Full Year Report 2016

“We reached profitability in 2016 and to maintain profitability it is essential for us to continue to improve productivity. To fully leverage the existing commercial infrastructure we aim to add more products to our commercial organization and this will be a key objective for the year.”

Nikolaj Sørensen, CEO and President

About Orexo

Orexo is a specialty pharmaceutical company commercializing its proprietary product Zubsolv® for treatment of opioid dependence in the US. Zubsolv is an advanced formulation of buprenorphine and naloxone using Orexo’s unique knowledge and expertise in sublingual drug delivery. R&D is focusing on reformulation of known substances to new improved products that meet great unmet medical needs by using its patented proprietary technologies. Orexo’s share is listed on Nasdaq Stockholm Mid Cap (STO:ORX) and is available as ADRs on OTCQX (ORXOY) in the US. Orexo’s global headquarters and R&D are based in Uppsala, Sweden.

For more information about Orexo please visit **www.orexo.com** or follow us on Twitter, **@orexoabpubl**, or LinkedIn.

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Future reporting dates

Publication of the Annual Report	Week 12, 2017
Interim Report January – March 2017	April 20, 2017, at 8.00am CET
Interim Report January – June 2017	July 11, 2017, at 8.00am CET
Interim Report January – September 2017	October 19, 2017, at 8.00am CET

This Full Year Report is covered in a conference call on the date of publication. Details on how to access the call is provided on page 2 and on Orexo's website, www.orexo.com.

Full Year Report 2016

Unless otherwise stated in this report, all data refers to the Group. Figures in parentheses relate to the corresponding period in 2015.

2016 - First profitable year

Fourth quarter 2016[1]

- Total net revenues MSEK 184.7 (228.3)
- Zubsolv® net revenue MSEK 128.2 (120.3)
- Net earnings MSEK 33.3 (-51.8)
- Earnings per share, before and after dilution, SEK 0.97/0.96 (-1.50)
- Cash and cash equivalents MSEK 282.4 (198.1)
- Together with Mundipharma Orexo made the first EU regulatory submission of a Marketing Authorisation Application (MAA) for Zubsolv for the treatment of opioid dependence
- FDA approved a new unique low 0.7mg/0.18mg dosage of Zubsolv
- The US District Court for the District of Delaware ruled in Orexo's favor in one of the patent infringement litigations against Actavis regarding Orexo´s ´996 patent protecting Zubsolv in the US. Patent ´330 declared invalid.
- The decision rendered by the US District Court for the District of Delaware regarding the validity of Orexo's ´330 patent protecting Zubsolv in the US has been appealed
- Completion of a bond buyback program amounting to a nominal value of MSEK 99

January - December 2016[1]

- Total net revenues MSEK 705.9 (646.2)
- Zubsolv net revenue MSEK 481.8 (416.7)
- Net earnings MSEK 29.0 (-210.0)
- Earnings per share, before and after dilution, SEK 0.84 (-5.74)
- Cash flow from operating activities MSEK 156.2 (-109.2)
- Cash and cash equivalents MSEK 282.4 (198.1)
- AstraZeneca acquired all rights to Orexo´s OX-CLI project for MUSD 5 (MSEK 40.8)
- Zubsolv was selected by the State of Maryland as the exclusive preferred buprenorphine/naloxone agent for the FFS Medicaid Formulary effective July 1, 2016
- A license agreement was signed with Mundipharma, which obtains Rest of the World[2] rights to Zubsolv
- The US Department of Health and Human Services (HHS) announced an increase in buprenorphine patient cap from 100 to 275
- The US Congress signed CARA[3] into law which grants the expansion of buprenorphine prescribing privileges to nurse practitioners and physicians assistants
- Completion of 1,080 patient REZOLV study and reported on important characteristics intended to improve opioid dependent patient outcomes

[1] *Certain 2015 and 2016 figures have been restated. See Note 1 for more information.*

[2] *All markets except the US*

[3] *Comprehensive Addiction and Recovery Act of 2016*

MSEK	**2016 Oct-Dec**	**2015 Oct-Dec Restated**	**2016 Jan-Dec**	**2015 Jan-Dec Restated**
Net revenues	184.7	228.3	705.9	646.2
EBIT	33.2	-44.3	51.7	-180.6
EBITDA	44.2	24.8	74.5	-100.0
Net Earnings	33.3	-51.8	29.0	-210.0
Earnings per share, before and after dilution, SEK	0.97/0.96	-1.50/ -1.49	0.84/0.84	-6.07/ -6.07
Cash flow from operating activities	N/A	N/A	156.2	-109.2
Cash and cash equivalents	282.4	198.1	282.4	198.1

For information regarding restatement of prior periods see note 1

Teleconference

CEO Nikolaj Sørensen and CFO Henrik Juuel will present the report at a teleconference on January 26, 2017, at 2:00pm CET. Please view instructions below on how to participate.
Internet: https://wonderland.videosync.fi/orexo-q4-report-2016
Telephone: +46 8 566 426 62 (SE), +44 20 300 898 04 (UK) or +1 855 753 2236 (US).
There will be a Q&A session and questions can also be sent in advance to ir@orexo.com at latest 11pm CET.
The presentation will be available at Orexo´s website one hour prior to the teleconference.

For further information, please contact:
Nikolaj Sørensen, CEO and President, or Henrik Juuel, EVP and CFO
Tel: +46 (0)18 780 88 00, E-mail: ir@orexo.com

CEO's comments

I am pleased to announce 2016 as the first year in the history of Orexo with full year positive earnings. This marks an important milestone for the company in the quest to become a sustainable specialty pharmaceutical company. The company is now standing on a solid financial foundation with five consecutive quarters of positive cash flow from operating activities and we project 2017 will continue with positive cash flow and EBIT on a full year basis.

The main growth driver has been Zubsolv®, with revenue growth of 15.6 percent compared to 2015. This growth was accomplished despite a loss in market share early in the year due to changes in the market access position. Continued improvement in market access for Zubsolv remains a key success factor moving forward. Even though Zubsolv was negatively impacted by some external market events in late 2016, in particular a large health care provider group decided to leave WellCare in December, we are starting 2017 with a better market access position compared to 2016.

Opioid dependency is a problem that continues to grow and therefore it´s encouraging to see that more than 2,600 physicians have been certified to expand their prescriber base up to 275 patients in their treatment programs in the US. About half of these physicians have already started to recruit more patients and we expect many of the remaining physicians to expand their patient base in 2017. Zubsolv is winning a disproportionate share of this market growth and we expect this to continue in 2017.

Another key event during the quarter was the first decision in our litigation against Actavis. Since Actavis has not appealed the validity of the decision on the '996 patent, Zubsolv exclusivity is now secured until at least until September 2019. We have appealed the decision concerning our 330' patent to the federal circuit and expect their decision to come within 12 months. Thus, with the appeal and two additional patents valid until 2032, which are subject to separate court cases, I maintain confident in the long term IP protection of Zubsolv.

We reached profitability in 2016 and now it is essential for us to continue to improve the productivity of our organization to maintain the profitability in 2017 and beyond. To fully leverage the existing commercial infrastructure we aim to add more products to our commercial organization and this will be a key objective for the year. In addition we expect a substantial improvement with regard to the cost of goods of Zubsolv with gradual impact starting in 2018[4]. In our development team we aim at advancing some of our early R&D projects into a concrete innovative product pipeline. My colleagues and I are looking forward to 2017 as a year with many opportunities to further strengthen Orexo.

