orexo

Interim Report Q3 2024

October 24, 2024

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

Q3 2024 highlights

- Total net revenues of SEK 136.5 m (156.1)
- EBITDA of SEK -0.7 m (-9.5)
- Net earnings of SEK -41.9 m (-33.3)
- US Commercial segment net revenues of SEK 131.0 m (140.4), in local currency USD 12.6 m (13.0)
- Cash flow from operating activities of SEK -13.4 m (-21.9), cash and cash equivalents of SEK 114.9 m (184.2)
- Earnings per share before and after dilution amounted to SEK -1.21 (-0.97)
- Orexo AB´s sustainability work ranked among the top five percent of all 70,000 businesses worldwide reviewed by EcoVadis
- For OX124, our 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 as well as further information from a new human factors study (HF study). A new HF study was successfully conducted in July.
- The financial guidance for 2024 reiterated.

Important events after the end of the period

- An exploratory phase 1 clinical study was initiated for OX640 in participants with allergic rhinitis.

Group net revenues

137 SEK M

Group EBITDA

-1 SEK M

Cash and cash equivalents

115 SEK M

SDG 3.5 net revenue ratio

96%

SEK m unless otherwise stated	2024 Jul-Sep	2023 Jul-Sep	2024 Jan-Sep	2023 Jan-Sep	2023 Jan-Dec
Net revenues	136.5	156.1	429.7	472.8	638.8
Cost of goods sold	-20.1	-22.8	-49.7	-68.8	-88.9
Operating expenses	-138.1	-161.9	-422.3	-505.0	-659.5
EBIT	-21.7	-28.6	-42.2	-100.9	-109.5
EBIT margin	-15.9%	-18.4%	-9.8%	-21.3%	-17.1%
EBITDA	-0.7	-9.5	20.2	-44.8	-32.5
Earnings per share, before dilution, SEK	-1.21	-0.97	-2.51	-3.19	-3.73
Earnings per share, after dilution, SEK	-1.21	-0.97	-2.51	-3.19	-3.73
Cash flow from operating activities	-13.4	-21.9	-38.8	-92.4	-95.0
Cash and cash equivalents	114.9	184.2	114.9	184.2	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 world-class, powder-based drug delivery technology, enabling outstanding bioavailability 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 molecules

Contact persons quarterly report

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Presentation

On October 24, 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=50048738

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-q3-report-2024

Prior to the call, presentation material will be available on the website under Investors/ Rapport archive

Financial calendar

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

A quarter of setbacks and achievements

CEO Comments in brief

The third quarter has been challenging, starting with the delay of OX124's approval and, from a financial perspective, we had a marginally negative EBITDA. This negative EBITDA result was primarily due to higher legal costs, retrospective adjustments of the Abstral® royalties and lower Zubsolv® sales. The development was partly compensated by a 15 percent drop in expenses. Zubsolv prescription volumes in the US are stable, but sales were negatively impacted by a reduction in inventory levels at wholesalers and a weakening USD.

Looking beyond the third quarter, I am pleased to see Zubsolv sales continuing to show stable demand and growth in some segments. We remain optimistic that we can get OX124, our high dose rescue medication for opioid overdose, approved and expand treatment alternatives for patients suffering from opioid use disorder. In the quarter we made progress in our business development efforts, attracting new companies to leverage our AmorphOX® technology, and we continue to see interest in OX640. Also, there are signs that we are making some progress to resolve the legal disputes in the US.

Stable Zubsolv demand

Zubsolv demand in terms of volume is stable in the quarter. However, as experienced at the beginning of the year, we have seen increased volatility in wholesaler inventories impacting sales negatively in individual quarters. The overall market growth has improved slightly to about 5 percent, primarily driven by double-digit growth in the Commercial segment, whereas Medicaid continues the negative trend seen since the middle of last year.

The Commercial segment is the most important for Zubsolv sales, and growth in the Commercial segment is likely to have a positive impact on sales and margins over time. In the third quarter, the Zubsolv net sales grew in the Commercial segment also when including United Health Group and Humana. The net sales growth in Commercial to a large extent mitigates the decline in the Public segment. The decline in the Public segment is primarily explained by increased rebates in Medicare and Medicaid.

Despite the delay in approval of OX124, the US team has continued to prepare for the launch and worked with multiple possible customer groups to further understand the potential value proposition of OX124. These learnings appear especially useful among patients who need multiple 4 mg doses to be revived. This is often required if a person has overdosed on illicitly manufactured fentanyl, which has an alarming prevalence in the US today. In addition, OX124 can play an important role in regions with cold winters as the data demonstrates it is resistant to freezing temperatures due to the AmorphOX® technology.

The EBIT contribution declined from our US operations due to lower sales and is expected to recover in the fourth quarter. The topline change is primarily explained by inventory fluctuations, adjustments in sales to institutions and also due to FX impacts. Costs in the US business have shown a minor decline comparing to last year. However, the EBIT contribution was negatively impacted by increasing non-repeating legal costs associated with the work to resolve the Subpoena investigation (for more information see Note 4).

FDA review causes further delay to OX124

As communicated in the Q2 report, approval of OX124 will be delayed. This is caused by the FDA's concerns with the results of the human factors study (HF study) and insufficient technical documentation of the final commercial product related to the device. During the quarter we have extensively reviewed the request from the FDA and submitted a briefing book to the FDA with a proposal on how to address their comments. Regarding the HF study, we have successfully updated the instructions for use and completed a new HF study with good results. We expect a final agreement with FDA on their data requirements during November, which will guide the timeline for approval. Unfortunately, it is evident that the resubmission of the data will be delayed into the middle of next year, provided the FDA agrees with the proposal and our suppliers and manufacturing partners can deliver according to the plan. The final timeline for approval of OX124 will be a result of the FDA's review time, which will be communicated after the data submission is complete.

> **OX124: We expect a final agreement with FDA on their data requirements during November, which will guide the timeline for approval.**

R&D pipeline advancing

We have continued to explore the ability for AmorphOX®, our powder-based drug delivery platform, to improve the drug delivery of larger molecules and have, during the quarter, generated additional data supporting longer term stability in protein-based pharmaceuticals. AmorphOX, can potentially address the issues seen with many biomolecules needing a cold chain, use of problematic ingredients to keep the product stable and high cost of goods. With AmorphOX, we can potentially open up for nasal delivery of many molecules that are currently delivered through injections. We are starting feasibility and proof of concept studies with several new partners, but they are still in early development and will need to pass proof of concept before starting a comprehensive development program. Most partnerships will cover part of Orexo's development costs, but our ambition is a business model where Orexo participates in the upside from commercialization through royalties.

