orexo

Interim Report Q1 2024

May 8, 2024

Starting 2024 with a positive EBITDA

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

Q1 2024 highlights

- Total net revenues of SEK 139.3 m (158.8)
- EBITDA of SEK 15.9 m (-41.1)
- Net earnings of SEK -8.9 m (-63.9)
- US Commercial segment net revenues of SEK 129.3 m (140.3), in local currency USD 12.4 m (13.5)
- Cash flow from operating activities of SEK -18.9 m (-61.6), cash and invested funds of SEK 198.0 m (278.9)
- Earnings per share before and after dilution amounted to SEK -0.26 (-1.86)
- MODIA® and Vorvida® were reimbursed within the US Veterans Affairs Federal Supply Schedule as of January 1, 2024
- Data from the clinical phase 1 study and stability data for OX640, a nasal epinephrine powder product, were presented at the American Academy of Allergy, Asthma & Immuniology Annual Meeting in Washington DC
- Orexo and Sobi agreed to advance feasibility study where AmorphOX® is tested with one of their biomolecules
- To refinance the existing bond a four year senior secured social bond of SEK 500 million was issued
- The new bond was classified as a social bond after a social financing framework was established, which underwent an independent review by Morningstar Sustainalytics.

Important events after the end of the period

- Second patent in the US granted for OX640.

Group net revenues
139 SEK M

Group EBITDA
16 SEK M

Cash and cash equivalents
198 SEK M

SEK m unless otherwise stated	2024 Jan-Mar	2023 Jan-Mar	2023 Jan-Dec
Net revenues	139.3	158.8	638.8
Cost of goods sold	-13.3	-28.7	-88.9
Operating expenses	-130.7	-189.4	-659.5
EBIT	-4.7	-59.3	-109.5
EBIT margin	-3.4%	-37.4%	-17.1%
EBITDA	15.9	-41.1	-32.5
Earnings per share. before dilution. SEK	-0.26	-1.86	-3.73
Earnings per share. after dilution. SEK	-0.26	-1.86	-3.73
Cash flow from operating activities	-18.9	-61.6	-95.0
Cash and invested funds	198.0	278.9	171.0

Unless otherwise stated in this report, all data refers to the Group, and numbers relate to the current quarter while numbers in parantheses relate to the corresponding period in 2023.

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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.

Commercialised products and products under development

Product	Indication	Technology	Partner	Exploratory	Preclinical	Phase 1	Phase 2	Phase 3	Registration	Approved/Launched US	Approved/Launched EU	Approved/Launched RoW	Expected launch
Commercialised products													
Zubsolv®	opioid use disorder	sublingual platform	accord							2013	2018		
Abstral®	breakthrough cancer pain	sublingual platform	KYOWA KIRIN							2011	2008	2009	
Edluar®	insomnia	sublingual platform	VIATRIS							2009	2012	2011	
MODIA®	opioid use disorder	broca platform	GAIA							2023			
Vorvida®	alcohol management	broca platform	GAIA							2020			
Deprexis®	depression	broca platform	GAIA							2020			
Pipeline products													
OX124	naloxone opioid overdose	AmorphOX											2024/2025
OX125	nalmefene opioid overdose	AmorphOX											
OX640	adrenaline allergic reactions	AmorphOX											
OX-MPI	vipoglanstat, endometriosis		GESYNTA PHARMA AB										

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Presentation

On May. 8, at 1 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=50048736

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-q1-report-2024

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

Financial calendar 2024

Interim Report Q2 2024 - July 17, at 8 am
Interim Report Q3 2024 - October 24, at 8 am
Interim Report Q4 2024, incl. Full Year Report, February 6, 2025, at 8 am

Creating a stable financial platform

CEO Comments in brief

I am pleased to report a significant improvement in our financial results with an EBITDA increasing SEK 57 million and amounted to SEK 16 million (-41). In addition to less non-repeating activities, it is driven by efficiency improvements and cost control. Improving our financial results was a cornerstone of successfully refinancing our corporate bond in the quarter, and we gained strong interest from investors with close to 100 percent oversubscription.

Our R&D projects continue to show progress, although OX124 is likely to require a longer review than the original PDUFA date in July based on recent request for additional documentation. Our ambition remains to launch the product in late 2024 or early 2025.

Successful refinancing of the corporate bond

The financial markets have been very volatile over the last few years, making the timing for refinancing the corporate bond an important consideration for management and the board of directors. In dialog with our financial advisors, we decided to complete the refinancing process in March, despite a less favourable market in terms of higher global interest rates than the last time we refinanced the bond. With long-term financing secured and continuous sizable profit contributions from our US Commercial operations, we are well positioned to continue with our R&D activities and the launch of OX124.

The improvements in EBITDA profitability last year together with strong cost control were both important criteria for new investors. In the light of that I'm pleased to see our operating expenses are continuing to decline, with a reduction of more than 30 percent from last year to SEK 131 million (SEK 110 million excluding depreciation). This level of operating expenses is well below our annualized guidance of SEK 530 million excluding depreciation.

Recognized sustainability work

Thanks to many years of thoughtful sustainability work and a strong ambition to continue improving the lives of people suffering from opioid dependence, we were able to classify the bond as a social bond. This allowed us to reach out to a growing number of investors who are committed to responsible investments. In addition, it's a great endorsement of our sustainability efforts, which underwent a rigorous independent review by Morningstar Sustainalytics.

The market for Zubsolv® showed a continued lower growth

The buprenorphine/naloxone market continues to grow at a low single digit rate, with growth of 3 percent from Q1 2023, which is in line with our guidance of 2–5 percent for the year. Zubsolv prescriptions declined by 4 percent from last year and 2 percent from Q4 2023. However, due to our price increase of 4 percent at the beginning of the year, sales to pharmacies increased compared to last year.

