Interim Report January-September 2016

“I am very pleased to see continued revenue growth from Zubsolv® and Abstral® leading the way to a good financial result in the third quarter.”

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

Year-End Report 2016	January 26, 2017, at 8.00am CET
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 Interim 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.

Interim Report January-September 2016

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

Strong Zubsolv® and Abstral® revenue growth.

Third quarter 2016

- Total net revenues MSEK 181.9 (139.5).
- Zubsolv net revenue MSEK 142.8 (110.8).
- Net earnings MSEK 36.0 (-46.1).
- Earnings per share, before and after dilution, SEK 1.04 (-1.33).
- Cash flow from operating activities MSEK 31.2 (-79.5).
- Cash and cash equivalents MSEK 276.9 (201.2).
- The US Department of Health and Human Services (HHS) announced an increase in buprenorphine patient cap from 100 to 275.
- The Congress signed CARA[1] into law which among others will expand the prescription rights to nurse practitioners and physicians assistants.
- Completion of 1,080 patient REZOLV study and reported on improved treatment of opioid dependent patients.

January - September 2016

- Total net revenues MSEK 521.2 (415.0).
- Zubsolv net revenue MSEK 419.5 (296.4).
- Net earnings MSEK 6.5 (-146.2).
- Earnings per share, before and after dilution, SEK 0.19 (-4.24).
- Cash flow from operating activities MSEK 73.7 (-108.5).
- Cash and cash equivalents MSEK 276.9 (201.2).
- 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.

Important events after the period

- Orexo together with Mundipharma made 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.

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

[2] *All markets except the US*

MSEK	**2016 Jul-Sep**	**2015 Jul-Sep**	**2016 Jan-Sep**	**2015 Jan-Sep**	**2015 Jan-Dec**
Net revenues	181.9	139.5	521.2	415.0	643.3
EBIT	43.0	-39.4	29.1	-124.7	-169.0
EBITDA	50.9	-33.9	48.8	-113.1	-88.3
Net Earnings	36.0	-46.1	6.5	-146.2	-198.0
Earnings per share, before and after dilution, SEK	1.04	-1.33	0.19	-4.24	-5.74
Cash flow from operating activities	31.2	-79.5	73.7	-108.5	-102.2
Cash and cash equivalents	276.9	201.2	276.9	201.2	198.1

Teleconference

CEO Nikolaj Sørensen and CFO Henrik Juuel will present the report at a teleconference on October 20, 2016, at 2:00pm CET.

Presentation slides are available via the link and on the website.

Internet: https://wonderland.videosync.fi/2016-10-20-orexo-q3-report

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CEO's comments

I am pleased with the positive EBIT and cash flow result of the third quarter. The result is primarily driven by positive Zubsolv® and Abstral® revenue growth with 30 percent versus Q3 2015. However, this quarter we also benefited from inventory built up in Maryland, lower expenses than expected and favorable currency development. In addition to the positive financial results the quarter has been highlighted by two significant events, the patient cap lift in the US and the progression towards launching Zubsolv in Europe as well.

In July the US Government ruled to take action and expand access to treatment of opioid dependence. I am encouraged to see over 1,500 physicians have received the certification to expand to 275 patients as of mid-October. Our ambition is to win a disproportionate share of the new patients in the regions where Zubsolv is reimbursed and have market access comparable to our main branded competitors. Though early in the process I am pleased to find this is beginning to occur especially with physicians covered by our field force today. With regards to market access we have maintained or improved our position with all major insurance plans and we have strengthened our position in all payer segments, both winning new contracts and renewing existing ones. Although encouraged by the improving market access especially in the public segment, an increased importance of the public segment will increase the average rebate level for Zubsolv US.

In Europe we took a first important step to be able to launch Zubsolv. We have worked intensively in collaboration with Mundipharma throughout the quarter to finalize the bio-equivalence study required to complete the European filing and prepare the dossier. Earlier than expected, on October 3rd, we submitted the file and expect approval in Q4 2017.

Apart from the progression of our commercialization of Zubsolv, the court case against Actavis has required a lot of our attention during the quarter and 2016. We maintain a high degree of confidence in the strengths of our patents i.e. they are valid and Actavis is infringing. In parallel with the court case our patent portfolio around Zubsolv has continued to expand and this has led to additional litigation processes against Actavis. The first decision from the court is expected in the fourth quarter of 2016.[1]

In August we finalized the REZOLV study and in early October, we announced the approval of a new low dosage of Zubsolv. These announcements mark the completion of the pharmaceutical and clinical development program for Zubsolv. With the finalization of the Zubsolv development programs we are now ready to look ahead and strengthen our long term product pipeline beyond Zubsolv. We are currently working on some early internal projects and are evaluating our opportunities moving forward together with the Board of Directors. My colleagues at Orexo and I are looking forward to the continued positive evolution of the company with confidence of an exciting future for Orexo.

Nikolaj Sørensen
CEO and President

[1] *For detailed information about the litigation processes against Actavis please see page 11*

The interim period January-September in numbers

Revenues

Launched products

Zubsolv® US revenue amounted to MSEK 142.4 (110.8) in Q3 corresponding to a 28.5 percent growth over same period last year and a growth of 26.2 percent over the previous quarter.

Versus the previous quarter demand increased by nearly 18 percent driven by market share gain primarily in the public segment with the exclusive agreement with the FFS Medicaid program in the state of Maryland effective from July 1, 2016 and sales into institutional settings which dispense medication directly to patients. The market share increased from 5.5 percent in Q2 to 6.2 percent in Q3.

