orexo

Interim Report Q4 2023,
incl. Full Year Report

February 8, 2024

Positive EBITDA in H2 setting the target for FY 2024

Orexo supports the UN's Agenda 2030 with a focus on:

Q4 2023 highlights

- Total net revenues of SEK 166.0 m (156.1)
- EBITDA of SEK 12.4 m (-53.1), EBITDA excluding costs for legal processes and external non-repeating clinical trials, SEK 23.4 m (-0.1)
- Net earnings of SEK -18.6 m (-91.8)
- US Pharma segment (Zubsolv® US) net revenues of SEK 151.3 m (142.6), in local currency USD 14.2 m (13.3), US Pharma EBIT of SEK 75.4 m (77.0)
- Cash flow from operating activities of SEK -2.6 m (-48.9), cash and invested funds of SEK 171.0 m (351.9)
- Earnings per share before and after dilution amounted to SEK -0.54 (-2.67)
- The MODIA® study didn't meet the primary end-points, but showed high rates of treatment response in both study arms, with no adverse events associated with the use of MODIA
- Robin Evers elected as board member at the Extraordinary General Meeting. He replaces Henrik Kjaer Hansen who has resigned. Kjaer Hansen has instead been appointed chairman of the Nomination Committee, representing Novo Holdings A/S.
- FDA accepted the New Drug Application filing for review of OX124, a high-dose rescue medication for opioid overdose with naloxone
- Financial outlook provided for 2024 on page 15.

Group net revenues

166 SEK M

Group EBITDA

12 SEK M

Cash and cash equivalents

171 SEK M

Important events after the end of the period

- MODIA and Vorvida® will be reimbursed within the US Veterans Affairs Federal Supply Schedule as of January 1, 2024.

SEK m unless otherwise stated	2023 Oct-Dec	2022 Oct-Dec	2023 Jan-Dec	2022 Jan-Dec
Net revenues	166.0	156.1	638.8	624.3
Cost of goods sold	-20.1	-25.9	-88.9	-102.6
Operating expenses	-154.5	-201.3	-659.5	-705.6
EBIT	-8.6	-71.1	-109.5	-183.9
EBIT margin	-5.2%	-45.6%	-17.1%	-29.5%
EBITDA	12.4	-53.1	-32.5	-115.2
Earnings per share. before dilution. SEK	-0.54	-2.67	-3.73	-5.17
Earnings per share. after dilution. SEK	-0.54	-2.67	-3.73	-5.17
Cash flow from operating activities	-2.6	-48.9	-95.0	-156.6
Cash and invested funds	171.0	351.9	171.0	351.9

Unless otherwise stated in this report, alla data refers to the Group, and numbers relate to the current quarter while numbers in parantheses relate to the corresponding period in 2022

Content

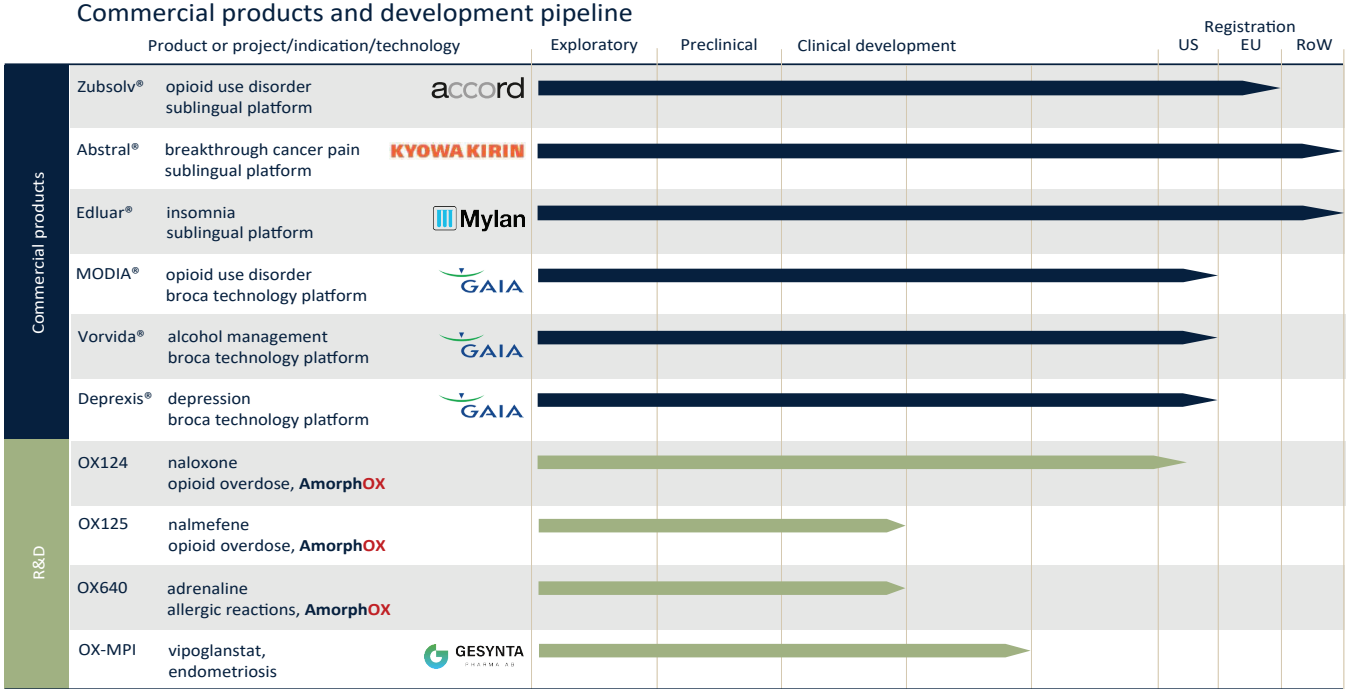
About Orexo

A commercial stage pharmaceutical company with three revenue generating pharmaceutical products

Profitable US commercial operations with a focus on one of the largest health crises in the US – opioid dependence

AmorphOX® - a world-class drug delivery platform leading to a new wave of products.

Commercial products and development pipeline



Contact persons quarterly report

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Presentation

On Feb. 8, at 2 pm CET analysts, investors and media are invited to attend a presentation, incl. a Q&A.

To attend via teleconference where you can ask questions verbally:

https://conference.financialhearings.com/teleconference/?id=2001504

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-q4-2023

Prior to the call, presentation material will be available on the website under Investors/Reports/Audiocasts.

Financial calendar 2024

Annual and Sustainability Report - March 28
Annual General Meeting 2024 - April 26, at 4 pm
Interim Report Q1 2024 - May 8, at 8 am
Interim Report Q2 2024 - July 17, at 8 am
Interim Report Q3 2024 - November 14, at 8 am
Interim Report Q4 2024, incl. Full Year Report, February 6, 2025, at 8 am

Strong recovery in financial results and FDA initiated the review of OX124

CEO Comments in brief

I am pleased to report a Q4 result delivering a positive EBITDA and strong Zubsolv® net sales both compared to Q4 2022 and Q3 2023. Zubsolv net sales year over year grew more than 6 percent in both SEK and USD, and nearly 8 percent quarter over quarter. I am also delighted to share that we are continuing to drive efficiencies across the business and have reduced operating expenses by 23 percent from last year. This recovery in financial performance is not driven by exchange rates, on the contrary, our EBITDA in H2 would have been nearly SEK 8 million higher if we had applied the exchange rates from end of 2022.

I am also pleased to announce that we, despite currency headwinds, reached our financial guidance for 2023, and in particular the positive EBITDA for H2. With relatively stable exchange rates and no other extraordinary events in 2024, we are confident we can reach a positive EBITDA for the FY 2024.

Continued growth in the Zubsolv market, but at a low rate

After the market decline in Q3 we are pleased to have seen positive market growth in Q4, although the growth rates remain in low single digits with the daily US buprenorphine/naloxone market at 3 percent. The annual market growth for 2023 was 4 percent, in line with the lower part of the guidance of 4-7 percent.

