orexo

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

Annual Report 2016

Contents

Our website is our foremost communication channel

In the spring of 2017 Orexo will launch a new Group website, **www.orexo.se**. Here we will regularly share information about the business and also continue to publish press releases about current events and financial reports.

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

First profitable year

Key events during the year

Q1
- AstraZeneca acquires all rights to Orexo's OX-CLI project
- New patent protecting Zubsolv® is listed in the US, patent 9,259,421, valid until September 2032

Q2
- Zubsolv is selected by the State of Maryland as the exclusive preferred buprenorphine/naloxone pharmaceutical for the FFS Medicaid Formulary
- A license agreement is signed with Mundipharma, which obtains the rights to Zubsolv outside the US

Q3
- The US Department of Health and Human Services (HHS) announces an increase in the buprenorphine patient cap from 100 to 275
- The US Congress signs CARA[1] into law which grants the expansion of buprenorphine prescribing privileges to nurse practitioners and physicians assistants

1) Comprehensive Addiction and Recovery Act of 2016

- The REZOLV study, including 1,080 patients and aiming to improve important treatment characteristics of opioid dependence, is completed
- New patent protecting Zubsolv is listed in the US, patent 9,439,900, valid until September 2032

Q4
- Together with Mundipharma, Orexo makes the first EU regulatory submission of a Marketing Authorisation Application (MAA) for Zubsolv, seeking approval for the treatment of opioid dependence in Europe
- The US Food and Drug Administration, FDA, approves a unique low 0.7mg/0.18mg dosage of Zubsolv
- The US District Court for the District of Delaware rules in Orexo's favor in one of the patent infringement litigations against Actavis regarding Orexo's patent 8,454,996 protecting Zubsolv in the US. Patent 8,940,330 is declared invalid.
- Orexo appeals the decision regarding the validity of patent '330
- Completion of a bond buyback program amounting to a nominal value of MSEK 99

16%

Net Sales increase of Zubsolv

275 patients

US HHS announces a lift in the patient cap from 100 to 275

Partnership is signed. A first important step for global launching of Zubsolv.

Key Figures

	2016	2015 Restated	2014 Restated	2013	2012
Net revenues, MSEK	705.9	646.2	570.3	429.4	326.3
Growth, %	9.2	13.3	32.8	31.6	63.5
Net earnings for the year, MSEK	29.0	–210.0	–56.6	–154.9	–85.9
Earnings per share, before dilution, SEK	0.84	–6.09	–1.70	–5.16	–2.92
Earnings per share, after dilution, SEK	0.84	–6.09	–1.70	–5.16	–2.92
Cash and cash equivalents, including short-term investments, MSEK	282.4	198.1	284.5	105.6	228.1
Shareholders' equity, MSEK	310.3	270.1	467.9	161.5	191.2
Average number of employees	99	98	111	106	111
Number of employees at year-end	102	90	108	108	97

For information regarding restatement see Note 38.

Orexo is a fully integrated specialty pharmaceutical company

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

Orexo's development model is characterized by lower costs, shorter lead times and lower risk

4 Orexo has developed four products from idea to patient

Vision

The aim and vision is to develop a growing profitable specialty pharmaceutical company which through its own sales can finance the development of new pharmaceuticals, within several therapeutic areas, based on Orexo's innovative technologies

"The key to our success can be found in our core values – customer focus, engagement, flexibility and simplicity. Values that characterize our employees' daily work."

Nikolaj Sørensen, President and CEO

Our drug delivery technologies improve pharmaceuticals

Orexo's development is based on innovations that have been made possible by the interaction between skillful researchers and experts from different scientific backgrounds. This innovative climate still characterizes Orexo in its work of continuing to develop products and helping patients worldwide through even better drugs.

Orexo develops improved products by combining well-known and well-documented substances with in-house innovative drug delivery technologies. Orexo is acknowledged as the world leader for sublingual formulation platforms. The sublingual formulation technology is to be found in all our current products. Several important steps were taken in 2016 to develop next generation drug delivery technologies. Development of products in the pipeline is governed by medical need and commercial potential. Orexo's development model is characterized by lower costs, shorter lead times and lower risk compared to the development of new substances.

Our key market is characterized by strong growth

Orexo's key market today is the American market for the treatment of opioid dependence using buprenorphine/naloxone. Orexo operates in the market through the commercialization of Zubsolv®, which is an effective drug for people with opioid dependence. Dying from an overdose is one of the most common causes of death in the US and the problem has been classified as an epidemic. Several important federal initiatives have been taken to increase access to treatment, and this creates scope for continued strong growth. The main market has a value of around 2.4 billion dollars, and in recent years has had annual growth of approximately 8 percent. Mundipharma, through its network of independent associated companies, has a presence in 48 countries and owns the rights to Zubsolv outside the US.

+8%

the average annual growth in the American market for the treatment of opioid dependence

Products approved worldwide

Orexo has developed four products from idea to patient. The products have proved to be of considerable value for patients worldwide.

Product	Zubsolv		Abstral		Edluar	Diabact[1]
Indication	Opioid dependence		Breakthrough cancer pain		Sleeping problems	Diagnosing stomach ulcer bacteria
Commercialization/ Partnership	orexo	mundipharma	SENTYNL	KYOWA KIRIN	Mylan	Several external partners
Market	US	ex US	US	EU and RoW	Globally	Globally

1) Diabact® is a product that belongs to Kibion, a subsidiary that Orexo sold in 2015.

Photo: Mats Lundqvist

We reached profitability and thereby passed an important milestone

2016 goes down in the company's history as the year when Orexo became profitable, largely due to strong sales and good cost control. In addition to the fact that we now stand on a steady financial foundation, the year was characterized by several operational successes. Amongst other things we took an important first step towards a global launch of Zubsolv® and we began developing the next generation of drug delivery technologies.

I am pleased to report that in 2016 we reached many of our objectives, both operational and financial. In particular I would like to highlight that we achieved positive earnings. The most important contributor was our product Zubsolv, with an increase in sales in the US of 16 percent. Our product Abstral® continues to grow in Europe and in combination with continued good cost control this also contributed to the positive result.

Double-edged first notification in the patent dispute with Actavis

2016 has been an eventful year, with significant positive progress in many areas. Read more in Orexo in Brief, pages 2–3. However, the year also presented a few noteworthy challenges. In particular the challenges from the loss of the CVS Caremark contract at the beginning of the year and the split decision by the District Court of Delaware in November with regard to our Zubsolv patents. The negative decision we later chose to appeal.

The task of the Board of Directors, myself and all employees is to manage these challenges and build our company on the basis of the progress we made in 2016. The company now stands on a solid financial foundation which is leading the way on the continued exciting journey in the evolution of Orexo.

"We remain confident there is significant growth potential yet to be materialized and translated into sales growth and capture of market share for Zubsolv."

We are now developing next generation drug delivery technologies

An important area for the long-term development of the company is the pipeline. The commercialization of Zubsolv® has been in the spotlight, but several assets in the pipeline have made good progress in 2016. Externally, our OX-CLI project that was acquired by AstraZeneca, is developing according to plan and the project is now in late preclinical stage. In collaboration with Mundipharma we have filed for approval of Zubsolv in Europe and additional markets are under assessment. Internally, we have continued the development of OX51 and have started the development of two new formulation technologies. One of them is an oral formulation technology and the other is targeted to be the next generation sublingual formulation technology. We have selected and are testing specific substances with relevance in therapeutic areas with unmet medical needs, where we believe we can improve the pharmaceutical by developing new and unique pharmaceutical formulations. Read more in Technologies, page 11.

Zubsolv captures a disproportionate share of expected market growth

Since the launch of Zubsolv in September 2013, we have gained deeper insight into the prerequisites for success in the US. These prerequisites define our commercial resource allocation and it is clear that market access and reimbursement are the most important drivers for our success. Market access and regional differences will steer our field force allocation. A strong and flexible field force is a critical success factor to ensure we can capture a disproportionate share of market growth. Data from IMS shows that 10.7 percent of the patients new to treatment are prescribed Zubsolv, compared to an overall market share of 6 percent in Q4.

Looking at these prerequisites for 2017 we are pleased to enter this year with improved market access. In combination with the legislative changes made in 2016 driving further market growth we are continuously reviewing the size of the field force and the regional re-allocation of resources.

However, since the implementation of the new legislation the number of physicians waivered to treat 275 patients has grown by about one tenth of the US Department of Health and Human Services' target in order to increase the number of patients by at least 150,000. As many of the physicians have only recently been waivered, the feedback from most of them is that they need to prepare their clinics to treat more patients. We remain confident there is significant growth potential yet to be materialized and translated into sales growth and capture of market share for Zubsolv. Read more in Sales, pages 18–20.

We expect to add more products to our commercial business

To fully leverage the existing organization we aim to start adding products to our commercial business and this will be an important activity during 2017. In the US, Orexo is targeting a unique segment of physicians focused on opioid dependence treatment. However, there are multiple prevalent co-morbidities for patients with opioid dependence and Orexo can offer a promotional channel to a group of physicians rarely addressed by other pharmaceutical companies.

Our employees – the key to success

The key to our success can be found in our core values; customer focus, engagement, flexibility and simplicity. These are values that characterize our employees' daily work. I am pleased to see we are receiving a good result and positive feedback in our annual employee survey.

I would also like to take this opportunity of doing some advertising for our new group website, **www.orexo.com**, that will be launched this spring. There I will continuously share my and Orexo's perspective on our company and progress.

Finally I want to thank our employees for their great efforts in 2016, both when we faced significant challenges and in the work to achieve important progress.

Uppsala, Sweden, March 2017

Nikolaj Sørensen
President and CEO

Vision, Objectives and Strategies

Leadership is the capacity to translate vision into reality

Objectives

- Remain a profitable company, with the immediate target of maintaining profability regarding EBITDA in 2017
- Make Zubsolv® available to more patients across the world. In the US, a short term objective in 2017 is to take a dis-proportionate share of new patients entering treatment, thus leading to increased market share. Outside the US, the immediate objective is approval for launch of Zubsolv in Europe and later expansion into new geographies.
- The long term ambition is to secure competitiveness from a cost perspective regarding all of Orexo's products, from innovation to effective global sourcing. A short term objective is to substantially reduce manufacturing costs for Zubsolv, with a gradual impact from 2018.
- To develop a portfolio of proprietary products with the short term objective of advancing at least one of our exploratory projects into our innovative development pipeline in 2017.
- Add products to our US commercial business. During 2017 we will have taken steps toward an enhanced portfolio.
- Remain an attractive employer with employees whose work is characterized by strong commitment!

Vision

The aim and vision is to develop a growing profitable specialty pharmaceutical company which through its own sales can finance the development of new pharmaceuticals, within several theraputic areas, based on Orexo's innovative technologies

Strategies

Maximize Zubsolv's potential

- Continue to win market share in the US through improved market access and by leveraging the anticipated market growth from increased access to treatment for patients. Continuously monitor the market dynamics and review if re-allocation or expansion, where feasible, of our field force is needed.
- Make Zubsolv® available to patients in new markets together with our partner Mundipharma
- Lower the manufacturing cost of Zubsolv to improve profit contribution and long term competitiveness.

Expand commercial portfolio with revenue generating products

- Through acquisitions or by establishment of partnership through in-licensing or co-promotion agreements
- Out-license products for other geographies than the US to share development risk and secure future royalty stream

Expand the pipeline

- Develop products for the oral tract and in particular sublingual products. The development work is led from Uppsala, Sweden, and is carried out in collaboration with external partners in order to achieve world-class technologies with strong patent protection.
- Based on our drug delivery expertise we also have options to develop improved pharmaceuticals also in therapeutic areas other than opioid dependence and pain. Orexo will work opportunistically where we see an opportunity to develop differentiated products based on our own innovative technologies.
- Products will be developed in therapeutic areas where Orexo can apply unique technology addressing patients' unmet needs and create a paradigm shift in delivery of the product. The commercial potential will be crucial for decisions to invest in these projects.
- Orexo will seek collaboration with partners where their technologies can accelerate development, lower the risk in the development or strengthen the IP for future Orexo products

Proven business model

Orexo's business is associated with lower risk, shorter development times and lower investments. Since the establishment of an in-house commercial organization in the US, Orexo is today a fully integrated specialty pharmaceutical company. The plan is that revenues from company sales will finance the development of new drugs.

KEY INPUTS

- High degree of innovation
- Proprietary drug delivery technologies developed in-house
- Experience from taking four products from idea to patient
- Products approved in multiple markets
- Fully integrated specialty pharmaceutical company
- Responsible leadership
- Committed and qualified employees

WHAT WE DO

Create value by development and commercialization of new drugs, on our own or together with partners, that

– offer considerable medical advantages

– meet large unmet needs

– have commercial potential

Read more:
About Orexo, pages 2–3

HOW WE GENERATE REVENUE

- Commercialization of in-house and/or licensed products on the American market
- Commercialization of in-house products through collaboration with partners in markets outside the US
- Milestone payments related to development projects and products launched through collaboration with partners in markets outside the US

Read more:
Sales, pages 18–20

Orexo's journey to becoming a fully integrated specialty pharmaceutical company

1995

Orexo is founded with a vision to develop improved pharmaceuticals, fulfilling unmet patient needs. This is done by optimization of the properties of well-documented substances in combination with Orexo's innovative drug delivery technologies. This approach is associated with less risk, shorter time to market and less investments required, compared to development of new chemical entities (NCE).

2005

Orexo is listed on the Nasdaq Stockholm stock exchange in anticipation of the launch of Abstral® and Edluar® in the US and Europe by partners. Both products are based on Orexo's proprietary sublingual tablet formulation.

2007

Orexo acquires the biotech company Biolipox with the ambition of broadening the business model to also include development of traditional NCEs. In 2016 AstraZeneca acquires the lead project from Biolipox, OX-CLI. Today OX-CLI is in late pre-clinical stage.

2010

Orexo issues new shares and Novo A/S enter Orexo as the largest shareholder. With the investment from Novo A/S the Board of Directors reviews the strategy and creates a vision of establishing a commercial business based on Orexo's proprietary products.

2013

Orexo establishes a commercial subsidiary in the US and launches Zubsolv® in September 2013. The launch is just ten weeks after FDA approval, in parallel with the establishment of Orexo's US business.

2016

After three years in the US Orexo sells Zubsolv for more than MSEK 480 and more than BSEK 1 gross, thereby reaching the first full year in history with profitability and with a positive profit. The US subsidiary contributes with positive profit and cash flow.

2017

In 2017 and beyond Orexo continues the development strategy of optimizing properties of well-documented substances and combining them with Orexo's innovative drug delivery technologies. Throughout the development process Orexo will seek partners and expertise whenever needed, to secure improvements and uniqueness of new products. These will be launched by Orexo in the US and partnered for other markets.

Innovation – our legacy

Orexo is a company built on innovations stemming from the interplay between talented researchers and experts with different scientific backgrounds. This innovation legacy still characterizes Orexo in the work of continuing to develop formulation technologies, thus benefiting patients around the world with improved drugs.

Culture

Orexo has created a workspace with an open minded environment where new product ideas are captured from all across the organization. In our view, transparency and multifunctional interactions are key drivers for establishment of an innovation culture. Orexo strives to initiate product development internally and maintain full control of the development process. However, we are increasingly working with selected external partners who can provide leading and unique expertise in the development programs.

Orexo has created a workspace with an open minded environment where new

product ideas

are captured from all across the organization

Talents

Orexo is a fully integrated specialty pharma company with expert competence in a multitude of scientific disciplines. Our talents are continuously fostered and advanced through individually compiled development plans. With the patient in focus, Orexo's innovative drug development process is characterized by engagement, flexibility and simplicity.

Process

Project and product ideas are captured from all employees within the organization. All ideas are evaluated and prioritized with regards to e.g. which unmet medical need is addressed, technical feasibility, patentability and commercial potential. This process is enabled by the multifunctional interplay between researchers and experts, and is a key to success.

Value

As a result of an innovative culture, talents and transparent processes, Orexo has been able to create a unique track record of developing proprietary innovative products with significant value for patients and societies around the world. To date Orexo has developed four products, Zubsolv®, Abstral®, Edluar® and Diabact®[1] which have been approved in multiple countries across the world. Both Abstral and Diabact have become the leading brand in several markets. During 2016, gross revenue for products developed by Orexo exceeded BSEK 2, thereby generating royalties for Abstral and Edluar in addition to net revenues for Zubsolv.

1) Divested together with former subsidiary Kibion.

Stepping into the future

Orexo has managed to develop innovative drugs of considerable value to patients all over the world. The patient's needs have been central in the development of all products' formulations, and the focus has been on improved administration. In 2016 the first steps were taken towards the future formulation technologies, with the ambition to develop innovative technologies for both oral and sublingual formulation of drugs.

Sublingual formulation technology

The sublingual space represents numerous opportunities as well as challenges for the delivery of drugs. Sublingual products need to be well tolerated by patients and properties such as taste and mouth feel are critical for successful treatment. Furthermore, the amount of saliva available under the tongue is limited, which sets significant requirements on the formulation in order to act efficiently. Orexo is recognized as a world leader in the development of efficient sublingual products. Zubsolv®, Abstral® and Edluar® all utilize Orexo's proprietary sublingual formulation platform based on interactive mixture principles, providing rapid onset and efficient absorption of the drug across the sublingual mucosa. In Zubsolv, this concept has been further refined, resulting in a product with highly efficient absorption across the sublingual mucosa. This enabled the development of a product with significantly improved efficiency compared with those of competitors.

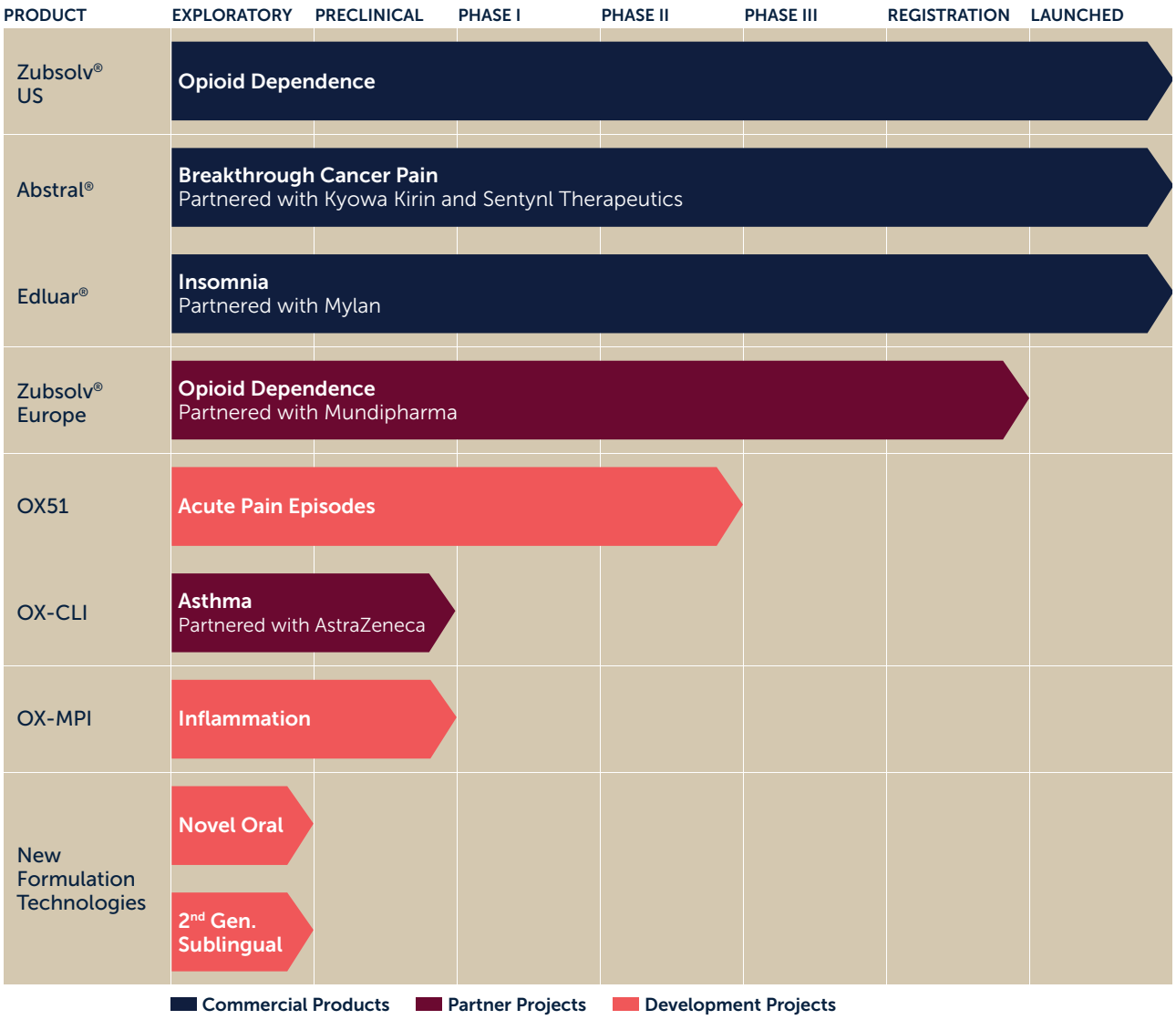
Orexo is currently developing its second-generation sublingual formulation technology. The aim is to perfect the sublingual delivery of drugs, thereby unlocking new active ingredients that are currently not possible to administer sublingually. Several active ingredients have been identified as promising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

Novel oral formulation technology

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

Products approved in multiple markets

The Orexo portfolio contains commercial products, partner projects as well as Orexo's own development projects. Our aim and ambition is to create value through development and commercialization of new drugs offering superior medical benefit addressing unmet medical needs.



Commercial Products

ZUBSOLV

Zubsolv®
– treatment of opioid dependence
Zubsolv is a product for the treatment of opioid dependence. Zubsolv has comparable efficacy and safety as well as the same active components as previously approved buprenorphine/naloxone sublingual formulations. However, Zubsolv offers unique advantages specifically designed to meet the needs of our patients:

- Higher bioavailability
- Fast dissolve time
- Preferred menthol flavor
- Broadest range of dose strengths

In July 2013, Zubsolv was approved for the maintenance treatment of opioid dependence by the US Food and Drug Administration, FDA, and in August 2015 the product also received approval for induction treatment of the same patient population. Zubsolv (buprenorphine and naloxone) sublingual tablet (CIII) should be used as part of a comprehensive treatment plan, which includes counseling and psychosocial support. Treatment should be initiated under the direction of physicians who are certified under the Drug Addiction Treatment Act of 2000 (DATA 2000).

