orexo

Interim Report Q4 2024, incl. Full Year Report

February 6, 2025

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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

Q4 2024 highlights

- Total net revenues of SEK 160.3 m (166.0)
- EBITDA of SEK 28.9 m (12.4)
- Impairment of intangible assets Deprexis® of SEK 71.1 m (0) and Vorvida® of SEK 28.1 m (0)
- Net earnings of SEK -116.2 m (-18.6), adjusted net earnings amounted to SEK -18.9 m (-18.6)
- US Commercial segment net revenues of SEK 152.1 m (151.3), in local currency USD 14.1 m (14.2)
- Cash flow from operating activities of SEK 6.2 m (-2.6), cash and cash equivalents of SEK 123.3 m (171.0)
- Earnings per share before and after dilution amounted to SEK -3.37 (-0.54)
- Orexo agreed with GAIA on terminating the partnership for Deprexis
- Friedrich von Bohlen und Halbach elected as new board member at an Extraordinary General Meeting
- Patent litigation against Sun Pharmaceutical Industries reagarding Zubsolv® in the US was resolved
- Collaboration entered with Abera Bioscience to develop nasal powder vaccines based on the drug delivery technology AmorphOX®
- Financial outlook for 2025 on page 16

Important events after the end of the period

- Positive topline data showed from clinical study of OX640, a nasal powder-based adrenaline product, in participants with allergic rhinitis
- Future rights to royalties for OX-MPI, a new treatment for endometriosis, converted to shares in Gesynta Pharma valued at SEK 19 m and recognized in Q4 2024

SEK m unless otherwise stated	2024 Oct-Dec	2023 Oct-Dec	2024 Jan-Dec	2023 Jan-Dec
Net revenues	160.3	166.0	590.0	638.8
Cost of goods sold	-22.3	-20.1	-72.1	-88.9
Operating expenses	-235.9	-154.5	-658.2	-659.5
EBIT	-98.0	-8.6	-140.3	-109.5
EBIT margin %	neg.	neg.	neg.	neg.
Adjusted EBIT	1.2	-8.6	-41.2	-109.5
Adjusted EBIT margin %	0.7	neg.	neg.	neg.
EBITDA	28.9	12.4	48.9	-32.5
Earnings per share, before dilution, SEK	-3.37	-0.54	-5.89	-3.73
Earnings per share, after dilution, SEK	-3.37	-0.54	-5.89	-3.73
Cash flow from operating activities	6.2	-2.6	-32.6	-95.0
Cash and cash equivalents	123.3	171.0	123.3	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.

Group net revenues
160 SEK M

Group EBITDA
29 SEK M

Cash and cash equivalents
123 SEK M

SDG 3.5 net revenue ratio
95%

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, that enhances bioavailability and stability for both small and large molecules, driving the next wave of development projects.

Commercialised products and products under development

Product	Indication	Technology	Partner	Exploratory phase	Preclinical phase	Clinical development phases	Registration	Approved/Launched US	Approved/Launched EU	Approved/Launched RoW
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	broca platform	GAIA					2023		
Pipeline products										
OX124	opioid overdose**	amorphOX®								
OX125	opioid overdose**	amorphOX®								
OX640	allergic reactions	amorphOX®								
Others	multiple***	amorphOX®								

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

Contact persons quarterly report

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Presentation

On Feburary 6, 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=5007431

When registered you will be provided phone numbers and a conference ID to access the conference.

To attend via webcast:
https://orexo.events.inderes.com/q4-report-2024

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

Financial calendar

Annual & Sustainability Report 2024, March 28
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

Resolving issues, unlocking more flexibility

CEO Comments in brief

We end 2024 with an intense fourth quarter. The settlement in the patent litigation for Zubsolv® was an important milestone which in combination with continued stable revenue from Zubsolv gives us confidence that Zubsolv US will be an important contributor to our financial stability and ability to finance investments in other growth drivers. With the settlement we can start the process to clean the table and set a strategy to drive the long-term growth and shareholder value.

Operationally, we saw mixed developments during the quarter. The timeline for OX124, our overdose rescue medication, has been extended, primarily due to delivery delays of components from one of our subcontractors. For OX640, our promising nasal drug for the treatment of anaphylaxis, we completed the second clinical study in December, this time in patients with allergic rhinitis. I am pleased with the successful data from the study, which further underscores that we have an exciting asset in our pipeline. Thanks to the AmorphOX technology we once again managed to show excellent bioavailability and we are confident OX640 will be a product with clear competitive advantages.

2024, and in particular the last quarter of the year, was very intense for Orexo and many open issues have been resolved. We started the year refinancing our corporate bond, reducing the financing risk, and continued to resolve financial and legal issues as we approached the end of the year.

The main concern for the past four years has been the patent litigation against Sun Pharmaceuticals and our need to protect our Zubsolv® business. Reaching a settlement not only removed the short-term risk to the exclusivity of Zubsolv, but also enabled a review of the corporate structure. Following the settlement, we completed an internal transaction where our wholly owned subsidiary acquired the intellectual properties and manufacturing of Zubsolv to the US market from the parent company. The transaction was based on an external valuation and the value is reflected in the shareholders' equity on the balance sheet of the parent company.

In line with the information in our Q3 interim report we are assessing the business segments in the company to focus our resources in the areas with greatest opportunity. Reflecting the continued difficult market conditions for reimbursement of digital health products not meeting the requirements in the new policy from the Center for Medicaid and Medicare Services (CMS), we will reduce our activities even further in this area. This will lead to reduced expenses but also result in an impairment of the value of Deprexis® and Vorvida® and negatively impacting the EBIT result in the quarter, but with no effect on cash flow.

On a more positive note, we agreed with Gesynta Pharma to convert our future rights to royalties from vipoglanstat (OX-MPI) to shares in Gesynta in connection with Gesynta's successful capital raise announced in January 2025. Orexo signed the agreement with Gesynta in December and the transaction had a positive impact on the P&L and balance sheet in Q4.

Zubsolv revenues of SEK 152 m are an increase of 16 percent from Q3, and we reached a positive EBITDA in the quarter of SEK 29 m, contributing to a stable cash position compared to Q3. Despite some increased expenses in Q4 to resolve patent litigation, the review of the balance sheet and OX640 study, I am pleased to share that we have delivered on the financial guidance with a positive EBITDA for the full year (SEK 49 m) and OPEX below SEK 530 m excluding depreciation (SEK 469 m).

Solving these issues, cleaning up our balance sheet, and strengthening the parent company equity has removed several layers of overhang for the company and also removed the risk of being forced into a capital raise due to a weak equity situation in the parent company.

Continued stabilization of Zubsolv demand and revenues

The market for daily treatment of buprenorphine/naloxone has continued to improve and grew 2 percent in Q4 over last year and full year growth is 3 percent, which is within the guidance of 2-5 percent for the year. The market growth supports the stable demand of Zubsolv year over year and I am pleased to see both demand and revenues grow from Q3. Despite the strong recovery of revenues in the fourth quarter, sales in USD are slightly lower both in the quarter and across the full year comparing to 2023. Our 2024 guidance was sales in USD "in line with 2023", and with a deviation of 2.6 percent, we were relatively close to meeting the target.

