orexo

Orexo develops and commercializes improved pharmaceuticals and digital therapies

Annual Report 2020

Content

The Business

About Orexo 2
The year in brief 4
CEO interview 6
Investment thesis 9
Markets 10
Case – our heroes 12
Objectives and strategies 13
Therapeutic areas 14
Case – our heroes 16
Pharmaceuticals 17
- Technologies 17
- Products 18
- Development projects 20

Digital Therapeutics 22
- Therapies 24

Sustainability Report

We improve the lives of people 28
Innovation and partnership 30
People and society 32
Sustainable supply chain 36
Environment and climate change 38
Responsible business 40
Auditor's opinion 43

The share 44

Board of Directors Report 46

Financial information in brief 52

Financial Reports and Notes

Reports 55
Notes 63
Assurance of the Board of Directors and President 85
Auditors Report 86
Reconciliation and definitions of key figures 90

Corporate Governance

Corporate Governance Report 93
Auditor's Report on the Corporate Governance Statement 98
Board of Directors 100
Management 102

Other Information

Shareholder Information 104
Glossary 105

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 blog.orexo.com

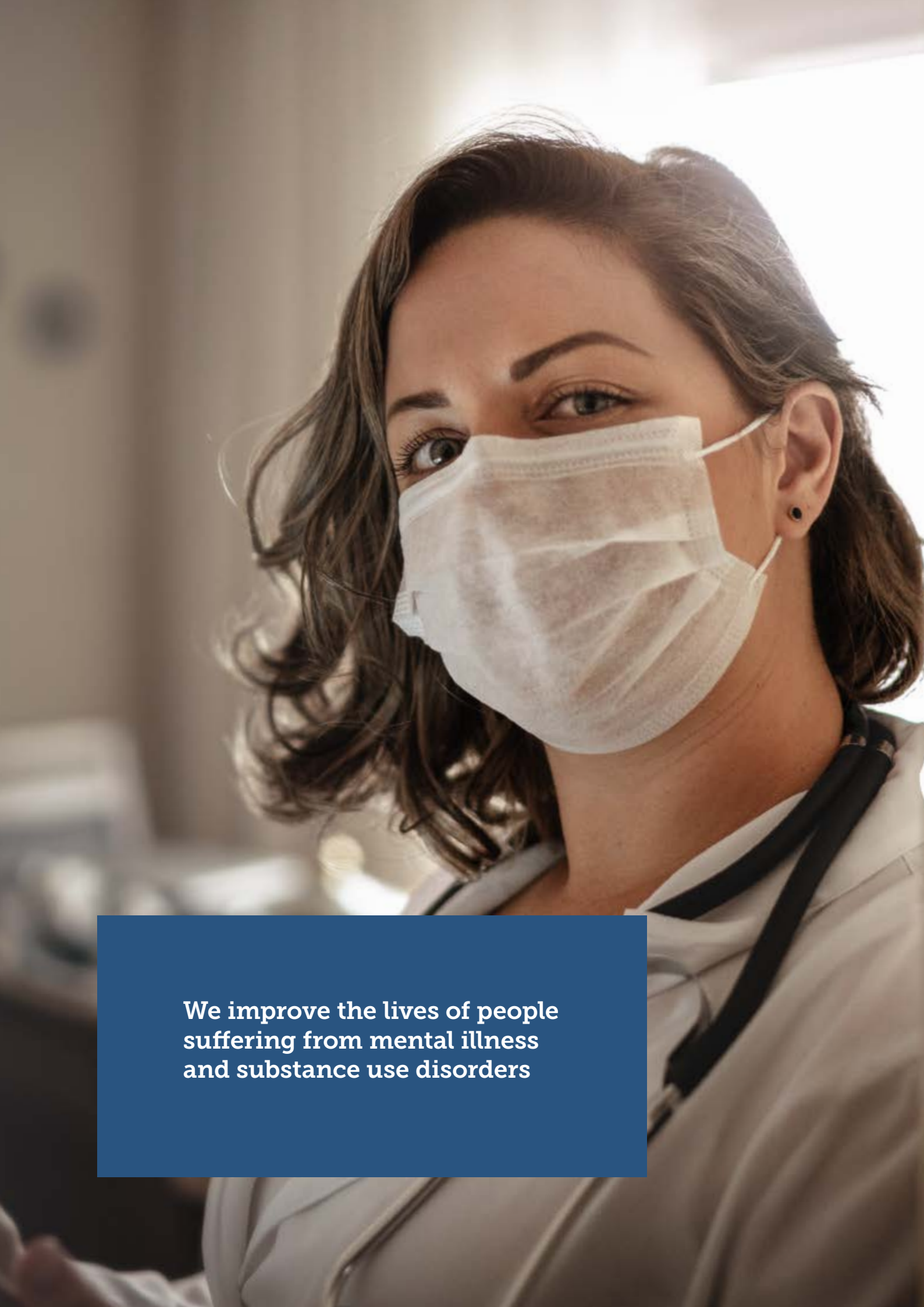
Orexo's formal annual report according to the Annual Accounts Act covers the pages 46–86

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

Cover page, image on the right:

Annika Fröling, Analytical Chemist

Photo: Jenny Lagerqvist



We improve the lives of people suffering from mental illness and substance use disorders

About Orexo

Orexo develops improved pharmaceuticals and digital therapies addressing unmet needs within the growing space of mental illness and substance use disorders. 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 2020 amounted to SEK 664 million and the number of employees was 138. 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.

Maria Sandström, Senior Formulation Scientist
Photo: Jenny Lagerqvist

Evidence-based digital therapies for patients 24/7

Access to qualified psychosocial support for patients suffering from mental illness and substance use disorders is crucial, but also limited. Orexo's evidence-based digital therapies are rooted in cognitive behavioral techniques and can increase access to treatment for patients and improve treatment outcomes.

Read about our digital therapies on pages 22–25

Mental illness and substance use disorders – areas of great human suffering

Built on our competences and where we believe we can make greatest impact we are focusing on improving the lives for patients suffering from mental illness and substance use disorders. The therapeutic areas are characterized by great human suffering and wider societal and economic impact all across the world.

Read about the therapeutic areas and our work for a sustainable world on pages 14–15 and 26–43

SEK160m

invested in DTx in 2020

The lead product, ZUBSOLV®, for the treatment of opioid dependence is an important profit and cash generator. Due to ZUBSOLV® revenues, Orexo has taken important steps to deliver on its strategy for growth to broaden the product portfolio through investments in the pharmaceutical pipeline and in digital therapeutics (DTx).

Orexo develops improved pharmaceuticals based on innovative Drug Delivery technologies

Orexo develops pharmaceuticals addressing areas of large unmet needs. In an effort to bring new pharmaceuticals to the market, well-known substances are combined with Orexo's innovative Drug Delivery technologies. Orexo is acknowledged as a leader for sublingual formulation platforms, having developed multiple products that have been approved worldwide. Several steps have been taken to develop new Drug Delivery platform's and the most advanced of our technologies is an intranasal formulation platform that has been developed to meet the demand for more powerful and efficient opioid overdose rescue medications.

Read about our technologies, pharmaceuticals and development projects on pages 17–21

15% Record-high growth on the US market for the treatment of opioid dependence using buprenorphine/naloxone in 2020

"Digital therapies and digital health will become an integral part of the healthcare landscape and represent a major growth opportunity for Orexo and its shareholders.

Nikolaj Sørensen, President and CEO. Read more in the CEO interview on pages 6–9

Strong presence in the growing US market

Since 2013, Orexo has established a strong presence in the world's largest pharmaceutical market – the US. Orexo is working closely with insurance companies to get products reimbursed, performing clinical studies, and managing its sales force, which covers a large part of the country. The addition of the digital therapeutic venture has also significantly broadened Orexo's product portfolio, which means that the sales force offer healthcare professionals evidence-based digital therapies, in addition to ZUBSOLV®.

Key Figures

SEK million	2020	2019	2018	2017	2016
Net revenues	663.6[1]	844.8	783.1	643.7	705.9
whereof ZUBSOLV® US net revenue	*623.3*	*719.2*	*621.5*	*485.8*	*481.8*
Cost of goods sold	–65.6	–105.6	–171.8	–164.4	–149.6
Operating expenses	–617.9	–508.0	–515.6	–421.9	–584.4
EBIT	–19.9	231.2	95.8	57.4	51.7
EBIT margin, %	–3.0	27.4	12.2	8.9	7.3
US Pharma EBIT	331.2	347.1	192.8	67.4	14.6
US Pharma EBIT marginal, %	53.1	48.3	31.0	13.9	3.0
EBITDA	19.0	272.1	116.6	78.2	73.1
Earnings per share, before dilution, SEK	–2.45	6.33	3.99	0.67	0.84
Earnings per share, after dilution, SEK	–2.45	6.20	3.93	0.67	0.84
Cash flow from operating activities	16.8	290.9	242.0	146.6	156.2
Cash and cash equivalents	505.3	816.8	589.8	327.9	282.4

[1] Reflects royalty from Abstral® exclusive sales in the EU and the US. The contracts for these markets ceased in late 2019, mainly as an effect of patent expiration.

From 2020, operations are monitored and presented in three business segments

- US Pharma – revenues and costs applying to sales of own pharmaceuticals in the US
- Digital Therapeutics (DTx) – revenues and costs applying to the digital therapeutic venture
- HQ & Pipeline – revenues and costs related to other part of the business, for example revenues from out-licensed pharmaceuticals and costs for R&D, business development, global regulatory and supply chain

A transformative year focusing on maximizing business opportunities

Q1

- Pipeline project OX338 showed promising results from the human PK-study, assessing novel ketorolac formulations for treatment of pain.
- Application for vorvida®, an evidence-based digital therapy for alcohol misuse, was submitted to FDA to enable commercialization in the US.
- A virtual Capital Markets Day was hosted in Stockholm, Sweden.
- Repurchased 14 percent of the company's outstanding corporate bonds with a nominal value of SEK 40.5 m.

Q2

- Completed the program to repurchase 500,000 of the company's ordinary shares.
- James Noble elected as Chairman of the Board and Charlotte Hansson elected as Board member at the Annual General Meeting. They replaced Martin Nicklasson and Kristina Schauman who have declined re-election.
- Global IP protection granted for the novel intranasal drug delivery platform until 2039.
- Acquired exclusive US rights from GAIA to commercialize deprexis®, a world-leading digital therapy to help patients manage symptoms of depression.
- Positive results from human PK-study for the pipeline project OX125 assessing novel intranasal nalmefene formulations for opioid overdose reversal.

Q3

- Accelerated launch of vorvida® and deprexis® based on FDA's "Public Health Emergency Policy" providing a fast pathway to market for digital therapies for treatment of psychiatric disorders due to the Covid-19 pandemic.
- Orexo US received subpoenas to provide US authorities with certain information with regards to ZUBSOLV® and other buprenorphine products.
- Infringement litigation against Sun Pharmaceutical was commenced in response to Sun Pharmaceutical has filed an Abbreviated New Drug Application with the US FDA for ZUBSOLV® in the US.
- Distribution partnership signed with GoGoMed to make evidence-based vorvida® and deprexis® available for adjunctive treatment of depression and management of problematic alcohol misuse respectively.
- To address issues of depression and alcohol misuse among employees in the wake of Covid-19 an agreement was signed with Trinity Health, North Dakota, offering the evidence-based digital therapies vorvida® and deprexis ®.
- Finalized development of a scalable proprietary platform to manage payment and reimbursement processes for current and future DTx products.

Robert Rönn, VP and Head of R&D
Photo: Jenny Lagerqvist

Q4

- Secured a preferred position for ZUBSOLV® as the only branded product on national commercial and Medicare Part D formularies of the largest Pharmacy Benefit Manager in the commercial payer segment in the US, Express Script, from January 1, 2021.
- Entered an exclusive license and supply agreement with Accord Healthcare for ZUBSOLV® in Europe.
- A new patent, expiring 2032, was issued for ZUBSOLV®, further strengthening the patent protection.
- The technical development of Orexo's third digital therapy modia™ was completed.
- Orexo ran an innovation challenge for patient entrepreneurs within substance use disorders, in partnership with Lyfebulb, an empowerment platform for patients with chronic diseases. Lief Therapeutics was announced the winner, after their presentation of a wearable device for reduction of stress and anxiety in real time from the use of heart rate variability biofeedback training.

BRIEF INTERVIEW
Geri-Lynn Utter, PSyD and Medical Science Liason at Orexo, about modia™

1. Tell us about the modia™
modia™ is a digital therapeutic rooted in evidence-based, cognitive behavioral therapy (CBT) treatment approaches, for the treatment of opioid use disorder (OUD). It is intended to be used as a part of a clinician supervised medication-assisted treatment (MAT) program. modia™ tailors content to the patient, providing a personalized and interactive psychotherapy tool that aims to teach skills to cope with the challenges related to this disease pace.

2. Why has Orexo developed a digital therapy for OUD?
At Orexo we have a strong dedication and understanding of this disease space. We know that the most efficient way to treat patients with OUD is to combine medication-assisted treatment, such as ZUBSOLV®, and psychotherapy. As a psychologist, I was afforded the opportunity to work with many individuals who have struggled with this disease, and learned that both accessibility and the quality of counseling is often inconsistent across the US. Developing a digital therapy, like modia™, will help to fill this gap.

3. Can digital therapies really replace meetings with psychologists or therapists?
This technology is not meant to replace the human aspect of the therapy process. I perceive digital therapeutics as a precursor to therapy or even as an extension of the therapist. Digital therapies, like modia™, are a clinical touchpoint or tool that the patient can interact with when they are feeling overwhelmed or stressed any time of day or night.


Geri-Lynn Utter, Medical Science Liason

Strategic milestones in neartime

- ✓ Acquired US rights to the scientifically proven digital therapies vorvida® and deprexis®
- ✓ Developed modia™, a digital therapy for opioid use disorder, to which Orexo owns the global rights
- ✓ Developed a scalable distribution and reimbursement platform for digital therapies
- ✓ Advanced the pharma pipeline in opioid use disorder and pain treatment

Nikolaj Sørensen,
President and CEO
Photo: Jenny Lagerqvist

Positioned for future growth

Despite a challenging year with Covid-19 we took several important steps in our ambition to diversify the business. The product portfolio was expanded with world-leading digital therapies and our flagship pharma project, OX124, progressed according to plan. With a strong financial position and continued robust profitability from our lead product ZUBSOLV®, which amounted to an EBIT margin of 53 percent (48), Orexo is well positioned to meet unmet patient needs in areas with strong growth.

With more than twenty years of experience in the pharma industry, what are the main changes you expect see in the near-future?
I believe the Covid-19 pandemic we have lived through during 2020 will have a significant impact on the industry. During the pandemic we have seen the accelerated development and approval of new vaccines and treatments, which has challenged conventional wisdom across the pharmaceutical industry. While this was in response to an acute and global crisis, it demonstrated that pharmaceutical drug development can be done faster and more efficiently, without jeopardizing patient safety. I believe this will impact how certain, more critical pharmaceutical drug development timelines will take shape. Secondly, I believe pharmaceutical companies will take the necessary steps to look 'beyond the pill', as more companies adopt digital health solutions to improve patient outcomes, in addition to the significant business opportunity associated with these new digital tools.

What are the most important drivers to fuel this development?
While I am confident this development would have happened naturally, the pandemic has accelerated the shift towards digital adoption considerably. However, the main driver of this development is the need for society to provide better care for an aging population that does not require a significant increase in resources. For the pharmaceutical industry, this will require the development of new products more efficiently. Technology will play a key role in this, with sophisticated new digital solutions improving quality of care and efficiency whilst requiring fewer resources.

One of Orexo's key objectives is to broaden the product portfolio in the US. In 2020 you launched two digital therapies in the US. How do the therapies complement Orexo's existing products and pipeline?
The entry into digital therapeutics is a result of a clear unmet need we identified in the treatment of opioid addiction i.e. the need to access qualified psychotherapy and counselling without a significant increase in costs and long waiting periods for patients. We believe a digital cognitive behavioral therapy built on a solid scientifically proven platform, such as modia™, is a solution that can be offered to patients/payers/insurers at a reasonable cost.

There are strong synergies from both a commercial and patient perspective given that ZUBSOLV® and all other buprenorphine products for the treatment of opioid addiction should be prescribed in combination with counseling and behavioral therapy. Our other two digital therapies, vorvida® for alcohol misuse and deprexis® for depression, have clear synergies from a technical platform perspective, but also from a treatment perspective as the correlation between patients suffering from opioid addiction and depression and alcohol misuse is significant.

What are the key priorities for your digital therapeutics venture going forward?
Digital therapies and digital health will become an integral part of the healthcare landscape and represent a major growth opportunity for Orexo and its shareholders. The Covid-19 pandemic has certainly accelerated the development of digital therapeutics and we are starting to see greater interest in potential applications and increased adoption of digital solutions. Orexo is operating in a high growth space with a lot of activity and collaboration, including an agreement with GoGoMeds who will focus on making Orexo's digital therapeutics available to various addiction services at US state level.

> "Technology will play a key role in this, with sophisticated new digital solutions improving quality of care and efficiency whilst requiring fewer resources.

I recognize that digital therapies are disruptive and require new treatment protocols, new pathways for reimbursement and, most importantly, require healthcare providers to have confidence in the improved treatment outcome. In light of this we have seen some initial challenges to the pace of adoption, and our priority for 2021 is to further demonstrate commercial proof of concept in terms of functional reimbursement pathways and adoption by leading healthcare providers.

“

We remain in a strong financial position with an increased underlying profit margin from our US Pharma operations and expect a strong profit contribution to continue from ZUBSOLV®.

Beyond entering the digital therapeutics market, are there other operational successes you would like to highlight in 2020?

I am proud of the resilience demonstrated by ZUBSOLV® in the open segment, where we have maintained demand, despite a declining commercial payer segment. I am also proud of the progress we have made with OX124, our late-stage rescue medication for opioid overdose. In 2020 the US FDA significantly changed the technical requirements for devices delivering rescue medications, which caused some delay in progressing OX124 and the need for additional investments in the project. However, I am pleased to say that the development team has responded well to the challenge and we are now on track to submit the OX124 application for approval in mid 2022.

In 2020 you invested heavily to drive future growth, which impacted the financial results. When do you expect the company to become profitable again?

We remain in a strong financial position with an increased underlying profit margin from our US Pharma operations and expect a strong profit contribution to continue from ZUBSOLV®. Thus the timing of a return to profitability is within our control as we plan our investments in 2021. For 2022 and beyond, we will continue to assess business opportunities – investing where it makes sense, and ensuring we remain in full control of the financial situation of the company.

The profitability from the US Pharma business is key for continued investments, but is an EBIT margin in the range of 45–50 percent sustainable in the long term?

After more than seven years in the market, the commercial investments needed for ZUBSOLV® are minimal, and during 2020 we saw continued sales demand for ZUBSOLV® in the Open segment despite the challenges arising from Covid-19.
In addition, we are expecting significant synergies with the launch of modia™, our digital therapeutics for opioid addiction. For these reasons I see limited risk of significant changes to the EBIT margin of ZUBSOLV® during the life time of the IP protection. For US Pharma, the EBIT margin is likely to decline with the launch of OX124 in 2023, as this product will be included in the US Pharma business and naturally will require commercial investments during launch.

Your therapeutic focus has broadened to include additional addiction disorders and mental health. What are the greatest unmet needs you see in this space?

Due to societal stigma, mental illness is an area where many disease indications lack efficient treatments and where patients have suffered due to being seen as less of a priority compared to other disease areas, such as cancer and cardiovascular disease. Mental illness can cause immense suffering, and for many suffering from substance us disorders it is a chronic disease with severe impact on quality of life. One area with significant unmet need is access to psychotherapy and counselling. For many, it is challenging to find a therapist when help is needed, it is also expensive and time-consuming. I believe digital therapies and health solutions have the potential to solve this problem by enabling healthcare providers to improve the treatment outcome, even with limited resources.

In what way can you make a difference here?

We have excellent staff across both sides of the Atlantic that continue to strive for innovative and efficient treatments to enhance the life of many people in need. This has led Orexo to progress towards a leading position in the digital therapeutics space, developing highly complementary therapeutics to our existing pharmaceuticals on the market and in the pipeline, underpinned by a solid financial position. This combination provides a good starting point to make a difference to patients. In the short term, I believe addressing some of the hurdles for digital therapies and other digital health solutions will benefit not only Orexo but also the entire industry, providing patients access to a wealth of new treatment options.

2020 will always be associated with Covid-19. How has the pandemic impacted your employees?

As for most people and businesses globally, Covid-19 has had a significant impact on how we operate at Orexo. Most notable was the decision in mid-March 2020 to stop all face-to-face activities with customers and colleagues and to direct our field force to work from home. In light of these challenges I was extremely pleased by the feedback we received from our employees in our annual employee satisfaction survey in late autumn 2020. We continue to be highly ranked compared to other companies using the same survey, despite the challenges to working conditions posed by Covid-19. We are also fortunate that we have not seen any major outbreaks among employees and no serious illness requiring hospital care.

How have you as a leader responded to these challenges?

The guiding principle must be to protect the health, safety and wellbeing of our employees, customers, and business partners. Following these principles, it was an easy decision to implement restrictions at the office and sales activities, despite the impact on the business in the short-term. It was also important for Orexo to quickly implement new tools, like video conferencing applications, to

enable a collaborative and positive work environment for those working from home, in addition to offering training opportunities for our field force in "virtual selling". I believe the most important explanation for our continued employee satisfaction comes from employees feeling confident that we prioritize their health and safety. We have provided job security and strong engagement with a growing and exciting pipeline, alongside the implementation of a new digital therapeutics strategy with an expert team in the US. Sustainability has also been brought to the center of our work, and you can read more about how we are progressing in this area by reading our Sustainability report on pages 26–43.

What are the key characteristics of your team that will enable Orexo to complete the transformative journey that has just started?
Entering a completely new business area, the most important characteristic for my team is agility. We know that payers, healthcare providers and patients are all new to these digital therapies and the market will evolve in parallel with the launch of new products. For Orexo this means we will need to be excellent in analyzing the market evolution and use our agility to respond to market needs and feedback. Many of our big potential partners will take time before committing and becoming ready to implement new solutions on a broad scale. For Orexo this means we need to continue to believe in the value of our products and work hard to establish strong partnership agreements, working together to improve outcomes for patients. We are already making good progress with the development of customized solutions, collaborating with companies such as Trinity Health, where Orexo has offered access to our digital therapies to their employees and are now moving into a full commercial partnership.

Finally, what should we keep our eyes on at Orexo for the year to come?
All three of our business segments will have a potential to reach important milestones during the next 12–18 months. Commercial progress with our digital therapies will be important and I will remain focused on securing larger business agreements with payers, healthcare providers, and commercial partners. For our pipeline, OX124 is the number one project to monitor and the first milestone will be the clinical trial starting late Q2 before filing with the FDA in mid 2022. For ZUBSOLV®, it will be important to follow our sales progress over each quarter, in particular how ZUBSOLV® performs in the open segment.

Uppsala, Sweden, March 2021

Nikolaj Sørensen
President and CEO

Investment thesis

1 **Product portfolio addressing large and growing markets**

Focusing on becoming a leader in the large and growing space of mental illness and substance use disorders. In parallel, Orexo is addressing the ongoing opioid epidemic, one of the largest health crises to take place in the US and a growing global concern.

2 **Strong cash conversion to support growth**

Lead product ZUBSOLV®, for the treatment of opioid use disorder, is a strong cash and profit contributor, enabling continued investments in on-market products and R&D.

3 **Leveraging our US commercial excellence**

Strategic focus on leveraging its commercial excellence and strong market access network in the US, by adding more products to the US commercial platform.

