orexo

Interim Report Q2 2024

July 17, 2024

Making progress, while the OX124 review time extended

WE SUPPORT UN GLOBAL COMPACT

GOLD | Top 5% ecovadis Sustainability Rating JUN 2024

Orexo is committed to the UN Global Compact corporate responsibility initiative and its principles in the areas of human rights, labor, environment and anti-corruption. Please read more on unglobalcompact.org

Q2 2024 highlights

- Total net revenues of SEK 154.0 m (157.7)
- EBITDA of SEK 5.0 m (5.6)
- Net earnings of SEK -35.9 m (-12.6)
- US Commercial segment net revenues of SEK 147.9 m (145.4), in local currency USD 13.9 m (13.8)
- Cash flow from operating activities of SEK -6.5 m (-12.7), cash and cash equivalents of SEK 139.7 m (251.1)
- Earnings per share before and after dilution amounted to SEK -1.04 (-0.37)
- Second patent in the US granted for OX640, a nasal epinephrine powder product
- The financial guidance for 2024 reiterated

Important events after the end of the period

- Orexo AB´s sustainability work ranked among the top five percent of all 70,000 businesses worldwide reviewed by EcoVadis
- For OX124, a high dose naloxone rescue medication for opioid overdose, a complete response letter was received from the FDA, requesting additional technical data on the final commercial product and additional data from a new human factor (HF) study. A new HF study was successfully conducted in early July.

Group net revenues

154 SEK M

Group EBITDA

5 SEK M

Cash and cash equivalents

140 SEK M

SDG 3.5 net revenue ratio

96%

SEK m unless otherwise stated	2024 Apr-Jun	2023 Apr-Jun	2024 Jan-Jun	2023 Jan-Jun	2023 Jan-Dec
Net revenues	154.0	157.7	293.2	316.8	638.8
Cost of goods sold	-16.3	-17.2	-29.6	-46.0	-88.9
Operating expenses	-153.5	-153.4	-284.2	-343.0	-659.5
EBIT	-15.8	-12.9	-20.5	-72.3	-109.5
EBIT margin	-10.3%	-8.2%	-7.0%	-22.8%	-17.1%
EBITDA	5.0	5.6	20.9	-35.4	-32.5
Earnings per share, before dilution, SEK	-1.04	-0.37	-1.30	-2.22	-3.73
Earnings per share, after dilution, SEK	-1.04	-0.37	-1.30	-2.22	-3.73
Cash flow from operating activities	-6.5	-12.7	-25.4	-70.5	-95.0
Cash and cash equivalents	139.7	251.1	139.7	251.1	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.

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 first-class, powder-based drug delivery technology, enabling outstanding bio-availability and stability of both small and large molecules.

Commercialised products and products under development

Product	Indication	Technology	Partner	Exploratory	Preclinical	Clinical development Phases	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	GRÜNENTHAL					2011	2008	2009	
Edluar®	insomnia	sublingual platform	VIATRIS					2009	2012	2011	
DMHP*	OUD, alcohol mgmt, depression	broca platform	GAIA					2023			
Pipeline products											
OX124	opioid overdose**	AmorphOX									
OX125	opioid overdose**	AmorphOX									
OX640	allergic reactions	AmorphOX									
Others	multiple***	AmorphOX									
OX-MPI	endometriosis		GESYNTA PHARMA AB								

* Digital Mental Health Programs, incl. MODIA®, Vorvida® and Deprexis®
** OX124 incl naloxone, OX125 nalmefen
*** Multiple, incl. both small & large molecule

Contact persons quarterly report

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Presentation

On July 17, 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=50048737

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-q2-report-2024/register

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

Financial calendar 2024-2025

Interim Report Q3 2024 - October 24, at 8 am
Interim Report Q4 2024, incl. Full Year Report, February 6, 2025, at 8 am
Interim Report Q1 2025 - May 6, at 8 am
Interim Report Q2 2025 - July 16, at 8 am
Interim Report Q3 2025 - October 23, at 8 am
Interim Report Q4 2025, incl. Full Year Report, February 5, 2026, at 8 am

Strong Zubsolv® recovery and focus on getting OX124 to the US market

CEO Comments in brief

I am pleased to report our Zubsolv sales grew slightly year on year, with a strong improvement from the first quarter. This is the third consecutive quarter that we have achieved a positive EBITDA, despite additional costs for a new human factor study (HF study) for OX124, increased legal expenses and a retrospective adjustment of Abstral® royalties. The improvement in Zubsolv sales was expected following the inventory adjustments at the beginning of the year and sales in the quarter to wholesalers and pharmacies have become more aligned. Both also grew slightly compared to last year. We have made good progress in preparing for the launch of our second medication on the US market, OX124, but close to the publication of this Interim Report we received feedback from the FDA with a request to complement the application with additional technical data from the final commercial product. In the quarter we addressed the initial concerns raised by the FDA in April and have recently successfully conducted a new HF study. We are investigating the implications of the new request, but we are optimistic we can address these new concerns expeditiously, but there will be a delay in the original time guidance.

Continued stabilization of Zubsolv sales and commercial preparations for OX124 accelerates

The buprenorphine/naloxone market continues to grow at a low rate of 3 percent. This is at the lower end of our guidance of 2-5 percent for the year and can be explained by considerable dynamics in the payer landscape. Since last summer, we have seen a trend in declining prescriptions to Medicaid patients and significant double-digit growth in patients with Commercial insurance. However, with the low market growth, this shift is rather driven by patients currently receiving treatment moving from Medicaid insurance to Commercial insurance than an inflow of new patients. Over the long term, a larger market share of Commercial insurance could benefit Orexo due to the excellent market access of Zubsolv in this segment, as well as more favourable pricing. To have a real impact on Zubsolv sales, we need to see growth in new patients since most physicians are hesitant to change medication for patients during treatment.

As expected, Zubsolv's revenues grew significantly from the first quarter, and even slightly over the last year, in both USD and SEK. The expenses from the US commercial operations are increasing compared to last year, primarily due to launch preparations for OX124, legal expenses associated with the Subpoena and efforts from Orexo to resolv the situation. In general, expenses have increased due to inflation in the quarter and the cost of the long-term incentive program has increased due to share price appreciation in the first half of 2024.