> **"The market growth supports the stable demand of Zubsolv year over year and I am pleased to see both demand and revenues grow from Q3.**

The market growth is driven by continued double-digit growth in the Commercial segment, whereas Medicaid continues the negative trend seen since mid-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. The price of Zubsolv was increased by January 1st and will support continued stable sales in 2025. The main uncertainty in the year is related to Medicare where a new pricing and rebate system was implemented by January 1, 2025. The new system is likely to have a positive net price impact on Zubsolv, but some payers have implemented policies to favor generic alternatives for certain patient groups which might have a negative impact primarily on volume and, to a lesser extent, net sales.

During the quarter we have worked intensively with our legal advisors to find a resolution to the subpoena and DOJ investigation initiated in 2020. Orexo maintains the position that Zubsolv has been promoted in a compliant and responsible manner, but the legal expenses and uncertainty associated with a court case make a settlement a more attractive option for Orexo.

FDA review of OX124 causes further delay

For OX124, our rescue medication for opioid overdose with naloxone, we have worked extensively to address the issues raised by the FDA and have presented a comprehensive plan to the agency to strengthen the documentation related to the reliability and stability of the device. A meeting has been completed with the FDA discussing the plan presented by Orexo, but the FDA has reserved the rights to review if the data is comprehensive enough when submitted. Unfortunately, the timeline of the submission of the new data remains uncertain. This is primarily related to delays in the supply of necessary components of the product from one of our suppliers. When we receive the delivery, we will immediately start the commercial manufacturing of OX124 and initiate the necessary testing. Thus, the final timeline for approval of OX124 is dependent on when the supplier can deliver the parts, our completion of the tests and the FDA´s review time, which will be communicated after the data submission is complete.

Positive topline data from the second clinical trial for OX640

With OX640 we are aiming at developing a nasal epinephrine product for anaphylaxis and in Q4 we reached an important development milestone as we conducted a new clinical study that showed strong data which was communicated in the beginning of the new year. The study improved our evidence of the impact on bioavailability of epinephrine in OX640 in patients with allergic rhinitis, but also provided more information about the dose required to ensure we have a competitive product. With the results it is evident the bioavailability of OX640 improves with allergic rhinitis, which is important since this is a common reaction to anaphylaxis. We will use this new data in our discussions with potential partners and it enable us to prepare our next step in the development, which is upscaling of the manufacturing of OX640 to commercial scale.

We have also started a collaboration with Abera Bioscience to develop nasal powder vaccines based on the AmorphOX® technology. Abera has an innovative and promising vaccine platform for the development of mucosal vaccines, as confirmed by their recent funding from CEPI (the Coalition for Epidemic Preparedness Innovation). The collaboration is fully in line with our strategic development of the AmorphOX platform and through the collaboration we will develop data that can be used to showcase the potential and value of our technology in vaccines.

Summary and outlook

From an EBITDA perspective, 2024 is the best year for Orexo since 2019, but from a net earnings perspective the year finishes with a negative result. This is to a large degree explained by the impairment of intangibles and has no cash impact. With the review of the balance sheet and changes to the corporate structure, Orexo is in a much more stable position with a positive equity in the parent company, limited exposure to impairment and more focused operations.

Solving many issues in 2024 enables us to focus our efforts to continue to develop the best strategy to ensure our commercial opioid use disorder products and pipeline products have a platform to thrive from and to create value for our shareholders.

> **"Solving many issues in 2024 enables us to focus our efforts to continue to develop the best strategy to ensure our commercial opioid use disorder products and pipeline products have a platform to thrive from and to create value for our shareholders.**

I want to take this opportunity to thank my colleagues at Orexo for their commitment to the company. We have been forced to address unexpected issues with short notice and, for more than four years, we have worked with the uncertainty of a patent litigation risking the main source of funds for the company. In light of these challenges, it is with immense pride that I and the managers continue to receive feedback from our annual employee engagement survey placing Orexo in the top tier of companies in terms of job satisfaction and commitment to Orexo.

Uppsala, Sweden, February 6, 2025

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 (OUD).[3] Latest available data is showing predicted number of reported 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 identified in more drug tests across the US, adding complications to rescue situations and possible treatment regimens.

In Q4, the buprenorphine/naloxone market grew 2 percent versus Q3 2024 and reached 6 percent versus Q4 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 law, effective January 1, 2023, removed the cap on the numbers of patients physicians can treat with MAT and now all physicians with a license to prescribe controlled drug substances can prescribe MAT for OUD.

The market has during 2023 and 2024 shifted from growth in Medicaid to the Commercial segment. In Medicaid, the market declined 2 percent vs Q4 2023, while the Commercial segment increased 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. However, during the quarter Medicaid volume has started to increase again, with 2 percent growth versus Q3 2024.

Developments during the quarter

The stabilization of Zubsolv prescriptions has continued and in Q4, Zubsolv volume grew 1 percent versus Q3 2024 and was flat versus Q4 2023.

In the Commercial segment Zubsolv declined with 3 percent versus last year and 1 percent Q3 2024, primarily explained by decline within United Health Group and Humana, although the change within these two plans was marginal during the quarter.

In the Public segment Zubsolv continues to grow with 2 percent from last year and 3 percent from Q3 2024. This is primarily due to Medicaid where Zubsolv volume grew 2 percent versus Q4 2023 and 4 percent from last quarter. This is above the market growth in Medicaid and was supported by the states where Zubsolv most recently gained access, such as New York Medicaid, which grew 11 percent versus Q4 2023, and Indiana, which grew 31 percent versus Q4 2023. Zubsolv also saw an increase in its large Medicaid payers where it has been accessible for a longer time, such as Michigan, which grew 6 percent versus Q3 2024, and Wisconsin, which grew 13 percent versus Q3 2024.

Zubsolv's best in class market access in the commercial payer segment is maintained at 98 percent in the quarter and next year. In the Public segment market access will decline from 51 to 50 percent due to changes in one Medicare payer. Within Medicare a new rebate system will be implemented in 2025 which may have impact on the market dynamics in this segment during 2025 and could impact Zubsolv volumes negatively since some payers have implemented policies making generic alternatives more affordable for certain patient groups. Medicare is today 19 percent of the total Zubsolv volumes, but less in terms of sales due to high rebates with some payers.

modia VORVIDA deprexis

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.

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.[6]

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.[7]

Developments during the quarter

Center for Medicaid and Medicare Services (CMS) has during the quarter published a proposal for reimbursement of digital health products. The policy which will be a guidance for all public and commercial payers defines certain standards for digital health products to meet to be considered for reimbursement. An assessment of these standards concluded that meeting them will require additional investments in technology and clinical evidence across the three digital health products MODIA, Vorvida and Deprexis. Orexo does not find additional investments can be justified in Deprexis and Vorvida due to lack of synergies with the commercial organization and have in agreement with the partner GAIA terminated the Deprexis contract, which has led to an impairment of the value of Deprexis in our balance sheet.

The opportunities for Vorvida will continue to be assessed and a discussion is ongoing with GAIA about the best path forward given the market conditions. The value of Vorvida on Orexo's balance sheet has relied on future access to reimbursement and with the new policy from CMS a new assessment has been made of the value potential from Vorvida. Without access to reimbursement, Orexo would need to promote Vorvida to new customer segments, that are not currently reached by the company's commercial organization, to generate revenue. However, since promotional tests targeting these customer segments have previously resulted in a negative return on investment, a decision was made to impair the full value of the Vorvida.

