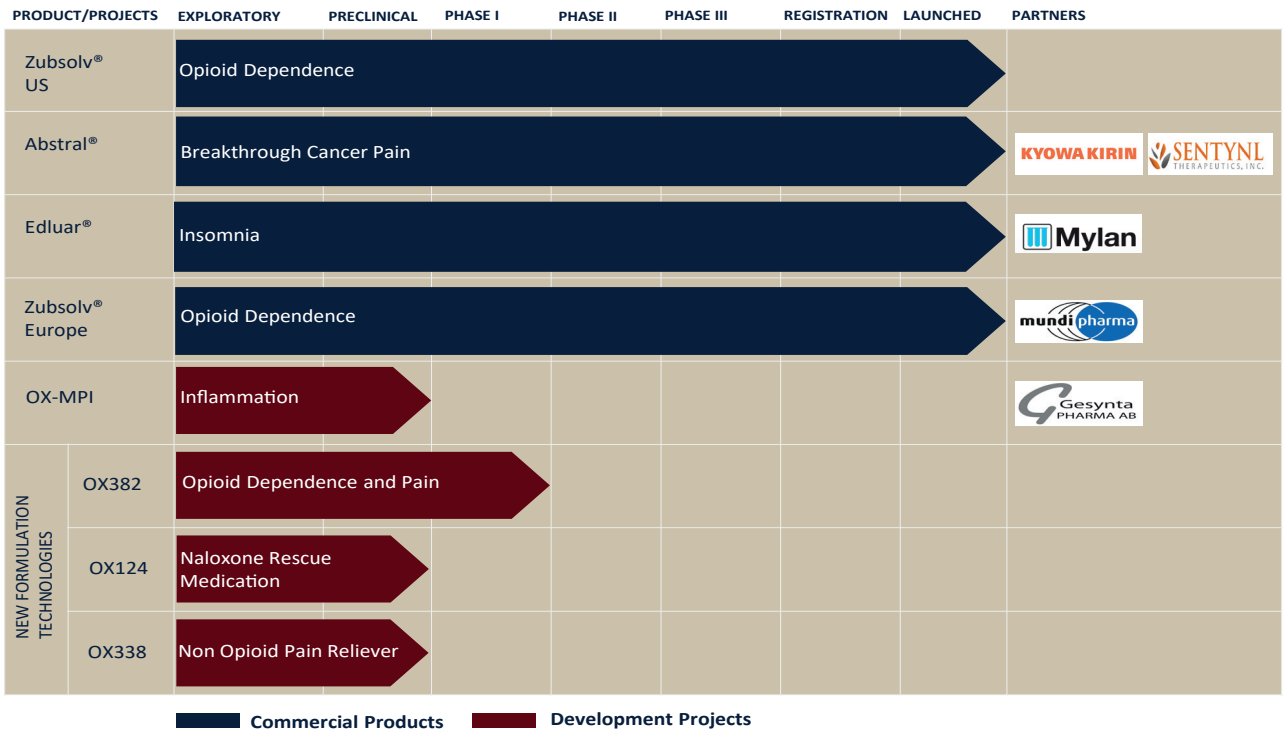
CASH FLOW FROM OPERATING ACTIVITIES, MSEK



Operations

Commercial products

PIPELINE OF COMMERCIAL PRODUCTS AND DEVELOPMENT PROJECTS



Zubsolv® US – treatment of opioid dependence

The second quarter of 2018 demonstrated a buprenorphine/naloxone market growth of 7.0 percent in volume compared to Q1 2018, and 12.3 percent over Q2 2017. The market forecast is continued growth, as the opioid epidemic continues to escalate and as more providers begin to take on a greater patient load by becoming waivered. Currently, greater than 4,000 waivered physicians can increase their patient load up to 275, while nurse practitioners and physicians assistants now total over 6,700 waivered to treat opioid dependency, compared to just 1,300 this quarter last year. Nurse Practitioners and Physicians Assistants first became eligible to receive a waiver to treat opioid dependency after passing of the CARA legislation.

