orexo

Interim Report Q4 2022, incl. Full Year Report

Important steps forward in a challenging environment

Q4 2022 highlights

- Total net revenues of SEK 156.1 m (144.0)
- EBITDA of SEK -53.1 m (-48.5), EBITDA excluding legal costs and costs for non-repeating clinical trials, SEK -0.1 m (-10.5)
- Net earnings of SEK -91.8 m (-66.0)
- US Pharma segment (ZUBSOLV® US) net revenues of SEK 142.6 m (133.6), in local currency USD 13.3 m (15.1), US Pharma EBIT of SEK 77.0 m (72.2)
- Cash flow from operating activities of SEK -48.9 m (-80.6), cash and invested funds of SEK 351.9 m (504.1) a reduction of SEK 92,0 m from SEK 443.9 m in Q3
- Earnings per share before and after dilution amounted to -2.67 (-1.92)
- Positive data announced from first clinical study for OX640
- Ed Kim, M.D., appointed as Chief Medical Officer, replacing Michael Sumner, M.D.
- Last patient enrolled in the clinical trial for MODIA®
- Financial outlook provided for 2023, see page 12

Important events after the period

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

SEK 156 m
Group revenues

SEK 77 m
US Pharma EBIT

SEK 352 m
Cash and invested funds

SEK m, unless otherwise stated	2022 Oct-Dec	2021 Oct-Dec	% change quarter	2022 Jan-Dec	2021 Jan-Dec	% change year
Net revenues	156.1	144.0	8.4%	624.3	565.0	10.5%
Cost of goods sold	-25.9	-20.3	27.8%	-102.6	-78.9	30.1%
Operating expenses	-201.3	-187.8	7.2%	-705.6	-700.2	0.8%
EBIT	-71.1	-64.1	11.0%	-183.9	-214.1	-14.1%
EBIT margin	-45.6%	-44.5%	1.1%	-29.5%	-37.9%	-8.4%
EBITDA	-53.1	-48.5	9.5%	-115.2	-161.0	-28.4%
Earnings per share, before dilution, SEK	-2.67	-1.92	39.1%	-5.17	-6.51	-20.6%
Earnings per share, after dilution, SEK	-2.67	-1.92	39.1%	-5.17	-6.51	-20.6%
Cash flow from operating activities	-48.9	-80.6	-39.4%	-156.6	-229.0	-31.6%
Cash and invested funds	351.9	504.1	-30.2%	351.9	504.1	-30.2%

Unless otherwise stated in this report, all data refers to the Group, and numbers relate to the current quarter while numbers in parentheses relate to the corresponding period in 2021.

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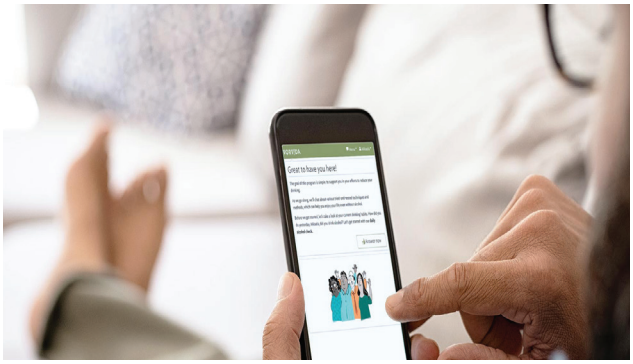
About Orexo
Orexo develops improved pharmaceuticals and digital therapies addressing unmet needs within the growing space of substance use disorders and mental health. The products are commercialized by Orexo in the US or via partners worldwide. The main market today is the American market for buprenorphine/naloxone 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.



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Presentation
At 2 pm CET the same day as the announcement of the report Orexo invites analysts, investors and media to attend a presentation where Nikolaj Sørensen, CEO and Fredrik Järrsten, CFO, will present the report and host a Q&A.

To attend via teleconference where you can ask questions verbally use this link:
https://conference.financialhearings.com/teleconference/?id=5003429
When registered you will be provided phone numbers and a conference ID to access the conference.

To attend via webcast:
https://ir.financialhearings.com/orexo-q4-2022

Prior to the call presentation material will be available on Orexo´s website Investors/Reports/Audiocasts.

Financial calendar 2023
Annual Report 2022 - March 24
Annual General Meeting 2023 - April 18, at 4 pm
Interim Report Q1 2023 - April 27, at 8 am
Interim Report Q2 2023 - July 18, at 8 am
Interim Report Q3 2023 - November 2, at 8 am
Interim Report Q4 2023, incl. Full Year Report, January 25, at 8 am

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

Well positioned to capture new market opportunities and reach profitability

In the quarter we saw steady progress in our pipeline, in particular the broadening of the application of amorphOX® to new categories of molecules, in partnership with leading international biopharmaceutical companies communicated early in 2023. It is also encouraging to see new market opportunities for ZUBSOLV® and MODIA® in the US due to the largest change in legislation for treatment of opioid use disorder (OUD) since the launch of ZUBSOLV®, removing most restrictions on the prescription of buprenorphine for the treatment of OUD. As expected, EBIT in Q4 was affected by high non-recurring operating costs and the continued strength of the USD. On a full year basis, our financial development compared to last year is positive with improved revenues and EBIT, although both affected by FX fluctuations. The main concern in the quarter is our digital therapies and consequently in beginning of 2023 we have re-organized our US commercial operations in the US to increase focus on sales and improve efficiencies.

New market opportunities in OUD
I am pleased to see a continued stable ZUBSOLV® demand comparing to the previous quarter. Market growth has been lower than our expectations in H2 resulting in a mild decline in USD net sales comparing to H1. Since the launch of ZUBSOLV® in 2013 we have faced a market with restrictions in who can prescribe ZUBSOLV® and, to how many patients. Late in December the US congress passed a bill to open up for most physicians in the US to treat OUD with buprenorphine i.e., removing the DATA 2000 waiver and cap on how many patients can be treated. This imminent change will over time transform the treatment of OUD in the US, creating growth opportunities for Orexo.

MATcore™ - a digital platform collecting Orexo´s offering within OUD
Orexo is uniquely positioned to leverage this new legislation, with our ability to offer both medication and psychosocial treatment with MODIA®. As a first step we have developed a new concept MATCore™ where we are collaborating with healthcare providers to develop a customized comprehensive digitized service to patients enabling access to medication, psychosocial support and general OUD resources. In Q4 a healthcare provider in Arizona has received a state grant to work with Orexo to implement MATCore™ customized for the regional patient population. In combination with the legislative changes, this new concept will open new avenues to expand the business, but requires a more integrated approach to the market across our business areas, US Pharma and Digital Therapeutics.

Changes in the Digital Therapeutics business area
In Q4 we have continued to see a high utilization of MODIA®. Orexo expects to receive the first payments in Q1 as reimbursement pathways are confirmed. MODIA® sales is highly complementary to our sales of ZUBSOLV® (and soon also OX124) and with the introduction of MATCore™, we envisage additional synergies between our pharmaceutical business and DTx. We have not yet seen any material revenues from our contract with Trinity Health and we are working with them to improve their primary care physicians´ confidence in the utilization of our digital therapies.

The main issue has been the need to “pull-through” the products with the physicians, which is similar to any pharmaceutical product i.e., we need sales people to educate and remind physicians about the benefit of these new products.

