Annual Report 2019

orexo

Develops and commercializes
improved pharmaceuticals and digital therapies

Content

Read more on our website

Our corporate website, www.orexo.com, is our primary communication channel. You are also welcome to follow us on other channels that are frequently updated with information regarding our business or our environment.

LinkedIn YouTube

Orexo's formal annual report according to the Annual Accounts Act covers the pages 36-75.

On images where Orexo's employees are included, employees are mentioned by name and title.

Cover page, top image: Andreas Fischer, Senior Principal Scientist and Annika Fröling, Analytical Chemist.

This page, Maria Sandström, Senior Formulation Scientist

Photo: Jenny Lagerqvist.

Orexo develops and commercializes improved pharmaceuticals and digital therapies – with the aim of becoming a leader within the treatment of addiction

About Orexo

Orexo develops improved pharmaceuticals and digital therapies addressing unmet needs mainly within the growing space of addiction. 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 commercializes its lead product Zubsolv® for treatment of opioid use disorder. Total net sales for 2019 amounted to SEK 845 million and the number of employees was 127. Orexo is listed on the Nasdaq Stockholm Mid Cap (ORX) and is available as ADRs on OTCQX (ORXOY) in the US. The company is headquartered in Uppsala, Sweden, where research and development activities are performed.

Core Values

- Customer focus
- Engagement
- Flexibility
- Simplicity

Entering digital therapeutics – new frontiers in patient care

Digital therapeutics (DTx) is set to become one of the most exciting and rapidly-growing areas of the life sciences industry over the current decade. With the acquisition of the rights to two digital therapies from GAIA AG and the building up of a new venture within digital therapeutics, Orexo is well positioned to lead this development within the addiction space.

To learn more about DTx read the interview with Dennis Urbaniak, EVP Digital Therapeutics, on pages 14–16.

14% Key market growth

The opioid problem in the US is on an epidemic level. In 2019 the use of synthetic opioids such as fentanyl caused an increasing number of deaths, while the overall number of overdose deaths declined slightly. There is still a huge need for treatment and in 2019 the dynamic buprenorphine/naloxone market grew by over 14 percent.[1]

[1] IQVIA Data

Read more, pages 10–11.

4 Developed pharmaceuticals approved worldwide

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

Read more, pages 20–21.

Sustainability – we make a difference

Orexo's ambition is to be recognized for the added value our products bring to patients and societies and we want to be a trusted partner for suppliers and other stakeholders.

Read the Sustainability report, pages 26–33.

SEK 817 m

The strong cash position enables Orexo to continue to deliver on its strategy to progress the R&D pipeline and to pursue further business development opportunities with the target to add more commercial stage products to the US commercial infrastructure.

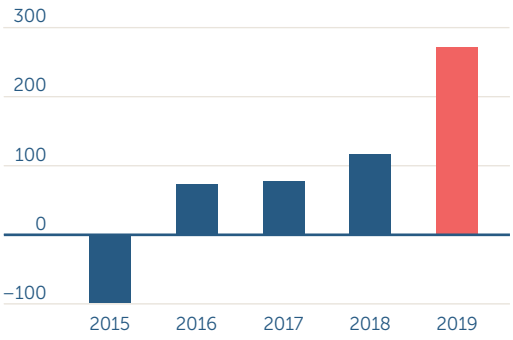
Read more about the strategy, pages 12–13.

Pipeline with significant future potential

Filling an unmet need among healthcare professionals and patients is the key in the work of developing new innovative treatments. The pipeline contains development projects with a primary therapeutic focus around addiction in all phases, from prevention to treatment.

Read more, pages 22–25.

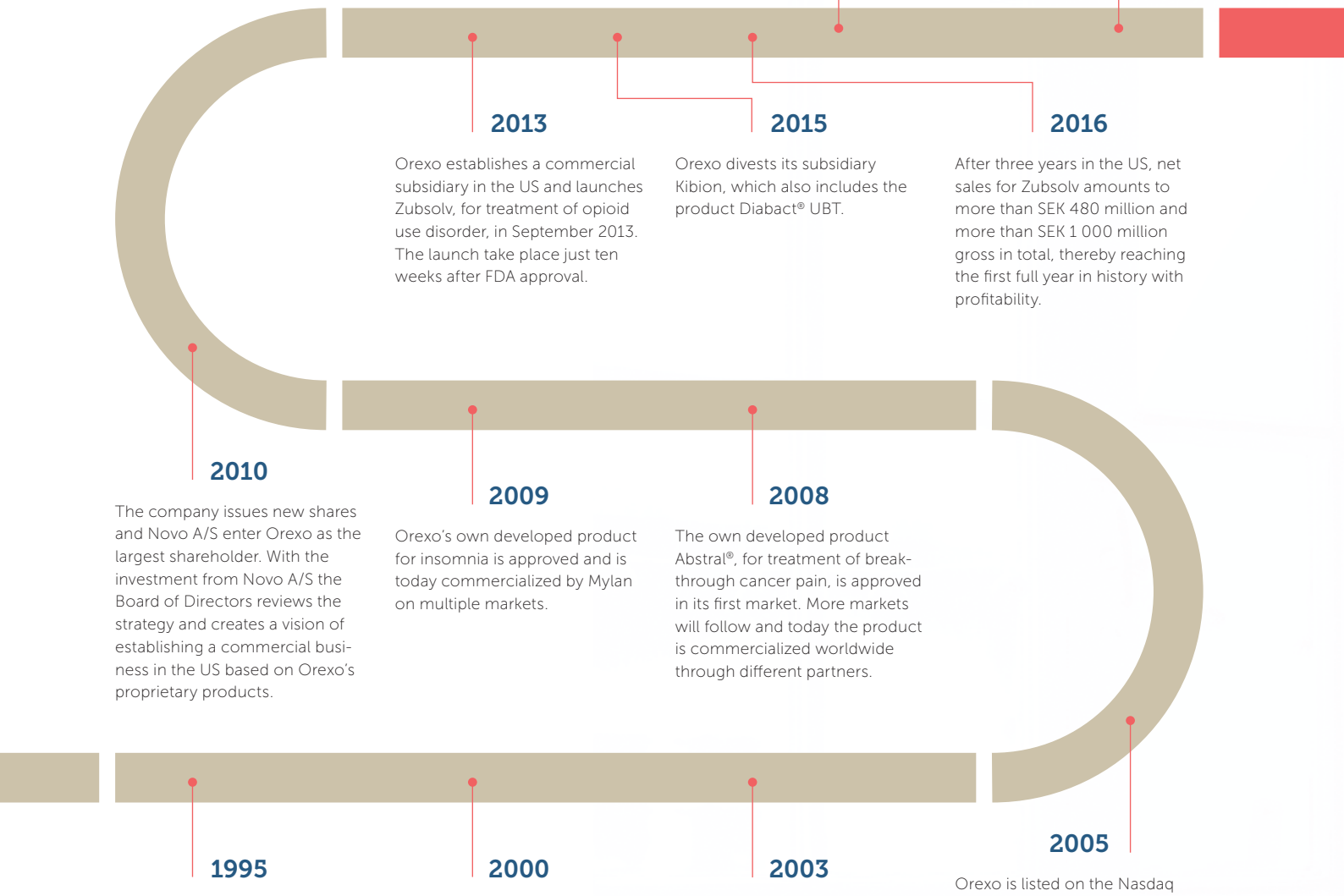
EBITDA, 2015–2019, SEK m



Key Figures

SEK million	2019	2018	2017	2016	2015
Net revenues	844.8	783.1	643.7	705.9	646.2
whereof Zubsolv® US net revenue	*719.2*	*621.5*	*485.8*	*481.8*	*416.7*
Cost of goods sold	–105.6	–171.8	–164.4	–149.6	–150.2
Operating expenses	–508.0	–515.6	–421.9	–584.4	–676.6
EBIT	231.2	95.8	57.4	51.7	–180.6
EBIT margin, %	27.4	12.2	8.9	7.3	–27.9
US EBIT	350.9	198.3	73.7	21.4	–109.1
US EBIT marginal, %	48.8	31.9	15.2	4.4	–26.2
EBITDA	272.1	116.6	78.2	73.1	–99.9
Earnings per share, before dilution, SEK	6.33	3.99	0.67	0.84	–6.09
Earnings per share, after dilution, SEK	6.20	3.93	0.67	0.84	–6.09
Cash flow from operating activities	290.9	242.0	146.6	156.2	–109.2
Cash and cash equivalents	816.8	589.8	327.9	282.4	198.1

Celebrating 25 years of R&D



1995

Orexo is founded with a vision to develop improved pharmaceuticals, fulfilling unmet patient needs. This is done by optimization of the properties of well-documented substances in combination with Orexo's innovative drug delivery technologies.

2000

The company's first own developed product Diabact UBT, for diagnosing of the gastric ulcer bacterium Helicobacter pylori, is approved in its first market. More markets will follow and today Diabact UBT is commercialized worldwide through different partners.

2003

New owners contribute with financing and several development projects are started.

2005

Orexo is listed on the Nasdaq Stockholm Stock Exchange.

2008

The own developed product Abstral®, for treatment of breakthrough cancer pain, is approved in its first market. More markets will follow and today the product is commercialized worldwide through different partners.

2009

Orexo's own developed product for insomnia is approved and is today commercialized by Mylan on multiple markets.

2010

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

2013

Orexo establishes a commercial subsidiary in the US and launches Zubsolv, for treatment of opioid use disorder, in September 2013. The launch take place just ten weeks after FDA approval.

2015

Orexo divests its subsidiary Kibion, which also includes the product Diabact® UBT.

2016

After three years in the US, net sales for Zubsolv amounts to more than SEK 480 million and more than SEK 1 000 million gross in total, thereby reaching the first full year in history with profitability.

2018

The company wins a multiyear patent battle against the generic company Teva/Actavis securing patent protection for Zubsolv® in the US until 2032. Shortly thereafter the company internalizes its sales force.

2019

Orexo enters a partnership with GAIA AG, a world leader within digital therapeutics, with the aim to develop digital therapies for treatment of opioid use disorder and heavy alcohol use.

The year in brief

– strong fundamentals in place to fuel strategy for future growth

Q1

- Positive results from human PK study assessing Orexo's new intranasal naloxone formulations (OX124) for opioid overdose reversal
- The US District Court of Delaware issues 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

Q2

- Zubsolv continues to demonstrate resilience to increased generic competition and with greater profit contribution from the US operations

Q3

- Orexo's partner, Gesynta Pharma AB, progresses OX-MPI into a phase 1 clinical trial
- Signs license and supply agreement for Zubsolv in Australia and New Zealand with Mundipharma Pty Ltd
- SEK 32.5 million, 10 percent, of the total corporate bond loan is prepaid
- Signs a partnership agreement with GAIA AG to develop a digital therapy for treatment of opioid use disorder, where Orexo will own the global rights to the therapy

Q4

- The partnership with GAIA AG is expanded when the exclusive rights to commercialize vorvida® in the US are acquired. vorvida is a digital therapy for heavy alcohol use with scientifically proven efficacy
- Appoints Dennis Urbaniak, one of the leading experts in digital health in the US, as EVP Digital Therapeutics
- Announces Capital Markets Day to be held in March 17, 2020, focusing on providing an update on the company's strategy, pipeline and the business opportunities within digital therapeutics

GAIA AG – A GLOBAL LEADER IN DIGITAL THERAPEUTICS

Focusing on evidence based research

GAIA is a global leader in digital therapeutics (DTx), launching its first product successfully in 2001. With its rigorous focus on research and development of evidence based, fully-automated online interventions the company continuously shifts benchmarks when it comes to effect sizes and safety profiles for digital therapeutics in neuroscience, immunology, oncology, or behavioral health.

Experienced team to lead the next generation digital solutions

With more than 140 experts in the field of medicine, psychology, behavioral medicine, software engineering as well as regulatory and market access, GAIA is one of the most experienced and largest global players in the development of next generation digital solutions to support and treat patients with a broad variety of medical conditions.

Nikolaj Sørensen,
President and CEO

Photo: Jenny Lagerqvist.

2019 – a record year further establishing a strong foundation for future growth

2019 delivered the strongest financial results ever for Orexo. This was driven by a stellar performance from our teams in Sweden and the US, who oversaw additional strategic objectives for the year with the advancement of our pipeline and two partnership agreements for digital therapeutics; a promising growth driver for Orexo's future. Over the course of 2020 we will work towards readying the company for the future by maintaining the sales and cash-generation from our lead product Zubsolv® despite increasing competition, by investing in the current pipeline, and by broadening our digital therapeutic capabilities.

A strong year financially and operationally

My colleagues and I are proud of what we have accomplished in the last year, both operationally and commercially. We have had a strong commercial year despite unprecedented market dynamics, with the leading player losing exclusivity and the introduction of several new generic products. We managed to overcome this intensified competition and continued to grow our revenues on a full year basis, resulting in an all-time-high financial performance across all key performance indicators. We are particularly proud of the contributions from Zubsolv in the US, where the EBIT margin surged and we closed the year above 50 percent in our US operations. As a result of an international team effort and performance, we managed to improve gross margins and maintain good control of our expenses. While we take pride in the financial performance in the individual year, the result is even more important for Orexo moving forward as a foundation for the company's increased investment in R&D, business development and the build-up of a new venture within digital therapeutics.

Addiction is a mental health issue requiring new innovative treatment solutions

There has been some improvement in access to treatment for opioid use disorder, which has resulted in a slight decline in fatalities as a result of an opioid overdose. However, there is still a high unmet need for new treatment options for opioid addiction as the use of fentanyl, is growing rapidly. The suffering from addiction is comparable to any mental disease and has significant negative ramification on the wider society and of course the individual patient. Recognizing that addiction might require treatment to go beyond existing medication and regiments, we decided to broaden our treatment offering by entering into digital therapeutics.

Digital therapeutics – new frontiers in patient care

Our decision to enter digital therapeutics is based on a significant unmet patient need as access to treatment in the US remains limited. International treatment guidelines and the label of all buprenorphine products require that patients are provided with psychological support in combination with medication. We have identified a significant number of patients still lack access to qualified counselling and that the inconvenience of intensive counselling in the crucial first months of treatment can result in poor adherence to treatment and prevent a positive treatment outcome, increasing the risk of relapse and death. Digital therapies could complement existing treatments and could provide patients with access to highly sophisticated and individualized support 24/7 and when they need it most. With two digital therapy agreements signed with GAIA AG in 2019 for opioid use disorder and heavy alcohol use,OXD01 and vorvida® respectively, we intend to develop OXD01 for a potential launch in the US in 2022, subject to regulatory approval, and plan to prepare vorvida for launch in the US market in the second half of 2020, pending feedback from the FDA.

> “Recognizing that addiction might require treatment to go beyond existing medication and regiments, we decided to broaden our treatment offering by entering into digital therapeutics.

"Looking ahead, we expect Zubsolv® to remain our main profit contributor and to be the foundation for our upcoming product launches."

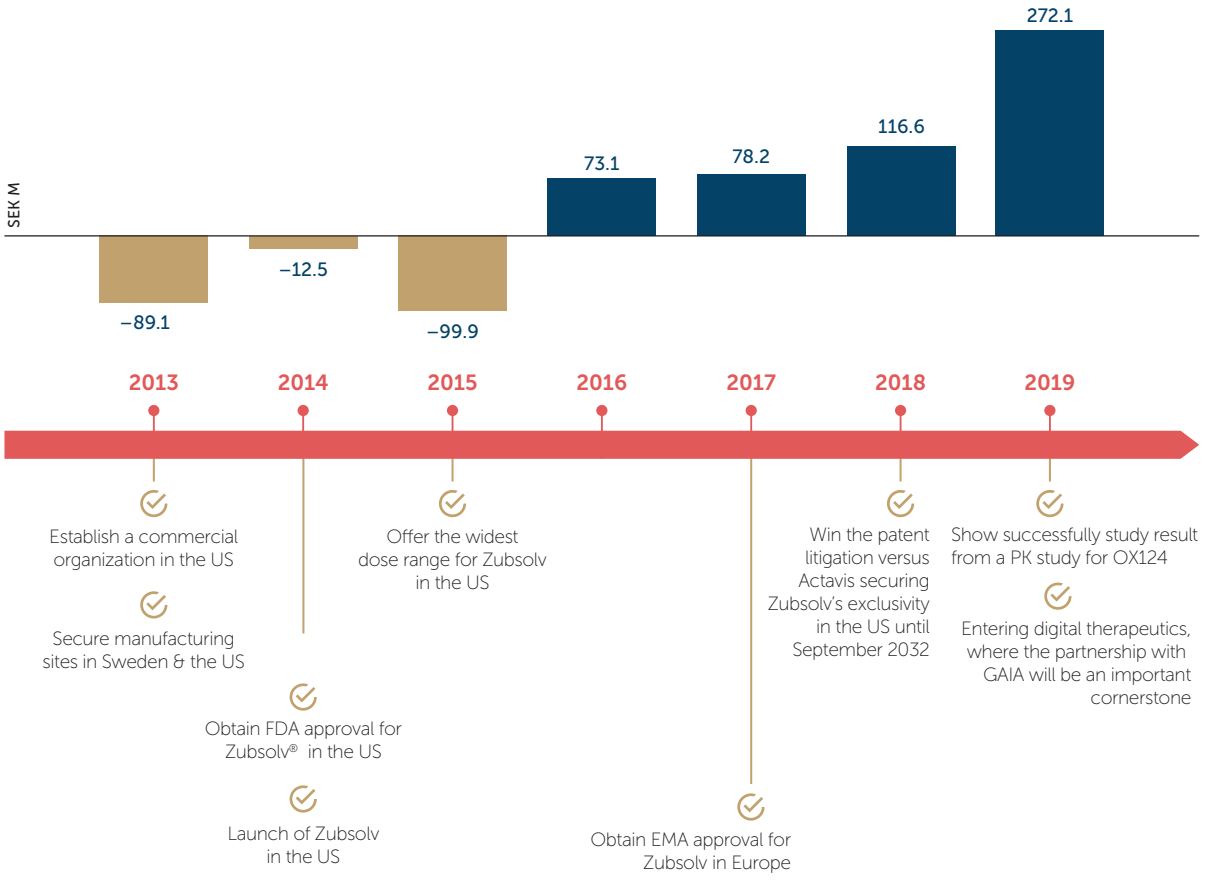
R&D – our strategic investments for growth

Our pharmaceutical pipeline has taken significant steps forward during 2019. We expect 2020 to be the final year of clinical development for OX124, a naloxone rescue medication for opioid overdose, with a pivotal pharmacokinetic trial planned for the second half of 2020 and filing with the FDA in 2021. In parallel, we are developing OX125, addressing the same market, but with nalmefene as the active ingredient. Both formulations are based on a novel nasal technology developed by Orexo to provide a rapidly acting rescue medication for opioid overdose. In the first clinical study of OX124, we demonstrated a superior pharmacokinetic profile compared to existing rescue medications, faster onset and higher bioavailability of the product. Considering the increasing number of patients overdosing on fentanyl, it is imperative we have treatment options, such as OX124, which offer increased probability of providing sufficient naloxone to reverse the overdose, as currently marketed products struggle to reverse the effects of such opioids. The naloxone rescue market is currently valued at USD 300 million, with strong double-digit growth as the opioid crisis continues in the US, making OX124 and OX125 potentially powerful products on the market.

Exciting outlook where Zubsolv® will continue to be a main profit contributor

Looking ahead, we expect Zubsolv to remain our main profit contributor and to be the foundation for our upcoming product launches. However, whilst OX124 and OX125 would enter a smaller market, it is faster growing compared to the market for Zubsolv. The clinical differentiation is also significantly more profound and we would expect a more substantial market share than with Zubsolv, if the current competitive landscape remains.

PROFITABILITY (EBITDA) AND ACHIEVED MILESTONES



In addition to our growing revenue in the pharmaceutical business, we are confident that digital therapies will be an integrated part of the future healthcare system. By entering this business area early, we are well-positioned to shape this innovative area of treatment, which we believe will be integral to our future business.