We know that the opioid epidemic is causing severe suffering and that there are many thousands of vulnerable people in need of treatment. While it is reassuring to know that this is being recognised at state and federal levels, the initiatives that have been taken so far have not yet made any notable impact. Unfortunately, increased use of drug combinations and synthetic opioids are reportedly increasing patient relapses and shortening the average period of time people stay in treatment. That said, we expect the market to continue growing in 2024, but at a slightly lower rate of 2-5 percent.

Strong Q4 Zubsolv net sales and stable demand

Zubsolv net sales recovered from Q3 and increased in both local currency and SEK. This improvement is explained by a normalization of inventory levels at the wholesalers in combination with stable demand. During 2024, we expect a continued stable development in net sales. Improving market access and increased market growth in segments where Zubsolv is reimbursed is important for future growth. We are pleased to report that from January 2024, Zubsolv will be reimbursed by New Hampshire Medicaid, further strengthening market access in the Public Segment. The value of improved market access is proven by the strong double-digit growth in demand with the payers where Zubsolv improved reimbursement in 2022 and 2023.

US Pharma continues to be a strong cash generator with an EBIT reaching SEK 75 million in Q4, equal to a margin of 49 percent. However, with the integration of our digital mental health programs into our US Pharma operations we increase our focus on the full US Commercial operations profit contribution and this improved 65 percent

from last year to SEK 46 million, mainly due to reduced expenses within digital mental health programs. Most operations in Orexo US are now managed by shared resources and starting Q1 2024, we will report all US commercial operations as one business unit in the P&L.

All digital mental health programs available within Veterans Affairs

The Digital Mental Health Program unit, earlier "Digital Therapeutics", changed leadership during 2023 and is now run by a small team of tenured and experienced colleagues with a strong focus on the opportunities within Veterans Affairs (VA). In the quarter Orexo signed a distribution agreement with Lovell Government Services who specialize in selling medical supplies to the VA and who are led and operated by veterans. Thanks to this collaboration with Lovell, we have managed to get MODIA® and Vorvida® on the Federal Supply Schedule from January 1, 2024, together with Deprexis®. This means we can start promoting all three products to the hospitals and clinics within the VA during Q1. Additionally, and together with our partner GAIA AG we are updating MODIA to meet the new regulatory pathway. This work will be finalized in Q1 2024 and will enable a re-lauch to a select group of customers under the FDA enforcement discretion.

R&D with all focus on FDA approval for OX124

During the quarter the FDA announced the PDUFA date for our high-dose naloxone rescue medication for opioid overdose, OX124, which is set for July 15, 2024. We know from similar approval processes that the PDUFA date could be delayed due to the complexity that comes with a drug-device combination. However, we expect approval during Q3 2024 if the review proceeds according to plan. We are encouraged by the fact that the FDA has started the review process. The first questions were received before Christmas and audits of the supply chain are scheduled to start during Q1.

US launch of OX124 approaching in a rapidly growing and dynamic market

OX124 comes with a high dose of naloxone. The high dose, combined with the drug's rapid absorption and high bioavailability, means that OX124 has the potential to contribute curbing the increased mortality from overdoses caused by the widespread misuse of synthetic opioids. We're approaching this launch in a rapidly growing market that's currently undergoing major changes, with the low-dose alternatives moving from prescription medications to over the counter. This move is unprecedented among rescue medications in the US and we are closely monitoring the market dynamics in order to optimize the launch plan for OX124. Once approved, we intend to initiate commercial activities during the second half of 2024, with a focus on obtaining reimbursement ahead of a broader launch into retail pharmacies early in 2025. We are confident we can take advantage of these recent developments to reach many people acutely in need of high-dose naloxone rescue medications.

Summary and outlook

Our expectations for Q4 were high and we needed to achieve improvements in sales and reduce expenses compared to Q3 to meet the guidance for the year. With increased Zubsolv® sales and lower costs, we are pleased to report we met our guidance for 2023 despite the significant strengthening of the SEK during December.

Zubsolv sales remain central to our financial performance and with continued stabilization of net sales and improving profit contribution from our US commercial operations we have a solid financial foundation to grow from. We are one year away from the maturity of the corporate bond and to address the upcoming maturity, Orexo has engaged ABG Sundal Collier and Carnegie Investment Bank as financial advisors to evaluate refinancing of the bond during 2024.

Finally, I would like to highlight and compliment my colleagues in Sweden and the US who are skilled, dedicated and highly motivated. Our employees are the key to our success, and I am delighted the annual survey results showed record-high outcomes.

My colleagues and I are looking forward to 2024. It promises to be an exciting and ambitious year for Orexo. Firstly, we are expecting to sign a partner agreement for the AmorphOX® platform. Secondly, we are anticipating FDA approval for our new pharmaceutical, OX124, and based on stable Zubsolv sales we are aiming to continue strengthening our financial performance reaching EBITDA profitability for the full year.

Uppsala, Sweden, February 8, 2024

Nikolaj Sørensen
President and CEO

Commercial products

Pharmaceuticals

Zubsolv® (buprenorphine and naloxone) sublingual tablet (CIII)

Zubsolv is indicated for the maintenance treatment of opioid use disorder (OUD) and should be used as part of a comprehensive treatment plan, which includes counseling and psychosocial support. The drug is based on Orexo´s sublingual drug delivery platform and is available in six dosage strengths.

Unmet need and market development

Misuse of opioids is a global problem but is of epidemic proportions in the US where an estimated 8.9 million people are misusing opioids.[1] Approximately 6.1 million people are dependent on opioids[2] and of these, around 2.4 million are undergoing MAT treatment.[3] The opioid crisis in the US has continued to accelerate mainly due to the Covid-19 pandemic and the prevalence of synthetic opioids, such as illicit fentanyl. Fatal opioid overdoses have reached record-high levels and according to latest available data the number exceeded 85,000 annually.[4] Nine out of ten opioid overdoses involve synthetic opioids.[5]

In Q4, the buprenorphine/naloxone market grew 1 percent versus Q3 2023 and grew 3 percent versus Q4 2022. Expectations are that the buprenorphine/naloxone market growth will be positively impacted over the long-term by the new law, the 'Mainstreaming Addiction Treatment Act'. The new law, effective January 1, 2023, removes the cap on the numbers of patients HCP´s can treat with medication-assisted treatment (MAT). Also, the requirements for prescribing MAT have been reduced and now all HCP´s with a license to prescribe controlled drug substances can prescribe MAT for OUD. In addition, the opioid litigation settlements of approx. USD 54 billion, are also expected to accelerate access to treatment.

Developments during the quarter

Zubsolv volume remained stable Q4 versus Q3 2023 and declined 4 percent versus Q4 2022 mainly due to lower volume with United Health Group (UHG) and Humana where Zubsolv previously has been exclusive. Compared to Q3 Zubsolv grew 1 percent within the open commercial segment and 1 percent in Medicaid, despite a market decline of 2 percent in Medicaid. At UHG and Humana Zubsolv declined 2 percent resulting in an overall stable Q4 over Q3.

Improved market access in Medicaid resulted in Zubsolv outpaced the Medicaid growth, growing 4 percent vs Q4 2022, compared to the market declining 1 percent. Zubsolv´s year over year growth in Medicaid is supported by the most recently improved market access e.g., Medicaid in Kentucky growing 19 percent, in New York growing 33 percent, and in Indiana growing 196 percent after gaining broader access in July 2023. The second and third largest Zubsolv Medicaid states, Michigan and Ohio, experienced growth of 2 percent and 6 percent, respectively.

Entering 2024, Zubsolv´s best in class market access in the commercial payer segment is maintained at 98 percent. Zubsolv´s public payer segment access was maintained at 50 percent which includes New Hampshire adding Zubsolv to its Medicaid formulary from January 1, 2024.

