orexo

A specialty pharmaceutical company which has developed four products – from idea to patient

Interim Report Q1 2017

Summary

Unless otherwise stated in this report, all data refers to the Group. Figures in parentheses relate to the corresponding period in 2016.

Financial overview Q1 2017

- Total net revenues SEK 127.4 million (151.0)
- Zubsolv® net revenue SEK 114.1 million (98.4)
- EBIT SEK -23.2 million (-26.2)
- EBITDA SEK -18.1 million (-19.4)
- Earnings per share, before and after dilution, SEK -1.00/-1.00 (-1.00/-1.00)
- Cash flow from operating activities SEK 28.2 million (33.5)
- Cash and cash equivalents SEK 250.6 million (233.0)
- Guidance issued in connection with Full Year Report 2016 confirmed

Other highlights Q1 2017

- Completion of another bond buyback program amounting to a nominal value of SEK 59 million
- Orexo commenced a patent infringement litigation against Actavis for their generic versions of Suboxone® and Subutex® tablets in the US

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Teleconference

CEO Nikolaj Sørensen and CFO Henrik Juuel will present the report at a teleconference on April 20, 2017, at 2:00pm CET. Please view instructions below on how to participate.
Internet: https://wonderland.videosync.fi/orexo-q1-report-2017. Telephone: (SE) +46 8 566 425 09, (UK) +44 20 300 89 807 or (US) +1 855 831 5945. There will be a Q&A session and questions can also be sent in advance to ir@orexo.com at latest 11am CET. The presentation will be available at Orexo´s website one hour prior to the teleconference.

Financial calender

Interim Report Q2 2017 – July 11, 2017, 8.00am CET
Interim Report Q3 2017 – October 19, 2017, 8.00am CET

Contents

CEO comments

Zubsolv® growth in the US drives improved profitability in the commercial operations

In a dynamic market environment, I am pleased to report that net sales for Zubsolv US in Q1 2017 increased with 15.9 percent from Q1 2016 and our US business continues to contribute positively to the Orexo revenues and earnings. With this growth and positive contribution from our US business, I can confirm our financial guidance of positive EBITDA for the full year.

We are encouraged to see an accelerating growth in the market for treatment of opioid dependence reaching 9.7 percent in the first quarter compared to a growth of 7.6 percent in Q4 2016. This is a trend break as Q1 traditionally is weaker than Q4. The growth this year is primarily driven by the physicians certified to expand to 275 patients and most of the growth is in the public segment. The commercial segment has followed the trend from previous years with Q1 slightly below Q4 volumes. We expect the commercial segment to improve in the next quarters and we are pleased to see the growth in commercial pick-up late in the quarter. This is important for Orexo as we have better market access, market share and pay less rebates in the commercial segment.

During the quarter, I have spent time in the US meeting healthcare professionals treating opioid dependence. The feedback on Zubsolv and our work in the US is positive, we have a strong brand awareness both as a company and on a product level with Zubsolv. However, market access remains an important driver of physicians' choice of medication and we need to work relentlessly to open up the market for more unrestricted access for Zubsolv. I know our message resonates well, but physicians need to move out of their comfort zone and direct their patients to get a treatment with Zubsolv versus a "drug" most patients have tried before even starting medical treatment, since they were buying it on the street as a part of their illicit opioid misuse.

Another key event during the quarter was a new litigation against Actavis for infringement of our patent 8,454,996 with their generic versions of Suboxone® and Subutex®. The validity of the '996 patent was confirmed by the district court and Actavis has not appealed the decision. Actavis has been successful with the generic version of Suboxone and was the market leader the first year after launch in March 2013. The total cumulated gross sales of the generic versions of Suboxone and Subutex exceed USD 500 million and Orexo will seek compensation for damages caused by Actavis's infringement of the '996 patent.

I remain confident that we will continue to see a positive development of Zubsolv and Orexo, spurred by improved market and volume growth in the US. Beyond Zubsolv in the US, our pipeline is progressing well. Zubsolv launch in Europe is anticipated early next year, we have concrete discussions with partners for OX51 and OX-MPI and we have some exciting new formulation technologies which could be ready for first clinical trials already this year. With our continued strengthening of our financial position, with six consecutive quarters with positive cash flow from operating activities, we are well positioned to capture the opportunities and continue the development of Orexo.

Nikolaj Sørensen
President and CEO

Orexo has guided positive EBITDA for the full year 2017, however negative for the first half year as Abstral® royalties are skewed towards second half year. For Q1 2017 EBITDA amounted to SEK -18.1 million (-19.4). Q1 2016 included a SEK 40.8 million (USD 5 million) milestone payment from AstraZeneca. Excluding this milestone payment the year-over-year EBITDA was improved by SEK 42.1 million driven by a nearly 16 percent growth in Zubsolv® US net revenue and significant cost reductions. The EBITDA performance is fully in line with the company's expectations and the full year EBITDA guidance is confirmed.