As a knock-on effect to the increased demand in Q3 wholesalers and pharmacies increased their order and inventory levels during the quarter. It is Orexo's assessment that current wholesaler inventory levels are somewhat above the level needed to supply current demand and a normalization could be expected in coming quarters if Zubsolv US demand does not increase at similar pace as Q3.

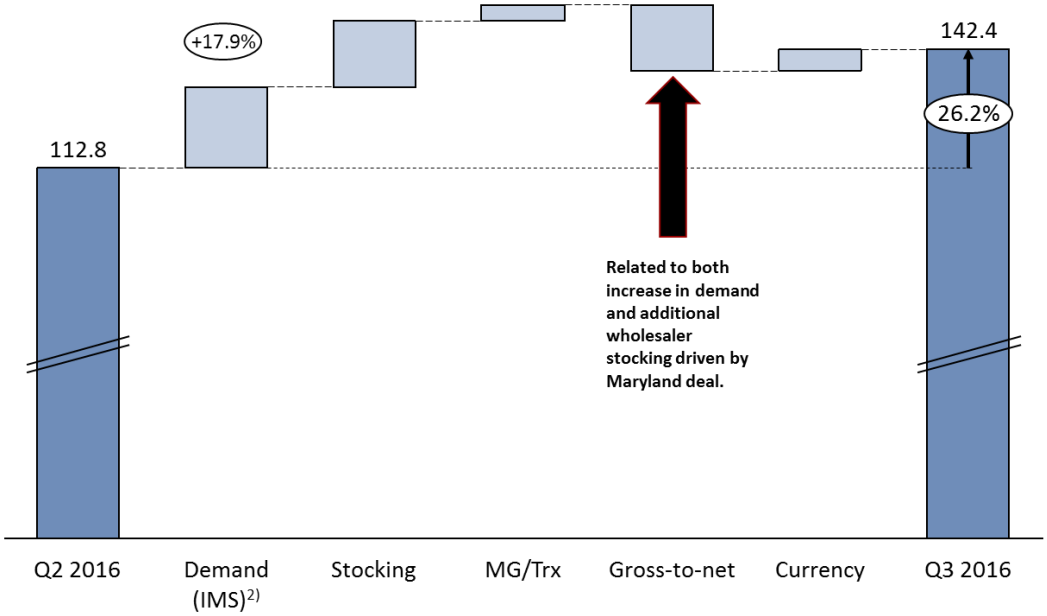
Five different dosage forms of Zubsolv are currently on the market and during the quarter we saw a shift in the mix, leading to a higher number of milligrams per Zubsolv tablet prescribed. The mix shift is caused by a rapid increase in market share, adding many new patients who reach their daily dosage with our new higher dosage strengths. With a higher price for the high dosage tablets, the increase in milligrams has a positive effect on Zubsolv US revenues.

The very sizeable Maryland business caused a change in payer mix which reduced the average gross-to-net ratio. The negative impact from a reduced gross-to-net comes from both the increased demand and the increased wholesaler stocking associated with increased demand in Maryland.

The development of the USD/SEK exchange rate had a positive impact on Zubsolv US revenue. In local currencies Zubsolv US Q3 revenue grew by 21.4 percent over the previous quarter.

For the period January-September Zubsolv US revenue amounted to MSEK 353.6 (296.4) corresponding to an increase of 19.3 percent.

Q3 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 36.8 (25.4) for the period July-September 2016 and to MSEK 50.4 (95.0) for the period January-September 2016. The Q3 increase over previous year is primarily explained by continued strong growth of Abstral sales in Europe. The YTD decrease compared to last year is explained by absence of the Abstral fixed royalty. This fixed royalty represented an amortization of the final fixed payment related to the 2012 agreement with ProStrakan and the fixed royalty was fully recognized in the P&L by May 2015.

Royalty revenues from Edluar® amounted to MSEK 2.3 (3.3) for the period July-September 2016 and MSEK 10.5 (10.8) for the period January-September 2016.

Collaboration project

A smaller milestone payment of MSEK 0.4 was earned under the agreement with Mundipharma during the quarter.

Total revenues

Total revenues during the period July-September 2016 amounted to MSEK 181.9 (139.5), an increase of 30.4 percent compared with the same period the previous year, driven by Zubsolv US and Abstral. For the period January-September 2016 total revenues amounted to MSEK 521.2 (415.0), a growth of 25.6 percent.

Total net revenues were distributed as follows

MSEK	**Jul-Sep 2016**	**Jul-Sep 2015**	**Jan-Sep 2016**	**Jan-Sep 2015**	**Jan-Dec 2015**
Zubsolv® US	142.4	110.8	353.6	296.4	416.7
Zubsolv – Rest of the World	0.4	-	65.9	-	-
Zubsolv – total	***142.8***	***110.8***	***419.5***	***296.4***	***416.7***
Abstral® royalties	36.8	25.4	50.4	37.6	77.2
Fixed royalty Abstral[1]	-	-	-	57.0	57.0
Milestone payment Abstral	-	-	-	0.4	66.0
Abstral – total	***36.8***	***25.4***	***50.4***	***95.0***	***200.2***
Edluar® royalties	2.3	3.3	10.5	10.8	13.6
Kibion	-	-	-	12.8	12.8
Other revenues[2]	-	-	40.8	-	-
Total	***181.9***	***139.5***	***521.2***	***415.0***	***643.3***

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

Costs and earnings

Cost of goods sold

Cost of goods (COGS) sold amounted to MSEK 38.3 (34.8) for the period July-September 2016 and MSEK 104.7 (103.8) for the period January-September 2016, and all relates to Zubsolv US. The volume of manufactured products were relatively high during the quarter which lead to increased efficiencies and positive COGS variances, however partly off-set by one-off costs related to necessary re-packing of tablets. The re-packing is a consequence of FDA approved longer shelf-life that needs to be reflected on the packaging. The re-packaging is expected to be largely complete by end of Q4 and is expected to add approximately MSEK 10 to a normal COGS level in Q4, 2016.