Digital mental health programs

MODIA® for OUD

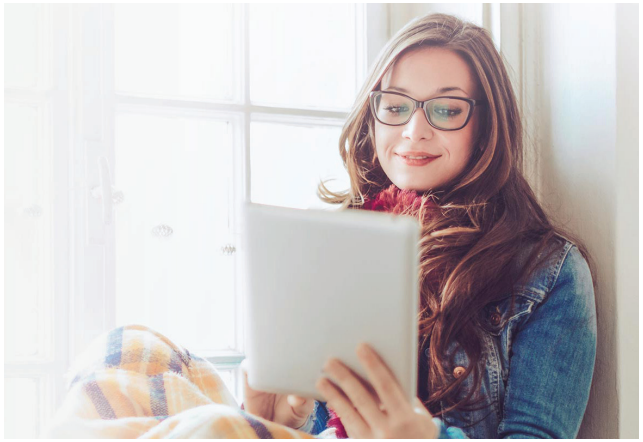
MODIA is a web-based software program intended to help OUD patients develop behavioral coping skills and provide educational information, reminders, and motivational guidance. MODIA is intended for use, over a period of six months, by patients engaged in a clinician directed medication assisted treatment (MAT) plan for OUD.

Deprexis® for depression

Deprexis is a three month online program that can help people create more positive thoughts and behaviors. The therapy is developed in consultation with psychologists, physicians and patients and is based on cognitive behavioural therapy techniques. Its effectiveness has been evaluated and published in twelve randomized clinical trials including more than 2,800 patients. Deprexis can be used as a standalone treatment or alongside traditional pharmaceuticals.[6]

Vorvida® for alcohol management

Vorvida is a six month online program that can break negative thought patterns and responses to change behavior around alcohol. The therapy is developed in consultation with psychologists, physicians and patients and is based on cognitive behavioural therapy techniques. The effectiveness of Vorvida is evaluated in a randomized clinical trial, including approx. 600 patients.[7]



modia deprexis VORVIDA

Developments during the quarter

Orexo´s partner GAIA updated the MODIA digital mental health program to comply with the new regulatory status as a mobile medical device under FDA´s enforcement discretion. The change in the program was necessary due to the failure to meet the primary endpoints in the MODIA study as reported in Q3. The completion of the update is planned for Q1 2024 and will enable a re-launch of MODIA.

Lack of efficient reimbursement and distribution channels has been a main issue for Orexo and competing digital therapies since launch. For Orexo the short term focus is on the Veterans Affairs, where there is a high prevalence of mental health issues and access to established reimbursement and distribution pathways. During the quarter Orexo has initiated a collaboration with Lovell Government Services (Lovell), which has extensive experience from marketing and selling medical devices within the Veterans Affairs (VA). In addition to accelerating the establishment of efficient processes for reimbursement and distribution of Deprexis, Orexo and Lovell has managed to get both MODIA and Vorvida added to the Federal Supply Schedule as of January 1, 2024, and commercialization to the VA in collaboration with Lovell will be initiated in the first quarter.

Longer term, progress is being made on a federal level in the US to establish a national reimbursement system for digital health solutions and therapies. An efficient reimbursement and distribution system is essential for Orexo's digital mental health programs to reach their full potential and the company is actively engaging with government representatives and other stakeholders to ensure an efficient system to the benefit of patients and the healthcare providers.

Due to extensive saving measures in the digital mental health business, the direct costs (excluding depreciation and allocated expenses from US Pharma) have been reduced by 42 percent in 2023. About 75 percent of the expenses for digital mental health programs are allocated expenses from US Pharma and the direct expenses are limited. As a consequence, revenues and costs for the digital mental health programs will be recorded in the US Commercial segment as of January 1, 2024,

AmorphOX® – a versatile drug delivery platform

Identified need

Amorphous materials are becoming more and more common in drug development and can be of great importance for the properties of the drug product. Amorphous materials 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 2039-2044.

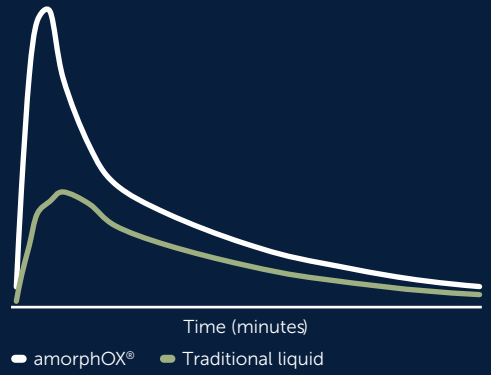
Clinically validated

The technology has successfully been validated in multiple clinical studies during the development of nasal rescue medications for opioid overdoses, one including naloxone (OX124) and one with nalmefene (OX125). In addition, it has also been clinically proven with epinephrine (OX640), a product for acute treatment for allergic reactions. Data has demonstrated qualities such as rapid absorption, excellent bioavailability and low variability.

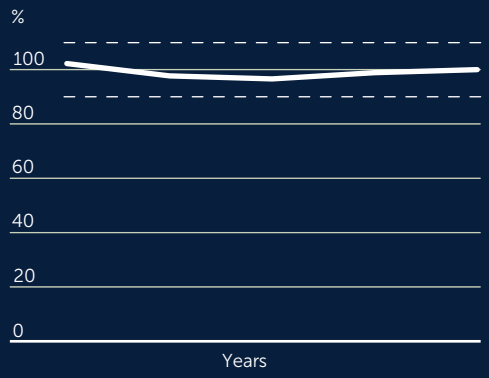
Wide applicability

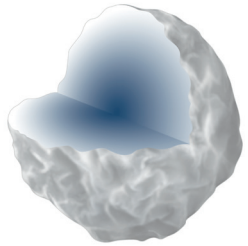
The technology works with a broad spectrum of active chemical substances, including small and large molecules,[8] and the properties of the powder can be tailored to meet specific needs such as particle size, dissolution, and mucosal retention. This makes it a versatile technology with broad applicability in pharmaceutical development across multiple therapeutic areas.

Plasma concentration



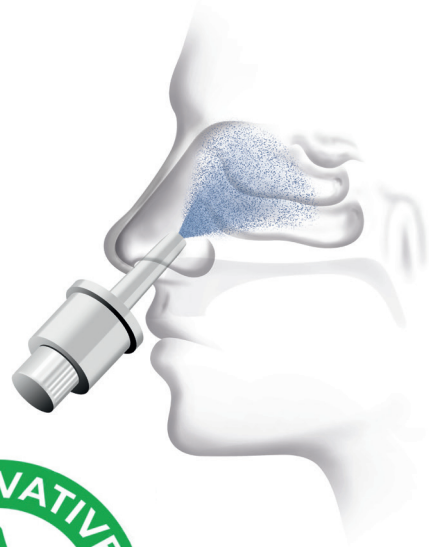
Amount of API





Successful clinical trials

Well tolerated
Higher exposure
Faster onset
Lower variability



PRESERVATIVES NO ADDED

amorphOX®

Products under development

Development projects based on the AmorphOX® drug delivery platform

OX124 – high-dose rescue medication for opioid overdose with naloxone

Project in brief

Opioid overdose is a life-threatening condition, characterized by loss of consciousness and respiratory depression. 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, such as illegal fentanyl.

Developments during the quarter

FDA announced acceptance of the New Drug Application (NDA) filing, which was submitted with the agency in September 2023. The review process was initiated during the quarter and the company is working diligently with the FDA to address any inquiries and requests. Prescription Drug User Fee Act (PDUFA) date is set to July 15, 2024, but recent review processes in the category indicate a risk of some delay.

Differentiation

Formulations of OX124 have shown more rapid absorption and substantially higher plasma concentrations of naloxone compared to the current market leader. These properties can be critical in avoiding brain damages and saving lives as well as preventing re-intoxification during the revival process. In addition, the AmorphOX powder-based technology, which is the backbone in OX124, contributes to improve stability of the active substance and reduces its sensitivity related to temperature changes. For users and lay-people[9] OX124 has the potential to become an efficient and reliable rescue medication also when the overdose is caused by synthetic opioids. OX124 has patents protecting the product until 2039.

