Annual Report

2018

orexo

A specialty pharmaceutical company
– with the aim of becoming a leader within addiction

Contents

Read more on our website

Our corporate website, www.orexo.com, is our foremost communication channel. You are also welcome to follow us in other channels that are updated continuously with information regarding our business or our environment. These are:

2018 – a pivotal year

Key events during the year

Q1

- The new year began with new exclusive contracts for Zubsolv® which considerably improved the market access in the US.
- Development project OX124, treatment of opioid overdose with naloxone, demonstrated positive data from in-vivo studies and progressed into clinical development.
- A new project OX338, for acute treatment of moderate to severe pain with ketorolac, was announced.

Q2

- Orexo communicated that the manufacturing efficiency program is expected to reduce the average cost per tablet by 25 percent, with full effect as from Q1 2019 compared to 2017.
- The launch of Zubsolv was initiated in the EU by Orexo's partner Munidpharma.

Q3

- Orexo won the patent litigation against Actavis in the American Court of Appeals, securing Zubsolv's exclusivity in the US until September 2032.
- The pipeline was expanded with the development project OX125, with the aim of developing a treatment of opioid overdose with nalmefene.
- Orexo communicated that the manufacturing efficiency program will further reduce costs and now expects reduction of the average cost per tablet with 35 percent, with full effect from the second half of 2019 compared to 2017.

Q4

- The US field force, which had previously been contracted, was internalized to further strengthen the commercial organization.
- Joseph DeFeo, former Head of Finance and Operations in the US subsidiary, was appointed as new EVP and CFO from November 1, 2018.
- A Capital Markets Day was hosted in Stockholm, Sweden. The keynote speaker was the former Governor of New Jersey, Chris Christie, who has also served as an advisor to President Trump on how to combat the #opioidcrisis.
- As of April 13, 2019, Orexo will regain the control of Zubsolv in all markets following a termination of the contract with Mundipharma. Orexo has initiated an assessment of the best route to maximize the potential of Zubsolv in markets outside the US.
- A first phase I clinical trial was initiated for OX124 and positive study results were received.
- An in-vivo study was performed for OX338 and positive study results were presented at the beginning of 2019.

28%
Zubsolv US, net revenues growth in 2018

SEK 117 m
EBITDA 2018

SEK 590 m
Cash and cash equivalents, December 31, 2018

Orexo won the patent litigation securing **Zubsolv's** exclusivity in the **US** until September **2032**

The pipeline increased from **2** to **5** projects

A fully integrated specialty pharmaceutical company

Orexo develops improved pharmaceuticals based on innovative drug delivery technologies. The focus is primarily on opioid addiction and pain but the aim is to address therapeutic areas where our competence and technologies can create value. The products are commercialized by Orexo in the US or via partners worldwide. The main market today is the American market for buprenorphine/naloxone products, where Orexo sells the product Zubsolv®. Total net sales for 2018 amounted to SEK 783.1 million and the number of employees was 129. Orexo is listed on the Nasdaq Stockholm Mid Cap (ORX) and is available as ADRs on OTCQX (ORXOY) in the US. The head office, where research and development is also performed, is situated in Uppsala, Sweden.

Developed 4 products approved worldwide[1]

Orexo has developed four products from concept to patient. The products have been approved in multiple markets and helped patients benefit from improved drugs worldwide.

Products, page 15

Our drug delivery technologies improve pharmaceuticals

Orexo develops improved products by combining well-known and well-documented substances with in-house innovative drug delivery technologies.

Technologies, page 13

Strategic focus on product expansion

One of Orexo's objectives for long-term growth is to broaden the US commercial platform, by M&A transactions, to leverage scale and expand sales.

Objectives and strategies, pages 8–9

Key figures

SEK million	2018	2017	2016	2015	2014
Net revenues	783.1	643.7	705.9	646.2	570.3
whereof Zubsolv US net revenue	*621.5*	*485.8*	*481.8*	*416.7*	*228.0*
Cost of goods sold	–171.8	–164.4	–149.6	–150.2	–107.4
Operating expenses	–515.6	–421.9	–584.4	–676.6	–487.9
EBIT	95.8	57.4	51.7	–180.6	–25.0
EBIT margin, %	12.2	8.9	7.3	–27.9	–4.4
US EBIT	198.3	73.7	21.4	–109.1	–100.4
US EBIT marginal, %	31.9	15.2	4.4	–26.2	–44.0
EBITDA	116.6	78.2	73.1	–99.9	–12.5
Earnings per share, before dilution, SEK	3.99	0.67	0.84	–6.09	–1.70
Earnings per share, after dilution, SEK	3.93	0.67	0.84	–6.09	–1.70
Cash flow from operating activities	242.0	146.6	156.2	–109.2	–487.3
Cash and cash equivalents	589.8	327.9	282.4	198.1	284.5

[1] One of the products, Diabact, was divested when the subsidiary Kibion was sold in 2015

We make a difference

"We work in the life science sector and at Orexo in the midst of one of the largest health crises ever in the US, which takes tens of thousands of lives per year. I strongly believe that many talents want to work in a company that makes a real difference in people's life and this is exactly what we offer at Orexo."

CEO interview, pages 4–7

14%

Key market characterized by strong growth

In the US the #opioidcrisis is accelerating and in 2017 70,200 Americans died of an overdose, mainly caused by use of opioids. There is a great need for treatment and the buprenorphine/naloxone market grew by more than 14 percent in 2018.

Key market, pages 18–19

Embracing all aspects of opioid addiction

Orexo's pipeline contains development projects with a primary therapeutic focus around opioid addiction in all phases, from prevention to treatment.

Development projects, pages 16–17

UN's sustainabilty goals 3 and 5 are in focus when Orexo report on its commitment for a sustainable world.

Sustainability Report, pages 24–31

Core Values

Customer focus
Engagement
Flexibility
Simplicity

Well positioned to become a leader in combatting the opioid epidemic

The US opioid crisis is one of the greatest health crises of modern times claiming more and more lives. With a strong operational and financial platform we are well positioned to address this growing epidemic. The progress seen to date will allow us to expand our commercial platform, advance our promising R&D projects and ultimately provide innovative and affordable treatments to patients suffering from opioid addiction.

Photo: Jenny Öhman

You have a strong year behind you. What were the highlights?

2018 was a great year for Orexo. The most pivotal highlight was the positive outcome in the patent litigation in September which allows us to focus on the future shape of the company and our ambitious growth strategy for 2019 and beyond. In addition to the successful patent outcome, we made sufficient progress towards reducing manufacturing costs and saw progress across our pipeline with the addition of thress new programs, including OX124 (naloxone for treatment of opioid overdose) which reported encouraging clinical data in early January of this year. The strength of this data reinforces our confidence in the commercial potential of this program, which I believe will address a high unmet need, providing an improved product for opioid overdose patients. Overall, 2018 was a strong year for Orexo, and I can not thank my team enough for their efforts and hard work.

You are ending the year with record profitability and a cash balance that continues to improve. What is driving this?

Since my appointment as CEO in 2013 I have invested much of my time to increase the profitability of the business and I am pleased to see these efforts beginning to bear fruit. This has been achieved by applying significant cost control measures and implementing a conservative investment strategy in order to improve cash-flow and profitability. Increased profitability was largely driven by sales of Zubsolv® in the US, with an increase of 28 percent from 2017. We have also seen the impact of our manufacturing efficiency program in 2018, which has improved our gross profit margin, and I expect this to have an even greater impact in 2019.

You have said that you will continue to be a profitable company. Can we expect the same strong financial performance in the future?

Our ambition is to continue to improve our profitability for 2019 including EBIT and EBITDA. Despite increased compe-

tition in the US, I feel confident that we are in a strong position to deliver further growth, particularly as we look to expand our commercial platform in this growing market with more products. Delivering on our strategy and further development of our pipeline will require continued investment in R&D, and although this may impact profitability in isolated quarters, it will ensure the longer-term growth of Orexo and the sustainability of the business.

You have developed Orexo from an R&D company to a profitable specialty pharmaceutical company. What was the greatest challenge and how did you tackle it?

I would not be leading a profitable specialty pharmaceutical company if it had not been for the support of my team and their perseverance through what has been a very challenging but rewarding year. The greatest challenge for me has been the time and energy spent on a lengthy legal process that has been outside of our control. The time invested in IP litigation not only impacted profitability but also required some difficult decisions when it came to the size of our workforce. However, I am pleased that these issues are now behind us and that thanks to the team and commitment of my colleagues here at Orexo, we are making good progress towards improving the current treatment offering for patients suffering from opioid addiction.

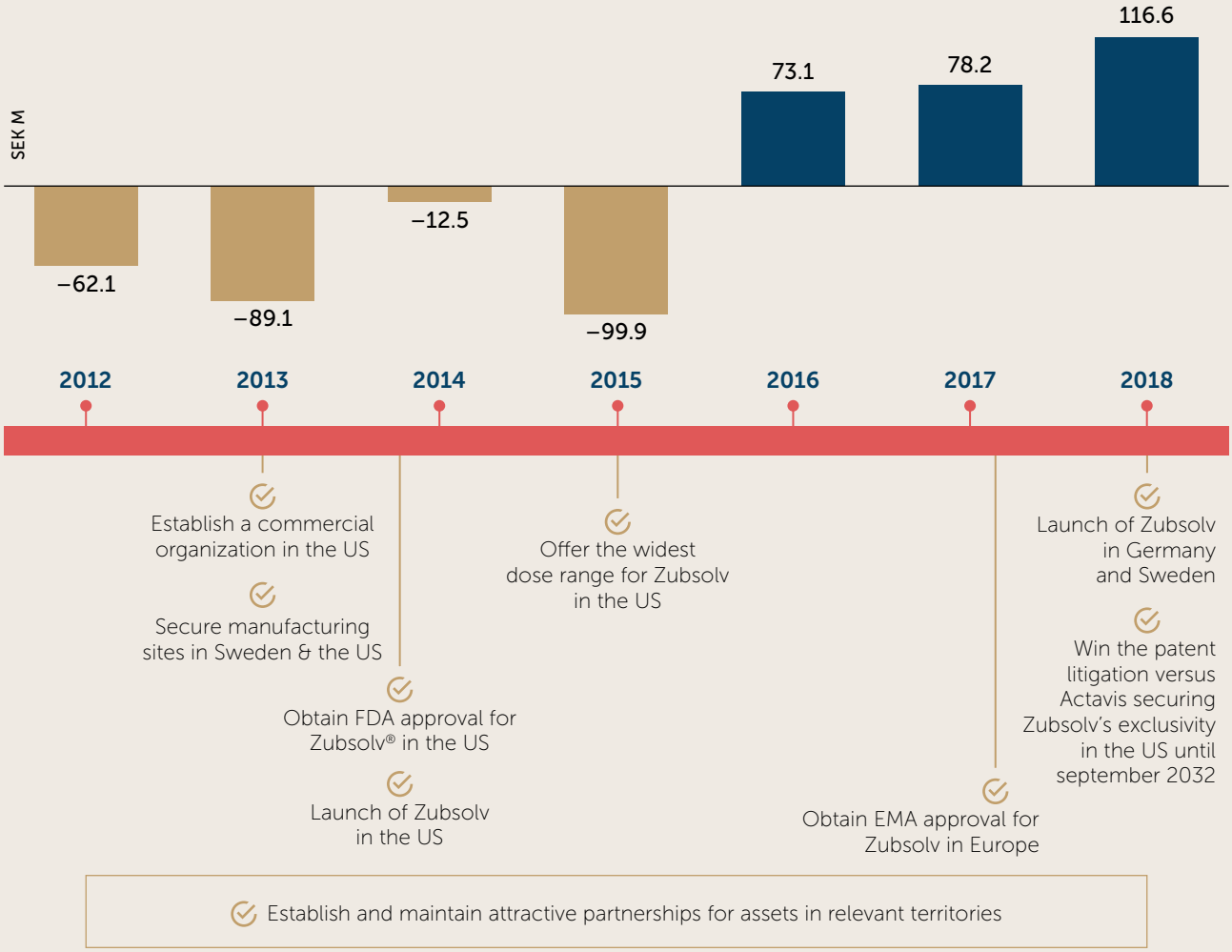
Orexo is one of the few Swedish pharmaceutical companies that have embraced the world's largest pharmaceuticals market in the US. What makes it so attractive?

As one the largest and fastest growing markets for opioid dependency, the US is a key market for Orexo. Although operating in the US has its challenges, it does offer a faster route to market for new treatments than e.g. in Europe.

Orexo finds itself at the epicentre of one of the largest health crises ever in the US. Can you describe the crisis briefly and is it isolated to the US?

The crisis is more prominent in the US than the rest of the world, however, opioid dependency and addiction has developed into a global issue. Part of the problem relates

PROFITABILITY (EBITDA) AND ACHIEVED MILESTONES



to liberal prescription of opioid pain killers for less serious injuries. Today opioid treatment sees greater regulation and is increasingly monitored, resulting in reduced access to opioid pain killers. Unfortunately, this has resulted in patients sourcing opioid pain killers illegally, where they also risk consuming opioids much stronger than would be prescribed by a physician. This in turn has led to an increase in overdoses and fatalities, which is an area of opioid addiction we are committed to tackling.

What is being done to combat the opioid crisis in the US?

The opioid crisis is being addressed from several angles and initiatives are focusing on both prescription and illegal opioids. There has been a decline in the prescription of opioids, which means that there is an even higher need for treatment as opioid dependent patients may be forced to reduce their doses of pain killers and make their dependence evident. Fortunately, we are seeing a positive trend in initiatives being implemented to improve access to treatment, which again has been an important contributor to the 28 percent growth Orexo experienced in the US market in 2018. I am pleased to see there is a strong consensus across the political and regulatory landscape on the need for greater access to treatment for opioid dependence.

Does the need for care disappear if the crisis is solved?

Opioid dependency is a chronic medical condition and many patients will need life-long treatment to avoid relapse. As we continue to see more initiatives to restrict the use and prescription of opioid pain killers, we would also hope to see new non-opioid and non-addictive alternatives to manage pain more effectively. However, this also means that we will likely see an increase in eligible patients who have developed opioid dependency over time, and who will require treatment to refrain from misuse or obtaining illegal substances.

Zubsolv® is a treatment for opioid dependence, but you are now developing products enabling you to take a broader approach in this area of treatment. Why?

The need for improved treatment is critical, and something we see every day as our staff visit thousands of clinics in the US each year. As a company operating in the opioid addiction space, we have a responsibility to address the challenges in the market, e.g. the lack of effective opioid overdose rescue medication, more alternatives for patients requiring Medication Assisted Treatment (MAT) and pain relief medications that are more effective and most importantly non-addictive. We have developed a diverse pipeline addressing all of these areas and will continue our R&D efforts to discover new ideas and products to improve treatment for opioid dependency and other addictions.

Which project do you believe has the greatest potential to reach the market first?

Our OX124 project is now the most advanced pipeline candidate. Based on the data we have seen in the first clinical study, I am confident in the commercial prospects of this project. From a market perspective, our pipeline projects have significant sales potential as they address unmet medical needs in niche areas. Our OX382 (buprenorphine for treatment of opioid dependence and pain) and OX338 (ketorolac for treatment of acute moderate to severe pain) projects will be differentiated through their unique delivery mechanism, a compelling marketing message versus currently available products.

You have a strong financial and operative platform. What do you think the company will look like in a few years' time?

I am very proud of what we have accomplished with Zubsolv, especially considering the complex and increasingly competitive market in the US and globally. However, there is a clear opportunity to expand our US commercial platform further, a key priority for the business over the coming year. Our focused R&D investments are starting to bear fruit and we would expect to have at least one product from our own pipeline in the market within four years.

Describe the strategy for getting there.

Based on our financial strength and established infrastructure, the strategy is to pursue business development or M&A opportunities to broaden our platform, i.e. non-organic growth. However, we need to continue developing the business we have established today, to ensure we are not dependent on finding the right external opportunity to continue our growth and R&D efforts.

Regarding M&A activities, what are you looking at specifically and where are the greatest synergies?

The simplest approach to M&A is to identify the areas where we already operate successfully to maximize possible synergies. As we are looking at commercial or near-commercial stage opportunities, the natural starting point would be in the US and within addiction, where we are active today. However, the overall addiction space is currently suffering from very limited pipeline developments and many projects are working with the same API as Orexo, i.e. buprenorphine and naloxone. In light of this we may look more opportunistically at adjacent areas, which include most of the CNS (Central Nervous System) space.

Human capital is usually a company's most important resource. How do you attract and keep talent?

We work in the life science sector and at Orexo in the midst of one of the largest health crises ever in the US, which takes tens of thousands of lives per year. I strongly believe many talents want to work in a company that makes a real difference in people's life and this is exactly what we offer at Orexo. Apart from that, I believe the best way to attract talent is to create a positive working environment, at Orexo this is evidenced by employees encouraging their friends to pursue a role within the company. Looking beyond the financial performance of the company, one of the areas I am most proud of is the positive feedback we receive from our employees both in Sweden and the US, in the yearly employee survey.

What do you most appreciate about your job?

There are many aspects I appreciate about my job, but knowing that our work every day is helping to provide treatment for some 50,000 patients who suffer from opioid dependence is a hugely motivating factor. Comparing Orexo today to when I joined the company in 2013, there is a strong "can do attitude" where we approach seemingly impossible hurdles with confidence. As a company we believe that we can solve any problem. I believe that the patent litigation is a good example of this – internally we believed we would win, and in September 2018 that was exactly what we did!


Photo: Jenny Öhman

Uppsala, Sweden, March 2019

Nikolaj Sørensen
President and CEO

Future value drivers

1. Growing key market

A business foremost addressing opioid addiction in the US which is one of the largest health crises ever in America and also a growing global concern.

2. Strong financial position and profitability

Fueled by the US commercial organization which is an important cash and profitability contributor on a Group level.

3. Strong track record of developing products

Orexo has developed four products with worldwide approval.

4. M&A and business development

Add commercial stage products in the US to leverage the commercial infrastructure and expand sales.

5. Expanding pipeline

Growing pipeline including several interesting projects to embrace all aspects of opioid addiction.

Ambitious route for long-term growth

Orexo has developed from being an R&D stage company to becoming a profitable fully integrated specialty pharmaceutical company with its own commercial business in the US. From a strong operational and financial platform, Orexo is aiming to become a leader in the field of opioid addiction. To achieve this, the commercial business will be broadened through M&A and proprietary products at the same time as profitability will grow.

Objectives & Strategies 2019 and onwards

1. Broaden the US commercial platform to leverage scale and expand sales.

2. Further accelerate Orexo US performance and EBIT contribution.

3. Launch at least one new product from the pipeline within 4 years.

Key success factors for Zubsolv® that can be applied to new products

[1] Return on Investment
[2] Contracted Manufacturing Organization
[3] Cost of Goods Sold

Opioid addiction is a treatable chronic disease

Opioid addiction is a chronic medical condition with a number of associated co-morbidities which often requires life-long treatment. Although there is an increased focus on improving all aspects of care, as well as proactive measures in place to tackle the opioid crisis in the US, there is still an urgent medical need for more efficient treatments covering all phases of opioid addiction.

Opioid addiction is a chronic medical condition which is comparable to other diseases such as type 2 diabetes or high blood pressure. The road to opioid addiction is complex, and can start with a prescription from a medical professional to treat short-term pain. Many patients are not aware of the addictive properties of opioids, or the adverse consequences related to long-term opioid use. Patients often experience a highly addictive euphoric sensation, which can lead to prolonged substance abuse. Over time, prolonged exposure to opioids can cause changes to the brain that result in a powerful urge to continue the use of the opioids, despite the consequences.

The causes of addiction in general are wide-ranging, with genetic factors thought to account for about 50 percent of an individual's susceptibility to developing addictive behaviour.[1] Environmental factors such as stress and exposure to the addictive substance also play a part in developing opioid addiction.[2] Although many patients may suffer for their entire lives, opioid addiction is a disease that can be treated.

Opioid addiction can affect anyone

In the US, opioid substance abuse is prevalent among all demographics, such as gender, age, ethnicity and socio-economic class. A root cause of opioid addiction, and the subsequent opioid crisis in the US, is the prescription of opioid-based pain medications, such as oxycodone and codeine, which is often prescribed to relieve pain from:

- tooth aches and dental procedures
- injuries
- surgeries
- chronic conditions such as cancer

[1] Addiction and Recovery
[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3898681/

It is estimated that approximately 8 to 12 percent of patients who are prescribed opioids for longer use become addicted.[3] The signs and symptoms of addiction can be physical, behavioural, and psychological, and are often linked with anxiety attacks, mood swings, nausea and depression.

The life as an opioid dependent

Patients with opioid dependence need to ensure a constant intake of opioids as they can experience withdrawal symptoms just hours after their last dose. These symptoms include, but are not limited to, cravings, anxiety, and sleeping problems and can impact the individual's ability to work and sustain relationships with family and friends. It is not uncommon for these patients to turn to unconventional ways of obtaining access to opioids, such as from the black market.

The short road to overdose

Unfortunately, efforts to limit access to prescription opioids appear to have resulted in an unintended consequence, as patients have resorted to heroin and stronger synthetic opioids, such as fentanyl, to compensate for the limited availability of prescription opioids, with fatal outcome. Patients who turn to heroin or synthetic opioids have an increased risk of experiencing an overdose, and fatalities relating to opioid overdoses have become the most common cause of death among Americans under the age of 50.[4] In 2017 more than 70,200 Americans died from a drug overdose, mainly caused by opioids.[5]

Opioid addiction can be treated

Opioid addiction is a treatable condition. As a result of its chronic nature and long-time repercussions, the effectiveness of treatment varies among patients, and treatment is often administered over long periods of time or chronically. Medication Assisted Treatments, MAT, are the most common therapies which are based on buprenorphine, methadone or naltrexone. Buprenorphine is often combined with the antagonist naloxone to help prevent misuse by injection. The gold standard for MAT in the US is buprenorphine/naloxone which can be taken under the tongue as a tablet or film. Methadone is most commonly administered orally under supervision while naltrexone is a monthly injection. MAT is normally provided in combination with behavioural counselling and psychological support.

