orexo

Annual and Sustainability Report **2022**

The opioid crisis is **one of the largest health crises in the US in modern times.** An epidemic with wide social and economic implications for societies.

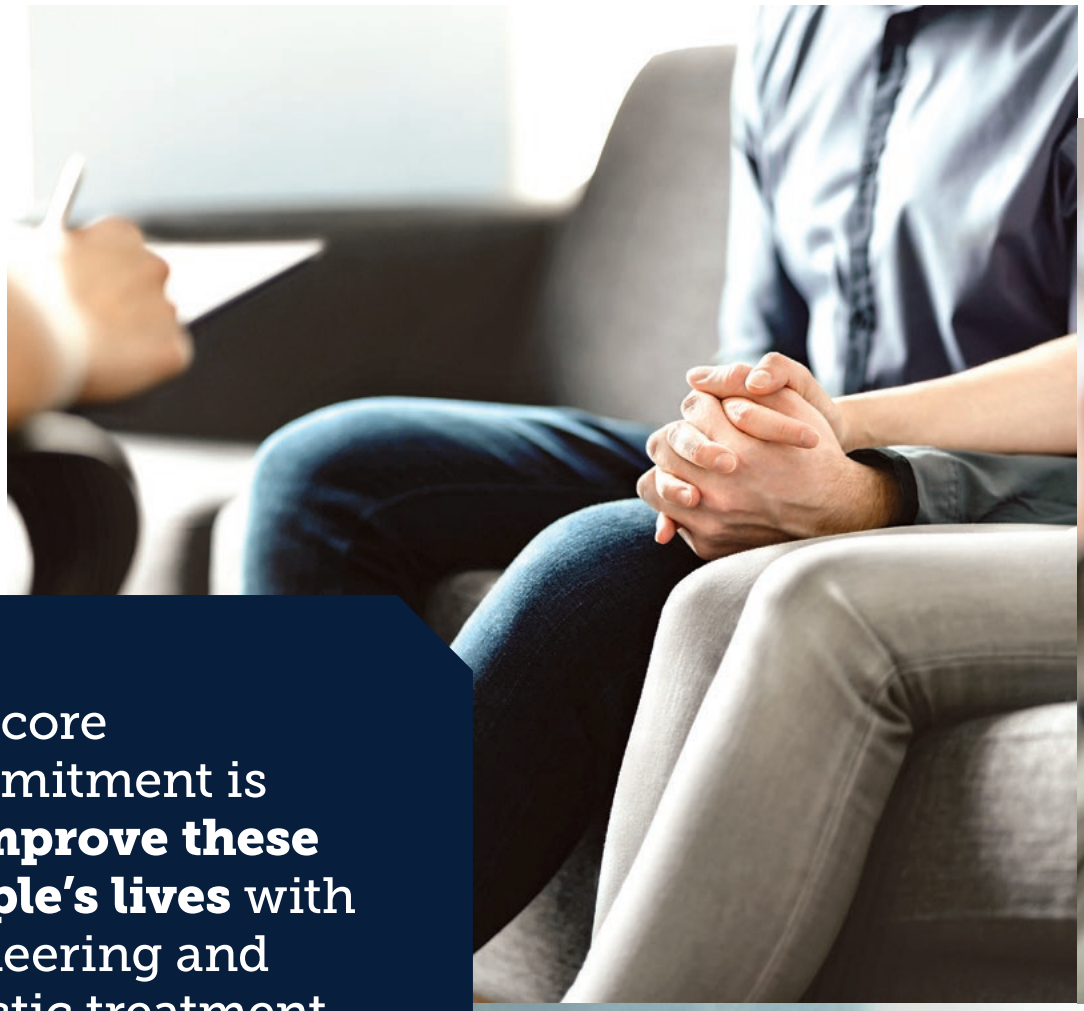
There is an extensive **treatment need**:

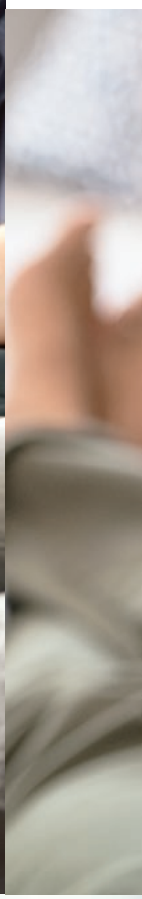
9,200,000
Americans are misusing opioids[1]

5,600,000
are dependent on opioids[2]

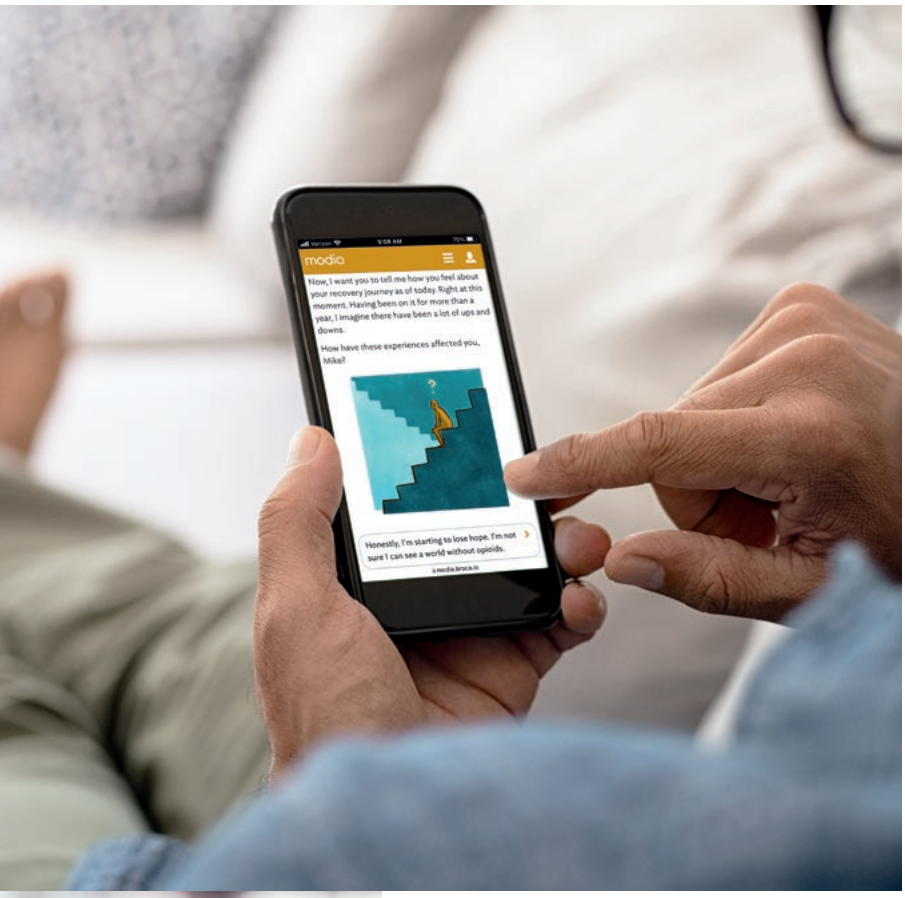
1,800,000
are undergoing treatment[3]

[1,2] Substance Abuse and Mental Health Services Administration 2021 NSDUH report. OUD numbers should not be compared with previously published estimates due to methodological changes and Covid-19 implications.
[3] Orexo data





Our core commitment is to **improve these people's lives** with pioneering and holistic treatment solutions.



MAT[1] treatment

Digital therapy

High-dose medication for opioid overdose

[1] Medication Assisted Treatment

Content

Orexo's formal annual report according to the Annual Accounts Act covers the pages 60–100.

Orexo **in brief**

Orexo develops improved pharmaceuticals addressing unmet needs, foremost within the growing space of mental illness and substance use disorders. To achieve better treatment results and help more people, Orexo also works with evidence-based digital therapies. The products are commercialized in the US, which is the main market, or via partners worldwide.

Empowering people suffering from opioid use disorder

The core mission is to improve life for people who are misusing, and dependent on, opioids. Many of these people are at greater risk of suffering with mental illness and other substance use disorders. We want to stand by their side. Orexo uses innovative pharmaceuticals and evidence-based digital therapies to empower these people on their journey to a healthier and happier life.

Making a difference for patients and societies

Mental illness and substance use disorders are areas of great human suffering and associated with comprehensive social and economic implications. Orexo is working broadly at federal and local levels in the US to enable more people to get access to treatment options that can make a difference to their lives and wider society.

Commercial presence in the US and a growing product portfolio

Orexo has been established in the US since 2013. The company works closely with insurance companies to get products reimbursed on the US market and the sales force is located in nearly all large metropolitan areas of the country. The investment in digital therapeutics has led to a broadening of the product portfolio. In addition to ZUBSOLV®, the sales representatives can now also offer physicians and healthcare professionals evidence-based digital therapies. In the first half of 2024, the product portfolio is expected to grow further through the launch of a high-dose medication for opioid overdose, OX124.

Read more on pages 30–33

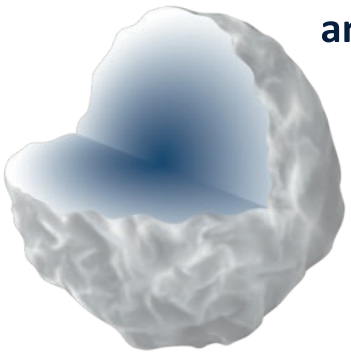
Commercial products in the US:

zubsolv modia VORVIDA deprexis

World-leading technology enabling new development projects

Orexo is developing pharmaceuticals targeting significant medical needs. By combining well-known substances with proprietary and proven drug delivery technologies, the timeline for the development of a new pharmaceutical is three-to-five years. amorphOX®, Orexo's novel drug delivery platform, has unique properties for the development of differentiated pharmaceuticals that need to be absorbed rapidly by the body and remain stable over time. The technology can be applied to a broad scope of active substances. In relation to pharmaceuticals that go beyond Orexo´s key therapeutic areas, the company intends to initiate partnership collaborations.

Read more on pages 22–29



amorphOX®

Three business areas

HQ & Pipeline

Development of pharmaceuticals performed at Orexo's headquarters in Uppsala, Sweden. Out-licensed pharmaceuticals on the market are included in the HQ & Pipeline business area.

Read more on pages 22–29

US Pharma

Commercialization of fully owned pharmaceuticals on the US market.

Read more on pages 30–33

Digital Therapeutics

Commercialization of Orexo's groundbreaking evidence-based digital therapeutics, primarily on the US market, which is in an early development stage.

Read more on pages 34–37

Advancing in a challenging environment

Business areas

HQ & Pipeline

- Orexo's partner Accord Healthcare initiated the launch of ZUBSOLV® in the EU. At year-end patients in Spain, Sweden, UK, the Baltic states, the Czech Republic, Slovenia and Romania had access to ZUBSOLV®.
- Positive data announced from the phase 1 clinical study for OX640, an emergency treatment for allergic reactions with nasal delivery.
- First patent granted for OX640 and refers to the European market. The patent expires in 2041.
- Orexo's formulation scientists announced a poster presentation including OX124 data at the annual Pharm Sci 360 hosted by the American Association of Pharmaceutical Scientists.
- Human factor studies and stability studies for OX124, high-dose medication for opioid overdose, were successfully conducted and were part of a new drug application submitted with the FDA, in the beginning of 2023.
- Multiple exploratory proof-of-concept studies were performed, applying amorphOX® to new drug substances, including both small and large molecules.

US Pharma

- ZUBSOLV® was added to New York State Medicaid MAT Preferred Drug formulary, as of March 22.
- ZUBSOLV's access to the Public payer segment increased from 42 to 48 percent. Access to the Commercial payer segment was stable at 98 percent.
- Launch of the commercial concept modiaONE™ allowing physicians who prescribe buprenorphine/naloxone to test the digital therapy; MODIA® with their patients.
- A new law was passed, making it easier for healthcare providers to get permission to treat opioid-dependent patients. Also the patient cap was lifted.
- Cumulated ZUBSOLV® net revenues passed SEK 4,500 million.

Digital Therapeutics

- A ten-year contract was signed with Veterans Affairs, providing access to deprexis®. In total approximately 15 million US citizens suffering from depression have the opportunity to get access to qualified psychosocial support.
- Orexo's partner, the Integrated Healthcare Network System, Trinity Health in North Dakota announced they have made vorvida® and deprexis® available to patients.
- The last patient was recruited to the MODIA® clinical trial. In total the study enrolled 437 participants at 35 sites across the US.
- A collaboration was initiated with the Wayside Recovery Treatment Center, which specializes in women with addiction in Minneapolis, and will offer 60 patients access to deprexis® and vorvida®.
- By year-end, the DTx portfolio had over 4,600 users across early access commercial programs and clinical trials. Of these 2,800 are using MODIA®.

Financial overview

SEK million	2022	2021	% change
Net revenues	624.3	565.0	10.5
whereof ZUBSOLV® US net revenue	*571.4*	*522.7*	*9.3*
Cost of goods sold	–102.6	–78.9	30.0
Operating expenses	–705.6	–700.2	1.0
EBIT	–183.9	–214.1	–14.8
EBIT margin, %	–29.5	–37.9	–22.2
US Pharma EBIT	308.4	278.2	10.9
US Pharma EBIT margin, %	54.0	53.2	1.5
EBITDA	–115.2	–161.0	–28.4
Earnings per share, before dilution, SEK	–5.17	–6.51	–20.5
Earnings per share, after dilution, SEK	–5.17	–6.51	–20.5
Cash flow from operating activities	–156.0	–229.0	–31.9
Cash and invested funds	351.9	504.1	–30.2

Organisation

- Fredrik Järrsten was announced as new EVP and CFO. Fredrik takes over the role from Joseph De Feo who has served as CFO since 2018.
- At the Annual General Meeting Christine Rankin and Michael J Matly were elected as board members. They replaced David Colpman and Kirsten Detrick who declined re-election.
- Edward Kim M.D., former clinical psychiatrist, was recruited as the new Chief Medical Officer. Edward replaced Mike Sumner, who had held the position since 2013.
- Results from the annual employee survey across Sweden and the US exceeded the already high results from previous years. E.g. more than 4 out of 5 employees are satisfied with working at Orexo.

Sustainability

- Through external analysis, stakeholder dialogue and the management's engagement, the sustainability agenda was updated to reflect Orexo's increased responsibility and future external requirements.
- By mapping our climate impact from own operations, Orexo took the first step to report in line with the Greenhouse Gas Protocol.
- By supporting vulnerable citizens in Texas and North Dakota with access to Orexo´s digital therapies, the company increased the access to our products among people that otherwise might not get help.
- To increase understanding, and enable reduction, of the sustainability impacts of our supply chain, Orexo continued to improve the process for supplier sustainability assessment, increased supplier interactions and extended the scope of suppliers to be assessed.

Net Revenues, the Group
624 SEK m

EBITDA, the Group
–115 SEK m

EBIT, US Pharma
308 SEK m

Cash & invested funds, the Group
352 SEK m

Nikolaj Sørensen,
President and CEO

Growing into a **broader and stronger Orexo**

By finalizing the development of OX124, and launching MODIA®, we have improved Orexo's offering for opioid dependent patients. Our strengthened position means that we are ready to benefit from the deregulation for physicians to treat patients, which is expected to increase access to care. Within our R&D operations, the amorphOX® technology platform was successfully tested with both small and large molecules. In addition, and as an effect of the slow development in DTx, the business area was merged with US Pharma at the beginning of the new year. The new organization is expected to further streamline the commercialization of our products on the US market.

Comprehensive offering for patients suffering from opioid dependence

When we initially decided to develop a digital therapy, it was in response to the urgent patient need to access counselling in combination with medication for treatment of opioid use disorder (OUD). A significant issue with effective and long-term sustainable treatment of OUD is the lack of access to counselling to support patients to change habits and behaviors that increase their risk of relapsing. 2022 was the year we first made MODIA® available to patients through an early trial program. And we are delighted that, to date, about 2,800 patients that are undergoing treatment with buprenorphine/naloxone benefitted from testing MODIA®. Combined with our medications the digital therapy enable Orexo to offer a more comprehensive offering for patients suffering from OUD. The strengthened position provides us with good opportunities to leverage the new legislation passed in late December, that expects to significantly increase access to treatment as it removes most restrictions to treat OUD patients with buprenorphine/naloxone.

To solve the opioid crisis in the US, new and more accessible approaches to treatment are needed

About 81,000 people died from opioid overdose in the US in 2022, the vast majority from opioids and in particular synthetic opioids, such as fentanyl. Orexo is one of the few companies actively developing innovative approaches to OUD. In addition, we are taking a public health approach to this complex and tragic opioid epidemic through regular and active discussions with the public health authorities across several states about how Orexo can help to make treatments available to a broader population. The result from this work is MATCore™, a digital platform that brings our products into one place and offers healthcare professionals education and support. With the inflow of more than USD 54 billion to the states and municipalities from the opioid damage litigations in the US, there will be an increasing availability of funds to develop and test new concepts. For Orexo, an array of opportunities may arise

> **Combined with our medications the digital therapy MODIA® enable Orexo to offer a more comprehensive offering for patients suffering from OUD.**

> **In 2022 we finalizied the development of our overdose resue medication and early in 2023 we filed an NDA application with the FDA.**

and, as a first step, we are collaborating with Alay Psychiatry Center in Arizona, which has been awarded a grant to implement MATCore™. To solve the opioid crisis in the US, new and more accessible approaches to treatment are needed and we are proud to be taking a leading role in developing and testing new concepts in close collaboration with established leaders in the field.

OX124 a high-dose medication targeting overdoses caused by fentanyl

With increasing amounts of illicitly manufactured synthetic fentanyl available online and on the streets, the risks of accidental death are high and growing. To meet the great need of medications effective in reversing overdoses caused by synthetic opioids we applied our expertise in drug delivery and developed the amorphOX® technology, that forming the backbone for the OX124 rescue medication. In 2022 we finalizied the development of our overdose resue medication and early in 2023 we filed an NDA application with the FDA. Early formulations of OX124 have demonstrated more rapid absorption and higher bioavailability compared with the market-leading naloxone rescue medication, even with the same dose as the comparator. Clinical differentiation is important in this market, which is likely to convert into a high-dose prescription market that includes OX124, and a low-dose over-the-counter market. We expect OX124 to be launched in the first half of 2024 and form a strong complement to our products for treatment of OUD.

amorphOX® a versatile drug delivery platform

The amorphOX® technology platform progressed significantly in 2022. We tested the technology with a broad range of molecules, from small molecules to large biomolecules like proteins and we obtained consistent results in terms of stability. In 2022 we also got the data from our fourth clinical trial applying the amorphOX® technology to OX640, with the aim of developing a rescue medication for allergic reactions. For the fourth time we demonstrated strong bio-availability data enabling us to progress the development towards final pivotal trials without additional dose-finding studies.

amorphOX® is a world-leading powder-based technology and is particularly suitable for nasal delivery. As the opportunities are beyond our capacity we have been seeking partnerships with companies with unique molecules, or an interest in molecules tested by Orexo to enter a development partnership. At the beginning of January 2023 we announced new partnerships with two international biotech companies to test their unique molecules. With patents for the amorphOX® platform reaching until 2042, we are expecting technology partnerships to become an important value generator for Orexo in the years to come.

Reimbursement routes key for DTx to start gaining traction

Together with our German partner GAIA AG, we are focusing on digital therapies with strong clinical evidence. Digital therapies are an excellent complement to existing healthcare as they have the potential to improve treatment outcomes and to accelerate access to care for patients on waiting lists or for those living in rural areas. A cornerstone of all healthcare is access to reimbursement from insurance companies.

> **With patents for the amorphOX® platform reaching until 2042, we are expecting technology partnerships to become an important value generator for Orexo in the years to come.**

> **I am proud we have highly motivated employees that want to make a difference by developing innovative treatment solutions that are benefitting patients, our shareholders and society more broadly.**

We knew this was a hurdle when entering the area, but with a significant inflow of funding to the industry and high attention during Covid-19, we were optimistic we would see good progress. This has not yet materialized, so meanwhile we have tested an alternative reimbursement route together with Trinity Health in North Dakota, the collaborative care model. The model has been successfully tested with the local insurance companies in North Dakota, who will reimburse deprexis® and vorvida®, but have yet to provide any material volumes of sales. We still believe the model is operational and attractive to all stakeholders, but it will require more education and support to the healthcare providers than anticipated.

A more traditional reimbursement pathway materialized in 2022 when deprexis® was included in the US Veterans Affairs Federal Supply Schedule. This is a 10-year contract that enables reimbursement of deprexis® to patients suffering from depression among the 15 million Americans covered by the Veterans Affairs (VA). Several initiatives are ongoing with stakeholders within the VA, but the learning from Trinity Health is that we need to ensure education and support of the healthcare workers to enable a successful launch.

To fully capitalize on the synergies between US Pharma and Digital Therapeutics, combined with strong growth opportunities within OUD treatment, we decided to merge the DTx business into US Pharma. As I will continue to follow up the businesses separately, we will keep our current segment reporting.

Ambitious sustainability agenda

During the year, we evaluated our sustainability strategy to reflect the increased demands and importance of sustainability. By integrating the results of stakeholder discussions and our materiality assessment, the focus remains on increasing patient access to treatments to improve the lives of people suffering from mental illness and substance use disorders. Everything we do at Orexo is underpinned by strong ethical foundations and a commitment to taking responsibility for our employees and our environmental footprint.

This is a strategy fully embraced by me and my colleagues and is also manifested in our support for the UN Global Compact principles and the UN Sustainable Development Goals, focusing on Goal 3.5 to prevent and treat drug abuse. Our full sustainability commitment and examples of what we are doing in this area you can find in our in-depth sustainability report on pages 44–59.

Strong commitment bringing new innovative treatments to patients

2022 has been a challenging year for the world, with the Covid-19 pandemic, Russia's invasion of Ukraine and disruption of supply chains all impacting the global economy. Orexo is not immune to the se events, and is affected by higher purchase prices, delays in receiving important elements to the OX124 supply chain, and the aftermath of Covid-19, which is still impacting many healthcare providers with high vacancies and staff turnover. In this environment I am very pleased to see how our employees in both the US and Sweden have remained committed, engaged and focused on taking our mission forwards.

The uncertainty from 2022 is likely to be maintained into 2023, but Orexo is ready for the year ahead. I am proud we have highly motivated employees that want to make a difference by developing innovative treatment solutions that are benefitting patients, our shareholders and society more broadly.

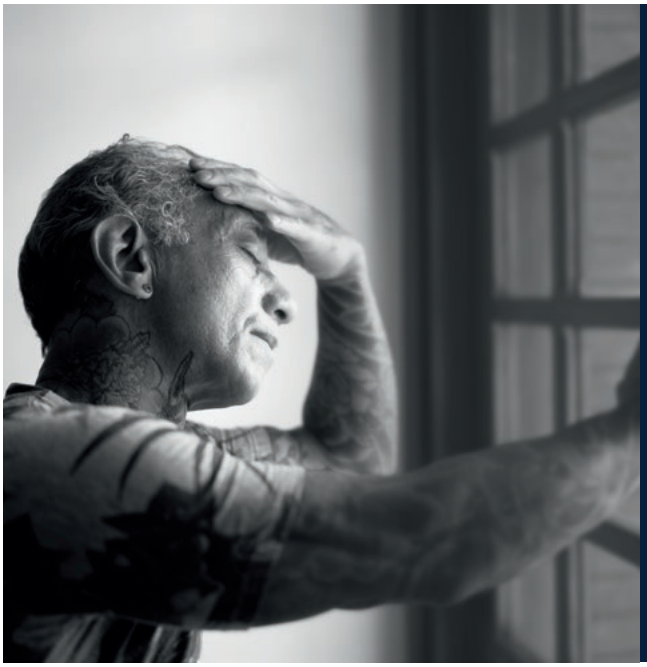
Uppsala, Sweden, March, 2023

Nikolaj Sørensen
President and CEO

A business supported **by underlying trends**

The growing misuse of drugs and the digitization of healthcare are strong societal trends that are shaping Orexo's markets together with increasing demands for sustainable operations. Orexo is responding with products that meet the needs of both markets and stakeholders.

Trends affecting Orexo



Drug misuse on the rise

Misuse of drugs is a growing global concern. Today about 284 million people are misusing drugs such as cannabis, opioids, amphetamines, cocaine, and ecstasy.[1] This is a surge of 26 percent since 2010, driven not only by an increase in drug misuse but also a growth in the world's population.[1] These developments also stem from a greater production of drugs, both synthetic and non-synthetic, all of which have become more accessible for people.

Consequences of drug abuse can have far-reaching effects on individuals and their families across generations. Using drugs drives mental illness and is especially harmful among young people in early adolescence. The impact on economies and societies is significant and hinders sustainable developments.

How is Orexo meeting the trend?
By working to increase access to care and offering an advancing portfolio of complementary treatment solutions, Orexo is contributing to combating the widespread opioid crisis in the US. Through partnerships, the company is also reaching patients in Europe.

[1] World Drug Report 2022

Digitization is sweeping across healthcare

An increased need for care combined with sky-rocketing costs have forced a reconsideration of healthcare service delivery. An ageing population is driving these developments, but also patients who increasingly see themselves as consumers of healthcare and require holistic and customized treatments with a high degree of accessibility. The Covid-19 pandemic led to disrupted global healthcare systems and reduced access to care, further fueling the ongoing digital and technological revolution of the healthcare sector.

How is Orexo meeting the trend?
Orexo's evidence-based digital therapies, for patients suffering with mental illness and substance use disorder, can prevent and manage, and in some cases also treat clinical disorders. When used together with traditional medicines, treatment results can be improved. Digital therapies can contribute to unburdening parts of the healthcare system by giving significantly more people access to qualified therapeutic treatment 24 hours a day.

All eyes on sustainability

Climate change continues to be the single biggest health threat facing humanity.[1] The past eight years are on track to be the warmest on record, fueled by ever rising greenhouse gas concentrations and accumulated heat.[2] Combating climate change will put huge demands on society. The work towards a change has increased tremendously mainly driven by voluntary initiatives and standards, but over the last few years regulatory requirements on investments and sustainability data transparency have sharpened greatly.

How is Orexo meeting the trend?
To help reduce the threat from climate change, Orexo is determined to contribute where possible. Orexo is continuing its sustainability journey and has seen the urgency to step up this work and to increase the ambition with a long-term plan.

[1] Climate change and health (who.int)
[2] Climate Reports | United Nations

Strategic agenda aiming at **capitalizing Orexo's assets**

The lead product, ZUBSOLV®, is an important cash generator that has paved the way for investments in future growth drivers. The focus has been on developing new improved pharmaceuticals built on the novel drug delivery platform; amorphOX®, and to invest in an innovative product category; evidence-based digital therapies. Based on a broader foundation, the key prioritization going forward is to accelerate revenue streams, and in combination with increased cost efficiency, strengthen the financial position.

Business strategy

Strategic priorities				
Strengthen financial position	Broadening the portfolio of commercial products	Maintaining ZUBSOLV's profit contribution and ensuring sustainable growth over time	Establishing a new profitable business area within digital therapeutics and create a new platform for growth	Expand and advance the pipeline, based on the amorphOX® platform
Milestones and focus areas in near term supporting above				
• Diversify revenue generators through launch of OX124 and digital therapies • Limit risk and expenses in pipeline through increased focus on revenue generating partnerships • Increased leverage of synergies in the commercial operations across US Pharma and digital therapies	• NDA approval by the FDA and launch of OX124 in the US • Develop OX640 towards regulatory approval • Evaluate the commercial potential of OX125 and consider bringing it to the market	• Leverage new legislation removing most restrictions on treatment of OUD, e.g. prescription of buprenorphine products • Establish the new business concept, MAT-Core™, utilizing Orexo's ability to partner with healthcare providers and offer both medication and digital therapies • Work in partnership with healthcare providers to create new treatment concepts financed through the cash received by states from the opioid litigations • Expand in the EU through our partner Accord Healthcare	• Increased leverage of the commercial synergies in Orexo's US commercial operations • Data from the MODIA® study (437 patients) and upgrade regulatory status of MODIA® to 510K license • Continue to develop the partnership with larger healthcare providers • Develop a business model for Veterans Affairs and establish a focused sales approach	• Enter partnerships with leading companies with proprietary molecules to develop new products • Continue to document advantages and ability for amorphOX® to provide benefits to a broad range of molecules • Partnering of Orexo internal projects to accelerate development

Sustainability strategy

Responsible business based on trust, transparency, integrity and no tolerance for corruption is central in all our activities and a foundation for our sustainability work	Increase **access to healthcare** by patient support and strengthening knowledge in substance abuse and mental illness	Reduce our impact on **environment and climate change** across all our activities and our products	In all **our teams**, create a healthy working climate where inclusion and diversity are a matter of course

Commitment to UN sustainability goals, with a focus on

Read more on pages 44–59

Business model including **the full value chain**

Orexo's business model is integrated and includes the entire value chain, from the innovation phase to product access and commercialization. Cross-functional teams bring together specialist competencies to evaluate new development projects funded by revenues from the company's own sales or out-licensing of products and development projects.