Market and commercialization

Upon approval, Orexo will meet an increased need of a powerful overdose rescue medications, where most overdoses today are caused by misuse of synthetic opioids, such as illegal fentanyl. During the latest twelve month period, ending August 2023, the predicted annual number of fatal opioid overdoses in the US counted for more than 85,000.[10] Nine out of ten opioid overdoses involve synthetic opioids.[11]

Driven by the need to increase access to overdose medication, low-dose products, including the market leader, have recently been approved by the FDA as non-prescription over the counter (OTC) products. Historically, OTC products in the US have had limited reimbursement from insurance companies and, when applying similar industry analogues going forward, this may provide an advantage to high-dose prescription naloxone products, such as OX124. In addition, high-dose prescription products are expected to benefit from the continued expansion of mandatory co-prescription of naloxone when prescribing opioids to at-risk patients suffering from pain.

	OX124 (high-dose naloxone)
Naloxon "Gold Standard"	✓
High-Dose Naloxone	✓
Powder	✓
Unique Device	✓
Does not freeze	✓
Long Shelf-Life	✓

If the FDA approves OX124 according to plan, Orexo will initiate the launch in late 2024 focusing on securing reimbursement by insurance companies ahead of a broader launch in the beginning of 2025. When launching the product, Orexo will benefit from its well-established network among insurance companies, its long experience and knowledge of treatment of patients with OUD, and particularly from its sales force covering large parts of the US, including twelve of the seventeen states with mandatory co-prescribing of naloxone when prescribing opioids to patients with severe pain. A large part of the market for OX124 is outside the existing focus areas of Orexo and to reach first responders, such as police and firefighters, which is made through centralized procurement, the existing account management team will be expanded with some new positions during late 2024 and 2025.

As with Zubsolv today, Orexo will establish financial patient support programs for OX124 to ensure affordability of even financially vulnerable patients.

OX125 –rescue medication for opioid overdose with nalmefene

Project in brief

The widespread use of synthetic opioids, also increases the need for effective and long-lasting rescue medications for use in rural areas where it takes long time for patients to reach emergency care units. With OX125, the aim is to develop an overdose rescue medication for situations where the treatment effect needs to be long-lasting while also being powerful and fast-acting. Nalmefene has a half-life of eight to eleven hours in the body versus one to two hours for naloxone.

OX125, also based on the proprietary drug delivery platform AmorphOX, has shown positive results from a human pharmacokinetic study. The study was a cross-over, comparative bioavailability study in healthy volunteers to

assess nalmefene absorption from three development formulations of OX125, compared to a nalmefene intramuscular injection. Data demonstrated extensive and rapid absorption across all three OX125 formulations as well as good tolerability.

Developments during the quarter

Preparations for a future ramp-up of the project was conducted during the quarter. Remaining time for development is relatively short since the synergies between OX124 and OX125 are significant in terms of development and product supply.

OX640 – epinephrine rescue medication for allergic reactions

Project in brief

The aim with OX640 is to develop a powder-based 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 handling and storage.

OX640 is based on AmorphOX® and its powder-based technology provides excellent chemical and physical stability. 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 worldwide.

OX640 is protected by granted patents both on the US and European markets. Furthermore, multiple patent applications have been filed protecting OX640 on a global basis until 2044.

Developments during the quarter

Orexo continued the process to prepare the next round of interactions with the FDA to agree on the pivotal clinical development program. The importance of this has accentuated following the unexpected complete response letter (CRL/ rejection of approval) by the agency to a competing liquid nasal epinephrine product, in September 2023. Feedback and agreement with FDA on the requirements to a pivotal clinical program is important in the partnership discussions around OX640.

The work to upscale the manufacturing process continued together with the establishment of a commercial supply chain, which will leverage on the existing supply chain for OX124. Stability studies continue to showcase great stability of OX640 and its ability to withstand large changes in temperature.

OX124, OX125 and OX640 will work independent on temperature

Early stage projects

The wide applications of the drug delivery platform AmorphOX entail Orexo to continuously conduct tests of the platform with new APIs, including both small and large molecules, and to perform stability studies. Three exploratory feasibility studies are on-going in collaboration with international pharmaceutical companies, of which two of these companies are working with biological drugs or vaccines. The first results of the exploratory feasibility studies where promising, with large biomolecules maintaining activity after formulation with the AmorphOX platform. Orexo continues to work with the potential partner companies to explore the value of the AmorphOX platform to their proprietary technology and as the development advance Orexo will receive compensation for specific development activities.

Orexo aims to continue to seek partnerships with other pharmaceutical and biotech companies to leverage the unique properties of AmorphOX to improve the formulation of their products, while in parallel advance other projects to feed Orexo's US commercial organization with more products.

Revenues from potential partners to cover specific development activities for projects related to the AmorphOX platform are recognized under Other Incomes.

Other development projects

OX-MPI – vipoglanstat for the treatment of endometriosis

OX-MPI (GS-248) is a drug candidate in clinical development. OX-MPI inhibits the proinflammatory enzyme mPGES-1, which via its product, prostaglandin E2, plays a key role in the chronic inflammatory disease endometriosis. This disease affects approximately 10 percent of women of reproductive age. Main symptoms of endometriosis are severe pain and reduced fertility, and there is a high need for nonhormonal treatment options.

Orexo's partner Gesynta Pharma owns all rights to the drug candidate.

Sustainability

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 UN principles 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.

In 2022 the sustainability strategy was updated based on e.g., stakeholder dialogues and a materiality assessment and involves today four focus areas:

1. Responsible business

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

2. Access to healthcare

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

3. Sustainable employees

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

4. Environment and Climate change

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

For in-depth information about the sustainability work view www.orexo.com or the 2022 Sustainability Report.

91%

..... of total net revenues in 2023 refers to SDG target 3.5, Prevent & Treat Substance Abuse

Developments during the quarter

The work to map the climate impact within Scope 3 in accordance with the GHG Protocol continued. A data summary for both 2022 and 2023 will be reported in the upcoming Sustainability Report.

Sustainability assessment of all suppliers linked to the AmorphOX delivery platform was finalized, and all suppliers are now approved in relation to the requirements of Orexo's Code of conduct for suppliers.

In the social area, the employee survey was finalized and again shows the same strong results as in previous years. More than nine out of ten employees are satisfied with working at Orexo both in Sweden and in the US, e.g. employees express they have a good work-life balance and that Orexo supports their well-being.

Financial development

Revenues

Total revenues amounted to SEK 166.0 m (156.1) for Q4. The increase is mainly explained by higher US Pharma revenues and higher HQ & Pipeline partner product related revenues partly offset by the weaker USD exchange rate. Total revenues amounted to SEK 638.8 m (624.3) for the full year.

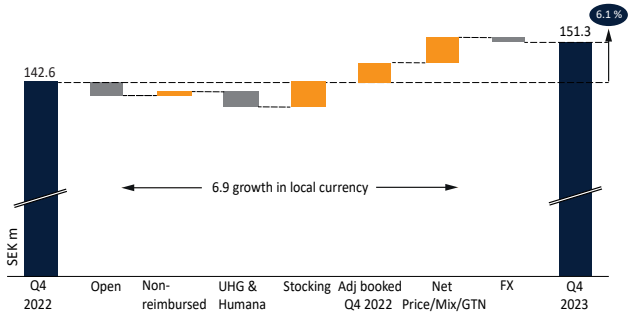
Revenues by segment

US Pharma revenues amounted to SEK 151.3 m (142.6) for Q4. The increase in US Pharma revenues is mainly driven by higher wholesaler stocking and favorable payer mix partly offset by lower demand and a negative impact of SEK 1.1 m from weaker USD exchange rate. Zubsolv® experienced lower demand mainly as a result of lower market growth, especially in the higher priced open segment. The demand in the previously exclusive plans United Health Group and Humana is lower year over year, but the decline has continued to slow down considerably in Q4. US Pharma revenues amounted to SEK 577.7 m (571.4) for the full year. In local currency US Pharma net revenues for Q4 amounted to USD 14.2 m (13.3) and for the full year to USD 54.4 m (56.5).

Digital Mental Health Programs (DMHP), earlier "Digital Therapeutics (DTx)", recognized net revenues for Q4 amounting to SEK 0.0 m (0.0) and to SEK 0.1 m (0.4) for the full year.