In the US, treatment usually takes place in private practices or at specialist medical clinics, and more rarely in hospitals. In Europe the treatment takes place in specialized treatment centres in the outpatient setting.[6]

[3] Vowles et al. Rates of opioid misuse, abuse, and addiction in chronic pain: a systematic review and data synthesis, Pain (April 2015)
[4] Drug Policy Alliance
[5] Center for Disease Control
[6] European Drug Report 2018 (EMCDDA)

CO-MORBIDITIES ASSOCIATED WITH OPIOID ADDICTION

- Overdose
- Depression
- Alcoholism
- Sleep disorders
- Bipolar disorder (Manic Depression)
- Adult Attention Deficit Hyperactivity Disorder
- Post-Traumatic Stress Disorder
- Schizophrenia

Innovation is the heart of what we do

Orexo is a company built on the principle of innovation, fueled by the interplay between researchers and experts with different scientific backgrounds. Today innovation remains at the core of the work of continuing to develop new formulation technologies and early stage projects to benefit patients globally 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.

Talents

Orexo is a fully integrated specialty pharmaceutical 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.

[1] Divested together with the former subsidiary Kibion in 2015

Future formulation technologies

Several important initiatives have been made to ensure that Orexo can develop new improved products through a combination of well-known and well documented substances via innovative in-house drug delivery technologies. The aim is to develop innovative technologies for both oral, sublingual and intranasal drug formulations.

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.

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 makes significant demands of 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.

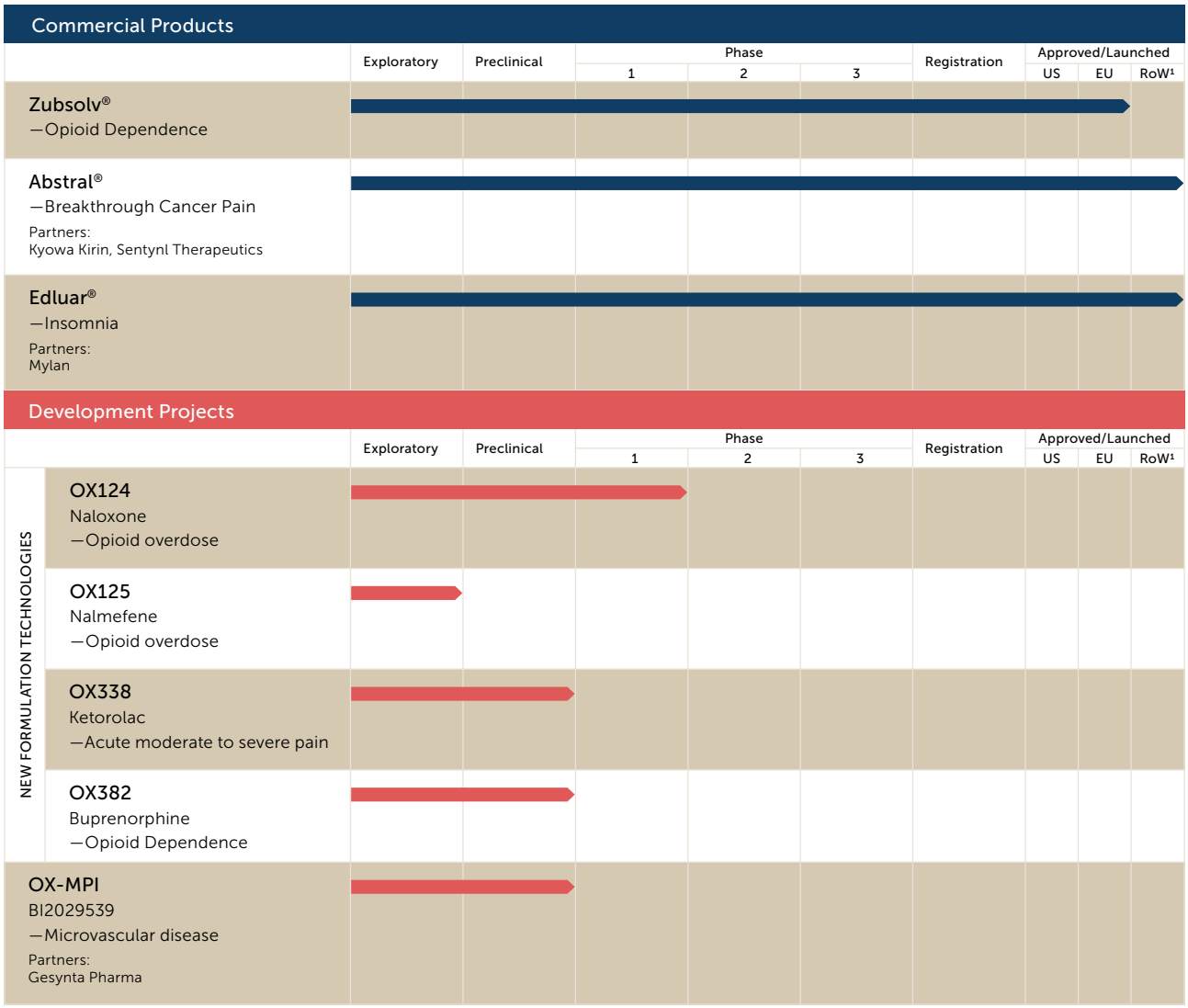
Orexo is currently developing its second-generation sublingual formulation technology. The aim is to perfect the sublingual delivery of drugs, thereby unlocking new active ingredients that are currently not possible to administer sublingually. Several active ingredients have been identified as promising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

Intranasal formulation technology

The intranasal route of administration is a viable route for many different active pharmaceutical ingredients offering significant advantages compared with other administration routes, even parenteral injections. For example, delivering drugs through the intranasal route avoids first pass metabolism of the active ingredient allowing for rapid and potentially extensive exposure of the drug. Orexo is currently developing a novel and unique intranasal formulation technology that allow for rapid and efficient delivery of various active ingredients. The technology is especially suitable for rescue medications such as naloxone and nalmefene for treatment of opioid overdoses.

Embracing all aspects of opioid addiction

Orexo has a strong history of developing new products approved in markets all over the world. In order to ensure a continued inflow of new improved drugs, the development work at the R&D department in Uppsala, Sweden, has intensified. Filling an unmet need among healthcare professionals and patients is the key in the work of developing new innovative products for treatment of opioid addiction in all phases.



[1] Rest of the World, excluding US and Europe

Commercial Products

ZUBSOLV®

Short facts	
Technology	Sublingual
Indication	Opioid dependence
Commercial rights	US, Orexo, ex-US Mundipharma[1]
Net Revenues in 2018	SEK 657.8 million
Partner	mundipharma
Patent protection	US and Europe until 2032

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

The broad choice of six different strengths offers the potential for finer titration and individualized dosing with potentially fewer tablets compared with existing substitution treatments.

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. In November 2017 the EU Commission approved Zubsolv for treatment of opioid dependence in Europe. Zubsolv should be used as part of a comprehensive treatment plan, which includes counseling and psychosocial support. Treatment should be initiated under the direction of certified physicians.

ABSTRAL®

Short facts	
Technology	Sublingual
Indication	Breakthrough cancer pain
Commercial rights	US, Sentynl Therapeutics, ex-US, Kyowa Kirin
Royalty in 2018	SEK 118.8 million
Partner	SENTYNL / KYOWA KIRIN
Patent protection	US and Europe until September 2019[2], Japan and Australia until 2024

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 under the tongue
- 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 multiple markets such as the US, Japan, South Korea, Middle East, Israeli, Australia, Malyaisia and Phillippines. 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.

EDLUAR®

Short facts	
Technology	Sublingual
Indication	Insomnia
Commercial rights	Worldwide, Mylan
Royalty in 2018	SEK 6.6 million
Partner	Mylan
Patent protection	US until 2031, Europe until 2025

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 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.

[1] As of April 13, 2019, Orexo will regain all rights to Zubsolv ex US, due to a portfolio re-organization at Mundipharma
[2] Royalty for sales in Europe will be received until December 31, 2019, when the European contract with Kyowa Kirin expires

DEVELOPMENT PROJECTS

OX124

Short facts	
API	Naloxone
Technology	Nasal
Indication	Rescue medication, opioid overdose
Development phase	Phase 1
Expected filing with FDA	2021
In-house or partnership	In-house

Unmet medical need

In 2017 more than 70,200 Americans died of an overdose. An increasing proportion died as a result of the use of synthetic opioid fentanyl and fentanyl analogs, which in 2017 were behind 30,000 of the deaths.[1] Currently available naloxone-based rescue medications struggle to reverse effects of such opioids.

OX125

API	Nalmefene
Technology	Nasal
Indication	Rescue medication, opioid overdose
Development phase	Preclinical
Expected filing with FDA	2022
In-house or partnership	In-house

See OX124 above.

OX338

API	Ketorolac
Technology	Sublingual
Indication	Acute moderate to severe pain
Development phase	Preclinical
Expected filing with FDA	2021 or 2022
In-house or partnership	In-house

For many opioid dependent patients, their dependence starts with the first exposure to opioids to treat short-term pain, e.g., after an accident or minor procedure. It is estimated that about 8–12 percent[2] of people who have been prescribed opioids for longer use will develop an addiction, and today approximately 4 to 5 million Americans are dependent opioid users.

In the wake of the opioid crisis, there is a tremendous need to find non-opioid alternatives to effectively treat acute pain and to avoid exposure to opioids.

OX382

API	Buprenorphine
Technology	Oral
Indication	Opioid dependence
Development phase	Preclinical
Expected filing with FDA	–
In-house or partnership	In-house

Today, buprenorphine products to treat opioid dependence are only available in sublingual/buccal tablets and film formulations which generally are less convenient than an oral administration route. As supervised treatment may be part of the patients care, e.g. for patients who receive treatment in methadone clinics, which is particularly common in Europe, the dissolve time can play a role in limiting patient access.

OX-MPI

API	BI1029539
Technology	Oral
Indication	Microvascular disease
Development phase	Preclinical
Expected filing with FDA	–
In-house or partnership	Partnership with Gesynta Pharma AB

–

[1] National Institute on Drug Abuse
[2] Vowles et al. Rates of opioid misuse, abuse, and addiction in chronic pain: a systematic review and data synthesis, Pain (April 2015)

Concept	Changes during the year	High level timeline[3]
OX124 is based on a novel and unique technology developed to provide a rapidly acting naloxone rescue medication with the aim to provide differentiated profile compared to currently marketed products and other products under development. Naloxone is a full opioid receptor antagonist which reverses the effects of opioid agonists, including the life threatening respiratory depressant effects occurring in an opioid overdose.	After successful preclinical results the project advanced into clinical stage development. A human pharmacokinetic study, OX124-001, assessing Orexo's novel nasal spray formulations in 20 healthy volunteers was performed. The study was a cross-over, comparative bioavailablity study comparing four development formulations of OX124 to Narcan® Nasal Spray 4 mg, the current market-leading naloxone rescue medication in the US. Positive results were received in beginning of 2019 showing that all formulations of OX124 were well tolerated and displayed substantially higher plasma concentrations of naloxone, sustained duration of elevated plasma concentrations, and equivalent or superior onset time when compared to Narcan.	The next step for the project is to continue to further optimize the formulation and prepare for a pivotal pharmacokinetic bridging study in 2020 in consultation with FDA. Assuming further successful development, Orexo expects to file OX124 with FDA in 2021 and start to launch the product in the US in 2022.
OX125 is based on a novel and unique technology developed to provide a rapidly acting nalmefene rescue medication with the aim to provide differentiated profile compared to currently marketed products and other products under development. Nalmefene is a full opioid receptor antagonist which reverses the effects of opioid agonists, including the life threatening respiratory depressant effects occurring in an opioid overdose. Nalmefene is a stronger, longer acting antagonist compared with naloxone.	The project was initiated and the positive results from the OX124 human PK-study meant that a decisions were made to intensify the development of the project.	To continue the formulation development and following posivite results Orexo expects to file OX125 with FDA in 2022.
OX338 is based on a new sublingual tablet formulation of ketorolac for acute treatment of moderate to severe pain. Ketorolac is a potent NSAID with analgesic effect comparable to many opioids used for short term pain management and can thus replace opioids for many procedures and indications reducing overall opioid consumption.	The formulation development continued and a Proof-of-Concept animal study was initiated. Positive results from this study was obtained early 2019 supporting further development and planning for a human pharmacokinetic study commencing during the second half of 2019.	Assuming further successful development, a pivotal pharmacokinetic and potentially also efficacy studies will be performed to allow for an application for approval to the FDA in 2021/2022 time.
OX382 is being developed as an oral, swallowable formulation containing buprenorphine and naloxone for the treatment of opioid dependence. Buprenorphine is a partial opioid receptor agonist used in medically assisted treatment of opioid dependence to alleviate symptoms of withdrawal and naloxone, an opioid receptor antagonist, is part of the formulation as an abuse deterrent. A swallowable formulation offers several advantages over currently available administrations routes for certain patient groups and treatment settings.	The formulation development has continued based on the insights gained from the result in the first clinical study performed in beginning of 2018.	Proof-of-Concept in-vivo studies will be initiated in beginning of 2019. Next phase is depending on results from this study.
The lead candidate drug in the OX-MPI program, BI1029539, has been identified as a highly selective anti-inflammatory compound targeting microsomal prostaglandin E synthase (mPGES-1).	The project is developing according to plan.	Fully managed by Gesynta Pharma AB.

[3] Timeline may change depending on trial outcomes and development strategy

The US #opioidcrisis is the greatest health crisis in modern time

Opioid abuse is currently the most common cause of death from drugs. The opioid problem in the US has caused an epidemic, where drug overdoses are claiming more and more lives. In addition to the unnecessary loss of life, the resources needed to address the issue are a huge economic burden. There is an increasing need for treatment, and the buprenorphine/naloxone market grew by over 14 percent in 2018.[1]

A global problem that has developed into an American health crisis

It is estimated that approximately 25 million people in the world are dependent on opioids.[2] The problem exists in both developed countries and in less developed countries but is by far the greatest in the US, where a fifth of those dependent on opioids live.[3] Worldwide at least 190,000 people die prematurely each year as a result of drugs and the majority of the deaths are caused by the use of opioids.[4] The problem is acute in the US, where more than 70,200[5] died of an overdose in 2017. Approximately 70 percent of these deaths were caused by opioid abuse. In the same year the opioid crisis in the US was classified as a Public Health Emergency, which means that resources should be allocated to avert or avoid public health crises. In Europe, with an estimated 1.3 million,[6] high-risk opioid users, opioid addiction is not as great a problem as in the US. However, there are several alarming signs that the problem is getting worse. The number of overdose-related deaths has increased for the fourth consecutive year.[7]

Opioid abuse costs societies substantial resources

From an economic point of view opioid dependence is a considerable problem. In addition to loss of life and lower quality of life, large costs are associated with lower productivity and a lack of resources, and there are also increased healthcare and correctional treatment costs. In the US costs related to opioid dependence are enormous and considerably higher than previously calculated. The Council of Economic Advisors, which is an advisory committee to the American President, came out in 2017 with the report entitled "The Underestimated Costs of the Opioid Crisis". This report shows that the cost to society of the opioid crisis amounted to USD 504 billion in 2015, or 2.8 percent of GDP. This amount is six times higher than the previous calculation, where loss of life as a result of overdoses had not been taken into account.

Market consists of three payer categories

The market for the treatment of opioid dependence using buprenorphine/naloxone can be divided into three different payer categories, 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. The Public category differs from the other categories in that it is to a great extent stringently controlled by insurance companies with regard to what drugs may be prescribed and which physician a patient can choose. Pharmacy Benefit Managers (PBM) play an important role, as they are responsible for assessing, on behalf of the insurance companies and employers, which drugs are to be covered by insurances.

Publicly financed care growing fastest and is characterized by price pressure

The Public category, publicly financed care, has grown the fastest in recent years, driven by the fact that more and more people have gained access to publicly financed healthcare through the Affordable Care Act and due to the fact that employers have become more restrictive in offering private healthcare insurances. The Commercial category has displayed lower growth in comparison to the Public category.

[1] IMS Data
[2] World Drug Report 2016
[3] UNODC World Drug Report 2014
[4] World Drug Report 2017
[5] Center of Disease Control
[6] European Drug Report 2017
[7] European Drug Report 2018

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

Market players

Besides Orexo there are two other players in the market, Indivior and BioScience Delivery, who offer treatment with products under their own brand name. Indivior, who commercialize Suboxone® film, are the market leader, with a market share of just under 65 percent.[8] However, their market share has displayed a negative trend in the past two years.[8] Orexo's market share for Zubsolv amounts to just over 5 percent and the corresponding figure for BioScience Delivery and their drug, Bunavail, is approximately 0.5 percent.[8] The remainder of the market is constituted by generic companies, whose share of the market has grown in recent years.[8]

Great need for treatment driving strong growth

A sharp increase in prescription of opioid painkillers over a little more than two decades is the primary reason that today there are an estimated 12 million people abusing opioids in the US.[9] Approximately 4 million are considered to be in need of treatment.[9] Of these, approximately 1.4 million receive so-called Medication Assisted Treatment, MAT, where the most common form of treatment is buprenorphine/naloxone, which is given to approximately 0.8 million.[9] The market for buprenorphine/naloxone products has grown substantially in recent years. Annual growth is approximately 14 percent and the value of the market is estimated to be more than USD 2.8 billion.[10] Considerable political and media focus has increased knowledge and awareness of opioid dependence and its risks, which has led to more people seeking help. The launch of the Affordable Care Act (ACA) healthcare reform, also known as Obamacare, has also resulted in more people gaining access to subsidized care.

Dynamic market with a positive outlook

Even though there are signs indicating that the number of prescriptions of opioid-based painkillers written out is declining in the US, there will continue to be a great need for treatment. An investigation carried out by Clarion Healthcare shows that the number of people in need of treatment will increase from today's 4 million Americans to 6 million in 2023. The increase is primarily explained by the fact that both the number of patients in need of treatment and the number of patients receiving treatment will increase by approximately 50 percent. According to the study, an increasing number of patients will be treated with buprenorphine/naloxone at the expense of other MAT treatments. Even though it is predicted that the market will grow, the market dynamic can increase due to new treatment alternatives and greater generic competition.

[8] IMS Data by year-end 2018/2019
[9] Clarion Healthcare
[10] IMS Data

14%

The buprenorphine/naloxone market growth in 2018

12 million

Estimated number of Americans abusing opioids

4 million

Estimated number of Americans who are considered to be in need of treatment

Zubsolv® sales increased by 28 percent in the US

Zubsolv hit a sales record in the US in 2018. This was driven by continuing strong growth in the market and considerably better market access. Approaching 2019, access to Zubsolv has further strengthened at the same time as the market is becoming increasingly dynamic, which can offer new opportunities to advance Zubsolv's position.

Zubsolv grew more than the market

Sales of Zubsolv increased by 28 percent in the US and amounted to SEK 621.5 million in 2018. Measured in local currency sales increased by 25 percent. The market for buprenorphine/naloxone products displayed strong growth and grew by 14 percent. Sales performance was driven above all by considerably improved market access for Zubsolv. The strong position is explained by the new exclusive contracts in the Commercial category, such as Humana Commercial and Envision RX, and by the recommended position at CVS Caremark. Access to patients also increased in the fastest growing category, Public, above all due to the exclusive contract with Humana Medicare Part D. However, in November Zubsolv lost its exclusive position at Wellcare Medicaid, which impacted sales volume negatively.

Fentanyl behind more and more fatal overdoses

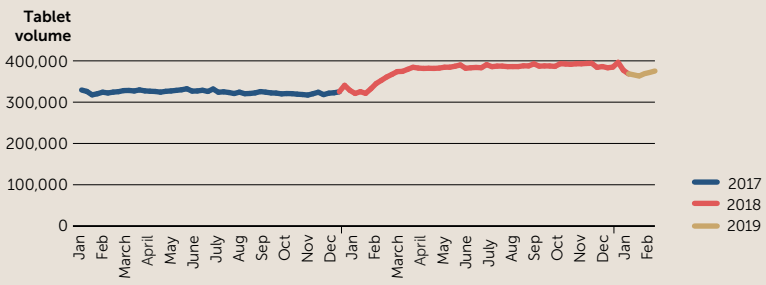
The opioid crisis continued to accelerate in the US. In 2017 more than 70,200 Americans died from an overdose, an increase of 11 percent in comparison with 2016.[1] Most overdoses are explained by abuse of opioids such as heroin and synthetic opioids such as fentanyl. Use of the latter opioid is increasing and is one of the explanations of the explosive increase in fatal overdoses in recent years. People have even started to talk about a fentanyl crisis and fresh figures show that in 2017 fentanyl-related mortality increased by 24 percent.[2]

Improved access to treatment

Since the ceiling was lifted in 2016, which means that certified physicians may go from treating 100 patients to 275, more than 4,400 waivered physicians have been certified to increase the number of patients they treat. The number of physicians newly waivered to treat their first opioid dependence patients has also risen steeply. Nurse practitioners and physicians assistants now total over 9,600 waivered to treat opioid dependency, which is considerably more than the previous year. While the number of prescribers is growing the market remains highly concentrated, with 6,000 prescribers accounting for approximately 80 percent of all prescriptions written. A federal bill was approved in 2018 which amongst

[1] Center of Disease and Control
[2] Center of Disease and Control

ZUBSOLV US SALES,[1] 2017 TO 2018 AND BEGINNING OF 2019



[1] Four weeks rolling average

11%

The increase in number of overdose deaths in the US, 2017 vs 2016

Source: IMS Data

other things expands the waiver eligibility to additional types of midlevel practitioners, and the application process is now underway.