Our discussions with potential partners for OX640 continue, and to strengthen the product profile we initiated a smaller exploratory study of OX640 in October. This study will improve our evidence of the impact on bioavailability of epinephrine in OX640 in patients with allergic rhinitis when comparing OX640 to an injectable in participants without allergic rhinitis. This is a question raised in several of the business development discussions and we know this data will be an important contribution to the overall business case for OX640. The result of the study is expected at the beginning of 2025.

Summary and outlook

Due to non-recurring events, we have a temporarily negative EBITDA. However, we expect Zubsolv® sales in the fourth quarter to increase compared to this quarter. Looking into 2025 we are working with the board to identify opportunities to improve the financial results and to strengthen the equity of the company. We are making progress in business development around our AmorphOX platform and pipeline products and in addition to continued stabilization of Zubsolv sales, we are thereby confident we can strengthen our financial results in 2025.

> **Looking into 2025 we are working with the board to identify opportunities to improve the financial results and to strengthen the equity of the company.**

A positive resolution of the legal processes, and particularly the patent litigation with Sun, is a condition to fully assess the value of our US business. When this process is concluded, we will need to define the best strategy to ensure our commercial opioid use disorder products and pipeline have a platform to thrive and reach as many patients as possible. In addition, our AmorphOX platform and its main potential is increasingly with partnerships outside our core commercial disease focus, which creates a natural need to assess the strategic options for the company.

Uppsala, Sweden, October 24, 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] Latest available data is showing predicted number of fatal opioid overdoses of more than 75,000 annually.[4] Nine out of ten opioid overdoses involve synthetic illicitly manufactured opioids.[5] Additionally adulterants, such as xylazine a veterinary tranquilizer are being mixed in with the illicit fentanyl and is being identifed in more drug tests across the US, adding complications to rescue situations and possible treatment regimens.

In Q3, the buprenorphine/naloxone market grew 1 percent versus Q2 2024 and market growth has developed positively since the first half of 2024 and now reaches 5 percent versus Q3 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 physicians can treat with MAT. Also, the requirements for prescribing MAT have been reduced and now all physicians 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 6 percent vs Q3 2023, while the Commercial segment increased 22 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 Q3 2024 versus Q2 2024 and declined 1 percent versus Q3 2023. The decline versus Q3 2023 is primarily driven by lower volumes with United Health Group and Humana, where Zubsolv previously had been the only buprenorphine/naloxone product on their formulary. This segment, however, is stabilizing and has declined only 1 percent in prescriptions versus Q2 2024.

Within the Commercial segment, Zubsolv grew 2 percent versus last year and remained stable versus Q2 2024 even when including United Health Group and Humana Commercial.

For the Public segment and thanks to improved market access formulary status earlier in 2024 in Medicaid, Zubsolv volume grew 1 percent versus Q2 2024, while the market declined 1 percent. In Medicaid, Zubsolv declined less than the market versus Q3 2023, with a 1 percent Zubsolv decline and 6 percent market decline. This was supported by New York Medicaid, which grew 8 percent versus Q3 2023, and Indiana, which grew 75 percent versus Q3 2023.

Zubsolv's best in class market access in the commercial payer segment is maintained at 98 percent and Zubsolv's public payer segment access maintained at 51 percent. With most of the reimbursement formularies published for 2025, there is no change expected to Zubsolv market access next year.

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 MAT plan for OUD, directed by a clinician.

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.[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' abilities to commercialize digital mental health programs. Center for Medicaid Services has during the quarter published a proposal for reimbursement of digital health products, the final policy and reimbursement level is not public and will be critical for the entire digital health industry. When the final policy is published, we will assess the opportunities for our digital mental health programs to comply with the requirements in collaboration with our partner GAIA.

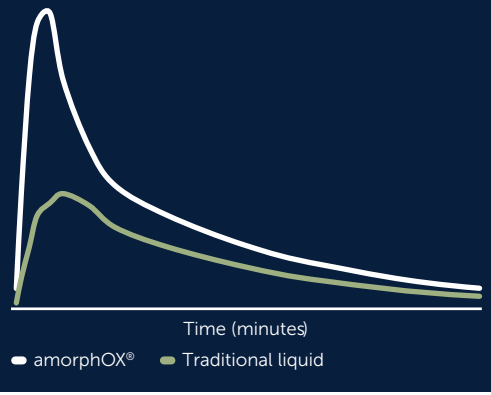
An efficient reimbursement and distribution system is crucial for Orexo to reach its full potential with the digital programs, and the company is actively working with authorities, insurance companies and other stakeholders to accelerate the creation of an efficient system that benefits patients and 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.

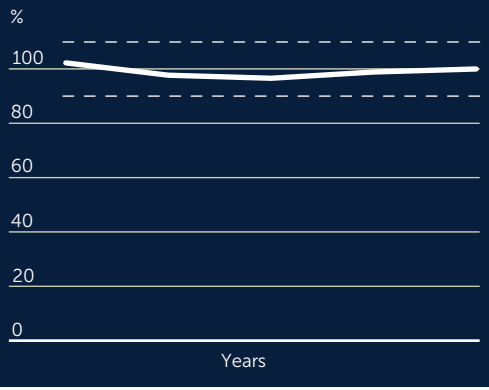
Clinically validated

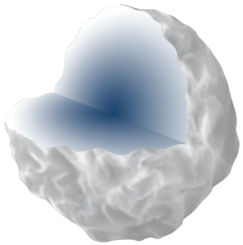
AmorphOX has successfully been validated in multiple clinical studies during the development of nasal rescue medications for opioid overdoses, one including naloxone (OX124) and one with nalmefene (OX125). In addition, it has also been clinically proven with epinephrine (OX640), a product for acute treatment 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 – an intranasal rescue medication for opioid overdose with a high dose of powder-based 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 and fentanyl analogues.

The final formulation of OX124 has shown significantly faster absorption and substantially higher plasma concentrations of naloxone compared to the reference intramuscular injection. In a cross-study comparison to the current market leader, OX124 shows substantially higher peak plasma concentrations and total exposure of naloxone. These properties can be critical in avoiding brain damage and saving lives as well as preventing renarcotization during the revival process. In addition, the AmorphOX technology, inherent to OX124, enables improved stability of the active substance and reduces its sensitivity to temperature changes.