Considering our priorities for 2020 and beyond, our focus is now to leverage the results of 2019 to build an even more exciting future for Orexo. We intend to maintain our pace and take existing pipeline projects to market within the next few years, to position Orexo as a key player within digital therapy and continue the search to acquire new products to complemet our existing business.

Limited impact of COVID-19

At the time of the publication of this Annual Report, the COVID-19 outbreak continues to evolve rapidly, with governmental guidance changing every day. At Orexo, our priority remains to ensure the wellbeing and safety of our employees, patients and our partners. We are monitoring the development of this situation closely, and based on currently available information suggesting that COVID-19 will likely reach a peak in late spring, we see it can cause some delays within our development chain, resulting in unexpected delays in our pharmaceutical projects. To try to avoid any delivery delays we are working proactively and closely with several parties across different geographies to assess future activities. For other areas in our company, such as the supply chain and sales, but also for our financial development, we currently see limited impact. We will continue to assess the situation and will be providing a further update in our Q1 report scheduled on April 28, 2020.

Thanks to our employees – together we make a difference!

I want to take this opportunity to thank all of our employees for their dedication and work during 2019 to improve the lives of the millions of patients suffering from addiction. We are excited to develop these opportunities over the year, with the ultimate goal of strengthening Orexo's future position. My team and I are looking forward to a prosperous 2020 and thank all our investors and stakeholders for their continued confidence in Orexo.

Uppsala, Sweden, March 2020

Nikolaj Sørensen
President and CEO

Investment thesis

1 Addressing large markets with significant patient needs

Focusing on becoming a leader within the large and growing space of addiction, alongside addressing the opioid epidemic, one of the largest health crises ever in the US and a growing global concern

2 Strong financial position and profitability

Fueled by the sales of the lead product Zubsolv which will continue to be an important cash and profitability contributor

3 Leverage the US commercial platform

Strategic focus on product portfolio expansion, through M&A and business development, to leverage the US commercial infrastructure

4 Expanding pipeline

Continues to build on the strong track record of developing products with worldwide approval by expanding the pipeline with multiple assets based on innovative drug delivery technologies and digital therapies addressing unmet medical need in addiction

5 Entering digital therapeutics, the new megatrend in life science

Digital therapeutics will become an integral part of the healthcare landscape and addiction is one of the therapeutic areas where it is most needed

Fentanyl is causing an increasing number of deaths in the US opioid epidemic

The opioid problem in the US is on an epidemic level. In 2019 the use of synthetic opioids such as fentanyl caused an increasing number of deaths, while the overall number of overdose deaths declined slightly. There is still a huge need for treatment and in 2019 the dynamic buprenorphine/naloxone market grew by over 14 percent.[1]

$696 billion

Opioid epidemic cost for the US society in 2018

14%

US buprenorphine/naloxone market growth in 2019

16.6 million

Heavy alcohol users in the US

Source: SMHSA, Substance Abuse and Mental Health Services Administration

A global problem and an American health crisis

According to the World Drug Report 2019 an increasing number of people are using opioids and collectively the number amounts to approximately 53 million people worldwide. Opioids continue to cause the most harm, accounting for two-thirds of the deaths attributed to drug use disorders.[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] The problem in the US has reached epidemic proportions, where more than 67,300 died of an overdose in 2018, a slight decrease comparing to 2017 when the corresponding number was about 70,200.[4] Approximately 70 percent of these deaths were caused by opioid abuse and the number who are dying from stronger synthetic opioids, such as fentanyl, continues to increase.[5] In 2017 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 problem as in the US. However, there are signals that synthetic opioids now also play a bigger role in Europe. One in every five of those entering drug treatment for an opioid-related problem now reports a synthetic opioid, rather than heroin, as their main problem drug.[7]

Opioid abuse costs societies substantial resources

From an economic point of view opioid addiction 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 addiction are enormous and considerably higher than previously calculated. The White House Council of Economic Advisors, which is an advisory committee to the American President, estimates that the opioid epidemic cost the US society USD 696 billion in 2018 and more than USD 2.5 trillion, between 2015–2018. This amount is much higher than what some other studies found, which can be explained by growing death toll in recent years and as it includes a broader societal cost of premature death.

Great need for treatment driving strong market 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.[8] 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 1 million.[8] The market for buprenorphine/naloxone products has grown substantially in recent years with an annual growth of approximately 14 percent.[9] 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.

Market consists of three payer segments

The market for the treatment of opioid addiction using buprenorphine/naloxone can be divided into three different payer segments, the public segment, where care is financed by public sector payers such as Managed Medicaid, FFS Medicaid and Medicare Part D.

[1] IQVIA Data
[2] World Drug Report, 2019
[3] UNODC World Drug Report 2014
[4] Center of Disease Control
[5] Center of Disease Control
[6] European Drug Report, 2019
[7] European Drug Report, 2019
[8] Clarion Healthcare
[9] IQVIA Data

Other segments are the commercial segment, which comprises private insurance companies and the cash segment, where patients themselves finance their care. The public segment differs from the others 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.

Looking at the market from a competitive perspective based on payers decision to make a product exclusive reimbursed or not, it can be divided in two segments, preferred formulary businesses or open formulary businesses (read more in the last paragraphs on this page).

Publicly financed care growing fastest

The public segment has grown the fastest in recent years and represents today 53 percent of the market. The development is 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 segment, representing 35 percent of the market is growing, but not in the same pace as the public segment. The cash segment (12 percent of the market) has displayed a flat development.

In beginning of 2020 Zubsolv® will increase its best-in-class coverage in the commercial segment from 97 to 98 percent. Zubsolv's coverage in the public segment amounts to 36 percent.

Increased generic presence

The market has historically constituted of multiple generics of Subutex® and Suboxone® tablets. In comparison with other pharmaceutical markets, generics have not had a significant price pressure effect. However, generics are favoured by the fact that many insurance companies in the public segment automatically give generics priority and thus indirectly put pressure on companies with new products to lower the price if insurance companies are to deviate from this principle. In beginning of 2019 the generic part of the market increased when four generics on the market leading drug Suboxone film entered the market. The launch of generics were launches at risk, as the patent disputes are still unresolved. The entrance of film generics has primarily impacted Suboxone film which saw its market share decline significantly. Zubsolv has been impacted by payers open up for more treatment alternatives. Despite the increased presence of generics 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 in the cash segment.

Suboxone film market share amounts to 29.9 percent, a decrease from 65.0 percent by end of 2018. Orexo's market share for Zubsolv amounts to just over 4.2 percent (5.0) and the corresponding number for BioScience Delivery and their drug, Bunavail®, is approximately 0.2 percent (0.5).[10] The remainder of the market is constituted by generic companies.[8]

Payers open up for more treatment alternatives offering opportunities for Zubsolv

The trend in the market is to open up for more treatment options, which is negative for Orexo in the short term but has potential to be positive in the long term. During the first half of 2019, generics were added to the preferred formulary lists by insurance companies previously only offering Zubsolv as a preferred alternative. The development has had a negative impact on the volume in 2019 but there have been a positive impact on the earnings as the rebates are much lower.

The number of exclusive positions for Zubsolv has reduced and only a few minor exclusive positions are left, making Zubsolv less dependent on exclusive positions.

When the payers open up for more treatments Zubsolv can be added to formulary lists which earlier have been blocked, by e.g. Indivior or generics. Positive signs in this direction have already been visible as Medicaid in Florida, Ohio, Alabama and Texas have added Zubsolv on their list and on these open formulary lists Zubsolv is growing faster than the market average.

Digital therapeutics – underlying key drivers for future growth

- Almost all industries have been transformed or are under transformation by digitalization, healthcare will not be an exception
- Growing population of technology users
- Increased focus on simplifying access to treatment
- Quality of digital therapies are improving and payers are starting to finance digital therapies along with more traditional treatments
- Increased importance of artificial intelligence to improve treatment outcomes

Alcohol addiction another major health crisis in the US

In the US approximately 16.6 million are heavy alcohol users.[11] Each year, more than 88,000 people die from alcohol-related causes,[12] making it the third leading preventable cause of death in the country. Alcohol misuse is also a big burden for the US society with yearly costs amounting to about USD 249 billion.[13]

[10] IQVIA Data as of year-end 2019/2020
[11] SMHSA, Substance Abuse and Mental Health Services Administration
[12] Sacks, J.J.; Gonzales, K.R.; Bouchery, E.E.; Tomedi, L.E.; and Brewer, R.D. 2010 National and state costs of excessive alcohol consumption. American Journal of Preventive Medicine49(5):e73–e79, 2015.
[13] SMHSA, Substance Abuse and Mental Health Services Administration

Ambitious road-map for long-term growth

Orexo has evolved from being a research and development company to becoming a profitable and fully integrated specialty pharmaceutical company with its own commercial business in the US. With a strong operational and financial foundation, Orexo is aiming to become a globally recognised leader in the field of addiction. To achieve this, the commercial business will be expanded further through a focus on business development activities, M&A and the launch of proprietary pharmaceuticals and digital therapies.

OBJECTIVES & STRATEGIES MARCH 2020 AND ONWARDS

1. **Broaden**
   the portfolio of commercial products to be promoted by our US organization

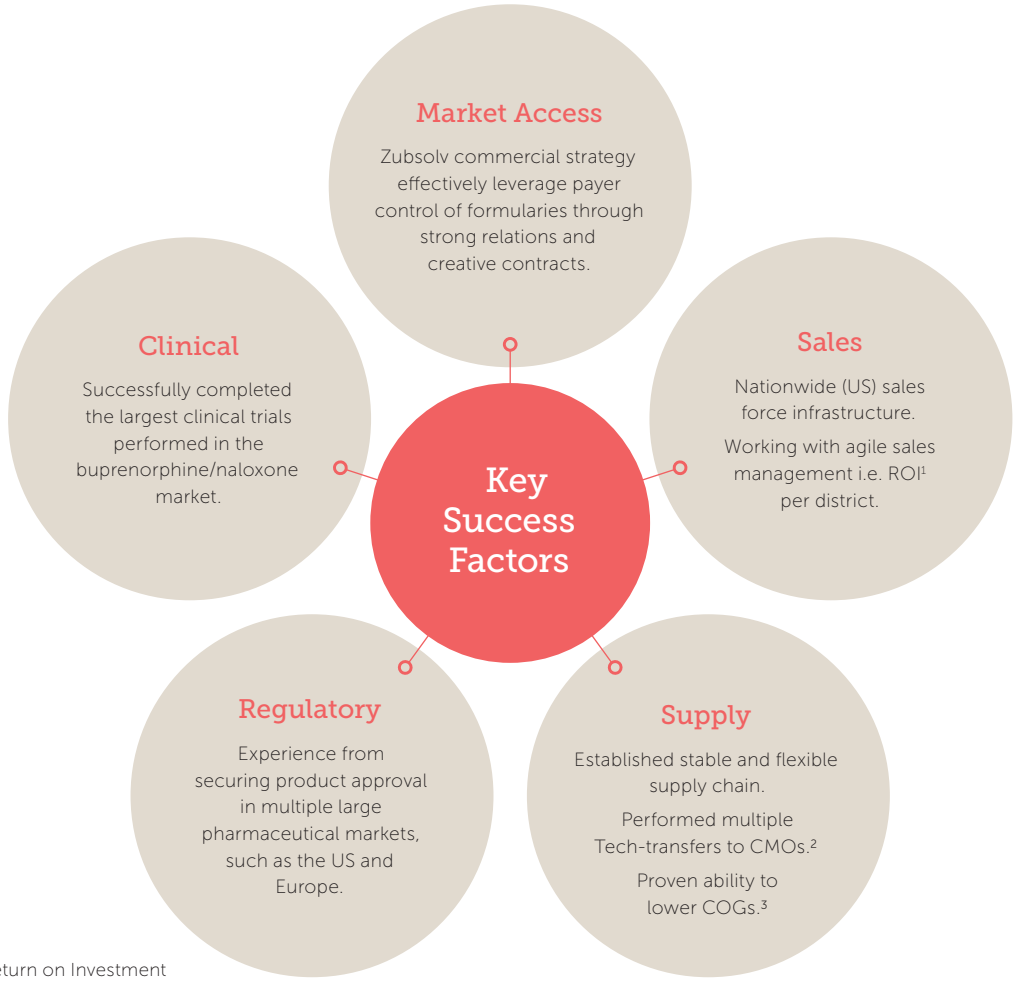
2. **Maintain**
   Zubsolv® profit contribution in 2020 and ensure it is sustainable and growing over time

3. **Establish**
   a new revenue generating business area within Digital Therapeutics and launch the first new product in 2020

4. **Launch**
   a new product from the pharmaceutical pipeline within the next two years

Annika Fröling, Analytical Chemist.
Photo: Jenny Lagerqvist.

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

DTx will be an integrated part of the global healthcare market

INTERVIEW WITH DENNIS URBANIAK, EVP DIGITAL THERAPEUTICS

Digital therapeutics (DTx) is set to become one of the most exciting and rapidly-growing areas of the life sciences industry over the next decade. With the acquisition of the rights to two digital therapies from GAIA and the appointment of Dennis Urbaniak, a thought leader in the digital health industry in the US, we are well positioned to lead this development within the complementary disease areas of our pharmaceutical business. Below you can read Dennis's view on this exciting and promising venture.

"There's is simply not enough qualified therapists to help provide medication assisted therapy, and in the US, the opioid problem has reached a crisis level that you haven't seen before."

Welcome to Orexo! In 2019 we broadened the business by entering digital therapeutics. You will lead this venture. Why are you the right person for this exciting job?

I come with over twenty five years of experience from the life sciences industry on both the client side and the service side. Within services, I have held positions as Chief Digital Officer at Havas Health & You, CEO at Havas Health Plus and Managing Director at Accenture Digital within Life Sciences. On the client side, I have held multiple senior positions within executive leadership, commercialization, marketing, and sales at Sanofi.

Within each of these aspects of my career, I have demonstrated a consistent ability to run businesses that drive results, as well as how to bring patient focused products to market successfully. From my commercial and marketing positions, I have learned the importance of the payer influences in the US and the need to carefully balance patient, provider, and payer needs. I have a strong understanding of the significant data science skills needed today, as well as the importance of user centered design to drive optimal user experiences.

From my collective positions, I have built an extensive global network within digital therapeutics covering important target groups such as patients, providers and payers. All together I believe my experiences will be key to successfully lead Orexo forward into digital therapeutics.

What do you think are the main drivers for this market?

There's huge enthusiasm in the market for digital therapeutics. I think we have come to a point where we've seen enough advances in technology and data capability. In parallel real world outcomes, that are not only clinical but also economic and patient satisfaction driven, have risen to the top of some of the payer's reimbursement criteria. With that in mind I think the key thing in the market now, as we go forward, is to show a strong ability to execute tremendous ideas in the space. We need to validate terrific pilots and concepts in the real world and then show that we can execute and drive them forward with scale.

Can you say that the US market is more mature than other markets?

There's lots of exciting startups and innovation happening in the digital therapeutic space globally. One thing I see in the US is that there's been enough DTx experiments where it's now beyond just conceptual. So I think in the US, it's not a matter of should we go into digital therapeutics. It's more about how and how fast can we? Which makes it a great market to learn from, and in the addiction space which is our focus, there's a tremendous need that has not being satisfied.

Can you also say that patients are more mature today to adapt to these new technologies?

Yes, I think that's very true. And it seems to go through all demographics such as gender, age and socio-economic class. There's a broad acceptance of the technologies and certain technologies have just gotten better to enable us to do things in a more seamless way and with a better user experience. That is why I believe that the data component and the user experience are two of the fundamental success factors for digital therapeutics going forward that are really going to make an impact.

Are there any barriers for the market to grow?

The main barrier is that people are used to do things a certain way and digital therapeutics don't fit nicely into that. But the good news are that we can see a lot of progresses that will push the forces in the right direction. Innovators are blazing the trail and pioneering and there are lots of bright spots and promises going forward. A specific one is in November last year when the Express Scripts, which is one of the largest pharmacy benefit manager in the US, published their first digital therapy formula. They evaluated over 100 different options and selected fifteen that are now on their list.

That a large payer like Express Scripts is taking this very seriously is an extremely important sign. It's also a sign that they're starting to look at different evidence and criteria for quality and standards and that's very exciting.

Are there segments that are more suitable for digital therapies than others?

I would say there are some that are more suitable. The most developed to date and with the clearest impact is in diabetes, particularly type 2, as this is such a massive problem worldwide that is not only related to traditional medications.

Addiction is another where there may not have been as much development, but there is a clear need. There's simply not enough qualified therapists to help provide medication assisted therapy, and in the US, the opioid problem has reached a crisis level that you haven't seen before. So this is one of the reasons I'm so excited to be here now. The impact that we're going to be able to show can be very significant and we're going to be able to do that at a very large scale, quite quickly.

What kind of impact will DTx have on groups such as patients, physicians and payers?

The patient perspective

Digital therapies can offer patients a precise and personalized solution. For patients suffering from addiction the key is to combine medication and therapy, and individuals who are most successful in recovery are those who are able to develop their own personalized plan that they can follow that works for them.

You can also learn about your unique needs and serve evidence driven recommendations that are very specific to you and I think that's very exciting. We can also do it in a way that you can interact with your digital therapeutic at home throughout the day. So instead of changing your lifestyle to conform to a management plan, it can fit your personal workflow and therefore it's much more likely that you're going to adopt this behavior and realize those benefits.

The physician perspective

If you look at providers the big challenge is that physicians and therapists don't have enough time to spend with patients. It's also very hard to find qualified specialists to even get visits and so a digital therapy can actually offer important counseling services, education services or support services that a doctor knows they need to provide but have

Dennis Urbaniak, EVP Digital Therapeutics

Photo: Jenny Lagerqvist.

WHAT WILL BE THE 3 MOST CRITICAL SUCCESS FACTORS FOR OREXO IN DIGITAL THERAPEUTICS?

1. We will have a relentless focus on customer experience and user experience. Our DTx need to be easy to use for our physicians and patients and UX design will be a key differentiating point.
2. We need to be great in collecting data, analyzing data and using data to inform these digital therapies to be even more precise so it can provide greater value for the patients, physicians and payers.
3. We will create novel business models that create broad market access. Working with our payers to show that the value our digital therapeutics will bring can be realized directly through the contracts that will be put in place around the outcomes that we will deliver in the market place.

"FDA has been very vocal, very open, very proactive about wanting to work quickly to facilitate the development of this new market."

been unable to because they haven't had the time themselves. It can now be an extension of the physician's or therapist's office that enable them to provide better care for their patients.

The payer perspective

For payers, it will be easier to measure tangible clinical benefits, economic benefits and patient satisfaction benefits in the real world, all of which are triggers for reimbursement. Digital therapies can also determine when to use a drug more appropriately and thereby get a better output from the drug as well as to provide services where there is no available therapeutic option. So for payers these are going to be much more efficient and effective tools to use. And the thing about health care is there's no extra money in the system anywhere so digital therapies can help to allocate resources to get better outcomes.

What is FDA's view on digital therapies?

This is another area that's really exciting for me because FDA has been very vocal, very open and very proactive about wanting to work quickly to facilitate the development of this new market. E.g. they have a separate division that's specifically looking at digital therapies and on their home page they're constantly updating information within this field. They have also opened up for faster regulatory pathways and they have started to write draft guidance on various different types of pathways depending upon the nature of the tool you're bringing forward. I am also happy to see that they have started to form coalitions around quality of data and evidence. All these actions taken by FDA are very important to drive the market going forward.

Will it be key to get an approval by FDA to get reimbursed by the payers?