Nikolaj Sørensen
CEO and President

[4] *Based on the currency exchange rates in December 2016.*

The period January-December in numbers

In preparing the financial statements for the period January-December 2016 some restatements relating to previous periods were identified. For consolidated financial statements see note 1.

Revenues

Launched products

Zubsolv® US revenue amounted to MSEK 128.2 (120.3) in Q4 corresponding to a 6.6 percent growth over same period last year and a decline of 10.0 percent from previous quarter.

Versus the previous quarter total demand was unchanged. While Zubsolv continued to grow its market share in the commercial segment this was off-set by a loss of market share in the Medicaid business. The Zubsolv Medicaid business suffered on two fronts. First, and as expected, Zubsolv lost market share in Maryland as some patients were transferred back to their prior medication. Secondly, the total WellCare business declined as the SelfRefind group of clinics discontinued participating in all WellCare insurance plans. The total market share declined from 6.2 percent in Q3 to 6.0 percent in Q4.

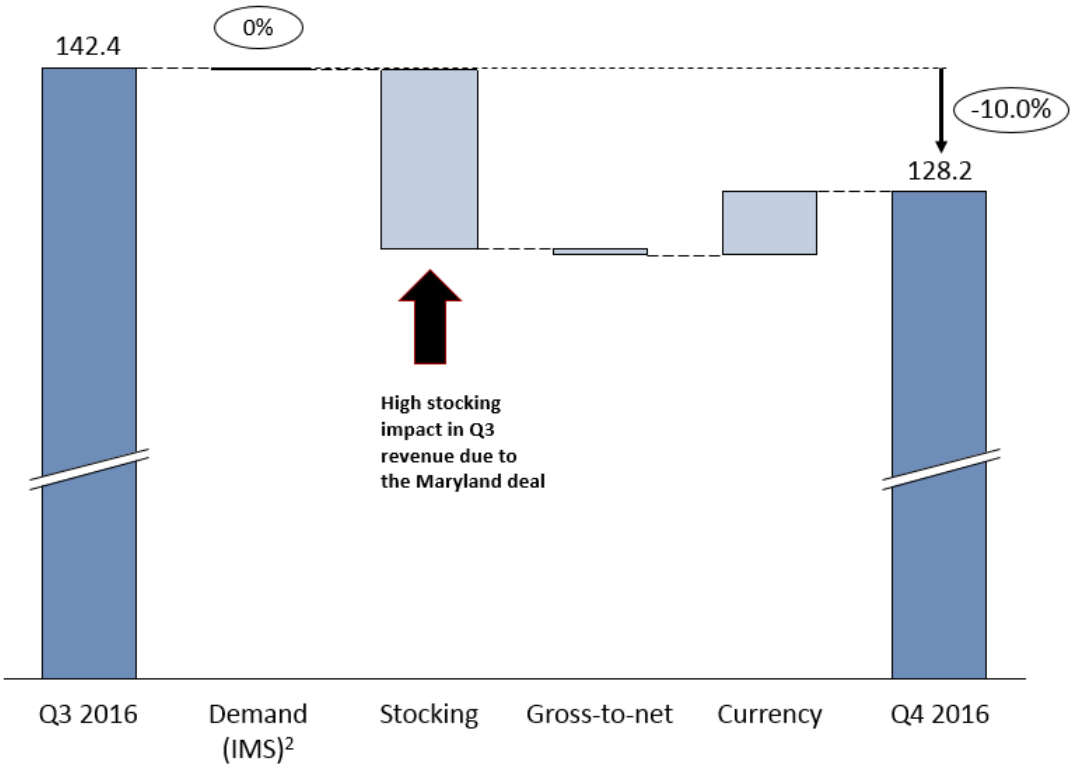
The Q3 2016 revenue included significantly increased stocking at wholesaler and pharmacy level due to the significant Maryland demand. The Q4 revenue numbers do not include any Zubsolv inventory build-up and hence this explains the difference between the two quarters.

The average gross-to-net ratio for Q4 2016 was marginally lower than previous quarter and the development of the USD/SEK exchange rate during the quarter had a moderate positive impact on revenue in SEK.

The full year gross-to-net ratio was positively impacted by both actual rebates and actual return rates being lower than accrued for in December 2015. Total impact estimated to approximately MUSD 3.

For the period January-December Zubsolv revenue amounted to MSEK 481.8 (416.7) corresponding to an increase of 15.6 percent despite the loss of the CVS Caremark agreement from January 1, 2016.

Q4 Zubsolv® US revenue growth (MSEK) by key drivers[1]



[1] Orexo analysis using IMS demand data

2 Includes IMS numbers and institutional sales

Total Abstral® royalties and milestone payments amounted to MSEK 52.2 (105.1) for the period October-December 2016 and to MSEK 102.6 (203.4) for the period January-December 2016. The decrease compared to last year is explained by a significant milestone payment and a fixed royalty component included in the previous year. Excluding these non-recurring items, Abstral driven revenue grew by 32 percent primarily by the continued strong performance of the product in Europe.

Royalty revenues from Edluar® amounted to MSEK 4.3 (2.9) for the period October-December 2016 and MSEK 14.8 (13.6) for the period January-December 2016.

Collaboration projects
For the period January-December revenue generated from collaboration projects amounted to MSEK 106.7 (0.0) and included milestone payments from AstraZeneca (OX-CLI project) and Mundipharma (Zubsolv RoW license).

Total revenues

Total revenues during the period October-December 2016 amounted to MSEK 184.7 (228.3), a decline of 19.1 percent compared with the same period the previous year, explained by the non-recurring Abstral milestone payment in Q4 2015. For the period January-December 2016 total revenues amounted to MSEK 705.9 (646.5), a growth of 9.7 percent.

Total net revenues were distributed as follows

MSEK	**2016 Oct-Dec**	**2015 Oct-Dec Restated**	**2016 Jan-Dec**	**2015 Jan-Dec Restated**
Zubsolv® US	128.2	120.3	481.8	416.7
Zubsolv – Rest of the World	-	-	65.9	-
Zubsolv – total	***128.2***	***120.3***	***547.7***	***416.7***
Abstral® royalties	52.2	39.5	100.4	77.2
Fixed royalty Abstral[1]	-	-	-	59.9
Milestone payment Abstral	-	65.6	2.2	66.0
Abstral – total	***52.2***	***105.1***	***102.6***	***203.1***
Edluar® royalties	4.3	2.9	14.8	13.6
Kibion	-	-	-	12.8
Other revenues[2]	-	-	40.8	-
Total	***184.7***	***228.3***	***705.9***	***646.2***

[1] For more information, see Revenues – Launched products
[2] Relates to the acquisition of OX-CLI by AstraZeneca

For information regarding restatement of prior periods see note 1

Costs and earnings

Cost of goods sold

Cost of goods (COGS) sold amounted to MSEK 34.2 (32.3) for the period October-December 2016 and MSEK 149.9 (150.2) for the period January-December 2016, and all relates to Zubsolv US. The re-packing and de-blistering project announced in Q3 2016 was not fully completed during Q4 2016. An extra cost of MSEK 6.5 was included for this project in Q4 2016 and the project is now expected to be finalized during the first half year 2017 with an additional impact of approximately MSEK 5 expected.