4 **Pipeline targeting unmet medical needs**

Continue to build on the strong experience of developing products with worldwide approval by expanding the pipeline with multiple short-time to market assets based on innovative drug delivery and digital technologies, addressing unmet medical needs.

5 **Entering digital therapeutics, a new evidence-based frontier in patient care**

Digital therapeutics increase access to treatment and improve treatment outcomes, and is set to become an integral part of the global healthcare landscape. Mental illness and substance use disorders are examples of areas where it is most needed.

Covid-19 fuels the need for Orexo's treatments

The Covid-19 pandemic, with society lockdowns and social distancing, have led to a significant increase in drug addiction and mental health issues globally. In the US, which is Orexo's key market, the opioid crisis has exacerbated and overdose death tolls are reaching record-high numbers. There is a great human suffering and to fill the treatment gap the need for therapies that go beyond traditional regimens, such as digital therapeutics, is significant.

$696 million

Opioid epidemic cost for the US society

15%

US buprenorphine/ naloxone market growth in 2020

16.6 million

Heavy alcohol users in the US

Source: SMHSA, Substance Abuse and Mental Health Services Administration

A global concern and large treatment needs

In recent years, it has become increasingly obvious the important role mental health plays in achieving global development goals, and therefore mental health has been included in the UN's goals for sustainable development. Depression is the leading cause of disability worldwide and suicide caused by depression is the second common death cause among people in the age of 15–29.[1] In the US there is an estimated 17 million US adults suffering from at least one major depressive episode on a yearly basis,[2] of which approximately 35 percent not receive treatment.

The use of drugs globally continues to spread. Approximately 270 million people are using drugs. Opioids continue to cause the most harm and stands for the majority of the drug related deaths.[3] The problem with opioid misuse is by far the greatest in the US where a fifth of those dependent on opioids live.[4] In the US it has reached epidemic proportions and is today the most common cause of deaths among Americans under 50 years. 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.[5] Approximately 4 million are considered to be in need of treatment.[6] 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 Americans.[7] The market for buprenorphine/naloxone products has grown substantially in recent years and in 2020 the growth amounted to 15 percent.[8]

Alcohol misuse is another serious health crisis in the US with more than 16.6 million suffering from heavy alcohol misuse.[9] Each year, more than 88,000 people die from alcohol-related causes,[10] making it the third leading preventable cause of death in the country. Approximately 20 percent of those diagnosed with alcohol use disorder (AUD) receive treatment, of which the majority attended self-help groups.[11]

Covid-19 exacerbates the crisis

The Covid-19 pandemic, with society lockdowns and social distancing, have led to a significant increase in mental health issues and substance use disorders. In the US the opioid crisis has exacerbated and data presented in the summer of 2020 indicated 83,000 Americans died of an overdose during the latest 12-months period, an increase of 21 percent.[12] Synthetic opioids continues to explain the large majority of the death tolls which amounts to more than 70 percent.[13] The Covid-19 pandemic expects to have a large impact on people's mental health and WHO highlighted the need for countries to take necessary measures to alleviate the impact on individuals, their families and society more broadly.[14] Recognizing the need for additional treatment solutions for rising mental health conditions, the FDA has introduced a "Public Health Emergency Policy" with the aim of increasing access to digital therapies within the area of psychiatric disorders during the Covid-19 pandemic.

[1] World Health Organization
[2] National Institute of Mental Health
[3] World Health Organization
[4] World Drug Report
[5] Clarion Healthcare
[6] IQVIA Data
[7] Clarion Healthcare
[8] IQVIA Data
[9] Substance Abuse and Mental Health Services Administration
[10] 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.
[11] Substance Abuse and Mental Health Services Administration
[12] Center of Disease Control and Prevention
[13] Center of Disease Control and Prevention
[14] https://www.un.org/sites/un2.un.org/files/un_policy_brief-Covid_and_mental_health_final.pdf

Large economic burden on societies
From an economic point of view drug addiction and mental illness are a considerable problem. In addition to loss of life and lower quality of life, large costs are associated with lower productivity and a lack of resources, and there are also increased healthcare and correctional treatment costs. In the US, costs related to opioid dependence are extensive, and in 2018 the opioid epidemic cost the US society USD 696 billion.[15] The costs continue to rise which can be explained by the growing death toll in recent years and as it includes a broader societal cost of premature death. Also the widespread alcohol misuse is a big burden for the American society with costs amounting to approximately USD 250 billion on an annual basis.[16]

The digitalization is fueled by Covid-19
Almost all industries have been transformed or are under transformation, as a result of the digitalization's progression. The healthcare sector, surrounded by an extensive regulation framework, has not developed in the same pace, but Orexo is convinced it is just a matter of time before digital health becomes an integrated part of all health care delivery. The health care sector all over the world is under pressure from an aging population and need to find ways to improve efficiency without jeopardizing quality, and improved use of digital health applications will be one solution to this.

Examples of others factors driving the development:
- Continuous increase in scientific evidence of the value from digital health products
- Covid-19 has significantly accelerated the utilization of non face to face interactions between healthcare providers and patients
- Digital health solutions offer a superior monitoring of treatment outcome and enables value based solutions
- Most payers in the US are recognizing the value of digital health solutions and are assessing how to finance and implements these
- Patients are increasingly becoming comfortable with sharing sensitive information on-line.

The Covid-19 pandemic with social distancing has resulted in that authorities, payers, caregivers and patients have approached digital solutions more quickly. Among others the demand for telemedicine surged and FDA has opened up for a fast track to market for digital therapies within the psychiatric field during the pandemic.

The buprenorphine/naloxone market in the US
The market for treatment of opioid dependence using buprenorphine/naloxone showed a record-high growth of 15 percent in 2020. The growth predominantly took place in the largest payer segment, where care is financed by the public sector payers, such as Managed Medicaid, FFS Medicaid and Medicare Part D. Care financed by private insurance companies, often signed by employers, comprised by the commercial payer segment, showed a weak development during the year. The Covid-19 pandemic resulting in a doubling of the unemployment in the US had a negative impact on the commercial payer segment while it gained public financed care and care where patients themselves finance their care. Generics part of the market continue to be dominant which mainly refers to the public financed care which is characterized by high price sensitivity.

[15] The White House Council of Economic Advisors
[16] Substance Abuse and Mental Health Services Administration

CASE – OUR HEROES
Liv

"From my experiences in recovery I have finally felt true joy. However, I don't believe that would've been possible without therapy."

My first therapy session felt like taking a gasp of fresh air. I learned that I had untreated complex trauma and that in order to recover I had to gain agency, autonomy, and build my self-esteem. Through therapy, I learned more effective coping strategies that were rooted in building capacity and resiliency, but also the belief that I have the ability to make sound and healthful decisions. I was encouraged to trust myself, develop my intuition and to build an identity. Too much of my former identity was linked to my unsuccessful experience with the 12-step recovery program and my history.

I didn't want to define myself by my addiction — or label myself by the pejorative term "alcoholic" — being the only thing about me; I wanted to define myself as my recovery being my superpower. And that is what therapy gave me: the confidence and the support to believe in myself and my abilities.

Had I not experienced addiction to such an acute state I wouldn't know the depths of what life is comparable to now: freedom, autonomy, agency, self-direction, and passion. I want to use my experience to help people clinically to find the kind of freedom I have found in therapy and recovery.

Visit our Blog to read Liv's full story – **blog.orexo.com**

With our Blog our mission is to shed light on lives affected by addiction and the road to recovery. The opinions expressed in this blog are solely those of the authors and do not necessarily reflect the views of Orexo AB or Orexo US Inc. The authors have been asked not to reveal specifics around potential medically assisted treatments or other therapy used to reach recovery to Orexo or the readers.

Route for long-term growth

The strategy for long-term growth is built on maximizing the potential of the strong commercial position on the US market. The lead product, ZUBSOLV®, which is an important profit and cash contributor, has paved the way for investments in novel pharmaceutical candidates and world-leading digital therapies, with the ambition to become a leading player within the large and growing space of mental illness and substance use disorders.

1 **Broadening ...**

... the portfolio of commercial products to be promoted by our US Pharma and Digital Therapeutic businesses.

2 **Maintaining ...**

... ZUBSOLV® profit contribution and ensure it is sustainable and growing over time.

3 **Establishing ...**

... a new revenue generating business area within digital therapeutics and have three revenue generating products in the market in 2021.

4 **Launching ...**

... OX124, an overdose rescue medication, in 2023 in the US.

Andreas Fischer, Senior Principal Scientist
Photo: Jenny Lagerqvist

Many with drug addiction are also suffering from mental illness

Being addictive to drugs is a chronic disease that affects both a person's brain and their behavior resulting in a significant impact on their quality of life. People suffering from drug addiction have a higher incidence of also experiencing other mental illnesses and vice versa. Taking a holistic treatment approach to all elements of an individual's mental health can have an instrumental impact on those peoples' lives.

Addiction related diseases are a chronic brain disease

Substance use disorders, SUD, also named drug addiction, is a chronic relapsing brain disease affecting the reward, memory, and motivation systems of the brain. It is caused by use of substances such as drugs, alcohol and nicotine. The reasons behind developing an addiction are wide-ranging, with genetic factors thought to account for a large part of a person's vulnerability to developing addictive behavior. Environmental factors such as stress and exposure to addictive substances also play a part in developing addiction.[1] Drug and alcohol addiction often have a strong impact on patients private and professional life.

Mental illness deeply impacting day-to-day living

Mental illness applies to a wide range of mental health conditions, affecting people's mood, thinking and behavior, leading to functional impairment impacting life activities. Examples of mental illness are anxiety, depression, schizophrenia, post-traumatic stress, ADHD[2] and bipolar disorder. Mental illness is thought to be caused by a variety of factors such as genetics, brain chemistry and environmental issues.

Mental illness can trigger a substance use disorder and vice versa

Mental illness frequently co-occurs with substance use disorders. The relationship between the two is bi-directional, meaning that people who abuse substances are more likely to suffer from mental illness, and the other way around. For example people who are depressed may drink or abuse drugs to lift their mood or escape from feelings of guilt or despair. While substances like alcohol, which is a depressant, can increase feelings of sadness or fatigue.

Studies show that 25 percent of people suffering from a serious mental illness[3] also have a SUD. While 17 percent of them with a SUD experienced a serious mental illness.[4] With respect to opioid use disorder, Orexo's own retrospective data from the RESOLV study performed in 2016, showed 32 percent of patients were diagnosed with co-existing depressive disorder to highlight just one of the co-existing mental illnesses many of these patients have.

Having a holistic treatment approach can have an instrumental impact on people's lives.

Access to health care and social services capable of providing treatment and social support is key for people suffering from mental illness and addiction diseases. The treatment gap is huge and from a co-occurring perspective, only about half of individuals with comorbid mental health and drug addiction received treatment in 2018.[5]

Having a holistic treatment approach for co-morbid SUD's and mental illness can have an instrumental impact on those peoples lives.[6] Cognitive behavioral therapy based techniques in conjunction with traditional pharmaceutical treatments have a long history in helping treat many mental illnesses, helping tosupport motivation and functional recovery to improve overall treatments results.

Opioid use disorder

Treatment of opioid use disorder (OUD) is often administered over long periods of time or chronically. Medication Assisted Treatments, or MAT for short, is the combination of a pharmacological treatment indicated for OUD along with behavioral based therapy. The most common treatments are based on buprenorphine, methadone or naltrexone. Buprenorphine is often combined with the

32%

share of patients with opioid dependence who also were diagnosed with depression, according to Orexo's RESOLV study

Treatment of opioid use disorder is often administered over long periods of time or chronically.

antagonist naloxone to help prevent misuse by intravenous injection. The most frequently used medication as part of a MAT program in the US is buprenorphine/naloxone which can be taken under the tongue as a tablet or film. Methadone is most commonly administered orally in a supervised setting while naltrexone is most frequently given as a monthly injection.

People where misuse of opioids has turned to illicit drug use face a large risk of suffering life-threatening overdoses where rescue medications such as naloxone are often required.

Alcohol abuse

Alcohol abuse and alcohol use is a growing challenge we are facing. Treatment may involve individual or group therapy, outpatient programs, or a residential inpatient stay where for example cognitive behavioral therapy is often used to coach patients to change behavior. Currently, there are only three medications approved by the FDA for the treatment of alcohol abuse and alcohol dependence. These medications are largely targeted to those who have already stopped drinking and are trying to maintain abstinence.[7] There remains a significant gap in helping individuals manage their drinking behavior.

Depression

Depression is a leading cause of disability around the world and contributes greatly to the global burden of mental health illness. There are many approaches to the management of depression with pharmacological and behavioral therapies being the cornerstone of many of the management approaches.

The short road to overdose

Patients with opioid use disorder need to ensure a constant intake of opioids as otherwise they can experience withdrawal symptoms just hours after their last dose of opioids.

It is not uncommon for these patients to turn to unconventional ways of obtaining access to opioids, such as from the illegal market.

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 often fatal outcomes.

Patients who turn to heroin or synthetic opioids have an increased risk of experiencing an overdose, and fatalities relating to opioid overdoses is one of the most common death causes among Americans under the age of 50.[8]

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3898681/

[2] Attention Deficit Hyperactivity Disorder

[3] According to SAMHSA (Substance Abuse and Mental Health Service Administration) serious mental illness refers to depression, schizophrenia, biopolar disorder and other mental disorders causing serious impairment

[4] SAMHSA, Center for Behavioral Health Statistics and Quality, National Survey on Drug Use and Health, Mental Health, Detailed Tables available at: https://www.samhsa.gov/data/population-data-nsduh.

[5] SAMHSA

[6] Kelly TM, Daley DC. Integrated Treatment of Substance Use and Psychiatric Disorders. Soc Work. Mueser KT, Gingerich S. Treatment of co-occurring psychotic and substance use disorders. Soc Work Public Health. 2013;28(3-4):424-439. doi:10.1080/19371918.2013.774676. Torrens M, Rossi PC, Martinez-Riera R, Martinez-Sanvisens D, Bulbena A. Psychiatric comorbidity and substance use disorders: treatment in parallel systems or in one integrated system? Subst Use Misuse. 2012;47(8-9):1005-1014. doi:10.3109/10826084.2012.663296. Kelly TM, Daley DC, Douaihy AB. Treatment of substance abusing patients with comorbid psychiatric disorders. Addict Behav. 2012;37(1):11-24. doi:10.1016/j.addbeh.2011.09.010. Public Health. 2013;28(0):388-406. doi:10.1080/19371918.2013.774673.

[7] Winslow BT, Onysko M, Hebert M. Medications for alcohol use disorder. Am Fam Physician. 2016;93(6):457-465.

[8] Drug Policy Alliance

CASE – OUR HEROES
Jerry

"I have learned a lot in my 3-years 10-months of sobriety."

Over the past two years, I have worked harder to build a sober foundation by surrounding myself with good, sober people who have taught me that you don't always have to drink or drug in order to feel happy or loved by others .

I would have to say medication-assisted treatment (MAT) saved my life. I know that a lot of people don't believe you are sober when you are on MAT, but I wish a lot of my friends who passed away from overdoses would have listened to me and used MAT as a way to help them in their recovery. Maybe, they would still be here today.

The best advice I can give for people who are struggling and who are really thinking about getting clean and sober is to take the leap – do it!

Yes, it is scary getting sober and changing your life. Yes, you will be faced with addressing the hurt and pain you have caused yourself and your loved ones, but it is worth it! Learning how to live a clean and sober life does not happen overnight, just like becoming addicted did not hapen overnight.

Today, I feel loved and wanted. My children, family and close friends want to be around me. Since being sober, my son who is 20-years old recently shared with me how happy he is to have his dad back in his life. Words could not accurately capture how good that made me feel.

Visit our Blog to read Jerry's full story – **blog.orexo.com**

With our blog our mission is to shed light on lives affected by addiction and the road to recovery. The opinions expressed in this blog are solely those of the authors and do not necessarily reflect the views of Orexo AB or Orexo US Inc. The authors have been asked not to reveal specifics around potential medically assisted treatments or other therapy used to reach recovery to Orexo or the readers.

Pioneering scalable drug delivery technologies

Orexo has taken important steps to continue pioneering scalable technologies for drug formulation, and build on our proven strong experience of developing new improved pharmaceutical products by combining known substances with our proprietary drug delivery technologies and with the ambition of delivering products addressing areas of large unmet needs.

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 poorly effective or not effective at all 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.

Developed pharma products approved on markets worldwide

Orexo has developed three pharmaceutical products that are commercialized by Orexo's own sales force in the US or worldwide through partners. The products have been developed through a combination of well-known substances combined with drug delivery technologies to address therapeutic areas, such as opioid use disorder and pain. The lead product, ZUBSOLV®, is today an important profit and cash generator paving the way for continued investments in the pharmaceutical pipeline and in digital therapies.

Short facts

ZUBSOLV®

Technology	Sublingual
Indication	Opioid use disorder (OUD). ZUBSOLV® should be used as part of a comprehensive treatment plan, which includes counseling and psycho-social support.
Market approvals	US, EU and Australia
Commercial rights	Orexo commercializes ZUBSOLV® in the US. Accord Healthcare owns the commercial rights in 29 European countries and launch will be initiated in H2 2021. Rights to other markets are owned by Orexo.
Partner	accord Make it better
Patent protection	In all major markets until 2032

Financial development 2020 – business segment US Pharma

US Pharma net revenues amounted to SEK 623.3 million (719.1). The decrease is mainly explained by lower demand at the payers, United Health Group and Humana, where the Orexo's pharmaceutical treatment for opioid use disorder, ZUBSOLV®, earlier held an exclusive position but where generics have been added to the formularies. The decline in demand at United Health Group and Humana levelled off at the end of the year and the exposure against exclusive agreements is limited. At the payers, CVS Caremark, Express Scripts and Optum, the demand increased. ZUBSOLV's volume also grew on the publicly financed plans, Ohio Medicaid and Michigan Medicaid. This development meant that the demand for ZUBSOLV® in the open segment was unchanged despite the payer segment Commercial, where Orexo has a strong position, decreased during the year as a result of the US unemployment rate doubling during Covid-19.

Lower adjustments of accrued product returns and the appreciation of the Swedish krona against the US-dollar impacted negatively. The price increase for ZUBSOLV® effective in beginning of 2020 had a positive impact.

ZUBSOLV's best-in-class reimbursement position in the commercial market segment remains, amounting to 99 percent. The coverage among public financed care amounts to 34 percent.

The EBIT contribution from US Pharma amounted to SEK 331.2 million (347.1), equal to an EBIT margin of 53.1 percent (48.3). The increase is explained by lower operating costs partly offset by lower sales and gross profit.

Segment US Pharma

Pharmaceuticals

PRODUCT/PROJECT		Exploratory	Preclinical	Phase 1	Phase 2	Phase 3	Registration	Approved and/or Launched US	Approved and/or Launched EU	Approved and/or Launched RoW[1]
ZUBSOLV®	Opioid Use Disorder *Partner: Accord Healthcare*									●
Abstral®	Breakthrough Cancer Pain *Partner: Kyowa Kirin*									
Edluar®	Insomnia *Partner: Mylan*									
OX124	Naloxone, opioid overdose									
OX125	Nalmefene, opioid overdose									
OX338	Ketorolac, moderate to moderately severe pain									
OX-MPI	BI1029539, microvascular disease *Partner: Gesynta Pharma*									

● Approved in Austalia. [1] Rest of the World.

● Abstral®

Technology	Sublingual
Indication	Breakthrough cancer pain
Market approvals	US, EU, RoW among others Japan, Australia, Saudi Arabia and South Korea
Commercial rights	RoW, Kyowa Kirin
Partner	KYOWA KIRIN
Patent protection	On RoW markets until 2024. For the US and the EU the patents expired in September 2019.

● Edluar®

Technology	Sublingual
Indication	Insomnia
Market approvals	US, EU
Commercial rights	Worldwide Mylan
Partner	Mylan
Patent protection	US until 2031, EU until 2025

Financial development 2020 – business segment HQ & pipeline

Royalty for Abstral® amounted to SEK 29.7 million (112.6). The decrease is explained by lower royalty for Abstral® in Europe which was received until December 31 2019 when the European contract with Kyowa Kirin expired and for the US royalty were received until October 31 2019 when Orexo's partner Sentynl withdrew Abstral® from the market. Royalty for Edluar® amounted to SEK 10.4 million (11.6). Total revenues from other products amounted to SEK 40.2 million (125.6) in 2020.

EBIT amounted to SEK –175.8 million (–115.0), mainly explained by lower Abstral® royalty and by costs for clinical trial of OX125 and as OX124 is approaching final clinical development, partly offset by lower legal IP costs.

● Segment HQ & pipeline

Multi-asset development pipeline

Based on clinical experience and strong relationship with healthcare professionals in the US the pharmaceutical development process at Orexo is characterized by early involvement of representatives from medical, commercial and manufacturing functions in each development program to translate insights into opportunities to provide solutions for unmet medical needs. One example is OX124, a rescue medication for opioid overdose, which is approaching final development with the aim to file with FDA in mid 2022.

Short facts

OX124

API	Naloxone
Technology	Nasal
Indication	Opioid overdose
Development phase	Finalized phase 1, will enter the final development stage – a pivotal bridging study in Q2 2021
Expected filing with FDA	In mid 2022
In-house or partnership	In-house

Unmet need
Available rescue medications have been developed for heroin overdoses, but most patients are dying from synthetic opioids like fentanyl today.

Our aim
Based on Orexo's novel intranasal formulation technology, the aim is to develop a rescue medication that is faster and longer-acting, and thus effective in reversing overdoses caused by synthetic opioids.

Differentiation
Results from the exploratory pharmacokinetic study (PK-study) in healthy volunteers showed significantly better PK-profile, such as faster and longer-acting, when compared to the market leading product. Novel, proprietary drug delivery technology with patent protection until 2039.

Progress during the year
Established a full commercial supply chain of both devices and API (naloxone). Positive feedback was recievied from FDA on the investigational new drug (IND) application and meant green light to proceed with the final clinical study, scheduled in Q2 2021. In parallell the work continued to prepare for a new drug application (NDA) which is expected to be filed with FDA in mid 2022.

During the year the first two patents were issued protecting the technology until 2039.

OX125

API	Nalmefene
Technology	Nasal
Indication	Opioid overdose
Development phase	Finalized phase 1
Expected filing with FDA	–
In-house or partnership	In-house

Unmet need
Available rescue medications have been developed for heroin overdoses, but most patients are dying from synthetic opioids like fentanyl today.

Our aim
Based on Orexo's novel intranasal formulation technology, the aim is to develop a powerful rescue medication for situations where very long-lasting effect is required, e.g., in remote areas, as response to long-acting opioids or for anti-terror stockpiling.

Differentiation
Results from the first exploratory human PK-study in healthy volunteers showed extensive and rapid absorption of nalmefene across all three OX125 formulations. As nalmefene has a longer half-life than naloxone, OX125 has the potential to be an effective response to the increased use of potent, long-acting synthetic opioids as well as protecting against renarcotization (second overdose) as the antagonist wears off. The technology has patent protection until 2039.

Progress during the year
The human PK study assessing Orexo's intranasal nalmefene formulations for opioid overdose reversal showed a positive result (see Differentiation above). As OX124 is approaching finalization most development resources were directed to that project. However, progress made related to OX124, will also be applicable to OX125, as the product candidate is based on the same intranasal formulation technology used for OX124.

During the year the first two patents were issued protecting the technology until 2039.

● Segment HQ & pipeline

Håkan Thorén, Analytical Chemist
Photo: Jenny Lagerqvist

OX338

API	Ketorolac
Technology	Sublingual
Indication	Moderate to moderately severe pain
Development phase	Finalized phase 1
Expected filing with FDA	–
In-house or partnership	In-house

Unmet need
Opioids are still used unnecessarily in many situations, further fueling the opioid crisis.