For MODIA our treatment support program for patients suffering from opioid dependence, there are synergies with the current commercial organization and customer relationships. On this basis we see continued opportunities to work with health care providers to develop comprehensive programs to support patients suffering from opioid dependence both with MODIA individually and under the umbrella concept MATCore®. During the quarter a health care provider received a grant to test a treatment program based on MATCore on a group of patients in the state of Ohio and we continue to work with healthcare providers in several states to broaden access to this program.

AmorphOX® – a world-class powder-based drug delivery platform

THE 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.

THE CHALLENGE

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.

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.

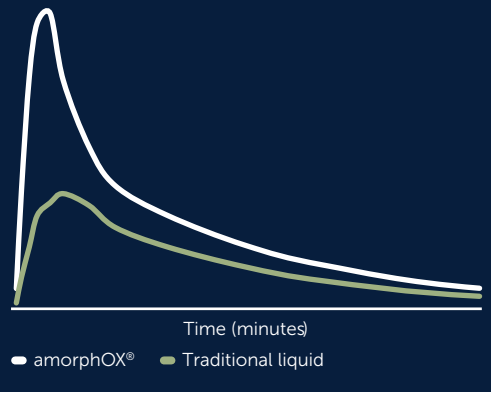
Clinically validated

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.

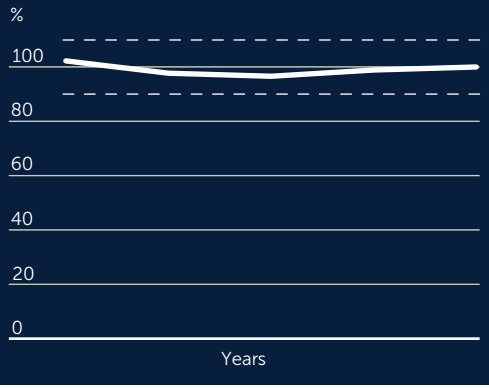
Wide applicability

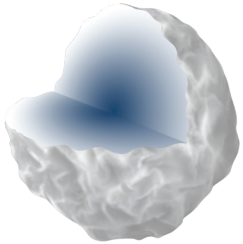
AmorphOX works with a broad spectrum of active chemical substances, including small and large molecules,[8] and the properties of the powder can be tailored to meet specific needs such as particle size, dissolution properties, and mucosal retention. This makes it a versatile technology with broad applicability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

Plasma concentration



Amount of API





Successful clinical trials

Well tolerated
Higher exposure
Faster onset
Lower variability

PRESERVATIVES NO ADDED

amorphOX®

Products under development

Development projects based on the AmorphOX® drug delivery platform

OX124 – 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.

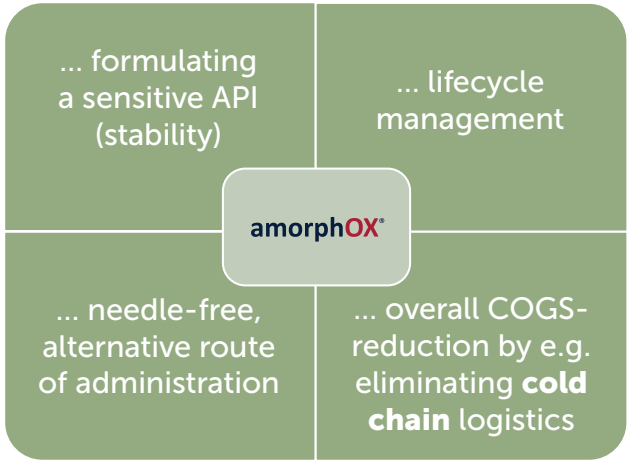
The final formulation of OX124 has shown significantly faster absorption and substantially higher plasma concentrations of naloxone compared to the reference intramuscular injection. In a cross-study comparison to the current market leader, OX124 shows substantially higher peak plasma concentrations 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

Following the receipt of a Complete Response Letter (CRL) from the US Food and Drug Administration (FDA) in the third quarter, the work continued preparing to generate updated technical data from the final commercial product and process as required by the agency. An important part of this work was the agency's feedback on the company's briefing book, which was shared with the FDA in the third quarter. The briefing book outlines the process to produce the new technical data regarding reliability and stability related to the device and manufacturing process. The plan was discussed with FDA but ultimately FDA reserves the right to decide whether the data are complete in connection with the submission of an updated New Drug Application (NDA) to the agency.

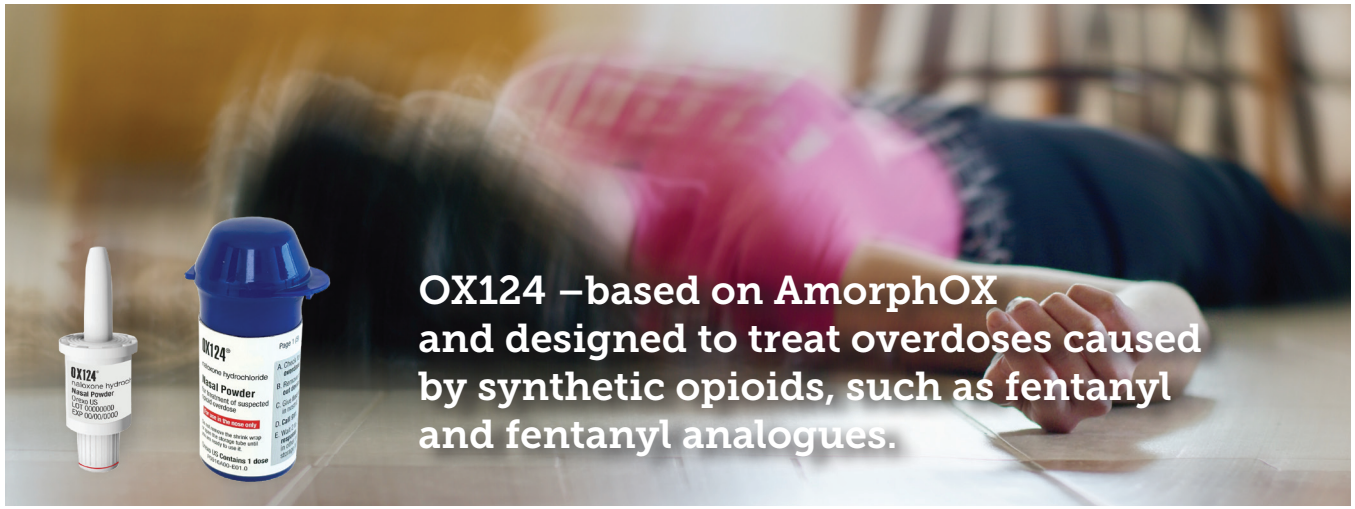
AmorphOX® – a versatile drug delivery platform with potential to solve some significant challenges



Partner (*EXAMPLES*)	A	B	C*	D
API	BM	V/AV)	V(VLP)	NCE
Improved stability and elimination of cold chain	✓	✓	✓	
New product opportunity	✓	✓		
New indication(s)	✓			
Improved speed of onset				✓
Improved patient convenience	✓	✓		✓
Prolonged IP	✓	✓	✓	✓

* Powder for pandemic preparedness

BM = Biomolecule | V (VLP) = Virus Like Particle
V (AV) = Attenuated Virus | NCE = New Chemical Entity



In preparing for commercial manufacturing of the final product, Orexo is dependent on external parties. A supplier of components has announced delivery delays, and this has impacted the timeline for production and testing. The timing of a potential approval of OX124 is dependent on the delivery of necessary components, manufacturing, testing and FDA's time for reviewing the 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 a 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.