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

Zubsolv has outpaced market growth in Q2 2018 over Q1 2018 and versus prior year. Quarter over quarter Zubsolv grew 8.6 percent, while the market grew 7.0 percent. Year to date Zubsolv grew 14.9 percent while the market grew 12.0 percent. Zubsolv was the only branded product in the category that grew its market share Q2 2018 over Q1 2018. When comparing Q2 2018 to the same quarter 2017 Zubsolv grew by 20.3 percent.

Zubsolv's weekly volume attained a new all-time high on May 4. When measuring volume within a rolling 4 week span, Zubsolv hit all-time highs 3 times this quarter. Zubsolv weekly average share in Q2 was 5.62 percent which exceeded the 5.52 percent in Q1. This success is attributable to Zubsolv growth across all payer segments and across formulary positions.

Zubsolv was the only branded product in the category that grew its market share Q2 2018 over Q1 2018

Quarter over quarter Zubsolv® grew 13.5 percent in Public and 8.3 percent in Commercial. However, a decline was seen in the cash segment as with all branded competitors.

Zubsolv has the best commercial access of any buprenorphine/naloxone product. In the commercial segment, Zubsolv is nearly universally reimbursed. In recent weeks, Zubsolv achieved expected volumes, with a 70 percent market share in Envision Rx, a much faster market share climb than first demonstrated with UHG Commercial. In the public segment, Zubsolv is 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 to control the prescriptions. Zubsolv has experienced variations in the final market share attained after exclusivity implementation, from United Health Group and WellCare with Zubsolv market share well above 75 percent, to Maryland which when Zubsolv was exclusive the market share attained was approximately 40 percent.

Zubsolv's performance and value is being driven by combining the Humana Medicare Part D and Envision commercial exclusive contracts impact with the value captured from the broader preferred formulary competitive status, including CVS Caremark Commercial. This is accomplished with Orexo's improved ability to compete in larger geographies for market share and volume in the growing public and commercial segments of the market. Within the competitive business segments where Zubsolv and at least one other competitor is available, the brand has made gains across 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 been the core driver of the volume gains 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 a large part of Zubsolv's commercial gains.

Based on the data available through June 15 (first 11 weeks of Q2), Zubsolv has grown 11.4 percent versus the same period in Q1 2018 within Zubsolv's exclusive formulary contracts driven primarily by UHC, Humana Medicare D, Humana and Envision Commercial, and Wellcare Managed Medicaid. On the competitive formularies where Zubsolv competes with generic tablets and other branded buprenorphine/naloxone brands Zubsolv succeeded to increase 2 percent which is the best among the branded competitors. The account demonstrating the largest volume growth in this group are CVS Caremark at 19 percent and ESI/Medco at 9 percent.

Market access has been a continual key growth driver for Zubsolv and the objective remains to improve the access position for Zubsolv with a focus on the growing Public segment.

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, as earlier communicated, been postponed to 2019.

As expected, the potential entrance of a generic Suboxone Film into the market has been a recent topic this quarter when FDA approved two generic versions of Suboxone Film. The issue is being addressed within the US Court system and a decision to block or allow the entrance of another generic into the market is expected to be announced in July. It is unlikely that one generic version of the film will have any significant impact on pricing. If more generic versions of the Suboxone Film is eventually entering the market it could potentially lead to some additional price pressure, however, we are already competing with multiple generics versions of Suboxone and Subutex tablets and the competitive pressure from other branded products with a sublingual formulation is likely to be significantly less intense, which can lead to opportunities for Orexo and Zubsolv in the US.

Paragraph IV litigations against Actavis regarding Zubsolv in the US
See Note 3.

Patent infringement litigation against Actvis for their generic versions of Suboxone® and Subutex® tablets in the US
See Note 3.