Selling expenses

Selling expenses amounted to MSEK 57.3 (70.8) for the period July-September 2016, in line with the level guided previously. Selling expenses for the period January-September 2016 amounted to MSEK 174.4 (225.6). The lower level in 2016 compared with previous year is explained by the optimization of the field force commenced late 2015. For the period October-December 2016 selling expenses is expected to amount to approximately MSEK 60.

Administrative expenses

Administrative expenses for the period July-September 2016 amounted to MSEK 33.4 (34.8), i.e. below the level previously guided. The amount still includes significant costs incurred in relation to the patent infringement case against Actavis, however the spend level has decreased after the court trial in June. For the period January-September 2016 the administrative expenses amounted to MSEK 131.2 (99.6). The expense level in Q4, 2016, is expected to amount to approximately MSEK 30-35, but this is dependent on progress in and development of legal disputes.

Research and development costs

For the period July-September 2016, research and development costs amounted to MSEK 24.1 (43.3), lower than previously guided as focus was on completion of the regulatory bio-equivalence study required for the Zubsolv EU regulatory submission. Under the signed license agreement for

Zubsolv® Rest of the World, Mundipharma will cover cost related to this study and the regulatory submission. For the period January-September 2016, R&D costs amounted to MSEK 97.8 (116.6). The expense level for Q4 is expected to amount to approximately MSEK 30-35, lower than previously guided as current internal projects are running in less expensive phases.

Costs for long-term incentive program
The Group's total costs for employee stock option programs during the period July-September 2016 amounted to MSEK -1.7 (-2.9). For the period January-September 2016, the costs amounted to MSEK 0.5 (-12.2).

Other income and expenses
Other income and expenses amounted to MSEK 14.1 (4.8) during the period July-September 2016 and for the period January-September 2016 it amounted to MSEK 16.0 (5.8). This is primarily comprised of exchange-rate gains/losses derived from revaluations of balance sheet items due to a higher SEK/USD rate.

Depreciation and amortization
Depreciation and amortization amounted to MSEK 7.9 (5.5) for the period July-September 2016 and to MSEK 19.7 (11.6) for the period January-September.

Net financial items
Net financial items for the period July-September 2016 amounted to MSEK -5.4 (-4.7) and to MSEK -17.3 (-16.0) for the period January-September. All the net financial items are related to financing activities.

Net Earnings
Net earnings amounted to MSEK 36.0 (-46.1) for the period July-September 2016 and to MSEK 6.5 (-146.2) for the period January-September 2016.

Cash flow and financial position
At September 30, 2016, cash and cash equivalents amounted to MSEK 276.9 (201.2) and interest-bearing liabilities to MSEK 496.2 (493.7).

Cash flow from operating activities was positive and amounted to MSEK 31.2 (-79.5) for the period July-September 2016 driven by a positive contribution from EBIT slightly off-set by changes in working capital. For the period January-September cash flow from operating activities was positive and amounted to MSEK 73.7 (-108.5).

The period July-September was the fourth consecutive quarter with a positive cash flow and this has further strengthened Orexo's financial position.

Shareholders' equity at September 30, 2016 was MSEK 270.9 (325.2). The equity/assets ratio was 25 (29) percent.

Investments in fixed assets
Investments in tangible and intangible fixed assets amounted to MSEK 1.0 (0.9) for the period July-September 2016. For the period January-September 2016, investments amounted to MSEK 1.2 (3.1).

Operations

Launched products

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

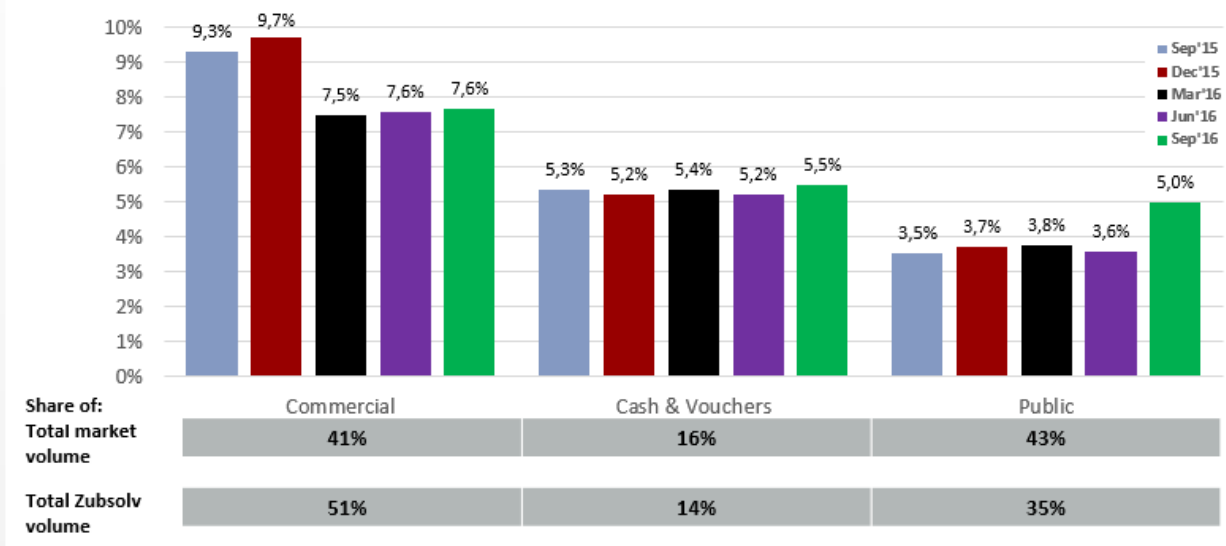
Overall the total market has increased 1.3 percent in volume compared to Q2 2016, and is up 6.9 percent compared to Q3 2015. During the last weeks of the quarter the first grouping of physicians received their certification to increase the number of patients from 100 to 275 and we anticipate growth rates to increase in Q4 and next year.