Product	Zubsolv
Indication	Opioid dependence
Commercialization	Orexo Inc., Mundipharma
Market	US, Global[1]

ABSTRAL

Abstral®
– treatment of breakthrough cancer pain
Abstral is a rapidly disintegrating sublingual tablet for management of 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 pain relief. Product advantages include:

- Rapid disintegration and absorption over mucous membrane
- Fast onset of pain relief
- User friendly – tablet easy to dose, store and handle

The product was initially approved for sales in Europe in 2008. Approval and launch in other major territories has followed, and Abstral is currently available in key markets such as US, Japan, Canada and EU. Globally, the market for Abstral has continued to grow rapidly over the years, and in Europe Abstral is the market leader among all fast-acting fentanyl-based products.

Product	Abstral
Indication	Breakthrough cancer pain
Commercialization	Sentynl Therapeutics,[2] Kyowa Kirin
Market	Global, ex US

EDLUAR

Edluar®
– treatment of short-term insomnia
Edluar is based on Orexo's sublingual tablet technology and the active substance zolpidem. The product offers treatment for short-term insomnia. Zolpidem is a well-documented substance that has been used in the treatment of insomnia for a long time. The Edluar tablet is placed under the tongue, where it rapidly dissolves and the active ingredient is absorbed through the mucous membrane.

Edluar was approved by the US Food and Drug Administration, FDA, in March 2009. In June 2012 Edluar was approved for registration in Europe.

Product	Edluar
Indication	Insomnia
Commercialization	Mylan
Market	Global

1) On June 30 2016, Mundipharma acquired the rights to commercialize Zubsolv outside of the US. On October 3 2016, a regulatory submission for Zubsolv was filed with the European Medicines Agency (EMA). Approval of Zubsolv for the treatment of opioid dependence in Europe is anticipated by the end of 2017.
2) Sentynl Therapeutics is a fully owned subsidiary of Zydus Cadila.

Partner projects

Zubsolv® ex US
– treatment of opioid dependence

Nearly 20 million people are suffering from opioid dependence outside of the US and the problem exists both in developed and less developed countries. Heroin remains the main opioid abused outside of the US, whilst countries continue to monitor for any signs of increased misuse of other opioids including prescription medicines.

As a result of the license agreement with Mundipharma, signed June 30, 2016, a new treatment option will potentially be made available to benefit patients with opioid dependence outside of the US. Mundipharma, through its network of independent associated companies, has a presence in 48 countries worldwide, and takes responsibility for all of the key markets where Zubsolv is not available today. The first important milestone in the collaboration was achieved on October 3, 2016, when a regulatory submission for Zubsolv was filed with the European Medicines Agency (EMA). Approval of Zubsolv for the treatment of opioid dependence in Europe is anticipated by the end of 2017.

OX-CLI
– respiratory tract diseases

The OX-CLI project is a Leukotriene C4 (LTC_4) synthase inhibitor program. The OX-CLI project is a new chemical entity (NCE) project, and aims to enable development of a novel treatment for respiratory diseases such as asthma and COPD.

AstraZeneca established collaboration with Orexo for OX-CLI in 2013 and has since been responsible for all investments, as well as all research and development activities. As the program has advanced into pre-clinical development with an identified development compound (Candidate Drug), AstraZeneca chose to exercise their option to acquire all rights to the OX-CLI project in Q1, 2016. In accordance with the option agreement, Orexo earned a milestone payment of MUSD 5 (MSEK 40.8) for the rights to OX-CLI.

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

Development projects

OX51
– prevention of acute episodes of pain

OX51 is a novel sublingual formulation comprising alfentanil. The project has been developed to meet the rapidly growing demand for effective pain relief during short surgical and diagnostic procedures, and ER/ ambulatory settings. A phase 2 study in patients undergoing prostate biopsy was successfully completed and supports the continuation of the development program. The commercial potential of OX51 is estimated to be substantial and Orexo aims to identify a partner for phase 3 clinical development and commercialization in select geographies.

OX-MPI
– treatment of inflammatory related pain or disease

The OX-MPI project is aimed to develop a highly selective anti-inflammatory drug, targeting the membrane bound PGE_2 synthase (mPGES-1), for the treatment of inflammatory pain or disease. The project has identified two selective and potent compound series protected by several granted patents. A Candidate Drug has been selected and material has been scaled-up for preclinical and clinical studies. Orexo is looking for a partner to progress the development into clinical trials and commercialization.

New formulation technologies
Novel oral formulation technology

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

2nd generation sublingual formulation technology

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

Opioid dependence is a growing global problem

There are 25 million people in the world who are dependent on opioids.[1] The problem is greatest in the US, where 33,091 people died of an overdose in 2015,[2]. This is an increase of over 15 percent from 2014. The American market for the treatment of opioid dependence is growing by almost 8 percent per year.[3] Despite increased political focus, most people are still without treatment.

Substantial market growing strongly

A large increase in the number of prescription painkillers and an increased offering of illegal drugs has led to more and more Americans dying of an overdose. During the period 1999–2014, mortality tripled and is today one of the most common causes of death.[4] The market for treating opioid dependence with buprenorphine/naloxone has displayed strong growth in recent years. Annual growth is approximately 8 percent and the gross market value is estimated to be more than BUSD 2,4.[3] Extensive political and media attention has increased the awareness and knowledge of opioid dependence and has led to more people seeking help. The launch of the Affordable Care Act has also meant that more people have gained access to reimbursed care. In spite of the efforts made, it is still only a small percentage who receive treatment. Market development is impacted above all by continued improvement in access to treatment, in the form of more physicians being granted approval to treat, physicians being able to treat more patients and improved reimbursement for treatment and drugs.

Three payer segments – Public growing fastest

The market consists of three payer segments: Commercial, which comprises private insurance companies, Cash & Vouchers, where patients themselves finance their care, and Public, where care is financed by public sector payers such as Managed Medicaid, FFS Medicaid and Medicare Part D. Public differs from the other segments in that it is to a great extent stringently controlled by payers with regard to what drugs may be prescribed and which physician you as a patient can choose. Pharmacy Benefit Managers (PBM) play an important role, as on behalf of the insurance companies and employers they are responsible for assessing which drugs are to be covered by insurance. The Public segment has grown the fastest in recent years, driven by the fact that more and more people have gained access to publicly financed healthcare and employers have become more restrictive in offering private healthcare insurance.

In 2015

33,091

Americans died of an overdose, an increase of 15% since 2014

One player dominant

The market is dominated by one player who had a monopoly on buprenorphine-based treatment over a long period of time and has thus been involved since the start of this market. This leading player has a strong position and a market share of just under 75 percent.[3] There are five generic company players and their collective market share amounts to just under 19 percent.[3] Orexo's share of the market is approximately 6 percent.[3] There is also a smaller company in the market, selling under its own brand. Their share of the market is less than 1 percent.[3]

Price pressure but not driven by generics

The market is generally characterized by price pressure. This is above all true in the Public segment, which is stringently controlled and which has seen discount levels increase. In comparison with other pharmaceutical markets for drugs, generics have not had a significant price pressure effect. However, generics are favored by the fact that many insurance companies in the Public segment automatically give generics priority and thus indirectly put pressure on companies with new products to lower the price if insurance

1) World Drug Report 2016
2) Center for Disease Control and prevention
3) IMS Data
4) https://www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm655051e1.pdf

companies are to deviate from this principle. Since the launch of Zubsolv® the list price of generics has been on a par with or a little higher than that of the drugs sold under patent-protected brand names, but recently there have been campaigns from individual generic companies which have reduced the price to patients in the Cash segment to somewhat lower levels.

Illegal market – a gateway to heroin

The lack of treatment availability has given rise to the growth of the illegal market. Drugs containing the opioid buprenorphine are frequently bought, sold and priced on the illegal market, which is governed by the quantity of buprenorphine per unit, which means that drugs with a higher bioavailability procure a lower "street" price. Increased focus on and control of overprescribing of drugs containing opioids often leads opioid dependent patients to the illegal market, where the price of heroin is considerably lower than pharmaceutically manufactured opioid products.[1] Heroin gives a faster high, but the strength of each dose greatly varies and may be mixed with synthetic opioids, which is one of the main reasons for the explosive increase in the number of overdoses and deaths. Two thirds of today's heroin abusers have previously abused prescription painkiller drugs.[2]

Global need for access to medical treatment

Almost 20 million people outside the US suffer from opioid dependence and the problem exists in both developed countries and in less developed countries.[3] Heroin continues to be the predominantly abused opioid outside the US and overdose deaths remain a significant concern. Today there is an estimated 1.3 million high-risk opioid users in Europe, and approximately 650,000 patients are being treated.[4]

BUSD 2.4

The value of the market for treatment of opioid dependence is estimated to be more than BUSD 2.4

2/3

of today's heroin abusers have previously abused prescription painkiller drugs

6%

Orexo's market share is approx. 6%

1) https://www.drugabuse.gov/publications/research-reports/relationship-between-prescription-drug-heroin-abuse/prescription-opioid-use-risk-factor-heroin-use
2) Grace Chang, MD MPH Professor of Psychiatry, Harvard Medical School, The Opioid Crisis in America, 11 October 2016
3) UNODC World Drug Report 2014
4) EMCDDA, European Drug Report, 2014, Indivior (November 2014)

Global forces increasing abuse of opioids and other drugs

The great increase in prescription painkiller drugs in the past decade has led to more and more Americans abusing opioids. This development is also the result of strong underlying global forces that go beyond tablet abuse and which have led to an explosion in the number of opioids and other drugs available and their abuse.

Social exclusion and mental ill health

Developed countries often have a larger percentage of drug consumption. Individuals with a higher socioeconomic status tend to introduce but also facilitate the establishment of illegal drug use.[1] However, it is usually socially and economically vulnerable people in these societies that develop an addiction or suffer from physical or mental impairment in connection with their abuse. People living on the fringe of society whose lives are characterized by long-term unemployment, social exclusion and shattered dreams are not seldom a hotbed for extensive drug dependence.

Migration

Flows of refugees can have an impact on the use of drugs. People fleeing from war and conflicts often live under difficult circumstances and often lack a social safety net. Studies demonstrate that people suffering from posttraumatic stress and depressions run a greater risk of being introduced to drugs. Being a refugee also means increased exposure to new drugs.[1]

Trafficking

Drug trafficking

With the spread of globalization, trade barriers have been removed, thus promoting world trade. At the same time, the ability of illegal drug cartels to reach out to more markets has been facilitated, which has led to drug trafficking growing. Increased efficiency of distribution channels and increased competition have also generally led to the lowering of drug prices among users.

Human trafficking

After drugs and weapons, human trafficking is the third largest and most profitable organized crime in the world. In 2012 the International Labour Organization (ILO) estimated that 21 million people were the victims of trafficking.[2] This type of crime is one of the most profitable, is growing the fastest and is strongly linked to drug abuse.[3]

Illegal drug industry

To reduce the risk of unlawful distribution and abuse, the market for drugs classified as narcotics is stringently regulated. At the same time it is estimated that more than 5.5 billion people each year have very little or no access to drugs classified as narcotics for the treatment of moderate or severe pain.[1] This development is one of several reasons for the great gains made by the illegal drug industry, which further increases the risk of abuse.

1) World Drug Report 2016
2) International Labour Organization
http://www.ilo.org/global/topics/forced-labour/lang--en/index.htm
3) U-fold, Uppsala University

Zubsolv broke sales record

Sales of Zubsolv® in the US displayed growth of 16 percent. One contributory factor was an exclusive agreement with the state of Maryland. At the same time definitive federal decisions were taken that pave the way for more opioid dependent patients receiving care. Orexo's position in the market continues to strengthen. The aim is to take a greater percentage of the new patients beginning treatment in 2017.

Sales of Zubsolv® in the USA amounted to MSEK 481.8. This was an increase of approximately 16 percent compared with the year before and was a strong recovery considering that 2016 began with a weaker position in the market. However, market share did not develop in the same manner and fell from 6.4 percent at the end of 2015 to 6.0 percent in the fourth quarter of 2016.

Federal decisions increase access

Several important federal decisions were taken for the 5 million Americans who are dependent on opioids. First the US Department of Health and Human Services (HHS) announced that the ceiling for how many patients a doctor may treat with buprenorphine per year was raised from 100 to 275. The change was introduced at the beginning of August 2016 and is applicable to those doctors who apply for certification. Shortly afterwards, the US Congress signed CARA,[1] which among other things means that nurse practitioners and physician assistants may also write buprenorphine prescriptions. This change will be implemented in 2017.

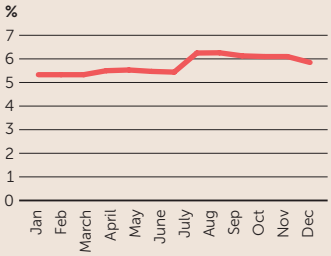
In addition to more people receiving care, the market has been given a chance to normalize. The decisions increase financial incentives for physicians to start or expand clinics and services offered by treating larger patient populations. Orexo anticipates that the decisions will have a limited impact on the market in the short term. Physicians need time to adapt their practice models and an effect will probably be visible above all in the longer term.

1) Comprehensive Addiction and Recovery Act

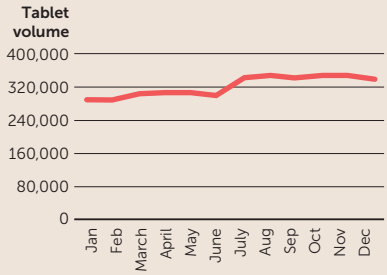
60%

of physicians certified at the end of 2016 were covered by the sales force, and a further 18% were within geographic reach

ZUBSOLV MARKET SHARE[1], 2016



ZUBSOLV TABLET VOLUME[1], 2016



Source: IMS

1) Four week rolling average

Maryland can open more doors

As of July 1, 2016 Zubsolv® became the only preferred product on FFS Medicaid's list for buprenorphine/naloxone products in the state of Maryland. In comparison with other states in the USA FFS Medicaid is largest in Maryland. The decision was based on the properties of the product, clinical data, the discount level and statements from a number of different categories of stakeholders supporting this decision. The agreement meant that the reduced sales volume in connection with Zubsolv losing its prioritized position with CVS Caremark as of January 1 2016 was quickly recovered. In the autumn the record for the number of tablets sold was equaled. After the initial increase, certain patients decided to return to their previously prescribed drug, which impacted market share negatively in Q4. The Maryland agreement is associated with large discounts, which is largely compensated for by lower selling expenses as Orexo does not need to expand its sales force in Maryland.

Since FFS Medicaid in Maryland introduced Zubsolv as the preferred product in the category, the state has seen a large decrease in the illegal distribution of drugs to prisons. This is a problem that gives rise to high costs for society associated with the epidemic of opioid addiction. Orexo's aim is to transfer the Maryland model to other American states.

Well-positioned for new opportunities

Since the HHS lifted the ceiling for how many patients a doctor may treat, the number of certified doctors has increased a great deal. From August, when the change was introduced, until the end of December, 2016, 2,600 were granted C275 certification. According to a market survey that Orexo completed during the summer, the C275 physicians expect that they will want to treat a further 100 more patients per year on average. The percentage of doctors that have applied for and been granted C275 certification is greater than the number who said that they planned to apply, which can lead to a somewhat lower average number of patients

The chance of Zubsolv gaining new market share depends on where growth takes place and above all the price subsidy for Zubsolv for new patients. Of the doctors certified at the end of 2016, 60 percent were covered by the sales force, and a further 18 percent were within geographic reach.

IMS data show that Zubsolv's share of previously untreated patients is

10.7%

In order to further improve the company's positioning, the sales force was redistributed somewhat towards the end of the year in order to strengthen our market access in those parts of the market where there is a good reimbursement and many recently certified doctors. Orexo continues to constantly evaluate changes in market dynamics and intends to increase the sales force in order to improve coverage of newly certified doctors where so possible and where we can see that the sales force can make a positive contribution to our profitability.

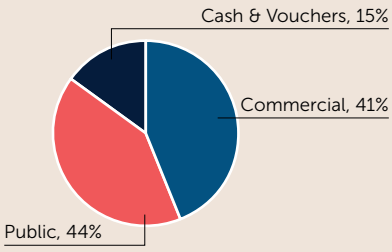
IMS data show that Zubsolv's share of previously untreated patients is 10.7 percent, which is higher than the average total market share. Orexo aims to continue to take a higher percentage of new patients in those regions where there is good coverage.

Zubsolv's share grew in two of three payer segments

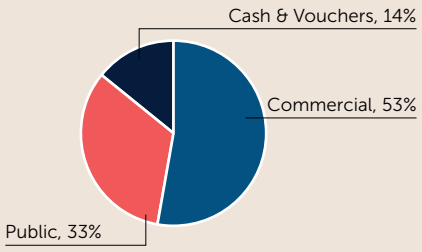
The Public segment continued to grow fastest of the payer segments, driven by the expansion in insurance coverage. The Public segment's volume increased by just over 16 percent. In order to take advantage of this market growth, Orexo increased its efforts in the segment, and this resulted in the Maryland agreement and generally improved access to the market from January 1, 2017 compared to the beginning of 2016. Even though certain patients in Maryland chose to return to previous treatment, Zubsolv's market share in the Public segment increased. The agreement in Maryland had a positive impact while Wellcare had a negative impact in December when a large group of treatment clinics in Kentucky decided to leave the insurance company.

The Commercial segment's volumes increased by 4.5 percent in 2016. Zubsolv's market share in the segment fell compared to 2015, which is explained by the formulary status change at CVS Caremark at the same time as the

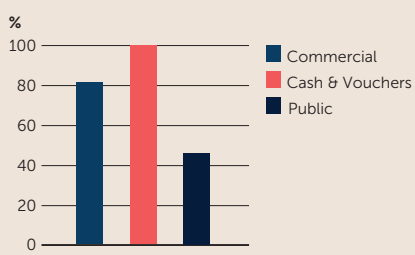
TOTAL MARKET VOLUME PER PAYER SEGMENT



TOTAL ZUBSOLV VOLUME PER PAYER SEGMENT



ZUBSOLV'S MARKET ACCESS PER PAYER SEGMENT



Source: IMS

agreements with the United Health Group, Express Scripts and CIGNA had a positive impact. Adjusted for CVS Caremark we saw an increased market share in this segment during the year.

Unlike the other payer segments, Cash & Vouchers' share of total market volume decreased by 7.7 percent. However, Zubsolv's market share increased marginally in the segment.

Improved access to treatment will probably mean that all the segments will grow in 2017 and that the Public segment will continue to display the fastest growth.

Market access continues to strengthen

Zubsolv® market access improved during the year, both through new agreements and improved positions in existing agreements. The new agreements include FFS Medicaid in Maryland, CIGNA and CDPHP. At the beginning of 2017, access to Zubsolv was further improved through the signing of a contract with a major insurance company within Medicare Part D and an insurer within Managed Medicaid, as well as some smaller regional insurance companies.

One step closer to global launch

During the year Mundipharma acquired the commercial rights to Zubsolv outside the USA. This means that patients who are dependent on opioids in the rest of the world (RoW) can gain access to a new treatment. With its network of independent associated companies in 48 countries, Mundipharma will be able to cover all the important markets where Zubsolv is not available today.

An important first milestone in the collaboration was reached in October, when a regulatory registration application for Zubsolv was submitted to the European Medicines Agency (EMA). Approval to be able to treat opioid dependence in Europe is expected in the fourth quarter of 2017. Europe is an important first step in the global launch of Zubsolv.

In addition to creating value through the launch of Zubsolv in RoW, other economies of scale are expected, such as increased production volumes, which over time will contribute to Orexo's gross margin.

Royalty revenues for Abstral reached over MSEK 100

Orexo's commercial partner, Kyowa Hakko Kirin, who own the rights to Abstral® outside the USA, continued to focus on getting the market to grow. Abstral, which treats breakthrough pain in cancer patients, was approved for sales during the year in Australia and six countries in the Middle East.

In the European Union, where Abstral is the market leader, sales increased by 9 percent compared to 2015 and amounted to MEUR 85 (MEUR 78). Orexo receives royalties on sales exceeding MEUR 42.5, which was achieved, one month earlier than expected, in July 2016. Variable royalty revenues were received during the year from Abstral's sales corresponding to MSEK 74.9, an increase of 29 percent. In accordance with the partnership agreement that was renegotiated in 2012, no fixed royalties were paid. These last impacted net sales in May 2015.

Sales of Abstral in the RoW region, that is markets outside the EU and USA, have continued to grow. Development was driven above all by strong demand in South Korea, Israel and Australia. Total sales in the region amounted to MUSD 9, an increase of 73 percent compared to 2015.

The American market continued to be characterized by tough competition and greater restrictions on the prescription of products containing Fentanyl, which resulted in negative market growth. Orexo's collaboration partner, Sentynl Therapeutics Inc., continued the work of relaunching Abstral.

Edluar's royalty revenues increased 8%

Mylan acquired Orexo's partner Meda AB and as a result of this the global rights for Edluar® were transferred to Mylan. Royalty revenues for Edluar during the year amounted to MSEK 14.8, an increase of 8 percent. As Mylan at the time of publication of the Annual Report had not given any information about total sales for 2016, the figure has been estimated on the basis of sales in the third quarter of 2016.

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

We care for our environment

Orexo's ambition is to be globally recognized for the added value our products bring to patients and societies and we want to be a trusted partner for suppliers and other stakeholders. We are aware that our direct and indirect operations have an impact on our environment. Orexo's long-term success is ensured by our commitment to integrating sustainability in all our business processes.

Focus on the entire value chain

Orexo's sustainability work includes the entire value chain, both internal work and collaboration with external parties. Orexo has therefore established both an internal Code of Conduct and a special Supplier Code of Conduct in order to make clear the standard that is to permeate the business.

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 must be taken into account internationally and in the various countries where a study is conducted. Since the studies are based on well-known compounds, the risk level is generally lower relative to clinical tests of new molecules.