HQ & Pipeline partner product related revenues for Q4 amounted to SEK 14.7 m (13.4). The increase is explained by higher Abstral® royalties partly offset by lower Zubsolv ex-US revenues related to sales of tablets to Orexo's partner Accord Healthcare and lower Edluar® royalties. HQ & Pipeline partner product related revenues amounted to SEK 61.1 m (52.6) for the full year.

ZUBSOLV US NET REVENUES DEVELOPMENT



NET REVENUES AND OPERATING EARNINGS PER SEGMENT

SEK m	Net Revenues				EBIT			
	2023 Oct-Dec	2022 Oct-Dec	2023 Jan-Dec	2022 Jan-Dec	2023 Oct-Dec	2022 Oct-Dec	2023 Jan-Dec	2022 Jan-Dec
Zubsolv US product sales	151.3	142.6	577.7	571.4	–	–	–	–
US Pharma – total	**151.3**	**142.6**	**577.7**	**571.4**	**75.4**	**77.0**	**283.1**	**308.4**
Digital Mental Health Programs (DMHP) product sales	0.0	0.0	0.0	0.4	–	–	–	–
DMHP – total	**0.0**	**0.0**	**0.0**	**0.4**	**-29.1**	**-49.0**	**-130.9**	**-189.1**
Abstral royalty	10.0	5.5	31.9	30.4	–	–	–	–
Edluar royalty	1.9	2.7	10.8	10.4	–	–	–	–
Zubsolv – ex-US	2.8	5.2	18.4	11.8	–	–	–	–
HQ & Pipeline – total	**14.7**	**13.4**	**61.1**	**52.6**	**-54.9**	**-99.1**	**-261.8**	**-303.2**
Total	**166.0**	**156.1**	**638.8**	**624.3**	**-8.6**	**-71.1**	**-109.5**	**-183.9**

Cost of goods sold

Cost of goods sold (COGS) amounted to SEK 20.1 m (25.9) for Q4. US Pharma amounted to SEK 15.3 m (20.6), the decrease is mainly due to favorable production costs. Royalty and technical infrastructure costs for DMHP amounted to SEK 2.7 m (2.8). HQ & Pipeline amounted to SEK 2.2 m (2.6) for Zubsolv ex-US from sale of tablets to Orexo's partner Accord Healthcare. COGS amounted to SEK 88.9 m (102.6) for the full year.

Operating expenses

Selling expenses amounted to SEK 43.5 m (52.2) for Q4. The decrease over the same period last year is mainly explained by significantly lower selling expenses in DMHP. Selling expenses amounted to SEK 181.5 m (199.0) for the full year.

Administrative expenses amounted to SEK 38.0 m (63.8) for Q4. The decrease is mainly explained by lower legal expenses for IP litigation and lower costs in DMHP. Administrative expenses amounted to SEK 188.0 m (202.3) for the full year.

Research and development costs amounted to SEK 65.4 m (88.2) for Q4. The decrease is mainly explained by the finalized MODIA® study in Q3 2023 and lower costs for OX124. Research and development costs amounted to SEK 303.1 m (318.0) for the full year.

Other operating income and expenses amounted to SEK -7.6 m (3.0) for Q4. This is mainly explained by higher exchange-rate losses of SEK -7.2 m (-4.7) derived from revaluations of parent company balance sheet items in foreign currency, predominantly in USD, lower received insurance reimbursement of SEK 0.5 m (7.2) for legal costs in the US and higher MATCore[12] related startup costs of SEK -1.3 m (0.0). Other operating income and expenses amounted to SEK 13.3 m (13.7) for the full year.

Operating profit

EBITDA amounted to SEK 12.4 m (-53.1) for Q4 and to SEK -32.5 m (-115.2) 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 23.4 m (-0.1) for Q4 and SEK 88.0 m (57.8) for the full year.

The EBIT contribution from US Pharma amounted to SEK 75.4 m (77.0) for Q4, equal to an EBIT margin of 49.8 percent (54.0). EBIT contribution from US Pharma amounted to SEK 283.1 m (308.4) for the full year, equal to an EBIT margin of 49.0 percent (54.0).

Total EBIT amounted to SEK -8.6 m (-71.1) for Q4 mainly explained by higher net revenues, lower costs of goods sold and lower operating expenses. Total EBIT amounted to SEK -109.5 m (-183.9) for the full year.

Net financial items and tax

Net financial items for Q4 amounted to SEK -10.9 m (-24.4) and is mainly explained by lower negative unrealized exchange rate impact of SEK -2.0 m (-18.2) derived from the parent company's foreign currency bank accounts mainly in USD. This was partly offset by lower interest income from bank accounts of SEK 1.1 m (2.2) explained by absence of short-term investments and higher costs of SEK -9.6 m (-7.8) for the corporate bond loan. Net financial items amounted to SEK -30.8 m (13.5) for the full year.

Total tax expenses amounted to SEK 0.9 m (3.7) for Q4. The decrease is mainly explained by lower positive adjustment to deferred tax assets related to temporary differences. Total tax expenses amounted to SEK 12.0 m (-7.2) for the full year. Orexo performs regular assessments of its deferred tax asset and makes adjustments according to the recognition requirements of IAS 12.

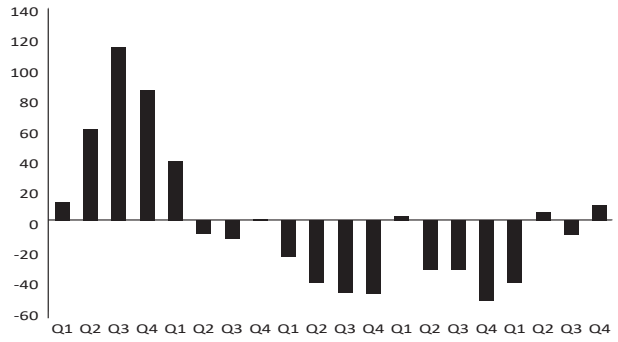
Net earnings

Net earnings amounted to SEK -18.6 m (-91.8) for Q4 and to SEK -128.3 m (-177.6) for the full year.

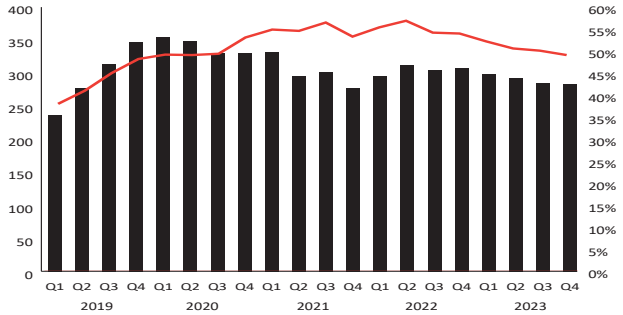
Cash and cash flow

Cash flow from operating activities amounted to SEK -2.6 m (-48.9) for Q4 and was primarily impacted by negative operating earnings and changes in working capital. Cash flow from operating activities amounted to SEK -95.0 m (-156.6) for the full year. As of December 31, 2023, cash and cash equivalents amounted to SEK 171.0 m (132.2) and short-term investments amounted to SEK 0.0 m (219.6). Cash and invested funds in total amounted to SEK 171.0 m (351.9) and interest-bearing liabilities to SEK 448.4 m (494.8), i.e. a negative net cash position including short-term investments of SEK -277.4 m (-142.9). Cash and cash equivalents were reduced by SEK 13.2 m from Q3 2023.

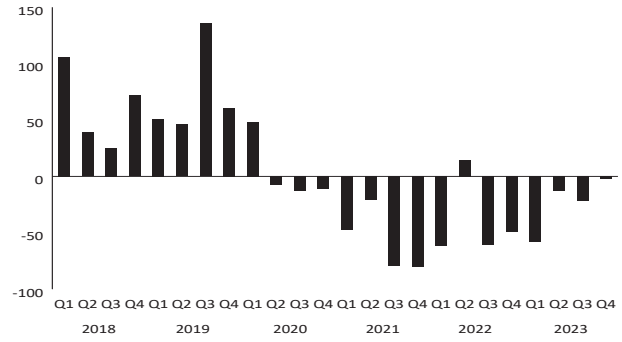
GROUP EBITDA, SEK m



US PHARMA EBIT MARGIN (LTM, SEK m) AND EBIT (LTM SEK m)[13]



CASH FLOW FROM OPERATING ACTIVITIES, SEK m



Investments

Gross investments in tangible and intangible fixed assets amounted to SEK 0.9 m (12.3) for Q4 and to SEK 19.2 m (23.9) for the full year. Lower investments for Q4 are mainly explained by absence of investments in equipment for OX124.