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 continued 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

In the quarter, the second clinical study for OX640 was conducted. The study was a cross-over study in 30 subjects assessing absorption and pharmacodynamic effects of epinephrine from two doses of OX640, with one of the doses also administered during ongoing allergic rhinitis symptoms. Exposure was compared to a commercial intramuscular injection.

In the beginning of 2025 topline data analysis were published demonstrating OX640 treatments achieved mean epinephrine plasma levels associated with clinical efficacy more rapidly than the intramuscular injection, with dose-dependent exposure levels. Absorption under allergic rhinitis conditions was significantly faster than under normal conditions, supporting rapid onset of effect also in patients with significant airway symptoms. OX640 formulations typically produced more pronounced increases in blood pressure and heart rate than the intramuscular injection, which are key effects for treatment of anaphylaxis.

Systemic safety was in line with the known pharmacology of epinephrine and local effects were transient and tolerated. No serious adverse events were reported from the study.

OX640 continues to show excellent results in ongoing stability studies. 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 to commercial manufacturing scale continued.

In the third 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.

If approved, OX640 has the potential to be a highly competitive needle-free epinephrine product with several differentiating properties, such as superior absorption and exposure, longer shelf life, less restrictive storage requirements, improved dose conformity and being preservative free.

In the quarter discussions continued with potential partners for further development and global 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.

In the quarter, a collaboration was initiated with Abera Bioscience ("Abera"), which develops platforms and vaccines based on over 30 years of research in the medical, molecular and microbiological field. The aim of the collaboration is to develop mucosal vaccines based on Abera's innovative and patented vaccine platform and in a first step focusing on Abera's influenza vaccine candidate. By combining Abera's unique expertise in molecular research with Orexo's powder-based drug delivery technology, AmorphOX, there is potential to develop nasal vaccines with improved chemical and physical stability. Stable vaccines may have longer shelf life and are easier to handle as they do not require cold chains to ensure reliability and efficacy.

Analytical chemist, Anneli Wennman on problem-solving from end-to-end

The project, which is in the exploratory pre-clinical phase, is funded by grants received by Abera, mainly from CEPI (the Coalition for Epidemic Preparedness Innovation).

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.

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 (Gesynta) owns all rights to the drug candidate and Orexo is entitled to receive rights to future transaction proceeds and royalty on future net revenues generated from the program.

After the end of the period, it was announced that Orexo´s rights to the project have been converted into shares in Gesynta in connection with the company's capital raising, at a value of SEK 19 m. With the proceeds from the capital raising Gesynta will advance the drug candidate into a clinical phase II study.

The agreement was signed in the fourth quarter and the value generated is recognized under other operating income in Orexo's Q4, 2024 results.

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

In preparation for Orexo's sustainability reporting for the 2025 financial year, which will align with the EU's CSRD directive, efforts continued to ensure the organization meets the new requirements. The primary focus was on implementing the double materiality analysis (DMA), with participation from representatives across multiple functions in both Sweden and the US. As part of this process, among other activities, the company's value chain was mapped to support decision-making.

Financial development

Net revenues

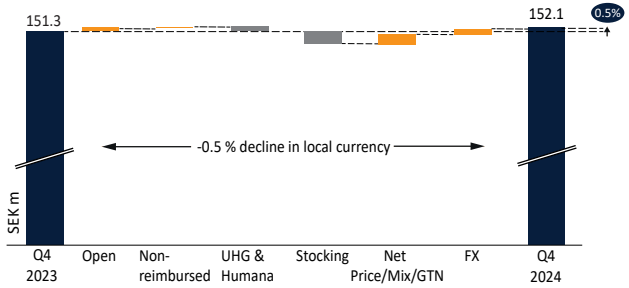
Total net revenues amounted to SEK 160.3 m (166.0) for Q4. The decrease is explained by lower net revenues in HQ & Pipeline segment. Total net revenues amounted to SEK 590.0 m (638.8) for the full year.

Revenues by segment

US Commercial revenues amounted to SEK 152.1 m (151.3) for Q4. The increase is driven by product sales of Zubsolv® in the US, primarily as a result of favorable payer mix and a positive FX impact of SEK 1.5 m partly offset by higher reduction of wholesaler inventories. US Commercial revenues amounted to SEK 560.3 m (577.7) for the full year. In local currency US Commercial net revenues for Q4 amounted to USD 14.1 m (14.2) and for the full year to USD 53.0 m (54.4).

HQ & Pipeline partner product related revenues for Q4 amounted to SEK 8.2 m (14.7). The decrease is mainly explained by lower Abstral® ROW royalties. Higher Zubsolv ex-US revenues are explained by higher sales of tablets to Orexo's partner Accord Healthcare partly offset by lower royalties from lower partner revenues. Higher Edluar royalties of SEK 3.6 m (1.9) are explained by positive adjustments from Q3 2024 partner reported royalties. HQ & Pipeline partner product related revenues amounted to SEK 29.7 m (61.1) for the full year.

ZUBSOLV US NET REVENUES DEVELOPMENT



Cost of goods sold

Cost of goods sold (COGS) amounted to SEK 22.3 m (20.1) for Q4. US Commercial amounted to SEK 20.2 m (17.9), the increase is mainly explained by unfavorable production costs for Zubsolv US and higher technical infrastructure costs for Digital Mental Health Programs (DMHP). HQ & Pipeline amounted to SEK 2.1 m (2.2) for Q4 where the decrease is due to favorable production costs for Zubsolv ex-US tablets sold to Orexo's partner Accord Healthcare. Cost of goods sold (COGS) amounted to SEK 72.1 m (88.9) for the full year.

Operating expenses

Impairment in Q4 of intangible assets Deprexis® of SEK 71.1 m (0.0) and Vorvida® of SEK 28.1 m (0.0) totalling SEK 99.2 m has been allocated SEK 14.6 m to Administrative expenses and SEK 84.6 m to Research and development costs.

Selling expenses amounted to SEK 48.4 m (43.5) for Q4. 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 191.3 m (181.5) for the full year.

Administrative expenses amounted to SEK 56.0 m (38.0) for Q4. The increase is mainly explained by impairment of DMHP intangible assets Deprexis of SEK 7.9 m (0.0) and Vorvida of SEK 6.7 m (0.0) in US Commercial, higher legal expenses for DOJ investigation in US Commercial and higher costs for

NET REVENUES AND EBIT PER SEGMENT

SEK m	Net revenue				EBIT			
	2024 Oct-Dec	2023 Oct-Dec	2024 Jan-Dec	2023 Jan-Dec	2024 Oct-Dec	2023 Oct-Dec	2024 Jan-Dec	2023 Jan-Dec
Zubsolv US product sales	152.1	151.3	560.3	577.7	–	–	–	–
Digital Mental Health Programs (DMHP) product sales	0.0	0.0	0.0	0.1	–	–	–	–
US Commercial – total	**152.1**	**151.3**	**560.3**	**577.7**	**-65.2**	**45.7**	**27.9**	**152.3**
Abstral® royalty	1.2	10.0	8.2	31.9	–	–	–	–
Edluar® royalty	3.6	1.9	12.5	10.8	–	–	–	–
Zubsolv – ex-US	3.4	2.8	8.9	18.4	–	–	–	–
HQ & Pipeline – total	**8.2**	**14.7**	**29.7**	**61.1**	**-32.8**	**-54.3**	**-168.3**	**-261.8**
Total	**160.3**	**166.0**	**590.0**	**638.8**	**-98.0**	**-8.6**	**-140.3**	**-109.5**

long term incentive programs following a higher share price. Administrative expenses amounted to SEK 165.3 m (188.0) for the full year.