Product supply and outsourced activities

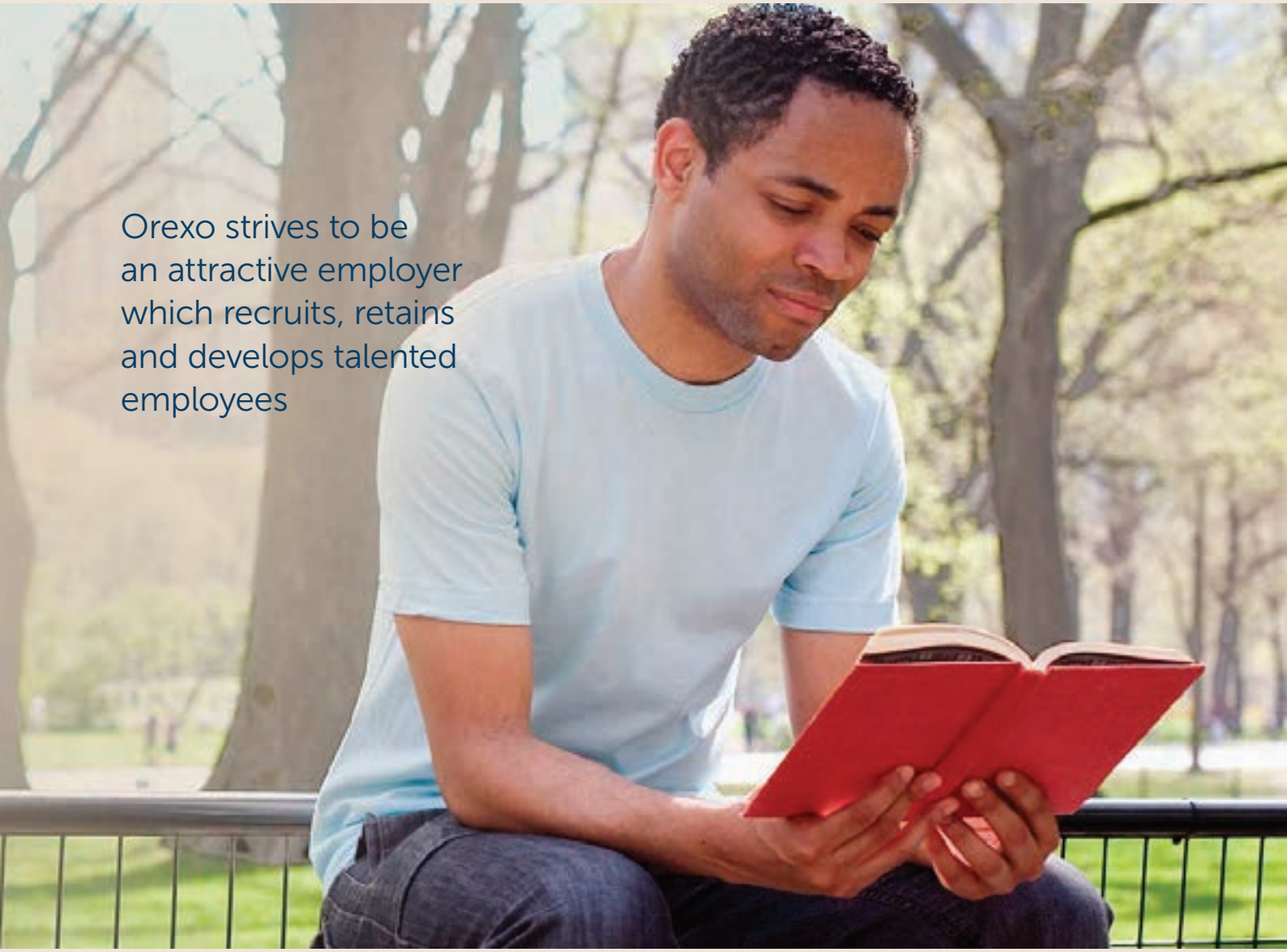
Orexo's Supplier Code of Conduct serves as a guide in the procurement of goods and services and informs suppliers of what Orexo expects. The Code covers business ethics, labor conditions, health and safety, product safety, supply chain integrity and the management system. The Code is applied in the evaluation of new potential suppliers and in collaboration with existing suppliers. Risk is assessed, as well as how Orexo can impact the supplier's work regarding environmental management and health and safety. Should a supplier not meet Orexo's requirements, the company will initiate a dialog to achieve improvements.

Environmental work

Within the overall sustainability work, Orexo focuses its environmental work on product development, the supply of goods and the handling of chemicals.

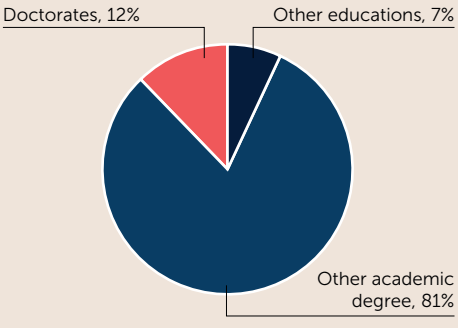
We are committed to continuing reduce the environmental impacts of our business and our products by increasing energy efficiency, reducing consumption of materials, improving waste management and by keeping emissions of pharmaceutical substances at low levels. In order to reduce business travel, the company encourages business meetings to be held by telephone or on the web.

In order to ensure that the company follows current environmental laws, regulations, directives 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 continually improving Orexo's environmental work and for employees receiving appropriate environmental training and information.



Orexo strives to be an attractive employer which recruits, retains and develops talented employees

LEVEL OF EDUCATION



In the US the total cost to society related to dependence on illegal drugs, including opioid dependence, amounts to

BUSD 193 per year

Social

Society

Orexo's main market today is the American market for treatment of opioid dependence. A large increase in the number of prescription drugs and an increased range of illegal drugs has made more and more Americans dependent. Overdose mortality tripled during the period 1999–2014 and is today one of the most common causes of death.[1] Socially exposed groups in society are particularly impacted, especially women.[2] Being dependent on opioids impacts not only the individual person but also many people in the immediate environment. In the USA the disease affects entire families and children are hardest hit.

Orexo's main product Zubsolv® is an effective drug for people suffering from opioid dependence. The drug should be used as part of a complete treatment plan, including counseling and psychosocial support.

Employees

Orexo strives to be an attractive employer which recruits, retains and develops talented employees. 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. At year-end, the Orexo Group had 102 (90) employees, including 55 (51) at Orexo AB, and 47 (39) at Orexo US, Inc. 44 (48) percent of the employees are women and 15 (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.

Employee survey

In order to capture points of view and identify areas for improvement, Orexo has carried out annual employee surveys since 2012. The surveys cover eleven different areas for improvement such as leadership, level of performance, learning at work, efficiency and target quality. The results for 2016 were the best ever at 81.5 points, which is to be compared with 80.0 points the previous year. A score of over 70 is classified as a high score and indicates that the conditions for employees carrying out their work are very good.[3]

Competence development

The employees' high level of expertise is a crucial success factor for Orexo. 12 percent hold doctorates and 81 percent hold other levels of academic degree. Approximately 21 percent of the employees are active in research and development. All employees have individual development plans and targets.

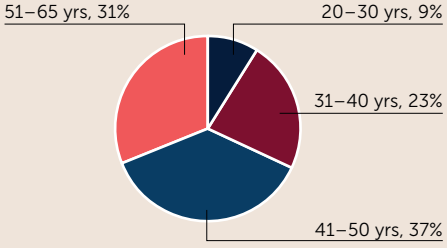
Company culture and core values

Several common activities were arranged for the employees during the year. Amongst other things, employees attended a seminar on how opioid dependent patients in Sweden are treated today and how they were treated historically. A workshop was also carried out to stimulate positive thinking and to learn the value of listening to and understanding other people. The aim of the activities is to further strengthen knowledge of Orexo's core values

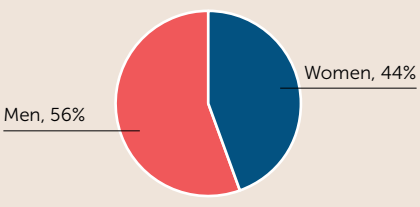
- customer focus
- engagement
- flexibility
- simplicity

1) https://www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm655051e1.pdf
2) World Drug Report 2016
3) Springlife

AGE DISTRIBUTION



GENDER DISTRIBUTION



Work environment

Orexo's health and safety program is coordinated by the company's safety committee and by safety delegates appointed by the staff. Risks in the working environment are regularly evaluated. Any incidents and accidents are followed up and appropriate measures are taken. Occupational health and safety training is conducted throughout the year.

Employee health

Orexo shall be a healthy and safe workplace. 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. Orexo also contributes towards fitness activities and preventive ergonomics.

In 2016 sick leave increased from 1.9 percent (2015) to 4.0 percent (2016). Despite the increase, the level is considered to be at a normal level, in comparison with other companies.

Economy

Business integrity and anti-corruption

Orexo is committed to compliance with all applicable anti-bribery and corruption laws like the US Foreign Corrupt Practices Act and the UK Bribery Act.

Neither Orexo nor any employee may accept, offer or pay bribes or directly or indirectly accept gifts, hospitality, fringes or compensation in any form from a third party which may be unlawful or which could in any way affect his or her professional judgment in performing any duty or service for Orexo or a third party. It is not allowed to offer or make payments or anything else of value either as an inducement to get a favorable decision or action in the interest of Orexo or any employee.

It is particularly important to observe the above with respect to national and international government officials, healthcare professionals and organizations, patients, suppliers and charities. Orexo does not allow agents, contractors, advisors or others working for us to engage in conduct that is against our principles.

Orexo's Supplier Code of Conduct serves as a guide in the procurement of goods and services

Society economy

The extensive dependence on opioids in the USA involves a considerable burden for society from an economic point of view. In addition to loss of life and lower quality of life, large costs are associated with lower productivity and a lack of resources, as well as increased costs related to healthcare and prison care. The American National Institute of Drug Abuse estimates that the total cost to society related to dependence on illegal drugs, including opioid dependence, amounts to BUSD 193 per year.[1]

Orexo's presence in the market means that, together with several other players, the company contributes to reducing the economic burden that opioid dependence involves for American society. A concrete example is when Zubsolv® was selected in 2016 by the state of Maryland as the only recommended buprenorphine/naloxone drug on their FFS Medicaid list. The introduction of Zubsolv has, amongst other things, reduced the smuggling of similar drugs into prisons, which has had a positive impact on costs for society.

1) https://www.drugabuse.gov/related-topics/trends-statistics

The 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 7,021 shareholders and the non-Swedish shareholding in the company amounted to 52 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 40 percent and the last price paid in 2016 was SEK 37.60 (62.75). This corresponds to a market capitalization of MSEK 1,298 (2,161). The highest closing price during the year for the Orexo share was SEK 62.00 quoted on April 1. The lowest quotation was SEK 32.90 on November 11.

Liquidity

In total 21 (33) million shares in Orexo were traded in 2016, corresponding to a value of approximately MSEK 967 (2,653). The daily average trading volume was 88,758 shares, corresponding to a value of MSEK 4.

Ownership

At year-end, Orexo had 7,021 (6,944) shareholders, of which 668 were registered as legal entities and 6,353 as private individuals. Of the share capital, 48 (43) percent is held by shareholders registered in Sweden and 52 (57) percent by non-Swedish shareholders. The largest proportion of shareholders registered outside Sweden can be found in Denmark at approximately 35 (35) percent.

The list on page 26 is by shareholder group, where a number of legal entities may be part of each group.

Issue and repurchase class C share

Orexo announced on September 22, 2016, that the company had resolved to issue and immediately thereafter repurchase 200,000 class C shares. The shares were issued and repurchased in accordance with the Long-Term Incentive Program (LTIP) 2016, which was adopted by the Annual General Meeting on April 15, 2016.

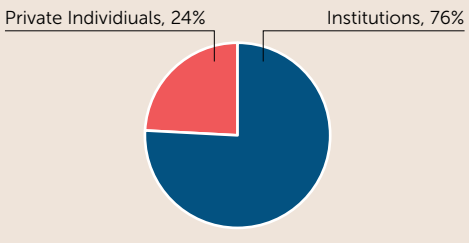
Danske Bank subscribed for the entire issue of new class C shares at a subscription price of SEK 0.40 per share, equal to the quota value of the shares. The entire issue of class C shares was thereafter repurchased by Orexo for SEK 0.40 per share.

The purpose of the share issue was to enable the future delivery of ordinary shares to participants in LTIP 2016. The class C shares will be converted into ordinary shares prior to delivery to qualifying participants in LTIP 2016. The Class C shares do not entitle to dividends.

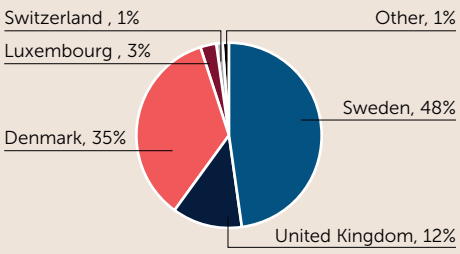
Analysts monitoring Orexo

- ABG, Sten Gustafsson
- Carnegie, Erik Hultgård
- Edison Group, Lala Gregorek
- Erik Penser Bankaktiebolag, Johan Löchen
- Redeye, Klas Palin

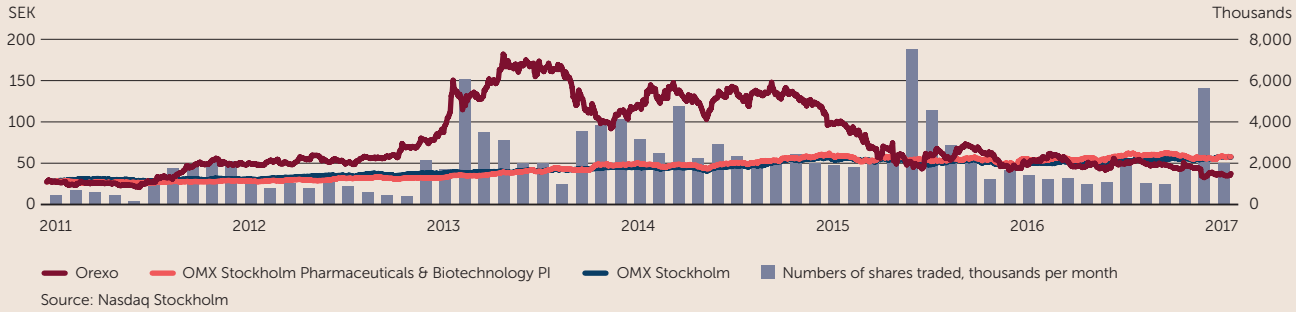
OWNERSHIP CATEGORIES



OWNERSHIP DISTRIBUTIONS PER COUNTRY

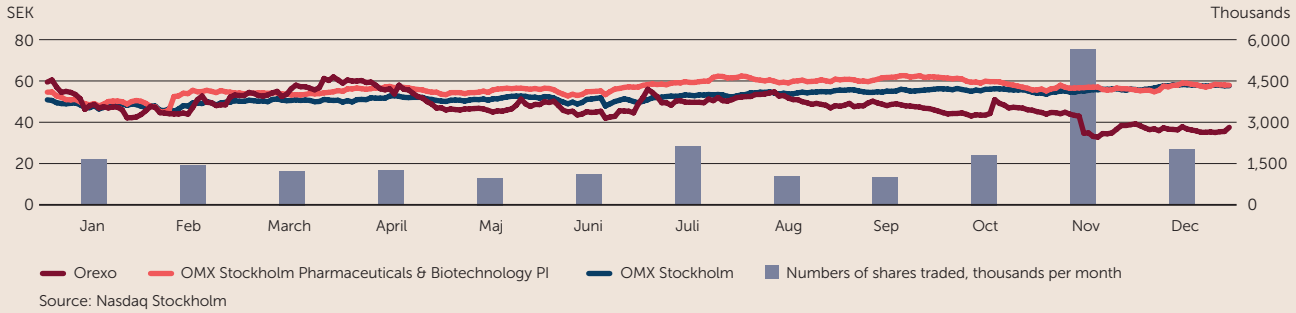


FIVE YEARS PERFORMANCE



Source: Nasdaq Stockholm

PERFORMANCE IN 2016



Source: Nasdaq Stockholm

SHAREHOLDERS, DECEMBER 31, 2016

	No. of Shares	Share Capital %
Novo A/S	9,643,184	27.7
HealthCap	3,960,020	11.4
Arbejdsmarkedets Tillaegspension (ATP)	2,040,633	5.9
Försäkringsaktiebolaget Avanza pension	1,506,663	4.3
Brohuvudet AB	1,000,000	2.9
Lancelot Avalon	786,611	2.3
Nordnet Pensionsförsäkring AB	591,263	1.7
Danske Capital Sverige	559,249	1.6
Danica Pension	499,674	1.4
Lundqvist Thomas	457,552	1.3
Eccenovo AB	393,832	1.1
Anders Walldov	330,000	0.9
SEB Investment Management	222,980	0.6
Others	12,878,665	36,9
Total number of shares[1]	**34,870,326**	**100.0**

1) As of December 31, 2016, the number of shares outstanding in the company was 34,870,326 of which 34,535,326 were common shares and 335,000 were C shares. All common shares carry one voting right and the C shares carry 1/10 of a voting right each. Thus there were 34,568,826 votes in the company as of December 31, 2016.

Owners known to Orexo
Source: Euroclear Sweden AB

OWNERSHIP STRUCTURE, DECEMBER 31, 2016

	No. of Shareholders	No. of Shares	Share Capital %
1–500	4,433	752,899	27.7
501–1,000	937	785,979	11.4
1,001–5,000	1,222	2,887,321	5.9
5,001–10,000	227	1,706,767	4.3
10,001–15,000	54	688,304	2.9
15,001–20,000	37	688,721	2.3
20,001–	111	27,025,335	1.7
Total	**7,021**	**34,535,326**	**100.0**

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, 2016. Orexo's registered office is in Uppsala, Sweden.

Operations

Orexo develops improved pharmaceuticals based on innovative Drug Delivery technologies. The focus is primarily on opioid dependence and pain but it is our aim to address other areas where our competence and technologies can create value. The products are commercialized by Orexo in the US or via selected partners worldwide. The main market today is the American market for the treatment of opioid dependence, where Orexo sells the product Zubsolv. 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.
- Diabact®, a tablet for diagnosis of the gastric ulcer bacterium helicobacter pylori. This product was divested together with the subsidiary Kibion in 2015.

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 and royalties and milestone payments from licensing agreements.

In order to commercialize previously developed products, Orexo has licensing agreements with Sentynl Therapeutics (US), Meda (global), ProStrakan, Kyowa Hakko Kirin (global excl. the US) and Mundipharma (global excl. the US). On June 30, 2016, Orexo could announce the signing of a license agreement with Mundipharma, granting Mundipharma the rights to Zubsolv in all markets outside of 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 and in March, 2016, AstraZeneca acquired all rights to the project. Future milestone payments can be expected from this project as defined development and commercial milestones are met and royalties can be expected on potential future revenue generated.

Organization

The US subsidiary, Orexo 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. Sales force leadership are employed directly by Orexo and ensures full control of all sales & marketing activities. As part of an incentive scheme top performing representatives are on a regular basis converted from InVentiv Health employment to Orexo employment. The mix of rented and Orexo employed sales force resources enables high flexibility and full control.

During the year, Orexo focused development operations on completing the ReZolv study (Retrospective Evaluation of Zubsolv® Outcomes – A Longitudinal View) and performing and completing the Zubsolv bio-equivalence study required for submission of Marketing Authorisation Application (MAA) to the European Medicines Agency. The submission of the MAA was announced on October 4th, 2016. Work also continued on early stage and non-disclosed development projects.

Orexo has broad-based competence throughout the value 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 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.

Orexo has established a Supplier Code of Conduct that will guide in the procurement of goods and services and inform suppliers on what Orexo expects. All new potential suppliers are being assessed in accordance with the Supplier Code of Conduct. The assessment includes key suppliers sustainability efforts and performance.

At year-end, Orexo had a total of 102 employees.

Key events

2016 was the third full year with Zubsolv® on the US market. Progress was made including the approval of a unique Zubsolv low dose formulation by the US FDA, the completion of the registry study (REZOLV), the signed license agreement of the ex-US global rights to Zubsolv and the submission of the Marketing Authorization Application for Zubsolv in the EU by Orexo and Mundipharma. Throughout the year Orexo spend significant resources managing the ongoing patent infringement litigations against Actavis where a decision was announced in November.

Split outcome in the patent infringement litigation against Actavis for Zubsolv in the US

In November, Orexo announced that the US District Court for the District of Delaware ruled in Orexo's favor in one of the patent infringement litigations against Actavis regarding Zubsolv in the US. The decision was rendered in the patent litigation regarding Actavis's generic Zubsolv 1.4 mg /0.36 mg and 5.7 mg/1.4 mg buprenorphine/naloxone products, and Orexo's US Patent Nos. 8,454,996 (expiring in September 2019) and 8,940,330 (expiring in September 2032). In the decision, the district court held that Orexo's '996 patent is valid and infringed by Actavis, and that Orexo's '330 patent is invalid. The decision prevents Actavis from commercializing their products in the US before September 24, 2019. The other litigations regarding infringement by Actavis on Orexo's IP for Zubsolv continues. In December, Orexo announced that the company had appealed the decision rendered by the US District Court for the District of Delaware on November 15, 2016 regarding the validity of Orexo's US Patent No. 8,940,330 (expiring in September 2032) protecting Zubsolv. Orexo believes that the District Court committed reversible legal and factual errors in reaching its decision on the validity of the '330 patent. Orexo has therefore appealed the District Court's decision to the Court of Appeals for the Federal Circuit.

FDA approved unique low dosage of Zubsolv in the US

In October, Orexo received approval from FDA of a new unique low dose, 0.7mg/0.18 mg of Zubsolv (buprenorphine/naloxone) sublingual tablet (CIII) for the treatment of opioid dependence. The new introduction extended Orexo's best-in-class offering of the broadest dosage range of any buprenorphine/naloxone product on the US market to six individual dosage strengths.

Orexo completed the 1,080 patient REZOLV study, demonstrating improved treatment of opioid dependent patients

In September, Orexo announced that the retrospective study REZOLV (Retrospective Evaluation of Zubsolv Outcomes – A Longitudinal View) had been completed as planned. The study, with 1,080 patients, is the largest retrospective study completed in the US aimed at optimizing the treatment of opioid dependence. The study results have generated an extensive amount of clinical data that Orexo will use in its dialogues with key stakeholders, including physicians, prescribers, politicians and payers, on how to advance the treatment of opioid dependence.