Zubsolv Europe – opioid dependence

In Q2, 2018, Zubsolv was launched in the EU by Orexo´s partner Mundipharma, who owns the commercial rights to Zubsolv outside the US. The first markets to enter were Germany and Sweden where re-imbursement has been obtained. Zubsolv is the first buprenorphine/naloxone sublingual tablet for the treatment of opioid dependence in Europe to be made available in up to six different strengths. This allows more individualized, flexible dosing and potentially fewer tablets compared with existing buprenorphine/naloxone therapies. The development of sales will depend on Mundipharma's ability to obtain favorable re-imbursement and commercialize Zubsolv in individual markets and providers' willingness to prescribe Zubsolv.

Zubsolv is the first bup/nal drug in Europe with six different strengths. This allows more individualized, flexible dosing and potentially fewer tablets

Abstral® - breakthrough cancer pain

Due to the timing of this report, Orexo has not yet received final data for Q2 sales of Abstral and Edluar® from our partners and hence the calculation of Q2 royalties is based on Orexo´s forecast and preliminary Q2 sales reports where available. For the same reason, the Abstral and Edluar sections below primarily refer to the sales development in Q1 2018.

Sales of Abstral in the EU amounted to EUR 23 million in Q1 2018, which is 2 percent higher compared with the same period in 2017. For the EU market Orexo receives royalty on sales exceeding EUR 42.5 million, which in 2017 happened in June and is also expected in June 2018.

In the US market net sales were 11 percent lower in Q1 2018 compared with the same period in 2017.
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 2.9 million in Q1 2018, which is an increase of 19 percent compared with Q1 2017.
Sales of Abstral in Japan increased 7 percent during the first local commercial quarter, December 2017 to February 2018, compared to the same period in 2017.

Edluar® - insomnia

Global sales of Edluar were 62 percent lower in Q1 2018 compared to Q1 2017 explained by a negative adjustment of prior period sales in the US. Total sales for Q1 2018 amounted to EUR 1.3 million (3.3).

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:
The formulation development has continued based on the insights gained from the result in the first clinical study performed in the previous quarter.

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:
Results from preclinical stage development supports advancements into phase 1 studies, starting in Q4 2018.

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 thus remove 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:
Formulation development has continued according to plan.

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

Changes during the quarter:
Progressing according to plan.

OX51 – acute pain epidodes
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. 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.

Changes during the quarter:
Discussions with potential partners have been ongoing.

OX124 - Results from preclinical stage development supports advancements into phase 1 studies, starting in Q4 2018

Parent Company

Net revenues for Q2 2018 amounted to SEK 89.3 million (113.7). Earnings before tax were SEK 25.5 million (6.2). Investments amounted to SEK 1.7 million (0.5). As of June 30 2018, cash and cash equivalents in the Parent Company amounted to SEK 241.5 million (145.4).

The tax asset was increased by SEK 1.9 million reflecting a new forecast and recent announced changes in the Swedish corporate tax rate.

Important events after the period

No important events after the period.

Outlook 2018

The first half year results, 2018, are in line with guidance provided previously and the full year outlook for 2018 is basically unchanged from previous guidance.

Orexo expects to deliver positive EBITDA for Q3 and Q4 of 2018, primarily driven by a continued strong Zubsolv® US contribution, Abstral® EU royalties and reduced Zubsolv COGS. The Zubsolv COGS reduction is expected to have full effect from December 2018. OPEX is expected to be approximately SEK 500 million and assumes higher spend on pipeline projects and on legal expenses related to the litigation against Actavis for their generic versions of Suboxone® and Subutex® tablets in the US. The outlook still assumes a positive outcome of the Actavis Zubsolv appeal case.

This outlook is based on current exchange rates (July 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.