Selling expenses

Selling expenses amounted to MSEK 66.2 (72.0) for the period October-December 2016, higher than previously guided primarily due to the USD/SEK currency development. Selling expenses for the period January-December 2016 amounted to MSEK 240.6 (297.5). The full year decrease is explained by the optimization of the field force commenced late 2015 which more than off-set the currency impact.

Administrative expenses

Administrative expenses for the period October-December 2016 amounted to MSEK 30.4 (41.8), in line with previous guidance. For the period January-December 2016 the administrative expenses amounted to MSEK 161.6 (141.5). The increase is explained by significant expenses related to IP litigations and by the USD/SEK development. Nearly half of the total administrative expenses for the year was spend on IP litigation cases.

Research and development costs

For the period October-December 2016, research and development costs amounted to MSEK 34.5 (56.0), in line with previous guidance. For the period January-December 2016 R&D costs amounted to MSEK 132.3 (172.6). The period January-December 2015 included significant costs

related to the REZOLV study and Zubsolv® Life Cycle Management (LCM) projects whereas the main 2016 activity, Zubsolv Pharmacokinetics (PK) study for EU submission, was financed by Mundipharma.

Costs for long-term incentive program
The Group's total costs for employee stock option programs during the period October-December 2016 amounted to MSEK 0.4 (2.0). For the period January-December 2016, the costs amounted to MSEK -0.7 (-10.2).

Other income and expenses
Other income and expenses amounted to MSEK 13.8 (-70.5) for the period October-December 2016 and to MSEK 29.9 (-65.0) for the period January-December 2016. This is primarily comprised of exchange-rate gains/losses derived from revaluations of balance sheet items in foreign currency. The period October-December 2016 was positively impacted by an earn-out settlement related to the divestment of the subsidiary Kibion. The divestment of Kibion, April 2015, has now been fully accounted for. Q4 2015 included an OX-MPI impairment charge of MSEK 62.

Depreciation and amortization
Depreciation and amortization amounted to MSEK 10.9 (69.1) for the period October-December 2016 and to MSEK 22.7 (80.7) for the period January-December. Q4 2015 included an OX-MPI impairment charge of MSEK 62.

Net financial items
Net financial items for the period October-December 2016 amounted to MSEK 1.2 (-6.0) and to MSEK -16.1 (-23.0) for the period January-December. All the net financial items are related to financing activities. Orexo corporate bonds with a nominal value of MSEK 99 were bought back in the market during December 2016 and Net financial items were positively impacted by this from the difference between book value and purchase price.

Net earnings
Net earnings amounted to MSEK 33.3 (-51.8) for the period October-December 2016 and to MSEK 29.0 (-210.0) for the period January-December 2016.

Cash flow and financial position

At December 31, 2016, cash and cash equivalents amounted to MSEK 282.4 (198.1) and interest-bearing liabilities to MSEK 397.8 (494.4).

Cash flow from operating activities was positive and amounted to MSEK 156.2 (-109.2) for the period January-December 2016 driven by positive operating earnings and improvements in working capital.

During the fourth quarter 2016 Orexo corporate bonds were bought back with a nominal value of MSEK 99. The impact of this bond buy-back is reflected in the cash flow from investing activities. Despite the cash outlay for the bond buy-back the total cash flow for the year was positive by MSEK 71.0.

Shareholders' equity at December 31, 2016 was MSEK 310.3 (270.1). The equity/asset ratio was 30 (26) percent.

The Board of Directors proposes that no dividend is paid for the financial year 2016.

Investments in fixed assets

Investments in tangible and intangible fixed assets amounted to MSEK 0.1 (1.1) for the period October-December 2016. For the period January-December 2016, investments amounted to MSEK 1.3 (4.1).

Operations

Launched products

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

Overall the total buprenorphine/naloxone market increased 3.0 percent in volume compared to Q3 2016, and is up 7.6 percent compared to Q4 2015. The market is predicted to continue to grow as more providers become waivered or current prescribers expand their patient cap limits to treat opioid dependence in 2017. Through the end of 2016 nearly 2,600 physicians have been waivered to increase their patient cap to 275 and approximately half of these physicians have begun to demonstrate expanded prescribing. In addition, nurse practitioners and physicians assistants will begin to receive training and waivers to prescribe buprenorphine based on the CARA Act and local state laws during 2017.

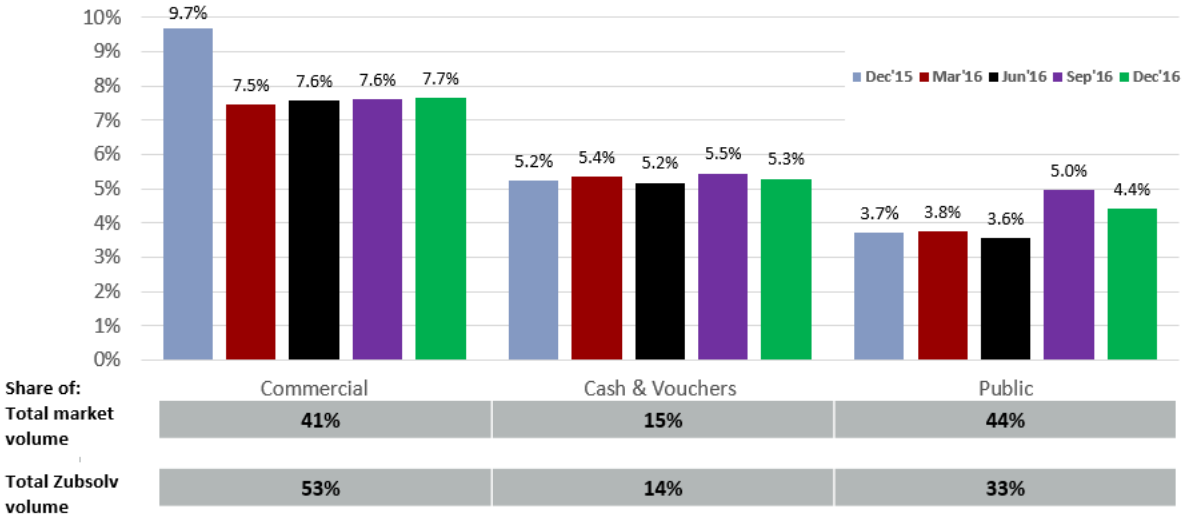
Zubsolv volumes were unchanged compared to Q3 2016 in terms of tablets dispensed to patients through pharmacies. The lack of growth was caused primarily by an event outside Orexo's control and influence. A large provider group, SelfRefind, in Kentucky withdrew completely from the insurer WellCare and required patients to switch to one of two other insurers. Zubsolv is the only preferred choice on formulary with WellCare and only on formulary with one of these two providers causing patients to shift to a competing pharmaceutical. Additionally, as previously reported Zubsolv remains the preferred formulary product on Maryland Medicaid though certain physicians are utilizing the states simple prior authorization process to switch back to Suboxone Film which is a non-preferred formulary product.