"Orexo is uniquely positioned to leverage this new legislation, with an ability to offer both medication and psychosocial treatment with MODIA®

Orexo has this capability in our US Pharma business and together with a broader opportunity to use ZUBSOLV® and MODIA® due to the legislative changes, we see increased synergies between our US Pharma and our Digital Therapeutics businesses.

Consequently, we have now 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. As I will continue to follow up the businesses separately, we will keep our current segment reporting. Expenses for Digital Therapeutics will decrease primarily due to lower costs related to senior management positions. More importantly 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.

"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

Capitalizing the amorphOX® drug delivery platform
Our main focus in R&D has been on OX124, our high-dose medication for opioid overdose, and the objective of filing with the FDA before end of 2022. This is now planned for early Q1 2023, primarily due to the delay in administrative processes and responses from the FDA. We are confident we will be ready to file early in Q1 2023 and the ambition is to launch in H1 2024, if the application is approved according to expected timelines.

In addition to the work with OX124, we have continue to strengthen the documentation of the benefits of our drug delivery platform amorphOX® when it is applied to new small molecules and large biomolecules. To fully test and develop differentiated products that go beyond our lead therapeutic areas in mental illness and substance use disorder, Orexo seeks collaboration with partners. Our partnerships with two leading international companies in biomolecules announced January 9, 2023, confirms the potential of and interest in amorphOX®. In 2023 we look forward to evolving these relationships and entering new partnerships with other leading companies.

Summary and outlook
With a solid cash position and profitable recurring ZUBSOLV® business Orexo stands on stable ground, enabling us to capture new market expansion opportunities in OUD and to leverage our new technology platform amorphOX®. In 2023 we expect to reach several major milestones for the company: including, potential FDA approval of OX124, data from the MODIA® clinical study, amorphOX® partnerships, launch of MATCore™, and the conclusion in the District Court of the SUN IP-litigation. The latter is scheduled for a court hearing starting January 30 and a decision is expected during the summer.

2022 has been a challenging year for the world, the life science industry, Orexo and our shareholders. My colleagues and I are confident that 2023 offers multitudinous opportunities and we are well positioned to have a more successful year, aiming to reach profitability in Q4.

Uppsala, Sweden, January 26, 2023

Nikolaj Sørensen
President and CEO

Business update

US Pharma

ZUBSOLV® - sublingual tablet for treatment of opioid use disorder

Late in Q4 the US congress passed a law, essentially removing restrictions on the prescribing limitations of buprenorphine products for the treatment of OUD. The new law, effective January 1, 2023, eliminates the DATA 2000 requirements for waiver and patient caps and now all physicians and non-physician prescribers of any controlled drug substance (including pain meds, ADHD meds etc.) will be required to complete a one-time, 8-hour training on substance use disorder at some point in time (to be determined) before their DEA licensing number can be renewed. With only 1.8 million Americans under medication assisted treatment (MAT) today, among a population of approximately 10.1 million misusing opioids, there is a great treatment gap.[1] The law provides a potential path forward for making MAT a more mainstream treatment across the US and will most likely fuel the buprenorphine/naloxone market. The law has been passed, but the details for practical implementation are still being worked out by government agencies.

In Q4 the buprenorphine/naloxone market was flat versus Q3 2022 and grew 3 percent versus last year. This slow growth from double-digit growth prior to 2020 can be attributed to limited access to treatment during Covid-19 and the broad availability of illicit fentanyl analogues across the US. Fentanyl is the cause for a significant increase in overdoses and according to physicians also makes the patients more difficult to treat with increased rate of relapse during the challenging induction of treatment phase of OUD therapy. The pandemic and constrain on healthcare resources continue to negatively impact access to OUD treatment. Expectations are that the buprenorphine/ naloxone market growth will be positively impacted as the Covid-19 pandemic wanes and by the new law (see above) significantly increasing access to MAT, through the withdrawal of current prescribing limitations.

On a year over year basis, Q4 2022 compared to Q4 2021, ZUBSOLV® demand declined 9 percent. This is a slowing decline compared to the prior quarter's year over year 11 percent decline, due to the continued impact from addition of generics to the formulary status at Humana and United Health Group. During Q4 ZUBSOLV's overall prescription volume declined 2 percent versus Q3 2022. Orexo´s core segment, the open segment, where ZUBSOLV® is reimbursed and competes on equal terms with both branded products and/or generics, was down 1 percent versus Q3 2022.

As previously reported, New York State's MAT Open Access law has been implemented by all Medicaid plans in the state effective March 22, 2022. This law requires all Medicaid plans reimburse all MAT products including ZUBSOLV® as preferred without any restrictions. Also, similar legislation was previously passed in Kentucky in 2021. New York State and Kentucky are the second and fourth, respectively, largest volume Medicaid states in this treatment area creating an important treatment growth opportunity. ZUBSOLV® New York State Medicaid volume has grown 12 percent in Q4 2022 over Q3 2022. ZUBSOLV® Kentucky Medicaid volume has grown 18 percent in Q4 2022 over Q3 2022.

ZUBSOLV's market access in the public payer segment maintained at 48 percent of patients having unrestricted access to ZUBSOLV®. ZUBSOLV's best in class market access in the Commercial payer segment maintained at 98 percent. These ZUBSOLV® reimbursement levels are confirmed by all large payers in the US.

MATCore™

MATCore™ is a digital platform for support in the treatment of OUD. Orexo has applied its deep expertise in OUD and understanding of the patient population to design this tool. Except from collecting Orexo´s current offering within OUD, MATCore™ is intended to provide patients with access to disease education, counseling, and other pertinent resources, coupled with nudges that have been shown to engage chronically ill patients in their well-being and therapy to help improve treatment persistence. In addition, MATCore™ collects and analyzes data and information through a variety of sources, enabling healthcare practitioners with key reports and analytics to assist in improving recovery and treatment outcomes.

During Q4, the State of Arizona's Office of the Attorney General issued it's first grant application process to local Arizona providers offering access to a portion of the state's opioid settlement funds. The purpose of this grant process was to review proposals that support treatment of OUD (opioid use disorder) and co-occurring conditions through evidence based, evidence informed, or promising programs or strategies for the citizens of Arizona.

Alay Psychiatry applied for and was awarded a grant from the Arizona State Attorney General's office with the express purpose to implement Orexo's MATCore™ product offering. Alay Psychiatry is an outpatient clinic with offices in Arizona that is dedicated to implementing innovative technologies to extend and improve treatment and access for OUD patients. Alay Psychiatry and Orexo will begin implementation of this grant award during Q1 2023.

[1] SAMHSA

Digital Therapeutics

modia deprexis® VORVIDA®

MODIA® – digital therapy for opioid use disorder
deprexis® – digital therapy for depression
vorvida® – digital therapy for alcohol management

The MODIA® early commercialization efforts gained momentum during Q4 2022. The number of patients utilizing the modiaOne™ early experience program has since start increased to over 2,800. In addition, multiple patients in clinics across three prioritized states are being processed in local billing and reimbursement tests to confirm the reimbursement pathway available in each state. During these tests, offices will be submitting claims for reimbursement from local Medicaid, Medicare, and commercial payers. As these initial claims come back approved, the clinics will execute direct contracts with Orexo for MODIA®, meaning the first reimbursed revenue for MODIA® is expected in Q1 2023. With our strategy for MODIA® to create awareness, confirm interest, gain trial via modiaONE™, then test reimbursement and contracting in each state, we are executing according to plan. With respect to the MODIA®, clinical trial recruitment was completed in Q4 at 437 patients in total. The clinical team is now working with sites to complete the study protocol and begin the process for data capture and analysis with an expected FDA 510K filing based on the study results in H2 2023. Pending FDA approval MODIA® is marketed under the Emergency Use Authorization pathway granted by the FDA.