Equity

Shareholders' equity at December 31, 2023, was SEK 58.9 m (193.9). The equity/asset ratio was 7.5 percent (17.5).

Parent company

Net revenues for Q4 amounted to SEK 114.1 m (128.2) of which SEK 99.4 m (114.7) was related to sales to Group companies. Net revenues amounted to SEK 494.0 m (348.2) for the full year of which SEK 432.9 m (295.6) was related to sales to Group companies.

Earnings before tax amounted to SEK -14.7 m (-75.6) for Q4. The development is mainly explained by lower operating expenses and lower negative net financial items partly offset by lower gross profit. Earnings before tax amounted to SEK -70.4 m (-196.8) for the full year.

Investments in equipment for the development organization for Q4 amounted to SEK 0.9 m (11.0) and to SEK 18.5 m (18.8) for the full year.

As of December 31, 2023, cash and cash equivalents in the parent company amounted to SEK 145.5 m (61.7) and short-term investments amounted to SEK 0.0 m (178.6) i.e. parent company's cash and invested funds amounted to SEK 145.5 m (240.3).

Parent company shareholders' equity at December 31, 2023, was SEK 162.1 m (109.2). The increase over the same period last year is mainly explained by a write-up of SEK 123.4 m (0) of the value of the holding of Orexo US Inc. in Orexo AB to the subsidiary's current net asset value. This was partly offset by negative earnings of SEK -70.4 m (-196.8) for the full year. See further "Risks and uncertainty factors" under "Other information".

Other information

Outcome financial outlook 2023

- The buprenorphine/naloxone market will grow 4-7 percent
  Outcome: 4 percent
- Group revenues will increase, with Zubsolv® US revenues being in line with 2022
  Outcome: Group revenues increased to SEK 639 m (624) and Zubsolv US revenues to SEK 578 m (571)
- Reduced OPEX in H2 compared to H1, which amounted to SEK 343 m including depreciation of SEK 37 m
  Outcome: SEK 316 m including depreciation of SEK 40 m
- EBITDA in balance in H2
  Outcome: SEK 3 m (11 at Constant Exchange Rates)

  All numbers are based on exchange rates in December 2023.

Financial outlook 2024

- The buprenorphine/naloxone market will grow 2-5 percent, based on current growth trajectory
- Zubsolv net sales in USD will be in line with 2023
- Cost control is a priority and OPEX excluding depreciation and amortization will decline from SEK 582 m in 2023 to below SEK 530 m in 2024
- Positive EBITDA for the FY 2024.

The financial outlook 2024 is based on a forward looking assumption of a USD/SEK exchange rate of 10.28 calculated as an average of December 2023 by the Riksbanken.

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 2022 and in the Interim Report Note 4, litigations. The continued commercialization of Zubsolv and digital mental health programs 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. In addition, expanded geopolitical risk increases the risk of shortage of material in the product supply chain.

Going concern update

Taking into account the shareholders equity in the parent company as per year end and the expected earnings in 2024, the board's assessment is that there is no longer any material uncertainty factor that could cast doubt regarding the entity's ability to continue as going concern. The group has sufficient funds for continued operations for at least the next twelve months and the interim report is prepared based on the assumption of going concern.

Following a decrease in the shareholders' equity in the parent company during the first 9 months 2023, the trend of lowering expenses and improving the result in the parent company has continued in Q4 and is expected to be improved further in 2024. Also, in Q4 the parent company's equity position increased significantly as a consequence of a write-up of the book value of Orexo AB's holding of Orexo US Inc., reflecting the subsidiary's current net asset value.

Glossary

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

Uppsala, Sweden, February 8, 2024

Nikolaj Sørensen
President and CEO

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

Key near-term triggers

1. **Reach EBITDA profitability on a full year basis**
2. **Zubsolv sales stabilized and improved access to patients**
3. **Enter into partnership for one of the projects under development**
4. **Digital mental health programs showing progress.**

References

1 Page 6, Substance Abuse and Mental Health Services Administration

2 Page 6, Substance Abuse and Mental Health Services Administration

3 Page 6, Substance Abuse and Mental Health Services Administration

4 Page 6, Center of Disease Control and Prevention

5 Page 6, Center of Disease Control and Prevention

6 Page 7, Jördis M. Zill, Eva Christalle, Björn Meyer, Martin Härter, and Jörg Dirmaier The Effectiveness of an Internet Intervention Aimed at Reducing Alcohol Consumption in Adults: Results of a Randomized Controlled Trial (Vorvida) Dtsch Arztebl Int 2019; 116: 127–33. DOI: 10.3238/arztebl.2019.0127

7 Page 7, Twomey et al. (2020), Zwerenz et al. (2017), Berger et al. (2018), Beevers et al. (2017), Klein et al. (2016), Meyer et al. (2015), Moritz et al. (2012), Berger et al. (2011), Meyer et al. (2009), Bücker et al. (2018), Fischer et al. (2015), Schröder et al. (2014)

8 Page 8, Enzymes, peptides and proteins

9 Page 9, E.g. police officers, prison personnel, family and relatives

10 Page 9, Center of Disease Control and Prevention

11 Page 9, Center of Disease Control and Prevention

12 Page 12, MATCore is a product concept where Orexo´s total offering within OUD is collected

13 Page 13, Last Twelve Months

Financial reports, notes and key figures

CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS

SEK m	Notes	2023 Oct-Dec	2022 Oct-Dec	2023 Jan-Dec	2022 Jan-Dec
Net revenues	9	166.0	156.1	638.8	624.3
Cost of goods sold		-20.1	-25.9	-88.9	-102.6
Gross profit		**145.9**	**130.2**	**550.0**	**521.7**
Selling expenses		-43.5	-52.2	-181.5	-199.0
Administrative expenses		-38.0	-63.8	-188.0	-202.3
Research and development expenses		-65.4	-88.2	-303.1	-318.0
Other operating income and expenses		-7.6	3.0	13.3	13.7
Operating earnings (EBIT)		**-8.6**	**-71.1**	**-109.5**	**-183.9**
Net financial items		-10.9	-24.4	-30.8	13.5
Earnings before tax		**-19.5**	**-95.5**	**-140.3**	**-170.4**
Tax	5	0.9	3.7	12.0	-7.2
Net earnings for the period		**-18.6**	**-91.8**	**-128.3**	**-177.6**
Earnings per share. before dilution. SEK		-0.54	-2.67	-3.73	-5.17
Earnings per share. after dilution. SEK		-0.54	-2.67	-3.73	-5.17

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

SEK m	2023 Oct-Dec	2022 Oct-Dec	2023 Jan-Dec	2022 Jan-Dec
Earnings for the period	**-18.6**	**-91.8**	**-128.3**	**-177.6**
Other comprehensive income	**—**	**—**	**—**	**—**
Items that may subsequently be reversed to the statement of operations:				
Exchange-rate differences	-14.7	3.4	-6.8	22.1
Other comprehensive earnings for the period, net after tax	**-14.7**	**3.4**	**-6.8**	**22.1**
Total comprehensive earnings for the period [1]	**-33.3**	**-88.4**	**-135.1**	**-155.5**