Our net sales, which are based on sales to wholesalers, have declined significantly due to a reduction in their inventories. This has led to a decline in the overall gross and net sales compared to last year and last quarter. This negative inventory adjustment is recurring in Q1 and follows similar patterns from previous years, although the outcome this year was much higher than last year. Orexo has no influence on wholesalers' inventory levels but we expect sales in the coming quarters to be more aligned with the sales to pharmacies.

Our US commercial operations continue to make healthy profit contributions with an EBITDA of SEK 43 million corresponding to a margin of 33 percent. The profit contribution this quarter has been negatively affected by the inventory adjustments at the wholesalers, and we expect profit contributions from Zubsolv® to improve in the next quarters. The overall commercial expenses will increase in the second half of 2024 when we accelerate preparations for the OX124 launch.

OX124 - commercial lead onboard

The FDA audit of OX124, our high-dose rescue medication for opioid overdoses, is making progress and audits of the suppliers have been completed. Based on questions and comments recently received, we need to make some changes related to the device and instructions for use, which will need to be documented and tested. With these changes, approval of OX124 is likely to come later than the communicated PDUFA date in July, this is in line with our previous guidance of a review time of ten to thirteen months, based on experience from similar drug-device combination products in the rescue market. We are still optimistic that we are well positioned for a launch in late 2024 or early 2025, pending FDA review schedule and approval of the product.

In parallel with the FDA review, we are starting to form the commercial team responsible for the launch of OX124. A key success factor of the launch is the recruitment of people with experience from the opioid rescue market. In the light of that we are pleased to have recruited a commercial lead who had a pivotal role in the commercialization of the main branded product in the market before it became OTC late last year. OX124 will have significant synergies with our Zubsolv and MODIA® commercial operations, but large parts of the market are in customer segments not addressed by Orexo today. We will continue to grow the team where we need to bring in colleagues with relevant experience in these customer segments as we approach the launch of OX124.

Expanding R&D pipeline in collaboration with other companies

Upon approval OX124 will be our next commercial product, while we also see significant potential in other applications of our drug delivery platform, AmorphOX®.
A key strategy for AmorphOX is to work with partners where our technology can add value to their molecules. A good example of this is our collaboration with Sobi. In 2023, we successfully tested AmorphOX on one of Sobi's molecules and, after promising initial results, the collaboration will now advance into the next phase. We're going to continue optimizing the formulation, expand the stability studies and review how AmorphOX can enable alternative drug delivery methods to the molecule. In addition to Sobi, we are exploring new application possibilities of the AmorphOX technology and this quarter we've agreed to test the technology on additional vaccines in collaboration with a vaccine company.

We're also continuing the development of OX640, our adrenaline product with nasal administration, and have received positive feedback from the FDA on our briefing book and proposed development plan. This feedback is instrumental in shaping the discussions we're having with potential partners as it's given us the clarity we needed to keep moving forwards. This, together with the new patent for OX640 granted in April and which extends its exclusivity in the US until November 2042, elevates the attractiveness of OX640 to potential partners. OX640 was also presented at the American Academy of Allergy, Asthma & Immunology conference, and the product's stability was of particular interest to clinicians, who provided very positive feedback about the opportunities this provides to patients and healthcare professionals.

Summary and outlook

It's been a decent first quarter in which we've continued strengthening our financial position through EBITDA profitability and successfully refinancing the corporate bond. We've also made progress with our R&D activities. Zubsolv® sales to pharmacies have been in-line with our expectations, but sales to wholesalers have been lower due to their inventory adjustments. We expect demand and sales to pharmacies to continue on the current trajectory which is also expected to improve sales and profit contribution from Zubsolv in the next quarters. Maintaining and improving EBITDA profitability is a top priority for 2024 to ensure we have the financial strength to launch OX124 in the US and continue developing projects based on the AmorphOX drug delivery technology.

Looking ahead, the main value drivers for Orexo are FDA approval of OX124 and progress in partnering with projects based on the AmorphOX drug delivery technology, such as with OX640. Advancing the collaboration with Sobi was an important milestone, but attracting new companies to test their molecules with AmorphOX is also critical to enable us to expand the potential of the platform. We continue to expect approval of OX124 in the second half of 2024 and are optimistic that we will both advance existing partnerships and start new collaborations around AmorphOX during 2024.

Uppsala, Sweden, May 8, 2024

Nikolaj Sørensen
President and CEO

US Commercial

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 medication-assisted treatment (MAT).[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 predicted number exceeded 83,000 annually.[4] Nine out of ten opioid overdoses involve synthetic opioids.[5]

In Q1, the buprenorphine/naloxone market grew 1 percent versus Q4 2023 and grew 3 percent versus Q1 2023. Expectations are that the buprenorphine/naloxone market growth will be positively impacted 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 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 declined 2 percent in Q1 2024 versus Q4 2023 and declined 4 percent versus Q1 2023, mainly due to lower volume with United Health Group and Humana where Zubsolv previously has been exclusive.
Compared to Q4 2023, Zubsolv remained flat in the open commercial segment while showing a decline year over year. The development in Q1 2024 followed a similar pattern from previous years where the demand is negatively impacted due to reset of the annual deductibles in the health insurances and the patients have to cover the majority of the expenses.

Thanks to improved market access in Medicaid, Zubsolv Medicaid volume only declined 2 percent in Q1 versus Q4 2023, while the market declined 3 percent. Zubsolv remained flat year over year in Medicaid, supported by the most recently improved market access e.g., Medicaid in Kentucky growing 10 percent, in New York growing 16 percent, and in Indiana growing 244 percent after gaining broader access in July 2023. Year over year the Medicaid market showed a decline of 8 percent.

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 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]

modia deprexis VORV!DA

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]

Developments during the quarter

The lack of efficient reimbursement and distribution channels has held back Orexo's and other players' ability to commercialize digital mental health programs. Progress is being made at a federal level in the US to establish a national reimbursement system for digital health products and therapies, which is expected to have a long-term positive impact on the new product category. An efficient reimbursement and distribution system is crucial for Orexo to reach its full potential with the digital programs, and the company is actively working with authorities, insurance companies and other stakeholders to accelerate the built up of an efficient system that benefits patients and healthcare providers.