Revenue sources
Sales are generated mainly from the lead product ZUBSOLV®. Since its launch on the American market, total net sales have amounted to SEK 4.5 billion. Other revenues come today from out-licensing of ZUBSOLV® or other drugs commercialized by partners, such as Abstral® and Edluar®. Revenues from the lead product have enabled investments in research and development as well as evidence-based digital therapies. Investments in these assets, for example the drug candidates OX124 and OX640, the formulation technology amorphOX® and the digital therapy MODIA®, are expected to generate future revenues from sales, including upfront and milestone payments, and royalties.

Pharmaceutical development
Orexo develops pharmaceuticals that meet large medical needs. Cross-functional teams bring together competencies in research and development, medical affairs, and business development to evaluate potential future projects. Orexo's long experience in developing pharmaceuticals that have reached approval in markets all over the world has brought extensive knowledge throughout the entire development chain. Central to the development process is building a strong patent portfolio that covers Orexo's products and development projects.

Product access
The presence on the American market provides the opportunity to have regular interactions with authorities, decision-makers, healthcare systems, insurance companies and patient organizations. In addition to pushing for decisions to be made that increase access to treatment, these interactions provide unique knowledge that is used, among other things, in the evaluation of new development projects. The sales force, which covers large parts of the country, meets daily with private practitioners, clinics and hospitals and is an important distribution channel for reaching out with treatments to those who need them most.

Sustainability
Pharmaceutical companies with their own commercial footprint have strong opportunities to contribute to better health and treatment options, but also face multiple risks related to ethic concerns. Orexo's Code of Conduct sets the basis for the sustainability work and underpins all business activities. Orexo's sustainability plan focuses on access to healthcare, employees, environment and climate change. With its outsourced production and supply Orexo depends on responsible suppliers and expects them to be socially and environmentally accountable based on the Supplier Code of Conduct and well-developed sustainability assessment processes.

Business Model

Commercialization of pharmaceuticals and digital therapies in the US

- Supply chain
- Stakeholder engagement and advocacy
- Pricing and reimbursement
- Sales and marketing
- Phase IV and RWE clinical trials

Revenue generating partnerships (current and potential)

- Supply chain (pending partner preference)
- Co-development
- Products outside OUD and mental illness

Pharmaceutical development based on drug delivery technologies

- Preclinical development
- Clinical development
- Regulatory Affairs
- Intellectual properties
- Partnering

Responsible business | **Quality** | **Sustainability**

"I joined Orexo **to make a difference** for people suffering from opioid use disorder"

Edward Kim, M.D., Chief Medical Officer, at Orexo

As Orexo continues to develop groundbreaking pharmaceutical treatments for patients, the company is also investing in digital therapeutics, focusing on MODIA® for opioid dependence. In this interview, Edward Kim, the new CMO, reflects on his clinical career, his reasons for joining Orexo and how he's supporting the company in its core mission to combat the US opioid crisis.

Extensive experience in psychiatry and public health

During my thirteen plus years in clinical practice as a psychiatrist, I valued getting to know my patients beyond their lab results and physical exams. Each person had a story to tell and life goals that went beyond managing their disease or condition. As my career progressed, I spent less time in direct patient care as a Medical Director for a large academic integrated delivery system in New Jersey.

I was passionate about finding ways to make evidence-based care available to more patients, and I haven't lost that. I saw the potential to help thousands of patients rather than just one at a time as a clinician. You never forget what brought you into healthcare; to make a difference to patients.

Since then, I've worked in several large pharmaceutical companies that have used their global reach to improve the lives of millions through innovation. But I was looking for something smaller and more intimate, yet with the digital leverage to make a large impact.

> **"You never forget what brought you into healthcare; to make a difference to patients.**

The opioid crisis is profoundly impacting many people's lives

The opioid crisis has been increasing steadily over the last several years, and it's evolving. Before the Covid-19 pandemic, fentanyl was beginning to emerge as a more common substance of abuse as opposed to heroin and other prescription opioids. With Covid-19, access to treatment was disrupted, and this contributed to a worsening of the epidemic. The growth in prescriptions for Medication Assisted Treatment (MAT) didn't keep pace with the increasing overdose deaths, and this was likely due to gaps in access to care.

Now that we're emerging from lockdown situations, fentanyl use has continued to rise. Today nine out of ten fatal opioid overdoses are caused by misuse of illicit fentanyl. Many of those are young people who should have a long life to look forward to.

Opioid use disorder can be treated

Opioid use disorder is a treatable condition. As a result of its chronic nature and long-time repercussions, the effectiveness of treatment varies among patients, and treatment is often administered over long periods of time, or chronically. MAT are commonly based on buprenorphine, methadone, or naltrexone. Buprenorphine is often combined with the antagonist naloxone to help prevent misuse by injection.

The gold standard for MAT in the US is buprenorphine/naloxone which can be taken under the tongue as a tablet or film. Methadone is most commonly administered orally under supervision while naltrexone or buprenorphine standalone are monthly injections. MAT should be provided in combination with psychosocial support.

Advocating for increased access to care is key to mitigating the growing crisis

Possibly as a result of stigma and bias, there's a long history of under-investment in this area leading to a significant shortage of addiction counsellors and clinicians trained in providing MAT. Clinicians sometimes don't take insurance due to burdensome paperwork and low reimbursement, leading to larger levels of unmet needs.

As a psychiatrist, I can relate to the challenges facing physicians. A core part of my role is advocating for the availability of all medications for opioid use disorder, regardless of who is making them. I believe that if a patient needs a specific formulation of a drug, they should be able to get what they and the prescriber believe is best without administrative hurdles.

> **A core part of my role is advocating for the availability of all medications for opioid use disorder, regardless of who is making them.**

Therefore, I warmly welcome the new legislation passed in late December 2022. It has the potential to make a huge difference for this underserved patient group as the cap for how many patients a physician can treat is eliminated. In addition, the new law will attract new categories of prescribers to embrace this disease area as they don't need to undergo a comprehensive training to get a waiver allowing them to treat patients with opioid dependence. Most importantly, the new legislation is an important step towards destigmatization of opioid dependence and its treatment.

> **Today nine out of ten fatal opioid overdoses are caused by misuse of illicit fentanyl. Many of those are young people who should have a long life to look forward to.**

Providing comprehensive patient support via MAT and Digital Therapeutics

The most effective treatments for opioid use disorder combine targeted pharmaceutical treatments with psychological therapies to reduce cravings and build new skills and habits to support a healthy lifestyle. When I worked for companies that exclusively developed innovative medicines, I was proud of the pharmaceutical advances. At Orexo, I'm thrilled that we can offer effective medications and digital therapies to provide more comprehensive patient support.

OUR HEROES
Dominique

Dad's overdose: now I know it's not my fault

My Dad, Eddie Harkins, died from an overdose when he was 54, on August 26, 2017.

Dad struggled with depression, alcohol, and drugs from the age of 9. He was abused by his Dad, who was an alcoholic and a Philadelphia cop.

I wasn't talking to him at the time as we'd had an argument about him using again. He was in full relapse and living with his Mom in Philadelphia. She found him in the bathroom around midnight but told me the next day.

I was at work and the next thing I knew I was on my way to hospital to say goodbye. I just shut down and let my sister listen. I couldn't believe this was my life. It was an out of body experience, like I was looking down on myself.

There was too much brain damage to keep Dad alive. He was brain dead and would have been hooked up to machines for the rest of his life. I had to give permission for them to turn off the life support machine.

We watched at the end of the bed as they were turning off and unplugging the machines. His chest didn't move. He was already dead. My Dad was 6 feet tall – it's crazy how such a little amount of fentanyl can kill you.

The worst thing is the guilt. I've said a lot of things I regret. The last time I saw my Dad we had an argument and I believed for a long time that if I hadn't said those things, he wouldn't have relapsed.

In some ways, Dad's overdose has helped shape the person I've grown into. Life is just hard; you have to choose your hard and work with it every day.

Visit our blog to read Dominique's full story
blog.orexo.com

OUR HEROES
Mike

My road to recovery

I've been in active recovery since January 11, 2016. That was my second day in jail, after I turned myself in. And the first full day I didn't stick a pill up my nose or in my mouth in 10 plus years. I woke up that day and knew the ride was over, I could finally get off that train.

The last 4 to 5 years, leading up to my jail sentence, I was just getting high to get by – survive. It definitely wasn't "fun" anymore. It was like a nightmare, except every day I woke up, the nightmare didn't seem to end. Getting clean is what finally ended the nightmare.

One of the main things that keeps me sober is knowing that if I use opioids again, I will be violating my probation, which means going back to jail for a very long time. The first time I went to jail, on drug related charges, I missed out on 9 months of my son's life. I try my best on a daily basis to ensure that I will not disappear from his life again due to my addiction.

Addiction consumes you, takes over your life and jeopardizes everyone and everything you love. Believe me, there are some days when I just want to use, but that would be like opening Pandora's box and losing everything all over again. Today I am a different person.

I used to carry a lot of shame and guilt when I was living that life. The hardest thing I had to do was forgive myself. Even today I haven't completely forgiven myself, but I'm working on it. I focus on the present and living each day with intention and purpose.

Read Mike's full story at **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. The authors have been asked not to reveal specifics around potential Medication Assisted Treatments or other therapy used to reach recovery to Orexo or the readers.

HQ & Pipeline

Scalable drug delivery platform central to new pharmaceuticals

Orexo's groundbreaking and clinically proven drug delivery platform, amorphOX®, works with various APIs, dosage forms and administration routes. In combination with an innovative working environment, where new ideas and concepts are highly valued, the platform is integral to the development of innovative pharmaceuticals targeting serious and extensive unmet needs.

Orexo has developed multiple drugs, from idea to approval in markets around the world. Well-documented and known substances are combined with patent protected drug delivery technologies, shortening the development of a pharmaceutical to about three to five years. The development process is based on innovations made possible by the interactions between skilled researchers and experts with different scientific backgrounds. High transparency and multifunctional collaborations make the innovation culture flourish.

High transparency and cross-functional collaboration between departments within business development and R&D, spark the innovative culture. In addition, a regular contact with the Medical Affairs department, located in the US, provides the team with significant knowledge based on contact with healthcare professionals and patients. When evaluating and prioritizing ideas, medical needs, technical implementation, intellectual property rights and commercial potential are all considered.

Targeting large unmet needs

Preventing and treating mental illness and opioid use disorder is not simply the company's function, but the purpose that inspires and galvanises our employees each day. It is a modern-day tragedy that the need for these treatments is growing globally, particularly in the US, which is Orexo's key market. Complex societal pressures, many associated with the Covid-19 pandemic, are perpetuating the opioid crisis in the US, complicated by the prevalence of illicitly manufactured synthetic fentanyl that is behind so many untimely deaths. Orexo's employees have the clinical experience, knowledge, and insights to transform these extensive unmet patient needs into opportunities for innovative solutions. Nine out of ten of the fatal overdoses are explained by misuse of potent synthetic opioids, such as fentanyl. As pharmaceuticals in the market today are designed to reverse opioid overdoses caused by misuse of heroin, there are immediate needs for more powerful rescue medications.

amorphOX® – a versatile drug delivery platform

OX124 is a potent rescue medication developed by Orexo that is highly effective against formidable synthetic opioids. Development of another overdose medication, OX125, is underway. Each contains different substances that fulfil specific needs and are targeting various groups on the market. amorphOX® was developed to meet the requirements for rapid absorption, high bioavailability, and stability. This new and scalable formulation platform can be used with a wide range of dosage forms, administration routes and substances, including both small and large molecules. Its broad applicability means that the technology can be used in the development of drugs in a wide range of diseases areas that go beyond Orexo's main therapeutic areas. Development of these drugs will take place in collaboration with other pharmaceutical companies. There is more about amorphOX® on page 24.

Partnerships and collaborations – cornerstones in the development of new drugs

When developing drugs within Orexo's main therapeutic areas of mental illness and substance use disorders, the ambition is to initiate

all product developments internally and maintain full control throughout the development process. To ensure the right levels of competence and efficiency, certain parts of the development phase, such as pre-clinical and clinical studies involve highly specialized external suppliers. This also refers to manufacturing of pharmaceuticals for various markets.

Orexo enjoys positive relations with the academy at Uppsala University. For many years, Orexo has benefitted from the valuable insights this connection brings into the company's research and development work. Among other things, Orexo participates in SweDeliver, an interdisciplinary collaboration between academia and the pharmaceutical industry, which is financially supported by Vinnova. The Faculty of Pharmacy at Uppsala University is the center's academic hub. The scientific focus is on research challenges in parenteral, oral and pulmonary drug delivery. Orexo also provides financial support, scientific expertise and mentorship to young researchers. This work usually takes place as part of the company's development work. In addition, Orexo frequently invites graduate students to write their master thesis in collaboration with the company.

Established supply chain for drugs with nasal delivery

During the development of OX124, a supply chain was established that ensures efficient and reliable supply of nasal drugs based on the amorphOX® platform. It shortens lead times, reduce costs and limits prospective risks around future nasal product developments based on amorphOX®, whether internally or in collaboration with other pharmaceutical companies.

Robust patent strategy

A strong patent portfolio that covers all existing and pipeline projects is central to the business. The patent strategy involves having the proper protection in place for the relevant markets for any given product. Specific patents are important assets, whether the company chooses to sell a product via a commercial partner or Orexo's own team brings it to the market. As a pharmaceutical company present on the US market, having enforceable patents listed in FDA's 'Orange Book' for the company's drug products is a very important part of the strategy. Orexo has an in-house IP department that collaborates closely with innovators and the development team, as well as with external counsel, to ensure that all aspects of new products are covered and that the foundations for the patents in the portfolio are in place. Orexo's global experience of patent enforcement is an invaluable asset in shaping this strategy.

Developments during the year

Orexo's primary focus area was preparing OX124, a nasal high-dose medication for opioid overdose, for approval by the US Food and Drug Administration, or FDA. In parallel, usability and stability studies were conducted with good results that complemented the data from the successful 2021 pivotal study, OX124-002. At the beginning of 2023, the NDA application was submitted with the FDA.

The first clinical trial was conducted for OX640, a nasal epinephrine medication for allergic reactions. The study primarily aimed to determine the relative bioavailability and absorption characteristics of investigational formulations versus an intramuscular epinephrine

amorphOX® – a versatile drug delivery platform

Successful trials

Well tolerated
Higher exposure
Faster onset
Lower variability

Identified need

Amorphous compounds are common in drug development and can be of great importance for the properties of the drug substance. Amorphous solids are non-crystalline and possess no long-range order, giving them unique and highly sought-after properties, such as very rapid dissolution in water. Historically however, amorphous drug compositions were found to degrade during storage due to chemical and physical instability. Orexo has a solution to this problem.

The solution

Orexo's proprietary drug delivery platform, amorphOX®, is a powder-based technology made up of particles that are built using the unique combination of a drug, carrier materials and, optionally, other excipients such as a permeability enhancer. The particles are presented as an amorphous composite of the various ingredients providing for excellent chemical and physical stability in both low and high temperatures, meanwhile the rapidly dissolving property is maintained. The platform is protected by patents and patent applications until 2042.

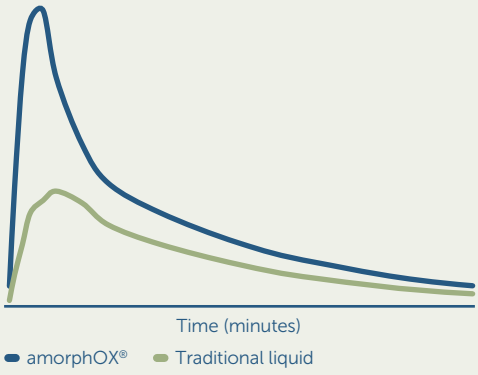
Clinically validated

The technology has successfully been proven in multiple clinical studies. It is validated in the development of various rescues medications including naloxone (OX124), nalmefen (OX125) and epinephrine (OX640), a treatment for allergic reactions. All use nasal delivery. Data has demonstrated it is rapidly dissolving, has excellent bioavailability and both chemical and physical stability.

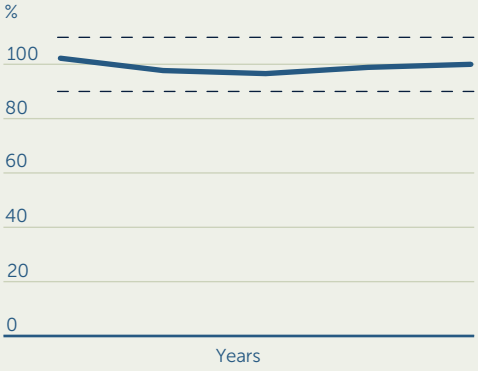
Wide applicability

The technology works with a broad spectrum of active chemical substances, including small and large molecules[1], and the properties of the powder can be tailored to meet specific needs such as particle size, dissolution, and mucosal retention. This makes it a versatile technology with broad applicability in pharmaceutical development across multiple therapeutic areas.

Plasma concentration



Amount of API



[1] Enzymes, peptides and proteins

auto-injector (EpiPen®) in healthy volunteers. The study results showed all four investigational formulations were extensively absorbed and rapidly achieved clinically relevant plasma levels of epinephrine (more detailed information follows). Scale-up will take place in the established supply chain for nasal medicines based on amorphOX®, which will accelerate development time.

Multiple exploratory proof-of-concept studies were performed, applying amorphOX® to new drug substances, including both small and large molecules. These studies included formulation assessments as well as evaluating absorption and bioavailability. Enzymes, peptides, and proteins have been tested and shown significantly improved stability data in a wide range of temperatures compared to other formulations.

The partner, Accord Healthcare, initiated the launch of ZUBSOLV® on the EU market. At the end of the year, patients in the UK, Romania, Sweden, Spain, Czech Republic, Slovenia and the three Baltic states had access to ZUBSOLV®. Accord Healthcare owns the rights to 29 countries in the EU and the work to reach out to more markets continues.

Focus going forward

As Orexo has finalized OX124 development, the focus will shift to OX640 and various exploratory and feasibility studies where both small and large molecules will be tested with amorphOX®. Based on feedback from the FDA, the next step for OX640 is to prepare for additional studies in healthy volunteers and participants with a known history of seasonal allergies. Large-scale commercial manufacturing will take place in the same supply chain as for OX124, which will shorten the development time and risks. In parallel, a partner is being sought for continued clinical development and potential commercialization.

OX640 will work independently of temperature

OX640 study: in-depth clinical data

In comparison to EpiPen®, and other approved epinephrine injection products, the OX640 formulations displayed comparable or higher;

- **A** total epinephrine exposure,
- **B** peak epinephrine exposure,
- **C** epinephrine exposure during the first 20 minutes after administration, and
- **D** proportion of subjects reaching clinically effective plasma levels of epinephrine during the first 20 minutes after administration.

In testing the feasibility of amorphOX®, together with APIs for the development of drugs that go beyond the main therapeutic area of mental illness and substance use disorders, Orexo will work with other pharmaceutical companies. Two examples are the ongoing feasibility studies applying amorphOX® to a protein-based pharmaceutical and a vaccine. The studies are being conducted in collaboration with two international biopharmaceutical and vaccine companies.

The strategic evaluation of the development project OX125, a nasal high-dose medication for opioid overdoses containing nalmefene, continues. The work was triggered by another company's acquisition, where the major asset included a nalmefene product. The event is an indication that the extremely potent nalmefene products may have an increasingly important role on the market.

The review of the ongoing stability studies for amorphOX®, which exceeded 24 months by year-end, will continue.

Collaboration with Uppsala University

In collaboration with SweDeliver at Uppsala University, a student was invited to conduct a six-week research project within the framework of the formulation platform, amorphOX®. During the year, around 20 students were invited to visit the development site and a number of lectures were held for students. The activities aim to maintain a good dialogue with students and attract talented future employees.

Formulation experts presented at the Sci 360 conference

Orexo's formulation experts participated in the annual Sci 360 conference organized by the American Association of Pharmaceutical Scientists in Boston, USA. In-depth clinical data for OX124 was presented to an audience of industry colleagues and academics.

Short facts HQ & Pipeline

Royalty 2022	SEK 53 m
EBIT 2022	SEK –303 m
EBIT margin	N.A.
Ongoing development projects	See pages 27-29

Out-licenced pharmaceuticals developed by Orexo

All are based on Orexo's sublingual drug delivery platform.

Abstral® for breakthrough cancer pain. Commercialized by Orexo' partner Kyowa Kirin who has all rights to markets ex-US and the EU. Patent protection on RoW markets until 2024.

KYOWA KIRIN

Edluar®, for insomnia. Orexo's partner, Mylan, has all rights to markets worldwide. Patent protection in the US until 2031 and in the EU until 2025.

Mylan

ZUBSOLV®, for the treatment of opioid use disorder. Accord Healthcare owns the rights to the EU market including 29 countries. Patent protection until 2032.

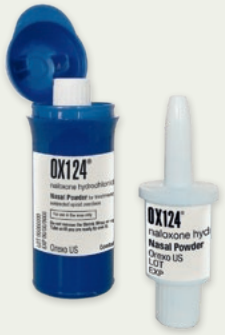
accord
We make it better

Pharmaceutical development pipeline

Project, API, indication, platform		Exploratory	Preclinical	Clinical Development Phases	Registration US	Registration EU	Registration RoW
OX124	Naloxone, opioid overdose, amorphOX®						
OX125	Nalmefene, opioid overdose, amorphOX®						
OX640	Epinephrine, allergic reaction, amorphOX®						
OX-MPI	BI1029539, endometriosis						

OX124

API	Naloxone
Technology	amorphOX®
Indication	Opioid overdose
Development phase	NDA submission with the FDA in beginning of 2023
Registration with the FDA	Ongoing
In-house development or via partnership	In-house
Commercialization	In the US, H1 2024. Markets ex-US are evaluated.
Patent	Patent protection until 2039



Unmet need
With a significant rise among people in the US that are overdosing, due to increased misuse of highly potent synthetic opioids, such as fentanyl, the need for new and more powerful rescue medications has never been greater.

Objective
The aim has been to develop a rescue medication that is faster and longer-acting, and thus effective in reversing overdoses caused by synthetic opioids. Registration with the FDA took place in early 2023.

Differentiation
Rapid absorption, substantially higher plasma concentrations of naloxone, and sustained duration of elevated plasma concentrations when compared with an injection product.

OX125

API	Nalmefene
Technology	amorphOX®
Indication	Opioid overdose
Development phase	Finalized exploratory human PK study
Registration with the FDA	—
In-house development or via partnership	In-house
Commercialization	Planned for the US and along with partners in the EU/RoW
Patent	Patent protection until 2039

Unmet need
The widespread use of synthetic opioids, such as fentanyl, also increases the need for rescue medicines that are effective in rural areas where distance to emergency units require more potent and longer lasting overdose treatment.

Objective
To develop an overdose rescue medication for situations where powerful, rapid and long-lasting effects are required.

Differentiation
As nalmefene has a longer half-life than naloxone, OX125 has the potential to be an even more effective response to the increased use of highly potent, long-acting synthetic opioids. Results from the first exploratory human PK study in healthy volunteers showed extensive and rapid absorption of nalmefene across three different formulations of OX125.

OX640

API	Epinephrine
Technology	amorphOX®
Indication	Allergic reaction
Development phase	Finalized phase I clinical study
Registration with the FDA	–
In-house development or via partnership	Currently in-house, but partnership is planned to be initiated during the development and for commercialization
Commercialization	Planned for the US and along with partners in the EU/RoW
Patent	Patent issued protecting OX640 on the EU market until 2041. Multiple patent applications filed for other territories

Unmet need

Today, allergic rescue products are needle-based auto-injectors that administer epinephrine to reverse life-threatening reactions (anaphylaxis). Whether self-administered or with the help of others, applying needle injections correctly is often intimidating, with the potential loss of precious life-saving minutes. Current solutions are costly and devices must be replaced frequently because epinephrine rapidly degrades during storage.

Objective

With decades of no innovation, products like EpiPen® dominate the market. Orexo will strive to bring to market a more fast-acting, intranasal product, which is key in life-saving situations. Additionally, the single-dose nasal administration is easy to use, easy to teach others and easy to learn for caregivers.

Differentiation

Built on our amorphOX® platform, OX640's dry-powder, single-use, intranasal delivery will provide rapid and extensive absorption with the potential for doubling the stability and shelf-life of current solutions. Moreover, OX640 is preservative-free with no sodium metabisulfite or other stability agents currently needed in today's devices. These preservatives can in itself cause allergic reactions.

OX-MPI

API	BI1029539
Technology	Oral
Indication	Endometriosis
Development phase	Phase II
Registration with the FDA	–
In-house development or via partnership	Managed by Orexo's partner GESYNTA PHARMA AB
Commercialization	–
Patent	–

Unmet need

Current treatments for endometriosis are inadequate for many patients due to limited efficacy and/or troublesome side effects.

Objective

Gesynta Pharma AB owns all the rights to OX-MPI (GS-248). The company aims to develop a non-hormonal, disease-modifying treatment for endometriosis, a painful chronic inflammatory disease that affects about 10 percent of women of reproductive age.

Differentiation

A treatment which is more effective and/or safer than currently approved treatments, and suitable for long-term use.

US Pharma

Advancing treatment options for patients with opioid dependence

The opioid situation in the US is one of the country's largest health crises. In 2022, important steps were taken, paving the way for more patients with opioid dependence to receive care and to prevent overdoses. In recent years, Orexo has expanded its therapeutic offering to deliver more person-centred treatments that blend psychosocial and pharmacological approaches to improve patient outcomes. Orexo is well positioned to take advantage of the new growth opportunities as more patients begin treatment.

Opioid misuse extensive in the US

Misuse of opioids is a global problem but is most prevalent in the US where about a fifth of people living with opioid use disorder are based.[1] A sharp increase in prescriptions of opioid painkillers over the last two decades is the primary reason that there are an estimated 9.2 million people misusing opioids in the US.[2] Approximately 5.6 million people are dependent on opioids.[3] Of these, around 1.8 million are undergoing treatment, with the most common being MAT.[4]

Synthetic fentanyl driving the opioid crisis

The Covid-19 pandemic disrupted the US healthcare system, reducing access to substance abuse treatments and exacerbating social and economic stresses, all of which led to increased misuse of opioids and accelerated the crisis. A significant increase in illegal manufacturing of fentanyl in Mexico has expanded access to synthetic fentanyl, a highly potent substance. Only an extremely small amount mixed with heroin or illegal painkillers poses danger to life. According to the latest available data, the predicted annual number of fatal opioid overdoses exceeded 81,000.[5] Nine out of ten opioid overdoses involve synthetic opioids, such as fentanyl.[6]

Major economic impact on US society

The misuse of opioids is causing complex and pervading challenges for the US. Untimely deaths and reduced quality of life are profoundly distressing for all the people touched by this opioid crisis. Economic problems are associated with lower productivity, healthcare costs, and rehabilitative treatment. The human and economic costs of the opioid epidemic in the US are staggering. According to the US Joint Economic Committee, the societal cost of the opioid crisis in 2020 amounted to USD 1.500 billion.[7] The amount is an increase of 37 percent since 2017, when the corresponding calculation was made.[8]

Advancing treatment options for patients

Since 2013, Orexo has contributed to fighting the opioid crisis in the US. From initially only being able to offer the medication assisted treatment, ZUBSOLV®, Orexo has developed MODIA®, an evidence-based digital therapy. MODIA®, meets the need of offering patients psychosocial support while staying on a medical treatment, such as ZUBSOLV®. To address the growing problem of overdoses involving synthetic opioids, such as fentanyl, Orexo has developed a life-saving high-dose medication.

>USD 1,500 billion

The US society cost for the opioid crisis in 2020

[1] World Drug Report
[2] Substance Abuse and Mental Health Services Administration
[3] Substance Abuse and Mental Health Services Administration
[4] Orexo data
[5] Center of Disease Control and Prevention, predicted numbers as of August 2022
[6] Center of Disease Control and Prevention, predicted numbers as of August 2022
[7] https://www.jec.senate.gov/public/index.cfm/democrats/issue-briefs?ID=CE55E977-B473-414F-8B88-53EB55EB7C7C
[8] https://www.jec.senate.gov/public/index.cfm/democrats/issue-briefs?ID=CE55E977-B473-414F-8B88-53EB55EB7C7C

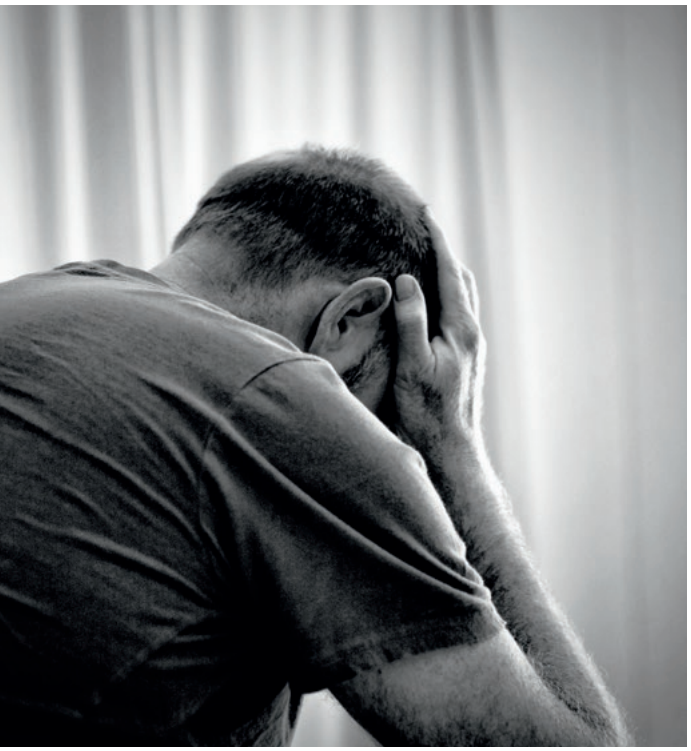
Each day, the sales force visit physicians, medical clinics and hospitals treating patients suffering from opioid use disorder. In addition, Orexo is working at both federal and state levels to collaborate with policymakers to increase access to pharmaceuticals and digital therapies within this treatment area, as well as reaching out to insurance companies for reimbursement of Orexo's products.