FDA review of OX124 extended

As communicated in the Q1 report, we anticipated a delay in approval of OX124, our high-dose rescue medication for opioid overdose, beyond the PDUFA date, July 15. The anticipated delay was caused by the FDA's concerns with the Instructions for Use. The FDA requested Orexo to document the effects of the updated instructions for use in a HF study, which was successfully completed recently. However, the FDA has now requested additional technical data from the final commercial product. Some of the data in the FDA application was based on manufacturing in a pilot scale, which Orexo and our advisors found to be sufficient. I am pleased

with how the team in Sweden and the US have tackled the concerns with the instructions for use, with significant agility and engagement. The new data from the HF study is ready to be submitted promptly, but due to the new data requested it is not possible to get approval within the communicated timeline of ten to thirteen months from submission of the NDA in September 2023. We will update the timelines when we have more information, but at the time of this quarterly report we do not see this request will change our financial guidance for 2024.

> **OX124: The new data from the Human Factor study is ready to be submitted promptly, but due to the new data requested it is not possible to get approval within the communicated timeline.**

R&D pipeline advancing

We have continued to explore the ability for AmorphOX®, our first-class drug delivery platform, to improve the drug delivery of larger molecules and during the quarter, we have generated additional supporting stability data in protein-based pharmaceuticals. A significant concern for many bio molecules is the need for a cold chain, use of problematic ingredients to keep the product stable and high cost of goods. We continue to generate data, both with partners like SOBI and with internally sourced APIs, showing that AmorphOX can reduce the need for a cold chain, create stable products with fewer additives. While our exploratory partnerships cover some of Orexo's expenses, our ambition is to enter partnerships generating milestones and royalty payments.

We continue to have intense discussions with potential partners for OX640 and, we are preparing the upscaling of the manufacturing to commercial batches to enable the pivotal clinical development program. In addition we plan to conduct a smaller exploratory study in patients with allergic rhinitis in Q4 this year to ensure we maintain commercial differentiation in this patient group as well. The regulatory pathway in the US has been clarified with the positive response by the FDA to our briefing book earlier this year. With a competing product receiving positive feedback from the EMA´s Human Medicine Committee on a nasal product, the regulatory risk has also decreased in Europe.

Yet another recognition for Orexo's sustainability work

Working with sustainability has been key to Orexo since the company was founded and this work has, over the years, become more and more formalized. In 2017, Orexo became a member of UN Global Compact, which supported our ability to qualify for a social financing framework when we recently refinanced the corporate bond. I am proud to share that our work has now resulted in a Gold Star rating by EcoVadis. The high score places Orexo among the top five percent of all 70,000 companies worldwide reviewed by EcoVadis annually. The rating is based on sustainability data related to Orexo´s business in Sweden.

Zubsolv EU starts to gain some traction, replacing Abstral contract expiry for some markets

We have worked intensively with our partner Accord Healthcare to establish a competitively priced supply chain for Europe and appreciate the investments and efforts Accord Healthcare have put into this. The European market for daily treatment is highly competitive and attractive pricing is important to win market share. We have seen some individual markets where Accord has made significant progress in the first half of 2024, and we are looking forward to seeing growing royalties as we proceed. Growing royalties from Zubsolv EU are welcome as we are expecting a decline in royalties from Abstral as agreements for some individual countries expire. Based on the reporting of royalties for Q1 from our new partner for Abstral in Europe, Grünenthal Meds, there was a need for an adjustment of Abstral royalty in Q2.

Summary and outlook

Zubsolv sales in the US is the foundation for Orexo´s financial stability in the short term, but growth is expected to come from the launch of OX124 and business development associated with the AmorphOX technology.

> **Zubsolv sales in the US is the foundation for Orexo´s financial stability in the short term, but growth is expected to come from the launch of OX124 and business development associated with the AmorphOX technology.**

We are making good progress in our larger projects, like OX640 and partnering with companies like SOBI and are optimistic that we will see progress in business development during the second half of 2024.

We maintain our guidance for 2024, but we see some risk to the Zubsolv revenue guidance with the wholesalers inventory adjustment in Q1. The OPEX and EBITDA guidance may be impacted by the non-recurring legal expenses associated with the Subpoena and a potential settlement as well as some additional expenses for the resubmission of OX124.

Uppsala, Sweden, July 17, 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 healthcare 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) for opioid use disorder.[3] The opioid crisis in the US has continued to accelerate especially in the post Covid-19 timeframe and the prevalence of misuse of synthetic opioids, in particular illicit fentanyl has been the main drug being supplied and abused. The number of fatal overdoses remains high, with predicted numbers indicating that 81,000 people died from overdoses in 2023.[4] Nine out of ten opioid overdoses involve synthetic illicitly manufactured opioids.[5]

In Q2, the buprenorphine/naloxone market grew 1 percent versus Q1 2024 and 3 percent versus Q2 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, removed 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. However, the adoption of treatment by a broader number of healthcare providers has been slower than the US government has expected.

Another driver for increased access to treatment is the opioid litigation settlements of approx. USD 54 billion.

The market since last summer has shifted from growth in Medicaid to the Commercial segment. In Medicaid the market declined 9 percent vs Q2 2023, while the Commercial segment increased with 19 percent. The decline in Medicaid is associated with removal of different emergency legislations during Covid-19 and a disenrollment in Medicaid to the benefit of Commercial insurance. The move from Medicaid to the Commercial segment explains the majority of the growth in Commercial.

Developments during the quarter

Zubsolv volume remained stable in Q2 2024 versus Q1 2024 and declined 4 percent versus Q2 2023. The decline versus Q2 2023 is primarily driven by lower volumes with United Health Group and Humana, where Zubsolv previously had been the only buprenorphine/naloxone product on formulary. This segment, however, is stabilizing and has grown 1 percent in prescriptions versus Q1 2024.

In the open segment where Zubsolv is reimbursed, Zubsolv remained stable versus Q1 2024 and declined 2 percent versus Q2 2023. Within the Commercial portion of the open segment, Zubsolv grew 1 percent versus Q1 2024, primarily driven by growth in CVS Caremark's national formulary.

Thanks to improved market access in Medicaid, Zubsolv Medicaid volume remained stable Q2 versus Q1 2024, while the market declined 1 percent. In Medicaid, Zubsolv also declined less than the market versus Q2 2023, with 4 percent Zubsolv decline and 9 percent market decline. This was supported by recently improved market access in New York, which grew 13 percent versus Q2 2023, and Indiana, which grew 261 percent versus Q2 2023.