Orexo welcomed increased access to treatment for patients with opioid dependence in the US

In July, Orexo publicly applauded the increased access to treatment for patients with opioid dependence in the US Administration's announcement on July 6. The cap on the number of patients that can be treated by physicians will increase from 100 to 275, starting 30 days after publication in the Federal Register.

Orexo signed license agreement with Mundipharma, regarding the ex US global rights to Zubsolv

In June, Orexo signed a license agreement granting Mundipharma's network of independent associated companies exclusive global rights to Zubsolv outside the US. Under the terms of the agreement, Orexo received an upfront payment of MSEK 65.4 (MEUR 7). Pending marketing authorizations and commercial milestones, Orexo will also be entitled to receive further milestone payments and up to low double digit royalties on future net sales. Orexo will also be compensated for specific expenses related to the work required to prepare Zubsolv for markets outside the US.

Orexo and Mundipharma announced EU regulatory submission for Zubsolv

In October, Orexo and Mundipharma filed the regulatory submission of a Marketing Authorization Application (MAA) for Zubsolv (buprenorphine and naloxone) sublingual tablet to the European Medicines Agency (EMA). If approved, Zubsolv would be the first fast dissolving buprenorphine and naloxone product available in six unique strengths for the treatment of opioid dependence in Europe. There are an estimated 1.3 million high-risk opioid users across Europe.

Orexo divested all rights to the OX-CLI project to AstraZeneca

In March, Orexo announced that AstraZeneca exercised its option and acquired all rights to the leukotriene C_4 synthase inhibitor program (OX-CLI project) aimed at developing a novel treatment of respiratory disorders such as asthma and COPD. Orexo received an up-front payment of MSEK 40.8 (MUSD 5). 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.

Completion of a bond buyback program
In December, Orexo announced that it has successfully completed a bond buyback program and in total purchased Orexo corporate bonds in the market with a nominal value of MSEK 99. The program was initiated on December 13, 2016, and completed by December 20, 2016.

Key Events After the Period
- In February Orexo completed another bond buyback program amounting to a nominal value of MSEK 59.
- In March Orexo commenced a patent infringement litigation against Actavis for their generic versions of Suboxone® and Subutex® tablets in the US.

Financial Performance

CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS

MSEK	2016	2015 Restated
Net revenues	705.9	646.2
Cost of goods sold	–149.6	–150.2
Gross profit	556.3	496.0
Selling expenses	–240.6	–297.5
Administrative expenses	–161.6	–141.5
Research and development costs	–132.3	–172.6
Other operating income and expenses	29.9	–65.0
Operating earnings	51.7	–180.6
Net financial items	–16.1	–23.0
Earnings after financial items	35.6	–203.6
Income tax	–6.5	–6.4
Net earnings for the period	29.0	–210.0

Revenues
Net revenues
Net revenues for the year amounted to MSEK 705.9 (646.2).

Net revenues were distributed as follows:

NET REVENUES

MSEK	2016	2015 Restated
Abstral® – royalty	100.4	77,2
Abstral – fixed royalty	–	59.9
Milestone payment Abstral	2.2	66.0
Abstral – total	102.6	203.1
Edluar® – royalty	14.8	13.6
Zubsolv® US	481.8	416.7
Zubsolv regionen RoW	65.9	–
Kibion	–	12.8
Other Total	40.8	–
Total	**705.9**	**646.2**

Launched products
During the year total revenues increased by 9.2 percent to MSEK 705.9 (646.2), with total Zubsolv revenue growth of 15.6 percent being the major driver.

The US buprenorphine/naloxone market grew by 7.7 percent during the same period. 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 2016 Orexo's level of access to reimbursement was 81 percent in the commercial segment and 45 percent in the public segment.

In July, 2016, the US Department of Health and Human Services (HHS) announced an increase in the buprenorphine patient cap from 100 to 275 patients and this change will enable an easier access to treatment and is expected to fuel further market growth. Zubsolv ended 2016 with a 5.8 percent market share.

On June 30, 2016, Orexo announced a new license agreement, granting Mundipharma rights to Zubsolv in all markets outside of the US. An upfront payment of MSEK 65,4 (MEUR 7) was received and pending marketing authorizations and commercial milestones Orexo is also entitled to receive further milestone payments and up to low double digit royalties on future net sales.

Total Abstral royalties and milestone payments during the year amounted to MSEK 102.6 (203.1).

Total variable Abstral royalties amounted to MSEK 100.4 (77.2) and the 30 percent growth was mainly driven by continued strong growth in the European region where Abstral is still the market leader in its segment. The fixed Abstral royalties for 2015 represents an amortization of the final fixed and unconditional payment which ceased in May 2015 and was related to the 2012 agreement with ProStrakan. The fixed royalties were fully recognized in the P&L by May 2015.

Royalty revenues from Edluar during the year amounted to MSEK 14.8 (13.6).

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

AstraZeneca acquired all rights to Orexo´s OX-CLI project for MSEK 40.8.

Expenses and earnings
Cost of goods sold
Cost of goods sold amounted to MSEK 149.6 (150.2) and this all relates to Zubsolv US revenue. During the second half of 2016 additional cost of approximately MSEK 6.5 was included for re-packing and de-blistering of Zubsolv tablets.

Selling expenses
Selling expenses amounted to MSEK 240.6 (297.5). The decline over previous year is explained by the US field force optimization commenced late 2015.

Administrative expenses
Administrative expenses amounted to MSEK 161.6 (141.5). The increase is primarily explained by higher costs related to protection of IP rights. Approximately half of the 2016 total administrative expenses were directly related to protection of IP rights.

Research and development costs
Research and development costs amounted to MSEK 132.3 (172.6). Clinical studies and other life cycle management

activities in the Zubsolv® program were completed during 2015 and explains the reduced costs. During 2016 the focus was mainly on the preparation for EU regulatory submission of a Marketing Authorization Application and the majority of the cost associated with this was re-imbursed by Mundipharma.

Expenses for the long-term incentive program
The Group's total costs for employee stock option programs amounted to MSEK –0.7 (–10.2).

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

EXPENSES FOR THE LONG-TERM INCENTIVE PROGRAM

MSEK	2016	2015
Administrative expenses	–0.7	–7.3
Research and development costs	–2.0	–4.6
Selling expenses	2.0	1.7
Total costs	**–0.7**	**–10.2**

Other income and expenses
Other income and expenses amounted to MSEK 29.9 (–65.0). The gain in 2016 was primarily related to revaluations of balance sheet items in foreign currency and an earn-out settlement related to the divestment of the subsidiary Kibion. The 2015 numbers were impacted by a write down of the OX-MPI asset amounting to MSEK 62.3.

Depreciation
Depreciation and amortization amounted to MSEK 21,4 (80.7). This includes amortization of previously capitalized R&D expenses related to the Zubsolv induction label. The 2015 numbers include the OX-MPI impairment charge of MSEK 62.3.

Net financial items
Net financial items amounted to MSEK –16.1 (–23.0). All the net financial items are related to financing activities. During fourth quarter of 2016 Orexo corporate bonds with a nominal value of MSEK 99 were bought back in the market and net financial items were positively impacted by the difference between book value and purchase price.

Income tax
Income tax for the year of MSEK –6.5 (–6.4) is mainly attributable to Orexo's operations in the US.

Net earnings
Net earnings amounted to MSEK 29.0 (–210.0). This was the first time in the history of Orexo with positive net earnings.

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

The interest-bearing liabilities are all associated with the Orexo corporate bond maturing in May 2018.

Positive cash flow before financing activities for the year amounted to MSEK 161.7 (–91.4) and was driven by positive contribution from both earnings and changes in working capital.

Shareholders' equity on December 31, 2016 was MSEK 310.3 (270.1) and the equity/assets ratio was 30 (26) 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 1.3 (4.1).

Parent Company
Net revenues amounted to MSEK 379.3 (518.9), whereof group internal sales amounted to MSEK 155,2 (305.0). Earnings after financial items were MSEK –95.8 (–162.3). During the fourth quarter of 2016 49 batches of Zubsolv were returned from Orexo Inc. to Orexo AB for de-blistering and re-packaging. During the same quarter 14 batches were sold back to Orexo Inc. These transactions had a negative impact on the parent company revenue, margin and net earnings. As of December 31, 2016, cash and cash equivalents in the Parent Company amounted to MSEK 211.7 (114.0).

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

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

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

The outlook is based on January 2017 exchange rates.

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 48. 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. The US payer structure and reimbursement system is very large and complex and therefore Orexo has established its own team of experienced people focusing only on improving market and reimbursement access for Zubsolv. The payers are constantly reviewing their formularies and this can lead to significant changes in market access. The year 2016 started with a reduction in access to the commercial segment as the pharmacy benefit manager (PBM) CVS Caremark chose to exclude Zubsolv from their standard formulary. In volume terms this loss was later compensated by the win of an exclusive FFS Medicaid contract with the state of Maryland effective July 1, 2016. By the end of 2016 Zubsolv had access to 81 percent of the commercial segment and 45 percent of the public segment in the US. 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.

With FDA's approval of the Zubsolv 0.7mg dose in October, 2016, Orexo finalized the planned life cycle management program for Zubsolv. Focus during 2016 was also on the preparation for EU regulatory submission of a Marketing Authorization Application for Zubsolv. Currently Orexo's R&D focus is directed towards exploratory work to develop new formulation platforms and products. As soon as any of the exploratory work shows proof of principle and intellectual rights have been secured details will be shared with the public. 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 historically had 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.

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 bypassed, 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. The decision in this litigation process was issued on November 15, 2016, by the US District Court of Delaware. The District Court held that Orexo's patent 8,454,996 is valid and infringed by Actavis and that the patent 8,940,330 is invalid. On December 7, 2016, Orexo appealed the District Court's decision relating to the validity of the '330 patent. The appeal process is ongoing.

Production process

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

Zubsolv is manufactured and packed for the US market by third party contractors located in the US and the manufacturing and packing 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 sub-suppliers. Orexo and its sub-suppliers 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.

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 2016 Orexo continued to improve the product lifetime and also test the established 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. During 2016 the US Department of Health and Human Services (HHS) announced an increase in the buprenorphine patient cap from 100 to 275 patients. This change is an example of a political decision with positive impact on the market for Zubsolv®.

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 cannot deliver services in time and of the necessary quality, this may have a negative impact on the results of the business.

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. At end of period Orexo had 102 employees.

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.

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 participant's interests with investor interest. For more detailed information, see Long-Term Incentive Programs Note 25.

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 2018. 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 five persons at the end of 2016. 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 25, 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 to the Chief Executive Officer and other members of management amount to not more than 20 percent of the 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 a notice of between zero and six 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 3 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
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.

Corrected errors
In connection with the introduction of new auditors and in connection with preparation of the full year report for 2016 historical numbers and significant accounting routines were reviewed. This led to a number of restatements affecting prior period statements. The nature and impact of the restatements are described in Note 38.

Largest shareholders
At the year end 2016 Orexo had two main shareholders with holdings more than 10% of total number of shares; Novo A/S 27.7% with 9 643 184 shares, plus HealthCap 11.4% with 3 960 020 shares.

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

Proposed appropriation of profit
The following funds are at the disposal of the Annual General Meeting:

SEK	
Share premium reserve	1,192,804,533
Profit carried forward	–1,138,215,312
Profit/loss for the year	–95,813,480
Total	**–41,224,259**

The Board proposes that the funds at their disposal SEK –1,138,215,312, remaining earnings SEK –95,813,480 and share premium reserve SEK 1,192,804,533, be carried forward.

Corporate Governance
Information on Orexo's application of the Swedish Code of Corporate Governance and more can be seen in the corporate governance report on page 75.

Financial information in brief
Group

STATEMENT OF OPERATIONS INFORMATION

MSEK	2016	2015 Restated	2014	2013	2012
Net revenues	705.9	646.2	570.3	429.4	326.3
Cost of goods sold	–149.6	–150.2	–107.4	–29.3	–27.9
Gross Profit	**556.3**	**496.0**	**462.9**	**400.0**	**298.4**
Selling expenses	–240.6	–297.5	–193.6	–125.1	–62.0
Administrative expenses	–161.6	–141.5	–113.0	–126.4	–82.6
Research and development costs	–132.3	–172.6	–197.8	–238.1	–216.2
Other operative income and expenses	29.9	–65.0	16.5	–50.1	–17.1
Operating earnings	**51.7**	**–180.6**	**–25.0**	**–139.7**	**–79.4**
Net financial items	–16.1	–23.0	–27.6	–13.7	–8.2
Earning after financial items	**35.6**	**–203.6**	**–52.6**	**–153.4**	**–87.6**
Income tax	–6.5	–6.4	–4.0	–1.5	1.7
Net earning for the year	**29.0**	**–210.0**	**–56.6**	**–154.9**	**–85.9**

BALANCE SHEET INFORMATION

MSEK	2016	2015 Restated	2014 Restated	2013	2012
Intangible fixed assets	138.2	155.5	259.2	194.8	135.2
Tangible fixed assets	22.1	24.7	29.1	33.3	35.1
Deferred tax	24.8	18.0	3.0	–	–
Financial fixed assets	–	2.1	1.2	–	18.5
Inventories	344.2	402.6	488.2	383.4	28.3
Account receivable	178.5	167.8	142.1	36.1	17.5
Other current assets	28.6	51.2	31.5	19.1	19.1
Cash and bank balance	282.4	198.1	284.5	105.6	228.1
Total assets	**1,018.8**	**1,020.0**	**1,238.8**	**772.3**	**481.8**
Shareholders' equity	310.3	270.1	467.9	161.5	191.2
Interest-bearing liabilities	397.8	494.4	493.8	241.1	120.6
Non-interest bearing liabilities and provisions	310.8	255.5	277.1	369.7	170.0
Total shareholders' equity and liabilities	**1,018.8**	**1,020.0**	**1,238.8**	**772.3**	**481.8**

CASH FLOW INFORMATION

MSEK	2016	2015 Restated	2014	2013	2012
Cash flow from operating activities before changes in working capital	67.5	–47.2	–35.5	–61.9	–61.0
Cash flow changes in working capital	88.7	–62.0	–451.8	–201.3	89.7
Cash flow from operating activities	156.2	–109.2	–487.3	–263.2	28.7
Acquisition of tangible and intangible assets	0.5	–4.0	–71.7	–107.5	–5.8
Sale of tangible assets	–	–	–	–	0.6
Sale of subsidiary	5.0	21.8	–	–	–
Sale of joint venture	–	–	–	–	12.1
Cash flow after investing activities	161.7	–91.4	–559.0	–370.7	35.6
Amortization of loans	–92.8	–1.2	–102.4	–3.0	–2.3
Borrowings	–	–	500.0	234.7	–
New share issues	2.2	3.8	189.7	19.4	0.8
Buyback of shares	–	–	–	–	–53.0
Sales of treasury shares	–	–	152.0	–	–
Cash flow for the year	71.1	–88.8	180.3	–119.6	–18.9
Cash and cash equivalents at year-end	282.4	198.1	284.5	105.6	228.1

KEY FIGURES

MSEK	2016	2015 Restated	2014 Restated	2013	2012
EBIT margin, %	7	–28	–4	–33	–24
Return on shareholder equity, %	10	–57	–18	–88	–34
Net debt, MSEK	115.4	296.3	780.7	346.7	348.7
Debt/equity ratio, %	128	183	106	149	63
Equity/assets ratio, %	30	26	37	21	40
Number of shares, before dilution	34,477,423	34,478,622	32,700,348	31,790,784	28,825,208
Number of shares, after dilution	34,574,412	34,478,622	32,700,348	31,790,784	28,825,208
Earnings per share, before dilution, SEK	0.84	–6.09	–1.70	–5.16	–2.92
Earnings per share, after dilution, SEK	0.84	–6.09	–1.70	–5.16	–2.92
Number of employees at the end of the period	102	90	108	108	97
Shareholders' equity, MSEK	310.3	270.1	467.9	161.5	191.2
Capital employed, MSEK	708.1	764.5	961.7	402.6	311.8
Working capital, MSEK	524.2	570.9	678.2	47.2	124.1

For alternative key figures see definitions and reconciliations of key figures on page 74.

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Consolidated statement of operations

MSEK	Notes	2016	2015 Restated*
Net revenues	5,6	705.9	646.2
Cost of goods sold	7	–149.6	–150.2
Gross profit		**556.3**	**496.0**
Selling expenses	7,8,9,10,11	–240.6	–297.5
Administrative expenses	7,8,9,10,11,32	–161.6	–141.5
Research and development costs	7,8,9,10,11	–132.3	–172.6
Other operating income and expenses	7,12,13	29.9	–65.0
Operating earnings		**51.7**	**–180.6**
Financial income	14	7.7	0.0
Financial expense	14	–23.8	–23.0
Earnings after financial items		**35.6**	**–203.6**
Tax on earnings for the year	15	–6.5	–6.4
Net earnings for the year		**29.0**	**–210.0**
Earnings for the year attributable to:			
Parent Company shareholders		29.0	–210.0
Non-controlling interests		–	–
Earnings per share during the year attributable to Parent Company shareholders(expressed in SEK)			
– before dilution	16	0.84	–6.09
– after dilution	16	0.84	–6.09

* See Note 38 corrected error for restatement.

Consolidated statement of comprehensive income

MSEK	Notes	2016	2015 Restated*
Net earnings for the year		**29.0**	**–210.0**
Other comprehensive income			
Items that may subsequently be reversed to the statement of operations:			
Change in fair value assets available for sale	19		0.9
Reclassification assets available for sale	19	–0.9	
Cash flow hedge			–2.9
Exchange-rate differences	17	6.2	3.4
Other comprehensive earnings for the year, net after tax		**5.3**	**1.4**
Comprehensive earnings for the year		**34.3**	**–208.6**
Comprehensive earnings attributable to:			
Parent Company shareholders		34.3	–208.6
Non-controlling interests		–	–

* See Note 38 corrected error for restatement.

Consolidated balance sheet

MSEK	Notes	2016	2015 Restated	2015 Jan 1st Restated*
ASSETS				
Fixed assets				
Tangible fixed assets	8,10	22.1	24.7	29.1
Intangible assets	9,10	138.2	155.5	259.2
Deferred tax assets		24.8	18.0	3.0
Financial assets that can be sold	18,19	–	2.1	1.2
Total fixed assets		**185.1**	**200.3**	**292.5**
Current assets				
Inventories	20	344.2	402.6	488.2
Accounts receivable	21	178.5	167.8	142.1
Other receivables	22	5.6	17.1	6.3
Prepayment and accrued income	23	23.0	34.1	25.2
Cash and cash equivalents	18,24	282.4	198.1	284.5
Total current assets		**833.7**	**819.7**	**946.3**
TOTAL ASSETS		**1,018.8**	**1,020.0**	**1,238.8**
SHAREHOLDERS' EQUITY AND LIABILITIES				
Shareholders' equity				
Share capital	25	13.9	13.8	13.7
Other contributed capital	25	1,848.6	1,842.8	1,832.1
Reserves	17,23	0.2	–6.0	–6.5
Accumulated deficit	25	–1,552.4	–1,580.5	–1,371.4
Total shareholder's equity		**310.3**	**270.1**	**467.9**
Long-term liabilities and provisions				
Provisions	26	1.3	6.7	9.0
Borrowings	18,27	397.8	494.4	493.8
Total long-term liabilities		**399.0**	**501.1**	**502.8**
Current liabilities				
Accounts payable	18,28	36.0	34.9	28.9
Provisions	26	163.9	121.8	70.0
Other liabilities	28	10.6	10.9	7.4
Accruals	28	99.0	81.2	161.8
Total current liabilities		**309.5**	**248.8**	**268.1**
Total liabilities		**708.5**	**749.9**	**770.9**
Total shareholders' equity and liabilities		**1,018.8**	**1,020.0**	**1,238.8**

* See Note 38 corrected error for restatement.

Changes in consolidated shareholders' equity

Attributable to Parent Company shareholders[1] MSEK	Notes	Share capital	Other contributed capital	Reserves	Accumulated deficit	Total share-holders' equity
Opening balance at January 1, 2015		**13.7**	**1,832.1**	**–9.3**	**–1,381.5**	**455.0**
Impact of restated shareholder's equity	38			2.8	10.1	12.9
Opening balance at January 1, 2015 restated		**13.7**	**1,832.1**	**–6.5**	**–1,371.4**	**467.9**
Comprehensive income						
Net earnings for the year					–210.0	–210.0
Other comprehensive income						
Translation differences				3.4		3.4
Cash flow hedge				–2.9		–2.9
Revaluation of shares					0.9	0.9
Total comprehensive income		**13.7**	**1,832.1**	**–6.0**	**–1,580.5**	**259.3**
Transactions with shareholders						
Employee stock options, value of employees' services	25		7.1			7.1
Buyback of company's own shares			–0.1			–0.1
New share issues		0.1	3.7			3.8
Total transactions with shareholders		**0.1**	**10.7**			**10.8**
Opening balance at January 1, 2016 Restated		**13.8**	**1,842.8**	**–6.0**	**–1,580.5**	**270.1**
Comprehensive income						
Net earnings for the year					29.0	29.0
Other comprehensive income						
Translation differences				6.2		6.2
Reclassification assets available for sale					–0.9	–0.9
Total comprehensive income		**13.8**	**1,842.8**	**0.2**	**–1,552.4**	**304.4**
Transactions with shareholders						
Employee stock options, value of employees' services	25		3.7			3.7
Buyback of company's own shares			–0.1			–0.1
New share issues		0.1	2.2			2.3
Total transactions with shareholders		**0.1**	**5.8**	**0.0**		**5.9**
Closing balance at December 31, 2016		**13.9**	**1,848.6**	**0.2**	**–1,552.4**	**310.3**

1) There are no non-controlling interests

Consolidated cash flow statement

MSEK	Notes	2016	2015 Restated*
Operating earnings		51.7	–180.6
Adjustment for non-cash items	29	44.1	158.5
Interest received		0.6	0.0
Interest paid		–21.4	–20.7
Tax paid		–7.5	–4.4
Cash flow from operating activities before changes in working capital		**67.5**	**–47.2**
Changes in working capital			
Change inventories		71.7	89.2
Change receivables		29.5	–63.9
Change current liabilities		–12.5	–87.3
Cash flow from operating activities		**156.2**	**–109.2**
Investing activities			
Acquisition of tangible fixed assets		–1.1	–0.3
Disposal of tangible fixed assets		1.9	0.0
Acquisition of intangible assets		–0.3	–3.7
Sale of subsidiary	13	5.0	21.8
Cash flow from investing activities		**5.5**	**17.8**
Financing activities			
New share issue		2.2	3.8
Buyback of corporate bonds	27	–92.8	–1.2
Cash flow from financing activities		**–90.6**	**2.6**
Cash flow for the year			
Cash and cash equivalents at the beginning of the period		198.1	284.5
Exchange-rate differences in cash and cash equivalents		13.3	2.5
Cash flow for the year		71.1	–88.8
Cash and cash equivalents at the end of the period	24	**282.4**	**198.1**

* See Note 38 corrected error for restatement.