There's a lot of drugs on the payers' lists with FDA approvals that have not done well with payer's so the FDA approval doesn't guarantee that you're going to get the acceptance. It certainly helps you in the discussion and brings a level of quality, but it depends on the category of therapy and the nature of your solution. My view is that we will always need to have an open discussion with FDA to find out the most efficient regulatory pathway to go, if it's a full blown approval similar to a drug or a different faster pathway like enforcement discretion. However, the most important thing for the payers today is they have to see that these tools work in the populations that they manage and the beautiful thing about digital therapies is you can actually do evidence generation with the payers directly within their own population and demonstrate and replicate those results at scale. Then the relationship with the payers and the evidence outcome is going to be really key. The payers are critical partners for digital therapies going forward and the companies that are going to be successful will include the payer's in their development regulatory pathway with FDA and if they can generate the right evidence base directly with the payers, a FDA approval will not be the only key for success.

Let's look in the more long term, what impact will digital therapeutics have on the healthcare sector?

From a user experience point of view I think the digital therapeutics will be ubiquitous in all stages of healthcare. By that I mean from pre diagnosis to post diagnosis. I think we'll start to collect data naturally through different tools and our ability to predict when to intervene in the pre diagnosis phase to diagnose much earlier than the normal is going to be a great opportunity and then introduce the right level of interventions. I also see that the precision that digital therapies offers means you can get your own unique treatment solution. Everyone will also have their own personalized wellness plans driven by digital therapies or treatment plans if they have reached a state of diagnosis and therefore the impact on outcomes will be significantly greater because we'll just be better utilizing our overall collective healthcare resources. So this could actually be one of those things, with all the negativity you hear about healthcare systems in general, this could be a lynchpin that could completely change everything.

In addition, I think that the data that we gather along the way will enable us to discover new therapies and new digital solutions because there's correlations we can't even see today that we will learn about and validate. That will lead to new discovery's that will bring even better solutions which is very exciting. I think in maybe, not five, but 10 to 15 years from now it's not going to be a drug therapy and a digital therapy. I think it's going to be inherently combined into just new medical solutions that happen to be digitally powered.

Opioid addiction is a chronic disease often requiring life-long treatment

Opioid use disorder 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 use disorder is a chronic medical condition which is comparable to other diseases such as type 2 diabetes or high blood pressure. The road to opioid use disorder 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 behavior.[1] Environmental factors such as stress and exposure to the addictive substance also play a part in developing opioid use disorder.[2] Although many patients may suffer for their entire lives, opioid use disorder is a disease that can be treated.

Opioid use disorder 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 use disorder, 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

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, behavioral, and psychological, and are often linked with anxiety attacks, mood swings, nausea and depression.

[1] Addiction and Recovery
[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3898681/
[3] Vowles et al. Rates of opioid misuse, abuse, and addiction in chronic pain: a systematic review and data synthesis, Pain (April 2015)

Alcoholism

Cronic disease

Problem drinking that becomes severe is given the medical diagnosis of alcohol use disorder or AUD. AUD is a chronic relapsing brain disease affecting the reward, memory, and motivation systems of the brain. It is characterized by compulsive alcohol use, loss of control over alcohol intake, and a negative emotional state when not using.[1]

Risk factors

Factors that increase the risk of this condition include depression or other psychiatric disorders and certain psychological traits, including impulsivity and low self-esteem. Stress, associating with others who abuse alcohol, and having easy access to alcohol also contribute to a person's risk.[2]

Treatment

Treatment for alcohol use disorder can vary, depending on needs. Treatment may involve individual or group counseling, outpatient programs, or a residential inpatient stay. Currently, there are only three medications approved by the FDA for the treatment of alcohol abuse and alcohol dependence. These medications are only for those who have already stopped drinking and are trying to maintain abstinence.[3]

[1] National Institute on Alcohol Abuse and Alcoholism
[2] Alcohol.org
[3] Winslow BT, Onysko M, Hebert M. Medications for alcohol use disorder. Am Fam Physician. 2016;93(6):457-465.

The life as an opioid addict

Patients with opioid use disorder 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 2018 more than 67,300 Americans died from a drug overdose, mainly caused by opioids.[5]

Opioid use disorder can be treated

Opioid use disorder 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 behavioral 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 centers in the outpatient setting.[6]

Other co-morbidities associated with opioid addiction

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

[4] Drug Policy Alliance
[5] Center for Disease Control
[6] European Drug Report 2018 (EMCDDA)

Next generation drug delivery technologies

Several important initiatives have been made to ensure that Orexo remains at the forefront of developing new improved products through a combination of well-known and widely documented substances which leverage Orexo's innovative in-house drug delivery technologies. Key to this success to date and in the future is cutting edge, innovative technologies for use across 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 or sub-optimal 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 and has proven to be superior over other commercially available nasal technologies.

Photo: Jenny Lagerqvist.

Products approved on markets worldwide

Since its inception, Orexo has developed four[1] pharmaceutical products that are commercialised by Orexo in the US or worldwide through partners. These products have been developed with a focus on innovative solutions to address patient need, mostly within opioid addiction and pain. Today, Orexo is a well-established business with the financial resources and expertise to drive R&D projects through to commercialization, as demonstrated by the success of the company's lead product, Zubsolv®.

[1] Of these four products, Diabact®, was divested in 2015.

Zubsolv®

Short facts

Technology	Sublingual
Indication	Opioid use disorder (OUD)
Market approvals	US, EU and Australia
Commercial rights	Orexo owns the global rights, except for Australia and New Zealand where Mundipharma Pty owns the rights
Net revenue in 2019	SEK 719.2 million
Partner	mundipharma
Patent protection	US, EU, Australia and New Zealand until 2032

Product advantages include:

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

Zubsolv is a product for the treatment of opioid use disorder based on Orexo's sublingual tablet technology. 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. 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
Market approvals	E.g. US, EU, Japan, South Korea, Middle East, Israeli, Australia, Malaysia and the Philippines[1]
Commercial rights	Worldwide ex-US, Kyowa Kirin
Royalty in 2019	SEK 112.6 million[1]
Partner	KYOWA KIRIN
Patent protection	Most markets ex-US and the EU, until 2024

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

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.

Edluar®

Short facts

Technology	Sublingual
Indication	Insomnia
Market approvals	US, EU
Commercial rights	Worldwide Mylan
Royalty in 2019	SEK 11.6 million
Partner	Mylan
Patent protection	US until 2031, EU 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.

[1] Effective January 1st, 2020, Orexo will not receive any royalty for sales in the EU and the US as the patents on corresponding markets expired in 2019.

Pipeline of potential future assets

Orexo has a strong track-record of developing new products that are approved in markets all over the world. In order to maintain a healthy pipeline of promising drug candidates, resources are invested into Orexo's R&D department in Uppsala, Sweden. In 2019 Orexo expanded its research and development efforts into digital therapeutics. The company entered two strategic partnerships with GAIA AG to develop digital therapies for opioid and alcohol use disorder, a new but complementary market set to drive future growth.

DIGITAL THERAPIES

DEVELOPMENT PROJECTS		Preclinical	Phase 3	Registration	Approved/ Launched: US	EU	RoW[1]
OXD01	Opioid use disorder *Partner: GAIA AG*						
OXD02/ vorvida®	Heavy alcohol use, incl. alcohol use disorder (AUD) *Partner: GAIA AG*					●	

PHARMACEUTICALS

DEVELOPMENT PROJECTS		Exploratory	Preclinical	Phase: 1	2	3	Registration	Approved/ Launched: US	EU	RoW[1]
OX124	Naloxone – Opioid overdose									
OX125	Nalmefene – Opioid overdose									
OX338	Ketrorolac – Moderate to moderately severe pain									
OX382	Buprenorphine – Opioid use disorder/pain									
OX-MPI	BI1029539 – Microvasular disease *Partner: Gesynta Pharma*									

● Launched by GAIA in Germany and Switzerland in 2019.

[1] Rest of the World.

Digital Therapies

OXD01

Short facts

Technology	The artificial intelligence (AI) system, broca®
Indication	Opioid use disorder (OUD)
Expected launching	In the US 2022
In-house or partnership	Partnership with GAIA AG

Unmet medical need

Medication assisted treatment, the current standard for opioid addiction, is the use of medications in combination with counseling and behavioral therapies to provide a "whole-patient" approach to the treatment of opioid use disorder (OUD). However, patients may not have optimal access to face-to-face clinical behavioral health services. Digital therapeutics can help bridge the gap between accessible services and optimal treatment of OUD.

Concept

OXD01 is a device-based digital therapeutic, designed to offer individuals diagnosed with OUD quality psychotherapy intervention based on cognitive behavioral therapy and motivational interviewing.

Changes during the year

The exclusive global commercial rights for OXD01 were acquired from GAIA in August 2019. Since the acquisitions a joint team bringing together GAIA's development expertise with Orexo's deep knowledge within OUD, has initiated the technical development of the new digital therapeutic.

High level timeline[1]

US launch is planned to take place in 2022, but will be dependent on selected regulatory pathway which will be discussed with FDA.

Subsequently, partnerships will be sought for commercialization in countries outside the US.

OXD02/vorvida®

Short facts

Technology	The artificial intelligence (AI) system, broca®
Indication	Heavy alcohol use, incl. alcohol use disorder (AUD)
Expected launching	In the US H2 2020
In-house or partnership	Partnership with GAIA AG

Unmet medical need

AUD is a major health crisis affecting approximately 14.5 million people in the United States.[2] Each year, more than 88,000 people die from alcohol-related causes,[3] making it the third leading preventable cause of death in the country. Alcohol misuse costs the United States about USD 249 billion per year.[4]

Concept

OXD02/vorvida is a device-based digital therapeutic, designed to offer individuals with heavy alcohol use quality psychotherapy intervention based on cognitive behavioral therapy and motivational interviewing. OXD02/vorvida is scientifically proven to reduce troublesome drinking patterns in adults with AUD.

Changes during the year

The exclusive US commercial rights for vorvida were acquired from GAIA in November 2019.

High level timeline[1]

Preparations for initiating launching in the US in H2 2020.

[1] Timeline may change depending on trial outcomes and development strategy
[2] Centers for Disease Control and Prevention (CDC)
[3] Sacks, J.J.; Gonzales, K.R.; Bouchery, E.E.; Tomedi, L.E.; and Brewer, R.D. 2010 National and state costs of excessive alcohol consumption. American Journal of Preventive Medicine 49(5):e73–e79, 2015
[4] Substance Abuse and Mental Health Services Administration (SAMHSA)

Pharmaceuticals

OX124

Short facts

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

Unmet medical need

In 2018 more than 67,300 Americans died of an overdose, a slight decrease comparing to 2017, however an increasing proportion died as a result of the use of the synthetic opioid fentanyl and fentanyl analogs.[1] Currently available naloxone-based rescue medications struggle to reverse effects of such opioids.

Concept

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.

Changes during the year

In beginning of 2019 positive results were received from a human pharmacokinetic study, OX124-001, assessing Orexo's novel nasal spray formulations in 20 healthy volunteers. 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.

The study results showed 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.

High level timeline

Continue to further optimize the formulation and prepare for a pivotal pharmacokinetic bridging study in H2 2020 in consultation with FDA. Assuming further successful development, Orexo expects to file with the FDA in 2021.

OX125

Short facts

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

Unmet medical need

See OX124 to the left and as nalmefene has a significantly longer half-life than naloxone, OX125 increases the possibility of survival for patients who have long distance to hospital care. Another target group is people who have overdosed on opioids that are not dependent on opioid drugs, that by mistake have got fentanyl in their bodies, and also people who risk getting synthetic opioids e.g. police and military in strikes against criminal producers of opioids.

Concept

Nalmefene is a stronger, longer acting antagonist compared with naloxone and thus increases the possibility of survival for specific target groups.

OX125 is based on the same nasal technology used for OX124.

Changes during the year

Preparations for the first human pharmacokinetic study.

High level timeline

Initiate the first pharmacokinetic study in H1 2020. Assuming successful project development the aim is to file with FDA in 2022.

OX338

Short facts

API	Ketorolac
Technology	Oral
Indication	Acute moderate to moderately severe pain
Development phase	Phase 1
Expected to file with FDA	2022
In-house or partnership	In-house

Unmet medical need

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.

Concept

OX338 is based on a new oral 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.

Changes during the year

The first human pharmacokinetic study was performed, evaluating novel formulations of ketorolac, a non-addictive, non-steroidal anti-inflammatory drug (NSAID) for the treatment of pain. The study results, recieved in beginning of 2020 demonstrated improved bioavailability and tolerability compared to the commercially available reference product. In addition, one of the formulations demonstrated more rapid absorption, which may be beneficial when immediate pain relief is needed.

High level timeline

To obtain a unique product profile further optimization of the fomulation is needed. Assuming further successful development, a filing with FDA is expected in 2022.

[1] Alcoholism: Clinical & Experimental Research, 7 januari, 2020.
[2] Centers for Disease Control and Prevention (CDC). Alcohol and Public Health: Alcohol-Related Disease Impact (ARDI). Average for United States 2006–2010 Alcohol-Attributable Deaths Due to Excessive Alcohol Use. https://go.usa.gov/xKBjQ

OX382

Short facts

API	Buprenorphine
Technology	Oral
Indication	Opioid use disorder
Development phase	Preclinical
Expected to file with FDA	–
In-house or partnership	In-house

Unmet medical need

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.

Concept

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.

Changes during the year

Results from the in-vivo animal Proof of Concept study conducted during Q1 2019 did not support progressing the current formulation into clinical phase. Options for continued development, assessing other formulation options, are ongoing.

High level timeline

Will be dependent on the outcome assessing other formulation options.

OX-MPI

Short facts

API	BI1029539
Technology	Oral
Indication	Microvascular disease
Development phase	Phase 1
Expected to file with FDA	–
In-house or partnership	Partnership with Gesynta Pharma AB

Unmet medical need

–

Concept

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).

Changes during the year

The first clinical trial, phase 1, initiated in Q3 2019 is ongoing.

High level timeline

The results are expected in the first half of 2020. Assuming further successful development, phase II clinical trials are planned to be conducted later in 2020.

From left, Håkan Thorén, Analytical Chemist and Lars Johnsson, Head of Analytical Development. Photo: Jenny Lagerqvist.

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 Anti-Corruption, Human Rights, Environment and Labor.

Yours sincerely

Nikolaj Sorensen
President and CEO

Sustainability agenda

Anti-corruption

Conduct responsible business based on trust, transparency, integrity and zero tolerance of corruption.

Target for 2019
Maintain implementation of Corporate Code of Conduct.

Human Rights

Manage social, ethical, environmental and human rights impacts throughout supply chain.

Target for 2019
Supplier evaluation in sustainability aspects.

Environment

Operate eco-efficiently and manage environmental impact across all activities.

Target for 2019
Adopt a risk-based approach and operate eco-efficiently.

Labor

Offer a great and safe workplace where everyone feels valued and respected.

Target for 2019
Create a diverse and equal workplace free from injuries or accidents.

UN GLOBAL COMPACT
COMMUNICATION ON PROGRESS

This is our **Communication on Progress** in implementing the principles of the **United Nations Global Compact** and supporting broader UN goals.

We welcome feedback on its contents.

Sustainability at Orexo

Orexo's vision is to bring value to patients and societies with its pharmaceutical innovations, but in order to create long-term value business approach must also be sustainable. Sustainability is about creating the right conditions to sustain business success – for today and for the generations to come.

BUSINESS COMPLIANCE AND ETHICS CODE			
Supplier Code of Conduct	US Comprehensive Compliance Policies	Safety, Health and Environment Policies	Human Resources Policies

Any given organization should take into consideration how their direct and indirect operations impact the environmental, economic and social environment. At Orexo, sustainability is a business approach where everyone is committed to conduct responsible business and with the ambition to integrate sustainability in all business processes.

GOVERNANCE AND POLICIES

Orexo demonstrates and implements the commitment to sustainable development through establishment of a Sustainability Group. Relevant corporate functions are included to influence corporate policies and strategies and to approve future actions in the sustainability agenda. Throughout the year, performance is reviewed quarterly against the agenda and progress of work is reported to senior management.

In order to achieve sustainability vision and goals, Orexo integrates and implements company values among employees and business partners with help of the company's policies. The policies set the company's minimum expectations and contain directions that help managers and employees in their daily work. The policies are aligned with international norms and well-recognized initiatives, such as the ILO Conventions and the UN Guiding Principles on Business and Human Rights. The Swedish organization, comprising Research and Development and Corporate Headquarters, 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. Working in an ethical manner is an important part of the business and the policy therefore applies to all directors, officers, employees, consultants and temporary staff at Orexo AB and its subsidiaries. The code has a zero tolerance for bribery and corrupt practices and 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.

US 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.

SUSTAINABLE CHANGE WITH INNOVATION

An important part of the ambition to build a more sustainable business is Orexo's contribution to the United Nations Sustainable Development Goals (SDGs). At Orexo, sustainability work contributes to several of the SDGs with a primary focus on SDG3 "Good health and well-being". This target is of especial importance as it is closely aligned with Orexo's ambition to strengthen the prevention and treatment of substance abuse.

Substance use and substance-use disorders is a global public health burden and is recognized by the UN as one of the targets that must be met to achieve the 2030 Agenda for Sustainable Development. Every day approximately 184 people die in the US as a result of drug use and opioids continue to cause the most harm, accounting for 70 percent of the deaths.[2] The availability of and access to treatment services remains limited as only 1 in 7 people suffering from drug use disorders receives treatment each year.[3] With the opioid crisis becoming the worst drug epidemic in US history and an increase of people worldwide suffering from drug use disorders along with fewer people getting access to treatment, Orexo is determined to push harder for action and progress on this issue. The key to addressing this is innovation. By broadening the development pipeline Orexo aims to make treatment available for more people and provide prescribers with more options within drug substitution therapy.

Creating shared values

Innovation and partnership are two key factors when addressing the sustainability challenges the pharmaceutical industry is facing. Orexo's partnership with GAIA AG, a global leader in digital therapeutics, is an example of the company's ambition to add value to both patient and society. With the partnership, therapies will be commercialized and bring benefits to the entire health system such as therapy precision and patient personalization. Given the cost for the society associated with drug abuse, digital therapies will also expand the access to healthcare and bring economic sustainability.

In November 2019, Orexo further strengthened the partnership with GAIA and acquired exclusive US rights to vorvida®, a fully automated digital therapy scientifically proven to reduce troublesome drinking patterns in adults with Alcohol Use Disorder (AUD). AUD is a disorder affecting approximately 14.5 million people[4] and causing more than 88,000 people dying each year.[5] With a cost of about USD 249 billion per year,[6] AUD has not only become the third leading preventable cause of death but also a major health crisis. With digital therapies as vorvida, Orexo will be able to continue to create shared values and have a positive impact on both the individual and the society.

SDG3
Healthy lives and well-being for all at all ages

[1] A recognized statement of ethical principles for medical research involving human subjects developed by the World Medical Association (WMA).
[2] Centers for Disease Control and Prevention
[3] World Drug Report 2019
[4] Centers for Disease Control and Prevention
[5] Sacks, J.J.; Gonzales, K.R.; Bouchery, E.E.; Tomedi, L.E.; and Brewer, R.D. 2010 National and state costs of excessive alcohol consumption. American Journal of Preventive Medicine49(5):e73–e79, 2015.
[6] Substance Abuse and Mental Health Services Administration (SAMHSA). Results from the 2017 National Survey on Drug Use and Health: Detailed Tables. Table 5.5A—Alcohol Use Disorder in Past Year Among Persons Aged 12 or Older, by Age Group and Demographic Characteristics: Numbers in Thousands, 2016 and 2017. https://www.samhsa.gov/data/sites/default/files/cbhsq-reports/NSDUHDetailedTabs2017/NSDUHDetailedTabs2017.htm.

Aiming for a sustainable future

As a participant of the UN Global Compact, Orexo's sustainability agenda is built around the ten principles on anti-corruption, human rights, environment and labor. These principles give the company the long-term focus and direction needed to drive positive change through the operation.