The payer market for Zubsolv 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 patients to directly access. During 2016, for the first time since launch, we have started to see demonstrable sales into institutional settings who dispense medication directly to patients. This volume is not captured by the weekly prescription audit reports. During Q4 the sales to these institutions accounted for approximately 2 percent of the overall sales of Zubsolv, but represent a very profitable business for Zubsolv.

The public segment continues to be the fastest growing payer segment and we expect this to continue. However, the cash and commercial markets are likely to increase also with the improved access to treatment following the legislative changes in the US. Orexo has been increasing efforts in the public segment to capitalize on these trends and one significant result is the agreement in Maryland from July 1. After the initial market share increase we have seen a flow back of patients in Maryland to their original medication in primarily August-September but some decline continued in Q4, which together with the provider group, SelfRefind, leaving WellCare resulted in a decline in market share in the public segment from 5.0 percent in September to 4.4 percent in December. Due to the high rebates for exclusive agreements in the public segment and that a share of the SelfRefind patients have continued with Zubsolv insured by other companies associated with less rebate, the effect on gross profit is limited of this decline in market share.

With the increased share of volume in the public segment and increased price pressure across all segments there will be a negative impact on the average gross-to-net ratio in 2017. However, all products have raised prices with 5-6 percent from January 1, which will compensate for a portion of the increased rebates.

Zubsolv® market share per type of payer segment, rolling 4 weeks, Dec. 2015-Dec. 2016[1]



1 IMS XPO PA: Dec'15 data: R4W WE 12/25/2015; Mar'16 data: R4W WE 03/25/2016; Jun'16 data: R4W WE 06/24/2016; Sept'16 data: R4W WE 09/23/2016; Dec'16 data: R4W WE 12/23/2016

Expansion of access to treatment

In the beginning of July, the US Department of Health and Human Services (HHS) decided to enable physicians to treat up to 275 patients under certain criteria (C275 physicians). Shortly after the HHS announcement the US Congress approved legislation, known as the "CARA bill", which will further expand buprenorphine prescribing rights to nurse practitioners and physician assistants. The expansion of prescription rights to nurse practitioners and physician assistants is being accelerated and training and wavering for prescribing rights is beginning in early 2017 creating another opportunity to accelerate market and Zubsolv growth.

The ambition for Zubsolv is to take a disproportionally higher share of the new patients in the market. IMS dataset shows Zubsolv's naive patient share is 10.7 percent (TRx), in comparison with the national average of 6.0 percent (TRx) in Q4 (October & November). The ability to win new market share for Zubsolv is depending on where the growth will take place and in particular the market access position for Zubsolv with the new patients. Of the physicians certified today about 60 percent have been covered by our sales force in Q4 and of the certified physicians at year-end 78 percent are within reach of our existing sale force territories.

Approximately 70 percent of the initial growth from the C275 physicians has been patients in the public segment, where Zubsolv has more restricted market access. To review Zubsolv's ability to win market share we have made an analysis excluding isolated market access events, included growth in cash, commercial, Medicaid with unrestricted access and where we have sales force coverage. With these adjustments we are beginning to observe some positive impact of the change on the development for the market and for Zubsolv in particular e.g.:

- The C275 physicians grew 7.7 percent from August to December, while the overall market grew 4.0 percent

- Zubsolv®'s market share of growth was 13.5 percent in commercial and cash, 3.5 percentage point higher than our base market share in this segment (before growth).
- Zubsolv's market share of growth was 14.8 percent in Medicaid 5.6 percentage points higher than our base market share in this segment

Orexo is continuously assessing the changing market dynamics and will expand the field force to improve the coverage of the C275 physicians where feasible. Improved market access is critical to gain a larger share of the overall growth, but current data shows Zubsolv has the ability to win market share when the market grow.

Commercial (private insurance)
(41% of the total market, 53% of Zubsolv business in December)

In the commercial segment, Zubsolv's market share increased by 0.1 percentage points and prescriptions increased 1.6 percent compared to Q3 2016. The largest contributor to Orexo market share and volume in the commercial segment, United Health Group has announced they intend to exit most of the Health Exchanges (Affordable Care Act) from January 1, 2017, although not a significant portion of the volume within United Health Group, this change is likely to have some impact on Zubsolv market share early in 2017. During Q4 Zubsolv was granted preferred status with Cigna and from January 1, 2017 Zubsolv will gain improved reimbursement on some smaller regional plans.

The commercial segment has grown 1.6 percent in volume compared to Q3 2016, and 4.5 percent compared to Q4 2015. Zubsolv has unrestricted access to 81 percent of the business in the commercial segment.

Cash (Cash & Vouchers, the patient pays)
(15% of the total market, 14% of Zubsolv business in December)

Zubsolv´s market share has declined from 5.5 percent to 5.3 percent in Q4 2016 in this segment. The cash market is the most sensitive market to price and discount programs which has impacted the dynamic in the segment when generic manufacturers use regional discount cards resulting in a price level below Zubsolv in some regions. This dynamic has been confined to a small number of states that implemented restrictions on physician payments for services. The cash segment is less likely to be directly impacted by the expansion in access to treatment, as the requirements for expanding to 275 patients encourages clinics and physicians that are more likely to accept insurance.

The cash segment has grown 0.1 percent in volume during Q4 compared to Q3 2016, and has declined 7.7 percent compared to Q4 2015. Zubsolv has access to 100 percent of the business in the cash segment.

Public (Managed Medicaid, FFS Medicaid, Medicare Part D)
(44% of the total market, 33% of Zubsolv business in December)

The public market continued with the fastest growth in the disease area driven by increased access to publicly financed insurances for opioid dependent patients. This segment has grown 5.4 percent in volume during Q4 compared to Q3, 2016, and 16.4 percent compared to Q4, 2015. During the quarter Zubsolv had access to 45 percent of the business in the public segment. The market share of Zubsolv decreased in this segment by 0.6 percentage points in Q4 from Q3 2016, primarily due to Maryland patients going back to their prior medication and SelfRefind leaving WellCare.

During the quarter, it is clear the prior authorization process allows for patients to switch back to their previous medication and the prescriptions of Zubsolv® in Maryland declined with around 16 percent in Q4 2016 from Q3 2016, and Zubsolv now accounts for about 40 percent of volume in Maryland FFS Medicaid.

From January 1, 2017 Zubsolv will for the first time gain preferred status with a large Medicare Part D insurance company, a large Managed Medicaid provider and some smaller public plans. All will be improvement from a non-covered to a preferred position in parity with at least one other branded competitor.

Paragraph IV litigation against Actavis

In May 2014, Actavis notified Orexo that it had filed an ANDA for generic Zubsolv 1.4 and 5.7 mg products in the US alleging that Orexo's patents were invalid and not infringed. In June 2014, Orexo initiated the litigation process against Actavis. The decision in this litigation process, involving Orexo's US patents 8,454,996 and 8,940,330, was issued on November 15, 2016, by the United States District Court for the District of Delaware. The District Court held that Orexo's '996 patent is valid and infringed by Actavis's generic Zubsolv 1.4 and 5.7 mg products. The District Court also held that Orexo's '330 patent is invalid. The '996 and '330 patents expire in September 2019 and September 2032, respectively.

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. Generally, the Federal Circuit takes about one year from the District Court decision to render a ruling on the appeal. 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.