Orexo's multi-year agreement with Veterans Affairs (VA) was expanded as of January 1, 2024, from only including Deprexis® to also include MODIA® and Vorvida. In the short and mid-term, the commercialization efforts are within VA, where reimbursement and distribution pathways are in place and mental health problems are extensive. For the VA, Orexo is partnering with Lovell Government Services, which has extensive experience from marketing and selling medical devices within the VA network.

While waiting for a national reimbursement system to be in place, Orexo has launched extensive savings programs, which have reduced direct costs after depreciation within the Digital Mental Health Program unit (DMHP) . The lower costs are, among other things, an effect of DMHP, late in 2022, became part of the US Pharma unit, now US Commercial. As of January 1, 2024, revenues and costs for the digital health programs are also reported in the US Commercial segment.

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.

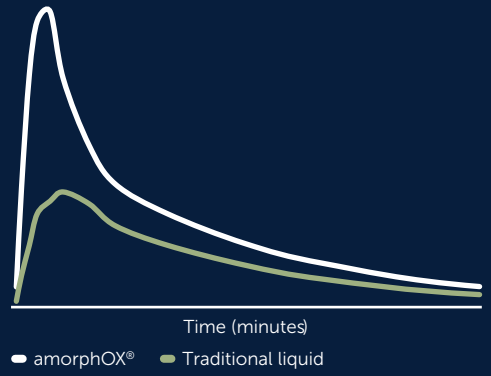
Clinically validated

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.

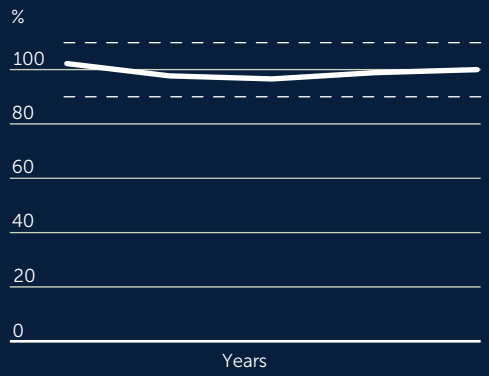
Wide applicability

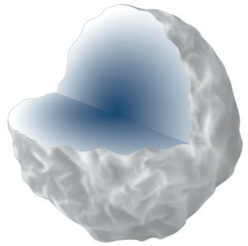
The technology works with a broad spectrum of active chemical substances, including small and large molecules,[8] and the properties of the powder can be tailored to meet specific needs such as particle size, dissolution, and mucosal retention. This makes it a versatile technology with broad applicability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

Plasma concentration



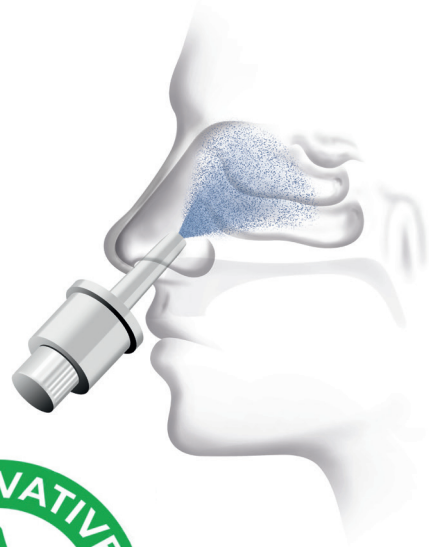
Amount of API





Successful clinical trials

Well tolerated
Higher exposure
Faster onset
Lower variability



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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 fentanyl.

Orexo submitted an NDA with the FDA on September 18, 2023, and in Q4, the agency announced that the application was accepted for review. As the standard review time is ten months, the Prescription Drug User Fee Act date, PDUFA date, was set to July 15, 2024. The latest review processes in this product category have taken longer time due to the complexity of a combination product with pharmaceutical and device. The review time for OX124 is expected to take more than ten months.

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 improved stability of the active substance and reduces its sensitivity related to temperature changes. For users and lay-people, OX124 has the potential to become an efficient and reliable rescue medication also when the overdose is caused by synthetic opioids. OX124 is protected by patents extending until 2039.

Developments during the quarter
The FDA review of the application is making progress with audits at the manufacturing sites successfully completed and questions received have been responded. However, the drug device combination is complex and recent review processes in the category indicate a risk of some delay. After the end of the quarter comments were received by the agency around the use of the product which means changes need to be made in the instructions for use and on the device to reduce the risk of failed delivery of the medication. These changes have to be tested and documented for the FDA and will lead to a delay in the communicated PDUFA date of July 15. However, the delay is expected to be in line with our previous guidance of a review time of ten to thirteen months and we continue to aim for a commercial launch in late 2024 or early 2025, subject to FDA approval.

In April, a commercial lead was recruited to be responsible for the commercialization of OX124. Our new colleague has previously played an essential role in the launch of the leading low-dose rescue medication on the market, and she has extensive knowledge of people at risk of having an overdose. Having Lisa onboard means that the work with setting the commercialization strategy will accelerate, and with a focus on taking advantage of the latest developments in the naloxone market, which, among other things, include identifying areas with the most significant growth potential and ensuring maximizing the synergies with Zubsolv® and MODIA®.

Market and commercialization

Upon approval, Orexo will meet an increased need of a powerful overdose rescue medication, where most overdoses today are caused by misuse of synthetic opioids, such as fentanyl. During the latest twelve months period, ending November 2023, the predicted annual number of fatal opioid overdoses in the US counted for more than 83,000.[9] Nine out of ten opioid overdoses involve synthetic opioids.[10]

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.