OX124 is protected by patents until 2039.

Developments during the quarter

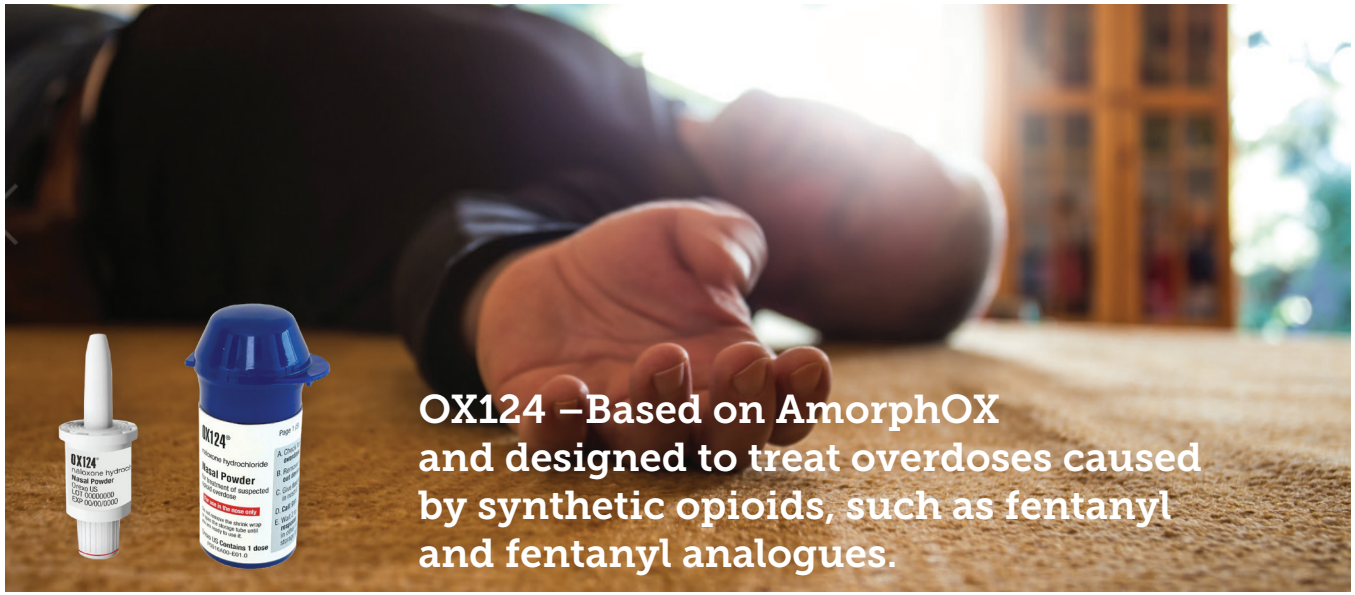
In the beginning of the quarter, a complete response letter (CRL) was received from the FDA regarding the New Drug Application (NDA) submitted in September 2023. The CRL indicated the need for an additional human factors (HF) study, which was in line with previous communication. Furthermore, additional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

After receiving FDA comments on the instructions for use (IFU) in early April 2024, Orexo quickly initiated a new HF study and successfully completed it in early July. In Q3, Orexo conducted an in-depth analysis of the FDA's request for additional technical data related to the drug-device combination from commercial scale manufacturing of the final product. The technical data previously submitted to the FDA was from pilot scale manufacturing and had been bridged to show commercial scale data, a standard approach in the pharmaceutical industry. To meet the agency's request for additional data, the decision has been made to test the final product at commercial scale, which requires preparation and documentation involving external parties. In Q3, Orexo compiled a briefing book outlining the process to produce the additional requested data and has submitted it to the FDA. Feedback is expected in an upcoming meeting with the agency. The outcome will determine the details of the NDA resubmission.

Market and commercialization

OX124 is expected to play an important role with those administering multiple doses of 4 mg intranasal naloxone, where synthetic opioids (especially illicitly manufactured fentanyl) are suspected. Furthermore, an area of potential exists in colder climates with freezing temperatures where the product is stored outside because the powder naloxone formulation has reduced sensitivity to temperature changes and does not freeze.

Upon approval, OX124 will meet an increased need for a high-dose naloxone overdose rescue medication given that most opioid overdoses are caused by strong synthetic opioids, such as illicitly manufactured fentanyl and fentanyl analogues. Latest available data is showing predicted number



of fatal opioid overdoses of more than 75,000 annually.[9] Nine out of ten opioid overdoses involves synthetic opioids.[10]

Driven by the need to increase access to overdose medication, low-dose naloxone 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 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. Orexo will establish financial patient support programs for OX124 to ensure affordability for the most financially vulnerable patients.

OX125 – an intranasal rescue medication for opioid overdose with powder-based 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 rooms. 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 naloxone's of one to two hours.

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.

OX125 is protected by patents until 2039.

Developments during the quarter

Activities during the quarter were kept at a low level. If the project is accelerated, the remaining time for development will be relatively short given the synergies between OX124 and OX125 are significant in terms of development and product supply.

OX640 – an intranasal rescue medication for allergic reactions with powder-based epinephrine

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

Progress was made according to plan in relation to the explorative phase 1 clinical study in subjects experiencing allergic rhinitis that was initiated after the end of the quarter. 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, no impact on the overall development plan and feasibility of OX640 from the study are expected.

OX640 continues to show excellent results in ongoing stability studies. Latest data shows that the dose of epinephrine in OX640 is unchanged after storage for 24 months in high temperature conditions (40°C/75% RH).

This is in stark contrast to other epinephrine products that may experience a decrease in epinephrine dose of more than 30 percent already after 12 months when stored in the same conditions. Preparations for scaling up manufacturing activities continued.

In the quarter, the US and EU regulatory authorities approved the first nasal drug product for the treatment of allergic reactions, including anaphylaxis. The announcement marks a potentially major shift in the market, with nasal products replacing auto-injectors as the current standard of care.

In parallel, discussions continued with potential partners for further development and commercialization.

OX640 is protected by patents until 2044.

Early stage projects

A core strategy to expand the use of the technology is to test AmorphOX® in combination with molecules controlled by other companies, both large pharmaceutical companies and smaller fully research-oriented businesses, with the aim of developing new improved medicines or collecting important data based on the technology.