During the litigation process, Orexo has received approval of several new strengths of Zubsolv (2.9, 8.6 and 11.4 mg), and Actavis has filed a new ANDA for these new strengths. Consequently, Orexo has initiated separate litigation processes for these new strengths. These lawsuits are based on the same patents as the initial process and the decision of the first litigation process may influence and control the decision in the litigation processes regarding the new strengths.

In addition, two new Zubsolv patents, US patents 9,259,421 and 9,439,900, have been issued and listed in the Orange Book with the FDA, after the initiation of the first litigation process. Both of these patents are related to the '330 patent and expire in September 2032. Orexo has initiated new litigation processes against Actavis involving all strengths (except the recently approved 0.7 mg strength) on the '421 and '900 patents.

Abstral® and Edluar®

Due to the timing of the Full year report, Orexo has not yet received final data for fourth quarter sales of Abstral and Edluar from our partners and hence the calculation of Q4 royalties is based on Orexo forecast and preliminary Q4 sales reports where available. For the same reason the Abstral and Edluar sections below primarily refer to the sales development in Q3 2016.

Abstral – for rapid relief from breakthrough pain in cancer patients

Sales of Abstral in the EU continue to grow and amounted to MEUR 21.7, which is an increase of 8.9 percent in Q3 2016 compared to Q3 2015. Orexo receives royalty on sales exceeding MEUR 42.5, which in 2016 was achieved in July.

In the US market, Orexo's partner since November 2015, Sentynl Therapeutics Inc. continued with its relaunch of Abstral during the quarter. In Q3 2016, net sales were 44 percent lower than same period in 2015, a significant reduction, but a very limited impact in absolute terms.

Sales of Abstral® in the region RoW (markets excluding EU and the US) have continued to grow. Total sales for the RoW reached MUSD 2.2 in Q3 2016, which is an increase of 91 percent compared with Q3 2015.

Orexo's commercial partner in Japan, Kyowa Hakko Kirin, continued to focus on growing the Japanese market for Abstral. Net sales grew by a double digit figure during the two first months of Q3, 2016, over the same period in 2015.

Edluar®- for treatment of short-term insomnia
Global sales of Edluar, commercialized by Mylan which in 2016 acquired our former partner Meda AB, were up 20 percent in Q3 2016 compared with Q3 2015. Total sales for the quarter amounted to MEUR 3.8 (3.1).

Edluar is likely to face generic competition in the North American markets during 2017 which is expected to have negative impact on sales in 2017 and beyond.

Development programs

OX51 – prevention of acute episodes of pain
OX51 is a new sublingual formulation containing alfentanil. The project has been developed to meet the rapidly growing demand for effective pain relief during short surgical and diagnostic procedures.

A placebo-controlled dose-finding study in patients undergoing prostate biopsy was completed in 2013. The results supported a continuation of the development of OX51 to the next phase in development towards a new product.

The commercial potential of OX51 is estimated to be substantial and Orexo is presently in the process of identifying the optimal partner for phase III and commercialization in various geographies. Discussions are ongoing with several companies.

OX-MPI – PGE2-inhibition-treatment of inflammatory related pain
The aim with this project is to develop a completely new class of products based on Orexo's prostaglandin research (selective inhibition of prostaglandin E2 synthase). In August 2014 Orexo's partner on this project, Boehringer Ingelheim, decided to return the project, including all immaterial property rights and results, to Orexo. Orexo still sees potential in the project due to a unique target, an identified development compound and several granted patents. The work to identify a new external partner for OX-MPI continues.

Collaboration projects

Zubsolv® Rest of the World
Nearly 20 million people are suffering from opioid dependence outside of the US[5] and the problem exists both in developed and less developed countries. Heroin remains the main opioid abused outside of the US, whilst countries continue to monitor for any signs of increased misuse of other opioids including prescription medicines. Opioid dependence has a severe burden on societies. Besides loss of life and reduced quality of life, large costs are related to loss in productivity and drain of resources, as well as increased costs related to healthcare and crime.[6]

[5] *UNODC World Drug Report 2014*
[6] *UNODC World Drug Report 2016*

Following the finalized collaboration with Mundipharma, a new treatment option will potentially be made available to benefit patients with opioid dependency outside of the US. Mundipharma, through its network of independent associated companies, has a presence in 48 countries worldwide, and takes responsibility for all of the key markets where Zubsolv® is not available today. The first important milestone in the collaboration was achieved on October 3, 2016, when a regulatory submission for Zubsolv was filed with the European Medicines Agency (EMA). Approval of Zubsolv for the treatment of opioid dependence in Europe, is anticipated by the end of 2017.

Today there are an estimated 1.3 million high-risk opioid users in Europe and approximately 644,000 patients who receive substitution treatment.[7]

Besides creating value from the launch of Zubsolv in the rest of the world, we are also expecting other scale effects, e.g. through increased production volumes, which overtime could considerably improve Orexo´s gross margin.

Pending future market authorization approvals and achievement of various commercial milestones entitle Orexo to receive further milestones payments along with up to low double digit royalties on future net sales.

OX-CLI - respiratory tract diseases
The OX-CLI project is a leukotriene C4 synthase inhibitor program. The OX-CLI compounds, based on a new chemical entity (NCE), could enable to develop a completely novel personalized treatment for respiratory diseases such as asthma and COPD.

AstraZeneca had established a collaboration with Orexo for OX-CLI in 2013 and has been responsible for all research and development activities and investments since 2013. As the program has advanced into pre-clinical development with an identified development compound (candidate drug), AstraZeneca has chosen to exercise their option to acquire all rights to the OX-CLI project. In accordance with the option agreement, Orexo earned a milestone payment of MUSD 5 during Q1, 2016, for the rights to OX-CLI.

After the acquisition of the rights to OX-CLI, AstraZeneca will continue the drug development without further involvement of Orexo. Future milestone payments can be expected if OX-CLI meets defined development and commercial objectives. In addition to the milestones, Orexo will receive a tiered single digit royalty on future net-revenue associated to sales of products based on the OX-CLI program.

Un-disclosed projects

Un-disclosed projects includes ideas and concepts. Once the commercial evaluation of market potential has been completed and patent applications have been filed more information about these projects will be communicated. At the present stage these projects have a limited impact on costs.

[7] *EMCDDA, European Drug Report, 2014, Indivior (2014).*

Parent Company

Net revenues for the period January-December 2016 amounted to MSEK 379.3 (518.9). Earnings before tax were MSEK -95.8 (-162.3). Investments amounted to MSEK 0.3 (2.2). As of December 31, 2016, cash and cash equivalents in the Parent Company amounted to MSEK 211.7 (114.0).

During Q4 2016 49 batches of Zubsolv® 5.7mg were returned from Orexo Inc. to Orexo AB for de-blistering and repacking. During the quarter 14 batches were sold back to Orexo Inc. transactions had a negative net impact on the parent company revenue, margin and net earnings.

Outlook 2017

In 2016 Orexo for the first time delivered a full year positive EBITDA and expects to repeat this in 2017, however with negative EBITDA in the first half year of 2017 due to the Abstral® royalties being skewed towards the second half year of 2017.

Zubsolv in the US will contribute with continued year over year net revenue growth, driven by market growth and market share gains. No material milestone payments from license partners are expected in 2017.

Full year OPEX is expected in the range of MSEK 500 to MSEK 510.

