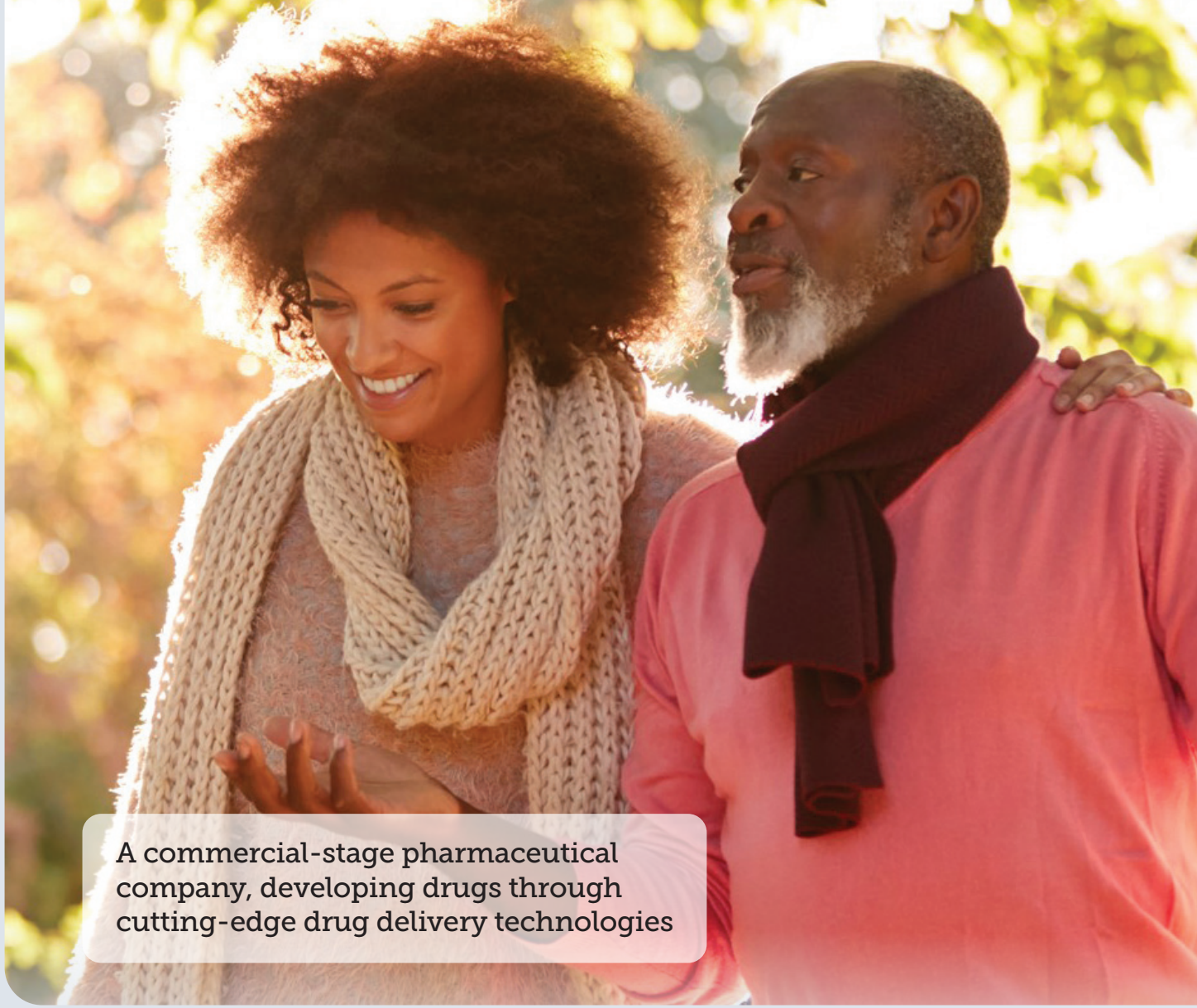
orexo

Interim Report Q3 2025

October 23, 2025

Unlocking the potential of the AmorphOX® technology



amorphOX®

GOLD | Top 5%
ecovadis
Sustainability Rating
AUG 2025

WE SUPPORT
UN GLOBAL COMPACT

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 2025 highlights

- Total net revenues of SEK 118.7 m (136.5)
- EBITDA of SEK -9.8 m (-0.7), including a negative impact from costs associated with LTIP programs of SEK -12.9 m
- Net earnings of SEK -29.8 m (-41.9)
- US Commercial segment net revenues of SEK 113.9 m (131.0), in local currency USD 12.0 m (12.6)
- Cash flow from operating activities of SEK -10.3 m (-13.4), cash and cash equivalents of SEK 105.6 m (114.9)
- Earnings per share before dilution and after dilution amounted to SEK -0.86 (-1.21)
- Positive in-vivo data showed for a powder-based intranasal GLP-1 agonist medication supported by the AmorphOX® technology
- The subsidiary, Orexo US Inc., awarded approx. SEK 75 m (USD 8 m) by BARDA for the development of OX390, an intranasal rescue medication for adulterated overdoses. Pending milestones and deliverables the award is valued up to approx. SEK 480 m (USD 50.9 m).
- 2025 financial outlook reiterated