Improved market access in 2019

At the beginning of 2019, Zubsolv's market access will further improve. Successful negotiations with insurance companies during the year mean that access in the Commercial category continues to be the best in the market and will increase from 96 to 97 percent with a new contract with the Blue Cross North Carolina insurance company. The aim is to increase access to the fastest growing Public category, something that was fulfilled when access to the category increased from 32 to 38 percent. The improved position is explained by new contracts with FFS Medicaid in Ohio, Alabama, Texas, Florida and Washington DC. Wellcare Medicaid's decision to add generics to their list of drugs means that Zubsolv loses its exclusive position. The decision will impact sales volume negatively, but will be partially compensated for by lower rebates.

Zubsolv well positioned in a dynamic market

The market is dynamic in nature and this can offer new opportunities to advance the company's position and thus expand the business in the US. Besides opportunities, also certain challenges are expected in connection with the launch of Suboxone® film generics, which can lead to increased price competition, but also open up for reimbursement of Zubsolv with payers that today only reimburse Suboxone film and thereby improve the market conditions. In order to ensure that Zubsolv continues to be a commercially attractive and a competitive product, measures have been taken, e.g. to lower production costs, to meet these challenges. This proactive strategy, together with improved market access in the Commercial and Public categories, strengthens Zubsolv's position in an increasingly competitive market.

Zubsolv® launched in Europe and registered in Australia

Zubsolv was launched by Mundipharma in Germany and Sweden, which resulted in a milestone payment of SEK 30.6 million.

The work of gaining access to other markets was begun. However, sales developed more weakly than expected. In December Mundipharma announced that they have decided to exit the partnership, due to a portfolio re-organization, enabling Orexo to regain the ex-US rights on April 13, 2019. This offers Orexo the opportunity to choose the best route to maximize Zubsolv's potential ex-US and to ensure that more patients gain access to the drug.

A registration application was submitted during the year for approval of Zubsolv in Australia.

Licensed products – Abstral® and Edluar®

Royalties for Abstral amounted to SEK 118.8 million, which is an increase of 4.9 percent. Most markets continue to display increased sales. In September 2019 the patents for Abstral in the EU expire. As the EU agreement with Kyowa Kirin runs until December 31, 2019, Orexo expects that royalty for the EU will decrease somewhat during the year compared to 2018, but will no longer be received in 2020. The EU's share of Abstral's total royalty amounts to approximately 80 percent.

Royalties for Edluar amounted to SEK 6.6 million, which is a large decrease during the year as sales the previous year came in at SEK 17.3 million. The decrease is explained by delivery problems.

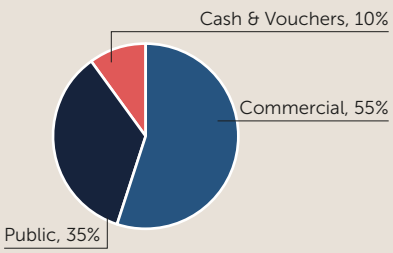
70,200

Americans died of an overdose in 2017, mainly caused by use of opioids

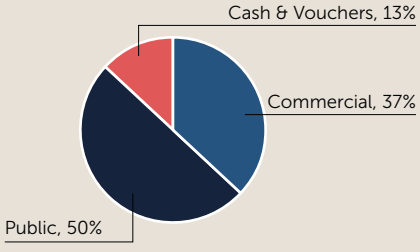
24%

The increase in number of overdoses related to fentanyl in the US, 2017 vs 2016

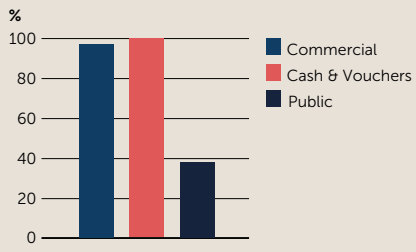
MARKET VOLUME PER PAYER CATEGORY



ZUBSOLV US VOLUME PER PAYER CATEGORY



ZUBSOLV US MARKET ACCESS PER PAYER CATEGORY



Source: IMS Data

The share

Orexo's share is listed on Nasdaq Stockholm and is available as American Depository Receipts (ADR) on OTCQX in the US. In 2018 the share price developed positively and the number of shares traded increased. In total Orexo had 6,362 shareholders and foreign ownership amounted to 47 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 increased by 42.96 percent and the last price paid in 2018 was SEK 58.90 (41.20). This corresponds to a market capitalization of SEK 2,032 million (1,423). The highest closing price during the year for the share was SEK 72.90 quoted on September 13. The lowest quotation was SEK 29.10 on July 3.

Liquidity

In total 29 million (28) shares were traded in 2018, corresponding to a value of approximately SEK 1,594 million (1,065). The daily average trading volume was 117,726 shares, corresponding to a value of SEK 6.4 million.

Ownership

At year-end, Orexo had 6,362 shareholders (7,115), of which 572 were registered as legal entities and 5,790 as private individuals. Of the share capital, 53 percent (43) is held by shareholders registered in Sweden and 47 percent (57) by non-Swedish shareholders. The largest proportion of shareholders registered outside Sweden can be found in Denmark at approximately 34 percent (29).

The list on page 23 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 June 15, 2018, that the company had resolved to issue and immediately thereafter repurchased 325,000 class C shares. The shares were issued and repurchased in accordance with the Long-Term Incentive Program (LTIP) 2018, which was adopted by the Annual General Meeting on April 12, 2018.

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 those participating in LTIP 2018. The class C shares were converted into ordinary shares prior to delivery to qualifying participants in LTIP 2018. The class C shares do not entitle to dividends.

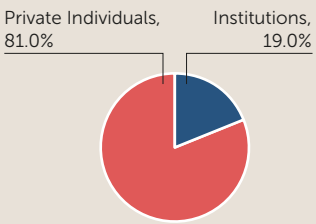
Capital Markets Day

On December 6, Orexo invited investors, analysts and media to participate in a Capital Markets Day. The company was foremost represented by members of the Board of Directors and the management team. The keynote speaker of the day was the former Governor of New Jersey, Chris Christie, who has also served as an advisor to President Trump on how to combat the opioid crisis.

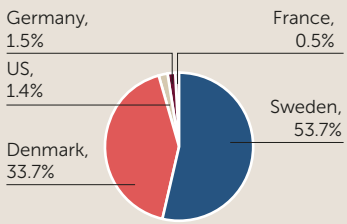
KEY FACTS

Orexo Share	
Listing:	Nasdaq Stockholm, Sweden
Number of shares:	35,450,456, of which 890,000 C shares
Market Capitalization, December 31, 2018:	SEK 2,032,155
ISIN code:	SE0000736415
Ticker code:	ORX
Orexo ADR	
Trading platform:	OTC, US
Deposit bank:	Citibank N.A.
ISIN code:	US68616W1027
Ticker code:	ORXOY
Ratio:	1:1

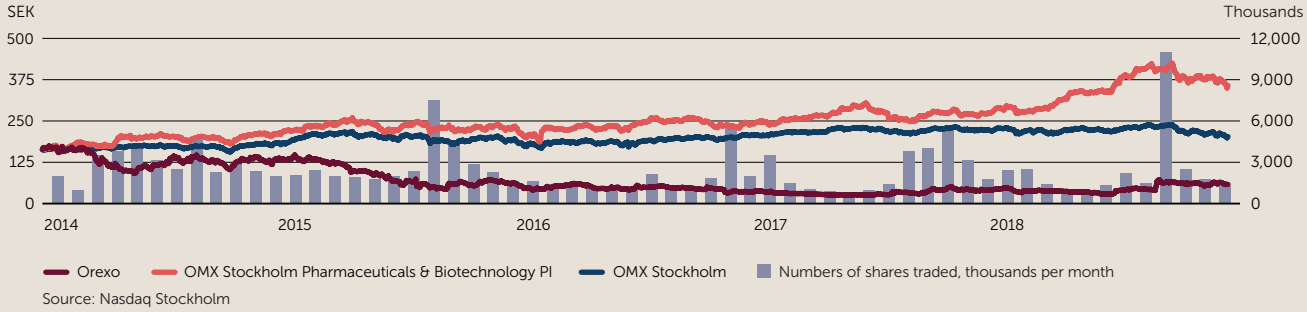
OWNERSHIP CATEGORIES, DECEMBER 31, 2018



OWNERSHIP DISTRIBUTIONS PER COUNTRY, DECEMBER 31, 2018

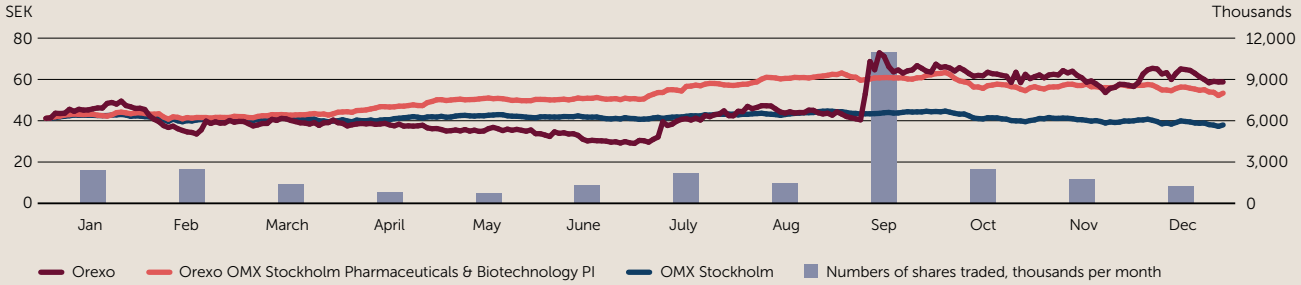


FIVE-YEAR PERFORMANCE



Source: Nasdaq Stockholm

PERFORMANCE IN 2018



Source: Nasdaq Stockholm

SHAREHOLDERS, DECEMBER 31, 2018

	No. of Common Shares	Share Capital %
Novo Holdings A/S	9,643,184	27.2
HealthCap	3,960,020	11.2
Arbejdsmarkedets Tillægspension (ATP)	2,040,633	5.8
HealthInvest Partners	1,700,000	4.8
Anders Walldov direct and indirectly	1,550,000	4.4
Avanza Pension	1,116,398	3.1
Lancelot Asset Management AB	450,000	1.3
Nordnet Pension Insurance	449,050	1.3
Danica Pension	373,257	1.1
Tomas Lundqvist	354,537	1.0
Eccenovo AB	330,000	0.9
Acadian Asset Management	261,839	0.7
Life Insurance Skandia	251,583	0.7
Huber, Reuss & Kollegen Vermögensverwalt	230,000	0.6
Total largest shareholders[1]	**22,710,501**	**64.1**
Others	**11,849,955**	**35.9**
Total	**34,560,456**	**100.0**

[1] As of December 31, 2018, the number of shares outstanding in the company was 35,450,456 of which 34,560,456 were common shares and 890,000 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 34,649,456 votes in the company as of December 31, 2018.
Source: Monitor by Modular Finance AB

OWNERSHIP STRUCTURE, DECEMBER 31, 2018

	No. of Shareholders	No. of Common Shares	Share Capital %
1–500	4,439	648,163	1.83
501–1,000	727	612,474	1.73
1,001–5,000	848	2,014,170	5.68
5,001–10,000	172	1,286,521	3.63
10,001–15,000	42	538,202	1.52
15,001–20,000	31	547,358	1.54
20,001–	103	28,913,568	84.07
Total	**6,362**	**34,560,456**	**100.00**

Analysts monitoring Orexo

- ABG Sundal Collier, Sten Gustavsson
- Carnegie, Erik Hultgård
- Edison Group, Andy Smith
- Nordea, Hans Mähler and Klas Pyk
- Redeye, Klas Palin

Sustainability Report 2018*

* This sustainability report includes the parent company Orexo AB and its subsidiaries.

Sustainability at Orexo

Orexo's ambition is to be recognized for the added value our products bring to our patients and we want to be a trusted partner for the way we work and operate when delivering benefits for patients, society, shareholders and other stakeholders – Orexo's Business Compliance and Ethics Code.

Orexo's efforts to create added value for patients and other stakeholders and to ensure access to quality pharmaceutical products has a positive impact on several sustainability aspects. In general the historical importance of adherence to local and global legislation and standards with regard to good practices within pharmaceutical development and international business conduct has pushed the Company towards a more sustainable business. The threshold for being classified as a sustainable company is constantly increasing and Orexo is committed to continuously addressing its footprint on social and environmental aspects.

In April 2017, Orexo signed a letter of commitment to support the ten principles of the UN Global Compact. Since April 2018 Orexo is not only a signatory of the compact, but a participant, facilitating Orexo's commitment to sustainable development by adopting globally recognized frameworks and initiatives in order to meet goals within the 2030 Agenda for Sustainable Development.

Orexo's sustainability agenda

In order to define corporate sustainability priorities for the fiscal year Orexo drafted an activity plan early in 2018 based on an internal stakeholder dialogue. The plan was endorsed by Orexo's Sustainability Group in the spring of 2017 and it sets out Orexo's ambitions and targets within the following four areas:

- Anti-corruption, see page 28.
- Human rights, see page 28.
- Environment, see page 29.
- Labor, see page 30.

Sustainability management and policies

To demonstrate and implement Orexo's commitment to sustainable development and to raise knowledge internally about the subject, the company established a Sustainability Group in 2017. The group reports on an as-needed basis to the Board of Directors and includes relevant corporate functions that can influence corporate policies and strategies. The group is led by Orexo's Chief Financial Officer and is convened by Orexo's Sustainability Manager

The Swedish organization comprises Research and Development and Corporate Headquarters, and is responsible for maintaining policies on a corporate level and enforcing global and local policies mainly in Sweden. The majority of Orexo's commercial activities are managed by Orexo US, Inc., which utilizes and enforces a Comprehensive Compliance Policy Program adapted for federal and state-level law and expectations.

Business Compliance and Ethics Code

Orexo's Business Compliance and Ethics Code acts as an umbrella policy for all other policies and is based on legislation, corporate values and recognized international standards, such as the International Bill of Human Rights, the Declaration of Helsinki[1] and the UN Global Compact, and applies to all directors, officers, employees, consultants and temporary staff at Orexo AB and its subsidiaries. The code also urges individuals to raise questions and report suspected violation of ethical business conduct, without retaliation or any threat of retaliation.

Supplier Code of Conduct

As a company with most of its activities outsourced, Orexo's main sustainability impacts and risks are within the supply of goods and services. Orexo's supplier management is based on the company's Supplier Code of Conduct, which describes Orexo's expectations for suppliers in a variety of sustainability aspects.

In order to enforce the Supplier Code of Conduct, Orexo utilizes processes and procedures to ensure that patient safety, occupational safety and health, product quality and other applicable business compliance and ethics aspects of suppliers are acceptable. The processes and the procedures also ensure that applicable commercial aspects like supplier reliability, financial stability and future commercial implications for the supply chain are adequately considered.

U.S. Comprehensive Compliance Policies

Orexo US, Inc. adheres to rules and regulations set out on a federal and state level by enforcing a comprehensive policy program that addresses the approach to marketing and promotion of pharmaceutical products, including, but not limited to, aspects such as expense and aggregate spend reporting and interaction with governments and healthcare professionals.

Safety, Health and Environment Polices

The Safety, Health and Environment policies and guidelines support managers and employees in their pursuit of a workplace free of injuries and illnesses and support the company's precautionary approach to environmental challenges.

Human Resources Policies

The policies describe the relationship between the employer and the employees and their respective obligations and rights. They cover matters such as recruitment, equal opportunities, discrimination, conflict of interest and health insurance and other employment benefits.

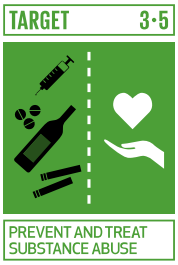
[1] A recognized statement of ethical principles for medical research involving human subjects developed by the World Medical Association (WMA).

#OPIOIDCRISIS

Substance use and substance-use disorders is a global public health burden and is also recognized by the United Nations as one of the targets within the 17 Sustainable Development Goals that must be met to achieve the 2030 Agenda for Sustainable Development.

Many countries still fail to provide adequate treatment and services to reduce the harm caused by substance abuse and only four countries worldwide have been classified as having high levels of coverage of opioid substitution therapy and needle and syringe programs. The result is that only one in six people worldwide suffering from drug-use disorders receives treatment.[2]

The US is a large and rapidly growing market for opioid dependence and Orexo has a broad presence in the country. The financial burden of the epidemic in 2015 was estimated at $504.0 billion[3] and approximately 70,200 deaths in 2017 were related to drug overdose.[4] Today, there is a broad political support for development and financing of measures that could curb the trend and address the lack of access to treatment. With the President's signature of the "Support for Patients and Communities Act" in October 2018, there is now also support in law for many of the improvements requested.



Orexo's key therapeutic area is within treatment of opioid dependence and ever since Zubsolv® was launched in the US, one of Orexo's main objectives has been to make treatment available for more people. Lately, Orexo has also put efforts into a broad development pipeline embracing all aspects of opioid addiction, from prevention to treatment. Provided that the development projects run according to plan, the company will be able to replace opioids in treatment of some acute pain conditions and thus minimizing the risk of developing addiction, saving lives through opioid overdose reversal and providing prescribers with more options within drug substitution therapy.

[2] World Drug Report 2018
[3] The Council of Economic Advisers, The Underestimated Cost of the Opioid Crisis
[4] https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm

United Nations Sustainable Development Goal 3 (SDG3)

United Nations Sustainable Development Goal 3 (SDG3) seeks to ensure healthy lives and promote well-being for all at all ages.

Target number 3.5 is of especial importance as it aims to strengthen the prevention and treatment of substance abuse, including narcotic drug abuse and harmful use of alcohol.

Follow OrexoABpubl on Twitter to read more about Orexo's efforts to fight the #opioidcrisis.

United Nations Sustainable Development Goal 5 (SDG5)

United Nations Sustainable Development Goal 5 (SDG5) seeks to achieve gender equality and empower all women and girls.

Orexo AB took the Women's Empowerment Principles Gender Gap Analysis Tool (WEPs tool) and updated the Equal Opportunities Plan during 2018. The plan was based on qualitative and quantitative data collected from the organization through HR management systems, an employee satisfaction survey and a specific survey on gender equality topics.

ANTI-CORRUPTION

A recognized risk for businesses within the healthcare sector is ethics and compliance violations in interactions with Healthcare Professionals (HCP), Healthcare Organizations and Government Officials. The legislation in this area is comprehensive in the US, with the Physician Payments Sunshine Act as an example where transparent disclosure of expenses in relations with HCPs is required. In order to complement the legislation and to communicate internally and externally what values should permeate Orexo's business conduct, Orexo formed the global and local policy program that was described earlier in the report.

Commitment	Target 2018	Progress
We are recognized as a reliable and professional partner with high integrity	Maintain implementation of Corporate Code of Conduct	Target met on-time in-full

Orexo US, Inc. adheres to rules and regulations set out on a federal and state level by enforcing a comprehensive policy program that addresses the approach to marketing and sales of products, including, but not limited to, aspects as expense and aggregate spend reporting and interaction with governments and healthcare professionals. Employees and other stakeholders are able to file confidential, anonymous reports via the telephone or the Internet and are also able to anonymously track the progress of their reports.

Through the revision of Orexo's corporate Business Compliance and Ethics Code in 2017, the Ten Principles of the UN Global Compact were further integrated with company core values. The Code is enforced through onboarding and continuous training and 91% of the organization have participated in training on compliance and ethics within the business conduct.

Following the positive outcome in the patent litigation against Actavis this year, Orexo decided to internalize the contract field force in the US, adding 33 employees to the payroll. All of them have been trained in Business Compliance and Ethics in accordance with Orexo US, Inc. guidelines.

Performance indicators	2017 (year-end data)		2018 (year-end data)	
	Parent company	Group	Parent company	Group
Implementation of Code of Conduct (of employees)	81%	89%	80%	91%

HUMAN RIGHTS

Through the Business Compliance and Ethics Code Orexo supports the International Bill of Human Rights and the ILO Declaration on Fundamental Principles and Rights at Work. The company's highest risks for violation of these rights are, however, in the Supply Chain, beyond the direct control of the company. Hence, in the Human Rights issue area the company works on enhancing external performance and this commitment is enforced through the Supplier Code of Conduct and the Supplier Management Principles.

All suppliers are categorized in segments based on their complexity and criticality (Tier A-D; A highest, D lowest) and initial and continual assessments are performed accordingly. The sustainability assessments currently focus on a handful of strategic suppliers and depending on the nature of the business and location of the assessed partner different sustainability aspects are evaluated and audited.

Commitment	Target 2018	Progress
We train our employees and assess our partners to reduce risks	Full integration of applicable Safety, Health and Environment issues in Orexo's tiered Corporate Social Responsibility due diligence process	Process updated and maintained
	Approved Tier A and new suppliers assessed according to integrated process	Assessment completion 83%

Orexo's main target for 2018 was to continue the integration of sustainability assessments into the Supplier Management Processes and to ensure that key suppliers were assessed according to the process.

At the end of 2018 almost all tier A suppliers had been off site audited with regards to all four sustainability issue areas (Environment, Human Rights, Labor and Anti-Corruption), with some minor remarks that are being monitored.

Performance of Orexo's Supplier Management Process with regard to sustainability

Performance indicators	Number of approved Suppliers			Sustainability Assessments performed		Number of approved Suppliers with open Sustainability issues		
	1–6	7–14	15–	Result	Target 2018	Major	Moderate	Minor
Tier A	•	–	–	83%	100%	NONE	NONE	2
Tier B	–	•	–	18%	20%	NONE	NONE	NONE
Tier C	–	–	•	0%	0%			
Tier D	–	–	•	0%	0%			

ENVIRONMENT

Orexo focuses its efforts within Environmental Management to where the greatest risks of adverse environmental impact are found and this risk-based approach identifies the supply of goods, product development and the handling of chemicals. Within these areas, the company is committed to monitoring and improving energy efficiency, consumption of materials and waste management and keeping emissions of pharmaceutical substances at low levels. Orexo has an Environmental Management System based upon ISO 14001 (not certified).