If the FDA approves OX124 according to plan, see above, Orexo will initiate the launch in late 2024 focusing on securing reimbursement by insurance companies ahead of a broader launch at the pharmacies 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 states with a high prevalence of people with opioid dependence. This coverage includes twelve of the seventeen states with mandatory co-prescription of naloxone when prescribing opioids to patients with severe pain. A large part of the market for OX124 is outside the existing customer segments of Orexo and to further enhance the competence and the presence among institutional clients, which not seldom are reached through centralized procurements, the existing account management team will be expanded with some new positions during late 2024 and early 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 potential future ramp-up of the project continued 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 European markets and in the US, where the patent protection was further strengthened in April when the United States Patent and Trademark Office granted yet another patent. Furthermore, multiple patent applications have been filed protecting OX640 on a global basis until 2044.

Developments during the quarter

After a constructive dialogue with the FDA, the remaining pivotal clinical development program for OX640 was established. The importance of clarifying the continued development route for OX640 follows from the agency's unexpected feedback to a competing liquid nasal epinephrine product, where that company was required to show data from an additional clinical study. Establishment of the remaining clinical development program is critical in partner discussions for OX640.

In February, Orexo presented OX640 at the American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting in Washington DC. The AAAAI program committee selected OX640 to be presented as an oral presentation, which was held by Orexo's advisor, Dr Anne K Ellis, Professor and Chair of the Division of Allergy & Immunology in the Department of Medicine at Queen's University (Kingston, Ontario, CA). Dr Ellis's presentation included data from the clinical phase 1 study and stability data from ongoing studies. The stability data for OX640 continues to be superior to competitors' data. In addition to the oral presentation, Orexo's SVP and Head of R&D, Robert Rönn, presented a poster with in-depth data for OX640.

Early stage projects

Orexo has tested enzymes, peptides, and proteins with the drug delivery technology AmorphOX® and seen retained activity and significant improvement in stability compared to other formulations in a wide range of storage temperatures. A core strategy to expand the use of the technology is to test AmorphOX in combination with molecules controlled by other companies. Multiple exploratory feasibility studies are ongoing in collaboration with several pharmaceutical companies. During the quarter, Orexo announced it had agreed with one of these companies, Sobi, to advance the feasibility study as data showed that their biomolecule retained activity after formulation with AmorphOX. The continued collaboration will evaluate if the AmorphOX technology could add unique properties to the product. In addition, a new collaboration was initiated with a vaccine company to test one of their vaccine candidates with the AmorphOX technology.

Orexo aims to continue to seek partnerships with pharmaceutical and biotech companies to leverage the unique properties of AmorphOX to improve the formulation of their products. In parallel the ambition is to 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 among patients with OUD and mental illness and develop new innovative medications meeting large unmet needs.

3. Sustainable employees

To create a healthy working climate, an inclusive and diverse culture in all teams.

4. Environment and climate change

Reduce 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 2023 Sustainability Report.

91%

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

Developments during the quarter

Ahead of the refinancing of the previous bond and in consultation with the transaction advisors, Carnegie Investment Bank and ABG Sundal Collier, a social financing framework was established. To get it approved, a review was conducted by Morningsstar Sustainalytics which included an analysis of how the proceeds from the issue of a new bond further could contribute to delivering on SDG 3, and more specifically targets 3.5 and 3.8[11]. In addition, a review of the sustainability work was carried out with a focus on overall strategy, governance and risk management.

Mapping of Scope 3 climate impact was completed in accordance with the GHG Protocol, and the summary for both 2022 and 2023 is reported in the 2023 Annual and Sustainability Report. With 2022 as the base year, Scope 1 and 2 emissions decreased by 3 percent in 2023, driven by lower emissions from sales travel by the sales force. The reduction in total greenhouse gas emissions was 10 percent, with capital goods having the largest impact, but travel and transportation also contributed.

The work to evaluate the sustainability work in the supply chain continued and a decision was made to use EcoVadis to evaluate a selection of suppliers in 2024.

Orexo's management evaluated the sustainability work for the past year and decided on goals and activities to be prioritized in 2024.

Financial development

Revenues

Total revenues amounted to SEK 139.3 m (158.8) for Q1. The decrease is mainly explained by lower US Commercial revenues, lower HQ & Pipeline partner product related revenues and by a weaker USD exchange rate for the period.

Revenues by segment

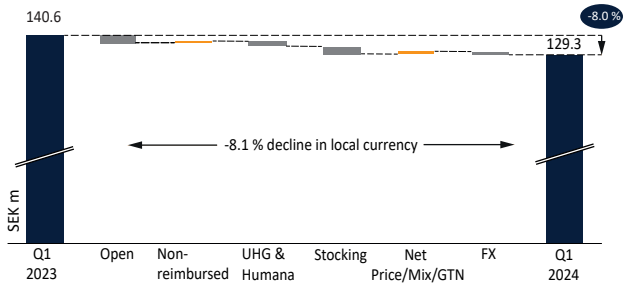
US Commercial revenues amounted to SEK 129.3 m (140.3) for Q1. The decrease is mainly driven by Zubsolv® US product sales especially due to higher wholesaler destocking but also lower demand and a negative impact of SEK 0.8 m from a weaker USD exchange rate partly offset by favorable payer mix. Zubsolv 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. In local currency US Commercial net revenues for Q1 amounted to USD 12.4 m (13.5). Digital Mental Health Programs (DMHP) recognized product sales for Q1 amounted to SEK 0.0 m (0.0).

HQ & Pipeline partner product related revenues for Q1 amounted to SEK 10.0 m (18.5). The decrease is mainly explained by lower Zubsolv ex-US revenues related to sales of tablets to Orexo's partner Accord Healthcare.

Cost of goods sold

Cost of goods sold (COGS) amounted to SEK 13.3 m (28.7) for Q1. US Commercial amounted to SEK 12.7 m (14.4), the decrease is mainly due to favorable production costs for Zubsolv US and lower royalty and technical infrastructure costs for DMHP. HQ & Pipeline amounted to SEK 0.5 m (14.3) the decrease is due to no sale of Zubsolv ex-US tablets to Orexo's partner Accord Healthcare.