Important events after the end of the period

- No important events after the end of the period

Group net revenues

119 SEK M

Group EBITDA

-10 SEK M

Cash and cash equivalents

106 SEK M

SDG 3.5 net revenue ratio

96%

SEK m unless otherwise stated	2025 Jul-Sep	2024 Jul-Sep	2025 Jan-Sep	2024 Jan-Sep	2024 Jan-Dec
Net revenues	118.7	136.5	383,2	429.7	590.0
Cost of goods sold	-7.1	-20.1	-36,3	-49.7	-72.1
Operating expenses	-132.7	-138.1	-394,7	-422.3	-658.2
EBIT	-21.1	-21.7	-47,8	-42.2	-140.3
EBIT margin %	neg.	neg.	neg.	neg.	neg.
EBITDA	-9.8	-0.7	-14,0	20.2	48.9
Earnings per share, before dilution, SEK	-0.86	-1.21	-2,47	-2.51	-5.89
Earnings per share, after dilution, SEK	-0.86	-1.21	-2,47	-2.51	-5.89
Cash flow from operating activities	-10.3	-13.4	21,9	-38.8	-32.6
Cash and cash equivalents	105.6	114.9	105,6	114.9	123.3

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 2024.

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 powder-based drug delivery technology, that improves bioavailability and stability for both small and large molecules, driving the next wave of development projects.

Commercialized 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
Commercial 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		
R&D	IRM – Intranasal Rescue Medications										
	IZIPRY™	naloxone, opioid overdose	amorphOX®								
	OX640	epinephrine, anaphylaxis	amorphOX®								
	OX390	NCE, overdose	amorphOX®	ASPR							
	OX125	nalmefene, opioid overdose	amorphOX®								
	Other disclosed projects in pre-clinical phase										
	OX472	semaglutide/GLP-1 receptor agonist	amorphOX®								
	Others	vaccine candidate	amorphOX®	abera BIOSCIENCE							

* Digital Mental Health Programs, incl. MODIA® & Vorvida®
OUD – Opioid Use Disorder
NCE – New Chemical Entity

Contact persons quarterly report

Nikolaj Sørensen, President and CEO,
Fredrik Järrsten, EVP and CFO, or Lena Wange,
IR & Communications Director.

Tel: +46 18 780 88 00, +1 855 982 7658,
E-mail: ir@orexo.com.

Presentation

On October 23, at 2 pm CEST analysts, investors and media are invited to attend a presentation, incl. a Q&A. Participants may access the event via live webcast or teleconference through the following link:

https://investorcaller.com/events/orexo/orexo-q3-report-2025

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

Published financial calendar

2026:
Interim Report Q4 2025, incl. Full Year Report, February 5, at 8 am.
Annual and Sustainability Report 2025 - March 27
Interim Report Q1 2026 - April 28, at 7 am
Annual General Meeting - May 7
Interim Report Q2 2026 - July 16, at 7 am
Interim Report Q3 2026 - October 22, at 7 am

2027:
Interim Report Q4 2026, incl. Full Year Report, February 4, at 7 am.

Unlocking the potential of the AmorphOX technology

CEO Comments in brief

Orexo has a strong track record of turning platform technologies into approved medicines. Our sublingual platform enabled multiple FDA-approved products, including Zubsolv® and Abstral®, that generated significant revenues for the company. Building on that success, we are now concentrating resources on the AmorphOX® platform, our next-generation formulation engine designed to unlock proprietary products and expand our pipeline.

During the quarter, we reached two key milestones that reinforce the scalability of the AmorphOX platform. The breakthrough with the GLP-1 agonist and the BARDA[1] financing secured for the OX390 project both strengthen the platform and its future potential. I am encouraged by the enthusiasm these developments have generated among our key stakeholders, and by the growing recognition of AmorphOX's long-term value.

From a financial perspective, EBITDA was negative, however, we would have reported positive EBITDA for the quarter absent provisions for social security fees related to the long-term incentive program following the positive share price development in the quarter. Zubsolv demand is stable, but top line sales were impacted by foreign exchange rate headwinds and significantly lower inventory levels with the wholesalers. We expect Zubsolv sales to improve in the fourth quarter consistently with historical seasonal patterns and we maintain our full-year guidance.