Zubsolv´s best in class market access in the commercial payer segment is maintained at 98 percent. Zubsolv´s public payer segment access increased by 1 percentage point to 51 percent, which includes the state of Utah adding Zubsolv to its Medicaid formulary, effective from July 2024.

modia deprexis VORVIDA

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]

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

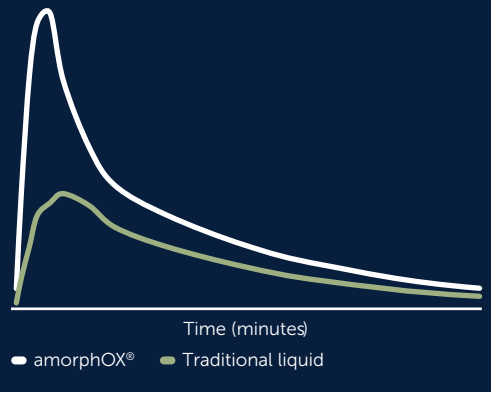
The lack of efficient reimbursement and distribution channels has held back Orexo's and other players' ability to commercialize digital mental health programs. Progress is being made at a federal level in the US to establish a national reimbursement system for digital health products and therapies, which 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.

AmorphOX® – a versatile powder-based drug delivery platform

Identified need

Amorphous materials are more and more common in drug development and can be of great importance for the properties of the drug product. These materials are non-crystalline and possess no long-range order, providing them with unique and highly attractive 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 developed a solution to this problem: AmorphOX.

Plasma concentration



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 resulting in 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.

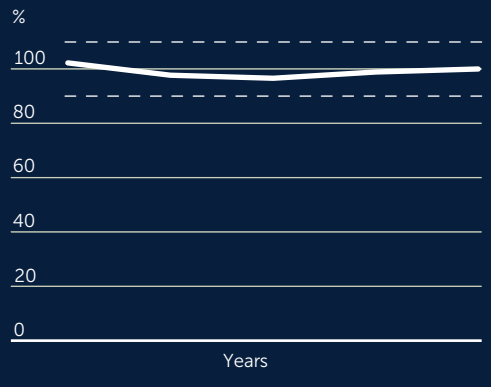
Clinically validated

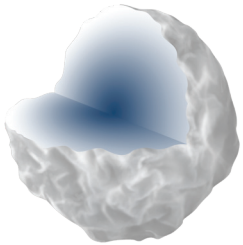
AmorphOX has successfully been validated in multiple clinical studies during the development of nasal rescue medications for opioid overdoses, one including naloxone (OX124) and one with nalmefene (OX125). In addition, it has also been clinically proven with epinephrine (OX640), a product for acute treatment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

Wide applicability

AmorphOX 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 properties, and mucosal retention. This makes it a versatile technology with broad applicability in pharmaceutical development across multiple therapeutic areas.

Amount of API





Successful clinical trials

Well tolerated
Higher exposure
Faster onset
Lower variability

amorphOX®

Products under development

Development projects based on the AmorphOX® drug delivery platform

OX124 – high-dose naloxone rescue medication for opioid overdose

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 and fentanyl analogues.

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 technology, which is the backbone in OX124, contributes to improved stability of the active substance and reduces its sensitivity related to temperature changes.

OX124 is protected by patents until 2039.

Developments during the quarter

After the end of the quarter Orexo received a complete response letter (CRL) from the FDA regarding the New Drug Application (NDA) submitted in September 2023. The CRL indicates the need for an additional human factors (HF) study, which is in line with previous communication. Furthermore additional technical data on the final commercial product has been requested. The CRL indicates there is no need for additional clinical or non-clinical studies.

After receiving comments from the FDA in early April 2024 regarding feedback on the use of the product, modifications have been made to the instructions for use. To meet FDA´s requirement, a new HF study has been successfully completed. The requirement from FDA to provide additional technical data was unexpected, and Orexo will now work expeditiously to address this to enable a resubmission of the NDA to the FDA as soon as possible. The review period following the resubmission of the NDA will be either two or six months, depending on the agency's classification of the resubmission.

The type of technical data required by FDA has already been generated from the pilot scale manufacturing and the data was included in the NDA. Orexo assessment is that the submitted data supports approval, however, FDA does not agree and has requested data from the established commercial scale manufacturing .

In parallel, the work accelerated on defining the commercialization strategy, among others including 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 and fentanyl analogues. In 2023, the predicted number of fatal opioid overdoses in the US counted for more than 81,000.[9] Nine out of ten opioid overdoses involved 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, public and private insurance programs in the US do not cover most OTC products, and patient out-of-pocket (OOP) costs could make those products prohibitive. Since OX124 will be a prescription

product, it is likely to be covered by insurance programs. Furthermore, OX124 may benefit from clinicians co-prescribing high-dose naloxone with prescription opioids.

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

OX125 – nalmefene rescue medication for opioid overdose

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.

Developments during the quarter

In parallel with the discussions with potential partners, the work continued to optimize the formulation and to document the excellent stability data. Also some minor work was conducted to prepare for an upscaling of the manufacturing to commercial batches.

In addition, preparations were made to being able to conduct an explorative phase 1 clinical study in patients experiencing allergic rhinitis in Q4 2024. The data from the study will ensure optimal choice of dose to maintain clinical differentiation. However, based on the strong results from the first clinical study of OX640, we do not expect any impact on the overall development plan and feasibility of OX640 from the study.

OX640 is protected by granted patents both on European markets and in the US. On the US market the patent protection was further strengthened during the quarter 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.

Early stage projects

Orexo has tested enzymes, peptides, and proteins with the drug delivery platform 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. The exploratory feasibility studies with other pharmaceutical companies, have progressed as planned during the quarter and we have seen excellent results in AmorphOX ability to retain activity in bio-molecules and aim at advancing these exploratory collaborations to patnerships based on milestone payments and royalty on future sales.

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

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.

Developments during the quarter

Orexo was awarded a Gold rating from EcoVadis, one of the world's most trusted provider of business sustainability ratings. The high score places Orexo among the top five percent of all 70,000 companies worldwide reviewed by EcoVadis annually. The rating is based on Orexo´s first year of reporting to the rating institute and mainly includes sustainability data related to Orexo´s business in Sweden, Orexo AB, covering Group headquarters functions, R&D, Regulatory Affairs, Quality & She, and Supply Chain. The EcoVadis assessment is based on sustainability criteria across four core themes: Environment, Labor & Human Rights, Ethics, and Sustainable Procurement.

For the second consecutive year, updated information was provided to the UN Global Compact on progress towards the Ten Principles and the Global Goals, known as CoP reporting.

A plan was established to implement CSRD in the sustainability reporting, and the double materiality analysis will be initiated in Q3, 2024.