ZUBSOLV US NET REVENUES DEVELOPMENT



NET REVENUES AND OPERATING EARNINGS PER SEGMENT

SEK m	Net Revenues			EBIT		
	2024 Jan-Mar	2023 Jan-Mar	2023 Jan-Dec	2024 Jan-Mar	2023 Jan-Mar	2023 Jan-Dec
Zubsolv US product sales	129.3	140.3	577.7	–	–	–
Digital Mental Health Programs (DMHP) product sales	–	0.0	0.1	–	–	–
US Commercial – total	**129.3**	**140.3**	**577.7**	**31.9**	**37.9**	**152.3**
Abstral® royalty	7.1	6.2	31.9	–	–	–
Edluar® royalty	2.7	1.3	10.8	–	–	–
Zubsolv – ex-US	0.2	10.9	18.4	–	–	–
HQ & Pipeline – total	**10.0**	**18.5**	**61.1**	**-36.6**	**-97.2**	**-261.8**
Total	**139.3**	**158.8**	**638.8**	**-4.7**	**-59.3**	**-109.5**

Operating expenses

Selling expenses amounted to SEK 43.5 m (45.5) for Q1. The decrease over the same period last year is mainly explained by lower selling expenses in US Commercial.

Administrative expenses amounted to SEK 34.9 m (66.5) for Q1. The decrease is mainly explained by significantly lower legal expenses for IP litigation in HQ & Pipeline.

Research and development costs amounted to SEK 56.6 m (78.5) for Q1. The decrease is mainly explained by the finalized MODIA® study in Q3 2023 and lower costs for OX124.

Other operating income and expenses amounted to SEK 4.3 m (1.1) for Q1. This is mainly explained by higher exchange-rate gains of SEK 3.5 m (1.0) derived from revaluations of parent company balance sheet items in foreign currency, predominantly in USD, higher received insurance reimbursement of SEK 0.4 m (-0.1) and higher rental income from subleased office space of SEK 0.3 m (0.0) partly offset by lower MATCore[12] related startup revenues of SEK 0.0 m (0.2).

Operating profit

EBITDA amounted to SEK 15.9 m (-41.1) for Q1.

The EBITDA contribution from US Commercial amounted to SEK 42.6 m (48.5) for Q1.

Total EBIT amounted to SEK -4.7 m (-59.3) for Q1 mainly explained by lower operating expenses partly offset by lower gross profit.

EBIT contribution from US Commercial amounted to SEK 31.9 m (37.9) for Q1, equal to an EBIT margin of 24.6 percent (27.0).

Net financial items and tax

Net financial items for Q1 amounted to SEK -5.0 m (-9.1) and is mainly explained by higher positive unrealized exchange rate impact of SEK +2.1 m (-1.5) derived from the parent company's foreign currency bank accounts mainly in USD and lower costs of SEK -7.7 m (-8.5) for the corporate bond loan. This was partly offset by lower interest income from bank accounts of SEK 0.9 m (1.4) explained by absence of short-term investments.

Total tax expenses amounted to SEK 0.9 m (4.6) for Q1. The decrease is mainly explained by lower positive adjustment to deferred tax assets related to temporary differences. Orexo performs regular assessments of its deferred tax asset and makes adjustments according to the recognition requirements of IAS 12.

Net earnings

Net earnings amounted to SEK -8.9 m (-63.9) for Q1.

Cash and cash flow

Cash flow from operating activities amounted to SEK -18.9 m (-61.6) for Q1 and was primarily impacted by negative changes in working capital. In the quarter Orexo issued senior secured callable floating rate social bonds of SEK 500 m at 3m STIBOR + 650 basis points per annum and announced results of the tender offer for its existing bonds. The first part of the transaction was recognized in Q1 and had a negative impact on receivables due to prepayment of own purchase of the new bond loan of SEK -25.0 m (0.0) while financial activities were impacted positively by sale of old Orexo owned bonds of SEK 48.8 m (0.0). The transaction of the new bond loan was completed and fully recognized in April.

As of March 31, 2024, cash and cash equivalents amounted to SEK 198.0 m (142.4) and short-term investments amounted to SEK 0.0 m (136.5). Cash and invested funds in total amounted to SEK 198.0 m (278.9) and interest-bearing liabilities to SEK 497.8 m (489.1), i.e. a negative net cash position including short-term investments of SEK -299.8 m (-210.2). Cash and cash equivalents were increased by SEK 27.0 m from Q4 2023.

Investments

Gross investments in tangible and intangible fixed assets amounted to SEK 1.2 m (0.8) for Q1, higher investments are mainly explained by investments in equipment for the development organization.

Equity

Shareholders' equity on March 31, 2024, was SEK 61.4 m (129.1). The equity/asset ratio was 7.4 percent (13.6).

Parent company

Net revenues for Q1 amounted to SEK 100.5 m (135.2) of which SEK 90.5 m (116.7) was related to sales to Group companies.

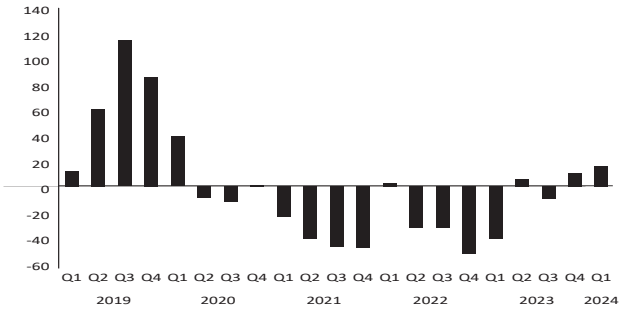
Earnings before tax amounted to SEK -2.4 m (-40.6) for Q1. The development is mainly explained by lower operating expenses and lower negative net financial items partly offset by lower gross profit.

Investments in equipment for the development organization for Q1 amounted to SEK 1.2 m (0.1).