The outlook is based on current exchange rates (January 2017).

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 2015. The continued commercialization of Zubsolv entails risk exposure of operational nature and Orexo is continuously exposed to risks in relation to the intellectual property rights and legal disputes as highlighted in Note 4 and on page 11, Paragraph IV litigation against Actavis.

Uppsala, Sweden, January 26, 2017
Orexo AB (publ.)

Nikolaj Sørensen
CEO and President

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

Consolidated statement of operations

MSEK	Notes	2016 Oct-Dec	2015 Oct-Dec	2016 Jan-Dec	2015 Jan-Dec Restated
	1				
Net revenues		184.7	228.3	705.9	646.2
Cost of goods sold		-34.2	-32.3	-149.6	-150.2
Gross profit		**150.5**	**196.0**	**556.3**	**496.0**
Selling expenses		-66.2	-72.0	-240.6	-297.5
Administrative expenses		-30.4	-41.8	-161.6	-141.5
Research and development costs		-34.5	-56.0	-132.3	-172.6
Other operating income and expenses		13.8	-70.5	29.9	-65.0
Operating earnings		**33.2**	**-44.3**	**51.7**	**-180.6**
Net financial items		1.2	-6.0	-16.1	-23.0
Earnings before tax		**34.4**	**-50.3**	**35.6**	**-203.6**
Tax		-1.1	-1.5	-6.5	-6.4
Net earnings for the period[1)]		**33.3**	**-51.8**	**29.0**	**-210.0**

Consolidated statement of comprehensive income

MSEK	2016 Oct-Dec	2015 Oct-Dec Restated	2016 Jan-Dec	2015 Jan-Dec Restated
Earnings for the period	**33.3**	**-51.8**	**29.0**	**-210.0**
Other comprehensive income				
Items that may subsequently be reversed to the statement of operations:				
Change in fair value assets available for sale				0.9
Reclassification assets available for sale	-0.9		-0.9	
Cash flow hedge				-2.9
Exchange-rate differences	4.1	-0.8	6.2	3.4
Other comprehensive earnings for the period, net after tax	**3.2**	**-0.8**	**5.3**	**1.4**
Total comprehensive earnings for the period [1]	**36.5**	**-52.6**	**34.3**	**-208.6**
Earnings per share, before dilution, SEK	0.97	-1.50	0.84	-6.07
Earnings per share, after dilution, SEK	0.96	-1.49	0.84	-6.07

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

Consolidated balance sheet

MSEK	Notes	2016 Dec 31	2015 Dec 31 Restated
	1		
ASSETS			
Fixed assets			
Tangible fixed assets		22.1	24.7
Intangible assets		138.2	155.5
Deferred tax assets		24.8	18.0
Other financial assets		-	2.1
Total fixed assets		**185.1**	**200.3**
Current assets			
Inventories		344.2	402.6
Accounts receivable and other receivables		207.1	219.0
Cash and cash equivalents		282.4	198.1
Total current assets		**833.7**	**819.7**
Total assets		**1,018.8**	**1,020.0**
SHAREHOLDERS' EQUITY AND LIABILITIES			
Total shareholders' equity		**310.3**	**270.1**
Long-term liabilities			
Provisions		1.3	3.9
Long-term liabilities, interest bearing		397.8	494.4
Total long-term liabilities		**399.0**	**498.3**
Current liabilities and provisions			
Provisions, current liabilities, non-interest bearing		309.5	251.6
Total liabilities		**708.5**	**749.9**
Total shareholders' equity and liabilities		**1,018.8**	**1,020.0**
Pledged assets	3	**-**	**100.0**

Consolidated changes in shareholders' equity

MSEK	2016 Dec 31	2015 Dec 31 Restated
Opening balance, shareholders' equity	**270.1**	**467.9**
Total comprehensive earnings for the period	34.3	-208.6
Employee stock options, vested amount	3.7	7.1
Buy back of shares	-0.1	-0.1
New share issue	2.3	3.8
Closing balance, shareholders' equity	**310.3**	**270.1**

Consolidated cash flow statements

MSEK	Notes	2016 Jan-Dec	2015 Jan-Dec Restated
	1		
Operating earnings		51.7	-180.6
Financial income and expenses		-28.3	-25.1
Adjustment for non-cash items	2	44.1	158.5
Cash flow from operating activities before changes in working capital		**67.5**	**-47.2**
Changes in working capital		**88.7**	**-62.0**
Cash flow from operating activities		**156.2**	**-109.2**
Acquisition of tangible and intangible fixed assets		-1.4	-4.1
Disposal of fixed assets		1.8	0.0
Sale of subsidiary		5.0	21.8
Cash flow from investing activities		**5.4**	**17.7**
New share issue		2.2	3.8
Change in loans		-92.8	-1.2
Cash flow from financing activities		**-90.6**	**2.6**
Cash flow for the period		**71.0**	**-88.9**
Cash and cash equivalents at the beginning of the period		**198.1**	**284.5**
Exchange-rate differences in cash and cash equivalents		13.3	2.5
Changes in cash and cash equivalents		71.0	-88.9
Cash and cash equivalents at the end of the period		**282.4**	**198.1**

Key Figures[1]

Orexo makes use of the key figures and believes 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.

	2016 Oct-Dec	2015 Oct-Dec Restated	2016 Jan-Dec	2015 Jan-Dec Restated
EBIT margin, %	18	-19	7	-28
Return on shareholder equity, %	11	-17	10	-58
Net debt, MSEK	115.4	296.3	115.4	296.3
Debt/equity ratio, %	128	183	128	183
Equity/assets ratio, %	30	26	30	26
Number of shares, before dilution	34,536,746	34,580,810	34,477,375	34,580,107
Number of shares, after dilution	34,579,512	34,873,345	34,574,337	34,580,107
Earnings per share, before dilution, SEK	0.97	-1.50	0.84	-6.07
Earnings per share, after dilution, SEK	0.96	-1.49	0.84	-6.07
Number of employees at the end of the period	102	90	102	90
Shareholders' equity, KSEK	310,300	270,100	310,300	270,100
Capital employed, KSEK	708,015	764,463	708,015	764,463
Working capital	524.2	568.1	524.2	568.1

[1] *Definitions and reconciliations of key figures are presented on the final page of this report*

Parent Company statement of operations

MSEK	Notes	2016 Oct-Dec	2015 Oct-Dec	2016 Jan-Dec	2015 Jan-Dec Restated[1]
Net revenues		72.3	225.2	379.3	518.9
Cost of goods sold		-17.5	-54.2	-83.6	-155.9
Gross profit		**54.8**	**171.0**	**295.7**	**363.0**
Selling expenses		-30.8	-56.6	-105.7	-226.9
Administrative expenses		-21.5	-33.5	-129.1	-108.1
Research and development costs		-26.8	-34.0	-141.8	-122.9
Other operating income and expenses		16.3	-7.9	24.3	4.5
Operating earnings		**-8.0**	**39.0**	**-56.6**	**-90.4**
Interest income and expenses		-3.9	-5.1	-16.2	-18.7
Impairment of shares in subsidiaries		-	-63.8	-	-63.8
Exchange rate adjustment		-32.1	-	-32.1	-
Sales of subsidiary		-	-	-	13.1
Other financial expenses		10.5	-0.7	9.3	-2.5
Net financial items		**-25.5**	**-69.6**	**-39.1**	**-71.9**
Earnings before tax		**-33.5**	**-30.6**	**-95.7**	**-162.3**
Tax		-	-	-	-
Earnings for the period		**-33.5**	**-30.6**	**-95.7**	**-162.3**