In Q4 the Wayside Recovery Center was awarded a grant from the state of Minnesota to provide access to both deprexis® and vorvida® for 60 patients. The Wayside Recovery Center is a specialized women's addiction treatment center with locations in Minneapolis and surrounding suburbs. The focus of this grant is to provide access to expecting mothers who have mental health and substance use disorder needs. This is a paid grant providing sales recognition for both therapies. Our efforts at Trinity Health in North Dakota are continuing with an emphasis on primary care physician training, patient identification and patient enrolment. Although Trinity Health has started with the first patients, additional efforts are needed to make primary care physicians comfortable with the enrolment process.

Efforts at the Veteran Affairs (VA) for deprexis® in Q4 followed the phased plan described in the Q3 report when the contract award was announced. The VA requires a unique administrative process and focus has been on detailed mapping of the prioritized regions and establish necessary contacts to ensure efficient pathways for patients to access deprexis®. The first collaboration with key stakeholders within the VA has been initiated with an ambition to define the pathways for enrolment, patient support and distribution of deprexis®.

Through Q4 2022, the Orexo DTx portfolio now has over 4,600 patients across early access commercial programs and clinical trials. The base investment focus for 2023 is highly targeted and prioritized to efforts that will continue to advance MODIA® reimbursed revenues, developing the Trinity Health model at targeted systems, and executing against the phased pull through plan at the VA. 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.

HQ & Pipeline

amorphOX® – a new proprietary drug delivery platform

Orexo's proprietary drug delivery platform, amorphOX®, is a powder using a unique combination of a drug, carrier materials and other ingredients. The particles are presented as an amorphous composite of the various ingredients providing for excellent chemical and physical stability, as well as rapid dissolution. The technology works for a broad scope of active ingredients, including both small and large molecules. amorphOX®, has been validated in several human clinical studies showing rapid and extensive drug exposure. In addition, studies have demonstrated outstanding stability of the substances after long period of storage in both low and high temperatures.

A commercial supply chain has been established for Orexo´s fully developed pharmaceutical candidate OX124. This will contribute to shorter timelines, reduced costs, and limit risks in the development of future products based on the amorphOX® platform using nasal delivery. Development of products based on the technology will be conducted by Orexo and in partnership with other pharmaceutical companies. Several patent applications directed to the amorphOX® platform have been filed or approved, which should serve to protect the technology until 2042.

The wide applications of the drug delivery platform amorphOX® entail Orexo to continuously conduct test the platform along with new APIs, including both small and large molecules. Also, stability studies are performed. In the quarter, the platform was successfully used to formulate covid-19 spike protein, showing excellent stability data.

In beginning of 2023, two exploratory feasibility studies were initiated applying amorphOX® to a protein based pharmaceutical and a vaccine. The studies are conducted in collaboration with leading international biopharmaceutical and vaccine companies.

Development projects based on the amorphOX® drug delivery platform

OX124 – high-dose medication for opioid overdose containing naloxone

Progress during the quarter:
All focus were allocated to compile the new drug application (NDA) for submission with the FDA before end of 2022. The submission has been dependent on feedback from the FDA, which was received in January, 2023, and resulted in a delay in the submission into early Q1. FDA´s reviewing and approval process is normally 10 months, but recent applications in the disease space has taken 13 months.

Project in brief:
Based on the proprietary drug delivery platform amorphOX®, Orexo has developed a high-dose naloxone rescue medication, OX124, designed to reverse opioid overdoses, including those from highly potent synthetic opioids. OX124 has shown more rapid absorption, substantially higher plasma concentrations of naloxone, and sustained duration of elevated plasma concentrations when compared to the current market leader. OX124 has patents protecting the product until 2039.

The US overdose medication market:
Upon approval, Orexo will meet a significant need of a powerful overdose rescue medication that may revive individuals who have overdosed on synthetic opioids, such as illegal fentanyl. During the latest 12-month period, ending August 2022, the predicted annual number of fatal overdoses in the US counted for more than 107.000.[1] The great majority refers to opioid overdoses, 75 percent, and of these 90 percent involved synthetic opioids.[2]

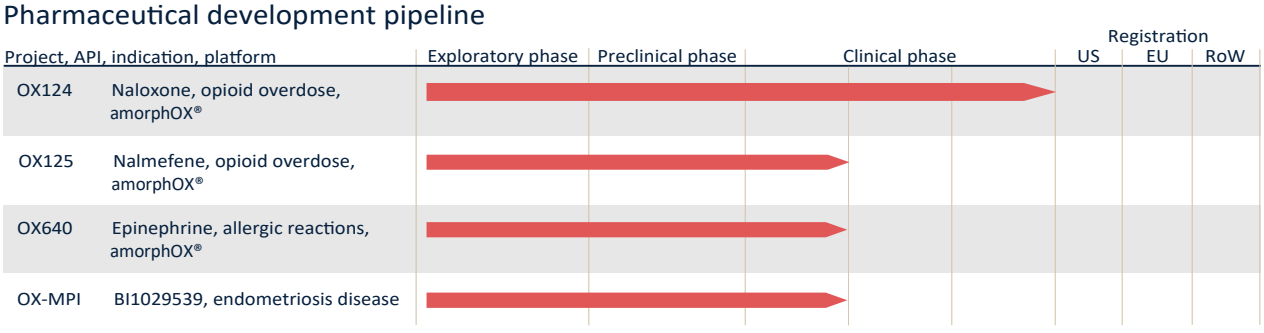
The market today is solely based on prescription products but is likely to convert into a low-dose OTC market and a high-dose prescription market. The increased availability of naloxone products is expected to grow the market from today's USD 300-500 million. OX124 will, as a high-dose prescription product, have access to reimbursement and act in a differentiated market to the OTC market, which is likely to include the current market leader and generics thereof. The large need for potent and longer-lasting overdose rescue medications will most likely propel the prescription market. In addition, future expansion of mandatory co-prescription of naloxone rescue medication will much likely also benefit the market for prescription products, such as OX124.

Commercialization:
A launch of OX124 in the US is planned to be initiated in the first half of 2024. The commercialization will benefit from Orexo´s long experience of getting products reimbursed by US insurance companies. In addition, the company´s well-established sales force visiting physicians, medical clinics, and minor hospitals on a daily basis across the US and its comprehensive experience of the patient category will gain the commercialization of OX124. To reach out to emergency staff and first responders, Orexo will most likely need to grow the sales force with account managers who has relevant experience from institutional sales.

OX125 – medication for opioid overdose containing nalmefene

Progress during the quarter:
Orexo has during a long period closely monitored the development of nalmefene products on the market for opioid overdose medication. Today, no nalmefene products have yet been approved, but a product has been filed for approval by a leading player in the OUD treatment space. Orexo continue to assess the potential for OX125 and have a short development timeline when the company decides to accelerate the development. The synergies between OX124 and OX125 are significant and most of the current development activities for OX124 are also applicable to OX125.