Our aim
Based on Orexo's novel oral formulation technology, the aim is to develop an opioid-level pain relief treatment for short-term pain (up to 5 days) without the risk of addiction.

Differentiation
Results from the exploratory PK-study in healthy volunteers showed significant better PK-profile, such as faster uptake and higher peak, when compared to nasal spray available on the market.

Progress during the year
Based on the positive outcome of the first clinical trial, formulation work has continued to ensure sufficient commercial differentiation. Most development resources for OX338 were redirected to OX124, as the project is approaching finalization, which will delay the development of OX338.

OX-MPI

API	BI1029539
Technology	–
Indication	Microvascular disease
Development phase	Phase 2
Expected filing with FDA	–
In-house or partnership	Partnership with Gesynta Pharma AB

Unmet need
Several severe microvascular complications currently have few or no approved pharmacological treatment options.

The aim
Gesynta Pharma, who owns all the rights to OX-MPI (GS-248), aims to develop a treatment for the microvascular diseases in chronic inflammatory conditions.

Differentiation
More effective and/or safer than currently approved treatments.

Progress during the year
The study results from the first human PK-study showed OX-MPI was safe and well tolerated with a pharmacokinetic profile supporting once daily dosing and with potent and durable effects on relevant antiinflammatory and vasoprotective biomarkers. The positive results enabled a continued development of the promising product candidate and in beginning of 2021 the clinical phase 2 study was initiated in patients suffering from systemic sclerosis. The study results are expected in late 2021.

● Segment HQ & pipeline

World-leading digital therapies with clinically proven efficacy

Digital therapeutics is set to become an integral part of the future healthcare landscape. Mental illness and substance use disorders are examples of areas where it is most needed. Orexo's digital therapies are rooted in cognitive behavioral therapy techniques and its efficacy has been demonstrated in numerous published clinical trials including thousands of patients. The therapies empower patients to overcome their challenges and can be used in their own privacy 24/7, standalone or combined with traditional pharmaceutical treatments.

Cognitive behavioral therapy is often the foundation for the treatment of mental illness. In depression, antidepressant drugs can be effective, but the best results are achieved if the patient also gives the opportunity to get psychosocial counseling. The same applies to the treatment of opioid dependence, where psychosocial counseling is required when prescribing medication-assisted treatment, such as Orexo's lead drug ZUBSOLV®. As access to qualified counseling is limited, Orexo provide multiple evidence-based digital therapies that patients have access to 24/7. The digital therapies include vorvida® for alcohol misuse, deprexis® to manage symptoms of depression and modia™ for opioid dependence. deprexis® which efficacy has been evaluated and published in eleven randomized controlled trials (RCTs) including more than 2,800 patients is a world-leading digital therapy to manage depression. All are available by Orexo on the US market.

>2,800

the total number of patients included in the 11 published RCTs for deprexis®

Product portfolio – digital therapies

PRODUCT/PROJECT		Technical development	Registration	Approved and/or Launched: US	EU[1]	RoW[1]
deprexis®	Symptoms of milde to severe depression *Partner: GAIA AG*					
vorvida®	Alcohol misuse, incl. alcohol use disorder *Partner: GAIA AG*					
modia™	Opioid use disorder *Partner: GAIA AG*					

[1] Launched on markets in the EU by GAIA directly or by other partners to them. For RoW only through partnerships.

Short facts

vorvida®

Technology	GAIA's proprietary artificial intelligence (AI)-expert system, broca®
Indication	Heavy alcohol misuse, incl. alcohol use disorder (AUD)
Period for use	6 months
Commercial rights	Orexo owns the exclusive rights to the US market
Partner	In-licensed from GAIA AG
Launch	July, 2020, in the US
Key advantages	• Based on cognitive behavioral therapy techniques • Strong clinical evidence • Highly individualized • To be used standalone or as a complement to traditional pharma treatments

deprexis®

Technology	GAIA's proprietary artificial intelligence (AI)-expert system, broca®
Indication	Symptoms of mild to severe depression
Period of use	3 months
Commercial rights	Orexo owns the exclusive rights to the US market
Partner	In-licensed from GAIA AG
Launch	July, 2020, in the US
Key advantages	• Based on cognitive behavioral therapy techniques • Strong clinical evidence • Highly individualized • To be used standalone or as a complement to traditional pharma treatments

In partnership with GAIA AG – a global leader in Digital Therapeutics

GAIA is a global leader in digital therapeutics, launching its first product successfully in 2001. With more than 150 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 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 multiple therapeutic areas.

Progress during the year

The collaboration with GAIA expanded in May by the acquisition of the US commercial rights to deprexis®. The evidence-based therapy can help patients manage symptoms of depression.

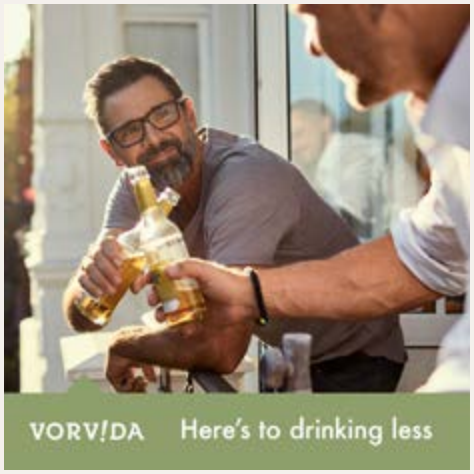
New FDA policy resulted in an accelerated launching

To increase access to digital solutions during the Covid-19 pandemic the FDA announced in April a Public Health Emergency Policy referring to the psychiatric area. The policy means providing help to people that among others are suffering from mental illness by giving access to digital solutions without any FDA clearance during the pandemic. Alarming data about increased mental illness along with the FDA policy triggered an accelerated launching of vorvida® and deprexis®. In the late of the summer the first contacts were made with payers, healthcare providers and distributors. To facilitate for all parties involved a scalable technical infrastructure was launched late in September with functionalities such as e-commerce, customer support and a service hub for insurance reimbursement.

First distribution agreements signed

During the autumn the first distribution agreements were signed with GoGoMeds, Trinity Health in North Dakota (ND) and Texas Nurses Association. GoGoMeds which is a digital

Segment Digital Therapeutics



modia™

Technology	GAIA's proprietary artificial intelligence (AI)-expert system, broca®
Indication	Opioid use disorder (OUD)
Period of use	6 months
Commercial rights	Orexo owns the global rights
Partner	Developed together with GAIA AG
Launch	To a selected group of clients in late Q1 2021 to collect clinical data, broader US launch in H2 2021.
Key advantages	• Based on cognitive behavioral therapy techniques • Highly individualized • Complement to traditional pharma treatments

pharmacy covering all states in the US will be able to provide vorvida® and deprexis® within their network of partners among employers. Trinity Health ND and Texas Nurses Association will provide Orexo's digital therapies to their own employees.

To speed up the reimbursement process new concepts were tested

Despite FDA's clear announcement about increasing access to digital solutions within the psychiatric areas during the Covid-19 pandemic, payers and healthcare providers did not adopted similar pragmatism to the reimbursement process to be able to reach out to patients. As a result of the development, new reimbursement processes were tested in parallel. The lead concept is a treatment program where Orexo in collaboration with selected healthcare providers, offers patients treatment under the supervision of a physician. Provided the physicians and the patients follow certain guidelines, this treatment program is currently available for reimbursement for a large portion of the US population. The program is being tested in Pennsylvania to ensure the reimbursement will meet expectations. The project plans to be finalized in Q1 2021.

modia™ ready to be tested with patients

The technical development of modia™ was finalized and after the end of the period a collaboration agreement was signed with payers to start to test modia™ with patients. A broader launch is planned to take place in the second half-year of 2021.

Financial development 2020 – business segment Digital Therapeutics

The recognized net revenues were SEK 30 thousand and deferred income SEK 100 thousand. Sales efforts was focused on building product awareness, creating commercial concepts and piloting different reimbursement pathways to simplify for payers to reimburse digital therapies. In accordance with IFRS 15 standard for revenue recognition the revenues need to be recognized throughout the validity of the license, referring to period of use.

EBIT amounted to SEK –175.4 million (–0.9), mainly explained by initial costs related to building up the business and enterprise platform and the continued launch of vorvida® and deprexis® and the development of modia™.

Segment Digital Therapeutics

What we do matters

Orexo strives to develop products that improve the quality of life for patients. In order to succeed, we must focus on sustainable operations. We do this by investing in innovation and partnerships, whilst taking responsibility for our business methods, reducing our climate impact and work for a sustainable supply chain. Our employees are our most important resource. To achieve our ambitions their well-being and our ability to offer a safe workplace where everyone feels respected and valued remains a top priority.

Cecilia Coupland, Vice President and Head of Operations, management representative in Orexo Sustainability Team

Sustainability report

We improve the lives of people 28
Innovation and partnership 30
People and society 32
Sustainable supply chain 36
Environment and climate change 38
Responsible business 40
Auditor's opinion 43

UN Global Compact

Human rights	
Principle 1 36–37, 40–42	Businesses should support and respect the protection of internationally proclaimed human rights; and
Princip 2 36–37, 40–42	make sure that they are not complicit in human rights abuses.
Labour	
Principle 3 33, 36–37	Businesses should uphold the freedom of association and the effective recognition of the right to collective bargaining;
Principle 4 36–37	the elimination of all forms of forced and compulsory labour;
Principle 5 36–37	the effective abolition of child labour; and
Principle 6 35, 36–37	the elimination of discrimination in respect of employment and occupation.
Environment	
Principle 7 38–39, 36–37	Businesses should support a precautionary approach to environmental challenges;
Principle 8 38–39, 36–37	undertake initiatives to promote greater environmental responsibility; and
Principle 9 38–39, 36–37	encourage the development and diffusion of environmentally friendly technologies.
Anti-Corruption	
Princip 10 40–42	Businesses should work against corruption in all its forms, including extortion and bribery.

Framework

UN Agenda 2030
The UN Sustainable Development Goals sets an ambitious and necessary agenda to lead the world towards more sustainable development. Orexo's operations has a direct and indirect impact on several of the goals. Orexo has the greatest impact on the sustainability goal number 3 "Good health and well-being".

UN Global Compact
The organizations that participate in the UN Global Compact commit themselves to living up to ten principles regarding human rights, environmental impact, working conditions and anti-corruption, and respect these throughout their value chain. As a participant in the UN Global Compact, Orexo's sustainability agenda builds on and follows these principles. The principles give the company the long-term focus and the direction required to create a positive change in the business.

ILO core conventions
Orexo complies with the International Labor Organization's (ILO) eight core conventions, which constitute a minimum standard for working conditions, all over the world. It is about basic human rights in working life.

UN Guiding Principles on Business and Human Rights
Orexo follows the UN's Guiding Principles on Business and Human Rights. These principles were adopted in 2011 and mean that an activity should not contribute to human rights violations and that companies should act to prevent such.

THE GLOBAL GOALS For Sustainable Development

THE GLOBAL COMPACT WE SUPPORT

UNION TO UNION LO, TCO & SACO GLOBAL

We improve the lives of people

People staying healthy, are able to work and take care of their loved ones is Orexo's ultimate goal and the company's biggest contribution to a sustainable society. On the way there, we will carry out our work in a way that benefits a sustainable ecosystem. Through a clear sustainability agenda that permeates the entire business, we are involved and contribute to a more sustainable world in the long term.

In recent years, it has become increasingly clear that mental health plays an important role in a well-functioning society. Depression is the most common disability and drug abuse, which can lead to chronic substance addiction, continues to be on a rise across the world.[1] About 270 million people use drugs in the world today. Opioids cause the most harm and account for the majority of drug-related deaths.[2] Opioid abuse is most common in the US, where one-fifth of those addicted to opioids live.[3] In the US, the problem has reached epidemic proportions. The most common cause of death for those under 50 is overdose, primarily caused by opioid abuse. Alcohol dependence is another serious health crisis in the US with 16.6 million people suffering from severe alcohol abuse.[4]

Impact of the pandemic

Mental illness and substance use disorders are on the rise in the wake of Covid-19 and in 2020, WHO called on countries to take measures necessary to alleviate the impact on individuals, families and communities. The financial consequences are far-reaching. In addition to loss of life and reduced quality of life, large costs are associated with lower productivity and lack of resources, as well as increased costs for health and prison care.

Treatments that save lives

Orexo develops and commercializes pharmaceuticals and digital therapies. The company's products are developed to meet the needs of patients who suffer from mental illness and substance use disorders. The products are commercialized in the US and since 2013, patients suffering from opioid dependence have been treated with Orexo's lead pharmaceutical ZUBSOLV®. In 2020, the company launched the evidence-based digital therapies vorvida® and deprexis® for the treatment of alcohol abuse and depression in the US market. modia™, a digital therapy for opioid addiction, will be launched in the US market in 2021. Major investments are also being made in the pharmaceutical pipeline, where the most advanced project, OX124, a rescue medication for opioid overdose, is expected to reach the US market in 2023.

Governance and guidelines

As part of its commitment to sustainable development, Orexo implements and communicates its ambitions in the area of sustainability through a sustainability group. The group includes representation from management and other relevant functions with the ability to influence the company's policies and strategies. Progress in sustainability work is reviewed quarterly and the results are reported to top management.

To achieve the company's sustainability goals, Orexo implements and integrates the company's values among its employees and business partners using the company's policies. Orexo's policies are intended to guide managers and employees in their day-to-day work and are in line with international standards and well-known initiatives, such as the ILO conventions and the UN Guiding Principles on Business and Human Rights. Orexo is also a participant in the UN Global Compact. For more information on frameworks see page 27. The Swedish head office, where research and development are also conducted, is responsible for developing and maintaining corporate governance both for the Swedish parent company and its subsidiary, Orexo Inc, in the US. The majority of the commercial activities are run by Orexo US Inc., which also manages a number of guidelines adapted to local expectations and conditions in the US. Further details regarding governance and guidelines are described under each focus area.

270

million people are drug abusers in the world today.

[1] World Drug Report
[2] World Health Organisation
[3] World Drug Report
[4] Substance Abuse and Mental Health Services

Orexo's sustainability agenda

Innovation and partnership

Finding more and better solutions is crucial to reach more patients and to achieve good health and well-being. Read more on pages 30–31.

Sustainable supply chain

All our production is outsourced to contracted manufacturers. Management of and collaboration with all suppliers are therefore of great importance for success. Read more on pages 36–37.

People and society

Orexo's staff is our most important asset and wellness; safety and being inclusive are high on the agenda. Orexo continues to work for a better society by reaching more patients and contributing to the local community. Read more on pages 32–35.

Environment and climate change

Working for better resource efficiency and reduced climate impact key within for our sustainability efforts. Read more on pages 38–39.

Responsible business

Orexo operates in a market and industry where ethics and transparency are instrumental. The overall corporate governance, the work for transparency and to combat corruption is described on pages 40–42.

Orexo is committed to contributing to a sustainable future by taking responsibility and integrating the sustainability agenda into the entire business. To contribute with the right focus and management of both risks and opportunities, the agenda includes activities with both short- and long-term objectives in areas that represent the most important sustainability challenges the company faces.

Orexo's sustainability agenda is based on four overall focus areas, which are a) Innovation and partnerships, b) People and society, c) Sustainable supply chain, and d) Environment and climate change. These focus areas were identified through risk assessments of the environmental impact, safety and health and through employee surveys. A dialogue with various parts of the organization and with external stakeholders has also been important for the identifiaction of focus areas.

Responsible business is central to all our activities and a foundation in the sustainability work. The company's code of conduct sets the framework and direction for our efforts in this space.

Orexo supports Agenda 2030 and our main focus is on Goal 3: Good health and well-being and in particular sub-goal 3.5: "Strengthen the prevention and treatment of substance abuse, including narcotic drug abuse and harmful use of alcohol.", which has a strong connection to our business' ambition to prevent and treat mental illness and addictive diseases.

To further develop the sustainability work in relation to Agenda 2030, Orexo will in 2021 participate in the UN Global Compact program "SDG Ambition Accelerator", a program that will contribute to set more ambitious and clear goals in line with the Sustainable Development Goals.

Innovation and partnership

Orexo's development is based on innovations made possible by the interaction between skilled researchers and experts with different scientific backgrounds. Innovation is at the core of the continued development of new formulation technologies and early development projects in order to be able to offer patients all over the world even better medicines.

Milestones and initiatives

Our ambition	• The ambition to become a leading player within the large and growing space of mental illness and substance use disorders
Important issues	• Prevent and treat substance use disorders and mental illness through new innovations and partnerships
Important milestones and initiatives 2020	• Launch of vorvida® and deprexis® in the US • Partnership with Accord Healthcare for the commercialization of ZUBSOLV® in Europe • Start of SweDelivery, a world-leading competence center for drug delivery • Lyfebulb challenge, where Orexo hosts an innovation challenge aimed at patient entrepreneurs

At Orexo, every year we are involved in many different collaborations and partnerships with stakeholders around the world to develop improved drugs and therapies to help people suffering from mental illness and substance use disorders. The relations and knowledge from these add great value to our research and development of future innovations and new products.

The financial stability that ZUBSOLV® has created has enabled us to make new investments in both partnerships, new own product development projects and to contribute to university-related projects. Orexo as a small but research-heavy company see the importance of good universities and educations. We contribute both financially and with knowledge to universities through various collaborations.

Accord Healthcare

In December 2020, Orexo entered into a licensing and delivery agreement with Accord Healthcare to make ZUBSOLV® available on the European market. The common goal is to ensure that people have increased access to treatment options. With the agreement, people in 29 additional countries will have access to ZUBSOLV®.

Partnership for digital therapy

To address the lack of psychosocial counseling in the treatment of opioid-dependent patients, Orexo entered into a partnership with GAIA in 2019 to develop a digital therapy for opioid dependence, modia™.

GAIA is a global leader in digital therapies (DTx) and successfully launched its first product in 2001. With a very clear focus on research and development of evidence-based, fully automated online interventions, the company continuously sets new benchmarks regarding clinical efficacy and safety profile for digital therapies in neuroscience, immunology, oncology and behavioral medicine.

With more than 140 experts in areas such as medicine, psychology, behavioral medicine, software development, as well as regulatory processes and health economics, GAIA is one of the world's most experienced and largest players in the development of next generation digital solutions to support and treat patients with a wide range of medical problems.

The cooperation with GAIA has deepened since Orexo acquired the evidence-based digital therapies vorvida® for alcohol abuse and deprexis® for depression.

29

additional countries will have access to ZUBSOLV®

From left, Andreas Fischer, Senior Principal Scientist, Jonas Sävmarker, Senior Principal Scientist and Anneli Wennman, Analytical Chemist
Photo: Jenny Lagerqvist

Innovations
In 2020, Orexo continued to have a strong focus on the OX124 development project, a project based on new technology for an intranasal formulation to develop an emergency drug that is faster and more long-acting and thus more effective in reversing overdoses caused by synthetic opioids. The project is on its way into the final development phase and is expected to reach the US market in 2023.

SweDeliver
In January 2020, SweDeliver, a world-leading research and competence center in drug supply, launched with Orexo as one of several industry partners. SweDeliver is based on interdisciplinary collaboration between academia and industry with financial support from Vinnova, Sweden's innovation agency. The Faculty of Pharmacy at Uppsala University is the academic hub of the center. The scientific focus is on important research challenges in parenteral, oral and pulmonary drug delivery. In addition to this, young researchers are given the opportunity for education and career development. The goal of the center is for research to lead to the development of new and improved drug treatments. Orexo provides financial support, scientific expertise, an industrial perspective, and mentorship to young researchers.

Collaboration with universities
Orexo continuously provides university students with thesis project opportunities. In 2020, we have had four students who have done their work with us. These collaborations primarily aim to strengthen the development of future pharmaceutical researchers, which ultimately benefits global health and well-being.

Lyfebulb challenge
Together with Lyfebulb, Orexo hosted an innovation challenge aimed at patient entrepreneurs in 2020. Lyfebulb is a platform for patient development that connects patients with industry with a focus on finding solutions to chronic diseases. The challenge was aimed at solutions for "Substance Use Disorder". The winner, Lief Therapeutics, had developed a portable device that helps reduce stress and anxiety in real time with the help of heart rate variability biofeedback training. The winner received a USD 25,000 grant.

People and society

Our staff are of the greatest importance to us. When our employees stay healthy, commitment and the right conditions are created for creativity and innovation. Our workplace must be both safe and healthy, so that every employee feels respected and is valued. We also believe that a diverse workplace creates greater opportunities for new perspectives and new ideas.

Goals and results

Our ambition	• To offer a safe and healthy workplace where everyone feels valued and respected • To offer safe and high-quality products that reach more patients
Important issues	• An equal and non-discriminatory workplace • Good health and well-being for our employees and a safe workplace • Increased access to safe products with a high quality
Goals and activities 2020	• Identify and carry out activities that highlight factors that cause stress and symptoms of stress, in order to reduce the risk of work-related fatigue • Handle changes in the physical and psychosocial work environment as a consequence of the prevailing pandemic
Important events and results 2020	• Introduction of monthly monitoring of the work situation • Targeted risk assessments specifically for remote work • Improved teleworking with new equipment and digital solutions • Start-up of programs giving healthcare professionals the opportunity to use our digital therapies free of charge

The year 2020 has been challenging for employees. Our focus during the year has been to ensure that our staff stay healthy under the changed circumstances. The pandemic has left its mark on our main market, the US, which in turn has led to indirect effects such as deteriorating psychosocial health and reduced access to care for certain groups.

Safety and access for patients

It is of utmost importance that medical devices and medicines meet the high standards that exist in order not to jeopardize patient safety. Quality work is high up on the agenda and we receive few complaints (less than one in one million packages sold). In addition to complying with legal requirements, we work continuously with product care. With this as a base we can proudly continue our work to ensure our products reach even more patients globally.

Increased access to ZUBSOLV®

For more patients to have access to ZUBSOLV® , we are currently running three programs that provide financial support to patients.

- ZUBSOLV® Patient Assistance Program. This program provides free ZUBSOLV® to those patients that meet the US poverty level requirements.
- ZUBSOLV® Co-pay assistance program. This program saves patients significant amounts of out-of-pocket money when they pick up their ZUBSOLV® prescription and use the co-pay card.
- ZUBSOLV® 15 tablet voucher program. A patient on ZUBSOLV® can get two free 15 tablet vouchers (30 ZUBSOLV® tablets in total).

The programs have been around since 2013 and have helped many patients. Nearly 3,000 patients have received help through the ZUBSOLV® Patient Assistance Program, more than 150,000 co-pay cards and over 200,000 tablet vouchers have been distributed.

3,000

patients has received help through the ZUBSOLV® Patient Assistance Program

The pandemic has increased the need for therapeutic support

The Covid-19 pandemic has left its mark on American society, especially among medical staff and healthcare workers at the forefront. During the pandemic, there has been an increase in levels of depression, anxiety and substance abuse among those who work in healthcare. In 2020, we launched two digital therapies through FDA approvals, vorvida® and deprexis®. These digital therapies have been scientifically proven to help people with alcohol dependence problems and depression through cognitive behavioral therapy. During the year, we had the opportunity to contribute our digital therapies in two programs for healthcare professionals. Orexo partnered with the Texas Nurses Association[1] and with Trinity Health in North Dakota,[2] and through these collaborations, all employees get access to the digital therapies free of charge. The use of the therapies is voluntary and completely anonymous.

During the fourth quarter, a total of 95 unique logins were distributed to staff within the programs. The work will continue in 2021 and will be further developed to include, among others, larger addiction clinics. We also offer all our employees and their families access to our digital therapies.