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, 2018
Orexo AB (publ)

Martin Nicklasson Chairman of the Board	Raymond Hill Board member	Staffan Lindstrand Board member
Kristina Schauman Board member	Henrik Kjaer Hansen Board member	David Colpman Board member
Kirsten Detrick Board member	Nikolaj Sørensen President and CEO	

Financial Reports and Notes

CONSOLIDATED STATEMENT OF OPERATIONS

SEK million	Notes	2018 Apr-Jun	2017 Apr-Jun	2018 Jan-Jun	2017 Jan-Jun	2017 Jan-Dec
Net revenues	6	199.7	159.1	339.4	286.4	643.7
Cost of goods sold		-37.6	-35.8	-86.0	-82.0	-164.4
Gross profit		**162.1**	**123.3**	**253.4**	**204.4**	**479.3**
Selling expenses		-48.6	-49.7	-92.0	-97.9	-190.5
Administrative expenses		-34.0	-22.4	-61.2	-48.8	-96.1
Research and development expenses		-37.0	-39.1	-82.4	-69.4	-134.2
Other operating income and expenses		2.9	-2.3	5.7	-1.9	-1.1
Operating earnings		**45.4**	**9.8**	**23.5**	**-13.6**	**57.4**
Net financial items		4.0	-5.1	1.0	-11.7	-27.7
Earnings before tax		**49.4**	**4.7**	**24.5**	**-25.2**	**29.7**
Tax	4	0.7	-1.6	-0.4	-6.4	-6.5
Net earnings for the period[1]		**50.1**	**3.1**	**24.1**	**-31.6**	**23.2**

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

SEK million	2018 Apr-Jun	2017 Apr-Jun	2018 Jan-Jun	2017 Jan-Jun	2017 Jan-Dec
Earnings for the period	**50.1**	**3.1**	**24.1**	**-31.6**	**23.2**
Other comprehensive income					
Items that may subsequently be reversed to the statement of operations:					
Exchange-rate differences	5.3	-1.9	6.5	-3.3	-7.5
Other comprehensive earnings for the period, net after tax	**5.3**	**-1.9**	**6.5**	**-3.3**	**-7.5**
Total comprehensive earnings for the period[1]	**55.4**	**1.2**	**30.6**	**-34.9**	**15.7**
Earnings per share, before dilution, SEK	1.45	0.09	0.70	-0.91	0.67
Earnings per share, after dilution, SEK	1.45	0.09	0.70	-0.91	0.67

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

CONSOLIDATED BALANCE SHEET

SEK million	2018 Jun 30	2017 Jun 30	2017 Dec 31
ASSETS			
Fixed assets			
Tangible fixed assets	20.3	20.8	20.1
Intangible fixed assets	112.1	129.8	121.0
Deferred tax assets	35.5	20.6	28.3
Other financial assets	7.8	—	7.1
Total fixed assets	**175.7**	**171.2**	**176.5**
Current assets			
Inventories	194.2	292.9	250.2
Accounts receivable and other receivables	308.8	217.8	249.3
Cash and cash equivalents	494.8	294.3	327.9
Total current assets	**997.8**	**805.0**	**827.4**
Total assets	**1,173.5**	**976.2**	**1,003.9**
SHAREHOLDERS' EQUITY AND LIABILITIES			
Total shareholders' equity	**361.3**	**275.8**	**329.1**
Long-term liabilities			
Provisions	3.9	0.6	5.8
Long-term liabilities, interest bearing	319.8	—	319.1
Total long-term liabilities	**323.7**	**0.6**	**324.9**
Current liabilities and provisions			
Provisions	307.9	290.4	200.9
Current liabilities, interest bearing	—	340.0	—
Current liabilities, non-interest bearing	180.6	69.4	149.0
Total current liabilities and provisions	**488.5**	**699.8**	**349.9**
Total liabilities	**812.2**	**700.4**	**674.8**
Total shareholders' equity and liabilities	**1,173.5**	**976.2**	**1,003.9**

CONSOLIDATED CHANGES IN SHAREHOLDERS' EQUITY

SEK million	2018 Jun 30	2017 Jun 30	2017 Dec 31
Opening balance, shareholders' equity	**329.1**	**310.3**	**310.3**
Total comprehensive earnings for the period	30.6	-34.9	15.7
Employee stock options, vested amount	1.5	0.4	3.0
Buy back of shares	—	—	—
New share issue	0.1	—	0.1
Closing balance, shareholders' equity	**361.3**	**275.8**	**329.1**

