## orexo

Annual Report 2015



**Zubsolv**® – in the US Now also approved for induction treatment



**Zubsolv**® – in the US Broadest dosage range in the disease area





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## A Snapshot of Orexo

Orexo is on the evolution path to become a sustainable strong specialty pharmaceutical company.

We develop new improved products by combining well-known and well-documented compounds with Orexo's innovative patented proprietary sublingual tablet technologies.

#### **COMPANY IN BRIEF**

- Founded in 1995
- Headquarters and R&D in Uppsala, Sweden
- Developed and launched four products
- Commercial operations in New Jersey, in the US
- 90 employees at year-end
   Orexo's share is listed in Sweden on Nasdaq Stockholm
   Mid Cap (STO:ORX) and is available as ADRs on OTCQX
   in the US under the symbol ORXOY.

## Our focus

#### **ZUBSOLV®**

- Orexo's product for treatment of opioid dependence currently targeting a rapidly growing need in the US, where already more than 5 million people are addicted to opioids.
- Maximize the commercial potential of Zubsolv for treatment of opioid dependence and expansion into new markets is the current main focus.

#### **ABSTRAL® AND EDLUAR®**

- Two out-licensed products which both comprise the proprietary sublingual treatment and generate royalties and milestones to Orexo on a global scale.
- Abstral, for cancer pain, and Edluar, for short term insomnia, are both addressing patients' needs worldwide.

ZUBSOLV REVENUES FROM SALES ON THE US MARKET 2015

416.7<sub>MSEK</sub>

ROYALTIES AND MILESTONES 2015 ABSTRAL + EDLUAR

213.8<sub>MSEK</sub>

## The Year in Brief

#### KEY EVENTS DURING THE YEAR

Q1	<ul> <li>Orexo broadened Zubsolv® product range by launching Zubsolv 8.6 mg/2.1 mg.</li> <li>New patent protecting Zubsolv listed in the US.</li> <li>Orexo commenced patent infringement litigation against Actavis concerning Abstral® in the US.</li> </ul>
Q2	<ul> <li>Orexo divested the subsidiary Kibion AB.</li> <li>FDA approved the medium tablet strength, 2.9 mg/0.8 mg, of Zubsolv.</li> <li>Orexo settled patent infringement litigation against Mylan regarding Edluar®.</li> <li>New clinical data established that Zubsolv is effective and well tolerated for maintenance treatment of opioid dependence, and increases patients' work productivity.</li> </ul>
Q3	<ul> <li>FDA approved Zubsolv for induction of therapy in patients.</li> <li>Orexo launched the new induction label coordinated with the launch of the two new dosages of Zubsolv 2.9 mg/0.8 mg and 11.4 mg/2.9 mg.</li> <li>New exclusive agreement with unnamed Pharmacy Benefit Manager in Managed Medicaid.</li> <li>Zubsolv excluded from CVS Caremark preferred position in 2016 after closed tender process.</li> <li>US Department of Health and Human Services announced intention to expand patient access to treatment of opioid dependence.</li> <li>First patients entered the new registry study REZOLV.</li> </ul>
04	<ul> <li>Orexo settled Abstral US patent litigation with Actavis.</li> </ul>

Orexo recorded OX-MPI non-cash impairment charge of MSEK 62	2.

Orexo announced new Abstral partner in the US.

■ Orexo received MGBP 5 milestone payment for Abstral in Europe.

Key figures					
	2015	2014	2013	2012	2011
Net revenues, MSEK	643.3	570.3	429.4	326.3	199.6
Growth, %	13	32.8	31.6	63.5	-5.2
Net earnings for the year, MSEK	-198.0	-56.6	-154.9	-85.9	-392.0
Earnings per share, before dilution, SEK	-5.74	-1.73	-5.16	-2.92	-14.43
Cash and cash equivalents, including short-term investments, MSEK	198.1	284.5	105.6	228.1	246.9
Shareholders' equity, MSEK	266.5	455.0	161.5	191.1	311.1
Average number of employees	98	111	106	111	110
Number of employees at year-end	90	108	108	97	118

OREXO ANNUAL REPORT 2015 THE YEAR IN BRIEF ■ 3

## CEO's Comments

"The continued commercialization of Zubsolv remains our top priority throughout 2016 with a focus on both growth and profitability. We are still in early phases of the life cycle of Zubsolv and we are committed to continue the development of the product."

Nikolaj Sørensen, President and CEO



28,647

no. of deaths linked to opioid drug overdose

+14% since 2013

28,647¹ – this is the number of people in the US who died in 2014 of drug overdose which involved some type of opioid. This number increased by 14 percent since 2013 and looking at heroin in isolation the number of deaths has tripled since 2010. There is no doubt opioid addiction has become one of the major health concerns in the US and a disease currently out of control. This development occurs despite the fact that diagnosis is easy and effective treatments exist. One of these treatments is Zubsolv®, developed and commercialized by Orexo. Our focus in 2015 has been to build a strong position for Zubsolv, with broader dosage range, a new induction indication, initiating a new registry study and to build a commercial position for Zubsolv. In parallel we have been active working with decision makers in the US to expand access to treatment with Zubsolv, as this is one of the main hurdles for improved treatment to stop the escalating mortality from opioid overdose.

These steps resulted in increased demand for Zubsolv leading to a revenue increase of 83 percent compared to 2014. Today we have the most comprehensive clinical documentation and the broadest dosage range of any product in this disease area. The new indication, the improved documentation and the broad dosage range have made Zubsolv more competitive and improved the opportunity for Orexo to broaden the commercial platform, reaching new physicians and differentiate towards the generic competition.

With the completion of our clinical program and our new dosages, we are well positioned to benefit from the anticipated changes from US authorities to expand access to treatment. We maintain a strong belief in the activities in 2015 to create attention around this topic, which will lead to significant changes in the coming years, improving access to treatment and creating growth opportunities for Zubsolv. The outspoken ambition of the current political administration in the US is to double the amount of prescribers, which would translate into significant market growth and we anticipate that these changes could have a dramatic positive effect on the market size for Zubsolv.

OREXO ANNUAL REPORT 2015 CEO'S COMMENTS ■ 4

Looking forward, the continued commercialization of Zubsolv® remains our top priority throughout 2016 with a focus on both growth and profitability. We are still in early phases of the life cycle of Zubsolv and we are committed to continue the development of the product. Our efforts to find the optimal partner for Zubsolv outside the US continued to progress well, even though no deal was closed in 2015. I anticipate a deal will be closed during the first half of 2016.

Our path forward is founded on Orexo's existing products, our proprietary technologies, competences, employees and partners. I believe that it is important for the company to stay focused and to build a solid business foundation by maximizing the value of the assets we control.

Although the focus is on growing the Zubsolv franchise, we continue to invest in the development and exploration of new product development opportunities. These efforts have progressed well and we have some new exciting ideas and concepts ready to be communicated when we have filed the necessary patents and have made the final commercial assessment of market potential. We remain very diligent in the allocation of resources and maintain flexibility in our cost base to meet all sales scenarios moving forward.

I am proud of the impressive commitment and effort by all our employees and consultants and I am convinced that 2016 and the years to come will provide exciting opportunities for Orexo.

Nikolaj Sørensen

President and CEO

OREXO ANNUAL REPORT 2015 CEO'S COMMENTS ■ 5

<sup>&</sup>lt;sup>1</sup> Source: CDC MMWR January 1, 2016/64(50);1378-82

## Strategy

#### **OUR STRATEGY**

Orexo develops improved specialty treatments and treatments for new areas of use – at a lower cost, in a shorter period of time and at a lower risk – by combining known pharmaceutical substances with its patented proprietary sublingual (under the tongue) technologies. In parallel Orexo continues to leverage its drug delivery formulation competences to develop new drug delivery platforms.

#### **OUR BUSINESS CONCEPT**

Orexo's business concept is to create value through the development and commercialization of new drugs offering superior medical benefit addressing unmet medical needs and commercial potential.

#### **OUR TOP PRIORITIES**

#### **ZUBSOLV® – US COMMERCIALIZATION**

- Continue improvement in US market access.
- Drive Zubsolv US market share in core segments: commercial and cash & vouchers.
- Further broaden and leverage the broadest dose range.
- Leverage the richest clinical dataset.
- Finalize REZOLV study.
- Leverage induction label to get more physicians into prescribing and more patients into treatment.

## PARTNERING OPPORTUNITIES

- Take Zubsolv global.
- OX-51 (phase III ready alfentanil compound for procedure-induced pain).

#### **FUTURE PIPELINE**

New drug delivery formulations.

## Orexo's launched products

#### **ZUBSOLV®**

Zubsolv is a sublingual tablet for treatment of opioid dependence. It was approved by the US Food and Drug Administration (FDA) on July 3, 2013 for maintenance treatment. In August 2015, it was approved by FDA for induction therapy for patients with opioid dependence. Zubsolv should be used as part of a complete treatment plan, including counseling and psychosocial support.

#### **ABSTRAL®**

Abstral is a product for rapid relief from breakthrough pain in cancer patients. Abstral is marketed by partners – Sentynl Therapeutics Inc. (US), Kyowa Hakko Kirin Co., Ltd. (Japan) and ProStrakan Group plc (Europe and the rest of the world).

#### **EDLUAR®**

Edluar is a product for the treatment of short-term insomnia. Meda AB has the global license for Edluar.

#### **KIBION**

Diabact® UBT, Heliprobe® System, and IRIS™ are breath test and technology platforms for the diagnosis of the gastric ulcer *Helicobacter pylori*. All products are marketed by Orexo's subsidiary Kibion AB, which was divested on April 30, 2015.



# The Monster "Accidental Opioid Addiction" cannot be tamed. It must be fought. Orexo is committed to helping millions of people reclaim their lives. Photo from the "Out the Monster" campaign

#### **ZUBSOLV® IN THE US**

## Opioid overdose epidemic in the US – in perspective

Opioid dependence is a treatable medical condition and a growing public health issue in the United States affecting nearly 5 million people.1 Prescription painkillers containing opioids are highly addictive, and regular or long-term use can lead to physical dependence.

Think about a small town America. Think about one town in particular. Let's say its population is close to 17,000 people. Now imagine that over the course of 12 months, every single one of those people died from a brain disease. And now imagine that the exact same thing is going to happen next year in another small town. And another town the year after that. Orexo believes it is about time someone did something more about it, since we know that opioid dependence can be successfully treated. Every day in America, something is killing 46 people.<sup>2</sup> Imagine 46 people a day, spread out over 365 days a year. The size of a small town. A small town of America. Simply wiped off the face of the earth

In 2012, 259 million opioid prescriptions were written for pain management.<sup>2</sup> Prescription opioids are a type of narcotic pain medication, prescribed to treat moderate or severe pain.

Opioid drugs work by binding to opioid receptors in the brain, spinal cord, and other areas of the body thereby reducing the intensity of pain signals that reach the brain.3

However, frequent opioid use can physically change the brain to the point where it needs opioids just to function normally.4 It is estimated that about 5 percent of people who have been prescribed opioids by their doctor will develop an addiction 5

## **ZUBSOLV® IN THE US, continued**

Misusing opioids does not mean these men and women are bad people. They are not lacking in morality. They were prescribed opioids by their doctors for genuine reasons. Post-childbirth pain. An injury suffered at work. Lingering pain from surgery. Managing the chronic pain associated with rheumatoid arthritis.

Long term use of opioids can lead to addiction.<sup>5</sup> And like other chronic diseases, such as diabetes or high blood pressure, the likelihood of developing addition is influenced by a combination of genetic an environmental factors. 4,6 So through possibly no desire or fault of their own, these men and women find themselves in the grasp of the Monster. At Orexo, we call this Monster "Accidental Opioid Addiction."

#### Out the Monster

Accidental opioid addiction can have deadly consequences. Approximately 17,000 people a year die in the US from an overdose of prescription pain relievers.2 This Monster does not just wound. It kills. Drug overdoses are the number one accidental killer in the US.7,8 It is not car crashes, it is not workplace accidents. And it is not complications from surgery. It is drug overdoses driven by opioid use.7



#### **OUT THE MONSTER CAMPAIGN**

Orexo's "Out the Monster" disease awareness campaign in the U.S. is featuring a provocative image of a monster to depict accidental opioid addiction. "Out the Monster" (www.outthemonster.com) came out on top with a Gold Lions Health Award at the Cannes Lions Festival in France, in June 2015. The Lions Health Awards recognize the most creative ideas in the healthcare and pharmaceutical communications industry. The campaign was in December also rewarded with two Global Awards in advertising in the categories: Educational Awareness (advertising to the consumer/patient) and Best Use of Media (digital).

www.outthemonster.com

Substance Abuse and Mental Health Services Administration, Results from the 2010 National Survey on Drug Use and Health: Summary of National Findings, NSDUH Series H-41, HHS Publication No. (SMA) 11-4658. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2011. "Opioid Painkiller Prescribing." Centers for Disease Control and Prevention. Center for Disease Control and Prevention, 1 July 2014. http://www.cdc.gov/vitalsigns/opioid-prescribing/Accessed March

<sup>9, 2016.</sup> "Prescription Drug Abuse.

<sup>.&</sup>quot; National Institute of Drug Abuse. N.p., Nov 2014. http://www.drugabuse.gov/publications/research-reports/prescription-drugs/opioids/how-do-opioids-affect-brain-body. Accessed February 18, 2015.
Medication-Assisted Treatment for Opioid Addiction: Facts for Families and Friends. N.p.: n.d., n.d. U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration. 2011. http://store.sam/bsa.gov/shin/content/SMA09-4443/SMA09-4443.pdf. Accessed February 18, 2015.
"Opioids and Chronic Pain I NIH MedlinePlus the Magazine." U.S. National Library of Medicine. U.S. National Library of Medicine, n.d.

http://www.nln.nih.gov/medlineplus/magazine/issues/spring11/articl

Policy Impact: Prescription Painkiller Overdoses, N.p.: National Center Injury Prevention and Control, 2011.

#### THE US MARKET FOR TREATMENT OF OPIOID DEPENDENCE

Healthcare providers in the US wrote 259 million prescriptions for opioid pain medications in 2012. This is enough for every American adult to have a bottle of pills.1

It is estimated that about 5 percent of people who have been prescribed opioids by their doctor will develop an addiction.<sup>2</sup> Thus, there are strong incentives for society to encourage the successful treatment of opioid dependence as the societal costs of the disease are high.

#### Improved access to treatment

During 2015 several initiatives were taken to improve access to treatment in the US. The discussion on how to address the epidemic of opioid dependence intensified. The United States Department of Health and Human Services (HHS) announced in September the urgency of an increased access to Medication Assisted Treatment (MAT).3 The announcement was based on HHS' and the US

Congress' objectives to expand patient treatment options and develop an evidence-based initiative focused on three promising areas: informing opioid prescribing practices, increasing the use of naloxone and increasing access to MAT.

Orexo will continue to monitor the progress of these initiatives and identify areas where the company can provide support for improving patient access to the treatment of opioid dependence.

#### Stronger competitive position

Orexo believes that the disease area has not yet received the full attention that it deserves due to a lack of scientific evidence and the establishment of treatment standards. The current movement towards larger specialized treatment centers should benefit patients and facilitate legislative changes to improve access to treatment. Orexo trusts that healthcare providers and patients will strongly benefit from a more scientifically based approach to the treatment of opioid dependence. Zubsolv® is the choice of treatment with the most comprehensive clinical data set in the industry. Knowing that opioid dependence can be successfully treated, Orexo is committed to helping millions of people reclaim their lives.



<sup>&#</sup>x27;Opioid Painkiller Prescribing." Centers for Disease Control and Prevention. Center for Disease Control and Prevention, 1 July 2014. http://www.cdc.gov/vitalsigns/opioid-prescribing/Accessed March 9, 2016. "Opioids and Chronic Pain I NIH MedlinePlus the Magazine." U.S. National Library of Medicine. U.S. National Library of Medicine, n.d.

http://www.nln.nih.gov/medlineplus/magazine/issues/spring11/articles/spring 11pg9.html

Accessed February 18, 2015.
HHS press release September 17, 2015. www.hhs.gov
http://www.hhs.gov/abut/thews/2015/09/17/hhs-hosts-50-state-convening-focusedpreventing-opioid-overdose-and-opioid-use-disorder.html. Accessed March 9, 2016.

#### MARKET ACCESS AND REIMBURSEMENT IN THE US

Today, less than half of those diagnosed with opioid dependence receive treatment. The prevalence of opioid dependence could be up to 10 times larger than the number of patients receiving medical assisted treatment (MAT) today.

#### Potential for dramatic increase in the market access

The demand and unmet need for the treatment of opioid dependence is significantly higher than the access available to treatment. In 2014 more than 10 million Americans used opioids for non-medical use and nearly 1 million used heroin.

On September 17, 2015, the Secretary of the HHS announced an initiative to significantly improve access to  ${\rm MAT.^1}$  The details of the changes in legislation are yet to be disclosed, but Orexo anticipates that the main elements will be an opportunity for more physicians to offer treatment, and opportunities for certain specific physician categories to treat more than the current limit of 100 patients.

A change in the current patient limit is likely to have an immediate effect on the number of patients treated, although it is unlikely that the physicians will immediately maximize a potential new limit as the initiation of treatment is time consuming. The main benefit will be the long term incentive for more patients to have greater choice and access to higher quality care as a larger number of physicians and addiction centers expand operations and invest in establishing the infrastructure required to receive and treat more opioid dependent patients.

#### President Obama combats the epidemic

On October 21, 2015 President Barack Obama issued a Memorandum to Federal Departments and Agencies directing two important steps to combat the prescription drug abuse and heroin epidemic: Prescriber Training and Improving Access to Treatment. The President is fighting the opioid epidemic by telling health care providers across the country that access to medication assisted treatment must be expanded and setting a 90-day deadline for opioid treatment reviews and action plans.<sup>2</sup> Orexo expects to see concrete initiatives during 2016.

#### Reimbursement

The reimbursement of Zubsolv® in the US is at very competitive levels for Orexo to continue to grow the business. In 2015 Orexo's level of access to reimbursement was 88 percent in the commercial segment and 38 percent in the public segment.

The public market is different than the commercial and cash & vouchers markets, as access to the market is tightly controlled by the payers that are contracted to manage the public funds available to pay for prescriptions.

The Pharmacy Benefit Managers (PBMs) have an important role since they are responsible for adjudicating payment of prescription pharmaceuticals and formulary recommendations on behalf of insurance companies and employers in the US.

Americans used opioids for non-medical use

Less than half of those diagnosed with opioid dependence receive treatment

HHS press release September 17, 2015. www.hhs.gov http://www.hhs.gov/about/news/2015/09/17/hhs-hosts-50-state-convening-focused-preventing-opioid-overdose-and-opioid-use-disorder.html. Accessed March 9, 2016.

<sup>&</sup>lt;sup>2</sup> FACT SHEET: Obama Administration Announces Public and Private Sector Efforts to Address Prescription Drug Abuse and Heroin Use. https://www.whitehouse.gov/the-press-office/2015/10/21/fact-sheet-obama-administration-announces-public-and-private-sector. Accessed March, 9 2016.

#### ZUBSOLV® – PERFORMANCE IN THE US MARKET

Zubsolv ended 2015 with a 6.4 percent market share1 which was an improvement of 0.7 percentage points since end of 2014. What is most encouraging about that growth is that 0.5 share points of the 0.7 points occurred during the second half of 2015 without any exclusive market access wins demonstrating our ability to sell in a very competitive environment. At year-end, Zubsolv was in a much stronger position compared to the beginning of the year.

Three distinct payer segments

The market for Zubsolv consists of three distinct payer segments: commercial (private insurance), cash & vouchers (patient) and public (Managed Medicaid, FFS Medicaid and Medicare Part D). Overall the total market has grown 7.8 percent end of 2015, compared to end of 2014.

#### Sales and market share increased overall

Zubsolv sales and market share increased overall driven by the most profitable segments, commercial and cash & vouchers. In the public segment multiple new agreements were signed with Pharmacy Benefit Managers (PBMs) enabling improved positions in 2016. The PBM is responsible for adjudicating payment of prescription pharmaceuticals and formulary recommendations on behalf of insurance companies and employers in the US.

For all PBMs, both in commercial and public (Managed Medicaid), the impact of an agreement and change in formulary position is dependent on the implementation by their insurance clients and both timing and impact on sales are associated with significant uncertainties.

In August, CVS Caremark, a PBM, announced their 2016 Standard Formulary List of Excluded Drugs for their commercial clients. Effective from January 1, Zubsolv has been removed from the preferred position.

#### Commercial (private insurance)

In the commercial segment Zubsolv market share increased by 4.0 percentage points and prescriptions grew by 94 percent during 2015, comparing with 2014. The growth was driven by increased market share among high Zubsolv prescribers and is not related to changes in the market access during the year.

#### Cash & vouchers (patient)

In the cash & vouchers segment Zubsolv market share increased by 1.7 percentage points and prescriptions grew by 42 percent during 2015, comparing with previous year.

#### Public (Managed Medicaid, FFS Medicaid and Medicare Part D)

The public market is different than the commercial and cash & vouchers markets, as access to the market is tightly controlled by the payers that are contracted to manage the public funds available to pay for prescriptions. Most payers have policies encouraging generic alternatives as a first choice, if they exist in the product category. With four generics in the market, some payers have been increasingly hesitant to give first line access to new branded competitors.

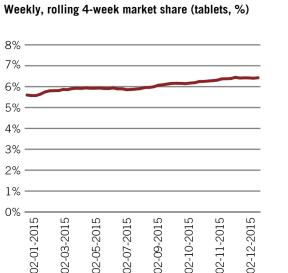
The overall growth during the year of this segment was 18 percent and at year-end Zubsolv was accessible for 38 percent of the patients. The growth in this segment came from patients previously in the cash & vouchers segment and coverage expansion was a result of the Affordable Care Act legislation in the US.



NPA monthly data December 2015.

## **ZUBSOLV® – PERFORMANCE IN THE US MARKET, continued**





Market share in terms of Orexo share of the total market quantity of tablets, film and patch of buprenorphine/naloxone.

Note: Weekly script data is based on extrapolation and is associated with uncertainties in the launch phase of new pharmaceuticals. Sources: Orexo analysis, IMS weekly data.

## ZUBSOLV® — CLINICAL AND PHARMACEUTICAL DEVELOPMENT

Zubsolv's competitive position continues to improve with the induction label and broader dosage range.

#### License to expand the market

Orexo has found that the induction phase of treatment is one of the key inhibitors for physicians to treat patients and expand their treatment services to more patients. The commercial launch of the new induction label was coordinated with the launch of the two new dosages Zubsolv 2.9 mg/0.8 mg and 11.4 mg/2.9 mg buprenorphine/naloxone in October.

In 2015, Orexo took several initiatives and important steps forward to deliver on the strategy to strengthen the commercialization and to meet the life cycle management objectives of Zubsolv.

- Completed the entire clinical study program initiated during the Zubsolv launch phase and initiated the new registry study, REZOLV (Retrospective Evaluation of Zubsolv Outcomes – A Longitudinal View). The first patients were entered in July.
- Zubsolv was approved for initiation (induction) of treatment by the US FDA in August. This new indication, together with the new approved additional dosages, makes the Zubsolv label more competitive and improves the opportunity for Orexo to broaden the commercial platform.
- Launched the 8.6 mg Zubsolv tablet in March which accelerated growth during the second half of 2015.
- Launched the 2.9 mg and 11.4 mg tablets in October and Orexo has thus the broadest range in the disease area.
- Initiated the search for the right partner for regulatory processes and the commercialization of Zubsolv in markets outside the US.

#### Zubsolv outside the US

Opioid dependency is a growing global concern. There are nearly 20 million people suffering from opioid dependence outside the US.¹ The problem exists both in developed and emerging countries and continues to be the highest burden to society among illicit drugs. Heroin is the main opioid abused outside the US, but prescription opioid consumption (e.g. oxycodone) is increasing rapidly across the world

Prescription opioid consumption is highest in developed markets but growing fastest in emerging markets from lower levels. In many markets, focus of drug policy has been on restricting use and harm reduction. Opioid replacement therapy, (e.g. methadone, buprenorphine, buprenorphine/naloxone), is offered in approximately 75 countries and currently there are approximately 1.6 million people in treatment outside the US, only approximately 10 percent of dependent population.

In the five largest EU countries there are more than 1.3 million opioid users, and about 700,000 patients are treated with substitution treatment.<sup>4</sup> A dramatic increase in prescription opioids has aggravated the problem in recent years, approximately 25 million patients are receiving opioids for pain.

#### Partnering process

During 2015 a process has been initiated to identify the optimal partner who will commercialize Zubsolv outside the US. By the end of the year, Orexo was engaged in discussions and in negotiations with several pharma companies.

UNODC World Drug Report 2014.

The Board of Regents of the University of Wisconsin System / DCAM Consortium, 2010.

<sup>3</sup> Harm Reduction International (The Global State of Harm Reduction 2012).

<sup>&</sup>lt;sup>4</sup> EMCDDA, European Drug Report, 2014, Indivior (November 2014).

#### COMPREHENSIVE CLINICAL DATA

In 2015 Orexo completed the clinical study program initiated during the Zubsolv® launch phase. During the summer the first patients were entered in the new registry study REZOLV. This study demonstrates Orexo's continued commitment to further improving clinical outcomes and education in the treatment of the opioid dependent patient.

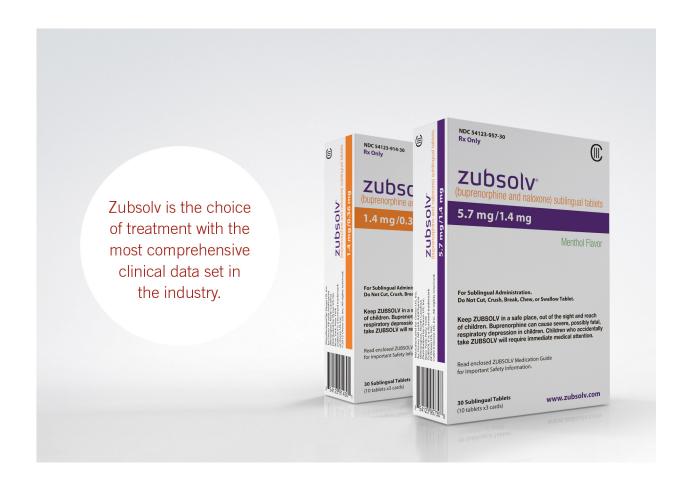
#### OX219-008 study results

In April Orexo announced data from a 24-week clinical trial, OX219-008, assessing the long-term safety and efficacy of Zubsolv (buprenorphine/naloxone) sublingual tablet (CIII) for the maintenance treatment of opioid dependence. The results established that Zubsolv is effective, well tolerated and demonstrated a safety profile consistent with the product labeling

for sublingual buprenorphine products. In addition less than 1 percent of the patients exited the study due to treatment failure, which further underpins the medical value of Zubsolv. The results also demonstrated an increase of 15 percent in employment by the patients participating in the study, which further strengthens the evidence of the societal value of effective treatment of opioid dependence.

#### **REZOLV** registry study

The first patients in the new registry study REZOLV (Retrospective Evaluation of Zubsolv Outcomes – A Longitudinal View) entered the study in July. The study demonstrates Orexo's continued commitment to further improving clinical outcomes and education in the treatment of the opioid dependent patient. This retrospective look at the use of Zubsolv in a real world setting aims to fill a significant gap in the knowledge base of how to best treat opioid dependency through examining and characterizing the impact of treatment and psychosocial factors on treatment outcomes. Factors such as patient and prescriber characteristics, care settings, patient agreements and behavioral therapies will be studied. Over 1,000 patients were enrolled in the REZOLV program with results expected in the middle of 2016.



OREXO ANNUAL REPORT 2015 OREXO'S LAUNCHED PRODUCTS ■ 15

## Abstral<sup>®</sup>

## Rapid relief from breakthrough pain in cancer patients



Abstral treats breakthrough cancer pain in patients already being treated with opioids. The product contains the pain-relieving substance fentanyl. Abstral allows doses to be customized according to individual requirements, which is essential for achieving optimal

Abstral is a rapidly disintegrating tablet that is placed under the tongue. The active ingredient is absorbed into the body through the mucosa, whereby the effect is fast and predictable. The tablet is easy to dose, store and handle.

The product was approved for sales in Europe in 2008. In January 2011, Abstral was approved by the FDA and was subsequently launched in the US in April 2011 by Orexo's partner ProStrakan. In February 2011, Abstral was approved in Canada. During 2012 Orexo acquired the US rights back from ProStrakan and subsequently sold these rights to Galena Biopharma in March 2013

In September 2013, Abstral was approved for sales in Japan, and launched in December 2013 by Kyowa Hakko Kirin. A company that is well-established within the field of cancer pain and has sold Fentos®Tape, a fentanyl plaster preparation, since 2010. The Japanese market for treatment of breakthrough cancer pain with rapid-acting fentanyl is still in the early stages.

In November 2015, Galena Biopharma Inc. divested its Abstral US business to the privately held company Sentynl Therapeutics Inc. as a consequence of Galena's change of strategy to focus on its clinical development program.

The total US market for fentanyl based products amounted to approximately MUSD 564 (billion SEK 4.8) in 2015 and is growing. The competition in the market is fierce. In December 2015, Abstral reached a market share of 4 percent of prescriptions compared to 5 percent in December 2014.

In 2015, Abstral sales continued to grow in the EU and amounted to MEUR 78 (MSEK 718), an increase of 16 percent compared to 2014. Orexo receives royalty on Abstral sales in Europe, for sales exceeding MEUR 42.5. During 2015, royalty revenues from Abstral sales amounted to MSEK 134 (220). The annual sales of Abstral in the EU exceeded MEUR 67.5 during 2015 which triggered a milestone payment in December of MGBP 5 (MSEK 66) from the commercial partner in Europe, ProStrakan Group plc.