Financial development

Revenues

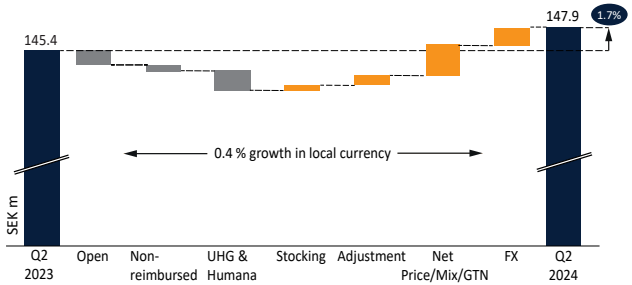
Total revenues amounted to SEK 154.0 m (157.7) for Q2 and to SEK 293.2 m (316.8) for H1. The decrease is mainly explained by lower HQ & Pipeline partner revenues partly offset by higher US Commercial revenues supported by a stronger USD exchange rate for the period.

Revenues by segment

US Commercial revenues amounted to SEK 147.9 m (145.4) for Q2. The increase is mainly driven by Zubsolv® US product sales especially due to favorable payer mix supported by a positive impact of SEK 1.9 m and from a stronger USD exchange rate. The demand in the previously exclusive plans United Health Group and Humana is lower year over year. US Commercial revenues amounted to SEK 277.2 m (286.0) for H1. In local currency US Commercial net revenues for Q2 amounted to USD 13.9 m (13.8) and for H1 to USD 26.3 m (27.3).

HQ & Pipeline partner product related revenues for Q2 amounted to SEK 6.0 m (12.3). The decrease is mainly explained by lower Abstral ROW royalties due to a negative true-up of Q1 2024 accrued royalties based on Orexo's partner Grünenthal Meds reporting. This was partly offset by higher Zubsolv ex-US revenues related to royalties and sales of tablets to Orexo's partner Accord Healthcare. HQ & Pipeline partner product related revenues amounted to SEK 16.1 m (30.8) for H1.

ZUBSOLV US NET REVENUES DEVELOPMENT



Cost of goods sold

Cost of goods sold (COGS) amounted to SEK 16.3 m (17.2) for Q2. US Commercial amounted to SEK 15.4 m (17.9), the decrease is mainly due to favorable production costs for Zubsolv US partly offset by higher technical infrastructure costs for Digital Mental Health Programs (DMHP). HQ & Pipeline amounted to SEK 0.9 m (-0.5) where the increase is due to higher sales of Zubsolv ex-US tablets to Orexo's partner Accord Healthcare and a positive true-up of accrued freight related costs in Q2 2023. Cost of goods sold (COGS) amounted to SEK 29.6 m (46.0) for H1.

Operating expenses

Selling expenses amounted to SEK 52.2 m (48.2) for Q2. The increase over the same period last year is mainly explained by higher selling expenses in US Commercial associated with the launch preparations of OX124. Selling expenses amounted to SEK 95.6 m (94.0) for H1.

Administrative expenses amounted to SEK 42.2 m (38.3) for Q2. The increase is mainly explained by higher legal expenses for DOJ investigation in US Commercial and higher costs for long term incentive programs due to higher share price. Administrative expenses amounted to SEK 77.1 m (104.7) for H1.

Research and development costs amounted to SEK 64.3 m (75.6) for Q2. The decrease is mainly explained by the finalized MODIA® study in Q3 2023 partly offset by higher costs

NET REVENUES AND EBIT PER SEGMENT

SEK m	Net Revenues					EBIT				
	2024 Apr-Jun	2023 Apr-Jun	2024 Jan-Jun	2023 Jan-Jun	2023 Jan-Dec	2024 Apr-Jun	2023 Apr-Jun	2024 Jan-Jun	2023 Jan-Jun	2023 Jan-Dec
Zubsolv US product sales	147.9	145.4	277.2	286.0	577.7	–	–	–	–	–
Digital Mental Health Programs (DMHP) product sales	0.0	0.0	0.0	0.1	0.1	–	–	–	–	–
US Commercial – total	**147.9**	**145.4**	**277.2**	**286.0**	**577.7**	**36.0**	**37.6**	**67.9**	**75.3**	**152.3**
Abstral® royalty	1.3	8.0	8.4	14.2	31.9	–	–	–	–	–
Edluar® royalty	3.3	4.0	6.0	5.3	10.8	–	–	–	–	–
Zubsolv – ex-US	1.5	0.2	1.7	11.2	18.4	–	–	–	–	–
HQ & Pipeline – total	**6.0**	**12.3**	**16.1**	**30.8**	**61.1**	**-51.9**	**-50.5**	**-88.5**	**-147.5**	**-261.8**
Total	**154.0**	**157.7**	**293.2**	**316.8**	**638.8**	**-15.8**	**-12.9**	**-20.5**	**-72.3**	**-109.5**

for OX124. Research and development costs amounted to SEK 120.9 m (154.0) for H1.

Other operating income and expenses amounted to SEK 5.2 m (8.6) for Q2. This is mainly explained by lower exchange-rate gains of SEK 0.0 m (4.8) derived from revaluations of parent company balance sheet items in foreign currency, predominantly in USD, and lower received insurance reimbursement of SEK 2.9 m (4.2). This is partly offset by higher partner reimbursement of R&D costs of SEK 1.1 m (0.3), higher rental income from subleased office space of SEK 0.3 m (0.1) and higher MATCore[11] related startup revenues of SEK 0.9 m (-0.7). Other operating income and expenses amounted to SEK 9.5 m (9.7) for H1.

Operating profit

EBITDA amounted to SEK 5.0 m (5.6) for Q2 and to SEK 20.9 m (-35.4) for H1.

The EBITDA contribution from US Commercial amounted to SEK 46.9 m (48.4) for Q2, and to SEK 89.6 m (96.7) for H1.

Total EBIT amounted to SEK -15.8 m (-12.9) for Q2 mainly explained by lower gross profit and moderately higher operating expenses. Total EBIT amounted to SEK -20.5 m (-72.3) for H1.

EBIT contribution from US Commercial amounted to SEK 36.0 m (37.6) for Q2, equal to an EBIT margin of 24.4 percent (25.8). EBIT contribution from US Commercial amounted to SEK 67.9 m (75.3) for H1, equal to an EBIT margin of 24.5 percent (26.3).