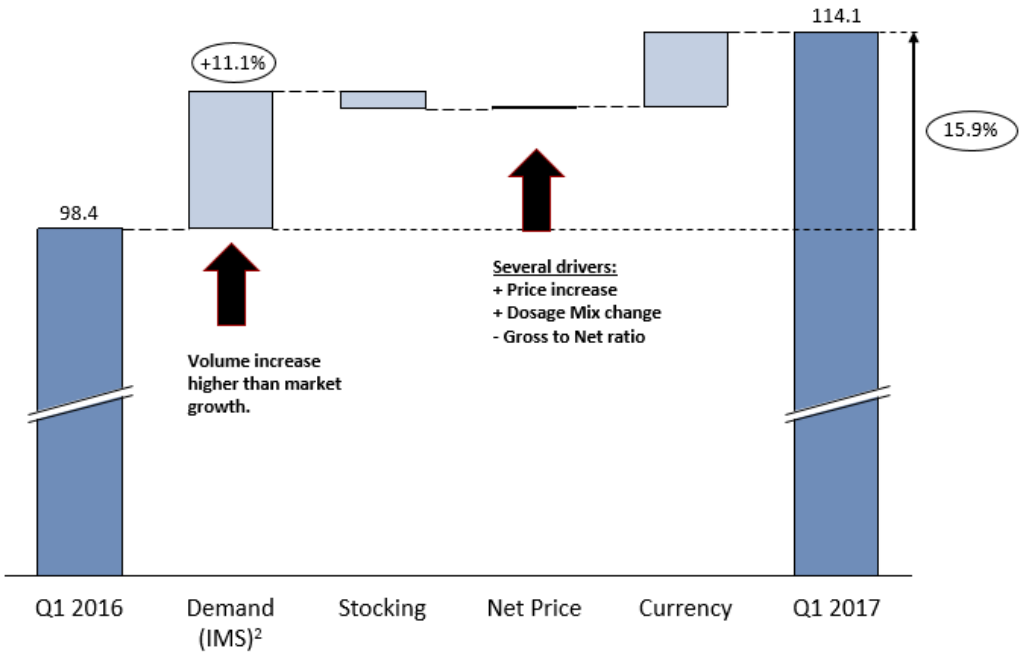
Revenues

Total revenues for Q1 2017 amounted to SEK 127.4 million (151.0) corresponding to a 15.6 percent increase when excluding the SEK 40.8 million (USD 5 million) OX-CLI milestone payment earned in Q1 2016. This growth was driven by Zubsolv US. When including the OX-CLI milestone total revenues declined by 15.7 percent.

Commercial products

Zubsolv US revenue amounted to SEK 114.1 million (98.4) in Q1 2017 corresponding to a 15.9 percent growth over same period last year. This growth was driven by an 11.1 percent volume growth that outperformed the general market growth during the period. Wholesaler inventory levels had a moderately negative impact on the growth. The net tablet price was positively impacted by the 6 percent price increase from January 2017 and by a positive dosage mix change. These positive net price drivers were largely off-set by higher gross-to-net deductions caused by continued high price pressure. Finally a stronger USD currency had a positive impact when comparing to first quarter 2016.

Q1 Zubsolv US revenue growth (SEK million) by key drivers[1]



[2] Includes IMS numbers and institutional sales

Abstral® revenues amounted to SEK 8.7 million (8.2) for Q1 2017.

Revenues from Edluar® amounted to SEK 4.6 million (3.6) for Q1 2017.

[1] Orexo analysis using IMS demand data

Partner projects
Q1 2016 included a milestone payment from AstraZeneca relating to the OX-CLI project amounting to SEK 40.8 million.

Total net revenues were distributed as follows

MSEK	**2017 Jan-Mar**	**2016 Jan-Mar**	**2016 Jan-Dec**
Zubsolv® US	114.1	98.4	481.8
Zubsolv – Rest of the World	-	-	65.9
Zubsolv – total	***114.1***	***98.4***	***547.7***
Abstral® royalties	8.7	8.2	100.4
Milestone payment Abstral	-	-	2.2
Abstral – total	***8.7***	***8.2***	***102.6***
Edluar® royalties	4.6	3.6	14.8
Other revenues[1]	-	40.8	40.8
Total	***127.4***	***151.0***	***705.9***

[1] Relates to the acquisition of OX-CLI by AstraZeneca

Costs and earnings

Cost of goods sold
Cost of goods (COGS) sold amounted to SEK 46.2 million (32.5) for Q1 2017, and all relates to Zubsolv US. The re-packing and de-blistering project announced in Q3 Interim Report 2016 was fully completed during Q1 2017 and had a negative impact on COGS for the quarter amounting to SEK 3.8 million.

Selling expenses
Selling expenses amounted to SEK 48.3 million (60.8) for Q1 2017. The lower level compared with previous year reflects a very targeted investment strategy focusing on geographies with good market access and potential for growth combined with the effect of implementing an increased span of control in the sales organization (i.e. more direct reports per regional manager).

Administrative expenses
Administrative expenses for Q1 2017 amounted to SEK 26.3 million (35.1). Q1 2016 included significantly higher costs related to IP litigations and this explains the reduced level in 2017.

Research and development costs
In Q1 2017 research and development costs amounted to SEK 30.3 million (45.0). Q1 2016 included significant costs related to the REZOLV study and Zubsolv Pharmacokinetics (PK) study for EU submission. The latter was later reimbursed by Mundipharma.

Costs for long-term incentive program
The Group's total costs for employee stock option programs during Q1 2017 amounted to SEK -0.9 million (0.9).