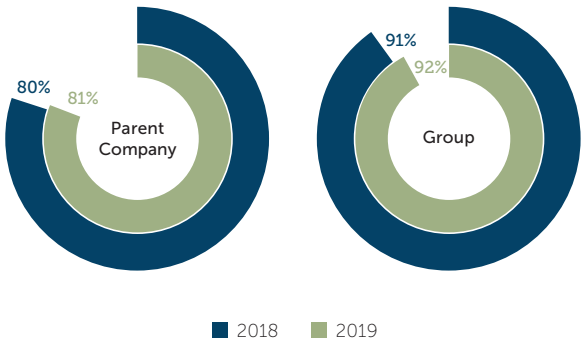
Orexo is commited to contribute to a sustainable future by taking ownership and integrating the sustainability agenda across the business. The agenda will give the focus to achieve sustainability goals while managing emerging risks and embracing opportunities by setting activities with both short-term and long-term goals in areas representing the most significant sustainability challenges facing the company as well as opportunities.

ANTI-CORRUPTION

Working in an ethical manner is an important part of Orexo's business. The company operates in locations that offer good business opportunities, but operations can also be in high-risk markets with exposure to serious risks. For business within the healthcare sector, one recognized risk is ethics and compliance violations in interactions with Healthcare Professionals, Healthcare Organizations and Government Officials. Orexo's policies are therefore important in order to set minimum expectations and to help employees in their daily work.

While compliance with laws and regulations is the highest priority, adopting a wider ethical approach is crucially important. To complement legislation and communicate internally and externally what values should permeate business conduct, Orexo enforces the Code of Conduct through onboarding and training. The Code has a zero tolerance for bribery and corruptive practices and urges individuals to raise questions and report suspected violation of ethical business conduct, without retaliation or any threat of retaliation. Through the revision in 2017, the ten principles of the UN Global Compact were also further integrated with company core values. In 2019, Orexo continued with the effort to implement the Code through onboarding and training in order to further ensure all employees know and practice company's core values. The implementation of the Code is to also ensure responsible business is conducted based on trust, transparency, integrity and zero tolerance of corruption in order to create a foundation for strong relationships with customers, colleagues and stakeholders.

Implementation of Code of Conduct (of employees)



HUMAN RIGHTS

In a global economy human rights should be basic rights, regardless of where everyone comes from or lives. For the most part, this globalization creates jobs and opportunities to help the economy grow as a whole, but in some parts human rights can also be violated. To achieve long-lasting and sustainable changes where human rights are integrated in all relevant processes, everyone needs to take ownership of their sustainability performance and contribute toward fair and equal societies. Orexo's ambition is to drive these values into the supply chain and to ensure that the company's high expectations are lived up to, no matter where in the world. This is especially important as most of Orexo's activities are outsourced.

With a supplier evaluation fully integrated with the company's supplier management process, Orexo continued to evaluate strategically important tier A and B suppliers in sustainability aspects in 2019. The ambition is to raise awareness and impose sustainability requirements on direct suppliers by preventing, mitigating and remediating sustainable impacts throughout the supply chain and beyond.

Performance of Orexo's Supplier Management Process with regards to Sustainability

	Sustainability Evaluations performed		Number of approved Suppliers with open Sustainability issues		
	Result	Target 2019	Major	Moderate	Minor
Tier A	100%	100%	0	0	3
Tier B	18%	20%	0	0	0
Tier C	0%	0%			
Tier D	0%	0%			

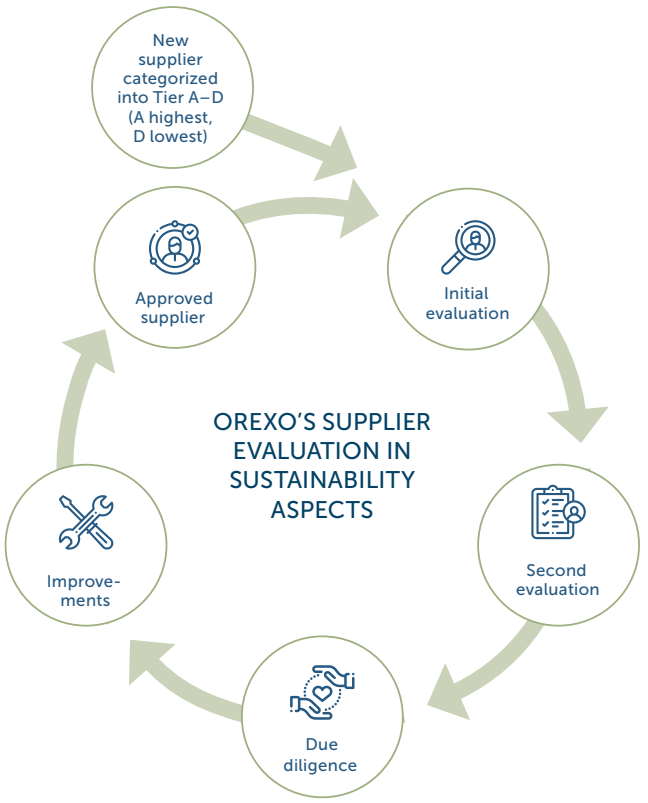
ENVIRONMENT

Orexo has a responsibility to embrace environmentally responsible business practices because the Earth is what human being is dependent on for her well-being and survival. Ecosystems and their services, such as access to clean air, clean water and shelter, are what societies rely on as well as resources that are the backbone of every economy. By acknowledging that the environment is a natural part of every business process, the operation needs to become eco-efficient across all activities. Environmental footprint must be reduced and the use of resources needs to be more thoughtful because being eco-efficient is not just about reducing environmental impact but it also reduces costs and allows for business long-term success.

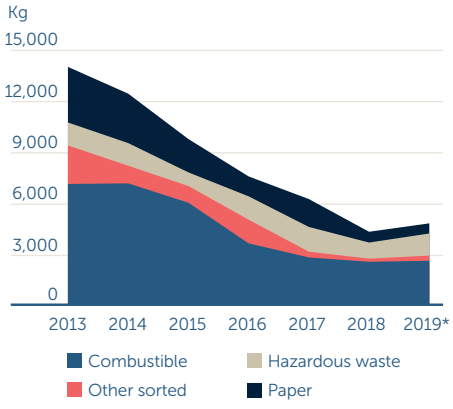
In 2019, Orexo adopted a risk-based approach in order to identify and evaluate the greatest environmental risks. The approach will focus efforts within environmental management to where the greatest risks of adverse environmental impact are found and proactively manage those. Key areas where greatest return on invested efforts can be realized were identified as:

- waste management for a sustainable use of resource
- managing carbon impact (continuing work in 2020)

Action plans for the identified environmental risks were also developed during 2019 in order to advance greater environmental responsibility.



Waste sources



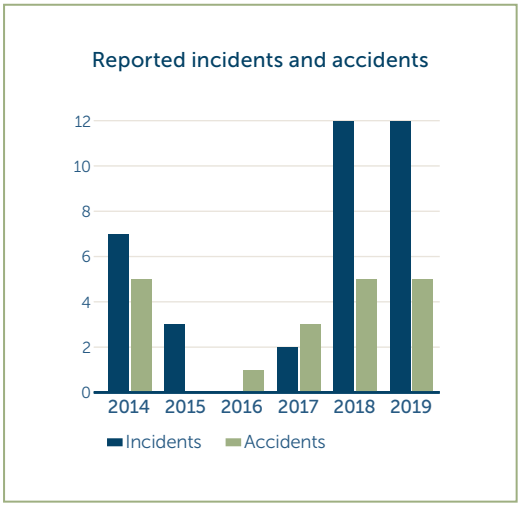
*Intensification of activities at the company's Swedish research facility during 2019

LABOR

At Orexo, sustainability starts with the people behind the scenes because employees are the ones who bring business to life and the base of the organization. As an employer, it is also an opportunity for Orexo to foster a more sustainable workforce to strengthen the competitiveness and to adapt to a fast changing environment. In order to build a sustainable workforce, Orexo's priority is the commitment of attracting and retaining the best individuals by investing in employees and offering a great and safe workplace where everyone feels valued and respected. The key to this mindset is a diverse, inclusive and equal environment.

Social sustainability is about identifying and managing the impacts, both positive and negative, business has on people. This is achieved by a proactive and systematic approach where progress is monitored on a regular basis to spot improvement areas for organizational growth. As a successful outcome of Orexo's constant work with the Equal Opportunities Plan, pay equity analysis in 2019 showed no gender gaps. In 2019, in depth-interviews were also conducted to gain further insight into the result of the employee survey.

As a result, Orexo's action plan to create a sustainable workforce extended to include activities around inclusiveness as well. The work and commitment to creating a better work culture and work-life balance will continue in year 2020 in order to contribute to more sustainable societies.



Performance indicators

	2019		2018	
	Parent	Group	Parent	Group
Types of employment[1]				
Number of employees	54	127	55	129
employees with a permanent contract	100%	100%	98%	99%
employees with a temporary contract	0%	0%	2%	1%
Temporary workers	15%	11%	13%	8%
Gender equality				
Female employees	54%	50%	55%	60%
women in management positions	38%	44%	33%	42%
women in executive management team	–	13%	–	0%
Women in board of directors	–	38%	–	29%
Other data				
Employee satisfaction index[2]	81	82	78	81
Employee absence due to illness	2%	1%	4%	2%

[1] Employees = Orexo's payroll
[2] Springlife – A score of 70 and above is classified as a high score and indicates that the conditions for employees carrying out their work are very good

AUDITOR'S OPINION

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 2019 on pages 26-32 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 24 March 2020
Ernst & Young AB

Björn Ohlsson
Authorized Public Accountant

From the left, Camilla Nordlund, Project Manager. Mikael Persson, Quality & Compliance Manager - Facility & Engineer Zillur Rahman, Executive Assistant to the CEO & Office Manager. Håkan Thorén, Analytical Chemist. Annika Fröling, Analytical Chemist. Photo: Jenny Lagerqvist.

The Share

Orexo's share is listed on Nasdaq Stockholm and is available as American Depository Receipts (ADR) on OTCQX in the US. In 2019 the share price developed positively and the number of shares traded increased. In total Orexo had 6,351 shareholders and foreign ownership amounted to 51 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 6.62 percent and the last price paid in 2019 was SEK 62.80 (58.90). This corresponds to a market capitalization of SEK 2,211 million (2,032). The highest closing price during the year for the share was SEK 85.70 quoted on March 21. The lowest quotation was SEK 51.60 on October 10.

Liquidity

In total 34 million (29) shares were traded in 2019, corresponding to a value of approximately SEK 2,341 million (1,594). The daily average trading volume was 138,130 shares (117,726) corresponding to a value of SEK 9.4 million (6.4).

Ownership

At year-end, Orexo had 6,351 shareholders (6,362), of which 590 were registered as legal entities and 5,761 as private individuals. Of the share capital, 49 percent (53) is held by shareholders registered in Sweden and 51 percent (47) by non-Swedish shareholders. The largest proportion of shareholders registered outside Sweden can be found in Denmark at approximately 34 percent (34). The list on page 35 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 12, 2019, that the company had resolved to issue and immediately thereafter repurchased 63,000 class C shares. The shares were issued and repurchased in accordance with the Long-Term Incentive Program (LTIP) 2019, which was adopted by the Annual General Meeting on April 11, 2019.

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 2019. The class C shares were converted into ordinary shares prior to delivery to qualifying participants in LTIP 2019. The class C shares do not entitle to dividends.

KEY FACTS

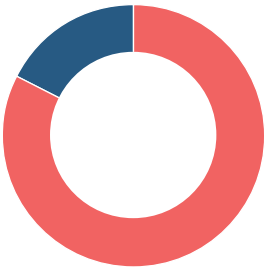
Orexo Share

Listing:	Nasdaq Stockholm, Sweden
Number of shares:	35,553,610, of which 842,971 C shares
Market Capitalization, December 31, 2019:	KSEK 2,211,068
ISIN code:	SE0000736415
Ticker code:	ORX

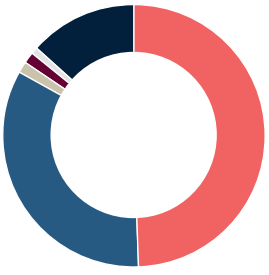
Orexo ADR

Trading platform:	OTC, US
Deposit bank:	Citibank N.A.
ISIN code:	US68616W1027
Ticker code:	ORXOY
Ratio:	1:1

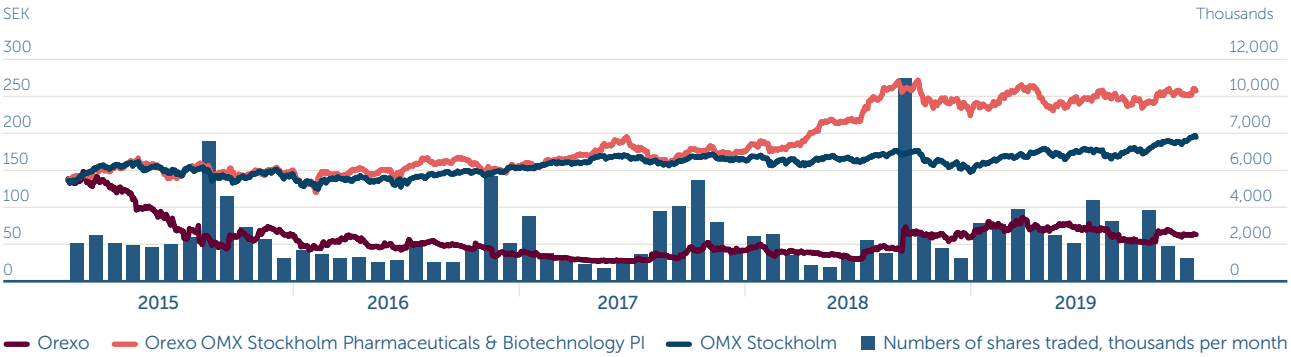
OWNERSHIP CATEGORIES, DECEMBER 31 2019



OWNERSHIP DISTRIBUTIONS PER COUNTRY, DECEMBER 31 2019

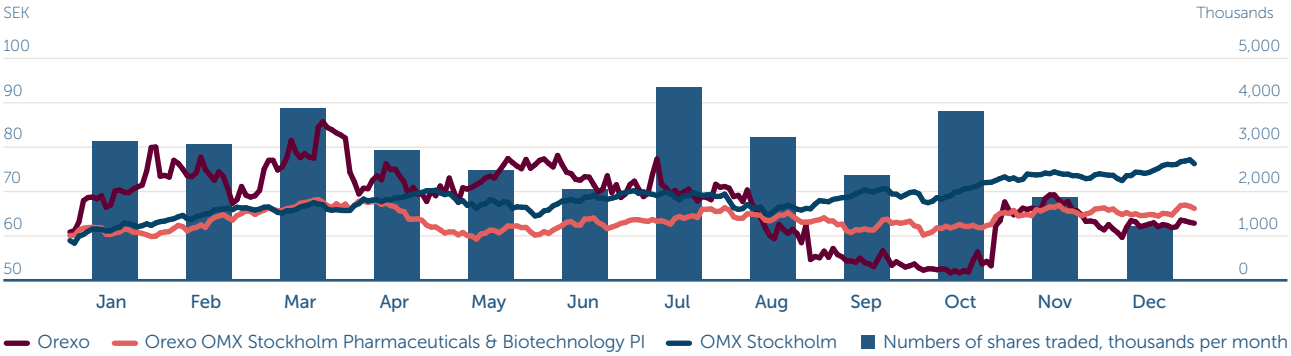


FIVE-YEAR PERFORMANCE



Source: Nasdaq Stockholm

PERFORMANCE IN 2019



Source: Nasdaq Stockholm

SHAREHOLDERS, DECEMBER 31 2019

Owners	No. of Common Shares	C shares	Share Capital (%)
Novo Holdings A/S	9,643,184		27.1
HealthCap	3,556,334		10.0
Arbejdsmarkedets Tillægspension (ATP)	2,040,633		5.7
HealthInvest Partners	1,650,000		4.6
Anders Walldov direct and indirectly	1,550,000		4.4
Avanza Pension	1,248,364		3.5
Orexo AB (publ)		842,971	2.4
Nordnet Pension Insurance	482,651		1.4
Lancelot Asset Management AB	450,000		1.3
Thomas Lundqvist	309,567		0.9
Danica Pension	271,874		0.8
Huber, Reuss & Kollegen Vermögens-verwaltung	261,000		0.7
Evli Funds	246,965		0.7
XACT Funds	217,837		0.6
SEB Funds	202,605		0.6
Total top 15	**22,131,014**		**64.6**
Others	**12,579,625**		**35.4**
Total[1]	**34,710,639**	**842,971**	**100.0**

OWNER STRUCTURE, DECEMBER 31 2019

	No. of Share-holders	No. of Common Shares	Share Capital %
1–500	4,250	652,675	1.84
501–1,000	718	602,734	1.70
1,001–5,000	781	1,798,685	5.06
5,001–10,000	156	1,144,923	3.22
10,001–15,000	52	647,883	1.82
15,001–20,000	27	491,438	1.38
20,001–	97	29,372,301	84.99
Total	**6,351**	**34,710,639**	**100.0**

Analysts monitoring Orexo

- Carnegie, Erik Hultgård
- Nordea, Klas Pyk
- Redeye, Klas Palin
- RX Securities, Samir Devani

[1] As of December 31, 2019, the number of shares outstanding amounted to 35,553,610. All common shares carry one voting right and the C shares carry 1/10 of a voting right each. Thus there are 34,794,936 votes in the company as of December 31, 2019.

Source: Monitor by Modular Finance AB

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, 2019. Orexo's registered office is in Uppsala, Sweden.

Operations

Orexo develops improved pharmaceuticals and digital therapies addressing unmet needs mainly within the growing space of addiction. 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 commercializes its lead product. Zubsolv® which 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, in the EU and in Australia. In the US the product is commercialized by Orexo whereas Mundipharma owned the rights to Zubsolv outside of the US until the partnership ended in April 2019 and all rights were transfered to Orexo.
- Abstral®, for the treatment of breakthrough pain in cancer patients, is approved for use in e.g. the EU, the US, Japan, South Korea, Middle East, Israeli and Australia. The product was sold in the US by Sentynl Therapeutics until October 31, 2019. The European contract with Kyowa Kirin expired as of December 31, 2019. Abstral patents for EU and the US expired in October 2019. For most other markets the patents are valid until September 2024.
- Edluar®, a sublingual tablet containing zolpidem to treat insomnia, is approved for use in the US, Canada and the EU and are sold in these markets by Mylan.
- Diabact®, a tablet for diagnosis of the gastric ulcer bacterium helicobacter pylori, 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 within the growing space of addiction. In addition the company develops digital therpies as a standalone or complementary treatment.

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 Parent company Orexo AB is responsible for the Group head quarter functions, R&D , Corporate Development , Global Regulatory, Supply Chain and Group Business Support.

The US subsidiary, Orexo Inc., is responsible for the US commercialization of Zubsolv and possesses a full commercial infrastructure.

Orexo today has commercial operations promoting Zubsolv to physicians in most larger cities in the US. During 2019 the key focus for the company has been to maintain the market access in light of the intensified competition from new generic entrants, while continuing to optimize the profit contribution from the US operations.

In Q3 2019, a license and supply agreement for Zubsolv for Australia and New Zealand was signed with Mundipharma Pty Ltd, who supported Orexo in obtaining marketing authorization in Australia. Subject to price and reimbursement decisions in Australia, the launch is planned to take place in 2020. Orexo will receive royalties on future net sales. In Australia, an estimated 735,000 people used opioids for nonmedical purposes in 2016-2017[1], and more than 50,000 people received pharmacotherapy treatment for opioid dependence in 2018[2]. The number of opioid-induced deaths among Australians aged 15–64 years amounted to 1,045 in 2016[3].

In Q3 2019 Orexo signed an agreement with GAIA AG, a global leader in digital therapeutics, for the development of a digital therapy for treatment of OUD. This was complemented with acquisition of exclusive US rights to commercialize vorvida®, a digital therapy for alcohol use disorder with scientifically proven efficacy.