Research and development costs amounted to SEK 162.9 m (65.4) for Q4. The increase is mainly explained by impairment of DMHP intangible assets Deprexis® of SEK 63.2 m (0.0) and Vorvida® of SEK 21.4 m (0.0) in HQ & Pipeline, accelerated amortization of activated Zubsolv clinical studies and higher costs for OX640 and OX124. Research and development costs amounted to SEK 340.0 m (303.1) for the full year.

Other operating income and expenses amounted to SEK 31.4 m (-7.6) for Q4. This is mainly explained by a positive impact of SEK 19.2 m (0.0) from the value recognition following conversion of rights to future proceeds and royalties from vipoglanstat (OX-MPI), to shares in Gesynta Pharma AB. Exchange-rate gains derived from revaluations of parent company balance sheet items in foreign currency, predominantly in USD, amounted to SEK 7.6 m (-7.2) and higher received insurance reimbursement contributed positively with SEK 4.6 m (0.5). Other operating income and expenses amounted to SEK 38.4 m (13.3) for the full year.

Operating profit

EBITDA amounted to SEK 28.9 m (12.4) for Q4 and to SEK 48.9 m (-32.5) for the full year.

The EBITDA contribution from US Commercial amounted to SEK 51.7 m (56.5) for Q4, and to SEK 177.2 m (196.0) for the full year.

Total EBIT amounted to SEK -98.0 m (-8.6) for Q4 and to SEK -140.3 m (-109.5) for the full year. Adjusted EBIT, i.e. exclusion of the onetime impairment of intangible assets Deprexis of SEK 71.1 m (0.0) and Vorvida of SEK 28.1 m (0.0), amounted to SEK 1.2 m (-8.6) for Q4 and SEK -41.2 m (-109.5) for the full year.

EBIT contribution from US Commercial amounted to SEK -65.2 m (45.7) for Q4, equal to an EBIT margin of -42.9 percent (30.2). EBIT contribution from US Commercial amounted to SEK 27.9 m (152.3) for the full year, equal to an EBIT margin of 5.0 percent (26.4). Adjusted EBIT contribution from US Commercial amounted to SEK 33.9 m (45.7) for Q4, equal to an adjusted EBIT margin of 22.3 percent (30.2) and adjusted EBIT of SEK 127.1 m (152.3) for the full year, equal to an adjusted EBIT margin of 22.7 percent (26.4).

Net financial items and tax

Net financial items for Q4 amounted to SEK -8.3 m (-10.9) and is mainly explained by higher bond loan costs of SEK -12.4 m (-10.6) partly offset by positive unrealized exchange rate impact of SEK 3.8 m (-2.0) derived from the parent company's foreign currency bank accounts in USD and lower interest income from bank accounts of SEK 0.6 m (2.1). Net financial items amounted to SEK -50.3 m (-30.8) for the full year.

Total tax expenses amounted to SEK -9.9 m (0.9) for Q4. The increase is mainly explained by negative adjustment of SEK -10.4 m (1.7) to deferred tax assets related to temporary differences. Total tax expenses amounted to SEK -12.4 m (12.0) for the full year. Orexo performs regular assessments of its deferred tax asset and adjusts according to the recognition requirements of IAS 12.

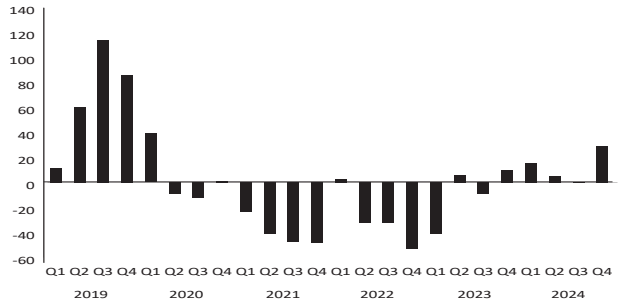
Net earnings

Net earnings amounted to SEK -116.2 m (-18.6) for Q4 and to SEK -203.0 m (-128.3) for the full year. Adjusted Net earnings i.e. exclusion of the onetime impairment of intangible assets Deprexis of SEK 71.1 m (0.0) and Vorvida of SEK 28.1 m, amounted to SEK -16.9 m (-18.6) for Q4 and SEK -103.9 m (-128.3) for the full year.

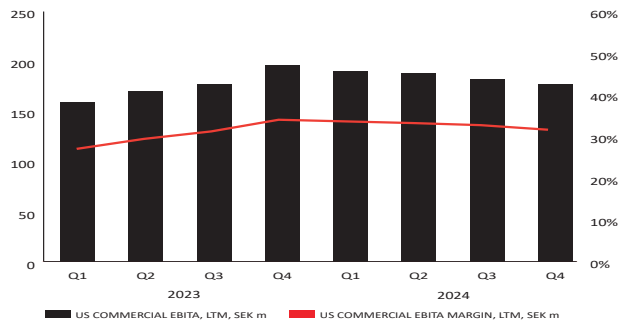
Cash and cash flow

Cash flow from operating activities amounted to SEK 6.2 m (-2.6) for Q4 and was primarily impacted by positive adjustment for non-cash items mainly due to impairment of intangible assets Deprexis of SEK 71.1 m (0.0) and Vorvida of

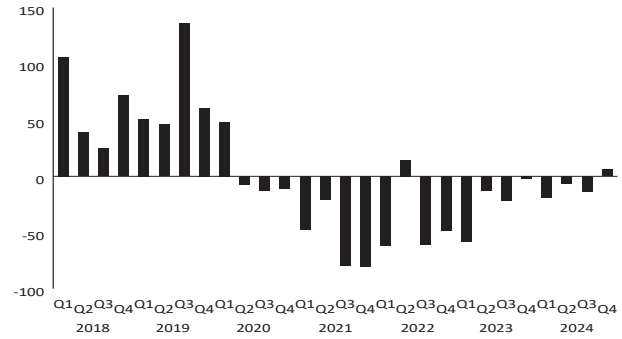
GROUP EBITDA, SEK m



US COMMERCIAL EBITDA MARGIN AND EBITDA (LTM[9], SEK m)



CASH FLOW FROM OPERATING ACTIVITIES, SEK m



SEK 28.1 m (0.0). This was partly offset by negative operating earnings, interest paid and negative changes in working capital. Cash flow from operating activities amounted to SEK -32.6 m (-95.0) for the full year.

As of December 31, 2024, cash and cash equivalents amounted to SEK 123.3 m (171.0) and interest-bearing liabilities to SEK 460.0 m (448.4), i.e. a negative net cash position of SEK -336.8 m (-277.4). Cash and cash equivalents increased by SEK 8.4 m from Q3 2024.

Investments

Gross investments in tangible and intangible fixed assets amounted to SEK 0.8 m (0.9) for Q4 and to SEK 4.6 m (19.2) for the full year. Lower investments are mainly explained by investments in equipment for the development organization.