Other income and expenses
Other income and expenses amounted to SEK 0.5 million (-3.8) for Q1 2017. This is primarily comprised of exchange-rate gains/losses derived from revaluations of balance sheet items in foreign currency.

Depreciation and amortization
Depreciation and amortization amounted to SEK 5.1 million (6.8) for Q1.

Net financial items
Net financial items for Q1 2017 amounted to SEK -6.6 million (-6.4). All the net financial items are related to financing activities.

Tax
Total tax for Q1 2017 amounted to SEK 4.8 million (1.9). The increase versus same period prior year was caused by a true-up of US tax estimates from previous periods.

Net earnings
Net earnings amounted to SEK -34.6 million (-34.5) for Q1 2017.

Cash flow and financial position

At March 31, 2017, cash and cash equivalents amounted to SEK 250.6 million (233.0) and interest-bearing liabilities to SEK 339.4 million (494.9). Orexo bonds bought back in the market have been netted out against liabilities on the balance sheet and are not included as cash equivalents.

Cash flow from operating activities was positive and amounted to SEK 28.2 million (33.5) for Q1 2017 driven by improvements in working capital.

During the first quarter 2017 Orexo corporate bonds were bought back with a nominal value of SEK 59 million. In total Orexo owns own bonds with a nominal value of SEK 158 million.

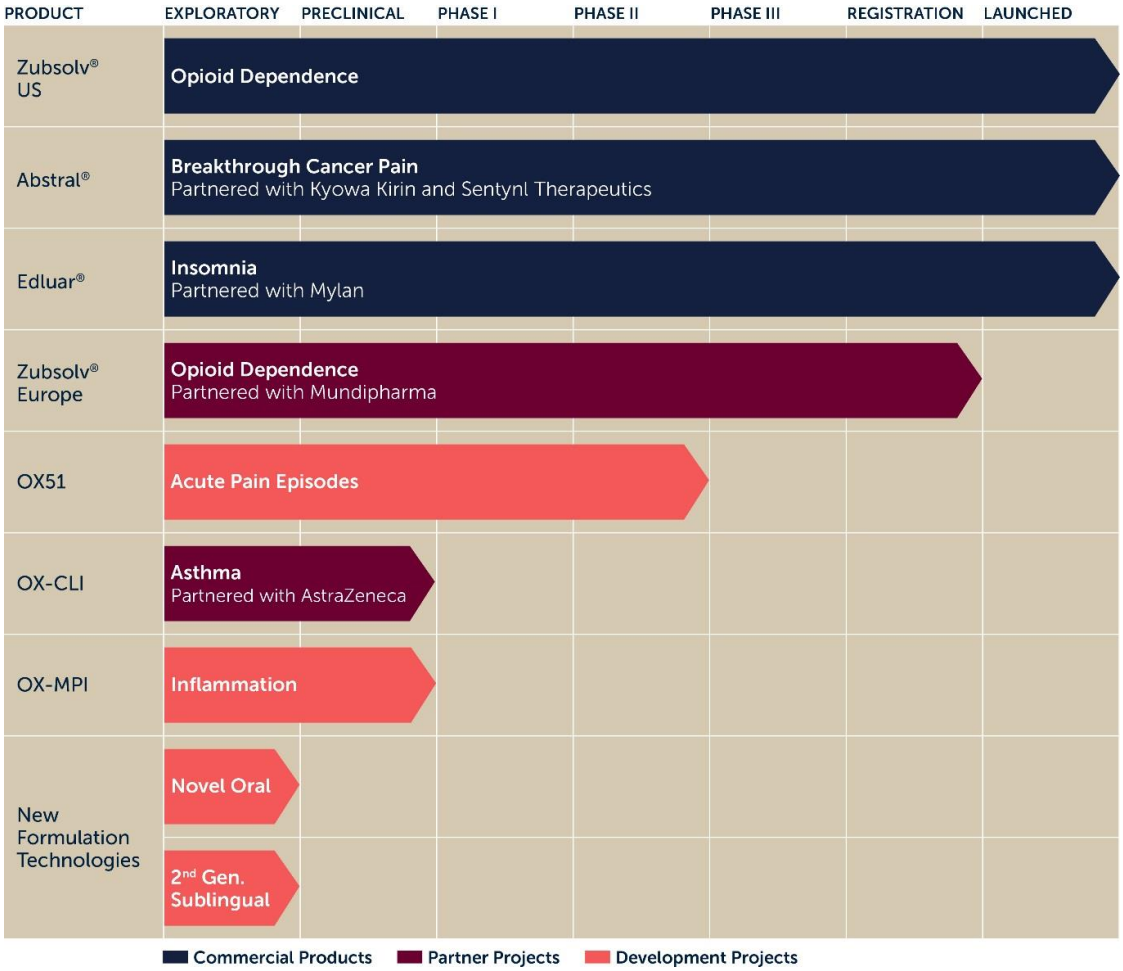
Shareholders' equity at March 31, 2017, was SEK 273.3 million (237.3). The equity/asset ratio was 29.2 (23.1) percent.

Investments in fixed assets

Investments in tangible and intangible fixed assets amounted to SEK 0.3 million (0.1) for Q1 2017.