Net financial items and tax

Net financial items for Q2 amounted to SEK -21.5 m (-2.9) and is mainly explained by higher bond loan costs of SEK -21.4 m (-9.3) of which SEK -8.2 m refers to non-recurring final transaction costs for the refinancing of the old corporate bond loan and SEK -13.2 m refers to recurring higher interest expense for the new corporate bond loan, negative unrealized exchange rate impact of SEK -0.8 m (5.3) derived from the parent company's foreign currency bank accounts mainly in USD and lower interest income from bank accounts of SEK 1.1 m (1.5) explained by absence of short-term investments. Net financial items amounted to SEK -26.6 m (-12.0) for H1.

Total tax expenses amounted to SEK 1.4 m (3.2) for Q2. The decrease is mainly explained by lower positive adjustment to deferred tax assets related to temporary differences. Total tax expenses amounted to SEK 2.3 m (7.8) for H1. Orexo performs regular assessments of its deferred tax asset and adjusts according to the recognition requirements of IAS 12.

Net earnings

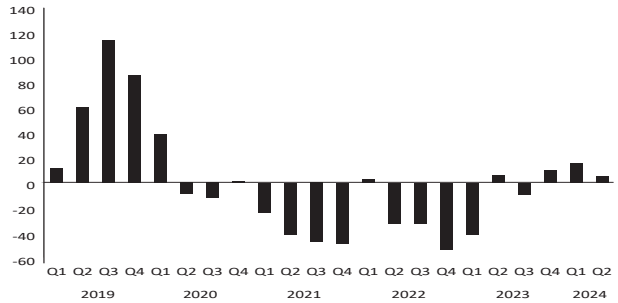
Net earnings amounted to SEK -35.9 m (-12.6) for Q2 and to SEK -44.8 m (-76.5) for H1.

Cash and cash flow

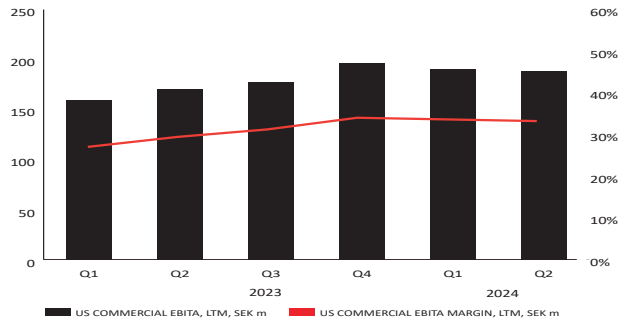
Cash flow from operating activities amounted to SEK -6.5 m (-12.7) for Q2 and was primarily impacted by negative operating earnings and interest paid partly offset by positive changes in working capital. Cash flow from operating activities amounted to SEK -25.4 m (-70.5) for H1.

The first part of the transaction for the senior secured callable floating rate social bonds of SEK 500 m at 3m STIBOR + 650 basis points per annum was recognized in Q1 this year. In the quarter the new bond loan was completed and fully recognized in the accounts. This had a negative impact on interest paid of SEK -7.7 m (0.0) from transaction costs for the refinancing of the old corporate bond loan and a positive impact on receivables of SEK 25.0 m (0.0) reversing the prepayment of own purchase of the new bond loan of SEK -25 m in Q1 while financial activities were impacted negatively by the closure of the purchase of new Orexo owned bonds of SEK 30.0 m (0.0) and issuance costs for the new bond loan of SEK 12.3 m (0.0).

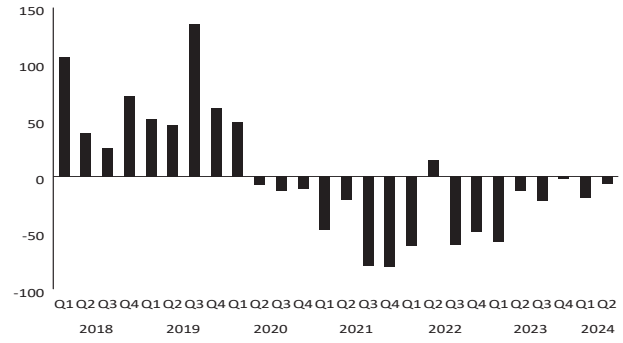
GROUP EBITDA, SEK m



US COMMERCIAL EBITDA MARGIN AND EBITDA (LTM[12], SEK m)



CASH FLOW FROM OPERATING ACTIVITIES, SEK m



As of June 30, 2024, cash and cash equivalents amounted to SEK 139.7 m (251.1) and interest-bearing liabilities to SEK 458.5 m (481.0), i.e. a negative net cash position of SEK -318.8 m (-229.9). Cash and cash equivalents were decreased by SEK 58.4 m from Q1 2024.

Investments

Gross investments in tangible and intangible fixed assets amounted to SEK 2.7 m (10.8) for Q2 and to SEK 3.8 m (11.6) for H1. Lower investments are mainly explained by investments in equipment for the development organization.

Equity

Shareholders' equity on June 30, 2024, was SEK 24.2 m (123.8). The equity/asset ratio was 3.1 percent (13.4).

Parent company

Net revenues for Q2 amounted to SEK 105.8 m (122.7) of which SEK 99.8 m (110.5) was related to sales to Group companies. Net revenues amounted to SEK 206.3 m (257.9) for H1 of which SEK 190.2 m (227.1) was related to sales to Group companies.

Earnings before tax amounted to SEK -28.5 m (2.6) for Q2. The development is mainly explained by lower gross profit and higher negative net financial items partly offset by lower operating expenses. Earnings before tax SEK -33.2 m (-37.9) for H1.

Investments in equipment for the development organization for Q2 amounted to SEK 2.7 m (10.8) and to SEK 3.8 m (10.8) for H1.

As of June 30, 2024, cash and cash equivalents in the parent company amounted to SEK 111.2 m (180.5).

Parent company shareholders' equity at June 30, 2024, was SEK 131.2 m (71.3). 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 -33.2 m (-37.9) in H1.

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 for 2024 is based on current circumstances as of July 2024. However, there is an increased risk in the Zubsolv net sales guidance due to the wholesaler inventory adjustment in Q1 2024. In addition, a potential settlement of the ongoing DOJ investigation (see note 4), and increased R&D expenses, related to the OX124 resubmission, may affect our cost projections and financial results.

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, July 17, 2024

Nikolaj Sørensen
President and CEO

Assurance by the Board of Directors and the CEO

The Board of Directors and the CEO give their assurance that the six-month report provides a fair and accurate view of the Company´s and the Group´s operations, financial positions and earnings and describes the significant risk and uncertainties facing the company and the companies included in the group.