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

CONDENSED CONSOLIDATED BALANCE SHEET

SEK m	Notes	2023 Dec 31	2022 Dec 31
ASSETS			
Fixed assets			
Tangible fixed assets		81.0	76.1
Intangible fixed assets		173.3	217.4
Right-of-use assets		24.5	46.0
Deferred tax assets	5	48.1	33.1
Other financial assets		0.8	0.9
Total fixed assets		**327.7**	**373.5**
Current assets			
Inventories		42.4	74.6
Accounts receivable and other receivables		245.5	309.0
Short-term investments		—	219.6
Cash and cash equivalents		171.0	132.2
Total current assets		**458.9**	**735.5**
Total assets		**786.6**	**1,109.0**
SHAREHOLDERS' EQUITY AND LIABILITIES			
Total shareholders' equity		**58.9**	**193.9**
Long-term liabilities			
Provisions		11.5	10.2
Long-term liabilities, interest bearing		448.4	494.8
Lease liabilities, long-term		4.5	24.2
Total long-term liabilities		**464.5**	**529.2**
Current liabilities and provisions			
Provisions		133.1	121.5
Current liabilities, non-interest bearing		109.2	243.7
Lease liabilities, current		20.9	20.6
Total current liabilities and provisions		**263.2**	**385.9**
Total liabilities		**727.7**	**915.1**
Total shareholders' equity and liabilities		**786.6**	**1,109.0**

CONDENSED CONSOLIDATED CHANGES IN SHAREHOLDERS' EQUITY

SEK m	2023 Dec 31	2022 Dec 31
Opening balance, shareholders' equity	**193.9**	**349.6**
Total comprehensive earnings for the period	-135.1	-155.5
Share-based payments	—	-0.1
Closing balance, shareholders' equity	**58.9**	**193.9**

CONDENSED CONSOLIDATED CASH FLOW STATEMENTS

SEK m	Notes	2023 Oct-Dec	2022 Oct-Dec	2023 Jan-Dec	2022 Jan-Dec
Operating earnings (EBIT)		-8.6	-71.1	-109.5	-183.9
Interest received		3.6	1.1	7.7	1.4
Interest paid		-10.5	-6.9	-37.6	-22.4
Income taxes paid		-0.4	3.6	-1.6	1.5
Adjustment for non-cash items	3	43.0	-4.4	99.8	-3.5
Cash flow from operating activities before changes in working capital		**27.2**	**-77.7**	**-41.2**	**-206.9**
Changes in working capital		**-29.8**	**28.8**	**-53.8**	**50.3**
Cash flow from operating activities		**-2.6**	**-48.9**	**-95.0**	**-156.6**
Acquisition of tangible and intangible fixed assets		-0.9	-12.3	-19.2	-23.9
Acquisition of short-term investments		0.0	-6.4	0.1	-295.6
Disposal of short-term investments		0.0	84.0	219.9	84.0
Sales of tangible assets		—	0.8	—	0.8
Cash flow from investing activities		**-0.9**	**66.2**	**200.8**	**-234.7**
Repayment of loans and lease liabilities		-5.6	-5.8	-70.1	-21.4
Cash from financing activities		**-5.6**	**-5.8**	**-70.1**	**-21.4**
Cash flow for the period		**-9.1**	**11.5**	**35.7**	**-412.8**
Cash and cash equivalents at the beginning of the period		**184.2**	**122.4**	**132.2**	**504.1**
Exchange-rate differences in cash and cash equivalents		-4.1	-1.6	3.1	40.9
Changes in cash and cash equivalents		-13.2	9.9	38.8	-371.8
Cash and cash equivalents at the end of the period		**171.0**	**132.2**	**171.0**	**132.2**

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.

	2023 Oct-Dec	2022 Oct-Dec	2023 Jan-Dec	2022 Jan-Dec
EBIT margin, %	-5.2	-45.6	-17.1	-29.5
Return on shareholder equity, %	-24.7	-37.3	-101.5	-65.4
Net debt, SEK m	277.4	142.9	277.4	143.1
Debt/equity ratio, %	761.3	255.2	761.3	255.2
Equity/assets ratio, %	7.5	17.5	7.5	17.5
Number of shares, before dilution	34,449,595	34,367,616	34,413,408	34,351,732
Number of shares, after dilution	34,449,595	34,367,616	34,413,408	34,351,732
Earnings per share, before dilution, SEK	-0.54	-2.67	-3.73	-5.17
Earnings per share, after dilution, SEK	-0.54	-2.67	-3.73	-5.17
Number of employees at the end of the period	116	126	116	126
Shareholders' equity, SEK m	58.9	193.9	58.9	193.9
Capital employed, SEK m	507.3	688.7	507.3	688.7
Working capital, SEK m	24.7	217.4	24.7	217.2

[2] Definitions and reconcilliations of key figures are presented on page 28 of this report

CONDENSED PARENT COMPANY STATEMENT OF OPERATIONS

SEK m	Notes	2023 Oct-Dec	2022 Oct-Dec	2023 Jan-Dec	2022 Jan-Dec
Net revenues		114.1	128.2	494.0	348.2
Cost of goods sold		-20.0	-25.8	-93.7	-72.4
Gross profit		**94.1**	**102.4**	**400.3**	**275.8**
Selling expenses		-24.0	-41.5	-119.4	-165.1
Administrative expenses		-18.2	-40.5	-94.9	-123.1
Research and development costs		-50.8	-73.5	-243.7	-266.9
Other operating income and expenses		-5.2	1.6	17.1	65.4
Operating earnings (EBIT)		**-4.2**	**-51.5**	**-40.6**	**-213.9**
Interest income and expenses		-7.9	-5.5	-31.3	-19.6
Other financial income and expenses		-2.6	-18.6	1.5	36.7
Net financial items		**-10.5**	**-24.1**	**-29.8**	**17.1**
Earnings before tax		**-14.7**	**-75.6**	**-70.4**	**-196.8**
Tax	5	—	—	—	—
Earnings for the period		**-14.7**	**-75.6**	**-70.4**	**-196.8**

PARENT COMPANY STATEMENT OF COMPREHENSIVE INCOME

SEK m	2023 Oct-Dec	2022 Oct-Dec	2023 Jan-Dec	2022 Jan-Dec
Earnings for the period	**-14.7**	**-75.6**	**-70.4**	**-196.8**
Other comprehensive income	—	**—**	—	**—**
Total comprehensive earnings for the period	**-14.7**	**-75.6**	**-70.4**	**-196.8**

CONDENSED PARENT COMPANY BALANCE SHEET

SEK m	2023 Dec 31	2022 Dec 31
ASSETS		
Fixed assets		
Intangible fixed assets	147.7	181.4
Tangible fixed assets	81.0	76.1
Shares in subsidiaries	286.2	161.2
Total fixed assets	**515.0**	**418.7**
Current assets		
Inventories	25.6	60.2
Accounts receivable and other receivables	52.8	50.1
Receivables from Group companies	71.0	69.2
Short-term investments	–	178.6
Cash and cash equivalents	145.5	61.7
Total current assets	**294.9**	**419.8**
Total assets	**809.8**	**838.6**
SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES		
Total shareholders' equity	**162.1**	**109.2**
Long-term liabilities		
Provisions	10.8	9.8
Bond loan	448.4	494.8
Total long-term liabilities	**459.3**	**504.5**
Current liabilities		
Accounts payable	10.3	32.0
Other liabilities	8.6	8.8
Liabilities to Group companies	144.7	144.7
Accrued expenses and deferred income	24.9	39.3
Total current liabilities	**188.4**	**224.8**
Total liabilities	**647.7**	**729.4**
Total shareholders' equity and liabilities	**809.8**	**838.6**

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 2022 Annual Report. None of the amended standards and interpretations that became effective January 1, 2023 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 Mental Health Programs and HQ & Pipeline. US Pharma segment comprises the distribution and sale of Zubsolv® for treatment of opioid use disorder in the US.

Digital Mental Health Programs segment comprises the distribution and sale of digital mental health programs in the US. This is a complement to existing treatments and provide patients with access to highly sophisticated and individualized support when they need it most.