The exploratory feasibility studies conducted along with external parties, such as Sobi, have progressed as planned during the quarter and we have seen excellent results in the ability of AmorphOX to retain activity in biomolecules. The ambition is to advance these exploratory collaborations to partnerships 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 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 AB´s sustainability work was ranked among the top five percent of all 70,000 businesses worldwide reviewed by EcoVadis. In preparation for the implementation of the CSRD directive, the implementation of the double materiality analysis was initiated. In addition, it was decided to start work on the certification of the laboratory operations through My Green Lab, and a working group was appointed that will be responsible for the certification.

Financial development

Revenues

Total revenues amounted to SEK 136.5 m (156.1) for Q3. The decrease is explained by lower revenues in both segments i.e. US Commercial and HQ & Pipeline. For the first nine months total revenues amounted to SEK 429.7 m (472.8).

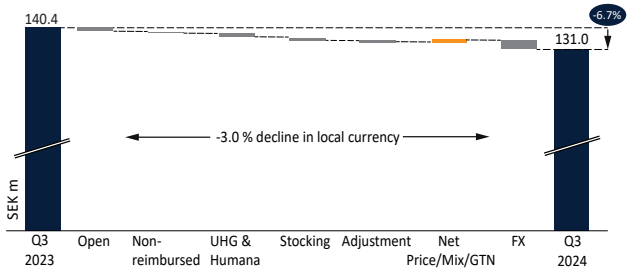
Revenues by segment

US Commercial revenues amounted to SEK 131.0 m (140.4) for Q3. The decrease is mainly driven by product sales of Zubsolv® in the US, primarily as a result of lower demand in the Open segment, where the public payer segment showed a decline which was not fully compensated by the growth in the commercial payer segment. A reduction in wholesaler inventories and a negative FX impact of SEK 5.1 m also contributed to the decline in sales, which was partly offset by a favorable payer mix. US Commercial revenues amounted to SEK 408.2 m (426.3) for the first nine months.

In local currency US Commercial net revenues for Q3 amounted to USD 12.6 m (13.0) and for the first nine months to USD 38.9 m (40.2).

HQ & Pipeline partner product related revenues for Q3 amounted to SEK 5.5 m (15.7). The decrease is mainly explained by lower Abstral ROW royalties coming from a retroactive adjustment of Q3 2023 and Q4 2023 royalties due to adjustments in partner reported royalties. Lower Zubsolv ex-US revenues are explained by lower sales of tablets to Orexo's partner Accord Healthcare partly offset by higher royalties from higher partner revenues. HQ & Pipeline partner product related revenues amounted to SEK 21.5 m (46.4) for the first nine months.

ZUBSOLV US NET REVENUES DEVELOPMENT



Cost of goods sold

Cost of goods sold (COGS) amounted to SEK 20.1 m (22.8) for Q3. US Commercial amounted to SEK 17.8 m (19.1), the decrease is mainly explained by favorable production costs for Zubsolv US partly offset by higher technical infrastructure costs for Digital Mental Health Programs (DMHP). HQ & Pipeline amounted to SEK 2.3 m (3.7) where the decrease is due to lower sales of Zubsolv ex-US tablets to Orexo's partner Accord Healthcare. Cost of goods sold (COGS) amounted to SEK 49.7 m (68.8) for the first nine months.

Operating expenses

Selling expenses amounted to SEK 47.2 m (44.7) for Q3. 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 142.8 m (138.7) for the first nine months.

Administrative expenses amounted to SEK 32.2 m (45.4) for Q3. The decrease is mainly explained by lower spending on DMHP programs partly offset by higher legal expenses for DOJ investigation in US Commercial and lower costs for long term incentive programs following a lower share price. Administrative expenses amounted to SEK 109.3 m (150.1) for the first nine months.

NET REVENUES AND EBIT PER SEGMENT

SEK m	Net Revenues					EBIT				
	2024 Jul-Sep	2023 Jul-Sep	2024 Jan-Sep	2023 Jan-Sep	2023 Jan-Dec	2024 Jul-Sep	2023 Jul-Sep	2024 Jan-Sep	2023 Jan-Sep	2023 Jan-Dec
Zubsolv US product sales	131.0	140.4	408.2	426.3	577.7	–	–	–	–	–
Digital Mental Health Programs (DMHP) product sales	–	–	–	0.1	0.1	–	–	–	–	–
US Commercial – total	**131.0**	**140.4**	**408.2**	**426.3**	**577.7**	**25.3**	**30.7**	**93.3**	**106.0**	**152.3**
Abstral® royalty	-1.4	7.7	7.0	21.9	31.9	–	–	–	–	–
Edluar® royalty	3.0	3.5	9.0	8.8	10.8	–	–	–	–	–
Zubsolv – ex-US	3.8	4.5	5.5	15.6	18.4	–	–	–	–	–
HQ & Pipeline – total	**5.5**	**15.7**	**21.5**	**46.4**	**61.1**	**-47.0**	**-59.3**	**-135.5**	**-206.9**	**-261.8**
Total	**136.5**	**156.1**	**429.7**	**472.8**	**638.8**	**-21.7**	**-28.6**	**-42.2**	**-100.9**	**-109.5**

Research and development costs amounted to SEK 56.2 m (83.7) for Q3. The decrease is mainly explained by lower costs for OX124, lower internal costs in HQ & Pipeline and lower spending on DMHP programs. Research and development costs amounted to SEK 177.1 m (237.7) for the first nine months.

Other operating income and expenses amounted to SEK -2.5 m (11.9) for Q3. This is mainly explained by exchange-rate losses of SEK -5.3 m (0.7) derived from revaluations of parent company balance sheet items in foreign currency, predominantly in USD, lower received insurance reimbursement of SEK 2.6 m (7.3) and absence of partner reimbursement of R&D costs of SEK 0.0 m (3.0). Other operating income and expenses amounted to SEK 7.0 m (21.5) for the first nine months.

Operating profit

EBITDA amounted to SEK -0.7 m (-9.5) for Q3 and to SEK 20.2 m (-44.8) for the first nine months.

The EBITDA contribution from US Commercial amounted to SEK 36.1 m (42.1) for Q3, and to SEK 125.7 m (138.8) for the first nine months.

Total EBIT amounted to SEK -21.7 m (-28.6) for Q3 and the improvement is mainly explained by 15 percent lower operating expenses partly offset by lower gross profit.

Total EBIT amounted to SEK -42.2 m (-100.9) for the first nine months.