CONSOLIDATED CASH FLOW STATEMENTS

SEK million	Notes	2018 Apr-Jun	2017 Apr-Jun	2018 Jan-Jun	2017 Jan-Jun	2017 Jan-Dec
Operating earnings		45.4	9.8	23.5	-13.6	57.4
Interest received		—	1.7	—	4.8	0.2
Interest paid		-6.0	-7.0	-13.1	-27.1	-35.2
Adjustment for non-cash items	2	30.0	42.8	90.7	62.9	87.9
Cash flow from operating activities before changes in working capital		**69.4**	**47.3**	**101.1**	**27.0**	**110.3**
Changes in working capital		**-30.4**	**1.7**	**43.8**	**49.9**	**36.3**
Cash flow from operating activities		**39.0**	**49.0**	**144.9**	**76.9**	**146.6**
Acquisition of tangible and intangible fixed assets		-1.7	-0.5	-1.7	-0.8	-1.6
Cash flow from investing activities		**-1.7**	**-0.5**	**-1.7**	**-0.8**	**-1.6**
New share issue		0.1	—	0.1	—	0.1
Change in loans		0.4	—	0.8	-59.0	-85.5
Cash from financing activities		**0.5**	**0.0**	**0.9**	**-59.0**	**-85.4**
Cash flow for the period		**37.8**	**48.5**	**144.1**	**17.2**	**59.6**
Cash and cash equivalents at the beginning of the period		**437.5**	**250.6**	**327.9**	**282.4**	**282.4**
Exchange-rate differences in cash and cash equivalents		19.5	-4.8	22.8	-5.3	-14.1
Changes in cash and cash equivalents		57.3	43.7	166.9	11.9	45.5
Cash and cash equivalents at the end of the period		**494.8**	**294.3**	**494.8**	**294.3**	**327.9**

Key Figures[1]

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

	2018 Apr- Jun	2017 Apr-Jun	2018 Jan-Jun	2017 Jan-Jun	2017 Jan-Dec
EBIT margin, %	22.7	6.2	6.9	-4.7	8.9
Return on shareholder equity, %	15.0	1.1	7.0	-10.8	7.3
Net debt, SEK million	-175.0	45.7	-175.0	45.7	-8.8
Debt/equity ratio, %	88.5	123.3	88.5	123.3	97.0
Equity/assets ratio, %	30.8	28.3	30.8	28.3	32.8
Number of shares, before dilution	34,581,327	34,539,585	34,581,327	34,539,585	34,561,142
Number of shares, after dilution	34,640,132	34,551,912	34,640,132	34,539,585	34,671,706
Earnings per share, before dilution, SEK	1.45	0.09	0.70	-0.91	0.67
Earnings per share, after dilution, SEK	1.45	0.09	0.70	-0.91	0.67
Number of employees at the end of the period	89	98	89	98	90
Shareholders' equity, SEK million	361.3	275.8	361.3	275.8	329.1
Capital employed, SEK million	681.1	615.8	681.1	615.8	648.2
Working capital, SEK million	14.5	150.9	14.5	150.9	149.6

[1] Definitions and reconciliations of key figures are presented on page 21 of this report

PARENT COMPANY STATEMENT OF OPERATIONS

SEK million	2018 Apr-Jun	2017 Apr-Jun	2018 Jan-Jun	2017 Jan-Jun	2017 Jan-Dec
Net revenues	89.3	113.7	147.9	236.0	477.8
Cost of goods sold	-24.9	-36.5	-50.7	-96.3	-167.4
Gross profit	**64.4**	**77.2**	**97.2**	**139.7**	**310.4**
Selling expenses	11.0	-16.9	10.3	-41.9	-73.3
Administrative expenses	-27.2	-16.5	-46.9	-35.2	-67.3
Research and development costs	-29.5	-30.2	-68.5	-53.9	-105.3
Other operating income and expenses	2.9	-2.4	5.7	-2.0	-1.2
Operating earnings	**21.6**	**11.2**	**-2.2**	**6.8**	**63.3**
Interest income and expenses	-3.7	-3.5	-7.3	-8.3	-14.6
Exchange rate adjustment	—	—	—	-1.3	-1.3
Other financial expenses	7.5	-1.5	8.3	-2.6	-12.3
Net financial items	**3.9**	**-5.0**	**1.0**	**-12.2**	**-28.2**
Earnings before tax	**25.5**	**6.2**	**-1.2**	**-5.4**	**35.1**
Tax	1.9	—	1.9	—	7.6
Earnings for the period	**27.4**	**6.2**	**0.7**	**-5.4**	**42.7**