The buprenorphine/naloxone market in the US

The buprenorphine/naloxone treatment market grew by 5 percent in 2022. This is Orexo's main market, where the company is present with the drug ZUBSOLV®. This represents a slowdown from 8 percent growth in 2021. The pandemic and its burden on healthcare resources continued to affect access to treatment for opioid use disorder. In addition, the prevalence of synthetic fentanyl makes it more difficult for physicians to treat patients, and physicians report they see more patients return to misusing opioids during the challenging treatment induction phase.

The growth predominantly took place in the largest payer segment, the Public 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 (Commercial payer segment), often signed by employers, showed a lower growth rate compared to the Public payer segment. The generics part of the market remained dominant, characterized by high price sensitivity.[1]

[1] Generics of Suboxone® Film and tablets and also of Subutex® tablets



Developments during the year

ZUBSOLV® is the only pharmaceutical for daily treatment on the market that is actively promoted to healthcare professionals. During the Covid-19 pandemic, there were fewer opportunities for the sales force to contact physicians. Site visits increased in 2022, although the number is not yet back to the pre-pandemic level.

A new law resulted in ZUBSOLV® becoming reimbursed within Medicaid in New York state and the patients in the Public payer segment who can get ZUBSOLV® reimbursed increased from 42 to 48 percent. The corresponding number for the Commercial payer segment continued to be at a high level and amounted to 98 percent at the end of the year.

Two various concepts for commercialization were developed, modiaONE™ and MATCore™. modiaONE™ is part of the MODIA® launch campaign, during which physicians treating patients for opioid use disorder are invited to test the digital therapy with their patients. modiaONE™ was launched in first quarter and at the end

98%

Part of patients in the Commercial payer segment who can get ZUBSOLV® reimbursed

Short facts US Pharma

Net revenues 2022	SEK 571 m
EBIT 2022	SEK 308 m
EBIT margin	54%
Pharmaceuticals	ZUBSOLV® for the treatment of opioid use disorder. Should be used along with psychosocial support. ZUBSOLV® is based on Orexo's sublingual drug delivery platform. Patent protection until 2032. Accord Healthcare owns the rights to the EU-market.
Target groups	Insurance companies, private practices, specialist medical clinics, and hospitals.

Distribution channels	Orexo's own sales force, incl. approximately 35 employees. The sales force also commercializes Orexo's digital therapies, focusing on MODIA®.
Key market	The buprenorphine/naloxone market
Key market growth in 2022	5%
Competition landscape	Suboxone® Film, generics on Suboxone® Film and Subutex®/ Suboxone® tablets
Percentage number of patients who can get the treatment reimbursed	The Commercial payer segment, 98% of the patients. The Public payer segment, 48% of the patients.

of the year, the number of patients testing MODIA® amounted to 2,800. The testing program started the process to convert to commercial contracts based on reimbursement of the therapy at the end of the year, when the first clinics in three prioritized states submitted reimbursement claims for the therapy.

MATCore™ is a digital platform developed to be implemented in collaboration with healthcare professionals providing a single access point to Orexo's offering within opioid use disorder. In addition to giving patients easy access to both pharmaceutical and therapy treatment, they can also access education within the therapeutic area and get practical support to facilitate treatment.

Further, healthcare providers gain access to data for effective follow-up and treatment alignment. Initial implementation of MATCore™ by healthcare providers will be supported by grants from the financial resources derived from paid damages by those held accountable for the opioid crisis. In late 2022, a clinic in Arizona, specializing in opioid use disorder, received a grant to be used to implement MATcore™ in their practice.

Positioned to take advantage of new growth opportunities

At the end of the year, a new law was passed that is expected to make it easier for healthcare providers to treat opioid-dependent patients. The new conditions mean that the ceiling for how many patients a physician or other prescribers can treat is removed. Previously, a prescriber was only allowed to treat up to 275 patients and had to follow burdensome administrative processes to treat opioid-dependent patients. Through the new law, a physician can choose how many patients to treat, and it is also now much easier to get permission to care for opioid-dependent patients.

These new prescribing freedoms across the US have come alongside damage payments of a collected value of approximately USD 54 billion to curb the opioid crisis and are expected to fuel market growth. By being able to offer MAT, digital psychosocial support, and soon a high-dose medication for opioid overdose, Orexo is uniquely positioned to take advantage of these growth opportunities.

Orexo is building a unique portfolio of innovative treatment solutions for opioid use disorder

MAT treatment

Digital therapy [1]

modia

High-dose medication for opioid overdose

[1] Clinical study ongoing, incl. 437 patients at 35 sites across the US

The opioid overdose rescue medication market

A The market value amounts to approximately USD 300–500 million. Since 2015 there has been one dominant provider, but their position has recently changed due to the newly available generics of their branded product.

B The market includes low-dose products developed for curbing opioid overdoses caused by misuse of heroin. Nine out of ten opioid overdoses now involve highly potent synthetic opioids, such as fentanyl, that require more powerful rescue medications.

C The market today is solely based on prescription products but is likely to convert into a low-dose OTC market and a prescription market, including the powerful high-dose products that are reimbursed by insurance companies.

D The scale of the need for potent and longer-lasting overdose rescue medications is expected to propel the prescription market. Continued expansion of mandatory co-prescription of naloxone rescue medication should also benefit the market for prescription products.

Digital therapies will increase access **to qualified psychosocial support**

Psychosocial support is becoming an increasingly common method of achieving improved outcomes for patients receiving medical treatment, particularly for mental illness and substance use disorder. MODIA®, Orexo's flagship product in digital therapeutics, meets a significant need for psychosocial support in the treatment of patients with opioid dependence. In 2022, more than 2,800 patients tested MODIA® while undergoing treatment with buprenorphine/naloxone.

Digital therapies increase access to psychosocial support

Digital therapeutics are a new and innovative form of treatment that make it possible to prevent and manage, and in some cases also treat, clinical disorders and chronic diseases. Orexo's digital therapies will help patients suffering from mental illness and substance use disorders. Support from a therapist or psychologist is becoming an increasingly common element of treatment plans to improve patient outcomes. As more and more people seek treatment, the lack of available psychosocial support increases. Digital therapies, which have proven clinical effectiveness, not only relieve healthcare services but also enable significantly more people to have access to qualified therapeutic treatments.

Based on cognitive behavioural therapy techniques

Orexo's digital therapies are developed by, or alongside GAIA AG, a company with considerable experience of developing evidence-based digital therapies within various therapeutic areas. The therapies are developed in consultation with psychologists, physicians and patients and are based on cognitive behavioural therapy techniques that empower patients in their efforts to make behaviour and lifestyle changes. These digital therapeutics can be used privately and are available 24 hours a day, helping to reduce the stigma that is often associated with mental illness and substance use disorders.

Digital therapies with clinically proven efficacy

Orexo's digital therapy deprexis® has been tested by GAIA AG in 13 clinical studies, with more than 2,800 individuals. The study results consistently showed positive clinical effects in patients with depression and better retention in combined ongoing medical treatment. The effectiveness of vorvida® has been tested in one clinical study with 608 individuals, and the data demonstrated a reduction in alcohol consumption during the six months that the therapy was tested. In addition, drinking patterns were improved. For MODIA®, a large clinical trial is ongoing with 437 participants at 35 sites across the US who sought treatment for documented moderate to severe opioid use disorder. The study evaluates whether the use of MODIA® in combination with sublingual buprenorphine/naloxone treatment is superior to sublingual buprenorphine/naloxone alone in reducing illicit opioid misuse. If the study demonstrates successful data, it will form the basis for an FDA 510K-application, applying for MODIA® to be classified as a prescription digital therapeutic.

Did you know this about DTx?

- Subsection of digital health
- Evidence-based therapeutic intervention
- Prevent, manage, or treat a medical disorder or disease
- Particularly applicable in the mental illness & addiction space
- Standalone or along with pharma treatment
- Available 24/7

Distinct reimbursement routes key to increasing access to DTx

Orexo is working with several other players, including industry associations, to increase awareness of the new product category and educate key opinion leaders, healthcare providers and payers. Lack of clear reimbursement routes is the main reason why access to evidence-based digital therapies is limited today. In 2022, several important steps were taken to improve reimbursement of prescription digital therapeutics.

An important milestone was when Highmark, a payer network in Pittsburg, recommended the insurance companies in their network expand reimbursement to also include prescription digital therapeutics cleared by the FDA. Highmark is the first large regional payer network to include digital therapeutics in their formularies and is also the first payer to create a medical policy indicating that FDA approved prescription digital therapeutics are considered medically necessary when prescribed by a physician. In addition a new bill, Access to

Prescription Digital Therapeutics Act of 2022, was introduced in the US Senate. This bill aims to amend the Social Security Act to provide Medicare coverage and reimbursement for prescription digital therapeutics. It is a step in the right direction towards the proper coding and benefits category for Medicaid among commercial payers.

Developments during the year

Due to the lack of fully established reimbursement routes, Orexo, together with the Integrated Healthcare Network, Trinity Health in North Dakota, tested a new pathway to obtain reimbursement when the digital therapies are added to an ongoing medication program, the so-called Collaborative Care Model (CoCM). As the health network's insurance companies approved reimbursement, according to CoCM, Trinity Health provided access to vorvida® and deprexis® among their patients. For prescribers to start treating patients, Orexo's educational work needs to expand, together with administrative support.

The modiaONE™ concept has allowed physicians to test MODIA® on a limited number of patients. The initiative has received a significant amount of interest, with over 2,800 patients enrolled from over 130 providers. With the success of the program, Orexo will now focus on moving from offering test programs to commercial contracting, supported by a customized reimbursement pathway in each state.

A ten-year contract was signed with Veterans Affairs (VA) providing reimbursed access to deprexis®. In total approximately 15 million US citizens at the Department of Veterans Affairs, the Department of Defense, and Indian Health Services will have access to qualified psychosocial support. Implementation within the VA follows a step-by-step process that initially focuses on establishing opportunities to market and distributing deprexis® within three of VA's 18 regions.

A collaboration was initiated with the Wayside Recovery Treatment Center, which specializes in women with addiction in Minneapolis, that will offer 60 patients access to deprexis® and vorvida®. The collaboration is financed by healthcare grants paid by the state of Minnesota.

Focus going forward

By the end of 2022, the DTx portfolio had over 4,600 patients across early access commercial programs and clinical trials. The next step is to focus on gaining traction and moving from test to commercial contracts for MODIA® and in parallel, work with Trinity Health and the VA to invite prescribers to start treating patients with DTx. This is mainly done through traditional sales work with focused efforts towards

2,800

number of patients testing MODIA® at year-end 2022

437

number of patients enrolled to the MODIA® clinical study

Underlying drivers to fuel future long-term growth

A Aging population and sky-rocketing costs are forcing the healthcare providers to rethink how to deliver healthcare to increase efficiency and value.

B Patients want to be seen as consumers and require holistic and customized treatments with access 24/7.

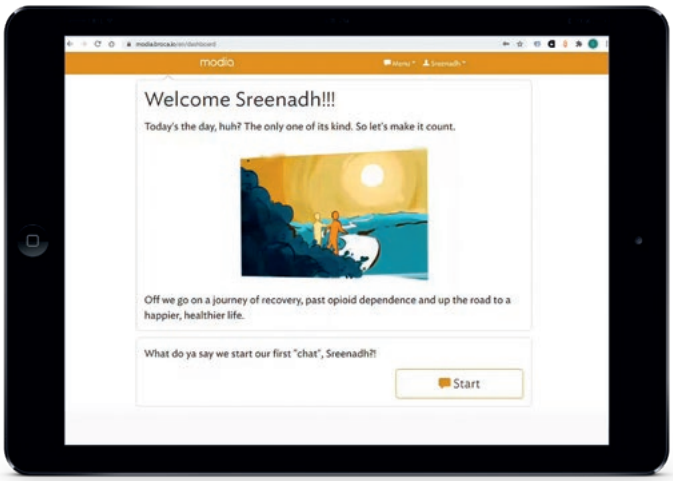
C Covid-19 has further pushed forward the ongoing tech revolution and the use of telemedicine is pervasive.

D Providers will be rewarded based on the ability to add patient value. Analyzing RWE data paves the way for efficient allocation of resources.

healthcare providers in Trinity Health and the VA to make them comfortable to start introducing these innovative treatments to patients. In addition, Orexo continues to work with policymakers, advocates, and other stakeholders at federal and local levels to help ensure policies and solutions are implemented that increase access to Orexo's products.

During the summer of 2023, data from the MODIA® study is expected. Positive data will be used to submit a so-called 510K application to the FDA to have MODIA® classified as a prescription digital therapeutic. This process should take approximately six months from submission to potential approval.

From January 2023, the DTx organization will be fully integrated into the US Pharma organization to ensure a more efficient and integrated approach to the full commercial operation in the US.



Recovery is a continuous process. MODIA® gives patients access to psychosocial support 24/7, on their computer, smartphone, or tablet.

Short facts Digital Therapeutics

Net Revenues 2022	SEK 0 m
EBIT 2022	SEK –189 m[1]
EBIT margin	N.A.
Therapeutics	**MODIA®:** 6 months therapy for opioid use disorder, should be used along with medical treatment. Extensive clinical trial ongoing, incl. more than 437 patients. **deprexis®**: 3 months evidence-based therapy, for depression. **vorvida®:** 6 months evidence-based therapy, for alcohol management. **MODIA®** and **vorvida®** are launched in the US through FDA's Emergency Use Authorization order and **deprexis®** is being marketed under enforcement discretion aligned with an earlier dialogue that GAIA AG had with the FDA.

Target groups	Insurance companies, larger healthcare providers, other target groups such as, employers, organizations and consumers are reached through partnerships.
Distribution channels	Through the US Pharma sales force, incl. approximately 35 sales representatives, and through partnerships.
Key market	Digital therapeutics for the treatment of mental illness and SUD. A market in a very early phase due to lack of viable reimbursement routes.
Key market growth 2022	N.A.
Competitiors	E.g. Pear Therapeutics, Dario Health, Twill and Silvercloud Health.
Percentage of patients who can get the therapies reimbursed	Reimbursement routes are not yet fully established.

[1] Impacted by direct and indirect operating expenses

The share

Orexo's share is listed on Nasdaq Stockholm and available as American Depository Receipts (ADR) on OTCQX Market in the US. At year-end, Orexo had a total of 7,158 shareholders and the non-Swedish shareholding amounted to 43 percent.

The Orexo share is listed on Nasdaq Stockholm Small Cap under the symbol ORX and can be traded on the US market, via an ADR available on OTCQX Market under the symbol ORXOY. During the year the share price decreased by 45 percent and the last price paid in 2022 was SEK 18.86 (34.50). This corresponds to a market capitalization of SEK 655 (1,198) million. The highest closing price during the year for the share was SEK 34.3 quoted on January 3. The lowest quotation was SEK 17.1 on April 27.

Liquidity

In total, 24 (25.8) million shares were traded in 2022, corresponding to a value of approximately SEK 543 (1,091) million. The daily average trading volume was 95,118 (102,114) shares, corresponding to a value of SEK 2.2 (4.3) million.

Ownership

At year-end, Orexo had 7,158 (7,272) shareholders, of which 580 were registered as legal entities and 6,578 as private individuals. Of the share capital, 57 (57) percent is held by shareholders registered in Sweden and 43 (43) percent by non-Swedish shareholders. The largest proportion of shareholders registered outside Sweden can be found in Denmark, whose holding amounts to 34 (34) percent.

Key Facts

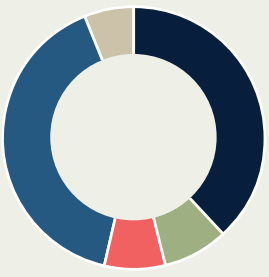
Orexo Share

Listing	Nasdaq Stockholm, Sweden
Number of Shares	34,710,639
Market Capitalization, December 31 2022	SEK 655 million
ISIN Code	SE0000736415
Ticker Code	ORX

Orexo ADR

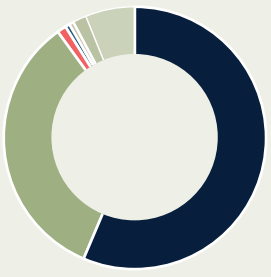
Trading Platform	OTC, US
Deposit Bank	Citibank N.A.
ISIN Code	US68616W1027
Ticker Code	ORXOY
Ratio	1:1

Ownership categories, December 31 2022



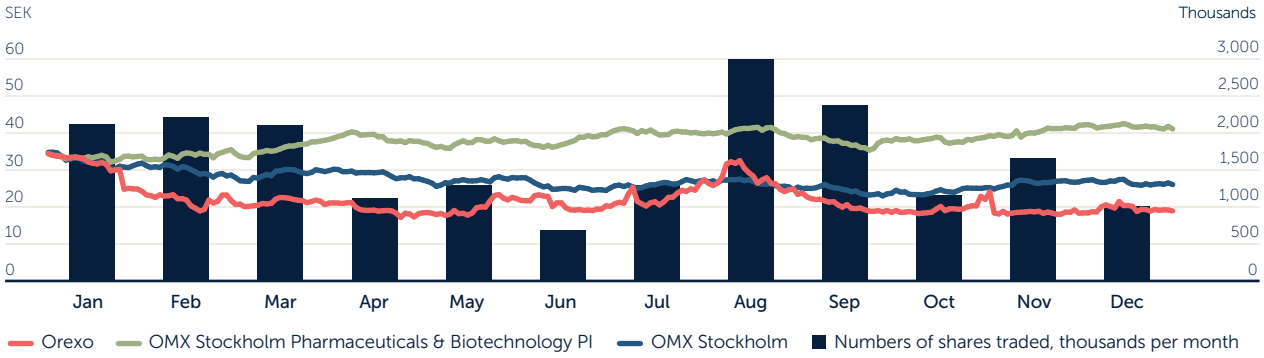
- Swedish private individuals 38.2%
- Swedish institutions 8.1%
- Non-Swedish institutions 7.5%
- Other 40.1%
- Anonymous ownership 6.1%

Ownership distribution per country, December 31 2022

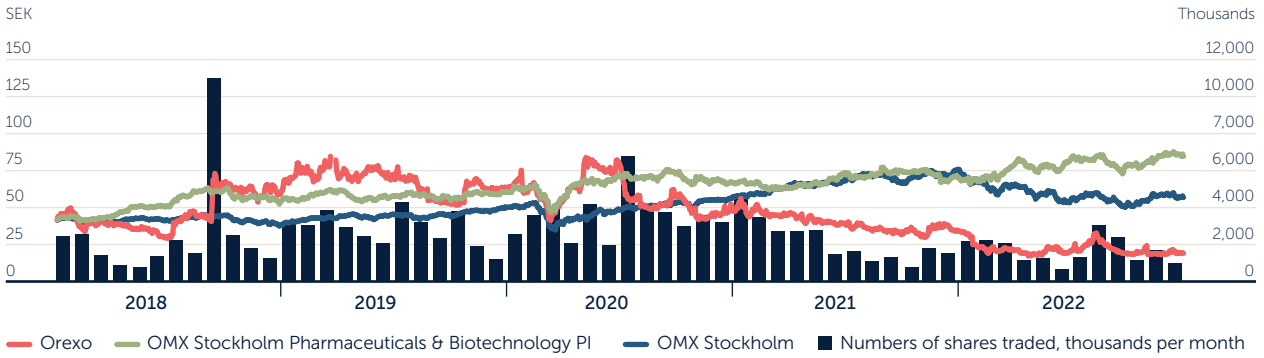


- Sweden 56.9%
- Denmark 33.9%
- Poland 1.2%
- Italy 0.5%
- US 0.3%
- Other 1.6%
- Anonymous ownership 6.1%

Performance in 2022



Five-year performance



Shareholders, December 31 2022

Owners	No. of Common Shares	Share of Capital (%)
Novo Holdings A/S	9,643,184	27.80
Avanza Pension	2,392,458	6.90
Arbejdsmarkedets Tillægspension (ATP)	1,780,633	5.10
Anders Walldov, directly and indirectly	1,600,000	4.60
Swedbank Insurance	1,008,453	2.90
Handelsbanken Funds	692,186	2.00
Nordnet Pension Insurance	577,038	1.70
Sixth Swedish National Pension Fund	390,931	1.10
Stefan Hansson	389,782	1.10
Orexo AB	343,023	1.00
Eccenovo AB	255,132	0.70
Håkan Lejonkula	235,000	0.70
Thomas Lundqvist	204,567	0.60
Christer Nyström	183,009	0.50
Consultinvest	176,445	0.50
Total top 15	**19,871,841**	**57.20**
Others	**14,838,798**	**42.80**
Total	**34,710,639**	**100.00**

Owner Structure, December 31 2022

	No. of Shareholders	No. of Common Shares	Share of Capital %
1–100	2,730	107,466	0.30
101–500	2,050	578,398	1.70
501–1,000	806	661,100	1.90
1,001–5,000	1,070	2,552,599	7.40
5,001–10,00	242	1,802,669	5.20
10,001–20,000	142	2,068,526	6.00
20,001–	118	24,824,377	71.50
Anonymous holdings	**–**	**2,115,504**	**6.10**
Total	**7,158**	**34,710,639**	**100.00**

Source page 38–39: Monitor by Modular Finance AB, Euroclear Sweden AB and Nasdaq Stockholm. Totals may deviate due to rounding.

Shareholder information

Communication and reporting

Website
Orexo's website, www.orexo.com, is the company's primary communication channel. It contains information on, among other things, Orexo´s history, operations, governance, and financial development as well as equity data. The website is also the company's information hub, including news, press releases and storytelling. Shareholders and other stakeholders are welcome to subscribe to information that the company publishes, which is easy to do via the link below.
https://orexo.se/investerare/prenumeration/

Financial information
All Orexo's public financial information is available on the website, such as quarterly reports, year-end reports and annual reports. In connection with the publication of quarterly reports and year-end reports, investors, analysts, and the media are invited to participate in a presentation facilitated by Orexo's management team. The presentation can also be viewed afterwards on the website.

Sustainabiliy work
Orexo's sustainability work is documented in the company's annual report. The sustainability report, and an overall presentation of Orexo's progress in this area, can be read on the website.

The blog portal and social media presence
On Orexo's blog, stories are shared from people affected by mental illness and substance use disorder. To contribute to increased knowledge of the therapeutic areas and to highlight good examples related to recovery, interviews with experts in the area are also published.

Shareholders and other stakeholders can also follow the company on Twitter, LinkedIn and Youtube.

blog.orexo.com

Investor Relations

Investor Relations activities
During the year, regular Investor Relations activities were performed to keep the financial market updated about the company's operations, environment and financial developments. The activities have taken place individually with investors and analysts based in the Nordics and outside the region. To reach current and potential investors, Orexo has also participated in multiple conferences, seminars, and events using a hybrid approach of physical and virtual meetings/presentations.

Analysts monitoring Orexo
- Carnegie, Erik Hultgård
- Erik Penser, Klas Palin
- RX Securities, Dr Samir Devani

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

Financial Calendar 2023

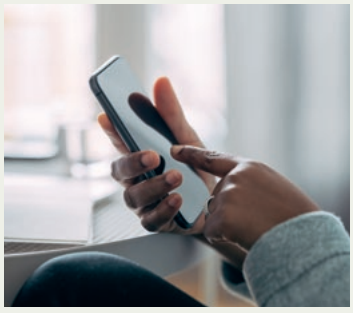
Annual General Meeting
April 18 2023

Interim Report Q1
April 27 2023

Interim Report Q2
July 18 2023

Interim Report Q3
November 2 2023

Interim Report Q4 incl. Full Year Report
January 25 2024



2023 Annual General Meeting

Invitation
The shareholders in Orexo AB are summoned to the Annual General Meeting (AGM), to be held on Tuesday April 18 2023, at 16.00 pm in Orexo's facilities at Rapsgatan 7E in Uppsala, Sweden.

Nomination Committee
Prior to the AGM, Orexo has appointed a Nomination Committee which represents approximately 38 percent of the number of votes in the company as of December 31 2022.

The Nomination Committee comprises:
- Christian Salling, Novo Holdings A/S, also Chairman of the Nomination Committee
- Claus Berner Møller, ATP
- Patrik Walldov, representative for Anders Walldov (incl. indirect holding via Brohuvudet AB)
- 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 in the meeting must be recorded in the share register maintained by Euroclear Sweden AB on Thursday April 6 2023, and notify Orexo of their intention to attend the meeting not later than on Wednesday April 12 2023 by post to Orexo AB, P.O. Box 303, SE-751 05 Uppsala, Sweden, by telephone +46 (0) 18 780 88 00, by telefax +46 (0) 18 780 88 88, or by e-mail to lena.wange@orexo.com.

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

Shareholders whose shares are registered in the name of a nominee 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, which may be temporary, must be duly effected in the share register maintained by Euroclear Sweden AB on Wednesday April 12 2023, and the shareholders must therefore advise their nominees well in advance of this date.

For detailed information about the AGM view Orexo´s website, https://orexo.com/about-us/corporate-governance/

Glossary

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

ADR
An American Depositary Receipt (ADR) is 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.

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

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

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

Cash segment
One of 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
Studies of the safety and efficacy of a drug in human beings.

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

Commercial 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.

CMO
Abbreviation of Contract Manufacturing Organisation

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.

DTx
Digital therapeutics (DTx), 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.

Epinephrine
A hormone used in emergency treatments of allergic reactions.

EUA
An Emergency Use Authorization (EUA) is an authorization granted by the FDA to allow the use of a drug prior to approval.

FDA
The United States Food and Drug Administration (FDA) 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.

IP
Abbreviation of Intellectual Properties.

Large molecules
New biological entities commonly created by the polymerization of smaller subunits such as protein.

MAT
Medication Assisted Treatment (MAT) is the use of medications, in combination with counseling and behavioral therapies, to provide a holstic approach to the treatment of substance use disorders.

Nalmefene
An opioid antagonist used to counter the effects of opioids.

Naloxone
An opioid antagonist used to counter the effects of opioids.

NDA
The New Drug Application (NDA) is the vehicle through which drug sponsors formally propose that the FDA approves a new pharmaceutical for sale and marketing in the US.

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 branded and/or generic products in the market. 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.

OUD
Abbreviation of Opioid Use Disorder. When someone is suffering from OUD they have a persistent desire or unsuccessful efforts to cut down or control opioid use. A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects. Craving, or a strong desire or urge to use opioids.

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

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

Public segment
One of three 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.

RCT
A randomized controlled trial (RCT) is a clinical trial that 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.

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

RWE
Real-World Evidence (RWE) is the clinical evidence about the usage and potential benefits or risks of a medical product derived from analysis of Real-World Data (RWD); data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources outside of a clinical trial setting.

Small molecules
Low molecular weight organic compounds, typically involved in a biological process as a substrate or product.

Sublingual
Under the tongue.

SUD
Abbreviation of Substance Use Disorder.

Sustainability

At the core of a sustainable society are health and well-being, the areas where Orexo makes its biggest impact. During 2022, important steps were taken to further strengthen the company´s social and environmental responsibility, which is crucial for long-term success and the opportunity to contribute to a sustainable society.

Orexo's business strategy and how it is operationalized during day-to-day work is shaped by the ethical code. The strategy supports Agenda 2030 and the Sustainable Development Goals and is also aligned with and international standards and well-known initiatives, including the International Labor Organization Conventions, and the UN Guiding Principles on Business and Human Rights. Orexo also participates in the UN Global Compact. Further details are shared in the Responsible business section and in each of the focus areas.

The management team and board take overall responsibility for Orexo's sustainability strategy and its implementation. On behalf of the management team, Cecilia Coupland, Senior Vice President and Head of operations, oversees sustainability matters together with the Sustainability Committee, which has representation from relevant functions across the entire business. The Sustainability Committee has the power to shape the strategies and policies as well as how these are delivered in practice.

Orexo has been progressing its sustainability agenda over the past several years as awareness has been growing, both within the company and across society as a whole.. This led to the 2021 sustainability review and initiated a process to evaluate, analyze and progress the company's environmental agenda.

Expectations and regulatory requirements have rapidly increased in the last few years. Orexo welcomes the increased focus on sustainability from investors and society as these questions are important, and the company is committed to continuing to improve its sustainability work. The review concluded that Orexo's policies and sustainability focus areas are well in line with global expectations. The review also examined how Orexo identifies risks, impacts and opportunities through a sustainability lens. The findings are summarized in the table on next page and following pages. The review concluded that there is a need to increase focus on climate, supply chain, retaining talented employees and a discussion about Orexo's role in improving global health in relation to the core business.

"Sustainability has never been more important than today. I am proud of the progress we have made during 2022."

"The finalization of our materiality analysis has enabled us to set a strategy for the entire business. We have also carried out a mapping of climate impact from own operations. This is the first step to report in line with the Greenhouse Gas Protocol. Furthermore, efforts in understanding the impact of our suppliers, will help us extend the scope in 2023."