An engaging workplace

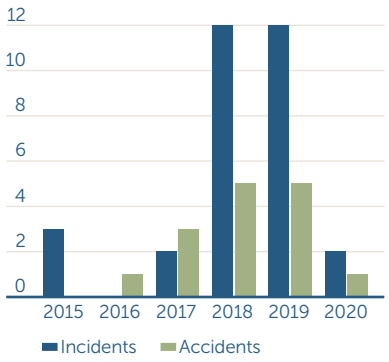
Orexo's employees contribute every day to the development of our business. The success of the business is based on the employees' commitment and well-being. Our priority is therefore to attract and retain the best individuals by offering a safe and healthy workplace where everyone feels valued and respected.

All work with health and safety in the workplace is governed by the company's overall work environment policy. This is linked to routines describing the relationship between the employer and employees and their respective obligations and rights. These include areas such as recruitment, equal treatment, gender equality, discrimination, conflicts of interest as well as health insurance and other employment benefits.

Working environment

Orexo's work with health and safety in the workplace is led by the company's safety committee. The basis of the work is the company-wide risk assessment which is updated annually. Goals and activities are decided based on the risk assessment as well as specific issues identified at discussions in regular meetings held by the safety committee. The greatest risks identified by the company are linked to psychosocial stress due to a high workload, but also risks linked to the handling of active pharmaceutical ingredients and other hazardous substances.

Reported accidents and incidents



In 2020, management, HR and the safety committee worked together to meet the health-related challenges posed by the pandemic. Measures included making sure each individual had regular dialogue with their manager, creating conditions for working remotely, and assessing the perceived effects of the pandemic on the physical and mental work environment. Working from home for a long time can result in a lack of inclusiveness and social interaction. This is a work environment risk and Orexo will continue this work in 2021. More information about how these issues have been handled can be seen in the section "Working conditions during the pandemic".

In order to better monitor the well-being of employees, monthly surveys were started in the autumn of 2020. In these surveys, questions are asked in three areas: Work situation, Well-being, and Communication & Participation. These surveys measure the situation for each department and group and can assist managers to create and engage in dialogue with their staff. It is also used to give an overall picture at a company level.

Our annual employee surveys[3] are a key factor in examining the work environment. The results are always discussed by management, but are primarily used as a tool at the group and department level to take concrete actions to improve the work environment. Each group has its challenges, which are reflected in the result. The results in recent years have been positive. However, it is our responsibility to investigate areas that do not have consistently positive results and not to become complacent due to positive evaluations and outcomes.

Many chemical substances, including active pharmaceutical ingredients, are handled in our labs. It is therefore important that solid risk assessments are carried out and that these substances are handled in an adequate manner.

[1] https://www.texasnurses.org/news/544391/Deprexis-Free-Digital-Therapy-for-Nurses.htm
[2] https://www.trinityhealth.org/digital-therapies-help-frontline-workers-cope-2/
[3] Springlife employee survey Orexo AB, DecisionWise Orexo US Inc

From left, Johanna Stenberg, Head of Group Accounting, Annika Fröling, Analytical Chemist, and Stephanie Fredriksson, Receptionist. Photo: Jenny Lagerqvist

Performance indicators

	2020		2019	
	Parent	Group	Parent	Group
Types of employment[1]				
Number of employees	53	138	54	127
employees with a permanent contract	98%	100%	100%	100%
employees with a temporary contract	2%	1%	0%	0%
Consultants	33%	18%	15%	11%
Gender equality				
Female employees	55%	59%	54%	50%
women in management positions	33%	40%	38%	44%
women in executive management team	13%	13%	13%	13%
Women in board of directors	38%	38%	38%	38%
Other data				
Employee satisfaction index[2]	80	82,5	81	82
Employee absence due to illness	1,8%	1%	2%	1%

[1] Include employees employed by the parent company Orexo AB or the subsidiary Orexo US Inc., consultants are excluded.
[2] Springlife (Orexo AB), DecisionWise (Orexo US Inc.). Values above 70 indicate that conditions in the workplace are good.

To make better assessments, Orexo always orders reports on active pharmaceutical ingredients from a toxicologist. Toxicological data is compiled in the reports and a hygienic limit value is calculated based on this data. This is done to supplement the sometimes deficient safety data sheets that are available from the suppliers in order to make better risk assessments. In 2020, 10 new active pharmaceutical ingredients were introduced.

In 2020, two incidents and one minor accident were reported. Both the accident and the incidents were related to the handling of chemical products in the labs. None of these were of serious nature or led to any personal injury. One of the incidents led to a clarification of the actions and procedures of the subcontractor who handles the goods receipt. This clarification stipulates that they must not handle broken goods since these may contain hazardous substances. Instead broken goods should be dealt with according to established routines and returned to the supplier.

Working conditions during the pandemic

The pandemic has affected Orexo in ways similar to most other companies. Different measures have been taken to ensure that Orexo contributes to reducing the spread of infection, including allowing all staff who can work from home to do so.

During the year the work has become more digital and we have learned to use the online platforms in new ways and on a completely different level. Some of the digitalization work that Orexo carried out in 2020 was to introduce Microsoft Teams throughout the company and to install video equipment that is integrated with Teams in several conference rooms to facilitate and enable better video meetings. Furthermore, software was installed on computers with the aim of being able to perform installations and updates automatically without having to attend the office.

The change has also meant new challenges for both our employees and leaders, such as switching to remote leadership, adapting to working from home and a lack of social contacts. We have systematically examined the work environment to see how this new reality has affected our employees. This has been done through regular conversations between managers and employees, but also through the monthly surveys that were started in the autumn.

Towards the end of the year, we added two questions about Covid-19 linked to both the physical and psychosocial work environment. The results showed, as expected, that many employees feel that their work environment has been negatively affected. We follow this closely and each manager has a dialogue with their staff and how we can support them during this challenging time. An important factor in dealing with both physical and mental stress is daily physical exercise. To promote this, a collaboration with IMR, the Institute for People in Motion, has started, and all our employees can work with their own health journey for 6 months from their individual starting points.

Diversity and gender equality

We are convinced that employees of different ages, genders, backgrounds and experiences contribute to new thinking and innovative solutions. Diversity and gender equality are therefore important for us to achieve our goals and ambitions.

Orexo protects everyone's equal rights and opportunities, as clarified in our Plan for equal rights and opportunities. Being able to combine employment at Orexo with parenthood is a matter of course, and whether it is through parental leave, childcare, or other accommodation, Orexo aims to have flexibility to get a work-life balance. As part of this, the company supplements the governmental parental benefits during the parental leave period and also provides a supplement for temporary parental benefit.

In the salary survey carried out during the year, no unreasonable salary differences were discovered.

The work against discrimination within Orexo aims to ensure equal rights for all employees in terms of working conditions, development opportunities, careers, employment and labour rights. Furthermore, the unique experiences and characteristics of each individual must be recognized and where they can contribute within the company, encouraged and utilized. Sexual harassment and abusive discrimination shall not occur and we shall have equal pay and working conditions for the same work. In 2021, we will continue the work on our Plan for Equal Rights and Opportunities.

Sustainable supply chain

A large part of the company's activities is outsourced to several suppliers and partners. We are dependent on subcontractors and partners for both the manufacturing of products and the supply of raw materials. Working towards a sustainable supply chain means that purchasing decisions and relationships that are created must take place in accordance with the company's principles and values from business ethics, work environment, human rights and the environmental impact.

Goals and results

Our ambition	• Ensure good management of social, ethical and environmental impacts throughout the supply chain
Important issues	• Continuous evaluation and follow-up of social, ethical and environmental impacts in the supply chain
Goals and activities 2020	• 100% of all A-suppliers and 20% of all B-suppliers must be evaluated.
Results 2020	• 100% of the A-suppliers evaluated

We see that there are risks around several aspects of our suppliers, although of course they vary from country to country and from supplier to supplier. Orexo's direct suppliers are located in countries with strong environmental and social legislation. The greatest risks here are connected to health, safety and environment. The next step in the supply chain may be found in many different parts of the world and it is therefore important to work to ensure that the direct suppliers in turn have good governance and processes. Orexo is committed to complying with the UN Guiding Principles on Business and Human Rights, and it is along the supply chain that we see the greatest risks linked to human rights.

It is the ambition of Orexo to prevent, remedy and improve sustainability work throughout the supply chain. By putting requirements on direct suppliers, an awareness of sustainability issues and a joint contribution to sustainable development are created.

Governance and guidelines

Orexo has adopted a Code of Conduct for Suppliers that clarifies expectations and minimum requirements for suppliers, including legal compliance, human rights, business ethics, safety, health and environmental impact. Orexo's ambition is to introduce these values throughout the supply chain to ensure that the high expectations of the company are met all over the world. In order to monitor and improve compliance with the supplier code, processes and approaches have been established that aim to ensure that risks regarding patient safety, product quality and a number of sustainability aspects are within an acceptable range. These processes and approaches also ensure that applicable commercial aspects, such as supply chain security, financial stability and other commercial risks in the supply chain are adequately investigated.

100%

of A-suppliers evaluated

Supplier evaluation

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

	Sustainability Evaluations performed		Number of approved Suppliers with open Sustainability issues		
	Result	Target 2020	Major	Moderate	Minor
Tier A	100%	100%	0	0	3
Tier B	15%	20%	0	0	0
Tier C	0%	0%			
Tier D	0%	0%			

Through the supplier evaluation process, Orexo evaluates strategically important A and B suppliers on the basis of sustainability aspects. A-suppliers supply Orexo with raw materials for products that are on the market or are contracted manufacturers of products. B-suppliers are other strategically important suppliers, including those that deliver to development projects. They will eventually be included among A-suppliers when product innovation approaches launch. The supplier evaluation covers legal compliance, as well as compliance with human rights, business ethics, safety, health and environmental impact, and is carried out through evaluation forms, interviews with the supplier and, if necessary, site visits. Supplier sustainability status is regularly monitored through supplier management.

In 2020, no additional all A-suppliers have been added, but a few new B-suppliers from on-going innovation projects. In 2021 evaluations of B-suppliers will be given priority and a review of the existing A-suppliers will also be carried out.


Photo: Jenny Lagerqvist

Environment and climate change

A sustainable future requires a joint responsibility for the environment. All human activity depends on ecosystems and their services, such as access to clean air, clean water, and natural resources. To contribute to a more sustainable world, Orexo works with activities to improve the company's environmental impact and to improve resource use.

Goals and results

Our ambition	• To operate resource-efficiently and to reduce the environmental impact of all activities.
Important issues	• Reduced greenhouse gas emissions • Reduced amounts of waste
Goals and activities 2020	• Improve quantification of identified environmental aspects to enable a correct prioritization and to be able to set more clear goals around environmental impact • Develop cooperation with our property owner to enable a reduction in energy consumption and direct carbon dioxide emissions
Results 2020	• Completed development of the environmental aspect assessment • Green agreement with our property owner

Towards a resource-efficient operation

The overall environmental work at Orexo is governed by the company's environmental policy and the guidelines linked to it. The company has an environmental group with representatives from all parts of the business, including management. The group proposes an environmental action plan based on the direction set by the sustainability team.

The environmental action plan is set on the basis of the environmental aspects identified as significant by the company. In 2020, the existing list of environmental aspects has been further developed through a more clear quantification and assessment of where Orexo has an impact as well as where the opportunities to influence are as large as possible. This work reinforces what has previously been identified as significant environmental aspects, i.e. waste and CO_2 emissions (primarily through travel), but also the environmental impact from contracted manufacturers and raw material suppliers. It has not been possible to make a direct quantification of the environmental impact from contracted manufacturers and raw material suppliers, but we are convinced that through our choices we can make an impact. Our work for better supplier sustainability is described earlier in this report (see page 36).

In 2020, no quantifiable goals have been set in relation to work with the environmental challenges. Focus has instead been on identifying where the impact is and which key performance indicators that are of importance. This work will continue in 2021.

Climate impact

Orexo rents its R&D facilities and the premises are shared with other tenants. As a tenant we depend on a good relationship with our property owner in order to influence our local climate footprint. Energy usage, in the form of heating, cooling and electricity is calculated based on the size of the used premises. Since individual measurements are not done, it is difficult to see the effects of energy reduction measures taken by any single tenant. In 2020 Orexo signed a green agreement with the property owner in which an expectation of co-operation on reducing the footprint through joint work is expressed. The R&D premises are today heated with district heating and cooled with district cooling.

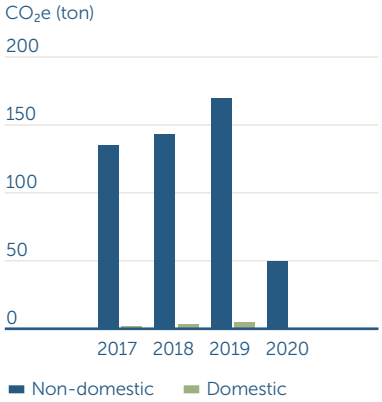
The electricity purchased is from renewable resources. Our goal with work on the green agreement is to reduce the overall consumption through improvements in our facilities.

Orexo has its main market in the United States. The contracted manufacturers for ZUBSOLV® and several of the raw material suppliers are also based in the US, as well as our own sales and marketing organization. This has historically necessitated a certain amount of business travel between the US and Sweden. Travel has changed drastically during 2020. While we do not see a complete travel stop in the future, we want to learn from 2020. An assessment has always been made as to whether a trip is necessary or not. In the future, the lessons learned from 2020 and our new digital working methods will give us another standard against which to evaluate which trips are necessary and which are not.

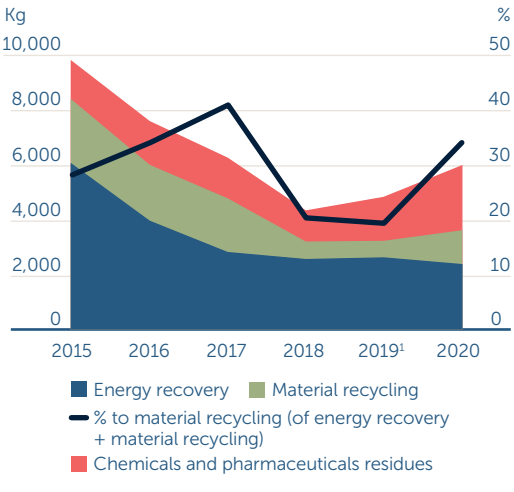
Waste and recycling

Above all, the ambition is to reduce the amount of waste that goes to energy recovery in favor of reuse and recycling. Orexo does not have its own production and we do not see that we have a specific waste source where a single effort would lead to a substantial reduction in the amount of waste. A dialogue has also been started with the recycling operator to gain access to better statistics on recycled fractions since we have seen that certain fractions have been missing in previous years. From 2020 and onwards, statistics will be available for all relevant fractions. The large reduction in total waste over time is mainly due to the fact that the nature of the business has changed and that all production is now done by contract manufacturers. In 2020 work was done to improve the sorting of waste by setting up additional recycling stations with clearer labeling. Through improved information and sorting, we see opportunities to move up in the waste hierarchy.

CO_2 emissons from flight travel



Waste fractions



¹ Intensification of activities at the company's Swedish research facility during 2019

Responsible business

Orexo operates in a market where there is a high risk for unethical business conduct and that more drugs than necessary will be prescribed. For us at Orexo, responsible business practices are a top priority and we have no tolerance for corruption.

Goals and results

Our ambition	• Conduct responsible business based on trust, transparency, integrity and no tolerance for corruption
Important issues	• Counter corruption • Work for openness and transparency
Goals and activities 2020	• Periodic revision of the code of conduct • > 90 percent of all employees must have read and signed the company's code of conduct • Evaluate the current whistleblower process for the Swedish company
Results 2020	• A periodic review has been made of the code of conduct and all employees have read and implemented the new version • An agreement has been concluded with a provider of an anonymized whistleblower service

Transparency and integrity along the value chain

Orexo's Code of Conduct "Business Compliance and Ethics Code" serves as an umbrella for all other policies and guidelines in the company and is based on corporate values, legislation and internationally recognized standards, such as the Universal Declaration of Human Rights, the Helsinki Declaration (1) and the Ten Principles of UN Global Compact. Orexo's Code of Conduct is the basis of the business and contains a compilation of responsibilities, values, attitudes and guidelines for the employees in their relationships with each other and the outside world. It describes expectations and requirements in the areas of human rights, personnel and labour law, the environmental impact and anti-corruption. It also describes ethical expectations regarding research and development as well as requirements regarding patient safety. The Code of Conduct must be followed by all board members, managers, employees, consultants and temporary staff at Orexo AB and all its subsidiaries. According to The Code of Conduct individuals are also expected to pay attention to and report suspected violations, without any type of punishment or threat of punishment being sanctioned by the company or representatives from the company (see the heading Whistleblower System.)

To ensure legal compliance and to manage risks and to achieve set sustainability ambitions, the

100%

implementation of the Code of Conduct.

Business Compliance and Ethics Code

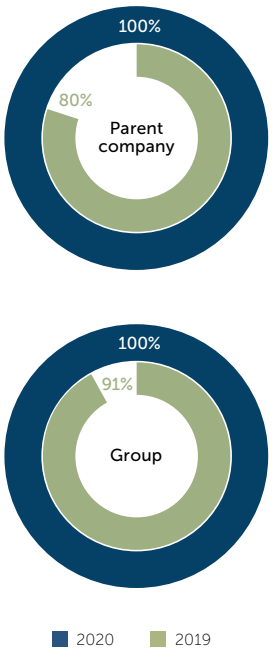
Supplier Code of Conduct	US Comprehensive Compliance Policies	Safety, Health and Environment Policies	Human Resources Policies

[1] A number of recognized ethical principles for medical research involving humans, developed by the World Medical Association (WMA).

company has several policies and guidelines linked to the Code of Conduct. These guide and support activities related to environment, safety and health work, but also to gender equality, equal treatment, discrimination and other requirements regarding human rights and anti-corruption.

To ensure good business ethics, and compliance with laws, regulations and the values and attitudes that should permeate the business, Orexo executes its Code of Conduct through implementation and training. The implementation is done through the company's document management system. The system clearly shows what policies and routines employees are expected to read. After reading each employee signs that they have reviewed and understood the material. All policies are reviewed at least once every two years. Specific Code of Conduct trainings has been held, and in the future these trainings will be part of the teacher-led introductory program in which all new employees participate. All employees within both the Parent Company and the Group have read and implemented the Code of Conduct

Implementation of the Code of Conduct (% employees)



Business ethics and anti-corruption

To work ethically is a matter of course for Orexo's business operations. Orexo operates in markets 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 unethical business and compliance violations in interactions with healthcare professionals, healthcare organizations and government officials. Orexo's Code of Conduct therefore sets minimum requirements and expectations and support the employees in their daily work.

Orexo has no tolerance for bribery or corruption. The Code of Conduct urges individuals to pay attention to and report suspected business ethics violations or unethical conduct, without retaliation or any threat of retaliation. Through the implementation and training of the Code of Conduct, Orexo ensures that operations are conducted in a responsible manner, based on trust, openness, integrity and no tolerance for corruption. In this way, a solid foundation is created for a continued strong relationship with customers, colleagues and stakeholders.

Whistleblower system where everyone can make their voice heard

Orexo must be a transparent, sound and open organization that complies with laws, regulations and the company's Code of Conduct. If someone suspects a serious violation has occurred, it is important that this is reported and that the reporting can be done anonymously. In the US operations there has been a well-functioning system for several years through an external supplier, Ethics Point. In 2020, no reports were made.

For the Swedish operations a review was made of the company's whistleblower possibilities in 2020. The review resulted in that the whistleblower process needed improvement. In autumn 2020 an agreement with an independent supplier of a whistleblowing system, WhistleB, was finalized. This system will improve the possibility of anonymous reporting as well as handling and communication in the reported cases. The system will be introduced during the first quarter of 2021.

Marketing and sales

Orexo has its main market in the USA, where the subsidiary Orexo US Inc is responsible for all sales. The subsidiary operates in accordance with laws and regulations established at the federal and state levels in the United States. The guidelines, collectively referred to as "US Comprehensive Compliance Policies", describe accepted marketing practices and activities related to drug sales, including the reporting of marketing expenses and interaction with government authorities and healthcare representatives. All employees in the United States are trained in these, both through teacher-led training and virtual training.

All sales representatives receive a specific week-long training held at the Orexo office in New Jersey. The training covers all marketing policies, federal laws and regulations related to drug sales and ethics related to their role as sales representative including interaction with physicians. At the end of the training, everyone takes a test to show that they have understood the material and the requirements. After this, there are periodic follow-ups of the training where the sales representative read and implement policies again. During 2020 nine sales representatives were trained.

Subpoena

On June 14, 2020, Orexo Inc received a subpoena requesting the provision of certain information to US authorities linked to ZUBSOLV® and other buprenophine products. Orexo has no knowledge of the reason for this subpoena. Orexo has engaged a legal counsel to assist in the event of further requests for information or other activities related to this. No further information has been received after 14 June 2020.

About the sustainability report

Areas	Pages
Environment	38–39
Social conditions	30–33
Staff	33–35
Human Rights	36–37
Anti Corruption	40–42

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 2020 on pages 26–42 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 den 22 mars 2021
Ernst & Young AB

Anna Svanberg
Authorized Public Accountant

From left, Cecilia Coupland, VP and Head of Operations, Nikolaj Sørensen, President and CEO, Johannes Doll, EVP and Chief Commercial Officer
Photo: Jenny Lagerqvist.

The share

Orexo's share is listed on Nasdaq Stockholm and available as American Depository Receipts (ADR) on OTCQX market in the US. During 2020 the number of shareholders increased by 39 percent and at the year-end Orexo had 8,814 shareholders, of which the non-Swedish ownership amounted to 47 percent.

The Orexo share is listed on Nasdaq Stockholm Mid Cap under the symbol ORX and available as ADRs on OTCQX under the symbol ORXOY. During the year the share price decreased by 20.38 percent and the last price paid in 2020 was SEK 50.00 (62.80). This corresponds to a market capitalization of SEK 1,736 million (2,211). The highest closing price during the year for the share was SEK 83.80 quoted on May 13. The lowest quotation was SEK 41.25 on March 16.

Liquidity

In total 42.5 million (34) shares were traded in 2020, corresponding to a value of approximately SEK 2,500 million (2,341).

The daily average trading volume was 167,984 shares (138,130), corresponding to a value of SEK 9.9 million (9.4).

Ownership

At year-end, Orexo had 8,814 shareholders (6,351), of which 706 were registered as legal entities and 8,108 as private individuals. Of the share capital, 53 percent (49) is held by shareholders registered in Sweden and 47 percent (51) by non-Swedish shareholders. The largest proportion of shareholders registered outside Sweden can be found in Denmark, at approximately 35 percent (34).

The list on page 45 is by shareholder group, where a number of legal entities may be part of each group.

Buy-back Program

On April 6, 2020, Orexo ended a repurchase program of its own shares. At the price of SEK 27.2 million 500,000 shares were repurchased, equivalent to approxmately 1.4 percent of the total number of issued ordinary shares.

39%

increase in number of shareholders in 2020.