PARENT COMPANY STATEMENT OF COMPREHENSIVE INCOME

SEK million	2018 Apr-Jun	2017 Apr-Jun	2018 Jan-Jun	2017 Jan-Jun	2017 Jan-Dec
Earnings for the period	**27.4**	**6.2**	**0.7**	**-5.4**	**42.7**
Other comprehensive income	—	—	—	—	—
Total comprehensive earnings for the period	**27.4**	**6.2**	**0.7**	**-5.4**	**42.7**

PARENT COMPANY BALANCE SHEET

SEK million	2018 Jun 30	2017 Jun 30	2017 Dec 31
ASSETS			
Fixed assets			
Intangible fixed assets	112.1	129.8	121.0
Tangible fixed assets	29.7	20.5	27.4
Shares in subsidiaries	151.0	149.3	150.6
Total fixed assets	**292.8**	**299.6**	**299.0**
Current assets			
Inventories	158.7	210.7	186.3
Accounts receivable and other receivables	133.6	156.0	158.4
Cash and bank balances	241.5	145.4	215.1
Total current assets	**533.8**	**512.1**	**559.8**
Total assets	**826.6**	**811.7**	**858.8**
SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES			
Shareholders' equity	**311.8**	**258.6**	**309.4**
Long-term liabilities			
Other provisions	3.5	0.6	4.9
Bond loan	319.8	—	319.1
Total long-term liabilities	**323.3**	**0.6**	**324.0**
Current liabilities			
Accounts payable	16.7	7.2	28.9
Bond loan	—	340.0	—
Other liabilities	11.2	18.5	6.6
Liabilities to Group companies	140.3	163.6	169.1
Accrued expenses and deferred income	23.3	23.2	20.8
Total current liabilities	**191.5**	**552.5**	**225.4**
Total liabilities	**514.8**	**553.1**	**549.4**
Total shareholders' equity and liabilities	**826.6**	**811.7**	**858.8**

Notes

1. Accounting policies

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

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

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

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

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

IFRS 16 Leases will replace IAS 17. According to the new standard, most leased assets must be recognized in the balance sheet and the lessee shall divide up the cost into interest payments and depreciation of the asset. The standard will be applied by the Group and the Parent Company as from January 1, 2019. Orexo's preliminary assessment is that most of the leasing agreements that are recognized as operational leasing agreements will be recognized in the balance sheet. This will also mean that the cost of these will be recognized, divided up into interest payments and depreciation.

2. Cash flow

ADJUSTMENT FOR NON-CASH ITEMS

SEK million	2018 Apr-Jun	2017 Apr-Jun	2018 Jan-Jun	2017 Jan-Jun	2017 Jan-Dec
Depreciation/amortization and impairment	5.2	4.6	10.3	10.0	20.8
Change in provisions	27.5	41.7	84.7	72.5	59.9
Share based payments	0.4	1.1	1.5	0.3	3.0
Exchange rate income and expenses	-3.1	-4.6	-5.8	-19.9	4.2
Total	**30.0**	**42.8**	**90.7**	**62.9**	**87.9**

3. Legal disputes

Paragraph IV litigations against Actavis regarding Zubsolv® in the US

On December 7, 2016, Orexo appealed the District Court's decision relating to the validity of the '330 patent to the Court of Appeals for the Federal Circuit. Actavis did not appeal the District Court's decision relating to the validity and infringement of the '996 patent, securing Zubsolv exclusivity on the US market until at least September 24, 2019. An oral session was held in the US Court of Appeals for the Federal Circuit on October 4, 2017. According to updated information from external parties some decisions from the Court of Appeals for the Federal Circuit now take more than nine months from the date of the oral session. The impact on the timing of the decision is due to an increased workload at the Court of Appeals. Neither Orexo, nor any other external parties, have any influence on the timing of the decision.