Sales of Abstral in the rest of the world (RoW) region (markets excluding EU and the US) continued to display strong growth, driven by sales in the Middle East, South Korea and Israel. Total sales for the RoW reached MUSD 5 in 2015, an increase of 357 percent compared to 2014.

## **Edluar**®

### Treatment of short-term insomnia



Edluar is based on the active ingredient zolpidem, which has long been used to treat insomnia. The Edluar tablet is placed under the tongue, where it rapidly dissolves and the active ingredient is absorbed through the mucosa.

Meda AB has acquired the global rights for Edluar. The product was approved by the FDA in March 2009 and in July 2011 the product was approved in Canada. During 2013, Edluar was launched in a number of European countries.

Orexo has not yet received the final data for the full year sales 2015 for Edluar from its commercial partner Meda AB, hence royalties are based on Orexo's estimate. Royalty revenues are estimated to amount to MSEK 13.6 (10.7), an increase of 27 percent compared to 2014.

## Kibion

## Breath test and instruments



Breath test and technology platforms for diagnosis of the gastric ulcer bacterium *Helicobacter pylori* 

 $\label{eq:dispersion} \mbox{Diabact}^{\circledast}\mbox{ UBT, Heliprobe}^{\circledast}\mbox{ System and IRIS}^{\mbox{\tiny $M$}}\mbox{ are products used to diagnose the gastric ulcer bacterium $\textit{Helicobacter pylori}$.}$ 

The subsidiary Kibion AB was divested on April 30, 2015. Kibion's sales for the first four months of the year amounted to MSEK 12.8.

OREXO ANNUAL REPORT 2015 OREXO'S LAUNCHED PRODUCTS ■ 17

## Innovative product development programs and collaboration projects

 A key component of Orexo's strategy is to develop new improved products by combining well-known and well-documented compounds with innovative formulation technologies. The objective is to develop new and patentable products with unique properties, which improve patient care and convenience.

From its own research and development, Orexo has developed several products with significant commercial potential, such as Zubsolv®, Abstral® and Edluar®. Besides resources devoted to Zubsolv clinical and pharmaceutical development, Orexo also has a number of other programs in the pipeline. All development activities are guided by unmet medical needs.

#### **Own development programs:**

#### 0X - 51

## Prevention of acute episodes of pain during diagnostic and therapeutic procedures

OX-51 is a novel sublingual formulation containing alfentanil. The product has been developed to meet the rapidly growing demand for effective pain relief during short surgical and diagnostic procedures.

The quick onset and offset, short duration, minimum of sedation and drowsiness, and convenient administration make OX-51 suitable for prevention of pain for a multitude of 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 OX-51 to the next phase in development towards a new product. In 2015, Orexo worked to scale-up the manufacturing process in preparation for a phase 3 clinical trial to be conducted by a future partner.

The commercial potential of OX-51 is estimated to be substantial and Orexo aims to identify a partner for phase 3 and commercialization in various geographies. At the end of 2015, discussions were ongoing with several companies.

## **Collaboration projects:**

#### **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. In August 2014, Orexo's partner, Boehringer Ingelheim, decided to return the project (selective inhibition of prostaglandin E2 synthase) to Orexo. All immaterial property rights and results obtained by Boehringer Ingelheim have been returned to Orexo.

Since 2005 Boehringer Ingelheim had been responsible for all research and development within the OX-MPI project.

The evaluation of the results from Boehringer Ingelheim has been completed, and Orexo still sees potential in the project due to a unique target, an identified development compound and several granted patents. Orexo still considers OX-MPI an attractive asset and Orexo has since the return of the project been working to identify a new partner. At the end of 2015 the process of identifying a new external partner for OX-MPI was ongoing.

#### **OX-CLI**

## Respiratory tract diseases

In January 2013, Orexo entered into a collaboration agreement with AstraZeneca regarding OX-CLI, a preclinical program for potential new treatment of respiratory tract diseases.

Under the agreement AstraZeneca gained the rights to perform extensive preclinical research and evaluation of compounds in Orexo's OX-CLI program. AstraZeenca has an option to acquire all

compounds linked to the program, whereby Orexo will receive milestone payments during the development phase and royalty payments based on future revenues. AstraZeneca is responsible for all development costs for the project.

## Other projects

Orexo continues to leverage its competences within pharmaceutical formulation and has projects aiming at developing new formulation platforms. By end of 2015 these projects were still in the exploratory phases.





## **Employees**

■ Orexo offers a dynamic and innovative place to work. The company fosters an environment where employees respect each other's views, competences and decisions. At Orexo, employees are given substantial responsibility and every person's contribution is important.

#### Attractive employer

Orexo strives to be an attractive employer which recruits, retains and develops talented employees. At year-end, Orexo Group had 90 (108) employees, including 51 (69) at Orexo AB, 0 (11) at Kibion AB and 39 (28) at Orexo US, Inc. During the first half of the year, Orexo started to recruit selected members of the contracted sales force to Orexo US, Inc. to strengthen the Orexo position on the US market. Orexo divested the subsidiary Kibion on April 30.

48 (52) percent of the employees are women. 27 percent of the managers are women. Management has extensive experience in the pharmaceutical industry and competences for all phases of drug development, including commercial operations and business development.

#### Competence development

The employees' high level of expertise is a crucial success factor for Orexo. 12 percent hold doctorates and 78 percent hold other levels of academic degrees. Approximately 23 percent of the employees were active in research and development during the year.

In 2015, an Orexo Leadership Program was initiated supporting managers based in Sweden in their leadership roles.

All employees have individual development plans. Orexo has an active knowledge exchange through international networks and in collaboration with academic institutions, for example Uppsala University in Sweden. During the year, operations were conducted in Uppsala Business Park, Sweden, and in New Jersey, the US.

#### Company culture and core values

At the beginning of the year an initiative focusing on company culture and core values was launched at Orexo's site in Sweden. The aim is to further foster a culture that improves employee performance and thereby strengthens Orexo values.

The initiative was well received internally throughout the year. In their daily work, employees strive to embrace the core values: customer focus, engagement, flexibility and simplicity.

#### Camaraderie and commitment

In September Orexo US, Inc. launched an internal communications series to motivate and inspire employees, demonstrating the value of Orexo's commitment to addiction patients and reinforcing the importance of the employees.

Every day a commitment photo and personal statement from an employee was distributed via email to all employees at both sites, both in the US and Sweden. The communication series provided an opportunity for employees to share their passion and commitment. Each statement detailed a commitment to helping patients and highlighted why the author is proud to work at Orexo. The purpose of the internal initiative was to help foster togetherness and commitment amongst employees.

#### **Employee dialog**

Orexo conducts since 2012 an annual employee survey to capture opinions and identify areas for improvement. In 2014, the results from the employee survey and its eleven measured targets were discussed in workshops across the organization. This led to the initiation of a process to improve cooperation between departments. During 2015, several initiatives and steps were taken to improve the metrics on identified and agreed targets, for example efficiency, quality and engagement. The results from the 2015 employee survey showed an overall strong positive development and resulted in all time high score, both in the US and Sweden. The Swedish results increased from a score of 69 (2014) in overall engagement to 80 (2015), which is a higher score than in most comparable companies.

In the US, the survey was conducted for the first time in 2015 and the result was a score of 69. This is slightly higher than other companies in the pharmaceutical industry. The US survey also included field force not directly employed by Orexo.

#### Work environment

A Business Compliance and Ethics Code, which applies to all employees, ensures that business ethics and sustainability permeate the core values in the day-to-day business operations.

Orexo's health and safety program is coordinated by the company's safety committee and by safety delegates appointed by the staff

Occupational risk assessments are carried out regularly. Any incidents and accidents are followed up and appropriate measures are taken. Occupational health and safety training is conducted throughout the year.

#### **Employee health**

All employees are part of a private healthcare and rehabilitation insurance program. In addition to quick access to care and rehabilitation, the insurance includes preventive care which is assessed to have contributed to reduced levels of sick leave. Orexo also contributes towards fitness activities and preventive ergonomics.

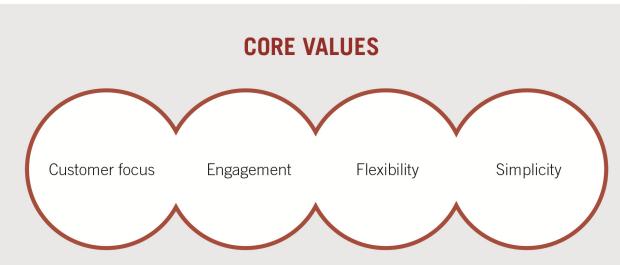
Sick leave at the Orexo Sweden Site amounted to 1.9 percent in 2015 (2 percent in 2014).

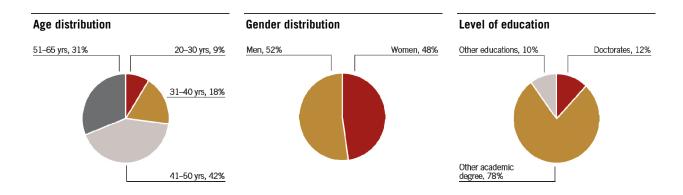
#### Performance management

Orexo has a systematic performance management process. Each department manager is responsible for identifying objectives that support the overall strategic objectives. At the beginning of each fiscal year, the employee sets his or her individual objectives in agreement with the manager. These objectives are followed up throughout the year. The individual employee objectives are evaluated in connection with performance reviews prior to salary reviews.

OREXO ANNUAL REPORT 2015 EMPLOYEES ■ 20







OREXO ANNUAL REPORT 2015 EMPLOYEES ■ 21

## Sustainability

■ Orexo's comprehensive Business Compliance and Ethics Code ensures that sustainability permeates business operations. The sustainability agenda is based on the company's core values of customer focus, engagement, flexibility and simplicity, and the work on sustainability focuses on the entire value chain.

#### **Environmental work**

An environmental impact assessment indicates that Orexo should focus its efforts on product development, manufacturing and the handling of chemicals.

Orexo continues to improve its environmental management and performance, for instance by increasing energy efficiency, reducing consumption of disposable materials and improving waste management.

A survey of all emissions of pharmaceutical substances into water was carried out during 2014 in Uppsala, Sweden, and showed that such emissions were low.

In order to ensure that the company follows current environmental laws and requirements and has satisfactory internal control, operations are conducted in line with Orexo's environmental management system. The system is aligned with ISO 14001, but there are at present no plans to certify the system accordingly. The environmental group, consisting of representatives from different parts of the company, is responsible for monitoring and improving Orexo's environmental work. In order to reduce business travel, the company encourages business meetings to be held by telephone or on the web.

The group also provides appropriate environmental training to employees.

#### Focus on the entire value chain

Orexo's sustainability work permeates the entire value chain. Objectives for 2015 included the initiation of a sustainability program aimed at key suppliers.

#### 1. Product development

Orexo focuses on developing new products on the basis of its proprietary drug delivery technology. Evaluation of product risks and safety aspects is an integral part of the product development process. The evaluation covers all phases of the product's life cycle.

Orexo conducts clinical studies in collaboration with external experts. Studies are designed in consultation with these partners, and risk and benefit assessments are conducted. The studies require regulatory approval, and regulations and ethical issues in the various countries are taken into account. Since the studies are based on well-known compounds, the risk level is generally lower relative to clinical tests of new molecules.

#### 2. Suppliers

During the year Orexo established a Supplier Code of Conduct that will guide in the procurement of goods and services and inform suppliers of what Orexo expects. The Code covers ethics, labor, health and safety, product security, supply chain integrity and the management system. From 2016 all new potential suppliers will be assessed in accordance with the Supplier Code of Conduct.

In 2015, Orexo also reviewed key suppliers' sustainability performance, including environmental management as well as health and safety. Should a supplier not meet Orexo's requirements, the company will initiate a dialog to achieve improvements.

#### 3. Manufacturing

In 2014, Orexo decided to move all manufacturing of Zubsolv® from the Swedish site to suppliers in the US. The facilities in Uppsala focus on new product development. The US manufacturing facilities are carefully assessed against Orexo's Supplier Code of Conduct.



OREXO ANNUAL REPORT 2015 SUSTAINABILITY ■ 22

## The Orexo Share

■ Orexo's share is listed on Nasdaq Stockholm and available as American Depository Receipts (ADRs) on OTCQX in the US. At year-end, Orexo had a total of 6,944 shareholders and the non-Swedish shareholding in the company amounted to 57 percent.

The Orexo share is listed on Nasdaq Stockholm Mid Cap under the symbol ORX and available as ADRs on OTCQX under the symbol ORXOY. During the year the share price decreased by 54 percent and the last price paid in 2015 was SEK 62.75 (135.50). This corresponds to a market capitalization of MSEK 2,161 (4,653). The highest closing price during the year for the Orexo share was SEK 148 quoted on January 28, 2015. The lowest quotation was SEK 43.50 on September 15, 2015.

#### Liquidity

In total 33.0 (34.4) million shares in Orexo were traded in 2015, corresponding to a value of approximately MSEK 2,653 (4,414). The daily average trading volume was 131,528 shares, corresponding to a value of MSEK 10.6.

#### Ownership

At year-end, Orexo had 6,944 (6,979) shareholders, of which 699 were registered as legal entities and 6,245 as private individuals. Of the share capital, 43 percent (51) is held by shareholders registered in Sweden and 57 percent (49) by non-Swedish shareholders. The largest proportion of shareholders registered outside Sweden can be found in Denmark at approximately 35 percent.

The list is by shareholder group, where a number of legal entities may be part of each group below.

#### Issue and repurchase Class C share

Orexo announced on June 17, 2015 that the company had resolved to issue and immediately thereafter repurchase 135,000 Class C shares. The shares were issued and repurchased in accordance with the Long-Term Incentive Program (LTIP) 2015, which was adopted by the Annual General Meeting on April 15, 2015.

Danske Bank subscribed for the entire issue of new Class C shares at a subscription price of SEK 0.40 per share, equal to the quota value of the shares. The entire issue of Class C shares was thereafter repurchased by Orexo for SEK 0.40 per share.

The purpose of the share issue was to enable the future delivery of ordinary shares to participants in LTIP 2015. The Class C shares will be converted into ordinary shares prior to delivery to qualifying participants in LTIP 2015. The Class C shares do not entitle to dividends.

#### **Analysts monitoring Orexo**

- ABG, Sten Gustafsson
- Carnegie Investment Bank, Erik Hultgård
- Danske Bank, Lars Kristian Hevring
- Edison Group, Lala Gregorek
- Erik Penser Bankaktiebolag, Johan Löchen
- Pareto Securities; Finlay Heppenstall, Daniel Thorsson, Niklas Oderud
- Redeye, Klas Palin

Shareholders at Dec 31, 2015		
•	No. of shares	%
Novo A/S	9,643,184	27.9%
HealthCap	3,960,020	11.5%
Arbejdsmarkedets Tillaegspension (ATP)	2,040,633	5.9%
Danske Capital Sverige	1,704,701	4.9%
Försäkringsaktiebolaget Avanza pension	1,291,423	3.7%
Brohuvudet AB	1,000,000	2.9%
Svolder AB	523,492	1.5%
Nordnet Pensionsförsäkring	512,540	1.5%
Lancelot Avalon	470,369	1.4%
Lundqvist, Thomas	457,552	1.3%
Rhenman HealthCare L/S Fund	262,956	0.8%
Länsförsäkringar fondförvaltning AB	223,918	0.6%
SEB Investment Management	220,301	0.6%
Others	12,269,721	35.5%
Total number of shares*	34,580,810	100.0%

Known shareholders in Orexo. Source: Euroclear Sweden AB.

Ownership struc	cture at Dec 31, 20	15	
•	No. of shareholders	No. of shares	%
1–500	4,613	765,226	66.4%
501-1,000	961	814,490	13.8%
1,001-5,000	1,009	2,359,954	14.5%
5,001–10,000	176	1,296,302	2.5%
10,001-15,000	51	649,181	0.7%
15,001–20,000	26	488,739	0.4%
20,001-	108	28,071,918	1.6%
Total	6,944	34,445,810	100%

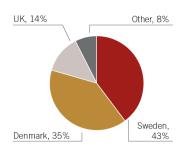
Shares outstanding: As of December 31, 2015, the number of shares outstanding in the company was 34,580,810, of which 135,000 were C shares and the rest common shares. All common shares carry one voting right and the C shares carry 1/10 of a voting right each.

OREXO ANNUAL REPORT 2015 THE OREXO SHARE ■ 23

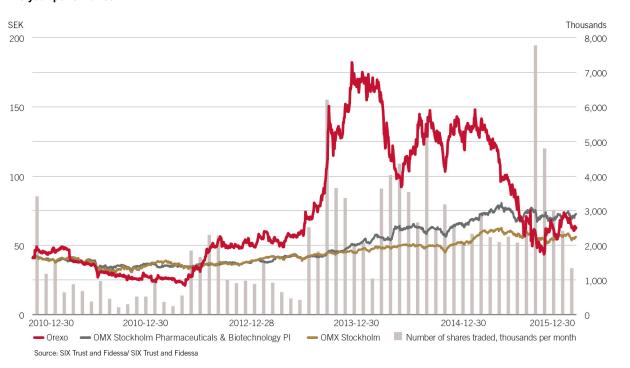


# Private individuals, 21% Institutions, 79%

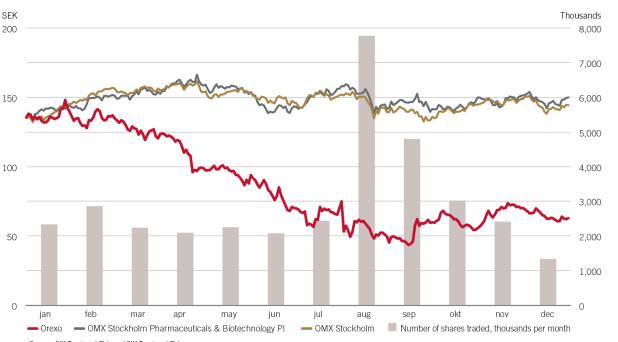
#### Ownership dist. per country



#### Five year performance



#### Performance in 2015



Source: SIX Trust and Fidessa/ SIX Trust and Fidessa

## Board of Directors' Report

■ The Board of Directors and the President of Orexo AB (publ), corporate registration number 556500-0600, hereby submit the Annual Report and consolidated financial statements for the fiscal year January 1 – December 31, 2015. Orexo's registered office is in Uppsala, Sweden.

#### Orexo's operations

Orexo is a specialty pharmaceutical company with commercial operations in the United States and R&D in Sweden focusing on the development of improved products using its proprietary sublingual (under the tongue) tablet technology platform. The Company's current focus is maximization of the commercial potential of Zubsolv®, a product for treatment of opioid dependence. Zubsolv was approved by the US Food and Drug Administration (FDA) on July 3, 2013, and launched on the US market on September 16, 2013. Orexo has developed the following proprietary commercial products:

- Zubsolv, for treatment of opioid dependence, is approved for use and launched in the US.
- Abstral®, for the treatment of breakthrough pain in cancer patients, is approved for use in the EU, the US, Canada and in Japan. The product is sold in Japan by Kyowa Hakko Kirin Co., Ltd., in Europe and the rest of the world by ProStrakan Group plc and in the US, by Sentynl Therapeutics Inc.
- Edluar®, a sublingual tablet containing zolpidem to treat short-term insomnia, is approved for use in the US, Canada and the EU and sold in these markets by Meda AB.

The company focuses on developing and commercializing new, improved pharmaceuticals by combining well-known substances with its innovative and proprietary sublingual tablet technology. This results in new, patentable products that improve patient care and convenience. Orexo's business model provides the opportunity to develop products with a lower level of development risk, and in a shorter time, compared to the development of new chemical substances.

Orexo's revenues derive from launched products, royalties, licensing agreements, research financing as part of licensing agreements and research collaboration.

In order to commercialize previously developed products, Orexo has licensing agreements with Sentynl Therapeutics (US), Meda (global), ProStrakan and Kyowa Hakko Kirin (global excl. the US).

Since 2013 Orexo also has a collaboration agreement with AstraZeneca regarding OX-CLI, a preclinical program for potential new treatment of respiratory tract diseases.

In August 2014, Orexo's partner Boehringer Ingelheim returned the OX-MPI project (selective inhibition of prostaglandin E2 synthase) to Orexo. Boehringer Ingelheim had been responsible for all research and development within the OX-MPI project since 2005. Orexo still sees potential in the project and was actively looking for a new partner throughout the year. However, as part of the annual impairment assessment process it was decided to fully write down the value of the asset with the consequence that a non-cash charge of MSEK 62 was recorded in the fourth quarter 2015.

#### Organization

In order to secure the successful development and launch of Zubsolv in the US, the expansion of the company's US commercial presence continued in 2015. The US subsidiary, Orexo US Inc., is responsible for the US commercialization of Zubsolv. Since July 1, 2014 Orexo's partner inVentiv Health has acted as contracted sales force partner with leadership and day-to-day management of field based activities conducted by Orexo. In an effort to further catalyze the sales of Zubsolv, the field force was expanded and changes were made in the commercial leadership structure and a strategy was initiated to convert selected top perfoming representatives of the field force into Orexo employees during the second quarter 2015.

To enhance Orexo's operational focus the subsidiary Kibion was divested per April 30, 2015.

During the year, Orexo focused development operations on its proprietary development programs around Zubsolv. With the exception of Zubsolv and OX-51, other development programs are run entirely by external partners and Orexo does not provide them with any development resources.

Orexo has broad-based competence throughout the development chain, with a focus on pharmaceutical formulation, clinical development, registration, pharmaceutical manufacturing and commercialization.

Orexo is working with highly competent external partners for the manufacture of products for commercial use, clinical trials and small-scale production. Orexo was manufacturing the product Diabact® for Kibion throughout the year at the facilities in Uppsala, Sweden. Manufacturing of Diabact is planned to be transferred to a third party during 2016.

Orexo also collaborates with contract research organizations for certain aspects of drug development, such as clinical studies. Orexo deploys a project-led organization, in which skills are combined based on the specific demands of individual projects.

During the year Orexo established a Supplier Code of Conduct that will guide in the procurement of goods and services and inform suppliers on what Orexo expects. From 2016 all new potential suppliers will be assessed in accordance with the Supplier Code of Conduct.

In 2015, Orexo also reviewed the key suppliers' sustainability performance, including environmental management as well as health and safety. Should a supplier not meet Orexo's requirements, the company will initiate a dialog to achieve improvements.

At year-end, Orexo had a total of 90 employees.

## Key events in 2015

■ 2015 was the second full year with Zubsolv® on the US market and Zubsolv remained the key focus area for Orexo. Progress was made including increased demand for Zubsolv, completion of the entire clinical study program initiated during the Zubsolv launch phase and the initiation of a new registry study, REZOLV. The final and most important milestone achieved was the US Food and Drug Administration (FDA) approval of Zubsolv for initiation of treatment (induction) in the US.

#### Zubsolv

Orexo broadened Zubsolv product range

In October, Orexo initiated the commercial launch of the new induction label coordinated with the launch of the two new dosages of Zubsolv 2.9 mg/0.8 mg and 11.4 mg/2.9 mg (buprenorphine/naloxone) sublingual tablets (CIII).

In March, Orexo launched the new Zubsolv tablet strength 8.6 mg/2.1 mg (buprenorphine/naloxone) sublingual tablet (CIII).

FDA approved Zubsolv for induction of buprenorphine maintenance therapy in patients suffering from opioid dependence

In August, FDA approved Zubsolv (buprenorphine/naloxone) sublingual tablet (CIII) for induction of buprenorphine/naloxone treatment of patients with opioid dependence. The approval was an expansion of the current indication for Zubsolv, originally approved by the FDA on July 3, 2013 and was based on data from two phase 3 studies demonstrating Zubsolv as an effective treatment for opioid dependence with a solid safety profile.

FDA approved medium dosage strength of Zubsolv
In June, FDA approved the medium dosage strength of Zubsolv
(buprenorphine/naloxone) sublingual tablet (CIII) for maintenance
treatment of opioid dependence. The new dosage strength 2.9
mg/0.71 mg complements the existing strengths of 1.4 mg/0.36

mg, 5.7 mg/1.4 mg, 8.6 mg/2.1 mg and 11.4 mg /2.9 mg tablets and enables patients to receive their optimal dose in one tablet. The approval took Orexo to the position of having the broadest dosage range of any product within opioid addiction treatment.

First patients entered the registry study, REZOLV
In July, the first patients entered the new registry study REZOLV
(Retrospective Evaluation of Zubsolv Outcomes – A Longitudinal View). The retrospective look at the use of Zubsolv in a real world setting aims to fill a significant gap in the knowledge base of how to host treat opinion dependency through examining and

to best treat opioid dependency through examining and characterizing the impact of treatment and psychosocial factors on treatment outcomes. Data is expected in the middle of 2016.

Orexo was excluded from CVS Caremark preferred position in 2016 after closed tender process

In August, Orexo announced that the pharmacy benefit manager (PBM) CVS Caremark had excluded Zubsolv from the standard formulary for 2016 for their commercial clients i.e. non-publicly funded insurance companies and employers.

New agreement with Managed Medicaid PBM

In August, Orexo announced that the company had signed a new multi-year agreement with a key PBM in Managed Medicaid. As for all agreements with PBMs, the impact and value are dependent on the decision by each of the PBM's clients (insurance companies and employers) to implement their recommendations.

New 24-week clinical study strengthened the evidence of the therapeutic value of Zubsolv for maintenance treatment of opioid dependence

In April, Orexo announced the data from a 24-week clinical study assessing the long-term safety and efficacy of Zubsolv



OREXO ANNUAL REPORT 2015 KEY EVENTS IN 2015 ■ 26

(buprenorphine/naloxone) sublingual tablet (CIII) for the maintenance treatment of opioid dependence. The result established that Zubsolv® is effective, well tolerated and demonstrated a safety profile consistent with the product labeling for sublingual buprenorphine products. In addition less than 1 percent of the patients exited the study due to treatment failure, which further underpins the medical value of Zubsolv. The results also demonstrated an increase of 15 percent in employment by the patients participating in the study, which further strengthen the evidence of the value of effective treatment of opioid dependence for the society.

The study 0X219-008 was an extension of Orexo's previous studies ISTART (Study 006) and Study 007.

New patent protecting Zubsolv listed in the US In February, a new patent covering Zubsolv was issued in the US. The patent is listed in the Orange Book by US FDA and expires in 2032.

#### Field based activities

During the second quarter 2015, a controlled expansion of the field force was initiated through the partner InVentiv Health. Orexo's disease awareness campaign wins Gold Lions Health Award in Cannes Lions Festival in June.

#### Abstral®

Orexo received MGBP 5 milestone payment for Abstral in Europe In December, Orexo announced that annual sales of Abstral in Europe passed MEUR 67.5 during 2015, which triggered a milestone payment of MGBP 5 (approx. MSEK 66) to Orexo from the commercial partner in Europe ProStrakan Group plc.

#### New Abstral partner in the US

In November, Orexo announced that the US Abstral partner, Galena Biopharma Inc, has divested its Abstral business to the privately held company Sentynl Therapeutics Inc. as a consequence of Galena's change of strategy to focus on its clinical development program.

Orexo commenced patent infringement litigation against Actavis concerning Abstral in the US

In February, Orexo announced that the company has filed a patent infringement action in United States District Court for the District of New Jersey, against Actavis Laboratories FL, Inc., Andrx Corporation, Actavis, Inc. and Actavis Pharma, Inc. (collectively "Actavis".) The infringement action was a response to a paragraphs IV notice letter received from Actavis, advising of Actavis's filing of an Abbreviated New Drug Application ("ANDA") with the US Food and Drug Administration seeking approval of generic versions of Abstral (fentanyl) sublingual tablets prior to the expiration of Orexo's patents listed in the Orange Book. Since November 19, 2015 Sentynl Therapeutics Inc. markets Abstral (fentanyl) sublingual tablets in the US.

Orexo settled Abstral US patent litigation with Actavis In October, Orexo announced that it has entered into a settlement and license agreement with Actavis Laboratories FL, Inc. to settle the patent litigation regarding Abstral in the US.

#### **Edluar®**

Orexo settled a patent infringement litigation
During the second quarter 2015, Orexo settled an older patent infringement litigation against Mylan regarding Edluar.

#### Organisation

Orexo divested its subsidiary Kibion

In April, Orexo announced the divestment of the subsidiary Kibion AB marketing breath test and technology platforms for the diagnosis of the gastric ulcer bacterium *Helicobacter pylori*.

The primary objective of the divestment was to further strengthen the core focus on the continued development of Orexo's pharmaceutical business and on maximizing the commercial opportunity of Zubsolv.

# Key Events After the End of the Fiscal Year

AstraZeneca acquired all rights to Orexo's OX-CLI project
In March 2016, Orexo announced that AstraZeneca exercised the company's option and acquired all rights to the leukotriene C4 synthase inhibitor program (OX-CLI-project). The OX-CLI-project is directed to develop a novel treatment of respiratory disorders such as asthma and COPD. In accordance with the option agreement

from 2013, Orexo AB will receive a payment of MUSD 5 for the rights to OX-CLI. Future milestone payments can be expected when 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.

OREXO ANNUAL REPORT 2015 KEY EVENTS IN 2015 ■ 27

## Financial Performance in 2015

Condensed consolidated statement of operations			
MSEK	2015 Jan–Dec	2014 Jan-Dec	
Net revenues	643.3	570.3	
Cost of goods sold	-136.1	-107.4	
Gross profit	507.2	462.9	
Selling expenses	-297.5	-193.6	
Administrative expenses	-141.5	-113.0	
Research and development costs	-172.6	-197.8	
Other operating income and expenses	-64.4	16.5	
Operating earnings <sup>1</sup>	-169.0	-25.0	
Net financial items	-22.1	-27.6	
Earnings after financial items	-191.1	-52.6	
Income tax	-6.9	-4.0	
Net earnings for the period	-198.0	-56.6	

Includes costs for employee stock options of MSEK -10.2 for the period January-December 2015 (MSEK 5.7 January-December 2014).