Operations

Pipeline of products and projects



Commercial products

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

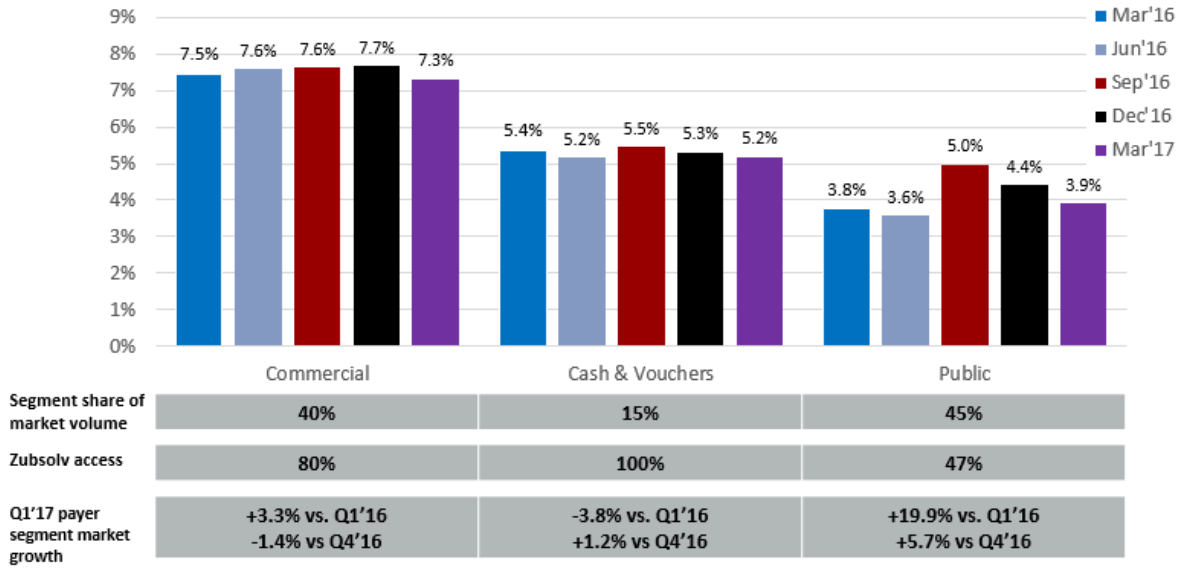
During Q1 2017 the total buprenorphine/naloxone market grew 2.5 percent in volume compared to Q4 2016, and grew 9.7 percent compared to Q1 2016. The market is forecasted to continue to grow as more providers become waivered and as currently waivered prescribers expand their patient limits to treat a greater number of opioid dependent patients in 2017. To date, almost 3,000 waivered physicians are eligible to increase their patient load to 275 and more than half of these physicians have begun to expand prescribing. In addition, nurse practitioners and physicians assistants have begun to receive training and waivers are being granted to prescribe buprenorphine based on the CARA Act and local state laws during 2017.

Due to market dynamics in payer segments unrelated to Orexo's payer strategy or Zubsolv's strong market access position, the brand's performance when comparing Q1 2017 to Q4 2016 demonstrated a decline of 6.6 percent in tablets dispensed to patients through pharmacies. This dip in tablets dispensed was driven primarily by two accounts, United Health Group and Wellcare as well as expected lower seasonal volumes in the commercial segment. United Health Group's decision to exit ACA healthcare exchanges, in all but three states, led to lower tablet volume. In addition, Wellcare Managed Medicaid market volume declined as well due to some patients changed insurance company in beginning of Q1 2017 and a large provider group's withdrawal from the insurer in mid-Q4 2016. Without these two market events, Zubsolv US would

have demonstrated approximately a 3 percent gain in volume in Q1 2017 over Q4 2016. The public segment continues to be the fastest growing of the three payer segments. The cash and commercial segments, while currently demonstrating limited growth, are likely to increase in 2017 with the improvements in patient access to treatment capacity along with changes to US laws impacting access to healthcare in the various payer segments.

With the increased share of volume in the public segment and increased price pressure across all segments there has been a negative impact on the gross to net ratio for 2017. However, Zubsolv® raised prices from January 1 2017, which will compensate for a portion of the increased rebates.

Zubsolv US market share per type of payer segment, rolling 4 weeks, Mar. 2016-Mar. 2017[2]



Expansion of access to treatment

The increase of the physician patient cap has begun to accelerate market growth, Q1 2017 grew 9.7 percent over Q1 2016. The historical annual market growth rate has been approximately 8 percent for the past two years. Among targeted physicians who grew their market volume and where Zubsolv had access outside of exclusive arrangements, Zubsolv continued to win disproportionate market share, with an increase from 6.0 percent in Q4 2016 to 6.8 percent market share in growth volumes in Q1 2017.

Commercial (private insurance)

(40% of the total market, 53% of Zubsolv business in March 2017)

In the commercial segment, Zubsolv's market share decreased by 0.4 percentage points and prescriptions decreased 5.5 percent compared to Q4 2016. The driver of this decline was the aforementioned exit of the United Health Group from the ACA health exchanges and anticipated seasonal low volumes. Excluding the changes in United Health Group Zubsolv commercial volume and market share increased in Q1 2017 over Q4 2016.

The commercial segment has declined 1.4 percent in volume compared to Q4 2016, and grew 3.3 percent compared to Q1 2016. Zubsolv had unrestricted access to 80 percent of the business in the segment.