Orexo's Environmental Aspect Assessment (EAA) is utilized to identify the highest potential environmental impacts and indicate where the greatest return on invested efforts can be realized.

The assessment is an effective tool to see where 'violation' of a sustainability aspect is more likely to occur and also to address potential legislative compliance issues.

During 2018 the company used the EAA as a base, and started to complement it with a higher degree of detail to find certain areas where Orexo could advance greater environmental responsibility. This environmental risk and benefit analysis is yet to be finalized.

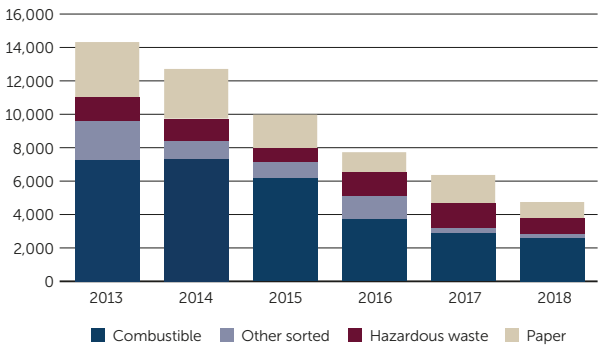
One aspect that is prioritized is reduction of the company's waste generation. Despite the intensification of activities at the company's Swedish research facility, the site was able to reduce its waste generation by 25% during the year.

Commitment	Target 2018	Progress
We are aware of our operational footprint and we continuously assess and minimize our environmental impact	Finalize the risk and benefit analysis to assess Orexo's current Environmental footprint and thus find improvement opportunities	Environmental risk and benefit analysis ongoing, but not finalized

Performance indicators

	2017	2018
Combustible waste [kg/employee at parent company]	53,8	47,1

Waste sources



LABOR

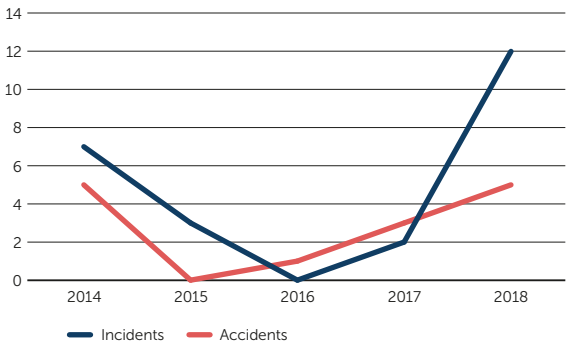
Through the Business Compliance and Ethics Code Orexo supports the International Labour Organization's Fundamental Principles and Rights at Work. Since the impacts of Orexo's outsourced business conduct are managed within the Human Rights issue area this section comprises information on the performance within the Orexo Group.

Orexo has slightly over a hundred employees in Sweden and the USA. As a company with its roots in Sweden and a subsidiary in another developed country, fundamental labor right standards such as abolition of child labor, maintaining freedom of association and elimination of forced and compulsory labor are generally both ethically and legislatively well developed. Orexo, however, recognizes the local and global challenges of inequality at work and work-related health issues.

Through the *Business Compliance and Ethics Code* Orexo condemns any form of harassment or discrimination, including such characteristics protected by applicable laws and regulations. To enforce the policy the Swedish organization maintains an Equal Opportunities Plan which has been revised during the year. Orexo AB initially took the Women's Empowerment Principles Gender Gap Analysis Tool (WEP's tool) and then updated the Equal Opportunities Plan. The plan was based on qualitative and quantitative data collected from the organization through HR management systems, an employee satisfaction survey and a specific survey on gender equality topics. The parent company received positive comments from employees concerning their ability to influence their working hours and working conditions and the opportunity to combine a career and parenthood. In order to meet the employees' high level of expectations on equality improvement, the company will strengthen its efforts in this area.

In 2017 a revised Safety & Health Risk Management Report and a new incident reporting procedure were launched in Sweden. The efforts to promote the use of incident reporting have raised the number of "near-miss" reports significantly during the last year, providing Orexo with new insights on how to enhance the health & safety of the employees.

Reported accidents and incidents



Incentive	Target 2018	Status
Our work on safety and health engage all employees	Ensure a work environment with equal opportunities and free from harassments	Equal opportunities assessment and issue mitigation according to plan
	Safety & Health Risk Management Report maintained and utilized to drive activities within prioritized areas	S&H RM Report annual update performed on-time, in-full and identified risks are monitored and mitigated accordingly

Performance indicators

	2017 (year-end data)		2018 (year-end data)	
	Parent company	Group	Parent company	Group
Types of employment[1]				
Number of employees	53	90	55	129
– employees with a permanent contract	98%	99%	98%	99%
– employees with a temporary contract	2%	1%	2%	1%
Temporary workers	10%	32%	13%	8%
Gender equality				
Female employees	51%	56%	55%	60%
– women in management positions	44%	47%	33%	42%
– women in executive management team	–	0%	–	0%
Women on board of directors	–	29%	–	29%
Other data				
Employee satisfaction index[2]	80	Not available	78	81
Employee absence due to illness	2%	1%	4%	2%

[1] Employees = Orexo's payroll; Workforce = Employees + Consultants
[2] Springlife (Parent company), DecisionWise (Orexo US, Inc.). Score above 70 indicates that the conditions for employees are good.

Statement by the CEO

Orexo's Sustainability Report is prepared in accordance with the Swedish Annual Accounts Act and it also act as our Communication on Progress according to the reporting guidelines of the UN Global Compact. I am pleased to reaffirm Orexo's support of the Ten Principles in the areas of Human Rights, Labor, Environment and Anti-Corruption.

Nikolaj Sorensen
President and CEO

Auditor's report on the statutory sustainability 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 statutory sustainability statement for the year 2018 on pages 24–31 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 RevR 12 *The auditor's opinion regarding the statutory sustainability 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 statutory sustainability statement has been prepared.

Uppsala 19 March 2019
Ernst & Young AB

Björn Ohlsson
Authorized Public Accountant

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, 2018. Orexo's registered office is in Uppsala, Sweden.

Operations

Orexo develops improved pharmaceuticals based on innovative Drug Delivery technologies. The current focus is primarily on opioid dependence and pain but the aim is to address other areas where the company's competence and technologies can create value. The products are commercialized by Orexo in the US or via partners worldwide. The main market today is the American market for buprenorphine/naloxone products, where Orexo sells Zubsolv® for treatment of opioid dependence. Zubsolv was approved by the US Food and Drug Administration (FDA) on July 3, 2013, and launched on the US market on September 16, 2013.

Orexo has to date developed the following proprietary commercial products:

- Zubsolv, for treatment of opioid dependence, is approved for use in the US and the EU. In the US the product is commercialized by Orexo whereas Mundipharma owns the rights to Zubsolv outside of the US. Launch of Zubsolv in a few countries in EU occurred in the first half of 2018. The partnership with Mundipharma will end in April 2019. All rights will be ransfered to Orexo then, and the work to identify new partners has been initiated.
- Abstral®, for the treatment of breakthrough pain in cancer patients, is approved for use in the EU, the US, Canada, Japan and a few additional markets. The product is sold in the US by Sentynl Therapeutics and outside of the US by Kyowa Kirin.
- Edluar®, a sublingual tablet containing zolpidem to treat insomnia, is approved for use in the US, Canada and the EU and sold in these markets by Mylan.
- 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 innovative and proprietary formulation technologies. 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.

Organization

The US subsidiary, Orexo Inc., is responsible for the US commercialization of Zubsolv and possesses a full commercial infrastructure. Since July 1, 2014 Orexo's partner Syneos (inVentiv Health) has acted as contracted sales force partner with day-to-day management of field based activities conducted by Orexo. Sales force leadership is employed directly by Orexo and ensures full control of all sales & marketing activities. In October 2018, Orexo Inc. internalized all salesforce representatives, and Syneos remains a partner only to manage the back office functions for the salesforce operations. During the year a key focus area for the commercial organization was to improve the market access situation for Zubsolv in the US.

The development organization focused during the year on progressing the pipeline of internal development projects. As a result, in the Q1 2018 Interim Report, Orexo was able to announce two new projects. The OX124 a rapidly acting naloxone medication for treatment of opioid overdose with a differentiated profile compared to currently marketed products for which a successful human pharmacokinetic (PK) study, OX124-001, was initiated in 20 healthy volunteers during Q4 2018 and with positive results communicated in beginning of 2019. The OX338 project based on a new sublingual tablet formulation of Ketorolac for acute treatment of moderate to severe pain. In the Q4 2018 Interim report a new project was announced the OX125 based on a novel and unique technology developed to provide a rapidly acting nalmefene medication for treatment of opioid overdose with the aim to provide differentiated profile compared to currently marketed products and other products under development.

Another key focus area for the development organization was the work to improve efficiencies within manufacturing with the aim of reducing cost of goods sold.

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

Orexo works with highly competent external partners for the manufacture of products for commercial use, clinical trials and manufacturing.

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 align requirements and expectations between Orexo and suppliers. All new potential suppliers are 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 129 employees.

Key events

2018 was the third consecutive year with full year positive earnings and positive cash flow and Orexo made progress on several fronts. The pipeline of internal projects progressed well, market access for Zubsolv® in the US was significantly improved with impact from 2018 and the financial situation was improved with continued positive cash flow.

Paragraph IV litigation against Actavis regarding Zubsolv in the US

On December 7, 2016, Orexo appealed the District Court's decision relating to the validity of the '330 patent to the Court of Appeals for the Federal Circuit. Actavis did not appeal the District Court's decision relating to the validity and infringement of the '996 patent, securing Zubsolv exclusivity on the US market until at least September 24, 2019. An oral session was held in the US Court of Appeals for the Federal Circuit on October 4, 2017.

On September 10, 2018, the US Court of Appeals for the Federal Circuit found Zubsolv US patent '330 to be valid, and reversed the invalidity decision previously rendered by the District Court of Delaware in November 2016. The same Court also denied Actavis's petition for rehearing regarding validity of the Zubsolv patent. The '330 patent and two new Zubsolv US patents, 9,259,421 and 9,439,900, listed in the Orange Book in 2016, are protecting Zubsolv in the US until 2032. Orexo then requested the US District Court of Delaware to issue a judgment that Actavis's generic Zubsolv products infringe the '330 patent, and will not be approved by FDA until September 2032. Such a judgement was issued by the Court after the period, on January 10, 2019.

The infringement judgement implicates that Orexo has fully won this patent litigation case which is now declared closed.

Patent infringement litigation against Actavis for their generic versions of Suboxone® and Subutex® tablets in the US

In March 2017, Orexo filed a patent infringement action in the 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 8,454,996 (the'996 patent). Actavis's generic version of Suboxone was approved by the FDA in February 2013 and their generic version of Subutex in February 2015. Orexo is seeking compensation for damages caused by Actavis's infringement of the '996 patent since the year of approval of these two products.The trial is scheduled for March 25–29, 2019.

A court decision will follow closely after, with the possibility to appeal from both sides.

Zubsolv US market access update

During the year Orexo improved the market access for Zubsolv in the US. Within the profitable commercial category access increased with the Blue Cross Blue Shield health plan wins. Additionally, access within the public category increased during the year and Zubsolv moved into a preferred product reimbursed accessible position on many state Medicaid Preferred Drug Lists in the last quarter of 2018 which will give Zubsolv greater public access in 2019.

Financial Performance

CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS

SEK million	2018	2017
Net revenues	783.1	643.7
Cost of goods sold	–171.8	–164.4
Gross profit	611.4	479.3
Selling expenses	–191.4	–190.5
Administrative expenses	–166.7	–96.1
Research and development costs	–166.8	–134.2
Other operating income and expenses	9.3	–1.1
Operating earnings	95.8	57.4
Net financial items	–3.6	–27.7
Earnings after financial items	92.2	29.7
Income tax	45.7	–6.5
Net earnings for the period	137.9	23.2

Revenues

Net revenues

Net revenues were distributed as follows:

NET REVENUES

SEK million	2018	2017
Zubsolv US	621.5	485.8
Zubsolv – Rest of World	36.2	5.6
Zubsolv – Total	**657.8**	**491.4**
Abstral – royalty	118.8	113.2
Edluar – royalty	6.6	17.3
OX-CLI	–	21.8
Total	**783.1**	**643.7**

Commercial products

Total net revenues for the year amounted to SEK 783.1 million (643.7). Higher Zubsolv® US revenue in 2018 explains the increase.

Zubsolv US revenue ended at SEK 621.5 million (485.8), 28 percent above the previous year's level. The US buprenorphine/naloxone market grew by low double digit rates.

Within the commercial category Zubsolv was nearly universally reimbursed in 2018, primarily driven by the new preferred position within CVS Caremark and with the exclusive preferred positions within Envision Rx and Humana. More than 80 percent of the market growth occurred in the public category, and Zubsolv had much improved access with the exclusive position with the Humana Medicaid Part D plan from January 1, 2018.

During Q4 Orexo shipped the last Zubsolv batches to Mundipharma. These products were invoiced at cost according to the agreement.

Total Abstral royalties during the year amounted to SEK 118.8 million (113.2), with region RoW being the key growth driver. In September 2019, the patents for Abstral in the EU will expire. As the EU contract with Kyowa Kirin runs until December 31, 2019, Orexo expects that royalty for the EU will decrease slightly during the year compared to 2018, but will cease for 2020. EU's share of Abstral's total royalty amounts to approximately 80 percent.

Royalty revenues from Edluar® during the year amounted to SEK 6.6 million (17.3) mainly explained by a temporary loss of business in US market due to supply issues which have now been resolved.

Expenses and earnings

Cost of goods sold

Cost of goods sold amounted to SEK 171.8 million (164.4). Approximately SEK 5 million relates to Zubsolv which was supplied to Mundipharma. The rest relates to Zubsolv for the US market.

Selling expenses

Selling expenses amounted to SEK 191.4 million (190.5) as a result of tight cost control and a very targeted investment approach focusing on US districts with good market access and growth opportunities.

Administrative expenses

Administrative expenses amounted to SEK 166.7 million (96.1). The higher expense level in 2018 is explained by significantly higher legal costs related to protection of IP rights.

Research and development costs

Research and development costs amounted to SEK 166.8 million (134.2). During 2018 the focus was mainly on OX124, progressing other early stage projects and the supply chain optimization project.

Expenses for the long-term incentive program

The Group's total costs for employee share based incentive programs amounted to SEK 2.1 million (3.0).

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

EXPENSES FOR THE LONG-TERM INCENTIVE PROGRAM

SEK million	2018	2017
Administrative expenses	–0.4	–1.4
Research and development costs	–1.2	–1.2
Selling expenses	–0.5	–0.4
Total costs incentive programs	**–2.1**	**–3.0**

Other income and expenses

Other income and expenses amounted to SEK 9.3 million (–1.1). Included are exchange-rate gains/losses derived from revaluation of operating receivables and payables in foreign currency and income/expenses from activities outside the scope of normal business operations.

Depreciation

Depreciation and amortization amounted to SEK 20.8 million (20.8). This includes amortization of previously capitalized R&D expenses related to the Zubsolv induction label.

Net financial items

Net financial items amounted to SEK –3.6 million (–27.7) explained by higher financial income mainly due to exchange rate gains of SEK 32.3 million (0.0) derived from foreign currency bank accounts.

Income tax

Income tax for the year amounted to SEK 45.7 million (–6.5) and was positively impacted by SEK 53.3 million due to adjustments of the parent company's deferred tax asset, driven by anticipated increased profitability.

Net earnings

Net earnings amounted to SEK 137.9 million (23.2).

Financial position

On December 31, 2018, cash and cash equivalents amounted to SEK 589.8 million (327.9) and interest-bearing liabilities to SEK 320.6 million (319.1).

The interest-bearing liabilities are all associated with corporate bonds. During Q4, 2017, Orexo refinanced the 2014 corporate bond by issuing a new SEK 325.0 million bond and redeeming the 2014 bond.

Positive cash flow from operating activities for the year amounted to SEK 242.0 million (146.6) and was driven by a positive contribution from both earnings and changes in working capital.

Shareholders' equity on December 31, 2018 was SEK 476.1 million (329.1) and the equity/assets ratio was 37 percent (33).

The profitable business operations and the current cash position have secured Orexo a strong financial platform for the execution of the company's strategy.

Investments

Gross investments in tangible and intangible fixed assets amounted to SEK 3.6 million (1.6).

Parent Company

Parent company's operations consist of Business Development, R&D, Global Lifecycle Management, Global regulatory, Supply Chain and Group Business Support. Net revenues amounted to SEK 407.6 million (477.8), of which group internal sales amounted to SEK 246.0 million (320.0). Earnings after financial items were SEK 52.0 million (35.1). As of December 31, 2018, cash and cash equivalents in the Parent Company amounted to SEK 303.2 million (215.1).

Outlook 2019

For 2019 Orexo expects to improve the positive EBITDA on a full year basis and on a quarterly basis the development will follow the same pattern as previous year.

Orexo believes that the overall volume of Zubsolv® sales in the US in 2019 will increase due to new wins in several states in the public category of Medicaid and further growth in Humana Med D exclusive position, despite increased competition from a potential launch of Suboxone® Film generics. However we do expect that a launch of corresponding generics will increase market risk and uncertainty but will also offer opportunities.

The manufacturing efficiency program is aimed to reduce the average Cost of Goods Sold (COGS) per tablet by 35 percent in H2, 2019 compared to 2017.

Full year OPEX is expected to stay at the same level as 2018 with approximately SEK 500 million. The final outcome is dependent on the cost of the IP litigation against Actavis for their generic versions of Suboxone and Subutex® and possible appeals after the court hearing in the District Court in March.

Additional investments may be needed if development programs reach clinical stage faster than anticipated. Orexo expects to advance at least one additional development program to phase I trial during 2019.

The first new partnerships for Zubsolv outside the US is expected to be initated in 2019.

The outlook is based on current exchange rates (January 2019).

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 pages 53–54. 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, including the generic film in early 2019.

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. 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 process 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.

During 2018 the development organization focused on progressing the pipeline of internal development projects. As a result, in the Q1 2018 Interim Report, Orexo was able to announce two new projects. The OX124 a rapidly acting naloxone medication for treatment of opioid overdose with a differentiated profile compared to currently marketed products. Positive results were received in beginning of 2019 showing that all formulations of OX124 were well tolerated and displayed substantially higher plasma concentrations of naloxone, sustained duration of elevated plasma concentrations, and equivalent or superior onset time when compared to Narcan®. The OX338 project based on a new sublingual tablet formulation of Ketorolac for acute treatment of moderate to severe pain. Positive results from this study was obtained early 2019 supporting further development and planning for a human pharmacokinetic study commencing during second half of 2019.

In the Q4 2018 Interim report third new project was announced the OX125 based on a novel and unique technology developed to provide a rapidly acting nalmefene medication for treatment of opioid overdose with the aim to provide differentiated profile compared to currently marketed products and other products under development. The positive results from the OX124 human PK-study meant that a decisions were made to intensify the development of the project.

Formulation development continued for the OX382 during the year based on the insights gained from the result in the first clinical study performed in beginning of the year. Besides current ongoing initiatives 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.

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 shareholders. 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 September 10, 2018, the US Court of Appeals for the Federal Circuit found Zubsolv® US patent '330 to be valid, and reversed the invalidity decision previously rendered by the District Court of Delaware in November 2016. The same Court also denied Actavis's petition for rehearing regarding validity of the Zubsolv patent. The '330 patent and two new Zubsolv US patents, 9,259,421 and 9,439,900, listed in the Orange Book in 2016, are protecting Zubsolv in the US until September 2032. Orexo then requested the US District Court of Delaware to issue a judgment that Actavis's generic Zubsolv products infringe the '330 patent, and will not be approved by FDA until September 2032. Such a judgement was issued by the Court after the period, on January 10, 2019. The infringement judgement implicates that Orexo has fully won this patent litigation case which is now declared closed.

In March 2017, Orexo filed a patent infringement action in the 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 8,454,996. Actavis's generic version of Suboxone was approved by the FDA in February 2013 and their generic version of Subutex in February 2015. Orexo is seeking compensation for damages caused by Actavis's infringement of the '996 patent since the launch of these two products. The trial is scheduled for March 25–29, 2019. A court decision will follow closely after, with the possibility to appeal from both sides.

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

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

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's lifetime. During 2018 Orexo continued to improve the product's lifetime and also to reduce the inventory level to an appropriate level.

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 and during 2017 HHS further allowed certified physician assistants and nurses to start prescribing buprenorphine for treatment of opioid dependence. These changes are examples of political decisions 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 staff is of very great importance for ensuring that there is adequate expertise in the company.

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 129 employees.

Environmental work
The company has prepared a Sustainability Report in accordance with the Swedish Annual Accounts Act and according to the reporting guidelines of the United Nations Global Compact. See pages 24–31.

Remuneration

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 2020. 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 2018.

The Board has appointed a Remuneration Committee to draw up proposals regarding remuneration and other terms of employment for the management.

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. All incentive programs are performance driven to align participant's interest with shareholder interest. For a description of the company's Long-Term Incentive Programs, please refer to Note 23, 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.

In 2018 the Board approved bonus beyond the guidelines for the two US participants of the Management Team. This was done as part of a special bonus scheme driven by US profit contribution to secure focus on profitability and to reflect American labor market that is requiring an increased share of variable remuneration in order to attract and retain key employees.

Largest shareholders

At year-end 2018 Orexo had two large shareholders with holdings of more than 10 percent of the total number of shares; Novo Holding A/S 27.2 percent with 9,643,184 shares, and HealthCap 11.2 percent with 3,960,020 shares.