EBIT contribution from US Commercial amounted to SEK 25.3 m (30.7) for Q3, equal to an EBIT margin of 19.3 percent (21.9). EBIT contribution from US Commercial amounted to SEK 93.3 m (106.0) for the first nine months, equal to an EBIT margin of 22.9 percent (24.8).

Net financial items and tax

Net financial items for Q3 amounted to SEK -15.4 m (-7.9) and is mainly explained by higher bond loan costs of SEK -13.4 m (-9.7), negative unrealized exchange rate impact of SEK -2.9 m (0.8) derived from the parent company's foreign currency bank accounts mainly in USD and lower interest income from bank accounts of SEK 0.9 m (1.3). Net financial items amounted to SEK -42.0 m (-19.9) for the first nine months..

Total tax expenses amounted to SEK -4.8 m (3.3) for Q3. The increase is explained by negative adjustment of SEK -3.6 m (4.5) to deferred tax assets related to temporary differences. Total tax expenses amounted to SEK -2.5 m (11.1) for the first nine months. 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 -41.9 m (-33.3) for Q3 and to SEK 86.7 m (-109.7) for the first nine months.

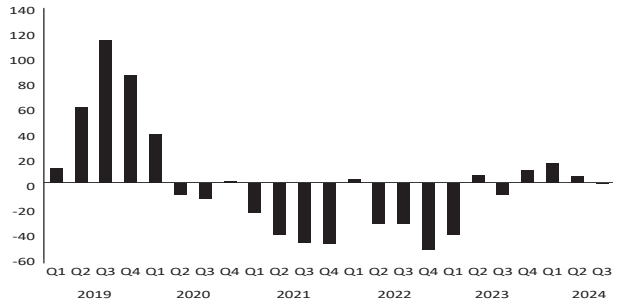
Cash and cash flow

Cash flow from operating activities amounted to SEK -13.4 m (-21.9) for Q3 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 -38.8 m (-92.4) for the first nine months.

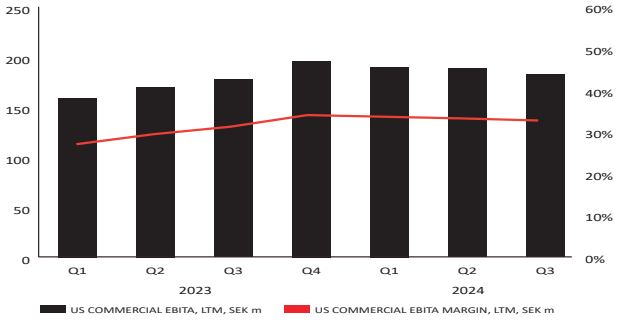
The transaction for the senior secured callable floating rate social bonds of SEK 500 m at 3 months STIBOR + 650 basis points per annum was fully recognized in the accounts in Q2. As of September 30, 2024 Orexo owns bonds of SEK 30.0 m (48.8).

As of September 30, 2024, cash and cash equivalents amounted to SEK 114.9 m (184.2) and interest-bearing liabilities to SEK 459.3 m (447.8), i.e. a negative net cash position of SEK -344.4 m (-263.6). Cash and cash equivalents were decreased by SEK 24.8 m from Q2 2024.

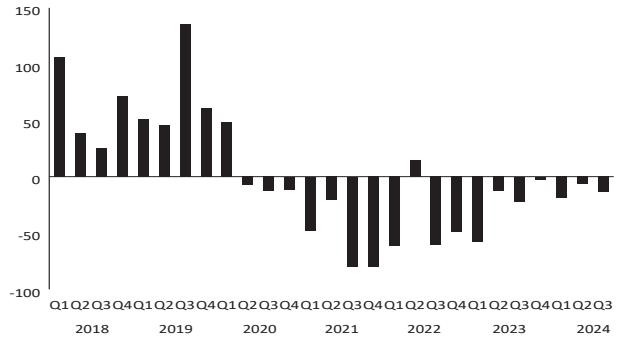
GROUP EBITDA, SEK m



US COMMERCIAL EBITDA MARGIN AND EBITDA (LTM[11], SEK m)



CASH FLOW FROM OPERATING ACTIVITIES, SEK m



Investments

Gross investments in tangible and intangible fixed assets amounted to SEK 0.0 m (6.7) for Q3 and to SEK 3.8 m (18.3) for the first nine months. Lower investments are mainly explained by investments in equipment for the development organization.

Equity

Shareholders' equity on September 30, 2024, was SEK -27.2 m (92.0). The equity/asset ratio was -3.9 percent (10.6).

Parent company

Net revenues for Q3 amounted to SEK 63.1 m (122.0) of which SEK 57.6 m (106.3) was related to sales to Group companies. Net revenues amounted to SEK 269.4 m (379.9) for the first nine months of which SEK 247.9 m (332.9) was related to sales to Group companies.

Earnings before tax amounted to SEK -57.5 m (-17.8) for Q3. The development is mainly explained by lower gross profit and negative net financial items partly offset by lower operating expenses. Earnings before tax SEK -88.4 m (-55.7) for the first nine months.

Investments in equipment for the development organization for Q3 amounted to SEK 0.0 m (6.7) and to SEK 3.8 m (17.6) for the first nine months.

As of September 30, 2024, cash and cash equivalents in the parent company amounted to SEK 76.5 m (140.7).

Parent company shareholders' equity at September 30, 2024, was SEK 73.6 m (53.4). 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.

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 October 2024. However, there is an increased risk in the Zubsolv net sales guidance due to inventory adjustment among the wholesalers, which affects the entire market. 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.

Going concern update

Third quarter net results add pressure on the financial position. However, the board's assessment is that substantial values is not reflected in the company's balance sheet and even considering the potential losses for the upcoming twelve months period, the equity situation in the parent company is not assessed to lead to an uncertainty about going concern.

The group has sufficient funds for continued operations for at least the next twelve months and the interim report is prepared on the assumption of going concern.

Glossary

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

Uppsala, Sweden, October 24, 2024

Nikolaj Sørensen
President and CEO

Review report

Orexo AB, corporate identity number 556500-0600

Introduction

We have reviewed the condensed interim report for Orexo AB as at September 30, 2024 and for the nine months period then ended. The Board of Directors and the Managing Director are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of review

We conducted our review in accordance with the International Standard on Review Engagements, ISRE 2410 Review of Interim Financial Statements Performed by the Independent Auditor of the Entity. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and other generally accepted auditing standards in Sweden. The procedures performed in a review do not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material respects, in accordance with IAS 34 and the Swedish Annual Accounts Act regarding the Group, and in accordance with the Swedish Annual Accounts Act regarding the Parent Company.