"My future vision is that we in the coming years will have a full understanding of our sustainability impact through our operations and value chain and are on plan with our sustainability KPI:s. Also, that we continue to be recognized as a responsible company that goes beyond our legal obligations for sustainability."

Cecilia Coupland
Senior Vice President and Head of Operations, management representative in Orexo's Sustainability Committee.

Own operations	Orexo's main market is in the United States. The headquarters, including R&D, are situated in Sweden. Sales and marketing are based in the US. The geographical reach of the company means that travel is a major environmental aspect, including regular driving by the sales force team. Energy usage in the laboratories in Sweden, where a strictly controlled environment is essential, is an additional aspect. Orexo relies heavily on recruiting and retaining talented employees with a diverse range of skills and capabilities to meet the strategic objectives. If Orexo fails to engage and retain a capable workforce, this poses a risk to the business. Additional operational risks requiring careful management, includes health and safety issues around chemical handling, driving and stress.
Research & Development	Orexo is continually innovating, bringing new technologies to the market, including the platform amorphOX®. This platform enables a groundbreaking needle-free drug administration route, creating new and exciting opportunities for people for whom traditional injections are problematic. With increased stability, it also provides opportunities for more environmentally protective products that have a longer shelf-life and less rigid storage conditions (no cooling required). Risks include not attracting the right competence to execute market delivery and counteracting legal and regulatory requirements.
Supply chain	Orexo outsources production and relies on good practices from its partners. The company needs to work closely with all contract manufacturers to understand the environmental impacts and ensure the workplace is safe with good working conditions. The commercial supply chain is found in countries with strong legislation, however, for suppliers further up the value chain, Orexo needs to ensure the contract manufacturers are also using those suppliers that meet the required expectations on labor, human rights and business ethics. Orexo is cognizant of the risks of not being made fully aware of any concerns associated with its suppliers and accepts the need to continue driving this forward. The goal is to gather a comprehensive understanding of the sustainable impacts linked to the supply chain, including the significant area of production.
Products	Orexo's core business is the treatment of mental illness and substance use disorders and a number of products to help patients have been developed. However, there are challenges with navigating the US healthcare system that impact the ability to reach all target patient groups. The digital therapies in Orexo's portfolio provide innovative opportunities to reach new patient groups. The need for therapy is greater than the resources in the healthcare system. Digital therapies can complement traditional treatments and reach a wider group of patients. Pharmaceuticals in the environment is a global concern. There is a risk for pharmaceuticals to reach the environment in the production and formulation of products. The regulatory requirements in the US on the handling of waste pharmaceutical products may also impose a risk for pharmaceuticals reaching the water.
Sales & Marketing	Orexo's business is within the healthcare sector and a recognized risk is unethical business and compliance violations in interactions with healthcare professionals. Sales and marketing employees have an important role in educating healthcare professionals to use Orexo's products correctly to optimize patient outcomes.

Sustainability review

The review process started with an analysis of the present situation internally and externally, followed by a stakeholder analysis, stakeholder dialogue and materiality assessment. These steps formed the basis for further developing the sustainability strategy.

Stakeholder analysis and review were important elements of this process. Orexo's key stakeholders include employees, investors, healthcare professionals, patients, suppliers, contract manufacturers and authorities. The stakeholder analysis and dialogue included interviews, but also web information searches and review of reports. In addition to climate, supply chain and contribution to global health, sustainable employees, work-life balance, gender equality and diversity were highlighted by stakeholders.

In the materiality assessment, Orexo has completed an assessment of the sustainability matters, looked at the impact, risks, and opportunities for the business. The result was then combined with stakeholder expectations. The selected topics for the materiality analysis are based on the internal/external analysis and identified risks. The work was led by the sustainability committee but also involved the management team and the board. The results are presented in the following graph.

By evaluating the results and to ensure a connection to the business, Orexo confirm the sustainability topics identified in previous years remain important but that there is a need to continue driving and developing the strategy, including finding the right long-term ambitions and targets.

Topics identified as the most important were: responsible manufacturing and transport, increased access to products, ethical business, climate change, responsible procurement, and employee well-being.

Materiality assessment

Orexo's sustainability strategy

The strategy involves four focus areas and refines all efforts from the previous year. It does not significantly change priorities, but clarifies the vision and further focuses the company's efforts. Sustainable supply chain has moved from being an area on its own to being integrated into responsible business and environment and climate change. More information about the 2022 sustainability strategy implementation, including KPIs and deliveries 2022 is presented on pages 48–57.

Orexo supports Agenda 2030 and the Sustainable Development Goals (SDGs). The company has also been a participant in the UN Global Compact since 2017, and its strategy aligns with both this and the SDGs. SDG 3: "Good health and well-being", and in particular target 3.5: "Strengthen the prevention and treatment of substance abuse, including narcotic drug abuse and harmful use of alcohol" continue to be core to Orexo's business.

Responsible business

Responsible business based on trust, transparency, integrity and no tolerance for corruption is central to all our activities and a foundation for our sustainability work

Sustainable employees

In all our teams, create a healthy working climate where inclusion and diversity are a matter of course

Access to healthcare

Increase access to healthcare by patient support and strengthening knowledge of substance abuse and mental illness

Environment and Climate change

Our ambition is to reduce our impact on environment and climate change across all our activities and our products

Responsible business

Operating in the pharmaceutical industry and marketing a controlled substance carry great responsibilities. Unethical business behaviors can result in drugs being over-prescribed, diversion and misuse of products, and unethical marketing. At Orexo, responsible business practices are always a top priority, and there is no tolerance for non-compliance.

Responsible business based on trust, transparency, integrity and no tolerance for corruption is central to all our activities and a foundation for our sustainability work

Sustainability topic	**Responsible employees**	**Responsible supply chain and procurement/sourcing**		**Transparency and reporting**
Long-term ambition	Ensure ethical behavior among all employees and board	Our material suppliers[1] have ethical standards consistent with Orexo's	Our material suppliers[1] have sustainability processes in place	Orexo is known as a transparent company
Target 2025	100% completion of Code of Conduct training 100% completed sustainability program training	100% of material suppliers[1] have a Code of Conduct or embrace Orexo Supplier Code of Conduct	100% of material suppliers[1] have an approved sustainability assessment	Completion of annual sustainability report and UN Global Compact report

Orexo engages with markets that offer good business opportunities, but operations can also take place in high-risk markets with exposure to serious issues such as bribery and corruption. Orexo's business practices are therefore heavily scrutinized by law enforcement and legislative bodies. To have a responsible business based on trust, transparency, integrity, and with zero tolerance for corruption is central to Orexo and a foundation for our sustainability work. Orexo outsources production and is highly dependent on the supply chain. It is vital to ensure suppliers and partners follow the same ethical standards as Orexo and it underpins everything the company does. Responsible business is at the heart of Orexo's sustainability plan.

Responsible employees

Orexo's Code of Conduct, also known as the Business Compliance and Ethics Code, serves as an umbrella for all Orexo's policies and guidelines. It is based on corporate values, legislation, and internationally recognized standards, such as the Universal Declaration of Human Rights, the Helsinki Declaration[2] and the Ten Principles of UN Global Compact. Orexo's Code of Conduct underpins the business and describes expectations and requirements in the areas of human rights, personnel and labor law, environment, and anti-corruption. It also describes ethical research and development expectations, as well as patient safety requirements.

[1] Supplier for commercial supply and other strategic deliveries
[2] A number of recognized ethical principles for medical research involving humans, developed by the World Medical Association (WMA).

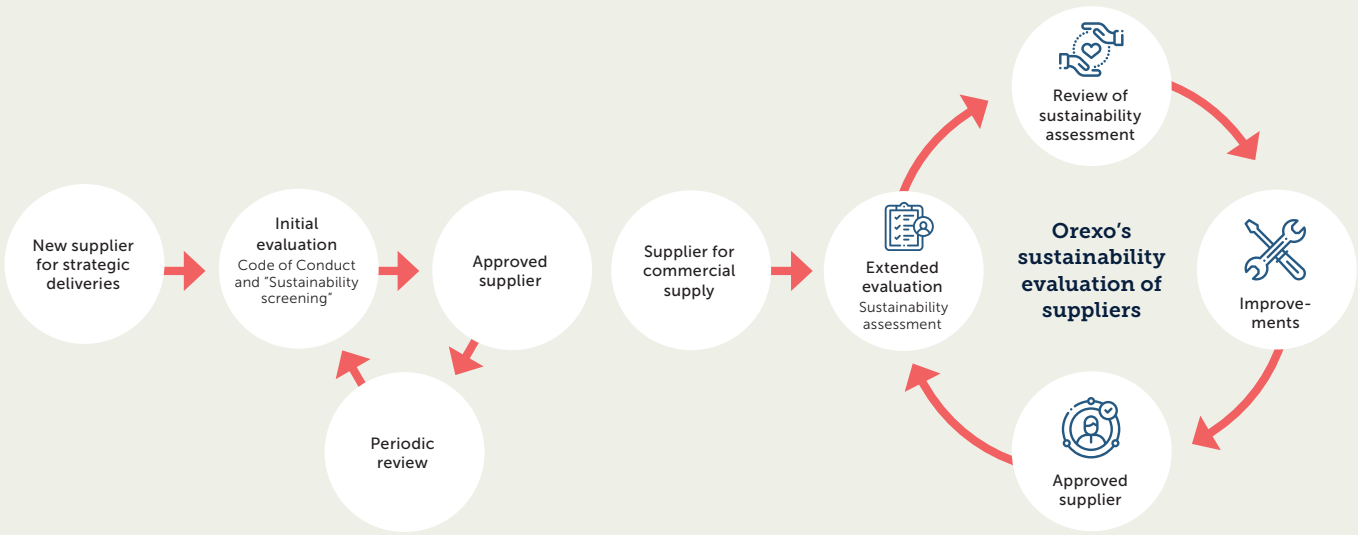
Business Compliance and Ethics Code					
Human rights	Labor and employment	Environmental care	Prevention of corruption and conflict of interest	Research and product development	Patient safety and benefits
Supplier Code of Conduct	US Comprehensive Compliance Policies	Safety, Health and Environment Policies	Human Resources Policies		

All board members, managers, employees, consultants, and temporary staff at Orexo AB and its subsidiaries must follow the Code of Conduct. All personnel and contractors are required to read and understand Orexo's Code of Conduct, which is done by implementaiton in the document handlings systems. In Sweden this is done at least biannually with each individual reviewing and reaffirming they understand and practice in accordance with the Business Compliance and Ethics Code. The US Code of Business Conduct and Ethics implements the company's Code of Conduct with the addition of specific requirements to ensure compliance with US legislation. It is reviewed and reaffirmed annually.

Supporting Orexo's Code of Conduct there is a Comprehensive Compliance Program consisting of policies and procedures that guide managers and employees in following the requirements in their day-to-day work. It is structured to mitigate legal and regulatory risks associated with research and development, quality control and the US commercial pharmaceutical operations. The Compliance program is also aligned with international standards and well-known initiatives, such as the International Labor Organization conventions and the UN Guiding Principles on Business and Human Rights.

Orexo's management systems assist personnel in accessing and tracking the policies and procedures relevant to their role. Policies and procedures are reviewed on an ongoing basis as the business evolves or at least once every two years. All new employees receive introductory training including the Code of Conduct, role-specific compliance requirements, and the Safety, Health and Environment framework. Orexo plans to develop even more comprehensive sustainability training as part of its long-term sustainability plan.

Supplier evaluation



Whistleblower system to make voices heard

Orexo must be a transparent, healthy, and open organization that complies with laws, regulations, and the company's Code of Conduct. The Code of Conduct urges individuals to heed and report suspected business ethics violations or unethical conduct, without fear or threat of retaliation.

If someone suspects that a serious violation has occurred, it must be reported. Orexo has processes and tools for anonymous reporting in place. The Swedish operations use the tool WhistleB and the US operations use Ethics Point. During 2022 one report was filed via Ethics point, which was investigated and solved internally.

Marketing and sales

For businesses within the healthcare sector, recognized risks include unethical business and compliance violations in interactions with healthcare professionals, healthcare organizations and government officials. Orexo has zero tolerance for any of these violations.

Orexo's main market is in the US, where the subsidiary Orexo US Inc is responsible for product commercialization. The subsidiary operates in accordance with laws and regulations established at the federal and state levels. The guidelines – US Comprehensive Compliance Policies – describe acceptable marketing practices and activities related to drug sales, including the reporting of marketing expenses and interactions with government authorities and healthcare representatives. All employees in the US are trained in these, both through teacher-led training and virtual training. New sales representatives receive specific training covering promotional policies, federal laws and regulations related to pharmaceutical sales and ethics. After this, there are periodic reminders and refreshers, with opportunities to discuss examples.

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. All information requested by the authorities was delivered. Orexo has not been provided with any background information to the requests and will continue to collaborate with the US authorities to ensure they receive the necessary information and to understand the scope of the investigations.

Responsible supply chain and purchasing

A sustainable supply chain means that purchasing decisions and relationships must align with the company's principles and values for business ethics, work environment, human rights, and the environment. Orexo's minimum requirements for suppliers are explained in the Supplier Code of Conduct.

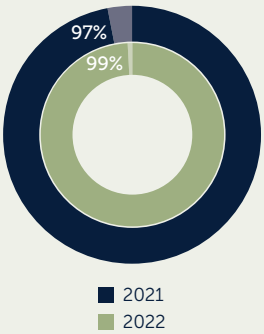
There are risks regarding several environmental, health, safety, and labor aspects of our suppliers. Although Orexo's direct suppliers are located in countries with strong legislation, there are still risks. And, as subcontractors[1] may be found in many different parts of the world, it is important to ensure that all direct suppliers have good governance and processes.

Orexo is working to prevent, remedy and improve sustainability work throughout the supply chain. By setting requirements on direct suppliers and building awareness of their responsibilities, Orexo can move the needle on sustainability jointly with the suppliers.

Orexo's Responsible Sourcing Program ensures the company's Supplier Code of Conduct and sustainability requirements are implemented. Orexo evaluates the sustainability aspects of strategically important suppliers, including those for commercial supply[2] (i.e. material suppliers).

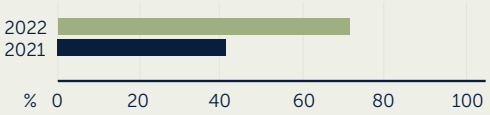
The evaluation of suppliers covers legal adherence, as well as compliance with human rights, business ethics, safety, health and environmental impacts. The evaluation also covers the supplier's handling of waste and wastewater, which is an important aspect to reduce the risk of pharmaceuticals being released into the environment. It is carried out through evaluation questionnaires, supplier interviews and, if necessary, site visits. Their sustainability statuses are continuously monitored through supplier management. During 2021–2022, all commercial suppliers were re-evaluated and the inclusion criteria for those needing initial sustainability screening was expanded.

Implementation Orexo's Code of Conduct (staff)

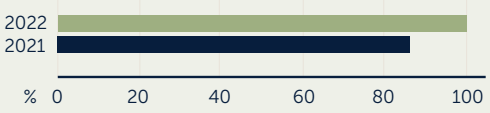


Suppliers
Evaluation of Code of Conduct and sustainability

Completion of initial supplier sustainability evaluation
(Supplier for commercial supply and other strategic deliveries)



Completion of extended supplier sustainability evaluation
(Supplier for commercial supply)



Extended data can be found in the Sustainability data summary

[1] Companies delivering chemicals, intermediates, and other materials to production.
[2] Commercial supply means goods for human use, commercial supply, and any related services.

Access to healthcare

Access to good healthcare is essential to improve treatment outcomes for patients and is fundamental to an equitable society. Orexo is determined to contribute to UN sustainable development goal 3, and more specifically 3.5 – to strengthen the prevention and treatment of substance abuse.

Increase access to healthcare by patient support and strengthening knowledge of substance abuse and mental illness

Sustainability topic	**Access to healthcare**	
Long-term ambition	More patients in economically or medically vulnerable areas have access to Orexo products	Orexo is engaged in multiple projects in collaboration with healthcare and other stakeholders to reach underserved patient groups
Target 2030	100% of Orexo products have patient assistance programs in place	Target covering number and reach of collaboration projects to be defined

Successfully improving treatments for patients and offering better access to healthcare is made possible through innovative pharmaceuticals based on the drug delivery platform amorphOX®. Orexo is working closely with several partners to enable its commercial stage drugs and digital therapies to reach more patients.

Acess to Orexo Products

To alleviate suffering and improve people's quality of life, equitable access to effective treatments is critical. Orexo is working with various groups including, lobbyists, authorities, policy makers, advocates, industrial organizations, and academia, to increase access to treatments as well as to create awareness and knowledge about digital therapies that have the potential to widen access to therapeutic support. Partnerships, collaborations, and financial assistance programs also extend patient reach, helping to widen access to care.

Orexo continues to support the removal of financial barriers that impede access to the company's products. To enable greater access to ZUBSOLV®, two programs are currently running. The ZUBSOLV® Co-pay assistance program saves patients significant costs for ZUBSOLV® by using the Co-pay card. The ZUBSOLV® 15 tablet voucher program provides up to two free 15 tablet vouchers. Additionally, a ZUBSOLV® Patient Assistance Program provides free products to patients that meet the US poverty level requirements. The continued reduction in the programs is explained by the lower market share due to the addition of generics to the formulary status at the insurance companies Humana and United Health Group.

In 2020, Orexo entered into a licensing and delivery agreement with Accord Healthcare to make ZUBSOLV® available on the EU market. There are estimated to be 1.3m high-risk opioid users in Europe[1], yet treatment rates are low. In Q2 2022, Accord Healthcare continued its EU launch. Since then, ZUBSOLV® has been made available in nine countries[2].

The need for therapeutic support

To address the lack of psychosocial counseling in the treatment of opioid-dependent patients, Orexo entered

[1] European Monitoring Centre for Drugs and Drug Addiction (EMCDDA).
[2] Sweden, the UK, Spain, the Czech Republic, Slovenia, Romania and the three Baltic states.

a partnership with GAIA in 2019 to develop a digital therapy for opioid use disorder, MODIA®. In 2022, a clinical trial was initiated. In addition to MODIA®, Orexo offers two more evidence-based digital therapies: vorvida® (for alcohol management) and deprexis® (for depression). Orexo strongly believes that digital therapies complement traditional treatments and enable more patients to access therapies. Orexo is working to increase awareness and knowledge about digital therapies and is collaborating with various groups to open viable reimbursement routes, which are critical to accessing patients.

Orexo continues to develop collaborations and partnerships for its digital therapies including the relationship with Trinity Health in North Dakota. Administrative processes and support systems were established in 2022 to enable effective patient access and reimbursement of vorvida® and deprexis® through a collaborative care model. Further, Orexo has initiated collaborations with Veterans Affairs, providing access to deprexis® for approximately 15 million veterans and their families. At the end of 2022 Orexo, together with the Wayside Recovery Center in Minneapolis, was awarded a grant for initiating a project to support pregnant women with mental health and substance use disorder needs. The project includes 60 patients who will get access to vorvida® and deprexis®.

Innovation and collaboration

Orexo's new proprietary drug delivery platform amorphOX® offers new opportunities to develop drugs with good chemical and physical stability, providing benefits for patients and the environment. The amorphOX® platform is well-suited to the development of drugs that can be administered intranasally, which is a simple and convenient way for patients to take medicines. The platform also provides an opportunity for pharmaceutical products with a longer shelf-life.

Overdoses from opioid misuse continue to cause many deaths. During 2022, Orexo finalized the development of OX124, a rescue medication designed to counteract overdoses caused by the most powerful synthetic opioids that are currently behind the majority of fatalities in the US. OX124 is based on the amorphOX® platform.

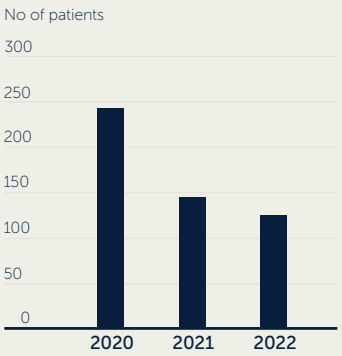
Orexo's new pharmaceutical candidate OX640, a nasal epinephrine product for the emergency treatment of allergic reactions, is also based on the amorphOX® platform. Epinephrine is a very unstable active ingredient sensitive to chemical degradation and today's commercially available epinephrine products have a limited shelf life. OX640 shows promising data and could provide a needle-free alternative with the potential for faster lifesaving treatment. Furthermore, the amorphOX® platform may provide for a product with twice the shelf-life compared to existing treatments, resulting in reduced wastage of unused medicine.

During 2022, Orexo initiated a feasibility study with a vaccine company, in which amorphOX® is applied to their product. Pending the outcome, this has the potential to lead to significantly improved distribution rates, particularly in remote areas with insufficient cold chains.

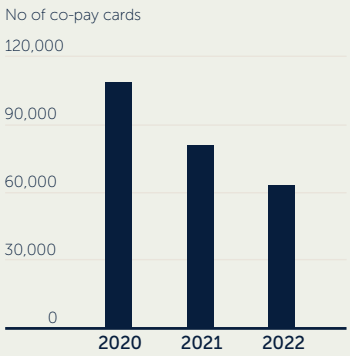
Orexo continues to provide financial support, scientific expertise, and an industry perspective to SweDeliver, an interdisciplinary collaboration between academia and industry, with the scientific focus on important research challenges in parenteral, oral, and pulmonary drug delivery. To strengthen the development of future pharmaceutical researchers, Orexo regularly provides university students with thesis project opportunities, hosts study visits and delivers lectures. Under the SweDeliver collaboration, last year Orexo had a student adding value to one of our important amorphOX® projects.

ZUBSOLV® patient programs

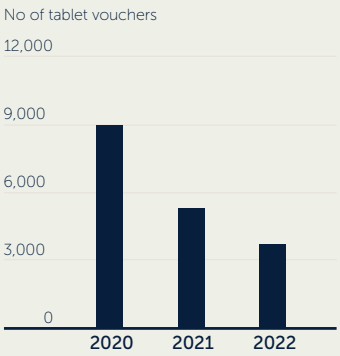
Patient assistant program



Co-pay assistance program



Tablet voucher program



Extended data can be found in the Sustainability data summary.

Sustainable Employees

Orexo's people are our strength. At Orexo one another's contributions are highly valued as it is understood that joint efforts are the key to the company's success. Orexo's workplaces must be safe and healthy environments where every employee feels respected and has the same opportunities. The company believes in an open-minded culture that sparks creativity and new ideas.

In all our teams, create a healthy working climate where inclusion and diversity are a matter of course

Sustainability topic	**Employer of choice**			**Inclusion and diversity**	
Long-term ambition	A safe and healthy workplace with no workplace accidents or work-related illnesses	Orexo's employees experience a good work-life balance	Orexo's employees are satisfied and proud of working for Orexo	Gender equality in management positions	Orexo is seen among employees as diverse and inclusive
Target 2030	No serious accidents No work-related illnesses	≥ 75 % experience a work-life balance (employee survey)	≥ 75 % are satisfied working at Orexo (employee survey)	% women in management positions	Target for diversity and inclusiveness to be defined 2023

Orexo's success is based on a commitment to the well-being of every employee. Attracting and keeping the best people means offering them mutually respectful workplaces where they are valued for their individuality as well as their professional capabilities.

The importance of wellness and health is governed by the company's overall Code of Conduct. There are connected policies and procedures in place that are structured to mitigate the risks associated with the work environment. These include governance of safety, health, recruitment, equal treatment, gender equality, discrimination, and conflicts of interest as well as health insurance and other employment benefits.

Safety and health of employees

Annual health and safety targets, and the workplace activities they encompass, are based on risk assessments and specific issues raised in the organization, such as through employee surveys. The greatest risks identified are linked to mental health, due to a high workload, but there are also risks linked to the handling of active pharmaceutical ingredients and other hazardous substances. The handling of hazardous substances is well mitigated through policies and routines. For the field-based salesforce in the US, driving is considered a significant risk. This is mitigated in a number of ways. Technical risk reduction is achieved by only choosing vehicles for the fleet that include multiple safety features, for example 5-star crash ratings and All Wheel Drive. Organiza-

tional approaches include policies that require extra vigilance in operating a vehicle, for example only "hands free" cellphone use and no other distractions while driving.

In addition to general risk assessments the overall work situation is monitored through annual employee surveys[1]. The results are followed up and evaluated by the management team and used as a tool at group and departmental levels to take concrete actions to improve the work environment. In 2022 the results across Sweden and the US exceeded the already high results of previous years, revealing that more than 4 out of 5 employees are satisfied with working at Orexo. The company continue to use a hybrid working model with the possibility of working 2 days from home. This flexibility is appreciated by the employees.

For the Sweden office, the employee survey shows acceptable workloads and a good work-life balance. Employees especially mention participation, learning at work and social climate. The 2021 employee survey in Sweden showed a need for further development in the area of goal orientation. During 2022, Orexo improved the communication of the company's vision and goals, and clarified the process of goal cascading, which resulted in better results than the survey last year. In the 2021 US employee survey professional development was pointed out as an area for improvement. During 2022 a Head of Training was appointed to improve tools and training for sales employees and to coach employees and managers on performance and development concerns.

Overall, the surveys show the company listens to employees and is not afraid to take bold steps to make improvements of both the work environment and the workplace.

An important way of achieving physical and mental well-being is daily physical exercise. To encourage this, gym facilities and fitness classes are offered free of charge in Sweden. Similarly in the US, employees are offered wellness benefits, one of which is a paid subscription to a program that offers virtual fitness classes in addition to mental health and other employee support resources. Orexo also offers an Employee Assistance Program (EAP) to support individuals with issues impacting mental and emotional well-being.

Major incidents or accidents are followed up and investigated in all Orexo operations and no major incidents or accidents happened during 2022. Orexo is pleased to see that the company's preventative measures have resulted in 5 years without any major incidents or accidents.

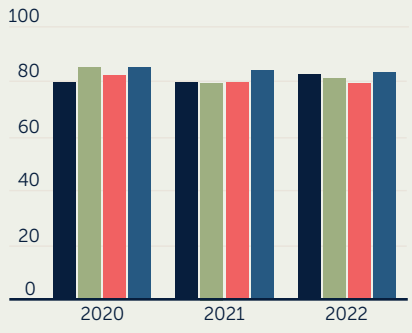
Diversity and gender equality

Employees of different ages, genders, backgrounds, and experiences contribute to new thinking and innovative solutions. Diversity and gender equality are therefore important for Orexo to achieve the company's goals and ambitions, and there are non-discrimination policies in place. Activities in the long-term sustainability plan include developing hiring processes to better promote diversity and inclusivity. In the US every new hire completes training on implicit bias and equal employment opportunity laws, and this is also given as refresher training annually to all employees.

In Sweden a survey was carried out in 2022 to ensure that the employees perceive Orexo as a workplace with equal conditions and opportunities for everyone. The survey did not show any deviations. In 2023 the plan is to move forward with education and information to proactively maintain this outcome.

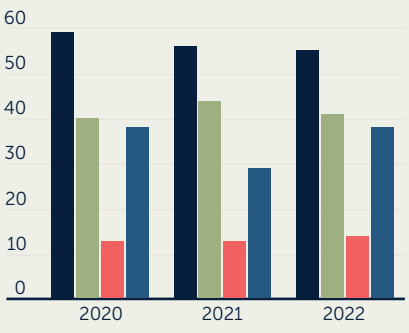
Further, equal pay surveys are conducted every year in Sweden. The 2022 surveys discovered no unreasonable salary differences. In the US salaries are not evaluated yearly, but regularly, and they are equitable.

Employee satisfaction & Work life balance (%)



- Employee satisfaction, Orexo AB
- Employee satisfaction, Orexo US, Inc.
- Work-life balance, Orexo AB
- Work-life balance, Orexo US, Inc.

Gender equality (%)



- Female employees
- Women in management positions
- Women in executive management team
- Women on the Board of directors

Extended data can be found in the Sustainability data summary.

[1] Springlife employee survey Orexo AB, DecisionWise Orexo US, Inc.

Environment and **climate change**

Climate change is the single biggest threat facing ecosystems and humanity. A sustainable future requires joint responsibility for the environment. All human activity depends on environmental ecosystems, including access to clean air, clean water, and natural resources. Orexo's ambition is to reduce resource use and to minimize the company's contribution to climate change from activities and products.

Our ambition is to reduce our impact on environment and climate change across all our activities and our products.

Sustainability topic	**Reduce climate impact and resource use**	**Reduce our product environmental footprint**
Long-term ambition	Reduce our greenhouse gas emissions throughout the supply chain	Reduce our "product environmental footprint" (carbon and material usage)
Target 2030	Reduce our greenhouse gas emissions (scope 1–3). Target to be set 2023	Target for reduction of carbon and material usage to be defined

The overall environmental work at Orexo is governed by the environmental policy and guidelines. The sustainability review identified climate change and responsible manufacturing and purchasing. This led to updated sustainability goals with two long-term targets to reduce its climate impact from the operations and from the products.

A data collection process has been started that will, in turn, inform exact targets. As Orexo's manufacturing of products, packing and supply to market are performed by contracted manufacturers, the focus will be on climate data in scope 3. Orexo has great confidence in its suppliers but remains accountable for understanding the environmental impact of the supply chain and intends to make a positive impact through influence and communication.