#### Revenues

Net revenues

Net revenues for the year amounted to MSEK 643.3 (570.3).

Net revenues were distributed as follows:

Net revenues		
MSEK	2015 Jan-Dec	2014 Jan-Dec
Abstral® – royalties	77.2	46.6
Abstral fixed royalty	57.0	173.6
Milestone payment Abstral	66.0	58.5
Total revenues from Abstral	200.2	278.7
Edluar® – royalty	13.6	10.7
Zubsolv®	416.7	228.0
Kibion AB	12.8	51.2
Total revenues from launched products	643.3	568.6
Partner-financed R&D costs	-	
License revenues	_	_
Other	_	1.7
Total	643.3	570.3

#### Launched products

During the year total revenues from Orexo's launched products increased by 13 percent to MSEK 643.3 (568.6), with Zubsolv revenue growth of 83 percent.

The US market for Zubsolv consists of three distinct payer segments: commercial (private insurance), cash & vouchers (the patient pays) and public (Managed Medicaid, FFS Medicaid and Medicare Part D). By the end of 2015 Orexo's level of access to reimbursement was 88 percent in the commercial segment and 38 percent in the public segment.

Zubsolv has grown by 102.8 percent in terms of number of tablets dispensed to patients compared to 2014 with one of the main driver being market share gain in the commercial segment. The commercial and cash & vouchers segments are the most profitable segments.

Zubsolv ended 2015 with a 6.4 percent market share which was an improvement of 0.7 percentage points since the end of 2014. 0.5 share points of the 0.7 points occurred during the second half of 2015 without any exclusive market access wins. This demonstrated Orexo's ability to sell in a very competitive environment.

Total Abstral royalties and milestone payments during the year amounted to MSEK 200.2 (278.7). The second and final sales milestone payment in the European Abstral agreement of MGBP 5.0 was earned in the fourth quarter when annual sales of Abstral in Europe passed MEUR 67.5.

Total variable Abstral royalties amounted to MSEK 77.2 (46.6) and the growth was mainly driven by continued strong growth in the European region where Abstral is still the market leader in its segment.

The fixed and un-conditional Abstral royalties for 2015 were MSEK 57.0 (173.6). This part represents an amortization of the final fixed and unconditional payment related to the 2012 agreement with ProStrakan. The fixed royalties were fully recognized in the P&L by May 2015. As these fixed payments have all been received the recognition in the P&L, there is no cash impact.

Royalty revenues from Edluar during the year amounted to MSEK 13.6 (10.7).

The subsidiary Kibion was divested per April 30, 2015. Kibion's sales for the first four months of the year amounted to MSEK 12.8.

#### **Expenses and earnings**

Cost of goods sold

Cost of goods sold amounted to MSEK 136.1 (107.4). The increase was driven by increased Zubsolv revenues.

#### Selling expenses

Selling expenses amounted to MSEK 297.5 (193.6). The increase over previous year is explained by no field force costs included for Q1 2014, field force expansion commenced in Q2 2015, and finally by an increased USD/SEK exchange rate. Prior to Q2, 2014, selling expenses were carried by Orexo's field force partner at the time, Publicis Touchpoint Solutions.

#### Administrative expenses

Administrative expenses amounted to MSEK 141.5 (113.0). Approximately half of these expenses are directly related to protection of IP rights.

#### Research and development costs

Research and development costs amounted to MSEK 172.6 (197.8). The costs are attributable to clinical studies and other life cycle management activities in the Zubsolv program.

#### Expenses for the long-term incentive program

The Group's total costs for employee stock option programs amounted to MSEK -10.2 (5.7). The decreased costs are due to reduced provisions for social security fees due to the development of the Orexo share price during the period.

The table below shows how expenses for the long-term incentive program are distributed:

MSEK	2015 Jan-Dec	2014 Jan-Dec
Administrative expenses	-7.3	3.9
Research and development costs	-4.6	0.4
Selling expenses	1.7	1.4
Total costs	-10.2	5.7

#### Other income and expenses

Other income and expenses amounted to MSEK –64.6 (16.5). The increase is mainly related to write down of the OX-MPI asset amounting to MSEK 62.3. Other than the write down, other income and expenses primarily comprised exchange-rate gains/losses from revaluation of balance sheet items in foreign currency.

#### Depreciation

Depreciation and amortization amounted to MSEK 18.4 (12.5). The increase was primarily driven by the initation of amortization of previously capitalized R&D expenses related to the Zubsolv® induction label.

#### Net financial items

Net financial items amounted to MSEK –22.1 (–27.6). All the net financial items are related to financing activities.

#### Income tax

Income tax for the year of MSEK -6.9 (–4.0) is mainly attributable to Orexo's operations in the US.

#### Net earnings

Net earnings amounted to MSEK -198.0 (-56.6).

#### Financial position

On December 31, 2015, cash and cash equivalents amounted to MSEK 198.1 (284.5) and interest-bearing liabilities to MSEK 494.4 (493.8).

Cash flow before financing activities for the year was MSEK -84.5.

Shareholders' equity on December 31, 2015 was MSEK 266.4 (455.0). The equity/assets ratio was 26 (37) percent.

Cash and cash equivalents, significant inventory values and potential business development income and cash provide Orexo with a good financial position.

#### Investments

Gross investments in tangible and intangible fixed assets amounted to MSEK 4.1 (71.7).

#### **Parent Company**

Net revenues amounted to MSEK 518.9 (398.5), whereof group internal sales amounted to MSEK 305.0 (109.0). Earnings after financial items were MSEK -161.8 (-65.4). During the fourth quarter 2015, a write down of shares for the subsidiary Biolipox AB was recorded amounting to MSEK 63.8 related to the write down of the OX-MPI asset. Investments amounted to MSEK 4.1 (71.3). As of December 31, 2015, cash and cash equivalents in the Parent Company amounted to MSEK 114.0 (247.2).

#### Risks

Significant risks and uncertainties

Significant risks are essentially the same for the Parent Company and the Group. The risks may be classified as financial and operational. The financial risks are described in Note 3 on page 44. A summary description of the operational risks attributable to research and development, production, sales and other risks is presented below.

#### Market risks

The main market risks for Orexo are price pressure, reimbursement restrictions by payers and the launch of new and competing products.

For Zubsolv to be successful in the US, it is of the utmost importance that Zubsolv has access to patients and reimbursement to the same extent as competitors. This is normally not the case for a relatively newly launched product and it takes time to achieve parity with competition as the US payer structure and reimbursement system is very large and complex. Orexo has established its own team of experienced people whose only task is to work on constantly improving market and reimbursement access for Zubsolv. During 2015 Orexo continued to improve the market access (reimbursement) for Zubsolv and reached 88 percent access in the commercial segment and 38 percent in the public segment. In August, Orexo announced that the pharmacy benefit manager (PBM) CVS Caremark had excluded Zubsolv from the standard formulary for 2016 for their commercial clients. This reduced the market access in the commercial segment to approximately 82 percent from January 1, 2016.

Orexo's products are sold in a highly competitive market, with competition from both other products and other treatment methods, and the launch of new products by competitors is an inherent market risk. In all markets for Orexo's products there is intensive development of new and improved treatments, which may prove to have a better clinical effect than those of today.

Orexo is constantly working to proactively analyze these risks and develop action plans for alternative market scenarios. This is being done together with local external expertise.

#### R&D does not achieve the expected results

Development of a new product is by nature a complicated and risky process that requires considerable financial resources. Orexo's strategy is to develop improved products at a lower cost, in a shorter period of time and at a lower risk by combining previously known substances with proprietary technologies. The process is controlled by a multidisciplinary organization that handles all critical issues during the development period on the way to an approved product. As Orexo is a relatively small organization, it is necessary to focus on a small number of prioritized projects with high market potential.

The development of these prioritized projects towards an approved product may fail or be delayed due to several factors, such as:

- Unfavorable results in clinical trials.
- Failure to gain the authority approval required for sales of the pharmaceutical product.
- A change in the requirements of the regulatory authorities.

Currently Orexo's R&D focus is directed towards Zubsolv® clinical trials and life cycle management projects as well as exploratory work to develop new formulation platforms. As with other R&D activities, there is a risk that the desired results are not met.

In addition to the development of its own products, Orexo has a number of development projects licensed to partners, where the partner in each case has complete responsibility for development. If these projects fail or for some reason are terminated, there are no future one-time payments and royalties.

In August 2014, Orexo's partner Boehringer Ingelheim decided to return the OX-MPI project (selective inhibition of prostaglandin E2 synthase) to Orexo. Since 2005 Boehringer Ingelheim had been responsible for all research and development within the OX-MPI project.

The evaluation of the results from Boehringer Ingelheim has been completed and Orexo still sees potential in the project due to a unique target, an identified development compound and several granted patents. The process to identify a new external partner to OX-MPI continues, however, as no patner was still not identified by the end of 2015 it was decided to record an impairment charge of SEK 62 related to the OX-MPI asset.

#### Difficulties in obtaining and protecting patents

Being able to obtain and maintain patents and other intellectual property rights protecting Orexo's technologies and products is an important part of Orexo's ability to create long-term value for its business. Obtaining patents related to pharmaceuticals is a complex process that involves both scientific and legal expertise. Even if a patent has been granted, it may later be challenged legally, declared invalid or by-passed, which may limit Orexo's ability to market its new products.

On February 5, 2015 Orexo announced that it had filed a patent infringement action in the US against Actavis related to Abstral. On October 27, 2015 Orexo announced that the case was settled.

On June 27, 2014 Orexo announced that it had filed a patent infringement action in the US against Actavis Elizabeth LLC and its parent company Actavis, Inc. related to Zubsolv. By December 31, 2015 the process was still ongoing.

#### **Production process**

Production and packing of Orexo's products is done by various external partners.

In August 2014, Orexo decided to move all manufacturing of Zubsolv from the Swedish site to suppliers in the US. The facilities in Uppsala, Sweden, focus on new product development. The US manufacturing facilities are carefully assessed against Orexo's Supplier Code of Conduct.

High demands on methods and processes are placed and these must meet "Good Manufacturing Practice" standards (GMP). Orexo constantly evaluates the fulfilment of GMP both internally and by all strategic subsuppliers. Orexo and its subsuppliers may be inspected by different authorities that have the power to grant approval. Orexo's production comprises highly potent controlled substances. There are strict rules and laws for these regarding manufacturing, storage, handling, freight, import and export, and waste management. Access to pharmaceutical ingredients may be uncertain and entail long delivery times. Orexo must therefore ensure that it can gain access to these substances at an early stage.

Before new products are launched, future production volumes must be assessed and production started before final regulatory approval has been received, thus allowing marketing and sales to begin.

To ensure safe supply of products that are vital to patients a significant inventory of Zubsolv must be maintained. Carrying a high inventory level creates a risk of write-offs of expired products. Orexo is constantly working to minimize this risk by managing the inventory according to demand and by working to improve the product lifetime. During 2015 Orexo continued to improve the product lifetime and also established a re-packaging process that allows further optimization of inventory levels.

#### Effect of political and regulatory decisions

The pharmaceutical market is greatly affected by political decisions that may affect, for example, reimbursement levels for pharmaceutical expenses and limits for the prescription of products. Especially the market for controlled substances is under tight surveillance and control by authorities who can change the market conditions with new policies and legislation.

#### Dependence on key persons

Orexo is dependent on a number of key persons within various different areas. The ability to recruit and retain qualified coworkers is of very great importance for ensuring that there is adequate expertise in the company. Orexo has also outsourced a number of activities critical to the business to external consultants and partners. One example of this is the commercial partnership that Orexo has entered with inVentiv Health, where the partner is responsible for the execution of certain field-based Zubsolv activities in the US. Where consultants and partners can not deliver services in time and of the necessary quality, this may have a negative impact on the results of the business.

#### Remuneration

#### Incentive programs

Orexo has introduced equity-based incentive programs in the form of employee stock options, warrants and shares with the aim of motivating and rewarding key employees through partial ownership, thereby promoting the Group's long-term interests. All incentive programs are performance driven to align participants interests with investor interest. For more detailed information, see Long-Term Incentive Programs Note 16.

Principles and guidelines for remuneration to senior executives. The Board of Directors proposes that the Annual General Meeting resolve to approve the Board of Directors' proposal concerning principles and guidelines for the remuneration of the company's management in accordance with what is stated below, to apply until the Annual General Meeting in 2016. The Board's proposal principally conforms to guidelines previously applied to the remuneration of the company's management. "Management" here refers to the Chief Executive Officer and the other members of the management group, which in addition to the Chief Executive Officer comprised four persons at the end of 2015. The Board has appointed a Remuneration Committee to draw up proposals regarding remuneration and other terms of employment for the management.

#### Motives

Orexo shall offer terms of employment that are in line with market rates so that the company can recruit and retain skilled personnel. Remuneration to the management shall comprise a fixed salary, variable remuneration, long-term incentive programs, pensions and other customary benefits. Remuneration is based on the individual's commitment and performance in relation to previously established goals, individual goals and goals for the entire company. Individual performance is continuously evaluated.

#### Fixed salary

Fixed salary is generally reviewed on an annual basis and shall be based on the qualitative performance of the individual. The fixed salary of the Chief Executive Officer and the management shall be in line with market conditions.

#### Variable remuneration

Variable remuneration shall take into account the individual's level of responsibility and degree of influence. The size of variable remuneration is based on the percentage of set goals met by the individual. Variable remuneration shall amount to no more than 40 percent of the fixed salary of the Chief Executive Officer and 30 percent of the fixed salary for the other members of the management. Furthermore, the Board of Directors shall have the option of allocating further variable non-recurring remuneration to the management when the Board deems it to be appropriate.

#### Long-term incentive programs

Orexo has adopted equity-based incentive programs intended to promote the company's long-term interests by motivating and rewarding the management of the company, among others.

For a description of the company's Long-Term Incentive Programs, please refer to Note 16, and to the company's website, www.orexo.com.

#### Other remuneration and terms of employment

The Chief Executive Officer and the other members of the management are covered by defined-contribution pension plans. The pension premiums paid by the company amount to not more than 20 percent of the Chief Executive Officer's monthly salary, while premiums for the other members of the management amount to between 20 and 25 percent of fixed annual salary.

The employment agreement with the Chief Executive Officer may be terminated with six months' notice. Employment agreements with the other members of the management may be terminated with notice of between three and 12 months. The Chief Executive Officer is entitled to severance pay equivalent to six months' salary if employment is terminated by the company. The other members of the management are entitled to severance pay equivalent to between zero and 12 months' salary if employment is terminated by the company.

The Board is entitled, if it assesses that this is warranted in an individual case, to assign company work to a Board member over and above the Board assignment, in which case the Board member may be granted reasonable remuneration.

#### Divergence from guidelines 2016

The Board is entitled to deviate from the above guidelines if the Board determines that there are special reasons in an individual case that warrant such action.

#### Dividend

The Board of Directors proposes that no dividend is paid for the financial year 2015.

#### Proposed disposition of earnings

The following earnings are available to the Annual General Meeting for appropriation:

Share premium reserve 1,186,906,353
Retained earnings -975,864,291
Earnings for the year -162,271,021
Accumulated surplus 48,771,041

The Board proposes that the accumulated surplus to be appropriated so that SEK 48,771,041 is carried forward.

OREXO ANNUAL REPORT 2015 FINANCIAL PERFORMANCE IN 2015 ■ 31

## Financial Report 2015

## Consolidated statement of operations

(SEK thousands)				
Group	NOTES	2015	2014	2013
Net revenues	6, 23	643,338	570,316	429,355
Cost of goods sold	24	-136,082	-107,442	-29,345
Gross profit		507,256	462,874	400,010
Selling expenses	7, 8, 9, 24, 28	-297,531	-193,568	-125,097
Administrative expenses	7, 8, 9, 24, 25, 28	-141,494	-113,026	-126,373
Research and development costs	7, 8, 9, 24, 28	-172,576	-197,822	-238,144
Other operating income	26, 36	34,569	38,560	17,664
Other operating expenses	24, 26	-99,210	-22,025	-67,749
Operating earnings		-168,986	-25,007	-139,689
Financial income		902	257	835
Financial expenses	27	-23,022	-27,804	-14,547
Earnings after financial items	27	-191,106	-52,554	-153,401
Income tax	29	-6,881	-4,031	-1,535
Net earnings for the year		-197,987	-56,584	-154,936
Earnings for the year attributable to:				
Parent Company shareholders		-197,987	-56,584	-154,936
Non-controlling interests		_	-	-
Earnings per share during the year attributable to Parent Company shareholders (expressed in SEK)				
– before dilution	31	-5.74	-1.73	-5.16
– after dilution	31	-5.74	-1.73	-5.16

The full loss for each year is attributable to Parent Company shareholders. There are no non-controlling interests.

# Consolidated statement of comprehensive income

(SEK thousands)				
Group	NOTES	2015	2014	2013
Net earnings for the year		-197,987	-56,584	-154,936
Other comprehensive income				
Items that may subsequently be reversed to statement of operations				
Cash flow hedge	17	2,838	-2,842	-8,755
Exchange-rate differences	17	-4,320	-266	-1,898
Other comprehensive income for the period, net after tax:		-1,482	-3,108	-10,653
Total comprehensive income for the period		-199,469	-59,692	-165,589
Total comprehensive income attributable to:				
Parent Company shareholders		-199,469	-59,692	-165,589

The notes on pages 41-68 constitute an integral part of this Annual Report.

OREXO ANNUAL REPORT 2015 FINANCIAL REPORT ■ 33

## Consolidated balance sheet

(SFK	thousands	١

	Dec 31, 2015	Dec 31, 2014	Dec 31, 2013
ASSETS			
Fixed assets			
Tangible fixed assets			
Equipment, renovation of the property of others, machinery and computers 7, 9	24,685	29,080	33,255
Intangible fixed assets			
Patents and intellectual property rights, proprietary intangible asset, acquired R&D and			
goodwill 8, 9	159,125	259,227	194,779
Financial assets			
Financial assets that can be sold 11, 12	2,060	1,158	
Total fixed assets	185,870	289,465	228,034
Current assets			
Inventories 13	398,925	478,144	383,410
Accounts receivable and other receivables 11, 14	233,385	173,797	55,243
Cash and cash equivalents 11, 15	198,124	284,480	105,643
Total current assets	830,434	936,421	544,296
TOTAL ASSETS	1,016,304	1,225,886	772,330
SHAREHOLDERS' EQUITY AND LIABILITIES			
SHAREHOLDERS' EQUITY AND LIABILITIES  Shareholders' equity attributable to Parent Company shareholders			
	13,834	13,738	13,166
Shareholders' equity attributable to Parent Company shareholders	13,834 1,842,953	13,738 1,832,144	13,166 1,479,460
Shareholders' equity attributable to Parent Company shareholders  Share capital 16		,	
Shareholders' equity attributable to Parent Company shareholders  Share capital 16 Other contributed capital 16, 18	1,842,953	1,832,144	1,479,460
Shareholders' equity attributable to Parent Company shareholders  Share capital 16 Other contributed capital 16, 18 Reserves 16, 17	1,842,953 -10,792	1,832,144 -9,310	1,479,460 -6,202
Shareholders' equity attributable to Parent Company shareholders  Share capital  Other contributed capital  Reserves  16, 17  Accumulated deficit  16  Total shareholders' equity	1,842,953 -10,792 -1,579,536	1,832,144 -9,310 -1,381,549	1,479,460 -6,202 -1,324,965
Shareholders' equity attributable to Parent Company shareholders  Share capital 16 Other contributed capital 16, 18 Reserves 16, 17 Accumulated deficit 16  Total shareholders' equity  Long-term liabilities	1,842,953 -10,792 -1,579,536 <b>266,459</b>	1,832,144 -9,310 -1,381,549 <b>455,023</b>	1,479,460 -6,202 -1,324,965 <b>161,459</b>
Shareholders' equity attributable to Parent Company shareholders  Share capital 16 Other contributed capital 16, 18 Reserves 16, 17 Accumulated deficit 16  Total shareholders' equity  Long-term liabilities Other provisions 18	1,842,953 -10,792 -1,579,536 <b>266,459</b> 3,914	1,832,144 -9,310 -1,381,549 <b>455,023</b>	1,479,460 -6,202 -1,324,965 <b>161,459</b> 9,645
Shareholders' equity attributable to Parent Company shareholders  Share capital 16 Other contributed capital 16, 18 Reserves 16, 17 Accumulated deficit 16  Total shareholders' equity  Long-term liabilities	1,842,953 -10,792 -1,579,536 <b>266,459</b>	1,832,144 -9,310 -1,381,549 <b>455,023</b>	1,479,460 -6,202 -1,324,965 <b>161,459</b>
Shareholders' equity attributable to Parent Company shareholders  Share capital 16 Other contributed capital 16, 18 Reserves 16, 17 Accumulated deficit 16  Total shareholders' equity  Long-term liabilities Other provisions 18 Borrowings 11, 19	1,842,953 -10,792 -1,579,536 <b>266,459</b> 3,914 494,334	1,832,144 -9,310 -1,381,549 <b>455,023</b> 9,006 493,762	1,479,460 -6,202 -1,324,965 <b>161,459</b> 9,645 104,081
Share capital 16 Other contributed capital 16, 18 Reserves 16, 17 Accumulated deficit 16 Total shareholders' equity  Long-term liabilities Other provisions 18 Borrowings 11, 19 Total long-term liabilities  Current liabilities  Current liabilities	1,842,953 -10,792 -1,579,536 <b>266,459</b> 3,914 494,334 <b>498,248</b>	1,832,144 -9,310 -1,381,549 <b>455,023</b> 9,006 493,762 <b>502,768</b>	1,479,460 -6,202 -1,324,965 <b>161,459</b> 9,645 104,081 <b>113,726</b>
Shareholders' equity attributable to Parent Company shareholders  Share capital 16 Other contributed capital 16, 18 Reserves 16, 17 Accumulated deficit 16 Total shareholders' equity  Long-term liabilities Other provisions 18 Borrowings 11, 19 Total long-term liabilities	1,842,953 -10,792 -1,579,536 <b>266,459</b> 3,914 494,334	1,832,144 -9,310 -1,381,549 <b>455,023</b> 9,006 493,762	1,479,460 -6,202 -1,324,965 <b>161,459</b> 9,645 104,081

OREXO ANNUAL REPORT 2015 FINANCIAL REPORT ■ 34

# Changes in consolidated shareholders' equity

Attributable to Parent Company shareholders¹ (SEK thousands)

(SEK thousands)			Other			Total
Group	NOTES	Share capital	contributed capital	Accumulated deficit	Reserves	hareholders' equity
Opening balance at January 1, 2013		11,983	1,344,789	-1,170,029	4,451	191,194
Comprehensive income						
Net earnings for the year				-154,936		-154,936
Other comprehensive income						
Translation differences					-1,898	-1,898
Cash flow hedge					-12,826	-12,826
Deferred tax					4,071	4,071
Total comprehensive income				-154,936	-10,653	-165,589
Transactions with shareholders						
Employee stock options, value of employees' services	16		3,547			3,547
New share issues	16	199	19,217			19,416
Conversion of convertible	16	984	111,907			112,891
Total transactions with shareholders		1,183	134,671			135,854
Opening balance at January 1, 2014	16	13,166	1,479,460	-1,324,965	-6,202	161,459
Comprehensive income						
Net earnings for the year				-56,584		-56,584
Other comprehensive income						
Translation differences					-266	-266
Cash flow hedge					-2,842	-2,842
Total comprehensive income				-56,584	-3,108	-59,692
Transactions with shareholders						
Employee stock options, value of employees' services	16		11,536			11,536
New share issues	16	572	192,911			193,483
Sale of company's own shares	16		155,836			155,836
Issue expenses	16		-7,599			-7,599
Total transactions with shareholders		572	352,684			353,256
Opening balance at January 1, 2015	16	13,738	1,832,144	-1,381,549	-9,310	455,023
Comprehensive income						
Net earnings for the year				-197,987		-197,987
Other comprehensive income						
Translation differences					-4,320	-4,320
Cash flow hedge					2,838	2,838
Total comprehensive income				-197,987	-1,482	-199,469
Transactions with shareholders						
Employee stock options, value of employees' services	16		7,121			7,121
Buyback of shares	16		-54			-54
New share issues	16	96	3,742			3,838
Total transactions with shareholders		96	10,809			10,905
		13,834				

<sup>&</sup>lt;sup>1</sup> There are no non-controlling interests.

OREXO ANNUAL REPORT 2015 FINANCIAL REPORT ■ 35

## Consolidated cash flow statement

(SEK thousands)			
Group NOTES	2015	2014	2013
Cash flow from operating activities			
Operating earnings	-168,986	-25,007	-139,689
Interest received	_	257	835
Interest paid	-20,553	-19,283	-6,830
Other financial items	-1,567	-8,521	-4,075
Tax paid	-6,881	-4,031	-1,535
Adjustment for non-cash items 34	78,592	21,045	89,430
Cash flow from operating activities before change in working capital	-119,395	-35,540	-61,864
Change in working capital			
Accounts receivable	-22,043	-105,989	-18,597
Other current receivables	-37,545	-12,565	8
Inventories	79,219	-94,734	-355,092
Current liabilities	2,663	-237,833	166,696
Provisions	-5,092	-639	5,648
Cash flow from operating activities	-102,193	-487,300	-263,201
Investing activities			
Acquisition of tangible and intangible fixed assets	-4,122	-71,723	-107,505
Divestment of machinery and equipment	_	24	_
Divestment of subsidiary	21,816	_	_
Cash flow from investing activities	17,694	-71,699	-107,505
Financing activities			
New share issue	3,838	193,483	19,415
Issue expenses	_	-7,599	_
Borrowings	_	500,000	234,661
Amortization of loans	-1,241	-102,355	-3,020
Sale of company's own shares 16	_	155,836	_
Cash flow from financing activities	2,597	739,365	251,056
Cash flow for the year			
Cash and cash equivalents at beginning of period	284,480	105,643	228,067
Exchange-rate differences in cash and cash equivalents	-4,454	-1,529	-2,774
Change in cash and cash equivalents	-81,902	180,366	-119,650
Cash and cash equivalents at end of period 15	198,124	284,480	105,643

# Parent Company statement of operations

(SEK thousands)				
Parent Company	NOTES	2015	2014	2013
Net revenues	6, 23	518,900	398,447	452,321
Cost of goods sold	24	-155,831	-64,168	-91,450
Gross profit		363,069	334,279	360,871
Selling expenses	7, 8, 9, 24, 28	-226,854	-157,507	-45,058
Administrative expenses	7, 8, 9, 24, 25, 28	-108,133	-74,645	-109,962
Research and development costs	7, 8, 9, 24, 28	-122,890	-160,660	-228,260
Other operating income	26	35,581	38,024	11,247
Other operating expenses	24, 26	-30,593	-19,013	-16,677
Operating earnings		-89,820	-39,522	-27,839
Earnings from financial investments				
Interest income	27	1,825	1,754	1,150
Interest expenses	27	-20,518	-19,646	-11,275
Other financial income	27	13,087	_	_
Other financial expenses	27	-66,364	-8,003	-6,314
Earnings after financial items		-161,790	-65,417	-44,278
Income tax	29	-481	-534	-1,446
Net earnings for the year		-162,271	-65,951	-45,724

# Parent Company statement of comprehensive income

(SFK	thousar	nds)

Parent Company NO	TES 2015	5 2014	2013
Net earnings for the period	-162,27	-65,951	-45,724
Other comprehensive income for the period, net after tax			
Total comprehensive income for the period	-162,271	-65,951	-45,724
Total comprehensive income attributable to:			
Parent Company shareholders	-162,27	-65,951	-45,724

## Parent Company balance sheet

(SFK	thousands)

Parent Company	NOTES	Dec 31, 2015	Dec 31, 2014	Dec 31, 2013
ASSETS		,	•	,
Fixed assets				
Intangible fixed assets				
Patents and intellectual property rights and proprietary intangible asset	8, 9	159,125	169,477	106,001
Tangible fixed assets				
Equipment, renovation of the property of others, machinery and computers	7, 9	23,727	27,169	31,453
Financial fixed assets				
Shares and participations in subsidiaries	10	148,504	208,853	202,178
Total fixed assets		331,356	405,499	339,632
Current assets				
Inventories	13	276,809	378,399	303,292
Current receivables				
Accounts receivable	14	284,171	92,616	98,484
Tax claims	14	2,435	2,224	3,080
Other receivables	14	14,664	3,117	3,912
Receivables from Group companies	14	10,543	127,197	64,953
Prepaid expenses and accrued income	14	8,873	7,526	9,071
Total current receivables		597,495	232,680	179,500
Cash and cash equivalents	15	114,003	247,162	48,652
Total current assets		706,975	858,241	531,444
TOTAL ASSETS		1,042,854	1,263,740	871,076
SHAREHOLDERS' EQUITY AND LIABILITIES				
Shareholders' equity				
Restricted shareholders' equity				
Share capital	16	13,834	13,738	13,166
Statutory reserve	16	290,751	290,751	290,751
		304,585	304,489	303,917
Non-restricted shareholders' equity				
Share premium reserve	16, 18	1,186,906	1,176,042	979,195
Accumulated deficit	16	-975,864	-909,859	-1,019,972
Net earnings for the year	16	-162,271	-65,951	-45,724
		48,771	200,232	-86,501
Total shareholders' equity		353,356	504,721	217,416
Long-term liabilities				
Other provisions	18	3,914	9,006	9,645
Long-term liabilities	19	494,334	491,906	100,000
Total long-term liabilities		498,248	500,912	109,645
Current liabilities				
Accounts payable	20	26,139	11,865	127,846
Other liabilities	19, 20	7,461	21,188	163,318
Liabilities to Group companies	20	101,724	101,713	101,241
Accrued expenses and deferred income	20	55,926	123,341	151,610
Total current liabilities		191,250	258,107	544,015
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		1,042,854	1,263,740	871,076
Pledged assets and contingent liabilities				
Pledged assets	21	100,000	138,924	232,249
Contingent liabilities	22	_	=.	_
	22			

# Changes in Parent Company's shareholders' equity

thousands)

			Statutory	Share premium	Accumulated	Total shareholders'
Parent Company	NOTES	Share capital	reserve	reserve	deficit	equity
Opening shareholders' equity at January 1, 2013		11,983	290,751	844,518	-1,019,972	127,280
Net earnings for the year					-45,724	-45,724
Total transactions recognized directly in shareholders' equity						0
Total recognized income and expenses					-45,724	-45,724
Employee stock options, value of employees' services	16			3,552		3,552
New share issues	16	199		19,217		19,416
Buyback of company's own shares	16	984		111,908		112,892
Opening shareholders' equity at January 1, 2014		13,166	290,751	979,195	-1,065,696	217,416
Net earnings for the year					-65,951	-65,951
Total transactions recognized directly in shareholders' equity						0
Total recognized income and expenses					-65,951	-65,951
Employee stock options, value of employees' services	16			11,536		11,536
New share issues	16	572		192,911		193,483
Sale of company's own shares	16				155,836	155,836
Issue expenses	16			-7,599		-7,599
Opening shareholders' equity at January 1, 2015		13,738	290,751	1,176,042	-975,810	504,721
Net earnings for the year					-162,271	-162,271
Total transactions recognized directly in shareholders' equity						0
Total recognized income and expenses					-162,271	-162,271
Employee stock options, value of employees' services	16			7,122		7,122
Buyback of shares	16				-54	-54
New share issues	16	96		3,742		3,838
Closing shareholders' equity at December 31, 2015		13,834	290,751	1,186,906	-1,138,135	353,356

## Parent Company cash flow statement

Parent Company NOTES	2015	2014	2013
Operating activities			
Operating earnings	-89,820	-39,522	-27,839
Interest received	1,825	1,754	1,150
Interest paid	-20,518	-19,646	-7,633
Other financial items	-53,277	-8,003	-6,314
Tax paid	-481	-534	-1,535
Adjustment for non-cash items 34	55,981	17,744	46,922
Cash flow from operating activities before change in working capital	-106,290	-48,207	4,751
Change in working capital			
Accounts receivable	-191,555	5,868	-80,426
Other current receivables	90,615	-59,048	-43,432
Inventories	101,590	-75,107	-284,803
Current liabilities	-48,208	-294,821	114,475
Provisions	-5,092	-639	5,648
Cash flow from operating activities	-158,940	-471,954	-283,787
Investing activities			
Acquisition of tangible and intangible fixed assets	-4,126	-71,280	-105,941
Divestment of machinery and equipment	_	24	
Investment in subsidiary	_		-32,249
Divestment of subsidiary	26,069		-
Cash flow from investing activities	21,943	-71,256	-138,190
Financing activities			
New share issue	3,838	193,483	19,415
Issue expenses	-	-7,599	-
Borrowings	_	500,000	234,661
Amortization of loans	_	-100,000	_
Sale of company's own shares 16	_	155,836	_
Cash flow from financing activities	3,838	741,720	254,076
Cash flow for the year			
Cash and cash equivalents at beginning of period	247,162	48,652	216,553
Change in cash and cash equivalents	-133,159	198,510	-167,901
Cash and cash equivalents at end of period 15	114,003	247,162	48,652

### Notes

(All figures in SEK thousands, unless otherwise stated)

#### **NOTE 1** GENERAL INFORMATION

Orexo AB (publ) 556500-0600, the Parent Company, and its subsidiaries (together the Group) are together an integrated pharma company with commercial operations in the United States and R&D in Sweden. The company develops improved products based on proprietary drug delivery technology. Orexo is responsible for the commercialization of its proprietary product Zubsolv®, for treatment of opioid dependence, on the American market.