Leveraging the AmorphOX technology in new high-growth pharmaceutical areas

After successful formulation and in-vitro testing, we proceeded with a first in-vivo study combining the AmorphOX technology with semaglutide. The study showed promising data with higher bioavailability than the commercially available oral tablet of semaglutide. This is the first in-vivo study, and based on the encouraging data, we will continue refining the formulation to enable higher dosing and prepare for an additional in-vivo proof-of-concept study before proceeding with the first exploratory trial in humans.

Data from the first in-vivo study are promising, as they confirm once again that AmorphOX is applicable to large molecules and that the technology can deliver GLP-1 agonists and, in all likelihood, other peptides via the nasal route. From a long-term strategic perspective, it opens a pathway for Orexo into one of the largest and fastest growing pharmaceutical categories currently, the GLP-1 agonists for diabetes, weight loss and likely even within CNS diseases.

BARDA partnership accelerates OX390 development

Another important step was the award from BARDA, where we will initially receive USD 8 million for the development of OX390. In total the partnership is valued at up to USD 51 million, pending milestones and deliverables, and will cover the majority of the development expenses of the OX390 project. OX390 is targeting the growing issue with adulteration of opioids and more specifically adulteration with alpha-2 agonists. When opioids are mixed with alpha-2 agonists the first responders have increased difficulty getting the patient back to consciousness and in-vivo studies indicate an alpha-2 agonist may increase the effect of opioid-induced respiratory depression up to 100 times.[2]

The formulation work has been ongoing for a while and we have completed a first pre-IND meeting with FDA. We are now finalizing the first AmorphOX formulations in preparation of the first in-vivo proof-of-concept study planned early next year. The BARDA award covers the majority of the development expenses, and the first payment, to cover incured costs, will be reported as income and have a positive impact on EBITDA starting Q4.

> **Data from the first in-vivo study are promising, as they confirm once again that AmorphOX® is applicable to large molecules and that the technology can deliver GLP-1 agonists and, in all likelihood, other peptides via the nasal route.**

In parallel we continue to work with potential partners to test the AmorphOX technology on their active substances. We have completed an external market assessment of the AmorphOX technology and believe there is a significant potential in large molecules moving forward, from peptides to protein-based pharmaceuticals, such as vaccines. The feedback from potential partners in the market assessment shows the importance of clinical evidence of the technology and ability to manufacture at scale which reinforces the importance of investments in advancing products to clinical stage.

Advancing Izipry™ and OX640 toward commercialization

During the quarter we have made good progress addressing the concerns raised by FDA related to Izipry, our overdose rescue medication, and initiated commercial scale manufacturing with the device and secondary packaging. Getting an AmorphOX product approved is a significant accomplishment. Based on discussions with regulatory agencies about our other AmorphOX-based pipeline products, there is significant value in having a product approved that is supported by the technology. However, the market for Izipry is highly competitive and we will continuously review the best go-to-market strategy to limit the financial exposure of the company.

For OX640, our nasal epinephrine rescue medication, we have started the process to upscale the manufacturing, leveraging the supply chain established for Izipry. In parallel, the first competing nasal product has been approved and launched in both the US and Europe. However, despite significant market investments, the first product on the market has yet to reach a sales trajectory in line with expectations. During the fourth quarter we will conduct a market survey to test the key differentiating parameters with OX640 and confirm the market potential of this product in light of the current market dynamics. We remain convinced that treatment of anaphylaxis will follow the same pattern as for opioid overdose, moving from injectable rescue medications to nasal delivery.

Demand for Zubsolv remained stable, but sales negatively impacted by reduced inventory at wholesalers

The Zubsolv sales to wholesalers and their reported sales to pharmacies show a steady development during 2025 with about 1 percent decline both comparing YTD with last year and quarter over quarter. However, net sales are significantly impacted by quarterly volatility of wholesalers' inventory of Zubsolv explaining most of the movement to Q2 2025. The inventory level entering 2025 was about 60 percent higher than the inventory level when exiting Q3 2025. Both of these numbers are extremes but follow a normal annual pattern with inventory levels being low in Q3 and increasing in the fourth quarter. Compared to last year net sales are impacted by some decline in demand led by the previous exclusive contract within United Health Group and Humana. We expect the inventory levels to normalize during the fourth quarter and contribute to an improvement in sales.