Equity

Shareholders' equity on December 31, 2024, was SEK -126.3 m (58.9).

Parent company

Net revenues for Q4 amounted to SEK 34.4 m (114.1) of which SEK 26.2 m (99.4) was related to sales to Group companies. Net revenues amounted to SEK 303.8 m (494.0) for the full year of which SEK 274.0 m (432.9) was related to sales to Group companies.

Total EBIT amounted to SEK 960.1 m (-4.2) for Q4 and to SEK 911.7 m (-40.6) for the full year. At December 31, assets in Orexo AB related to the U.S. Zubsolv® business were divested to a wholly owned subsidiary Biolipox AB. The internal transaction was completed at a fair market value of SEK 1,138.9 m assessed by an independent external party. Value recognition following conversion of rights to future proceeds and royalties from vipoglanstat (OX-MPI), to shares in Gesynta AB had a positive impact of SEK 19.2 m (0.0). This was partly offset by impairment of intangible assets Deprexis® of SEK 71.1 m (0.0) and Vorvida® of SEK 28.1 m (0.0).

Earnings before tax amounted to SEK 953.8 m (-14.7) for Q4 and to SEK 865.3 m (-70.4) for the full year.

Investments in equipment for the development organization for Q4 amounted to SEK 0.8 m (0.9) and to SEK 4.6 m (18.5) for the full year.

As of December 31, 2024, cash and cash equivalents in the parent company amounted to SEK 61.2 m (145.5).

Parent company shareholders' equity at December 31, 2024, was SEK 1,027.4 m (162.1). The increase over the same period last year is mainly explained by the internal transaction with the sale of assets related to the US Zubsolv business to the wholly owned subsidiary Biolipox AB at a fair market value of SEK 1,138.9 m.

Other information

Outcome financial outlook 2024

- The buprenorphine/naloxone market will grow 2-5 percent, based on current growth trajectory. **Outcome:** 3 percent.
- Zubsolv® net sales in USD will be in line with 2023. **Outcome:** USD 53.0 m versus 54.4 in 2023. The deviation is primarily due to inventory adjustments at wholesalers, which Orexo highlighted in the Q2 2024 Interim Report as an increased risk to achieve the target.
- 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. **Outcome:** SEK 469 m.
- Positive EBITDA for the FY 2024. **Outcome:** SEK 48.9 m.

Financial outlook 2025

- The buprenorphine/naloxone market will grow 2-5 percent, based on current growth trajectory.
- Zubsolv net sales in USD in the range of USD 50-55 m.
- Opex excluding depreciation and amortization in the range of SEK 460-500 m.
- Positive EBITDA for the FY 2025.

The financial outlook 2025 is based on a forward looking assumption of a USD/SEK exchange rate of 10.50.

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, Disputes. The continued commercialization of Zubsolv 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

In the fourth quarter, the parent company's equity position improved significantly as a consequence of the internal transaction with sale of assets to Orexo's wholly owned subsidiary Biolipox AB.

The group also 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/

Uppsala, Sweden, February 6, 2025

Nikolaj Sørensen
President and CEO

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

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8 Page 8, Enzymes, peptides and proteins

9 Page 14, Last Twelve Months

Financial reports, notes and key figures

CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS

SEK m	Notes	2024 Oct-Dec	2023 Oct-Dec	2024 Jan-Dec	2023 Jan-Dec
Net revenues	9	160.3	166.0	590.0	638.8
Cost of goods sold		-22.3	-20.1	-72.1	-88.9
Gross profit		**138.0**	**145.9**	**517.9**	**550.0**
Selling expenses		-48.4	-43.5	-191.3	-181.5
Administrative expenses		-56.0	-38.0	-165.3	-188.0
Research and development expenses		-162.9	-65.4	-340.0	-303.1
Other operating income and expenses		31.4	-7.6	38.4	13.3
Operating earnings (EBIT)		**-98.0**	**-8.6**	**-140.3**	**-109.5**
Net financial items		-8.3	-10.9	-50.3	-30.8
Earnings after financial items		**-106.3**	**-19.5**	**-190.6**	**-140.3**
Income tax	5	-9.9	0.9	-12.4	12.0
Net earnings for the period		**-116.2**	**-18.6**	**-203.0**	**-128.3**
Earnings per share, before dilution, SEK		-3.37	-0.54	-5.89	-3.73
Earnings per share, after dilution, SEK		-3.37	-0.54	-5.89	-3.73

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

SEK m	2024 Oct-Dec	2023 Oct-Dec	2024 Jan-Dec	2023 Jan-Dec
Earnings for the period	**-116.2**	**-18.6**	**-203.0**	**-128.3**
Other comprehensive income				
Items that may subsequently be reversed to the statement of operations:				
Translation differences	17.2	-14.7	17.9	-6.8
Other comprehensive earnings for the period. net after tax	**17.2**	**-14.7**	**17.9**	**-6.8**
Total comprehensive earnings for the period [1]	**-99.0**	**-33.3**	**-185.1**	**-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 Dec 31	2023 Dec 31
ASSETS			
Fixed assets			
Tangible fixed assets		64.7	81.0
Intangible assets		26.9	173.3
Right-of-use assets		16.4	24.5
Deferred tax assets	5	38.9	48.1
Other financial assets		1.6	0.8
Total fixed assets		**148.4**	**327.7**
Current assets			
Inventories		60.1	42.4
Accounts receivable		198.5	197.6
Other receivables		35.2	15.1
Prepayment and accrued income		29.4	32.7
Cash and cash equivalents		123.3	171.0
Total current assets		**446.4**	**458.9**
TOTAL ASSETS		**594.8**	**786.6**
SHAREHOLDERS' EQUITY AND LIABILITIES			
Total shareholders' equity		**-126.3**	**58.9**
Long-term liabilities			
Provisions		24.0	11.5
Interest bearing liabilities	6	460.0	448.4
Lease liabilities, long-term		6.0	4.5
Total long-term liabilities		**490.0**	**464.5**
Current liabilities and provisions			
Accounts payable		41.5	36.5
Provisions		112.1	133.1
Other liabilities		9.1	10.5
Accrued expenses		58.2	62.2
Lease liabilities, current		10.0	20.9
Total current liabilities		**231.1**	**263.2**
Total liabilities		**721.1**	**727.7**
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		**594.8**	**786.6**

CONDENSED CONSOLIDATED CHANGES IN SHAREHOLDERS' EQUITY

SEK m	2024 Dec 31	2023 Dec 31
Opening balance, shareholders' equity	**58.9**	**193.9**
Total comprehensive earnings for the period	-185.1	-135.1
Closing balance, shareholders' equity	**-126.3**	**58.9**