Key Facts

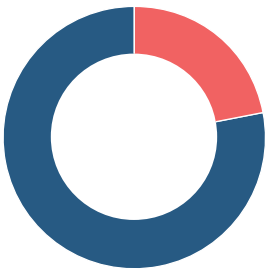
Orexo Share

Listing:	Nasdaq Stockholm, Sweden
Number of Shares:	34,710,639
Market Capitalization, December 31, 2020:	SEK 1,735 m
ISIN Code:	SE0000736415
Ticker Code:	ORX

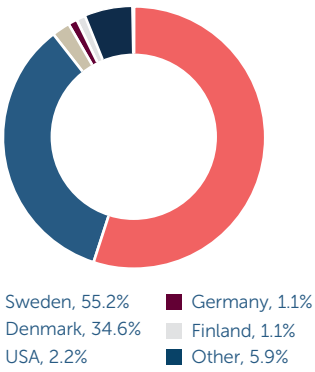
Orexo ADR

Trading Platform:	OTC, US
Deposit Bank:	Citibank N.A.
ISIN Code:	US68616W1027
Ticker Code:	ORXOY
Ratio:	1:1

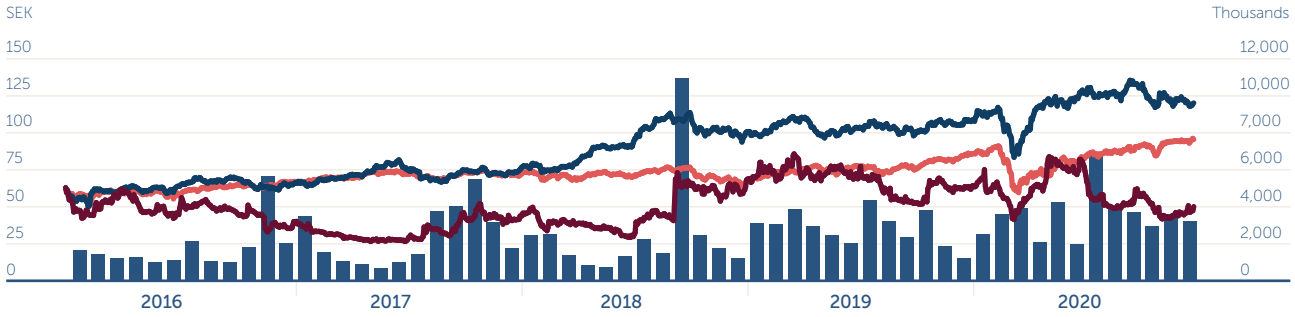
Ownership categories, December 31 2020



Ownership distribution per country, December 31 2020

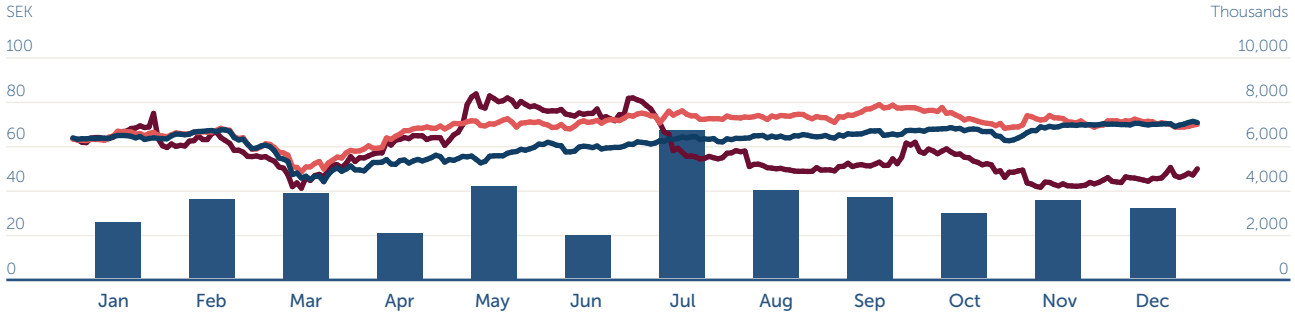


Five-year performance



Source: Nasdaq Stockholm

Performance in 2020



Source: Nasdaq Stockholm

Shareholders, December 31 2020[1]

Owners	No. of Common Shares	Share of Capital (%)
Novo Holdings A/S	9,643,184	27.8%
HealthCap	3,556,334	10.2%
Avanza Pension	2,220,840	6.4%
Arbejdsmarkedets Tillægspension (ATP)	2,040,633	5.9%
Anders Walldov, direct and indirect	1,600,000	4.6%
Lancelot Asset Management AB	625,000	1.8%
Orexo AB	415,766	1.2%
Nordnet Pension Insurance	360,578	1.0%
Swedbank Insurance	347,178	1.0%
Evli Funds	336,476	1.0%
Thomas Lundqvist	254,567	0.7%
Kungl. Vetenskapsakademien (KVA)	220,000	0.6%
Handelsbanken Funds	206,518	0.6%
SEB Funds	202,605	0.6%
Huber, Reuss & Kollegen Vermögensverwaltung	200,000	0.6%
Total top 15	**22,229,679**	**64.0%**
Others	**12,480,960**	**36.0%**
Total	**34,710,639**	**100.0%**

[1] Including buyback of shares.

Source: Monitor by Modular Finance AB and Euroclear Sweden AB

Owner Structure, December 31 2020

	No. of Shareholders	No. of Common Shares	Share of Capital %
1–500	6,430	894,629	2.58
501–1 000	935	771,186	2.22
1 001–5 000	1,051	2,403,566	6.92
5 001–10 000	200	1,534,117	4.42
10 001–15 000	67	844,825	2.43
15 001–20 000	32	574,330	1.65
20 001–	99	27,687,986	79.77
Total	**8,814**	**34,710,639**	**100.0**

Analysts monitoring Orexo

- Carnegie, Erik Hultgård
- Nordea, Sten Gustavsson
- Redeye, Gergana Almqvist
- RX Securities, Samir Devani

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, 2020. 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. Digital therapy deprexis® was launched on July 1, 2020 and vorvida® on July 20, 2020 on the US market.

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 Accord Healthcare has an exclusive licensing agreement for the commercialization of ZUBSOLV® in 29 European countries with the first launches expected to start in H2 2021.
- 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 therapies 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 pharma products and digital therapies for which it possesses a full commercial infrastructure. Orexo today has commercial operations promoting ZUBSOLV® to physicians in most larger cities in the US. During 2020 sales force activity was impacted by the Covid-19 pandemic, restricting face to face access by our field force to waivered healthcare providers. 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 Q2 2020 Orexo aquired exclusive US rights from GAIA to commercialize deprexis®, a world-leading digital therapy to help patients manage the symptoms of depression.

In Q4 2020, an exclusive licensing agreement was signed with Accord Healthcare, for the commercialization of ZUBSOLV® in 29 European countries, with the first launches expected to start in H2 2021. There are estimated to be 1.3 million high-risk opioid users in Europe[1], yet treatment rates are low with around 50 percent of people with opioid dependence receiving some form of substitution treatment and this can vary greatly between countries[2]. Orexo will be responsible for product supply and will receive double-digit royalties on future net sales.

The development organization focused during the year on progressing the pipeline of internal development projects. As a result, in the Q2 2020 Interim Report, Orexo announced positive study results from human PK study assessing Orexo's novel intranasal nalmefene formulations (OX125) for opioid overdose reversal. In Q4 2020 a new patent for ZUBSOLV®, with protection until 2032, was issued by the US Patent and Trademark Office (USPTO).

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

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

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

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

Orexo has established a Supplier Code of Conduct that will guide in the procurement of goods and services and align requirements and expectations between Orexo and suppliers. All new potential suppliers are assessed in accordance with the Supplier Code of Conduct. The assessment includes key suppliers sustainability efforts and performance.

At year end, Orexo had a total of 138 (127) employees.

[1] European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) 2019, https://www.emcdda.europa.eu

[2] EMCDDA – Tackling Opioid Dependence 2019, https://www.emcdda.europa.eu/best-practice/briefings/tackling-opioid-dependence_en

Key events

2020 has seen progress on many fronts, with US Pharma improved EBIT margin, Digital Therapeutics (DTx) testing new reimbursement routes and launching new commercialization concepts and we also reported an exclusive license and supply agreement for ZUBSOLV® in Europe.

Legal disputes

On July 14, 2020, Orexo's US subsidiary received subpoenas for the purpose of enabling US authorities to obtain certain information in relation to sales and marketing of ZUBSOLV® and other buprenorphine products. Orexo has no knowledge of the background to the requests and is collaborating with the US authorities to ensure they receive the necessary information and to understand the scope of the investigations.

On August 10, 2020, the company announced it has received a "paragraph IV" patent certification notice from Sun Pharmaceutical Industries Limited ("Sun"). The Notice Letter advises Orexo of Sun's filing of an Abbreviated New Drug Application ("ANDA") with the US Food and Drug Administration (FDA) seeking approval of generic versions of ZUBSOLV® before the expiration of Orexo's patents listed in the Orange Book.

Orexo currently has five patents listed in the Orange Book (US Patent Nos. 8,470,361; 8,658,198; 8,940,330; 9,259,421 and 9,439,900) with expiration dates ranging from December 2027 to September 2032. In addition, a new ZUBSOLV® patent with expiration date September 2032, US Patent No. 10,874,661, was issued by the US Patent and Trademark Office on December 29, 2020. As a respons to above notice Orexo on September 13, 2020, filed a patent infringement action in the US District Court for the District of New Jersey, against Sun. The filing statutorily precludes FDA from approving Sun's ANDA for 30 months, or until a district court decision finds the patents to be invalid or not infringed, whichever occurs first.

ZUBSOLV® US market access update

2020 was a challenging year for executing the ZUBSOLV® commercial plan as COVID-19 spread across the U.S. with many states and municipalities instituting restrictions and lockdowns at various times causing significant reduction in customer meetings. Accordingly, this negatively impacted normal office-based access to waivered HCP targets. Earlier in the year, mid-March through June the sales force was all but locked out of offices and utilized virtual means to sell ZUBSOLV® and vorvida®. Throughout 2020, Orexo prioritized employee and customer safety while attempting to execute the ZUBSOLV®/DTx plan. Sales force office access is gradually improving and is expected to continue to improve as restrictions begin to ease. Despite the limitations, ZUBSOLV® continued to grow year over year in the reimbursed open formulary businesses of the market. The previously exclusive reimbursement contracts and cash segments of the market saw continued declines but have diminished to the lowest level since the formulary changes were made. There's also been continued improvement in ZUBSOLV® market access; ESI & Cigna have listed ZUBSOLV® as the only preferred branded product on their Commercial and Medicare formularies.

Financial Performance

Condensed consolidated statement of operations

SEK million	2020	2019
Net revenues	663.6	844.8
Cost of goods sold	–65.6	–105.6
Gross profit	598.0	739.2
Selling expenses	–286.6	–191.9
Administrative expenses	–102.8	–139.6
Research and development costs	–224.9	–181.3
Other operating income and expenses	–3.6	4.8
Operating earnings	–19.9	231.2
Net financial items	–18.4	–3.3
Earnings after financial items	–38.3	227.9
Income tax	–46.1	–8.8
Net earnings for the period	–84.4	219.1

Revenues

Net revenues

Net revenues were distributed as follows:

Net revenues

SEK million	2020	2019
ZUBSOLV® US product sales	623.3	719.2
US Pharma – total	**623.3**	**719.2**
Digital Therapeutics (DTx) product sales	0.0	–
Digital Therapeutics (DTx) – total	**0.0**	**–**
Abstral® – royalty	29.7	112.6
Edluar® – royalty	10.4	11.6
ZUBSOLV® – ex US	0.1	0.1
OX-MPI	–	1.4
HQ & Pipeline – total	**40.2**	**125.6**
Total	**663.6**	**844.8**

Commercial products

Total net revenues for the year amounted to SEK 663.6 million (844.8). Lower ZUBSOLV® US revenue in 2020 and expiration of the Abstral® contracts for the US and European markets in 2019 explain the decrease.

ZUBSOLV® US revenue ended at SEK 623.3 million (719.2), 13 percent below the previous year's level. The US buprenorphine/naloxone market grew by double digit rates.

Within the commercial payer segment, ZUBSOLV® was nearly universally reimbursed in 2020. Total Commercial volume declined due to United Healthcare's addition of generics to a formerly exclusive ZUBSOLV® formulary. However ZUBSOLV® saw growth in the national formularies of all 3 major national PBMs CVS Caremark, Express Scripts, Optum.

Within the public category, Ohio Medicaid and Michigan Medicaid were the major ZUBSOLV® growth drivers, leveraging the improved formulary positions gained in 2019. Overall, ZUBSOLV®'s public volume declined due to the addition of generics to the formerly exclusive Humana Medicare, as well as loss of access in Pennsylvania Medicaid.

In 2020, the Open segment of the market where ZUBSOLV® retains the greatest reimbursement position, had limited growth due to Covid-19 and the fluctuating employment rate.

In Q2 2020 Orexo acquired exclusive US rights from GAIA to commercialize deprexis®, a world-leading digital therapy to help patients manage the symptoms of depression. Sales efforts commenced during Q4 2020 and focused on piloting different reimbursement pathways and commercial concepts, this was to ensure good cost control. Lack of broad scale commercial efforts limited revenues from fully paid licenses during the quarter. The recognized net revenues amounted to SEK 30 thousand and deferred income to SEK 100 thousand. In accordance with IFRS 15 standard for revenue recognition the revenues will be recognized throughout the validity of the license.

Total Abstral® royalties during the year amounted to SEK 29.7 million (112.6). 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 10.4 million (11.6).

Expenses and earnings

Cost of goods sold

Cost of goods sold amounted to SEK 65.6 million (105.6), explained by US Pharma of SEK 61.0 million (105.6) and technical infrastructure costs of SEK 4.6 million (–) for deprexis® and vorvida®.

Selling expenses

Selling expenses amounted to SEK 286.6 million (191.9), the increase is due to launch preparations for vorvida® and deprexis® partly offset by lower selling expenses in US Pharma.

Administrative expenses
Administrative expenses amounted to SEK 102.8 million (139.6). The lower expense level in 2020 is explained by significantly lower legal costs related to protection of IP rights.

Research and development costs
Research and development costs amounted to SEK 224.9 million (181.3) explained by the clinical trial of OX125 and as OX124 is approaching final clinical development, partly offset by lower internal costs.

Other income and expenses
Other income and expenses amounted to SEK –3.6 million (4.8) mainly explained by exchange-rate losses derived from revaluations of parent company balance sheet items in foreign currency, predominantly in USD.

Depreciation
Depreciation and amortization amounted to SEK 38.9 million (40.9). The decrease is mainly related to lower deprecations for right-of-use-assets. This also includes amortization of previously capitalized R&D expenses related to the ZUBSOLV® induction label and DTx milestones.

Net financial items
Net financial items amounted to SEK –18.4 million (–3.3) explained by negative unrealized exchange rate impact of SEK 11.6 million derived from the parent company's foreign currency bank accounts mainly in USD and by lower earned interest on bank accounts in the US of SEK 6.9 million. This was partly offset by lower costs of SEK 3.4 million for the corporate bond loan.

Income tax
Income tax for the year amounted to SEK –46.1 million (–8.8) and was negatively impacted by decreased parent company tax asset of SEK –49.0 million (–11.8) due to lower expected profits following continued investment in DTx and positively impacted by adjustment to deferred tax assets of SEK 3.9 million (3.0) related to temporary differences.

Orexo performs regular assessments of its deferred tax asset and makes adjustments according to the recognition requirements of IAS 12.

Net earnings
Net earnings amounted to SEK –84.4 million (219.1).

Segment reporting
Orexo Group has its operations in Sweden and the US. With effect from Q1 2020, operations are monitored and presented in the segments US Pharma, Digital Therapeutics (DTx) and HQ & Pipeline. See Note 6.

US Pharma
US Pharma net revenues amounted to SEK 623.3 million (719.1).

The decrease in US Pharma revenues was driven by lower demand due to competition in previously exclusive plans, declining Commercial segment due to increased unemployment as a result of Covid-19 and lower adjustments of accrued product returns, partly offset by improved pricing. Also unfavourable exchange rates had a negative impact. In local currency US Pharma net revenues amounted to USD 67.6 million (76.0) .

The EBIT contribution from US Pharma amounted to SEK 331.2 million (347.1), equal to an EBIT margin of 53.1 percent (48.3). The increase is explained by lower operating costs partly offset by lower sales and gross profit.

DTx
Sales efforts during the last quarter of the year focused on piloting different reimbursement pathways and commercial concepts, this was to ensure we maintain good cost control. Lack of broad scale commercial efforts limited revenues from fully paid licenses during the quarter.

The recognized net revenues were SEK 30 thousand and deferred income SEK 100 thousand. In accordance with IFRS 15 standard for revenue recognition the revenues will be recognized throughout the validity of the license.

EBIT amounted to SEK –175.4 million (–0.9), mainly explained by initial costs related to building up the business and enterprise platform and the continued launch of vorvida® and deprexis®.

HQ & Pipeline
Partner revenues amounted to SEK 40.2 million (125.6) mainly explained by reduced Abstral® royalty which amounted to SEK 29.7 million (112.6). Abstral® royalty for sales in Europe was received until December 31 2019, when the European contract with Kyowa Kirin expired. Abstral® royalty for sales in the US were received until October 31 2019, when Orexo's partner Sentynl withdrew Abstral® from the market. Edluar® royalty amounted to SEK 10.4 million (11.6).

EBIT amounted to SEK –175.8 million (–115.0), mainly explained by lower Abstral® royalty and by costs for the clinical trial of OX125 and as OX124 is approaching final clinical development, partly offset by lower legal IP costs.

Financial position
On December 31, 2020, cash and cash equivalents amounted to SEK 505.3 million (816.8) and interest-bearing liabilities to SEK 224.5 million (289.6).

The interest-bearing liabilities are all associated with corporate bonds. During the year Orexo bought back bonds equal to SEK 66.6 million and repurchased 500,000 of its ordinary shares for SEK 27.3 million.

Positive cash flow from operating activities for the year amounted to SEK 16.8 million (287.0) and was driven by changes in working capital. Shareholders' equity on December 31, 2020 was SEK 558.5 million (706.4) and the equity/assets ratio was 45.3 percent (47.1).

The cash position enables Orexo to pursue its strategy to launch the digital therapies in the US, to progress the development pipeline and to launch OX124.

Investments
Gross investments in tangible and intangible fixed assets amounted to SEK 189.8 million (32.0). Higher investment is mainly explained by payment of non-refundable milestones for DTx therapies, investments in the DTx enterprise platform and in equipment for the development organization.

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 446.4 million (534.0), of which group internal sales amounted to SEK 406.2 million (408.5). Earnings after financial items were SEK –23.5 million (231.1), mainly explained by lower partner revenues and higher expenses related to launch of DTx and development projects. As of December 31, 2020, cash and cash equivalents in the Parent Company amounted to SEK 361.3 million (469.0).

Outlook 2021
With the Covid-19 pandemic continuing, the financial outlook is associated with significant uncertainties in 2021. Orexo will continue to conservatively manage the cost base to reflect the market environment.

- The buprenorphine/naloxone market will continue to show a double-digit growth.
- Normal seasonal decline for ZUBSOLV® US in Q1 2021 from Q4 2020, then a stabilization and growth of ZUBSOLV® US quarterly net sales when the impact of Covid-19 has disappeared.
- Total OPEX will increase in 2021 from 2020, with OX124 driving increased R&D expenses and DTx investments will increase, but the increase will depend on DTx sales progression and market environment.
- US Pharma EBIT margin will be in the range of 45–50 percent.
- The outlook is based on exchange rates in December, 2020.

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.

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.

The commercialization rights in relation to several of the Group's other pharmaceuticals and digital therapies are held by the Group's various commercialization partners. The Group is therefore dependent on maintaining relevant distribution and commercialization arrangements in order to commercialize its products. There is a risk of such commercialization arrangements are terminated and that the Group is unable to replace such partnership in a timely manner, or at all, which could lead to lost business opportunities, delayed deliveries or increased costs.

Furthermore, the Group relies on third party partnerships to market and distribute its products, conduct clinical trials and develop and manufacture certain products utilizing the Issue's innovative drug-delivery platforms. Should such third parties fail to fulfil its contractual obligations vis-á-vis the Group, whether of financial or operational nature, fail to meet deadlines or expected levels of quality or accuracy, the Group's marketing activities and clinical trials may be extended, delayed or terminated. Any failure by such partners would negatively affect the Group's ability to develop, commercialize and license its products, which would have a negative effect on the Issuer's business and results of operations. The company considers that the probability of the above risks occurring is medium. If the risks would materialize, the Issuer considers the potential negative impact to be low.

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 2020 the development organization focused on progressing the pipeline of internal development projects. As a result, in the Q2 2020 Interim Report, Orexo announced positive study results from human PK study assessing Orexo's novel intranasal nalmefene formulations (OX125) for opioid overdose reversal. In Q4 2020 a new patent for ZUBSOLV®, with protection until 2032, was issued by the US Patent and Trademark Office (USPTO)..

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 August 10, 2020, the company announced it has received a "paragraph IV" patent certification notice from Sun Pharmaceutical Industries Limited ("Sun"). The Notice Letter advises Orexo of Sun's filing of an Abbreviated New Drug Application ("ANDA") with the US Food and Drug Administration (FDA) seeking approval of generic versions of ZUBSOLV® before the expiration of Orexo's patents listed in the Orange Book.

Orexo currently has five patents listed in the Orange Book (US Patent Nos. 8,470,361; 8,658,198; 8,940,330; 9,259,421 and 9,439,900) with expiration dates ranging from December 2027 to September 2032. In addition, a new ZUBSOLV® patent with expiration date September 2032, US Patent No. 10,874,661, was issued by the US Patent and Trademark Office on December 29, 2020. As a respons to above notice Orexo on September 13, 2020, filed a patent infringement action in the US District Court for the District of New Jersey, against Sun. The filing statutorily precludes FDA from approving Sun's ANDA for 30 months, or until a district court decision finds the patents to be invalid or not infringed, whichever occurs first.

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.

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 coronavirus disease, Covid-19, has became a global pandemic.

Based on currently available information, 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 non or limited impact, both related to funding and performance.

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 138 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[1]
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 2020. 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 2021. 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 2021 for approval are excluded for the same reason. The proposed plans include similar performance criteria as 2020 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.

[1] The guidelines were adopted by the Annual General Meeting on April 16, 2020 and are forward-looking.

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 2020 Orexo had two large shareholders with holdings of more than 10 percent of the total number of shares; Novo Holding A/S 27.8 percent with 9,643,184 shares, and HealthCap 10.2 percent with 3,556,334 shares.

Number of shares

Company shares total 34,710,639 (including buyback of shares) an there are 34,710,639 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	1,186,055
Loss carried forward	–894,344
Profit/loss for the year	–72,499
Total	**219,212**

The Board proposes that the funds at their disposal SEK 219,212 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 92.