Reduce climate impact and resource use

A sustainable supply chain means that purchasing decisions and relationships must align with the company's ethical principles. Upholding Orexo's sustainable responsibilities is achieved through the environmental, social and governance (ESG) requirements and by reviewing and choosing good suppliers. While the company does not yet have empirical data that evidences the environmental impact of its supply chain, this is a focus area to enable a better understanding. Despite that it is still important to minimize any negative environmental consequences of Orexo's own operations in Sweden and the US.

During 2022, Orexo started implementing the Greenhouse Gas protocol and mapped the activities in scope 1 and 2. Orexo's scope 1 emissions come from the sales team's car fleet. For the offices and the lab operations there are no scope 1 emissions. Regarding scope 2 emissions, all facilities are leased and shared with other tenants. The facilities use energy for electricity, heating and cooling.

In the Swedish offices and R&D facilities there is a "green agreement" that requires the premises to be heated and cooled with climate compensated district heating/cooling. The electricity is purchased from renewable resources, so the scope 2 emissions in Sweden are zero. The agreement also sets out an expectation of cooperation to reduce the environmental footprint. In 2022 a project was initiated together with the landlord to look for energy reduction opportunities in the facilities.

The Orexo offices in the US are a small part of a bigger complex. The complex is ENERGY STAR certificated, a third-party reviewed verification that the building is energy efficient.

The energy usage for the US offices is calculated based on the size of the offices and the total energy consumption in the building. Heating and cooling are based on electricity and hence all energy usage comes down to a total use of electricity. In 2022, Orexo approached the landlord for more information, but to date these details are pending.

In 2023 Orexo will extend the work to influence scope 3 emissions through full implementation of the Greenhouse Gas protocol. An important part of the scope 3 work will be to reduce the emissions caused by business travel, production, and commercial supply.

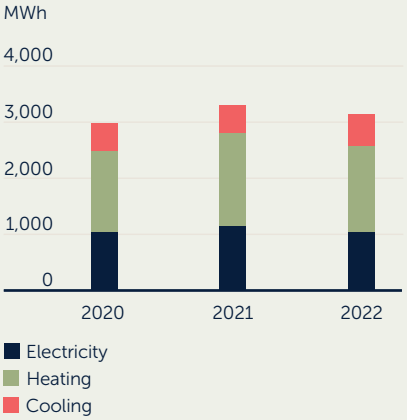
Orexo's main commercial market is in the US. The contracted manufacturers for ZUBSOLV® and several of the raw material suppliers are based in the US, as well as our own sales and marketing organization. This reduces the need for business travel as well as transport in the supply chain, but some travel is still needed due to the geographical reach of the organization. Orexo is always improving digital working methods and carefully assesses the necessity of any travel requirements.

Waste management is another important area. The company reuses and recycles in favor of waste for incineration. In 2022 waste management was not prioritized, but in 2023 Orexo will carry out a renewed waste analysis. In the US, lage amounts of printed material is used. The company is working on reducing its consumption by paperless marketing, this achieved an 28 % reduction between 2020 and 2022.

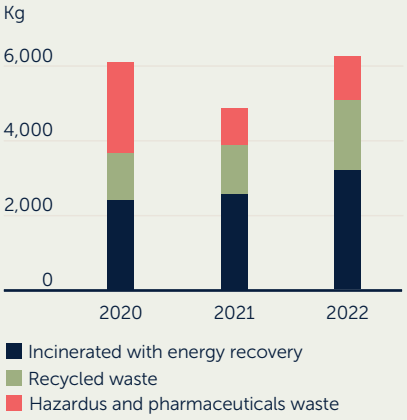
Product environmental footprint reduction

The environmental footprint of a product is, to a large extent, decided in the design phase. In the sustainability plan Orexo's ambition is to reduce its product environmental footprint by introducing sustainability as clear part of the product development process. This will integrate sustainability in decision-making. The quantification of environmental impacts and the possibilities for improvements as well as ensuring safety, health and environmental aspects of projects will be considered throughout the product development.

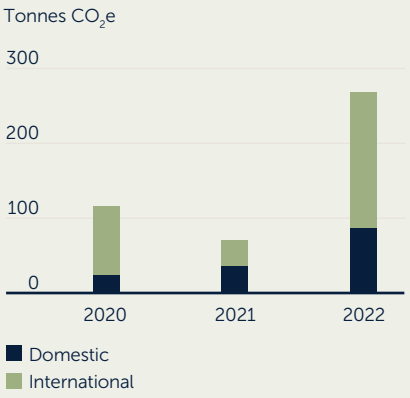
Energy



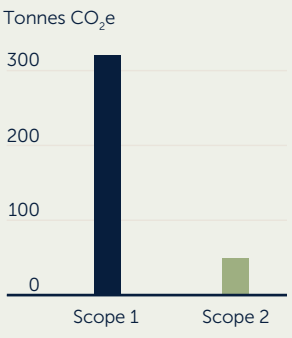
Waste



Flight travel



Climate impact



Extended data can be found in the Sustainability data summary.

Sustainability **data summary**

Responsible business

	2018			2019			2020			2021			2022		
	Orexo AB	Orexo US, Inc.	Orexo group	Orexo AB	Orexo US, Inc.	Orexo group	Orexo AB	Orexo US, Inc.	Orexo group	Orexo AB	Orexo US, Inc.	Orexo group	Orexo AB	Orexo US, Inc.	Orexo group
Responsible employees															
Implementation code of conduct (%)	85	100	94	83	100	93	100	100	100	94	100	97	99	100	99

	2021	2022
	Orexo group	Orexo group
Sustainable supply chain		
Total number of suppliers for commercial supply and other strategic deliveries	29	24
Completion of initial supplier sustainability evaluation (%)	41	71
Number of suppliers for commercial supply	7	7
Completion of extended supplier sustainability evaluation (%)	86	100

Sustainable employees

	2018			2019			2020			2021			2022		
	Orexo AB	Orexo US, Inc.	Orexo group	Orexo AB	Orexo US, Inc.	Orexo group	Orexo AB	Orexo US, Inc.	Orexo group	Orexo AB	Orexo US, Inc.	Orexo group	Orexo AB	Orexo US, Inc.	Orexo group
Employment															
Number of employees	55	74	129	54	73	127	53	85	138	54	67	121	58	69	127
employees with permanent contract (%)	98	100	99	100	100	100	98	100	99	96	100	98	100	99	99
employees with temporary contract (%)	2	0	1	0	0	0	2	0	1	4	0	2	0	1	1
Staff turnover (%)	9	—	—	17	—	—	4	—	—	11	—	—	9	37	24
Number of employees + consultants	63	77	140	63.5	79	142.5	79	89	168	72	73	145	77	74	151
consultants (%)	13	4	8	15	8	11	33	4	18	25	8	17	33	7	19
Gender equality															
Female employees (%)	55	64	60	54	47	50	55	61	59	57	55	56	52	58	55
women in management positions (%)	33	50	42	38	50	44	30	54	43	44	44	44	42	40	41
women in executive management team (%)	n/a	n/a	0	n/a	n/a	13	n/a	n/a	13	n/a	n/a	13	n/a	n/a	14
women in board of directors (%)	n/a	n/a	29	n/a	n/a	29	n/a	n/a	38	n/a	n/a	29	n/a	n/a	38
Health and safety															
Employee satisfaction index (%)	78	83	n/a	81	83	n/a	80	85	n/a	80	79	n/a	83	81	n/a
Employee work-life balance (%)	—	—	n/a	—	—	n/a	82	85	n/a	80	84	n/a	79	83	n/a
Employee absence due to illness (%)	3.9	1.1	0.0	1.7	1.2	1.4	1.8	0.5	1.0	0.9	0.7	0.8	1.8	1.0	1.4
Serious accidents	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Accidents	5	0	5	5	0	5	1	1	2	1	0	1	1	0	1
Serious incidents	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Incidents	12	0	12	12	0	12	2	0	2	4	0	4	2	0	2

Access to healthcare

	2018	2019	2020	2021	2022
	Orexo group	Orexo group	Orexo group	Orexo group	Orexo group
ZUBSOLV® Patient Programs					
Patient Assistant Program (number of patients)	542	451	243	145	125
Co-pay assistance program (number of co-pay cards)	170,232	150,452	108,826	81,225	63,392
Tablet voucher program (number of tablet vouchers)	36,947	23,420	8,957	5,325	3,727

Environment and climate change

	2018			2019			2020			2021			2022		
	Orexo AB	Orexo US, Inc.	Orexo group	Orexo AB	Orexo US, Inc.	Orexo group	Orexo AB	Orexo US, Inc.	Orexo group	Orexo AB	Orexo US, Inc.	Orexo group	Orexo AB	Orexo US, Inc.	Orexo group
Energy															
Electricity (MWh)	829.6	—	—	989.1	—	—	855.5	173.8	1,029.3	938.4	166.1	1,104.4	863.8	159.4	1,023.2
Heat (MWh)	1,681.8	—	—	1,627.7	—	—	1,433.5	0.0	1,433.5	1,672.7	0.0	1,672.7	1,535.7	0.0	1,535.7
Cooling (MWh)	448.7	—	—	464.3	—	—	506.3	0.0	506.3	493.1	0.0	493.1	567.5	0.0	567.5
Total energy usage (MWh)	2,960.1	—	—	3,081.0	—	—	2,795.4	173.8	2,969.2	3,104.2	166.1	3,270.3	2,967.0	159.4	3,126.4
Share renewable energy (%)	100.0	—	—	100.0	—	—	100.0	0.0	94.1	100.0	0.0	94.9	100.0	0.0	94.9
Waste															
Incinerated with energy recovery (kg)	2,588	— *	2,588	2,650	— *	2,650	2,400	— *	2,400	2,550	— *	2,550	3,150	— *	3,150
Recycled waste (kg)	651	— *	651	615	— *	615	1,259	— *	1.,259	1,333	— *	1,333	1,886	— *	1,886
Hazardous and pharma waste (kg)	1,160	— *	1,160	1,641	— *	1,641	2,424	— *	2,424	976	— *	976	1,217	— *	1,217
Total (kg)	4,399	— *	4,399	4,906	— *	4,906	6,083	— *	6,083	4,859	— *	4,859	6,253	— *	6,253
Recycled materials vs energy recocery (%)	20.1	— *	20.1	18.8	— *	18.8	34.4	— *	34.4	34.3	— *	34.3	37.5	— *	37.5
Flight travel															
Domestic (tonnes CO_2e)	4.6	—	—	8.1	—	—	0.6	18.9	19.5	0.0	33.0	33.0	1.0	83.1	84.1
International (tonnes CO_2e)	229.9	—	—	272.0	—	—	79.4	14.8	94.2	34.6	0.0	34.6	177.0	5.8	182.8
Total (tonnes CO_2e)	234.5	—	—	280.1	—	—	80.0	33.7	113.7	34.6	33.0	67.6	178.0	88.9	266.9
Total carbon emission															
Scope 1 (tonnes CO_2e)	—	—	—	—	—	—	—	—	—	—	—	—	0	323	323
Scope 2 (tonnes CO_2e)	—	—	—	—	—	—	—	—	—	—	—	—	0	47	47

* Waste handling included in rental agreement, no data available.

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 2022 on pages 44–59 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.

Stockholm, March 28 2023
Ernst & Young AB.

Anna Svanberg
Authorized Public Accountant.

Board of directors' report

The board of directors and the president of Orexo AB (publ), corporate registration number 556500-0600, hereby submit the Annual Report and consolidated financial statements for the fiscal year January 1–December 31, 2022. Orexo's registered office is in Uppsala, Sweden.

Operations

Orexo develops improved pharmaceuticals and digital therapies addressing unmet needs within the growing space of substance use disorders and mental health. 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 it's 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. In Q4 2021 an awareness and educational campaign for MODIA® was initiated focusing on our existing ZUBSOLV® customers.

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.
- 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, Israel 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. The patents are valid until September 2024 in Japan and Australia .
- 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.

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 evidence-based 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 2022 sales force activity was still 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.

For DTx we continued to see a high utilization of MODIA®. Orexo expects to receive the first payments in Q1 2023 as reimbursement pathways are confirmed. MODIA® sales is highly complementary to our sales of ZUBSOLV® and with the introduction of MATCore™, we envisage additional synergies between our pharmaceutical business and DTx. Consequently, we have taken the step to integrate the two businesses into one organization with one manager, Bob DeLuca. With this change the existing US Pharma business will take full responsibility and accountability for driving sales of digital solutions and the resources in the Digital Therapeutics business area will be integrated into the US Pharma. We will continue to follow up the businesses separately and keep our current segment reporting. The re-organization will increase our agility and ability to prioritize resources across the business in the US to the areas with the greatest opportunities.

The development organization focused during the year on progressing the pipeline of internal development projects. The main focus has been on OX124, our highdose medication for opioid overdose, and the objective of filing with the FDA before end of 2022, which happened in January 2023, primarily due to the delay in administrative processes and responses from the FDA. In the Q4 2022 Interim Report, Orexo announced positive data from phase 1 clinical study for OX640, a nasal epinephrine rescue medication for allergic reactions. Futhermore in the same quarter Orexo shared information about exploratory feasibility studies of amorphOX® initiated in collaboration with two leading biopharmaceutical and vaccine companies. The amorphOX™ platform has several significant advantages to a broad range of products, such as rapid dissolve time and excellent stability. It is a very dynamic platform which will form the backbone of Orexo's pharmaceutical developments in the coming years.

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 126 (121) employees.

Key events

The business

Within the R&D function the development of the high-dose medication for opioid overdose containing naloxone, OX124, was finalized. In addition, the first clinical study for OX640, medication for allergic reactions containing epinephrine, was successfully conducted. OX124 and OX640 are based on the drug delivery platform amorphOX®, which in 2022 also was tested with other substances, including both small and large molecules. During the year Orexo's partner, Accord Healtcare, initiated the launch of ZUBSOLV® in the EU.

In the US, ZUBSOLV® was added to the New York Medicaid MAT list and through the modiaONE™ concept physicians prescribing buprenorphine/nalxonce got the opportunity to test MODIA® among their patients. Late in December a new law was passed expected to increase access to treatment among patients with OUD in the US.

The MODIA® clinical study continued during and in total 437 patients were recruited. In addition to the accelerated launch of MODIA® a ten-year contract was signed with Veterans Affairs providing access to deprexis® among up to 15 million Americans suffering from depression. During the year Trinity Health in North Dakota announced that patients in their network will have access to deprexis® and vorvida®.

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. All information requested by the authorities have been delivered. Orexo has no knowledge of the background to the requests and will continue to collaborate 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.

As a response 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..

Orexo has currently ten patents listed in the Orange Book (US Patent Nos. 8,470,361; 8,658,198; 8,940,330; 9,259,421; 9,439,900; 10,874,661;10,946,010; 11,020,387, 11,020,388 and 11,433,066) with expiration dates ranging from December 2027 to September 2032.

In Q4 2022 the work continued to prepare for the trial that started on January 30, 2023, in the US District Court for the District of New Jersey. The outcome of the trial is expected during the summer of 2023.

ZUBSOLV® US market access update

The business environment set by the Covid-19 pandemic continues to cause challenges for ZUBSOLV®. While access to waivered physicians' offices has recovered, face-to-face access to the physicians themselves remains at half of pre-pandemic levels. Despite the limitations, ZUBSOLV® a had mild year over year decline in the reimbursed open formulary segment of the market. The previously exclusive reimbursement contracts and non-reimbursed segments of the market saw continued declines.

Financial Performance

Condensed consolidated statement of operations

SEK million	2022	2021
Net revenues	624.3	565.0
Cost of goods sold	–102.6	–78.9
Gross profit	**521.7**	**486.1**
Selling expenses	–199.0	–280.4
Administrative expenses	–202.3	–151.5
Research and development costs	–318.0	–272.3
Other operating income and expenses	13.7	4.0
Operating earnings	**–183.9**	**–214.1**
Net financial items	13.5	–8.4
Earnings after financial items	**–170.4**	**–222.5**
Income tax	–7.2	–1.0
Net earnings for the period	**–177.6**	**–223.5**

Revenues

Net revenues

Net revenues were distributed as follows:

Net revenues

SEK million	2022	2021
ZUBSOLV® US product sales	571.4	522.7
US Pharma – total	**571.4**	**522.7**
Digital Therapeutics (DTx) product sales	0.4	1.1
Digital Therapeutics (DTx) – total	**0.4**	**1.1**
Abstral® – royalty	30.4	32.1
Edluar® – royalty	10.4	9.1
ZUBSOLV® – ex US	11.8	0.0
HQ & Pipeline – total	**52.6**	**41.2**
Total	**624.3**	**565.0**

Commercial products

Total net revenues for the year amounted to SEK 624.3 million (565.0). The increase is driven by higher ZUBSOLV® US revenue due to stronger USD exchange rate and launch of Zubsolv Ex-US in the EU by Orexo's partner Accord Healthcare.

ZUBSOLV® US revenue ended at SEK 571.4 million (522.7), 9 percent above the previous year's level. The US buprenorphine/naloxone market grew by 5.0% slowed down temporarily by Covid-19.

Within the commercial payer segment, ZUBSOLV® was nearly universally reimbursed in 2022. This segment saw the smallest annual market growth of any payer segment. Total ZUBSOLV® commercial volume declined, with the majority of the decline coming from the formerly exclusive payers UHC and Humana Commercial and non-reimbursed segment. ZUBSOLV® volume grew mildly in the Caremark national formulary.

Within the public payer segment, ZUBSOLV® increased its reimbursement to almost half of the total public market. This access increase was driven by gaining coverage in New York Medicaid, the 3rd largest single formulary state. The public segment is both the largest and fastest growing segment. Total ZUBSOLV® public volume declined, due to the formerly exclusive payer Humana Medicare D.

In the open public segment ZUBSOLV® volume grew mildly. ZUBSOLV® almost doubled in volume in New York Medicaid, and more than doubled in volume in Kentucky Medicaid. Kentucky Medicaid is the 2nd largest single formulary state. Large states such as California and Illinois grew in volume as well.

DTx sales efforts have focused on testing new reimbursement routes and new commercialization concepts. The recognized net revenues amounted to SEK 0.4 million (1.1).

Total Abstral® royalties during the year amounted to SEK 30.4 million (32.1). 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 (9.1).

Zubsolv Ex-US revenues amounted to SEK 11.8 million (–).

Expenses and earnings

Cost of goods sold

Cost of goods sold amounted to SEK 102.6 million (78.9), explained by US Pharma of SEK 85.2 million (67.5). Royalties and technical infrastructure costs for DTx amounted to SEK 10.9 million (11.0). Cost of goods sold for Zubsolv Ex-US amounted to SEK 6.6 million (0.4).

Selling expenses

Selling expenses amounted to SEK 199.0 million (280.4), the decrease is due to significantly lower selling expenses in DTx.

Administrative expenses

Administrative expenses amounted to SEK 202.3 million (151.5). The higher expense level in 2022 is mainly explained by negative impact of stronger USD exchange rate and by higher legal expenses for IP litigation.

Research and development costs

Research and development costs amounted to SEK 318.0 million (272.3) explained by negative impact of stronger USD exchange rate, higher costs for the MODIA® study and OX640 project.

Other income and expenses

Other income and expenses amounted to SEK 13.7 million (4.0) mainly explained by exchange-rate gains derived from revaluations of parent company balance sheet items in foreign currency, predominantly in USD.

Depreciation

Depreciation and amortization amounted to SEK 68.7 million (53.0). The increase is mainly related to amortization of DTx milestones and depreciation of DTx enterprice platform. This also includes amortization of previously capitalized R&D costs of SEK 15.4 million (15.4) related to the ZUBSOLV® induction label.

Net financial items

Net financial items amounted to SEK 13.5 million (–8.4) explained by higher positive unrealized exchange rate impact of SEK 37.3 million (25.0) derived from the parent company's foreign currency bank accounts mainly in USD partly and by higher interest income of SEK 4.0 million (–) from short-term cash investments. This was partly offset by higher costs of SEK 25.5 million (14.3) for the bond loan.

Income tax

Income tax for the year amounted to SEK –7.2 million (–1.0) explained by negative adjustment to deferred tax assets related to temporary differences of SEK –3.4 million (3.4) partly offset by lower tax in the US of SEK –3.9 million (–4.5).

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 –177.6 million (–223.5).

Segment reporting

Orexo Group has its operations in Sweden and the US. 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 571.4 million (522.7).

The increase in US Pharma revenues was driven by stronger USD exchange rate and improved pricing. This was partly offset by lower ZUBSOLV® demand mainly due to overall market growth rates, which still remain below pre-Covid levels and due to competition in the previously exclusive plans United Health Group and Humana. Also, lower positive adjustments of accrued product returns had a negative impact. In local currency US Pharma net revenues amounted to USD 56.5 million (60.9) .

The EBIT contribution from US Pharma amounted to SEK 308.4 million (278.2), equal to an EBIT margin of 54.0 percent (53.2). The increase is explained by higher sales and gross profit.

Digital Therapeutics (DTx)

Sales efforts during the year focused testing new reimbursement routes and new commercialization concepts. The recognized net revenues were SEK 0.4 million (1.1).

EBIT amounted to SEK –189.1 million (–249.7), mainly explained by significantly lower selling costs.

HQ & Pipeline

Partner revenues amounted to SEK 52.6 million (41.2) mainly explained by ZUBSOLV® ex-US revenues related to sales in the EU by Orexo's partner Accord Healthcare. Edluar® royalty amounted to SEK 10.4 million (9.1). Abstral® royalty amounted to SEK 30.4 million (32.1).

EBIT amounted to SEK –303.2 million (–242.6), mainly explained by higher costs for the clinical trial of MODIA®, for OX640 and by higher legal IP costs.

Financial position

On December 31, 2022, cash and cash equivalents amounted to SEK 132.2 million (504.1)) and short-term investments amounted to SEK 219.6 million (–). The company has invested surplus cash in certificates of deposits and in US treasuries. Deposits with maturity from 6 months to 12 months are recorded as short-term investments. Cash and invested funds in total amounted to SEK 351.9 million (504.1) and interest-bearing liabilities to SEK 494.8 million (492.3), i.e. a negative net cash position including short-term investments of SEK –142.9 million (11.7).

The interest-bearing liabilities are all associated with corporate bonds. Orexo has senior unsecured callable floating rate bonds in the amount of SEK 500 million, under a framework of SEK 1,000 m with final maturity in February 2025 (the "New Bonds"). The Bonds carry a floating rate interest of 3-month Stibor + 3.75 percent per annum.

Negative cash flow from operating activities for the year amounted to SEK –156.6 million (–229.0) and was driven by negative operating earnings.

Shareholders' equity on December 31, 2022 was SEK 193.9 million (349.6) and the equity/assets ratio was 17.5 percent (27.4).

See p. 63 going concern uncertainty factors.

Investments

Gross investments in tangible and intangible fixed assets amounted to SEK 23.9 million (52.9), mainly explained by lower investments in the DTx enterprise platform and in equipment for the development organization in 2022.

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 348.2 million (365.9), of which group internal sales amounted to SEK 295.6 million (324.7). Earnings after financial items were SEK –196.8 million (–219.8), mainly explained by higher net financial items SEK 17.1 million (–5.6) mainly due to positive unrealized exchange rate impact derived from the parent company's foreign currency bank accounts mainly in USD. As of December 31, 2022, cash and cash equivalents in the parent company amounted to SEK 61.7 million (444.5) and short-term investments amounted to SEK 178.6 million (-) i.e. companys cash and invested funds amounted to SEK 240.3 million (444.5).

Outlook 2023

- The buprenorphine/naloxone market will grow 4–7 percent, based on current growth trajectory. The new legislation, effective January 1, 2023, will have a positive effect over time, but due to uncertainty related to timeline of the implementation its impact on market growth in 2023 is excluded.
- Group revenues will increase, with ZUBSOLV® US revenues being in line with 2022.
- OPEX H1 2023, slightly higher than H2 2022 (SEK 385 million), but H2 2023 will decline versus the same comparision period.
- EBITDA will reach balance in H2.

All numbers are based on exchange rates in December 2022.

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 81-82. A summary description of the operational risks attributable to research and development, production, sales and other risks is presented below.

For further information regarding financial risk see Note 3.

Going concern uncertainty factors

The shareholders' equity in the parent company is expected to decrease during the first half of 2023 and it cannot be ruled out that the shareholders' equity in the parent company may become less than half of the registered share capital unless measures are taken. This means that there are uncertainty factors related to events or conditions which may cast significant doubt regarding the entity's ability to continue as a going concern.

However, the group has sufficient funds in the form of cash and short-term investments for continued operations for at least the next twelve months and the expected negative development of the shareholders' equity in the parent company will be managed primarily through improved profitability, value-enhancing business development and cost savings and secondarily through a potential addition of external capital in some form.

The board and the CEO continuously assess the parent company's and the group's liquidity and financial resources in both the short and long term.

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.

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.

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.

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

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 126 employees.

Sustainable governance and guidelines

The company has prepared a separate Sustainability Report in accordance with the Swedish Annual Accounts Act and according to the reporting guidelines of the United Nations Global Compact. See sustainability report on pages 44–59.

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. 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. 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 for approval are excluded for the same reason. 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

[1] The guidelines were adopted by the Annual General Meeting on April 21, 2022 and are forward-looking.

remuneration shall amount to a maximum of 40 percent of the annual fixed cash salary for the CEO, up to 30 percent of the annual fixed cash salary for other members of the executive management in Sweden and up to 60 percent of the annual fixed cash salary for members of the executive management employed in the US subsidiary. The majority of the variable remuneration shall be based on the sales development and the financial results at group and subsidiary level. The percentage rate in relation to US employees reflects the subsidiary's significance for the group's earnings as well as an American labor market that is requiring an increased share of variable remuneration in order to attract and retain key employees. Furthermore, the board of directors shall have the option of allocating further variable non-recurring remuneration to the management when the board deems it to be appropriate. Such allocation of non-recurring remuneration may, after consolidation with other variable remuneration, amount to a maximum of 70 percent of the annual fixed cash salary.

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

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

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

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

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

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

Salary and employment conditions for employees

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

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

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

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

Derogation from the guidelines

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

Annual General Meeting

The same guidelines for remuneration will be proposed for the annual general meeting 2023.

Largest shareholders

At year-end 2022 Orexo had one shareholder 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.

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 accumulated loss

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

	SEK
Share premium reserve	1,187,617,020
Loss carried forward	–1,186,604,847
Profit/loss for the year	–196,806,892
Total	**–195,794,720**

The Board proposes that the funds at their disposal SEK –195,794,720 is to 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 108.

Financial information in brief – Group

Statement of operations information

SEK million	2022	2021	2020	2019	2018
Net revenues	624.3	565.0	663.6	844.8	783.1
Cost of goods sold	–102.6	–78.9	–65.6	–105.6	–171.8
Gross Profit	**521.7**	**486.1**	**598.0**	**739.2**	**611.4**
Selling expenses	–199.0	–280.4	–286.6	–191.9	–191.4
Administrative expenses	–202.3	–151.5	–102.8	–139.6	–166.7
Research and development costs	–318.0	–272.3	–224.9	–181.3	–166.8
Other operative income and expenses	13.7	4.0	–3.6	4.8	9.3
Operating earnings	**–183.9**	**–214.1**	**–19.9**	**231.2**	**95.8**
Net financial items	13.5	–8.4	–18.4	–3.3	–3.6
Earning after financial items	**–170.4**	**–222.5**	**–38.3**	**227.9**	**92.2**
Income tax	–7.2	–1.0	–46.1	–8.8	45.7
Net earning for the year	**–177.6**	**–223.5**	**–84.4**	**219.1**	**137.9**

Balance sheet information

SEK million	2022	2021	2020	2019	2018
Intangible fixed assets	217.4	248.9	252.8	113.9	103.9
Tangible fixed assets	76.1	65.9	47.3	22.0	20.0
Right-of-use assets	46.0	59.2	67.8	57.0	0.0
Deferred tax	33.1	33.4	32.7	85.5	92.8
Other financial assets	0.9	0.8	0.7	1.4	10.4
Inventories	74.6	92.3	108.4	131.8	173.6
Accounts receivable	246.5	214.0	165.2	233.8	264.5
Other current assets	62.6	55.2	52.6	38.8	31.6
Short-term investments	219.6	–	–	–	–
Cash and bank balance	132.2	504.1	505.3	816.8	589.8
Total assets	**1,109.0**	**1,273.7**	**1,232.9**	**1,501.1**	**1,286.7**
Shareholders' equity	193.9	349.6	558.5	706.4	476.1
Interest-bearing liabilities	494.8	492.3	291.0	344.3	320.6
Non-interest bearing liabilities and provisions	420.3	431.7	383.4	450.3	489.9
Total shareholders' equity and liabilities	**1,109.0**	**1,273.7**	**1,232.9**	**1,501.1**	**1,286.7**

Cash flow information

SEK million	2022	2021	2020	2019	2018
Cash flow from operating activities before changes in working capital	–206.9	–245.5	–35.2	252.5	127.9
Cash flow changes in working capital	50.3	16.5	52.0	34.5	114.1
Cash flow from operating activities	–156.6	–229.0	16.8	287.0	242.0
Acquisition of tangible, intangible and financial assets	–23.9	–52.9	–189.7	–32.0	–6.2
Sale of tangible assets	0.8	–	–	–	–
Acquisition short-term investments	–295.6	–	–	–	–
Disposal of financial assets	84.0	–	0.6	9.5	–
Cash flow after investing activities	–391.3	–281.9	–172.3	264.6	235.8
Amortization of loans	–21.4	–239.5	–84.0	–55.8	–
Borrowings	–	490.1	–	–	–
New share issues	–	–	–	2.0	0.1
Buyback of shares	–	–	–27.3	–	–0.1
Cash flow for the year	–412.8	–31.2	–283.7	210.8	235.8
Cash and cash equivalents at year-end	132.2	504.1	505.3	816.8	589.8

Other key figures

	2022	2021	2020	2019	2018
EBIT margin, %	–29.5	–37.9	–3.0	27.4	12.2
Return on shareholder equity, %	–65.4	–49.2	–13.3	37.1	34.3
Net debt, SEK million[1]	143.1	–11.7	–280.8	–527.2	–269.2
Debt/equity ratio, %	255.2	140.8	40.2	41.0	67.3
Equity/assets ratio, %	17.5	27.4	45.3	47.1	37.0
Number of shares, before dilution	34,351,732	34,319,649	34,398,815	34,621,646	34,560,456
Number of shares, after dilution	34,351,732	34,319,649	34,398,815	35,348,484	35,095,980
Earnings per share, before dilution, SEK	–5.17	–6.51	–2.45	6.33	3.99
Earnings per share, after dilution, SEK	–5.17	–6.51	–2.45	6.20	3.93
Number of employees at the end of the period	126	121	138	127	129
Shareholders' equity, SEK million	193.9	349.6	558.5	706.4	476.1
Capital employed, SEK million	688.7	841.9	783.0	996.0	796.7
Working capital, SEK million	217.2	–18.8	–50.5	–56.7	–13.7

For alternative key figures see definitions and reconciliations of key figures on page 99.
[1] Net debt calculated exclusive of leases.