The Parent Company is the limited liability company Orexo AB (publ), with its registered office in Uppsala, Sweden. The address of the company's head office is Virdings allé 32 A, Uppsala, Sweden.

The Parent Company is listed on NASDAQ Stockholm.

The Board of Directors approved these consolidated financial statements for publication on March 18, 2016.

The statement of operations and balance sheet will be presented to the Annual General Meeting on April 15, 2016 for adoption.

#### NOTE 2 SUMMARY OF IMPORTANT ACCOUNTING POLICIES

The most significant accounting policies applied during the preparation of these consolidated financial statements are specified below. Unless otherwise stated, these policies have been applied consistently for all years presented.

#### 2.1 Basis for preparation of the financial statements

The consolidated financial statements for Orexo were prepared in accordance with the Swedish Annual Accounts Act, RFR 1 Supplementary Accounting Rules for Groups, as well as International Financial Reporting Standards (IFRS) and interpretations as adopted by the EU. They have been prepared in accordance with the cost method, with the exception of financial assets that can be sold and financial assets and liabilities, which have been valued at fair value via the statement of operations.

The Parent Company applies the same accounting policies as the Group, except in instances as specified in Note 4 "Accounting policies of the Parent Company". Any deviations that occur between the policies of the Parent Company and the Group are due to restrictions in the ability to apply IFRS to the Parent Company pursuant to the Swedish Annual Accounts Act (ÅRL) and the Pension Obligations Vesting Act and, in some instances, for tax purposes.

#### Going concern principle

The consolidated financial statements for Orexo are prepared on the basis of the going concern principle. Note 3, "Financial risk management", describes Orexo's financial risks and policies.

#### ${\bf 2.1.1} \ {\bf Amendments} \ {\bf to} \ {\bf accounting} \ {\bf policies} \ {\bf and} \ {\bf disclosures}$

#### (a) New and amended standards applied by the Group

None of the IFRS or IFRS IC interpretations that have come into force are expected to have any significant impact on the Group.

#### (b) New standards and interpretations of existing standards that have not yet been applied by the Group

- IFRS 15 "Revenue from contracts with customers" is the new standard for reporting of revenue. According to IFRS 15, a revenue should be recognized when the customer gains control of the goods or services. IFRS 15 replaces IAS 18, Revenue, and IAS 11, Construction Contracts. IFRS 15 comes into force on January 1, 2018. Earlier application is permitted. The Group has not yet evaluated the effects of the introduction of the standard.
- IFRS 9, "Financial instruments", deals with the classification, measurement and reporting of financial assets and liabilities and introduces new rules for the reporting of insurance. The full version of IFRS 9 was issued in July 2014. It replaces those parts of IAS 39 which deal with the classification and measurement of financial instruments and introduces a new model for impairment. The standard is to be applied for fiscal years beginning in January 2018. Earlier application is permitted. The Group has not yet evaluated the effects of the introduction of the standard.
- IFRS 16 "Leases". In January 2016 IASB issued a new lease standard that will replace IAS 17 Leases and the related interpretations IFRIC 4, SIC-15 and SIC-27. The standard requires assets and liabilities arising from all leases, with some exceptions, to be recognized on the balance sheet. This model reflects that, at the start of a lease, the

lessee obtains the right to use an asset for a period of time and has an obligation to pay for that right. The standard is effective for annual period beginning on or after 1 January 2019. Early adoption is permitted if IFRS 15 Revenue from Contracts with Customers is also applied. EU has not yet adopted the standard. The group has not yet assessed the impact of IFRS 16.

None of the other IFRS or IFRS IC interpretations which have not yet come into force are expected to have any significant impact on the Group.

#### 2.2 Consolidated financial information

#### Subsidiaries

Subsidiaries are all companies where the Group has a controlling interest. The Group controls a company when it is exposed to or is entitled to a variable return from its holding in the company and is able to impact the return through its interest in the company.

Subsidiaries are included in the consolidated financial statements as of the date on which the controlling interest is transferred to the Group. They are excluded from the consolidated financial statements as of the date on which the controlling interest ceases to apply.

The purchase method is used to recognize the Group's business combinations.

Intra-Group transactions, balance-sheet items and non-realized gains and losses resulting from intra-Group transactions are eliminated. Where necessary, the accounting policies for subsidiaries have been adjusted to guarantee consistent application of the Group's policies.

#### 2.3 Segment reporting

Operating segments are recognized in a manner that corresponds to the structure of internal reports submitted to the chief operating decision maker. The chief operating decision maker is responsible for the allocation of resources and assessment of the operating segment's results. For the Group, this function has been identified as Executive Management.

Executive Management assesses the operation in its entirety, i.e. as a segment.

#### 2.4 Translation of foreign currency

#### (a) Functional currency and reporting currency

Items included in the financial reports of the different units in the Group are valued in the currency used in the economic environment in which each company mainly operates (functional currency). In the consolidated financial statements SEK is used, which is the Parent Company's functional currency and reporting currency.

#### (b) Transactions and balance sheet items

Transactions in foreign currencies are translated to the functional currency using the exchange rates prevailing on the transaction date. Exchange-rate gains and losses arising from the payment of such transactions and in the translation of monetary assets and liabilities in foreign currency at the closing date are recognized in the statement of operations among "Other operating income" and "Other operating expenses".

#### (c) Group companies

The earnings and financial position of all Group companies (none of which use a high inflation currency as their functional currency) that use a functional currency other than the reporting currency are restated at the Group's reporting currency as follows:

- assets and liabilities for each of the balance sheets are restated at the exchange rate applicable on the closing date;
- income and expenses for each of the statements of operations are translated at an average currency exchange rate, and
- all exchange-rate differences are recognized in other comprehensive income.

Exchange-rate differences arising as a consequence of the translation of net investment in foreign operations and of borrowing and other currency instruments identified as hedges for such investments are recognized in the consolidated financial statements. An accumulated gain or loss in shareholders' equity is recognized in the statement of operations when a foreign operation is divested either wholly or in part.

Goodwill and adjustments of fair value arising in the event of acquisition of a foreign operation are treated as assets and liabilities for this operation and translated at the exchange rate on the closing date.

#### 2.5 Tangible fixed assets

Tangible fixed assets are recognized at cost, less depreciation. Subsequent expenditures are added to the carrying amount of the asset or recognized as a separate asset, depending on which is appropriate, only when it is probable that the future economic benefits related to the asset will accrue to the Group and the cost of the asset can be measured reliably. Expenses incurred for repairs and maintenance are recognized as costs.

Tangible fixed assets are depreciated over the estimated useful life of the asset. When the depreciation amount for assets is determined, the asset's residual value is taken into account where appropriate.

Straight-line depreciation methods are used for all types of tangible fixed assets. The following depreciation periods are applied:

Renovation of the property of others 20 years Machinery and equipment 5 years Computers 3 years

In the event that an asset's carrying amount exceeds its estimated recoverable value, the asset is immediately impaired to its recoverable value under "Other operating income" and "Other operating expenses".

The residual value and useful life of assets are tested on every closing date and adjusted where necessary.

Gains and losses from sales are determined by means of a comparison between the sales proceeds and carrying amount and are recognized as "Other operating income" and "Other operating expenses" in the statement of operations.

#### 2.6 Intangible assets

Intangible assets are recognized in the balance sheet when it is probable that the future economic benefits related to the asset will accrue to the Group and the asset's value can be measured reliably. Development expenses are capitalized and recognized in the balance sheet as intangible assets if the criteria for recognition in the balance sheet as stipulated in IAS 38 Intangible Assets are satisfied.

Group intangible fixed assets consist of:

#### (a) Acquired research and development

Acquired R&D consists of acquired individual projects and the surplus values arising in conjunction with business combinations. Ongoing R&D projects acquired through business combinations are recognized at cost as "Acquired R&D". Expenses for continuing research in acquired projects are booked as they arise. Following initial recognition, the assets are recognized in line with the cost method, meaning that Acquired R&D is recognized at cost after deductions for any accumulated amortization and impairment. Amortization according to plan commences when the R&D project in question results in a product that can be used.

#### (b) Patents and rights

Patents and rights are recognized at cost. Patents and rights have a limited useful life and are recognized at cost less accumulated amortization. Amortization is applied straight-line in an effort to distribute the cost of patents and rights across their estimated useful life. The following amortization periods are applied:

Patents and rights 3–5 years IT systems 3 years

#### (c) Proprietary intangible asset

The proprietary intangible asset consists of clinical studies and registration expenses for these that are considered to contribute to future economic advantages for the Group. These studies are linked to products that have already been commercialized. Other clinical studies are carried as an expense.

The assets have a limited useful life and are recognized at cost less accumulated amortization. Amortization is applied straight-line in an effort to distribute the cost of proprietary intangible assets across their estimated useful life, which is 10 years.

#### 2.7 Impairment of non-financial assets

Assets with an indeterminate useful life are not depreciated/amortized in consolidation but are instead reviewed annually, or in the event of any indication of a decline in value, to identify any impairment requirement. Assets that are depreciated/amortized are assessed in terms of the value of decline whenever events or conditions indicate that the carrying amount is perhaps no longer recoverable. An impairment loss is recognized in the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of the asset's fair value less selling expenses and value in use. In the case of assets other than financial assets and goodwill that were previously impaired, a test is conducted on the closing date to determine whether a reversal is warranted.

#### 2.8 Inventories

Inventories are recognized at the lower of cost and net sales value. Cost is determined on the basis of the first in, first out (FIFO) principle. The cost for finished products and work in progress consists of raw materials, direct salaries, other direct costs and attributable indirect manufacturing costs (based on normal manufacturing capacity). Loan expenses are not included. The net sales value is the estimated sales price in current operations, less deductions for applicable variable selling expenses.

#### 2.9 Financial instruments

Financial instruments are recognized in the balance sheet when the Group becomes a party in accordance with the contractual terms of the instrument. Receivables are recognized in the balance sheet once an invoice is submitted and liabilities are recognized once the counterparty has fulfilled its obligations and a contractual obligation to pay exists.

The purpose for which the financial asset or liability was acquired determines classification. Group financial assets and liabilities are classified in the categories shown below:

- Loan receivables and accounts receivable
- Financial assets that can be sold
- Other financial liabilities

The Group's operations primarily focus on the development, production and sale of the Group's products and services. The Group does not actively trade in financial instruments that are not related to the Group's operations. Because of this, the financial assets and liabilities recognized in the balance sheet are primarily cash and cash equivalents, accounts receivable, accounts payable and borrowing.

During the year, financial instruments consisted of accounts receivable, loan receivables and financial assets that can be sold. Loan receivables and accounts receivable are financial assets that are not derivatives, that have determined or determinable payments and that are not listed on an active market. These are classified as current assets, if they have a due date of up to 12 months after the balance sheet date. If the due date is more than 12 months after the balance sheet date, the asset is classified as a fixed asset. Loan receivables and accounts receivable are recognized initially at their fair value plus transaction costs and, following the acquisition date, at amortized cost using the effective interest method. Financial assets that can be sold are assets that are not derivatives and where it is identified that the assets can be sold. They are included in fixed assets if Executive Management does not intend to divest the asset within 12 months. Refer also to Notes 12, 13, 15 and 16.

#### 2.10 Offset of financial instruments

Financial assets and liabilities are offset and recognized at a net amount in the balance sheet only when there is a legal right to offset the recognized amounts and an intention to settle with a net amount or simultaneously realize the asset and settle the liability.

#### 2.11 Cash and cash equivalents

Cash and cash equivalents include cash, bank balances and other current investments that mature within three months of the date of acquisition and which are exposed only to a minor risk of value fluctuation.

#### 2.12 Accounts receivable

Accounts receivable are initially measured at fair value and subsequently at amortized cost, using the effective interest method, less any provisions for value losses. A provision for value loss in accounts receivable is made when

there is objective evidence that the Group will not receive all the amounts due pursuant to the original conditions underlying the receivables. The size of the provision is determined as the difference between the asset's carrying amount and the present value of the estimated future cash flows, discounted using an effective rate of interest. The provision amount is recognized in the statement of operations.

#### 2.13 Provisions

Provisions are recognized in the balance sheet when the Group has a legal or informal undertaking as a result of an event that has occurred and when it is probable that an outflow of resources will be required to settle the undertaking.

The provision is recognized in the amount expected to be required to settle the undertaking.

#### 2.14 Accounts payable

Accounts payable are obligations to pay for goods or services that were acquired from suppliers in the course of operating activities. Accounts payable are classified as current liabilities if they mature within one year or earlier (or during a normal business cycle if it is longer than one year). Otherwise, accounts payable are recognized as long-term liabilities.

Accounts payable are initially recognized at fair value and subsequently at amortized cost by applying the effective interest method.

#### 2.15 Borrowings

Borrowings are initially recognized at net fair value after transaction costs. Borrowings are subsequently recognized at amortized cost and any difference between the amount received (net after transaction costs) and the repayment amount is recognized in the statement of operations allocated over the borrowing period by applying the effective interest method.

Borrowings are classified as a current liability unless the Group has an unconditional right to defer payment of the liability by at least 12 months.

#### 2.16 Shareholders' equity

Transaction costs that may be directly attributed to the issuance of new shares or options are recognized net after tax in shareholders' equity as a deduction from the issue proceeds.

The following are recognized as "Other contributed capital":

- The difference between the share's quotient value and the redemption price of exercised warrants.
- The difference between the share's quotient value and the calculated value of newly issued shares and warrants (option premium).
- Employee stock options, value of employees' services.
- Profit from shares repurchased by the Parent Company.

#### 2.17 Current and deferred income tax

The tax expense for the period comprises current tax calculated on the basis of the taxable earnings for the period according to current tax rates. The current tax expense is adjusted by changes in deferred tax assets and liabilities attributable to temporary differences and non-utilized losses.

The current tax expense is estimated on the basis of the tax regulations on the closing date that are decided, or have essentially been decided, in the countries in which the Parent Company and its subsidiaries are active and generate taxable income.

Deferred tax is recognized on all temporary differences that arise between carrying amounts of assets and liabilities and their value for tax purposes in the consolidated financial statements.

Deferred income tax is calculated using tax rates (and legislation) that have been decided or announced by the closing date and are expected to apply when the deferred tax asset in question is realized or the deferred tax liability is settled.

Deferred tax assets are recognized to the extent that it is likely that future taxable income will be available, against which temporary differences can be used

As Orexo has historically made losses, no value of the loss carry-forwards has been recognized in the balance sheet. Note 30 presents, amongst other things, the estimated accumulated loss carry-forwards for tax purposes in the Group.

Current and deferred tax is recognized in the statement of operations, except when the tax refers to items that are recognized directly against share-holders' equity or in other comprehensive income. In these cases, tax is also recognized in shareholders' equity or in other comprehensive income.

#### 2.18 Employee benefits

#### (a) Pension obligations

A defined-contribution pension plan is a pension plan according to which the Group pays fixed fees to a publicly or privately administrated pension insurance scheme and for which the Group has no further payment obligations once the fees are paid.

The Group uses only defined-contribution pension plans. Prepaid fees are recognized as an asset to the extent that cash repayments or a reduction in future payments may be credited to the Group.

#### (b) Share-based payments

The Group has a number of share-based payment plans whereby the company receives services in return for the Group's equity instruments. Information on these can be found in note 16.

#### Employee stock options program

The value of the employee stock options program is recognized as a personnel cost, with a corresponding increase in share equity. The total amount that is expensed is based on the fair value of the allotted options:

- including all market-related conditions,
- excluding any effect of service conditions and non-market-related vesting conditions (for example, the employee remains employed at the company for a stipulated period of time), and excluding the effect of conditions that are not vesting conditions,
- including internal operational targets approved by the Board.

Non-market-related vesting conditions are taken into account in the assumption of the number of options that are expected to be vested. The total cost is recognized over the entire vesting period, which is the period during which all of the stipulated vesting conditions are to be fulfilled. At the end of each reporting period, the company reviews its assessment of how many shares can be expected to be vested based on the non market-related vesting conditions. Any divergences from the original assessments prompted by the review are recognized in the statement of operations and a corresponding adjustment is made in shareholders' equity.

The company issues new shares when the stock options are exercised. Received payments, after deductions for any directly attributable transaction costs, are credited to share capital (the quotient value) and other contributed capital when the stock options are exercised.

Social security expenses on the benefits that are expected to arise in conjunction with value increases are recognized over the vesting period with due consideration of value changes.

#### Share awards

The fair value of the performance based share awards that are allotted to employees free of charge are entered as an expense over the vesting period, which corresponds to the period when the remuneration is vested and the services are performed. The fair value is calculated as of the day the share awards are allotted and recognized in shareholder equity. Assessment of how many shares are expected to be vested is based on non-market-related vesting conditions. Estimates are reconsidered at the end of each reporting period and any deviations are recognized in the statement of operations and corresponding adjustments are made in shareholders' equity.

Social security expenses on the benefits that are expected to arise in conjunction with value increases are recognized over the vesting period with due consideration of value change.

#### (c) Severance payments

Severance payments are made when the Group serves notice to an employee prior to the normal pension date or when an employee voluntarily accepts redundancy in exchange for such remuneration. The Group recognizes severance payments when it is clearly obliged to give notice to an employee according to a detailed formal plan with no possibility of it being revoked, or to provide remuneration in conjunction with termination of employment as a result of an offer made to encourage voluntary redundancy. Benefits due more than 12 months after the closing date are discounted at their present value.

#### (d) Accounting policies for bonus plan

The Group has a bonus system that covers members of the Executive Management team and key persons. The bonus system is based on achievement of company goals and is paid out in proportion to annual salary. During the fiscal year, the estimated bonuses vested for the year are calculated and expensed. Payment of the vested bonus is made in the subsequent year, normally in June.

#### 2.19 Revenue recognition

Revenues comprise the fair value of goods and services sold, excluding value-added tax, rebates, returned goods and after eliminated intra-Group sales. Revenues are recognized as follows:

#### a) Sale of goods

Revenues from the sale of goods are recognized on the date of delivery to the customer, that is, the date on which ownership rights are transferred to the customer, who thereby assumes the financial risk. The subsidiary Orexo US Inc is the company where there is sale of goods.

Revenues are recognized when they are invoiced to the wholesaler. Goods purchased from Orexo may be returned, and thus provision is made for expected returns.

#### b) License revenues

Orexo's license agreements usually include one or more of the following types of income:

- A lump-sum payment on the signing of the agreement normally without repayment obligation. This normally pertains to the right to register, market and sell Orexo's patent-protected products within a particular geographic area, or it may also constitute payment for the transfer of technology or know-how to the business partner. In the event a lump-sum payment covers more than one delivery (for example, the transfer of rights and technology), income is distributed on the basis of the fair value for each part-delivery.
- Payment for research collaboration. These payments are received on an ongoing basis and are recognized over the period to which they pertain and during which the work is conducted. Milestone payments are triggered when a research target or sales target is attained in line with the definitions in each agreement, such as the granting of a patent, termination of clinical testing or approval of registrations. Such payment is recognized when all the terms and conditions pursuant to the agreement have been met.

#### c) Royalty revenues

Royalties are normally received on a rolling basis when distributors recognize sales. Recognition is in the same period during which sales were made. When royalties are paid in advance, the revenue is recognized in the periods that payment is for.

#### d) Interest income

Interest income is recognized over the time to maturity using the effective interest method.

#### 2.20 Leasing

Leasing is classified in the consolidated financial statements either as financial or operational leasing, pursuant to IAS 17, Leasing Agreements. Financial leasing is the case when the financial risks and benefits associated with ownership are essentially transferred to the lessee. In other cases, leasing is operational leasing.

In the case of agreements classified as financial leasing, the object is recognized as a fixed asset in the consolidated balance sheet.

#### 2.21 Cost of goods and services sold

The cost of goods sold comprises the materials cost for the products the Group itself sells on the market. The cost of services sold, relating to research collaborations, is recognized as development costs.

#### NOTE 3 FINANCIAL RISK MANAGEMENT

The Group's operations is exposed to a number of risks. These risks can be categorized into operational risks and financial risks. The financial risks are described below.

#### Financial risks and policies

To efficiently manage financial risks, Orexo has drawn up a series of guidelines and a detailed financial policy in respect of the manner in which such risks are to be managed and mitigated. Orexo's financial policy also establishes the distribution of responsibility and reporting instructions for Executive Management. The main purpose of Orexo's financing operation is to limit negative deviations in the financial results, shareholders' equity and cash flow as the result of fluctuations in interest rates or exchange rates and underlying market conditions.

The President of the Group is responsible for producing, implementing and following up the Group's financial policy, which is subsequently approved by the Board of Directors. The Group's CFO is responsible for the day-to-day financial administration and reports regularly to the Group President.

#### 3.1. Currency risks

Orexo's financial statements are prepared in SEK. The Group sells its products in countries other than Sweden and receives revenues in currencies other than SEK, primarily in dollars, euros and pounds. The company's American subsidiary, Orexo US Inc., has expenses in USD. Revenues and expenses in foreign currency give rise to transaction exposure. The Group has assets (accounts receivable) and liabilities (accounts payable) in foreign currencies, as well as investments in the form of net wealth in foreign subsidiaries. This gives rise to translation exposure.

A substantial share of Orexo's transaction exposure is attributable to the sale and manufacture of Zubsolv® in the US and royalty income for the Group's products in currencies other than SEK. The license agreements written with counterparties are frequently denominated in some other currency than SEK, primarily USD, EUR or GBP.

The Group has the option of hedging transaction exposure. The financial policy permits exchange-rate hedging instruments to be used to eliminate or minimize the currency risks arising in the Group. Currency hedging must always be linked to a confirmed underlying exposure. The permitted hedging instruments are currency futures, acquired currency options (call and put options), currency accounts and loans in foreign currency.

A substantial share of Orexo's sales is in currencies other than SEK, primarily USD, which leads to a certain amount of currency exposure. During the 2015 fiscal year, sales in USD accounted for 71 percent (42) of net revenues, with sales in EUR accounting for 11 percent (13) and sales in GBP for 10 percent (35). During the same period, 84 percent (81) of total operating expenses were in foreign currency with 97 percent (93) in USD, 1 percent (5) in EUR and 2 percent (2) in GBP.

In currencies in which the Group has flows in the same currency, the flows are to be matched to the greatest extent possible.

A change in value of USD against SEK of 10 percent entails a change in revenues of approximately MSEK 44 and in expenses of about MSEK 49.

The corresponding change in EUR entails a change in revenues of approximately MSEK 7 and has no material impact in expenses, and in GBP a change in revenues of approximately MSEK 7 and has no material impact in expenses. The effect of the change in the value of USD on earnings is due to the fact that a large part of the Group's revenues and expenses are attributable to manufacturing and sales of Zubsolv, which are in the US. Translation exposure arises when the Group's equity is influenced by exchange-rate fluctuations when assets and liabilities for foreign subsidiaries are translated to SEK. This exposure is not hedged at present. A 10 percent movement in USD entails an impact on equity of approximately MSEK 9.

#### 3.2 Interest-rate risk

The primary objective of Orexo's interest-rate risk management is to reduce the negative effects of interest-rate movements on earnings. To reduce the impact of interest-rate movements on earnings, Orexo mainly uses short-term investments and aims for the time to maturity of financial liabilities to correspond as far as possible to the time to maturity of financial assets. At year-end, all of Orexo's cash and cash equivalents were invested in short-term assets.

Orexo's policy is that all financial investments apart from bank balances must be made in financial instruments with high liquidity and low credit risk

The Group had interest-bearing liabilities totaling MSEK 494.3 on December 31, 2015 and these are attributable to a corporate bond loan. This loan has a variable interest rate, STIBOR + 4 percent (STIBOR is calculated as zero at the lowest).

The impact on earnings of a change in interest rates of 0.5 percent would entail an increase/decrease of MSEK 2.5.

#### 3.3 Credit risk and counterparty risk

Credit and counterparty risk is the risk that the counterparty will not fulfill its undertakings to repay a liability or pay interest on such a liability and the risk associated with balances with credit institutions.

For the Group, there are mainly three categories of payment flows in which credit risks could arise: in the subsidiary Orexo US Inc's sales to distributors, in the payment flows from Orexo's license agreements with other parties and in the investment of surplus liquidity in bank instruments.

With regard to Orexo US Inc's distributors, credit risks are reviewed on an ongoing basis based on the customer's financial position and other factors.

An extensive evaluation of the counterparty is always undertaken prior to the signing of a license agreement.

Accounts receivable are continuously monitored, with checks performed on due customer invoices. Of total accounts receivable at December 31, 2015, the four largest customers accounted for 88 percent. No other single customer accounted for more than 2 percent of total accounts receivable. Note 14 presents the amounts due.

The Group's financial transactions shall only be carried out with banks or financial instruments with an official rating not below A1/P1/K1.

#### 3.4 Financing risk

Liquidity risk is defined as the risk that Orexo will be unable to fulfill its undertakings to repay or refinance its debts on time or at a reasonable cost. Liquidity risk is managed by means of sufficient cash and cash equivalents to ensure continuing operations.

Cash flow forecasts are prepared each month. Executive Management continuously monitors forecasts to ensure that the Group has sufficient cash funds to meet the requirements of continuing business operations.

The table below shows the Group's contractual non-discounted cash flows from financial liabilities, distributed on the basis of the period remaining to maturity on the closing date.

At December 31, 2015	Less than 1 year	Between 1 and 2 years	Between 2 and 5 years
Accounts payable	34,893		_
Accrued costs	20,328		_
Borrowings	22,500	530,000	_

At December 31, 2014	Less than 1 year	Between 1 and 2 years	Between 2 and 5 years
Accounts payable	28,850		
Accrued costs	24,712		
Borrowings	25,082	46,902	507,500

At December 31, 2013	Less than 1 year	Between 1 and 2 years	Between 2 and 5 years
Accounts payable	138,009		
Accrued costs	37,169	_	
Borrowings	141,868	105,375	1,810

#### 3.5 Commercial market risk and inventory risk

Orexo's most important market risks are price pressure, limited price subsidies and the launch of new competing products.