Pharmaceutical development pipeline



[1] Center for disease control and prevention
[2] Center for disease control and prevention

Project in brief:
The widespread use of synthetic opioids, such as illicit fentanyl, also increases the need for rescue medications that are effective in rural areas where distance to emergency units require more potent and longer lasting overdose treatment. With OX125, the aim is to develop an overdose rescue medication for situations where powerful, rapid, and long-lasting effects are required.

OX640 – epinephrine rescue medication for allergic reactions

Progress during the quarter:
Early in Q4, successful data was communicated for the first clinical study for OX640. The study primarily aimed to determine the relative bioavailability and absorption characteristics of investigational OX640 formulations versus an intramuscular epinephrine auto-injector (EpiPen®) in healthy volunteers.

Data showed all four investigational OX640 formulations were extensively absorbed and rapidly achieved clinically relevant plasma levels of epinephrine. In comparison to EpiPen®, and to other approved epinephrine injection products, the OX640 formulations displayed comparable or higher; (i) total epinephrine exposure, (ii) peak epinephrine exposure, (iii) epinephrine exposure during the first 20 minutes after administration, and (iv) proportion of subjects reaching clinically effective plasma levels of epinephrine during the first 20 minutes after administration. Furthermore, the OX640 formulations displayed concentration dependent effects on blood pressure and heart rate, parameters used as surrogate markers for clinical efficacy.

Local and systemic safety findings were generally consistent with known effects of epinephrine and there were no findings that raised any safety concerns.

The next step in the development will be to finalize the formulation for large scale commercial manufacturing and establish the commercial supply chain leveraging the supply chain in place for OX124. Based on current feedback from the FDA and with availability of final commercial product, the final step is to conduct additional studies in healthy volunteers and in participants known to have a history of seasonal allergies. Orexo expects filing with the FDA is possible in 2025.

OX640 has one granted patent protecting the product on the European market until 2041. Orexo has multiple patent applications filed in other territories and expect to continuously strengthen the patent portfolio for OX640.

Orexo is seeking partnership for the continued clinical development and for potential commercialization of the product globally.

Project in brief:
The aim with OX640 is to develop a nasal epinephrine product for the emergency treatment of allergic reactions. Epinephrine is commonly used for the emergency treatment of allergic reactions, including anaphylaxis. Epinephrine is a very unstable active ingredient sensitive to chemical degradation, which is the reason why today's commercial epinephrine products have limited shelf-life with restrictive storage conditions.

OX640 is based on Orexo's proprietary drug delivery platform amorphOX® and has shown promising chemical and physical stability data. In addition to providing allergic patients with a more convenient, needle-free alternative to auto-injectors currently on the market, an epinephrine product that provides greater flexibility in relation to how it can be handled and stored should provide significant benefits to patients and healthcare systems.

Other development projects

OX-MPI – endometriosis disease, BI1029539

OM-MPI (GS248) is a non-hormonal clinical-stage drug candidate targeting the pro-inflammatory enzyme mPGES-1, which via its product prostaglandin E2 plays a key role in inducing and maintaining endometriosis lesions. Endometriosis is a chronic inflammatory disease affecting approximately 10 percent of all women in reproductive age.

Orexo´s partner Gesynta Pharma owns all rights to the product.

ZUBSOLV® - sublingual tablet for the treatment of opioid use disorder in the EU

Orexo's partner Accord Healthcare continued to launch ZUBSOLV® in the EU and in Q4 also patients in Romania got access to ZUBSOLV®. Since the initiation of the launch in Q2 2022 the drug is available in nine European countries and except from Romania these markets are Sweden, Spain, the UK, the Czech Republic, Slovenia and the three Baltic states.

The commercialization of ZUBSOLV® in the EU has the potential to cover 29 European countries and are fully managed by Accord Healthcare which has in-licensed the rights from Orexo. Orexo is responsible for product supply and will receive double digit royalty on net sales.

There are estimated to be 1.3 million high-risk opioid users in Europe, yet treatment rates are low.[1] Approximately 50 percent of people with opioid dependence are receiving some form of substitution treatment across Europe, although this varies greatly between countries.[2]

[1] European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)
[2] EMCDDA – Tackling Opioid Dependence

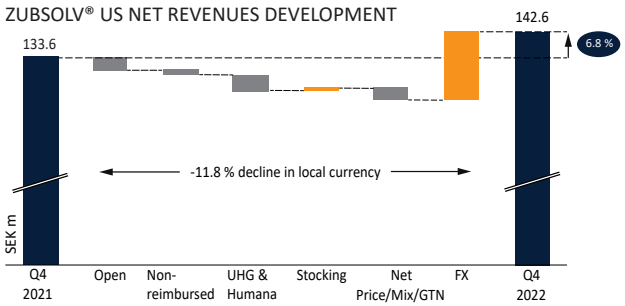
Financial overview

Revenues

Total revenues amounted to SEK 156.1 m (144.0) for Q4 and to SEK 624.3 m (565.0) for the full year. The increase is mainly explained by higher US Pharma revenues, driven by stronger USD exchange rate.

Revenues by segment

US Pharma revenues amounted to SEK 142.6 m (133.6) for Q4. The increase in US Pharma revenues is mainly driven by stronger USD exchange rate and wholesaler stocking. 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. Net revenues were also affected by a negative true-up of Gross to Net accruals of SEK 4.1 m (-).



In local currency US Pharma net revenues for Q4 amounted to USD 13.3 m (15.1). US Pharma revenues amounted to SEK 571.4 m (522.7) for the full year.

Digital Therapeutics (DTx) recognized net revenues for Q4 amounting to SEK 0.0 m (0.3) and to SEK 0.4 m (1.1) for the full year.

HQ & Pipeline partner product related revenues for Q4 amounted to SEK 13.4 m (10.1). The increase is mainly explained by ZUBSOLV® ex-US revenues related to sales in the EU by Orexo's partner Accord Healthcare. HQ & Pipeline partner product amounted to SEK 52.6 m (41.2) for the full year.

Costs of goods sold

Cost of goods sold (COGS) amounted to SEK 25.9 m (20.3) for Q4. US Pharma amounted to SEK 20.6 m (17.2) mainly due to unfavorable exchange-rate impact vs prior year and negative production variances. Royalty and technical infrastructure costs for DTx amounted to SEK 2.8 m (2.7). HQ & Pipeline amounted to SEK 2.6 m (0.4) for ZUBSOLV® ex-US sales in the EU by Orexo's partner Accord Healthcare. Cost of goods sold (COGS) amounted to SEK 102.6 m (78.9) for the full year.

Operating expenses

Selling expenses amounted to SEK 52.2 m (70.9) for Q4. The decrease over the same period last year is mainly explained by significantly lower selling expenses in DTx. This is partly offset by negative impact of stronger USD exchange rate. Selling expenses amounted to SEK 199.0 m (280.4) for the full year.

Administrative expenses amounted to SEK 63.8 m (39.1) for Q4 and to SEK 202.3 m (151.5) for the full year. The increase is mainly explained by negative impact of stronger USD exchange rate and by higher legal expenses for IP litigation.

Research and development costs amounted to SEK 88.2 m (80.0) for Q4. The increase is mainly explained by negative impact of stronger USD exchange rate and costs related to the MODIA® study. Research and development costs amounted to SEK 318.0 m (272.3) for the full year.