Stockholm, October 24, 2024

Ernst & Young AB

Oskar Wall
Authorized Public Accountant

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, Last Twelve Months

Financial reports, notes and key figures

CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS

SEK m	Notes	2024 Jul-Sep	2023 Jul-Sep	2024 Jan-Sep	2023 Jan-Sep	2023 Jan-Dec
Net revenues	9	136.5	156.1	429.7	472.8	638.8
Cost of goods sold		-20.1	-22.8	-49.7	-68.8	-88.9
Gross profit		**116.4**	**133.3**	**380.1**	**404.1**	**550.0**
Selling expenses		-47.2	-44.7	-142.8	-138.7	-181.5
Administrative expenses		-32.2	-45.4	-109.3	-150.1	-188.0
Research and development expenses		-56.2	-83.7	-177.1	-237.7	-303.1
Other operating income and expenses		-2.5	11.9	7.0	21.5	13.3
Operating earnings (EBIT)		**-21.7**	**-28.6**	**-42.2**	**-100.9**	**-109.5**
Net financial items		-15.4	-7.9	-42.0	-19.9	-30.8
Earnings before tax		**-37.1**	**-36.6**	**-84.2**	**-120.8**	**-140.3**
Tax	5	-4.8	3.3	-2.5	11.1	12.0
Net earnings for the period		**-41.9**	**-33.3**	**-86.7**	**-109.7**	**-128.3**
Earnings per share, before dilution, SEK		-1.21	-0.97	-2.51	-3.19	-3.73
Earnings per share, after dilution, SEK		-1.21	-0.97	-2.51	-3.19	-3.73

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

SEK m	2024 Jul-Sep	2023 Jul-Sep	2024 Jan-Sep	2023 Jan-Sep	2023 Jan-Dec
Earnings for the period	**-41.9**	**-33.3**	**-86.7**	**-109.7**	**-128.3**
Other comprehensive income	—	—	—	—	—
Items that may subsequently be reversed to the statement of operations:					
Exchange-rate differences	-9.3	8.0	0.6	7.1	-6.8
Other comprehensive earnings for the period. net after tax	**-9.3**	**8.0**	**0.6**	**7.1**	**-6.8**
Total comprehensive earnings for the period [1]	**-51.2**	**-25.3**	**-86.1**	**-102.6**	**-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 Sep 30	2023 Sep 30	2023 Dec 31
ASSETS				
Fixed assets				
Tangible fixed assets		68.8	85.4	81.0
Intangible fixed assets		142.6	186.4	173.3
Right-of-use assets		20.8	29.1	24.5
Deferred tax assets	5	48.9	49.2	48.1
Other financial assets		1.5	0.8	0.8
Total fixed assets		**282.6**	**350.9**	**327.7**
Current assets				
Inventories		54.3	64.6	42.4
Accounts receivable and other receivables		245.2	269.3	245.5
Cash and cash equivalents		114.9	184.2	171.0
Total current assets		**414.4**	**518.1**	**458.9**
Total assets		**697.0**	**869.0**	**786.6**
SHAREHOLDERS' EQUITY AND LIABILITIES				
Total shareholders' equity		**-27.2**	**92.0**	**58.9**
Long-term liabilities				
Provisions		13.5	10.0	11.5
Long-term liabilities, interest bearing		459.3	447.8	448.4
Lease liabilities, long-term		7.2	9.6	4.5
Total long-term liabilities		**480.0**	**467.3**	**464.5**
Current liabilities and provisions				
Provisions		116.8	131.4	133.1
Current liabilities, non-interest bearing		114.5	157.0	109.2
Lease liabilities, current		12.9	21.3	20.9
Total current liabilities and provisions		**244.3**	**309.7**	**263.2**
Total liabilities		**724.3**	**777.0**	**727.7**
Total shareholders' equity and liabilities		**697.0**	**869.0**	**786.6**

CONDENSED CONSOLIDATED CHANGES IN SHAREHOLDERS' EQUITY

SEK m	2024 Sep 30	2023 Sep 30	2023 Dec 31
Opening balance, shareholders' equity	**58.9**	**193.9**	**193.9**
Total comprehensive earnings for the period	-86.1	-102.6	-135.1
Share-based payments	—	-0.7	—
Closing balance, shareholders' equity	**-27.2**	**92.0**	**58.9**