To be successful in the US it is of the utmost importance that Zubsolv® obtains price subsidies on a par with those of competitors. This takes time to achieve in the large and complex American insurance system. Orexo has a market access team of experienced employees whose sole task is to improve Zubsolv's price subsidies.

Contacts with insurance companies and public payers in the US market are often tendered and the process to win is highly competitive. Contracts once won can be lost in later tender processes, like the example with CVS Caremark, that in 2015 announced that Zubsolv would no longer be on their list of preferred products for 2016. The market acess team constantly work with payers to improve patient acess to an reimbursement of Zubsolv.

Orexo's products are sold in a market characterized by tough competition from other products and methods of treatment, and there is always a risk that competitors launch new products. In all of Orexo's markets there is intense development of new and improved treatments that can prove to have a better clinical effect than those that already exist.

Orexo is constantly and proactively working to analyze these risks and develop action plans for different market scenarios. This work is done in collaboration with local external specialists.

In order to secure delivery of the products which are critical for patients, Orexo must hold considerable inventories of Zubsolv. High inventory levels

entail a risk of impairment of products that have expired. Orexo is constantly working to minimize this risk by adapting inventories to demand, and through the work on improving the product's shelf life.

#### 3.6 Capital structure

The Group's objective for its capital structure is to safeguard the Group's ability to continue its operations so it can generate a return for the share-holders and benefits for other stakeholders, as well as maintain an optimum capital structure to keep capital costs down.

The Group's capital is assessed on the basis of its equity/assets ratio. The equity/assets ratio at December 31, 2015, 2014 and 2013 is presented in the table below.

	2015	2014	2013
Shareholders' equity	266,459	455,023	161,459
Total assets	1,016,304	1,225,886	772,330
Equity/assets ratio	26%	37%	21%

#### 3.7 Financial instruments valued at fair value

The table below shows financial instruments valued at fair value, on the basis of how they are classified in the fair value hierarchy.

Level 1: Listed prices in derivative markets for identical assets and liabilities. Level 2: Observable data for assets or liabilities other than listed prices included in level 1.

Level 3: Data for assets or liabilities not based on observable markets.

At December 31, 2013	Level 1	Level 2	Level 3
Financial assets/liabilities that can be sold			
Bank loans	_	241,074	
Total assets/liabilities	-	241,074	_
At December 31, 2014	Level 1	Level 2	Level 3
Financial assets/liabilities that can be sold			
Listed securities	1,158	_	_
Bank loans	_	4,330	_
Bond loans	_	500,000	-
Total assets/liabilities	1,158	504,330	_
At December 31, 2015	Level 1	Level 2	Level 3
Financial assets/liabilities that can be sold			
Listed securities	2,060	_	_
Bond loans	_	450,000	_
Total assets/liabilities	2,060	450,000	_

The fair values of listed securities are based on the current market value of the shares at the closing date.

The fair value of the bond loan is established using valuation techniques. When doing this, market information has been used wherever possible when this is available, while company-specific information is used as little as possible.

#### NOTE 4 ACCOUNTING POLICIES OF THE PARENT COMPANY

#### 4.1 Basis for preparation of the financial statements

Orexo AB, the Parent Company, has prepared its annual accounts in accordance with the Swedish Annual Accounts Act and the Swedish Financial Accounting Standards Council's recommendations RFR 2. RFR 2 stipulates that the Parent Company must apply International Financial Reporting Standards (IFRS) as adopted by the EU, to the extent that this is possible within the framework of the Swedish Annual Accounts Act and the Pension Obligations Vesting Act and taking into account the relationship between accounting and taxation. The recommendation specifies the exceptions and additions to be made in relation to IFRS.

Consequently, the Parent Company applies the policies presented in Note 2 of the consolidated financial statements, with the exceptions outlined below. The policies are applied consistently to all years presented, unless otherwise stated.

Preparing financial statements that comply with applicable regulations requires the use of some important estimates for accounting purposes. Furthermore, it is required that Executive Management conducts certain assessments in the application of the company's accounting policies. The areas that involve a high degree of complex assessment or areas in which assumptions and estimates are of material importance for the company's Annual Report are outlined in Note 5.

#### Presentation forms

The statement of operations and balance sheet comply with the forms set down in the Swedish Annual Accounts Act, meaning that the differences compared with the consolidated financial statements primarily pertain to financial income and expenses, provisions and the statement of changes in shareholders' equity.

#### 4.2 Segment reporting

Information is provided only on the distribution of net revenues by geographic markets.

#### 4.3 Shares and participations in subsidiaries

Shares and participations in subsidiaries are recognized at cost with deductions for any impairment. Additional purchase prices are recognized as payment for future services included in the cost. Dividends received are recognized as revenues insofar as they derive from profits earned after the acquisition. Dividends that exceed these profits are regarded as a repayment of investment and reduce the carrying amount of the participation.

When there are indications that shares and participations in subsidiaries have declined in value, an estimate is made of the recoverable amount. If this is lower than the carrying amount, impairment is applied. Impairment

losses are recognized in the items "Results from participations in Group companies".

#### 4.4 Financial instruments

Financial assets are classified in a different manner in the Parent Company's balance sheet than in the consolidated balance sheet. The notes on the financial assets show the manner in which the items in the balance sheet relate to the classification used in the consolidated balance sheet and in the consolidated accounting policies. The company applies measurement at fair value in line with the Swedish Annual Accounts Act (ÅRL) 4: 14 a-d and the description of the accounting policies in Note 2 for the Group thus also applies to the Parent Company, except as regards accounting for the effects on earnings.

#### 4.5 Group and shareholders' contributions

Shareholders' contributions granted are recognized as an increase in the value of shares and participations. An assessment is then made as to whether there is a need for impairment of the value of the shares and participations in question.

In the recognition of Group contributions, the Group can either apply the main rule or the alternative rule. The rule chosen shall be applied consistently to all Group contributions.

Under the main rule, Group contributions received from subsidiaries are recognized as revenue in the Parent Company's statement of operations and Group contributions granted by the Parent Company are recognized as an increase in participations in affiliated companies. In the subsidiaries both contributions granted and contributions received are recognized as equity.

Under the alternative rule, both contributions received and contributions granted are recognized as appropriations. The Group did not have any Group contributions during the period.

#### 4.6 Deferred income tax

Amounts allocated to untaxed reserves represent taxable temporary differences. Due to the relationship between accounting and taxation, however, in a legal entity deferred tax liabilities on untaxed reserves are recognized as part of untaxed reserves.

#### 4.7 Leasing

All leasing agreements, irrespective of whether they are financial or operational, are recognized as operational leasing (rental agreements).

#### NOTE 5 CRITICAL ACCOUNTING ESTIMATES AND JUDGEMENTS

Estimates and judgments are continuously evaluated and are based on historical experience and other factors, including expectations of future events deemed reasonable under prevailing circumstances.

#### 5.1 Critical estimates and assessments for accounting purposes

The Group makes assessments and assumptions about the future. The resulting accounting estimates will, by definition, seldom correspond to the actual results. Estimates and assumptions that entail a significant risk of material adjustment to the recognized amounts of assets and liabilities during the next fiscal year are outlined below.

#### (a) Impairment testing of acquired research and development

Research and drug development are characterized by significant operative risks. Several factors affect the probability of a drug project resulting in an approved preparation. The risk of not reaching the market diminishes as a project passes through the various phases in the research and development process. At December 31, 2015 the Group had one acquired R&D project in the clinical phase.

The value of acquired R&D is tested annually to ensure that the carrying amount does not exceed the recoverable amount. This impairment testing includes experience-based estimates of the amount of future incoming and outgoing payments. The probability of the occurrence of income-generating events and the probability that the projects will result in products that reach the market are estimated based on available industry statistics. These probabilities vary depending on the phase of development that the R&D projects are in. Future incoming and outgoing payments are adjusted to the level of probability and subsequently discounted by applying a rate that reflects the cost of capital and risk. If an acquired R&D project were to be discontinued, the carrying amount of the project would be immediately written down to zero and the impairment loss would be charged to earnings. For further information, refer to Note 8.

There was impairment of acquired R&D of 62,277 during the year, which means that at December 31, 2015, acquired R&D amounted to 0 (62,277).

#### b) Impairment testing of proprietary intangible asset

The value of proprietary intangible assets is tested annually to ensure that the carrying amount does not exceed the recoverable amount. This impairment testing includes experience-based estimates of the amount of future incoming and outgoing payments. The probability of the occurrence of income-generating events and the probability that the projects will result in products that reach the market are estimated based on available industry statistics. These probabilities vary depending on the phase of development that the R&D projects are in. Future incoming and outgoing payments are adjusted to the level of probability and subsequently discounted by applying a rate that reflects the cost of capital and risk. For more information, see note 8.

During the year there was no impairment of proprietary intangible assets.

#### (c) Royalty revenues

Royalties may be impacted by external factors, including sales limitations or price regulations initiated by authorities in the countries in which sales are conducted. This is out of the control of the company and information of this nature does not normally reach the company until it is already too late. Because of this, it can be difficult to estimate royalty revenues, which in turn can lead to erroneous allocation to a particular period.

#### (d) Revenues from sale of goods

Revenues from Zubsolv are recognized when they are invoiced to wholesalers. Revenues for Zubsolv are now calculated as gross income invoiced to wholesalers, with a deduction for actual and estimated discounts to public and private insurance providers ("the payers"), provisions for potential

returns, costs for patient support programs and fees to wholesalers and distributors. As not all of the volume invoiced to wholesalers has reached patients at the closing date, several of the deductions from gross income are partly based on estimates.

#### (e) Inventory valuation

In order to ensure delivery of Zubsolv® in the American market, Orexo has established a substantial inventory level of raw materials, semi-finished products and finished products. The valuation of the inventory and the assessment of the risk of potential depreciation of receivables is based on continually updated market forecasts and assumptions regarding the shelf-life of various chemical compounds. In most cases, raw materials have long shelf-lives, while the shelf-life of semi-finished products and finished products is based on documented stability studies. During 2015 the shelf-life of semi-finished products and finished products was extended with regard to Zubsolv, based on positive stability data, thus reducing the risk of future depreciation.

### 5.2 Critical judgments in the application of the company's accounting policies

#### (a) Assessment as to whether a license agreement entails the divestment or a transfer of rights

Certain license agreements entail that global rights are transferred to a business partner. Since Orexo retains the intellectual property rights, which may be retrieved under certain circumstances, these agreements are not recognized as though the licensing agreement implies a divestment. For Orexo, this means that these assets remain in the balance sheet item "Acquired research and development".

During the year Orexo decided to write-down the OX-MPI project. Orexo still considers that OX-MPI is an attractive asset and will continue the dialog with potential partners, but as part of the annual testing of the value, the decision was taken to write down the value of the asset in its entirety. This write-down means that Orexo no longer has any acquired R&D left on the balance sheet

#### (b) Research and development

Costs attributable to research are expensed as they arise. Costs attributable to development projects are recognized as intangible assets in the balance sheet in cases in which these costs may be expected to generate future financial benefits. Other development costs are expensed as they arise. Development costs that are expensed are not recognized as an asset in subsequent periods. For 2015, these costs amounted to 172,576 (197,822).

As Orexo has now begun to independently conduct and finance development projects through to later phases, it is assessed that some of the Group's development expenditures meet the requirements stated in IAS 38 and may thereby be recognized as an asset. During 2015 the Group continued to recognize costs for two clinical studies and registration costs for

these as an asset amounting to KSEK 914. These studies belong to the application for an expanded area of use for Zubsolv which was approved by the FDA, the US Food and Drug Administration, in August 2015.

#### (c) Revenue recognition

Executive Management assesses the probability of whether future financial value will accrue to the Group on the basis of a number of factors, such as the customer's payment history and credit worthiness. If the Group deems a receivable to be doubtful, a provision is made until it is possible to determine whether or not the Group will receive payment.

During the year, the Group received lump-sum payments from a number of collaboration partners. These payments have been in the form of payments both with and without demands for future services in return from the Group. A licensing agreement permits Orexo's partners to register, market and sell the Group's patented products within a certain geographic area for a specified time. Lump-sum payments received and considered remuneration for this exclusivity are recognized directly. Wherever lump-sum payments are considered to be remuneration for future services in return, the revenue is distributed over time based on the implications of such services, e.g. when a lump-sum payment is received and a research collaboration agreement is in place, remuneration is distributed straight-line over the time the research collaboration continues.

A milestone payment is an item of revenue related to achieved goals specified in the agreement with the partner in question. Such goals may include the start of clinical trials or the granting of product registration approval by an authority. Revenues from intermediate milestone payments are recognized once the goal has been achieved and the Group has fulfilled its undertakings.

In 2012 Orexo and ProStrakan Group plc renegotiated the conditions of the commercial collaboration regarding Abstral, whereby the royalty conditions were restructured. The agreement means amongst other things that Orexo receives payments in the form of royalty revenues for sales of Abstral in ProStrakan's territories. Part of the royalty rate has been replaced by fixed one-time amounts, which are partly received earlier than what would probably have been the case otherwise. The fixed amounts that have been received have been allocated to future periods in order to reflect the financial thrust of the agreement. The final fixed royalty amounts were recognized in the statement of operations in May 2015. The agreement also includes variable royalties, which are entered as revenue as and when sales are made.

#### (d) Deferred tax assets

Orexo has significant loss carry-forwards as historically the company has made large losses. No value of the loss carry-forwards has been recognized in the balance sheet, as it is difficult to assess when the losses can be set off against surpluses. The loss carry-forwards for tax purposes in the Group amounted to MSEK 1,449 (1,340) at December 31, 2015.

#### NOTE 6 SEGMENT INFORMATION

The Group has defined its operating segments based on the information used by Executive Management to make strategic decisions and Executive Management assesses the operations as a single unit, meaning that the company has only one segment.

The Group's operations are conducted primarily in the geographic areas below. Sales figures are based on the country in which the customer is located. There are no sales between geographic areas.

	Group			Parent Company		
	2015	2014	2013	2015	2014	2013
Sales distributed geographically						
Sweden	13,690	10,924	10,615	13,828	16,102	12,032
UK	185,747	269,352	247,220	188,585	269,122	243,808
Other EU countries	2,013	9,829	6,684	_		_
East Asia	3,794	4,771	23,325	2,811	3,024	20,383
US	428,425	236,260	106,107	313,676	110,199	176,098
Other countries	9,669	39,180	35,405	_		
Total	643,338	570,316	429,356	518,900	398,447	452,321

The company's four largest customers combined account for 88 (80) percent of the company's net revenues. They contribute 29 (47) percent, 23 (12) percent, 18 (11) percent and 18 (10) percent, respectively.

Assets and investments outside Sweden amount to MSEK 1.0 (1.5).

#### NOTE 7 TANGIBLE FIXED ASSETS

Group	Equipment and machinery	Computers	Renovation of others' property	Art and non-depreciable equipment	Financial leasing	Total
Fiscal year 2013						
Opening balance	7,800	343	26,586	394	0	35,123
Purchases	2,037	616	=	=	=	2,653
Disposal	=	=	=	=	=	-
Depreciation	-2,481	-231	-1,809	=	=	-4,521
Exchange-rate differences	=	=	=	=	=	-
Closing balance	7,356	728	24,777	394	0	33,255
At December 31, 2013						
Cost	33,650	2,099	36,174	394	1,894	74,211
Accumulated depreciation and impairment	-26,294	-1,371	-11,397		-1,894	-40,956
Carrying amount	7,356	-1,5/1 <b>728</b>	24,777	394	-1,094 <b>0</b>	33,255
carrying amount	7,330	728	24,777	354	<u> </u>	33,233
Fiscal year 2014						
Opening balance	7,356	728	24,777	394	0	33,255
Purchases	94	541		12	=	647
Disposal	=	_	-126	=	-1,894	-2,020
Accumulated depreciation disposal	=	_		=	1,894	1,894
Depreciation	-2,706	-484	-1,807	=	=	-4,997
Exchange-rate differences	301	_		=	=	301
Closing balance	5,045	785	22,844	406	0	29,080
At December 31, 2014						
Cost	33,744	2,640	36,174	406	0	72,964
Accumulated depreciation and impairment	-28,699	-1,855	-13,330	_	0	-43,884
Carrying amount	5,045	785	22,844	406	0	29,080
carrying amount	3,043	703	22,044	400		23,000
Fiscal year 2015						
Opening balance	5,045	785	22,844	406	0	29,080
Purchases	82	251		_	_	333
Disposal	-	_	_	-	-	_
Accumulated depreciation disposal			-	_	-	_
Depreciation	-2,046	-513	-1,798	_	_	-4,357
Disposal through sale of subsidiary	-467	_	_	_	_	-467
Exchange-rate differences	96	_	_	_	_	96
Closing balance	2,710	523	21,046	406	0	24,685
At December 31, 2015						
Cost	32,965	2,879	36,174	406	-	72,426
Accumulated depreciation and impairment	-30,255	-2,356	-15,128	0	=	-47,741
Carrying amount	2,710	523	21,046	406	0	24,685

23,727 of the tangible fixed assets are attributable to the Parent Company. Leasing expenses amounting to 371 (627) (648) for the leasing of equipment, machinery and computers are included in the statement of operations.

#### NOTE 8 INTANGIBLE FIXED ASSETS

Group	Goodwill	Acquired R&D	Patents and rights	Proprietary intellectual property right	Other	Total
Fiscal year 2013	4004	noquilou nuz		property right		
Opening balance	25,827	106,200	0	=	3,059	135,086
Purchases	_	_	11,940	91,474	1,301	104,715
Disposal	_	_	_	_	_	_
Amortization	_		-1,622	-	-53	-1,675
Impairment	-	-43,923		-		-43,923
Exchange-rate differences	576			-		576
Closing carrying amount	26,403	62,277	10,318	91,474	4,307	194,779
At December 31, 2013	,		,	,		,
Cost	26,406	435,062	25,205	91,474	5,089	583,236
Accumulated amortization and impairment		-372,785	-14,887		-782	-388,454
Exchange-rate differences	-3	_		-		-3
Carrying amount	26,403	62,277	10,318	91,474	4,307	194,779
Fiscal year 2014						
Opening balance	26,403	62,277	10,318	91,474	4,307	194,779
Purchases	_	=	5,791	61,167	4,010	70,968
Disposal	_	=	=	_	=	_
Amortization	_	=	-6,553	_	-976	-7,529
Impairment	_	=	=	_	=	_
Exchange-rate differences	1,009	=	=	=	=	1,009
Closing carrying amount	27,412	62,277	9,556	152,641	7,341	259,227
At December 31, 2014						
Cost	26,403	435,062	30,996	152,641	9,099	654,201
Accumulated amortization and impairment	_	-372,785	-21,440	-	-1,758	-395,983
Exchange-rate differences	1,009	_	_	_	_	1,009
Carrying amount	27,412	62,277	9,556	152,641	7,341	259,227
Fiscal year 2015						
Opening balance	27,412	62,277	9,556	152,641	7,341	259,227
Purchases				914	2,829	3,743
Disposal	-	_	_	-	_	_
Amortization	-	_	-5,910	-6,408	-1,791	-14,109
Impairment	-	-62,277	_		_	-62,277
Disposal through sale of subsidiary	-26,974	_	_	-	-47	-27,021
Exchange-rate differences	-438		-	-	-	-438
Closing carrying amount	_	_	3,646	147,147	8,332	159,125
At December 31, 2015						
Cost	26,403	435,062	30,996	153,555	11,928	657,944
Accumulated amortization and impairment	-26,974	-435,062	-27,350	-6,408	-3,549	-499,343
Exchange-rate differences	571	=	=	=	-47	524
Carrying amount		_	3,646	147,147	8,332	159,125

#### Proprietary intangible asset at December 31, 2015

A proprietary intangible asset amounting to 147,147 (152,641) is attributable to expenses for clinical studies and a registration expense for these studies. Executive Management assesses that these will give the Group future economic benefits in the form of expanded use of Zubsolv. The expanded label approved by the FDA, the US Food and Drug Administration, in August 2015 and in conjunction with this amortization was begun.

#### Impairment testing of Proprietary intangible asset

The value of these assets is tested once a year to determine any impairment requirements, and also on other occasions if there are indications that impairment is necessary. There was no impairment of proprietary intangible assets during the year.

#### Acquired R&D at December 31, 2015

Acquired R&D amounting to 0 (62,777) is attributable to the OX-MPI project, that was part of the acquisition of Biolipox AB in 2007.

During the year Orexo decided to write down the OX-MPI project. Orexo still considers that OX-MPI is an attractive asset and will continue the dialog with potential partners, but as part of the annual testing of the value, the decision was taken to write down the value of the asset in its entirety.

When an acquired R&D project begins to generate sales revenues or royalties, planned amortization begins over the expected useful life. The acquired R&D projects have not yet begun to generate such revenues and thus no amortization has been applied.

#### Impairment testing of Acquired R&D

The value of acquired R&D projects is tested once a year to determine any impairment requirements, and also on other occasions if there are indications that impairment is necessary.

Research and drug development are characterized by significant operative risks. The risk that a project will not result in a product that reaches the market diminishes as the project passes through the various phases of the development process. The R&D projects acquired by the company are all in the early phases. If a project is closed down, the result is impairment and removal of the project from the balance sheet. There was impairment of acquired research and development of 62,277 during the year.

Parent Company	2015	2014	2013
Accumulated cost			
Opening cost	187,900	116,931	12,367
Purchases during the year	3,743	70,969	104,564
Disposals and scrapping	_	-	_
Closing accumulated cost	191,643	187,900	116,931
Accumulated amortization according to plan			
Opening amortization according to plan	-18,423	-10,930	-9,308
Amortization during the year according to plan	-14,095	-7,493	-1,622
Disposals and scrapping	-	_	_
Closing accumulated amortization according to plan	-32,518	-18,423	-10,930
Carrying amount	159,125	169,477	106,001

Parent Company intangible assets comprise patents, rights, a proprietary intellectual property right and IT systems.

Most of the assets that were capitalized during the year are proprietary intellectual property and IT systems.

#### NOTE 9 DEPRECIATION/AMORTIZATION AND IMPAIRMENT

Depreciation, amortization and impairment are divided up into type of cost as follows:

		Group		Parent Company		
	2015	2014	2013	2015	2014	2013
Tangible fixed assets						
Sales	390	214	96	_	_	_
Administration	1,903	2,284	1,892	1,823	1,852	1,892
Research and development	2,064	2,499	2,533	1,952	2,499	2,516
Total tangible fixed assets	4,357	4,997	4,521	3,775	4,351	4,408
Intangible assets						
Sales	_	=	-	_	_	-
Administration	11	_	-	11	_	-
Research and development	8,187	976	53	8,173	939	-
Cost of goods sold	5,911	6,554	1,622	5,911	6,554	1,622
Other operating expenses	62,277	_	43,923	_	_	_
Total intangible assets	76,386	7,530	45,598	14,095	7,493	1,622
Financial assets						
Other financial expenses	_	_	_	63,896	-	_
Total financial assets	_	_	-	63,896	-	-
Total depreciation/amortization and impairment	80,743	12,527	50,119	81,766	11,844	6,030

#### NOTE 10 SHARES IN SUBSIDIARIES

Direct and indirect holdings Dec 31, 2015	Corp. Reg. No.	Reg. office	Number of shares	Shareholding	Cost/Contribution	Accumulated impairment	Carrying amount
Pharmacall AB	556569-1739	Uppsala	1,000	100%	100	0	100
Biolipox AB	556588-3658	Stockholm	12,883,944	100%	505,773	399,840	105,933
Pharmakodex Ltd	05268159	UK	684,664	100%	82,245	82,245	0
Orexo US Inc	0101013414	US	100	100%	42,471	0	42,471

The Group divested the subsidiary Group Kibion AB during the year.

Change in carrying amount of direct holdings

	Opening						Closing
2013	carrying amount	Cost	Contribution	Sales	Impairment	Disposal	carrying amount
Pharmacall AB	100	_	=	-			100
Kibion AB	=	_	-	_	-		_
Orexo US Inc	_	32,249	_	_	_		32,249
Biolipox AB	169,829	_	-	_	-		169,829
Pharmakodex Ltd	2,239	_		_	_	2,239	
Total	172,168	32,249	_	_	-	2,239	202,178
2014							
Pharmacall AB	100	_	-	_	-		100
Kibion AB	=	_	-	_	-		_
Orexo US Inc	32,249	_	6,675	_	-		38,924
Biolipox AB	169,829	_		_	-		169,829
Pharmakodex Ltd	=	-	-	_	-	_	_
Total	202,178	-	6,675	_	-	-	208,853
2015							
Pharmacall AB	100		_		_	_	100
Orexo US Inc	38,924	_	3,547	_	-		42,471
Biolipox AB	169,829		_		63,896		105,933
Pharmakodex Ltd	-	_	-	_	-	_	_
Total	208,853	-	3,547	-	63,896	-	148,504

#### NOTE 11 FINANCIAL INSTRUMENTS BY CATEGORY

December 31, 2013	Derivatives used for hedging purposes	Loans and accounts receivable	Other financial liabilities	Financial assets that can be sold	Total
Assets in the balance sheet					
Accounts receivable and other receivables (excluding interim receivables)		36,146			36,146
Cash and cash equivalents		105,643			105,643
Total		141,789			141,789
Liabilities in the balance sheet					
Borrowings (excl. liabilities in respect of financial leasing)			241,074		241,074
Accounts payable and other liabilities (excl. non-financial liabilities)			267,802		267,802
Total			508,876		508,876
December 31, 2014					
Assets in the balance sheet					
Accounts receivable and other receivables (excluding interim receivables)		142,135			142,135
Cash and cash equivalents		284,480			284,480
Financial assets that can be sold				1,158	1,158
Total		426,615		1,158	427,773
Liabilities in the balance sheet					
Borrowings (excl. liabilities in respect of financial leasing)			496,236		496,236
Accounts payable and other liabilities (excl. non-financial liabilities)			113,444		113,444
Total			609,680		609,680
December 31, 2015					
Assets in the balance sheet					
Accounts receivable and other receivables (excluding interim receivables)		176,186			176,186
Cash and cash equivalents		198,124			198,124
Financial assets that can be sold				2,060	2,060
Total		374,310		2,060	376,370
Liabilities in the balance sheet					
Borrowings (excl. liabilities in respect of financial leasing)			494,334		494,334
Accounts payable and other liabilities (excl. non-financial liabilities)			55,221		55,221
Total			549,555		549,555

#### NOTE 12 FINANCIAL ASSETS THAT CAN BE SOLD

	Group			Parent Company		
	2015	2014	2013	2015	2014	2013
Listed securities – US	2,060	1,158	_	-	_	_
Total	2,060	1,158	_	-	-	_

The subsidiary Biolipox AB received a milestone payment during 2014 which was paid in the form of listed securities. The value at the time of acquisition amounted to 1,676. During the fiscal year 2015 impairment of 902 was reversed. These shares are listed on NASDAQ in the US.

#### NOTE 13 INVENTORIES

	Group Parent Company					
	2015	2014	2013	2015	2014	2013
Raw materials and work in progress	272,214	380,786	305,685	272,214	378,399	303,292
Finished products	126,711	97,358	77,725	4,595	=	
Total	398,925	478,144	383,410	276,809	378,399	303,292

#### Group

The cost of inventories expensed is included in the items "Cost of goods sold" and "Research and development costs" and amounted to 120,229 (91,836) (21,790).

#### Parent Company

The cost of inventories expensed is included in the items "Cost of goods sold" and "Research and development costs" and amounted to 139,978 (50,319) (83,895).

#### NOTE 14 ACCOUNTS RECEIVABLE AND OTHER RECEIVABLES

	Group			Parent Company		
	2015	2014	2013	2015	2014	2013
Accounts receivable	164,178	142,135	36,146	284,171	92,616	98,484
VAT receivable	1,857	3,338	4,433	1,857	2,672	3,912
Other receivables	15,243	3,974	3,525	25,786	130,767	68,033
Prepaid rents	4,095	4,119	5,606	4,095	4,053	4,956
Other interim receivables	48,012	20,231	5,533	4,778	2,572	4,115
Total	233,385	173,797	55,243	320,687	232,680	179,500

#### Group

## Impairment losses on accounts receivable amounted to 0 (148) (0). The carrying amount corresponds to fair value since all receivables are current and are due within one year

#### **Parent Company**

Impairment losses on accounts receivable amounted to 0 (0) (0). The carrying amount corresponds to fair value.

Carrying amounts per currency for the Group's accounts receivable are as follows:

	Group			Parent Company		
	2015	2014	2013	2015	2014	2013
SEK	3,288	2,823	4,586	3,288	124	2,638
USD	125,761	98,900	3,767	245,754	63,910	80,103
EUR	35,129	40,314	27,578	35,129	28,582	15,743
Other currencies	-	98	215	_	_	
Total	164,178	142,135	36,146	284,171	92,616	98,484

#### Accounts receivable due

At December 31, 2015, accounts receivable amounting to 121,829 (12,525) (5,733) fell due for payment without any impairment requirement being considered necessary.

These apply to a few independent customers who have previously settled their overdue invoices. An age analysis of these accounts receivable is presented below:

	Group			Parent Company		
	2015	2014	2013	2015	2014	2013
Less than 43 days	120,000	8,241	5,006	2,194	_	
44 days and older	1,829	4,284	727	1,048	_	_
Total	121,829	12,525	5,733	3,242	_	_

#### NOTE 15 CASH AND CASH EQUIVALENTS

	Group			Group Parent Company		
	2015	2014	2013	2015	2014	2013
Cash and bank balances	198,124	284,480	105,643	114,003	247,162	48,652
Total	198,124	284,480	105,643	114,003	247,162	48,652

#### Credit quality of financial assets

The credit quality of financial assets that have neither fallen due for payment nor are in need of impairment can be assessed by referring to an external credit rating (if available) or to the counterparty's payment history. All of the Group's financial assets have the credit rating A1-.