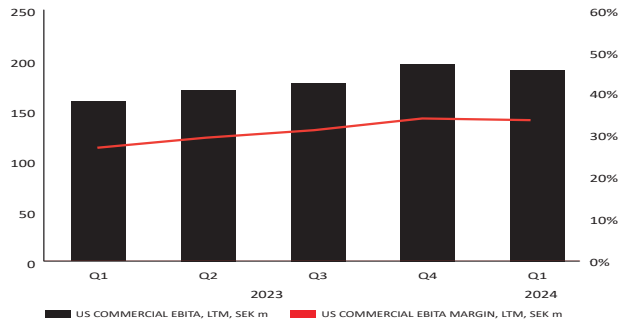
As of March 31, 2024, cash and cash equivalents in the parent company amounted to SEK 163.1 m (68.4) and short-term investments amounted to SEK 0.0 m (116.0) i.e. parent company's cash and invested funds amounted to SEK 163.1 m (184.4).

Parent company shareholders' equity on March 31, 2024, was SEK 159.7 m (68.6). The increase over the same period last year is mainly explained by a write-up of SEK 123.4 m (0.0) of the value of the holding of Orexo US Inc. in Orexo AB to the subsidiary's current net asset value in Q4 2023. This was partly offset by negative earnings of SEK -2.4 (-40.6) in Q1.

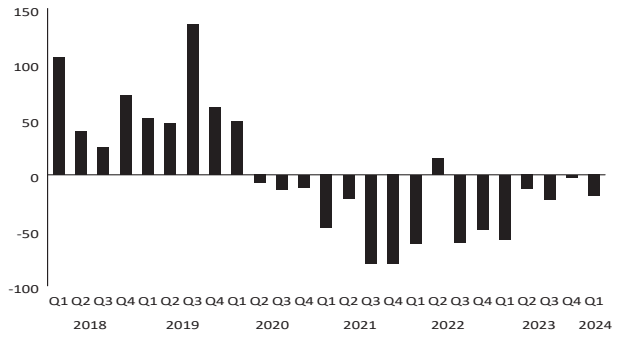
GROUP EBITDA, SEK m



US COMMERCIAL EBITDA MARGIN AND EBITDA (LTM[13], SEK m)



CASH FLOW FROM OPERATING ACTIVITIES, SEK m



Other information

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 and Sustainability Report for 2023 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.

Glossary

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

Uppsala, Sweden, May 8, 2024

Nikolaj Sørensen
President and CEO

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

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 10, Center of Disease Control and Prevention

10 Page 10, Center of Disease Control and Prevention

11 Page 12, SDG 3.8: 3.8 Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all

12 Page 13, MATCore is a product concept where Orexo´s total offering within OUD is collected

13 Page 14, Last Twelve Months

Financial reports, notes and key figures

CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS

SEK m	Notes	2024 Jan-Mar	2023 Jan-Mar	2023 Jan-Dec
Net revenues	9	139.3	158.8	638.8
Cost of goods sold		-13.3	-28.7	-88.9
Gross profit		**126.0**	**130.1**	**550.0**
Selling expenses		-43.5	-45.5	-181.5
Administrative expenses		-34.9	-66.5	-188.0
Research and development expenses		-56.6	-78.5	-303.1
Other operating income and expenses		4.3	1.1	13.3
Operating earnings (EBIT)		**-4.7**	**-59.3**	**-109.5**
Net financial items		-5.0	-9.1	-30.8
Earnings before tax		**-9.8**	**-68.5**	**-140.3**
Tax	5	0.9	4.6	12.0
Net earnings for the period		**-8.9**	**-63.9**	**-128.3**
Earnings per share, before dilution, SEK		-0.26	-1.86	-3.73
Earnings per share, after dilution, SEK		-0.26	-1.86	-3.73

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

SEK m	2024 Jan-Mar	2023 Jan-Mar	2023 Jan-Dec
Earnings for the period	**-8.9**	**-63.9**	**-128.3**
Other comprehensive income	**—**	**—**	**—**
Items that may subsequently be reversed to the statement of operations:			
Exchange-rate differences	11.4	-0.9	-6.8
Other comprehensive earnings for the period. net after tax	**11.4**	**-0.9**	**-6.8**
Total comprehensive earnings for the period [1]	**2.5**	**-64.8**	**-135.1**

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

CONDENSED CONSOLIDATED BALANCE SHEET

SEK m	Notes	2024 Mar 31	2023 Mar 31	2023 Dec 31
ASSETS				
Fixed assets				
Tangible fixed assets		76.1	73.3	81.0
Intangible fixed assets		165.3	207.2	173.3
Right-of-use assets		23.8	38.9	24.5
Deferred tax assets	5	50.9	39.6	48.1
Other financial assets		0.8	0.9	0.8
Total fixed assets		**316.9**	**360.0**	**327.7**
Current assets				
Inventories		71.7	64.7	42.4
Accounts receivable and other receivables		243.3	245.7	245.5
Short-term investments		—	136.5	—
Cash and cash equivalents		198.0	142.4	171.0
Total current assets		**513.0**	**589.3**	**458.9**
Total assets		**829.9**	**949.3**	**786.6**
SHAREHOLDERS' EQUITY AND LIABILITIES				
Total shareholders' equity		**61.4**	**129.1**	**58.9**
Long-term liabilities				
Provisions		13.4	6.1	11.5
Long-term liabilities. interest bearing		—	489.1	448.4
Lease liabilities. long-term		5.9	19.1	4.5
Total long-term liabilities		**19.3**	**514.4**	**464.5**
Current liabilities and provisions				
Provisions		140.9	127.4	133.1
Current liabilities. interest bearing		497.8	—	—
Current liabilities. non-interest bearing		92.2	156.2	109.2
Lease liabilities. current		18.3	22.2	20.9
Total current liabilities and provisions		**749.2**	**305.7**	**263.2**
Total liabilities		**768.5**	**820.1**	**727.7**
Total shareholders' equity and liabilities		**829.9**	**949.3**	**786.6**