Cash (Cash & Vouchers, the patient pays)

(14% of the total market, 14% of Zubsolv business in March 2017)

[2] IMS XPO PA: 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; Mar´ 17 data: R4W WE 03/10/2017

Zubsolv´s market share during the quarter has been relatively stable at 5.2 in Q1 2017 versus 5.3 percent in Q4 2016 in this segment. The cash market is the most sensitive market to price and discount programs. During the quarter discount cards for generic products resulting in a price level below all branded products have impacted the cash segment dynamics and generic products have gained market share.

The cash segment has grown 1.2 percent in volume during Q1 2017 compared to Q4 2016, and has declined 3.8 percent compared to Q1 2016. Zubsolv® has access to 100 percent of the business in the cash segment.

Public (Managed Medicaid, FFS Medicaid, Medicare Part D)
(45% of the total market, 32% of Zubsolv business in March 2017)

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 5.7 percent in volume during Q1 compared to Q4 2016, and 19.9 percent compared to Q1 2016. During the quarter Zubsolv had access to 47 percent of the business in the public segment. The market share of Zubsolv decreased in this segment by 0.5 percentage points in Q1 2017 from Q4 2016, primarily driven by some patients utilized the possibility to change to other insurance companies than Wellcare as of January 1 as well as a rapidly growing Public payer segment.

Zubsolv won a preferred position with CareSource in Ohio from January 1, 2017, however during the quarter CareSource has announced a change to only grant generic products a preferred position. This had limited impact on Zubsolv, but drove overall generic market share capture during the quarter.

Paragraph IV litigations against Actavis regarding Zubsolv in the US
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. 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 new ANDAs 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.

Patent infringement litigation against Actavis for their generic versions of Suboxone® and Subutex® tablets in the US
In March 2017 Orexo filed a patent infringement action in United States District Court for the District of Delaware against Actavis Elizabeth LLC, Actavis Pharma, Inc., and their parent company Teva (collectively "Actavis"). Orexo alleges that Actavis's generic versions of Suboxone and Subutex tablets infringe Orexo's US Patent No. 8,454,996 (the '996 patent). Actavis's generic version of Suboxone was approved by the FDA in February 2013 and their generic version of Subutex in February 2015. Orexo is seeking compensation for damages caused by Actavis's infringement of the '996 patent since approval of these two products.

Abstral® - breakthrough cancer pain

Due to the timing of this Interim Report, Orexo has not yet received final data for first quarter sales of Abstral and Edluar® from our partners and hence the calculation of Q1 royalties is based on Orexo forecast and preliminary Q1 sales reports where available. For the same reason the Abstral® and Edluar® sections below primarily refer to the sales development in Q4 2016.

Sales of Abstral in the EU continue to grow and amounted to MEUR 22.4, which is an increase of 8 percent in Q4 2016 compared to Q4 2015. Orexo receives royalty on sales exceeding EUR 42.5 million, 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 Q4 2016, net sales were 36 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 3 in Q4 2016, which is an increase of 36 percent compared with Q4 2015.

Orexo's commercial partner in Japan, Kyowa Hakko Kirin, continued to focus on growing the Japanese market for Abstral. Net sales remained in the same level in Q4, 2016, as during the same period in 2015.

Edluar - insomnia

Global sales of Edluar, commercialized by Mylan which in 2016 acquired our former partner Meda AB, were up 6 percent in Q4 2016 compared with Q4 2015. Total sales for the quarter amounted to MEUR 4.6 (4.4).

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.

Partner projects

Zubsolv® Europe – opioid dependence

In June, 2016, Mundipharma acquired the rights to Zubsolv outside the US (Rest of the World, RoW). The first important milestone in the collaboration was achieved in October, 2016, when a regulatory submission for Zubsolv RoW 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. In parallel other markets are evaluated outside Europe and the US.

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 a tired single digit royalty on future net sales.

OX-CLI – asthma

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.

In March 2016 AstraZeneca exercised their option to acquire all rights to OX-CLI. AstraZeneca will continue the drug development without any 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.

Development projects

OX51 – acute pain episodes
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.

To be able to take the project into phase III discussions with partners are ongoing.

OX-MPI – inflammation
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).

Discussions with an external partner for OX-MPI is ongoing.

New Formulation Technologies

Novel oral formulation technology
Many active ingredients face major challenges when administered by the oral route. For example, incomplete dissolution in the GI-tract, poor intestinal absorption and extensive metabolism may all limit bioavailability. Consequently, many drugs are not effective when administered orally. Orexo is currently developing a new formulation technology that can overcome these issues, enabling oral administration of drugs for which this route is not feasible today. The project is in the exploratory phase, and several active substances have been identified as promising candidates for this technology.

2nd generation sublingual formulation technology
Orexo is currently developing its second-generation sublingual formulation technology. The aim is to perfect the Sublingual delivery of drugs, thereby unlocking new active ingredients that are currently not possible to administer sublingually. The project is in the exploratory phase, and several active ingredients have been identified as promising candidates for this technology.

Parent Company

Net revenues for Q1 2017 amounted to SEK 122.4 million (52.6). Earnings before tax were SEK -11.6 million (-102.3). Investments amounted to SEK 0.3 million (0.1). As of March 31, 2017, cash and cash equivalents in the Parent Company amounted to SEK 160.8 million (163.3).