Zubsolv performance when compared to Q2 2016 demonstrated a growth of 14.5 percent in tablets dispensed to patients through pharmacies.

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. 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 Q3 the sales to these institutions accounted for slightly less than 2 percent of the overall sales of 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 resulting in a jump in market share in the public segment from 3.6 percent in June to 5.0 percent in September. After the initial market share increase we have seen a flow back of patients in Maryland to their original medication in August-September, which is partly compensated by a disproportional high market share for Zubsolv with the first physicians receiving their certification to treat 275 patients.

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



[1] *IMS XPO PA: Sept'15 data: R4W WE 9/25/2015; 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*

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 will be implemented the earliest in mid to late 2017 as this requires development of training programs, definition of certification requirements and budget assignment.

The first physicians received their C275 certification in late August and through last week greater than 1,500 physicians over time have received their certification. Based on Orexo market research, we completed this summer, we expect each of these physicians to treat around 100 patients more than today. In total the HHS expect the number of patients treated to increase from 600,000 today to 750,000, which is likely to be a conservative number based on the number of physicians who have received their C275 certification in the first month.

The ambition for Orexo is to take a disproportionally higher share of the new patients in the market. In the market research Zubsolv's® market share of new patients is close to 10 percent in comparison with the national average of 6.2 percent in Q3. The ability to win new market share for Zubsolv is depending on where the growth will take place and in particular the market access for Zubsolv with the new patients. Of the physicians certified today 52 percent are covered by our sales force, an additional 26 percent are within geographies covered and the remaining 22 percent are outside the reach of our existing territory.

Based on the first limited data available, we start to see some positive impact of the change on the development for the market and for Zubsolv in particular e.g:

- The C275 physicians grow 3.9 percent compared to August, while the overall market declined 0.4 percent.
- 76 percent of the growth was in the public segment where Zubsolv has limited market access
- Zubsolv's market share of this growth with C275 physicians was 7 percent of the total growth despite the limited market access.
- Isolating the 52 percent of the physicians covered by our field force today the market share of the growth was 15 percent which significantly exceeds our national share and historic share with these physicians.

It should be noted this data is based on a few weeks of data, where many of the C275 physicians have not started to recruit new patients and the data can be biased by other factors than changes in certification e.g. for Zubsolv the sales dynamic in Maryland. Orexo is continuously assessing the changing market dynamics and will expand the field force to improve the coverage of the C275 physicians where feasible. As a consequence the selling cost for Q4 is expected to be slightly higher than Q3.

Commercial (private insurance)

(41% of the total market, 51% of Zubsolv business in September)

In the commercial segment, Zubsolv's market share increased by 0.1 percentage points and prescriptions increased 1.5 percent compared to Q2 2016. This increase is driven by United, Express Scripts, and other commercial plans.

During the quarter most of the formularies for 2017 has been finalized and Zubsolv has either improved the reimbursement or maintained its' current status. One of the more noteworthy changes is

with CIGNA, the fifth largest commercial health plan in the US, who from October 15th will remove the prior authorization and steps edits that were required to get Zubsolv® previously. CIGNA has commercial formularies affecting 7.5 million pharmacy lives with large patient populations in regions where Zubsolv has a higher market share e.g. in Texas and Florida. Additionally, Zubsolv will improve its' current formulary position with two additional regional plans affecting approximately 1.6 million commercial members within these health plans.

The commercial segment has grown 0.7 percent in volume compared to Q2 2016, and 2.9 percent compared to Q3 2015. Zubsolv® has unrestricted access to 81 percent of the business in the commercial segment.

Cash (Cash & Vouchers, the patient pays)
(16% of the total market, 14% of Zubsolv business in September)

Zubsolv´s market share has increased from 5.2 percent to 5.5 percent in Q3 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 decreased 1.7 percent in volume during Q3 compared to Q2 2016, and has declined 4.1 percent compared to Q3 2015. Zubsolv has access to 100 percent of the business in the cash segment.

Public (Managed Medicaid, FFS Medicaid, Medicare Part D)
(43% of the total market, 35% of Zubsolv business in September)

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 2.6 percent in volume during Q3 compared to Q2, 2016, and 14.6 percent compared to Q3, 2015. During the quarter Zubsolv had access to 43 percent of the business in the public segment. The market share of Zubsolv increased in this segment by 1.4 percentage points from Q2 2016, primarily explained by the improved reimbursement in Maryland.