[1]***Reclassification due to tax MSEK 0.5 between tax line and other operating income and expenses***

Parent company statement of comprehensive income

MSEK	2016 Oct-Dec	2015 Oct-Dec	2016 Jan-Dec	2015 Jan-Dec Restated
Earnings for the period	**-33.5**	**-30.6**	**-95.7**	**-162.3**
Other comprehensive income				
Total comprehensive earnings for the period[1]	**-33.5**	**-30.6**	**-95.7**	**-162.3**

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

Parent Company balance sheet

MSEK	Notes	2016 Dec 31	2015 Dec 31 Restated[1]
ASSETS			
Fixed assets			
Tangible and intangible fixed assets		159.8	179.3
Shares in subsidiaries		149.7	148.5
Total fixed assets		**309.5**	**327.8**
Current assets			
Inventories		269.6	276.8
Accounts receivable and other receivables		76.8	324.3
Cash and bank balances		211.7	114.0
Total current assets		**558.1**	**715.1**
Total assets		**867.5**	**1,042.9**
SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES			
Shareholders' equity		**263.5**	**353.4**
Long-term liabilities		**399.0**	**498.2**
Current liabilities		**205.0**	**191.3**
Total liabilities		**604.1**	**689.5**
Total shareholders' equity and liabilities		**867.5**	**1,042.9**
Pledged assets	3	**-**	**100.0**

[1] *Reclassification between intangible assets and other receivables with MSEK 3.6*

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 2015 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 2016

No new or amended International Financial Reporting Standards have come into effect that have any significant impact on the Group.

Restatements

In connection with the introduction of new auditors and in connection with preparation of the full year report for 2016 historical numbers and significant accounting routines were reviewed. This led to a number of restatements affecting prior period statements. The nature and impact of the restatements are described below.
Furthermore the restatements have affected the opening balance 2016 with an equity effect of MSEK 3,7 and the third quarter income statement have been adjusted with MSEK -10,7 related to currency exchange effects on inventory.

Consolidated statement of operations

MSEK	Ref:	2015 Oct-Dec Original	Restate-ment	2015 Oct-Dec Restated	2015 Jan-Dec Original	Restate-ment	2015 Jan-Dec Restated
Net revenues	1	228.3		228.3	643.3	2.9	646.2
Cost of goods sold	2	-32.3		-32.3	-136.1	-14.1	-150.2
Gross profit		**196.0**		**196.0**	**507.2**	**-11.2**	**496.0**
Selling expenses		-72.0		-72.0	-297.5		-297.5
Administrative expenses		-41.8		-41.8	-141.5		-141.5
Research and development costs		-56.0		-56.0	-172.6		-172.6
Other operating income and expenses	3	-70.5		-70.5	-64.5	-0.5	-65.0
Operating earnings		**-44.3**		**-44.3**	**-168.9**	**-11.6**	**-180.6**
Net financial items	4	-6.0		-6.0	-22.1	-0.9	-23.0
Earnings before tax		**-50.3**		**-50.3**	**-191.1**	**-12.6**	**-203.6**
Tax	5	-1.5		-1.5	-6.9	0.5	-6.4
Net earnings for the period[1]		**-51.8**		**-51.8**	**-197.9**	**-12.1**	**-210.0**

1) Reversal of wrongly recorded hedge on Abstral® fixed royalty
2) More precise elimination of intercompany profits in Orexo Inc. inventory after implementation of an ERP system in Supply Chain
3) Reclassification of State Franchise taxes from Tax line
4) Change in fair value of assets available for sale
5) Reclassification of State Franchise taxes from Tax line

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

Consolidated statement of comprehensive income

MSEK	2015 Oct-Dec Original	Restate-ment	2015 Oct-Dec Restated	2015 Jan-Dec Original	Restate-ment	2015 Jan-Dec Restated
Earnings for the period	**-51.8**		**-51.8**	**-197.9**	**-12.1**	**-210.0**
Other comprehensive income						
Items that may subsequently be reversed to the statement of operations:						
Change in fair value assets available for sale				-	0.9	0.9
Reclassification assets available for sale						
Cash flow hedge				2.8	-5.7	-2.9
Exchange-rate differences	-8.5	7.7	-0.8	-4.3	7.7	3.4
Other comprehensive earnings for the period, net after tax	**-8.5**	**7.7**	**-0.8**	**-1.5**	**2.9**	**1.4**
Total comprehensive earnings for the period [1]	**-60.3**	**7.7**	**-52.6**	**-199.4**	**-9.2**	**-208.6**
Earnings per share, before dilution, SEK	-1.50		-1.50	-5.74	-0.33	-6.07
Earnings per share, after dilution, SEK	-1.50	0.01	-1.49	-5.74	-0.33	-6.07

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

Consolidated balance sheet

MSEK	Notes	2015 Dec 31 Original	Restatement	2015 Dec 31 Restated
ASSETS				
Fixed assets				
Tangible fixed assets		24.7		24.7
Intangible assets		159.1	-3.6	155.5
Deferred tax assets			18.0	18.0
Other financial assets		2.1		2.1
Total fixed assets		**185.9**	**14.4**	**200.3**
Current assets				
Inventories		398.9	3.7	402.6
Accounts receivable and other receivables		233.4	-14.4	219.0
Cash and cash equivalents		198.1		198.1
Total current assets		**830.4**	**-10.7**	**819.7**
Total assets		**1,016.3**	**3.7**	**1,020.0**
SHAREHOLDERS' EQUITY AND LIABILITIES				
Total shareholders' equity		**266.4**	**3.7**	**270.1**
Long-term liabilities				
Provisions		3.9		3.9
Long-term liabilities, interest bearing		494.4		494.4
Total long-term liabilities		**498.3**		**498.3**
Current liabilities and provisions				
Provisions, current liabilities, non-interest bearing		251.6		251.6
Total liabilities		**749.9**		**749.9**
Total shareholders' equity and liabilities		**1,016.3**	**3.7**	**1,020.0**
Pledged assets	3	**100.0**		**100.0**

Consolidated changes in shareholders' equity

MSEK	2015 Dec 31 Original	Restatement	2015 Dec 31 Restated[1]
Opening balance, shareholders' equity	**455.0**	**12.9**	**467.9**
Total comprehensive earnings for the period	-199.5	-9.2	-208.6
Employee stock options, vested amount	7.1	0.0	7.1
Buy back of shares	-0.1	0.0	-0.1
New share issue	3.8	0.0	3.8
Closing balance, shareholders' equity	**266.4**	**3.7**	**270.1**

[1]*Reclassification in opening balance 2015 related to inventory of MSEK 10 and hedge MSEK 2.9, totally MSEK 12.9*