CONDENSED CONSOLIDATED CASH FLOW STATEMENTS

SEK m	Notes	2024 Jul-Sep	2023 Jul-Sep	2024 Jan-Sep	2023 Jan-Sep	2023 Jan-Dec
Operating earnings (EBIT)		-21.8	-28.6	-42.3	-100.9	-109.5
Interest received		0.8	1.2	3.4	4.1	7.7
Interest paid		-13.7	-10.1	-47.7	-27.1	-37.6
Income taxes paid		0.1	-0.4	-1.5	-1.2	-1.6
Adjustment for non-cash items	3	12.9	11.9	49.2	56.7	99.8
Cash flow from operating activities before changes in working capital		**-21.8**	**-26.0**	**-38.9**	**-68.4**	**-41.2**
Changes in working capital		**8.4**	**4.1**	**0.1**	**-24.0**	**-53.8**
Cash flow from operating activities		**-13.4**	**-21.9**	**-38.8**	**-92.4**	**-95.0**
Acquisition of tangible and intangible fixed assets		—	-6.7	-3.8	-18.3	-19.2
Acquisition of short-term investments		—	0.1	—	0.1	0.1
Disposal of short-term investments		-0.7	0.0	-0.7	219.9	219.9
Cash flow from investing activities		**-0.7**	**-6.6**	**-4.5**	**201.7**	**200.8**
Amortization of lease liability		-5.9	0.0	-17.1	0.0	-21.4
Change of repurchased part in bond		0.0	-39.1	6.5	-64.6	-48.7
Cash from financing activities		**-5.9**	**-39.1**	**-10.6**	**-64.6**	**-70.1**
Cash flow for the period		**-20.0**	**-67.6**	**-54.0**	**44.7**	**35.7**
Cash and cash equivalents at the beginning of the period		**139.7**	**251.1**	**171.0**	**132.2**	**132.2**
Exchange-rate differences in cash and cash equivalents		-4.7	0.7	-2.1	7.2	3.1
Changes in cash and cash equivalents		-24.8	-66.9	-56.1	52.0	38.8
Cash and cash equivalents at the end of the period		**114.9**	**184.2**	**114.9**	**184.2**	**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 Jul-Sep	2023 Jul-Sep	2024 Jan-Sep	2023 Jan-Sep	2023 Jan-Dec
EBIT margin, %	-15.9	-18.4	-9.8	-21.3	-17.1
Return on shareholder equity, %	2,764.4	-30.9	-547.8	-76.7	-101.5
Net debt, SEK m	344.4	263.6	344.4	263.6	277.4
Debt/equity ratio, %	-1,688.5	486.8	-1,688.5	486.8	761.3
Equity/assets ratio, %	-3.9	10.6	-3.9	10.6	7.5
Number of shares, before dilution	34,505,226	34,420,649	34,477,143	34,392,914	34,413,408
Number of shares, after dilution	34,505,226	34,420,649	34,477,143	34,392,914	34,413,408
Earnings per share, before dilution, SEK	-1.21	-0.97	-2.51	-3.19	-3.73
Earnings per share, after dilution, SEK	-1.21	-0.97	-2.51	-3.19	-3.73
Number of employees at the end of the period	113	118	113	118	116
Shareholders' equity, SEK m	-27.2	92.0	-27.2	92.0	58.9
Capital employed, SEK m	432.0	539.8	432.0	539.8	507.3
Working capital, SEK m	55.2	24.2	55.2	24.2	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 Jul-Sep	2023 Jul-Sep	2024 Jan-Sep	2023 Jan-Sep	2023 Jan-Dec
Net revenues		63.1	122.0	269.4	379.9	494.0
Cost of goods sold		-17.6	-22.4	-52.9	-73.7	-93.7
Gross profit		**45.5**	**99.6**	**216.5**	**306.2**	**400.3**
Selling expenses		-29.6	-33.2	-85.3	-95.4	-119.4
Administrative expenses		-9.8	-16.1	-40.9	-76.7	-94.9
Research and development costs		-44.1	-68.7	-138.6	-192.9	-243.7
Other operating income and expenses		-5.2	8.1	0.0	22.3	17.1
Operating earnings (EBIT)		**-43.2**	**-10.3**	**-48.3**	**-36.4**	**-40.6**
Interest income and expenses		-10.6	-8.7	-30.6	-23.4	-31.3
Other financial income and expenses		-3.7	1.2	-9.5	4.1	1.5
Net financial items		**-14.3**	**-7.5**	**-40.1**	**-19.3**	**-29.8**
Earnings before tax		**-57.5**	**-17.8**	**-88.4**	**-55.7**	**-70.4**
Tax	5	—	—	—	—	—
Earnings for the period		**-57.5**	**-17.8**	**-88.4**	**-55.7**	**-70.4**

PARENT COMPANY STATEMENT OF COMPREHENSIVE INCOME

SEK m	2024 Jul-Sep	2023 Jul-Sep	2024 Jan-Sep	2023 Jan-Sep	2023 Jan-Dec
Earnings for the period	**-57.5**	**-17.8**	**-88.4**	**-55.7**	**-70.4**
Other comprehensive income	—	—	—	—	—
Total comprehensive earnings for the period	**-57.5**	**-17.8**	**-88.4**	**-55.7**	**-70.4**

CONDENSED PARENT COMPANY BALANCE SHEET

SEK m	2024 Sep 30	2023 Sep 30	2023 Dec 31
ASSETS			
Fixed assets			
Intangible fixed assets	124.4	155.9	147.7
Tangible fixed assets	68.8	85.4	81.0
Shares in subsidiaries	287.7	162.4	286.2
Total fixed assets	**480.9**	**403.6**	**515.0**
Current assets			
Inventories	30.9	33.9	25.6
Accounts receivable and other receivables	48.6	53.7	52.8
Receivables from Group companies	90.1	76.7	71.0
Cash and cash equivalents	76.5	140.7	145.5
Total current assets	**246.1**	**305.0**	**294.9**
Total assets	**727.1**	**708.7**	**809.8**
SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES			
Total shareholders' equity	**73.6**	**53.4**	**162.1**
Long-term liabilities			
Provisions	12.7	9.3	10.8
Bond loan	459.3	447.8	448.4
Total long-term liabilities	**472.0**	**457.1**	**459.3**
Current liabilities			
Accounts payable	9.6	15.3	10.3
Other liabilities	8.5	12.3	8.6
Liabilities to Group companies	144.7	144.7	144.7
Accrued expenses and deferred income	18.7	25.8	24.9
Total current liabilities	**181.5**	**198.1**	**188.4**
Total liabilities	**653.5**	**655.2**	**647.7**
Total shareholders' equity and liabilities	**727.1**	**708.7**	**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®.

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 Jul-Sep	2023 Jul-Sep	2024 Jan-Sep	2023 Jan-Sep	2023 Jan-Dec
US Commercial					
Net revenues	131.0	140.4	408.2	426.4	577.7
Operating earnings (EBIT)	25.3	30.7	93.3	106.0	152.3
Depreciation and amortization	-10.8	-11.4	-32.4	-32.9	-43.7
EBITDA	36.1	42.1	125.7	138.8	196.0
HQ & Pipeline					
Net revenues	5.5	15.7	21.5	46.4	61.1
Operating earnings (EBIT)	-47.0	-59.3	-135.5	-206.9	-261.8
Depreciation and amortization	-10.2	-7.8	-30.0	-23.2	-33.3
EBITDA	-36.8	-51.6	-105.5	-183.7	-228.4
Group					
Net revenues	136.5	156.1	429.7	472.8	638.8
Operating earnings (EBIT)	-21.7	-28.6	-42.2	-100.9	-109.5
Depreciation and amortization	-21.0	-19.2	-62.4	-56.1	-77.0
EBITDA	-0.7	-9.5	20.2	-44.8	-32.5
Net financial items	-15.4	-7.9	-42.0	-19.9	-30.8
Earnings before tax	-37.1	-36.6	-84.2	-120.8	-140.3

3. Cash flow

ADJUSTMENT FOR NON-CASH ITEMS

SEK m	2024 Jul-Sep	2023 Jul-Sep	2024 Jan-Sep	2023 Jan-Sep	2023 Jan-Dec
Depreciation/amortization and impairment	21.0	19.2	62.4	56.1	77.0
Realization results	—	—	—	—	0.0
Change in provisions	-13.6	-6.6	-15.6	4.1	18.2
Share based payments	—	0.0	—	0.0	0.0
Other non cash items	0.2	0.0	0.5	3.1	3.1
Exchange rate income and expenses	5.3	-0.7	1.8	-6.5	1.4
Total	**12.9**	**11.9**	**49.2**	**56.7**	**99.8**

4. Disputes

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. Next step in the process is for the court to schedule a date for an oral hearing, which has so far not been done. Although this scheduling is outside Orexo's control, the company expects the oral hearing to be held no later than mid 2025.