Dividend

The Board of Directors proposes that no dividend is paid for the financial year 2018.

Number of shares

Company shares total 35,450,456 – whereof 34,560,456 are ordinary shares and 890,000 class C shares. There are 34,649,456 votes in the company.

Proposed appropriation of profit

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

SEK thousands	
Share premium reserve	1,198,323
Loss carried forward	–1,191,631
Profit/loss for the year	105,311
Total	**112,003**

The Board proposes that the funds at their disposal SEK 112,003 thousands be carried forward.

Corporate Governance

Information on Orexo's application of the Swedish Code of Corporate Governance and more can be found in the corporate governance report on page 79.

Financial information in brief
Group

STATEMENT OF OPERATIONS INFORMATION

SEK million	2018	2017	2016	2015	2014
Net revenues	783.1	643.7	705.9	646.2	570.3
Cost of goods sold	–171.8	–164.4	–149.6	–150.2	–107.4
Gross Profit	**611.4**	**479.3**	**556.3**	**496.0**	**462.9**
Selling expenses	–191.4	–190.5	–240.6	–297.5	–193.6
Administrative expenses	–166.7	–96.1	–161.6	–141.5	–113.0
Research and development costs	–166.8	–134.2	–132.3	–172.6	–197.8
Other operative income and expenses	9.3	–1.1	29.9	–65.0	16.5
Operating earnings	**95.8**	**57.4**	**51.7**	**–180.6**	**–25.0**
Net financial items	–3.6	–27.7	–16.1	–23.0	–27.6
Earning after financial items	**92.2**	**29.7**	**35.6**	**–203.6**	**–52.6**
Income tax	45.7	–6.5	–6.5	–6.4	–4.0
Net earning for the year	**137.9**	**23.2**	**29.0**	**–210.0**	**–56.6**

BALANCE SHEET INFORMATION

SEK million	2018	2017	2016	2015	2014
Intangible fixed assets	103.9	121.0	138.2	155.5	259.2
Tangible fixed assets	20.0	20.1	22.1	24.7	29.1
Deferred tax	92.8	28.3	24.8	18.0	3.0
Other financial assets	10.4	7.1	7.9	2.1	1.2
Inventories	173.6	250.2	344.2	402.6	488.2
Account receivable	264.5	218.4	178.5	167.8	142.1
Other current assets	31.6	30.9	20.7	51.2	31.5
Cash and bank balance	589.8	327.9	282.4	198.1	284.5
Total assets	**1,286.7**	**1,003.9**	**1,018.8**	**1,020.0**	**1,238.8**
Shareholders' equity	476.1	329.1	310.3	270.1	467.9
Interest-bearing liabilities	320.6	319.1	397.8	494.4	493.8
Non-interest bearing liabilities and provisions	489.9	355.7	310.7	255.5	277.1
Total shareholders' equity and liabilities	**1,286.7**	**1,003.9**	**1,018.8**	**1,020.0**	**1,238.8**

CASH FLOW INFORMATION

SEK million	2018	2017	2016	2015	2014
Cash flow from operating activities before changes in working capital	127.9	110.3	67.5	–47.2	–35.5
Cash flow changes in working capital	114.1	36.3	88.7	–62.0	–451.8
Cash flow from operating activities	242.0	146.6	156.2	–109.2	–487.3
Acquisition of tangible, intangible and financial assets	–6.2	–1.6	–1.7	–4.0	–71.7
Sale of tangible assets	–	–	1.9	–	–
Sale of subsidiary	–	–	5.0	21.8	–
Cash flow after investing activities	235.8	145.0	161.7	–91.4	–559.0
Amortization of loans	–	–404.7	–92.8	–1.2	–102.4
Borrowings	–	319.2	–	–	500.0
New share issues	0.1	0.1	2.2	3.8	189.7
Buyback of shares	–0.1	–	–	–	–
Sales of treasury shares	–	–	–	–	152.0
Cash flow for the year	235.8	59.6	71.1	–88.8	180.3
Cash and cash equivalents at year-end	589.8	327.9	282.4	198.1	284.5

OTHER KEY FIGURES

	2018	2017	2016	2015	2014
EBIT margin, %	12.2	8.9	7.3	–27.9	–4.4
Return on shareholder equity, %	34.3	7.3	10.0	–56.9	–18.0
Net debt, SEK million	–269.2	–8.8	115.4	296.3	211.7
Debt/equity ratio, %	67.3	97.0	128.2	183.0	106.0
Equity/assets ratio, %	37.0	32.8	30.5	26.5	37.1
Number of shares, before dilution	34,560,456	34,540,271	34,477,423	34,478,622	32,700,348
Number of shares, after dilution	35,095,980	34,650,835	34,574,337	34,478,622	32,700,348
Earnings per share, before dilution, SEK	3.99	0.67	0.84	–6.09	–1.70
Earnings per share, after dilution, SEK	3.93	0.67	0.84	–6.09	–1.70
Number of employees at the end of the period	129	90	102	90	108
Shareholders' equity, SEK million	476.1	329.1	310.3	270.1	467.9
Capital employed, SEK million	796.7	648.2	708.1	764.5	961.7
Working capital, SEK million	–13.7	149.6	233.9	370.0	383.8

For alternative key figures see definitions and reconciliations of key figures on page 76

Financial Reports 2018

Consolidated Statement of Operations

SEK million	Notes	2018	2017
Net revenues	5	783.1	643.7
Cost of goods sold	6	–171.8	–164.4
Gross profit		**611.4**	**479.3**
Selling expenses	6, 8, 9, 31	–191.4	–190.5
Administrative expenses	6, 8, 9, 29, 31	–166.7	–96.1
Research and development costs	6, 8, 9, 31	–166.8	–134.2
Other operating income	7, 10	18.5	38.1
Other operating expenses	6, 10	–9.2	–39.3
Operating earnings		**95.8**	**57.4**
Financial income	11	35.3	0.2
Financial expense	11	–38.9	–27.9
Earnings after financial items		**92.2**	**29.7**
Tax	12	45.7	–6.5
Net earnings for the year		**137.9**	**23.2**
Earnings for the year attributable to:			
Parent Company shareholders		137.9	23.2
Non–controlling interests		–	–
Earnings per share during the year attributable to Parent Company shareholders (expressed in SEK)			
– before dilution	13	3.99	0.67
– after dilution	13	3.93	0.67

Consolidated Statement of Comprehensive Income

SEK million	Notes	2018	2017
Net earnings for the year		**137.9**	**23.2**
Other comprehensive income			
Items that may subsequently be reversed to the statement of operations:			
Translation differences	16	7.0	–7.5
Other comprehensive earnings for the year, net after tax		**7.0**	**–7.5**
Comprehensive earnings for the year		**144.9**	**15.7**
Comprehensive earnings attributable to:			
Parent Company shareholders		144.9	15.7
Non–controlling interests		–	–

Consolidated Balance Sheet

SEK million	Notes	2018	2017
ASSETS			
Fixed assets			
Tangible fixed assets	8, 14	20.0	20.1
Intangible assets	8, 15	103.9	121.0
Deferred tax assets	30	92.8	28.3
Other financial assets	17	10.4	7.1
Total fixed assets		**227.2**	**176.5**
Current assets			
Inventories	18	173.6	250.2
Accounts receivable	19	264.5	218.4
Other receivables	20	5.9	7.4
Prepayment and accrued income	21	25.7	23.5
Cash and cash equivalents	17, 22	589.8	327.9
Total current assets		**1,059.5**	**827.4**
TOTAL ASSETS		**1,286.7**	**1,003.9**
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity			
Share capital	23	14.2	14.1
Other contributed capital	23	1,853.6	1,851.6
Reserves	16	–0.3	–7.3
Profit carried forward including net earnings for the year	24	–1,391.4	–1,529.3
Total shareholder's equity		**476.1**	**329.1**
Long–term liabilities and provisions			
Provisions	24	6.5	5.8
Interest bearing liabilities	17, 25	320.6	319.1
Total long–term liabilities		**327.1**	**324.9**
Current liabilities			
Accounts payable	17	47.7	45.5
Provisions	24	265.8	200.9
Other liabilities	26	4.9	6.3
Accruals	26	165.0	97.2
Total current liabilities		**483.4**	**349.9**
Total liabilities		**810.5**	**674.8**
Total shareholders' equity and liabilities		**1,286.7**	**1,003.9**

Changes in Consolidated Shareholders' Equity

Attributable to Parent Company shareholders[1] SEK million	Notes	Share capital	Other contributed capital	Reserves	Profit carried forward including Net earnings for the year	Total shareholders' equity
Opening balance at January 1, 2017		**13.9**	**1,848.6**	**0.2**	**–1,552.4**	**310.3**
Comprehensive income						
Net earnings for the year					23.2	23.2
Other comprehensive income						
Translation differences				–7.5		–7.5
Total comprehensive income		**0.0**	**0.0**	**–7.5**	**23.2**	**15.7**
Transactions with shareholders						
Share based compensation	23		3.0			3.0
New share issues		0.1				0.1
Total transactions with shareholders		**0.1**	**3.0**			**3.1**
Closing balance at December 31, 2017		**14.1**	**1,851.6**	**–7.3**	**–1,529.3**	**329.1**
Opening balance at January 1, 2018						
Comprehensive income						
Net earnings for the year					137.9	137.9
Other comprehensive income						
Translation differences				7.0		7.0
Total comprehensive income		**0.0**	**0.0**	**7.0**	**137.9**	**144.9**
Transactions with shareholders						
Share based compensation	23		2.1			2.1
New share issues		0.1	–0.1			0.0
Total transactions with shareholders		**0.1**	**2.0**	**0.0**	**0.0**	**2.1**
Closing balance at December 31, 2018		**14.2**	**1,853.6**	**–0.3**	**–1,391.4**	**476.1**

[1] There are no non–controlling interests

The number of outstanding shares has increased from 35,104,585 per 31 December 2017 to 35,450,456 per 31 December 2018. This has been done through issuance of 325,000 C shares and 20,871 from exercise of options. The quota value per share on December 31, 2018 is 0.4.

Consolidated Cash Flow Statement

SEK million	Notes	2018	2017
Operating earnings		95.8	57.4
Adjustment for non-cash items	32	61.9	87.9
Interest received		3.1	0.2
Interest paid		–14.8	–15.6
Tax paid		–18.1	–19.6
Cash flow from operating activities before changes in working capital		**127.9**	**110.3**
Changes in working capital			
Change in inventories		83.5	83.2
Change in receivables		–22.3	–70.5
Change in current liabilities		52.9	23.6
Cash flow from operating activities		**242.0**	**146.6**
Investing activities			
Acquisition of tangible fixed assets	14	–2.9	–1.1
Acquisition of intangible assets	15	–0.7	–0.5
Acquisition of financial assets		–2.5	–
Cash flow from investing activities		**–6.2**	**–1.6**
Financing activities			
New share issue		0.1	0.1
Buyback of shares		–0.1	–
Issuance of corporate bonds	25	–	319.2
Buyback of corporate bonds	25	–	–404.7
Cash flow from financing activities		**0.0**	**–85.4**
Cash flow for the year		**235.8**	**59.6**
Cash and cash equivalents at the beginning of the period		327.9	282.4
Exchange-rate differences in cash and cash equivalents		26.1	–14.1
Change in liquidity		261.9	45.5
Cash and cash equivalents at the end of the period	22	**589.8**	**327.9**

Parent Company Statement of Operations

SEK million	Notes	2018	2017
Net revenues	5	407.6	477.8
Cost of goods sold	6	–116.2	–167.4
Gross profit		**291.4**	**310.4**
Selling expenses	6, 8, 9, 31	–10.3	–73.3
Administrative expenses	6, 8, 9, 29, 31	–135.2	–67.3
Research and development costs	6, 8, 9, 31	–138.3	–105.3
Other operating income	7, 10	63.2	38.1
Other operating expenses	6, 10	–12.6	–39.3
Operating earnings		**58.1**	**63.3**
Other interest income and similar income	11	32.8	1.0
Other interest expenses and similar expenses	11	–38.9	–29.2
Net financial items		**–6.1**	**–28.2**
Earnings before tax		**52.0**	**35.1**
Tax on earnings for the year	12	53.3	7.6
Net earnings for the year		**105.3**	**42.7**

Parent Company Statement of Comprehensive Income

SEK million	Notes	2018	2017
Net earnings for the year		105.3	42.7
Other comprehensive income for the period, net after tax		–	–
Total comprehensive income for the period		**105.3**	**42.7**

Parent Company Balance Sheet

SEK million	Notes	2018	2017
ASSETS			
Fixed assets			
Patents and intellectual property rights and proprietary intangible asset	8, 15	103.9	121.0
Equipment, renovation of the property of others	8, 14	20.0	19.8
Deferred tax assets	30	60.9	7.6
Shares and participations in group companies	27	152.3	150.6
Total fixed assets		**337.1**	**299.0**
Current assets			
Inventories	18	155.3	186.3
Accounts receivable	19	63.0	61.1
Tax claims	12	2.7	2.7
Other receivables	20	3.2	4.7
Receivables from group companies		85.7	79.1
Prepaid expenses and accrued income	21	12.2	10.8
Cash and bank	22	303.2	215.1
Total current assets		**625.3**	**559.8**
TOTAL ASSETS		**962.4**	**858.8**
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity			
Restricted shareholders' equity			
Share capital	23	14.2	14.1
Statutory reserve		290.8	290.8
Total restricted shareholders' equity		**305.0**	**304.9**
Non-restricted shareholders' equity			
Share premium reserve	23	1,198.1	1,195.9
Accumulated deficit		–1,191.4	–1,234.1
Net earnings for the year		105.3	42.7
Total non-restricted shareholders' equity		**111.9**	**4.5**
Total shareholders' equity		**416.9**	**309.4**
Long-term liabilities			
Other provisions	24	4.9	4.9
Long-term liabilities	25	320.6	319.1
Total long-term liabilities		**325.5**	**324.0**
Current liabilities			
Accounts payable		19.6	28.9
Other liabilities	26	5.0	6.6
Liabilities to group companies		143.2	169.1
Accrued expenses and deferred income	26	52.3	20.8
Total current liabilities		**220.1**	**225.4**
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		**962.4**	**858.8**

Changes in Parent Company Shareholders' Equity

SEK million	Notes	Share capital	Statutory reserve	Share premium reserve	Accumulated deficit including Net earnings for the year	Total shareholders' equity
Opening shareholders' equity at January 1, 2017		**13.9**	**290.8**	**1,192.9**	**–1,234.1**	**263.5**
Net earnings for the year					42.7	42.7
Other comprehensive income						–
Total comprehensive income					**42.7**	**42.7**
Share based compensation	23			3.0		3.0
New share issues		0.1				0.1
Closing shareholders' equity at December 31, 2017		**14.1**	**290.8**	**1,195.9**	**–1,191.4**	**309.4**
Opening shareholders' equity at January 1, 2018						
Net earnings for the year					105.3	105.3
Other comprehensive income						–
Total comprehensive income					**105.3**	**105.3**
Share based compensation	23			2.1		2.1
New share issues		0.1				0.1
Closing shareholders' equity at December 31, 2018		**14.2**	**290.8**	**1,198.1**	**–1,086.2**	**416.9**

Parent Company Cash Flow Statement

SEK million	Notes	2018	2017
Operating activities			
Operating earnings		58.1	63.3
Adjustment for non-cash items	32	14.4	30.4
Interest received		0.5	0.9
Interest paid		–14.8	–15.6
Tax paid		–	–
Cash flow from operating activities before change in working capital		**58.2**	**79.0**
Change in working capital			
Change in inventories		31.0	83.3
Change in accounts receivable and other current receivables		–1.9	–85.5
Change in current liabilities		–5.4	19.7
Cash flow from operating activities		**81.9**	**96.5**
Investing activities			
Acquisition of tangible fixed assets	14	–2.9	–1.1
Acquisition of intangible assets	15	–0.7	–0.5
Cash flow from investing activities		**–3.6**	**–1.6**
Financing activities			
New share issue		0.1	0.1
Buyback of shares		–0.1	–
Issuance of corporate bonds	25	–	319.2
Buyback of corporate shares	25	–	–404.7
Cash flow from financing activities		**0.0**	**–85.4**
Cash flow for the year		**78.3**	**9.5**
Cash and cash equivalents at beginning of period		215.1	211.7
Exchange-rate differences in cash and cash equivalents		9.8	–6.1
Change in liquidity		88.1	3.4
Cash and cash equivalents at end of period	22	**303.2**	**215.1**

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 19, 2019

The statement of operations and balance sheet will be presented to the Annual General Meeting on April 11, 2019 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. It has been prepared in accordance with the cost method unless otherwise stated below

The Parent Company applies the same accounting policies as the Group. 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.

2.1.1 Amendments to accounting policies and disclosures

IFRS 16 Leasing has not entered into force at the closing date and it has not been applied in the preparation of the Group and the parent company financial reports, see (b) below. Other new or changed standards or interpretations published by the IASB are not expected to have any impact on the Group's or the parent company's financial statements.

(a) New and amended standards applied by the Group

- IFRS 15 Revenue from contracts with customers, replaces all of the earlier published standards and interpretations that handle revenue with one overall model for revenue recognition. The Group applies the new standard in its entirety from January 1, 2018 and an evaluation has been made regarding IFRS 15 and its effects on the company's accounts which did not result in material changes except further disclosure requirements, see Note 5. The Group applies the standard retroactively for each previously reported reporting period.
- IFRS 9 Financial instruments, comprises accounting for financial assets and liabilities and replace IAS 39. The Group applies it the new standard in its entirety as of January 1, 2018 and one assessment of IFRS 9 and its effects on the company's accounts shows that there is no material impact.

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

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 the cost into interest payments and depreciation of the asset. The standard is applied by the Group and the Parent Company as from January 1, 2019. Orexo applies the simplified transition method and the main impact on Orexo's accounts derive from the accounting of lease contracts premises. The in-depth effect on the balance sheet in the Group as of January 1, 2019, are a lease asset (right-of use) and a leasing debt respectively of SEK 74.1 million each.

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.

The parent company's bank balances in foreign currency are translated to the functional currency according to the exchange rates applicable on the transaction date. Exchange-rate gains and losses arising from the translation are recognized in the statement of operations financial income and 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 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:

Improvements leasehold	20 years
Machinery and equipment	5 years
Computers	3–5 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 until the project reaches the stage that the activation criterias under IAS 38 are met. 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	5 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 for held assets 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). 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. A receivable is recognized when the company has performed and there is a contractual obligation for the counterparty to pay. A liability is recognized when the counterparty has performed and there is a contractual obligation to pay. The business model for which the financial asset or liability was acquired or entered into and the nature of the contractual cash flows is crucial for the classification. Group financial assets and liabilities are classified in the categories shown below:
- Financial assets at amortized cost
- Financial liabilities at amortized cost

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 interest-bearing liabilities. During the financial year and the comparative year, the Group did not have any financial instruments that are valued at fair value, either through profit or other comprehensive income. During the comparative year, the Group held financial assets classified as loan receivables and accounts receivable according to IAS 39. These have in all material respects been reported in the same way as financial assets at amortized cost according to IFRS 9.

Financial assets classified at amortized cost are initially measured at fair value with the addition of transaction costs. Receivables against customers are initially recognized at the invoiced value. After the first accounting opportunity, the assets are valued according to the effective interest method. Assets classified at amortized cost are held according to the business model to collect contractual cash flows

that are only payments of principal amounts and interest on the outstanding capital amount. The assets are covered by a loss reserve for expected loan losses.

Financial liabilities recognized at amortized cost are initially measured at fair value including transaction costs. After the first accounting date, they are valued at accrued acquisition value according to the effective interest method.

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 reported at amortized cost less depreciation. 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 Interest-bearing liabilities

Interest-bearing liabilities are reported at accrued acquisition value. 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.

2.15 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.

2.16 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.

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.

2.17 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 23.

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 over the vesting period. 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.

(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.

2.18 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 when ownership rights are transferred to the customer, which usually is when the goods are delivered to the retailers which are the Group's customers. The transaction price is usually not known at the time of delivery, as the final price depends on the discount that will be paid to the public or private insurers which pays the patients' drug costs. Because the final transaction price is not known, the Group estimates a discount deduction from a statistical model that is based on prescription data. Retailers have the right to return unsold goods, and therefore the Group estimates a deduction for expected future returns. Revenues from the sale of goods is only reported to the extent that it is very likely that a substantial reversal of accumulated revenue which is reported does not occur when the uncertainty associated with the estimated price deduction ceases.

(b) 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. In cases where royalty income for the period is not known, these are estimated based on the company's forecast. Income from royalties is reported only to the extent that it is very likely that an essential reversal of reported accumulated revenues does not occur when the uncertainty associated with the estimated sales ceases.

(c) License revenues
Revenue from milestone payments is reported at that time when the commitment to transfer intellectual property rights to the counterparty has been fulfilled, and the uncertainty about it that the milestone will be achieved has ceased. Orexo's license agreement usually includes one or more of the following types milestone payments:

- One-time compensation when entering into an agreement. Usually refers to the right to register, market and sell Orexos patent protected products within a specified geographical area but can also constitute compensation for technology or knowledge transfer that must take place to the partner.
- Compensation for research collaboration. These are obtained continuously and is reported over the time it relates and the work is performed. Milestones fall out when research goals or sales targets have reached according to definitions in each agreement, for example when granting of patent, termination of clinical trial or approval of registrations. Such remuneration is reported when all the conditions for remuneration according to the agreement is met, and the uncertainty thus has ceased.

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

2.19 Leasing
Leases where the lessor maintains all risks and benefits of ownership of the asset or assets are classified as operating leases. Leasing fees are expensed on a straight-line basis in the income statement during the contract period. Initial consideration is given to any incentives received upon the signing of the lease. Orexo has only entered into leases that are reported as operating leases.