#### **Shares outstanding**

As of December 31, 2015, the number of shares outstanding in the company was 34,580,810, of which 135,000 were C shares and the rest common shares. All common shares carry one voting right and the C shares carry 1/10 of a voting right each. The quotient value of each share is 0.4.

The change in the number of shares during the year is shown in the table below. All shares issued have been fully paid for.

During the year Orexo AB resolved to carry out a new share issue and immediately afterwards bought back 135,000 C shares. The shares were issued and bought back in accordance with the performance-based incentive program, LTIP 2015, which was adopted by the Annual General Meeting on April 15, 2015.

Orexo AB bought back 1,121,124 Orexo shares on Nasdaq Stockholm during 2012. The total amount that was paid for the shares was MSEK 53. These shares were sold during 2014 for a value of MSEK 155.8.

Shares outstanding at December 31, 2013	32,911,908
Subscription for shares through conversion of convertible	1,371,922
Subscription for shares through exercise of employee stock op-	
tions	61,867
Shares outstanding at December 31, 2014	34,345,697
Subscription for shares through new issue	135,000
Subscription for shares through exercise of employee stock op-	
tions	100,113
Shares outstanding at December 31, 2015	34,580,810

In December 2015, 2,953 Board stock options were exercised. At December 31, these had not yet been registered as shares.

#### Authorization from the Annual General Meeting

At the Annual General Meeting on April 15, 2015, the Board received authorization, upon one or more occasions, with or without deviation from shareholders' preemptive rights, against cash payment, through offsetting or through a non-cash consideration, or otherwise subject to certain conditions, to resolve to issue new shares. However, such share issues may not result in the company's registered share capital or number of shares in the company increasing by more than a total of 10 percent, or result in the company's share capital exceeding the highest share capital permitted at any given time in accordance with the Articles of Association.

Development of share capital

	•	Change in number	Change in share	Total number of	Total share capital	Quotient value
Year	Transaction	of shares	capital (SEK)	shares	(SEK)	(SEK)
2014	New issue <sup>1</sup>	1,371 922	548,766	34,283,830	13,713,532	0.4
2014	New issue <sup>2</sup>	61,867	24,747	34,345,697	13,738,279	0.4
2015	New issue <sup>3</sup>	135,000	54,000	34,480,697	13,792,279	0.4
2015	New issue <sup>4</sup>	100,113	40,045	34,580,810	13,832,324	0.4

New issue of 1,371,922 shares.

#### Share-based payments

Orexo has introduced share-based payments in the form of share awards, employee stock options and warrants designed to motivate and reward through ownership, thereby promoting the company's long-term interests.

Ownership rights to the warrants have been transferred on commercial terms to employees or other participants in the incentive program directly through allotment, while the stock options and share awards are vested, provided that the holder remains employed or is a Board member in Orexo on this date.

At December 31, 2015, there were a total of 1,894,965 options outstanding, providing an entitlement to subscription of 1,777,728 new shares in

Orexo and the exchange of 117,237 options against shares in Orexo. The number of options issued by Biolipox AB is 35,873 and each option entitles the holder to exchange it for one share in Orexo AB and a corresponding number of shares is held by the independent company Pyrinox AB. The number of share awards is 81,364 and each share award provides entitlement to one share.

The table on the next page shows a summary of the changes in the number of options and share awards outstanding during the period January 1, 2015 to December 31, 2015, split across each category.

New issue of 61,867 shares through the exercise of 41,698 employee stock options.

<sup>3</sup> New issue of 135,000 C shares.

New issue of 100,113 shares through the exercise of 100,113 employee stock options.

	Opening Jan 1, 2015	Change	Closing Dec 31, 2015	Redeemable
Options/share awards directed at Board and employees				
Of which: Approved and allotted employee/Board stock options and share awards	2,049,438		2,049,438	
Exercised	, , , , , , ,	-103,066	-103,066	
Forfeited		-214,684	-214,684	
Allotted		127,404	127,404	
Approved, unallotted stock options <sup>2</sup>	497,417		497,417	
Total options/share awards directed at Board and employees Employee stock options utilized from Biolipox AB (non-diluting, included in newly issued shares in conjunction with acquisition of Biolipox)	<b>2,546,855</b> 689	-190,346	<b>2,356,509</b> 689	1,045,246
Forfeited		-689	-689	
Warrants taken over from Biolipox for cash flow hedging of social security fees (non-diluting)	36,473	-600	35,873	
Total options from Biolipox <sup>1</sup>	37,162	-1,289	35,873	35,873
Total outstanding options and share awards	2,584 017	-191,635	2,392,382	

The average exercise price during the year was SEK 40.33 per share.

Average subscription price per category

	Outst.					Outst.	
Category	Jan 1, 2015	Additional	Allotted	Redeemed	Forfeited	Dec 31, 2015	Redeemable
Employee/Board stock options, Orexo AB	75.98	_	130.08	40.33	118.49	74.39	54.36
Hedge warrants, Biolipox AB	0.25	_	_	0.25	_	0.25	0.25

#### Exercised during the year

During the period January – December 2015, 103,066 Board/employee stock options from Orexo's options programs were exercised.

#### Allotment during the year

94,904 share awards were allotted free of charge during 2015. Of these share awards, 50% are time-based and 50% are share-price based. The final date for exercising these options is June 16, 2018. During 2015 32,500 performance shares were also allotted, of which 50% are time-based and 50% share-price based. The final date for exercising these options is February 16, 2019. The financial and operational targets for 2015 did not meet the 80% threshold set by the Board of Directors in relation to the LTIP 2015 program and hence the share awards pertaining to performance target 1 under this program will forfeit in 2016.

The market value of the time-based portion of the shares was determined using the Black&Scholes method, while a Monte Carlo simulation was used for the share-price based portion. The market values and subscription prices are presented in the following table:

LTIP allotment 2015	Number	Allotment price	time-based	Market value share-price based portion
I TIP allotment		p00	portion	Buccu portion
January 16, 2015	25,000	129.2	57.04	51.4
LTIP allotment				
February 17, 2015	7,500	133.0	32.10	25.7
LTIP allotment				
June 16, 2015	94,904		39.76	34.5
	127,404			

- Risk-free rate of interest: -0.18 0.43 percent
- volatility: 35%
- estimated dividend: SEK 0

#### Performance criterion LTIP 2011

#### Performance criterion 1

For any vesting of Share-Price Based Performance Shares to occur, the increase in the Share Price shall correspond to the amounts set forth below. The increase in the Share Price as set forth below shall be calculated for a period not exceeding five years, meaning that the Share Price must have been achieved within a continuous five-year period.

Increase in	Vesting percentage of Share-Price Based Performance Shares (also conditional upon the fulfilment of
> 60 percent	Performance Criterion 2 below)  33 percent
> 100 percent	66 percent
> 150 percent	100 percent

These categories correspond to a five-year average return performance of approximately 10 percent, 15 percent and 20 per cent per annum, respectively.

#### Performance criterion 2

In addition to satisfaction of Performance Criterion 1, for any vesting to occur the Share Price shall have outperformed the NASDAQ OMX Stockholm Biotechnology PI Index for a 90-day period immediately prior to such day when Performance Criterion 1 above is satisfied. The determination of satisfaction of Performance Criterion 2 shall be made continuously as long as Performance Criterion 1 is satisfied, where the above-mentioned 90-day period shall be the period immediately prior to each such determination.

The Board shall be entitled to determine that Performance Shares have not been vested to the extent that it has been established that vesting has occurred on the basis of manifestly misstated information.

#### Performance criterion LTIP 2015

#### Performance Criterion 1

This target pertains to the fulfilment of the financial and operational targets for the financial year 2015 as established by the board of directors and relates to Orexo's key KPIs as for example revenue, profitability and achieved milestones, etc. Performance achievement of individual targets is weighted into an overall average performance achievement. The outcome will be measured lineally, meaning that none of the Share Awards will vest unless a minimum threshold of 80 percent of the overall average performance of the financial and operational targets is achieved, and all Share Awards will vest and entitle to one share each if 100 percent of the overall average performance is achieved. When calculating the overall performance achievement, individual targets may account for a maximum of 120 percent achievement, but the overall average performance is capped at 100 percent. If the minimum threshold is achieved 80 percent of Share Awards subject to Performance Target 1 will vest.

All data regarding options issued by Biolipox AB are restated using a factor of 0.45854, which corresponds to the computed value of the options related to the share price for the Orexo share on the acquisition date. The reported data regarding the options issued by Biolipox refers to the number of shares for which each option may be exchanged after recalculation.

<sup>2</sup> All 497,417 unalloted options will be cancelled due to new LTI program implemented during 2015

#### Performance Criterion 2

This target pertains to the development of the Orexo share price over the period from the date of the annual general meeting 2015 up to and including April 14, 2018. The share price will be measured as the volume weighted average share price 20 trading days prior to measurement date. Measurement dates are date defined as date of the annual general meeting 2015 and April 14, 2018. Should the Orexo share price increase by 60 percent, then 100 percent will be allotted, 66 percent will be allotted should the Orexo share price increase by 40 percent and 33 percent will be allotted should the Orexo share price increase by 20 percent. In between these figures, allotment of shares on the basis of the Share Awards will occur linearly. These categories correspond to a three-year average annual increase of approximately 17 percent, 12 percent and 7 percent per annum. In addition to satisfaction of the Performance Target 2 set out above, for any vesting to occur, the development of the Orexo share price shall have outperformed the Nasdaq Stockholm Pharmaceuticals & Biotechnology PI during the measurement period from the date of the annual general meeting 2015 up to and including April 14, 2018.

#### Forfeited options during the year

214,684 performance shares have been forfeited during 2015, both because employees have left the company and because performance criteria have not been met.

#### Costs related to company option programs

The company's expenses for the employee stock option program for 2015 amounted to MSEK -10.2 (5.7).

The expenses for the programs pertain both to estimated costs for the value of the employee vesting during the period, marked-to-market at the time of allotment, as well as the vested portion during the period of the estimated payroll overhead on the changes in value. The company will need to pay social security fees on the gain that may arise in conjunction with the exercise of employee stock options, calculated as the difference between the exercise price of the stock option and the market value of the share. The reduced costs are due to reduced provisions for social security fees due to the performance of Orexo's shares during the year.

#### Detailed description of changes during the year

The table on the next page provides a detailed description of Orexo's share-based incentive program in respect of changes during the year, subscription prices, lifetimes and potential dilution.

	Number of shares to which securities provide	Supplement	Allotment	Redeemed	Forfeited	Number of shares to which securities provide s	Sub- scription		Number of shares and
Type of security	entitlement at Jan 1, 2015	during the year	during the year	during the year	during the year	entitlement at Dec 31, 2015	price (SEK)	Program runs until	voting rights <sup>1</sup>
Approved and allotted options									
Employee stock options									
2005/2006	30,600				-30,600		113	Dec 31, 2015	
Employee stock options 2006/2016 Employee stock options	39,275			-1,200	-4,625	33,450	119	Dec 31, 2016	
2007/2017	28,500	_	_	-6,500	_	22,000	44	Dec 31, 2017	
Board stock options 2008/2015 Employee stock options	2,953	_	-	-2,953	_		0.4	Dec 31, 2015	
2008/2018	39,625			-8,375		31,250	51	Dec 31, 2018	
Board stock options 2009/2016	4,259	_	_	_	_	4,259	0.4	Dec 31, 2016	
Board stock options 2010/2017	4,358	-	_	_	_	4,358	0.4	Dec 31, 2017	
Board stock options 2011/2018	4,118	_	_	_	_	4,118	0.4	Dec 31, 2018	
Performance-based incentive program 2011/2021	152,750			-36,094	-5,094	111,562	47.8	Feb 16, 2021	
Performance-based incentive	,				,				
program 2011/2021 Performance-based incentive	122,500				-1,388	121,112	29	Feb 16, 2021	
program 2011/2021	124,500	_		-11,850	-1,088	111,562	25.6	Feb 16, 2021	
Performance-based incentive program 2011/2021 Performance-based incentive	43,750	=	=	-36,094	-7,656	=	26.4	Feb 16, 2021	
program 2011/2021	285,000	=	-	_	-3,375	281,625	51.8	Feb 16, 2021	
Performance-based incentive program 2011/2021						200 797	EC O		
Performance-based incentive	313,500				-3,713	309,787	56.8	Feb 16, 2021	
program 2011/2021 Performance-based incentive	28,500	_	_	_	-338	28,162	59.3	Feb 16, 2021	
program 2011/2021	136,666	_			-24,016	112,650	75.6	Feb 16, 2021	
Performance-based incentive program 2011/2021	19,000	=	-	-	-225	18,775	131.6	Feb 16, 2021	
Performance-based incentive program 2011/2021	23,750	_	-	-	-23,750	-	123.5	Feb 16, 2021	
Performance-based incentive program 2011/2021	38,000	_	_	_	-450	37,550	130.5	Feb 16, 2021	
Board stock options 2013/2018	183,334		_	_	-3,750	179,584	52.4	Dec 31, 2018	
Performance-based incentive program 2011/2021	279,500	_			-57,676	221,824	165.1	Feb 16, 2021	
Performance-based incentive program 2011/2021	20,000	_		_	-150	19,850	112.9	Feb 16, 2021	
Performance-based incentive program 2011/2021	25,000				-188	24,812	115.8	Feb 16, 2021	
Performance-based incentive	,	<del>_</del>				,			
program 2011/2021 Performance-based incentive	10,000				-75	9,925	128.5	Feb 16, 2021	
program 2011/2021 Performance-based incentive	30,000				-7,669	22,331	137.4	Feb 16, 2021	
program 2011/2021	10,000				-75	9,925	139.9	Feb 16, 2021	
Performance-based incentive program 2011/2021	7,500				-56	7,444	140.1	Feb 16, 2021	
Performance-based incentive program 2011/2021	35,000	_	_	_	-10,187	24,813	131.7	Feb 16, 2021	
Performance-based incentive program 2011/2021	7,500	_	_	_	-7,500	_	129.9	Feb 16, 2021	
Performance-based incentive program 2011/2021		_	25,000	_	_	25,000	129.2	Feb 16, 2021	
Performance-based incentive									
program 2011/2021 Share awards	<del>_</del> _		7,500 94,904		-7,500 -13,540	81,364	133.0	Feb 16, 2021 Jun 18, 2018	
			J4,JU4		-10,040	01,304		Juli 10, 2010	
Approved, unallotted options Performance-based incentive	407.417					407.417		Fab 16 2021	
program 2011/2021	497,417		-	-	-	497,417		Feb 16, 2021	
Subtotal Options attributable to the acquisition of Richipov	2,546,855		127,404	-103,066	-214,684	2,356,509			
quisition of Biolipox Employee stock options BX OP									
VIII	689				-689		0.25	Dec 31, 2015	No dilution
Hedge warrants	36,473			-600		35,873	0.25	Dec 31, 2016	No dilution
	37,162	_		-600	-689	35,873			
Subtotal Total number of securities in	07,102					,			

 $<sup>^{\</sup>rm 1}$  After full dilution through the exercise of warrants.

Changes in number of outstanding options 2014

	Opening Jan 1, 2014	Change	Closing Dec 31, 2014	Redeemable
Options directed at Board and employees				
Of which:				
Approved and allotted employee stock options	1,792,721		1,792,721	
Exercised		-58,867	-58,867	
Forfeited		-133,916	-133,916	
Allotted		449,500	449,500	
Approved, unallotted options	829,667	-332,250	497,417	
Total options directed at Board and employees	2,622,388	-75,533	2,546,855	997,605
Employee stock options utilized from Biolipox AB (non-diluting, in- cluded in newly issued shares in conjunction with acquisition of Bi- olipox)	2,524		2,524	
Exercised		-1,835	-1,835	
Warrants taken over from Biolipox for cash flow hedging of social security fees (non-diluting)	38,123	-1,650	36,473	
Total options from Biolipox	40,646	-3,485	37,162	37,162
Total outstanding options	2,663,035	-79,018	2,584,017	

The average exercise price during the year was SEK 45.89 per share.

All data regarding options issued by Biolipox AB are restated using a factor of 0.45854, which corresponds to the computed value of the options related to the share price for the Orexo share on the acquisition date. The reported data regarding the options issued by Biolipox refers to the number of shares for which each option may be exchanged after recalculation.

#### Exercised during the year

For the period January–December 2014, 58,867 Board/employee stock options from Orexo's options programs were exercised. During the period, 1,835 of Biolipox's employee stock options were also exercised, whereby the holders exchanged their options for 1,835 Orexo shares, which had been held by the independent company Pyrinox AB. The exercise of these options did not require Orexo to issue additional shares.

#### Allotment during the year

 $449,\!500$  performance shares were allotted free of charge during 2014. Of these performance shares, 50% are time-based and 50% are share-price based.

The final date for exercising the options is February 16, 2021. The market value of the time-based portion of the shares was determined using the Black&Scholes method, while a Monte Carlo simulation was used for the share-price based portion. The market values and the allotment prices are presented in the following table:

LTIP allotment 2014	Number	Allotment price	Market value time based portion	Market value share-price based portion
LTIP allotment February 15, 2014	304,500	165.10	57.04	51.4
LTIP allotment May 2, 2014	20,000	112.9	32.10	25.7
LTIP allotment July 7, 2014	25,000	115.8	39.76	34.5
LTIP allotment November 5, 2014	10,000	128.5	43.06	31.6
LTIP allotment November 17, 2014	30,000	137.4	41.92	33.7
LTIP allotment November 26, 2014	10,000	139.9	40.34	32.5
LTIP allotment December 1, 2014	7,500	140.1	36.78	30.6
LTIP allotment December 11, 2014	35,000	131.7	36.20	30.5
LTIP allotment December 16, 2014	7,500	129.9	32.60	27.4
	449,500			

■ Risk-free rate of interest: 0.06 – 1.73 percent

volatility: 35%

estimated dividend: SEK 0

All information regarding options issued by Orexo AB has been restated to take into account the 1:250 share split conducted in November 2005. The 2005 Annual Report states that older option certificates provide entitlement to subscribe for 250 shares after the split. The reported data regarding options issued by Orexo AB refer to the number of shares to which each option provides entitlement to subscribe for shares following the share split.

#### Performance criterion 1

For any vesting of Share-Price Based Performance Shares to occur, the increase in the Share Price shall correspond to the amounts set forth below. The increase in the Share Price as set forth below shall be calculated for a period not exceeding five years, meaning that the Share Price must have been achieved within a continuous five-year period.

Increase in share price	Vesting percentage of Share-Price Based Performance Shares (also conditional upon fulfilment of Performance Criterion 2 below)
> 60 percent	33 percent
> 100 percent	66 percent
> 150 per- cent	100 percent

These categories correspond to a five-year average return performance of approximately 10 percent, 15 percent and 20 per cent per annum, respectively.

#### Performance criterion 2

In addition to satisfaction of Performance Criterion 1, for any vesting to occur the Share Price shall have outperformed the NASDAQ OMX Stockholm Biotechnology PI Index for a 90-day period immediately prior to such day when Performance Criterion 1 above is satisfied. The determination of satisfaction of Performance Criterion 2 shall be made continuously as long as Performance Criterion 1 is satisfied, where the above-mentioned 90-day period shall be the period immediately prior to each such determination.

The Board shall be entitled to determine that Performance Shares have not been vested to the extent that it has been established that vesting has occurred on the basis of manifestly misstated information.

#### Forfeited options during the year

During 2014, 133,916 performance shares were forfeited, partly due to the fact that employees had left the company and partly because performance criteria had not been met.

Changes in number of outstanding options 2013

	Opening Jan 1, 2013	Change	Closing Dec 31, 2013	Redeemable
Options directed at employees				
Of which:				
Approved and allotted employee stock options	1,784,251		1,784,251	
Exercised		-469,466	-469,466	
Forfeited		-627,064	-627,064	
Allotted		1,105,000	1,105,000	
Approved, unallotted options	380,000	449,667	829,667	
Total	2,164,251	458,137	2,622,388	987,555
Approved and allotted Board stock options	10,000		10,000	
Exercised		-10,000	-10,000	
Total				
Warrants held by subsidiaries for cash flow hedging of social security fees	78.000		78,000	
Forfeited	78,000	-78.000	-78,000 -78,000	
Total		70,000	70,000	
Total options directed at Board and employees Employee stock options utilized from Biolipox AB (non-diluting, in-	2,252,251	370,137	2,622,388	
cluded in newly issued shares in conjunction with acquisition of Biolipox)	4,303		4,303	
Forfeited		_		
Exercised		-1,779	-1,779	
Warrants taken over from Biolipox for cash flow hedging of social security fees (non-diluting)	39,373	-1,250	38,123	
Total options from Biolipox	43,676	-3,029	40,646	40,646
Total outstanding options	2,295,927	367,108	2,663,035	

The average exercise price during the year was SEK 38.57 per share.

garding options issued by Biolipox AB are restated using a factor of 0.45854, which corresponds to the computed value of the options related to the share price for the Orexo share on the acquisition date. The reported data regarding the options issued by Biolipox refers to the number of shares for which each option may be exchanged after recalculation. These options were approved at General Meetings of shareholders, but have not yet been al-

#### Exercised during the year

For the period January-December 2013, 469,466 employee stock options from Orexo's options programs were exercised. During the period January-December 2013, 1,779 of Biolipox's employee stock options were also exercised, whereby the holders exchanged their options for 1,779 Orexo shares, which had been held by the independent company Pyrinox AB. The exercise of these options did not require Orexo to issue additional shares.

#### Allotment during the year

905,000 performance shares were allotted free of charge during 2013. Of these performance shares, 50% are time-based and 50% are share-price based.

The final date for exercising the options is February 16, 2021.

The market value of the time-based portion of the shares was determined using the Black&Scholes method, while a Monte Carlo simulation was used for the share-price based portion.

All information regarding options issued by Orexo AB has been restated to take into account the 1:250 share split conducted in November 2005. The 2005 Annual Report states that older option certificates provide entitlement to subscribe for 250 shares after the split. The reported data regarding options issued by Orexo AB refer to the number of shares to which each option provides entitlement to subscribe for shares following the share split. All data re-

The market values and the allotment prices are presented in the following table:

LTID allatarant 2012	Normalian		Market value time-based por-	Market value share-price
LTIP allotment 2013	Number	Allotment price	tion	based portion
LTIP allotment May 2013	300,000	51.80	19.72	15.5
LTIP allotment June 2013	330,000	56.80	19.72	15.5
LTIP allotment June 2013	30,000	59.30	19.72	15.5
LTIP allotment August 2013	160,000	75.60	28.22	23.5
LTIP allotment October 2013	40,000	130.50	43.66	37.5
LTIP allotment October 2013	25,000	123.50	48.68	41.7
LTIP allotment November 2013	20,000	131.60	44.04	37.4
	905,000			

- Risk-free rate of interest: 1.17 2.03 percent
- volatility: 35%
- estimated dividend: SEK 0

#### Performance criterion 1

For any vesting of Share-Price Based Performance Shares to occur, the increase in the Share Price shall correspond to the amounts set forth below. The increase in the Share Price as set forth below shall be calculated for a period not exceeding five years, meaning that the Share Price must have been achieved within a continuous five-year period.

Increase in share price	Vesting percentage of Share-Price Based Performance Shares (also conditional upon fulfilment of Performance Criterion 2below)
> 60 percent	33 percent
> 100 percent	66 percent
> 150 percent	100 percent

These categories correspond to a five-year average return performance of approximately 10 percent, 15 percent and 20 per cent per annum, respectively.

#### Performance criterion 2

In addition to satisfaction of Performance Criterion 1, for any vesting to occur the Share Price shall have outperformed the NASDAQ OMX Stockholm Biotechnology PI Index for a 90-day period immediately prior to such day when Performance Criterion 1 above is satisfied. The determination of satisfaction of Performance Criterion 2 shall be made continuously as long as

Performance Criterion 1 is satisfied, where the above-mentioned 90-day period shall be the period immediately prior to each such determination.

The Board shall be entitled to determine that Performance Shares have not been vested to the extent that it has been established that vesting has occurred on the basis of manifestly misstated information.

The Chairman of the Board program 2013/2018 was adopted during 2013. In conjunction with the evaluation of different commercial alternatives for the introduction of Zubsolv® on the American market, the Chairman of the Board assumed the role of Executive Chairman of the Board for a period of time. This assignment as Executive Chairman of the Board involved considerably more extensive work than that involved in the normal Chairman of the Board assignment.

During the year, 200,000 Chairman of the Board options were therefore allotted free of charge. The subscription price for these was set at SEK 52.40. The final date for exercising the options is April 11, 2018.

#### Forfeited options during the year

During the year, the Board resolved to cancel options that provided entitlement to 270,000 shares, which reduces the dilution in conjunction with full exercise of all outstanding warrants by about 0.8 percentage points. The cancelled options refer to Board stock options from the Board shareholder program 2012/2017. These have not been exercised as certain conditions have not been met. During 2013 no Biolipox employee stock options were cancelled

#### NOTE 17 RESERVES

	Translation reserve	Hedge reserve	Total
Opening balance at January 1, 2013	-9,985	14,436	4,451
Exchange-rate differences	-1,898		-1,898
Cash flow hedge		-11,224	-11,224
Tax, cash flow hedge		2,469	2,469
Opening balance at January 1, 2014	-11,883	5,681	-6,202
Exchange-rate differences	-266		-266
Cash flow hedge		-2,842	-2,842
Opening balance at January 1, 2015	-12,149	2,839	-9,310
Exchange-rate differences	-4,320		-4,320
Cash flow hedge		2,838	2,838
Closing balance at December 31, 2015	-16,469	5,677	-10,792

#### NOTE 18 PROVISIONS

	Group			Parent Company		
	2015	2014	2013	2015	2014	2013
Estimated costs, social security fees, employee stock options	3,914	9,006	9,645	3,914	9,006	9,645
Total	3,914	9,006	9,645	3,914	9,006	9,645

Provisions primarily refer to estimated costs for social security fees in respect of employee stock option programs, which have been recognized in accordance with UFR 7. The long-term portion of social security fees is

recognized as provisions, the remaining portion recognized as a current liability.

#### NOTE 19 BORROWINGS

	Group			Parent Company		
	2015	2014	2013	2015	2014	2013
Bank loan, short-term portion	_	1,856	104,081	_		100,000
Total	-	1,856	104,081	-	_	100,000

	Group			Parent Company			
	2015	2014	2013	2015	2014	2013	
Bank loan, long-term portion	_	2,474	136,993	_	-	134,631	
Corporate bonds	494,334	491,906	-	494,334	491,906	_	
Total	494,334	494,380	136,993	494,334	491,906	134,631	

The long-term portion consists of a bond loan amounting to a total of MSEK 500. It matures on May 9, 2018. The loan has a variable interest rate of STIBOR 3 months +4 percent (STIBOR is calculated as zero at the lowest) and has a total framework amount of SEK 1 billion. There are no covenants. The loan agreement contains limitations regarding any change in the company's ownership structure, so-called change-of-control. Pursuant to IAS

39, the bond loan should be recognized after a deduction for transaction costs, which are distributed over the duration of the loan. This accounts for the difference between MSEK 500 and the amount in the note.

The full terms and conditions of the bond loan are available on the company website, <a href="https://www.orexo.com">www.orexo.com</a>.

#### NOTE 20 ACCOUNTS PAYABLE AND OTHER LIABILITIES

	Group			Parent Company		
	2015	2014	2013	2015	2014	2013
Accounts payable	34,893	28,850	138,009	26,139	11,865	127,846
Employee withholding tax	1,843	3,220	3,374	1,258	1,448	1,723
Deduction, social security fees	931	1,233	1,685	931	1,121	1,428
Deduction, special salary tax	2,169	2,988	2,781	2,169	2,763	2,530
Other current liabilities	31,798	118,497	197,080	104,827	117,566	258,880
Accrued salaries	11,685	15,561	11,497	3,141	5,938	6,348
Accrued vacation pay	6,344	9,261	9,281	6,344	8,577	8,557
Accrued social security fees	3,159	3,861	3,645	3,159	3,637	3,417
Other interim liabilities	158,775	24,712	37,169	43,282	45,310	34,982
Deferred income	_	59,882	92,624	-	59,882	98,304
Total	251,597	268,095	497,145	191,250	258,107	544,015

#### NOTE 21 PLEDGED ASSETS

	Group			Parent Company		
	2015	2014	2013	2015	2014	2013
Chattel mortgages for bank commitment	100,000	100,000	200,000	100,000	100,000	200,000
Pledging of all shares in Kibion AB	_	21,962	17,927	_	-	
Pledging of all shares in Orexo US Inc	_		_	_		32,249
Total	100,000	121,962	217,927	100,000	100,000	232,249

#### NOTE 22 CONTINGENT LIABILITIES

	Group			Parent Company		
	2015	2014	2013	2015	2014	2013
Additional purchase price, Inflazyme	-	_	40,800	_	_	
Guarantee commitment	-	-	-	-	-	_
Total	_	_	40,800	_	_	_

In conjunction with the acquisition of Inflazyme, an additional purchase price was agreed that would be conditional on certain goals being achieved. This additional purchase price was initially recognized as a provision and contingent liability, as the latter was not deemed to be a likely payment. In 2010, the Inflazyme project was downgraded, which meant that the full additional purchase price was recognized as a contingent liability. As the project has now been discontinued, it is no longer assessed to constitute a contingent liability.

Warrants were issued to Pyrinox AB as cash flow hedging for social security fees in respect of employee stock options issued by Biolipox. Orexo has pledged to cover any deficits over and above that covered by the warrants until they expire in December 31, 2016.

Orexo has collateral with Danske Bank comprising chattel mortgages of MSEK 100.