Effective July 1, 2016 Zubsolv is the exclusive preferred product on the State of Maryland fee for service formulary which is the largest FFS Medicaid state in the US. Other products will remain accessible for patients, but require a prior authorization and as mentioned in the Q2 report, the firmness of the prior authorization requirement will have significant impact on the market share of Zubsolv in Maryland. 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 13 percent from July to September, and Zubsolv accounts for about half of volume in Maryland FFS Medicaid. We expect the market in Maryland is about to stabilize and have less impact on the overall market share in Q4 and beyond.

The market access position in the public segment is improving beyond Maryland and from January 1st 2017, Zubsolv will be the preferred branded product with the one of the largest Medicare part D plans in the US, the plan today represents about 0.92 percent of the total market of Buprenorphine/Naloxone products. Similar to the Maryland agreement the potential for Zubsolv is depending on the firmness of the prior authorization process.

The REZOLV study

The REZOLV retrospective study (Retrospective Evaluation of Zubsolv Outcomes – A Longitudinal View) was completed as planned in August, 2016. With 1,080 patients, the study is the largest retrospective study completed in the US aimed at optimizing the treatment of opioid dependence. Factors such as patient and prescriber characteristics, care settings, patient agreements and behavioral therapies have been studied.

The REZOLV study was a success with 978 of the 1,080 patients in total confirmed as being evaluable for treatment efficacy. From the patients evaluable for treatment, 77.6 percent (n=759) were determined to have been a treatment success, defined as a patient who completed 28 days of treatment and tested negative for opiates on the last follow-up drug screen.

The study results have generated an extensive amount of clinical data that Orexo will use in its dialogues with key stakeholders, including physicians, new and existing prescribers, politicians and payers, on how to advance the treatment of opioid dependence. The completion of the REZOLV study further strengthens Orexo's position as the market player with the most substantial clinical database.

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 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, is expected during the fourth quarter following completion of the trial in June this year. The '996 and '330 patents expire in September 2019 and September 2032, respectively.

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 new ANDAs for these new strengths. Consequently, Orexo has initiated separate litigation processes for these new strengths, with trial date set for October 2017. These lawsuits are based on the same patents as the initial process and the decision of the first litigation process may influence 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 and have the same expiration date as the '330 patent (September 2032). Orexo has initiated new litigation processes against Actavis involving all strengths (except the recently approved 0.7 mg strength) on the '421 patent, which issued in February 2016. The decision in the first process may have an impact on whether and how the process regarding the '421 patent proceeds. The '900 patent was issued in September 2016 and has recently been listed in the Orange book. Actavis has not yet notified Orexo whether it is seeking to market a 0.7 mg product or whether it intends to challenge the newly issued '900 patent.

Abstral® and Edluar®

Due to the early timing of the Q3 report, Orexo has not yet received final data for third quarter sales of Abstral and Edluar. Data included in this report are based on Orexo's forecast and available sales reports for Q2 from our partners.

Abstral – for rapid relief from breakthrough pain in cancer patients

Sales of Abstral in the EU continue to grow and amounted to MEUR 20.6, which is an increase of 6 percent in Q2 2016 compared to Q2 2015. Orexo receives royalty on sales exceeding MEUR 42.5, which was achieved in July, one month earlier than expected.

In the US market, Orexo's partner since November 2015, Sentynl Therapeutics Inc. continued with its relaunch of Abstral® during the quarter. In Q2 2016, and still in launch face, net sales were 4 percent lower than same period in 2015.

Sales of Abstral in the region RoW (markets excluding EU and the US) have continued to grow. Total sales for the RoW reached MUSD 2.4 in Q2 2016, which is an increase of 111 percent compared with Q2 2015. Two milestones were recorded during the Q3 2016, KUSD 200 upon registration approval for six countries within Middle East region and KUSD 50 upon registration approval in Australia.
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 Q2, 2016, over the same period in 2015.

Edluar®- for treatment of short-term insomnia
Global sales of Edluar, commercialized by Meda AB, were 12 percent lower in Q2 2016 compared with Q2 2015. Total sales for the quarter amounted to MEUR 2.9 (3.3).

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 inflammatoric 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[1] 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.[2]

[1] *UNODC World Drug Report 2014*
[2] *UNODC World Drug Report 2016*

Following the collaboration with Mundipharma, a new treatment option will potentially be made available to benefit patients with opioid dependency outside of the US. Mundipharma, through it's 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.[3]

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 market authorization and commercial milestones Orexo is entitled to receive further milestones payment and 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 new personalized treatment for respiratory diseases 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. When commercial evaluation of market potential have been completed and patent applications filed more information about these projects will be communicated. At the present stage these projects have a limited impact on costs.

Parent Company

Net revenues for the period January-September 2016 amounted to MSEK 307.0 (293.7). Earnings before tax were MSEK -62.1 (-131.2). Investments amounted to MSEK 0.3 (2.2). As of September 30, 2016, cash and cash equivalents in the Parent Company amounted to MSEK 164.0 (104.1).

[3] *EMCDDA, European Drug Report, 2014, Indivior (November 2014)*

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 6 and on page 11, Operations, Launched products, Zubsolv US and Paragraph IV litigation against Actavis.

Uppsala,Sweden, October 20, 2016
Orexo AB (publ.)