CONDENSED CONSOLIDATED CHANGES IN SHAREHOLDERS' EQUITY

SEK m	2024 Mar 31	2023 Mar 31	2023 Dec 31
Opening balance. shareholders' equity	**58.9**	**193.9**	**193.9**
Total comprehensive earnings for the period	2.5	-64.7	-135.1
Share-based payments	—	0.0	—
Closing balance. shareholders' equity	**61.4**	**129.1**	**58.9**

CONDENSED CONSOLIDATED CASH FLOW STATEMENTS

SEK m	Notes	2024 Jan-Mar	2023 Jan-Mar	2023 Jan-Dec
Operating earnings (EBIT)		-4.7	-59.3	-109.5
Interest received		1.8	0.4	7.7
Interest paid		-10.3	-7.7	-37.6
Income taxes paid		-0.5	-1.1	-1.6
Adjustment for non-cash items	3	18.1	19.6	99.8
Cash flow from operating activities before changes in working capital		**4.3**	**-48.2**	**-41.2**
Changes in working capital		**-23.3**	**-13.4**	**-53.8**
Cash flow from operating activities		**-18.9**	**-61.6**	**-95.0**
Acquisition of tangible and intangible fixed assets		-1.2	-0.8	-19.2
Acquisition of short-term investments		—	—	0.1
Disposal of short-term investments		—	83.9	219.9
Cash flow from investing activities		**-1.2**	**83.1**	**200.8**
Amortization of Lease liability		-5.5	-7.8	-21.4
Change of repurchased part in bond		48.8	—	-48.7
Cash from financing activities		**43.3**	**-7.8**	**-70.1**
Cash flow for the period		**23.2**	**13.8**	**35.7**
Cash and cash equivalents at the beginning of the period		**171.0**	**132.2**	**132.2**
Exchange-rate differences in cash and cash equivalents		3.8	-3.6	3.1
Changes in cash and cash equivalents		27.0	10.2	38.8
Cash and cash equivalents at the end of the period		**198.0**	**142.4**	**171.0**

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.

	2024 Jan-Mar	2023 Jan-Mar	2023 Jan-Dec
EBIT margin, %	-3.4	-37.3	-17.1
Return on shareholder equity, %	-14.8	-39.5	-101.5
Net debt, SEK m	-299.8	210.2	277.4
Debt/equity ratio, %	810.7	378.9	761.3
Equity/assets ratio, %	7.4	13.6	7.5
Number of shares, before dilution	34,449,595	34,367,616	34,413,408
Number of shares, after dilution	34,449,595	34,367,616	34,413,408
Earnings per share, before dilution, SEK	-0.26	-1.86	-3.73
Earnings per share, after dilution, SEK	-0.26	-1.86	-3.73
Number of employees at the end of the period	113	122	116
Shareholders' equity, SEK m	61.4	129.1	58.9
Capital employed, SEK m	559.2	618.3	507.3
Working capital, SEK m	63.6	141.2	24.7

[2] Definitions and reconcilliations of key figures are presented on page 26 of this report

CONDENSED PARENT COMPANY STATEMENT OF OPERATIONS

SEK m	Notes	2024 Jan-Mar	2023 Jan-Mar	2023 Jan-Dec
Net revenues		100.5	135.2	494.0
Cost of goods sold		-17.9	-33.8	-93.7
Gross profit		**82.6**	**101.4**	**400.3**
Selling expenses		-25.4	-30.4	-119.4
Administrative expenses		-15.1	-46.5	-94.9
Research and development costs		-43.4	-61.9	-243.7
Other operating income and expenses		3.7	5.8	17.1
Operating earnings (EBIT)		**2.3**	**-31.6**	**-40.6**
Interest income and expenses		-6.5	-7.0	-31.3
Other financial income and expenses		1.8	-2.0	1.5
Net financial items		**-4.7**	**-9.0**	**-29.8**
Earnings before tax		**-2.4**	**-40.6**	**-70.4**
Tax	5	—	—	—
Earnings for the period		**-2.4**	**-40.6**	**-70.4**

PARENT COMPANY STATEMENT OF COMPREHENSIVE INCOME

SEK m	2024 Jan-Mar	2023 Jan-Mar	2023 Jan-Dec
Earnings for the period	**-2.4**	**-40.6**	**-70.4**
Other comprehensive income	—	—	—
Total comprehensive earnings for the period	**-2.4**	**-40.6**	**-70.4**

CONDENSED PARENT COMPANY BALANCE SHEET

SEK m	2024 Mar 31	2023 Mar 31	2023 Dec 31
ASSETS			
Fixed assets			
Intangible fixed assets	140.7	173.1	147.7
Tangible fixed assets	76.1	73.3	81.0
Shares in subsidiaries	286.8	160.6	286.2
Total fixed assets	**503.6**	**407.0**	**515.0**
Current assets			
Inventories	37.5	45.0	25.6
Accounts receivable and other receivables	67.0	50.9	52.8
Receivables from Group companies	82.0	87.3	71.0
Short-term investments	—	116.0	—
Cash and cash equivalents	163.1	68.4	145.5
Total current assets	**349.6**	**367.6**	**294.9**
Total assets	**853.3**	**774.6**	**809.8**
SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES			
Total shareholders' equity	**159.7**	**68.6**	**162.1**
Long-term liabilities			
Provisions	12.5	5.8	10.8
Bond loan	—	489.1	448.4
Total long-term liabilities	**12.5**	**494.9**	**459.3**
Current liabilities			
Accounts payable	11.4	26.8	10.3
Bond loan	497.8	—	—
Other liabilities	7.7	11.5	8.6
Liabilities to Group companies	144.9	144.7	144.7
Accrued expenses and deferred income	19.3	28.1	24.9
Total current liabilities	**681.1**	**211.1**	**188.4**
Total liabilities	**693.6**	**706.0**	**647.7**
Total shareholders' equity and liabilities	**853.3**	**774.6**	**809.8**