Other operating income and expenses amounted to SEK 3.0 m (2.1) for Q4, mainly explained by a received insurance reimbursement for legal costs in the US partly

NET REVENUES AND OPERATING EARNINGS PER SEGMENT

SEK m	Net Revenues				EBIT			
	2022 Oct-Dec	2021 Oct-Dec	2022 Jan-Dec	2021 Jan-Dec	2022 Oct-Dec	2021 Oct-Dec	2022 Jan-Dec	2021 Jan-Dec
ZUBSOLV® US product sales	142.6	133.6	571.4	522.7	—	—	—	—
US Pharma – total	**142.6**	**133.6**	**571.4**	**522.7**	**77.0**	**72.2**	**308.4**	**278.2**
Digital Therapeutics (DTx) product sales	0.0	0.3	0.4	1.1	—	—	—	—
Digital Therapeutics (DTx) – total	**0.0**	**0.3**	**0.4**	**1.1**	**-49.0**	**-63.8**	**-189.1**	**-249.7**
Abstral® royalty	5.5	8.3	30.4	32.1	—	—	—	—
Edluar® royalty	2.7	1.8	10.4	9.1	—	—	—	—
ZUBSOLV® - ex US	5.2	—	11.8	—	—	—	—	—
HQ & Pipeline segment – total	**13.4**	**10.1**	**52.6**	**41.2**	**-99.1**	**-72.5**	**-303.2**	**-242.6**
Total	**156.1**	**144.0**	**624.3**	**565.0**	**-71.1**	**-64.1**	**-183.9**	**-214.1**

offset by exchange-rate losses derived from revaluations of parent company balance sheet items in foreign currency, predominantly in USD. Other operating income and expenses amounted to SEK 13.7 m (4.0) for the full year.

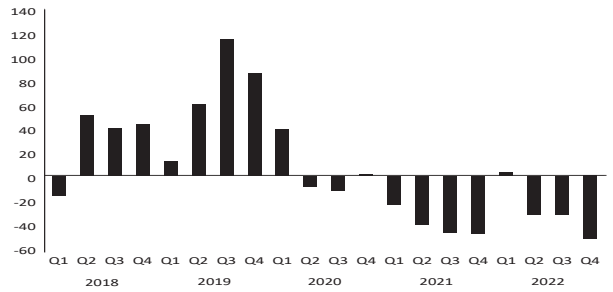
Operating profit

EBITDA amounted to SEK -53.1 m (-48.5) for Q4 and to SEK -115.2 m (-161.0) for the full year. Exclusion of costs for legal processes and external non-repeating costs for clinical studies, would result in an EBITDA of SEK -0.1 m (-10.5) for Q4 and SEK 57.8 m (-37.9) for the full year, significantly affected by increased R&D expenses and by negative Gross to Net accruals of SEK 4.1 m (-).

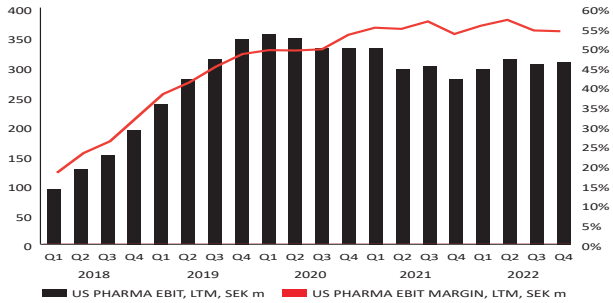
The EBIT contribution from US Pharma amounted to SEK 77.0 m (72.2) for Q4, equal to an EBIT margin of 54.0 percent (54.0). EBIT contribution from US Pharma amounted to SEK 308.4 m (278.2) for the full year, equal to an EBIT margin of 54.0 percent (53.2).

Total EBIT amounted to -71.1 m (-64.1) for Q4 mainly explained by negative impact of SEK -6.8 m from stronger USD exchange rate and high litigation costs, the MODIA® study and OX124. Total EBIT amounted to -183.9 m (-214.1) for the full year.

GROUP EBITDA, SEK m



US PHARMA EBIT MARGIN (LTM[1], SEK m) AND EBIT (LTM[1], SEK m)



Net financial items and tax

Net financial items for Q4 amounted to SEK -24.4 m (-2.1) and is mainly explained by negative unrealized exchange rate impact of SEK -18.2 m (4.0) derived from the parent company's foreign currency bank accounts mainly in USD. Higher interest rate had a negative impact on costs for corporate bonds of SEK 7.8 m (5.5). This was partly offset by interest income of SEK 2.2 m (-) from short-term cash investments. Net financial items amounted to SEK 13.5 m (-8.4) for the full year.

Total tax expenses amounted to SEK 3.7 m (0.3) for Q4. The increase is mainly explained by positive adjustment to deferred tax assets related to temporary differences. Total tax expenses amounted to SEK -7.2 m (-1.0) for the full year. Orexo performs regular assessments of its deferred tax asset and makes adjustments according to the recognition requirements of IAS 12.

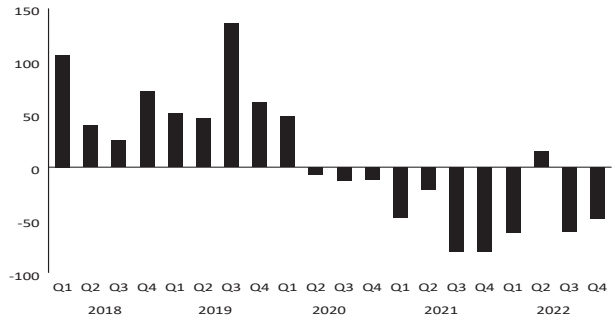
Net earnings

Net earnings amounted to SEK -91.8 m (-66.0) for Q4 and to SEK -177.6 (-223.5) for the full year.

Cash and cash flow

Cash flow from operating activities amounted to SEK -48.9 m (-80.6) for Q4 and was primarily impacted by negative operating earnings. Cash flow from operating activities amounted to SEK -156.6 m (-229.0) for the full year.

CASH FLOW FROM OPERATING ACTIVITIES, SEK m



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. As of December 31, 2022, cash and cash equivalents amounted to SEK 132.2 m (504.1) and short-term investments amounted to SEK 219.6 m (-).
Cash and invested funds in total amounted to SEK 351.9 m (504.1) and interest-bearing liabilities to SEK 494.8 m (492.3), i.e. a negative net cash position including short-term investments of SEK -142.9 m (11.7). Cash and invested funds were reduced by SEK 92.0 m from Q3.

[1] Last Twelve Months

Investments

Gross investments in tangible and intangible fixed assets amounted to SEK 12.3 m (2.9) for Q4 and to SEK 23.9 m (52.9) for for the full year. Higher investments for Q4 are mainly explained by investments in equipment for the development organization.

Equity

Shareholders' equity at December 31, 2022, was SEK 193.9 m (349.6). The equity/asset ratio was 17.5 percent (27.4).

Parent company

Net revenues for Q4 amounted to SEK 128.2 m (91.5) of which SEK 114.7 m (81.3) was related to sales to Group companies. Net revenues amounted to SEK 348.2 m (365.9) for the full year of which SEK 295.6 m (324.7) was related to sales to Group companies.