Financial reports and notes

Consolidated statement of operations

SEK million	Notes	2022	2021
Net revenues	5	624.3	565.0
Cost of goods sold	7	–102.6	–78.9
Gross profit		**521.7**	**486.1**
Selling expenses	7, 9, 10, 31	–199.0	–280.4
Administrative expenses	7, 9, 10, 29, 31	–202.3	–151.5
Research and development costs	7, 9, 10, 31	–318.0	–272.3
Other operating income	8, 11	37.8	10.9
Other operating expenses	7, 11	–24.0	–6.9
Operating earnings		**–183.9**	**–214.1**
Financial income	12	74.8	38.3
Financial expense	12	–61.4	–46.7
Earnings after financial items		**–170.4**	**–222.5**
Income tax	13	–7.2	–1.0
Net earnings for the year		**–177.6**	**–223.5**
Earnings for the year attributable to:			
Parent company shareholders		–177.6	–223.5
Earnings per share during the year attributable to parent company shareholders (expressed in SEK)			
– before dilution	14	–5.17	–6,51
– after dilution	14	–5.17	–6,51

Consolidated statement of comprehensive income

SEK million	Notes	2022	2021
Net earnings for the year		**–177.6**	**–223.5**
Other comprehensive income			
Items that may subsequently be reversed to the statement of operations:			
Translation differences	17	22.1	13.0
Other comprehensive earnings for the year, net after tax		**22.1**	**13.0**
Comprehensive earnings for the year		**–155.5**	**–210.5**
Comprehensive earnings attributable to:			
Parent company shareholders		–155.5	–210.5
Non–controlling interests		–	–

Consolidated balance sheet

SEK million	Notes	2022 Dec 31	2021 Dec 31
ASSETS			
Fixed assets			
Tangible fixed assets	9, 15	76.1	65.9
Intangible assets	9, 16	217.4	248.9
Right-of-use assets	31	46.0	59.2
Deferred tax assets	30	33.1	33.4
Other financial assets	18	0.9	0.8
Total fixed assets		**373.5**	**408.2**
Current assets			
Inventories	19	74.6	92.3
Accounts receivable	20	246.5	214.0
Other receivables	21	25.9	24.1
Prepayment and accrued income	22	36.6	31.1
Short-term investments	18, 23	219.6	–
Cash and cash equivalents	18, 23	132.2	504.1
Total current assets		**735.5**	**865.5**
TOTAL ASSETS		**1,109.0**	**1,273.7**
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity			
Share capital		14.2	14.2
Other contributed capital	24	1,815.9	1,816.0
Reserves	17	21.7	–0.4
Profit carried forward including net earnings for the year		–1,657.9	–1,480.2
Total shareholder's equity		**193.9**	**349.6**
Long–term liabilities and provisions			
Provisions	24, 25	10.2	13.5
Interest bearing liabilities	18, 26	494.8	492.3
Lease liabilities, long-term	31	24.2	38.0
Total long–term liabilities		**529.2**	**543.9**
Current liabilities			
Accounts payable	18	86.6	49.2
Provisions	25	121.5	160.1
Other liabilities	27	21.5	16.9
Accrued expenses	27	135.6	133.7
Lease liabilities, current	31	20.6	20.2
Total current liabilities		**385.9**	**380.2**
Total liabilities		**915.1**	**924.1**
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		**1,109.0**	**1,273.7**

Changes in consolidated shareholders' equity

Attributable to parent company shareholders[1] SEK million	Notes	Share capital	Other contributed capital	Reserves[2]	Profit carried forward including Net earnings for the year	Total shareholders' equity
Opening balance at January 1, 2021		**14.2**	**1,814.4**	**–13.4**	**–1,256.7**	**558.5**
Comprehensive income						
Net earnings for the year					–223.5	–223.5
Other comprehensive income						
Translation differences				13.0		13.0
Total comprehensive income		**0.0**	**0.0**	**13.0**	**–223.5**	**–210.5**
Transactions with shareholders						
Share-based payments	24		1.5			1.5
Total transactions with shareholders		**0.0**	**1.5**	**0.0**	**0.0**	**1.5**
Closing balance at December 31, 2021		**14.2**	**1,816.0**	**–0.4**	**–1,480.2**	**349.6**
Opening balance at January 1, 2022		**14.2**	**1,816.0**	**–0.4**	**–1,480.2**	**349.6**
Comprehensive income						
Net earnings for the year					–177.6	–177.6
Other comprehensive income						
Translation differences				22.1		22.1
Total comprehensive income		**0.0**	**0.0**	**22.1**	**–177.6**	**–155.5**
Transactions with shareholders						
Share-based payments	24		–0.1			–0.1
Total transactions with shareholders		**0.0**	**–0.1**	**0.0**	**0.0**	**–0.1**
Closing balance at December 31, 2022		**14.2**	**1,815.9**	**21.7**	**–1,657.9**	**193.9**

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

The total number of shares as of December 31, 2022, was 34,710,639, of which 343,023 were owned by the company. The number of outstanding shares thus amounts to 34,367,616 as of December 31, 2022.

Consolidated cash flow statement

SEK million	Notes	2022	2021
Operating earnings		-183.9	–214.1
Adjustment for non-cash items	32	–3.5	–16.8
Interest received		1.4	0.0
Interest paid		–22.4	–22.9
Tax paid		1.5	8.2
Cash flow from operating activities before changes in working capital		**–206.9**	**–245.5**
Changes in working capital			
Change in inventories		36.4	27.8
Change in receivables		10.1	–21.8
Change in current liabilities		3.8	10.6
Cash flow from operating activities		**–156.6**	**–229.0**
Investing activities			
Acquisition of tangible fixed assets	15	–18.8	–24.7
Acquisition of intangible assets	16	–5.1	–28.1
Acquisition of short-term investments		–295.6	–
Disposal of short-term investments		84.0	–
Sales of tangible fixed assets		0.8	–
Cash flow from investing activities		**–234.7**	**–52.9**
Financing activities			
Issuance of loans		–	490.1
Repayment of loans	26,31	–21.4	–239.5
Cash flow from financing activities		**–21.4**	**250.6**
Cash flow for the year		**–412.8**	**–31.2**
Cash and cash equivalents at the beginning of the period		504.1	505.3
Exchange-rate differences in cash and cash equivalents		40.9	30.0
Change in liquidity		–371.8	–1.2
Cash and cash equivalents at the end of the period	23	**132.2**	**504.1**

Parent company statement of operations

SEK million	Notes	2022	2021
Net revenues	5	348.2	365.9
Cost of goods sold	7	–72.4	–71.2
Gross profit		**275.8**	**294.7**
Selling expenses	7, 9, 10, 31	–165.1	–227.3
Administrative expenses	7, 9, 10, 29, 31	–123.1	–92.3
Research and development costs	7, 9, 10, 31	–266.9	–226.0
Other operating income	8, 11	88.8	43.6
Other operating expenses	7, 11	–23.4	–6.9
Operating earnings		**–213.9**	**–214.2**
Other interest income and similar income	12	76.2	38.3
Other interest expenses and similar expenses	12	–59.1	–43.8
Net financial items		**17.1**	**–5.6**
Earnings before tax		**–196.8**	**–219.8**
Tax on earnings for the year	13	–	–
Net earnings for the year		**–196.8**	**–219.8**

Parent company statement of comprehensive income

SEK million	Notes	2022	2021
Net earnings for the year		–196.8	–219.8
Other comprehensive income for the period, net after tax		–	–
Total comprehensive income for the period		**–196.8**	**–219.8**

Parent company balance sheet

SEK million	Notes	2022 Dec 31	2021 Dec 31
ASSETS			
Fixed assets			
Patents, intellectual property rights, proprietary intangible assets and software	9, 16	181.4	214.2
Equipment, machinery, renovation of the property of others	9, 15	76.1	65.9
Shares and participations in group companies	28	161.2	162.5
Total fixed assets		**418.7**	**442.6**
Current assets			
Inventories	19	60.2	67.8
Accounts receivable	20	18.0	5.6
Other receivables	21	9.4	7.6
Receivables from group companies		108.8	82.6
Prepaid expenses and accrued income	22	22.8	19.7
Short-term investments		178.6	–
Cash and bank	23	61.7	444.5
Total current assets		**459.5**	**627.7**
TOTAL ASSETS		**878.2**	**1,070.2**
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		1,187.6	1,187.6
Accumulated deficit		–1,186.6	–966.8
Net earnings for the year		–196.8	–219.8
Total non-restricted shareholders' equity		**–195.8**	**1.0**
Total shareholders' equity		**109.2**	**306.0**
Long-term liabilities			
Other provisions	24, 25	9.8	12.8
Interest bearing liabilities	26	494.8	492.3
Total long-term liabilities		**504.5**	**505.1**
Current liabilities			
Accounts payable		32.0	17.1
Other liabilities	27	8.8	9.1
Liabilities to group companies		184.3	207.9
Accrued expenses and deferred income	27	39.3	25.0
Total current liabilities		**264.5**	**259.1**
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		**878.2**	**1,070.2**

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, 2021		**14.2**	**290.8**	**1,186.1**	**–966.8**	**524.2**
Net earnings for the year					–219.8	–219.8
Other comprehensive income						
Total comprehensive income		**0.0**	**0.0**	**0.0**	**–219.8**	**–219.8**
Share based payments	24			1.6		1.6
New share issues						
Closing shareholders' equity at December 31, 2021		**14.2**	**290.8**	**1,187.6**	**–1,186.6**	**306.0**
Opening shareholders' equity at January 1, 2022		**14.2**	**290.8**	**1,187.6**	**–1,186.6**	**306.0**
Net earnings for the year					–196.8	–196.8
Other comprehensive income						
Total comprehensive income		**0.0**	**0.0**	**0.0**	**–196.8**	**–196.8**
Closing shareholders' equity at December 31, 2022		**14.2**	**290.8**	**1,187.6**	**–1,383.4**	**109.2**

The total number of shares as of December 31, 2022, was 34,710,639, of which 343,023 were owned by the company. The number of outstanding shares thus amounts to 34,367,616 as of December 31, 2022.

Parent company cash flow statement

SEK million	Notes	2022	2021
Operating activities			
Operating earnings		–213.9	–214.2
Adjustment for non-cash items	32	30.6	22.5
Interest received		3.1	0.0
Interest paid		–23.1	–22.9
Tax paid		–	–
Cash flow from operating activities before change in working capital		**–203.3**	**–214.6**
Change in working capital			
Change in inventories		7.6	23.1
Change in accounts receivable and other current receivables		–35.3	–2.2
Change in current liabilities		5.4	26.8
Cash flow from operating activities		**–225.7**	**–167.0**
Investing activities			
Acquisition of tangible fixed assets	15	–18.8	–24.8
Acquisition of intangible fixed assets	16	–	–10.2
Acquisition of short-term investments		–234.4	–
Disposal of short-term investments		63.2	–
Sales of tangible fixed assets		0.8	–
Cash flow from investing activities		**–189.2**	**–35.0**
Financing activities			
Issuance of loans	26	–	490.1
Repayment of loans	26	–	–224.8
Cash flow from financing activities		**0.0**	**265.4**
Cash flow for the year		**–414.9**	**63.4**
Cash and cash equivalents at beginning of period		444.5	361.3
Exchange-rate differences in cash and cash equivalents		32.1	19.8
Change in liquidity		–382.8	83.2
Cash and cash equivalents at end of period	23	**61.7**	**444.5**

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 drugs and digital therapies that meet an important need in the growing the field of mental illness and addictive disorders. The products are commercialized by Orexo in the United States or through partners worldwide.The main market today is the US market for buprenorphine/naloxone products where Orexo sells its leading product ZUBSOLV® for the treatment of opioid dependence.

The parent company is the limited liability company Orexo AB (publ), with its registered office in Uppsala, Sweden. The address of thecompany'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 23, 2022.

The statement of operations and balance sheet will be presented to the Annual General Meeting on April 18, 2023, 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), RFR 2 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

The 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

Updated standards and interpretations from IASB and IFRIC interpretations that came into effect for the year ended December 31, 2022 have had no material impact on the Group. The Group has not early adopted any standards, interpretations or amendments that have been issued but are not yet effective.

(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 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 as other comprehensive income. 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 as cost, less depreciation and impairment, if any. 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 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 and impairment, if any. 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, short-term investments, 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. 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 amortized cost. 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 compensation plans in the form of share rights and employee stock options. During the vesting period the incentive program is reported as a cost and a long-term provision. Outstanding share programs and employee stock option programs are reported in accordance with IFRS 2 Share-based Payment.

Employee stock options give the right to subscribe for new shares in Orexo. Share rights gives one share per share right. Share rights and employee stock options are earned provided that the holder is still either an employee or a board member in Orexo on the vesting date,

Share rights and employee stock options whose earnings are dependent on performance conditions which are not market conditions are valued with the Black & Scholes model, and options and share rights whose earnings are dependent on performance conditions that are market conditions are valued through Monte Carlo simulations. The share price and the risk-free interest rate used are those valid at the valuation date. In assessing the volatility which is taken into account in the valuation, it is based on the historical volatility in the share during an interval between 2–7 years.

Based on the assessment that there is an in-substance obligation for the company to settle share-based payments instruments in cash, the accounting treatment for cash-based instruments is applied. This means that a provision is recorded based on the fair value of the instrument as per above, and which is revalued at each reporting date. More detailed description of the long-term incentive programs 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 long-term liabilities. 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 long-term liabilities.

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 share awards are entered as an expense over the vesting period, with a corresponding increase in long-term liabilities. 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 long-term liabilities.

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.

Note 2 cont.

(c) Severance payments
Severance payments are made when the Group serves notice to an employee prior to the normal pension date or when an employee voluntarily accepts redundancy in exchange for such remuneration. The Group recognizes severance payments when it is clearly obliged to give notice to an employee according to a detailed formal plan with no possibility of it being revoked, or to provide remuneration in conjunction with termination of employment as a result of an offer made to encourage voluntary redundancy.

(d) Accounting policies for bonus plans
The Group has a bonus system that covers members of the Executive Management team and key persons. The bonus system is based on achievement of company goals and is paid out in proportion to annual salary. During the fiscal year, the estimated bonuses vested for the year are calculated and expensed.

2.18 Revenue recognition
Revenues comprise the fair value of goods and services sold, excluding value-added tax, rebates, returned goods and after eliminated intra-Group sales.

Revenues are recognized as follows:

(a) Sale of goods
Revenues from the sale of goods are recognized on the date when control is 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.
- License revenues for Digital Therapeutics (DTx) are recognized over the time during which the license is granted, as the license grant has been determined to be a "right to access" performance obligation. In cases where there is a right to return products, an estimated returns rate is applied which reduces the net revenues. Revenues from licenses are only reported to the extent that it is very likely that a substantial reversal of revenue reported will not occur.

(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 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 operational risks are described in the Board of Directors report on pages 63–64. 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 2022 fiscal year, sales in USD accounted for 96 (98) percent of net revenues and sales in EUR accounting for 4 (2) percent. During the same period, 43 (67) percent of total operating expenses were in USD,

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 0.5 million.

The corresponding change in GBP entails a change of approximately SEK 0.3 million and in EUR of approximately SEK 0.8 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 4.7 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.

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 494.8 million on December 31, 2022 and these are attributable to a corporate bond loan. This loan has a variable interest rate, STIBOR +3.75 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 2,5 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, 2022, the four largest customers accounted for 98 percent. No other single customer accounted for more than 2 percent of total accounts receivable. Note 20 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, 2022	Less than 1 year	Between 1 and 2 years	Between 2 and 5 years
Accounts payable	86.6	—	—
Accrued costs	135.6	—	—
Interest bearing liabilities	18.8	37.5	502.2
Leasing	22.9	36.3	—

At December 31, 2021	Less than 1 year	Between 1 and 2 years	Between 2 and 5 years
Accounts payable	49.2	—	—
Accrued costs	133.7	—	—
Interest bearing liabilities	18.8	37.5	502.2
Leasing	20.8	45.6	—

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 2021 ZUBSOLV® had access to 98 percent of the commercial category and 48 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 2022'.

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, 2022 and 2021 is presented in the table below:

	2022	2021
Shareholders' equity	193.9	349.6
Total assets	1,109.0	1,273.7
Equity/assets ratio	**17%**	**27%**

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 intangible assets

Amortization of intangible assets related to Digital Therapeutics was begun in October 2020 for vorvida® , in November 2020 for deprexis® and in April 2022 for MODIA® after the products first sales or commercial availability in the US. Assets consist of milestone payments for licenses and similar rights as well as intangible assets related to enterprise platform. Amortization will be carried out over a period of 10 years. 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 are projected is longer than five years, due to the early phase of commercialization the Digital Therapeutics products are currently in. No indication of impairment need has been identified during the year.

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. Amortization 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 write-down 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 1,540 million (1,364) at December 31, 2022. 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

Note 4 cont.

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.

(d) Going concern

The board and the CEO continuously assess the group's liquidity and financial resources in both the short and long term. At the end of the year, the assessment was made that the group will have the necessary liquidity for continued operation of the business through at least 2023. The shareholders' equity in the parent company is expected to decrease during the first half of 2023 and it cannot be ruled out that the shareholders' equity in the parent company may become less than half of the registered share capital unless measures are taken. This means that there are uncertainty factors related to events or conditions which may cast significant doubt regarding the entity's ability to continue as a going concern. The expected negative development of the shareholders' equity in the parent company will be managed primarily through improved profitability, value-enhancing business development and cost savings and secondarily through a potential addition of external capital in some form.

NOTE 5 REVENUE FROM CONTRACTS WITH CUSTOMERS

	2022					
Group	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**vorvida®**	**deprexis®**	**Total**
Segment						
US Pharma	571.4	–	–	–	–	**571.4**
Digital Therapeutics	–	–	–	0.3	0.1	**0.4**
HQ & Pipeline	11.8	30.4	10.4	–	–	**52.6**
Total revenue from contracts with customers	**583.2**	**30.4**	**10.4**	**0.3**	**0.1**	**624.3**
Geographical markets						
US	571.4	–	2.5	0.3	0.1	**574.2**
EU	11.8	29.3	4.5	–	–	**45.6**
Rest of the world	–	1.2	3.4	–	–	**4.5**
Total revenue from contracts with customers	**583.2**	**30.4**	**10.4**	**0.3**	**0.1**	**624.3**

Of the group's total revenue, over 88% (89%) consists of sales to three customers.

	2021					
Group	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**vorvida®**	**deprexis®**	**Total**
Segment						
US Pharma	522.7	–	–	–	–	**522.7**
Digital Therapeutics	–	–	–	1.0	0.1	**1.1**
HQ & Pipeline	–	32.1	9.1	–	–	**41.2**
Total revenue from contracts with customers	**522.7**	**32.1**	**9.1**	**1.0**	**0.1**	**565.0**
Geographical markets						
US	522.7	–	2.9	1.0	0.1	**526.8**
EU	–	31.0	3.1	–	–	**34.1**
Rest of the world	–	1.1	3.0	–	–	**4.2**
Total revenue from contracts with customers	**522.7**	**32.1**	**9.1**	**1.0**	**0.1**	**565.0**

	2022						
Parent company	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**vorvida®**	**deprexis®**	**MODIA®**	**Total**
Segment							
US Pharma (intragroup)	294.0	–	–	–	–	–	**294.0**
Digital Therapeutics (intragroup)	–	–	–	0.2	0.1	1.4	**1.6**
HQ & Pipeline	11.8	30.4	10.4	–	–	–	**52.6**
Total revenue from contracts with customers	**305.7**	**30.4**	**10.4**	**0.2**	**0.1**	**1.4**	**348.2**
Geographical markets							
US	294.0	–	2.5	0.2	0.1	1.4	**298.1**
EU	11.8	29.3	4.5	–	–	–	**45.6**
Rest of the world	–	1.2	3.4	–	–	–	**4.5**
Total revenue from contracts with customers	**305.7**	**30.4**	**10.4**	**0.2**	**0.1**	**1.4**	**348.2**

Note 5 cont.

	2021						
Parent company	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**vorvida®**	**deprexis®**	**MODIA®**	**Total**
Segment							
US Pharma (intragroup)	324.0	–	–	–	–	–	**324.0**
Digital Therapeutics (intragroup)	–	–	–	0.7	0.1	–	**0.7**
HQ & Pipeline	–	32.1	9.1	–	–	–	**41.2**
Total revenue from contracts with customers	**324.0**	**32.1**	**9.1**	**0.7**	**0.1**	–	**365.9**
Geographical markets							
US	324.0	–	2.9	0.7	0.1	–	**327.6**
EU	–	31.0	3.1	–	–	–	**34.1**
Rest of the world	–	1.1	3.0	–	–	–	**4.2**
Total revenue from contracts with customers	**324.0**	**32.1**	**9.1**	**0.7**	**0.1**	–	**365.9**

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 113.4 million (139.4) 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 8.1 million (20.7) at the balance sheet date. During the period, the Group reversed provisions for discounts and returns from previous periods to an amount of SEK 10.2 million (6.7). 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.

Licenses

License revenues for Digital Therapeutics (DTx) are recognized over the time during which the license is granted, as the license grant has been determined to be a "right to access" performance obligation. In cases where there is a right to return products, an estimated returns rate is applied which reduces the net revenues. Revenues from licenses are only reported to the extent that it is very likely that a substantial reversal of revenue reported will not occur.

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	2022	2021
US Pharma		
Net revenues	571.4	522.7
Operating earnings (EBIT)	308.4	278.2
Depreciation and amortization	–15.4	–15.4
Digital Therapeutics		
Net revenues	0.4	1.1
Operating earnings (EBIT)	–189.1	–249.7
Depreciation and amortization	–25.7	–18.6
HQ & Pipeline		
Net revenues	52.6	41.2
Operating earnings (EBIT)	–303.2	–242.6
Depreciation and amortization	–27.7	–19.1
Group		
Net revenues	624.3	565.0
Operating earnings (EBIT)	–183.9	–214.1
Depreciation and amortization	–68.7	–53.0
Net financial items	13.5	–8.4
Earnings before tax	–170.4	–222.5

Revenues from customer in Sweden amounted to SEK 7.0 million during 2022
Fixed assets in Sweden amounted to SEK 14.7 million at December 31. 2022
Intangible assets in Sweden amounted to SEK 181.4 million at December 31. 2022

NOTE 7 COSTS BY TYPE OF COST

	Group		Parent company	
	2022	2021	2022	2021
Raw materials and consumables	102.6	78.9	72.4	71.2
Other external expense	405.7	402.2	433.2	433.1
Personnel costs	244.9	249.0	81.1	76.0
Depreciation/amortization and impairment	68.7	53.0	40.8	36.6
Total	**822.0**	**783.1**	**627.5**	**616.8**

NOTE 8 OTHER OPERATING INCOME

	Group		Parent company	
	2022	2021	2022	2021
Exchange gains	30.2	10.8	30.2	10.8
Other income	7.4	0.1	58.4	32.9
Gains on disposal of assets	0.2	–	0.2	–
Total	**37.8**	**10.9**	**88.8**	**43.6**

Other income in the parent company 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. Other income in the group consists of a insurance reimbursement.

NOTE 9 DEPRECIATION/AMORTIZATION AND IMPAIRMENT

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

	Group		Parent company	
	2022	2021	2022	2021
Tangible fixed assets				
Sales	–	–	–	–
Administration	1.9	1.9	1.9	1.9
Research and development	6.2	4.3	6.2	4.3
Total tangible fixed assets	**8.1**	**6.2**	**8.1**	**6.2**
Intangible assets				
Selling	–	–	–	–
Administration	0.3	0.3	0.3	0.3
Research and development	41.4	34.4	32.4	30.1
Total intangible assets	**41.7**	**34.6**	**32.7**	**30.4**
Right-of use assets				
Selling	3.1	0.3	–	–
Administration	5.2	1.6	–	–
Research and development	10.7	10.5	–	–
Total right-of use assets	**18.9**	**12.3**	**0.0**	**0.0**
Total depreciation/amortization and impairment	**68.7**	**53.0**	**40.8**	**36.6**

NOTE 10 REMUNERATION TO EMPLOYEES

Average number of employees

Group	2022 Average number of employees	Of whom women	2021 Average number of employees	Of whom women
Sweden	58	30	57	26
USA	87	44	78	50
Total for Group	**144**	**73**	**135**	**76**

Parent company	2022 Average number of employees	Of whom women	2021 Average number of employees	Of whom women
Sweden	58	30	57	26
Total for parent company	**58**	**30**	**57**	**26**

	Group		Parent company	
Costs and remuneration to all employees and board, SEK thousands	2022	2021	2022	2021
Salaries, remuneration and social security fees				
Salaries and other remuneration to the Board, President and Executive Management	36,156	43,691	19,159	24,612
Salaries and other remuneration to other employees	137,461	142,947	34,480	35,981
Pension cost for the Board, President and Executive Management[1]	2,346	2,161	1,834	1,710
Pension cost for other employees[1]	12,437	11,934	7,532	7,202
Social security fees for the Board, President and Executive Management[2]	5,408	3,995	5,222	4,435
Social security fees for other employees[2]	17,771	17,385	10,886	10,721
Other personnel costs	19,549	24,088	1,959	2,096
Total	**231,128**	**246,200**	**81,072**	**86,756**

[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 2022, SEK thousands

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	1,500	–	–	–	–	–	1,500
Henrik Kjaer Hansen, Board member[1]	0	–	–	–	–	–	0
Fred Wilkinson, Board member	400	–	–	–	–	–	400
Staffan Lindstrand, Board member	450	–	–	–	–	–	450
Mary Pat Christie, Board member	400	–	–	–	–	–	400
Charlotte Hansson, Board member	600	–	–	–	–	–	600
Christine Rankin, Board member	367	–	–	–	–	–	367
Michael J Matly, Board member	267	–	–	–	–	–	267
David Colpman, Board member	150	–	–	–	–	–	150
Kirsten Detrick, Board member	133	–	–	–	–	–	133
Subtotal	**4,267**	**0**	**0**	**0**	**0**	**0**	**4,267**
President and senior executives							
Nikolaj Sørensen, President and CEO	3,681	1,209	114	771	316	–	6,092
Other senior executives (5)	10,185	3,012	737	1,834	929	–	16,697
Total	**18,133**	**4,222**	**851**	**2,606**	**1,245**	**0**	**27,056**

[1] Refrained from Board fee

Costs and remuneration to the board, president and senior executives 2021, SEK thousands

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]	1,500	–	–	–	–	–	1,500
Henrik Kjaer Hansen, Board member[2]	0	–	–	–	–	–	0
Fred Wilkinson, Board member	400	–	–	–	–	–	400
Staffan Lindstrand, Board member	350	–	–	–	–	–	350
Mary Pat Christie, Board member	400	–	–	–	–	–	400
Charlotte Hansson, Board member[1]	600	–	–	–	–	–	600
David Colpman, Board member	450	–	–	–	–	–	450
Kirsten Detrick, Board member	400	–	–	–	–	–	400
Subtotal	**4,100**	**0**	**0**	**0**	**0**	**0**	**4,100**
President and senior executives							
Nikolaj Sørensen, President and CEO	3,617	1,354	110	748	4,022	–	9,851
Other senior executives (6)	19,828	7,288	980	1,413	2,384	–	31,894
Total	**27,545**	**8,642**	**1,090**	**2,161**	**6,407**	**0**	**45,845**

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

Board members and senior executives

	2022		2021	
	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	6	83%	7	86%
Parent company				
Board members	8	63%	8	63%
President and other senior executives	4	75%	4	75%

Remuneration to CEO and senior executives consists 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 page 60. Refer to Note 24 for a description of the share-based remuneration

Other senior executives, as of December 31, 2022 refers to Robert A. DeLuca, Michael Sumner (until June 2022), Edward Kim (from October 2022), Joseph DeFeo (until September 2022), Robert Rönn, Cecilia Coupland, Dennis Urbaniak (until December 2022) och Fredrik Järrsten (from June 2022).