The development organization focused during the year on progressing the pipeline of internal development projects. As a result, in the Q1 2019 Interim Report, Orexo announced positive study results from an in-vivo study supporting advancement into a human pharmacokinetic for new tablet formulations of ketorolac for acute treatment of moderate to severe pain (OX338) and from human PK study assessing Orexo's new intranasal naloxone formulations (OX124) for opioid overdose reversal. The 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.

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

[1] Opioid harm in Australia and comparisons between Australia and Canada. Australian Government, Australian Institute of Health and Welfare.
[2] National Opioid Pharmacotherapy Statistics Annual Data collection (NOPSAS) 2018, AIHW.
[3] Opiod-, amphetamine-, and cocaine-induced deaths in Australia: August 2018. National Drug and Alcohol Reasearch Centre.

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 127 employees.

Key events

2019 was the fourth 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 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 was seeking compensation for damages caused by Actavis's infringement of the '996 patent since the year of approval of these two products. On March 29 the District Court of Delaware declared that Actavis does not infringe the '996 patent with their generic versions of Suboxone and Subutex. In Q2 2019 Orexo filed a motion for a new trial in the District Court of Delaware. On December 11 the District Court denied Orexo´s motion for a new trial. Orexo is disappointed with the decision, but as it doesn´t have any impact on Orexo's business, the company has together with its lawyers decided not to appeal. Actavis will not be able to claim Orexo for any compensation related to incurred legal costs.

Zubsolv US market access update

The year saw continued sales growth, above market average, of Zubsolv in the reimbursed open formulary businesses of the market fully compensating for the decline in the previously exclusive reimbursement contracts and cash segment. In the fourth quarter this decline levelled off, and we are now entering a period where Zubsolv will be less dependent on individual exclusive contracts with insurance companies.

Financial Performance

Condensed consolidated statement of operations

SEK million	2019	2018
Net revenues	844.8	783.1
Cost of goods sold	–105.6	–171.8
Gross profit	739.2	611.4
Selling expenses	–191.9	–191.4
Administrative expenses	–139.6	–166.7
Research and development costs	–181.3	–166.8
Other operating income and expenses	4.8	9.3
Operating earnings	231.2	95.8
Net financial items	–3.3	–3.6
Earnings after financial items	227.9	92.2
Income tax	–8.8	45.7
Net earnings for the period	219.1	137.9

Revenues

Net revenues

Net revenues were distributed as follows:

Net revenues

SEK million	2019	2018
Zubsolv US	719.2	621.5
Zubsolv – Rest of World	0.1	36.2
Zubsolv – Total	**719.3**	**657.8**
Abstral® – royalty	112.6	118.8
Edluar® – royalty	11.6	6.6
OX-MPI	1.4	–
Total	**844.8**	**783.1**

Commercial products

Total net revenues for the year amounted to SEK 844.8 million (783.1). Higher Zubsolv US revenue in 2019 explains the increase.

Zubsolv US revenue ended at SEK 719.2 million (621.5), 16 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 2019. Commercial volume growth of Zubsolv was primarily driven by the new exclusive brand position within CVS Caremark and continued growth within Express Scripts and Optum.

Within the public category, Humana Medicare D contributed most to Zubsolv volume growth, despite the addition of generic film to their formulary. Newly gained access in Ohio Medicaid, and improved access in Michigan Medicaid and California Medicaid were the other major contributors to Zubsolv volume growth. Total public volume declined for Zubsolv due to WellCare Medicaid restricting Zubsolv and all other products except generic tablets.

The portion of the market where Zubsolv is accessible (Open formulary) has begun contributing a similar proportion of market growth year over year as compared to the non-accessible portion, giving Zubsolv more opportunities for growth.

Total Abstral royalties during the year amounted to SEK 112.6 million (118.8). Royalties for sales in Europe were received until December 31, 2019 when the European contract with Kyowa Kirin expired. Patents for Abstral expired in October in all markets except in Japan and Australia where they are valid until September 2024.

Royalty revenues from Edluar® during the year amounted to SEK 11.6 million (6.6).

Expenses and earnings

Cost of goods sold

Cost of goods sold amounted to SEK 105.6 million (171.8) all relates to Zubsolv® for the US market.

Selling expenses

Selling expenses amounted to SEK 191.9 million (191.4) 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 139.6 million (166.7). The lower expense level in 2019 is explained by significantly lower legal costs related to protection of IP rights.

Research and development costs

Research and development costs amounted to SEK 181.3 million (166.8). During 2019 the focus was mainly on OX124 and on OX338.

Other income and expenses

Other income and expenses amounted to SEK 4.8 million (9.3). 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 41.0 million (20.8). The increase is mainly related to IFRS 16 standard which is applied by the Group as of January 01, 2019. This also includes amortization of previously capitalized R&D expenses related to the Zubsolv induction label.

Net financial items

Net financial items amounted to SEK –3.3 million (–3.7) explained by lower financial income mainly due to lower exchange rate gains derived from foreign currency bank accounts.

Income tax

Income tax for the year amounted to SEK -8.8 million (45.7) and was negatively impacted by SEK -11.8 million due to adjustments of the parent company's deferred tax asset, driven by anticipated decreased profitability mainly due to reduction in Abstral® royalties and investments in advancing Orexo's pipeline towards commercialization. The parent company tax asset increased by SEK 53.3 million during the previous year.

Net earnings

Net earnings amounted to SEK 219.1 million (137.9).

Financial position

On December 31, 2019, cash and cash equivalents amounted to SEK 816.8 million (589.8) and interest-bearing liabilities to SEK 289.6 million (320.6).

The interest-bearing liabilities are all associated with corporate bonds. During Q3, 2019, Orexo prepaid SEK 32.5 million (10 percent) of the total corporate bond loan.

Positive cash flow from operating activities for the year amounted to SEK 290.9 million (242.0) and was driven by a positive contribution from both earnings and changes in working capital.

Shareholders' equity on December 31, 2019 was SEK 706.4 million (476.1) and the equity/assets ratio was 47 percent (37).

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 35.9 million (3.6). Higher investment is mainly explained by payment of non-refundable first milestones in total of SEK 26.6 million.

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 534.0 million (407.8), of which group internal sales amounted to SEK 408.5 million (246.0). Earnings after financial items were SEK 231.1 million (52.0). As of December 31, 2019, cash and cash equivalents in the Parent Company amounted to SEK 469.0 million (303.2).

Outlook 2020

For 2020 Orexo expects that the buprenorphine/naloxone market will continue to show a double-digit growth.

Net sales of Zubsolv in the US is expected to be in line with 2019. The open businesses will grow, while the previously highly rebated exclusive segments, including cash, will decrease.

Due to increased R&D investments OPEX will reach a level of SEK 550-600 million.

Due to a decrease in the Abstral royalty of approximately SEK 85 million, as an effect of expiration of IP protection in the US and the EU, and increased investments in R&D, EBITDA will decrease.

US EBIT margin from Zubsolv US will be in the range of 45–50 percent.

The outlook is based on exchange rates in December 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 56–58. A summary description of the operational risks attributable to research and development, production, sales and other risks is presented below.

For further information regarding finacial risk see Note 3.

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 2019 the development organization focused on progressing the pipeline of internal development projects. As a result, in the Q1 2019 Interim Report, Orexo was able to announce positive results from human PK study assessing Orexo's new intranasal naloxone formulations (OX124) for opioid overdose reversal 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®.

In the Q4 2019 the first human pharmacokinetic study was performed for the OX338 project based on a new oral tablet formulation of Ketorolac for acute treatment of moderate to severe pain. The study results, received in beginning of 2020, showed promising results, but with a need to further optimize the formulation in order to obtain a unique product profile.

Continued preparations for the first human pharmacokinetic study are ongoing in the first half of 2020 for 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.

Results from the in-vivo animal Proof of Concept study conducted during Q1 2019 the OX382 did not support progressing the current formulation into clinical phase. Options for continued development, assessing other formulation options, are ongoing.

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 (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 was seeking compensation for damages caused by Actavis's infringement of the '996 patent since the year of approval of these two products. On March 29 the District Court of Delaware declared that Actavis does not infringe the ´996 patent with their generic versions of Suboxone and Subutex. In Q2 2019 Orexo filed a motion for a new trial in the District Court of Delaware. On December 11 the District Court denied Orexo´s motion for a new trial. Orexo is disappointed with the decision, but as it doesn´t have any impact on Orexo´s business, the company has together with its lawyers decided not to appeal. Actavis will not be able to claim Orexo for any compensation related to incurred legal costs.

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 2019 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.

Risks related to COVID-19
At the time for publication of the Annual Report the global spreading-risk of the coronavirus disease, COVID-19, has increased. Based on currently available information suggesting that COVID-19 will likely reach a peak in late spring, the current risk the company sees is that it could cause some delays within the development chain which can result in unexpected delays in the pharmaceutical projects. Currently the company is working with several parties in different geographies to avoid any delivery delays. Within other operational areas, such as the supply chain and sales, Orexo sees limited impact on its business. From a financial perspective Orexo currently expects COVID-19 to have no or limited impact, both related to funding and performance. This assumes the restrictions imposed on travel and social interaction in the US declines during the spring.

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 127 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 26–33.

Remuneration
Guidelines for executive remuneration
The executive management of Orexo AB (publ) ("Orexo" or the "company") falls within the provisions of these guidelines. Executive management refers to board members, the CEO and other members of the executive management, which comprised eight persons by the end of 2019. The guidelines are forward-looking, i.e. they are applicable to remuneration agreed, and amendments to remuneration already agreed, after adoption of the guidelines by the annual general meeting 2020. These guidelines do not apply to any remuneration decided or approved by the general meeting.

Remuneration under employments subject to other rules than Swedish may be duly adjusted to comply with mandatory rules or established local practice, taking into account, to the extent possible, the overall purpose of these guidelines.

The guidelines' promotion of the company's business strategy, long-term interests and sustainability
The company's business strategy is the following.

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 substance use disorder. To achieve this, the commercial business will be broadened through business development, M&A and launch of proprietary pharmaceuticals and digital therapies.

Orexo's objectives and strategies onwards is to broaden the US commercial platform to leverage scale and expand sales, further accelerate Orexo US performance and EBIT construction as well as to launch at least one new product from the pipeline within three years.

A prerequisite for the successful implementation of the company's business strategy and safeguarding of its long-term interests, including its sustainability, is that the company is able to recruit and retain qualified personnel. To this end, it is necessary that the company offers competitive remuneration. These guidelines enable the company to offer the executive management a competitive total remuneration. Long-term share-related incentive plans have been implemented in the company. Such plans have been resolved by the general meeting and are therefore excluded from these guidelines. The long-term share-related incentive plans for certain senior executives and key employees within the Orexo group and for Group Management Team and US Leadership Team employees, respectively, proposed by the board of directors and submitted to the annual general meeting 2020 for approval are excluded for the same reason. The proposed plans differ from the existing long-term share-related incentive plans but include similar performance criteria as existing plans for senior executives and key employees. The current plans include certain executives and key employees within the Orexo group. The performance criteria used to assess the outcome of the plans are distinctly linked to the business strategy and thereby to the company's long-term value creation, including its sustainability. These performance criteria currently comprise the share price development, the surpassing of a certain index or the meeting of certain financing and operating objectives, and thereby organic growth and product development. Further, the plans are conditional upon certain holding periods.

Variable cash remuneration covered by these guidelines shall aim at promoting the company's business strategy and long-term interests, including its sustainability.

Types of remuneration, etc.
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 executive 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, both individual goals and goals for the entire company. Individual performance is continuously evaluated.

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 executive management shall be in line with market conditions.

The executive management may be offered cash bonuses. The satisfaction of criteria for awarding variable cash remuneration shall be measured over a period of one year. 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 predetermined and measurable criteria which can be financial or non-financial. They may also be individualized, quantitative or qualitative objectives. The criteria shall be designed so as to contribute to the company's business strategy and long-term interests, including its sustainability, by for example being clearly linked to the business strategy or promoting the executive's long-term development. To which extent the criteria for awarding variable cash remuneration has been satisfied shall be evaluated/determined when the measurement period has ended. The remuneration committee is responsible for the evaluation of the variable cash remuneration to the CEO and the other executives. For financial objectives, the evaluation shall be based on the latest financial information made public by the company. The variable remuneration shall amount to a maximum of 40 percent of the annual fixed cash salary for the CEO, up to 30 percent of the annual fixed cash salary for other members of the executive management in Sweden and up to 60 percent of the annual fixed cash salary for members of the executive management employed in the US subsidiary. The majority of the variable remuneration shall be based on the

sales development and the financial results at group and subsidiary level. The percentage rate in relation to US employees reflects the subsidiary's significance for the group's earnings as well as an American labor market that is requiring an increased share of variable remuneration in order to attract and retain key employees. 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. Such allocation of non-recurring remuneration may, after consolidation with other variable remuneration, amount to a maximum of 70 percent of the annual fixed cash salary.

The CEO and the other members of the executive management are covered by defined contribution pension plans, including health insurance (Sw. sjukförsäkring). Variable cash remuneration shall not qualify for pension benefits except to the extent required by mandatory collective agreement provisions applicable to the executive. The pension premiums paid by the company to the CEO and other members of the executive management may amount to not more than 20 percent of the annual fixed cash salary.

The employment agreement with the CEO may be terminated with six months' notice. Employment agreements with the other members of the executive management may be terminated with a notice of between zero and six months. The CEO is entitled to severance pay equivalent to six months' salary if employment is terminated by the company. The other members of the executive management are entitled to severance pay equivalent to between 3 and 12 months' salary if employment is terminated by the company. Upon notice from the executive, there is no right to severance pay.

In addition, remuneration may be paid for non-compete undertakings. Such remuneration shall compensate for loss of income and shall only be paid in so far as the previously employed executive is not entitled to severance pay. The remuneration shall be based on the fixed cash salary at the time of termination of employment and be paid during the time the non-compete undertaking applies, however not for more than 12 months following termination of employment.

Executives may be awarded customary other benefits, such as company car and travel between the place of residence and the workplace. Such other benefits may amount to not more than 20 percent of the fixed annual cash salary.

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.

For employments governed by rules other than Swedish, pension benefits and other benefits may be duly adjusted for compliance with mandatory rules or established local practice, taking into account, to the extent possible, the overall purpose of these guidelines. Executives who are expatriates to or from Sweden may receive additional remuneration and other benefits to the extent reasonable in light of the special circumstances associated with the expat arrangement, taking into account, to the extent possible, the overall purpose of these guidelines. Such benefits may not in total exceed 30 percent of the fixed annual cash salary.

Salary and employment conditions for employees

In the preparation of the board of directors' proposal for these remuneration guidelines, salary and employment conditions for employees of the company have been taken into account by including information on the employees' total income, the components of the remuneration and increase and growth rate over time, in the remuneration committee's and the board of directors' basis of decision when evaluating whether the guidelines and the limitations set out herein are reasonable.

The decision-making process to determine, review and implement the guidelines

The board of directors has established a remuneration committee. The committee's tasks include preparing the board of directors' decision to propose guidelines for executive remuneration. The board of directors shall prepare a proposal for new guidelines at least every fourth year and submit it to the general meeting. The guidelines shall be in force until new guidelines are adopted by the general meeting.

The remuneration committee shall also monitor and evaluate programs for variable remuneration for the executive management, the application of the guidelines for executive remuneration as well as the current remuneration structures and compensation levels in the company. The members of the remuneration committee are independent of the company and its executive management. The CEO and other members of the executive management do not participate in the board of directors' processing of and resolutions regarding remuneration-related matters in so far as they are affected by such matters.

Derogation from the guidelines

The board of directors may temporarily resolve to derogate from the guidelines, in whole or in part, if in a specific case there is special cause for the derogation and a derogation is necessary to serve the company's long-term interests, including its sustainability, or to ensure the company's financial viability. As set out above, the remuneration committee's tasks include preparing the board of directors' resolutions in remuneration-related matters. This includes any resolutions to derogate from the guidelines.

Largest shareholders

At year-end 2019 Orexo had two large shareholders with holdings of more than 10 percent of the total number of shares; Novo Holding A/S 27.1 percent with 9,643,184 shares, and HealthCap 10.0 percent with 3,556,334 shares.

Dividend

The Board of Directors proposes that no dividend is paid for the financial year 2019.

Number of shares

Company shares total 35,553,610 – whereof 34,710,639 are ordinary shares and 842,971 class C shares. There are 34,794,936 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	1,206,085
Loss carried forward	–1,086,346
Profit/loss for the year	219,273
Total	**339,012**

The Board proposes that the funds at their disposal SEK 339,012 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 82.

Financial information in brief – Group

Statement of operations information

SEK million	2019	2018	2017	2016	2015
Net revenues	844.8	783.1	643.7	705.9	646.2
Cost of goods sold	–105.6	–171.8	–164.4	–149.6	–150.2
Gross Profit	**739.2**	**611.4**	**479.3**	**556.3**	**496.0**
Selling expenses	–191.9	–191.4	–190.5	–240.6	–297.5
Administrative expenses	–139.6	–166.7	–96.1	–161.6	–141.5
Research and development costs	–181.3	–166.8	–134.2	–132.3	–172.6
Other operative income and expenses	4.8	9.3	–1.1	29.9	–65.0
Operating earnings	**231.2**	**95.8**	**57.4**	**51.7**	**–180.6**
Net financial items	–3.3	–3.6	–27.7	–16.1	–23.0
Earning after financial items	**227.9**	**92.2**	**29.7**	**35.6**	**–203.6**
Income tax	–8.8	45.7	–6.5	–6.5	–6.4
Net earning for the year	**219.1**	**137.9**	**23.2**	**29.0**	**–210.0**

Balance sheet information

SEK million	2019	2018	2017	2016	2015
Intangible fixed assets	113.9	103.9	121.0	138.2	155.5
Tangible fixed assets	22.0	20.0	20.1	22.1	24.7
Right-of-use assets	57.0	0.0	0.0	0.0	0.0
Deferred tax	85.5	92.8	28.3	24.8	18.0
Other financial assets	1.4	10.4	7.1	7.9	2.1
Inventories	131.8	173.6	250.2	344.2	402.6
Accounts receivable	233.8	264.5	218.4	178.5	167.8
Other current assets	38.8	31.6	30.9	20.7	51.2
Cash and bank balance	816.8	589.8	327.9	282.4	198.1
Total assets	**1,501.1**	**1,286.7**	**1,003.9**	**1,018.8**	**1,020.0**
Shareholders' equity	706.4	476.1	329.1	310.3	270.1
Interest-bearing liabilities	344.3	320.6	319.1	397.8	494.4
Non-interest bearing liabilities and provisions	450.3	489.9	355.7	310.7	255.5
Total shareholders' equity and liabilities	**1,501.1**	**1,286.7**	**1,003.9**	**1,018.8**	**1,020.0**

Cash flow information

SEK million	2019	2018	2017	2016	2015
Cash flow from operating activities before changes in working capital	252.5	127.9	110.3	67.5	–47.2
Cash flow changes in working capital	34.5	114.1	36.3	88.7	–62.0
Cash flow from operating activities	287.0	242.0	146.6	156.2	–109.2
Acquisition of tangible, intangible and financial assets	–32.0	–6.2	–1.6	–1.7	–4.0
Sale of tangible assets	–	–	–	1.9	–
Disposal of financial assets	9.5	–	–	–	–
Sale of subsidiary	–	–	–	5.0	21.8
Cash flow after investing activities	264.6	235.8	145.0	161.7	–91.4
Amortization of loans	–55.8	–	–404.7	–92.8	–1.2
Borrowings	–	–	319.2	–	–
New share issues	2.0	0.1	0.1	2.2	3.8
Buyback of shares	–	–0.1	–	–	–
Cash flow for the year	210.8	235.8	59.6	71.1	–88.8
Cash and cash equivalents at year-end	816.8	589.8	327.9	282.4	198.1

Other key figures

	2019	2018	2017	2016	2015
EBIT margin, %	27.4	12.2	8.9	7.3	–27.9
Return on shareholder equity, %	37.1	34.3	7.3	10.0	–56.9
Net debt, SEK million[1]	–527.2	–269.2	–8.8	115.4	296.3
Debt/equity ratio, %	41.0	67.3	97.0	128.2	183.0
Equity/assets ratio, %	47.1	37.0	32.8	30.5	26.5
Number of shares, before dilution	34,621,646	34,560,456	34,540,271	34,477,423	34,478,622
Number of shares, after dilution	35,348,484	35,095,980	34,650,835	34,574,337	34,478,622
Earnings per share, before dilution, SEK	6.33	3.99	0.67	0.84	–6.09
Earnings per share, after dilution, SEK	6.20	3.93	0.67	0.84	–6.09
Number of employees at the end of the period	127	129	90	102	90
Shareholders' equity, SEK million	706.4	476.1	329.1	310.3	270.1
Capital employed, SEK million	996.0	796.7	648.2	708.1	764.5
Working capital, SEK million	–56.7	–13.7	149.6	233.9	370.0

For alternative key figures see definitions and reconciliations of key figures on page 80.
[1] Net debt calculated exclusive of leases.