Parent Company statement of operations

MSEK	Notes	2016	2015 Restated*
Net revenues	5,6	379.3	518.9
Cost of goods sold	7	–83.6	–155.9
Gross profit		**295.7**	**363.0**
Selling expenses	7,8,9,10,11	–105.8	–226.9
Administrative expenses	7,8,9,10,11,32	–129.1	–108.1
Research and development costs	7,8,9,10,11	–141.8	–122.9
Other operating income and expenses	7,12	24.3	4.5
Operating earnings		**–56.7**	**–90.4**
Interest income and expenses	14	–16.2	–18.7
Impairment of shares in subsidiaries	14	–	–63.8
Sales of subsidiary	14	–	13.1
Other financial expenses	14	–22.8	–2.5
Net financial items		**–39.1**	**–71.9**
Earnings before tax		**–95.8**	**–162.3**
Tax	15	–	0.0
Net earnings for the year		**–95.8**	**–162.3**

* See Note 38 corrected error for restatement.

Parent Company statement of comprehensive income

MSEK	Notes	2016	2015
Net earnings for the year		–95.8	–162.3
Other comprehensive income for the period, net after tax		–	–
Total comprehensive income for the period		**–95.8**	**–162.3**

Parent Company balance sheet

MSEK	Notes	2016	2015 Restated*
ASSETS			
Fixed assets			
Patents and intellectual property rights and proprietary intangible asset	9,10	138.2	155.5
Equipment, renovation of the property of others	8,10	21.6	23.7
Shares and participations in subsidiaries	30	149.7	148.5
Total fixed assets		**309.5**	**327.8**
Current assets			
Inventories	20	269.6	276.8
Current receivables			
Accounts receivable	21	51.4	284.2
Tax claims	22	2.7	2.4
Other receivables	22	2.9	18.3
Receivables from Group companies	23	12.1	10.5
Prepaid expenses and accrued income	23	7.7	8.9
Total current receivables		**76.8**	**324.3**
Cash and cash equivalents	24	211.7	114.0
Total current assets		**558.1**	**715.1**
TOTAL ASSETS		**867.6**	**1,042.9**
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity			
Restricted shareholders' equity			
Share capital	25	13.9	13.8
Statutory reserve		290.8	290.8
		304.7	**304.6**
Non-restricted shareholders' equity			
Share premium reserve	25,26	1,192.9	1,186.9
Accumulated deficit		–1,138.2	–975.9
Net earnings for the year		–95.8	–162.3
		–41.2	**48.7**
Total shareholders' equity		**263.5**	**353.4**
Long-term liabilities			
Other provisions	26	1.3	6.7
Long-term liabilities	27	397.8	494.3
Total long-term liabilities		**399.1**	**501.0**
Current liabilities			
Accounts payable	28	20.4	26.1
Other liabilities	28	7.0	7.5
Liabilities to Group companies	28	152.5	101.7
Accrued expenses and deferred income	28	25.1	53.1
Total current liabilities		**205.0**	**188.5**
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		**867.6**	**1,042.9**

* See Note 38 corrected error for restatement.

Changes in Parent Company shareholders' equity

MSEK	Notes	Share capital	Statutory reserve	Share premium reserve	Accumulated deficit	Total share-holders' equity
Opening shareholders' equity at January 1, 2015		**13.7**	**290.8**	**1,176.0**	**–975.8**	**504.7**
Net earnings for the year					–162.3	–162.3
Total transactions recognized directly in shareholders' equity						–
Total recognized income and expenses					**–162.3**	**–162.3**
Employee stock options, value of employees' services	25			7.2		7.2
Buyback of shares					–0.1	–0.1
New share issues		0.1		3.7		3.8
Opening shareholders' equity at January 1, 2016		**13.8**	**290.8**	**1,186.9**	**–1,138.2**	**353.4**
Net earnings for the year					–95.8	–95.8
Total transactions recognized directly in shareholders' equity						–
Total recognized income and expenses					**–95.8**	**–95.8**
Employee stock options, value of employees' services	25			3.7		3.7
New share issues		0.1		2.3		2.3
Buyback of shares					–0.1	–0.1
Closing shareholders' equity at December 31, 2016		**13.9**	**290.8**	**1,192.9**	**–1,234.1**	**263.5**

Parent Company cash flow statement

MSEK	Notes	2016	2015 Restated*
Operating activities			
Operating earnings		–52.9	–90.3
Interest received		5.1	1.8
Interest paid		–21.0	–20.7
Tax paid		–	–
Adjustment for non-cash items	29	2.5	14.9
Cash flow from operating activities before change in working capital		**–66.3**	**–94.3**
Change in working capital			
Accounts receivable and other current receivables		225.7	–101.0
Inventories		3.4	101.6
Current liabilities		13.8	–66.9
Cash flow from operating activities		**176.6**	**–160.6**
Investing activities			
Acquisition of tangible fixed assets		–1.1	–0.3
Acquisition of intangible fixed assets		–0.3	–3.7
Divestment of subsidiary		5.0	26.1
Cash flow from investing activities		**3.6**	**22.1**
Financing activities			
New share issue		2.2	3.8
Buyback of corporate bonds		–92.8	–
Cash flow from financing activities		**–90.6**	**3.8**
Cash flow for the year			
Cash and cash equivalents at beginning of period		114.0	247.2
Exchange-rate differences in cash and cash equivalents		7.9	1.5
Change in cash and cash equivalents		89.8	–134.7
Cash and cash equivalents at end of period	24	**211.7**	**114.0**

* See Note 38 corrected error for restatement.

Notes

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's share is listed on Nasdaq Stockholm.

The Board of Directors approved these consolidated financial statements for publication on March 15, 2017.

The statement of operations and balance sheet will be presented to the Annual General Meeting on April 6, 2017 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 paragraph 2.22 "Basis for preparation of the financial statements for 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.

Please see even Note 38.

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.

2.1.1 Amendments to accounting policies and disclosures

A number of new and changed IFRS have not yet come into force and have not been applied in advance in the presentation of the Group's and the Parent Company's financial reports. Below are described the IFRS that may in the future have an impact on the Group's or the Parent Company's financial reports. Other new or changed standards or interpretations that IASB has published are not expected to have an impact on the Group's or the Parent Company's financial reports.

(a) New and amended standards applied by the Group

None of the IFRS or IFRS IC interpretations that have come into force has had any significant impact on the Group.

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

- IFRS 9 Financial instruments covers the recognition of financial assets and liabilities and replaces IAS 39. As in IAS 39 financial assets are classified into different categories, of which some are measured at amortized cost and others at fair value. To assess how financial instruments are to be recognized pursuant to IFRS 9, a company must consider the contractual cash flows and the business model under which the instrument is held. IFRS 9 also introduces a new model for impairment of financial assets. The purpose of the new model is, amongst other things, that credit losses shall be recognized earlier than under IAS 39. For financial liabilities IFRS 9 is by and large consistent with IAS 39. Changed criteria for hedge accounting can lead to more financial hedging strategies meeting the requirements for hedge accounting pursuant to IFRS 9 compared to under IAS 39. IFRS 9 comes into force on January 1, 2018. The standard will be applied by the Group and the Parent Company as from January 1, 2018. Orexo's preliminary assessment is that the standard will not have a significant impact on the Group's or the Parent Company's financial reports.
- IFRS 15 Revenue from contracts with customers replaces all previously issued standards and interpretations that deal with revenues in a coherent model of revenue recognition. The standard is based on the principle that a revenue shall be recognized when promised goods or services have been transferred to the customer, that is when the customer has gained control of them, which may occur over a period of time or at a given point in time. The revenue shall be the amount that the company expects to receive in exchange for the goods or services supplied. IFRS 15 comes into force for fiscal years beginning on January 1, 2018 or later. The standard will be applied by the Group and the Parent Company as from January 1, 2018. During the year the Group began to evaluate the effects of the standard. The Group will evaluate the effects of the introduction of the standard in 2017.
- IFRS 16 Leases will replace IAS 17. According to the new standard, most leased assets must be recognized in the balance sheet and the lessee shall divide up the cost into interest payments and depreciation of the asset. The EU is expected to approve the standard during 2017. IFRS 16 is expected to come into force for fiscal years beginning on January 1, 2019 or later, but early application is expected to be possible if IFRS 15 is also applied. The standard is expected to be applied by the Group and the Parent Company as from January 1, 2019. During the year the Group began to evaluate the effects of the standard. Orexo's preliminary assessment is that most of the leasing agreements that are recognized as operational leasing agreements in these financial reports will be recognized in the balance sheet. This will also mean that the cost of these will be recognized, divided up into interest payments and depreciation.

2.2 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 segments' results. For the Group, this function has been identified as Executive Management. Executive Management assesses the operation in its entirety, i.e. as one 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 approved and 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 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. Tests for obsolete stock is performed on quarterly basis based on sales forecast and shelf life of material in inventory.

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 Note 19.

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 carryforwards has been recognized in the balance sheet. Note 33 presents, amongst other things, the estimated accumulated loss carryforwards 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 shareholders' 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 25.

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 plans

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. Refer even to paragraph about assessments.

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 sales are recognized.

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 sold

The cost of goods sold comprises the materials cost for the products the Group itself sells on the market.

2.22 Basis for preparation of the financial statements for Parent Company

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 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 4.

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.

2.23 Shares and participations in subsidiaries
Shares and participations in subsidiaries are recognized at cost with deductions for any impairment.

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".

2.24 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.

2.25 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.

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.

2.26 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.

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

NOTE 3 FINANCIAL AND OPERATIONAL RISK MANAGEMENT

The Group's operations are 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 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. 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 currency 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 operating expenses is in currencies other than SEK, primarily USD, which leads to a certain amount of currency hedging. During the 2016 fiscal year, sales in USD accounted for 78 (71) percent of net revenues and sales in EUR accounting for 22 (11) percent. During the same period, 86 (84) percent of total operating expenses were in foreign currency with 98 (97) percent in USD, 1 (1) percent in EUR and 1 (2) percent 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 the value of USD against SEK of 10 percent and with balance sheet exposure at the closing date entails a change in other operating income and expenses of approximately MSEK 2. The corresponding change in EUR entails a change of approximately MSEK 0.2 and has no material impact, and in GBP has no material impact. The effect of the change in the value of USD on earnings is primarily due to the fact that a large part of the Group's internal receivables and liabilities are attributable to Orexo Inc in the USA. 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 7.8.

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 397.8 on December 31, 2016 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 2.0.

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, 2016, the six largest customers accounted for 89 percent. No other single customer accounted for more than 2 percent of total accounts receivable. Note 21 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 Liquidity 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, 2016	Less than 1 year	Between 1 and 2 years	Between 2 and 5 years
Accounts payable	36.0	–	–
Accrued costs	273.5	–	–
Borrowings	16.0	407.1	–

At December 31, 2015 Restated	Less than 1 year	Between 1 and 2 years	Between 2 and 5 years
Accounts payable	34.9	–	–
Accrued costs	216.7	–	–
Borrowings	22.5	530.0	–

3.5 Commercial market risk and inventory risk

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

To be successful in the US it is of the utmost importance that Zubsolv® obtains reimbursements on a par with those of competitors. Due to the complex American market, with many different payers and a complicated reimbursement system, Orexo has established a professional team focusing only on improving market access and reimbursement for Zubsolv. The payers are constantly reviewing their formularies and this can lead to significant changes in market access. By the end of 2016 Zubsolv had access to 81 percent of the commercial segment and 45 percent of the public segment in the US.

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 develops 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.

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 strategy of creating 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 bypassed, which may limit Orexo's ability to market new products. For an update on ongoing litigation cases see the 'Financial Performance in 2016' section.

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 shareholders 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, 2016 and 2015 is presented in the table below:

	2016	2015 Restated
Shareholders' equity	310.3	270.1
Total assets	1,018.8	1,020.0
Equity/assets ratio	**30%**	**26%**

NOTE 4 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.

4.1 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 proprietary intangible assets
Amortization of proprietary intangible assets was begun in August 2015 after the FDA approved Zubsolv® for initiation of buprenorphine for maintenance treatment of patients with opioid dependence. Impairment will be carried out over a period of 10 years. Testing to ensure that the carrying amount does not exceed the recoverable amount is thereby only carried out in the event of a significantly negative event that can create an urgent need for impairment. This impairment testing comprises a risk analysis that 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 an interest rate that reflects the cost of capital and risk. For further information, refer to Note 9.

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

(b) Research and development
Costs attributable to research are expensed as they arise. Assessments of which costs can be capitalized or not are done. Costs attributable to development projects are recognized as intangible assets in the balance sheet when these costs are expected to generate financial benefits in the future. Other development costs are expensed as they arise. Development costs that are expensed are not recognized as an asset in subsequent periods. In 2016 these costs amounted to MSEK 132.3 (172.6).

(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 in some cases be difficult to estimate royalty revenues.

(d) Revenues from sale of goods
Revenues from Zubsolv are recognized when they are invoiced to wholesalers. Revenues for Zubsolv are 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. The shelf-life of semi-finished products and finished products is based on documented stability studies. During 2016 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 impairment.

(f) Deferred tax assets
Orexo has significant loss carry-forwards as historically the company has made losses. No value of the loss carry-forwards has been recognized in the balance sheet, as it is difficult to assess if and when the losses can be set off against surpluses. The loss carry-forwards for tax purposes in the Group amounted to MSEK 1,458 (1,449) at December 31, 2016.

4.2 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 also 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"

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. 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.

(b) 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.

NOTE 5 GEOGRAPHIC DISTRIBUTION OF REVENUES

Sales distributed geographically	Group		Parent Company	
	2016	2015 Restated	2016	2015
Sweden	55.6	13.7	55.6	13.8
UK	155.5	188.6	155.5	188.6
Other EU countries	–	2.0	–	–
East Asia	3.6	3.8	3.6	2.8
US	491.2	428.4	164.6	313.7
Other countries	–	9.7	–	–
Total	**705.9**	**646.2**	**379.3**	**518.9**

The company's four largest customers combined account for 75 (88) percent of the company's net revenues. They contribute 13 (29) percent, 22 (23) percent, 22 (19) percent and 17 (17) percent, respectively.
Fixed assets outside Sweden amount to MSEK 0.4 (1.0).
Geographical distribution of royalties and licence revenue are based on the conterparts registered office.

NOTE 6 DISTRIBUTION OF REVENUES PER CATEGORY

	Group		Parent Company	
	2016	2015 Restated	2016	2015
Sales, products	481.8	429.4	155.3	301.6
Royalties	115.2	150.8	115.2	150.7
License revenues	68.0	66.0	68.0	66.0
Partner-financed R&D costs	–	–	–	–
Other	40.8	0.0	40.8	0.6
Total	**705.9**	**646.2**	**379.3**	**518.9**

Royalties intend percentage of reported licensees sale.
License revenues intend milestones.
Other revenues refers to collaboration agreement of project OX-CLI that was aquired by AstraZeneca in March 2016.

NOTE 7 COSTS BY TYPE OF COST

	Group		Parent Company	
	2016	2015 Restated	2016	2015 Restated
Raw materials and consumables	124.0	134.3	58.0	140.0
Other external income and costs	346.2	465.2	298.8	398.1
Personnel costs	162.6	146.6	58.4	53.4
Depreciation/amortization and impairment	21.4	80.7	20.8	17.9
Total	**654.2**	**826.8**	**436.0**	**609.3**

NOTE 8 TANGIBLE FIXED ASSETS

Group	Equipment and machinery	Computers	Improvement expenses other's property	Total
Fiscal year 2015				
Opening balance	5.5	0.8	22.8	29.1
Purchases	0.1	0.3	–	0.4
Disposal through sale of subsidiary	–0.5	–	–	–0.5
Accumulated depreciation disposal	–	–	–	0.0
Depreciation	–2.0	–0.5	–1.8	–4.4
Exchange-rate differences	0.1	0,0	0.0	0.1
Closing balance	**3.1**	**0.5**	**21.0**	**24.7**
At December 31, 2015				
Cost	33.4	2.9	36.2	72.4
Accumulated depreciation and impairment	–30.3	–2.4	–15.1	–47.7
Carrying amount	**3.1**	**0.5**	**21.0**	**24.7**
Fiscal year 2016				
Opening balance	3.1	0.5	21.0	24.7
Purchases	0.3	0.7	–	1.0
Disposal	–	–	–	0.0
Accumulated depreciation disposal	–	–	–	0.0
Depreciation	–1.3	–0.6	–1.6	–3.5
Disposal through sale of subsidiary	–	–	–	0.0
Exchange-rate differences	0.0	0.0	0.0	0.0
Closing balance	**2.1**	**0.6**	**19.4**	**22.1**
At December 31, 2016				
Cost	33.7	3.6	36.2	73.5
Accumulated depreciation and impairment	–31.6	–3.0	–16.8	–51.4
Carrying amount	**2.1**	**0.6**	**19.4**	**22.1**

Parent Company	Equipment and machinery	Computers	Improvement expenses other's property	Total
Fiscal year 2015				
Opening balance	4.2	0.1	22.8	27.1
Purchases	0.1	0.3	–	0.4
Disposal	–	–	–	0.0
Accumulated depreciation disposal	–	–	–	0.0
Depreciation	–1.9	–0.1	–1.8	–3.8
Exchange-rate differences	0.0	0.0	0.0	0.0
Closing balance	**2.4**	**0.3**	**21.0**	**23.7**
At December 31, 2015				
Cost	29.9	1.1	36.2	67.2
Accumulated depreciation and impairment	–27.5	–0.8	–15.1	–43.4
Carrying amount	**2.4**	**0.3**	**21.0**	**23.7**
Fiscal year 2016				
Opening balance	2.4	0.3	21.0	23.7
Purchases	0.3	0.7	–	1.0
Disposal	–	–	–	0.0
Accumulated depreciation disposal	–	–	–	0.0
Depreciation	–1.2	–0.2	–1.6	–3.1
Disposal through sale of subsidiary	–	–	–	0.0
Exchange-rate differences	0.0	0.0	0.0	0.0
Closing balance	**1.5**	**0.8**	**19.4**	**21.6**
At December 31, 2016				
Cost	30.2	1.8	36.2	68.2
Accumulated depreciation and impairment	–28.7	–1.0	–16.7	–46.5
Carrying amount	**1.5**	**0.8**	**19.4**	**21.6**

NOTE 9 INTANGIBLE FIXED ASSETS

Group	Goodwill	Acquired R&D	Patents and rights	Proprietary intellectual property right	Other	Total
Fiscal year 2015						
Opening balance	27.4	62.3	6.0	152.6	7.3	255.6
Purchases	–	–	–	0.9	2.8	3.7
Disposal	–	–	–	–	–	0.0
Amortization	–	–	–6.0	–6.4	–1.8	–14.1
Impairment	–	–62.3	–	–	–	–62.3
Disposal through sale of subsidiary	–27.0	–	–	–	0.0	–27.0
Exchange-rate differences	–0.4	0.0	0.0	0.0	0.0	–0.4
Closing carrying amount	**0.0**	**0.0**	**0.0**	**147.1**	**8.3**	**155.5**
At December 31, 2015						
Cost	–	435.1	27.4	153.6	11.9	627.9
Accumulated amortization and impairment	–	–435.1	–27.4	–6.4	–3.5	–472.4
Carrying amount	**0.0**	**0.0**	**0.0**	**147.1**	**8.3**	**155.5**
Fiscal year 2016						
Opening balance	–	0.0	0.0	147.1	8.3	155.5
Purchases	–	–	–	–	0.3	0.3
Disposal	–	–	–	–	–	0.0
Amortization	–	–	–	–15.4	–2.3	–17.7
Impairment	–	–	–	–	–	0.0
Disposal through sale of subsidiary	–	–	–	–	–	0.0
Exchange-rate differences	0.0	0.0	0.0	0.0	0.0	0.0
Closing carrying amount	**0.0**	**0.0**	**0.0**	**131.7**	**6.4**	**138.2**
At December 31, 2016						
Cost	–	435.1	27.4	153.6	12.2	628.2
Accumulated amortization and impairment	–	–435.1	–27.4	–21.8	–5.8	–490.0
Carrying amount	**0.0**	**0.0**	**0.0**	**131.7**	**6.4**	**138.2**

Proprietary intangible asset at December 31, 2016
A proprietary intangible asset amounting to MSEK 131.7 (147.1) 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 (initiation of treatment of opioid dependence) was approved by the FDA, the US Food and Drug Administration, in August 2015 and in conjunction with this amortization was begun and will occur over a time period of 10 years. During the year there was no impairment of proprietary intangible assets.

Research and development costs
Research and development costs during the period amounted to MSEK 132.3 (172.6). The full year 2015 included considerable costs related to the REZOLV study and the Life Cycle Management project for Zubsolv, while the most extensive activity in 2016, that is the PK study to enable the submission of a registration application to the EU, was financed by Mundipharma.

Parent Company	2016	2015
Accumulated cost		
Opening cost	188.0	184.3
Purchases during the year	0.3	3.7
Disposals and scrapping	–	–
Closing accumulated cost	188.4	188.0
Accumulated amortization according to plan		
Opening amortization according to plan	–32.5	–18.4
Amortization during the year according to plan	–17.7	–14.1
Disposals and scrapping	–	–
Closing accumulated amortization according to plan	–50.2	–32.5
Carrying amount	**138.2**	**155.5**

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

NOTE 10 DEPRECIATION/AMORTIZATION AND IMPAIRMENT

Depreciation, amortization and impairment are divided up by function as follows:

	Group		Parent Company	
	2016	2015	2016	2015
Tangible fixed assets				
Sales	0.5	0.4	–	–
Administration	1.8	1.9	1.7	1.8
Research and development	1.4	2.1	1.4	2.0
Total tangible fixed assets	**3.7**	**4.4**	**3.1**	**3.8**
Intangible assets				
Sales	–	–	–	–
Administration	0.1	0.0	0.1	0.0
Research and development	17.6	8.2	17.6	8.2
Cost of goods sold	–	5.9	–	5.9
Other operating expenses	–	62.3	–	–
Total intangible assets	**17.7**	**76.4**	**17.7**	**14.1**
Financial assets				
Other financial assets	–	–	–	63.9
Total financial assets	–	–	–	**63.9**
Total depreciation/amortization and impairment	**21.4**	**80.7**	**20.8**	**81.8**

2015 Group recorded OX-MPI non-cash impairment charge of MSEK 62 resulting in Parent Company writing down of shares for the subsidiary Biolipox AB amounting to MSEK 63.8.