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. 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 1,459 million as of December 31 2017 and refers to the Swedish companies. Of these, SEK 9.4 million has been capitalized as per June 30, 2018. 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. Important events after the period

No important events after the period.

6. Revenue from contracts with customers

SEK million	2018 Apr-Jun				
Type of revenue	**Zubsolv®**	**Abstral®**	**Edluar®**	**OX-CLI**	**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-CLI**	**Total**
US	158.4	1.3	-2.0	—	**157.7**
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	2017 Apr-Jun				
Type of revenue	**Zubsolv**	**Abstral**	**Edluar**	**OX-CLI**	**Total**
Sales, products	124.1	—	—	—	**124.1**
Royalties	—	9.8	3.4	—	**13.2**
Milestones	—	—	—	21.8	**21.8**
Total revenue from contracts with customers	**124.1**	**9.8**	**3.4**	**21.8**	**159.1**
Geographical markets	**Zubsolv**	**Abstral**	**Edluar**	**OX-CLI**	**Total**
US	124.1	1.0	2.1	—	**127.2**
EU	—	3.9	0.2	21.8	**25.9**
Rest of the world	—	4.9	1.1	—	**6.0**
Total revenue from contracts with customers	**124.1**	**9.8**	**3.4**	**21.8**	**159.1**

SEK million	2018 Jan-Jun				
Type of revenue	**Zubsolv**	**Abstral**	**Edluar**	**OX-CLI**	**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-CLI**	**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	2017 Jan-Jun				
Type of revenue	**Zubsolv®**	**Abstral®**	**Edluar®**	**OX-CLI**	**Total**
Sales, products	238.2	—	—	—	**238.2**
Royalties	—	18.4	8.0	—	**26.4**
Milestones	—	—	—	21.8	**21.8**
Total revenue from contracts with customers	**238.2**	**18.4**	**8.0**	**21.8**	**286.4**
Geographical markets	**Zubsolv**	**Abstral**	**Edluar**	**OX-CLI**	**Total**
US	238.2	3.3	4.6	—	**246.1**
EU	—	4.6	0.3	21.8	**26.7**
Rest of the world	—	10.5	3.1	—	**13.6**
Total revenue from contracts with customers	**238.2**	**18.4**	**8.0**	**21.8**	**286.4**

SEK million	2017 Jan-Dec				
Type of revenue	**Zubsolv**	**Abstral**	**Edluar**	**OX-CLI**	**Total**
Sales, products	491.4	—	—	—	**491.4**
Royalties	—	113.2	17.3	—	**130.5**
Milestones	—	—	—	21.8	**21.8**
Total revenue from contracts with customers	**491.4**	**113.2**	**17.3**	**21.8**	**643.7**
Geographical markets	**Zubsolv**	**Abstral**	**Edluar**	**OX-CLI**	**Total**
US	485.8	5.1	10.2	—	**501.1**
EU	5.6	88.6	0.8	21.8	**116.8**
Rest of the world	—	19.5	6.3	—	**25.8**
Total revenue from contracts with customers	**491.4**	**113.2**	**17.3**	**21.8**	**643.7**

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

Definitions and reconciliations of key figures

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

Margins	Definition/calculation	Purpose
Gross margin	Gross profit divided by net revenues	Gross Margin is used to measure the relative direct profitability from sold products
Operating margin (EBIT margin)	Operating earnings as a percentage of net revenues	Operating profit margin is used for measuring the operational profitability
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 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
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

EBITDA SEK million	2018 Apr-Jun	2017 Apr-Jun	2018 Jan-Jun	2017 Jan-Jun	2017 Jan-Dec
EBIT	45.4	9.8	23.5	-13.6	57.4
Depreciation and amortization	5.2	5.2	10.3	10.4	20.8
EBITDA	**50.6**	**15.0**	**33.8**	**-3.2**	**78.2**