Earnings before tax amounted to SEK -75.6 m (-66.6) for Q4. The development is mainly explained by higher administrative expenses and higher net financial items, partly offset by higher gross profit. Earnings before tax SEK -196.8 m (-219.8) for the full year. Investments in equipment for the development organization for Q4 amounted to SEK 11.0 m (6.1) and to SEK 18.8 m (35.0) for the full year.

As of December 31, 2022, cash and cash equivalents in the parent company amounted to SEK 61.7 m (444.5) and short-term investments amounted to SEK 178.6 m (-) i.e. companys cash and invested funds amounted to SEK 240.3 m (444.5).

Parent company shareholders' equity at December 31, 2022, was SEK 109.2 m (306.0).

Other information

Outcome financial outlook 2022

- Due to the continuing pandemic the buprenorphine/naloxone market will show a growth pace in line with 2021, and reach a level of 5-8 percent
  Outcome: 5 percent
- In H2 ZUBSOLV® net sales in USD will increase comparing to H1
  Outcome: showed a mild decline of USD 1.5 m mainly explained by unexpected slowdown of market growth in H2
- OPEX will be SEK 700-725 m based on the appreciation of the USD in Q3
  Outcome: SEK 705.6 m
- US Pharma EBIT margin will exceed 50 percent on a full year basis
  Outcome: 53.4 percent

Financial 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 m), 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.

Forward looking statements

This report includes forward-looking statements. Actual results may differ from those stated. Internal and external factors may affect Orexo's results.

Risks and uncertainty factors

Significant risks and uncertainties are presented in the Annual Report for 2021 and in the Interim Report Note 4, litigations. The continued commercialization of ZUBSOLV® and digital therapies entails risk exposure of an operational nature. Orexo is continuously exposed to risks in relation to development projects, the intellectual property rights and changes related to commercialization and development partners. The Covid-19 pandemic continues to drive uncertainty in the market and together with the war in Ukraine, this increase the risk for shortage of material in the supply chain.

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 will be less than half of the registered share capital unless measures are taken. This means that there are uncertainty factors that can give rise to doubts regarding the continued operation of the business. However, the group has sufficient funds 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.

Glossary

View https://orexo.com/glossary-defintions/

Uppsala, Sweden, January 26, 2023

Nikolaj Sørensen
President and CEO

This report has not been reviewed by the company's auditors.

Financial reports, notes and key figures

CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS

SEK m	Notes	2022 Oct-Dec	2021 Oct-Dec	2022 Jan-Dec	2021 Jan-Dec
Net revenues	9	156.1	144.0	624.3	565.0
Cost of goods sold		-25.9	-20.3	-102.6	-78.9
Gross profit		**130.2**	**123.7**	**521.7**	**486.1**
Selling expenses		-52.2	-70.9	-199.0	-280.4
Administrative expenses		-63.8	-39.1	-202.3	-151.5
Research and development expenses		-88.2	-80.0	-318.0	-272.3
Other operating income and expenses		3.0	2.1	13.7	4.0
Operating earnings (EBIT)		**-71.1**	**-64.1**	**-183.9**	**-214.1**
Net financial items		-24.4	-2.1	13.5	-8.4
Earnings before tax		**-95.5**	**-66.2**	**-170.4**	**-222.5**
Tax	5	3.7	0.3	-7.2	-1.0
Net earnings for the period[1]		**-91.8**	**-66.0**	**-177.6**	**-223.5**
Earnings per share, before dilution, SEK		-2.67	-1.92	-5.17	-6.51
Earnings per share, after dilution, SEK		-2.67	-1.92	-5.17	-6.51

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

SEK m	2022 Oct-Dec	2021 Oct-Dec	2022 Jan-Dec	2021 Jan-Dec
Earnings for the period	**-91.8**	**-66.0**	**-177.6**	**-223.5**
Other comprehensive income	—	—	—	—
Items that may subsequently be reversed to the statement of operations:				
Exchange-rate differences	3.4	3.9	22.1	13.0
Other comprehensive earnings for the period, net after tax	**3.4**	**3.9**	**22.1**	**13.0**
Total comprehensive earnings for the period [1]	**-88.4**	**-62.1**	**-155.5**	**-210.5**

[1] All equity and earnings for the respective period are attributable to the Parent Company's shareholders

CONDENSED CONSOLIDATED BALANCE SHEET

SEK m	Notes	2022 Dec 31	2021 Dec 31
ASSETS			
Fixed assets			
Tangible fixed assets		76.1	65.9
Intangible fixed assets		217.4	248.9
Right-of-use assets		46.0	59.2
Deferred tax assets	5	33.1	33.4
Other financial assets		0.9	0.8
Total fixed assets		**373.5**	**408.2**
Current assets			
Inventories		74.6	92.3
Accounts receivable and other receivables		309.0	269.2
Short-term investments		219.6	—
Cash and cash equivalents		132.2	504.1
Total current assets		**735.5**	**865.5**
Total assets		**1 109.0**	**1 273.7**
SHAREHOLDERS' EQUITY AND LIABILITIES			
Total shareholders' equity		**193.9**	**349.6**
Long-term liabilities			
Provisions		10.2	13.5
Long-term liabilities, interest bearing		494.8	492.3
Lease liabilities, long-term		24.2	38.0
Total long-term liabilities		**529.2**	**543.9**
Current liabilities and provisions			
Provisions		121.5	160.1
Current liabilities, non-interest bearing		243.7	199.9
Lease liabilities, current		20.6	20.2
Total current liabilities and provisions		**385.9**	**380.2**
Total liabilities		**915.1**	**924.1**
Total shareholders' equity and liabilities		**1 109.0**	**1 273.7**

CONSOLIDATED CHANGES IN SHAREHOLDERS' EQUITY

SEK m	2022 Dec 31	2021 Dec 31
Opening balance, shareholders' equity	**349.6**	**558.5**
Total comprehensive earnings for the period	-155.5	-210.5
Share-based payments	-0.1	1.5
Closing balance, shareholders' equity	**193.9**	**349.6**

CONDENSED CONSOLIDATED CASH FLOW STATEMENTS

SEK m	Notes	2022 Oct-Dec	2021 Oct-Dec	2022 Jan-Dec	2021 Jan-Dec
Operating earnings (EBIT)		-71.1	-64.1	-183.9	-214.1
Interest received		1.1	0.0	1.4	0.0
Interest paid		-6.9	-4.9	-22.4	-22.9
Income taxes paid		3.6	8.2	1.5	8.2
Adjustment for non-cash items	3	-4.4	26.4	-3.5	-16.8
Cash flow from operating activities before changes in working capital		**-77.7**	**-34.4**	**-206.9**	**-245.5**
Changes in working capital		**28.8**	**-46.2**	**50.3**	**16.5**
Cash flow from operating activities		**-48.9**	**-80.6**	**-156.6**	**-229.0**
Acquisition of tangible and intangible fixed assets		-12.3	-2.9	-23.9	-52.9
Acuisition of short-term investments		-6.4	—	-295.6	—
Disposal of short-term investments		84.0	—	84.0	—
Sales of tangible assets		0.8	—	0.8	—
Cash flow from investing activities		**66.2**	**-2.9**	**-234.7**	**-52.9**
New loan		—	—	—	490.1
Repayment of loans		-5.8	-5.5	-21.4	-239.5
Cash from financing activities		**-5.8**	**-5.5**	**-21.4**	**250.6**
Cash flow for the period		**11.5**	**-89.0**	**-412.8**	**-31.2**
Cash and cash equivalents at the beginning of the period		**122.4**	**588.1**	**504.1**	**505.3**
Exchange-rate differences in cash and cash equivalents		-1.6	5.0	40.9	30.0
Changes in cash and cash equivalents		9.9	-84.0	-371.8	-1.2
Cash and cash equivalents at the end of the period		**132.2**[1]	**504.1**	**132.2**[1]	**504.1**

[1] Cash and cash equivalents excluding invested surplus cash of SEK 132.2 m in short-term assets, certificates of deposits and in US treasuries. As of December 31, 2022, cash and invested funds amounted to SEK 351.9 m (504.1)

Key Figures[2]

Orexo makes use of the key figures below and believe they are useful for readers of the financial reports as a complement to other performance measures when assessing implementation of strategic investments and the Group's ability to meet financial objectives and commitments.