NOTE 11 REMUNERATION TO EMPLOYEES

Average number of employees

Group	2016 Average number of employees	Of whom men	2015 Average number of employees	Of whom men
Sweden	53	22	58	25
USA	46	22	38	24
Germany	–	–	2	1
Total for Group	**99**	**44**	**98**	**50**

Parent Company	2016 Average number of employees	Of whom men	2015 Average number of employees	Of whom men
	53	22	56	24
Total for Parent Company	**53**	**22**	**56**	**24**

	Group		Parent Company	
Costs and remuneration to all employees and Board, SEK thousand	2016	2015	2016	2015
Salaries, remuneration and social security fees				
Salaries and other remuneration to the Board, President and Executive Management	20,685	18,745	11,583	11,770
Salaries and other remuneration to other employees	97,318	97,795	31,634	30,590
Pension cost for the Board, President and Executive Management[1]	1,683	1,945	1,394	1,529
Pension cost for other employees[1]	9,209	10,145	6,492	7,412
Social security fees for the Board, President and Executive Management[2]	1,573	–3,014	2,219	–3,950
Social security fees for other employees[2]	11,599	6,432	6,876	2,499
Other personnel costs	18,520	16,388	4,387	5,362
Total	**160,587**	**148,436**	**64,584**	**55,212**

[1] Pertains in its entirety to defined-contribution pension plan.
[2] Pertains to estimated costs for social security fees for employee stock option program.

Note 11 cont.

Costs and remuneration to the Board, President and senior executives 2016, SEK thousands

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	700	–	–	–	85	–	785
Michael Shalmi, Board member	200	–	–	–	–	–	200
Raymond Hill, Board member	200	–	–	–	–	–	200
Staffan Lindstrand, Board member	200	–	–	–	–	–	200
Kristina Schauman, Board member	400	–	–	–	–	–	400
David Colpman, Board member	200	–	–	–	–	–	200
Kirsten Detrick, Board member (9 months)	133	–	–	–	–	–	133
Subtotal	**2,033**	**–**	**–**	**–**	**85**	**–**	**2,118**
President and senior executives							
Nikolaj Sørensen, President and CEO	2,991	1,059	102	610	556	–	5,318
Other senior executives (5)	11,364	2,647	211	1,073	2,033	–	17,328
Total	**16,388**	**3,706**	**313**	**1,683**	**2,674**	**–**	**24,764**

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

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	700	–	–	–	343	–	1,043
Michael Shalmi, Board member	200	–	–	–	–	–	200
Raymond Hill, Board member	200	–	–	–	–	–	200
Staffan Lindstrand, Board member	200	–	–	–	–	–	200
Kristina Schauman, Board member	400	–	–	–	–	–	400
David Colpman, Board member (8 months)	133	–	–	–	–	–	133
Subtotal	**1,833**	**–**	**–**	**–**	**343**	**–**	**2,176**
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	**13,668**	**4,886**	**240**	**1,848**	**4,071**	**–**	**24,713**

Board members and senior executives	2016		2015	
	Number on the closing date	of whom men	Number on the closing date	of whom men
Group (incl. subsidiaries)				
Board members	10	80%	9	89%
President and other senior executives	6	100%	5	100%
Parent Company				
Board members	7	71%	6	83%
President and other senior executives	4	100%	3	100%

Other benefits refers primarily to 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 81.

The number of shares and options held by the President and senior executives is shown in the information regarding the Board on page 80 and Management on page 81. Refer to Note 25 for a description of the 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.

NOTE 12 EXCHANGE-RATE DIFFERENCES

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

Restated	Group		Parent Company	
	2016	2015	2016	2015
Other operating income	56.4	24.9	56.4	24.9
Other operating expenses	–42.6	–25.1	–42.6	–25.1
Total	**13.9**	**–0.2**	**13.9**	**–0.2**

NOTE 13 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®. At group level a loss of MSEK 5.3 was recognized at the time of sale. According to a supplementary purchase price clause in the purchase agreement a cash payment would be received if the subsidiary reached certain profitability measures during the period April 2015 to March 2019. In 2016 this clause was settled and MSEK 5 was paid to Orexo AB and this has earlier been reported as other financial income. There are no more outstanding payments from the sale of Kibion.

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

	Apr 30, 2015
Intangible fixed assets	27.0
Tangible fixed assets	0.5
Inventories	7.8
Current receivables	11.4
Cash and cash equivalents	4.3
Total assets	**51.0**
Long-term liabilities	0.6
Current liabilities	8.0
Total liabilities	**8.6**
Net assets	**42.4**

NOTE 14 FINANCIAL INCOME AND EXPENSES

	Group		Parent Company	
	2016	2015 Restated	2016	2015
Interest expenses				
Bank loans	–	0.0	–	–
Corporate bonds	–20.7	–20.5	–20.7	–20.5
Group	–	–	–	0.0
Other	0.0	0.0	0.0	0.0
Interest income				
Bank	0.6	0.0	0.6	0.0
Group	–	–	3.9	1.8
Other	0.0	0.0	0.0	0.0
Financial expenses				
Impairment of shares in subsidiaries	–	–	–	–63.9
Costs, corporate bonds	–2.6	–2.5	–2.6	–2.5
Capital gain from shares	0.9	–	–	–
Exchange rate effect	–	–	32.1	–
Other	–0.5	0.0	–	–
Financial income				
Sale of subsidiary	–	–	–	13.1
Earnout sale of subsidiary	–	–	5.0	–
Buy-back bond	6.2	–	6.2	–
Other	–	–	0.6	–
Total	**–16.1**	**–23.0**	**–39.1**	**–71.9**

NOTE 15 TAX

	Group		Parent Company	
	2016	2015 Restated	2016	2015 Restated
Current tax	–13.3	–21.4	–	–
Deferred tax	6.8	15.0	–	–
Total	**–6.5**	**–6.4**	**0.0**	**0.0**
Difference between the Group's tax expense and tax expense based on current tax rate				
Recognized pre-tax earnings	35.6	–203.6	–95.8	–161.8
Tax under current tax rate	–7.8	44.8	21.1	35.6
Tax effect of foreign tax rates	0,2	–3.2	–	–
Tax effect of non-taxable income	1.1	0.2	1.1	2.9
Tax effect of non-deductible costs	0.0	–14.9	0.0	–14.1
Unrecognized carry-forward losses	–	–33.3	–22.2	–24.4
Tax on earnings for the year according to the statement of operations	**–6.5**	**–6.4**	**0**	**0**

NOTE 16 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	
	2016	2015 Restated*
Earnings used for the calculation of earnings per share before dilution, MSEK	29.0	–210.0
Average number of shares before dilution	34,477,423	34,478,622
Earnings per share before dilution (SEK per share)	0.84	–6.09
Average number of shares after dilution	34,574,412	34,478,622
Earnings per share after dilution (SEK per share)	0.84	–6.09
Options outstanding	1,784,794	1,859,092

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.

* See Note 38 corrected error for restatement.

NOTE 17 RESERVES

	Translation reserve	Hedge reserve	Total
Opening balance at January 1, 2015 Restated	**–9.4**	**2.9**	**–6.5**
Exchange-rate differences	3.4	0.0	3.4
Cash flow hedge	–	–2.9	–2.9
Opening balance at January 1, 2016 Restated	**–6.0**	**–**	**–6.0**
Exchange-rate differences	6.2	0.0	6.2
Closing balance at December 31, 2016	**0.2**	**0.0**	**0.2**

NOTE 18 INFORMATION ON FINANCIAL INSTRUMENTS IN THE GROUP

Classification and categorization of assets and liabilities in the Group

December 31, 2016	Financial assets that can be sold	Loans and accounts receivable	Total financial assets	Non-financial assets	Total
Assets					
Tangible fixed assets	–	–	**0.0**	22.1	**22.1**
Intangible fixed assets	–	–	**0.0**	138.2	**138.2**
Deferred tax asset	–	–	**0.0**	24.8	**24.8**
Inventories	–	–	**0.0**	344.2	**344.2**
Financial assets	–	–	**0.0**	–	**0.0**
Accounts receivable	–	178.5	**178.5**	–	**178.5**
Other current receivables	–	–	**0.0**	5.6	**5.6**
Prepaid expenses and accrued income	–	–	**0.0**	23.0	**23.0**
Cash and cash equivalents	–	282.4	**282.4**	–	**282.4**
Total assets	**–**	**460.9**	**460.9**	**557.9**	**1,018.8**

December 31, 2016	Financial liabilities measured at fair value via statement of operations	Financial libailities measured at amortized cost	Total financial liabilities	Non-financial liabilities	Total
Shareholders' equity and liabilities					
Shareholders' equity	–	–	**0.0**	310.3	**310.3**
Long-term liabilities, provision	–	–	**0.0**	1.3	**1.3**
Borrowings	–	397.8	**397.8**	–	**397.8**
Accounts payable	–	36.0	**36.0**	–	**36.0**
Provisions	–	–	**0**	163.9	**163.9**
Other current liabilities	–	6.2	**6.2**	4.4	**10.6**
Prepaid expenses	–	77.1	**77.1**	21.9	**99.0**
Total shareholders' equity and liabilities	**–**	**517.1**	**517.1**	**501.8**	**1,018.8**

Measurement at fair value contains a measurement hierarchy for input data for measurements. The three levels are:

Level 1: Listed prices (unadjusted) in active markets for identical assets and liabilities that the company has access to at the time of measurement.

Level 2: Other input data than listed prices included in Level 1 which are directly or indirectly observable for the asset or liability. It may also be other input data than listed prices that are observable for the asset or liability, such as interest-rate levels, yield curves, volatility and multiples.

Level 3: Non-observable input data for the asset or liability. At this level assumptions should be taken into account that market players would use when pricing the asset or liability, including assumptions regarding risk.

For all items above, with the exception of borrowings and bonds, the carrying amount is an approximation of the fair value, and therefore these items are not divided up into levels in the measurement hierarchy. The bond whose fair value is valued according to Level 2 amounted to MSEK 377 (based on liquid trading price), the carrying value amounted to MSEK 397.8. Other borrowings have variable interest rates so book values in all material deemed to approximate fair values. Description of Company's borrowings can be found in Note 27.

Note 18 cont.

Classification and categorization of assets and liabilities in the Group 2015

December 31, 2015	Financial assets that can be sold	Loans and accounts receivable	Total financial assets	Non-financial assets	Total
Assets					
Tangible fixed assets	–	–	**0.0**	24.7	**24.7**
Intangible fixed assets	–	–	**0.0**	155.5	**155.5**
Deferred tax asset	–	–	**0.0**	18.0	**18.0**
Inventories	–	–	**0.0**	402.6	**402.6**
Financial assets	2.1	–	**2.1**	–	**2.1**
Accounts receivable	–	167.8	**167.8**	–	**167.8**
Other current receivables	–	–	**0.0**	17.1	**17.1**
Prepaid expenses and accrued income	–	–	**0.0**	34.1	**34.1**
Cash and cash equivalents	–	198.1	**198.1**	–	**198.1**
Total assets	**2.1**	**365.9**	**368.0**	**652.0**	**1,020.0**

December 31, 2015	Financial liabilities measured at fair value via statement of operations	Financial libailities measured at amortized cost	Total financial liabilities	Non-financial liabilities	Total
Shareholders' equity and liabilities					
Shareholders' equity	–	–	**0.0**	270.1	**270.1**
Long-term liabilities, provision	–	–	**0.0**	3.9	**3.9**
Borrowings	–	494.4	**494.4**	–	**494.4**
Accounts payable	–	34.9	**34.9**	–	**34.9**
Provisions	–	–	**0.0**	125	**124.7**
Other current liabilities	–	5.9	**5.9**	5	**10.9**
Prepaid expenses	–	60.1	**60.1**	21.1	**81.2**
Total shareholders' equity and liabilities	**–**	**595.3**	**595.3**	**424.8**	**1,020.0**

For all items above, with the exception of borrowings, the carrying amount is an approximation of the fair value, and therefore these items are not divided up into levels in the measurement hierarchy.

Contingent consideration is valued according to level 3, the calculation of contingent consideration is dependent on the divested business, sales development between April 2015 and March 2019. The additional purchase price is valued at 0 MSEK (see Note 13).

Assets available for sale are measured at level 1 in valuation hierarchy and fair value amounted to 2.1 MSEK.

The bond whose fair value is valued according to Level 2 amounted to 377 MSEK (based on liquid trading price), the carrying value amounted to 494,4 MSEK. Other borrowings have variable interest rates so book values in all material deemed to approximate fair values. Description of Company's borrowings can be found in Note 27.

NOTE 19 FINANCIAL ASSETS THAT CAN BE SOLD

	Group		Parent Company	
	2016	2015	2016	2015
Listed securities	–	2.1	–	–
Total	**–**	**2.1**	**–**	**–**

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 MSEK 1.7. During the fiscal year 2016 the total holding was sold.

NOTE 20 INVENTORIES

	Group		Parent Company	
	2016	2015 Restated	2016	2015
Raw materials	132.6	132.5	132.6	132.5
Work in progress	109.3	139.7	109.3	139.7
Finished products	102.3	130.4	27.6	4.6
Total	**344.2**	**402.6**	**269.5**	**276.8**

Group
The cost of inventories expensed is included in the items "Cost of goods sold" and "Research and development costs" and amounted to MSEK 124.0 (134.3).

Parent Company
The cost of inventories expensed is included in the items "Cost of goods sold" and "Research and development costs" and amounted to MSEK 58.0 (140.0).

NOTE 21 ACCOUNTS RECEIVABLE

Group
Impairment losses on accounts receivable amounted to MSEK 0.2 (0.0). 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 MSEK 0.0 (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	
	2016	2015	2016	2015
SEK	0.4	3.3	0.4	3.3
USD	133.3	125.8	6.2	245.8
EUR	44.9	35.1	44.9	35.1
Other currencies	–	–	–	–
Total	**178.5**	**164.2**	**51.4**	**284.2**

Note 21 cont.

Credit concentration
The Group has a limited number of customers, which means that a certain risk of credit centration exists.

Of the Group's total accounts receivable, MSEK 157.8 (111.9) is held by the Group's four largest customers. Each of the following:

	Group	
	2016	2015
Customer 1	51.2	44.4
Customer 2	43.8	40.9
Customer 3	36.3	24.1
Customer 4	26.5	2.6
Total	**157.8**	**111.9**

Accounts receivable due
At December 31, 2016, accounts receivable amounting to MSEK 0.6 (5.0) 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	
	2016	2015 Restated	2016	2015 Restated
Less than 43 days	0.1	3.0	0.1	2.4
44 days and older	0.5	2.0	–	1.3
Total	**0.6**	**5.0**	**0.1**	**3.7**

NOTE 22 OTHER RECEIVABLES

	Group		Parent Company	
	2016	2015	2016	2015
VAT receivable	2.7	1.9	2.7	1.9
Tax receivable	2.7	2.4	–	–
Invoiced expenses	–	12.0	–	12.0
Other	0.2	0.8	0.2	4.4
Total	**5.6**	**17.1**	**2.9**	**18.3**

NOTE 23 PREPAID EXPENSES AND ACCRUED INCOME

	Group		Parent Company	
	2016	2015	2016	2015
Prepaid rents	4.1	4.1	4.1	4.1
Other interim receivables	18.9	30.0	3.6	4.8
Total	**23.0**	**34.1**	**7.7**	**8.9**

NOTE 24 CASH AND CASH EQUIVALENTS

	Group		Parent Company	
	2016	2015	2016	2015
Cash and bank balances	282.4	198.1	211.7	114.0
Total	**282.4**	**198.1**	**211.7**	**114.0**

The Group has no unused credit facilities at December 31, 2016.

NOTE 25 SHARE-RELATED PAYMENTS

Orexo has introduced share-based payments in the form of share awards and employee stock options designed to motivate and reward through ownership, thereby promoting the company's long-term interests. Share awards and employee stock options are vested provided that the holder remains employed or is a Board member in Orexo on this date, see below for detailed descriptions of the performance criterias for the specific programs. At December 31, 2016 there were a total of 1,820,667 options outstanding, providing entitlement to subscription for 1,480,412 new shares in Orexo. 340,255 provide entitlement to an exchange for 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 304,382 and each share award provides entitlement to one share. Options and share awards are paid for through shareholders' equity.

Cost per fiscal year	Total cost
2015	–10,200
2016	–700

Employee stock options/share awards allotted	Number	Exercise price, weighted average
At Jan 1, 2015	**2,049,438**	**76**
Allotted during the period	127,404	33
Redeemed during the period	–103,066	37
Forfeited during the period	–214,684	111
At Dec 31, 2015	**1,859,092**	**71**
Allotted during the period	270,200	–
Redeemed during the period	–93,322	29
Forfeited during the period	–251,176	72
At Dec 31, 2016	**1,784,794**	**63**
Approved unallotted options Dec 31, 2016[1]	**497,417**	

[1]All 497,417 unallotted options will be cancelled due to a new LTI (long-term incentive) program implemented during 2015 and 2016.

Employee stock options/share awards per year	Number outstanding at Dec 31, 2016	Number vested at Dec 31, 2016	Exercise price, range	Value per allotted option, range	Volatility, option, weighted average	Value per share, range	Value per option weighted average	Maturity date
2008	19,000	19,000	44.0	11.5	25%	45	45	2017-12-31
2009	31,250	31,250	51.0	12.0	35%	46	46	2018-12-31
2010	4,358	4,358	0.4	37.9	35%	38	38	2017-12-31
2011	219,926	213,676	29.0–47.8	6.15–19.19	35%	28.2–39.7	34	2021-02-16
2011 Board	4,118	4,118	0.4	43.33	35%	44	44	2018-12-31
2013	724,332	511,332	51.8–131.6	15.5–44.04	35%	24.2–130.6	54	2021-02-16
2013 Board	162,916	162,916	52.4	15.5–19.72	35%	57	57	2018-04-11
2014	290,762	43,962	112.9–165.1	25.7–57.04	35%	106.6–166.8	151	2021-02-16
2015 Old program	23,750	1,250	129.2	27.4–32.6	35%	121	121	2021-02-16
2015 New program	34,182	0	0.0	13.3–78.8	35%	78.9	78.9	2018-06-18
2016	270,200	0	0.0	20.4–49.5	35%	49.5	49.5	2019-05-30
Total employee stock options/share awards	**1,784,794**							

During 2016 the company allotted 270,200 employee stock options, of which the CEO and other senior executives were allotted 98,500, corresponding to 36.5 percent. The financial and operational targets set by the Board for 2016 reached a score of 66.3 percent and hence 33.7 percent of the allocated share awards pertaining to performance target 1 will forfeit in 2017. In total 251,176 options were forfeited during 2016.

Changes in and holdings of employee stock options/share awards at the closing date for the CEO and Board members.

Owned by	Number outstanding at Jan 1, 2016	Change	Number outstanding at Dec 31, 2016
CEO Nikolaj Sörensen	384,388	3,000	387,388
Board member Martin Nicklasson	179,584	–16,667	162,917
Board member Michael Shalmi	0	0	0
Board member Raymond Hill	12,735	–4,259	8,476
Board member Staffan Lindstrand	0	0	0
Board member Kristina Schauman	0	0	0
Board memberDavid Colpman	0	0	0

Performance criteria 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 Share price	Vesting percent of Shareprice shares (also stipulated in fulfillment of Performance criterion 2 below)
> 60 percent	33 percent
> 100 percent	66 percent
> 150 percent	100 percent

These categories correspond to an average annual return over five years of approximately 10, 15 and 20 percent respectively.

Note 25 cont.

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 the 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 criteria 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 such as revenue, profitability and achieved milestones, etc. Performance achievement of individual targets is weighted into an overall average performance achievement. The outcome will be measured linearly, 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 acheived. 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.

Performance criterion 2

This target pertains to the development of the Orexo share price over the period from the date of the 2015 Annual General Meeting 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 the measurement date. The measurement dates are date defined as the date of the 2015 Annual General Meeting 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 Performance Target 2 set out above, for any vesting to occur, the developmentof the Orexo share price shall have outperformed the Nasdaq Stockholm Pharmaceuticals & Biotechnology PI during the measurement period from the date of the 2015 Annual General Meeting up to and including April 14, 2018.

Performance criteria LTIP 2016

Performance criterion 1

This target pertains to the fulfilment of the financial and operational targets for the financial year 2016 as established by the Board of Directors and relates to Orexo's key KPIs such as revenue, profitability and achieved milestones, etc. Performance achievement of individual targets is weighted into an overall average performance achievement. The outcome will be measured linearly, 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 acheived. 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.

Performance criterion 2

This target pertains to the development of the Orexo share price over the period from the date of the 2016 Annual General Meeting up to and including April 14, 2019. The share price will be measured as the volume weighted average share price 60 trading days prior to the measurement date. The measurement dates are date defined as the date of the 2016 Annual General Meeting and April 14, 2019. 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 Performance Target 2 set out above, for any vesting to occur, the developmentof the Orexo share price shall have outperformed the Nasdaq Stockholm Pharmaceuticals & Biotechnology PI during the measurement period from the date of the 2016 Annual General Meeting up to and including April 14, 2019.

NOTE 26 PROVISIONS

	Group
Long-term provisions	**Personnel**
On January 1, 2016	**6.7**
Additional provisions	0.7
Utilized during the year	–0.7
Reversed unused amounts	–5.4
Per December 31 2016	**1.3**

Long-term provisions primarily refer to estimated costs for social security fees in respect of employee stock option programs.

	Group
Short-term provisions	**Rebates and chargebacks**
On January 1, 2016	**121.8**
Additional provisions	494.8
Utilized during the year	–429.9
Reversed unused amounts	–31.2
Exchange rate difference	8.3
Per December 31 2016	**163.9**

Short-term provisions primarily refer to estimated costs for accrued rebates and chargebacks.