RETURN ON SHAREHOLDERS' EQUITY	2018 Apr-Jun	2017 Apr-Jun	2018 Jan-Jun	2017 Jan-Jun	2017 Jan-Dec
Shareholders' equity beginning balance	305.4	273.3	329.1	310.3	310.3
Shareholders' equity ending balance	361.3	275.8	361.3	275.8	329.1
Average shareholders' equity	333.3	274.6	345.2	293.1	319.7
Net earnings	50.1	3.1	24.1	-31.6	23.2
Return on shareholders' equity %	**15.0**	**1.1**	**7.0**	**-10.8**	**7.3**

OPERATING EXPENSES SEK million	2018 Apr-Jun	2017 Apr-Jun	2018 Jan-Jun	2017 Jan-Jun	2017 Jan-Dec
Selling expenses	-48.6	-49.7	-92.0	-97.9	-190.5
Administrative expenses	-34.0	-22.4	-61.2	-48.8	-96.1
Research and development costs	-37.0	-39.1	-82.4	-69.4	-134.2
Other operating income and expenses	2.9	-2.3	5.7	-1.9	-1.1
Operating expenses	**-116.7**	**-113.5**	**-229.9**	**-218.0**	**-421.9**

GROSS INVESTMENTS SEK million	2018 Apr-Jun	2017 Apr-Jun	2018 Jan-Jun	2017 Jan-Jun	2017 Jan-Dec
Investments in tangible fixed assets	1.7	0.4	1.7	0.6	1.1
Investments in intangible fixed assets	—	0.1	—	0.1	0.5
Gross investments	**1.7**	**0.5**	**1.7**	**0.7**	**1.6**

Glossary

Alfentanil
A potent synthetic opioid analgesic drug, used for anesthesia in surgery
American Depositary Receipt (ADR)
An instrument that is issued by a depositary bank that represents ownership of a company's underlying shares. ADR programs are created to facilitate US investors to hold shares in non-US companies and trade them in the same way as US securities.
ANDA
An Abbreviated New Drug Application (ANDA) is an application for a US generic drug approval for an existing licensed medication or approved drug
Anesthesia
Procedure for lowering a patient's consciousness to enable a Medical procedure to proceed without pain for the patient
Breakthrough pain
A short, intensive period of pain that occurs in addition to chronic levels of long-term pain even though these are treated by regular painkillers
Buprenorphine
A potent opioid partial agonist first used as a pain-relieving substance, but now most commonly used to help patients withdraw from more addictive opioid drugs such as morphine
CARA
The Comprehensive Addiction and Recovery Act (CARA) became law in the US in July 2016. CARA authorizes a series of grants aimed at among other things developing treatment programs which further expands buprenorphine prescribing rights to nurse practitioners and physician assistants
Cash & vouchers segment
One of the three distinct payer segments in the US market for treatment of opioid dependence. In this segment, the patient is paying for the prescriptions out of pocket
CHMP
The Committee for Medicinal Products for Human Use
CLI
Cysteinyl Leukotriene Inhibitor
Clinical studies/Clinical trials
Studies of the safety and efficacy of a drug in human beings
Commercial segment
One of the three distinct payer segments in the US market for treatment of opioid dependence. The commercial segment is funded by private insurances or employers
Drug delivery
The process through which a pharmaceutical may be introduced to the patient that enables the active compound to function as intended
EMA
The European Medicine Agency
FDA
The US Food and Drug Administration
Fentanyl
An opioid with a similar effect on human patients as morphine. Used mainly within anesthesia and analgesia
GMP
Good Manufacturing Practice
HHS
The US Department of Health and Human Services
In Vitro studies
In an in vitro study; living matter is examined outside of its natural context e.g. in a test-tube
IP
Intellectual Properties
Naloxone
An opioid inverse agonist used to counter the effects of opioids
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