Nikolaj Sørensen
CEO and President

Review report

Orexo AB, corporate identity number 556500-0600

Introduction

We have reviewed the condensed interim report for Orexo AB as at September 30, 2016 and for the nine months period then ended. The Board of Directors and the Managing Director are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of review

We conducted our review in accordance with the International Standard on Review Engagements, ISRE 2410 Review of Interim Financial Statements Performed by the Independent Auditor of the Entity. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and other generally accepted auditing standards in Sweden.

The procedures performed in a review do not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Other matters

The review of the interim report per 30 September 2015 and the audit of the annual accounts for the year 2015 were performed by another auditor who submitted an unmodified review report and auditor's report.

Conclusion

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

Uppsala, Sweden, October 20, 2016

Ernst & Young AB

Björn Ohlsson
Authorized Public Accountant

Consolidated statement of operations

MSEK	Notes	2016 Jul-Sep	2015 Jul-Sep	2016 Jan-Sep	2015 Jan-Sep	2015 Jan-Dec
Net revenues		181.9	139.5	521.2	415.0	643.3
Cost of goods sold	2	-38.3	-34.8	-104.7	-103.8	-136.1
Gross profit		**143.6**	**104.7**	**416.5**	**311.2**	**507.2**
Selling expenses	2	-57.3	-70.8	-174.4	-225.6	-297.5
Administrative expenses	2	-33.3	-34.8	-131.2	-99.6	-141.5
Research and development costs	2	-24.1	-43.3	-97.8	-116.6	-172.6
Other operating income and expenses	2	14.1	4.8	16.0	5.8	-64.6
Operating earnings		**43.0**	**-39.4**	**29.1**	**-124.7**	**-169.0**
Net financial items		-5.4	-4.7	-17.3	-16.0	-22.1
Earnings before tax		**37.6**	**-44.1**	**11.8**	**-140.8**	**-191.1**
Tax		-1.7	-2.0	-5.3	-5.4	-6.9
Net earnings for the period[1)]		**36.0**	**-46.1**	**6.5**	**-146.2**	**-198.0**

Consolidated statement of comprehensive income

MSEK	2016 Jul-Sep	2015 Jul-Sep	2016 Jan-Sep	2015 Jan-Sep	2015 Jan-Dec
Earnings for the period	**36.0**	**-46.1**	**6.5**	**-146.2**	**-198.0**
Other comprehensive income					
Items that may subsequently be reversed to the statement of operations:					
Cash flow hedge	-	-	-	2.8	2.8
Exchange-rate differences	-7.7	0.1	-8.6	4.2	-4.3
Other comprehensive earnings for the period, net after tax	**-7.7**	**0.1**	**-8.6**	**7.0**	**-1.5**
Total comprehensive earnings for the period [1]	**28.3**	**-46.0**	**-2.1**	**-139.2**	**-199.5**
Earnings per share, before dilution, SEK	1.04	-1.33	0.19	-4.24	-5.74
Earnings per share, after dilution, SEK	1.04	-1.33	0.19	-4.24	-5.74

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

Consolidated balance sheet

MSEK	Notes	2016 Sep 30	2015 Sep 30	2015 Dec 31
ASSETS				
Fixed assets				
Tangible fixed assets		23.1	25.6	24.7
Goodwill		-	-	-
Acquired research and development		-	62.3	-
Other intangible fixed assets		142.4	164.0	159.1
Financial assets		-	2.3	2.1
Total fixed assets		**165.5**	**254.2**	**185.9**
Current assets				
Inventories		360.8	430.0	398.9
Accounts receivable and other receivables		269.4	224.6	233.4
Cash and cash equivalents		276.9	201.2	198.1
Total current assets		**907.1**	**855.8**	**830.4**
Total assets		**1,072.6**	**1,110.0**	**1,016.3**
SHAREHOLDERS' EQUITY AND LIABILITIES				
Total shareholders' equity	3	**270.9**	**325.2**	**266.4**
Long-term liabilities				
Provisions		2.4	3.9	3.9
Long-term liabilities, interest bearing		496.1	493.7	494.4
Total long-term liabilities		**498.5**	**497.6**	**498.3**
Current liabilities				
Current liabilities, non-interest bearing		303.2	287.2	251.6
Total current liabilities		**303.2**	**287.2**	**251.6**
Total liabilities		**801.7**	**784.8**	**749.9**
Total shareholders' equity and liabilities		**1,072.6**	**1,110.0**	**1,016.3**
Pledged assets		**-**	**100.00**	**100.0**

Consolidated changes in shareholders' equity

MSEK	2016 Sep 30	2015 Sep 30	2015 Dec 31
Opening balance, shareholders' equity	**266.4**	**455.0**	**455.0**
Total comprehensive earnings for the period	-2.1	-139.2	-199.5
Employee stock options, vested amount	4.5	5.5	7.1
Buy back of shares	-	0.1	-
New share issue	2.1	3.8	3.8
Closing balance, shareholders' equity	**270.9**	**325.2**	**266.4**