Financial information in brief – Group

Statement of operations information

SEK million	2020	2019	2018	2017	2016
Net revenues	663.6	844.8	783.1	643.7	705.9
Cost of goods sold	–65.6	–105.6	–171.8	–164.4	–149.6
Gross Profit	**598.0**	**739.2**	**611.4**	**479.3**	**556.3**
Selling expenses	–286.6	–191.9	–191.4	–190.5	–240.6
Administrative expenses	–102.8	–139.6	–166.7	–96.1	–161.6
Research and development costs	–224.9	–181.3	–166.8	–134.2	–132.3
Other operative income and expenses	–3.6	4.8	9.3	–1.1	29.9
Operating earnings	**–19.9**	**231.2**	**95.8**	**57.4**	**51.7**
Net financial items	–18.4	–3.3	–3.6	–27.7	–16.1
Earning after financial items	**–38.3**	**227.9**	**92.2**	**29.7**	**35.6**
Income tax	–46.1	–8.8	45.7	–6.5	–6.5
Net earning for the year	**–84.4**	**219.1**	**137.9**	**23.2**	**29.0**

Balance sheet information

SEK million	2020	2019	2018	2017	2016
Intangible fixed assets	252.8	113.9	103.9	121.0	138.2
Tangible fixed assets	47.3	22.0	20.0	20.1	22.1
Right-of-use assets	67.8	57.0	0.0	0.0	0.0
Deferred tax	32.7	85.5	92.8	28.3	24.8
Other financial assets	0.7	1.4	10.4	7.1	7.9
Inventories	108.4	131.8	173.6	250.2	344.2
Accounts receivable	165.2	233.8	264.5	218.4	178.5
Other current assets	52.6	38.8	31.6	30.9	20.7
Cash and bank balance	505.3	816.8	589.8	327.9	282.4
Total assets	**1,232.9**	**1,501.1**	**1,286.7**	**1,003.9**	**1,018.8**
Shareholders' equity	558.5	706.4	476.1	329.1	310.3
Interest-bearing liabilities	291.0	344.3	320.6	319.1	397.8
Non-interest bearing liabilities and provisions	383.4	450.3	489.9	355.7	310.7
Total shareholders' equity and liabilities	**1,232.9**	**1,501.1**	**1,286.7**	**1,003.9**	**1,018.8**

Cash flow information

SEK million	2020	2019	2018	2017	2016
Cash flow from operating activities before changes in working capital	–35.2	252.5	127.9	110.3	67.5
Cash flow changes in working capital	52.0	34.5	114.1	36.3	88.7
Cash flow from operating activities	16.8	287.0	242.0	146.6	156.2
Acquisition of tangible, intangible and financial assets	–189.7	–32.0	–6.2	–1.6	–1.7
Sale of tangible assets	–	–	–	–	1.9
Disposal of financial assets	0.6	9.5	–	–	–
Sale of subsidiary	–	–	–	–	5.0
Cash flow after investing activities	–172.3	264.6	235.8	145.0	161.7
Amortization of loans	–84.0	–55.8	–	–404.7	–92.8
Borrowings	–	–	–	319.2	–
New share issues	–	2.0	0.1	0.1	2.2
Buyback of shares	–27.3	–	–0.1	–	–
Cash flow for the year	–283.7	210.8	235.8	59.6	71.1
Cash and cash equivalents at year-end	505.3	816.8	589.8	327.9	282.4

Other key figures

	2020	2019	2018	2017	2016
EBIT margin, %	–3.0	27.4	12.2	8.9	7.3
Return on shareholder equity, %	–13.3	37.1	34.3	7.3	10.0
Net debt, SEK million[1]	–280.8	–527.2	–269.2	–8.8	115.4
Debt/equity ratio, %	40.2	41.0	67.3	97.0	128.2
Equity/assets ratio, %	45.3	47.1	37.0	32.8	30.5
Number of shares, before dilution	34,398,815	34,621,646	34,560,456	34,540,271	34,477,423
Number of shares, after dilution	34,398,815	35,348,484	35,095,980	34,650,835	34,574,337
Earnings per share, before dilution, SEK	–2.45	6.33	3.99	0.67	0.84
Earnings per share, after dilution, SEK	–2.45	6.20	3.93	0.67	0.84
Number of employees at the end of the period	138	127	129	90	102
Shareholders' equity, SEK million	558.5	706.4	476.1	329.1	310.3
Capital employed, SEK million	783.0	996.0	796.7	648.2	708.1
Working capital, SEK million	–50.5	–56.7	–13.7	149.6	233.9

For alternative key figures see definitions and reconciliations of key figures on page 90.
[1] Net debt calculated exclusive of leases.

From left, Anneli Wennman, Analytical Chemist, Jonas Sävmarker, Senior Principal Scientist and Maria Sandström, Senior Formulation Scientist
Photo: Jenny Lagerqvist.

Financial Reports and Notes

Consolidated Statement of Operations 55
Consolidated Statement of Comprehensive Income 55
Consolidated Balance Sheet 56
Changes in Consolidated Shareholders' Equity 57
Consolidated Cash Flow Statement 58
Parent Company Statement of Operations 59
Parent Company Statement of Comprehensive Income 59
Parent Company Balance Sheet 60
Changes in Parent Company Shareholders' Equity 61
Parent Company Cash Flow Statement 62
Notes 63
Assurance of the Board of Directors and President 86
Auditor's Report 87

Consolidated Statement of Operations

SEK million	Notes	2020	2019
Net revenues	5	663.6	844.8
Cost of goods sold	7	–65.6	–105.6
Gross profit		**598.0**	**739.2**
Selling expenses	8, 9, 10, 31	–286.6	–191.9
Administrative expenses	7, 9, 10, 29, 31	–102.8	–139.6
Research and development costs	7,9, 10, 31	–224.9	–181.3
Other operating income	8, 11	17.6	13.4
Other operating expenses	7, 11	–21.2	–8.6
Operating earnings		**–19.9**	**231.2**
Financial income	12	60.7	46.4
Financial expense	12	–79.1	–49.7
Earnings after financial items		**–38.3**	**227.9**
Tax	13	–46.1	–8.8
Net earnings for the year		**–84.4**	**219.1**
Earnings for the year attributable to:			
Parent Company shareholders		–84.4	219.1
Earnings per share during the year attributable to Parent Company shareholders (expressed in SEK)			
– before dilution	14	–2.45	6.33
– after dilution	14	–2.45	6.20

Consolidated Statement of Comprehensive Income

SEK million	Notes	2020	2019
Net earnings for the year		**–84.4**	**219.1**
Other comprehensive income			
Items that may subsequently be reversed to the statement of operations:			
Translation differences	17	–16.5	3.4
Other comprehensive earnings for the year, net after tax		**–16.5**	**3.4**
Comprehensive earnings for the year		**–100.9**	**222.5**
Comprehensive earnings attributable to:			
Parent Company shareholders		–100.9	222.5
Non–controlling interests		–	–

Consolidated Balance Sheet

SEK million	Notes	2020	2019
ASSETS			
Fixed assets			
Tangible fixed assets	9, 15	47.3	22.0
Intangible assets	9, 16	252.8	113.9
Right-of-use assets	31	67.8	57.0
Deferred tax assets	30	32.7	85.5
Other financial assets	18	0.7	1.4
Total fixed assets		**401.3**	**279.9**
Current assets			
Inventories	19	108.4	131.8
Accounts receivable	20	165.2	233.8
Other receivables	21	25.7	20.3
Prepayment and accrued income	22	26.9	18.4
Cash and cash equivalents	18, 23	505.3	816.8
Total current assets		**831.6**	**1,221.2**
TOTAL ASSETS		**1,232.9**	**1,501.1**
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity			
Share capital		14.2	14.2
Other contributed capital	24	1,814.4	1,861.4
Reserves	17	–13.4	3.1
Profit carried forward including net earnings for the year		–1,256.7	–1,172.3
Total shareholder's equity		**558.5**	**706.4**
Long–term liabilities and provisions			
Provisions	24, 25	25.7	10.7
Interest bearing liabilities	18, 26	–	289.6
Lease liabilities, long-term		47.4	33.3
Total long–term liabilities		**73.1**	**333.6**
Current liabilities			
Accounts payable	18	47.0	49.4
Provisions	25	197.3	269.3
Other liabilities	27	6.2	4.7
Accrued expenses	27	107.2	116.2
Lease liabilities, current		19.1	21.4
Interest bearing liabilities, current	18, 26	224.5	–
Total current liabilities		**601.3**	**461.0**
Total liabilities		**674.4**	**794.6**
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		**1,232.9**	**1,501.1**

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, 2019		**14.2**	**1,853.6**	**–0.3**	**–1,391.4**	**476.1**
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	24		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**
Opening balance at January 1, 2020		**14.2**	**1,861.4**	**3.1**	**–1,172.3**	**706.4**
Comprehensive income						
Net earnings for the year					–84.4	–84.4
Other comprehensive income						
Translation differences				–16.5		–16.5
Total comprehensive income		**0.0**	**0.0**	**–16.5**	**–84.4**	**–100.9**
Transactions with shareholders						
Share-based payments	24		–19.7			–19.7
Buyback of shares			–27.3			–27.3
Total transactions with shareholders		**0.0**	**–47.0**	**0.0**	**0.0**	**–47.0**
Closing balance at December 31, 2020		**14.2**	**1,814.4**	**–13.4**	**–1,256.7**	**558.5**

[1] There are no non–controlling interests
[2] Note 17

The number of outstanding shares has decreased from 35,553,610 per 31 December 2019 to 34,710,639 (including 415 766 shares held by the company) per 31 December 2020. This has been done through cancellation of 842,971 C-shares.

Consolidated Cash Flow Statement

SEK million	Notes	2020	2019
Operating earnings		–19.9	231.2
Adjustment for non-cash items	32	–7.1	41.3
Interest received		3.0	9.9
Interest paid		–11.8	–17.7
Tax paid		0.6	–12.2
Cash flow from operating activities before changes in working capital		**–35.2**	**252.5**
Changes in working capital			
Change in inventories		10.1	43.3
Change in receivables		25.2	45.1
Change in current liabilities		16.7	–53.9
Cash flow from operating activities		**16.8**	**287.0**
Investing activities			
Investments in tangible fixed assets	15	–29.4	–5.0
Investments in intangible assets	16	–160.3	–27.0
Disposal of financial assets		0.6	9.5
Cash flow from investing activities		**–189.1**	**–22.4**
Financing activities			
New share issue		–	2.0
Buyback of shares		–27.3	–
Repayment of loans	26,31	–84.0	–55.8
Cash flow from financing activities		**–111.3**	**–53.7**
Cash flow for the year		**–283.7**	**210.8**
Cash and cash equivalents at the beginning of the period		816.8	589.8
Exchange-rate differences in cash and cash equivalents		–27.8	16.1
Change in liquidity		–311.5	227.0
Cash and cash equivalents at the end of the period	23	**505.3**	**816.8**

Parent Company Statement of Operations

SEK million	Notes	2020	2019
Net revenues	5	446.4	534.0
Cost of goods sold	7	–79.7	–98.6
Gross profit		**366.7**	**435.3**
Selling expenses	7, 9, 10, 31	–190.7	–6.6
Administrative expenses	7, 9, 10, 29, 31	–53.1	–105.6
Research and development costs	7, 9, 10, 31	–180.1	–152.3
Other operating income	8, 11	70.2	75.6
Other operating expenses	7, 11	–20.2	–8.4
Operating earnings		**–7.2**	**238.0**
Other interest income and similar income	12	59.9	40.0
Other interest expenses and similar expenses	12	–76.2	–46.9
Net financial items		**–16.3**	**–6.9**
Earnings before tax		**–23.5**	**231.1**
Tax on earnings for the year	13	–49.0	–11.8
Net earnings for the year		**–72.5**	**219.3**

Parent Company Statement of Comprehensive Income

SEK million	Notes	2020	2019
Net earnings for the year		–72.5	219.3
Other comprehensive income for the period, net after tax		–	–
Total comprehensive income for the period		**–72.5**	**219.3**

Parent Company Balance Sheet

SEK million	Notes	2020	2019
ASSETS			
Fixed assets			
Patents and intellectual property rights and proprietary intangible asset	9, 16	234.4	113.9
Equipment, renovation of the property of others	9, 15	47.2	22.0
Deferred tax assets	30	–	49.0
Shares and participations in group companies	28	160.4	155.6
Total fixed assets		**442.0**	**340.6**
Current assets			
Inventories	19	90.9	113.4
Accounts receivable	20	21.5	46.4
Other receivables	21	8.0	6.3
Receivables from group companies		65.1	153.5
Prepaid expenses and accrued income	22	16.7	7.8
Cash and bank	23	361.3	469.0
Total current assets		**563.5**	**796.5**
TOTAL ASSETS		**1,005.5**	**1,137.1**
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	24	1,186.1	1,206.1
Accumulated deficit		–894.3	–1,086.3
Net earnings for the year		-72.5	219.3
Total non-restricted shareholders' equity		**219.3**	**339.1**
Total shareholders' equity		**524.2**	**644.0**
Long-term liabilities			
Other provisions	24, 25	24.5	8.2
Interest bearing liabilities	26	–	289.6
Total long-term liabilities		**24.5**	**297.8**
Current liabilities			
Accounts payable		17.3	22.8
Interest bearing liabilities	26	224.5	–
Other liabilities	27	6.2	4.7
Liabilities to group companies		187.2	144.7
Accrued expenses and deferred income	27	21.6	23.1
Total current liabilities		**456.8**	**195.3**
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		**1,005.5**	**1,137.1**

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, 2019		**14.2**	**290.8**	**1,198.1**	**–1,086.2**	**416.9**
Net earnings for the year					219.3	219.3
Other comprehensive income						–
Total comprehensive income					**219.3**	**219.3**
Share based payments	24			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**
Opening shareholders' equity at January 1, 2020		**14.2**	**290.8**	**1,206.1**	**–867.0**	**644.0**
Net earnings for the year					–72.5	–72.5
Other comprehensive income						
Total comprehensive income		**0.0**	**0.0**	**0.0**	**–72.5**	**–72.5**
Share based payments	24			–20.0		–20.0
Buyback shares					–27.3	–27.3
Closing shareholders' equity at December 31, 2020		**14.2**	**290.8**	**1,186.1**	**–966.8**	**524.2**

The number of outstanding shares has decreased from 35,553,610 per 31 December 2019 to 34,710,639 per 31 December 2020. This has been done through cancellation of 842,971 C-shares.

Parent Company Cash Flow Statement

SEK million	Notes	2020	2019
Operating activities			
Operating earnings		–7.2	238.0
Adjustment for non-cash items	32	23.0	23.1
Interest received		2.2	3.5
Interest paid		–11.8	–15.2
Tax paid		–	–
Cash flow from operating activities before change in working capital		**6.3**	**249.4**
Change in working capital			
Change in inventories		22.5	41.9
Change in accounts receivable and other current receivables		95.6	–44.5
Change in current liabilities		35.7	–24.8
Cash flow from operating activities		**160.1**	**222.0**
Investing activities			
Investments in tangible fixed assets	15	–29.3	–5.0
Investments in intangible assets	16	–139.4	–27.0
Cash flow from investing activities		**–168.7**	**–32.0**
Financing activities			
New share issue		–	2.0
Buyback of shares		–27.3	–
Buyback of corporate bond	26	–66.6	–32.5
Cash flow from financing activities		**–93.9**	**–30.5**
Cash flow for the year		**–102.5**	**159.5**
Cash and cash equivalents at beginning of period		469.0	303.2
Exchange-rate differences in cash and cash equivalents		–5.2	6.3
Change in liquidity		–107.7	165.8
Cash and cash equivalents at end of period	23	**361.3**	**469.0**

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 22, 2021.

The statement of operations and balance sheet will be presented to the Annual General Meeting on April 16, 2021, 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

No new standards, amendments or interpretations of existing standards have been applied by the Group during the financial year

(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.

2.4 Translation of foreign currency

(a) Functional currency and reporting currency

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

(b) Transactions and balance sheet items

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

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

(c) Group companies

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

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

Note 2 cont.

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	3–10 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 24.

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

Orexo AB applies IFRS 16. According to the 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.

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 2020 fiscal year, sales in USD accounted for 92 (89) percent of net revenues and sales in EUR accounting for 8 (13) percent. During the same period, 70 (72) percent of total operating expenses were in foreign currency with 63 (68) percent in USD, 3 (1) percent in EUR and 3(3) 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 2.2 million.

The corresponding change in GBP entails a change of approximately SEK 0.6 million and in EUR of approximately SEK 0.1 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 11.9 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 224.5 million on December 31, 2020 and these are attributable to a corporate bond loan. This loan has a variable interest rate, STIBOR +4.50 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 1.1 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, 2020, the three largest customers accounted for 94 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, 2020	Less than 1 year	Between 1 and 2 years	Between 2 and 5 years
Accounts payable	47.0	—	—
Accrued costs	107.2	—	—
Interest bearing liabilities	226.3	—	—
Leasing	19.7	56.1	—

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	—	—
Interest bearing liabilities	13.3	304.2	—
Leasing	22.0	39.6	—

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 2020 ZUBSOLV® had access to 99 percent of the commercial category and 34 percent of the public category in the US.

Note 3 cont.

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

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

In order to secure delivery of the products which are critical for patients, Orexo must hold considerable inventories of ZUBSOLV®. High inventory levels entail a risk of impairment of products that have expired. Orexo is constantly working to minimize this risk by adapting inventories to demand, and through the work on improving the product's shelf life.

Being able to obtain and maintain patents and other intellectual property rights protecting Orexo's technologies and products is an important part of Orexo's strategy of creating long-term value for its business. Obtaining patents related to pharmaceuticals is a complex process that involves both scientific and legal expertise. Even if a patent has been granted, it may later be challenged legally, declared invalid or bypassed, which may limit Orexo's ability to market new products. For an update on ongoing litigation cases see the section 'Corporate Governance Report 2020'.

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, 2020 and 2019 is presented in the table below:

	2020	2019
Shareholders' equity	558.5	706.4
Total assets	1,232.9	1,501.1
Equity/assets ratio	**45%**	**47%**

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 1,188 million (1,180) at December 31, 2020. No deferred tax assets for tax-loss carry-forwards have 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 2020 these costs amounted to SEK 224.9 million (181.3).

NOTE 5 REVENUE FROM CONTRACTS WITH CUSTOMERS

	2020						
Group	ZUBSOLV®	Abstral®	Edluar®	OX-MPI	vorvida®	deprexis®	Total
Segment							
US Pharma	623.3	–	–	–	–	–	**623.3**
Digital Therapeutics	–	–	–	–	0.0	0.0	**0.0**
HQ & Pipeline	0.1	29.7	10.4	0.0	–	–	**40.2**
Total revenue from contracts with customers	**623.4**	**29.7**	**10.4**	**0.0**	**0.0**	**0.0**	663.6
Geographical markets							
US	623.3	0.0	3.1	–	0.0	0.0	**624.4**
EU	0.1	28.9	2.7	0.0	–	–	**31.7**
Rest of the world	–	0.8	4.7	–	–	–	**5.5**
Total revenue from contracts with customers	**623.4**	**29.7**	**10.4**	**0.0**	**0.0**	**0.0**	663.6

	2019						
Group	ZUBSOLV®	Abstral®	Edluar®	OX-MPI	vorvida®	deprexis®	Total
Segment							
US Pharma	719.2	–	–	–	–	–	**719.2**
Digital Therapeutics	–	–	–	–	–	–	**0.0**
HQ & Pipeline	0.1	112.6	11.6	1.4	–	–	**125.6**
Total revenue from contracts with customers	**719.3**	**112.6**	**11.6**	**1.4**	**0.0**	**0.0**	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**	**0.0**	**0.0**	844.8

	2020						
Parent Company	ZUBSOLV®	Abstral®	Edluar®	OX-MPI	vorvida®	deprexis®	Total
Segment							
US Pharma (intragroup)	406.2	–	–	–	–	–	**406.2**
Digital Therapeutics	–	–	–	–	–	–	**0.0**
HQ & Pipeline	0.1	29.7	10.4	–	–	–	**40.2**
Total revenue from contracts with customers	**406.3**	**29.7**	**10.4**	**0.0**	**0.0**	**0.0**	446.4
Geographical markets							
US	406.2	–	3.1	–	–	–	**409.3**
EU	0.1	28.9	2.7	–	–	–	**31.7**
Rest of the world	–	0.8	4.7	–	–	–	**5.5**
Total revenue from contracts with customers	**406.3**	**29.7**	**10.4**	**0.0**	**0.0**	**0.0**	446.4

	2019						
Parent Company	ZUBSOLV®	Abstral®	Edluar®	OX-MPI	vorvida®	deprexis®	Total
Segment							
US Pharma (intragroup)	408.5	–	–	–	–	–	**408.5**
Digital Therapeutics	–	112.6	11.6	–	–	–	**124.1**
HQ & Pipeline	0.1	–	–	1.4	–	–	**1.5**
Total revenue from contracts with customers	**408.6**	**112.6**	**11.6**	**1.4**	**0.0**	**0.0**	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**	**0.0**	**0.0**	534.0

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 170.3 million (211.9) 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 27.0 million (57.4) at the balance sheet date. During the period, the Group reversed provisions for discounts and returns from previous periods to an amount of SEK 29.2 million (28.5). 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.

NOT 6 DISTRIBUTION OF REVENUE AND EBIT PER SEGMENT

US Pharma segment comprises the distribution and sale of ZUBSOLV® for treatment of opioid use disorder in the US. Digital Therapeutics segment comprise the distribution and sale of digital therapies which complement existing treatments and provide patients with access to highly sophisticated and individualized support when they need it most in the US. HQ & Pipeline consists of the Group head quarter functions, R&D, Business Development, Global Regulatory and Supply Chain.

SEK m	2020 Jan–Dec	2019 Jan–Dec
US Pharma		
Net revenues	623.3	719.2
Operating earnings (EBIT)	331.2	347.1
Depreciation and amortization	–15.4	–15.4
Digital Therapeutics		
Net revenues	0.0	–
Operating earnings (EBIT)	–175.4	–0.9
Depreciation and amortization	–3.2	–
HQ & Pipeline		
Net revenues	40.2	125.6
Operating earnings (EBIT)	–175.8	–115.0
Depreciation and amortization	–20.3	–25.6
Group		
Net revenues	663.6	844.8
Operating earnings (EBIT)	–19.9	231.2
Depreciation and amortization	–38.9	–40.9
Net financial items	–18.4	–3.3
Earnings before tax	–38.3	227.9

Revenues from customer in Sweden amounted to SEK 10.7 million during 2020
Fixed assets in Sweden amounted to SEK 33.1 million at December 31, 2020
Intangibile assets in Sweden amounted to SEK 234.4 million at December 31, 2020

NOTE 7 COSTS BY TYPE OF COST

	Group		Parent Company	
	2020	2019	2020	2019
Raw materials and consumables	65.6	105.6	79.7	98.6
Other external expense	354.7	247.0	322.7	164.7
Personnel costs	220.6	224.8	78.3	79.9
Depreciation/amortization and impairment	38.9	41.0	23.0	20.0
Total	**679.9**	**618.4**	**503.7**	**363.1**

NOTE 8 OTHER OPERATING INCOME

	Group		Parent Company	
	2020	2019	2020	2019
Exchange gains	17.8	10.5	17.8	10.5
Other income	–0.2	2.9	52.4	65,2
Gains on disposal of assets	–	–	–	–
Total	**17.6**	**13.4**	**70.2**	**75.6**

Other income mainly 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 9 DEPRECIATION/AMORTIZATION AND IMPAIRMENT

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

	Group		Parent Company	
	2020	2019	2020	2019
Tangible fixed assets				
Sales	–	–	–	–
Administration	1.8	1.8	1.8	1.8
Research and development	2.2	1.2	2.2	1.2
Total tangible fixed assets	**4.1**	**3.0**	**4.1**	**3.0**
Intangible assets				
Selling	0.5	–	–	–
Administration	0.4	0.3	0.4	0.3
Research and development	18.6	16.7	18.6	16.7
Total intangible assets	**19.5**	**16.9**	**18.9**	**16.9**
Right-of use assets				
Selling	2.0	5.2	–	–
Administration	2.6	4.4	–	–
Research and development	10.8	11.3	–	–
Total right-of use assets	**15.3**	**21.0**	–	–
Total depreciation/amortization and impairment	**38.9**	**41.0**	**23.0**	**20.0**

NOTE 10 REMUNERATION TO EMPLOYEES

Average number of employees

Group	2020 Average number of employees	Of whom men	2019 Average number of employees	Of whom men
Sweden	55	25	54	25
USA	80	32	76	30
Total for Group	**135**	**57**	**130**	**55**

Parent Company	2020 Average number of employees	Of whom men	2019 Average number of employees	Of whom men
Sweden	55	25	54	25
Total for Parent Company	**55**	**25**	**54**	**25**

	Group		Parent Company	
Costs and remuneration to all employees and Board, SEK thousands	2020	2019	2020	2019
Salaries, remuneration and social security fees				
Salaries and other remuneration to the Board, President and Executive Management	45,703	33,942	23,064	20,877
Salaries and other remuneration to other employees	125,329	123,656	28,080	25,154
Pension cost for the Board, President and Executive Management[1]	2,112	1,533	1,694	1,215
Pension cost for other employees[1]	11,329	10,417	6,880	6,835
Social security fees for the Board, President and Executive Management[2]	3,010	7,056	3,405	5,728
Social security fees for other employees[2]	13,724	16,838	7,347	10,376
Other personnel costs	33,343	27,985	7,753	4,605
Total	**234,551**	**221,427**	**78,223**	**74,790**

[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 10 cont.