2.20 Cost of goods sold
Cost of goods sold consists of the cost of goods for the products that the Group sells. This includes costs for raw materials, direct and indirect cost of goods.

2.21 Basis for preparation of the financial statements for the 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.

Presentation forms
The statement of operations and balance sheet comply with the forms set down in the Swedish Annual Accounts Act.

(a) 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".

(b) 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.

c) 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.

d) 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 and euros. Revenues and expenses in foreign currency give rise to transaction exposure. The Group has assets (accounts receivable and liquid funds) 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 and EUR.

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. No hedging instruments have been used by the Group during the year.

A substantial share of Orexo's operating expenses is in currencies other than SEK, primarily USD, which leads to a certain amount of currency risks. During the 2018 fiscal year, sales in USD accounted for 83 (83) percent of net revenues and sales in EUR accounting for 17 (17) percent. During the same period, 77 (77) percent of total operating expenses were in foreign currency with 61 (74) percent in USD and 1 (1) percent in EUR.

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 SEK 5,8 million.

The corresponding change in EUR entails a change of approximately SEK 0.03 million and 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 SEK 9.1 million.

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 SEK 320.6 million on December 31, 2018 and these are attributable to a corporate bond loan. This loan has a variable interest rate, STIBOR +4.5 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 SEK 1.6 million.

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 two categories of payment flows in which credit risks could arise: in the subsidiary Orexo US Inc's sales to distributors and in the payment flows from Orexo's license agreements with other parties.

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, 2018, the four largest customers accounted for 72 percent. No other single customer accounted for more than 2 percent of total accounts receivable. Note 19 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, 2018	Less than 1 year	Between 1 and 2 years	Between 2 and 5 years
Accounts payable	47.7	–	–
Accrued costs	165.0	–	–
Borrowings	14.6	14.6	337.9

At December 31, 2017	Less than 1 year	Between 1 and 2 years	Between 2 and 5 years
Accounts payable	45.5	–	–
Accrued costs	97.2	–	–
Borrowings	14.6	14.6	352.5

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

Note 3 cont.

this can lead to significant changes in market access. By the end of 2018 Zubsolv® had access to 97 percent of the commercial category and 38 percent of the public category 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 section 'Corporate Governance Report 2018'.

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, 2018 and 2017 is presented in the table below:

	2018	2017
Shareholders' equity	476.1	329.1
Total assets	1,286.7	1,003.9
Equity/assets ratio	**37%**	**33%**

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 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.

No indication of impairment need has been identified during the year.

(b) 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 has occured. When reporting the royalty income, an estimate of the sale of the period is required.

(c) Revenues from sale of goods

Revenues from Zubsolv are recognized when they are delivered 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. Since 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.

(d) Inventory valuation

In order to ensure safe supply of Zubsolv in the American market, Orexo has established 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.

(e) Deferred tax assets

Orexo has significant loss carry-forwards as historically the company has made losses. Carry-forwards losses are activated only to the extent that it is probable that the deductions can be offset against surplus on future taxation. The loss carry-forwards for tax purposes in the Group amounted to SEK 1,414 million (1,459) at December 31, 2018 from which SEK 60.9 million has been activated.

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"

(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.

(c) Research and development

Costs attributable to research are expensed as they arise. Assessments of which costs can be capitalized or not are done continuously. 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 2018 these costs amounted to SEK 166.8 million (134.2).

NOTE 5 REVENUE FROM CONTRACTS WITH CUSTOMERS

	2018				
Group	**Zubsolv®**	**Abstral®**	**Edluar®**	**OX-CLI**	**Total**
Type of revenue					
Sales, products	626.9	–	–	–	**626.9**
Royalties	0.1	118.8	6.6	–	**125.4**
Milestones	30.8	–	–	–	**30.8**
Total revenue from contracts with customers	**657.8**	**118.8**	**6.6**	**0.0**	**783.1**
Geographical markets					
US	621.5	4.8	0.7	–	**627.0**
EU	36.2	90.1	1.2	–	**127.5**
Rest of the world	–	24.0	4.7	–	**28.6**
Total revenue from contracts with customers	**657.8**	**118.8**	**6.6**	**0.0**	**783.1**

	2017				
Group	**Zubsolv**	**Abstral**	**Edluar**	**OX-CLI**	**Total**
Summa					
Sales, products	491.4	–	–	–	**491.4**
Royalties	–	113.2	17.3	–	**130.5**
Milestones	–	–	–	21.8	**21.8**
Total revenue from contracts with customers	**491.4**	**113.2**	**17.3**	**21.8**	**643.7**
Geographical markets					
US	485.5	5.1	10.2	–	**501.0**
EU	5.6	88.6	0.8	21.8	**116.8**
Rest of the world	–	19.5	6.3	–	**25.8**
Total revenue from contracts with customers	**491.4**	**113.2**	**17.3**	**21.8**	**643.7**

	2018				
Parent Company	**Zubsolv**	**Abstral**	**Edluar**	**OX-CLI**	**Total**
Type of revenue					
Sales, products (intragroup)	246.0	–	–	–	**246.0**
Sales, products	5.3	–	–	–	**5.3**
Royalties	0.1	118.8	6.6	–	**125.4**
Milestones	30.8	–	–	–	**30.8**
Total revenue from contracts with customers	**282.2**	**118.8**	**6.6**	**0.0**	**407.6**
Geographical markets					
US	246.0	4.8	0.7	–	**251.3**
EU	36.2	90.1	1.2	–	**127.5**
Rest of the world	–	24.0	4.7	–	**28.6**
Total revenue from contracts with customers	**282.2**	**118.8**	**6.6**	**0.0**	**407.6**

Note 5 cont.

Parent Company	2017 Zubsolv®	Abstral®	Edluar®	OX-CLI	Total
Summa					
Sales, products (intragroup)	320.0	–	–	–	**320.0**
Sales, products	5.6	–	–	–	**5.6**
Royalties	–	113.2	17.3	–	**130.5**
Milestones	–	–	–	21.8	**21.8**
Total revenue from contracts with customers	**325.6**	**113.2**	**17.3**	**21.8**	**477.8**
Geographical markets					
US	320.0	5.1	10.2	–	**335.2**
EU	5.6	88.6	0.8	21.8	**116.8**
Rest of the world	–	19.5	6.3	–	**25.7**
Total revenue from contracts with customers	**325.6**	**113.2**	**17.3**	**21.8**	**477.8**

Sales, products
Revenues for the sale of goods are reported in its entirety at the time when the control of the goods is transferred to the counterparty, which is usually when the goods are delivered to the wholesalers who are the Group's customers. The transaction price is usually not known at the time of delivery, as the final price is dependent on the discount that will be paid to the public or private insurers who pay patients' drug costs. Since the final transaction price is not known, the Group estimates a discount deduction based on a statistical model that is based, among other things, on prescription data. The cumulative discount deduction is reported in the item provisions, and amounted to SEK 225.2 million (176.2) at the balance sheet date. Retailers have the right to return unsold goods, and the Group therefore estimates a deduction for expected future returns. The accumulated return deduction is reported under the item provisions, and amounted to SEK 40.6 million (24.7) at the balance sheet date. During the period, the Group reversed provisions for discounts and returns from previous periods to an amount of SEK 21.0 million (0.0). Estimates of discounts and returns are associated with significant uncertainty, see Note 4.

Royalties
Revenues from royalties are recognized at the time when the commitment to transfer intellectual property rights to the counterparty has been fulfilled, and the sales that form the basis of royalties have occurred. In practice, this means that revenues from royalties for such products where the transfer of the intellectual property rights has already taken place are reported when the sale of the goods that form the basis of royalties takes place. The Group usually does not receive information on actual sales in connection with the financial statements, and therefore estimates earned royalties during the end of the period. The estimate of earned royalties is associated with significant uncertainty, see Note 4.

Milestones
Revenues from milestone payments are reported at the time when the obligation to transfer intellectual property rights to the counterparty has been fulfilled, and the uncertainty about the milestone being achieved has ceased. In practice, this means that revenue from milestone payments for such products where the transfer of the intellectual property assets has already taken place are reported when the milestones are achieved.

Other
The Group's sales are mainly based on payment terms on 0–45 days, and no elements of significant financing components exist. The Group reports receivables against counterparties at the time of sale, and at the balance sheet date there were no contractual assets or contractual liabilities. No significant unfulfilled or partially fulfilling performance commitments existed on the balance sheet date.

NOTE 6 COSTS BY TYPE OF COST

	Group		Parent Company	
	2018	2017	2018	2017
Raw materials and consumables	171.8	147.6	116.2	150.6
Other external expense	361.3	298.9	168.3	212.7
Personnel costs	165.1	157.2	66.1	68.8
Depreciation/amortization and impairment	20.8	20.8	20.6	20.6
Total	**718.9**	**624.5**	**371.2**	**452.7**

NOTE 7 OTHER OPERATING INCOME

	Group		Parent Company	
	2018	2017	2018	2017
Exchange gains	18.5	13.3	18.5	13.3
Other income	–	0.2	44.7	0.2
Gains on disposal of assets	–	24.6	–	24.6
Total	**18.5**	**38.1**	**63.2**	**38.1**

Other income refers to a transfer pricing related regulation, i.e. the profit of the US subsidiary is regulated to a percentage of sales. Excess profit goes to the parent company.

NOTE 8 DEPRECIATION/AMORTIZATION AND IMPAIRMENT

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

	Group		Parent Company	
	2018	2017	2018	2017
Tangible fixed assets				
Sales	0.2	0.2	–	–
Administration	1.8	1.8	1.8	1.8
Research and development	1.0	1.1	1.0	1.1
Total tangible fixed assets	**3.0**	**3.1**	**2.8**	**2.9**
Intangible assets				
Administration	0.2	0.1	0.2	0.1
Research and development	17.6	17.6	17.6	17.6
Total intangible assets	**17.8**	**17.7**	**17.8**	**17.7**
Total depreciation/amortization and impairment	**20.8**	**20.8**	**20.6**	**20.6**

NOTE 9 REMUNERATION TO EMPLOYEES

Average number of employees

Group	2018 Average number of employees	Of whom men	2017 Average number of employees	Of whom men
Sweden	55	25	54	24
USA	48	17	42	18
Total for Group	**103**	**42**	**96**	**42**

Parent Company	2018 Average number of employees	Of whom men	2017 Average number of employees	Of whom men
Sweden	55	25	54	24
Total for Parent Company	**55**	**25**	**54**	**24**

	Group		Parent Company	
Costs and remuneration to all employees and Board, SEK thousands	2018	2017	2018	2017
Salaries, remuneration and social security fees				
Salaries and other remuneration to the Board, President and Executive Management	27,279	28,415	15,957	16,781
Salaries and other remuneration to other employees	89,632	89,669	30,448	30,046
Pension cost for the Board, President and Executive Management[1]	2,080	1,565	1,794	1,288
Pension cost for other employees[1]	8,829	9,580	6,563	7,183
Social security fees for the Board, President and Executive Management[2]	4,152	5,800	3,571	5,146
Social security fees for other employees[2]	13,745	13,839	9,513	10,021
Other personnel costs	17,122	16,165	2,460	3,391
Total	**162,839**	**165,032**	**70,305**	**73,856**

[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 9 cont.

Costs and remuneration to the Board, President and senior executives 2018

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	–	–	–	–	–	700
Henrik Kjaer Hansen, Board member	200	–	–	–	–	–	200
Raymond Hill, Board member	200	–	–	–	–	–	200
Staffan Lindstrand, Board member	300	–	–	–	–	–	300
Kristina Schauman, Board member	400	–	–	–	–	–	400
David Colpman, Board member	200	–	–	–	–	–	200
Kirsten Detrick, Board member	200	–	–	–	–	–	200
Subtotal	**2,200**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**2,200**
President and senior executives							
Nikolaj Sørensen, President and CEO	3,126	1,228	104	575	317	–	5,349
Other senior executives (5)	15,342	4,530	215	1,506	603	–	22,195
Total	**20,668**	**5,758**	**319**	**2,080**	**920**	**0.0**	**29,744**

Costs and remuneration to the Board, President and senior executives 2017

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	650	–	–	–	122	–	772
Michael Shalmi, Board member	200	–	–	–	–	–	200
Raymond Hill, Board member	200	–	–	–	–	–	200
Staffan Lindstrand, Board member	250	–	–	–	–	–	250
Kristina Schauman, Board member	400	–	–	–	–	–	400
David Colpman, Board member	200	–	–	–	–	176	376
Kirsten Detrick, Board member	200	–	–	–	–	–	200
Subtotal	**2,100**	**0.0**	**0.0**	**0.0**	**122**	**176**	**2,398**
President and senior executives							
Nikolaj Sørensen, President and CEO	3,012	1,198	102	647	506	–	5,465
Other senior executives (5)	14,701	5,232	256	918	1,009	–	22,117
Total	**19,813**	**6,430**	**358**	**1,565**	**1,637**	**176**	**29,980**

Board members and senior executives	2018		2017	
	Number on the closing date	of whom men	Number on the closing date	of whom men
Group (incl. subsidiaries)				
Board members	7	71%	7	71%
President and other senior executives	6	100%	6	100%
Parent Company				
Board members	7	71%	7	71%
President and other senior executives	4	100%	4	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, 2018 refers to Robert A. DeLuca, Michael Sumner, Johannes Doll, Jesper Lind (senior executive until December 31, 2018), Henrik Juuel (CFO until October 31, 2018) and Joseph DeFeo (CFO from November 1, 2018).

The number of shares and options held by the President and senior executives is shown in the information regarding the Board on page 86 and Management on page 87. Refer to Note 23 for a description of the share-based remuneration.

NOTE 10 EXCHANGE-RATE DIFFERENCES

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

Restated	Group		Parent Company	
	2018	2017	2018	2017
Other operating income	18.5	13.3	18.5	13.3
Other operating expenses	–12.3	–17.4	–12.3	–17.4
Total	**6.2**	**–4.1**	**6.2**	**–4.1**

NOTE 11 FINANCIAL INCOME AND EXPENSES

	Group		Parent Company	
	2018	2017	2018	2017
Financial income				
Interest income from group	–	–	–	0.1
Other interest income	3.0	0.1	0.5	0.1
Buyback of corporate bonds	–	0.1	–	0.1
Exchange rate effect	32.3	–	32.3	–
Other financial income	–	–	–	0.7
Total financial income	**35.3**	**0.2**	**32.8**	**1.0**
Financial expenses				
Interest expense from corporate bonds	–14.8	–14.8	–14.8	–14.8
Other interest expense	–0.1	–	–0.1	–
Borrowingcosts, corporate bonds	–1.6	–7.1	–1.6	–7.1
Exchange rate effect	–22.4	–6.0	–22.4	–7.3
Total financial expenses	**–38.9**	**–27.9**	**–38.9**	**–29.2**
Net Financial items	**–3.6**	**–27.7**	**–6.1**	**–28.2**

NOTE 12 TAX

	Group		Parent Company	
	2018	2017	2018	2017
Current tax	–18.8	–10.0	–	–
Deferred tax	64.5	3.5	53.3	7.6
Total	**45.7**	**–6.5**	**53.3**	**7.6**
Difference between the Group's tax expense and tax expense based on current tax rate				
Recognized pre-tax earnings	92.2	29.7	52.0	35.1
Tax under current tax rate	–20.3	–6.5	–11.4	–7.7
Tax effect of foreign tax rates	–0.7	–5.0	–	–
Tax effect of non-taxable income	–	–	–	–
Tax effect of non-deductible costs	–0.3	–0.2	–0.3	–0.2
Recognized carry-forward losses	60.9	7.6	60.9	7.6
Unrecognized carry-forward losses	11.5	7.9	6.5	7.9
Effect of change in tax rate	–5.4	–10.3	–2.4	–
Tax on earnings for the year according to the statement of operations	**45.7**	**–6.5**	**53.3**	**7.6**

NOTE 13 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	
	2018	2017
Earnings used for the calculation of earnings per share before dilution, MSEK	137.9	23.2
Average number of shares before dilution	34,560,456	34,540,271
Earnings per share before dilution (SEK per share)	3.99	0.67
Average number of shares after dilution	35,095,980	34,650,835
Earnings per share after dilution (SEK per share)	3.93	0.67
Options outstanding	1,627,514	1,664,510

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 and share rights.

	2018	2017
Average number of shares before dilution	34,560,456	34,540,271
Potential shares from options and share rights	535,524	110,564
Average number of shares after dilution	35,095,980	34,650,835

NOTE 14 TANGIBLE FIXED ASSETS

Group	Equipment and machinery	Computers	Improvement expenses other's property	Total
Fiscal year 2017				
Opening balance	33.7	3.6	36.2	73.5
Acquisitions	1.1	–	–	1.1
Outgoing accumulated acqusitions	**34.8**	**3.6**	**36.2**	**74.6**
Ingoing depreciation	–31.6	–3.0	–16.8	–51.4
Depreciation	–0.9	–0.4	–1.8	–3.1
Accumulated depreciation	**–32.5**	**–3.4**	**–18.6**	**–54.5**
At December 31, 2017				
Cost	34.8	3.6	36.2	74.6
Accumulated depreciation and impairment	–32.5	–3.4	–18.6	–54.5
Carrying amount	**2.3**	**0.2**	**17.7**	**20.1**
Fiscal year 2018				
Opening balance	34.8	3.6	36.2	74.6
Acquisitions	2.9	–	–	2.9
Outgoing accumulated acqusitions	**37.7**	**3.6**	**36.2**	**77.5**
Ingoing depreciation	–32.5	–3.4	–18.6	–54.5
Depreciation	–1.0	–0.2	–1.8	–3.0
Accumulated depreciation	**–33.4**	**–3.5**	**–20.4**	**–57.5**
At December 31, 2018				
Cost	37.7	3.6	36.2	77.5
Accumulated depreciation and impairment	–33.4	–3.5	–20.4	–57.5
Carrying amount	**4.3**	**0.1**	**15.8**	**20.0**

Note 14 cont.

Parent Company	Equipment and machinery	Computers	Improvement expenses other's property	Total
Fiscal year 2017				
Opening balance	30.2	1.8	36.2	68.2
Acquisitions	1.1	–	–	1.1
Outgoing accumulated acqusitions	**31.3**	**1.8**	**36.2**	**69.3**
Ingoing depreciation	–28.7	–1.0	–16.7	–46.5
Depreciation	–0.7	–0.4	–1.8	–2.9
Accumulated depreciation	**–29.4**	**–1.4**	**–18.5**	**–49.4**
At December 31, 2017				
Cost	31.3	1.8	36.2	69.3
Accumulated depreciation and impairment	–29.4	–1.4	–18.5	–49.4
Carrying amount	**1.9**	**0.4**	**17.7**	**19.8**
Fiscal year 2018				
Opening balance	31.3	1.8	36.2	69.3
Acquisitions	2.9	–	–	2.9
Outgoing accumulated acqusitions	**34.2**	**1.8**	**36.2**	**72.2**
Ingoing depreciation	–29.4	–1.4	–18.5	–49.4
Depreciation	–0.7	–0.3	–1.8	–2.8
Accumulated depreciation	**–30.1**	**–1.7**	**–20.3**	**–52.2**
At December 31, 2018				
Cost	34.2	1.8	36.2	72.2
Accumulated depreciation and impairment	–30.1	–1.7	–20.3	–52.2
Carrying amount	**4.1**	**0.1**	**15.9**	**20.0**

NOTE 15 INTANGIBLE FIXED ASSETS

Group	Acquired R&D	Patents and rights	Proprietary intellectual property right	Other	Total
Fiscal year 2017					
Opening balance	435.1	27.4	153.6	12.2	628.3
Acquisitions	–	–	–	0.5	0.5
Outgoing accumulated acqusitions	**435.1**	**27.4**	**153.6**	**12.7**	**628.8**
Accumulated amortization and impairment	–435.1	–27.4	–21.8	–5.8	–490.1
Amortization	–	–	–15.3	–2.4	–17.7
Accumulated amortization and impairment	**–435.1**	**–27.4**	**–37.1**	**–8.2**	**–507.8**
At December 31, 2017					
Cost	435.1	27.4	153.6	12.7	628.8
Accumulated amortization and impairment	–435.1	–27.4	–37.1	–8.2	–507.8
Carrying amount	**0.0**	**0.0**	**116.5**	**4.5**	**121.0**
Fiscal year 2018					
Opening balance	435.1	27.4	153.6	12.7	628.8
Acquisitions	–	–	–	0.7	0.7
Outgoing accumulated acqusitions	**435.1**	**27.4**	**153.6**	**13.4**	**629.5**
Accumulated amortization and impairment	–435.1	–27.4	–37.1	–8.2	–507.8
Amortization	–	–	–15.4	–2.4	–17.8
Accumulated amortization and impairment	**–435.1**	**–27.4**	**–52.5**	**–10.6**	**–525.6**
At December 31, 2018					
Cost	435.1	27.4	153.6	13.4	629.5
Accumulated amortization and impairment	–435.1	–27.4	-52.5	–10.6	–525.6
Carrying amount	**0.0**	**0.0**	**101.1**	**2.8**	**103.9**

Note 15 cont.