The number of shares and options held by the President and senior executives is shown in the information regarding the Board on page 114 and Management on page 116.

NOTE 11 EXCHANGE-RATE DIFFERENCES

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

	Group		Parent company	
	2022	2021	2022	2021
Other operating income	30.2	10.8	30.2	10.8
Other operating expenses	–23.4	–6.9	–23.4	–6.9
Total	**6.8**	**3.9**	**6.8**	**3.9**

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

NOTE 12 FINANCIAL INCOME AND EXPENSES

	Group		Parent company	
	2022	2021	2022	2021
Financial income				
Interest from Group	–	–	2.0	–
Other interest income	4.0	0.0	3.4	0.0
Exchange rate effect	70.8	38.2	70.8	38.2
Total financial income	**74.8**	**38.3**	**76.2**	**38.3**
Financial expenses				
Interest expense from corporate bonds	–23.0	–18.1	–23.0	–18.1
Other interest expense	–2.3	–2.8	–	–
Borrowing costs, corporate bonds	–2.5	–7.3	–2.5	–7.3
Exchange rate effect	–33.6	–18.4	–33.6	–18.4
Total financial expenses	**–61.4**	**–46.7**	**59.1**	**–43.8**
Net financial items	**13.5**	**–8.4**	**17.1**	**–5.6**

NOTE 13 TAX

	Group		Parent company	
	2022	2021	2022	2021
Current tax	–3.9	–4.5	–	–
Deferred tax	–3.3	3.5	–	–
Total	**–7.2**	**–1.0**	**0.0**	**0.0**
Difference between the Group's tax expense and tax expense based on current tax rate				
Recognized pre-tax earnings	–170.4	–222.5	–196.8	–219.8
Tax under current tax rate	35.1	45.8	40.5	45.3
Tax effect of foreign tax rates	–1.8	–6,5	–	–
Tax effect of non-deductible costs	–0.1	–0.1	–0.1	–0.1
Tax relating to previous years	–	5,0	–	–
Unrecognized carry-forward losses	–40.4	–45.2	–40.4	–45.2
Tax on earnings for the year according to the statement of operations	**–7.2**	**–1.0**	**0.0**	**0.0**

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	**2022**	**2021**
Earnings used for the calculation of earnings per share before dilution, MSEK	–177.6	–223.5
Average number of shares before dilution	34,351,732	34,319,649
Earnings per share before dilution (SEK per share)	–5.17	–6.51
Average number of shares after dilution	34,351,732	34,319,649
Earnings per share after dilution (SEK per share)	–5.17	–6.51
Options/share rights outstanding	2,797,675	1,629,022

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	**2022**	**2021**
Average number of shares before dilution	34,351,732	34,319,649
Potential shares from options and share rights	0	0
Average number of shares after dilution	34,351,732	34,319,649

NOTE 15 TANGIBLE FIXED ASSETS

Group	**Equipment and machinery**	**Computers**	**Improvement expenses other's property**	**Total**
Fiscal year 2021				
Opening balance	64.6	1.1	36.0	101.7
Additions	25.2	—	—	25.2
Disposals	—	—	—	—
Outgoing accumulated acqusitions	**89.9**	**1.1**	**36.0**	**127.0**
Ingoing depreciation	–29.9	–1.1	–23.9	–54.9
Acumulated depreciation disposal	—	—	—	—
Depreciation	–4.4	—	–1.8	–6.2
Accumulated depreciation	**–34.3**	**–1.1**	**–25.7**	**–61.1**
At December 31, 2021				
Cost	89.9	1.1	36.0	127.0
Accumulated depreciation and impairment	–34.3	–1.1	–25.7	–61.1
Carrying amount	**55.6**	**0.0**	**10.3**	**65.9**
Fiscal year 2022				
Opening balance	89.9	1.1	36.0	127.0
Additions	18.8	0.0	0.0	18.8
Disposals	–0.9	0.0	0.0	–0.9
Outgoing accumulated acqusitions	**107.8**	**1.1**	**36.0**	**144.9**
Ingoing depreciation	–34.3	–1.1	–25.7	–61.1
Acumulated depreciation disposal	0.3	0.0	0.0	0.3
Depreciation	–6.2	0.0	–1.8	–8.1
Accumulated depreciation	**–40.1**	**–1.1**	**–27.6**	**–68.8**
At December 31, 2022				
Cost	107.8	1.1	36.0	144.9
Accumulated depreciation and impairment	–40.1	–1.1	–27.6	–68.8
Carrying amount	**67.6**	**0.0**	**8.4**	**76.1**

Note 15 cont.

Parent company	Equipment and machinery	Computers	Improvement expenses other's property	Total
Fiscal year 2021				
Opening balance	64.6	1.1	36.0	101.7
Additions	25.2	—	—	25.2
Disposals	—	—	—	—
Outgoing accumulated acquisitions	**89.9**	**1.1**	**36.0**	**127.0**
Ingoing depreciation	–29.9	–1.1	–23.9	–54.9
Accumulated depreciation disposal	—	—	—	—
Depreciation	–4.4	—	–1.8	–6.2
Accumulated depreciation	**–34.3**	**–1.1**	**–25.7**	**–61.1**
At December 31, 2021				
Cost	89.9	1.1	36.0	127.0
Accumulated depreciation and impairment	–34.3	–1.1	–25.7	–61.1
Carrying amount	**55.6**	**0.0**	**10.3**	**65.9**
Fiscal year 2022				
Opening balance	89,9	1,1	36,0	127,0
Additions	18,8	0,0	0,0	18,8
Disposals	–0,9	0,0	0,0	–0,9
Outgoing accumulated acquisitions	**107,8**	**1,1**	**36,0**	**144,9**
Ingoing depreciation	–34,3	–1,1	–25,7	–61,1
Accumulated depreciation disposal	0,3	0,0	0,0	0,3
Depreciation	–6,2	0,0	–1,8	–8,1
Accumulated depreciation	**–40,1**	**–1,1**	**–27,6**	**–68,8**
At December 31, 2022				
Cost	107,8	1,1	36,0	144,9
Accumulated depreciation and impairment	–40,1	–1,1	–27,6	–68,8
Carrying amount	**67.6**	**0.0**	**8.4**	**76.1**

NOTE 16 INTANGIBLE FIXED ASSETS

Group	Acquired R&D	Patents and rights	Proprietary intellectual property right	Software	Total
Fiscal year 2021					
Opening balance	435.1	192.1	153.6	33.9	814.7
Additions	—	10.2	—	18.0	28.1
Exchange rate differences	—	—	—	2.6	2.6
Outgoing accumulated acquisitions	**435.1**	**202.3**	**153.6**	**54.4**	**845.4**
Accumulated amortization and impairment	–435.1	–30.6	–83.2	–13.1	–562.0
Amortization	—	–14.4	–15.4	–4.9	–34.6
Accumulated amortization and impairment	**–435.1**	**–45.0**	**–98.5**	**–18.0**	**–596.6**
At December 31, 2021					
Cost	435.1	202.3	153.6	54.4	845.4
Accumulated amortization and impairment	–435.1	–45.0	–98.5	–18.0	–596.6
Carrying amount	**0.0**	**157.3**	**55.1**	**36.4**	**248.9**
Fiscal year 2022					
Opening balance	435.1	202.3	153.6	54.4	845.4
Additions	—	—	—	5.1	5.1
Exchange rate differences	—	—	—	5.2	5.2
Outgoing accumulated acquisitions	**435.1**	**202.3**	**153.6**	**64.7**	**855.7**
Accumulated amortization and impairment	–435.1	–45.0	–98.5	–18.0	–596.6
Amortization	—	–16.7	–15.4	–9.7	–41.7
Accumulated amortization and impairment	**–435.1**	**–61.7**	**–113.9**	**–27.6**	**–638.3**
At December 31, 2022					
Cost	435.1	202.3	153.6	64.7	855.7
Accumulated amortization and impairment	–435.1	–61.7	–113.9	–27.6	–638.3
Carrying amount	**0.0**	**140.6**	**39.7**	**37.1**	**217.5**

Note 16 cont.

Parent company	Acquired R&D	Patents and rights	Proprietary intellectual property right	Software	Total
Fiscal year 2021					
Opening balance	435.1	192.1	153.6	15.0	795.8
Additions	—	10.2	—	—	10.2
Outgoing accumulated acqusitions	**435.1**	**202.3**	**153.6**	**15.0**	**805.9**
Accumulated amortization and impairment	–435.1	–30.1	–83.2	–13.1	–561.5
Amortization	—	–14.4	–15.4	–0.7	–30.4
Accumulated amortization and impairment	**–435.1**	**–44.5**	**–98.5**	**–13.8**	**–591.9**
At December 31, 2021					
Cost	435.1	202.3	153.6	15.0	805.9
Accumulated amortization and impairment	–435.1	–44.5	–98.5	–13.8	–591.9
Carrying amount	**0.0**	**157.8**	**55.1**	**1.2**	**214.2**
Fiscal year 2022					
Opening balance	435.1	202.3	153.6	15.0	805.9
Additions	—	—	—	—	—
Outgoing accumulated acqusitions	**435.1**	**202.3**	**153.6**	**15.0**	**805.9**
Accumulated amortization and impairment	–435.1	–44.5	–98.5	–13.8	–591.9
Amortization	—	–16.7	–15.4	–0.7	–32.7
Accumulated amortization and impairment	**–435.1**	**–61.2**	**–113.9**	**–14.4**	**–624.6**
At December 31, 2022					
Cost	435.1	202.3	153.6	15.0	805.9
Accumulated amortization and impairment	–435.1	–61.2	–113.9	–14.4	–624.6
Carrying amount	**0.0**	**141.1**	**39.7**	**0.6**	**181.4**

Proprietary intangible asset at December 31, 2022

A proprietary intangible asset amounting to SEK 39.7 million (55.1) is attributable to expenses for clinical studies and a registration expense for these studies. 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. Intangible assets for Digital Therapeutics amounting to SEK 177.2 million (192.6) consist of milestone payments for licenses and similar rights as well as intangible assets related to enterprise platform. Amortization was begun when products became available commercially in 2020 and 2022 land will occur over a time period of 10 years.

Research and development costs

Research and development costs during the period amounted to SEK 318.0 million (272.3).

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

Impairment testing

During the year the group has performed impairment tests of its intangible assets related to Digital Therapeutics. As of December 31, 2022 the group has intangible assets for Digital Therapeutics of SEK 177.2 million, consisting of milestone payments for licenses and similar rights as well as intangible assets related to enterprise platform. The impairment tests were performed based on discounted cash flows for the years 2023 to 2032 for vorvida® and deprexis®, both launched in 2020, and 2023 to 2032 for MODIA®, which has been commercially available since 2022. 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 and earning positive cash flows. 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 risk-adjusted discount rate (WACC) of 14.0% was applied to the tests. The tests performed did not indicate any impairment.

The products are currently earning limited revenue, and the recoverable value is entirely dependent on substantial future sales growth to earn positive cash flows. A reasonably possible change in key assumtions would hence cause the carrying amount to exceed the recoverable amount, as such growth may not materialize or be lower than anticipated. The recoverable amount of assets related to vorvida® exceeds the carrying amount by SEk 71 million, and an increase in WACC, everything else held equal, to 25.7%, would result in the assets having a recoverable amount equal to their carrying amount. The recoverable amount of assets related to deprexis® exceeds the carrying amount by SEK 267 million, and an increase in WACC, everything else held equal, to 37.6%, would result in the assets having a recoverable amount equal to their carrying amount. The recoverable amount of assets related to MODIA® exceeds the carrying amount by SEK 158 million, and an increase in WACC, everything else held equal, to 26.3%, would result in the assets having a recoverable amount equal to their carrying amount.

NOTE 17 RESERVES

Group	Translation reserve
Opening balance at January 1, 2021	**–13.4**
Translation differences	13.0
Closing balance at December 31, 2021	**–0.4**
Opening balance at January 1, 2022	**–0.4**
Translation differences	22.1
Closing balance at December 31, 2022	**21.7**

NOTE 18 INFORMATION ON FINANCIAL INSTRUMENTS IN THE GROUP

Classification and categorization of assets and liabilities in the group 2022

December 31, 2022	Financial assets measured at amortized cost	Total financial assets	Non-financial assets	Total
Assets				
Tangible fixed assets	–	**0.0**	76.1	**76.1**
Intangible fixed assets	–	**0.0**	217.4	**217.4**
Right-of-use asset	–	**0.0**	46.0	**46.0**
Deferred tax asset	–	**0.0**	33.1	**33.1**
Inventories	–	**0.0**	74.6	**74.6**
Financial assets	0.9	**0.9**	–	**0.9**
Accounts receivable	246.5	**246.5**	–	**246.5**
Other current receivables	–	**0.0**	25.9	**25.9**
Prepaid expenses and accrued income	–	**0.0**	36.6	**36.6**
Short-term investment	219.6	**219.6**	–	**219.6**
Cash and cash equivalents	132.2	**132.2**	–	**132.2**
Total assets	**599.2**	**599.2**	**509.8**	**1,109.0**

December 31, 2022	Financial liabilities measured at amortized cost	Total financial liabilities	Non-financial liabilities	Total
Shareholders' equity and liabilities				
Shareholders' equity	–	**0.0**	193.9	**193.9**
Long-term liabilities, provision	–	**0.0**	10.2	**10.2**
Leasing, long-term	24.2	**24.2**	–	**24.2**
Borrowings	494.8	**494.8**	–	**494.8**
Accounts payable	86.6	**86.6**	–	**86.6**
Provisions	–	**0.0**	121.5	**121.5**
Other current liabilities	99.3	**99.3**	18.5	**117.8**
Leasing, short-term	20.6	**20.6**	–	**20.6**
Prepaid expenses	27.4	**27.4**	12.0	**39.3**
Total shareholders' equity and liabilities	**752.8**	**752.8**	**356.2**	**1,109.0**

Classification and categorization of assets and liabilities in the Group 2021

December 31, 2021	Financial assets measured at amortized cost	Total financial assets	Non-financial assets	Total
Assets				
Tangible fixed assets	–	**0.0**	65.9	**65.9**
Intangible fixed assets	–	**0.0**	248.9	**248.9**
Right-of-use asset	–	**0.0**	59.2	**59.2**
Deferred tax asset	–	**0.0**	33.4	**33.4**
Inventories	–	**0.0**	92.3	**92.3**
Financial assets	0.8	**0.8**	–	**0.8**
Accounts receivable	214.0	**214.0**	–	**214.0**
Other current receivables	–	**0.0**	24.1	**24.1**
Prepaid expenses and accrued income	–	**0.0**	31.1	**31.1**
Cash and cash equivalents	504.1	**504.1**	–	**504.1**
Total assets	**718.9**	**718.9**	**554.9**	**1,273.7**

December 31, 2021	Financial liabilities measured at amortized cost	Total financial liabilities	Non-financial liabilities	Total
Shareholders' equity and liabilities				
Shareholders' equity	–	**0.0**	349.6	**349.6**
Long-term liabilities, provision	–	**0.0**	13.5	**13.5**
Leasing, long-term	38.0	**38.0**	–	**38.0**
Borrowings	492.3	**492.3**	–	**492.3**
Accounts payable	49.2	**49.2**	–	**49.2**
Provisions	–	**0.0**	160.1	**160.1**
Other current liabilities	112.5	**112.5**	13.2	**125.6**
Leasing, short-term	20.2	**20.2**	–	**20.2**
Prepaid expenses	13.0	**13.0**	12.0	**25.0**
Total shareholders' equity and liabilities	**725.1**	**725.1**	**548.4**	**1,273.7**

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 reported value of the bond loan amounted to SEK 494.8 million, the fair value according to level 2 amounted to a substantially equal amount.

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	
	2022	2021	2022	2021
Raw materials	27.9	47.5	27.9	47.5
Work in progress	26.9	17.0	26.9	17.0
Finished products	19.7	27.8	5.4	3.3
Total	**74.6**	**92.3**	**60.2**	**67.8**

The cost of goods from inventory expensed in the Group amounted to SEK 98.4 million (79.0) and in the parent company to SEK 50.3 million (57.0). Write-downs amounted to SEK 4.3 million (0.0).

NOTE 20 ACCOUNTS RECEIVABLE

Impairment losses on accounts receivable amounted to SEK 0.0 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	
	2022	2021	2022	2021
SEK	0.0	0.0	0.0	0.0
USD	235.4	211.2	7.0	2.7
EUR	11.0	2.8	11.0	2.8
Total	**246.5**	**214.0**	**18.0**	**5.6**

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 224.5 million (205.3) is held by the Group's four largest customers. Each of the following:

	Group	
	2022	2021
Customer 1	109.8	88.8
Customer 2	59.0	79.4
Customer 3	48.4	34.6
Customer 4	7.2	2.5
Total	**224.5**	**205.3**

Accounts receivable due

At December 31. 2022. accounts receivable amounting to SEK 4.5 million (57.8) 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	
	2022	2021	2022	2021
Less than 30 days	3.4	47.1	3.4	0.0
31 days and older	1.1	10.7	0.7	–
Total	**4.5**	**57.8**	**4.1**	**0.0**

NOTE 21 OTHER RECEIVABLES

	Group		Parent company	
	2022	2021	2022	2021
VAT receivable	3.4	4.1	3.4	4.1
Tax receivable	19.2	19.2	2.7	2.7
Other	3.3	0.8	3.3	0.8
Total	**25.9**	**24.1**	**9.4**	**7.6**

NOTE 22 PREPAID EXPENSES AND ACCRUED INCOME

	Group		Parent company	
	2022	2021	2022	2021
Prepaid rents	–	–	4.7	4.1
FDA annual fee	15.4	12.5	–	–
Other prepayments	21.2	18.6	18.1	15.6
Total	**36.6**	**31.1**	**22.8**	**19.7**

NOTE 23 CASH, CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS

	Group		Parent company	
	2022	2021	2022	2021
Cash and bank balances	132.2	504.1	61.7	444.5
Short-term investments	219.6	–	178.6	–
Total	**351.9**	**504.1**	**240.3**	**444.5**

As of December 31, 2022, cash and cash equivalents amounted to SEK 132.2 million (504.1) and short-term investments amounted to SEK 219.6 million (-). Cash and invested funds in total amounted to SEK 351.9 million (504.1)

The Group has no unused credit facilities at December 31, 2022.

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

	Group		Parent company	
	2022	2021	2022	2021
SEK	29.5	210.2	28.0	208.6
USD	99.3	291.8	30.3	233.8
EUR	3.4	1.4	3.4	1.4
GBP	0.0	0.7	0.0	0.7
Total	**132.2**	**504.1**	**61.7**	**444.5**

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-BASED 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, 2022 there were a total of 2,797,675 options and share awards outstanding. These consist of 2,013,646 options that qualify for subscription of shares in Orexo. The number of share awards is 784,029 and each share award provides entitlement to one share in Orexo.

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
2021	–2.8
2022	1.2

Employee stock options/share awards allotted	Number	Exercise price, weighted average
At Dec 31, 2020	**1,630,875**	**74**
Allotted during the period	961,974	45
Redeemed during the period	–319,134	29
Forfeited during the period	–644,693	78
At Dec 31, 2021	**1,629,022**	**57**
Allotted during the period	1,817,278	20
Redeemed during the period	–104,580	–
Forfeited during the period	–544,045	41
At Dec 31, 2022	**2,797,675**	**36**

Employee stock options/ share awards per year	Number outstanding at Dec 31, 2022	Number vested at Dec 31, 2022	Exercise price, range	Value per allotted option, range	Volatility, option, weighted average	Value per share, range	Value per option weighted average	Maturity date
2020 LTIP Stay on	14,786	0	55.9	22.0–57.0	57%	57.00	39.50	2023-08-31–2024-08-03
LTIP 2020 Options	316,671	0	78.6	27.7	56%	76.20	27.70	2023-06-29
LTIP 2020 PSU	135,735	0	0.0	76.2	56%	76.20	76.20	2023-06-29
2021 LTIP Stay on	2,864	0	37.19	14.7–38.6	55%	38.62	26.66	2024-08-31–2025-08-02
LTIP 2021 Options	535,730	0	45.3	13.1	56%	39.90	13.10	2024-06-15
LTIP 2021 PSU	139,968	0	0.0	39.9	56%	39.90	39.90	2024-06-15
LTIP 2022 Options	1,142,665	0	20.23	5.6	50%	17.98	5.58	2025-05-12
LTIP 2022 PSU	490,030	0	0.0	18.0	50%	17.98	17.98	2025-05-12
2022 LTIP Stay on Options	9,613	0	20.23–37.19	5.6–6.7	51%	19.38–20.59	5.79	2025-07-01–2026-05-31
2022 LTIP Stay on PSU	9,613	0	0.0	19.4–20.6	52%	19.38–20.59	20.36	2025-07-01–2026-05-31
Total employee stock options/share awards	**2,797,675**							

Employee stock options/ share awards per year	Number outstanding at Dec 31, 2021	Number vested at Dec 31, 2021	Exercise price, range	Value per allotted option, range	Volatility, option, weighted average	Value per share, range	Value per option weighted average	Maturity date
LTIP 2019	178,600	0	0.0	40.4–73.1	38%	73.1	60.0	2022-06-15
LTIP 2021 Options	20,802	0	55.9	22.0–57.0	57%	57.0	39.5	2023-08-31–2024-08-03
LTIP 2021 PSU	365,661	0	78.6	27.7	56%	76.2	27.7	2023-06-29
LTIP 2020 PSU	156,685	0	0.0	76.2	56%	76.2	76.2	2023-06-29
2021 LTIP Stay on	6,074	0	37.2	14.7–38.6	55%	38.6	26.7	2024-08-31–2025-08-02
LTIP 2021 Options	630,830	0	45.3	13.1	56%	39.9	13.1	2024-06-15
LTIP 2021 PSU	270,370	0	0.0	39.9	56%	39.9	39.9	2024-06-15
Total employee stock options/share awards	**1,629,022**							

During 2022 the company allotted 1 817,278 employee stock options, of which the CEO and other senior executives were allotted 566,692, corresponding to 31 percent. The financial and operational targets set by the Board for 2022 reached a score of 80 percent and hence 20 percent of the allocated share awards pertaining to performance target 2 will forfeit. In total 544,045 options were forfeited during 2022.

As of December 31, 2022 the liability for LTIP amounted to SEK 10.2 million, see note 25. Changes in and holdings of employee stock options/share awards at the closing date for the CEO and Board members.

Note 24 cont.

Owned by	Number outstanding at Jan 1, 2022	Change	Number outstanding at Dec 31, 2022
President and CEO Nikolaj Sørensen	192,960	165,160	358,120
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 Michael J Matlyk	0	–	0
Board member Christine Rankin	0	–	0

Performance criteria LTIP 2020

LTIP 2020 is a program program based on share awards and employee stock options where 33% of the shares are vested based on employment and 67% is vested based on the company's operational performance. Of each Participant's granted Employee Stock Options, 100 percent will pertain to Performance Target 1, meaning that no Employee Stock Options will vest unless the performance target is met. The allotment of Shares that each participant later may receive depends on achievement of the Performance Targets.

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 achieved. When calculating the overall performance achievement, individual targets may account for a maximum of 120 percent achievement, but the overall average performance is capped at 100 percent. If performance achievement falls below 80 percent for an individual target, this individual target accounts for zero in the calculation of the overall average achieved.

Performance criteria LTIP 2021

LTIP 2021 is a program based on share awards and employee stock options where 33% of the shares are vested based on employment and 67% is vested based on the company's operational performance and time. Of each Participant's granted Employee Stock Options, 100 percent will pertain to Performance Target 1, meaning that no Employee Stock Options will vest unless the performance target is met. The allotment of Shares that each participant later may receive depends on achievement of the Performance Targets.

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 2021 as established by the board of directors and relates to the Company's key KPIs as for example revenue, profitability and achieved milestones, etc. Performance achievement of individual targets is weighted into an overall average performance achievement. The outcome will be measured lineally; meaning that from zero to 100 percent of the Share Awards will Vest depending on the overall average rate of performance of the financial and operational targets. All Share Awards will Vest and entitle to one Share each if 100 percent of the overall average performance is achieved. When calculating the overall performance achievement, individual targets may account for a maximum of 120 percent achievement, but the overall average performance is capped at 100 percent. If performance achievement falls below 80 percent for an individual target, this individual target accounts for zero in the calculation of the overall average achieved.

Performance criteria LTIP 2022

LTIP 2022 is a program based on share awards and employee stock options where 33% of the shares are vested based on employment and 67% is vested based on the company's operational performance and time. Of each Participant's granted Employee Stock Options, 100 percent will pertain to Performance Target 1, meaning that no Employee Stock Options will vest unless the performance target is met. The allotment of Shares that each participant later may receive depends on achievement of the Performance Targets.

Performance criterion 1

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

Performance criterion 2

This Performance Condition pertains to the fulfilment of the financial and operational targets for the financial year 2022 as established by the board of directors and relates to the Company's key KPIs as for example revenue, profitability and achieved milestones, etc. Performance achievement of individual targets is weighted into an overall average performance achievement. The outcome will be measured lineally; meaning that from zero to 100 percent of the Share Awards will Vest depending on the overall average rate of performance of the financial and operational targets. All Share Awards will Vest and entitle to one Share each if 100 percent of the overall average performance is achieved. When calculating the overall performance achievement, individual targets may account for a maximum of 120 percent achievement, but the overall average performance is capped at 100 percent. If performance achievement falls below 80 percent for an individual target, this individual target accounts for zero in the calculation of the overall average achieved.

NOTE 25 PROVISIONS

Long-term provisions	Group 2022	Group 2021	Parent company 2022	Parent company 2021
On January 1	**13.5**	**25.7**	**12.8**	**24.5**
Additional provisions	–1.8	–4.7	–1.5	—4.3
Utilized during the year	–1.5	–7.5	–1.5	—7.4
Reversed unused amounts	—	—	—	—
Per December 31	**10.2**	**13.5**	**9.8**	**12.8**

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 2022	Group 2021	Parent company 2022	Parent company 2021
On January 1	**160.1**	**197.3**	**0.0**	**0.0**
Additional provisions	633.7	599.0	—	—
Utilized during the year	–686.5	–644.0	—	—
Reversed unused amounts	–10.3	–12.9	—	—
Exchange rate difference	24.4	20.6	—	—
Per December 31	**121.5**	**160.1**	**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, 2021	**226.3**	**226.3**
Repurchase bond	–224.8	–224.8
Issuance of bonds	490.1	490.1
Interest expenses	18.1	18.1
Interest paid	–17.2	–17.2
Recognition of loan issuance cost	2.4	2.4
December 31, 2021	**495.0**	**495.0**
January 1, 2022	**495.0**	**495.0**
Repurchase bond	—	—
Interest expenses	23.0	23.0
Interest paid	–21.4	–21.4
Recognition of loan issuance cost	2.5	2.5
December 31, 2022	**499.0**	**499.0**

The long-term portion consists of a bond loan amounting to a total of SEK 500.0 million. It matures on February 11, 2025. The loan has a variable interest rate of STIBOR 3 months +3.75 percent (STIBOR is calculated as zero at the lowest) and has a total framework amount of SEK 1,000 million. The loan agreement contains limitations regarding any change in the company's ownership structure, so-called change-of-control, and quarterly reporting of maintenance test and, when applicable, incurrence test.