	2022 Oct-Dec	2021 Oct-Dec	2022 Jan-Dec	2021 Jan-Dec
EBIT margin, %	-45.6	-44.5	-29.5	-37.9
Return on shareholder equity, %	-37.3	-17.3	-65.4	-49.2
Net debt, SEK m	142.9	-11.7	142.9	-11.7
Debt/equity ratio, %	255.2	140.8	255.2	140.8
Equity/assets ratio, %	17.5	27.4	17.5	27.4
Number of shares, before dilution	34,367,616	34,327,907	34,351,732	34,319,649
Number of shares, after dilution	34,367,616	34,327,907	34,351,732	34,319,649
Earnings per share, before dilution, SEK	-2.67	-1.92	-5.17	-6.51
Earnings per share, after dilution, SEK	-2.67	-1.92	-5.17	-6.51
Number of employees at the end of the period	126	121	126	121
Shareholders' equity, SEK m	193.9	349.6	193.9	349.6
Capital employed, SEK m	688.7	841.9	688.7	841.9
Working capital, SEK m	217.4	-18.8	217.4	-18.8

[2] Definitions and reconcilliations of key figures are presented on page 22 of this report

CONDENSED PARENT COMPANY STATEMENT OF OPERATIONS

SEK m	Notes	2022 Oct-Dec	2021 Oct-Dec	2022 Jan-Dec	2021 Jan-Dec
Net revenues		128.2	91.5	348.2	365.9
Cost of goods sold		-25.8	-15.3	-72.4	-71.2
Gross profit		**102.4**	**76.2**	**275.8**	**294.7**
Selling expenses		-41.5	-57.6	-165.1	-227.3
Administrative expenses		-40.5	-24.2	-123.1	-92.3
Research and development costs		-73.5	-68.0	-266.9	-226.0
Other operating income and expenses		1.6	8.5	65.4	36.8
Operating earnings (EBIT)		**-51.5**	**-65.1**	**-213.9**	**-214.2**
Interest income and expenses		-5.5	-4.8	-19.6	-18.0
Other financial income and expenses		-18.6	3.4	36.7	12.5
Net financial items		**-24.1**	**-1.5**	**17.1**	**-5.6**
Earnings before tax		**-75.6**	**-66.6**	**-196.8**	**-219.8**
Tax	5	—	—	—	—
Earnings for the period		**-75.6**	**-66.6**	**-196.8**	**-219.8**

PARENT COMPANY STATEMENT OF COMPREHENSIVE INCOME

SEK m	2022 Oct-Dec	2021 Oct-Dec	2022 Jan-Dec	2021 Jan-Dec
Earnings for the period	**-75.6**	**-66.6**	**-196.8**	**-219.8**
Other comprehensive income	—	—	—	—
Total comprehensive earnings for the period	**-75.6**	**-66.6**	**-196.8**	**-219.8**

CONDENSED PARENT COMPANY BALANCE SHEET

SEK m	2022 Dec 31	2021 Dec 31
ASSETS		
Fixed assets		
Intangible fixed assets	181.4	214.2
Tangible fixed assets	76.1	65.9
Shares in subsidiaries	161.2	162.5
Total fixed assets	**418.7**	**442.6**
Current assets		
Inventories	60.2	67.8
Accounts receivable and other receivables	159.0	115.4
Short-term investments	178.6	—
Cash and cash equivalents	61.7	444.5
Total current assets	**459.5**	**627.7**
Total assets	**878.2**	**1 070.2**
SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES		
Total shareholders' equity	**109.2**	**306.0**
Long-term liabilities		
Provisions	9.8	12.8
Bond loan	494.8	492.3
Total long-term liabilities	**504.5**	**505.1**
Current liabilities		
Accounts payable	32.0	17.1
Other liabilities	8.8	9.1
Liabilities to Group companies	184.3	207.9
Accrued expenses and deferred income	39.3	25.0
Total current liabilities	**264.5**	**259.1**
Total liabilities	**769.0**	**764.2**
Total shareholders' equity and liabilities	**878.2**	**1 070.2**

Notes

1. Accounting policies
This report was prepared pursuant to IAS 34. Orexo applies IFRS as approved by the EU on its condensed consolidated financial statements.

The accounting policies are in line with those applied in the preparation of the 2021 Annual Report. None of the amended standards and interpretations that became effective January 1, 2022 have had significant impact on the Group's financial reporting.

The Parent Company's financial statements were prepared in accordance with RFR 2 (Swedish Financial Reporting Board's recommendation) and Chapter 9 of the Swedish Annual Accounts Act.

2. Segment Reporting
Operations are monitored and presented in the segments US Pharma, Digital Therapeutics and HQ & Pipeline.
US Pharma segment comprises the distribution and sale of ZUBSOLV® for treatment of opioid use disorder in the US.

Digital Therapeutics segment comprises 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. Net revenues comprises all partner revenues for ZUBSOLV® – ex US, Abstral® and Edluar®.

No operating segments have been aggregated to form the above reportable operating segments.
The President and CEO is the chief operating decision maker and monitors the operating results of the group's segments separately for the purpose of making decisions about resource allocation and performance assessment. Segment performance is evaluated based on EBIT and is measured consistently with EBIT in the consolidated financial statements.

DISTRIBUTION OF REVENUE AND EBIT PER SEGMENT

SEK m	2022 Oct-Dec	2021 Oct-Dec	2022 Jan-Dec	2021 Jan-Dec
US Pharma				
Net revenues	142.6	133.6	571.4	522.7
Operating earnings (EBIT)	77.0	72.2	308.4	278.2
Depreciation and amortization	-3.8	-3.8	-15.4	-15.4
Digital Therapeutics				
Net revenues	0.0	0.3	0.4	1.1
Operating earnings (EBIT)	-49.0	-63.8	-189.1	-249.7
Depreciation and amortization	-6.8	-5.1	-25.7	-18.6
HQ & Pipeline				
Net revenues	13.4	10.1	52.6	41.2
Operating earnings (EBIT)	-99.1	-72.5	-303.2	-242.6
Depreciation and amortization	-7.4	-6.7	-27.7	-19.1
Group				
Net revenues	156.1	144.0	624.3	565.0
Operating earnings (EBIT)	-71.1	-64.1	-183.9	-214.1
Depreciation and amortization	-18.0	-15.6	-68.7	-53.0
Net financial items	-24.4	-2.1	13.5	-8.4
Earnings before tax	-95.5	-66.2	-170.4	-222.5

3. Cash flow

ADJUSTMENT FOR NON-CASH ITEMS

SEK m	2022 Oct-Dec	2021 Oct-Dec	2022 Jan-Dec	2021 Jan-Dec
Depreciation/amortization and impairment	18.0	15.6	68.7	53.0
Realization results	-0.2	—	-0.2	—
Change in provisions	-27.0	12.7	-64.9	-67.4
Share based payments	0.0	0.0	-0.1	1.5
Exchange rate income and expenses	4.7	-2.0	-7.0	-3.9
Total	**-4.4**	**26.4**	**-3.4**	**-16.8**

4. Litigations

Subpoena related to sales and marketing of ZUBSOLV®
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.