Consolidated cash flow statements

MSEK	Notes	2016 Jul-Sep	2015 Jul-Sep	2016 Jan-Sep	2015 Jan-Sep	2015 Jan-Dec
Operating earnings		43.1	-39.3	29.0	-124.7	-169.0
Financial income and expenses		-7.1	-6.8	-22.5	-21.5	-29.0
Adjustment for non-cash items	4	6.2	2.6	20.2	7.5	78.6
Cash flow from operating activities before changes in working capital		**42.2**	**-43.5**	**26.7**	**-138.7**	**-119.4**
Changes in working capital		**-11.0**	**-36.0**	**47.0**	**30.2**	**17.2**
Cash flow from operating activities		**31.2**	**-79.5**	**73.7**	**-108.5**	**-102.2**
Acquisition of tangible and intangible fixed assets		-1.0	-0.9	-1.2	-3.1	-4.1
Sale of subsidiary		-	-	11.0	21.8	21.8
Cash flow from investing activities		**-1.0**	**-0.9**	**9.8**	**18.7**	**17.7**
New share issue		2.1	-	2.1	3.8	3.8
Change in loans		-	-	-	-1.2	-1.2
Cash flow from financing activities		**2.1**	**-**	**2.1**	**2.7**	**2.6**
Cash flow for the period		**32.3**	**-80.4**	**85.6**	**-87.1**	**-81.9**
Cash and cash equivalents at the beginning of the period		**252.9**	**282.1**	**198.1**	**284.5**	**284.5**
Exchange-rate differences in cash and cash equivalents		-8.3	-0.5	-6.8	3.8	-4.5
Changes in cash and cash equivalents		32.3	-80.4	85.6	-87.1	-81.9
Cash and cash equivalents at the end of the period		**276.9**	**201.2**	**276.9**	**201.2**	**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 Jul-Sep	2015 Jul-Sep	2016 Jan-Sep	2015 Jan-Sep	2015 Jan-Dec
EBIT margin, %	24	-28	6	-30	-26
Return on shareholder equity, %	14	-13	2	-37	-55
Net debt, MSEK	219.2	292.5	219.2	292.5	296.3
Debt/equity ratio, %	183	152	152	152	186
Equity/assets ratio, %	25	29	25	29	26
Number of shares, before dilution	34,531,107	34,580,810	34,531,107	34,580,107	34,580,107
Number of shares, after dilution	34,588,445	34,580,810	34,588,445	34,580,107	34,580,107
Earnings per share, before dilution, SEK	1.04	-1.33	0.19	-4.24	-5.74
Earnings per share, after dilution, SEK	1.04	-1.33	0.19	-4.24	-5.74
Number of employees at the end of the period	102	101	102	101	90
Shareholders' equity, KSEK	270,900	325,178	270,900	325,178	266,459
Capital employed, KSEK	767,000	818,900	767,000	818,900	760,800
Working capital	602.4	568.6	602.4	568.6	578.8

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

Parent Company statement of operations

MSEK	Notes	2016 Jul-Sep	2015 Jul-Sep	2016 Jan-Sep	2015 Jan-Sep	2015 Jan-Dec
Net revenues		86.9	84.9	307.0	293.7	518.9
Cost of goods sold		-11.5	-29.6	-66.1	-101.7	-155.9
Gross profit		**75.4**	**55.3**	**240.9**	**192.0**	**363.0**
Selling expenses		-17.2	-46.7	-74.9	-170.3	-226.9
Administrative expenses		-24.0	-28.3	-107.6	-74.6	-108.1
Research and development costs		-16.4	-33.4	-115.0	-88.9	-122.9
Other operating income and expenses		9.7	4.9	8.1	26.0	5.0
Operating earnings		**27.5**	**-48.2**	**-48.5**	**-115.8**	**-89.9**
Interest income and expenses		-3.9	-3.9	-12.3	-13.6	-18.7
Impairment of shares in subsidiaries		-	-	-	-	-63.8
Sales of subsidiary		-	-	-	-	13.1
Other financial expenses		-0.6	-0.6	-1.3	-1.8	-2.5
Net financial items		**-4.5**	**-4.5**	**-13.6**	**-15.4**	**-71.9**
Earnings before tax		**23.0**	**-52.7**	**-62.1**	**-131.2**	**-161.8**
Tax		-	-	-0.1	-0.5	-0.5
Earnings for the period		**23.0**	**-52.7**	**-62.2**	**-131.7**	**-162.3**

Parent company statement of comprehensive income

MSEK	2016 Jul-Sep	2015 Jul-Sep	2016 Jan-Sep	2015 Jan-Sep	2015 Jan-Dec
Earnings for the period	**23.0**	**-52.7**	**-62.2**	**-131.7**	**-162,3**
Other comprehensive income					
Items that may subsequently be reversed to the statement of operations:					
Cash flow hedge	-	-	-	-	-
Exchange-rate differences	-	-	-	-	-
Other comprehensive earnings for the period, net after tax	**-**	**-**	**-**	**-**	**-**
Total comprehensive earnings for the period[1]	**23.0**	**-52.7**	**-62.2**	**-131.7**	**-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 Sep 30	2015 Sep 30	2015 Dec 31
ASSETS				
Fixed assets				
Tangible and intangible fixed assets		165.0	188.5	182.9
Shares in subsidiaries		148.7	211.5	148.5
Total fixed assets		**313.7**	**400.0**	**331.4**
Current assets				
Inventories		271.6	317.9	276.8
Accounts receivable and other receivables		237.0	244.9	320.7
Cash and bank balances		164.0	104.1	114.0
Total current assets		**672.6**	**666.9**	**711.5**
Total assets		**986.3**	**1,066.9**	**1,042.9**
SHAREHOLDERS' EQUITY. PROVISIONS AND LIABILITIES				
Shareholders' equity		**295.6**	**382.2**	**353.4**
Long-term liabilities		**498.5**	**497.6**	**498.2**
Current liabilities		**192.2**	**187.1**	**191.3**
Total liabilities		**690.7**	**684.7**	**689.5**
Total shareholders' equity and liabilities		**986.3**	**1,066.9**	**1,042.9**
Pledged assets		**-**	**100.0**	**100.0**

Notes

1. Accounting policies

- This interim 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.