Parent company	Acquired R&D	Patents and rights	Proprietary intellectual property right	Other	Total
Fiscal year 2017					
Opening balance	435.1	27.4	153.6	12.2	628.3
Awcquisitions	–	–	–	0.5	0.5
Outgoing accumulated acqusitions	**435.1**	**27.4**	**153.6**	**12.7**	**628.8**
Accumulated amortization and impairment	–435.1	–27.4	–21.8	–5.8	–490.1
Amortization	–	–	–15.3	–2.4	–17.7
Accumulated amortization and impairment	**–435.1**	**–27.4**	**–37.1**	**–8.2**	**–507.8**
At December 31, 2017					
Cost	435.1	27.4	153.6	12.7	628.8
Accumulated amortization and impairment	–435.1	–27.4	–37.1	–8.2	–507.8
Carrying amount	**0.0**	**0.0**	**116.5**	**4.5**	**121.0**
Fiscal year 2018					
Opening balance	435.1	27.4	153.6	12.7	628.8
Acquisitions	—	—	—	0.7	0.7
Outgoing accumulated acqusitions	**435.1**	**27.4**	**153.6**	**13.4**	**629.5**
Accumulated amortization and impairment	–435.1	–27.4	–37.1	–8.2	–507.8
Amortization	—	—	-15.4	–2.4	–17.8
Accumulated amortization and impairment	**–435.1**	**–27.4**	**–52.5**	**–10.6**	**–525.6**
At December 31, 2018					
Cost	435.1	27.4	153.6	13.4	629.5
Accumulated amortization and impairment	–435.1	–27.4	–52.5	–10.6	–525.6
Carrying amount	**0.0**	**0.0**	**101.1**	**2.8**	**103.9**

Proprietary intangible asset at December 31, 2018
A proprietary intangible asset amounting to SEK 101.1 million (116.5) 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 SEK 166.8 million (134.2).

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

NOTE 16 RESERVES

	Translation reserve	Total
Opening balance at January 1, 2017	**0,2**	**0,2**
Translation differences	–7,5	–7,5
Closing balance at December 31, 2017	**–7,3**	**–7,3**
Translation differences	–7.0	–7.0
Closing balance at December 31, 2018	**–0.3**	**–0.3**

NOTE 17 INFORMATION ON FINANCIAL INSTRUMENTS IN THE GROUP

Classification and categorization of assets and liabilities in the Group 2018

December 31, 2018	Loans and accounts receivable	Total financial assets	Non-financial assets	Total
Assets				
Tangible fixed assets	–	**0.0**	20.0	**20.0**
Intangible fixed assets	–	**0.0**	103.9	**103.9**
Deferred tax asset	–	**0.0**	92.8	**92.8**
Inventories	–	**0.0**	173.6	**173.6**
Financial assets	10.4	**10.4**	–	**10.4**
Accounts receivable	264.5	**264.5**	–	**264.5**
Other current receivables	–	**0.0**	5.9	**5.9**
Prepaid expenses and accrued income	–	**0.0**	25.7	**25.7**
Cash and cash equivalents	589.8	**589.8**	–	**589.8**
Total assets	**864.7**	**864.7**	**421.9**	**1,286.7**

December 31, 2018	Financial liabilities measured at amortized cost	Total financial liabilities	Non-financial liabilities	Total
Shareholders' equity and liabilities				
Shareholders' equity	–	**0.0**	476.1	**476.1**
Long-term liabilities, provision	–	**0.0**	6.5	**6.5**
Borrowings	320.6	**320.6**	–	**320.6**
Accounts payable	47.7	**47.7**	–	**47.7**
Provisions	–	**0.0**	265.8	**265.8**
Other current liabilities	135.1	**135.1**	2.8	**137.9**
Prepaid expenses	22.3	**22.3**	9.7	**32.0**
Total shareholders' equity and liabilities	**525.7**	**525.7**	**760.9**	**1,286.7**

Note 17 cont.

Classification and categorization of assets and liabilities in the Group 2017

December 31, 2017	Accounts receivable and loans	Total financial assets	Non-financial assets	Total
Assets				
Tangible fixed assets	–	**0.0**	20.1	**20.1**
Intangible fixed assets	–	**0.0**	121.0	**121.0**
Deferred tax asset	–	**0.0**	28.3	**28.3**
Inventories	–	**0.0**	250.2	**250.2**
Financial assets	7.1	**7.1**	–	**7.1**
Accounts receivable	218.4	**218.4**	–	**218.4**
Other current receivables	–	**0.0**	7.4	**7.4**
Prepaid expenses and accrued income	–	**0.0**	23.5	**23.5**
Cash and cash equivalents	327.9	**327.9**	–	**327.9**
Total assets	**553.4**	**553.4**	**450.5**	**1,003.9**

December 31, 2017	Financial libailities measured at amortized cost	Total financial liabilities	Non-financial liabilities	Total
Shareholders' equity and liabilities				
Shareholders' equity	–	**0.0**	329.1	**329.1**
Long-term liabilities, provision	–	**0.0**	5.8	**5.8**
Borrowings	319.1	**319.1**	–	**319.1**
Accounts payable	45.5	**45.5**	–	**45.5**
Provisions	–	**0.0**	200.9	**200.9**
Other current liabilities	2.0	**2.0**	12.2	**14.2**
Prepaid expenses	86.4	**86.4**	2.9	**89.3**
Total shareholders' equity and liabilities	**453.0**	**453.0**	**550.9**	**1,003.9**

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 SEK 327.4 million (based on liquid trading price), the carrying value amounted to SEK 320.6 million.

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 25.

NOTE 18 INVENTORIES

	Group		Parent Company	
	2018	2017	2018	2017
Raw materials	109.8	124.4	109.8	124.4
Work in progress	44.1	60.5	44.1	60.6
Finished products	19.7	65.3	1.4	1.3
Total	**173.6**	**250.2**	**155.3**	**186.3**

The cost of goods from inventory expensed in the Group amounted to SEK 172.7 million (148.0) and in the Parent Company to SEK 111.7 million (153.8).

NOTE 19 ACCOUNTS RECEIVABLE

Impairment losses on accounts receivable amounted to SEK 0.3 million (0.0) in the Group. The carrying amount corresponds to fair value since all receivables are current and are due within one year.

In the Parent company Impairment losses on accounts receivable amounted to SEK 0.0 million (0.0). The carrying amount corresponds to fair value.

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

	Group		Parent Company	
	2018	2017	2018	2017
SEK	3.0	–	3.0	–
USD	210.7	164.0	9.2	6.7
EUR	50.8	54.4	50.8	54.4
Total	**264.5**	**218.4**	**63.0**	**61.1**

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, SEK 236.3 million (190.1) is held by the Group's four largest customers. Each of the following:

	Group	
	2018	2017
Customer 1	78.8	67.7
Customer 2	61.3	48.4
Customer 3	51.0	46.3
Customer 4	45.1	27.8
Total	**236.3**	**190.1**

Accounts receivable due

At December 31, 2018, accounts receivable amounting to SEK 40.5 million (12.5) 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	
	2018	2017	2018	2017
Less than 30 days	34.4	9.9	–	–
31 days and older	6.1	2.6	–	–
Total	**40.5**	**12.5**	**0.0**	**0.0**

NOTE 20 OTHER RECEIVABLES

	Group		Parent Company	
	2018	2017	2018	2017
VAT receivable	2.7	2.1	2.7	2.1
Tax receivable[1]	2.7	2.7	–	–
Other	0.5	2.6	0.5	2.6
Total	**5.9**	**7.4**	**3.2**	**4.7**

[1] See Note 12.

NOTE 21 PREPAID EXPENSES AND ACCRUED INCOME

	Group		Parent Company	
	2018	2017	2018	2017
Prepaid rents	4.1	4.1	4.1	4.1
Other interim receivables	21.5	19.4	8.1	6.7
Total	**25.7**	**23.5**	**12.2**	**10.8**

NOTE 22 CASH AND CASH EQUIVALENTS

	Group		Parent Company	
	2018	2017	2018	2017
Cash and bank balances	589.8	327.9	303.2	215.1
Total	**589.8**	**327.9**	**303.2**	**215.1**

The Group has no unused credit facilities at December 31, 2018.

Reported amounts in SEK million per currency for the Group's cash and cash equivalents is presented below:

	Group		Parent Company	
	2018	2017	2018	2017
SEK	25.7	36.1	11.6	21.9
USD	482.2	223.9	209.7	125.4
EUR	81.9	67.6	81.9	67.6
GBP	0.1	0.2	0.1	0.2
Total	**589.8**	**327.9**	**303.2**	**215.1**

NOTE 23 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.

As of December 31, 2018 there were a total of 1,784,814 options outstanding, providing entitlement to subscription for 877,719 new shares in Orexo and 750,962 provide entitlement to an exchange for shares in Orexo. The number of share awards is 750,962 and each share award provides entitlement to one share. Options and share awards are paid for through shareholders' equity.

Options and share options whose earnings are dependent on non-market conditions of performance are valued with the Black & Scholes model, and options and share options whose earnings are dependent on performance conditions that are market terms are valued through Monte Carlo simulations.

The share price and the risk-free rate used are the valid ones at the valuation date. The volatility taken into account in the valuation is based on the historical volatility of the stock over a period of 2–7 years.

Cost per fiscal year	Total cost
2017	–3.0
2018	–2.1

Employee stock options/share awards allotted	Number	Exercise price, weighted average
At Dec 31, 2016	**1,784,794**	**63**
Allotted during the period	298,000	–
Redeemed during the period	–20,871	23
Forfeited during the period	–397,413	80
At Dec 31, 2017	**1,664,510**	**75**
Allotted during the period	399,650	–
Redeemed during the period	–15,368	37
Forfeited during the period	–421,278	88
At Dec 31, 2018	**1,627,514**	**78**

Employee stock options/share awards per year	Number outstanding at Dec 31, 2018	Number vested at Dec 31, 2018	Exercise price, range	Value per allotted option, range	Volatility, option, weighted average	Value per share, range	Value per option weighted average	Maturity date
2011 (LTIP2011)	95,909	95,909	29.0—47.8	7.37	35%	28.2	28.2	2021-02-16
2013 (LTIP2011)	607,401	569,068	51.8—131.6	15.5—44.04	35%	24.2—130.6	53.6	2021-02-16
2014 (LTIP2011)	173,242	54,442	112.9—165.1	25.7—57.04	35%	106.6—166.8	151.3	2021-02-16
2016 (LTIP2016)	140,831	0	0.0	20.4—49.5	35%	49.5	49.5	2019-05-30
2017 (LTIP2017)	214,913	0	0.0	7.5—27.4	35%	27.4	27.4	2020-06-21
2018 (LTIP2018)	395,200	0	0.0	7.1—30.2	38%	30.2	30.2	2021-06-30
Total employee stock options/share awards	**1,627,514**							

Employee stock options/share awards per year	Number outstanding at Dec 31, 2017	Number vested at Dec 31, 2017	Exercise price, range	Value per allotted option, range	Volatility, option, weighted average	Value per share, range	Value per option weighted average	Maturity date
2009 (LTIP2008)	31,250	31,250	51.0	12.0	35%	45.8	45.8	2018-12-31
2011 (LTIP2011)	95,909	95,909	29.0–47.8	7.7	35%	28.2	28.2	2021-02-16
2011 Board	4,118	4,118	0.4	43.3	35%	43.7	43.7	2018-12-31
2013 (LTIP2011)	662,178	533,178	51.8–131.6	15.5–44.0	35%	24.2–130.6	53.6	2021-02-16
2013 Board	157,300	157,300	52.4	15.5–19.7	35%	57.2	57.2	2018-04-11
2014 (LTIP2011)	219,421	47,221	112.9–165.1	25.7–57.0	35%	106.6–166.8	151.3	2021-02-16
2015 (LTIP2015)	24,297	0	0.0	13.3–78.8	35%	78.9	78.9	2018-06-18
2016 (LTIP2016)	179,787	0	0.0	20.4–49.5	35%	49.5	49.5	2019-05-30
2017 (LTIP2017)	290,250	0	0.0	7.5–27.4	35%	27.4	27.4	2020-06-21
Total employee stock options/share awards	**1,664,510**							

During 2018 the company allotted 399,650 employee stock options, of which the CEO and other senior executives were allotted 164,000, corresponding to 41 percent. The financial and operational targets set by the Board for 2018 reached a score of 100 percent and hence none of the allocated share awards pertaining to performance target 1 2018 will forfeit. In total 421,278 options were forfeited during 2018.

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

Note 23 cont.

Owned by	Number outstanding at Jan 1, 2018	Change	Number outstanding at Dec 31, 2018
CEO Nikolaj Sörensen	411,494	61,154	472,648
Board member Martin Nicklasson	157,300	–157,300	0
Board member Henrik Kjaer Hansen	0	–	0
Board member Raymond Hill	4,118	–4,118	0
Board member Staffan Lindstrand	0	–	0
Board member Kristina Schauman	0	–	0
Board member Kirsten Detrick	0	–	0
Board member David Colpman	0	–	0

Performance criteria LTIP 2011
LTIP2011 is a stock option program where half of the options are vested based on the stock price development and the remaining are vested based on the company's operational performance and time.

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.

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 2016, LTIP 2017 and LTIP 2018
LTIP2016, LTIP2017 and LTIP2018 are share-based programs where half of the shares are vested based on the share price development and the remaining vested based on the company's operational performance and time.

Performance criterion 1
This target pertains to the fulfilment of the financial and operational targets for the financial year 2016, 2017 and 2018 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 100 percent of the overall average performance of the financial and operational targets is achieved for LTIP2017 and LTIP2018. For LTIP2016, 80 percent of the overall average performance of the financial and operational targets has to be acheived. 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 for LTIP2016, from the date of the 2017 Annual General Meeting up to and including April 5, 2020 for LTIP2017 and from the date of the 2018 Annual General Meeting up to and including April 11, 2021 for LTIP2018. The share price will be measured as the volume weighted average share price 60 trading days prior to the measurement date for LTIP2016, LTIP2017 and LTIP2018. The measurement dates are date defined as the date of the 2016 Annual General Meeting and April 14, 2019, the 2017 Annual General Meeting and April 5, 2020 and the 2018 Annual General Meeting and April 11, 2021. 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 for LTIP2016, from the date of the 2017 Annual General Meeting up to and including April 5, 2020 for LTIP2017 and from the date of the 2018 Annual General Meeting up to and including April 11, 2021 for LTIP2018.

NOTE 24 PROVISIONS

	Group		Parent Company	
Long-term provisions	**2018**	**2017**	**2018**	**2017**
On January 1	**5.8**	**1.2**	**4.9**	**1.3**
Additional provisions	1.5	7.7	–	3.7
Utilized during the year	–	–0.1	–0.1	–0.1
Reversed unused amounts	-0.8	–3.0	0.1	–
Per December 31	**6.5**	**5.8**	**4.9**	**4.9**

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

	Group		Parent Company	
Short-term provisions, rebates and chargebacks	**2018**	**2017**	**2018**	**2017**
On January 1	**200.9**	**163.9**	**0.0**	**0.0**
Additional provisions	786.4	529.9	–	–
Utilized during the year	-718.4	–477.3	–	–
Reversed unused amounts	-21.0	–	–	–
Exchange rate difference	18.0	–15.6	–	–
Per December 31	**265.8**	**200.9**	**0.0**	**0.0**

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

NOTE 25 BORROWINGS

	Group	Parent Company
January 1, 2017	**400.6**	**400.6**
Repurchase bond	–404.7	–404.7
Net gain/loss from repurchase	–0.1	–0.1
Issuance of bonds	319.2	319.2
Interest expenses	14.8	14.8
Interest paid	–15.6	–15.6
Recognition of loan issuance cost	7.1	7.1
Other non-cash items	–0.2	–0.2
January 1, 2018	**321.1**	**321.1**
Repurchase bond	14.8	14.8
Interest paid	–14.8	–14.8
Recognition of loan issuance cost	1.5	1.5
December 31, 2018	**322.6**	**322.6**

The long-term portion consists of a bond loan amounting to a total of SEK 325 million. It matures on November 13, 2021. The loan has a variable interest rate of STIBOR 3 months +4.5 percent (STIBOR is calculated as zero at the lowest) and has a total framework amount of SEK 500 million. There are no covenants. The loan agreement contains limitat limitations regarding any change in the company's ownership structure, so-called change-of-control.

In 2017, the company redeemed the previous bond of SEK 342 million.

Note 25 cont.

	Group	Parent Company
2017-12-31		
Interest-bearing liabilities	319.1	319.1
Accrued interest costs	2.0	2.0
	321.1	**321.1**
2018-12-31		
Interest-bearing liabilities	320.6	320.6
Accrued interest costs	2.0	2.0
	322.6	**322.6**

NOTE 26 ACCRUED EXPENSES AND OTHER LIABILITIES

	Group		Parent Company	
Other liabilities	**2018**	**2017**	**2018**	**2017**
Employee withholding tax	1.7	1.5	1.7	1.5
Deduction, social security fees	1.2	1.2	1.2	1.2
Deduction, special salary tax	2.0	2.1	2.0	2.1
Other current liabilities	–	1.6	0.1	1.9
Sum Other liabilities	**4.9**	**6.3**	**5.0**	**6.6**

	Group		Parent Company	
Accrued expenses	**2018**	**2017**	**2018**	**2017**
Accrued salaries	15.3	12.2	2.5	2.9
Accrued vacation pay	4.7	5.3	4.7	5.3
Accrued social security fees	2.4	2.7	2.4	2.7
Accrued expenses interest rates	2.0	2.0	2.0	2.0
Other accrued expenses	47.4	43.2	–	–
Trade allowance	40.2	15.9	–	–
Wholesaler fee reserve	53.0	15.9	40.7	8.0
Sum Accrued expenses	**165.0**	**97.2**	**52.3**	**20.8**
Sum Other liabilities and Accrued expenses	**169.9**	**103.6**	**57.3**	**27.4**

NOTE 27 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	106.0
Orexo US Inc	101013414	USA	100	100%	44.6	–	44.6

All holdings are owned directly.

Change in carrying amount of direct holdings

2017	Opening carrying amount	Acqusition	Contribution	Sales	Impairment	Closing carrying amount
Pharmacall AB	0.1	–	–	–	–	0.1
Orexo US Inc	43.7	–	0.8	–	–	44.5
Biolipox AB	106.0	–	–	–	–	106.0
Total	**149.8**	**0.0**	**0.8**	**0.0**	**0.0**	**150.6**

2018	Opening carrying amount	Acquisition	Contribution	Sales	Ipairment	Closing carrying amount
Pharmacall AB	0.1	–	–	–	–	0.1
Orexo US Inc	44.5	–	1.7	–	–	46.2
Biolipox AB	106.0	–	–	–	–	106.0
Total	**150.6**	**0.0**	**1.7**	**0.0**	**0.0**	**152.3**

NOTE 28 PLEDGED ASSETS AND CONTINGENT LIABILITIES

	Group		Parent Company	
	2018	2017	2018	2017
Chattel mortgages for bank commitment	–	–	–	–
Guarantee commitment	–	–	–	–
Total	**0.0**	**0.0**	**0.0**	**0.0**

No collateral or contingent liabilities exist as at 31 December 2018.

NOTE 29 AUDITORS' FEES

	Group		Parent Company	
	2018	2017	2018	2017
Audit assignment				
Ernst & Young	2.6	3.1	2.6	3.1
Non-auditing assignments				
Ernst & Young	0.3	0.1	0.3	0.1
Tax advice				
Ernst & Young	–	0.1	–	0.1
Other services				
Ernst & Young	–	0.3	–	0.3
Total	**2.8**	**3.6**	**2.8**	**3.6**

NOTE 30 DEFERRED TAX

The tax-loss carry-forward in the Group amounts to SEK 1,414 million (1,459) as of December 31, 2018 and refers to the Swedish companies. Deferred tax assets of SEK 60.9 million have been capitalized as of December 31, 2018 of the total loss carry-forwards, which, according to the company's assessment, corresponds to the amount that meets the requirements for capitalization according to IAS 12. There is no time limit for when the remaining tax-loss carry-forwards can be utilized.

	Group		Parent Company	
	2018	2017	2018	2017
Deferred tax assets				
Capitalized tax loss carryforwards	60.9	7.6	60.9	7.6
Temporary differences in current provision	31.9	20.7	–	–
Total	**92.8**	**28.3**	**60.9**	**7.6**

Temporary differences for short-term provisions are related to non-deductible short-term provisions for sales rebates, returns, distribution and other relevant deductions in Orexo Inc. Deferred tax of SEK 60.9 million relating to Swedish companies in the Group has been activated during the period.

Deferred tax assets have, in view of the taxable income attributable to the Swedish companies in recent years, been reported only insofar as management estimates that there are factors convincingly suggesting that sufficient taxable surpluses will be generated in the future.

NOTE 31 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 relating to leasing of equipment, machinery and computers amounting to SEK 0.3 million (0.4) and leasing expenses relating to rental agreements amounting to SEK 15.6 million (16.1) are included in the income statement.

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 April 30, 2024. The nominal value of future leasing fees for lease agreements that cannot be terminated is as follows:

	Group		Parent Company	
	2018	2017	2018	2017
Falls due for payment within one year	21.4	19.0	13.3	16.8
Falls due for payment later than one year but within five years	58.4	35.2	39.9	35.2
Falls due for payment later than 5 years	0.2	–	–	–
Total	**80.0**	**54.2**	**53.2**	**52.0**

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 standard will be applied by the Group and the Parent Company as from January 1, 2019. Orexo applies the simplified transition method and the main impact on Orexo's accounts arise from the reporting of lease contract for premises. The opening effect on the consolidated balance sheet as of January 1, 2019 is that a lease asset (right-of-use asset) and a lease liability are added, each at SEK 74.1 million. The Parent company will apply the simplification rule in RFR 2 and will therefore continue to report leasing costs in accordance with existing rules for operational leasing.

NOTE 32 DISCLOSURES ON THE CASH FLOW STATEMENT

	Group		Parent Company	
	2018	2017	2018	2017
Adjustments for items not included in cash flow comprise the following:				
Depreciation and impairment	20.8	20.8	20.6	19.6
Gain/loss on disposal	–	–	–	–
Change in provisions	45.6	59.9	–0.1	3.9
Change in fair value of financial instruments	–	–	–	–
Share based payments	2.1	3.0	2.1	3.0
Exchange rate income and expense	–6.5	4.2	–6.5	3.9
Other non-cash items	–	–	–1.7	–
Total	**61.9**	**87.9**	**14.4**	**30.4**

NOTE 33 RELATED PARTY TRANSACTIONS

Purchases and sales between Group companies

The following transactions took place between the companies in the Group:

	2018	2017
Forward invoicing of costs		
Orexo US Inc	3.5	0.4
Sale of goods and services		
Orexo US Inc	246.0	318.7
Total	**249.5**	**319.1**

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 9.