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 have been no significant related parties transactions with related parties during the period other than sales of goods between Orexo AB and Orexo Inc and remuneration to the board, president and senior executives.

8. Important events after the end of the period

› An exploratory phase 1 clinical study was initiated for OX640 in participants with allergic rhinitis.

9. Revenue from contracts with customers

	2024 Jul–Sep						
SEK m	Zubsolv®	Abstral®	Edluar®	Vorvida®	Deprexis®	MODIA®	Total
Segment							
US Commercial	131.0	—	—	—	0.0	—	**131.0**
HQ & Pipeline	3.8	-1.4	3.0	—	—	—	**5.5**
Total revenue from contracts with customers	**134.8**	**-1.4**	**3.0**	**0.0**	**0.0**	**0.0**	**136.5**
Geographical markets							
US	131.0	—	—	0.0	0.0	0.0	**131.0**
EU & UK	3.8	-1.5	3.0	—	—	—	**5.3**
Rest of the world	—	0.2	—	—	—	—	**0.2**
Total revenue from contracts with customers	**134.8**	**-1.4**	**3.0**	**0.0**	**0.0**	**0.0**	**136.5**

	2024 Jan–Sep						
SEK m	Zubsolv®	Abstral®	Edluar®	Vorvida®	Deprexis®	MODIA®	Total
Segment							
US Commercial	408.2	—	—	—	0.0	—	**408.2**
HQ & Pipeline	5.5	7.0	9.0	—	—	—	**21.5**
Total revenue from contracts with customers	**413.7**	**7.0**	**9.0**	**0.0**	**0.0**	**0.0**	**429.7**
Geographical markets							
US	408.2	—	—	0.0	0.0	0.0	**408.2**
EU & UK	5.5	6.5	9.0	—	—	—	**21.0**
Rest of the world	—	0.6	—	—	—	—	**0.6**
Total revenue from contracts with customers	**413.7**	**7.0**	**9.0**	**0.0**	**0.0**	**0.0**	**429.7**

	2023 Jul-Sep						
SEK m	Zubsolv	Abstral	Edluar	Vorvida	Deprexis	MODIA	Total
Segment							
US Commercial	140.4	—	—	0.0	0.0	—	**140.4**
HQ & Pipeline	4.5	7.7	3.5	—	—	—	**15.7**
Total revenue from contracts with customers	**144.9**	**7.7**	**3.5**	**0.0**	**0.0**	**0.0**	**156.1**
Geographical markets							
US	140.4	—	0.4	0.0	0.0	—	**140.8**
EU & UK	4.5	7.5	2.3	—	—	—	**14.3**
Rest of the world	—	0.2	0.8	—	—	—	**1.0**
Total revenue from contracts with customers	**144.9**	**7.7**	**3.5**	**0.0**	**0.0**	**0.0**	**156.1**

	2023 Jan–Sep						
SEK m	Zubsolv	Abstral	Edluar	Vorvida	Deprexis	MODIA	Total
Segment							
US Commercial	426.3	—	—	0.0	0.0	—	**426.4**
HQ & Pipeline	15.6	21.9	8.8	—	—	—	**46.4**
Total revenue from contracts with customers	**442.0**	**21.9**	**8.8**	**0.0**	**0.0**	**0.0**	**472.8**
Geographical markets							
US	426.3	—	1.6	0.0	0.0	—	**428.0**
EU & UK	15.6	21.3	4.9	—	—	—	**41.9**
Rest of the world	—	0.6	2.3	—	—	—	**2.9**
Total revenue from contracts with customers	**442.0**	**21.9**	**8.8**	**0.0**	**0.0**	**0.0**	**472.8**

	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 Jul-Sep	2023 Jul-Sep	2024 Jan-Sep	2023 Jan-Sep	2023 Jan-Dec
EBIT	-21.7	-28.6	-42.2	-100.9	-109.5
Depreciation and amortization	21.0	19.2	62.4	56.1	77.0
EBITDA	**-0.7**	**-9.5**	**20.2**	**-44.8**	**-32.5**

OPERATING EXPENSES SEK m	2024 Jul-Sep	2023 Jul-Sep	2024 Jan-Sep	2023 Jan-Sep	2023 Jan-Dec
Selling expenses	-47.2	-44.7	-142.8	-138.7	-181.5
Administrative expenses	-32.2	-45.4	-109.3	-150.1	-188.0
Research and development costs	-56.2	-83.7	-177.1	-237.7	-303.1
Other operating income and expenses	-2.5	11.9	7.0	21.5	13.3
Operating expenses	**-138.1**	**-161.9**	**-422.3**	**-505.0**	**-659.5**

RETURN ON SHAREHOLDERS' EQUITY	2024 Jul-Sep	2023 Jul-Sep	2024 Jan-Sep	2023 Jan-Sep	2023 Jan-Dec
Shareholders' equity beginning balance	24.2	123.8	58.9	193.9	193.9
Shareholders' equity ending balance	-27.2	92.0	-27.2	92.0	58.9
Average shareholders' equity	-1.5	107.9	15.8	142.9	126.4
Net earnings	-41.9	-33.3	-86.7	-109.7	-128.3
Return on shareholders' equity %	**2,764.4**	**-30.9**	**-547.8**	**-76.7**	**-101.5**

GROSS INVESTMENTS SEK m	2024 Jul-Sep	2023 Jul-Sep	2024 Jan-Sep	2023 Jan-Sep	2023 Jan-Dec
Investments in tangible fixed assets	—	6.7	2.5	17.6	18.5
Investments in intangible fixed assets	—	0.0	1.4	0.7	0.7
Gross investments	**0.0**	**6.7**	**3.8**	**18.3**	**19.2**

Orexo is a Swedish pharmaceutical company with 30 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.

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