#### NOTE 23 DISTRIBUTION OF REVENUES

		Group		Parent Company			
	2015	2014	2013	2015	2014	2013	
Sales, products	429,408	279,214	56,128	301,521	103,626	77,277	
Royalties	147,879	230,927	254,723	150,717	233,765	254,723	
License revenues	66,034	58,460	112,377	66,034	58,460	112,377	
Partner-financed R&D costs	-	_	6,127	-	_	6,192	
Other	17	1,715	_	628	2,596	1,752	
Total	643,338	570,316	429,355	518,900	398,447	452,321	

#### NOTE 24 COSTS BY TYPE OF COST

		Group		Parent Company			
	2015	2014	2013	2015	2014	2013	
Raw materials and consumables	120,229	91,836	21,790	139,978	50,319	83,895	
Other external costs	499,295	375,153	347,810	433,051	333,145	269,456	
Personnel costs	146,626	154,366	166,998	53,402	80,685	132,026	
Depreciation/amortization and impairment	80,743	12,527	50,111	81,766	11,844	6,030	
Total	846,893	633,882	586,709	708,197	475,993	491,407	

During the year there was impairment of acquired R&D projects to the tune of MSEK 62.2.

#### NOTE 25 AUDITORS' FEES

		Group			Parent Company		
	2015	2014	2013	2015	2014	2013	
Audit assignment							
PWC	2,616	2,595	2,145	2,102	1,987	1,788	
Silver Levene	_	_	52		-		
Non-auditing assignments							
PWC	_	_			_		
Tax advice							
PWC	1,097	1,956	696	226	861	631	
Other services							
PWC	748	262	589	748	262	589	
Total	4,461	4,813	3,482	3,076	3,110	3,008	

#### NOTE 26 EXCHANGE-RATE DIFFERENCES

The statement of operations includes exchange-rate differences on operating receivables and operating liabilities as follows:

		Group		Parent Company			
	2015	2014	2013	2015	2014	2013	
Other operating income	32,824	37,978	11,757	31,957	35,714	9,271	
Other operating expenses	-31,641	-17,007	-10,158	-30,593	-14,086	-7,587	
Total	1,183	20,971	1,599	1,364	21,628	1,684	

#### NOTE 27 FINANCIAL INCOME AND EXPENSES

		Group		Pai	rent Company	
	2015	2014	2013	2015	2014	2013
Interest expenses						
Bank loans	-24	-4,054	-895	_	-3,911	-702
Convertible bond	_	_	-9,570	-		-9,570
Corporate bonds	-20,494	-15,156	_	-20,494	-15,156	
Group	_	_	_	-12	-472	-994
Other	-28	-61	-10	-12	-107	-9
Interest income						
Bank	1	239	811	1	231	787
Group	_		_	1,823	1,518	362
Other	1	6	27	1	5	1
Financial expenses						
Impairment of shares in subsidiaries	_		_	-63,896		-2,239
Costs, corporate bonds	-2,468	-1,619	_	-2,468	-1,619	
Other	-11	-6,902	-4,075	_	-6,384	-4,075
Financial income						
Sale of subsidiary	-	_	_	13,087		
Reversal of impairment of shares	902	_	-	-		
Total	-22,120	-27,547	-13,712	-71,970	-25,895	-16,439

 $\label{thm:company} \mbox{Financial expenses in the Parent Company are attributable to the corporate bond loan.}$ 

#### NOTE 28 REMUNERATION TO EMPLOYEES

Average	number	٥f	emn	ovees
Avelage	HUHHDEI	UI	cilibi	Oyees

Group	2015 Average number of employees	Of whom men	2014 Average number of employees	Of whom men	2013 Average number of employees	Of whom men
Sweden	58	25	79	29	83	31
US	38	24	27	20	17	12
Germany	2	1	5	3	6	4
Total for Group	98	50	111	52	106	47

Parent Company	2015 Average number of employees	Of whom men	2014 Average number of employees	Of whom men	2013 Average number of employees	Of whom men
	56	24	72	28	72	28
Total for Parent Company	56	24	72	28	72	28

		Group		Parent Company		
Costs and remuneration to all employees and Board	2015	2014	2013	2015	2014	2013
Salaries, remuneration and social security fees						
Salaries and other remuneration to the Board, President and Senior executives	18,661	23,195	18,270	11,686	13,887	12,933
Salaries and other remuneration to other employees	97,795	84,993	69,650	30,590	39,519	46,699
Pension cost for the Board, President and Senior executives <sup>1</sup>	1,945	2,951	2,214	1,529	2,384	1,833
Pension cost for other employees <sup>1</sup>	10,145	11,234	9,331	7,412	9,045	8,597
Social security fees for the Board, President and Senior executives <sup>2</sup>	-3,040	-119	30,327	-3,976	-1,795	28,445
Social security fees for other employees <sup>2</sup>	6,432	16,566	30,455	2,499	12,730	28,741
Other personnel costs	16,388	16,995	8,218	5,362	6,364	6,245
Total	148,326	155,815	168,465	55,102	82,134	133,493

Pertains in its entirety to defined-contribution pension plan.

Of which -17,348 (-5,857) (36,454) pertains to estimated costs for social security fees for employee stock option program.

#### Principles for remuneration

Board fees, including fees to the Board Chairman and remuneration for work on Board Committees, are set by the shareholders at the Annual General Meeting.

The Board's Remuneration Committee comprises Martin Nicklasson, Michael Shalmi and Raymond Hill. The Remuneration Committee convenes as needed and is charged with the task of preparing decision data for the Board regarding wages, salaries and bonuses, as well as the task of making decisions on certain issues regarding remuneration paid to the President and other senior executives who, in addition to the President, comprise five persons. The Remuneration Committee held 1 (1) meeting during the year.

#### Guidelines approved by the 2015 Annual General Meeting

#### Reasons

Orexo shall offer market terms so that the company can recruit and retain skilled personnel. Remuneration to Executive Management shall comprise fixed salary, variable remuneration, long-term incentive programs, pension and other customary benefits. Remuneration is based on the individual's commitment and performance in relation to previously established goals, both individual goals and company-wide goals. Individual performance is continuously evaluated.

#### Fixed salary

Fixed salary is generally reviewed on an annual basis and shall be based on the qualitative performance of the individual. The fixed salary of the President and other senior executives shall be in line with market conditions.

#### Variable remuneration

Variable remuneration shall take into account the individual's level of responsibility and degree of influence. The size of variable remuneration is based on the percentage of set goals met by the individual. Variable remuneration shall not exceed 40 percent of fixed salary for the President and 30

percent of fixed salary for other senior executives. In addition, the Board shall have the option of allotting further variable remuneration to senior executives when the Board deems such action to be appropriate.

#### Long-term incentive programs

Orexo has adopted share-based incentive programs that are designed to promote the company's long-term interests by motivating and rewarding the company's senior executives. For a description of the company's long-term incentive programs, see Note 16 and the company website, <a href="https://www.orexo.com">www.orexo.com</a>.

#### Other remuneration and terms of employment

The President and other senior executives are covered by defined-contribution pension plans. Pension premiums paid by the company amount to a maximum of 20 percent of the President's monthly salary, while pension premiums for other senior executives amount to between approximately 20 - 25 percent of fixed annual salary.

The employment agreement with the President may be terminated with a notice period of six months. Employment agreements with other senior executives may be terminated with a period of notice of between three and twelve months. The President is entitled to severance pay if the company terminates employment corresponding to six months' salary. Severance pay for other senior executives if the company terminates employment amounts to between zero and twelve months' salary.

#### Deviation from guidelines

The Board is entitled, if it assesses that it is justified in an individual case, to give a member of the Board an assignment to carry out work for the company over and above the work involved in the Board assignment, whereupon the member of the Board may be granted reasonable compensation.

Costs and remuneration to the Board, President and senior executives 2015

SEK thousands	Basic salary/ Board fees	Variable remuneration	Other benefits	Pension costs	Share-based payment	Other remuneration	Total remuneration
Board of directors							
Martin Nicklasson, Chairman	683		_	_	343	_	1,026
Michael Shalmi, Board member	183		_	_	_	_	183
Raymond Hill, Board member	183		_	_	_	_	183
Staffan Lindstrand, Board member	200	_	_	_	_	_	200
Kristina Schauman, Board member	367		_	_	_	_	367
David Colpman, Board member (8 months)	133		_	_	_	_	133
Subtotal	1,749	_	_	_	343	-	2,092
President and senior executives							
Nikolaj Sørensen, President and CEO	2,865	1,023	60	584	800	=	5,332
Other senior executives (5)	8,970	3,863	180	1,264	2,928	-	17,205
Total	13,584	4,886	240	1,848	4,071	_	24,629

#### Costs and remuneration to the Board, President and senior executives 2014

	Basic salary/	Variable			Share-based	Other	Total
SEK thousands	Board fees	remuneration	Other benefits	Pension costs	payment	remuneration	remuneration
Board of Directors							
Martin Nicklasson, Chairman	633	_	_	_	755	_	1,388
Michael Shalmi, Board member	150	_	_	_	_	_	150
Raymond Hill, Board member	150	_	_		_	_	150
Staffan Lindstrand, Board member	183	_	_		_	_	183
Kristina Schauman, Board member	283	_	_		_	_	283
Scott Myers, Board member (4 mths)	50	_	_		_	_	50
Subtotal	1,449	-	_	_	755	-	2,204
President and senior executives							
Nikolaj Sørensen, President and CEO	3,024	1,080		870	1,382		6,356
Other senior executives (6)	12,110	3,792	143	1,792	4,653	-	22,490
Total	16,583	4,872	143	2,662	6,790	_	31,050

For 2015, provisions for variable remuneration to senior executives were made in the amount of MSEK 4.9.

Other benefits refer primarily to a company car and travel between the place of residence and the workplace.

Other senior executives, as of December 31, refers to the 5 people presented on page 80.

The number of shares and options held by the President and senior executives is shown in the information regarding the Board on page 79 and Management on page 80. Refer to Note 16 for a description of share-based remuneration.

Orexo has not granted loans or guarantees or provided collateral on behalf of the company's Board members, senior executives or auditors. None of the Board members, senior executives or auditors has directly or indirectly through associated companies or their immediate families been involved in business deals with Orexo on non-commercial terms.

#### Board members and senior executives

	Number on date, of	2015 the closing whom men	2014 Number on the closing date, of whom men		2013 Number on the closing date, of whom mer	
Group (incl. subsidiaries)						
Board members	9	89%	10	90%	11	91%
President and other senior executives	5	100%	8	88%	8	87%
Parent Company						
Board members	6	83%	5	80%	6	83%
President and other senior executives	3	100%	7	86%	5	80%

#### NOTE 29 INCOME TAX

		Group			Parent Company	
	2015	2014	2013	2015	2014	2013
Current tax for the year	-6,881	-4,031	-1,535	-481	-534	-1,446
Current tax attributable to previous years	_	_	_	_		_
Deferred tax	_	=	-	-	-	-
Total	-6,881	-4,031	-1,535	-481	-534	-1,446
Difference between the Group's tax expense and tax expense based on the current tax rate						
Recognized pre-tax earnings	-191,106	-52,554	-153,401	-161,790	-65,417	-44,278
Tax under current tax rate	42,043	11,562	33,748	35,594	14,392	9,741
Tax effect of tax rate US	-3,249	-	-	-	=	-
Tax effect of non-deductible costs	-14,920	-33	-2,341	-14,112	-27	-2,831
Tax effect of non-taxable income	202		-	2,879	-	-
Increase in unrecognized deferred tax asset	24,076	11,529	31,407	24,361	14,365	6,910
Tax on earnings for the year according to the statement of operations	-6,881	-4,031	-1,535	-481	-534	-1,446

#### Tax rate

The current tax rate is the tax rate for income tax in the Group. The approximated tax rate is 22.0 percent (22.0).

#### NOTE 30 DEFERRED INCOME TAX

Deferred tax assets and deferred tax liabilities are netted when there is a legal netting right. Deferred tax liabilities pertaining to temporary differences in the consolidated financial statements in conjunction with the acquisition of Biolipox's (2007) acquired R&D were netted against the tax-loss carryforwards in Biolipox.

In 2011, 2013 and 2015 the acquired R&D was impaired, resulting in a reduction in the netted loss carry-forwards in Biolipox. After the impairment applied in 2015, acquired R&D is 0.

	Group			Pa	rent Company	,
	2015	2014	2013	2015	2014	2013
Deferred income tax						
Deferred tax assets						
- related to netted loss carry-forwards in Biolipox	-	13,700	13,700	-	_	-
- related to other loss carry-forwards	318,909	281,133	282,340	241,788	212,229	197,864
- correction of loss carry-forwards carried over	-3,324	-	-	751	5,198	-
- correction of loss carry-forwards carried over Kibion						
Loss carry-forwards not asset recognized	-315,585	-294,833	-296,040	-242,539	-217,427	-197,864
Deferred tax liability						
- to be paid after more than 12 months	_	_	_	_	_	-
- to be paid within 12 months	_	_	-	_	_	-
<ul> <li>to be paid after more than 12 months and related to temporary differences in acquired R&amp;D</li> </ul>	-	-13,700	-13,700	_	-	-
Deferred income tax, net	0	0	0	0	0	0

Recognized deferred tax liabilities amounted to 0 at the beginning of the year and 0 at year-end. The deferred tax liabilities relate to cash flow hedging.

Deferred tax assets are recognized for tax-loss carry-forwards to the extent that it is probable that they can be applied through future taxable profits. These have not been capitalized due to the difficulty of assessing when capitalized loss carry-forwards can be set off against future surpluses.

Loss carry-forwards in the Group amounted to MSEK 1,449 (1,340). The reduction of the loss carry-forwards is due to the fact that the subsidiary Pharmakodex's loss was forfeited in connection with the liquidation of the company. There is no time limit restriction on when it can be applied.

Gross changes in respect of deferred tax are as follows:

	2015	2014	2013
Opening balance	_		4,071
Tax on amortization of intellectual property rights in the Group	_	_	
Tax on cash flow hedging	_		-4,071
Closing balance	_	_	_

#### NOTE 31 EARNINGS PER SHARE

Earnings per share before dilution are calculated by dividing the earnings attributable to the Parent Company by a weighted average number of common shares outstanding during the period, as shown in the presentation below.

		Group			
	2015	2014	2013		
Earnings used for the calculation of earnings per share before dilution	-197,987	-56,584	-154,936		
Average number of shares before dilution	34,478,298	32 657,223	30,018,262		
Earnings per share before dilution (SEK per share)	-5.74	-1.73	-5.16		
Options outstanding	1,894,965	2,584,017	2,663,035		

For calculating the earnings per share after dilution, the weighted average number of common shares outstanding is adjusted for the dilution effects of all potential common shares. The potential common shares in the Parent Company are represented by employee stock options, warrants and convertibles. In terms of convertibles, dilution has been increased by all shares that a convertible issue can produce.

As earnings are negative, the same earnings per share are recognized after dilution as before dilution

#### NOTE 32 SHARE DIVIDEND

No dividend was paid in 2015. The Board will propose to the Annual General Meeting on April 15, 2016 that no divided be paid for the 2015 fiscal year.

#### NOTE 33 UNDERTAKINGS

### Undertakings relating to operational leasing in which Group companies are the lessees

The Group leases various types of machinery and other technical plant in accordance with cancelable operational leasing agreements. Information on the leasing expenses recognized in the statement of operations during the year is shown in Note 7.

The Orexo Group has two rental agreements. Orexo AB has entered into a rental agreement that runs until December 31, 2017. Orexo US Inc's rental agreement runs until December 31, 2019. The comparative figures for 2013 and 2014 also include rental agreements for Kibion AB and Kibion GmbH

The nominal value of future leasing fees for lease agreements that cannot be terminated is as follows:

	Group			Parent Company		
	2015	2014	2013	2015	2014	2013
Falls due for payment within one year	18,806	19,389	17,224	16,600	16,600	15,091
Falls due for payment later than one year but within five years	21,089	39,975	7,263	16,600	33,200	
Falls due for payment later than 5 years	_		1,771	-		
Total	39,895	59,364	26,258	33,200	49,800	15,091

#### NOTE 34 DISCLOSURES ON THE CASH FLOW STATEMENT

	Group			Parent Company		
	2015	2014	2013	2015	2014	2013
Adjustments for items not included in cash flow comprise the following:						
Depreciation/amortization and impairment	80,743	12,527	50,556	17,870	11,844	6,030
Employee stock options, value of employees' services	-10,281	5,680	40,001	-12,698	5,680	40,001
Financial expenses, convertible bond	_		-1,127	_		-1,899
Capital gain, sale of subsidiary	5,292	_	_	-13,087	_	
Impairment, shares in subsidiaries	_	_	_	63,896	=	2,239
Other	2,838	2,838	_	_	220	551
Total	78,592	21,045	89,430	55,981	17,744	46,922

#### NOTE 35 RELATED PARTY TRANSACTIONS

Purchases	and	sales	hetween	Group	companies

Fulchases and sales between Gloup Companies					
The following transactions took place between the companies in the Group:	2015	2014	2013		
Forward invoicing of costs, which are recognized as net revenues					
Biolipox AB	_	-	_		
Orexo US Inc	386	_	_		
Kibion AB	227	2,259	1,404		
Sale of goods and services					
Biolipox AB	_	-	1,600		
Orexo US Inc	301,521	103,626	77,277		
Kibion GmbH	1,346	3,325	3,168		
Kibion AB	_	308	412		
Pharmacall	2	2	_		
Total	303,482	109,520	83,861		

The Group has no losses or doubtful credits on receivables from related parties.

Remuneration and other commitments regarding pensions and similar benefits to Board members and the President and CEO, see Note 28.

There have been no other related party transactions.

#### NOTE 36 SALE OF SUBSIDIARY

On April 30, 2015, the subsidiary Kibion AB was divested. The main aim of the divestment was to further strengthen the focus on the continued development of the pharmaceutical business and to maximize the commercial potential of Zubsolv®.

In the event that operations in the subsidiary achieve certain measures of profitability during the period April 2015 until March 2019, in accordance with the supplementary purchase price clause in the purchase agreement, a further cash payment will be received. At the time of sale, the fair value of the conditional purchase price was MSEK -5.3. This has been recognized in Other operating expenses.

The carrying amounts of assets and liabilities at the time of sale (April 30, 2015) were:

	Apr 30, 2015
Intangible fixed assets	27,019
Tangible fixed assets	470
Inventories	7,778
Current receivables	11,434
Cash and cash equivalents	4,253
Total assets	50,954
Long-term liabilities	602
Current liabilities	7,991
Total liabilities	8,593
Net assets	42,361

#### NOTE 37 EVENTS AFTER THE CLOSING DATE

#### AstraZeneca acquired all rights to Orexo's OX-CLI project

In March 2016, Orexo announced that AstraZeneca exercised the company's option and acquired all rights to the leukotriene C4 synthase inhibitor program (OX-CLI-project). The OX-CLI-project is directed to develop a novel treatment of respiratory disorders such as asthma and COPD. In accord-

ance with the option agreement from 2013, Orexo AB will receive a payment of MUSD 5 for the rights to OX-CLI. Future milestone payments can be expected when 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.

#### NOTE 38 INFORMATION ABOUT OREXO AB (PUBL)

Orexo AB (publ) has its registered office in Uppsala, Sweden, and the address of the company's head office is Virdings allé 32 A, SE-751 05 Uppsala, Sweden, telephone +46 (0)18 780 88 00.

The statements of operations and balance sheets will be subject to adoption at the Annual General Meeting to be held on April 15, 2016.

# Assurance of the Board of Directors and President

The Board of Directors and President hereby give their assurance that the consolidated financial statements have been prepared in accordance with the International Financial Reporting Standards (IFRS), as adopted by the EU, and present a true and fair view of the Group's financial position and earnings. The Annual Report has been prepared in accordance with generally accepted accounting principles and presents a true and fair view of the Parent Company's financial position and earnings.

The Board of Directors' Report for the Group and the Parent Company presents a true and fair review of the Group's and the Parent Company's operations, financial positions and earnings and describes the significant risks and uncertainties facing the Parent Company and the companies included in the Group.

Uppsala, March 18, 2016

Orexo AB (publ)

Martin Nicklasson Chairman of the Board

Raymond G. Hill Board member Staffan Lindstrand Board member Kristina Schauman Board member

Michael Shalmi Board member David Colpman Board member

Nikolaj Sørensen President and CEO

Our audit report was submitted on March 18, 2016.

PricewaterhouseCoopers AB

Lars Kylberg Authorized Public Accountant Auditor in charge Mikael Winkvist Authorized Public Accountant

## Auditor's Report

To the annual meeting of the shareholders of Orexo AB (publ)
Corporate identity number 556500-0600

#### Report on the annual accounts and consolidated accounts

We have audited the annual accounts and consolidated accounts of Orexo AB for the year 2015. The annual accounts and consolidated accounts of the company are included in the printed version of this document on pages 25-69.

### Responsibilities of the Board of Directors and the Managing Director for the annual accounts and consolidated accounts

The Board of Directors and the Managing Director are responsible for the preparation and fair presentation of these annual accounts and consolidated accounts in accordance with International Financial Reporting Standards, as adopted by the EU, and the Annual Accounts Act, and for such internal control as the Board of Directors and the Managing Director determine is necessary to enable the preparation of annual accounts and consolidated accounts that are free from material misstatement, whether due to fraud or error.

#### Auditor's responsibility

Our responsibility is to express an opinion on these annual accounts and consolidated accounts based on our audit. We conducted our audit in accordance with International Standards on Auditing and generally accepted auditing standards in Sweden. Those standards require that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the annual accounts and consolidated accounts are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the annual accounts and consolidated accounts. The procedures selected depend on the auditor's judgement, including the assessment of the risks of material misstatement of the annual accounts and consolidated accounts, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the company's preparation and fair presentation of the annual accounts and consolidated accounts in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the Board of Directors and the Managing Director, as well as evaluating the overall presentation of the annual accounts and consolidated accounts.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

#### **Opinions**

In our opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the parent company as of December 31, 2015 and of its financial performance and its cash flows for the year then ended in accordance with the Annual Accounts Act. The consolidated accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the group as of December 31, 2015 and of their financial performance and cash flows for the year then ended in accordance with International Financial Reporting Standards, as adopted by the EU, and the Annual Accounts Act. The statutory administration report is consistent with the other parts of the annual accounts and consolidated accounts.

We therefore recommend that the annual meeting of shareholders adopt the income statement and balance sheet for the parent company and the group.

#### Report on other legal and regulatory requirements

In addition to our audit of the annual accounts and consolidated accounts, we have also audited the proposed appropriations of the company's profit or loss and the administration of the Board of Directors and the Managing Director of Orexo AB for the year 2015.

#### Responsibilities of the Board of Directors and the Managing Director

The Board of Directors is responsible for the proposal for appropriations of the company's profit or loss, and the Board of Directors and the Managing Director are responsible for administration under the Companies Act.

#### Auditor's responsibility

Our responsibility is to express an opinion with reasonable assurance on the proposed appropriations of the company's profit or loss and on the administration based on our audit. We conducted the audit in accordance with generally accepted auditing standards in Sweden.

As a basis for our opinion on the Board of Directors' proposed appropriations of the company's profit or loss, we examined whether the proposal is in accordance with the Companies Act.

As a basis for our opinion concerning discharge from liability, in addition to our audit of the annual accounts and consolidated accounts, we examined significant decisions, actions taken and circumstances of the company in order to determine whether any member of the Board of Directors or the Managing Director is liable to the company. We also examined whether any member of the Board of Directors or the Managing Director has, in any other way, acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

#### **Opinions**

We recommend to the annual meeting of shareholders that the disposable gain be dealt with in accordance with the proposal in the statutory administration report and that the members of the Board of Directors and the Managing Director be discharged from liability for the financial year.

Uppsala, March 18, 2016

PricewaterhouseCoopers AB

Lars Kylberg Authorized Public Accountant Auditor in charge Mikael Winkvist Authorized Public Accountant

OREXO ANNUAL REPORT 2015 AUDITOR'S REPORT ■ 70

## Definitions of Key Figures

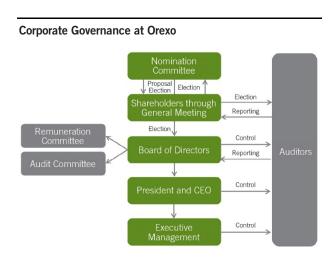
Key figures and certain other operational information and information per share have been defined as follows:

Number of shares after dilution	Calculation of dilution from options issued by the company until 2005 has been made in accordance with IAS 33.
Return on total capital	Operating profit/loss plus financial income as a percentage of average total assets.
Return on shareholders' equity	Profit/loss for the period as a percentage of average shareholders' equity.
Return on employed capital	Operating profit/loss plus financial income as a percentage of average capital employed.
Current ratio	Current assets as a percentage of current liabilities.
Gross margin	Gross profit divided by net revenues.
EBITDA	Earnings before interest, taxes, depreciation, and amortization.
Shareholders' equity per share, before dilution	Shareholders' equity divided by total number of shares before dilution at the end of the period.
Shareholders' equity per share, after dilution	Shareholders' equity divided by total number of shares after dilution at the end of the period.
Average number of employees	Average number of full-year employees for the period.
Cash flow from operating activities per share, before dilution	Cash flow from operating activities divided by the average number of outstanding shares before dilution.
Cash flow from operating activities per share, after dilution	Cash flow from operating activities divided by the average number of outstanding shares after dilution.
Acid-test ratio	Current assets, excluding inventories, as a percentage of current liabilities.
Capital turnover rate	Net revenues divided by average operating capital.
Net debt	Current and long-term interest-bearing liabilities, including pension liabilities, less cash and cash equivalents.
Operating capital	Total assets, less non-interest-bearing liabilities and provisions less cash and cash equivalents.
Earnings per share, before dilution	Profit/loss for the period divided by the average number of outstanding shares before dilution.
Earnings per share, after dilution	Profit/loss for the period divided by the average number of outstanding shares after dilution.
Return on equity	Profit/loss for the year divided by average shareholders' equity.
Interest-coverage ratio	Profit/loss after financial items plus interest expenses and similar items, divided by interest expenses and similar items.
Working capital, net	Non-interest-bearing current assets less non-interest-bearing current liabilities.
Working capital, net/net revenues	Average working capital, net, divided by net revenues.
Operating margin	Operating profit/loss 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.
Profit margin	Profit/loss after financial items expressed as a percentage of net revenues.

OREXO ANNUAL REPORT 2015 DEFINITIONS OF KEY FIGURES ■ 71

# Corporate Governance Report for Orexo AB (publ)

- Orexo is a Swedish public limited liability company, with its registered office in Uppsala, Sweden. The company's shares are listed on Nasdaq (Mid Cap) Stockholm, with American Depositary Receipts (ADRs) traded on OTCQX under the symbol ORXOY. Corporate Governance in Orexo is based on applicable laws, rules and recommendations such as the Swedish Code of Corporate Governance ("the Code"), Orexo's articles of association and internal regulations and guidelines.
- The aim of corporate governance at Orexo is to create a clear division of roles and responsibilities between shareholders, the Board of Directors and Management.
- The company's auditors have reviewed this report.



The governance, management and control of Orexo are divided between the General Meeting of Shareholders, the Board of Directors and the President.

# External regulations influencing corporate governance

- Swedish Companies Act
- Regulations governing external reporting
- Nasdaq Stockholm rules for issuers
- OTCQX rules for companies trading ADRs on OTCQX
- Swedish Code of Corporate Governance

# Internal rules of significance for corporate governance

- Articles of Association
- Formal work plan for the Board of Directors (including terms of reference for Board Committees)
- Terms of reference for the President
- Guidelines for remuneration of senior executives
- Finance policy
- IT policy
- Financial guidelines
- HR guidelines
- Code of Conduct

### Shareholders

Orexo's share has been listed on Nasdaq Stockholm since 2005. On January 2, 2014, Orexo advanced to the Mid Cap segment. At year-end, the total number of shares amounted to 34,580,810 (34,345,697), distributed among 6,944 (6,979) shareholders.

The 10 largest shareholders held 62.5 (63.1) percent of the outstanding shares, management 0.2 (0.1) percent and other shareholders 37.3 (36.8) percent. At December 31, 2015, two shareholders each held shares representing 10 percent or more of the company – Novo A/S, 27.9 percent, and HealthCap, 11.5 percent. Non-Swedish shareholders accounted for approximately 57 (49) percent of the total number of shares. Institutions and industrial owners hold the majority of shares. At year-end, 79 (82) percent of the shares were held by legal entities, and 21 (18) percent by private individuals. Since November 13, 2013, the share is available in the US as an ADR on the OTCQX market.

### Articles of Association

The Articles of Association are adopted by the General Meeting of Shareholders and outline a number of mandatory tasks of a fundamental nature for the company. Notification of the convening of the General Meetings is issued through an advertisement being placed on Orexo's website and in Post- och Inrikes Tidningar (Official Swedish Gazette). Confirmation that a General Meeting has been convened shall be announced in the Svenska Dagbladet newspaper. The Articles of Association state that Orexo shall conduct research and development, and manufacture, market and sell pharmaceuticals and diagnostic preparations. Orexo's Articles of Association also state that the Board of Directors shall have its registered office in Uppsala, Sweden, and shall consist of a minimum of three and a maximum of nine members, with a maximum of three deputies. The Articles of Association contain no special provisions on the appointment or dismissal of Board members. Amendments to the Articles of Association are made in accordance with the provisions of the Swedish Companies Act following a resolution of the General Meeting. The complete Articles of Association are available at www.orexo.com.

### **General Meeting of Shareholders**

Orexo's highest decision-making body is the General Meeting, at which every shareholder who is entered in the share register and who has provided notification of their attendance within the stipulated time is entitled to participate and vote for the amount of shares held. Shareholders can also be represented by proxy at General Meetings. One share entitles the holder to one vote at General Meetings, and there are no limits as to how many votes each shareholder can cast at a General Meeting. Resolutions at General Meetings are passed with a simple majority, unless the Companies Act stipulates a higher percentage of the shares and votes represented at the Meeting.