Paragraph IV litigations against Sun Pharmaceutical Industries Ltd
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 will start 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.

5. Deferred tax

The tax effect of the Group's temporary differences are related to non-deductible current provisions for sales rebates, sales allowances, distribution, sales returns and other relevant deductions in the company's US operations.
The tax-loss carry-forward in the Group amounts to SEK 1,540 m as of December 31, 2022 and refers to the Swedish companies. Deferred tax assets for tax losses carried forward are only recognized to the extent that it is probable that taxable profits will be available against which the losses can be utilized. The Group's tax losses carried forward at the balance sheet date have not been recognized as deferred tax assets, as the recognition criteria under IAS 12 have not been met. There is no time limit for when the remaining loss carryforwards can be utilized.

6. Financial instruments

The Group's financial instruments consists of current receivables, non-current receivables, short-term investments, cash and cash equivalents, current non-interest bearing liabilities, current interest-bearing liabilities and long-term interest-bearing liabilities. The financial instruments held by the group are recognized at amortized cost using the effective interest method. The group does not hold any financial instruments which are reported at fair value. The fair value of financial instruments held at the balance sheet date is significantly the same as the book value.

7. Related parties

There were no significant related parties transactions during the period.

8. Important events after the period

› Exploratory feasibility studies of amorphOX® initiated in collaboration two leading biopharmaceutical and vaccine companies

9. Revenue from contracts with customers

SEK m	2022 Oct-Dec					
Segment	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**vorvida®**	**deprexis®**	**Total**
US Pharma	142.6	—	—	—	—	**142.6**
Digital Therapeutics	—	—	—	0.0	0.0	**0.0**
HQ & Pipeline	5.2	5.5	2.7	—	—	**13.4**
Total revenue from contracts with customers	**147.9**	**5.5**	**2.7**	**0.0**	**0.0**	**156.1**
Geographical markets	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**vorvida®**	**deprexis®**	**Total**
US	142.6	—	0.8	0.0	0.0	**143.4**
EU & UK	5.2	5.2	1.1	—	—	**11.6**
Rest of the world	—	0.3	0.8	—	—	**1.1**
Total revenue from contracts with customers	**147.9**	**5.5**	**2.7**	**0.0**	**0.0**	**156.1**

SEK m	2021 Oct-Dec					
Segment	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**vorvida®**	**deprexis®**	**Total**
US Pharma	133.6	—	—	—	—	**133.6**
Digital Therapeutics	—	—	—	0.3	0.0	**0.3**
HQ & Pipeline	—	8.3	1.8	—	—	**10.1**
Total revenue from contracts with customers	**133.6**	**8.3**	**1.8**	**0.3**	**0.0**	**144.0**
Geographical markets	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**vorvida®**	**deprexis®**	**Total**
US	133.6	0.0	0.7	0.3	0.0	**134.5**
EU	—	8.0	0.9	—	—	**8.9**
Rest of the world	—	0.3	0.3	—	—	**0.6**
Total revenue from contracts with customers	**133.6**	**8.3**	**1.8**	**0.3**	**0.0**	**144.0**

SEK m	2022 Jan-Dec					
Segment	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**vorvida®**	**deprexis®**	**Total**
US Pharma	571.4	—	—	—	—	**571.4**
Digital Therapeutics	—	—	—	0.3	0.0	**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**	**0.0**	**624.3**
Geographical markets	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**vorvida®**	**deprexis®**	**Total**
US	571.4	—	2.5	0.3	0.0	**574.2**
EU & UK	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**	**0.0**	**624.3**

SEK m	2021 Jan-Dec					
Segment	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**vorvida®**	**deprexis®**	**Total**
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	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**vorvida®**	**deprexis®**	**Total**
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**

Geographical distribution of royalties and milestones is based on the counterparts registered office.

Definitions and reconciliations of key figures

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 short-term investments and 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 short-term investments and cash and cash equivalents
Debt/equity ratio	Interest bearing 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 and interest bearing liabilities, 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

KEY FIGURES AND CERTAIN OTHER OPERATING INFORMATION ARE RECONCILED AS FOLLOWS

EBITDA SEK m	2022 Oct-Dec	2021 Oct-Dec	2022 Jan-Dec	2021 Jan-Dec
EBIT	-71.1	-64.1	-183.9	-214.1
Depreciation and amortization	18.0	15.6	68.7	53.0
EBITDA	**-53.1**	**-48.5**	**-115.2**	**-161.0**
External costs for clinical studies	28.4	24.8	96.4	63.5
IP litigation and subpoena	24.6	13.2	76.6	59.6
EBITDA excluding external costs for clinical studies. IP litigation and subpoena	**-0.1**	**-10.5**	**57.8**	**-37.9**

CASH AND INVESTED FUNDS	2022 Oct-Dec	2021 Oct-Dec	2022 Jan-Dec	2021 Jan-Dec
Short-term investments	219.6	—	219.6	—
Cash and cash equivalents	132.2	504.1	132.2	504.1
Cash and invested funds	**351.9**	**504.1**	**351.9**	**504.1**

RETURN ON SHAREHOLDERS' EQUITY	2022 Oct-Dec	2021 Oct-Dec	2022 Jan-Dec	2021 Jan-Dec
Shareholders' equity beginning balance	298.4	411.7	349.6	558.5
Shareholders' equity ending balance	193.9	349.6	193.9	349.6
Average shareholders' equity	246.1	380.6	271.8	454.1
Net earnings	-91.8	-66.0	-177.6	-223.5
Return on shareholders' equity %	**-37.3**	**-17.3**	**-65.4**	**-49.2**

OPERATING EXPENSES SEK m	2022 Oct-Dec	2021 Oct-Dec	2022 Jan-Dec	2021 Jan-Dec
Selling expenses	-52.2	-70.9	-199.0	-280.4
Administrative expenses	-63.8	-39.1	-202.3	-151.5
Research and development costs	-88.2	-80.0	-318.0	-272.3
Other operating income and expenses	3.0	2.1	13.7	4.0
Operating expenses	**-201.3**	**-187.8**	**-705.6**	**-700.2**

GROSS INVESTMENTS SEK m	2022 Oct-Dec	2021 Oct-Dec	2022 Jan-Dec	2021 Jan-Dec
Investments in tangible fixed assets	11.0	6.1	18.8	24.7
Investments in intangible fixed assets	1.3	-3.2	5.1	28.1
Gross investments	**12.3**	**2.9**	**23.9**	**52.9**

This information is information that Orexo AB (publ.) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication through the agency of the contact persons set out above at 8 am CET on January 26, 2023.