NOTE 27 BORROWINGS

	Group	Parent Company
January 1, 2015	**493.8**	**491.9**
Cost corporate bond	2.5	2.5
Bank loan, short-term portion	–1.9	–
January 1, 2016	**494.4**	**494.4**
Cost corporate bond	2.4	2.4
Buy back corporate bond	–99.0	–99.0
December 31, 2016	**397.8**	**397.8**

The long-term portion consists of a bond loan amounting to a total of MSEK 342. 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.

During 2016, the company have performed buy back bond transactions for a nominal amount of MSEK 99.

NOTE 28 SHORT TERM LIABILITIES

	Group		Parent Company	
	2016	2015	2016	2015
Employee withholding tax	1.6	1.9	1.2	1.3
Deduction, social security fees	0.9	0.9	0.9	0.9
Deduction, special salary tax	1.9	2.2	1.9	2.2
Other current liabilities	6.2	5.9	3.0	3.1
Sum Other liabilities	**10.6**	**10.9**	**7.0**	**7.5**
Accrued salaries	14.0	11.6	2.2	3.1
Accrued vacation pay	5.3	6.3	5.3	6.3
Accrued social security fees	2.6	3.2	2.6	3.2
Liabilities to Group companies	–	–	152.5	101.7
Other interim liabilities	77.1	60.1	15.0	40.6
Sum Accrued expences	**99.0**	**81.2**	**177.6**	**154.9**
Total	**109.6**	**92.2**	**184.6**	**162.4**

NOTE 29 DISCLOSURES ON THE CASH FLOW STATEMENT

	Group		Parent Company	
	2016	2015 Restated	2016	2015 Restated
Adjustments for items not included in cash flow comprise the following:				
Depreciation and impairment	25.0	80.7	24.4	17.9
Gain/loss on disposal	–5.0	16.3	–	–
Change in provisions	42.0	55.7	–2.6	–5.1
Change in fair value of financial instruments	0.2	–	–	–
Share based payments	3.7	7.1	2.5	3.5
Exchange rate income and expense	–21.8	–1.3	–21.8	–1.4
Total	**44.1**	**158.5**	**2.5**	**14.9**

NOTE 30 SHARES IN SUBSIDIARIES AND JOINT VENTURES

Direct and indirect holdings Dec 31, 2016	Corp. Reg. No.	Reg. office	Number of shares	Shareholding	Cost/Contribution	Accumulated impairment	Carrying amount
Pharmacall AB	556569-1739	Uppsala	1,000	100%	0.1	–	0.1
Biolipox AB	556588-3658	Stockholm	12,883,944	100%	505.8	–399.8	105.9
Pharmakodex Ltd	5268159	Storbritannien	684,664	100%	82.2	–82.2	0.0
Orexo US Inc	101013414	USA	100	100%	43.6	–	43.6

All holdings are owned directly.

Change in carrying amount of direct holdings

2015	Opening carrying amount	Acqusition	Contribution	Sales	Impairment	Closing carrying amount
Pharmacall AB	0.1	–	–	–	–	0.1
Orexo US Inc	38.9	–	3.5	–	–	42.5
Biolipox AB	169.8	–	–	–	–63.9	105.9
Kibion AB	–	–	–	–	–	–
Pharmakodex Ltd	–	–	–	–	–	–
Total	**208.9**	**–**	**3.5**	**–**	**–63.9**	**148.5**

2016						
Pharmacall AB	0.1	–	–	–	–	0.1
Orexo US Inc	42.5	–	1.2	–	–	43.6
Biolipox AB	105.9	–	–	–	–	105.9
Pharmakodex Ltd	–	–	–	–	–	–
Total	**148.5**	**–**	**1.2**	**–**	**–**	**149.7**

NOTE 31 PLEDGED ASSETS AND CONTINGENT LIABILITIES

	Group		Parent Company	
	2016	2015	2016	2015
Chattel mortgages for bank commitment	–	100	–	100
Guarantee commitment	–	–	–	–
Total	**–**	**100**	**–**	**100**

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.

Until June 28, 2016, Orexo had commitments to Danske Bank consisting of chattel mortgages of MSEK 100.

NOTE 32 AUDITORS' FEES

	Group		Parent Company	
	2016	2015	2016	2015
Audit assignment				
Ernst & Young	1.9	–	1.9	–
PWC[1]	0.1	2.6	–	2.1
Non-auditing assignments				
Ernst & Young	3.2	–	3.2	–
PWC[1]	0.8	–	0.8	–
Tax advice				
Ernst & Young	0.3	–	0.3	–
PWC[1]	0.9	1.1	0.1	0.2
Other services				
PWC[1]	–	0.7	–	0.7
Total	**7.2**	**4.5**	**6.2**	**3.1**

1) The amounts for 2016 PWC relates to time spent before the annual general meeting.

NOTE 33 DEFERRED TAX

The tax-loss carry-forward in the Group amounts to SEK 1,458 million (1,449). These have not been capitalized due to the difficulty of assessing when capitalized loss carry-forwards can be set off against future surpluses. There is no time limit when they can be utilized.

The following table specifies the tax of the Group's temporary differences.

	Group		Parent Company	
	2016	2015 Restated	2016	2015 Restated
Deferred tax assets				
Temporary differences in current provision	24.8	18.0	–	–
Total	**24.8**	**18.0**	**0.0**	**0.0**

These differences are related to non-deductible current provisions for sales rebates, sales allowances, distribution, sales returns and other relevant deductions in company's US operations.

NOTE 34 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.

Leasing expenses amounting to MSEK 0.4 (0.4) for the leasing of equipment, machinery and computers are included in the statement of operations.

The Orexo Group has two rental agreements. Orexo AB has entered into a rental agreement that runs until December 31, 2019. Orexo US Inc's rental agreement runs until December 31, 2019. The nominal value of future leasing fees for lease agreements that cannot be terminated is as follows:

	Group		Parent Company	
	2016	2015	2016	2015
Falls due for payment within one year	18.0	18.8	15.6	16.6
Falls due for payment later than one year but within five years	36.0	21.1	31.1	16.6
Falls due for payment later than 5 years	–	–	–	–
Total	**54.0**	**39.9**	**46.7**	**33.2**

NOTE 35 RELATED PARTY TRANSACTIONS

Purchases and sales between Group companies

The following transactions took place between the companies in the Group:	2016	2015
Forward invoicing of costs, which are recognized as net revenues		
Biolipox AB	–	–
Orexo US Inc	4.5	0.4
Kibion AB	–	0.2
Sale of goods and services		
Biolipox AB	–	–
Orexo US Inc	123.1	301.5
Kibion GmbH	–	1.3
Kibion AB	–	–
Pharmacall	–	0.0
Total	**127.6**	**303.5**

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 11.

There have been no other related party transactions.

NOTE 36 EVENTS AFTER THE CLOSING DATE

Company completed a limited bond buyback program and in total purchased Orexo corporate bonds in the market with a nominal value of MSEK 59. The program was initiated on February 8, 2017, and completed by February 17, 2017. After the purchase Orexo owns own bonds with a nominal value of MSEK 158.

Company filed a patent infringement action in United States District Court for the District of Delaware against Actavis Elizabeth LLC, Actavis Pharma, Inc., and their parent company Teva (collectively "Actavis"). Orexo alleges that Actavis's generic versions of Suboxone and Subutex tablets infringe Orexo's US Patent No. 8,454,996 (the '996 patent).

NOTE 37 APPROPRIATION OF PROFIT

Proposed appropriation of profit

The following funds are at the disposal of the Annual General Meeting:

Share premium reserve	1,192,804,533
Profit carried forward	–1,138,215,312
Profit/loss for the year	–95,813,480
Total	**–41,224,259**

The Board proposes that the funds at their disposal SEK –1,138,215,312, remaining earnings SEK –95,813,480 and share premium reserve SEK 1,192,804,533, be carried forward.

NOT 38 CORRECTED ERROR

Consolidated statements of operations

MSEK	Ref:	2015 Original	Restate-ment	2015 Restated
Net revenues	1	643.3	2.9	646.2
Cost of goods sold	2	–136.1	–14.1	–150.2
Gross profit		**507.2**	**–11.2**	**496.0**
Selling expenses		–297.5		–297.5
Administrative expenses		–141.5		–141.5
Research and develop-ment costs		–172.6		–172.6
Other operating income and expenses	3	–64.5	–0.5	–65.0
Operating earnings		**–168.9**	**–11.7**	**–180.6**
Financial income		0.9	–0.9	0.0
Financial expense		–23.0		–23.0
Earnings after financial items		**–191.0**	**–12.6**	**–203.6**
Tax on earnings for the year	5	–6.9	0.5	–6.4
Net earnings for the year		**–197.9**	**–12.1**	**–210.0**
Earnings for the year attributable to:				
Parent Company shareholders		**–197.9**	**–12.1**	**–210.0**
Non-controlling interests				
Earnings per share during the year attributable to Parent Company share-holders (expressed in SEK)				
– before dilution		–5.74	–0.35	–6.09
– after dilution		–5.74	–0.35	–6.09

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

Consolidated statements of comprehensive income

MSEK	2015 Original	Restate-ment	2015 Restated
Net earnings for the year	**–197.9**	**–12.1**	**–210.0**
Other comprehensive income			
Items that may subsequently be reversed to the statement of operations:			
Change in fair value assets available for sale		0.9	0.9
Reclassification assets available for sale			
Cash flow hedge	2.8	–5.7	–2.9
Exchange-rate differences	–4.3	7.7	3.4
Other comprehensive earnings for the year, net after tax	**–1.5**	**2.9**	**1.4**
Comprehensive earnings for the year	**–199.4**	**–9.2**	**–208.6**
Comprehensive earnings attributable to:			
Parent Company shareholders	–199.4	–9.2	–208.6
Non-controlling interests	–	–	–

Consolidated balance sheet

MSEK	2015 Original	Restate-ment	2015 Restated
ASSETS			
Fixed assets			
Tangible fixed assets	24.7		24.7
Intangible assets	159.1	–3.6	155.5
Deferred tax assets	–	18.0	18.0
Financial assets that can be sold	2.1		2.1
Total fixed assets	**185.9**	**14.4**	**200.3**
Current assets			
Inventories	398.9	3.7	402.6
Accounts receivable	164.2	3.6	167.8
Other receivables	17.1		17.1
Prepayment and accrued income	52.1	–18.0	34.1
Cash and cash equivalents	198.1		198.1
Total current assets	**830.4**	**–10.7**	**819.7**
TOTAL ASSETS	**1,016.3**	**3.7**	**1,020.0**
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity			
Share capital	13.8		13.8
Other contributed capital	1,842.9	–0.1	1,842.8
Reserves	–10.8	4.8	–6.0
Accumulated deficit	–1,579.5	–1.0	–1,580.5
Total shareholder's equity	**266.4**	**3.7**	**270.1**
Long-term liabilities and provisions			
Provisions	3.9	2.8	6.7
Borrowings	494.4		494.4
Total long-term liabilities	**498.3**	**2.8**	**501.1**
Current liabilities			
Accounts payable	34.9		34.9
Provisions	121.8		121.8
Other liabilities	13.7	–2.8	10.9
Accruals	81.2		81.2
Total current liabilities	**251.6**	**–2.8**	**248.8**
Total liabilities	**749.9**		**749.9**
Total shareholders' equity and liabilities	**1,016.3**	**3.7**	**1,020.0**

Reclassification between intangible assets and other receivables with MSEK 3.6.

Reclassification between deferred tax assets and prepayment and accrued income with MSEK 18.0.

Reclassification of social fees for LTI programs between Current liabilities and long-term other provisions with MSEK 2.8.

Note 38 cont.

Consolidated cash flow

MSEK	2015 Original	Restate-ment	2015 Restated
Operating earnings	–169.0	–11.6	–180.6
Adjustment for non-cash items	77.0	81.5	158.5
Interest received	–	0.0	0.0
Interest paid	–20.6	–0.1	–20.7
Tax paid	–6.8	2.4	–4.4
Cash flow from operating activities before changes in working capital	**–119.4**	**72.2**	**–47.2**
Changes in working capital			
Change inventories	79.2	10.0	89.2
Change receivabes	–22.0	–41.9	–63.9
Change current liabilities	–40.0	–47.3	–87.3
Cash flow from operating activities	**–102.2**	**–7.0**	**–109.2**
Investing activities			
Acquisition of tangible and intangible fixed assets	–4.0	3.7	–0.3
Disposal of tangible assets	0.0		0.0
Acquisition of intangible assets	0.0	–3.7	–3.7
Sale of subsidiary	21.8		21.8
Cash flow from investing activities	**17.8**	**0.0**	**17.8**
Financing activities			
New share issue	3.8		3.8
Buyback of corporate bonds	–1.2		–1.2
Cash flow from financing activities	**2.6**		**2.6**
Cash flow for the year			
Cash and cash equivalents at the beginning of the period	284.5		284.5
Exchange-rate differences in cash and cash equivalents	–4.5	7.0	2.5
Cash flow for the year	–81.8	–7.0	–88.8
Cash and cash equivalents at the end of the period	**198.1**		**198.1**

Parent company statement of operations

MSEK	2015 Original	Restate-ment	2015 Restated
Net revenues	518.9		518.9
Cost of goods sold	–155.9		–155.9
Gross profit	**363.0**		**363.0**
Selling expenses	–226.9		–226.9
Administrative expenses	–108.1		–108.1
Research and development costs	–122.9		–122.9
Other operating income and expenses	5.0	–0.5	4.5
Operating earnings	**–89.9**	**–0.5**	**–90.4**
Interest income and expenses	–18.7		–18.7
Impairment of shares in subsi-diaries	–63.8		–63.8
Sales of subsidiary	13.1		13.1
Other financial expenses	–2.5		–2.5
Exchange rate adjustment	–		–
Net financial items	**–71.9**		**–71.9**
Earnings before tax	**–161.8**	**–0.5**	**–162.3**
Tax	–0.5	0.5	0.0
Net earnings for the year	**–162.3**	**0.0**	**–162.3**

Parent Company balance sheet

MSEK	2015 Original	Restate-ment	2015 Restated
ASSETS			
Fixed assets			
Patents and intellectual property rights and proprietary intangible asset	159.1	–3.6	155.5
Equipment, renovation of the property of others	23.7		23.7
Shares and participations in subsidiaries	148.5		148.5
Total fixed assets	**331.4**	**–3.6**	**327.8**
Current assets			
Inventories	276.8		276.8
Current receivables			
Accounts receivable	284.2		284.2
Tax claims	2.4		2.4
Other receivables	14.7		14.7
Receivables from Group companies	10.5		10.5
Prepaid expenses and accrued income	8.9	3.6	12.5
Total current receivables	**320.7**	**3.6**	**324.3**
Cash and cash equivalents	114.0		114.0
Total current assets	**711.5**	**3.6**	**715.1**
TOTAL ASSETS	**1,042.9**		**1,042.9**
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity			
Restricted shareholders' equity			
Share capital	13.8		13.8
Statutory reserve	290.8		290.8
	304.6		**304.6**
Non-restricted shareholders' equity			
Share premium reserve	1,186.9		1,186.9
Accumulated deficit	–975.9		–975.9
Net earnings for the year	–162.3		–162.3
	48.7		**48.7**
Total shareholders' equity	**353.4**		**353.4**
Long-term liabilities			
Other provisions	3.9	2.8	6.7
Long-term liabilities	494.3		494.3
Total long-term liabilities	**498.2**	**2.8**	**501.0**
Current liabilities			
Accounts payable	26.1		26.1
Other liabilities	7.5		7.5
Liabilities to Group companies	101.7		101.7
Accrued expenses and deferred income	55.9	–2.8	53.1
Total current liabilities	**191.3**	**–2.8**	**188.5**
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES	**1,042.9**		**1,042.9**

Reclassification between intangible assets and Prepaid expenses and accrued income with MSEK 3.6.

Reclassification of social fees for LTI programs between Current liabilities and long-term other provisions with MSEK 2,8.

Parent Company cash flow statement

MSEK	2015 Original	Restate-ment	2015 Restated
Operating activities			
Operating earnings	–89.8	–0.5	–90.3
Interest received	1.8		1.8
Interest paid	–20.5	–0.2	–20.7
Other financial items	–53.3	53.3	–
Tax paid	–0.5	0.5	–
Adjustment for non-cash items	56.0	–41.1	14.9
Cash flow from operating activities before change in working capital	**–106.3**	**12.0**	**–94.3**
Change in working capital			
Accounts receivable and other current receivables	–101.0		–101.0
Inventories	101.6		101.6
Current liabilities	–53.3	–13.6	–66.9
Cash flow from operating activities	**–159.0**	**–1.6**	**–160.6**
Investing activities			
Acquisition of tangible fixed assets	–4.1	3.8	–0.3
Acquisition of intangible fixed assets	–	–3.7	–3.7
Divestment of subsidiary	26.1		26.1
Cash flow from investing activities	**22.0**	**0.1**	**22.1**
Financing activities			
New share issue	3.8		3.8
Cash flow from financing activities	**3.8**		**3.8**
Cash flow for the year			
Cash and cash equivalents at beginning of period	247.2		247.2
Exchange-rate differences in cash and cash equivalents	–	1.5	1.5
Change in cash and cash equivalents	–133.2	–1.5	–134.7
Cash and cash equivalents at end of period	**114.0**		**114.0**

Earnings per share

MSEK	2015 Original	Restatement	2015 Restated
Number of shares, before dilution	34,580,810	–102,188	34,478,622
Number of shares, after dilution	34,873,345	–394,723	34,478,622
Earnings per share, before dilution, SEK	–5.74	–0.35	–6.09
Earnings per share, after dilution, SEK	–5.74	–0.35	–6.09

Number of shares recalculated from average number to weighted average number.

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 15, 2017

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

Kirsten Detrick
Board member

Nikolaj Sørensen
President and CEO

Our audit report was submitted on March 15, 2017.

Ernst & Young Aktiebolag

Björn Ohlsson
Authorized Public Accountant
Auditor in charge

Auditor's report

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

Report on the annual accounts and consolidated accounts
Opinions
We have audited the annual accounts and consolidated accounts of Orexo AB for the year 2016. The annual accounts and consolidated accounts of the company are included on pages 27–69 in this document.

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 31 December 2016 and its financial performance and cash flow 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 31 December 2016 and their financial performance and cash flow for the year then ended in accordance with International Financial Reporting Standards (IFRS), 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 general meeting of shareholders adopts the income statement and balance sheet for the parent company and the group.

Basis for Opinions
We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

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

Other matters
The audit of the annual accounts for 2015 was performed by another auditor who submitted an auditor´s report dated 18 March 2016, with unmodified opinions in the Report on the annual accounts.

Key Audit Matters
Key audit matters of the audit are those matters that, in our professional judgment, were of most significance in our audit of the annual accounts and consolidated accounts of the current period. These matters were addressed in the context of our audit of, and in forming our opinion thereon, the annual accounts and consolidated accounts as a whole, but we do not provide a separate opinion on these matters.

Opening balances
First year audits require some additional considerations which are not applicable to continued audits. These are meant to gain sufficient understanding of the business and the environment in which it operates to plan an audit strategy. Since circumstances may have been present at the beginning of the year which have been effect on the financial statements for the year 2016, we are also required to perform audit procedures to verify that these do not contain material misstatements which affect the financial statements for 2016. Since errors in the opening balances could have significant effects on the financial statements for 2016 we have assessed that this a significant audit matter.

Our audit procedures are designed to verify that opening balances have been correctly transferred to 2016 or have been appropriately adjusted as necessary, and that appropriate accounting policies have been used for the opening balances. We have also performed additional audit procedures over opening balances as has been determined to be necessary. Our procedures have included corrections of errors which have affected the opening balances. In the annual report for 2016 disclosures are provided regarding these under Note 38. We have assessed whether disclosures provided are adequate.

Revenue recognition
Sales revenues for 2016 were MSEK 705.9 in the consolidated income statement. Revenue from the sale of goods is recognized at the time of delivery to the customer, which is the point in time when ownership is transferred to the customer who then also assumes the economic risk. Revenue from one-time licenses fees are allocated based on the fair value of each delivery, and revenues from research collaborations are recognized over the period which they relate to. Royalty revenue is recognized when distributors report sale of goods that generates royalty for Orexo.

Revenue from the sale of goods is calculated as gross revenue invoiced to wholesalers with deduction of actual and estimated rebates to public and private insurers, provisions for potential returns, cost of patient support programs and fees to wholesalers and distributors. The gross-to-net adjustments are based partly on management's estimates. Revenue recognition connected to royalty require management to assess at what point in time each respective delivery has been completed. In total, revenue recognition for the group contains significant elements of judgment, and for this reason revenue recognition has been assessed as a

significant audit matter. A description of the judgments on which revenue recognition is based is described in the section "Important estimations and judgments for accounting purposes" in Note 4.

We have performed audit procedures including review of agreements, review of processes and sample cutoff testing. We have also performed audit procedures on calculation models and assumptions on which the gross-to-net adjustments determined by management are based. We have assessed whether disclosures provided are adequate.

Impairment of internally generated intangible assets

Internally generated intangible assets are recorded at MSEK 138.2 in the group balance sheet as of 31 December 2016. In the event of any impairment indicators, Orexo assesses whether recorded value exceeds the recoverable value for these assets. Recoverable value is determined through generally accepted models for discounted cash flow valuation and include management's assessment of future cash flows and other significant assumptions such as discount rates and growth which may have a large impact on the calculated recoverable amount. For this reason, management's impairment test of internally generated intangible assets has been assessed to be a significant audit matter. A description of the impairment test is provided under Note 9 and of the section "Important estimations and assumptions for accounting purposes" in Note 4.

During our audit we have assessed management's models, estimations and assumptions on which the recoverable value of intangible assets is based. We have reviewed and compared management's previous forecasts to actual outcomes and reviewed the reasonableness of forecasts and assumptions on which the impairment test for the year is based. We have also reviewed assumptions made to comparable entities in the sector in which the company operates. We have, with the support of our valuation specialists, reviewed the company's model and method for performing the impairment test and have assessed the company's internal sensitivity analyses, and performed sensitivity analyses of key assumptions and possible factors which could affect these. We have assessed whether disclosures provided are adequate.

Inventory

Inventory is recorded at MSEK 344.2 in the group balance sheet per 31 December 2016, and consists of raw materials, in-process-products and finished goods. The valuation of inventory and assessment of risk for potential write-downs are based on market forecasts and assumptions made regarding shelf-life of different chemical compounds. The shelf-life of inventory is partly based on documented stability studies.