Financial Reports 2019

From left: Anneli Wennman, Analytical Chemist and Malin Gidlund, Head of Pharmaceutical Development
Photo: Jenny Lagerqvist.

Consolidated Statement of Operations

SEK million	Notes	2019	2018
Net revenues	5	844.8	783.1
Cost of goods sold	6	–105.6	–171.8
Gross profit		**739.2**	**611.4**
Selling expenses	6, 8, 9, 31	–191.9	–191.4
Administrative expenses	6, 8, 9, 29, 31	–139.6	–166.7
Research and development costs	6, 8, 9, 31	–181.3	–166.8
Other operating income	7, 10	13.4	18.5
Other operating expenses	6, 10	–8.6	–9.2
Operating earnings		**231.2**	**95.8**
Financial income	11	46.4	35.3
Financial expense	11	–49.7	–38.9
Earnings after financial items		**227.9**	**92.2**
Tax	12	–8.8	45.7
Net earnings for the year		**219.1**	**137.9**
Earnings for the year attributable to:			
Parent Company shareholders		219.1	137.9
Non–controlling interests			–
Earnings per share during the year attributable to Parent Company shareholders (expressed in SEK)			
– before dilution	13	6.33	3.99
– after dilution	13	6.20	3.93

Consolidated Statement of Comprehensive Income

SEK million	Notes	2019	2018
Net earnings for the year		**219.1**	**137.9**
Other comprehensive income			
Items that may subsequently be reversed to the statement of operations:			
Translation differences	16	3.4	7.0
Other comprehensive earnings for the year, net after tax		**3.4**	**7.0**
Comprehensive earnings for the year		**222.5**	**144.9**
Comprehensive earnings attributable to:			
Parent Company shareholders		222.5	144.9
Non–controlling interests		–	–

Consolidated Balance Sheet

SEK million	Notes	2019	2018
ASSETS			
Fixed assets			
Tangible fixed assets	8, 14	22.0	20.0
Intangible assets	8, 15	113.9	103.9
Right-of-use assets	31	57.0	–
Deferred tax assets	30	85.5	92.8
Other financial assets	17	1.4	10.4
Total fixed assets		**279.9**	**227.2**
Current assets			
Inventories	18	131.8	173.6
Accounts receivable	19	233.8	264.5
Other receivables	20	20.3	5.9
Prepayment and accrued income	21	18.4	25.7
Cash and cash equivalents	17, 22	816.8	589.8
Total current assets		**1,221.2**	**1,059.5**
TOTAL ASSETS		**1,501.1**	**1,286.7**
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity			
Share capital		14.2	14.2
Other contributed capital	23	1,861.4	1,853.6
Reserves	16	3.1	–0.3
Profit carried forward including net earnings for the year		–1,172.3	–1,391.4
Total shareholder's equity		**706.4**	**476.1**
Long–term liabilities and provisions			
Provisions	24	10.7	6.5
Interest bearing liabilities	17, 25	289.6	320.6
Lease liabilities, long-term		33.3	–
Total long–term liabilities		**333.6**	**327.1**
Current liabilities			
Accounts payable	17	49.4	47.7
Provisions	24	269.3	265.8
Other liabilities	26	4.7	4.9
Accrued expenses	26	116.2	165.0
Lease liabilities, current		21.4	–
Total current liabilities		**461.0**	**483.4**
Total liabilities		**794.6**	**810.5**
Total shareholders' equity and liabilities		**1,501.1**	**1,286.7**

Changes in Consolidated Shareholders' Equity

Attributable to Parent Company shareholders[1] SEK million	Notes	Share capital	Other contributed capital	Reserves[2]	Profit carried forward including Net earnings for the year	Total shareholders' equity
Opening balance at January 1, 2018		**14.1**	**1,851.6**	**–7.3**	**–1,529.3**	**329.1**
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 payments	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**
Opening balance at January 1, 2019						
Comprehensive income						
Net earnings for the year					219.1	219.1
Other comprehensive income						
Translation differences				3.4		3.4
Total comprehensive income		**0.0**	**0.0**	**3.4**	**219.1**	**222.5**
Transactions with shareholders						
Share-based payments	23		5.8			5.8
New share issues			2.0			2.0
Total transactions with shareholders		**0.0**	**7.8**	**0.0**	**0.0**	**7.8**
Closing balance at December 31, 2019		**14.2**	**1,861.4**	**3.1**	**–1,172.3**	**706.4**

[1] There are no non–controlling interests
[2] Note 16

The number of outstanding shares has increased from 35,450,456 per 31 December 2018 to 35,553,610 per 31 December 2019. This has been done through issuance of 63,000 C shares and 20,871 from exercise of options. The quota value per share on December 31, 2019 is 0.4.

Consolidated Cash Flow Statement

SEK million	Notes	2019	2018
Operating earnings		231.2	95.8
Adjustment for non-cash items	32	41.3	61.9
Interest received		9.9	3.1
Interest paid		–17.7	–14.8
Tax paid		–12.2	–18.1
Cash flow from operating activities before changes in working capital		**252.5**	**127.9**
Changes in working capital			
Change in inventories		43.3	83.5
Change in receivables		45.1	–22.3
Change in current liabilities		–53.9	52.9
Cash flow from operating activities		**287.0**	**242.0**
Investing activities			
Acquisition of tangible fixed assets	14	–5.0	–2.9
Acquisition of intangible assets	15	–27.0	–0.7
Acquisition of financial assets		–	–2.5
Disposal of financial assets		9.5	–
Cash flow from investing activities		**–22.4**	**–6.2**
Financing activities			
New share issue		2.0	0.1
Buyback of shares		–	–0.1
Repayment of loans	25,31	–55.8	–
Cash flow from financing activities		**–53.7**	**0.0**
Cash flow for the year		**210.8**	**235.8**
Cash and cash equivalents at the beginning of the period		589.8	327.9
Exchange-rate differences in cash and cash equivalents		16.1	26.1
Change in liquidity		227.0	261.9
Cash and cash equivalents at the end of the period	22	**816.8**	**589.8**

Parent Company Statement of Operations

SEK million	Notes	2019	2018
Net revenues	5	534.0	407.6
Cost of goods sold	6	–98.6	–116.2
Gross profit		**435.3**	**291.4**
Selling expenses	6, 8, 9, 31	–6.6	–10.3
Administrative expenses	6, 8, 9, 29, 31	–105.6	–135.2
Research and development costs	6, 8, 9, 31	–152.3	–138.3
Other operating income	7, 10	75.6	63.2
Other operating expenses	6, 10	–8.4	–12.6
Operating earnings		**238.0**	**58.1**
Other interest income and similar income	11	40.0	32.8
Other interest expenses and similar expenses	11	–46.9	–38.9
Net financial items		**–6.9**	**–6.1**
Earnings before tax		**231.1**	**52.0**
Tax on earnings for the year	12	–11.8	53.3
Net earnings for the year		**219.3**	**105.3**

Parent Company Statement of Comprehensive Income

SEK million	Notes	2019	2018
Net earnings for the year		219.3	105.3
Other comprehensive income for the period, net after tax			–
Total comprehensive income for the period		**219.3**	**105.3**

Parent Company Balance Sheet

SEK million	Notes	2019	2018
ASSETS			
Fixed assets			
Patents and intellectual property rights and proprietary intangible asset	8, 15	113.9	103.9
Equipment, renovation of the property of others	8, 14	22.0	20.0
Deferred tax assets	30	49.0	60.9
Shares and participations in group companies	27	155.6	152.3
Total fixed assets		**340.6**	**337.1**
Current assets			
Inventories	18	113.4	155.3
Accounts receivable	19	46.4	63.0
Other receivables	20	6.3	5.9
Receivables from group companies		153.5	85.7
Prepaid expenses and accrued income	21	7.8	12.2
Cash and bank	22	469.0	303.2
Total current assets		**796.5**	**625.3**
TOTAL ASSETS		**1,137.1**	**962.4**
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity			
Restricted shareholders' equity			
Share capital		14.2	14.2
Statutory reserve		290.8	290.8
Total restricted shareholders' equity		**305.0**	**305.0**
Non-restricted shareholders' equity			
Share premium reserve	23	1,206.1	1,198.1
Accumulated deficit		–1,086.3	–1,191.4
Net earnings for the year		219.3	105.3
Total non-restricted shareholders' equity		**339.1**	**111.9**
Total shareholders' equity		**644.0**	**416.9**
Long-term liabilities			
Other provisions	24	8.2	4.9
Long-term liabilities	25	289.6	320.6
Total long-term liabilities		**297.8**	**325.5**
Current liabilities			
Accounts payable		22.8	19.6
Other liabilities	26	4.7	5.0
Liabilities to group companies		144.7	143.2
Accrued expenses and deferred income	26	23.1	52.3
Total current liabilities		**195.3**	**220.1**
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		**1,137.1**	**962.4**

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, 2018		**14,1**	**290,8**	**1 195,9**	**–1 191,4**	**309,4**
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**
Opening shareholders' equity at January 1, 2019						
Net earnings for the year					219.3	219.3
Other comprehensive income						–
Total comprehensive income					**219.3**	**219.3**
Share based compensation	23			5.8		5.8
New share issues				2.0		2.0
Closing shareholders' equity at December 31, 2019		**14.2**	**290.8**	**1,206.1**	**–867.0**	**644.0**

The number of outstanding shares has increased from 35,450,456 per 31 December 2018 to 35,553,610 per 31 December 2019. This has been done through issuance of 63,000 C shares and 20,871 from exercise of options. The quota value per share on December 31, 2019 is 0.4.

Parent Company Cash Flow Statement

SEK million	Notes	2019	2018
Operating activities			
Operating earnings		238.0	58.1
Adjustment for non-cash items	32	23.1	14.4
Interest received		3.5	0.5
Interest paid		–15.2	–14.8
Tax paid		–	–
Cash flow from operating activities before change in working capital		**249.4**	**58.2**
Change in working capital			
Change in inventories		41.9	31.0
Change in accounts receivable and other current receivables		–44.5	–1.9
Change in current liabilities		–24.8	–5.4
Cash flow from operating activities		**222.0**	**81.9**
Investing activities			
Acquisition of tangible fixed assets	14	–5.0	–2.9
Acquisition of intangible assets	15	–27.0	–0.7
Cash flow from investing activities		**–32.0**	**–3.6**
Financing activities			
New share issue		2.0	0.1
Buyback of shares			–0.1
Issuance of corporate bonds	25	–	–
Buyback of corporate shares	25	–32.5	–
Cash flow from financing activities		**–30.5**	**0.0**
Cash flow for the year		**159.5**	**78.3**
Cash and cash equivalents at beginning of period		303.2	215.1
Exchange-rate differences in cash and cash equivalents		6.3	9.8
Change in liquidity		165.8	88.1
Cash and cash equivalents at end of period	22	**469.0**	**303.2**

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 24, 2020.

The statement of operations and balance sheet will be presented to the Annual General Meeting on April 16, 2020, 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.

Refer also to 2.21

2.1.1 Amendments to accounting policies and disclosures

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

(a) New and amended standards applied by the Group

IFRS 16 Leases has replaced IAS 17. According to the new standard, most leased assets must be recognized in the balance sheet and the lessee shall report leasing costs as interest payments and depreciation of the asset. The standard is applied by the Group as from January 1, 2019. The Parent Company applies the exception rule in RFR 2. Orexo applied 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 was that a lease asset (right-of-use assets) and a lease liability were added, each at SEK 71.4 million. The P&L effect for 2019 amounted to SEK -0,9 million. The marginal borrowing rate at the time of transition was 4,5%. Refer also to note 31.

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

No new standards or interpretations of existing standards that have not yet been applied by the Group during the financial year.

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.

Note 2 cont.

(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 indefinite 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 statement of operations or other comprehensive income.

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 initial recognition, 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 expected credit losses is recorded based on the Group's forward-looking expected credit losses (ECL). An analysis of expected credit losses is performed, taking into account historical, current and forward-looking factors. The effect of recognition of the provision amount is reported 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.

Note 2 cont.

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

For the comparative year 2018, 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.

For the current year IFRS 16 Leases has replaced IAS 17. According to the new standard, most leased assets must be recognized in the balance sheet and the lessee shall report leasing costs as interest payments and depreciation of the asset. The standard is applied by the Group as from January 1, 2019. The Parent Company applies the exception rule in RFR 2.

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 operating expenses over the lease period.

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.

Note 3 cont.

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 or in the prior 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 2019 fiscal year, sales in USD accounted for 89 (83) percent of net revenues and sales in EUR accounting for 13 (17) percent. During the same period, 72 (77) percent of total operating expenses were in foreign currency with 68 (61) percent in USD, 1 (1) percent in EUR and 3 (4) percent in GBP.

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

A change in the value of USD against SEK of 10 percent and with balance sheet exposure at the closing date entails a change in other operating income and expenses of approximately SEK 13.1 million.

The corresponding change in GBP entails a change of approximately SEK 0.4 million and in EUR of approximately SEK 0.2 million, neither has 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 11.2 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 289.6 million on December 31, 2019 and these are attributable to a corporate bond loan. This loan has a variable interest rate, STIBOR +4.536 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 1.4 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, 2019, the four largest customers accounted for 92 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 according to credit rating from Moody's.

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, 2019	Less than 1 year	Between 1 and 2 years	Between 2 and 5 years
Accounts payable	49.4	—	—
Accrued costs	116.2	—	—
Borrowings	13.3	304.2	—
Leasing	22.0	39.6	—

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

3.5 Commercial market risk and inventory risk

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

To be successful in the US it is of the utmost importance that Zubsolv obtains reimbursements on a par with those of competitors. Due to the complex American market, with many different payers and a complicated reimbursement system, Orexo has established a professional team focusing only on improving market access and reimbursement for Zubsolv. The payers are constantly reviewing their formularies and this can lead to significant changes in market access. By the end of 2019 Zubsolv had access to 97 percent of the commercial category and 37 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

Note 3 cont.

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 2019'.

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, 2019 and 2018 is presented in the table below:

	2019	2018
Shareholders' equity	706.4	476.1
Total assets	1,501.1	1,286.7
Equity/assets ratio	**47%**	**37%**

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 1 180 million (1,414) at December 31, 2019 from which SEK 49,0 million has been capitalized.

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.

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 2019 these costs amounted to SEK 181.3 million (166.8).

NOTE 5 REVENUE FROM CONTRACTS WITH CUSTOMERS

	2019				
Group	Zubsolv®	Abstral®	Edluar®	OX-MPI	Total
Type of revenue					
Sales, products	719.2	–	–	–	**719.2**
Royalties	0.1	112.6	11.6	–	**124.2**
Milestones	–	–	–	1.4	**1.4**
Total revenue from contracts with customers	**719.3**	**112.6**	**11.6**	**1.4**	**844.8**
Geographical markets					
US	719.2	2.2	4.4	–	**725.8**
EU	0.1	87.3	2.2	1.4	**90.9**
Rest of the world	–	23.1	4.9	–	**28.0**
Total revenue from contracts with customers	**719.3**	**112.6**	**11.6**	**1.4**	**844.8**

	2018				
Group	Zubsolv	Abstral	Edluar	OX-MPI	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**

	2019				
Parent Company	Zubsolv	Abstral	Edluar	OX-MPI	Total
Type of revenue					
Sales, products (intragroup)	408.5	–	–	–	**408.5**
Sales, products	–	–	–	–	**0.0**
Royalties	0.1	112.6	11.6	–	**124.2**
Milestones	–	–	–	1.4	**1.4**
Total revenue from contracts with customers	**408.6**	**112.6**	**11.6**	**1.4**	**534.0**
Geographical markets					
US	408.5	2.2	4.4	–	**415.1**
EU	0.1	87.3	2.2	1.4	**90.9**
Rest of the world	–	23.1	4.9	–	**28.0**
Total revenue from contracts with customers	**408.6**	**112.6**	**11.6**	**1.4**	**534.0**

	2018				
Parent Company	Zubsolv	Abstral	Edluar	OX-MPI	Total
Summa					
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.

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 211.9 million (225.2) 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 57.4 million (40.6) at the balance sheet date. During the period, the Group reversed provisions for discounts and returns from previous periods to an amount of SEK 28,5 million (21.0). 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	
	2019	2018	2019	2018
Raw materials and consumables	105.6	171.8	98.6	116.2
Other external expense	247.0	361.3	164.7	168.3
Personnel costs	224.8	165.1	79.9	66.1
Depreciation/amortization and impairment	41.0	20.8	20.0	20.6
Total	**618.4**	**718.9**	**363.1**	**371.2**

NOTE 7 OTHER OPERATING INCOME

	Group		Parent Company	
	2019	2018	2019	2018
Exchange gains	10.5	18.5	10.5	18.5
Other income	2.9	–	65,2	44.7
Gains on disposal of assets	–	–	–	–
Total	**13.4**	**18.5**	**75.6**	**63.2**

Other income manily 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	
	2019	2018	2019	2018
Tangible fixed assets				
Sales	–	0.2	–	–
Administration	1.8	1.8	1.8	1.8
Research and development	1.2	1.0	1.2	1.0
Total tangible fixed assets	**3.0**	**3.0**	**3.0**	**2.8**
Intangible assets				
Administration	0.3	0.2	0.3	0.2
Research and development	16.7	17.6	16.7	17.6
Total intangible assets	**16.9**	**17.8**	**16.9**	**17.8**
Right-of use assets	**21.0**	**–**	**–**	**–**
Total depreciation/amortization and impairment	**41.0**	**20.8**	**20.0**	**20.6**

NOTE 9 REMUNERATION TO EMPLOYEES

Average number of employees

Group	2019 Average number of employees	Of whom men	2018 Average number of employees	Of whom men
Sweden	54	25	55	25
USA	76	30	48	17
Total for Group	**130**	**55**	**103**	**42**

Parent Company	2019 Average number of employees	Of whom men	2018 Average number of employees	Of whom men
Sweden	54	25	55	25
Total for Parent Company	**54**	**25**	**55**	**25**

	Group		Parent Company	
Costs and remuneration to all employees and Board, SEK thousands	2019	2018	2019	2018
Salaries, remuneration and social security fees				
Salaries and other remuneration to the Board, President and Executive Management	33,942	27,279	20,877	15,957
Salaries and other remuneration to other employees	123,656	89,632	25,154	30,448
Pension cost for the Board, President and Executive Management[1]	1,533	2,080	1,215	1,794
Pension cost for other employees[1]	10,417	8,829	6,835	6,563
Social security fees for the Board, President and Executive Management[2]	7,056	4,152	5,728	3,571
Social security fees for other employees[2]	16,838	13,745	10,376	9,513
Other personnel costs	27,985	17,122	4,605	2,460
Total	**221,427**	**162,839**	**74,790**	**70,305**

[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 2019

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	800	–	–	–	–	–	800
Henrik Kjaer Hansen, Board member	400	–	–	–	–	–	400
Fred Wilkinson, Board member	300	–	–	–	–	–	300
Staffan Lindstrand, Board member	350	–	–	–	–	–	350
Mary Pat Christie, Board member	300	–	–	–	–	–	300
Kristina Schauman, Board member	500	–	–	–	–	–	500
David Colpman, Board member	350	–	–	–	–	–	350
Kirsten Detrick, Board member	300	–	–	–	–	–	300
Subtotal	**3,300**	**0**	**0**	**0**	**0**	**0**	**3,300**
President and senior executives							
Nikolaj Sørensen, President and CEO	3,235	1,289	105	658	773	–	6,060
Other senior executives (6)	17,012	5,631	537	875	1,567	–	25,622
Total	**23,547**	**6,921**	**642**	**1,533**	**2,339**	**0**	**34,982**

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**

Board members and senior executives

	2019		2018	
	Number on the closing date	Of whom men	Number on the closing date	Of whom men
Group (incl. subsidiaries)				
Board members	8	63%	7	71%
President and other senior executives	7	86%	6	100%
Parent Company				
Board members	8	63%	7	71%
President and other senior executives	5	80%	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, 2019 refers to Robert A. DeLuca, Michael Sumner, Johannes Doll, Joseph DeFeo, Robert Rönn and Cecilia Coupland.