Costs and remuneration to the Board, President and senior executives 2020

SEK thousands	Basic salary/ Board fees	Variable remuneration	Other benefits	Pension costs	Share-based payment	Other remuneration	Total remuneration
Board of directors							
James Noble, Chairman[1]	699	–	–	–	–	–	699
Henrik Kjaer Hansen, Board member[2]	0	–	–	–	–	–	0
Fred Wilkinson, Board member	300	–	–	–	–	–	300
Staffan Lindstrand, Board member	350	–	–	–	–	–	350
Mary Pat Christie, Board member	300	–	–	–	–	–	300
Charlotte Hansson, Board member[1]	333	–	–	–	–	–	333
David Colpman, Board member	350	–	–	–	–	–	350
Kirsten Detrick, Board member	300	–	–	–	–	–	300
Subtotal	**2,630**	**0**	**0**	**0**	**0**	**0**	**2,630**
President and senior executives							
Nikolaj Sørensen, President and CEO	3,428	1,354	89	692	3,133	–	8,697
Other senior executives (6)	20,287	7,696	812	1,420	3,774	2,533	36,523
Total	**26,345**	**9,050**	**901**	**2,112**	**6,908**	**2,533**	**47,850**

[1] New members since the Annual General meeting in April 2020
[2] Refrained from Board fee

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**

Board members and senior executives

	2020		2019	
	Number on the closing date	Of whom men	Number on the closing date	Of whom men
Group (incl. subsidiaries)				
Board members	8	63%	8	63%
President and other senior executives	8	88%	7	86%
Parent Company				
Board members	8	63%	8	63%
President and other senior executives	5	80%	5	80%

Remuneration to CEO and senior executives consits of fixed salary, varibale remuneration, share-based remuneration, pension and other benefits (mainly company car). All employees are covered by defined-contribution plans including health insurance. Variable remuneration refers to variable bonuses based on the fixed portion of basic salary. The employment agreement with the CEO may be terminated with a six-month notice period. Employment agreements for other senior executives can be terminated with between zero and six months' notice. For a further description, see the board of directors report on pages 50–51. Refer to Note 24 for a description of the share-based remuneration

Other senior executives, as of December 31, 2020 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 100 and Management on page 102.

NOTE 11 EXCHANGE-RATE DIFFERENCES

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

	Group		Parent Company	
	2020	2019	2020	2019
Other operating income	17.8	10.5	17.8	10.5
Other operating expenses	–20.2	–8.3	–20.2	–8.3
Total	**–2.4**	**2.2**	**–2.4**	**2.2**

For exchange rate effect in net financial items see Note 12.

NOTE 12 FINANCIAL INCOME AND EXPENSES

	Group		Parent Company	
	2020	2019	2020	2019
Financial income				
Other interest income	1.6	9,9	0.8	3.5
Buyback bond	1.4	–	1.4	–
Exchange rate effect	57.7	36.5	57.7	36.5
Total financial income	**60.7**	**46.4**	**59.9**	**40.0**
Financial expenses				
Interest expense from corporate bonds	–11.8	–14.3	–11.8	–14.3
Other interest expense	–2.9	–2.9	0.0	–0.1
Borrowing costs, corporate bonds	–1.5	–2.3	–1.5	–2.3
Exchange rate effect	–62.9	–30.2	–62.9	–30.2
Total financial expenses	**–79.1**	**–49.7**	**–76.2**	**–46.9**
Net Financial items	**–18.4**	**–3.3**	**–16.3**	**–6.9**

NOTE 13 TAX

	Group		Parent Company	
	2020	2019	2020	2019
Current tax	–5.2	–2.5	–	–
Deferred tax	–40.9	–6.3	–49.0	–11.8
Total	**–46.1**	**–8.8**	**–49.0**	**–11.8**
Difference between the Group's tax expense and tax expense based on current tax rate				
Recognized pre-tax earnings	–38.3	227.9	–23.4	231.1
Tax under current tax rate	8.2	–48.8	5.0	–49.5
Tax effect of foreign tax rates	–0.3	–3.0	–	–
Tax effect of non-deductible costs	–0.1	–0.3	–0.1	–0.3
Recognized carry-forward losses	–53.9	43.3	–53.9	38.0
Tax on earnings for the year according to the statement of operations	**–46.1**	**–8.8**	**–49.0**	**–11.8**

NOTE 14 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	**2020**	**2019**
Earnings used for the calculation of earnings per share before dilution, MSEK	–84.4	219.1
Average number of shares before dilution	34,398,815	34,621,646
Earnings per share before dilution (SEK per share)	–2.45	6.33
Average number of shares after dilution	34,398,815	35,348,484
Earnings per share after dilution (SEK per share)	–2.45	6.20
Options/share rights outstanding	1,630,875	1,505,307

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	**2020**	**2019**
Average number of shares before dilution	34,398,815	34,621,646
Potential shares from options and share rights	0	726,839
Average number of shares after dilution	34,398,815	35,348,484

NOTE 15 TANGIBLE FIXED ASSETS

Group	**Equipment and machinery**	**Computers**	**Improvement expenses other's property**	**Total**
Fiscal year 2019				
Opening balance	37.7	3.6	36.2	77.5
Additions	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**
Fiscal year 2020				
Opening balance	39.2	2.9	36.2	78.2
Additions	29.4	–	–	29.4
Disposals	–	–	–	–
Outgoing accumulated acqusitions	**68.6**	**2.9**	**36.2**	**107.7**
Ingoing depreciation	–31.1	–3.0	–22.2	–56.3
Acumulated depreciation disposal	–	–	–	–
Depreciation	–2.3	–	–1.8	–4.1
Accumulated depreciation	**–33.4**	**–3.0**	**–24.0**	**–60.4**
At December 31, 2020				
Cost	68.6	2.9	36.2	107.7
Accumulated depreciation and impairment	–33.4	–3.0	–24.0	–60.4
Carrying amount	**35.2**	**–0.1**	**12.2**	**47.3**

Note 15 cont.

Parent Company	Equipment and machinery	Computers	Improvement expenses other's property	Total
Fiscal year 2019				
Opening balance	34.2	1.8	36.2	72.2
Additions	5.0	—	—	5.0
Disposals	–3.5	–0.7	—	–4.3
Outgoing accumulated acquisitions	**35.7**	**1.1**	**36.2**	**72.9**
Ingoing depreciation	–30.1	–1.7	–20.3	–52.2
Accumulated 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**
Fiscal year 2020				
Opening balance	35.7	1.1	36.2	72.9
Additions	29.3	—	—	29.3
Disposals	—	—	—	—
Outgoing accumulated acquisitions	**65.0**	**1.1**	**36.2**	**102.3**
Ingoing depreciation	–27.7	–1.1	–22.1	–51.0
Accumulated depreciation disposal	—	—	—	—
Depreciation	–2.3	—	–1.8	–4.1
Accumulated depreciation	**–30.0**	**–1.1**	**–23.9**	**–55.1**
At December 31, 2020				
Cost	65.0	1.1	36.2	102.3
Accumulated depreciation and impairment	–30.0	–1.1	–23.9	–55.1
Carrying amount	**35.0**	**0.0**	**12.3**	**47.2**

NOTE 16 INTANGIBLE FIXED ASSETS

Group	Acquired R&D	Patents and rights	Proprietary intellectual property right	Other	Total
Fiscal year 2019					
Opening balance	435.1	27.4	153.6	13.4	629.5
Additions	—	26.4	—	0.6	27.0
Outgoing accumulated acquisitions	**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**
Fiscal year 2020					
Opening balance	435.1	53.7	153.6	14.0	656.4
Additions	—	140.4	—	19.9	160.3
Exchange rate differences		–2.0			–2.0
Outgoing accumulated acquisitions	**435.1**	**192.1**	**153.6**	**33.9**	**814.7**
Accumulated amortization and impairment	–435.1	–27.4	–67.8	–12.2	–542.5
Amortization	—	–3.2	–15.4	–0.9	–19.5
Accumulated amortization and impairment	**–435.1**	**–30.6**	**–83.2**	**–13.1**	**–562.0**
At December 31, 2020					
Cost	435.1	211.1	153.6	15.0	814.8
Accumulated amortization and impairment	–435.1	–30.6	–83.2	–13.1	–562.0
Carrying amount	**0.0**	**180.5**	**70.4**	**1.9**	**252.8**

Note 16 cont.

Parent company	Acquired R&D	Patents and rights	Proprietary intellectual property right	Other	Total
Fiscal year 2019					
Opening balance	435.1	27.4	153.6	13.4	629.5
Additions	–	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**
Fiscal year 2020					
Opening balance	435.1	53.7	153.6	14.0	656.4
Additions	–	138.4	–	1.0	139.4
Outgoing accumulated acqusitions	**435.1**	**192.1**	**153.6**	**15.0**	**795.8**
Accumulated amortization and impairment	–435.1	–27.4	–67.8	–12.2	–542.5
Amortization	–	–2.7	–15.4	–0.9	–18.9
Accumulated amortization and impairment	**–435.1**	**–30.1**	**–83.2**	**–13.1**	**–561.5**
At December 31, 2020					
Cost	435.1	192.1	153.6	15.0	795.8
Accumulated amortization and impairment	–435.1	–30.1	–83.2	–13.1	–561.5
Carrying amount	**0.0**	**162.0**	**70.4**	**1.9**	**234.4**

Proprietary intangible asset at December 31, 2020

A proprietary intangible asset amounting to SEK 70.4 million (85.8) 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 224.9 million (181.3).

Parent Company intangible assets comprise patents, rights, a proprietary intellectual property right and IT systems. Investments consists mainly of non-refundable milestones of SEK 138.4 million for DTx and of SEK 1.0 million in software.

Impairment testing

During the year the company has performed impairment tests of its intangible assets related to Digital Therapeutics. As of December 31, 2020 company has intangible assets for Digital Therapeutics of SEK 162.2 million, consisting of milestone payments for licenses and similar rights. The impairment tests were performed based on discounted cash flows for the years 2021 to 2029. The most significant assumption utilized was projected future revenue growth, as the value of the assets is dependent on the company successfully commercializing the products. The period for which cash flows were projected was longer than five years, due to the early phase of commercialization the Digital Therapeutics products are currently in. A discount rate (WACC) of 12.9% was applied to the tests. The tests performed did not indicate any impairment.

NOTE 17 RESERVES

	Translation reserve	Total
Opening balance at January 1, 2019	**–0.3**	**–0.3**
Translation differences	3.4	3.4
Closing balance at December 31, 2019	**3.1**	**3.1**
Opening balance at January 1, 2020	**3.1**	**3.1**
Translation differences	–16.5	–16.5
Closing balance at December 31, 2020	**–13.4**	**–13.4**

NOTE 18 INFORMATION ON FINANCIAL INSTRUMENTS IN THE GROUP

Classification and categorization of assets and liabilities in the Group 2020

December 31, 2020	Financial assets measured at amortized cost	Total financial assets	Non-financial assets	Total
Assets				
Tangible fixed assets	–	**0.0**	47.3	**47.3**
Intangible fixed assets	–	**0.0**	252.8	**252.8**
Right-of-use asset	–	**0.0**	67.8	**67.8**
Deferred tax asset	–	**0.0**	32.7	**32.7**
Inventories	–	**0.0**	108.4	**108.4**
Financial assets	0.7	**0.7**	–	**0.7**
Accounts receivable	165.2	**165.2**	–	**165.2**
Other current receivables	–	**0.0**	25.7	**25.7**
Prepaid expenses and accrued income	–	**0.0**	26.9	**26.9**
Cash and cash equivalents	505.3	**505.3**	–	**505.3**
Total assets	**671.2**	**671.2**	**561.6**	**1,232.9**

December 31, 2020	Financial liabilities measured at amortized cost	Total financial liabilities	Non-financial liabilities	Total
Shareholders' equity and liabilities				
Shareholders' equity	–	**0.0**	558.5	**558.5**
Long-term liabilities, provision	–	**0.0**	25.7	**25.7**
Leasing, long-term	47.4	**47.4**	–	**47.4**
Borrowings	224.5	**224.5**	–	**224.5**
Accounts payable	47.0	**47.0**	–	**47.0**
Provisions	–	**0.0**	197.3	**197.3**
Other current liabilities	86.2	**86.2**	5.7	**91.9**
Leasing, short-term	19.1	**19.1**	–	**19.1**
Prepaid expenses	7.3	**7.3**	14.2	**21.5**
Total shareholders' equity and liabilities	**431.5**	**431.5**	**801.4**	**1,232.9**

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**

For all items above 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 224.5 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 26.

NOTE 19 INVENTORIES

	Group		Parent Company	
	2020	2019	2020	2019
Raw materials	68.1	89.9	68.1	89.9
Work in progress	22.8	23.5	22.8	23.5
Finished products	17.6	18.4	0.0	0.0
Total	**108.4**	**131.8**	**90.9**	**113.4**

The cost of goods from inventory expensed in the Group amounted to SEK 63.5 million (100.9) and in the Parent Company to SEK 82.8 million (103.8). Write-downs amounted to SEK 2.1 million (4.6).

NOTE 20 ACCOUNTS RECEIVABLE

Impairment losses on accounts receivable amounted to SEK 0.2 million (0.2) 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	
	2020	2019	2020	2019
SEK	0.0	0.0	0.0	0.0
USD	161.3	191.3	17.7	3.9
EUR	3.8	42.5	3.8	42.5
Total	**165.1**	**233.8**	**21.5**	**46.4**

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

	Group	
	2020	2019
Customer 1	62.3	92.1
Customer 2	41.4	43.0
Customer 3	31.5	42.3
Customer 4	17.5	37.5
Total	**152.7**	**214.9**

Accounts receivable due

At December 31, 2020, accounts receivable amounting to SEK 1.5 million (2.8) 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	
	2020	2019	2020	2019
Less than 30 days	0.0	0.4	0.0	0.0
31 days and older	1.5	2.4	0.0	0.6
Total	**1.5**	**2.8**	**0.0**	**0.6**

NOTE 21 OTHER RECEIVABLES

	Group		Parent Company	
	2020	2019	2020	2019
VAT receivable	3.8	2.5	3.8	2.5
Tax receivable[1]	20.4	16.8	2.7	2.7
Other	1.5	1.0	1.5	1.0
Total	**25.7**	**20.3**	**8.0**	**6.3**

[1]See note 13

NOTE 22 PREPAID EXPENSES AND ACCRUED INCOME

	Group		Parent Company	
	2020	2019	2020	2019
Prepaid rents	–	–	4.1	–
FDA annual fee	10.3	11.4	–	–
Other interim receivables	16.6	7.0	12.6	7.8
Total	**26.9**	**18.4**	**16.7**	**7.8**

NOTE 23 CASH AND CASH EQUIVALENTS

	Group		Parent Company	
	2020	2019	2020	2019
Cash and bank balances	505.3	816.8	361.3	469.0
Total	**505.3**	**816.8**	**361.3**	**469.0**

The Group has no unused credit facilities at December 31, 2020.

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

	Group		Parent Company	
	2020	2019	2020	2019
SEK	100.8	54.2	94.8	38.2
USD	394.4	685.9	256.4	354.2
EUR	10.0	76.0	10.0	76.0
GBP	0.0	0.7	0.0	0.7
Total	**505.3**	**816.8**	**361.3**	**469.0**

Orexo has made the assessment there is no need for a reserve for expected credit losses as the group is not exposed to significant credit risk for cash and cash equivalents. 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 24 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, 2020 there were a total of 1,630,875 options and share awards outstanding. These consist of 879,411 options that qualify for subscription of shares in Orexo. The number of share awards is 751,464 and each share award provides entitlement to one share in Orexo. Orexo converted earlier equity-settled longterm incentive programs to be cash-settled, based on changes in group policy for how such instruments are to be settled. This change in classification causes fair value changes of affected program instruments, driven mainly by changes in value of the underlying Orexo stock, to be reported through the income statement.

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
2019	–5.8
2020	–10.9

Employee stock options/share awards allotted	Number	Exercise price, weighted average
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**
Allotted during the period	646,812	78
Redeemed during the period	–489,174	54
Forfeited during the period	–32,070	79
At Dec 31, 2020	**1,630,875**	**74**

Employee stock options/share awards per year	Number outstanding at Dec 31, 2020	Number vested at Dec 31, 2020	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)	268,945	268,945	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
2018 (LTIP2018)	343,100	0	0.0	7.1–30.2	38%	30.2	30.2	2021-06-30
2019 (LTIP2019)	212,950	0	0.0	40.4–73.1	38%	73.1	73.1	2022-06-15
2020 (LTIP2020 PSU)	182,005	0	0.0	50.0-76.2	56%	75.4	75.4	2023-06-29
2020 (LTIP2020 options)	424,819	0	0.0	10.7-26.57	56%	75.4	75.4	2023-06-29
2020 (Stay on PSU)	13,409	0	0.0	57.0	57%	56.4	56.4	2023-08-03
2020 (Stay on options)	13,409	0	0.0	22.0	57%	56.4	56.4	2023-08-31
Total employee stock options/share awards	**1,630,875**							

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**							

During 2020 the company allotted 646,812 employee stock options, of which the CEO and other senior executives were allotted 290,438, corresponding to 45 percent. The financial and operational targets set by the Board for 2020 reached a score of 100 percent and hence none of the allocated share awards pertaining to performance target 2 will forfeit. In total 32,070 options were forfeited during 2020. As of December 31, 2020 the liability for LTIP amounted to SEK 23.0 million. See not 25.

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, 2020	Change	Number outstanding at Dec 31, 2020
President and CEO Nikolaj Sörensen	475,723	–121,240	354,483
Board member James Noble	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 Charlotte Hansson	0	–	0
Board member Kirsten Detrick	0	–	0
Board member David Colpman	0	–	0

Note 24 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 2018

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 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 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.

Rules for LTIP2020

LTIP 2020 is a share-based program where 33% of the shares are vested based on employment, 67% is 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 2020 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 mimum threshold of 100 percent of the overall average performance of the financial and operational targets is achieved for LTIP 2020. 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.

NOTE 25 PROVISIONS

Long-term provisions	Group 2020	Group 2019	Parent Company 2020	Parent Company 2019
On January 1	**10.7**	**6.5**	**8.2**	**4.9**
Additional provisions	18.0	4.3	19.0	3.5
Utilized during the year	–2.9	–0.2	–2.7	–0.2
Reversed unused amounts	–	–	–	–
Per December 31	**25.7**	**10.7**	**24.5**	**8.2**

Long-term provisions primarily refer to estimated costs for incentive programs settled in cash, as well as estimated costs for social security fees in respect of employee incentive programs.

Short-term provisions, rebates and chargebacks	Group 2020	Group 2019	Parent Company 2020	Parent Company 2019
On January 1	**269.3**	**265.8**	**0.0**	**0.0**
Additional provisions	606.3	802.8	–	–
Utilized during the year	–616.4	–781.1	–	–
Reversed unused amounts	–29.2	–28.5	–	–
Exchange rate difference	–32.6	10.3	–	–
Per December 31	**197.3**	**269.3**	**0.0**	**0.0**

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

NOTE 26 BORROWINGS

	Group	Parent Company
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**
January 1, 2020	**291.4**	**291.4**
Repurchase bond	–66.6	–66.6
Interest expenses	11.8	11.8
Interest paid	–11.8	–11.8
Recognition of loan issuance cost	1.5	1.5
December 31, 2020	**226.3**	**226.3**

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 +4.50 percent (STIBOR is calculated as zero at the lowest) and has a total framework amount of SEK 500 million.. The loan agreement contains limitations regarding any change in the company's ownership structure, so-called change-of-control. No other covenants exists.

	Group	Parent Company
2019-12-31		
Interest-bearing liabilities	289.6	289.6
Accrued interest costs	1.8	1.8
	291.4	**291.4**
2020-12-31		
Interest-bearing liabilities	224.5	224.5
Accrued interest costs	1.8	1.8
	226.3	**226.3**

NOTE 27 ACCRUED EXPENSES AND OTHER LIABILITIES

Other liabilities	Group 2020	Group 2019	Parent Company 2020	Parent Company 2019
Employee withholding tax	2.1	1.5	2.1	1.5
Deduction, social security fees	1.5	1.3	1.5	1.3
Deduction, special salary tax	2.1	2.0	2.1	2.0
Other current liabilities	0.5	–	0.5	–
Sum Other liabilities	**6.2**	**4.7**	**6.2**	**4.7**

Accrued expenses	Group 2020	Group 2019	Parent Company 2020	Parent Company 2019
Accrued salaries	19.0	18.9	2.7	3.8
Accrued vacation pay	6.7	5.6	6.7	5.6
Accrued social security fees	3.2	3.1	3.2	3.1
Accrued expenses interest rates	1.8	1.8	1.8	1.8
Trade allowance	41.7	51.8	–	–
Wholesaler fee reserve	8.3	16.3	–	–
Other accrued expenses	26.6	18.8	7.2	8.9
Sum Accrued expenses	**107.2**	**116.2**	**21.6**	**23.1**
Sum Other liabilities and Accrued expenses	**113.4**	**120.9**	**27.8**	**27.8**

NOTE 28 SHARES IN SUBSIDIARIES AND JOINT VENTURES

Direct and indirect holdings Dec 31, 2020	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	–	106.0
Orexo US Inc	101013414	USA	100	100%	54.3	–	54.3
Total							**160.4**

All holdings are owned directly.
Shareholders Equity amounted to SEK 94.0 thousand and net revenue amounted to SEK –3.0 thousand in Pharmacall AB[1]
Shareholders Equity amounted to SEK 146.2 million and net revenue amounted to SEK –2.0 thousand in Biolipox AB[1]
Shareholders Equity amounted to SEK 111.9 million and net revenue amounted to SEK 13.8 million in Orexo US Inc[1]

Change in carrying amount of direct holdings

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**

2020	Opening carrying amount	Acquisition	Contribution	Sales	Impairment	Closing carrying amount
Pharmacall AB	0.1	–	–	–	–	0.1
Orexo US Inc	49.5	–	4.8	–	–	54.3
Biolipox AB	106.0	–	–	–	–	106.0
Total	**155.6**	**0.0**	**4.8**	**0.0**	**0.0**	**160.4**

[1] Shareholders Equity and net revenue refers to established numbers as of December 31, 2019.

NOTE 29 AUDITORS' FEES

	Group		Parent Company	
	2020	2019	2020	2019
Audit assignment				
Ernst & Young	1.7	2.6	1.7	2.6
Non-auditing assignments				
Ernst & Young	0.4	0.6	0.4	0.6
Tax advice				
Ernst & Young	0.4	1.0	0.4	1.0
Other services				
Ernst & Young	–	–	–	–
Total	**2.5**	**4.3**	**2.5**	**4.3**

Audit assignment refers to the auditing of the annual report and accounting records as well as the administration of the Board and the President, other tasks required by the company's auditors, and advisory services and other assistance required as a result of observations arising from such audits or such other tasks. Everything else comes under other assignments.

NOTE 30 DEFERRED TAX

The tax-loss carry-forward in the Group amounts to SEK 1,188 million (1,180) as of December 31, 2020 and refers to the Swedish companies. No deferred tax assets for tax-loss carry-forwards have been capitalized as per December 31, 2020. There is no time limit for when the remaining tax-loss carry-forwards can be utilized.