	Group	Parent company
2021-12-31		
Interest-bearing liabilities	492.3	492.3
Accrued interest costs	2.7	2.7
	495.0	**495.0**
2022-12-31		
Interest-bearing liabilities	494.8	494.8
Accrued interest costs	4.2	4.2
	499.0	**499.0**

NOTE 27 ACCRUED EXPENSES AND OTHER LIABILITIES

Other liabilities	Group 2022	Group 2021	Parent company 2022	Parent company 2021
Employee withholding tax	2.0	1.7	2.0	1.7
Social security fees	1.6	1.5	1.6	1.5
Special salary tax	2.3	2.2	2.3	2.2
Other current liabilities	15.6	11.4	2.9	3.7
Sum Other liabilities	**21.5**	**16.9**	**8.8**	**9.1**

Accrued expenses	Group 2022	Group 2021	Parent company 2022	Parent company 2021
Accrued salaries	26.3	24.3	2.6	2.5
Accrued vacation pay	6.5	6.0	6.5	6.0
Accrued social security fees	2.8	2.5	2.8	2.5
Accrued expenses interest rates	4.2	2.7	4.2	2.7
Trade allowance	21.1	44.0	—	—
Wholesaler fee reserve	39.9	21.9	—	—
Other accrued expenses	34.7	32.4	23.2	11.3
Sum accrued expenses	**135.6**	**133.7**	**39.3**	**25.0**
Sum other liabilities and accrued expenses	**157.1**	**150.6**	**48.1**	**34.1**

NOTE 28 SHARES IN SUBSIDIARIES AND JOINT VENTURES

Direct and indirect holdings Dec 31, 2022	Corp. Reg. No.	Reg. office	Number of shares	Shareholding	Cost/ Contribution	Accumulated impairment	Carrying amount
Biolipox AB	556588-3658	Stockholm		100%	106.0	—	106.0
Orexo US Inc	90-0643931	USA		100%	55.2	—	55.2
Orexo Pharmaceuticals Inc	87-3270695	USA		100%	0.0	—	0.0
Total							**161.2**

All holdings are owned directly, except Orexo Pharmaceuticals Inc, which is owned by Orexo US Inc.
Shareholders Equity amounted to SEK 146.2 million and net revenue amounted to SEK 4.9 thousand in Biolipox AB[1]
Shareholders Equity amounted to SEK 146.0 million and net revenue amounted to SEK 11.5 million in Orexo US Inc[1]
Shareholders Equity amounted to SEK 0.0 million and net revenue amounted to SEK 0.0 million in Orexo Pharmaceuticals Inc

Change in carrying amount of direct holdings

2021	Opening carrying amount	Acquisition	Contribution	Sales	Impairment	Closing carrying amount
Pharmacall AB	0.1	—	—	–0.1	—	0.0
Biolipox AB	106.0	—	—	—	—	106.0
Orexo US Inc	54.3	—	2.2	—	—	56.4
Orexo Pharmaceuticals Inc	—	0.0	—	—	—	0.0
Total	**160.4**	**0.0**	**2.2**	**–0.1**	**0.0**	**162.4**

2022	Opening carrying amount	Acquisition	Contribution	Sales	Impairment	Closing carrying amount
Biolipox AB	106.0	—	—	—	—	106.0
Orexo US Inc	56.4	—	–1.2	—	—	55.2
Orexo Pharmaceuticals Inc	0.0	—	—	—	—	0.0
Total	**162.4**	**0.0**	**–1.2**	**0.0**	**0.0**	**161.2**

[1] Shareholders Equity and net revenue refers to established numbers as of December 31, 2021.

NOTE 29 AUDITORS' FEES

	Group		Parent company	
	2022	2021	2022	2021
Audit assignment				
Ernst & Young	2.6	1.8	2.6	1.8
Non-auditing assignments				
Ernst & Young	0.6	0.3	0.6	0.3
Tax advice				
Ernst & Young	—	—	—	—
Other services				
Ernst & Young	—	—	—	—
Total	**3.1**	**2.1**	**3.1**	**2.1**

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 1,540 million (1,364) as of December 31, 2022 and refers to the Swedish companies. No deferred tax assets for tax-loss carry-forwards have been capitalized as per December 31, 2022. There is no time limit for when the remaining tax-loss carry-forwards can be utilized.

	Group		Parent company	
	2022	2021	2022	2021
Deferred tax assets				
Temporary differences in current provision	18.8	11.6	—	—
Other temporary differences	14.4	21.8	—	—
Total	**33.1**	**33.4**	—	**—**

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, as well as intercompany gains on inventory. 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 until the increase is known. 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 2022 amounted to SEK 0.4 million.

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

Group	Offices	Motor vehicles	Other	Total
1 January 2021	58.6	7.8	1.4	67.8
Disposals	—	–1.2	—	–1.2
Additions	1.3	1.5	—	2.9
Depreciation expense	–14.7	–3.1	–0.5	–18.4
Translation difference	4.1	3.8	0.2	8.1
31 December 2021	**49.3**	**8.8**	**1.1**	**59.2**
1 January 2022	49.3	8.8	1.1	59.2
Disposals	—	–1.1	—	–1.1
Additions	3.6	0.1	0.0	3.7
Depreciation expense	–15.3	–3.1	–0.5	–18.9
Translation difference	1.7	1.4	0.1	3.2
31 December 2022	**39.3**	**6.1**	**0.6**	**46.0**

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

Group	Offices	Motor vehicles	Other	Total
1 January 2021	57.8	7.2	1.5	66.5
Disposals	—	–1.2	—	–1.2
Additions	1.3	1.5	—	2.9
Interest expense	2.6	0.3	0.1	2.9
Payments	–14.2	–0.4	–0.2	–14.8
Translation difference	1.5	0.5	0.1	2.1
31 December 2021	**48.9**	**7.9**	**1.5**	**58.3**
1 January 2021	48.9	7.9	1.5	58.3
Disposals	—	–1.1	—	–1.1
Additions	3.6	0.1	0.0	3.7
Interest expense	2.0	0.3	0.0	2.4
Payments	–19.2	–2.1	–0.3	–21.6
Translation difference	2.3	0.9	0.1	3.3
31 December 2022	**37.8**	**5.8**	**1.3**	**44.9**

	Group	
	2022	2021
Depreciation of right of use assets	–18.9	–18.4
Interest expense on lease liabilities	–3.7	–2.9
Expenses for short-term leases	–0.4	–0.3
Variable lease payments	—	—
Total lease amounts in statement of operations	**–23.0**	**–21.5**
Total cash outflow for leases	21.6	14.8

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

	Group		Parent company	
	2022	2021	2022	2021
Within one year	22.9	20.8	15.2	13.7
After one year but not more than five years	36.3	45.6	17.5	28.9
More than five years	—	—	—	—
Summa	**59.1**	**66.4**	**32.6**	**42.6**

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	
	2022	2021	2022	2021
Adjustments for items not included in cash flow comprise the following:				
Depreciation and impairment	68.7	53.0	42.1	34.5
Gain/loss on disposal	–0.2	—	–0.2	—
Change in provisions	–64.9	–67.4	–3.0	–11.7
Share based payments	–0.1	1.5	—	1.6
Exchange rate income and expense	–7.0	–3.9	–7.0	–3.9
Other non-cash items	—	—	–1.2	2.1
Total	**–3.5**	**–16.8**	**30.6**	**22.5**

NOTE 33 RELATED PARTY TRANSACTIONS

Purchases and sales between Group companies

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

	2022	2021
Forward invoicing of costs		
Orexo US Inc	–20.9	–22.9
Sale of goods and services		
Orexo US Inc	295.6	324.7
Marketing support		
Orexo US Inc	–106.9	–194.1
Total	**167.9**	**107.7**

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. All transactions have been performed within market conditions.

NOTE 34 SUBSEQUENT EVENTS

Exploratory feasibility studies of amorphOX® initiated in collaboration with two leading biopharmaceutical and vaccine companies in January 2023.

Trial in paragraph IV litigation against Sun Pharmaceutical Industries Ltd took place at the end of January and beginning of February 2023, in the US District Court for the District of New Jersey. The outcome of the trial is expected during the summer of 2023.

New Drug Application was submitted to FDA for OX124, a high-dose rescue medication for opioid overdose, in February 2023. FDA´s ordinary review process is 10 months, but recent review processes in the category have been about 13 months. Orexo is planning to initiate the US launch during H1 2024.

NOTE 35 APPROPRIATION OF PROFIT

Proposed appropriation of profit

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

SEK	
Share premium reserve	1,187,617,020
Loss carried forward	–1,186,604,847
Profit/loss for the year	–196,806,892
Total	**–195,794,720**

The Board proposes that the funds at their disposal SEK –195,794,720 be carried forward.

NOTE 36 PLEDGED ASSETS AND CONTINGENT LIABILITIES

No collateral or contingent liabilities exists as of December 31, 2022, or as of December 31, 2021.

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 23, 2023

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

Christine Rankin
Board member

Michael J Matly
Board member

Mary Pat Christie
Board member

Nikolaj Sørensen
President and CEO

Our audit report was submitted on March 28, 2023

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 2022. The annual accounts and consolidated accounts of the company are included on pages 60–100 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 2022 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 2022 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.

Material uncertainty related to going concern

We draw attention to the Board of Director's report and Note 4 in the financial statements, where it is stated that shareholders' equity in the parent company is expected to decrease during the first half of 2023 and that it cannot be ruled out that the shareholders' equity in the parent company may become less than half of the registered share capital unless measures are taken.

This means that the Board of Directors and the Managing Director have concluded that there are uncertainty factors related to events or conditions which may cast significant doubt regarding the entity's ability to continue as a going concern. The Board of Directors and the Managing Director have determined that the expected negative development of the shareholders' equity in the parent company will be managed primarily through improved profitability, value enhancing business development and cost savings and secondarily through a potential addition of external capital. The Board of Directors and the Managing Director disclose in the Board of Director's report and Note 4 that they continuously assess the parent company's and the group's liquidity and financial resources in both the short and long term.

These events or conditions, along with other matters as set forth in the report, indicate that a material uncertainty exists that may cast significant doubt on the Company's ability to continue as a going concern. Our opinion is not modified in respect of this matter.

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 2022 was MSEK 624.3 in the consolidated income statement and MSEK 348.2 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 payers and provisions for expected future 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 for 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 217.4 in the consolidated balance sheet and MSEK 181.4 in the parent company balance sheet as of December 31, 2022. The Company tests, when there is an indication of impairment, but at least annually for intangible assets not yet in use, 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. 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 1–59 and 105–118. 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

Report on the audit of the administration and the proposed appropriations of the company's profit or loss

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 2022 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.

The auditor's examination of the ESEF report

Opinion

In addition to our audit of the annual accounts and consolidated accounts, we have also examined that the Board of Directors and the Managing Director have prepared the annual accounts and consolidated accounts in a format that enables uniform electronic reporting (the Esef report) pursuant to Chapter 16, Section 4(a) of the Swedish Securities Market Act (2007:528) for Orexo AB for the financial year 2022.

Our examination and our opinion relate only to the statutory requirements.

In our opinion, the Esef report has been prepared in a format that, in all material respects, enables uniform electronic reporting.

Basis for opinion

We have performed the examination in accordance with FAR's recommendation RevR 18 Examination of the ESEF report. Our responsibility under this recommendation is described in more detail in the Auditors' responsibility section. We are independent of Orexo AB 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 evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

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 Esef report in accordance with Chapter 16, Section 4(a) of the Swedish Securities Market Act (2007:528), and for such internal control that the Board of Directors and the Managing Director determine is necessary to prepare the Esef report without material misstatements, whether due to fraud or error.

Auditor's responsibility

Our responsibility is to obtain reasonable assurance whether the Esef report is in all material respects prepared in a format that meets the requirements of Chapter 16, Section 4(a) of the Swedish Securities Market Act (2007:528), based on the procedures performed.

RevR 18 requires us to plan and execute procedures to achieve reasonable assurance that the Esef report is prepared in a format that meets these requirements.

Reasonable assurance is a high level of assurance, but it is not a guarantee that an engagement carried out according to RevR 18 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 aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of the Esef report.

The audit firm applies ISQC 1 Quality Control for Firms that Perform Audits and Reviews of Financial Statements, and other Assurance and Related Services Engagements and accordingly maintains a comprehensive system of quality control, including documented policies and procedures regarding compliance with professional ethical requirements, professional standards and legal and regulatory requirements.

The examination involves obtaining evidence, through various procedures, that the Esef report has been prepared in a format that enables uniform electronic reporting of the annual and consolidated accounts. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement in the report, whether due to fraud or error. In carrying out this risk assessment, and in order to design audit procedures that are appropriate in the circumstances, the auditor considers those elements of internal control that are relevant to the preparation of the Esef report by the Board of Directors and the Managing Director, but not for the purpose of expressing an opinion on the effectiveness of those internal controls. The examination also includes an evaluation of the appropriateness and reasonableness of assumptions made by the Board of Directors and the Managing Director.

The procedures mainly include a validation that the Esef report has been prepared in a valid XHTML format and a reconciliation of the Esef report with the audited annual accounts and consolidated accounts.

Furthermore, the procedures also include an assessment of whether the consolidated statement of financial performance, financial position, changes in equity, cash flow and disclosures in the Esef report have been marked with iXBRL in accordance with what follows from the Esef regulation.

Ernst & Young AB, Hamngatan 26, 111 47, Stockholm, was appointed auditor of Orexo AB by the general meeting of the shareholders on 21 April 2022 and has been the company's auditor since 15 April 2016.

Stockholm 28 March 2023
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	2022	2021
EBIT	–183.9	–214.1
Depreciation and amortization	68.7	53.0
EBITDA	**–115.2**	**–161.0**
External costs for clinical studies	96.4	63.5
IP litigation and subpoena costs	76.6	59.6
EBITDA excluding external costs for clinical studies. IP litigation and subpoena	**57.8**	**–37.9**

Cash and invested funds SEK million	2022	2021
Short-term investments	219.6	–
Cash and cash equivalents	132.2	504.1
Cash and invested funds	**351.9**	**504.1**

Return on shareholders' equity SEK million	2022	2021
Shareholders' equity beginning balance	349.6	558.5
Shareholders' equity ending balance	193.9	349.6
Average shareholders' equity	271.8	454.1
Net earnings	–177.6	–223.5
Return on shareholders' equity %	**–65.4**	**–49.2**

Operating expenses SEK million	2022	2021
Selling expenses	–199.0	–280.4
Administrative expenses	–202.3	–151.5
Research and development costs	–318.0	–272.3
Other operating income and expenses	13.7	4.0
Operating expenses	**–705.6**	**–700.2**

Gross investments SEK million	2022	2021
Investments in tangible fixed assets	18.8	24.7
Investments in intangible fixed assets	5.1	28.1
Operating expenses	**23.9**	**52.9**

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

Margins	Definition/calculation	Purpose
Gross margin	Gross profit divided by net revenues	Gross Margin is used to measure the relative direct profitability from sold products
Operating margin (EBIT margin)	Operating earnings as a percentage of net revenues	Operating profit margin is used for measuring the operational profitability

Return	Definition/calculation	Purpose
Return on equity	Net earnings for the period as a percentage of average shareholders' equity	Return on equity is used to measure profit generation, given the resources attributable to the owners of the parent company

Capital structure	Definition/calculation	Purpose
Cash and invested funds	Short-term investments plus cash and cash equivalents	Cash and invested funds is used to measure how much cash company has available in short-term from bank balances and invested funds
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 excluding cash and cash equivalents less current liabilities excluding interest bearing 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

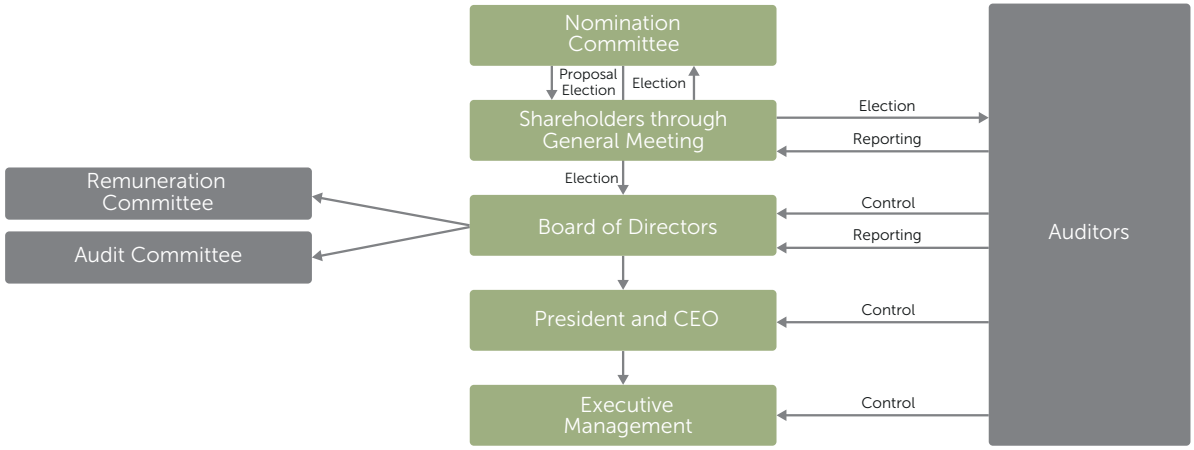
Corporate governance

Corporate governance report for Orexo AB (publ)

Orexo is a Swedish public limited liability company, with its registered office in Uppsala, Sweden. The company's shares are listed on Nasdaq (Small 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 (34,710,639), distributed among 7,158 shareholders (7,272).

The 10 largest shareholders held 54.0 percent (58.3) of the outstanding shares, management 0.5 percent (0.4) and other shareholders 45.5 percent (41.3). At December 31, 2022 one shareholder held shares representing 10 percent or more of the company – Novo Holding A/S, 27.8 percent. Non-Swedish shareholders accounted for approximately 43 percent (43) of the total number of shares. Institutions and industrial owners hold the majority of shares. At year-end, 62 percent (74) of the shares were held by legal entities, and 38 percent (26) 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 2022

The Annual General Meeting was held on Tuesday, April 21, 2022 in Uppsala. At the Meeting:

- James Noble, Staffan Lindstrand, Henrik Kjaer Hansen, Mary-Pat Christie, Fred Wilkinson and Charlotte Hansson were re-elected as Board members. Christine Rankin and Michael J Matly were elected as new members of the board.
- James Noble was re-elected as Chairman of the Board.
- Ernst and Young Aktiebolag was re-elected as auditor.
- A resolution was adopted that fees for Board members should amount to SEK 3,550,000, with SEK 900,000 paid to the Chairman of the Board, SEK 300,000 to each of the other Board members, and a total of SEK 400,000 distributed between the members of the Audit Committee, so that the Chairman of the committee receives SEK 200,000 and SEK 200,000 is distributed between the other committee members for their work on the committee, and in total 150,000 to be allocated to the members of the remuneration committee in equal parts between the members of the committee, and that fees to the auditor should be paid against approved accounts.
- Further, the annual general meeting resolved on an additional board fee in accordance with the nomination committee's proposal to the board members James Noble, Staffan Lindstrand, Fred Wilkinson, Mary Pat Christie, Charlotte Hansson, Christine Rankin and Michael J Matly of SEK 1,050,000, subject to (i) the board member's acquisition of shares in Orexo for the entire part (after taxes) of such additional board fee as soon as possible following the annual general meeting's resolution and the pay-out of the additional board fee, and (ii) the board member's commitment not to sell the shares during the board member's entire tenure on the Orexo board. The additional board fee is to be allocated as follows: SEK 450,000 to the chairman, corresponding to 50 percent of the ordinary board fee to the chairman, and SEK 100,000 to each of Staffan Lindstrand,- Fred Wilkinson, Mary Pat Christie, Charlotte Hansson, Christine Rankin and Michael J Matly, corresponding to 33 percent of the ordinary board fee to such board members. In the event that the board member, before the succeeding annual general meeting, is dismissed due to breach of his/her obligations as a board member or leaves the board at his/her own request, the board member must repay the entire additional board fee (after taxes).
- The Board's motion concerning guidelines for remuneration to the management was approved.

- The motion concerning the appointment of a Nomination Committee for AGM 2023 was approved.
- The balance sheet and income statement for the parent company and the Group for the 2021 fiscal year were adopted. It was resolved that there should be no dividend for 2021 and that the results of the company shall be carried forward.
- The Annual General Meeting granted Board members and the President discharge from liability for the 2021 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 adopt a long-term incentive program for senior executives and key employees within the Orexo group.
- 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 2022 Annual General Meeting can be found at www.orexo.com.

Annual General Meeting 2023

The Annual General Meeting of Orexo AB will be held on Tuesday, April 18, 2023. 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 2022 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 as per September 30, 2022, 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 17, 2022. The Committee held 1 (2) 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 2022:

Name	Representatives
Christian Salling	Novo Holding A/S, and Chairman of the Nomination Committee
Patrik Walldov	Representantative for Anders Walldov (incl. indirect holding via Brohuvudet AB)
Claus Berner Møller	Arbejdsmarkedets Tillaegspension (ATP)
James Noble	Chairman of the Board of Orexo

Combined, the Nomination Committee represents about 38 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

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	14/14	2/2	4/4
Charlotte Hansson	Board member	■	2020	13/14	–	4/4
Henrik Kjaer Hansen	Board member	■	2018	13/14	–	–
Mary-Pat Christie	Board member	■	2019	13/14	–	–
Staffan Lindstrand	Board member	■	2002	14/14	2/2	–
Fred Wilkinson	Board member	■	2019	14/14	–	–
Christine Rankin	Board member	■	2021	9/9	1/1	3/3
Michael J Matly	Board member	■	2021	9/9	–	–

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

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 Staffan Lindstrand, Henrik Kjaer Hansen, Charlotte Hansson, Mary-Pat Christie, Fred Wilkinson, Christine Rankin and Michael J Matly. For a more detailed description of Board members, please refer to page 114.

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 (16) meetings, of which 14 (16) 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 2022 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. Further, the annual general meeting resolved on an additional board fee in accordance with the nomination committee's proposal to the board members James Noble, Staffan Lindstrand, Fred Wilkinson, Mary Pat Christie, Charlotte Hansson, Christine Rankin and Michael J Matlyn of SEK 1,050,000, subject to (i) the board member's acquisition of shares in Orexo for the entire part (after taxes) of such additional board fee as soon as possible following the annual general meeting's resolution and the pay-out of the additional board fee, and (ii) the board member's commitment not to sell the shares during the board member's entire tenure on the Orexo board. The additional board fee is to be allocated as follows: SEK 450,000 to the chairman, corresponding to 50 percent of the ordinary board fee to the chairman, and SEK 100,000 to each of Staffan Lindstrand, Fred Wilkinson, Mary Pat Christie, Charlotte Hansson, Christine Rankin and Michael J Matly, corresponding to 33 percent of the ordinary board fee to such board members. In the event that the board member, before the succeeding annual general meeting, is dismissed due to breach of his/her obligations as a board member or leaves the board at his/her own request, the board member must repay the entire additional board fee (after taxes).

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 110. 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 one, 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 Christine Rankin.

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 employee stock options and share awards 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), Christine Rankin and Staffan Lindstrand. During the year, the Remuneration Committee was convened on 2 (2) occasions 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 2022 EY was re-elected as auditors until the Annual General Meeting 2023. The external auditors discuss the external audit plan and risk management with the Audit Committee. The auditors perform a review of the interim report for the third quarter, and audit the annual accounts and consolidated financial statements. The auditors also express an opinion on whether this Corporate Governance Report has been prepared in accordance with, and whether certain disclosures herein are consistent with, the annual accounts and consolidated financial statements. The auditors report the results of their audit of the annual accounts and consolidated financial statements, their review of the Corporate Governance Report in the auditor's report, and a separate opinion on the Corporate Governance Report, in a presentation to the AGM. In addition, the auditors present detailed findings from their reviews to the Audit Committee three times per year, and to the Board in its entirety once per year.

For information regarding fees for the company's auditors, see Note 29.

President and the Management

The President leads the work of the Management Team and makes decision in consultation with them. At the end of 2022 the Management Team consisted of six 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 116.

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 com-

pany'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 2023 Annual General Meeting (convening notice, Nomination Committee proposals, presentation of the work of the Nomination Committee, etc.).

Board of directors

James Noble

Chairman of the Board of Directors since 2020.

M.A. from the University of Oxford.

Other appointments
Chairman of the Board of Pneumagen Ltd, Ingenox Therapeutics, and another private UK-based cancer research company. Board member of Adaptimmune and Lava Therapeutics.

Previous experience
Co-founder and CEO of Adaptimmune and Immunocore. Board member and Deputy Chairman of GW Pharmaceuticals until its acquisition by Jazz Pharmaceuticals. Chairman and CEO of Avidex, which was acquired by Medigene. Other positions as Board member include companies, such as Medigene, PowderJect Pharmaceuticals and CuraGen Corporation.

Holdings 2022
28,000 shares, and bonds of a nominal value of SEK 2,500,000.

Staffan Lindstrand

Board member since 2002.

M.Sc. in Engineering.

Other appointments
Partner of HealthCap since 1997, Board member of HealthCap AB, Doctrin AB, Elsa Science AB, GET.ON Institut für Online Gesundheitstrainings GmbH, and The Swedish Association of Exchange-listed companies.

Previous experience
Ten years in investment banking.

Holdings 2022
27,630 shares.

Charlotte Hansson

Board member since 2020.

MSc. in Business Administration from Handelshögskolan at the University of Gothenburg.

Other appointments
CFO at Tele 2 AB.

Previous experience
CFO at Systembolaget AB, CFO & Executive VP at Cision AB, CFO at Addici AB and various positions within business controlling at Modern Times Group.

Holdings 2022
5,500 shares.

Henrik Kjaer Hansen

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 experience
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.

Holdings 2022
Does not hold any shares in Orexo.

Dependent in relation to the company's largest shareholders.

Christine Rankin

Board member since 2022.

BSc. in Business Administration and Economics from Stockholm University

Other appointments
Board member at CoinShares International Ltd and SVP Corporate Control at Veoneer Inc.

Previous experience
Board member at Adventure Box Technology AB and at Technopolis Plc, CFO at Cherry AB, interim CFO/ Head of Finance at Serneke Group, Head of Corporate Control at Spotify and Partner/Head of the US Capital Markets group in Sweden at PwC.

Holdings 2022
2,675 shares.

Michael J Matly

Board member since 2022.

MBA from Harvard Business School, Medical Doctorate from Mayo Clinic College of Medicine, and Bachelor of Science from Cornell University.

Other appointments
Co-Founder och Managing Partner på 111° West Capital.

Previous experience
Managing Director at Montreux Growth Partners and Director within Business Development and Investments at Mayo Clinic.

Holdings 2022
2,820 shares.

Mary Pat Christie

Board member since 2019.

MBA.

Other appointments
Board member of Hackensack Meridian Health's Carrier Clinic and Restaurant Technologies.

Previous experience
Managing Director at Angelo Gordon & Co., where she focused on business development of new fund strategies and new strategic alliances. Prior to that at Cantor Fitzgerald as an Institutional Salesperson and was an original partner at the Seaport Group. Christie was also the founder of Mendham Capital Management. Her career also includes high level roles at JP Morgan, Donaldson, Lufkin & Jenrette, and Fleet Bank.

Holdings 2022
3,965 shares.

Fred George Wilkinson

Board member since 2019.

MBA., B.Sc. Pharmacy

Other appointments
Board member of Alter Pharma Group.

Previous experience
Chief Executive Officer and Board member of Impax Laboratories, Inc., President of the Specialty business at Watson Pharmaceuticals, Inc. (currently Allergan), President of Duramed Pharmaceuticals, Inc., Chief Executive Officer of Columbia Laboratories, and multiple positions at Sandoz Pharmaceutical Corporation, Inc.

Holdings 2022
5,200 shares.

Management

Nikolaj Sørensen

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, Moberg Pharma AB and Gesynta Pharma AB.

Previous experience
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 management consultant at Boston Consulting Group (BCG), leading several projects within M&A, commercial transformation, and turn-arounds.

Holdings 2022
121,605 shares and stock options/share awards entitling to 362,544 shares.

Fredrik Järrsten

EVP and Chief Financial Officer since 2022

B.Sc. and M.Sc. majoring in Accounting and Finance at the Stockholm School of Economics, Sweden, and International Business at the University of Michigan – Stephen M. Ross School of Business, US.

Previous experience
CFO Vivesto AB, 2021–juni 2022. CFO och vVD Karolinska Development AB, 2018-2020. CFO Bactiguard AB, 2014-2017. Prior to holding various positions as CFO Fredrik Järrsten served as Director Business Development at Aleris AB, 2006-2013. Additionally Fredrik Järrsten has worked as Investment Manager at Litorina Kapital and within Corporate Finance at Lazard and SEB Enskilda.

Holdings 2022
10,500 shares and stock options/share awards entitling to 103,200 shares.

Robert A. DeLuca

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 experience
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.

Holdings 2022
8,568 shares and stock options/share awards entitling to 185,889 shares.

Edward Kim

Chief Medical Officer since 2022.

MBA in Healthcare Management from University of Massachusetts, US, MD from Thomas Jefferson University, US and AB in Biology from Harvard University, US.

Previous experience
Extensive experience in medical affairs, health economics and outcomes research, and clinical development across multiple senior positions within the pharmaceutical industry. Most recently served as VP and Head of Medical Affairs at Biohaven Pharmaceuticals. Over a decade of experience in clinical practice, academia, and hospital administration as a board-certified psychiatrist.

Holdings 2022
Does not hold any shares or stock options/share awards in Orexo.

Robert Rönn

SVP and Head of R&D since 2019, employed since 2007.

MSc in Chemical Engineering and PhD in Medicinal Chemistry, Uppsala University, Sweden.

Previous experience
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.

Holdings 2022
7,121 shares and stock options/share awards entitling to 140,422 shares.

Cecilia Coupland

SVP and Head of Operations since 2019, employed since 2006.

MSc in Chemical Engineering, Uppsala University, Sweden.

Previous experience
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.

Holdings 2022
11,014 shares stock options/share awards entitling to 134,699 shares.

Auditor's report on the corporate governance report

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 2022 on pages 107–117 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.

Stockholm, Sweden, March 28, 2023
Ernst & Young AB

Anna Svanberg
Authorized Public Accountant

Production Solberg. Photo Oskar Hökerberg pages 8, 14, 23, 49 and 51. Jenny Lagerqvist pages 27, 40, 68 and 107. GettyImages and iStockphoto. The people in the photos are models. The photos are used for illustrative purposes only.

ABOUT OREXO

Orexo develops improved pharmaceuticals and digital therapies addressing unmet needs within the growing space of substance use disorders and mental health. 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 2022 amounted to SEK 624 million and the number of employees was 126. Orexo is listed on the Nasdaq Stockholm Main Market (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.