During Q1 2017 2 batches of Zubsolv® 5.7mg were returned from Orexo Inc. to Orexo AB for de-blistering and repacking. During the quarter 35 batches were sold back to Orexo Inc. and these transactions had a positive net impact on the parent company revenue, margin and net earnings.

Outlook 2017

All elements of the outlook for 2017 provided together with the 2016 Full Year report is confirmed. The outlook is repeated below.

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 SEK 500 million to SEK 510 million.

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 2016. 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, April 20, 2017
Orexo AB (publ.)

Nikolaj Sørensen
President and CEO

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

Consolidated statement of operations

MSEK	Notes 1	2017 Jan-Mar	2016 Jan-Mar	2016 Jan-Dec
Net revenues		127.4	151.0	705.9
Cost of goods sold		-46.2	-32.5	-149.6
Gross profit		**81.2**	**118.5**	**556.3**
Selling expenses		-48.3	-60.8	-240.6
Administrative expenses		-26.3	-35.1	-161.6
Research and development costs		-30.3	-45.0	-132.3
Other operating income and expenses		0.5	-3.8	29.9
Operating earnings		**-23.2**	**-26.2**	**51.7**
Net financial items		-6.6	-6.4	-16.1
Earnings before tax		**-29.8**	**-32.6**	**35.6**
Tax		-4.8	-1.9	-6.5
Net earnings for the period[1]		**-34.6**	**-34.5**	**29.0**

Consolidated statement of comprehensive income

MSEK	2017 Jan-Mar	2016 Jan-Mar	2016 Jan-Dec
Earnings for the period	**-34.6**	**-34.5**	**29.0**
Other comprehensive income			
Items that may subsequently be reversed to the statement of operations:			
Change in fair value assets available for sale			
Reclassification assets available for sale	-	-	-0.9
Cash flow hedge	-	-	-
Exchange-rate differences	-1.4	0.8	6.2
Other comprehensive earnings for the period, net after tax	**-1.4**	**0.8**	**5.3**
Total comprehensive earnings for the period [1]	**-36.0**	**-33.7**	**34.3**
Earnings per share, before dilution, SEK	-1.00	-1.00	0.84
Earnings per share, after dilution, SEK	-1.00	-1.00	0.84

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

Consolidated balance sheet

MSEK	Notes	2017 Mar 31	2016 Mar 31 Restated	2016 Dec 31
	1			
ASSETS				
Fixed assets				
Tangible fixed assets		21.5	23.7	22.1
Intangible assets		133.9	149.8	138.2
Deferred tax assets		21.1	24.8	24.8
Other financial assets		-	1.4	-
Total fixed assets		**176.5**	**199.7**	**185.1**
Current assets				
Inventories		316.8	386.2	344.2
Accounts receivable and other receivables		192.2	208.0	207.1
Cash and cash equivalents		250.6	233.0	282.4
Total current assets		**759.6**	**827.2**	**833.7**
Total assets		**936.1**	**1,026.9**	**1,018.8**
SHAREHOLDERS' EQUITY AND LIABILITIES				
Total shareholders' equity		**273.3**	**237.3**	**310.3**
Long-term liabilities				
Provisions		0.8	2.6	1.3
Long-term liabilities, interest bearing		339.4	494.9	397.8
Total long-term liabilities		**340.2**	**497.5**	**399.0**
Current liabilities and provisions				
Provisions, current liabilities, non-interest bearing		322.7	292.1	309.5
Total current liabilities and provisions		**322.7**	**292.1**	**309.5**
Total liabilities		**662.9**	**789.6**	**708.5**
Total shareholders' equity and liabilities		**936.1**	**1,026.9**	**1,018.8**

Consolidated changes in shareholders' equity

MSEK	2017 Mar 31	2016 Mar 31	2016 Dec 31
Opening balance, shareholders' equity	**310.3**	**266.4**	**270.1**
Restatement	**-**	3.7	**-**
Restated opening balance, shareholders' equity	**310.3**	**270.1**	**270.1**
Total comprehensive earnings for the period	-36.0	-33.7	34.3
Employee stock options, vested amount	-0.9	0.9	3.7
Buy back of shares	-	-	-0.1
New share issue	-	-	2.3
Closing balance, shareholders' equity	**273.4**	**237.3**	**310.3**

Consolidated cash flow statements

MSEK	Notes	2017 Jan-Mar	2016 Jan-Mar	2016 Jan-Dec
	1			
Operating earnings		-23.2	-26.2	51.7
Financial income and expenses		-16.9	-8.3	-28.3
Adjustment for non-cash items	2	20.1	38.0	44.1
Cash flow from operating activities before changes in working capital		**-20.0**	**3.5**	**67.5**
Changes in working capital		**48.2**	**30.0**	**88.7**
Cash flow from operating activities		**28.2**	**33.5**	**156.2**
Acquisition of tangible and intangible fixed assets		-0.3	-0.1	-1.4
Disposal of fixed assets		-	-	1.8
Sale of subsidiary		-	-	5.0
Cash flow from investing activities		**-0.3**	**-0.1**	**5.4**
New share issue		-	-	2.2
Change in loans		-59.0	-	-92.8
Cash from financing activities		**-59.0**	**-**	**-90.6**
Cash flow for the period		**-31.1**	**33.4**	**71.0**
Cash and cash equivalents at the beginning of the period		**282.4**	**198.1**	**198.1**
Exchange-rate differences in cash and cash equivalents		-0.7	1.5	13.3
Changes in cash and cash equivalents		-31.1	33.4	71.0
Cash and cash equivalents at the end of the period		**250.6**	**233.0**	**282.4**

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.