CONDENSED CONSOLIDATED CASH FLOW STATEMENTS

SEK m	Notes	2024 Oct-Dec	2023 Oct-Dec	2024 Jan-Dec	2023 Jan-Dec
Operating earnings (EBIT)		-98.0	-8.6	-140.3	-109.5
Interest received		4.2	3.6	7.7	7.7
Interest paid		-12.6	-10.5	-60.2	-37.6
Income taxes paid		0.1	-0.4	-1.5	-1.6
Adjustment for non-cash items	3	114.6	43.0	163.7	99.8
Cash flow from operating activities before changes in working capital		**8.3**	**27.2**	**-30.6**	**-41.2**
Changes in working capital		**-2.1**	**-29.8**	**-2.0**	**-53.8**
Cash flow from operating activities		**6.2**	**-2.6**	**-32.6**	**-95.0**
Acquisition of tangible and intangible fixed assets		-0.8	-0.9	-4.6	-19.2
Acquisition of short-term investments		—	0.0	—	0.1
Disposal of short-term investments		0.0	—	-0.7	219.9
Cash flow from investing activities		**-0.8**	**-0.9**	**-5.3**	**200.8**
Amortization of lease liability		-4.9	0.0	-22.0	-21.4
Repayment of loans		0.0	-5.6	6.5	-48.7
Cash from financing activities		**-4.9**	**-5.6**	**-15.5**	**-70.1**
Cash flow for the period		**0.5**	**-9.1**	**-53.5**	**35.7**
Cash and cash equivalents at the beginning of the period		**114.9**	**184.2**	**171.0**	**132.2**
Exchange-rate differences in cash and cash equivalents		7.9	-4.1	5.8	3.1
Changes in cash and cash equivalents		8.4	-13.2	-47.7	38.8
Cash and cash equivalents at the end of the period		**123.3**	**171.0**	**123.3**	**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 Oct-Dec	2023 Oct-Dec	2024 Jan-Dec	2023 Jan-Dec
EBIT margin, %	-61.1	-5.2	-23.8	-17.1
Return on shareholder equity, %	neg.	-24.7	neg.	-101.5
Net debt, SEK m	336.8	277.4	336.8	277.4
Debt/equity ratio, %	neg.	761.3	neg.	761.3
Equity/assets ratio, %	neg.	7.5	neg.	7.5
Number of shares, before dilution	34,505,226	34,449,595	34,491,050	34,413,408
Number of shares, after dilution	34,505,226	34,449,595	34,491,050	34,413,408
Earnings per share, before dilution, SEK	-3.37	-0.54	-5.89	-3.73
Earnings per share, after dilution, SEK	-3.37	-0.54	-5.89	-3.73
Number of employees at the end of the period	110	116	110	116
Shareholders' equity, SEK m	-126.3	58.9	-126.3	58.9
Capital employed, SEK m	333.8	507.3	333.8	507.3
Working capital, SEK m	92.0	24.7	92.0	24.7

[2] Definitions and reconcilliations of key figures are presented in the end of this report

CONDENSED PARENT COMPANY STATEMENT OF OPERATIONS

SEK m	Notes	2024 Oct-Dec	2023 Oct-Dec	2024 Jan-Dec	2023 Jan-Dec
Net revenues		34.4	114.1	303.8	494.0
Cost of goods sold		-10.2	-20.0	-63.2	-93.7
Gross profit		**24.1**	**94.1**	**240.5**	**400.3**
Selling expenses		-39.6	-24.0	-124.9	-119.4
Administrative expenses		-17.2	-18.2	-58.2	-94.9
Research and development costs		-150.3	-50.8	-288.8	-243.7
Other operating income and expenses	7	1,143.1	-5.2	1,143.1	17.1
Operating earnings (EBIT)		**960.1**	**-4.2**	**911.7**	**-40.6**
Interest income and expenses		-9.3	-7.9	-39.9	-31.3
Other financial income and expenses		3.0	-2.6	-6.5	1.5
Net financial items		**-6.3**	**-10.5**	**-46.4**	**-29.8**
Earnings before tax		**953.8**	**-14.7**	**865.3**	**-70.4**
Income tax	5	—	—	—	—
Earnings for the period		**953.8**	**-14.7**	**865.3**	**-70.4**

PARENT COMPANY STATEMENT OF COMPREHENSIVE INCOME

SEK m	2024 Oct-Dec	2023 Oct-Dec	2024 Jan-Dec	2023 Jan-Dec
Earnings for the period	**953.8**	**-14.7**	**865.3**	**-70.4**
Other comprehensive income	—	—	—	—
Total comprehensive earnings for the period	**953.8**	**-14.7**	**865.3**	**-70.4**

CONDENSED PARENT COMPANY BALANCE SHEET

SEK m	Notes	2024 Dec 31	2023 Dec 31
ASSETS			
Fixed assets			
Patents, intellectual property rights, proprietary intangible assets and software		24.1	147.7
Equipment, machinery, renovation of the property of others		64.7	81.0
Shares and participations in group companies		291.8	286.2
Total fixed assets		**380.6**	**515.0**
Current assets			
Inventories		6.8	25.6
Accounts receivable		6.8	23.8
Other receivables		30.3	10.6
Receivables from Group companies	7	1,049.4	71.0
Prepaid expenses and accrued income		15.1	18.4
Cash and cash equivalents		61.2	145.5
Total current assets		**1,169.6**	**294.9**
TOTAL ASSETS		**1,550.2**	**809.8**
SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES			
Total shareholders' equity		**1,027.4**	**162.1**
Long-term liabilities			
Other provisions		22.3	10.8
Interest bearing liabilities		460.0	448.4
Total long-term liabilities		**482.4**	**459.3**
Current liabilities			
Accounts payable		11.6	10.3
Other liabilities		7.6	8.6
Liabilities to Group companies		—	144.7
Accrued expenses and deferred income		21.2	24.9
Total current liabilities		**40.4**	**188.4**
Total liabilities		**522.8**	**647.7**
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		**1,550.2**	**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.

No standards, amendments and interpretations that came into effect for the financial year beginning after January 1, 2025 are expected to have any material impact on the group's financial statements and have not been applied in the preparation of this financial statement.

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 Oct-Dec	2023 Oct-Dec	2024 Jan-Dec	2023 Jan-Dec
US Commercial				
Net revenues	152.1	151.3	560.3	577.7
Operating earnings (EBIT)	-65.2	45.7	27.9	152.3
Depreciation and amortization	-116.9	-10.8	-149.3	-43.7
EBITDA	51.7	56.5	177.2	196.0
HQ & Pipeline				
Net revenues	8.2	14.7	29.7	61.1
Operating earnings (EBIT)	-32.8	-54.3	-168.3	-261.8
Depreciation and amortization	-9.9	-10.2	-39.9	-33.3
EBITDA	-22.8	-44.1	-128.3	-228.4
Group				
Net revenues	160.3	166.0	590.0	638.8
Operating earnings (EBIT)	-98.0	-8.6	-140.3	-109.5
Depreciation and amortization	-126.8	-21.0	-189.2	-77.0
EBITDA	28.9	12.4	48.9	-32.5
Net financial items	-8.3	-10.9	-50.3	-30.8
Earnings before tax	-106.3	-19.5	-190.6	-140.3

3. Cash flow

ADJUSTMENT FOR NON-CASH ITEMS

SEK m	2024 Oct-Dec	2023 Oct-Dec	2024 Jan-Dec	2023 Jan-Dec
Depreciation/amortization and impairment	126.8	21.0	189.2	77.0
Change in provisions	-4.7	14.2	-20.3	18.2
Share based payments	—	0.0	—	0.0
Other non cash items	0.0	0.0	0.5	3.1
Exchange rate income and expenses	-7.6	7.9	-5.8	1.4
Total	**114.6**	**43.0**	**163.7**	**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

On December 15, 2024, Orexo announced that the company has entered into a settlement agreement with Sun Pharmarceutical Industries (Sun) to resolve the patent litigation regarding Zubsolv® (buprenorphine and naloxone) sublingual tablet (CIII), for the treatment of opioid use disorder in the US.