The estimates and assumptions which management make may have a large impact on whether there is a write-down need, and for this reason we have assessed inventory valuation to be a significant audit matter. A description of assumptions on which management's judgments are based is described in the section "Important estimations and assumptions for accounting purposes" in Note 4.

In our audit we have assessed and reviewed management's process for determined whether there is a write-down need, by assessing market forecasts, stability studies and assumptions made. We have also assessed the reasonableness of forecasted future cash flows and growth forecasts based on the circumstances which were known at the balance sheet date. We have assessed whether disclosures provided are adequate.

Other Information than the annual accounts and consolidated accounts

This document also contains other information than the annual accounts and consolidated accounts and is found on pages 1–26. The Board of Directors and the Managing Director are responsible for this other information.

Our opinion on the annual accounts and consolidated accounts does not cover this other information and we do not express any form of assurance conclusion regarding this other information.

In connection with our audit of the annual accounts and consolidated accounts, our responsibility is to read the information identified above and consider whether the information is materially inconsistent with the annual accounts and consolidated accounts. In this procedure we also take into account our knowledge otherwise obtained in the audit and assess whether the information otherwise appears to be materially misstated.

If we, based on the work performed concerning this information, conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Responsibilities of the Board of Directors and the Managing Director

The Board of Directors and the Managing Director are responsible for the preparation of the annual accounts and consolidated accounts and that they give a fair presentation in accordance with the Annual Accounts Act and, concerning the consolidated accounts, in accordance with IFRS as adopted by the EU. The Board of Directors and the Managing Director are also responsible for such internal control as they 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.

In preparing the annual accounts and consolidated accounts, The Board of Directors and the Managing Director are responsible for the assessment of the company's and the group's ability to continue as a going concern. They disclose, as applicable, matters related to going concern and using the going concern basis of accounting. The going concern basis of accounting is however not applied if the Board of Directors and the Managing Director intends to liquidate the company, to cease operations, or has no realistic alternative but to do so.

The Audit Committee shall, without prejudice to the Board of Director's responsibilities and tasks in general, among other things oversee the company's financial reporting process.

Auditor's responsibility

Our objectives are to obtain reasonable assurance about whether the annual accounts and consolidated accounts as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinions. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual accounts and consolidated accounts.

As part of an audit in accordance with ISAs, we exercise professional judgment and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the annual accounts and consolidated accounts, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinions. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of the company's internal control relevant to our audit 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.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Board of Directors and the Managing Director.
- Conclude on the appropriateness of the Board of Directors' and the Managing Director's use of the going concern basis of accounting in preparing the annual accounts and consolidated accounts. We also draw a conclusion, based on the audit evidence obtained, as to whether any material uncertainty exists related to events or conditions that may cast significant doubt on the company's and the group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the annual accounts and consolidated accounts or, if such disclosures are inadequate, to modify our opinion about the annual accounts and consolidated accounts. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause a company and a group to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the annual accounts and consolidated accounts, including the disclosures, and whether the annual accounts and consolidated accounts represent the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient and appropriate audit evidence regarding the financial information of the entities or business activities within the group to express an opinion on the consolidated accounts. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our opinions.

We must inform the Board of Directors of, among other matters, the planned scope and timing of the audit. We must also inform of significant audit findings during our audit, including any significant deficiencies in internal control that we identified.

We must also provide the Board of Directors with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

From the matters communicated with the Board of Directors, we determine those matters that were of most significance in the audit of the annual accounts and consolidated accounts, including the most important assessed risks for material misstatement, and are therefore the key audit matters. We describe these matters in the auditor's report unless law or regulation precludes disclosure about the matter or when, in extremely rare circumstances, we determine that a matter should not be communicated in the auditor's report because the adverse consequences of doing so would reasonably be expected to outweigh the public interest benefits of such communication.

Report on other legal and regulatory requirements

Opinions

In addition to our audit of the annual accounts and consolidated accounts, we have also audited the administration of the Board of Directors and the Managing Director of Orexo AB for the year 2016 and the proposed appropriations of the company's profit or loss.

We recommend to the general meeting of shareholders that the profit be appropriated 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.

Basis for Opinions

We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

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

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. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the company's and the group's type of operations, size and risks place on the size of the parent company's and the group's equity, consolidation requirements, liquidity and position in general.

The Board of Directors is responsible for the company's organization and the administration of the company's affairs. This includes among other things continuous assessment of the company's and the group's financial situation and ensuring that the company's organization is designed so that the accounting, management of assets and the company's financial affairs otherwise are controlled in a reassuring manner. The Managing Director shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and among other matters take measures that are necessary to fulfill the company's accounting in accordance with law and handle the management of assets in a reassuring manner.

Auditor's responsibility

Our objective concerning the audit of the administration, and thereby our opinion about discharge from liability, is to obtain audit evidence to assess with a reasonable degree of assurance whether any member of the Board of Directors or the Managing Director in any material respect:

- has undertaken any action or been guilty of any omission which can give rise to liability to the company, or
- in any other way has acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

Our objective concerning the audit of the proposed appropriations of the company's profit or loss, and thereby our opinion about this, is to assess with reasonable degree of assurance whether the proposal is in accordance with the Companies Act.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that can give rise to liability to the company, or that the proposed appropriations of the company's profit or loss are not in accordance with the Companies Act.

As part of an audit in accordance with generally accepted auditing standards in Sweden, we exercise professional judgment and maintain professional scepticism throughout the audit. The examination of the administration and the proposed appropriations of the company's profit or loss is based primarily on the audit of the accounts. Additional audit procedures performed are based on our professional judgment with starting point in risk and materiality. This means that we focus the examination on such actions, areas and relationships that are material for the operations and where deviations and violations would have particular importance for the company's situation. We examine and test decisions undertaken, support for decisions, actions taken and other circumstances that are relevant to our opinion concerning discharge from liability. 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.

Uppsala, March 15, 2017
Ernst & Young AB

Björn Ohlsson
Authorized Public Accountant

Definitions and reconciliations of key figures

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

Capital employed
Interest-bearing liabilities and shareholders' equity

Debt/equity ratio
Interest-bearing liabilities divided by shareholders' equity

EBIT
Earnings before net financial items and tax, the same as Operating earnings

EBITDA
Earnings before interest, taxes, depreciation and amortization. EBIT plus depreciation

Earnings per share, before dilution
Net earnings for the period after tax divided by the weighted average number of shares outstanding after dilution during the period

Equity/assets ratio
Shareholders' equity as a percentage of total assets

Gross Revenues
Grand total of all invoiced sales transactions reported in a period, without any deductions

Gross to net ratio
Net Revenues divided by Gross Revenues

Investments
Value of an investment before depreciation

Net debt
Current and long-term interest-bearing liabilities including pension liabilities, less cash and cash equivalents

Net earnings
Operating Earnings plus Net Financial Items plus tax

Net financial items
Financial revenue minus financial cost

Net Revenues
Gross Revenues less deductions for sales rebates, sales allowances, distribution, sales returns and other relevant deductions

Number of shares after dilution
Shares at the end of the period adjusted for the dilutive effect of potential shares

Operating expenses
A non-capital expense incurred in daily operating activities

Operating margin
Operating earnings as a percentage of net revenues

Return on shareholders' equity
Net earnings for the period as a percentage of average shareholders' equity

Working capital
Current assets less current liabilities

Zubsolv® net revenue
Revenue net of discounts and returns

Orexo makes use of the key figures and believes they are useful for readers of the financial reports as a complement to other performance measures when assessing implementation of strategic investments and the Group's ability to meet financial objectives and commitments. Key figures and certain other operating information per share are reconciled as follows:

EBITDA MSEK	2016	2015 Restated	2014	2013	2012
EBIT	51.7	–180.6	–25.0	–139.7	–79.4
Plus: interest, taxes, depreciation and amortization	22.7	80.7	12.5	50.1	17.3
EBITDA	**74.4**	**–99.9**	**–12.5**	**–89.6**	**–62.1**

Return on shareholders' equity	2016	2015 Restated	2014 Restated	2013	2013
Average shareholders' equity	290.2	369.0	314.7	176.4	251.2
Divided by: Net earnings	29.0	–210.0	–56.6	–154.9	–85.9
Return on shareholders' equity %	**10**	**–57**	**–18**	**–88**	**–34**

Net debt MSEK	2016	2015 Restated	2014	2013	2012
Current and long-term interest-bearing liabilities including pension liabilities	397.8	494.4	496.2	241.1	120.6
Less: cash and cash equivalents.	–282.4	–198.1	–284.5	–105.6	–228.1
Net debt	**115.4**	**296.3**	**211.7**	**135.5**	**–107.5**

Operating expenses MSEK	2016	2015 Restated	2014	2013	2013
Selling expenses	–240.6	–297.5	–193.6	–125.1	–62.0
Administrative expenses	–161.6	–141.5	–113.0	–126.4	–82.6
Research and development costs	–132.3	–172.6	–197.8	–238.1	–216.2
Other operating income and expenses	29.9	–65.0	16.5	–50.1	–17.1
Operating expenses	**–504.6**	**–676.6**	**–487.9**	**–539.7**	**–377.9**

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 under the symbol ORX and 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.

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

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

Examples of external regulations influencing corporate governance

- Swedish Companies Act
- Regulations governing external reporting, such as the accounting law and the Annual Report law
- Nasdaq Stockholm rules for issuers
- OTCQX rules for companies trading ADRs on OTCQX
- Swedish Code of Corporate Governance (the Code, www.bolagsstyrning.se)

Examples of 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 34,870,326 (34,580,810), distributed among 7,021 (6,944) shareholders.

The 10 largest shareholders held 60.5 (62.5) percent of the outstanding shares, management 0.2 (0.2) percent and other shareholders 39.3 (37.3) percent. At December 31, 2016, two shareholders each held shares representing 10 percent or more of the company – Novo A/S, 27.7 percent, and HealthCap, 11.4 percent. Non-Swedish shareholders accounted for approximately 52 (57) percent of the total number of shares. Institutions and industrial owners hold the majority of shares. At year-end, 76 (79) percent of the shares were held by legal entities, and 24 (21) 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.

Annual General Meeting
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 2016
The Annual General Meeting was held on Friday, April 15, 2016 in Uppsala. At the Meeting:

- Raymond G. Hill, Staffan Lindstrand, Martin Nicklasson, Kristina Schauman, Michael Shalmi and David Colpman were re-elected as Board members. Kirsten Detrick was elected as new Board member. Martin Nicklasson was re-elected as Chairman of the Board.
- Ernst and Young Aktiebolag was elected as new auditor.
- A resolution was adopted that fees for Board members should amount to a total of SEK 2,100,000, 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 2015 fiscal year were adopted.
- The Annual General Meeting granted Board members and the President discharge from liability for the 2015 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 2016 Annual General Meeting can be found at www.orexo.com.

Annual General Meeting 2017
The Annual General Meeting of Orexo will be held on Thursday, April 6, 2017, at 4:00 p.m. at the company's premises at Virdings allé 32 A, Uppsala, Sweden.

Nomination Committee
The 2016 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 2016, 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 September 29, 2016. 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 Annual General Meeting 2017

Name	Representatives
Kasim Kutay	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 of Directors have a responsibility to the shareholders for the Group´s management and organization, monitors the predident´s work and continuously follows the business development and the reliability of the internal control within the company. 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, Kristina Schauman and Kirsten Detrick. For a more detailed description of Board members, please refer to page 80.

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 17 (16) meetings, of which 11 (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 2,100,000, 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	17/17	1/1	6/6
David Colpman	Board member		2015	17/17	–	–
Kristina Schauman	Board member		2012	16/17	–	6/6
Michael Shalmi	Board member		2010	12/17	1/1	–
Raymond G. Hill	Board member		2008	17/17	1/1	–
Staffan Lindstrand	Board member		2002	17/17	–	4/6
Kirsten Detrick	Board member		2016	12/12[1]	–	–

[1] Kirsten Detrick was elected Board member at the Annual General Meeting on April 15, 2016.

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

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 26. 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 6 (5) 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 and President´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.

Auditors
Orexo´s auditors is the auditing firm EY, with Authorised Public Accountant Björn Ohlsson as auditor in charge. At the AGM 2016 EY was elected as auditors until the AGM 2017. The external auditors discuss the external audit plan and risk management with the Audit Committee. The auditors perform a review of the interim report for the third quarter, and audit the annual accounts and consolidated financial statements. The auditors also express an opinion on whether this Corporate Governance Report has been prepared in accordance with, and whether certain disclosures herein are consistent with, the annual accounts and consolidated financial statements. The auditors report the results of their audit of the annual accounts and consolidated financial statements, their review of the Corporate Governance Report in the auditor´s report, and a separate opinion on the Corporate Governance Report, in a presentation to the AGM. In addition, the auditors present detailed findings from their reviews to the Audit Committee three times per year, and to the Board in its entirety once per year.

For information regarding fees for the company's auditors, see Note 32.

President and the Management
The President leads the work of the extended Management Team and makes decision in consultation with them. At the end of 2016 the extended Management Team consisted of five persons in addition to the President. The extended Management Team hold regular meetings under the supervision of the President. For a more detailed description of the CEO and the management, see page 81.

Board of Directors' Report on Internal Control and Risk Management regarding Financial Reporting
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, 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, commercial performance and 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. During the year these procedures were updated to reflect the new EU Market Abuse Regulation (MAR) adopted in Sweden as of July 3, 2016.

Follow-up

Orexo's management conducts bi-weekly performance follow-up, with an analysis of deviations from the budget and plans. 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.

Internal audit

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 Governance
- Information from General Meetings of previous years
- Information from the Nomination Committee
- Information about remuneration principles for senior executives
- Corporate governance reports from 2009 onwards
- Information for the 2017 Annual General Meeting (convening notice, Nomination Committee proposals, presentation of the work of the Nomination Committee, etc.)

Board of Directors







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 Zealand Pharma A/S and Farma Investment AS. Board member of Basilea Pharmaceutica Ltd., BioInvent International AB and Biocrine AB. Member of the Royal Academy of Engineering Sciences (IVA).
Previous appointments: CEO at Swedish Orphan Biovitrum AB 2007–2010. Astra/AstraZeneca 1978–1989 and 1991–2007, e.g. 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 10,000 shares and stock options entitling to 162,916 shares.[1]

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. Board member of HRA Pharma. Advisor to Sunstone Capital.
Previous appointments: Former Head of Global Business Development 201–2014, Senior Vice President of Business Development at Shire plc 1999–2012. Various business development and commercial positions at Glaxo Wellcome, Novo Nordisk and Boots Pharmaceuticals.
Does not hold any shares in Orexo.

Kirsten Detrick (b. 1965)

Board member since April 2016.
MBA.
Other appointments:
General Manager at Takeda Pharma GmbH since July, 2016. Managing Director at Takeda Austria GmbH and Takeda Osteuropa Holding GmbH since July, 2016.
Previous appointments: Vice President Global Marketing, Therapeutic Area Commercial Lead – GI at Takeda Pharmaceuticals, Executive Director positions within US as well as Global Marketing and Commercialization at Amgen Inc. 2004–2013, Senior Director positions within Marketing at Bristol-Myers Squibb 1991–2004. Former member of the board of Southern California Biomedical Council and member of Healthcare Businesswomen's Association.
Does not hold any shares in Orexo.

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 the Pharmaceutical Sciences Expert Advisory Panel, Royal Pharmaceutical Society. Non-Executive Director of Covagen (sold to J&J Sep 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 until 2008.
Holds stock options entitling to 8,746 shares.[1]

Staffan Lindstrand (b. 1962)

Board member since 2002.
M.Sc. in Engineering.
Other appointments: Partner of HealthCap since 1997, 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.[1]

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 and BEWi Group AB.
Previous appointments: CFO at OMX, Carnegie, Apoteket AB, CEO at Apoteket AB and Group Treasurer at Investor AB.
Holds 20,000 shares (and 4,000 by legal entity).[1]

Michael Shalmi (b. 1965)

Board member since 2010.
M.D., MBA.
Other appointments: Managing Director and Head of Large Investments, Novo A/S.
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.

1) As per December 31, 2016

Management






Nikolaj Sørensen (b. 1972)

Chief Executive Officer since February 2013, employed since 2011.
B.Sc., and M.Sc., Copenhagen Business School, Denmark.
Previous appointments: Several senior management positions both international and in Sweden at Pfizer Inc and the Boston Consulting Group (BCG).
Holds 33,000 shares and stock options entitling to 387,888 shares.[1]

Robert A. DeLuca (b. 1961)

President of Orexo US Inc. since 2013.
R. Ph.
Other appointments: Member of the St. John's College of Pharmacy Dean's Advisory Board, American Society of Addiction Medicine, 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, ScheringPlough, Berlex and Pharmacia, and most recently served as Chief Commercial Officer at Archimedes Pharmaceuticals.
Holds 2,703 shares and stock options entitling to 238,931 shares.[1]

Johannes Doll (b. 1981)

EVP and Head of Corporate Development since 2016. Has worked as an advisor for Orexo since 2013. Member of the management team since, 2016.
B.Sc., WHU Otto Beisheim School of Management, Germany. MBA, McCombs School of Business at the University of Texas, US.
Previous appointments: Extensive experience from the global pharmaceutical industry and private equity sector working at McKinsey & Company, 2005–2013.
Holds 10,000 shares and stock options entitling to 13,500 shares.[1]

Henrik Juuel (b. 1965)

EVP and Chief Financial Officer since 2013.
M.Sc., University of Aarhus, Denmark and University of Leuven, Belgium.
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 entitling to 157,334 shares.[1]

Jesper Lind (b. 1960)

Chief Operating Officer since November 2013.
M.Sc., Royal Institute of Technology Stockholm, Sweden and Sydney University, Sydney, Australia
Previous appointments: Extensive senior global pharmaceutical manufacturing and supply chain experience from AstraZeneca, Pharmacia Biosensor and Alfa-Laval.
Holds 2,000 shares and stock options entitling to 69,000 shares.[1]

Michael Sumner (b. 1965)

Chief Medical Officer since 2013.
MB BS, MRCP (UK), MBA.
Other appointments: Scientific Advisory Board FirstString Research Inc.
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.
Holds 2,300 shares and stock options entitling to 82,334 shares.[1]

1) As per December 31, 2016

Auditor's report on the corporate governance statement

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

Engagement and responsibility
It is the Board of Directors who is responsible for the corporate governance statement for the year 2016 on pages 75–81 and that it has been prepared in accordance with the Annual Accounts Act.

The scope of the audit
Our examination has been conducted in accordance with FAR's auditing standard RevU 16 The auditor's examination of the corporate governance statement. This means that our 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. We believe that the examination has provided us with sufficient basis for our opinions.

Opinions
A corporate governance statement has been prepared. Disclosures in accordance with chapter 6 section 6 the second paragraph points 2–6 the Annual Accounts Act and chapter 7 section 31 the second paragraph the same law are consistent with the annual accounts and the consolidated accounts and are in accordance with the Annual Accounts Act.

Uppsala, Sweden, March 15, 2017
Ernst & Young AB

Björn Ohlsson
Authorized Public Accountant

Shareholder Information

2017 Annual General Meeting
The Annual General Meeting of Orexo AB will be held on Thursday, April 6, 2017 at 4.00pm 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, March 31, 2017, and notify Orexo of their intention to attend the meeting not later than the same day, Friday, March 31, 2017 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 www.orexo.com.

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 reregistration well before Friday, March 31, 2017 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, www.orexo.com.

Contact Investor Relations
+46 (0)18 780 88 00
ir@orexo.com or
lena.wange@orexo.com

Financial calendar 2017

2017 Annual General Meeting	April 6, 2017, at 4.00pm CET
Interim Report January–March 2017	April 20, 2017, at 8.00am CET
Interim Report January–June 2017	July 11, 2017, at 8.00am CET
Interim Report January–September 2017	October 19, 2017, at 8.00am CET

Glossary

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

American Depositary Receipt (ADR)
An instrument that is issued by a depositary bank that represents ownership of a company's underlying shares. ADR programs are created to facilitate US investors to hold shares in non-US companies and trade them in the same way as US securities.

Anaesthesia
Procedure for lowering a patient's consciousness to enable a medical procedure to proceed without pain for the patient

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

Breakthrough pain
A short, intensive period of pain that occurs in addition to chronic levels of long-term pain even though these are treated by regular painkillers

Buprenorphine
A potent opioid partial agonist first used as a pain-relieving substance, but now most commonly used to help patients withdraw from more addictive opioid drugs such as morphine

CARA
The Comprehensive Addiction and Recovery Act (CARA) became law in the US in July 2016. CARA authorizes a series of grants aimed at among other things developing treatment programs which further expands buprenorphine prescribing rights to nurse practitioners and physician assistants

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

CLI
Cysteinyl Leukotriene Inhibitor

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

Commercial segment
One of the three distinct payer segments in the market for treatment of opioid dependence. The commercial segment is funded by private insurances or employers

Drug delivery
The process through which a pharmaceutical may be introduced to the patient that enables the active compound to function as intended

EMA
The European Medicine Agency

FDA
The US Food and Drug Administration

Fentanyl
An opioid with a similar effect on human patients as morphine. Used mainly within anasthesia and analgesia

GMP
Good Manufacturing Practice

HHS
The US Department of Health and Human Services

IP
Intellectual Properties

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

NCE
New Chemical Entity

Opioids
Collective term for compounds that act via opioid receptors on nerve cells, mainly in the central nervous system

PBM (Pharmacy Benefit Manager)
Responsible for management of costs associated with prescription pharmaceuticals and recommendations on behalf of insurance companies and employers in the US

PGE
Prostaglandin (PG) E2 – biologically active mediator derived from arachidonic acid and involved in inflammatory conditions

Phase I studies
Studies mainly of the safety of a drug. Performed on healthy human volunteers

Phase II studies
Studies of the safety and efficacy of a drug in appropriate doses. Performed on a limited number of patients

Phase III studies
Studies of the safety and efficacy of a drug in a clinical setting. Performed on a large number of patients

Preclinical development/Preclinical studies
Studies of the safety and efficacy of a drug prior to evaluation in humans. Can be performed on animals and in various cell systems

Public segment
One of three distinct payer segments in the market for treatment of opioid dependence. The public segment covers state and federal funded reimbursement programs i.e. Managed Medicaid, FFS Medicaid, Medicare Part D

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

Sublingual
Under the tongue

Zolpidem
A pharmaceutical substance used to treat temporary or short-term insomnia

www.orexo.com

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

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

Production Solberg