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	2023 Oct-Dec	2022 Oct-Dec	2023 Jan-Dec	2022 Jan-Dec
US Pharma				
Net revenues	151.3	142.6	577.7	571.4
Operating earnings (EBIT)	75.4	77.0	283.1	308.4
Depreciation and amortization	-3.8	-3.8	-15.6	-15.4
Digital Mental Health Programs				
Net revenues	0.0	0.0	0.1	0.4
Operating earnings (EBIT)	-29.1	-49.0	-130.9	-189.1
Depreciation and amortization	-7.0	-6.8	-28.1	-25.7
HQ & Pipeline				
Net revenues	14.7	13.4	61.1	52.6
Operating earnings (EBIT)	-54.9	-99.1	-261.8	-303.2
Depreciation and amortization	-10.2	-7.4	-33.3	-27.7
Group				
Net revenues	166.0	156.1	638.8	624.3
Operating earnings (EBIT)	-8.6	-71.1	-109.5	-183.9
Depreciation and amortization	-21.0	-18.0	-77.0	-68.7
Net financial items	-10.9	-24.4	-30.8	13.5
Earnings before tax	-19.5	-95.5	-140.3	-170.4

3. Cash flow

ADJUSTMENT FOR NON-CASH ITEMS

SEK m	2023 Oct-Dec	2022 Oct-Dec	2023 Jan-Dec	2022 Jan-Dec
Depreciation/amortization and impairment	21.0	18.0	77.0	68.7
Realization results	0.0	-0.2	0.0	-0.2
Change in provisions	14.2	-27.0	18.2	-64.9
Share based payments	0.0	0.0	0.0	-0.1
Other non cash items	0.0	—	3.1	—
Exchange rate income and expenses	7.9	4.7	1.4	-7.0
Total	**43.0**	**-4.4**	**99.8**	**-3.5**

4. Litigations

US government agency investigation related to Zubsolv® sales

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 will continue to cooperate 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

In 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 with the US Food and Drug Administration seeking approval of generic versions of Zubsolv before the expiration of Orexo's patents.

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 trial was conducted in January 2023, and was followed by closing arguments at the end of the same quarter. On June 30, 2023, (US Time Zone) the District Court for the District of New Jersey ruled in favor of Orexo against Sun. The district court found that Orexo´s patents are valid and infringed by Sun.

On July 24, 2023, Sun appealed the District Court decision to the US Court of Appeals for the Federal Circuit. In Q4 Sun submitted their written arguments and Orexo submitted their responsive written arguments in January 2024. An oral hearing is expected to be held during the year.

Orexo has in total 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.

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 1,576 m as of December 31, 2023 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, cash and cash equivalents, current noninterest 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

- MODIA® and Vorvida® will be reimbursed within the US Veterans Affairs Federal Supply Schedule as of January 1, 2024.

9. Revenue from contracts with customers

SEK m	2023 Oct-Dec					
Segment	**Zubsolv®**	**Abstral®**	**Edluar®**	**Vorvida®**	**Deprexis®**	**Total**
US Pharma	151.3	—	—	—	—	**151.3**
Digital Mental Health Programs	—	—	—	0.0	0.0	**0.0**
HQ & Pipeline	2.8	10.0	1.9	—	—	**14.7**
Total revenue from contracts with customers	**154.1**	**10.0**	**1.9**	**0.0**	**0.0**	**166.0**
Geographical markets	**Zubsolv**	**Abstral**	**Edluar**	**Vorvida**	**Deprexis**	**Total**
US	151.3	—	0.6	0.0	0.0	**151.9**
EU & UK	2.8	9.8	0.6	—	—	**13.1**
Rest of the world	—	0.2	0.8	—	—	**1.0**
Total revenue from contracts with customers	**154.1**	**10.0**	**1.9**	**0.0**	**0.0**	**166.0**

SEK m	2023 Jan-Dec					
Segment	**Zubsolv**	**Abstral**	**Edluar**	**Vorvida**	**Deprexis**	**Total**
US Pharma	577.7	—	—	—	—	577.7
Digital Mental Health Programs	—	—	—	0.0	0.0	0.1
HQ & Pipeline	18.4	31.9	10.8	—	—	61.1
Total revenue from contracts with customers	**596.1**	**31.9**	**10.8**	**0.0**	**0.0**	**638.8**
Geographical markets	**Zubsolv**	**Abstral**	**Edluar**	**Vorvida**	**Deprexis**	**Total**
US	577.7	—	2.2	0.0	0.0	579.9
EU & UK	18.4	31.1	5.4	—	—	55.0
Rest of the world	—	0.8	3.1	—	—	4.0
Total revenue from contracts with customers	**596.1**	**31.9**	**10.8**	**0.0**	**0.0**	**638.8**

SEK m	2022 Oct-Dec					
Segment	**Zubsolv**	**Abstral**	**Edluar**	**Vorvida**	**Deprexis**	**Total**
US Pharma	142.6	—	—	—	—	142.6
Digital Mental Health Programs	—	—	—	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	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	2022 Jan-Dec					
Segment	**Zubsolv**	**Abstral**	**Edluar**	**Vorvida**	**Deprexis**	**Total**
US Pharma	571.4	—	—	—	—	**571.4**
Digital Mental Health Programs	—	—	—	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	**Zubsolv**	**Abstral**	**Edluar**	**Vorvida**	**Deprexis**	**Total**
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**

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 profitabilityfrom sold products
Operating margin (EBITmargin)	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 and amortization	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	2023 Oct-Dec	2022 Oct-Dec	2023 Jan-Dec	2022 Jan-Dec
EBIT	-8.6	-71.1	-109.5	-183.9
Depreciation and amortization	21.0	18.0	77.0	68.7
EBITDA	**12.4**	**-53.1**	**-32.5**	**-115.2**
External costs for clinical studies	1.0	28.4	56.7	96.4
IP litigation and subpoena	10.0	24.6	63.7	76.6
EBITDA excluding external costs for clinical studies. IP litigation and subpoena	**23.4**	**-0.1**	**88.0**	**57.8**

CASH AND INVESTED FUNDS	2023 Oct-Dec	2022 Oct-Dec	2023 Jan-Dec	2022 Jan-Dec
Short-term investments	—	219.6	—	219.6
Cash and cash equivalents	171.0	132.2	171.0	132.2
Cash and invested funds	**171.0**	**351.9**	**171.0**	**351.9**

RETURN ON SHAREHOLDERS' EQUITY	2023 Oct-Dec	2022 Oct-Dec	2023 Jan-Dec	2022 Jan-Dec
Shareholders' equity beginning balance	92.0	298.4	193.9	349.6
Shareholders' equity ending balance	58.9	193.9	58.9	193.9
Average shareholders' equity	75.4	246.1	126.4	271.8
Net earnings	-18.6	-91.8	-128.3	-177.6
Return on shareholders' equity %	**-24.7**	**-37.3**	**-101.5**	**-65.4**

OPERATING EXPENSES SEK m	2023 Oct-Dec	2022 Oct-Dec	2023 Jan-Dec	2022 Jan-Dec
Selling expenses	-43.5	-52.2	-181.5	-199.0
Administrative expenses	-38.0	-63.8	-188.0	-202.3
Research and development costs	-65.4	-88.2	-303.1	-318.0
Other operating income and expenses	-7.6	3.0	13.3	13.7
Operating expenses	**-154.5**	**-201.3**	**-659.5**	**-705.6**

GROSS INVESTMENTS SEK m	2023 Oct-Dec	2022 Oct-Dec	2023 Jan-Dec	2022 Jan-Dec
Investments in tangible fixed assets	0.9	11.0	18.5	18.8
Investments in intangible fixed assets	0.0	1.3	0.7	5.1
Gross investments	**0.9**	**12.3**	**19.2**	**23.9**

Orexo is a Swedish pharmaceutical company with over 25 years of experience developing improved pharmaceuticals based on proprietary formulation technologies that meet large medical needs. On the US market, Orexo provides innovative treatment solutions for patients suffering from opioid use disorder and adjacent diseases. Products targeting other therapeutic areas are developed and commercialized worldwide with leading partners. Total net sales in 2023 amounted to SEK 639 million, and the number of employees to 116. Orexo is listed on Nasdaq Stockholm's main list and is available as an ADR on OTCQX (ORXOY) in the US.

For more information about Orexo please visit, www.orexo.com.
You can also follow Orexo on Linkedin, X and YouTube and also read our blog.

blog.orexo.com

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