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

Uppsala, Sweden, July 17, 2024
Orexo AB (publ)

James Noble
Chairman of the bord

Robin Evers
Bord member

Staffan Lindstrand
Board member

Christine Rankin
Board member

Fred Wilkinson
Board member

Nikolaj Sørensen
President and CEO

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, 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)

7 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

8 Page 8, Enzymes, peptides and proteins

9 Page 9, Center of Disease Control and Prevention

10 Page 9, Center of Disease Control and Prevention

11 Page 14, MATCore is a product concept where Orexo´s total offering within OUD is collected

12 Page 14, Last Twelve Months

Financial reports, notes and key figures

CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS

SEK m	Notes	2024 Apr-Jun	2023 Apr-Jun	2024 Jan-Jun	2023 Jan-Jun	2023 Jan-Dec
Net revenues	9	154.0	157.7	293.2	316.8	638.8
Cost of goods sold		-16.3	-17.2	-29.6	-46.0	-88.9
Gross profit		**137.7**	**140.5**	**263.7**	**270.8**	**550.0**
Selling expenses		-52.2	-48.2	-95.6	-94.0	-181.5
Administrative expenses		-42.2	-38.3	-77.1	-104.7	-188.0
Research and development expenses		-64.3	-75.6	-120.9	-154.0	-303.1
Other operating income and expenses		5.2	8.6	9.5	9.7	13.3
Operating earnings (EBIT)		**-15.8**	**-12.9**	**-20.5**	**-72.3**	**-109.5**
Net financial items		-21.5	-2.9	-26.6	-12.0	-30.8
Earnings before tax		**-37.3**	**-15.8**	**-47.1**	**-84.3**	**-140.3**
Tax	5	1.4	3.2	2.3	7.8	12.0
Net earnings for the period		**-35.9**	**-12.6**	**-44.8**	**-76.5**	**-128.3**
Earnings per share, before dilution, SEK		-1.04	-0.37	-1.30	-2.22	-3.73
Earnings per share, after dilution, SEK		-1.04	-0.37	-1.30	-2.22	-3.73

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

SEK m	2024 Apr-Jun	2023 Apr-Jun	2024 Jan-Jun	2023 Jan-Jun	2023 Jan-Dec
Earnings for the period	**-35.9**	**-12.6**	**-44.8**	**-76.5**	**-128.3**
Other comprehensive income	—	—	—	—	—
Items that may subsequently be reversed to the statement of operations:					
Exchange-rate differences	-1.4	8.0	10.1	7.1	-6.8
Other comprehensive earnings for the period. net after tax	**-1.4**	**8.0**	**10.1**	**7.1**	**-6.8**
Total comprehensive earnings for the period [1]	**-37.3**	**-4.6**	**-34.7**	**-69.4**	**-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 Jun 30	2023 Jun 30	2023 Dec 31
ASSETS				
Fixed assets				
Tangible fixed assets		73.7	81.4	81.0
Intangible fixed assets		154.4	197.8	173.3
Right-of-use assets		24.8	34.0	24.5
Deferred tax assets	5	53.2	44.8	48.1
Other financial assets		0.8	0.3	0.8
Total fixed assets		**306.9**	**358.2**	**327.7**
Current assets				
Inventories		69.2	67.1	42.4
Accounts receivable and other receivables		257.5	250.5	245.5
Cash and cash equivalents		139.7	251.1	171.0
Total current assets		**466.4**	**568.7**	**458.9**
Total assets		**773.3**	**926.9**	**786.6**
SHAREHOLDERS' EQUITY AND LIABILITIES				
Total shareholders' equity		**24.2**	**123.8**	**58.9**
Long-term liabilities				
Provisions		18.9	3.8	11.5
Long-term liabilities, interest bearing		458.5	481.0	448.4
Lease liabilities, long-term		8.1	14.3	4.5
Total long-term liabilities		**485.5**	**499.1**	**464.5**
Current liabilities and provisions				
Provisions		131.3	144.1	133.1
Current liabilities, non-interest bearing		115.9	138.0	109.2
Lease liabilities, current		16.4	21.8	20.9
Total current liabilities and provisions		**263.6**	**304.0**	**263.2**
Total liabilities		**749.1**	**803.1**	**727.7**
Total shareholders' equity and liabilities		**773.3**	**926.9**	**786.6**

CONDENSED CONSOLIDATED CHANGES IN SHAREHOLDERS' EQUITY

SEK m	2024 Jun 30	2023 Jun 30	2023 Dec 31
Opening balance, shareholders' equity	**58.9**	**193.9**	**193.9**
Total comprehensive earnings for the period	-34.7	-69.4	-135.1
Share-based payments	—	-0.7	—
Closing balance, shareholders' equity	**24.2**	**123.8**	**58.9**