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 2023 Annual Report. None of the amended standards and interpretations that became effective January 1, 2024 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 Commercial and HQ & Pipeline. US Commercial segment comprises the distribution and sale of Zubsolv® for treatment of opioid use disorder and 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	2024 Jan-Mar	2023 Jan-Mar	2023 Jan-Dec
US Commercial			
Net revenues	129.3	140.3	577.7
Operating earnings (EBIT)	31.9	37.9	152.3
Depreciation and amortization	-10.8	-10.6	-43.7
EBITDA	42.6	48.5	196.0
HQ & Pipeline			
Net revenues	10.0	18.5	61.1
Operating earnings (EBIT)	-36.6	-97.2	-261.8
Depreciation and amortization	-9.9	-7.6	-33.3
EBITDA	-26.7	-89.6	-228.4
Group			
Net revenues	139.3	158.8	638.8
Operating earnings (EBIT)	-4.7	-59.3	-109.5
Depreciation and amortization	-20.6	-18.2	-77.0
EBITDA	15.9	-41.1	-32.5
Net financial items	-5.0	-9.1	-30.8
Earnings before tax	-9.8	-68.5	-140.3

3. Cash flow

ADJUSTMENT FOR NON-CASH ITEMS

SEK m	2024 Jan-Mar	2023 Jan-Mar	2023 Jan-Dec
Depreciation/amortization and impairment	20.6	18.2	77.0
Realization results	—	—	0.0
Change in provisions	1.0	2.4	18.2
Share based payments	—	0.0	0.0
Other non cash items	0.0	—	3.1
Exchange rate income and expenses	-3.5	-1.0	1.4
Total	**18.1**	**19.6**	**99.8**

4. Litigations

Subpoena issued by the US authorities

On July 14, 2020, Orexo became aware of an investigation by the US authorities and the investigation is ongoing. Based on communications from the US authorities, the company believes the investigation concerns principally certain historic marketing messaging campaigns and whether they were compliant with law. Other areas of interest to the government are Orexo's selection of healthcare providers to market, as well as Orexo's voucher and copay programs. Orexo's position to the government has been that its investigation concerns have no merit, but Orexo is also seeking to negotiate a settlement of the matter. Orexo as of this date is not aware of any filed civil or criminal case related to the investigation.

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, 2023, 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 for Zubsolv (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 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 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 end of the period

- Second patent in the US granted for OX640, a nasal epinephrine powder product.

9. Revenue from contracts with customers

	2024 Jan–Mar						
SEK m	Zubsolv®	Abstral®	Edluar®	Vorvida®	Deprexis®	MODIA®	Total
Segment							
US Commercial	129.3	–	–	–	–	–	**129.3**
HQ & Pipeline	0.2	7.1	2.7	–	–	–	**10.0**
Total revenue from contracts with customers	**129.4**	**7.1**	**2.7**	**0.0**	**0.0**	**0.0**	**139.3**
Geographical markets							
US	129.3	–	0.2	–	–	–	**129.5**
EU & UK	0.2	6.9	2.3	–	–	–	**9.4**
Rest of the world	–	0.2	0.2	–	–	–	**0.4**
Total revenue from contracts with customers	**129.4**	**7.1**	**2.7**	**0.0**	**0.0**	**0.0**	**139.3**

	2023 Jan–Mar						
SEK m	Zubsolv	Abstral	Edluar	Vorvida	Deprexis	MODIA	Total
Segment							
US Commercial	140.3	–	–	0.0	0.0	–	140.3
HQ & Pipeline	10.9	6.2	1.3	–	–	–	18.5
Total revenue from contracts with customers	**151.2**	**6.2**	**1.3**	**0.0**	**0.0**	**0.0**	**158.8**
Geographical markets							
US	140.3	–	0.7	0.0	0.0	–	141.0
EU & UK	10.9	6.1	0.1	–	–	–	17.2
Rest of the world	–	0.1	0.5	–	–	–	0.7
Total revenue from contracts with customers	**151.2**	**6.2**	**1.3**	**0.0**	**0.0**	**0.0**	**158.8**

	2023 Jan–Dec						
SEK m	Zubsolv	Abstral	Edluar	Vorvida	Deprexis	MODIA	Total
Segment							
US Commercial	577.7	–	–	0.0	0.0	–	577.7
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**	**0.0**	**638.8**
Geographical markets							
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**	**0.0**	**638.8**

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	2024 Jan-Mar	2023 Jan-Mar	2023 Jan-Dec
EBIT	-4.7	-59.3	-109.5
Depreciation and amortization	20.6	18.2	77.0
EBITDA	**15.9**	**-41.1**	**-32.5**

OPERATING EXPENSES SEK m	2024 Jan-Mar	2023 Jan-Mar	2023 Jan-Dec
Selling expenses	-43.5	-45.5	-181.5
Administrative expenses	-34.9	-66.5	-188.0
Research and development costs	-56.6	-78.5	-303.1
Other operating income and expenses	4.3	1.1	13.3
Operating expenses	**-130.7**	**-189.4**	**-659.5**

CASH AND INVESTED FUNDS	2024 Jan-Mar	2023 Jan-Mar	2023 Jan-Dec
Short-term investments	—	136.5	—
Cash and cash equivalents	198.0	142.4	171.0
Cash and invested funds	**198.0**	**278.9**	**171.0**

GROSS INVESTMENTS SEK m	2024 Jan-Mar	2023 Jan-Mar	2023 Jan-Dec
Investments in tangible fixed assets	—	0.1	18.5
Investments in intangible fixed assets	1.2	0.7	0.7
Gross investments	**1.2**	**0.8**	**19.2**

RETURN ON SHAREHOLDERS' EQUITY	2024 Jan-Mar	2023 Jan-Mar	2023 Jan-Dec
Shareholders' equity beginning balance	58.9	193.9	193.9
Shareholders' equity ending balance	61.4	129.1	58.9
Average shareholders' equity	60.2	161.5	126.4
Net earnings	-8.9	-63.8	-128.3
Return on shareholders' equity %	**-14.8**	**-39.5**	**-101.5**

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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