There have been no other related party transactions.

NOTE 34 EVENTS AFTER THE CLOSING DATE

Positive results the OX124 human PK-study of new internasal Naloxone formulations for reversal of effects occuring in an opioid overdose.

The US District Court of Delaware issued a final, non-appealable judgement that Actavis's generic Zubsolv products infringe the US patent ´330, preventing Actavis from launching their infringing generics in the US until 2032.

NOTE 35 APPROPRIATION OF PROFIT

Proposed appropriation of profit

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

SEK thousands	
Share premium reserve	1,198,323
Loss carried forward	–1,191,631
Profit/loss for the year	105,311
Total	**112,003**

The Board proposes that the funds at their disposal SEK 112,003 thousands be carried forward.

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, Sweden, March 19, 2019

Orexo AB (publ)

Martin Nicklasson
Chairman of the Board

Raymond G. Hill
Board member

Staffan Lindstrand
Board member

Kristina Schauman
Board member

Henrik Kjaer Hansen
Board member

David Colpman
Board member

Kirsten Detrick
Board member

Nikolaj Sørensen
President and CEO

Our audit report was submitted on March 19, 2019

Ernst & Young Aktiebolag

Björn Ohlsson
Authorized Public Accountant

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 2018. The annual accounts and consolidated accounts of the company are included on pages 32-71 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 2018 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 2018 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.

Our opinions in this report on the annual accounts and consolidated accounts are consistent with the content of the additional report that has been submitted to the parent company's audit committee in accordance with the Audit Regulation (537/2014) Article 11.

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. This includes that, based on the best of our knowledge and belief, no prohibited services referred to in the Audit Regulation (537/2014) Article 5.1 have been provided to the audited company or, where applicable, its parent company or its controlled companies within the EU.

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

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. For each matter below, our description of how our audit addressed the matter is provided in that context.

We have fulfilled the responsibilities described in the Auditor's responsibilities for the audit of the financial statements section of our report, including in relation to these matters. Accordingly, our audit included the performance of procedures designed to respond to our assessment of the risks of material misstatement of the financial statements. The results of our audit procedures, including the procedures performed to address the matters below, provide the basis for our audit opinion on the accompanying financial statements.

Revenue from contracts with customers

Description	How our audit addressed this key audit matter
Revenue from contracts with customers for 2018 was MSEK 783.1 in the consolidated income statement and MSEK 407.6 MSEK in the parent company income statement. As is stated in Note 5, revenue from the sale of goods is calculated net of deductions including actual and estimated rebates to public and private insurers and provisions for potential returns. These gross-to-net adjustments are based partly on management's estimates. The extent of deductions of revenue from rebates and returns and the accounting for royalties connected to licensing agreements are affected by estimates and judgments made by management. A description of the judgments on which revenue recognition is based is provided in the section "Important estimations and judgments for accounting purposes" in Note 4. In summary, revenue recognition for the group contains significant elements of judgment, and for this reason revenue recognition has been determined to be a key audit matter.	I In our audit we have reviewed the company's processes over revenue recognition, and reviewed significant agreements to assess whether the accounting for these is compliant with relevant standards. We have also performed sample testing of accruals. We have also reviewed the calculation models on which the deductions from gross sales are based, as well as the reasonableness of key assumptions on which the calculations are based, such as the distribution between different payer categories and expected future returns. Finally, we have reviewed disclosures provided in the annual report.

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 1–31 and 76–88. 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 skepticism 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.

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 2018 and the proposed appropriations of the company's profit or loss.

We recommend to the general meeting of shareholders that the profit be appropriated (loss be dealt with) in accordance with the proposal in the statutory administration report and that the members of the Board of Directors and the Managing Director be discharged from liability for the financial year.

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 skepticism 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.

Ernst & Young AB, Jakobsbergsgatan 24, 111 44, Stockholm, was appointed auditor of Orexo AB by the general meeting of the shareholders on the 12 April 2018 and has been the company's auditor since the 15 April 2016.

Uppsala 19 March, 2019
Ernst & Young AB

Björn Ohlsson
Authorized Public Accountant

Reconciliations and Definitions of Key Figures

Group

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

EBITDA SEK million	2018	2017
EBIT	95.8	57.4
Depreciation and amortization	20.8	20.8
EBITDA	**116.6**	**78.2**

Return on shareholders' equity	2018	2017
Average shareholders' equity	402.6	319.7
Net earnings	137.9	23.2
Return on shareholders' equity %	**34.3**	**7.3**

Net debt SEK million	2018	2017
Current and long-term interest-bearing liabilities including pension liabilities	320.6	319.1
Cash and cash equivalents.	–589.8	–327.9
Net debt	**–269.2**	**–8.8**

Operating expenses SEK million	2018	2017
Selling expenses	–191.4	–190.5
Administrative expenses	–166.7	–96.1
Research and development costs	–166.8	–134.2
Other operating income and expenses	9.3	–1.1
Operating expenses	**–515.6**	**–421.9**

US EBIT SEK million and EBIT margin %	2018	2017
Consolidated operating earnings	95.8	57.4
Non US related items impacting operating earnings	–102.5	–16.3
US EBIT	**198.3**	**73.7**
US EBIT margin %	**31.9**	**15.2**

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

Margins	Definition/calculation	Purpose
Gross margin	Gross profit divided by net revenues	Gross Margin is used to measure the relative direct profitability from sold products
Operating margin (EBIT margin)	Operating earnings as a percentage of net revenues	Operating profit margin is used for measuring the operational profitability
Return	**Definition/calculation**	**Purpose**
Return on equity	Net earnings for the period as a percentage of average shareholders' equity	Return on equity is used to measure profit generation, given the resources attributable to the owners of the Parent Company
Capital structure	**Definition/calculation**	**Purpose**
Net Debt	Current and long-term interest-bearing liabilities including pension liabilities, less cash and cash equivalents	The net debt is used as an indication of the ability to pay off all debts if these became due simultaneously on the day of calculation, using only available cash and cash equivalents
Debt/equity ratio	Total liabilities divided by shareholders' equity	The debt/equity ratio measures how much debt a company is using to finance its assets relative to the amount of value represented in shareholder's equity.
Equity/assets ratio	Shareholders' equity as a percentage of total assets	This ratio is an indicator of the company's leverage used to finance the firm
Working capital	Current assets less current liabilities	Working capital is used to measure the company's ability, besides cash and cash equivalents, to meet current operational obligations
Capital employed	Interest-bearing liabilities and shareholders' equity	Capital employed measures the amount of capital used and serves as input for the return on capital employed
Gross investments	Value of investment before amortization	Gross investments is a measure of the company's investments in tangible and intangible fixed assets
Data per share	**Definition/calculation**	**Purpose**
Number of shares after dilution	Shares at the end of the period adjusted for the dilutive effect of potential shares	Is used to calculate earnings per share after dilution
Earnings per share, before dilution	Net earnings for the period after tax divided by the average number of shares outstanding before dilution during the period	The earnings per share before dilution measures the amount of net profit that is available for payment to its shareholders per share before dilution
Earnings per share, after dilution	Net earnings for the period after tax divided by the average number of shares outstanding after dilution during the period	The earnings per share after dilution measures the amount of net profit that is available for payment to its shareholders per share after dilution
Other definitions	**Definition/calculation**	**Purpose**
Gross Revenues	Grand total of all invoiced sales transactions reported in a period, without any deductions	Reflects the company's invoiced revenues without any deductions
Net Revenues	Gross Revenues less deductions for sales rebates, sales allowances, distribution, sales returns and other relevant deductions	Reflects the company's invoiced revenues after deductions
Gross to net ratio	Net Revenues divided by Gross Revenues	Reflects a relative portion of net revenue as percentage of gross revenue
Operating expenses	An expense incurred in daily operating activities. Expense related to financing is not considered part of daily operating activities.	Operating expenses reflect costs for selling, administration, research and development, depreciation and other operating income and operating expenses
US EBIT (SEK)	US net revenues (SEK) less consolidated US cost of goods sold (SEK) less US operating expenses (SEK)	Profit measure which illustrates direct contribution (SEK) from US business
EBIT	Earnings before net financial items and tax, the same as Operating earnings	This measure enables the profitability to be compared across locations where corporate taxes differ and irrespective the financing structure of the company
EBITDA	Earnings before interest, taxes, depreciation and amortization. EBIT plus depreciation	Profit measure which is more closely correlated with cash flow as non-cash items like Depreciation and Amortization are excluded
Earnings after financial items	Operating earnings (EBIT) plus financial income less financial expense	Earnings after financial items reflects earnings after, any results from participations in Group and associated companies, results from securities and receivables that fall within the type of fixed assets as well as interest expenses and interest income

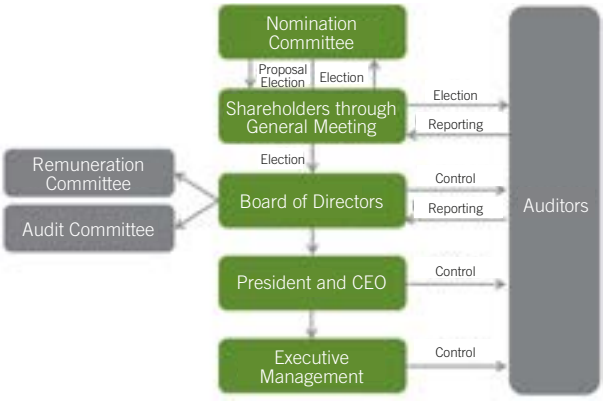
Corporate Governance 2018

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
- IR policy
- IT policy
- Financial guidelines
- HR guidelines
- Business Compliance and Ethics code

Shareholders

Orexo's share has been listed on Nasdaq Stockholm since 2005. At year-end, the total number of shares amounted to 35,450,456 (35,104,585), distributed among 6,261 shareholders (7,115).

The 10 largest shareholders held 62.7 percent (59.1) of the outstanding shares, management 0.2 percent (0.2) and other shareholders 37.1 percent (40.7). At December 31, 2018, two shareholders each held shares representing 10 percent or more of the company – Novo Holding A/S, 27.2 percent, and HealthCap, 11.2 percent. Non-Swedish shareholders accounted for approximately 47 percent (57) of the total number of shares. Institutions and industrial owners hold the majority of shares. At year-end, 81 percent (77) of the

shares were held by legal entities, and 19 percent (23) 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 2018
The Annual General Meeting was held on Thursday, April 12, 2018 in Uppsala. At the Meeting:

- Raymond G. Hill, Staffan Lindstrand, Martin Nicklasson, Kristina Schauman, David Colpman and Kirsten Detrick were re-elected as Board members. Henrik Kjaer Hansen was elected as a new member of the board,
- Martin Nicklasson was re-elected as Chairman of the Board.
- Ernst and Young Aktiebolag was re-elected as auditor.
- A resolution was adopted that fees for Board members should amount to a total of SEK 2,200,000, 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 400,000 distributed between the members of the Audit Committee, so that the Chairman of the committee receives SEK 200,000 and SEK 200,000 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 2019 was approved.
  The balance sheet and income statement for the Parent Company and the Group for the 2017 fiscal year were adopted.
- The Annual General Meeting granted Board members and the President discharge from liability for the 2017 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 2018 Annual General Meeting can be found at www.orexo.com.

Annual General Meeting 2019
The Annual General Meeting of Orexo will be held on Thursday, April 11, 2019, at 4:00 p.m. at the company's premises at Virdings allé 32 A, Uppsala, Sweden.

Nomination Committee
The 2018 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 2018, in addition to the Chairman of the Board. The composition of the Nomination Committee was announced on Orexo's website and in a press release on October 8, 2018. 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 2019:

Name	Representatives
Michael Shalmi	Novo Holding 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. They monitor the president'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, Henrik Kjaer Hansen, Kristina Schauman and Kirsten Detrick. For a more detailed description of Board members, please refer to page 86.

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 relevant 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 12 (16) meetings, of which 8 (8) 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 2018 Annual General Meeting resolved that Board fees should amount to SEK 2,200,000, 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 400,000 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 200,000.

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	12/12	5/5	3/4
David Colpman	Board member	■	2015	10/12	–	–
Kristina Schauman	Board member	■	2012	12/12	–	4/4
Michael Shalmi	Board member	■	2010	3/4	5/5	–
Henrik Kjaer Hansen	Board member	■	2018	8/8	–	–
Raymond G. Hill	Board member	■	2008	10/12	5/5	–
Staffan Lindstrand	Board member	■	2002	10/12	–	4/4
Kirsten Detrick	Board member	■	2016	10/12	–	–

■ 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 23. 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. Matters addressed in the Audit Committee is reported to the Board on a regular basis and the minutes are distributed to the Board.

During the year, the Audit Committee was convened on 4 (4) 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 equity instruments 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), Henrik Kjaer Hansen and Raymond G. Hill. During the year, the Remuneration Committee was convened on 5 (2) 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 Annual General Meeting 2018 EY was re-elected as auditors until the Annual General Meeting 2019. 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 29.

President and the Management
The President leads the work of the Management Team and makes decision in consultation with them. At the end of 2018 the Management Team consisted of five persons in addition to the President. The Management Team hold regular meetings under the supervision of the President. For a more detailed description of the CEO and the management, see page 87.

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 risk map 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 set of control procedures that will minimize the risks and impact in these areas. In addition, new and existing risks are identified, addressed and regulated through a process of discussion in forums such as the the Management Team, The Board of Directors and Audit Committee.

Control activities
In light of the risks identified on the risk map, 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 map are examples of such policy documents.

The finance and and controller functions 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. These procedures are continuously updated to secure compliance with the EU Market Abuse Regulation (MAR).

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. Routines and reporting is 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 2019 Annual General Meeting (convening notice, Nomination Committee proposals, presentation of the work of the Nomination Committee, etc.).

Auditor's Report on the Corporate Governance Statement

To the 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 2018 on pages 79–83 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 19, 2019
Ernst & Young AB

Björn Ohlsson
Authorized Public Accountant

Glossary

Alfentanil
A potent synthetic opioid analgesic drug, used for anesthesia 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.

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 painkiller.s

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 payer category
One of the three distinct payer categories in the US market for treatment of opioid dependence. In this category, the patient is paying for the prescriptions out of pocket.

CHMP
The Committee for Medicinal Products for Human Use.

CLI
Cysteinyl Leukotriene Inhibitor.

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

Commercial payer category
One of the three distinct payer categories in the US market for treatment of opioid dependence. The commercial category 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 anesthesia and analgesia.

GMP
Good Manufacturing Practice.

HHS
The US Department of Health and Human Services.

In Vitro studies
In an in vitro study; living matter is examined outside of its natural context e.g. in a test-tube.

IP
Intellectual Properties.

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

LTM
Last Twelve Months.

NSAID
Non-steroid anti-inflammatory drugs which are active against pain, inflammation and fever.

NTRx
Tablets per prescription divided by 30.

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.

Proof of Concept studies
A Proof of Concept study is performed to get a first indication of an idea's practical feasibility.

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

Reimbursement
Contribution from the state or insurance company in order to reduce the price of drugs / treatment for the patient Sublingual
Under the tongue.

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

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 Kymab Ltd. Board member of Basilea Pharmaceutica Ltd. 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 14,300 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 and Forendo Pharma Ltd.
Previous appointments: Former Head of Global Business Development 2012–2014, 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.
Holds 1,580 shares.[1]

Kirsten Detrick (b. 1965)

Board member since April 2016.
MBA.
Other appointments: 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, Various marketing and commercial positions 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.[1]

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.
Does not hold any shares.[1]

Staffan Lindstrand (b. 1962)

Board member since 2002.
M.Sc. in Engineering.
Other appointments: Partner of HealthCap since 1997, Board member of HealthCap AB, PulmonX Inc., Doctrin AB 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.
M.Sc. Business and Administration.
Other appointments: Board member and Chairman of the Audit Committee of ÅF AB, BillerudKorsnäs AB, Coor Service Management AB and Ellos Group Holding AB. Board member of BEWiSynbra Group AB and Nordic Entertainment Group AB.
Previous appointments: Board member Livförsäkringsbolaget Skandia ömsesidigt and Apoteket AB. 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]

Henrik Kjaer Hansen (b. 1976)

Board member since 2018.
BSc. in Business Administration and a MSc. in Applied Economic and Finance at Copenhagen Business School.
Other appointments: Senior Director, Principal Investments, Novo Holdings A/S. Board member of Xellia Pharmaceutical.
Previous appointments: Prior to joining Novo Holdings A/S, Kjaer Hansen was employed as a Senior Vice President in Moelis & Co. in London, focusing on healthcare M&A transactions. Other previous employments include Deutsche Bank and ABN AMRO, all in London.
Does not hold any shares.[1]

[1] As of December 31, 2018

Management[1]







Nikolaj Sørensen (b. 1972)

Chief Executive Officer since February 2013, employed since 2011.
B.Sc., and M.Sc., Copenhagen Business School, Denmark.
Previous appointments: Senior management positions at Pfizer Inc. with a focus on commercialization in Europe and Chairman of the Board and Managing Director at Pfizer AB. Prior to Pfizer Nikolaj Sørensen served as a management consultant at Boston Consulting Group (BCG), leading several projects within M&A, commercial transformation, and turn-arounds.
Holds 38,000 shares and stock options/share awards entitling to 472,648 shares.[2]

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, Schering Plough, Berlex and Pharmacia, and most recently served as Chief Commercial Officer at Archimedes Pharmaceuticals.
Holds 2,703 shares and stock options/share awards entitling to 265,627 shares.[2]

Johannes Doll (b. 1981)

EVP and Head of Corporate Development since 2016.
Johannes Doll has worked as an advisor to Orexo since 2013.
MBA, McCombs School of Business at the University of Texas, US. and a Master in Management (Dipl. Kaufmann), WHU Otto Beisheim School of Management, Germany.
MBA.
Previous appointments: Johannes Doll has worked with McKinsey & Company from 2004 to 2013, advising clients in the global pharmaceutical and private equity industry, with a focus on M&A, commercial transformation, and turn-arounds.
Holds 10,000 shares and stock options/share awards entitling to 51,265 shares.[2]

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 prior to joining Orexo held the position of Vice President Clinical and Medical Affairs at Shire.
Holds 2,300 shares and stock options/share awards entitling to 88,840 shares.[2]

Joseph DeFeo (b. 1961)

EVP and Chief Financial Officer since November 1, 2018. Joined Orexo US Inc. in 2013 as Vice President, Finance & Administration.
Bachelor degree in accounting from Clarion University, US, and a MBA in finance from St. Joseph's University, US.
Previous appointments: Previous appointments: Prior to joining Orexo, Joseph DeFeo has worked in several senior finance positions among others establishing of US operations for a large Italian pharmaceutical company, Head of International Treasury and led finance for the commercial operations in the US for two major pharmaceutical companies.
Holds stock options/share awards entitling to 57,101 shares.[2]

Cecilia Coupland (b. 1976)

VP and Head of Operations as of January 2019, employed since 2006.
MSc in Chemical Engineering, Uppsala University, Sweden.
Previous appointments: Head of Supply Chain & Planning at Orexo since 2014 and prior to that extensive experience of global pharmaceutical manufacturing and supply chain management, as well as drug development and project management, from various key positions at AstraZeneca and Orexo AB.
Holds stock options/share awards entitling to 14,883 shares.[2]

Robert Rönn (b. 1976)

VP and Head of R&D as of January 2019, employed since 2007.
MSc in Chemical Engineering and PhD in Medicinal Chemistry, Uppsala University, Sweden.
Previous appointments: Head of Pharmaceutical Development & IP at Orexo AB since 2016 and prior to that extensive experience of drug discovery and development, as well as patent prosecution and litigation, from various key positions at Biolipox AB and Orexo AB.
Holds 125 shares and stock options/share awards entitling to 16,759 shares.[2]

[1] Management as of January 1, 2019
[2] As of December 31, 2018

Shareholder Information

2019 Annual General Meeting
The Annual General Meeting of Orexo AB will be held on Thursday, April 11, 2019 at 4.00 pm CET at Orexo AB, Virdings allé 32A in Uppsala, Sweden. The visiting address is Rapsgatan 7E.

Registration, etc.
Shareholders who wish to participate in the meeting must be recorded in the share register maintained by Euroclear Sweden AB on Friday, April 5, 2019, and notify Orexo of their intention to attend the meeting not later than the same day, Friday, April 5, 2019 by post to Orexo AB, P.O. Box 303, SE 751 05 Uppsala, Sweden, by telephone +46 (0) 18 780 88 00, 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, April 5, 2019 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 2019

2019 Annual General Meeting	April 11, 2019, at 4.00 pm CET
Interim Report Q1 2019	May 2, 2019 at 8.00 am CET
Interim Report Q2 2019	July 11, 2019 at 8.00 am CET
Interim Report Q3 2019	October 24, 2019 at 8.00 am CET
Full Year Report 2019 incl. Q4	January 30, 2020 at 8.00 am CET

ABOUT OREXO

Orexo develops improved pharmaceuticals based on innovative drug delivery technologies. The focus is primarily on opioid addiction and pain but the aim is to address therapeutic areas where our competence and technologies can create value. The products are commercialized by Orexo in the US or via partners worldwide. The main market today is the American market for buprenorphine/naloxone products, where Orexo sells the product Zubsolv®. Total net sales for 2018 amounted to SEK 783.1 million and the number of employees was 129. Orexo is listed on the Nasdaq Stockholm Mid Cap (ORX) and is available as ADRs on OTCQX (ORXOY) in the US. The head office, where research and development is also 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.

Production Solberg