For 2026 most insurance companies have published their formularies, and we are pleased to maintain our 99 percent coverage within the commercial segment without any rebate changes. In the less profitable public segment the coverage is 48 percent, a decrease with 1 percentage point due to a change at a minor Medicare insurance plan.

Strategic steps toward 2026 and beyond

Moving into the fourth quarter we will finalize our plans for 2026 and are reviewing all of our activities to ensure we invest in the areas with the highest value potential for our shareholders. The plans for 2026 will take into account our financial situation to ensure we maintain good liquidity. The BARDA grant will cover a significant amount of the costs for one of our key projects, but we will also work diligently to ensure we have the financial capacity to advance our other core projects, through leveraging our existing assets and partnering of projects.

> **Moving into the fourth quarter we will finalize our plans for 2026 and are reviewing all of our activities to ensure we invest in the areas with the highest value potential for our shareholders.**

Uppsala, Sweden, October 23, 2025

Nikolaj Sørensen
President and CEO

US Commercial

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

Misuse of opioids is a global healthcare problem but is of epidemic proportion in the US. It is estimated that 8.9 million people aged 12 or older in the US are currently misusing opioids.[3] Of these, around 5.7 million are dependent on opioids, and approx. 2.3 million are receiving medication-assisted treatment (MAT).[4] Latest available data is showing predicted number of reported fatal opioid overdoses of more than 50,000 annually.[5] Nine out of ten of these involve synthetic illicitly manufactured opioids, such as fentanyl.[6] Additionally adulterants, such as xylazine, a veterinary tranquilizer, are being mixed in with the fentanyl and is being identified in more drug tests across the US, adding complications to rescue situations and possible treatment regimens. Although recent opioid overdose data show a decline in deaths, likely due to increased access to treatment and other interventions, the mortality rate remains high.

Developments during the quarter

In Q3, the buprenorphine/naloxone market grew 1 percent versus Q2 2025 and grew 4 percent versus Q3 2024, showing single digit quarter over quarter growth in all insured patient segments and single digit declines in the cash segment. The recently approved law, One Big Beautiful Bill, is proposed to result in reductions to Medicaid funding. The implications of these changes for access to care among individuals with OUD are not yet clear, but the developments are being closely monitored.

Although adoption has lagged behind projections, the Mainstreaming Addiction Treatment Act is expected to have a positive impact on the long-term growth of the buprenorphine/naloxone market.

The market has in recent years shifted from growth in Medicaid to the Commercial segment. In Medicaid, the market grew 2 percent vs Q3 2024, while the Commercial segment increased 8 percent.

Zubsolv total volume was flat versus Q2 2025. Within the Open segment where demand was unchanged, some large payers grew including Commercial Caremark, Commercial Optum, and Michigan Medicaid, while others offset the growth with declines, such as Commercial Express Scripts and Maryland Medicaid. Volume grew 1 percent in the non-reimbursed segment and declined 2 percent in the formerly exclusive segment comprising United Health Group Commercial (UHG) and Humana Medicare D.

Compared to Q3 2024 Zubsolv volume declined 7 percent. Zubsolv declined 3 percent in the Open segment, but the majority of the decline was driven by a decrease in UHG Commercial and Humana Medicare D. The Humana Medicare decrease is driven by the new rebate policy implemented January 1, 2025. While this policy led to unfavorable formulary changes that prioritize generics at Humana, it had a favorable net price impact for Zubsolv in other Medicare plans.

Zubsolv's best in class market access in the Commercial payer segment maintains at 99 percent. In the Public payer segment, Alabama Medicaid restricting Zubsolv declined public access by approx. 1 percentage point to 48 percent.

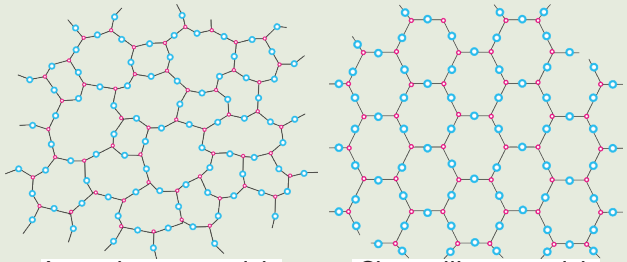
Zubsolv's 99 percent Commercial access could be a potential advantage if OUD patients need to shift due to changes in Medicaid coverage due to the new legislation, One Big Beautiful Bill.

AmorphOX®

– The next-generation drug delivery technology unlocks a broad range of new opportunities in the development of innovative drugs.

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 aqueous solutions.



Amorphous materials are non-crystalline and unstable, but offer rapid dissolution in drug delivery.