Consolidated cash flow statements

MSEK	Notes	2015 Jan-Dec Original	Restate-ment	2015 Jan-Dec Restated
Operating earnings		-169.0	-11.6	-180.6
Financial income and expenses		-29.0	3.9	-25.1
Adjustment for non-cash items	2	78.6	79.9	158.5
Cash flow from operating activities before changes in working capital		**-119.4**	**72.2**	**-47.2**
Changes in working capital		**17.2**	**-79.2**	**-62.0**
Cash flow from operating activities		**-102.2**	**-7.0**	**-109.2**
Acquisition of tangible and intangible fixed assets		-4.1		-4.1
Sale of subsidiary		21.8		21.8
Cash flow from investing activities		**17.7**		**17.7**
New share issue		3.8		3.8
Change in loans		-1.2		-1.2
Cash flow from financing activities		**2.6**		**2.6**
Cash flow for the period		**-81.9**	**-7.0**	**-88.9**
Cash and cash equivalents at the beginning of the period		**284.5**		**284.5**
Exchange-rate differences in cash and cash equivalents		-4.5	7.0	2.5
Changes in cash and cash equivalents		-81.9	-7.0	-88.9
Cash and cash equivalents at the end of the period		**198.1**		**198.1**

2. Cash flow

Adjustment for non-cash items

MSEK	2016 Jan-Dec	2015 Jan-Dec Restated
Depreciation/amortization and impairment	25.0	80.7
Gain/loss on disposal	-5.0	16.3
Change in provisions	42.0	55.7
Change in fair value of financial instruments	0.2	-
Share based payments	3.7	7.1
Exchange rate income and expenses	-21.8	-1.3
Total	**44.1**	**158.5**

3. Pledged assets and contingent liabilities

Warrants were issued to Pyrinox AB as cash-flow hedging for social security fees pertaining to the employee stock options issued by Biolipox. Orexo has pledged to handle any deficits exceeding the cover provided by the warrants during their lifetime through December 31, 2016. A MSEK 100 chattel mortgage related to previous bank engagements was cancelled during Q2, 2016.

4. Legal disputes

On June 27, 2014 Orexo AB announced that it had filed a patent infringement action in United States against Actavis Elizabeth LLC and its parent company Actavis, Inc. The lawsuit was filed in response to an Abbreviated New Drug Application ("ANDA") filed by Actavis. In its application, Actavis seeks to market and sell generic versions of Orexo's patented Zubsolv® (buprenorphine and naloxone) products in the US prior to the expiration of Orexo's US patents. The decision in this litigation process was issued on November 15, 2016, by the United States District Court for the District of Delaware.The District Court held that Orexo's 8,454,996 patent is valid and infringed by Actavis's and that 8,940,330 patent is invalid. 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. Generally, the Federal Circuit takes about one year from the District Court decision to render a ruling on the appeal.

For more detailed information about the litigation with Actavis please see page 11.

5. Important events after the period

No material events occurred after the period.

Definitions and reconciliations of key figures

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

Number of shares after dilution	Shares at the end of the period adjusted for the dilutive effect of potential shares
Zubsolv® net revenue	Revenue net of discounts and returns
EBIT	Earnings before net financial items and tax, the same as Operating earnings
EBITDA	Earnings before interest, taxes, depreciation and amortization. EBIT plus depreciation
Gross Revenues	Grand total of all invoiced sales transactions reported in a period, without any deductions
Net Revenues	Gross Revenues less deductions for sales rebates, sales allowances, distribution, sales returns and other relevant deductions
Gross to net ratio	Net Revenues divided by Gross Revenues
Operating expenses	A non-capital expense incurred in daily operating activities
Net financial items	Financial revenue minus financial cost
Net earnings	Operating Earnings plus Net Financial Items plus tax
Investments	Value of an investment before depreciation
Return on shareholders' equity	Net earnings for the period as a percentage of average shareholders' equity
Net debt	Current and long-term interest-bearing liabilities including pension liabilities, less cash and cash equivalents
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
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
Operating margin	Operating earnings as a percentage of net revenues
Debt/equity ratio	Interest-bearing liabilities divided by shareholders' equity
Equity/assets ratio	Shareholders' equity as a percentage of total assets
Capital employed	Interest-bearing liabilities and shareholders' equity
Working capital	Current assets less current liabilities

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

EBITDA MSEK	**2016 Oct-Dec**	**2015 Oct-Dec Restated**	**2016 Jan-Dec**	**2015 Jan-Dec Restated**
EBIT	33.2	-44.3	51.7	-180.6
Depreciation and amortization	10.9	69.1	22.7	80.7
EBITDA	**44.1**	**24.8**	**74.4**	**-99.9**

Return on shareholders' equity	**2016 Oct-Dec**	**2015 Oct-Dec**	**2016 Jan-Dec**	**2015 Jan-Dec**
Average shareholders' equity	290.6	297.6	290.2	362.5
Net earnings	33.3	-51.8	29.0	-210.0
Return on shareholders' equity %	**11**	**-17**	**10**	**-58**

Net debt MSEK	**2016 Oct-Dec**	**2015 Oct-Dec**	**2016 Jan-Dec**	**2015 Jan-Dec**
Current and long-term interest-bearing liabilities including pension liabilities	397.8	494.4	397.8	494.4
Cash and cash equivalents	-282.4	-198.1	-282.4	-198.1
Net debt	**115.4**	**296.3**	**115.4**	**296.3**

Operating expenses MSEK	**2016 Oct-Dec**	**2015 Oct-Dec**	**2016 Jan-Dec**	**2015 Jan-Dec**
Selling expenses	-66.2	-72.0	-240.6	-297.5
Administrative expenses	-30.4	-41.8	-161.6	-141.5
Research and development costs	-34.5	-56.0	-132.3	-172.6
Other operating income and expenses	13.8	-70.5	16.0	-65.0
Operating expenses	**-117.3**	**-240.3**	**-504.6**	**-676.6**

Glossary

Alfentanil
A potent synthetic opioid analgesic drug, used for anaesthesia in surgery

ANDA
An Abbreviated New Drug Application (ANDA) is an application for a US generic drug approval for an existing licensed medication or approved drug

Anaesthesia
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

Cash & vouchers market
One of the three distinct payer segments in the US Zubsolv® market. In this segment, the patient is paying for the prescriptions out of pocket

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

CLI
Cysteinyl Leukotriene Inhibitor

Clinical studies/Clinical trials
Studies of the safety and efficacy of a drug in human beings

Commercial market
One of the three distinct payer segments in the US Zubsolv market. The commercial market 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 to morphine. Used mainly within anesthesia and analgesia

HHS
The US Department of Health and Human Services

Naloxone
An opioid inverse agonist used to counter the effects of opioids

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 acting upon arachidonic acid locally 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 and appropriate doses. Performed on a limited number of patients

Phase III studies
Studies of the safety and efficacy of a drug in a clinical situation. 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

Public Market
One of three distinct payer segments in the US Zubsolv® market. The public market covers state and federal funded reimbursement programs i.e. Managed Medicaid, FFS Medicaid, Medicare Part D

REZOLV
The REZOLV (Retrospective Evaluation of Zubsolv Outcomes - A Longitudinal View) study is a medical record review conducted to examine and characterize the impact of treatment and psychosocial factors on the early outcomes of patients who utilized Zubsolv therapy for opioid dependence. The data was collected from 1,080 patients being treated by 134 physicians across 87 US treatment sites of which 80 were private practices and 7 were institutional sites.

Sublingual
Under the tongue