The number of shares and options held by the President and senior executives is shown in the information regarding the Board on page 90 and Management on page 91.

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:

	Group		Parent Company	
Restated	2019	2018	2019	2018
Other operating income	10.5	18.5	10.5	18.5
Other operating expenses	–8.3	–12.3	–8.3	–12.3
Total	**2.2**	**6.2**	**2.2**	**6.2**

NOTE 11 FINANCIAL INCOME AND EXPENSES

	Group		Parent Company	
	2019	2018	2019	2018
Financial income				
Other interest income	9,9	3.0	3.5	0.5
Exchange rate effect	36.5	32.3	36.5	32.3
Total financial income	**46.4**	**35.3**	**40.0**	**32.8**
Financial expenses				
Interest expense from corporate bonds	–14.3	–14.8	–14.3	–14.8
Other interest expense	–2.9	–0.1	–0.1	–0.1
Borrowingcosts, corporate bonds	–2.3	–1.6	–2.3	–1.6
Exchange rate effect	–30.2	–22.4	–30.2	–22.4
Total financial expenses	**–49.7**	**–38.9**	**–46.9**	**–38.9**
Net Financial items	**–3.3**	**–3.6**	**–6.9**	**–6.1**

NOTE 12 TAX

	Group		Parent Company	
	2019	2018	2019	2018
Current tax	-2.5	–18.8	–	–
Deferred tax	-6.3	64.5	-11.8	53.3
Total	**-8.8**	**45.7**	**-11.8**	**53.3**
Difference between the Group's tax expense and tax expense based on current tax rate				
Recognized pre-tax earnings	227.9	92.2	231.1	52.0
Tax under current tax rate	-48.8	–20.3	-49.5	–11.4
Tax effect of foreign tax rates	-3.0	–0.7	–	–
Tax effect of non-taxable income	–	–	–	–
Tax effect of non-deductible costs	-0.3	–0.3	-0.3	–0.3
Recognized carry-forward losses	43.3	60.9	38.0	60.9
Unrecognized carry-forward losses	–	11.5	–	6.5
Effect of change in tax rate	–	–5.4	–	–2.4
Tax on earnings for the year according to the statement of operations	**-8.8**	**45.7**	**-11.8**	**53.3**

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	
Group	2019	2018
Earnings used for the calculation of earnings per share before dilution, MSEK	219.1	137.9
Average number of shares before dilution	34,621,646	34,560,456
Earnings per share before dilution (SEK per share)	6.33	3.99
Average number of shares after dilution	35,348,484	35,095,980
Earnings per share after dilution (SEK per share)	6.20	3.93
Options/share rights outstanding	1,505,307	1,627,514

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.

Group	2019	2018
Average number of shares before dilution	34,621,646	34,560,456
Potential shares from options and share rights	726,839	535,524
Average number of shares after dilution	35,348,484	35,095,980

NOTE 14 TANGIBLE FIXED ASSETS

Group	Equipment and machinery	Computers	Improvement expenses other's property	Total
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**
Fiscal year 2019				
Opening balance	37.7	3.6	36.2	77.5
Acquisitions	5.0	—	—	5.0
Disposals	–3.5	–0.7	—	–4.3
Outgoing accumulated acqusitions	**39.2**	**2.9**	**36.2**	**78.2**
Ingoing depreciation	–33.5	–3.6	–20.4	–57.5
Acumulated depreciation disposal	3.5	0.7	—	4.2
Depreciation	–1.1	–0.1	–1.8	–3.0
Accumulated depreciation	**–31.1**	**–3.0**	**–22.2**	**–56.3**
At December 31, 2019				
Cost	39.2	2.9	36.2	78.2
Accumulated depreciation and impairment	–31.1	–3.0	–22.2	–56.3
Carrying amount	**8.1**	**–0.1**	**14.0**	**22.0**

Note 14 cont.

Parent Company	Equipment and machinery	Computers	Improvement expenses other's property	Total
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**
Fiscal year 2019				
Opening balance	34.2	1.8	36.2	72.2
Acquisitions	5.0	—	—	5.0
Disposals	–3.5	–0.7	—	–4.3
Outgoing accumulated acqusitions	**35.7**	**1.1**	**36.2**	**72.9**
Ingoing depreciation	–30.1	–1.7	–20.3	–52.2
Acumulated depreciation disposal	3.5	0.7	—	4.2
Depreciation	–1.1	–0.1	–1.8	–3.0
Accumulated depreciation	**–27.7**	**–1.1**	**–22.1**	**–51.0**
At December 31, 2019				
Cost	35.7	1.1	36.2	72.9
Accumulated depreciation and impairment	–27.7	–1.1	–22.1	–50.9
Carrying amount	**8.0**	**0.0**	**14.1**	**22.0**

NOTE 15 INTANGIBLE FIXED ASSETS

Group	Acquired R&D	Patents and rights	Proprietary intellectual property right	Other	Total
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**
Fiscal year 2019					
Opening balance	435.1	27.4	153.6	13.4	629.5
Acquisitions	—	26.4	—	0.6	27.0
Outgoing accumulated acqusitions	**435.1**	**53.8**	**153.6**	**14.0**	**656.4**
Accumulated amortization and impairment	–435.1	–27.4	–52.5	–10.6	–525.6
Amortization	—	—	–15.4	–1.6	–16.9
Accumulated amortization and impairment	**–435.1**	**27.4**	**–67.8**	**–12.2**	**–542.5**
At December 31, 2019					
Cost	435.1	53.8	153.6	14.0	656.4
Accumulated amortization and impairment	–435.1	–27.4	–67.8	–12.2	–542.5
Carrying amount	**0.0**	**26.4**	**85.8**	**1.8**	**113.9**

Note 15 cont.

Parent company	Acquired R&D	Patents and rights	Proprietary intellectual property right	Other	Total
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**
Fiscal year 2019					
Opening balance	435.1	27.4	153.6	13.4	629.5
Acquisitions	—	26.4	—	0.6	27.0
Outgoing accumulated acqusitions	**435.1**	**53.8**	**153.6**	**14.0**	**656.4**
Accumulated amortization and impairment	–435.1	–27.4	–52.5	–10.6	–525.6
Amortization	—	—	–15.4	–1.6	–16.9
Accumulated amortization and impairment	**–435.1**	**–27.4**	**–67.8**	**–12.2**	**–542.5**
At December 31, 2019					
Cost	435.1	53.8	153.6	14.0	656.4
Accumulated amortization and impairment	–435.1	–27.4	–67.8	–12.2	–542.5
Carrying amount	**0.0**	**26.4**	**85.8**	**1.8**	**113.9**

Proprietary intangible asset at December 31, 2019

A proprietary intangible asset amounting to SEK 85.8 million (101.1) is attributable to expenses for clinical studies and a registration expense for these studies. Executive Management assesses that these will give the Group future economic benefits in the form of expanded use of Zubsolv®. The expanded label (initiation of treatment of opioid dependence) was approved by the FDA, the US Food and Drug Administration, in August 2015 and in conjunction with this amortization was begun and will occur over a time period of 10 years. During the year there was no impairment of proprietary intangible assets.

Research and development costs

Research and development costs during the period amounted to SEK 181.3 million (166.8).

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

Impairment testing of Proprietary intangible asset

The company has performed impairment tests of its intangible assets related to the Digital Therapeutics as these are not ready for use. There was no impairment of intangible assets during the year.

NOTE 16 RESERVES

	Translation reserve	Total
Opening balance at January 1, 2018	**–7.3**	**–7.3**
Translation differences	7.0	7.0
Closing balance at December 31, 2018	**–0.3**	**–0.3**
Translation differences	3.4	3.4
Closing balance at December 31, 2019	**3.1**	**3.1**

NOTE 17 INFORMATION ON FINANCIAL INSTRUMENTS IN THE GROUP

Classification and categorization of assets and liabilities in the Group 2019

December 31, 2019	Financial assets measured at amortized cost	Total financial assets	Non-financial assets	Total
Assets				
Tangible fixed assets	–	**0.0**	22.0	**22.0**
Intangible fixed assets	–	**0.0**	113,9	**113.9**
Right-of-use asset	–	**0.0**	57.0	**57.0**
Deferred tax asset	–	**0.0**	85.5	**85.5**
Inventories	–	**0.0**	131.8	**131.8**
Financial assets	1.4	**1.4**	–	**1.4**
Accounts receivable	233.8	**233.8**	–	**233.8**
Other current receivables	–	**0.0**	20.3	**20.3**
Prepaid expenses and accrued income	–	**0.0**	18.4	**18.4**
Cash and cash equivalents	816.8	**816.8**	–	**816.8**
Total assets	**1,052.0**	**1,052.0**	**448.9**	**1,501.1**

December 31, 2019	Financial liabilities measured at amortized cost	Total financial liabilities	Non-financial liabilities	Total
Shareholders' equity and liabilities				
Shareholders' equity	–	**0.0**	706.4	**706.4**
Long-term liabilities, provision	–	**0.0**	10.7	**10.7**
Leasing, long-term	33.3	**33.3**	–	**33.3**
Borrowings	289.6	**289.6**	–	**289.6**
Accounts payable	49.4	**49.4**	–	**49.4**
Provisions	–	**0.0**	269.3	**269.3**
Other current liabilities	–	**0.0**	4.7	**4.7**
Leasing, short-term	21.4	**21.4**	–	**21.4**
Prepaid expenses	103.8	**103.8**	12.4	**116.2**
Total shareholders' equity and liabilities	**497.5**	**497.5**	**1,003.6**	**1,501.1**

Classification and categorization of assets and liabilities in the Group 2018

December 31, 2018	Financial assets measured at amortized cost	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 libailities 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**

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 294.7 million (based on liquid trading price), the carrying value amounted to SEK 289.6 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	
	2019	2018	2019	2018
Raw materials	89.9	109.8	89.9	109.8
Work in progress	23.5	44.1	23.5	44.1
Finished products	18.4	19.7	0.0	1.4
Total	**131.8**	**173.6**	**113.4**	**155.3**

The cost of goods from inventory expensed in the Group amounted to SEK 100.9 million (172.7) and in the Parent Company to SEK 103.8 million (111.7).

NOTE 19 ACCOUNTS RECEIVABLE

Impairment losses on accounts receivable amounted to SEK 0.2 million (0.3) 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	
	2019	2018	2019	2018
SEK	0.0	3.0	0.0	3.0
USD	191.3	210.7	3.9	9.2
EUR	42.5	50.8	42.5	50.8
Total	**233.8**	**264.5**	**46.4**	**63.0**

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

	Group	
	2019	2018
Customer 1	92.1	78.8
Customer 2	43.0	61.3
Customer 3	42.3	51.0
Customer 4	37.5	45.1
Total	**214.9**	**236.3**

Accounts receivable due

At December 31, 2019, accounts receivable amounting to SEK 2.8 million (40.5) 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	
	2019	2018	2019	2018
Less than 30 days	0.4	34.4	0.0	–
31 days and older	2.4	6.1	0.6	–
Total	**2.8**	**40.5**	**0.6**	**0.0**

NOTE 20 OTHER RECEIVABLES

	Group		Parent Company	
	2019	2018	2019	2018
VAT receivable	2.5	2.7	2.5	2.7
Tax receivable[1]	16.8	2.7	2.7	2.7
Other	1.0	0.5	1.0	0.5
Total	**20.3**	**5.9**	**6.3**	**5.9**

[1]See note 12

NOTE 21 PREPAID EXPENSES AND ACCRUED INCOME

	Group		Parent Company	
	2019	2018	2019	2018
Prepaid rents	–	4.1	–	4.1
FDA annual fee	11.4	10.4	–	–
Other interim receivables	7.0	11.1	7.8	8.1
Total	**18.4**	**25.7**	**7.8**	**12.2**

NOTE 22 CASH AND CASH EQUIVALENTS

	Group		Parent Company	
	2019	2018	2019	2018
Cash and bank balances	816.8	589.8	469.0	303.2
Total	**816.8**	**589.8**	**469.0**	**303.2**

The Group has no unused credit facilities at December 31, 2019.

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

	Group		Parent Company	
	2019	2018	2019	2018
SEK	54.2	25.7	38.2	11.6
USD	685.9	482.2	354.2	209.7
EUR	76.0	81.9	76.0	81.9
GBP	0.7	0.1	0.7	0.1
Total	**816.8**	**589.8**	**469.0**	**303.2**

Orexo has made the assessment there is no need for a reserve for expected credit losses. This is driven by the fact that cash and cash equivalents are held entirely in banks, Nordea and Danske Bank, whom have minimal credit risk.

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, 2019 there were a total of 1,505,307 options and share awards outstanding. These consist of 724,638 options that qualify for subscription of shares in Orexo. The number of share awards is 780,669 and each share award provides entitlement to one share in Orexo. 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
2018	–2.1
2019	–5.8

Employee stock options/share awards allotted	Number	Exercise price, weighted average
At Dec 31, 2017	**1,664,510**	**75**
Allotted during the period	399,650	0
Redeemed during the period	–15,368	37
Forfeited during the period	–421,278	88
At Dec 31, 2018	**1,627,514**	**78**
Allotted during the period	228,750	0
Redeemed during the period	–138,492	0
Forfeited during the period	–212,465	152
At Dec 31, 2019	**1,505,307**	**64**

Employee stock options/share awards per year	Number outstanding at Dec 31, 2019	Number vested at Dec 31, 2019	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)	97,763	97,763	29.0	6.15-7.37	35%	28.2	28.2	2021-02-16
2013 (LTIP2011)	552,400	552,400	51.2–131.6	15.5-43.8	35%	24.2–130.6	53.6	2021-02-16
2014 (LTIP2011)	74,475	74,475	112.9–165.1	14.7-21.9	35%	106.6–166.8	151.3	2021-02-16
2017 (LTIP2017)	205,719	0.0	0.0	7.5–27.4	35%	27.4	27.4	2020-06-21
2018 (LTIP2018)	351,350	0.0	0.0	7.1–30.2	38%	30.2	30.2	2021-06-30
2019 (LTIP2019)	223,600	0.0	0.0	40.4–73.1	38%	73.1	73.1	2022-06-15
Total employee stock options/share awards	**1,505,307**							

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**							

During 2019 the company allotted 228,750 employee stock options, of which the CEO and other senior executives were allotted 96,450, corresponding to 43 percent. The financial and operational targets set by the Board for 2019 reached a score of 100 percent and hence none of the allocated share awards pertaining to performance target 2 will forfeit. In total 212,465 options were forfeited during 2019.

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

Owned by	Number outstanding at Jan 1, 2019	Change	Number outstanding at Dec 31, 2019
CEO Nikolaj Sörensen	472,648	3,075	475,723
Board member Martin Nicklasson	0	–	0
Board member Henrik Kjaer Hansen	0	–	0
Board member Fred Wilkinson	0	–	0
Board member Mary Pat Christie	0	–	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

Note 23 cont.

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 2017 and LTIP 2018

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 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. 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 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 LTIP2017 and LTIP2018. The measurement dates are date defined as the date of 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 development of the Orexo share price shall have outperformed the Nasdaq Stockholm Pharmaceuticals & Biotechnology PI during the measurement period 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.

Performance criteria LTIP 2019

LTIP2019 is a share-based program where 20% of the shares are vested based on employment, 40% based on the share price development and the remaining vested based on the company's operational performance and time.

Performance criterion 1

This target is fulfilled if the holder is employed at the end of the vesting period.

Performance criterion 2

This target pertains to the fulfilment of the financial and operational targets for the financial year 2019 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 LTIP2019. 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 2 will vest.

Performance criterion 3

This target pertains to the development of the Orexo share price over the period from the date of the 2019 Annual General Meeting up to and including April 11, 2022. The share price will be measured as the volume weighted average share price 60 trading days prior to the measurement dates. The measurement dates are date defined as the date of the 2019 Annual General Meeting and April 11, 2022. If the Orexo share's share price exceeds Nasdaq Stockholm Midcap GI Index during the measurement period 100% will vest. If not, all share rights under Performance Objective 3 is forfeitted.

NOTE 24 PROVISIONS

Long-term provisions	Group 2019	Group 2018	Parent Company 2019	Parent Company 2018
On January 1	**6.5**	**5.8**	**4.9**	**4.9**
Additional provisions	4.3	1.5	3.5	—
Utilized during the year	-0.2	—	-0.2	-0.1
Reversed unused amounts	—	-0.8	—	0.1
Per December 31	**10.7**	**6.5**	**8.2**	**4.9**

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

Short-term provisions, rebates and chargebacks	Group 2019	Group 2018	Parent Company 2019	Parent Company 2018
On January 1	**265.8**	**200.9**	**0.0**	**0.0**
Additional provisions	802.8	786.4	—	—
Utilized during the year	–781.1	–718.4	—	—
Reversed unused amounts	–28.5	–21.0	—	—
Exchange rate difference	10.3	18.0	—	—
Per December 31	**269.3**	**265.8**	**0.0**	**0.0**

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

NOTE 25 BORROWINGS

	Group	Parent Company
January 1, 2018	**321.1**	**321.1**
Interest expenses	14.8	14.8
Interest paid	–14.8	–14.8
Recognition of loan issuance cost	1.5	1.5
Other non-cash items	0.0	0.0
January 1, 2019	**322.6**	**322.6**
Repurchase bond	–32.5	–32.5
Interest expenses	14.3	14.3
Interest paid	–14.5	–14.5
Recognition of loan issuance cost	1.5	1.5
December 31, 2019	**291.4**	**291.4**

The long-term portion consists of a bond loan amounting to a total of SEK 292.5 million. It matures on November 13, 2021. The loan has a variable interest rate of STIBOR 3 months +4.536 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 limitations regarding any change in the company's ownership structure, so-called change-of-control.

	Group	Parent Company
2018-12-31		
Interest-bearing liabilities	320.6	320.6
Accrued interest costs	2.0	2.0
	322.6	**322.6**
2019-12-31		
Interest-bearing liabilities	289.6	289.6
Accrued interest costs	1.8	1.8
	291.4	**291.4**

NOTE 26 ACCRUED EXPENSES AND OTHER LIABILITIES

Other liabilities	Group 2019	Group 2018	Parent Company 2019	Parent Company 2018
Employee withholding tax	1.5	1.7	1.5	1.7
Deduction, social security fees	1.3	1.2	1.3	1.2
Deduction, special salary tax	2.0	2.0	2.0	2.0
Other current liabilities	—	—	—	0.1
Sum Other liabilities	**4.7**	**4.9**	**4.7**	**5.0**

Accrued expenses	Group 2019	Group 2018	Parent Company 2019	Parent Company 2018
Accrued salaries	18.9	15.3	3.8	2.5
Accrued vacation pay	5.6	4.7	5.6	4.7
Accrued social security fees	3.1	2.4	3.1	2.4
Accrued expenses interest rates	1.8	2.0	1.8	2.0
Trade allowance	51.8	47.4	—	—
Wholesaler fee reserve	16.3	40.2	—	—
Other accrued expenses	18.8	53.0	8.9	40.7
Sum Accrued expenses	**116.2**	**165.0**	**23.1**	**52.3**
Sum Other liabilities and Accrued expenses	**120.9**	**169.9**	**27.8**	**57.3**

NOTE 27 SHARES IN SUBSIDIARIES AND JOINT VENTURES

Direct and indirect holdings Dec 31, 2019	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%	106.0	–	49.5
Orexo US Inc	101013414	USA	100	100%	49.5	–	106.0

All holdings are owned directly.