The Annual General Meeting elects members to the Board of Directors and sets Board fees. The other mandatory tasks of the Annual General Meeting include adopting the company's balance sheet and income statement, passing resolutions on the appropriation of earnings from operations, remuneration guidelines for senior executives and decisions concerning discharge from liability for Board members and the President. The Annual General Meeting also elects the company's auditor and sets the auditors' fees. In accordance with the Articles of Association, the Annual General Meeting shall be held in either Uppsala or Stockholm.

### Annual General Meeting 2015

The Annual General Meeting was held on Wednesday, April 15, 2015 in Uppsala. At the Meeting:

- Raymond G. Hill, Staffan Lindstrand, Martin Nicklasson, Kristina Schauman and Michael Shalmi were re-elected as Board members. David Colpman was elected as new Board member. Martin Nicklasson was re-elected as Chairman of the Board.
- PricewaterhouseCoopers AB was re-elected as auditor.
- A resolution was adopted that fees for Board members should amount to a total of SEK 1,900,000, with SEK 600,000 paid to the Chairman of the Board, SEK 200,000 to each of the other Board members, and a total of SEK 300,000 distributed between the members of the Audit Committee, so that the Chairman of the committee receives SEK 200,000 and SEK 100,000 is distributed between the other committee members for their work on the committee. The fee may be invoiced by a company in such a way that it is cost-neutral for Orexo.
- The Board's motion concerning guidelines for remuneration to the management was approved.
- The motion concerning the appointment of a Nomination Committee for AGM 2016 was approved.
- The balance sheet and income statement for the Parent Company and the Group for the 2014 fiscal year were adopted.
- The Annual General Meeting granted Board members and the President discharge from liability for the 2014 fiscal year.
- A resolution was adopted in accordance with the Board's proposal concerning authorization of the Board to resolve to issue shares.
- A resolution was adopted in accordance with the Board's proposal concerning authorization of the Board to repurchase and transfer the company's own shares.

- The Board's motion concerning a long-term incentive program for senior executives and key employees was approved.
- A resolution was adopted in accordance with the Board's proposal concerning authorization of the Board to issue and repurchase Class C shares and transfer of own ordinary shares.

Complete information about the 2015 Annual General Meeting can be found at <a href="https://www.orexo.com">www.orexo.com</a>.

### **Annual General Meeting 2016**

The Annual General Meeting of Orexo will be held on Friday, April 15, 2016, at 4:00 p.m. at the company's premises at Virdings allé 32 A, Uppsala, Sweden.

### **Nomination Committee**

The 2015 Annual General Meeting adopted a resolution that the Company should have a Nomination Committee. The Nomination Committee represents the company's shareholders. It is tasked with creating the best possible basis for the General Meeting's resolutions regarding the election of Board members and Board fees and with submitting proposals concerning, for example, the appointment of auditors and auditors' fees. The Nomination Committee comprises representatives of the three largest shareholders in terms of voting rights on the final banking day in August 2015, in addition to the Chairman of the Board. The composition of the Nomination Committee was announced on Orexo's website and in a press release on October 15, 2015. The Committee held 1 (1) meeting during the year.

Through the Chairman of the Board, the Nomination Committee reviewed the evaluation of the Board's work and received information regarding developments in the company. The principal requirements to be imposed on the Board of Orexo and the importance of independent Board members were discussed.

No special remuneration was paid for participation in the Nomination Committee.

# Nomination Committee for the 2016 Annual General Meeting

Name	Representatives
Eivind Kolding	Novo A/S, and Chairman of the Nomination Committee
Björn Odlander	HealthCap
Claus Berner Møller	Arbejdsmarkedets Tillaegspension (ATP)
Martin Nicklasson	Chairman of the Board of Orexo

Combined, the Nomination Committee represents about 45 percent of the number of shares and votes in the company, based on shareholder data at the time of appointment.

### **Board of Directors**

The Board's responsibility is regulated in the Companies Act and the formal work plan that is established annually. The formal work plan establishes the division of the Board's work between the Board in its entirety and the Board's various committees and between the Board and the President. It also sets out the items to be addressed at Board meetings and the manner in which the President provides the Board with information and reports. The Board has appointed Audit and Remuneration Committees from within its ranks.

At year-end, Orexo's Board of Directors consisted of Chairman Martin Nicklasson and Board members David Colpman, Raymond G. Hill, Staffan Lindstrand, Michael Shalmi and Kristina Schauman. For a more detailed description of Board members, please refer to page 79.

### The work of the Board

The Board's formal work plan establishes the items to be addressed at the scheduled Board meetings. Following presentations by the Audit Committee and President, the Board reviews all interim reports prior to publishing. The company's long-term targets and strategy and its budget are evaluated and approved by the Board. At each Board meeting, the President or another senior executive reports on the business situation and the status of development projects.

In addition to the statutory Board meeting, at least six scheduled Board meetings must be held. At the Board meeting during which the annual audit is to be considered, the Board meets with the auditors without the participation of the company's management.

It is incumbent upon the Board to ensure that the guidelines for remuneration to senior executives approved by the Annual General Meeting are followed and that the Annual General Meeting proposes guidelines for remuneration to senior executives.

Each year, the Board's work is evaluated by way of discussions and through external assessment. The results of the evaluation are presented to the Board and Orexo's Nomination Committee and form the basis for proposals for Board members.

In matters concerning ownership, Orexo is represented by the Chairman of the Board.

During the year, the Board held 16 (15) meetings, of which 9 (9) were telephone conferences or meetings by circulation. The Board mainly addressed and resolved on issues concerning the company's strategic direction, the status of projects, the follow-up of financial performance, financing, investment matters, external reporting, budget planning and follow-up. These issues are addressed by the Board in its entirety. Orexo's auditor participated at the Board meeting that approved the financial statements and presented the audit at this meeting.

#### Remuneration of the Board

The Annual General Meeting resolved that Board fees should amount to SEK 1,900,000, of which SEK 600,000 was to be paid to the Chairman of the Board, SEK 200,000 to each of the other Board members, and a total of SEK 300,000 to be divided among the members of the Audit Committee, so that the Chairman of the committee receives SEK 200,000 and the other committee members share SEK 100,000.

Composition of the Board							
Name	Function	Independent	Elected	Present at Board meetings	Present at Remuneration Committee	Present at Audit Committee	
Martin Nicklasson	Chairman of the Board		2012	16/16	1/1	4/5	
David Colpman	Board member		2015	9/13*	_	_	
Kristina Schauman	Board member		2012	15/16	=	5/5	
Michael Shalmi	Board member		2010	12/16	1/1	-	
Raymond G. Hill	Board member		2008	14/16	1/1	-	
Staffan Lindstrand	Board member		2002	15/16	_	5/5	

Independent in relation to Orexo and its management
Independent in relation to Orexo, its management and the company's largest shareholders

<sup>\*</sup>David Colpman was elected Board member at the Annual General Meeting on April 15, 2015.

### Composition of the Board

Board members, their positions and whether or not they are considered to be independent in relation to Orexo, its management and the company's largest shareholders are stated in the table on page 74. Orexo's Board of Directors is deemed to have satisfied the requirements of the Code in respect of independence, as all members elected by the Meeting have been deemed to be independent in relation to Orexo and its management and all of these members, with the exception of two, have also been deemed to be independent in relation to the company's largest shareholders.

### **Audit Committee**

Orexo's Audit Committee is primarily concerned with ensuring compliance with established principles for financial reporting and internal controls. The Audit Committee must also remain informed about the audit of the Annual Report and consolidated accounts, inspect and monitor the impartiality and independence of the auditor, paying particularly close attention to instances where the auditor provides the company with services outside the scope of the audit, and assist in the preparation of proposals to the General Meeting in respect of auditor selection. The Audit Committee presents the final version of Orexo's interim reports and of the Annual Report to the Board for approval and publication. The Audit Committee meets prior to the publication of each interim report, in connection with the auditor's review of the internal control over the financial reporting and when otherwise necessary. The aforementioned issues are addressed by the Committee and the Board makes resolutions on the basis of the proposals produced. Orexo's auditor attends the meetings of the Audit Committee before the publishing of the interim reports and to present the outcome of the review of the internal control. During the year, the Audit Committee was convened on 5 (6) occasions. At least one of the members of the Committee must be independent in relation to the company and Executive Management, and also be independent in relation to the

company's largest shareholders and have accounting or auditing expertise. The Committee is currently made up of Kristina Schauman (Chairman), Martin Nicklasson and Staffan Lindstrand.

### **Remuneration Committee**

The Remuneration Committee is tasked with addressing matters concerning salaries and other terms of employment, pension benefits and bonus systems, including any allocation of warrants under the terms of approved incentive programs for the President and the senior executives and managers, as well as remuneration issues of principle nature. The Committee shall meet as often as required. The above issues are addressed by the Committee and the Board makes resolutions on the basis of the proposals from the Committee. The Committee should possess the requisite knowledge and expertise to deal with issues related to the remuneration of senior executives. The Remuneration Committee comprises Martin Nicklasson (Chairman), Michael Shalmi and Raymond G. Hill. During the year, the Remuneration Committee was convened on 1 (1) occasion and managed other issues with written communication.

### Evaluation of the Board's work

The work of the Board, similar to that of the President, is evaluated annually in a systematic and structured process. The Nomination Committee is informed of the results of the evaluation.

# President and the Management

The President leads the work of the Executive Management and the extended Global Management Team and makes decisions in consultation with the rest of the management. At the end of 2015, Executive Management consisted of three people and the extended Global Management Team consisted of five people. Both the Executive Management Team and Global Management Team hold regular meetings under the supervision of the President.

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# Board of Directors' Report on Internal Control and Risk Management regarding Financial Reporting

■ Internal governance, control and risk management concerning financial reporting are fundamental factors in Orexo's business control.

The aim of Orexo's risk management systems and processes is to ensure that the shareholders can have the utmost confidence in the financial operation and presented reports, including the information given in this Annual Report and all interim reports. Orexo has established a methodology for developing, implementing, driving and evaluating internal controls and risk management in respect of all parts of the company, including financial reporting.

This methodology conforms to internationally established standards in the industry and comprises a framework with five principal components: control environment, risk assessment, control activities, information and communication, and follow-up and evaluation.

### **Control environment**

Pursuant to the Swedish Companies Act, the Board of Directors is responsible for the internal control and governance of the company. To maintain and develop a functional control environment, the Board has implemented a process of risk mapping and established a number of basic control documents and procedures that are of importance to financial reporting. These include the formal work plan for the Board of Directors and the terms of reference for the President, and accounting and reporting instructions, which are reviewed and approved annually by the Board.

In addition, the control environment is continuously updated and secured by means of continuous monitoring and regular evaluations of risk profiles within various functions.

Responsibility for the daily work of maintaining the control environment is primarily incumbent on the President. He reports regularly to the Board of Directors and the Audit Committee pursuant to established procedures. In addition, the Board also receives regular reports directly from the company's auditor. Company managers have defined authorities, control functions and responsibilities within their respective areas for financial and internal controls.

### Risk assessment

Orexo regularly conducts evaluations of financial risks and other risks that may impact financial reporting. These reviews extend to all parts of the company and are carried out to ensure that there is no significant risk of errors occurring in financial reporting. There are several areas where the control of financial information is particularly important, and Orexo has established a comprehensive risk layout that highlights a number of key potential risks in the financial reporting system.

The company continuously monitors and evaluates these areas and regularly examines other areas in order to create a comprehensive set of control procedures that will minimize the risks in these areas. In addition, new and existing risks are identified, addressed and regulated through a process of discussion in forums such as the Executive Management team, Board and Audit Committee.

### **Control activities**

In light of the risks identified in the risk layout, and the continuous monitoring of the methods used to manage financial information, Orexo has developed control activities that ensure good internal control of all aspects of financial reporting. A number of policy documents and procedures have been applied throughout the year to manage reporting and accounting. Standard procedures, attestation systems, financial guidelines and the risk layout are examples of such policy documents.

An additional level of control in the financial system has been achieved by separating the company's financial and controller functions. These units are responsible for ensuring that financial reporting is correct, complete and timely. Orexo strives to continually improve its internal control systems and has, on occasion, engaged external specialists when validating these controls.

## Information and communication

Orexo is a listed company in one of the most regulated markets in the world – healthcare. In addition to the highly exacting requirements that Nasdaq Stockholm and the supervisory authorities impose on the scope and accuracy of information, Orexo also employs internal information and communication control functions designed to ensure that correct financial and other corporate information is communicated to employees and other stakeholders.

The Board receives monthly reports concerning financial performance, the status of Orexo's development projects and other relevant information.

The corporate intranet provides detailed information about applicable procedures in all parts of the company and describes the control functions and how they are implemented.

The security of all information that may affect the market value of the company and mechanisms to ensure that such information is communicated in a correct and timely fashion are the cornerstones of the company's undertaking as a listed company. These two factors, and the procedures for managing them, ensure that

financial reports are received by all players in the financial market at the same time, and that they provide an accurate presentation of the company's financial position and performance.

### Follow-up

Orexo's management conducts monthly performance follow-up, with an analysis of deviations from the budget and the preceding period. Orexo's controller function also conducts monthly controls, evaluations and follow-ups of financial reporting. Because much of the company's product development is carried out in project form, this is followed up on a continuous basis from a financial perspective. After the commercialization of Zubsolv®, new routines and reporting have been implemented to secure continuous follow-up on all aspects of the Zubsolv business, e.g. manufacturing, sales performance, wholesaler orders, sales force performance, inventory levels etc. The Board of Directors and the Audit Committee review the Annual Report and interim reports prior to publication. The Audit Committee discusses special accounting policies, internal control framework, risks and other issues associated with the reports. The company's external auditor also participates in these discussions.

Orexo has no separate internal audit function. The Board annually evaluates the need for such a function and, considering the size and structure of the company, has found no basis for establishing a separate internal audit function. The Board of Directors monitors the internal control over financial reporting through regular follow-ups by the Audit Committee and the Board.

### Further information about Orexo's corporate governance

The following information is available at www.orexo.se (in Swedish) and www.orexo.com (in English):

- Articles of Association
- Information about the Swedish Code of Corporate Govern-
- Information from General Meetings of previous years
- Information from the Nomination Committee
- Information about remuneration principles for senior execu-
- Corporate governance reports from 2009 onwards
- Information for the 2016 Annual General Meeting (convening notice, Nomination Committee proposals, presentation of the work of the Nomination Committee, etc.)

# Auditor's Report on the Corporate Governance Statement

To the annual meeting of the shareholders of Orexo AB, corporate identity number 556500-0600

It is the Board of Directors who is responsible for the Corporate Governance Statement for the year 2015 on pages 72-77 and that it has been prepared in accordance with the Annual Accounts Act.

We have read the Corporate Governance Statement and based on that reading and our knowledge of the company and the group we believe that we have a sufficient basis for our opinions. This means that our statutory examination of the Corporate Governance Statement is different and substantially less in scope than an audit conducted in accordance with International Standards on Auditing and generally accepted auditing standards in Sweden.

In our opinion, a Corporate Governance Statement has been prepared and its statutory content is consistent with the annual accounts and the consolidated accounts.

Uppsala, March 18, 2016 PricewaterhouseCoopers AB

Lars Kylberg Authorized Public Accountant 
Authorized Public Accountant Auditor in charge

Mikael Winkvist

# **Board of Directors**













### 1. Martin Nicklasson, Chairman of the Board of Directors (b. 1955)

Board member since 2012

M.Sc. Pharm. PhD and Associate Professor at the Faculty of Pharmacy, Uppsala University. Other appointments: Chairman of the Board of Basilea Pharmaceutica Ltd., Zealand Pharma A/S and Farma Holding AS; and Board member of PledPharma AB, Premier Research Group Limited and Biocrine AB. Member of the Royal Academy of Engineering Sciences (IVA). Previous appointments: CEO at Swedish Orphan Biovitrum AB 2007-2010. Astra/Astra-Zeneca 1978-1989 and 1991-2007, amongst other things responsible for global drug development and marketing and business development within AstraZeneca Ltd. and CEO of AstraZeneca Sweden AB. CEO of Astra Hässle AB and responsible for R&D within KABI. Holds 7,000 shares and stock options entitling to 179,584 shares.\*

## 2. Raymond G. Hill (b. 1945)

Board member since 2008 B. Pharm., Ph.D., D.Sc (Hon) F. Med. Sci. Other appointments: Visiting Professor at Bristol and Imperial Universities, Member of UK Government Advisory Council on Misuse of Drugs. President Emeritus at the British Pharmacological Society; Member of Finance Committee, Academy of Medical Sciences. Non-Executive Director of Covagen (sold to J&J Sept 2014), Asceneuron, Addex and Avilex. Previous appointments: 25 years of experience from pharmaceuticals industry, mostly in basic drug discovery research, initially for Parke Davis, followed by Smith Kline & French and then Merck. Executive Director of Pharmacology at the Neuroscience Research Centre 1990-2002, followed by a position as Executive Director, Licensing and External Research, Europe for Merck

Holds stock options entitling to 12,735 shares.\*

### 3. Kristina Schauman (b. 1965)

Board member since 2012 B.Sc. Business and Economics. Other appointments: Board member and Chairman of the Audit Committee of Apoteket AB, ÅF AB, BillerudKorsnäs AB, Coor Service Management AB and Ellos Group Holding AB. Board member of Livförsäkringsbolaget Skandia, ömsesidigt.

Previous appointments: CFO at OMX, Carnegie, Apoteket AB, CEO at Apoteket AB and Group Treasurer at Investor AB. Board member of Vasakronan AB and Apoteket Pension Trust. Holds 10,000 shares (and 4,000 by legal entity).\*

### 4. Staffan Lindstrand (b. 1962)

Board member since 2002.

M.Sc. in Engineering.

Other appointments: Partner of HealthCap since 1997 and is currently, inter alia, Board member of HealthCap AB, PulmonX Inc., 20/10 Perfect Vision AG and The Swedish Association of Exchange-listed Companies. Previous appointments: Ten years in investment banking. Holds 981 shares.\*

### 5. Michael Shalmi (b. 1965)

Board member since 2010. M.D., MBA.

Other appointments: Senior Partner in Novo A/S investment unit Novo Growth Equity. Previous appointments: 15 years at Novo Nordisk; V.P. International Marketing, Corporate VP Haemostasis and Chief Medical Officer BioPharm, V.P. of Haematology Business Unit, V.P. BioPharm Business Unit, and Corporate V.P. Global Development, Clinical Operations Management at Novo Nordisk HQ. Does not hold any shares in Orexo.

### 6. David Colpman (b. 1961)

Board member since 2015.

B.Sc. Pharmacy.

Other appointments: Director of Colpman Consulting Ltd since 2014. Member of the Royal Pharmaceutical Society. Advisor to Sunstone

Previous appointments: Former Head of Global Business Development, Senior Vice President of Business Development at Shire plc. Various business development and commercial positions at Glaxo Wellcome, Novo Nordisk and Boots Pharmaceuticals. Does not hold any shares in Orexo.

<sup>\*</sup> As per December 31, 2015

# Management











EM, Member of Executive Management GMT, Member of Global Management Team

### 1. Nikolaj Sørensen (b. 1972)

Chief Executive Officer since February 2013, employed since 2011.

M.Sc. Business and Economics. *Previous appointments:* International commercial experience of the pharmaceuticals industry from Pfizer and Boston Consulting Group (BCG).

Holds 25,000 shares and stock options entitling to 384,888 shares.\*

### 2. Henrik Juuel (b. 1965)

EVP and Chief Financial Officer since 2013. M.Sc. Economics and Business Administration. *Previous appointments:* Extensive relevant experience from senior international management positions within the life science industry, including senior finance positions for Novo Nordisk and positions as CFO for NNE Pharmaplan and GN Resound. Holds 25,000 shares and stock options enti-

Holds 25,000 shares and stock options entitling to 146,168 shares.\*

### 3. Robert A. DeLuca (b. 1961)

President of Orexo US Inc. since 2013.

Other appointments: Treasurer and Trustee – Academy of Managed Care Pharmacy Foundation, Member of the St. John's College of Pharmacy Advisory Board, Academy of Managed Care Pharmacy and the American and New Jersey Pharmacists Associations. Previous appointments: Extensive experience establishing commercial operations in the US with a combined background in market access, marketing, and sales. Has held leadership positions at multinational pharmaceutical companies including Sanofi-Aventis, Schering-Plough, Berlex and Pharmacia, and most recently served as Chief Commercial Officer at Archimedes Pharmaceuticals.

Holds 2,703 shares and stock options entitling to 236,832 shares.\*

# 4. Jesper Lind (b. 1960)

Biosensor and Alfa-Laval.

Chief Operating Officer since November 2013. M.Sc. Chemical Engineering. *Previous appointments*: Extensive senior global pharmaceutical manufacturing and supply chain experience from AstraZeneca, Pharmacia

Holds 2,000 shares and stock options entitling to 59,600 shares.\*

### 5. Michael Sumner (b. 1965)

Chief Medical Officer since 2013. MB BS, MRCP (UK), MBA

Previous appointments: Extensive experience within the pharmaceutical industry from Novartis Pharmaceuticals, Aventis Behring, Novo Nordisk and most recently held the position of Vice President Clinical and Medical Affairs at Shire.

Other appointments: Scientific Advisory Board FirstString Research Inc.

Holds 2,300 shares and stock options entitling to 73,418 shares.\*

## Åsa Holmgren (b. 1965)

Head of Regulatory Affairs since 2008 until August 2015.

### Peter Edman (b. 1954)

Chief Scientific Officer since 2012 until June 2015.

<sup>\*</sup> As per December 31, 2015

# Financial Information in Brief

The tables below present financial information for the Orexo Group for the fiscal years 2011 to 2015.

Statement of operations information					
MSEK	2015	2014	2013	2012	2011
Net revenues	643.3	570.3	429.4	326.3	199.6
Cost of goods sold	-136.1	-107.4	-29.3	-27.9	-29.0
Gross profit	507.2	462.9	400.0	298.4	170.6
Selling expenses	-297.5	-193.6	-125.1	-62.0	-50.1
Administrative expenses	-141.5	-113.0	-126.4	-82.6	-49.6
Research and development costs	-172.6	-197.8	-238.1	-216.2	-194.4
Other operating income and expenses	-64.6	16.5	-50.1	-17.1	-268.0
Operating earnings	-169.0	-25.0	-139.7	-79.4	-391.5
Net financial items	-22.1	-27.6	-13.7	-8.2	-7.9
Earnings after financial items	-191.1	-52.6	-153.4	-87.6	-399.4
Income tax	-6.9	-4.0	-1.5	1.7	7.4
Net earnings for the year	-198.0	-56.6	-154.9	-85.9	-392.0
Balance sheet information					
MSEK	2015	2014	2013	2012	2011
Intangible fixed assets	159.1	259.2	194.8	135.2	150.9
Tangible fixed assets	24.7	29.1	33.3	35.1	39.2
Financial fixed assets	2.1	1.2	-	18.5	-
Inventories	398.9	478.1	383.4	28.3	26.7
Accounts receivable	164.2	142.1	36.1	17.5	56.9
Other current assets	69.2	31.7	19.1	19.1	25.5
Cash and bank balances	198.1	284.5	105.6	228.1	246.9
Total assets	1 016.3	1 225.9	772.3	481.8	546.1
Shareholders' equity	266.5	455.0	161.5	191.2	311.1
Interest-bearing liabilities	494.3	496.2	241.1	120.6	120.9
Non-interest-bearing liabilities and provisions	255.5	274.7	369.7	170.0	114.1
Total shareholders' equity and liabilities	1 016.3	1 225.9	772.3	481.8	546.1
Cash flow information					
MSEK	2015	2014	2013	2012	2011
Cash flow from operating activities before changes in working capital	-119.4	-35.5	-61.9	-61.0	-117.2
Cash flow from changes in working capital	17.2	-451.8	-201.3	89.7	_
Cash flow from operating activities	-102.2	-487.3	-263.2	28.7	-117.2
Acquisition of tangible and intangible assets	-4.1	-71.7	-107.5	-5.8	-4.7
Acquisition of subsidiaries	-	=	_	_	-10.3
Sale of tangible assets	_	=	-	0.6	_
Sale of subsidiary	21.8				
Sale of joint venture	_	=	-	12.1	_
Cash flow after investing activities	-84.5	-559.0	-370.7	35.6	-132.3
Funds from issue of convertible bonds	_	_	_	_	_
Amortization of loans	-1.2	-102.4	-3.0	-2.3	
Borrowings	_	500.0	234.7		11.7
New share issues	3.8	189.7	19.4	0.8	232.0
Buyback of shares	_			-53.0	-
Sales of treasury shares	_	152.0			=
<del></del>	-81.9	180.3	-119.6	-18.9	111.5
Cash flow for the year	-01.9	100.5	-119.0	-10.5	

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Key figures						
	2015	2014	2013	2012	2011	
Growth in net revenues, %	12.8	32.8	31.6	63.5	-5.2	
Margins and profitability						
Gross margin, %	78.8	81.2	93.2	91.4	85.5	
Profit margin, %	-29.7	-9.2	-35.7	-26.8	-200.1	
Operating margin, %	-26.2	-4.4	-32.5	-24.3	-196.1	
Return on total capital, %	-14.5	-2.6	-24.4	-13.9	-52.7	
Return on shareholders' equity, %	-52.9	-27.5	-88.3	-32.8	-77.7	
Return on capital employed, %	-10.2	-3.9	-48.1	-19.9	-63.3	
Capital structure						
Working capital, net, MSEK	380.7	385.7	78.5	-92.8	1.7	
Working capital, net/net revenues, %	59.6	7	-1.7	-14.0	-0.2	
Operating capital, MSEK	562.7	666.7	296.9	83.7	185.2	
Capital turnover rate, multiple	104.7	91.4	225.6	242.7	64.2	
Shareholders' equity, MSEK	266.5	455.0	161.5	191.2	311.1	
Net debt, MSEK	-296.2	-211.8	-135.4	-107.5	-125.9	
Debt/equity ratio, multiple	185.5	109.1	154	63	39	
Equity/assets ratio, %	26.2	37.1	20.9	39.7	57.0	
Current ratio, %	325.0	349.3	109.5	173.5	301.4	
Employees						
Average number of employees	98	111	106	111	110	
Number of employees at year-end	90	108	108	97	118	
Personnel expenses, MSEK	146.6	154.4	167.0	138.1	117.6	
Data per share						
Before dilution						
Average number of shares, thousands	34 478	32 657	30 018	29 449	27 167	
Number of shares at end of period, thousands	34 581	34 346	31 791	28 825	29 865	
Earnings per share after tax, SEK	-5.74	-1.73	-5.16	-2.92	-14.43	
Shareholders' equity, SEK	7.71	13.25	5.08	6.63	10.42	
Cash flow from operating activities per share, SEK	-2.96	-14.92	-8.77	0.97	-4.32	
Dividend, SEK	_	-	-	=	=	
After dilution						
Average number of shares, thousands	34 988	33 610	32 449	32 101	29 706	
Number of shares at end of period, thousands	34 873	35 307	32 977	31 645	32 371	
Earnings per share after tax, SEK	-5.74	-1.73	-5.16	-2.92	-14.43	
Shareholders' equity, SEK	7.64	12.89	4.90	6.04	9.61	
Cash flow from operating activities per share, SEK	-2.92	-14.50	-8.11	0.89	-4.32	

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# Other Information

### 2016 Annual General Meeting

The Annual General Meeting of Orexo AB will be held on Friday, April 15, 2016 at 4:00 p.m. at Orexo AB, Virdings allé 32A in Uppsala, Sweden.

### Registration, etc.

Shareholders who wish to participate in the meeting must be recorded in the share register maintained by Euroclear Sweden AB on Friday, April 8, 2016, and notify Orexo of their intention to attend the meeting not later than on Monday, April 11, 2016 by post to Orexo AB, P.O. Box 303, SE 751 05 Uppsala, Sweden, by telephone +46 (0) 18 780 88 00, by telefax +46 (0) 18 780 88 88, or by e-mail to lena.wange@orexo.com.

The notification shall set forth the name, personal/corporate identity number, the number of shares held, telephone number (daytime) and, where applicable, number of assistants (not more than two) that the shareholder intends to bring to the meeting. Shareholders to be represented by proxy should submit a power of attorney (original document) and a certificate of registration or equivalent together with the notification of attendance. A proxy form is available at <a href="https://www.orexo.com">www.orexo.com</a>.

Shareholders whose shares are registered in the name of a nominee/custodian must temporarily re-register their shares in their own names to be entitled to participate in the meeting. Shareholders must inform their nominee/custodian of such re-registration well before Friday, April 8, 2016 by which date such re-registration must have been executed.

Full information about the Annual General Meeting can be found on the company's website, <a href="https://www.orexo.com">www.orexo.com</a>.

### Financial calendar 2016

Annual Report 2016 Annual General Meeting Interim Report, January–March 2016 Interim Report, January–June 2016 Interim Report, January–September 2016 March 22, 2016 April 15, 2016, at 4:00 p.m. CET April 21, 2016 July 12, 2016 October 20, 2016 Contact Investor Relations +46 (0)18 780 88 00 lena.wange@orexo.com

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# Glossary

### 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.

#### Alfentanii

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

### 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.

### 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.

### Fentanyl

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

### GMP

Good Manufacturing Practice.

### Joint Venture

A partnership in which companies combine assets or resources externally to form a new separate entity to work on the development of a project.

### Mucoadhesive

Something which sticks to the surface of the mucosa.

#### 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.

### Opioid analgesic

Pain-relieving compound derived from synthetic or natural opium or morphine.

### 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.

### **Pharmacokinetics**

The processes by which a pharmaceutical is absorbed, distributed and eliminated by the body.

### Pharmacological properties

The characteristics or properties of a pharmaceutical, especially those which make it medically effective.

### 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 the 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.

### Sublingual

Under the tongue.

# Transmucosal

Administration of a drug through the mucosa.

### Zolpiden

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