The agreement resolves the patent litigation commenced in July, 2020, by Orexo following Sun's filing of an Abbreviated New Drug Application ("ANDA") seeking approval to market generic versions of Zubsolv in the US prior to the expiration of Orexo's patents listed in FDA's Orange Book for Zubsolv.

On July 1, 2023, the US District Court for the District of New Jersey ruled in favor of Orexo. The district court found that Orexo´s patents are valid and infringed by Sun. Following the ruling Sun appealed the district court's decision to the US Court of Appeals for the Federal Circuit which was communicated on July 24, 2023.

The settlement agreement allows Sun to enter the US market with its generic versions of Zubsolv in September 2030. Zubsolv is protected by 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. The settlement agreement does not implicate its patent protection.

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 712 m as of December 31, 2024 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.

The long-term interest-bearing debt consists of a social bond loan amounting to a total of SEK 500 m that matures on March 28, 2028 with a floating interest rate of STIBOR 3 months +6.5 per cent (STIBOR is calculated as a minimum of zero). The loan agreement contains restrictions regarding any change in the company's ownership structure, so-called change-of-control, as well as quarterly reporting of maintenance tests and, where applicable, incurrence tests. The Company has successfully met the maintenance test in each reported quarter and does not foresee any future circumstances that would complicate the fulfilment of these.

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, remuneration to the board, president and senior executives and sale of assets related to the US Zubsolv business between Orexo AB and Biolipox AB. The transactions were carried out at arm's length with assessed market levels.

8. Important events after the end of the period

- Positive topline data showed from clinical study of OX640, a nasal powder-based adrenaline product, in participants with allergic rhinitis
- Future rights to royalties for OX-MPI, a new treatment for endometriosis, converted to shares in Gesynta Pharma valued at SEK 19 m and recognized in Q4 2024

9. Net revenue from contracts with customers

	2024 Oct-Dec						
SEK m	Zubsolv®	Abstral®	Edluar®	Vorvida®	Deprexis®	MODIA®	Total
Segment							
US Commercial	152.1	–	–	–	0.0	–	**152.1**
HQ & Pipeline	3.4	1.2	3.6	–	–	–	**8.2**
Total revenue from contracts with customers	**155.5**	**1.2**	**3.6**	**0.0**	**0.0**	**0.0**	**160.3**
Geographical markets							
US	152.1	–	–	–	0.0	–	**152.1**
EU & UK	3.4	1.0	3.6	–	–	–	**8.0**
Rest of the world	–	0.2	–	–	–	–	**0.2**
Total revenue from contracts with customers	**155.5**	**1.2**	**3.6**	**0.0**	**0.0**	**0.0**	**160.3**

	2024 Jan–Dec						
SEK m	Zubsolv®	Abstral®	Edluar®	Vorvida®	Deprexis®	MODIA®	Total
Segment							
US Commercial	560.3	–	–	–	0.0	–	**560.3**
HQ & Pipeline	8.9	8.2	12.5	–	–	–	**29.7**
Total revenue from contracts with customers	**569.2**	**8.2**	**12.5**	**0.0**	**0.0**	**0.0**	**590.0**
Geographical markets							
US	560.3	–	–	–	0.0	–	**560.3**
EU & UK	8.9	7.5	12.5	–	–	–	**29.0**
Rest of the world	–	0.7	–	–	–	–	**0.7**
Total revenue from contracts with customers	**569.2**	**8.2**	**12.5**	**0.0**	**0.0**	**0.0**	**590.0**

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

	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**

10. Divestment of US Zubsolv business to the wholly owned subsidiary Biolipox AB as of December 31

	Parent company statement of operations				Parent company statement of operations excluding the sold business			
SEK m	2024 Oct-Dec	2023 Oct-Dec	2024 Jan-Dec	2023 Jan-Dec	2024 Oct-Dec	2023 Oct-Dec	2024 Jan-Dec	2023 Jan-Dec
Net revnues	34.4	114.1	303.8	494.0	8.2	14.7	29.7	61.0
Operating earnings (EBIT)	960.1	-4.2	911.7	-40.6	-144.8	-84.6	-325.4	-392.9

At December 31, assets in Orexo AB related to the U.S. Zubsolv business were divested to the wholly owned subsidiary Biolipox AB. The internal transaction was completed at a fair market value of SEK 1,138.9 m assessed by an independent external party.

Definitions and reconciliations of key figures

KEY FIGURES AND CERTAIN OTHER OPERATING INFORMATION PER SHARE ARE DEFINED AS FOLLOWS

Margins	Definition/calculation	Purpose
Gross margin	Gross profit divided by net revenues	Gross Margin is used to measure the relative direct profitability from sold products
Operating margin (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
ADJUSTED EBIT	Earnings before net financial items and tax, the same as Operating earnings excluding impairment of intangible assets of Deprexis and Vorvida	This measure enables the profitability to be compared across locations where corporate taxes differ and irrespective the financing structure of the company over time without impact of onetime impairment of intangible assets of Deprexis and Vorvida
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 Oct-Dec	2023 Oct-Dec	2024 Jan-Dec	2023 Jan-Dec
EBIT	-98.0	-8.6	-140.3	-109.5
Depreciation and amortization	126.8	21.0	189.2	77.0
EBITDA	**28.9**	**12.4**	**48.9**	**-32.5**

OPERATING EXPENSES SEK m	2024 Oct-Dec	2023 Oct-Dec	2024 Jan-Dec	2023 Jan-Dec
Selling expenses	-48.4	-43.5	-191.3	-181.5
Administrative expenses	-56.0	-38.0	-165.3	-188.0
Research and development costs	-162.9	-65.4	-340.0	-303.1
Other operating income and expenses	31.4	-7.6	38.4	13.3
Operating expenses	**-235.9**	**-154.5**	**-658.2**	**-659.5**

ADJUSTED EBIT SEK m	2024 Oct-Dec	2023 Oct-Dec	2024 Jan-Dec	2023 Jan-Dec
EBIT	-98.0	-8.6	-140.3	-109.5
Impairment of intangible assets Deprexis	71.1	—	71.1	—
Impairment of intangible assets Vorvida	28.1	—	28.1	—
Adjusted EBIT, i.e. exclusion of impairment of intangible assets	**1.2**	**-8.6**	**-41.2**	**-109.5**

GROSS INVESTMENTS SEK m	2024 Oct-Dec	2023 Oct-Dec	2024 Jan-Dec	2023 Jan-Dec
Investments in tangible fixed assets	0.6	0.9	3.1	18.5
Investments in intangible fixed assets	0.2	0.0	1.6	0.7
Gross investments	**0.8**	**0.9**	**4.6**	**19.2**

RETURN ON SHAREHOLDERS' EQUITY SEK m	2024 Oct-Dec	2023 Oct-Dec	2024 Jan-Dec	2023 Jan-Dec
Shareholders' equity beginning balance	92.0	92.0	58.9	193.9
Shareholders' equity ending balance	-126.3	58.9	-126.3	58.9
Average shareholders' equity	-17.2	75.4	-33.7	126.4
Net earnings	-116.0	-18.6	-203.0	-128.3
Return on shareholders' equity %	**neg.**	**-24.7**	**neg.**	**-101.5**

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 2024 amounted to SEK 590 million, and the number of employees to 110. 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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