Change in carrying amount of direct holdings

2018	Opening carrying amount	Acqusition	Contribution	Sales	Impairment	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**

2019	Opening carrying amount	Acquisition	Contribution	Sales	Impairment	Closing carrying amount
Pharmacall AB	0.1	–	–	–	–	0.1
Orexo US Inc	46.2	–	3.3	–	–	49.5
Biolipox AB	106.0	–	–	–	–	106.0
Total	**152.3**	**0.0**	**3.3**	**0.0**	**0.0**	**155.6**

NOTE 28 PLEDGED ASSETS AND CONTINGENT LIABILITIES

	Group		Parent Company	
	2019	2018	2019	2018
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 2019.

NOTE 29 AUDITORS' FEES

	Group		Parent Company	
	2019	2018	2019	2018
Audit assignment				
Ernst & Young	2.6	2.6	2.6	2.6
Non-auditing assignments				
Ernst & Young	0.6	0.3	0.6	0.3
Tax advice				
Ernst & Young	1.0	–	1.0	–
Other services				
Ernst & Young	–	–	–	–
Total	**4.3**	**2.8**	**4.3**	**2.8**

NOTE 30 DEFERRED TAX

The tax-loss carry-forward in the Group amounts to SEK 1,180 million (1,414) as of December 31, 2019 and refers to the Swedish companies. Deferred tax assets of SEK 49.0 million have been capitalized as of December 31, 2019 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	
	2019	2018	2019	2018
Deferred tax assets				
Capitalized tax loss carryforwards	49.0	60.9	49.0	60.9
Temporary differences in current provision	26.1	31.9	–	–
Other temporary differences	10.4	–	–	–
Total	**85.5**	**92.8**	**49.0**	**60.9**

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 49.0 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 LEASING

The Group has leases for mainly premises, cars and other equipment used in the business.

The term of the lease extends between 3–6 years.

The Group also has certain leases for machines with rental terms of 12 months or less and leases for equipment with low value. The Group applies the exceptions to short-term leasing agreements and leasing of low-value assets for these leases. The costs for these agreements are shown below.

During the year, the Group did not have any revenue from releasing rights of use, nor any profits or losses from sale and leaseback transactions.

The Groups leasing contracts regarding facilities in Sweden is subject to variable leasing fees in the form of indexation, which is not included in the valuation of leasing liabilities. The Group has no other costs relating to variable leasing fees that are not included in the valuation of leasing liabilities.

Leasing of low value assets in 2019 amounted to SEK 0.3 million.

Carrying amounts of right-of-use assets recognised and the movements during the period:

Group	Offices	Motor vehicles	Other	Total
1 January 2019	60.9	12.4	0.8	74.1
Disposals	—	–2.3	—	–2.3
Additions	0.9	2.5	0.4	3.8
Depreciation expense	–14.5	–5.0	–0.2	–19.7
Translation difference	0.4	0.7	—	1.1
31 December 2019	**47.7**	**8.3**	**1.0**	**57.0**

Set out below are the carrying amounts of lease liabilities (included under interest-bearing loans and borrowings) and the movements during the period:

Group	Offices	Motor vehicles	Other	Total
1 January 2019	58.8	11.8	0.7	71.4
Disposals	—	–2.4	—	–2.4
Additions	0.9	2.5	0.4	3.8
Interest expense	2.4	0.5	0.0	2.8
Payments	–18.3	–3.3	–0.3	–21.9
Translation difference	0.5	0.4	—	0.9
31 December 2019	**44.3**	**9.4**	**0.9**	**54.6**

	Group	
	2019	2018
Costs for short-term leases	—	—
Total cash outflow för leases	**22.2**	**15.9**

Set out below is the effect of the transition to IFRS 16 between 2018-12-31 and 2019-01-01:

Group	2018-12-31	Effect of transition to IFRS 16	2019-01-01
Assets			
Right-of-use assets	—	74.1	74.1
Accrued income and prepaid expenses	25.7	–2.7	23.0
Total	**25.7**	**71.4**	**97.1**
Shareholders' Equity, provisions and liabilities			
Lease liabilities, long-term	—	52.0	52.0
Lease liabilities, short-term	—	19.4	19.4
Total	**0,0**	**71.4**	**71.4**

Set out below is the nominal value of future leasing fees for non-cancellable leasing contracts:

	Group		Parent Company	
	2019	2018	2019	2018
Within one year	22.0	21,4	13.8	13,3
After one year but not more than five years	39.6	58,4	27.4	39,9
More than five years	—	0,2	—	—
Summa	**61.5**	**80,0**	**41.2**	**53,2**

Reconciliation of operational lease commitments	Group
Commitments for operating leases per December 31, 2018 according to IAS 17	80,0
Effects due to discounting	–8,6
Opening balance as of 1 January 2019	**71,4**

The group has no lease extension options which have been determined as virtually certain to be utilized, and hence has not included any such extensions in the calculation of lease liabilities.

NOTE 32 DISCLOSURES ON THE CASH FLOW STATEMENT

	Group		Parent Company	
	2019	2018	2019	2018
Adjustments for items not included in cash flow comprise the following:				
Depreciation and impairment	41.0	20.8	20.0	20.6
Gain/loss on disposal	—	—	—	—
Change in provisions	–2.7	45.6	3.4	–0.1
Change in fair value of financial instruments	—	—	—	—
Share based payments	5.8	2.1	5.8	2.1
Exchange rate income and expense	–2.7	–6.5	–2.7	–6.5
Other non-cash items	—	—	–3.3	–1.7
Total	**41.3**	**61.9**	**23.1**	**14.4**

NOTE 33 RELATED PARTY TRANSACTIONS

Purchases and sales between Group companies

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

	2019	2018
Forward invoicing of costs		
Orexo US Inc	10.5	3.5
Sale of goods and services		
Orexo US Inc	408.5	246.0
Marketing support		
Orexo US Inc	–59.5	–34.4
Total	**359.5**	**215.1**

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

OX338 showed promising results from the human PK study, assessing novel ketorolac formulations for treatment of pain.

On February 17, 2020 the board of Orexo AB resolved to initiate a repurchase program of ordinary shares. The repurchases may comprise a maximum of 500,000 shares.

Currently, COVID-19, is assessed to have limited impact on the company, from an operational and financial perspective. For more information, read the The Board of Directors Report, Risks.

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	1 206 085
Loss carried forward	–1 086 346
Profit/loss for the year	219 273
Total	**339 012**

The Board proposes that the funds at their disposal SEK 339 012 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 24, 2020

Orexo AB (publ)

Martin Nicklasson
Chairman of the Board

Fred Wilkinson
Board member

Staffan Lindstrand
Board member

Kristina Schauman
Board member

Henrik Kjaer Hansen
Board member

David Colpman
Board member

Kirsten Detrick
Board member

Mary Pat Christie
Board member

Nikolaj Sørensen
President and CEO

Our audit report was submitted on March 24, 2020

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 2019. The annual accounts and consolidated accounts of the company are included on pages 36-75 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 2019 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 2019 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 2019 was MSEK 844.8 in the consolidated income statement and MSEK 534.0 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, returns etc. 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.	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 1-35 and 80-92. 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 2019 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 11 April 2019 and has been the company's auditor since the 15 April 2016.

Uppsala, Sweden, March 24, 2020
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	2019	2018
EBIT	231.2	95.8
Depreciation and amortization	41.0	20.8
EBITDA	**272.1**	**116.6**

Return on shareholders' equity	2019	2018
Average shareholders' equity	591.3	402.6
Net earnings	219.1	137.9
Return on shareholders' equity %	**37.1**	**34.3**

Net debt SEK million	2019	2018
Current and long-term interest-bearing liabilities including pension liabilities	289.6	320.6
Cash and cash equivalents.	–816.8	–589.8
Net debt	**–527.2**	**–269.2**

Operating expenses SEK million	2019	2018
Selling expenses	–191.9	–191.4
Administrative expenses	–139.6	–166.7
Research and development costs	–181.3	–166.8
Other operating income and expenses	4.8	9.3
Operating expenses	**–508.0**	**–515.6**

US EBIT SEK million and EBIT margin %	2019	2018
Consolidated operating earnings	231.2	95.8
Non US related items impacting operating earnings	–119.7	–102.5
US EBIT	**350.9**	**198.3**
US EBIT margin %	**48.8**	**31.9**

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 2019

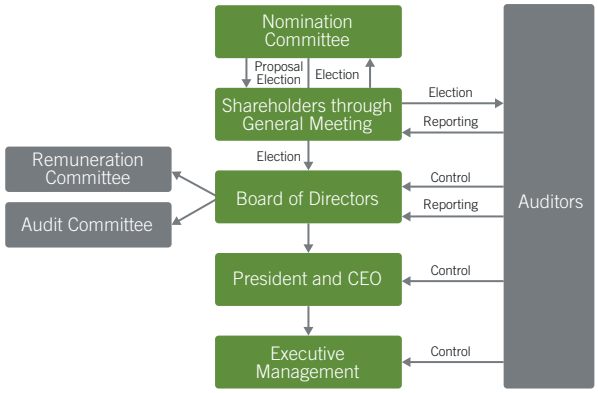
From left: Nikolaj Sørensen, President & CEO and Robert Rönn, VP and Head of R&D.
Photo: Jenny Lagerqvist.

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 35,553,610 (35,450,456), distributed among 6,243 shareholders (6,261).

The 10 largest shareholders held 61.2 percent (62.7) of the outstanding shares, management 0.2 percent (0.2) and other shareholders 38.6 percent (37.1). At December 31, 2019, two shareholders each held shares representing 10 percent or more of the company – Novo Holding A/S, 27.1 percent, and HealthCap, 10.0 percent. Non-Swedish shareholders accounted for approximately 38 percent (47) of the total number of shares. Institutions and industrial owners hold the majority of shares. At year-end, 78 percent (81) of the shares were held by legal entities, and 22 percent (19) 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 2019

The Annual General Meeting was held on Thursday, April 11, 2019 in Uppsala. At the Meeting:

- Staffan Lindstrand, Henrik Kjaer Hansen, Martin Nicklasson, Kristina Schauman, David Colpman and Kirsten Detrick were re-elected as Board members. Mary-Pat Christie and Fred Wilkinson were elected as new members 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 3,300,000, with SEK 650,000 paid to the Chairman of the Board, SEK 300,000 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, and in total 150,000 to be allocated to the members of the remuneration committee in equal parts between the members of the committee.
- The Board's motion concerning guidelines for remuneration to the management was approved.
- The motion concerning the appointment of a Nomination Committee for AGM 2020 was approved.
- The balance sheet and income statement for the Parent Company and the Group for the 2018 fiscal year were adopted.
- The Annual General Meeting granted Board members and the President discharge from liability for the 2018 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 2019 Annual General Meeting can be found at www.orexo.com.

Annual General Meeting 2020

The Annual General Meeting of Orexo will be held on Thursday, April 16, 2020, at 4:00 p.m. at the company's premises at Virdings allé 32 A, Uppsala, Sweden.

Nomination Committee

The 2019 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 2019, 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 14, 2019. 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 2020:

Name	Representatives
Christian Salling	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 44 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, Staffan Lindstrand, Henrik Kjaer Hansen, Kristina Schauman, Kirsten Detrick, Mary-Pat Christie and Fred Wilkinson. For a more detailed description of Board members, please refer to page 90.

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 (12) 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.

Remuneration of the Board

The 2019 Annual General Meeting resolved that Board fees should amount to SEK 3,300,000, of which SEK 650,000 was to be paid to the Chairman of the Board, SEK 300,000 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, and in total 150,000 to be allocated to the members of the remuneration committee in equal parts between the members of the committee.

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.

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	4/4	4/4
David Colpman	Board member	■	2015	12/12	4/4	–
Kristina Schauman	Board member	■	2012	12/12	–	4/4
Henrik Kjaer Hansen	Board member	■	2018	12/12	–	3/3
Mary-Pat Christie	Board member	■	2019	7/7	–	–
Raymond G. Hill	Board member	■	2008	5/5	–	–
Staffan Lindstrand	Board member	■	2002	10/12	4/4	1/1
Fred Wilkinson	Board member	■	2019	7/7	–	–
Kirsten Detrick	Board member	■	2016	12/12	–	–

■ Independent in relation to Orexo and its management
■ Independent in relation to Orexo, its management and 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 Henrik Kjaer Hansen.

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 required knowledge and expertise to deal with issues related to the remuneration of senior executives. The Remuneration Committee comprises Martin Nicklasson (Chairman), David Colpman and Staffan Lindstrand. During the year, the Remuneration Committee was convened on 4 (5) 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 2019 EY was re-elected as auditors until the Annual General Meeting 2020. 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 2019 the Management Team consisted of seven 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 91.

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 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 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 2020 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 2019 on pages 83–87 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 24, 2020
Ernst & Young AB

Björn Ohlsson
Authorized Public Accountant

Glossary

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

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

Anesthesia
Procedure for lowering a patient's consciousness to enable a Medical procedure to proceed without pain for the patient

Artificial intelligence
Artificial intelligence (AI) is the simulation of human intelligence processes by machines, especially computer systems

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

Broca®
GAIA's proprietary intelligence system, based on artificial intelligence, underpins the development of digital therapies targeting multiple therapy areas

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

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

CHMP
The Committee for Medicinal Products for Human Use

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

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

Digital therapeutics (DTx)
Digital therapeutics, a subset of digital health, are evidence-based therapeutic interventions driven by high quality software programs to prevent, manage, or treat a medical disorder or disease

Digital health
Digital health is the convergence of digital technologies with health and healthcare to enhance the efficiency of healthcare delivery and make medicine more personalized and precise

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

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

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

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

Board member since 2012. M.Sc. Pharm. PhD and Associate Professor at the Faculty of Pharmacy, Uppsala University. ***Other appointments:*** Chairman of the Board of 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]

2 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 2,636 shares.[1]

3 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]

4 Fred Wilkinson (b. 1956)

Board member since 2019. MDA., B.Sc. Pharmacy. ***Other appointments:*** Fred currently serves as board member of Alter Pharma Group. ***Previous appointments:*** Has served as President and Chief Executive Officer of Impax Laboratories, Inc. from 2014 until December 2016. Prior to that, Fred held the position of President of the Specialty business at Watson Pharmaceuticals, Inc. (currently Allergan) from 2009 through 2014. Other previous employments include among others President of Duramed Pharmaceuticals, Inc., Chief Executive Officer of Columbia Laboratories, and multiple positions at Sandoz Pharmaceutical Corp. Fred has previously served as board member of Impax Laboratories, Inc., Columbia Laboratories, Inc., Moksha8 Pharmaceuticals, Inc. and Somerset Pharmaceuticals, Inc. Does not hold any shares in Orexo.[1]

5 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 881 shares.[1]

6 Kristina Schauman (b. 1965)

Board member. Board member since 2012. M.Sc. Business and Administration. ***Other appointments:*** Board member and Chairman of the Audit Committee of ÅF Pöyry AB, Billerud-Korsnäs AB, Coor Service Management Holding AB and Diaverum AB. Board member of BEWiSynbra Group AB and Nordic Entertainment Group AB. ***Previous appointments:*** Board member Livförsäkringsbolaget Skandia ömsesidigt, Ellos Group Holding AB 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].

7 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]

8 Mary Pat Christie (b. 1963)

Board member since 2019. MBA. ***Other appointments:*** Board member of Hackensack Meridian Health's Carrier Clinic and Restaurant Technologies. ***Previous appointments:*** Managing Director at Angelo Gordon & Co., where she focused on business development of new fund strategies and new strategic alliances. Prior to that Mrs Christie worked at Cantor Fitzgerald as an Institutional Salesperson and was an original partner at the Seaport Group. Mary Pat was also the founder of Mendham Capital Management. Her career also includes high level roles at JP Morgan, Donaldson, Lufkin & Jenrette, and Fleet Bank. Does not hold any shares in Orexo.[1]

[1] As of December 31, 2019

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 46,715 shares and stock options/share awards entitling to 475,723 shares.[1]

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 5,184 shares and stock options/share awards entitling to 266,754 shares.[1]

3 Johannes Doll (b. 1981)

EVP and Chief Commercial Officer. EVP and CCO since October 2019, employed since 2016. MBA, University of Texas, and Dipl. Kaufmann, WHU Otto Beisheim School of Management, Germany. Johannes Doll worked as an advisor to Orexo during the period 2013-2016 when he was recruited as the EVP and Head of Corporate Development. Since October 2019, Johannes Doll is the company´s Chief Commercial Officer. His responsibilities also include Orexo's activities related to Business Development, M&A, Ex-US markets, Orexo's internal pipeline projects, Regulatory Affairs, and Purchasing. ***Previous appointments:*** Johannes Doll has worked with McKinsey & Company from 2004 to 2013, advising clients in the global pharmaceutical and private equity industry. Holds 18,930 shares and stock options/share awards entitling to 53,840 shares.[1]

4 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 6,765 shares and stock options/share awards entitling to 89,266 shares.[1]

5 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 3,639 shares and stock options/share awards entitling to 63,954 shares.[1]

6 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 516 shares and stock options/share awards entitling to 23,410 shares.[1]

[1] As of December 31, 2019

7 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 25,310 shares.[1]

8 Dennis Urbaniak (f. 1969)

EVP Digital Health. Has held the position as EVP Digital Health since he started to work for the company, December 2, 2019. Monmouth University, US, BS Business Administration/Marketing/English. ***Other appointments:*** Member of HIMSS (Healthcare Information and Management Systems Society).
Previous appointments: Chief Digital Officer, Havas Health & You, Chief Executive Officer, Havas Health Plus. Prior to Havas Health & You, Managing Director Accenture Digital Life Sciences Analytics and Janssen Client Account Lead. Before joining Accenture, twenty years at Sanofi in various sales and marketing roles including US Diabetes Business Unit Head, VP of Innovation and New Customer Channels, Lovenox US brand lead, Plavix marketing, sales operations, sales management, and field sales. Previous volunteer experience as Board Member and Board Chair, Diabetes Hands Foundation; Executive Council Chairman, Center for Healthcare Innovation, and Executive Advisor to Monmouth University School of Science.

Shareholder Information

2020 Annual General Meeting

The Annual General Meeting of Orexo AB will be held on Thursday, April 16, 2020 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 10, 2020, and notify Orexo of their intention to attend the meeting not later than the same day, Friday, April 10, 2020 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 10, 2020 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 2020

2020 Annual General Meeting	April 16, 2020, at 4.00 pm CET
Interim Report Q1 2020	April 28, 2020 at 8.00 am CET
Interim Report Q2 2020	July 16, 2020 at 8.00 am CET
Interim Report Q3 2020	November 4, 2020 at 8.00 am CET
Full Year Report 2020 incl. Q4	January 28, 2021 at 8.00 am CET

ABOUT OREXO

Orexo develops improved pharmaceuticals and digital therapies addressing unmet needs mainly within the growing space of addiction. 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 commercialize its lead product Zubsolv® for treatment of opioid use disorder. Total net sales for 2019 amounted to SEK 845 million and the number of employees was 127. Orexo is listed on the Nasdaq Stockholm Mid Cap (ORX) and is available as ADRs on OTCQX (ORXOY) in the US. The company is headquartered in Uppsala, Sweden, where research and development activities are performed.

For more information about Orexo please visit, www.orexo.com. You can also follow Orexo on Twitter, @orexoabpubl, LinkedIn and YouTube.

Production Solberg