CONDENSED CONSOLIDATED CASH FLOW STATEMENTS

SEK m	Notes	2024 Apr-Jun	2023 Apr-Jun	2024 Jan-Jun	2023 Jan-Jun	2023 Jan-Dec
Operating earnings (EBIT)		-15.8	-12.9	-20.5	-72.3	-109.5
Interest received		0.8	2.2	2.6	2.9	7.7
Interest paid		-23.6	-8.6	-33.9	-17.0	-37.6
Income taxes paid		-1.1	-0.5	-1.6	-0.8	-1.6
Adjustment for non-cash items	3	18.2	21.9	36.3	44.8	99.8
Cash flow from operating activities before changes in working capital		**-21.4**	**2.0**	**-17.1**	**-42.4**	**-41.2**
Changes in working capital		**14.9**	**-14.7**	**-8.3**	**-28.1**	**-53.8**
Cash flow from operating activities		**-6.5**	**-12.7**	**-25.4**	**-70.5**	**-95.0**
Acquisition of tangible and intangible fixed assets		-2.7	-10.8	-3.8	-11.6	-19.2
Acquisition of short-term investments		—	-0.8	—	—	0.1
Disposal of short-term investments		—	136.8	—	219.9	219.9
Cash flow from investing activities		**-2.7**	**125.1**	**-3.8**	**208.3**	**200.8**
Amortization of Lease liability		-5.7	-5.2	-11.2	-10.5	-21.4
Change of repurchased part in bond		-42.3	-8.8	6.5	-15.0	-48.7
Cash from financing activities		**-48.0**	**-14.0**	**-4.7**	**-25.5**	**-70.1**
Cash flow for the period		**-57.1**	**98.5**	**-34.0**	**112.3**	**35.7**
Cash and cash equivalents at the beginning of the period		**198.0**	**142.4**	**171.0**	**132.2**	**132.2**
Exchange-rate differences in cash and cash equivalents		-1.2	10.1	2.6	6.5	3.1
Changes in cash and cash equivalents		-58.4	108.6	-31.3	118.8	38.8
Cash and cash equivalents at the end of the period		**139.7**	**251.1**	**139.7**	**251.1**	**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 Apr-Jun	2023 Apr-Jun	2024 Jan-Jun	2023 Jan-Jun	2023 Jan-Dec
EBIT margin, %	-10.3	-8.2	-7.0	-22.8	-17.1
Return on shareholder equity, %	-83.8	-10.0	-107.8	-48.1	-101.5
Net debt, SEK m	318.8	229.9	318.8	229.9	277.4
Debt/equity ratio, %	1,894.7	388.5	1,894.7	388.5	761.3
Equity/assets ratio, %	3.1	13.4	3.1	13.4	7.5
Number of shares, before dilution	34,504,154	34,415,773	34,467,781	34,383,668	34,413,408
Number of shares, after dilution	34,504,154	34,415,773	34,467,781	34,383,668	34,413,408
Earnings per share, before dilution, SEK	-1.04	-0.37	-1.30	-2.22	-3.73
Earnings per share, after dilution, SEK	-1.04	-0.37	-1.30	-2.22	-3.73
Number of employees at the end of the period	112	120	112	120	116
Shareholders' equity, SEK m	24.2	123.8	24.2	123.8	58.9
Capital employed, SEK m	482.7	604.8	482.7	604.8	507.3
Working capital, SEK m	63.1	13.6	63.1	13.6	24.7

[2] Definitions and reconcilliations of key figures are presented on page 29 of this report

CONDENSED PARENT COMPANY STATEMENT OF OPERATIONS

SEK m	Notes	2024 Apr-Jun	2023 Apr-Jun	2024 Jan-Jun	2023 Jan-Jun	2023 Jan-Dec
Net revenues		105.8	122.7	206.3	257.9	494.0
Cost of goods sold		-17.4	-17.5	-35.3	-51.3	-93.7
Gross profit		**88.4**	**105.2**	**171.0**	**206.6**	**400.3**
Selling expenses		-30.2	-31.7	-55.6	-62.2	-119.4
Administrative expenses		-16.0	-14.1	-31.1	-60.6	-94.9
Research and development costs		-51.0	-62.3	-94.4	-124.2	-243.7
Other operating income and expenses		1.4	8.4	5.1	14.2	17.1
Operating earnings (EBIT)		**-7.4**	**5.4**	**-5.1**	**-26.1**	**-40.6**
Interest income and expenses		-13.5	-7.8	-22.3	-14.7	-31.3
Other financial income and expenses		-7.6	5.0	-5.9	3.0	1.5
Net financial items		**-21.1**	**-2.8**	**-28.2**	**-11.8**	**-29.8**
Earnings before tax		**-28.5**	**2.6**	**-33.2**	**-37.9**	**-70.4**
Tax	5	—	—	—	—	—
Earnings for the period		**-28.5**	**2.6**	**-33.2**	**-37.9**	**-70.4**

PARENT COMPANY STATEMENT OF COMPREHENSIVE INCOME

SEK m	2024 Apr-Jun	2023 Apr-Jun	2024 Jan-Jun	2023 Jan-Jun	2023 Jan-Dec
Earnings for the period	**-28.5**	**2.6**	**-33.2**	**-37.9**	**-70.4**
Other comprehensive income	—	—	—	—	—
Total comprehensive earnings for the period	**-28.5**	**2.6**	**-33.2**	**-37.9**	**-70.4**

CONDENSED PARENT COMPANY BALANCE SHEET

SEK m	2024 Jun 30	2023 Jun 30	2023 Dec 31
ASSETS			
Fixed assets			
Intangible fixed assets	132.7	164.8	147.7
Tangible fixed assets	73.7	81.4	81.0
Shares in subsidiaries	289.6	159.8	286.2
Total fixed assets	**496.0**	**406.0**	**515.0**
Current assets			
Inventories	33.9	39.1	25.6
Accounts receivable and other receivables	53.0	58.5	52.8
Receivables from Group companies	110.4	83.4	71.0
Cash and cash equivalents	111.2	180.5	145.5
Total current assets	**308.5**	**361.4**	**294.9**
Total assets	**804.5**	**767.4**	**809.8**
SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES			
Total shareholders' equity	**131.2**	**71.3**	**162.1**
Long-term liabilities			
Provisions	17.7	3.6	10.8
Bond loan	458.5	481.0	448.4
Total long-term liabilities	**476.2**	**484.6**	**459.3**
Current liabilities			
Accounts payable	22.1	26.9	10.3
Other liabilities	10.0	11.2	8.6
Liabilities to Group companies	144.7	144.7	144.7
Accrued expenses and deferred income	20.3	28.8	24.9
Total current liabilities	**197.1**	**211.5**	**188.4**
Total liabilities	**673.3**	**696.2**	**647.7**
Total shareholders' equity and liabilities	**804.5**	**767.4**	**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 Apr-Jun	2023 Apr-Jun	2024 Jan-Jun	2023 Jan-Jun	2023 Jan-Dec
US Commercial					
Net revenues	147.9	145.4	277.2	286.0	577.7
Operating earnings (EBIT)	36.0	37.6	67.9	75.3	152.3
Depreciation and amortization	-10.8	-10.8	-21.6	-21.5	-43.7
EBITDA	46.9	48.4	89.6	96.7	196.0
HQ & Pipeline					
Net revenues	6.0	12.3	16.1	30.8	61.1
Operating earnings (EBIT)	-51.9	-50.5	-88.5	-147.5	-261.8
Depreciation and amortization	-10.0	-7.7	-19.8	-15.4	-33.3
EBITDA	-41.9	-42.8	-68.7	-132.1	-228.4
Group					
Net revenues	154.0	157.7	293.2	316.8	638.8
Operating earnings (EBIT)	-15.8	-12.9	-20.5	-72.3	-109.5
Depreciation and amortization	-20.8	-18.5	-41.4	-36.9	-77.0
EBITDA	5.0	5.6	20.9	-35.4	-32.5
Net financial items	-21.5	-2.9	-26.6	-12.0	-30.8
Earnings before tax	-37.3	-15.8	-47.1	-84.3	-140.3