	Group		Parent Company	
	2020	2019	2020	2019
Deferred tax assets				
Capitalized tax loss carryforwards	–	49.0	–	49.0
Temporary differences in current provision	24.7	26.1	–	–
Other temporary differences	8.0	10.4	–	–
Total	**32.7**	**85.5**	–	**49.0**

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. No deferred tax 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 2020 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	–14.9	–4.5	–0.2	–19.7
Translation difference	0.4	0.7	—	1.1
31 December 2019	**47.3**	**8.8**	**1.0**	**57.0**
1 January 2020	47.3	8.8	1.0	57.0
Disposals	—	–0.7	—	–0.7
Additions	26.9	1.5	0.8	29.2
Depreciation expense	–13.9	–1.0	–0.3	–15.3
Translation difference	–1.7	–0.7	0.0	–2.4
31 December 2020	**58.6**	**7.8**	**1.4**	**67.8**

Set out below are the carrying amounts of lease liabilities (included under interest-bearing loans and borrowings) a.8nd 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	–17.2	–4.4	–0,3	–21.9
Translation difference	0.5	0.4	—	0.9
31 December 2019	**45.4**	**8.4**	**0.9**	**54.6**
1 January 2020	45.4	8.4	0.9	54.6
Disposals	—	–0.7	—	–0.7
Additions	26.9	1.5	0.8	29.2
Interest expense	2.5	0.3	0.0	2.8
Payments	–15.4	–1.3	–0.2	–17.0
Translation difference	–1.6	–0.9	0.0	–2.5
31 December 2020	**57.8**	**7.2**	**1.5**	**66.5**

	Group	
	2020	2019
Costs for short-term leases	—	—
Total cash outflow for leases	17.3	22.2

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

	Group		Parent Company	
	2020	2019	2020	2019
Within one year	19.7	22.0	13.3	13.8
After one year but not more than five years	56.1	39.6	41.0	27.4
More than five years	0.6	—	—	—
Summa	**76.4**	**61.5**	**54.3**	**41.2**

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	
	2020	2019	2020	2019
Adjustments for items not included in cash flow comprise the following:				
Depreciation and impairment	38.9	41.0	23.0	20.0
Gain/loss on disposal	—	—	—	—
Change in provisions	–28.5	–2.7	16.3	3.4
Change in fair value of financial instruments	—	—	—	—
Share based payments	–19.7	5.8	–18.7	5.8
Exchange rate income and expense	2.4	–2.7	2.4	–2.7
Other non-cash items	—	—	—	–3.3
Total	**–7.1**	**41.3**	**23.0**	**23.1**

NOTE 33 RELATED PARTY TRANSACTIONS

Purchases and sales between Group companies

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

	2020	2019
Forward invoicing of costs		
Orexo US Inc	11.4	10.5
Sale of goods and services		
Orexo US Inc	406.2	408.5
Marketing support		
Orexo US Inc	137.4	–59.5
Total	**555.0**	**359.5**

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

Remuneration and other commitments regarding pensions and similar benefits to Board members and the President and CEO, see Note 10.

There have been no other related party transactions.

NOTE 34 EVENTS AFTER THE CLOSING DATE

A new patent for OX124, overdose rescue medication, was issued by the US Patent and Trademark Office protecting the technology until 2039.

Orexo successfully issued senior unsecured callable floating rate bonds in the amount of SEK 500 million, under a framework of SEK 1,000 million with final maturity in February 2025 (the "New Bonds"). The New Bonds carry a floating rate interest of 3-month Stibor + 375 bps per annum.

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	1,186,055
Loss carried forward	–894,344
Profit/loss for the year	–72,499
Total	**219,212**

The Board proposes that the funds at their disposal SEK 219,212 thousand be carried forward.

NOTE 36 PLEDGED ASSETS AND CONTINGENT LIABILITIES

No collateral or contingent liabilities exists as of December 31, 2020.

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 22, 2021

Orexo AB (publ)

James Noble
Chairman of the Board

Fred Wilkinson
Board member

Staffan Lindstrand
Board member

Charlotte Hansson
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 22, 2021

Ernst & Young Aktiebolag

Anna Svanberg
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 2020. The annual accounts and consolidated accounts of the company are included on pages 46–86 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 2020 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 2020 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 2020 was MSEK 663.6 in the consolidated income statement and MSEK 446.4 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.

Intangible assets

Description	How our audit addressed this key audit matter
Intangible assets are recorded at MSEK 252.8 in the consolidated balance sheet and MSEK 234.4 in the parent company balance sheet as of December 31, 2020. The Company tests, when there is an indication of impairment, that carrying amounts do not exceed estimated recoverable amounts for these assets. Recoverable amounts are determined through generally adopted models utilizing discounted cash flows based on management's assessments of future cash flows and other significant assumptions such as discount rate and growth that can have a major impact on the estimated recoverable amount. The impairment test of intangible assets performed by management has therefore been considered to be a key audit matter. A description of the impairment test is provided in Note 16 and in the section "Important estimates and assessments for accounting purposes" in Note 4.	In our audit we have reviewed management's models, assessments and assumptions that are utilized for calculating the recoverable amount of the intangible assets. We have reviewed and compared management's forecasts from prior periods against outcomes, and reviewed the plausibility of the forecasts and assumptions underlying this year's impairment test. We have also reviewed assumptions made against comparable companies in the industry in which the Company operates. With the support of our valuation specialists, we have reviewed the company's models and method for conducting impairment tests. We have conducted our own sensitivity analyses of key assumptions and possible impact factors. 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 1–45 and 90–105. The report on management remuneration is also considered to be other information. 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, actions taken to eliminate threats or related safeguards applied.

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 2020 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 16 April 2020 and has been the company's auditor since 15 April 2016.

Stockholm 22 March 2021
Ernst & Young AB

Anna Svanberg
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	2020	2019
EBIT	–19.9	231.2
Depreciation and amortization	38.9	41.0
EBITDA	**19.0**	**272.1**

Return on shareholders' equity SEK million	2020	2019
Average shareholders' equity	632.5	591.3
Net earnings	–84.4	219.1
Return on shareholders' equity %	**–13.3**	**37.1**

Net debt SEK million	2020	2019
Current and long-term interest-bearing liabilities including pension liabilities	224.5	289.6
Cash and cash equivalents.	–505.3	–816.8
Net debt	**–280.8**	**–527.2**

Operating expenses SEK million	2020	2019
Selling expenses	–286.6	–191.9
Administrative expenses	–102.8	–139.6
Research and development costs	–224.9	–181.3
Other operating income and expenses	–3.6	4.8
Operating expenses	**–617.9**	**–508.0**

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
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

Corporate Governance Report for Orexo AB (publ) 93
Auditor's report on the corporate governance statement 98
Board of Directors 100
Management 102
Glossary 105

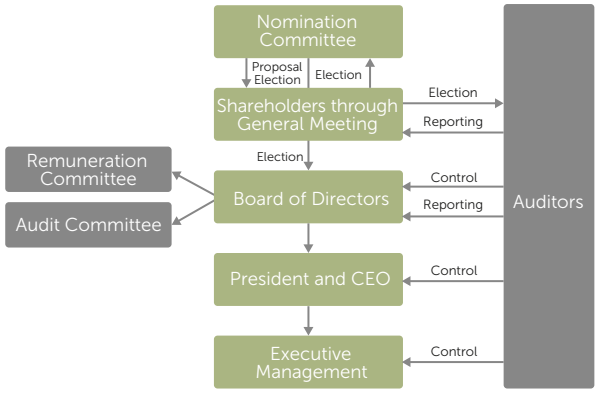
From left, Håkan Thorén, Analytical Chemist and Lars Johnsson, Head of Analytical Development. Photo: Jenny Lagerqvist

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 34,710,639 (35,553,610), distributed among 8,814 shareholders (6,243).

The 10 largest shareholders held 61.7 percent (61.2) of the outstanding shares, management 0.5 percent (0.2) and other shareholders 37.8 percent (38.6). At December 31, 2020, two shareholders each held shares representing 10 percent or more of the company – Novo Holding A/S, 27.8 percent, and Health-Cap, 10.2 percent. Non-Swedish shareholders accounted for approximately 47 percent (38) of the total number of shares. Institutions and industrial owners hold the majority of shares. At year-end, 78 percent (78) of the shares were held by legal entities, and 22 percent (22) 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 2020

The Annual General Meeting was held on Thursday, April 16, 2020 in Uppsala. At the Meeting:

- Staffan Lindstrand, Henrik Kjaer Hansen, David Colpman, Kirsten Detrick, Mary-Pat Christie and Fred Wilkinson were re-elected as Board members. James Noble and Charlotte Hansson were elected as new members of the board,
- James Nobel was elected as new 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 3,550,000, with SEK 900,000 paid to the Chairman of the Board, SEK 300,000 eto 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 2021 was approved.
- The balance sheet and income statement for the Parent Company and the Group for the 2019 fiscal year were adopted.
- The Annual General Meeting granted Board members and the President discharge from liability for the 2019 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.
- A resolution was adopted in accordance with the Board's proposal concerning to amend the performance-based long-term incentive program with stock options for the chief executive officer, senior management and key employees within the Orexo group.
- A resolution was adopted in accordance with the Board's proposal concerning reduction of the share capital with cancellation of class C shares and bonus issue.
- The Board's motions concerning a long-term incentive program for senior executives and key employees and a long-term incentive program for for certain Global Management Team employees and US Leadership Team employees were approved.

Complete information about the 2020 Annual General Meeting can be found at www.orexo.com.

Extraordinary General Meeting 2020

The Extraordinary General Meeting was held on Tuesday, May 19, 2020 in Uppsala. At the Meeting:

- The Board's motions concerning a long-term incentive program for senior executives and key employees and concerning a long-term incentive program for for certain Global Management Team employees and US Leadership Team employees within Orexo group were approved.

Annual General Meeting 2021

The Annual General Meeting of Orexo AB will be held on Thursday, April 13, 2021. On the basis of temporary statutory rules in order to mitigate the spread of Covid-19 the meeting will be conducted by advance voting only, without physical presence of shareholders, proxies and third parties. Full information about the Annual General Meeting can be found on the company's website, https://orexo.com/about-us/corporate-governance/.

Nomination Committee

The 2020 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 2020, 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 13, 2020. The Committee held 11 (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 2021:

Name	Representatives
Christian Salling	Novo Holding A/S, and Chairman of the Nomination Committee
Björn Odlander	HealthCap
Claus Berner Møller	Arbejdsmarkedets Tillaegspension (ATP)
James Noble	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 James Noble and Board members David Colpman, Staffan Lindstrand, Henrik Kjaer Hansen, Charlotte Hansson, Kirsten Detrick, Mary-Pat Christie and Fred Wilkinson. For a more detailed description of Board members, please refer to page 100.

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 14 (12) meetings, of which 14 (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 2020 Annual General Meeting resolved that Board fees should amount to SEK 3,550,000, of which SEK 900,000 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

Name	Function	Independent	Elected	Present at Board meetings	Present at Remuneration Committee	Present at Audit Committee
James Noble	Chairman of the Board	■	2020	7/7	1/1	3/3
David Colpman	Board member	■	2015	14/14	4/4	–
Charlotte Hansson	Board member	■	2020	7/7	–	3/3
Henrik Kjaer Hansen	Board member	■	2018	14/14	–	4/4
Mary-Pat Christie	Board member	■	2019	12/14	–	–
Staffan Lindstrand	Board member	■	2002	14/14	4/4	–
Fred Wilkinson	Board member	■	2019	14/14	–	–
Kirsten Detrick	Board member	■	2016	13/14	–	–

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

Composition of the Board

Board members, their positions and whether or not they are considered to be independent in relation to Orexo, its management and the company's largest shareholders are stated in the table on page 45. Orexo's Board of Directors is deemed to have satisfied the requirements of the Code in respect of independence, as all members elected by the Meeting have been deemed to be independent in relation to Orexo and its management and all of these members, with the exception of two, have also been deemed to be independent in relation to the company's largest shareholders.

Audit Committee

Orexo's Audit Committee is primarily concerned with ensuring compliance with established principles for financial reporting and internal controls. The Audit Committee must also remain informed about the audit of the Annual Report and consolidated accounts, inspect and monitor the impartiality and independence of the auditor, paying particularly close attention to instances where the auditor provides the company with services outside the scope of the audit, and assist in the preparation of proposals to the General Meeting in respect of auditor selection. The Audit Committee presents the final version of Orexo's interim reports and of the Annual Report to the Board for approval and publication. The Audit Committee meets prior to the publication of each interim report, in connection with the auditor's review of the internal control over the financial reporting and when otherwise necessary. The aforementioned issues are addressed by the Committee and the Board makes resolutions on the basis of the proposals produced. Orexo's auditor attends the meetings of the Audit Committee before the publishing of the interim reports and to present the outcome of the review of the internal control. Matters addressed in the Audit Committee is reported to the Board on a regular basis and the minutes are distributed to the Board.

During the year, the Audit Committee was convened on 4 (4) occasions. At least one of the members of the Committee must be independent in relation to the company and Executive Management, and also be independent in relation to the company's largest shareholders and have accounting or auditing expertise. The Committee is currently made up of Charlotte Hansson (Chairman), James Noble 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 James Noble (Chairman), David Colpman and Staffan Lindstrand. During the year, the Remuneration Committee was convened on 4 (4) 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 Anna Svanberg as auditor in charge. At the Annual General Meeting 2020 EY was re-elected as auditors until the Annual General Meeting 2021. 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 30.

President and the Management

The President leads the work of the Management Team and makes decision in consultation with them. At the end of 2020 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 102.

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 2021 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 2020 on pages 93–97 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 22, 2021
Ernst & Young AB

Anna Svanberg
Authorized Public Accountant

Photo: Jenny Lagerqvist.

Board of Directors

James Noble

(b. 1959)
Chairman of the Board of Directors since 2020.
M.A. from the University of Oxford.

Other appointments:
Board member of Adaptimmune since 2008. Board member and Deputy Chairman of GW Pharmaceuticals since 2007.

Previous appointments:
Brings more than 30 years of industry experience from both the private and the public sector, which includes: being co-founder of Adaptimmune and founder and CEO of Immunocore. Has also been Chairman and CEO of Avidex, which was aquired by Medigene. James has held several positions as board member at companies including, among others, Medigene, PowderJect Pharmaceuticals and CuraGen Corporation.

Does not hold any shares.[1]

Staffan Lindstrand

(b. 1962)
Board member since 2002.
M.Sc. in Engineering.

Other appointments:
Partner of HealthCap since 1997, Board member of HealthCap AB, PulmonX Inc., Doctrin AB and The Swedish Association of Exchange-listed Companies.

Previous appointments:
Ten years in investment banking.

Holds 881 shares.[1]

Charlotte Hansson

(b. 1969)
Board member since 2020.
MSc. in Business Administration from Handelshögskolan at the University of Gothenburg.

Other appointments:
CFO at Systembolaget AB, since 2015.

Previous appointments:
Has been Group CFO & Executive VP at Cision AB. Charlotte has also been Group CFO at Addici AB. Before this she had an extensive career within business controlling, with many year at, for instance, Modern Times Group (MTG).

Does not hold any shares.[1]

Henrik Kjaer Hansen

(b. 1976)
Board member since 2018.
BSc. in Business Administration and a MSc. in Applied Economic and Finance at Copenhagen Business School.

Other appointments:
Senior Director, Principal Investments, Novo Holdings A/S. Board member of Xellia Pharmaceutical.

Previous appointments:
Prior to joining Novo Holdings A/S, Kjaer Hansen was employed as a Senior Vice President in Moelis & Co. in London, focusing on healthcare M&A transactions. Other previous employments include Deutsche Bank and ABN AMRO, all in London.

Does not hold any shares.[1]

[1] As of December 31, 2020

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]

Kristen 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 in Orexo.[1]

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]

Fred Wilkinson

(b. 1956)
Board member since 2019.
MBA., 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]

[1] As of December 31, 2020

Management

Nikolaj Sørensen

(b. 1972)
President and CEO since 2013, employed since 2011. B.Sc., and M.Sc., Copenhagen Business School, Denmark.

Other appointments:
Member of the Board, Bioservo Technologies AB.

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 72,665 shares and stock options/share awards entitling to 354,483 shares.[1]

Robert A. DeLuca

(b. 1961)
President of Orexo US Inc. since 2013.
R. Ph.

Other appointments:
Member of the St. John's College of Pharmacy Dean's Advisory Board, American Society of Addiction Medicine, Academy of Managed Care Pharmacy and the American and New Jersey Pharmacists Associations.

Previous appointments:
Extensive experience establishing commercial operations in the US with a combined background in market access, marketing, and sales. Has held leadership positions at multinational pharmaceutical companies including Sanofi-Aventis, Schering Plough, Berlex and Pharmacia, and most recently served as Chief Commercial Officer at Archimedes Pharmaceuticals.

Holds 8,568 shares and stock options/share awards entitling to 181,448 shares.[1]

Joseph DeFeo

(b. 1961)
EVP and Chief Financial Officer since 2018, employed since 2013.
Bachelor degree in accounting from Clarion University, US, and a MBA in finance from St. Joseph's University, US.

Previous appointments:
Vice President, Finance & Administration at Orexo US Inc., 2013-2017. 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 82,054 shares.[1]

Johannes Doll

(b. 1981)
EVP and Chief Commercial Officer, since 2019, employed since 2016. MBA, University of Texas, and Dipl. Kaufmann, WHU Otto Beisheim School of Management, Germany.

Previous appointments:
EVP and Head of Corporate Development at Orexo, 2016-2018. Advisor to Orexo, 2013-2015. Prior to Orexo Johannes Doll worked as a management consultant at McKinsey & Company from 2004 to 2013, advising clients in the global pharmaceutical and private equity industry.

Holds 43,970 shares and stock options/share awards entitling to 78,216 shares.[1]

[1] As of December 31, 2020

Dennis Urbaniak

(b. 1969)
EVP Digital Therapeutics since 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, Managing Director Accenture Digital Life Sciences Analytics and Janssen Client Account Lead. Twenty years at Sanofi in various sales and marketing director roles. 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.

Holds 6,000 shares and stock options/share awards entitling to 33,400 shares.[1]

Michael Sumner

(b. 1965)
Chief Medical Officer since 2013.
MB BS, MRCP (UK), MBA.

Other appointments:
Scientific Advisory Board FirstString Research Inc.

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

Holds 21,805 shares and stock options/share awards entitling to 103,942 shares.[1]

Cecilia Coupland

(b. 1976)
VP and Head of Operations since 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 2,132 shares and stock options/share awards entitling to 43,996 shares.[1]

Robert Rönn

(b. 1976)
VP and Head of R&D since 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 1,741 shares and stock options/share awards entitling to 45,896 shares.[1]

[1] As of December 31, 2020

Shareholder Information

2021 Annual General Meeting

The Annual General Meeting (AGM) of Orexo AB will be held on Thursday, April 13, 2021. On the basis of temporary statutory rules in order to mitigate the spread of Covid-19 the AGM will be conducted by advance voting only, without physical presence of shareholders, proxies and third parties.

Orexo's Nomination Committee for the AGM 2021

Prior to the AGM in 2021, Orexo has appointed a Nomination Committee which represents approximately 44 percent of the number of votes in the company as of September 30, 2020.

The Nomination Committee comprises:

- Christian Salling, Novo Holdings A/S, also Chairman of the Nomination Committee
- Björn Odlander, HealthCap
- Claus Berner Møller, Arbejdsmarkedets Tillaegspension (ATP)
- James Noble, Chairman of the Board of Orexo

The Nomination Committee will prepare proposals to the AGM regarding Chairman of the Meeting, Chairman of the Board, Board members, Board member fees, any remuneration for committee work, and fees to the auditor, as well as principles for the composition of the Nomination Committee.

The Nomination Committee's proposals are presented in the Notice of the AGM and on Orexo's website, https://orexo.com/about-us/corporate-governance/.

Registration, advance voting etc.

Shareholders who wish to participate, through advance voting, must be recorded in the share register maintained by Euroclear Sweden AB on Thursday 1 April 2021, and notify Orexo of their intention to participate by casting their advance votes no later than on Monday 12 April 2021.

Shareholders whose shares are registered in the name of a nominee through a bank or a securities institution must temporarily re-register their shares in their own names to be entitled to participate in the meeting. Such registration must be duly effected in the share register maintained by Euroclear Sweden AB on Wednesday 7 April 2021.

The shareholders may only exercise their voting rights at the AGM by voting in advance, so-called postal voting in accordance with section 22 of the Act (2020:198) on temporary exceptions to facilitate the execution of general meetings in companies and other associations.

Full information about the AGM can be found on the company's website, https://orexo.com/about-us/corporate-governance/

Contact Investor Relations

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

Financial Calendar 2021

2021 Annual General Meeting	April 13, 2021
Interim Report Q1 2021	April 29, 2021, at 8.00 am CET
Interim Report Q2 2021	July 15, 2021, at 8.00 am CET
Interim Report Q3 2021	November 3, 2021, at 8.00 am CET
Full Year Report 2021 incl. Q4	January 27, 2022, at 8.00 am CET

Glossary

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

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

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

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

Cognitive behavioral therapy techniques, CBT
Cognitive behavioral therapy techniques, CBT are used to alter mal-adaptive thought patterns. The cognitive behavioral therapy is used in the treatment of various disorders related to mood, personality, anxiety, substance abuse, etc.

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

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

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

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

Food and Drug Administration, FDA
The United States Food and Drug Administration is a federal agency of the Department of Health and Human Services, HHS. The FDA is responsible for protecting and promoting public health through the control and supervision of food safety, tobacco products, pharmaceuticals and other medicinal products

Investigational New Drug, IND
The FDA's Investigational New Drug (IND) program is the means by which a pharmaceutical company obtains permission to start human clinical trials before a marketing application for the drug has been approved

Ketorolac
Ketorolac is a nonsteroidal anti-inflammatory drug (NSAID) used to treat moderate to severe pain.

Medication assisted treatment, MAT
Medication assisted treatment (MAT) is the use of medications, in combination with counseling and behavioral therapies, to provide a "whole-patient" approach to the treatment of substance use disorders

Naloxone
An opioid antagonist used to counter the effects of opioids

New Drug Application, NDA
The NDA application is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the US

Non-steroidal anti-inflammatory drugs, NSAIDs
Non-steroidal anti-inflammatory drugs which are active against pain, inflammation and fever

Open market
ZUBSOLV's total business where the pharmaceutical is reimbursed and competes with other products in the market both branded and/or generics. Open formulary business excludes recent formulary changes in United Health Group and Humana, the cash payer segment, and payers where it is not reimbursed

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

Pharmacokinetic study, PK study
A clinical study investigating the absorption, distribution, metabolism and elimination of a drug by the body. Pharmacokinetics (PK) is the study of how an organism affects a drug, whereas pharmacodynamics (PD) is the study of how the drug affects the organism. Both together influence dosing, benefit, and adverse effects, as seen in PK/PD models.

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 payer segment
One of three 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

Randomized controlled trial, RCT
A randomized controlled trial, RCT is a clinical trial aims to reduce certain sources of bias when testing the effectiveness of new treatments; this is accomplished by randomly allocating subjects, treating them differently, and then comparing them with respect to a measured response

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

Rest of World, RoW
Rest of World, RoW refers to countries or territories other than United States (US) and European countries (EU)

Sublingual
Under the tongue

ABOUT OREXO

Orexo develops improved pharmaceuticals and digital therapies addressing unmet needs within the growing space of mental illness and substance use disorders. 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 2020 amounted to SEK 664 million and the number of employees was 138. 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