	2017 Jan-Mar	2016 Jan-Mar Restated	2016 Jan-Dec
EBIT margin, %	-18	-17	7
Return on shareholder equity, %	-12	-14	10
Net debt, MSEK	88.8	261.9	115.4
Debt/equity ratio, %	124.2	208.6	128.2
Equity/assets ratio, %	29.2	23.1	30.5
Number of shares, before dilution	34,539,585	34,447,779	34,477,375
Number of shares, after dilution	34,539,585	34,447,779	34,574,337
Earnings per share, before dilution, SEK	-1.00	-1.00	0.84
Earnings per share, after dilution, SEK	-1.00	-1.00	0.84
Number of employees at the end of the period	102	93	102
Shareholders' equity, MSEK	273.3	237.3	310.3
Capital employed, MSEK	612.7	732.2	708.1
Working capital, MSEK	436.9	552.6	524.2

[1] Definitions and reconciliations of key figures are presented on page 19 of this report

Parent Company statement of operations

MSEK	Notes	2017 Jan-Mar	2016 Jan-Mar	2016 Jan-Dec
Net revenues		122.4	52.6	379.3
Cost of goods sold		-59.8	-2.0	-83.6
Gross profit		**62.6**	**50.6**	**295.7**
Selling expenses		-25.1	-39.3	-105.7
Administrative expenses		-18.7	-28.4	-129.1
Research and development costs		-23.7	-76.8	-141.8
Other operating income and expenses		0.4	-4.1	24.3
Operating earnings		**-4.5**	**-98.0**	**-56.6**
Interest income and expenses		-4.8	-4.3	-16.2
Impairment of shares in subsidiaries		-	-	-
Exchange rate adjustment		-1.3	-	-32.1
Sales of subsidiary		-	-	-
Other financial expenses		-1.0	-	9.3
Net financial items		**-7.1**	**-4.3**	**-39.1**
Earnings before tax		**-11.6**	**-102.3**	**-95.7**
Tax		-	-	-
Earnings for the period		**-11.6**	**-102.3**	**-95.7**

Parent company statement of comprehensive income

MSEK	2017 Jan-Mar	2016 Jan-Mar	2016 Jan-Dec
Earnings for the period	**-11.6**	**-102.3**	**-95.7**
Other comprehensive income	**-**	**-**	-
Total comprehensive earnings for the period[1]	**-11.6**	**-102.3**	**-95.7**

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

Parent Company balance sheet

MSEK	Notes	2017 Mar 31	2016 Mar 31	2016 Dec 31
ASSETS				
Fixed assets				
Tangible and intangible fixed assets		155.0	176.3	159.8
Shares in subsidiaries		148.6	148.7	149.7
Total fixed assets		**303.6**	**325.0**	**309.5**
Current assets				
Inventories		231.4	291.9	269.6
Accounts receivable and other receivables		143.0	203.8	76.8
Cash and bank balances		160.8	163.3	211.7
Total current assets		**535.2**	**659.0**	**558.1**
Total assets		**838.8**	**984.0**	**867.5**
SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES				
Shareholders' equity		**251.3**	**251.8**	**263.5**
Long-term liabilities		**340.1**	**497.6**	**399.0**
Current liabilities		**247.4**	**234.6**	**205.0**
Total liabilities		**587.5**	**732.2**	**604.1**
Total shareholders' equity and liabilities		**838.8**	**984.0**	**867.5**
Pledged assets	**3**	**-**	**100.0**	**-**

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 2016 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

The company refers to the annual report 2016 Note 38 for more information on adjusted financial statements.

2. Cash flow

Adjustment for non-cash items

MSEK	2017 Jan-Mar	2016 Jan-Mar	2016 Jan-Dec
Depreciation/amortization and impairment	5.4	6.8	25.0
Gain/loss on disposal	-	-	-5.0
Change in provisions	30.8	30.6	42.0
Change in fair value of financial instruments	-	-	0.2
Share based payments	-0.8	0.6	3.7
Exchange rate income and expenses	-15.3	-	-21.8
Total	**20.1**	**38.0**	**44.1**

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.

In March 2017 Orexo filed a patent infringement action in United States District Court for the District of Delaware against Actavis. Orexo alleges that Actavis's generic versions of Suboxone and Subutex tablets infringe Orexo's US Patent No. 8,454,996 (the '996 patent). Actavis's generic version of Suboxone was approved by the FDA in February 2013 and their generic version of Subutex in February 2015. Orexo is seeking compensation for damages caused by Actavis's infringement of the '996 patent since approval of these two products.

For more detailed information about the litigation with Actavis please see page 8.