3. Cash flow

ADJUSTMENT FOR NON-CASH ITEMS

SEK m	2024 Apr-Jun	2023 Apr-Jun	2024 Jan-Jun	2023 Jan-Jun	2023 Jan-Dec
Depreciation/amortization and impairment	20.8	18.5	41.4	36.9	77.0
Realization results	—	—	—	—	0.0
Change in provisions	-2.9	8.2	-2.0	10.7	18.2
Share based payments	—	0.0	—	0.0	0.0
Other non cash items	0.3	0.0	0.3	3.1	3.1
Exchange rate income and expenses	0.0	-4.8	-3.5	-5.8	1.4
Total	**18.2**	**21.9**	**36.3**	**44.8**	**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

› Orexo AB´s sustainability work ranked among the top five percent of all 70,000 businesses worldwide reviewed by EcoVadis

› For OX124, a high dose naloxone rescue medication for opioid overdose, a complete response letter was received from the FDA, requesting additional technical data on the final commercial product and additional data from a new human factor (HF) study. A new HF study was successfully conducted in early July.

9. Revenue from contracts with customers

	2024 Apr–Jun						
SEK m	Zubsolv®	Abstral®	Edluar®	Vorvida®	Deprexis®	MODIA®	Total
Segment							
US Commercial	147.9	–	–	–	0.0	–	**147.9**
HQ & Pipeline	1.5	1.3	3.3	–	–	–	**6.0**
Total revenue from contracts with customers	**149.4**	**1.3**	**3.3**	**0.0**	**0.0**	**0.0**	**154.0**
Geographical markets							
US	147.9	–	–	–	0.0	–	**147.9**
EU & UK	1.5	1.1	3.3	–	–	–	**5.8**
Rest of the world	–	0.2	–	–	–	–	**0.2**
Total revenue from contracts with customers	**149.4**	**1.3**	**3.3**	**0.0**	**0.0**	**0.0**	**154.0**

	2024 Jan–Jun						
SEK m	Zubsolv®	Abstral®	Edluar®	Vorvida®	Deprexis®	MODIA®	Total
Segment							
US Commercial	277.2	–	–	–	0.0	–	**277.2**
HQ & Pipeline	1.7	8.4	6.0	–	–	–	**16.1**
Total revenue from contracts with customers	**278.9**	**8.4**	**6.0**	**0.0**	**0.0**	**0.0**	**293.2**
Geographical markets							
US	277.2	–	–	–	0.0	–	**277.2**
EU & UK	1.7	8.0	6.0	–	–	–	**15.7**
Rest of the world	–	0.4	–	–	–	–	**0.4**
Total revenue from contracts with customers	**278.9**	**8.4**	**6.0**	**0.0**	**0.0**	**0.0**	**293.2**

	2023 Apr-Jun						
SEK m	Zubsolv	Abstral	Edluar	Vorvida	Deprexis	MODIA	Total
Segment							
US Commercial	145.4	–	–	0.0	0.0	–	145.4
HQ & Pipeline	0.2	8.0	4.0	–	–	–	12.3
Total revenue from contracts with customers	**145.6**	**8.0**	**4.0**	**0.0**	**0.0**	**0.0**	**157.7**
Geographical markets							
US	145.4	–	–	0.0	0.0	–	145.4
EU & UK	0.2	7.8	4.0	–	–	–	12.0
Rest of the world	–	0.2	–	–	–	–	0.2
Total revenue from contracts with customers	**145.6**	**8.0**	**4.0**	**0.0**	**0.0**	**0.0**	**157.7**

	2023 Jan–Jun						
SEK m	Zubsolv	Abstral	Edluar	Vorvida	Deprexis	MODIA	Total
Segment							
US Commercial	286.0	–	–	0.0	0.0	–	286.0
HQ & Pipeline	11.2	14.2	5.3	–	–	–	30.8
Total revenue from contracts with customers	**297.1**	**14.2**	**5.3**	**0.0**	**0.0**	**0.0**	**316.8**
Geographical markets							
US	286.0	–	–	0.0	0.0	–	286.0
EU & UK	11.2	13.9	5.3	–	–	–	30.4
Rest of the world	–	0.4	–	–	–	–	0.4
Total revenue from contracts with customers	**297.1**	**14.2**	**5.3**	**0.0**	**0.0**	**0.0**	**316.8**

	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	—	—	0.0	0.0	—	577.7
EU & UK	18.4	31.1	10.8	—	—	—	60.3
Rest of the world	—	0.8	—	—	—	—	0.8
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**
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 Apr-Jun	2023 Apr-Jun	2024 Jan-Jun	2023 Jan-Jun	2023 Jan-Dec
EBIT	-15.8	-12.9	-20.5	-72.3	-109.5
Depreciation and amortization	20.8	18.5	41.4	36.9	77.0
EBITDA	**5.0**	**5.6**	**20.9**	**-35.4**	**-32.5**

OPERATING EXPENSES SEK m	2024 Apr-Jun	2023 Apr-Jun	2024 Jan-Jun	2023 Jan-Jun	2023 Jan-Dec
Selling expenses	-52.2	-48.2	-95.6	-94.0	-181.5
Administrative expenses	-42.2	-38.3	-77.1	-104.7	-188.0
Research and development costs	-64.3	-75.6	-120.9	-154.0	-303.1
Other operating income and expenses	5.2	8.6	9.5	9.7	13.3
Operating expenses	**-153.5**	**-153.4**	**-284.2**	**-343.0**	**-659.5**

RETURN ON SHAREHOLDERS' EQUITY	2024 Apr-Jun	2023 Apr-Jun	2024 Jan-Jun	2023 Jan-Jun	2023 Jan-Dec
Shareholders' equity beginning balance	61.4	129.1	58.9	193.9	193.9
Shareholders' equity ending balance	24.2	123.8	24.2	123.8	58.9
Average shareholders' equity	42.8	126.5	41.6	158.9	126.4
Net earnings	-35.9	-12.6	-44.8	-76.5	-128.3
Return on shareholders' equity %	**-83.8**	**-10.0**	**-107.8**	**-48.1**	**-101.5**

GROSS INVESTMENTS SEK m	2024 Apr-Jun	2023 Apr-Jun	2024 Jan-Jun	2023 Jan-Jun	2023 Jan-Dec
Investments in tangible fixed assets	2.5	10.8	2.5	10.8	18.5
Investments in intangible fixed assets	0.2	0.0	1.4	0.7	0.7
Gross investments	**2.7**	**10.8**	**3.8**	**11.6**	**19.2**

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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