2. Costs distributed by type of cost

MSEK	2016 Jul-Sep	2015 Jul-Sep	2016 Jan-Sep	2015 Jan-Sep	2015 Jan-Dec
Raw materials and supplies	38.9	32.5	88.8	91.7	120.2
Other external costs	78.7	118.0	316.5	362.5	499.3
Personnel costs	40.6	34.1	117.5	105.5	146.6
Depreciation/amortization and impairment	7.9	5.5	19.7	11.6	80.7
Total	**166.1**	**190.1**	**542.5**	**571.3**	**846.8**

Research and development costs encompass costs for personnel, premises, external costs for clinical trials, pharmaceutical registration and laboratory services, and the depreciation/amortization of equipment, acquired patents and other intangible assets.

3. Shareholders' equity

Shares outstanding

The number of shares outstanding as of September 30, 2016, was 34,666,107, of which 34,531,107 were common shares and 135,000 were C shares. All common shares carry one voting right and the C shares 1/10 of a voting each.

Number of shares outstanding at January 1, 2016	34,580,810
Subscription for shares through exercise of employee stock options	85,297
Shares outstanding at September 30, 2016	34,666,107

Options

As of September 30, 2016, a total of 2,272,447 options were outstanding that carry rights to new subscription of 1,517,119 shares in Orexo and the exchange of 340,255 options for shares in Orexo. Each option issued by Biolipox AB provides entitlement to the exchange of one share in Orexo AB, and a corresponding number of shares are held by the independent company Pyrinox AB.

The list below shows the change in the number of options during the period distributed by category.

Options to employees and Board members	Opening, Jan 1, 2016	Change	Closing, Sep 30, 2016
Of which:			
Approved and allotted employee stock options	1,666,773		1,666,773
Exercised		-82,344	-82,344
Allotted		270,2	270,2
Expired		-307,791	-307,791
Approved and allotted Board options	192,319		192,319
Expired		-	-
Employee stock options approved by AGM, unallotted	497,417	-	497,417
Warrants held by subsidiaries as cash flow hedging for social security fees	35,873		35,873
Total number of options outstanding	**2,392,382**	**-119,935**	**2,272,447**

During the period January-September 2016, no employee stock options from Orexo's options program were exercised.

Number of shares after full dilution

Shares outstanding at September 30, 2015	34,666,107
Employee stock options allotted	1,517,119
	36,299,284

4. Cash flow

Adjustment for non-cash items

MSEK	2016 Jul-Sep	2015 Jul-Sep	2016 Jan-Sep	2015 Jan-Sep	2015 Jan-Dec
Depreciation/amortization and impairment	7.9	5.5	19.7	11.6	80.7
Estimated costs for employee stock options program	-1.7	-2.9	0.5	-12.2	-10.2
Cash flow hedge	-	-	-	2.8	2.8
Sales of subsidiary	-	-	-	5.3	5.3
Total	**6.2**	**2.6**	**20.2**	**7.5**	**78.6**

5. 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.

6. 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. Because Orexo AB timely initiated a lawsuit against Actavis, the FDA is statutorily precluded from approving Actavis´ ANDA for 30 months, or until a district court decision finding the patents invalid or not infringed, whichever occurs earlier. In June, 2016, the case was trialed at court in the US state of Delaware. The 30 month stay period ends in November, 2016.

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

7. Important events after the period

- Orexo, together with Mundipharma, made 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.

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 Jul-Sep**	**2015 Jul-Sep**	**2016 Jan-Sep**	**2015 Jan-Sep**	**2015 Jan-Dec**
EBIT	43.0	-39.4	29.1	-124.7	-169.0
Depreciation and amortization	7.9	5.5	19.7	11.6	80.7
EBITDA	**50.9**	**-33.9**	**48.8**	**-113.1**	**-88.3**

Return on shareholders' equity	**2016 Jul-Sep**	**2015 Jul-Sep**	**2016 Jan-Sep**	**2015 Jan-Sep**	**2015 Jan-Dec**
Average shareholders' equity	254.3	347.1	267.25	390.1	360.7
Net earnings	36.0	-46.1	6.5	-146.2	198.0
Return on shareholders' equity %	**14**	**-13**	**2**	**-37**	**-55**

Net debt MSEK	**2016 Jul-Sep**	**2015 Jul-Sep**	**2016 Jan-Sep**	**2015 Jan-Sep**	**2015 Jan-Dec**
Current and long-term interest-bearing liabilities including pension liabilities	496.1	493.7	496.1	493.7	494.4
Cash and cash equivalents	-276.9	-201.2	-276.9	-201.2	-198.1
Net debt	**219.2**	**292.5**	**219.2**	**292.5**	**296.3**

Operating expenses MSEK	**2016 Jul-Sep**	**2015 Jul-Sep**	**2016 Jan-Sep**	**2015 Jan-Sep**	**2015 Jan-Dec**
Selling expenses	-57.3	-70.8	-174.4	-225.6	-297.5
Administrative expenses	-33.3	-34.8	-131.2	-99.6	-141.5
Research and development costs	-24.1	-43.3	-97.8	-116.6	-172.6
Other operating income and expenses	14.1	4.8	16.0	5.8	-64.6
Operating expenses	**-100.6**	**-144.1**	**-387.4**	**-436,0**	**-676.2**

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.