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	**2017 Jan-Mar**	**2016 Jan-Mar**	**2016 Jan-Dec**
EBIT	-23.2	-26.2	51.7
Depreciation and amortization	5.1	6.8	21.4
EBITDA	**-18.1**	**-19.4**	**73.1**

Return on shareholders' equity	**2017 Jan-Mar**	**2016 Jan-Mar Restated**	**2016 Jan-Dec**
Average shareholders' equity	291.8	253.7	290.2
Net earnings	-34.6	-34.5	29.0
Return on shareholders' equity %	**-12.0**	**-14.0**	**10.0**

Net debt MSEK	**2017 Jan-Mar**	**2016 Jan-Mar**	**2016 Jan-Dec**
Current and long-term interest-bearing liabilities including pension liabilities	339.4	494.9	397.8
Cash and cash equivalents	-250.6	-233.0	-282.4
Net debt	**88.8**	**261.9**	**115.4**

Operating expenses MSEK	**2017 Jan-Mar**	**2016 Jan-Mar**	**2016 Jan-Dec**
Selling expenses	-48.3	-60.8	-240.6
Administrative expenses	-26.3	-35.1	-161.6
Research and development costs	-30.3	-45.0	-132.3
Other operating income and expenses	0.5	-3.8	29.9
Operating expenses	**-104.4**	**-144.7**	**-504.6**

Glossary

Alfentanil
A potent synthetic opioid analgesic drug, used for anaesthesia in surgery
American Depositary Receipt (ADR)
An instrument that is issued by a depositary bank that represents ownership of a company's underlying shares. ADR programs are created to facilitate US investors to hold shares in non-US companies and trade them in the same way as US securities.
Anaesthesia
Procedure for lowering a patient's consciousness to enable a Medical procedure to proceed without pain for the patient
ANDA
An Abbreviated New Drug Application (ANDA) is an application for a US generic drug approval for an existing licensed medication or approved drug
Breakthrough pain
A short, intensive period of pain that occurs in addition to chronic levels of long-term pain even though these are treated by regular painkillers
Buprenorphine
A potent opioid partial agonist first used as a pain-relieving substance,but now most commonly used to help patients withdraw from more addictive opioid drugs such as morphine
CARA
The Comprehensive Addiction and Recovery Act (CARA) became law in the US in July 2016. CARA authorizes a series of grants aimed at among other things developing treatment programs which further expands buprenorphine prescribing rights to nurse practitioners and physician assistants
Cash & vouchers segment
One of the three distinct payer segments in the market for treatment of opioid dependence. In this segment, the patient is paying for the prescriptions out of pocket
CLI
Cysteinyl Leukotriene Inhibitor
Clinical studies/Clinical trials
Studies of the safety and efficacy of a drug in human beings
Commercial segment
One of the three distinct payer segments in the market for treatment of opioid dependence. The commercial segment is funded by private insurances or employers
Drug delivery
The process through which a pharmaceutical may be introduced to the patient that enables the active compound to function as intended
EMA
The European Medicine Agency
FDA
The US Food and Drug Administration
Fentanyl
An opioid with a similar effect on human patients as morphine. Used mainly within anasthesia and analgesia
GMP
Good Manufacturing Practice
HHS
The US Department of Health and Human Services
IP
Intellectual Properties
Naloxone
An opioid inverse agonist used to counter the effects of opioids
NCE
New Chemical Entity
Opioids
Collective term for compounds that act via opioid receptors on nerve cells, mainly in the central nervous system
PBM (Pharmacy Benefit Manager)
Responsible for management of costs associated with prescription pharmaceuticals and recommendations on behalf of insurance companies and employers in the US
PGE
Prostaglandin (PG) E2 – biologically active mediator derived from arachidonic acid and involved in inflammatory conditions
Phase I studies
Studies mainly of the safety of a drug. Performed on healthy human volunteers
Phase II studies
Studies of the safety and efficacy of a drug in appropriate doses. Performed on a limited number of patients
Phase III studies
Studies of the safety and efficacy of a drug in a clinical setting. Performed on a large number of patients
Preclinical development/Preclinical studies
Studies of the safety and efficacy of a drug prior to evaluation in humans. Can be performed on animals and in various cell systems
Public segment
One of three distinct payer segments in the market for treatment of opioid dependence. The public segment covers state and federal funded reimbursement programs i.e. Managed Medicaid, FFS Medicaid, Medicare Part D
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
Zolpidem
A pharmaceutical substance used to treat temporary or short-term insomnia

This information is information that Orexo AB (publ.) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 8.00am CET on April 20, 2017.

www.orexo.com

About Orexo
Orexo develops improved pharmaceuticals based on innovative drug delivery technologies. The focus is primarily on opioid dependence and pain but it is also our aim to address other therapeutic areas where our competence and technologies can create value. The products are commercialized by Orexo in the US or via selected partners worldwide. The main market today is the American market for the treatment of opioid dependence, where Orexo sells the product Zubsolv®. Total net sales for 2016 amounted to SEK 705.9 million and the number of employees was 102. Orexo is listed on the Nasdaq Stockholm Mid Cap (ORX) index and is available as ADRs on OTCQX (ORXOY) in the US. The head office, where also research and development is performed, is situated in Uppsala, Sweden.

For more information about Orexo, please visit www.orexo.com. You can also follow Orexo on Twitter, @orexoabpubl, LinkedIn and YouTube. For more information about Zubsolv in the US, see the product and market websites www.zubsolv.com and www.rise-us.com.