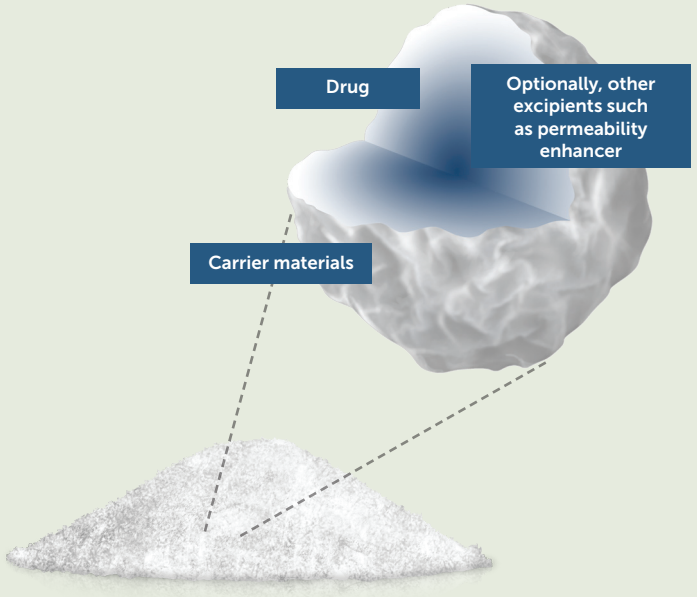
The challenge

Historically, amorphous drug compositions were found to degrade during storage due to chemical and physical instability. Orexo has developed a solution: AmorphOX.

The solution

AmorphOX is a powder-based technology providing the stability needed for amorphous materials.

It is 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.



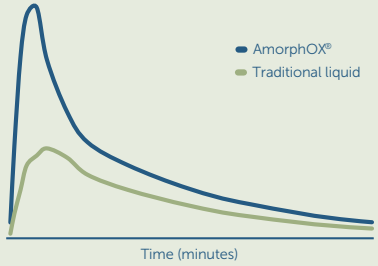
The unique strengths

AmorphOX® is validated in multiple clinical trials

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 the treatment of allergic reactions, including anaphylaxis. Data has demonstrated qualities such as rapid absorption, excellent bioavailability and improved handling and storage properties.

Plasma concentration

Superior pharmaco-kinetic (PK) properties with more rapid onset, higher peak and overall exposure.



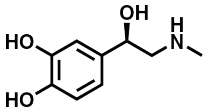
AmorphOX's unique properties ensure physical and chemical stability

When AmorphOX is tested with various APIs 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 dis-solving property is maintained.

Examples: Chemical degradation after accelerated stability studies at 40°C/75% RH

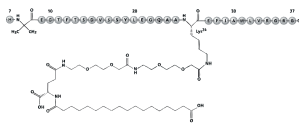
Small molecules

Epinephrine
0.3% after 24 months



Peptides

Semaglutide
0.1% after 62 months



Biologics

Protein (spike protein).
Retained activity after
3 months (40°C).

AmorphOX is a versatile platform

AmorphOX works with a broad spectrum of active chemical substances, including small molecules, peptides and biologics, 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.

amorphOX®

Products under development

Intranasal rescue medications

IZIPRY™ – for opioid overdose with a high dose of powder-based naloxone

The project in brief

Opioid overdose is a life-threatening condition, characterized by loss of consciousness and respiratory depression. Based on the AmorphOX® technology, Orexo has developed a high-dose naloxone rescue medication, Izipry, designed to reverse opioid overdoses, including those from highly potent synthetic opioids, such as fentanyl and fentanyl analogues.

Differentiation and IP

Izipry 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, Izipry shows substantially higher peak plasma concentrations and total exposure of naloxone. These properties can be critical in avoiding brain damage, saving lives. In addition, studies have shown that the AmorphOX technology improves the stability by formulating naloxone as a powder rather than as a liquid. The enhanced stability allows Izipry to remain unaffected at sub-zero temperatures.

Izipry is protected by patents until 2039.

Developments during the quarter

As the critical components for commencing commercial manufacturing were delivered in the previous quarter, production of the final product was initiated. In parallel, preparations continued for the start of new stability and reliability studies, which are planned to begin in Q4 2025 and will be based on the final commercial product. These studies are a response to the complete response letter (CRL) received in Q3 2024, in which the FDA requested updated technical data from the final commercial product. The most recently communicated timeline to submit an updated new drug application to the FDA in the summer of 2026 remains unchanged.

Market and commercialization

Upon approval, Izipry will address the need for high-dose opioid overdose treatments, particularly for cases involving synthetic opioids such as fentanyl. The product is intended for situations where multiple doses of 4 mg intranasal naloxone would be required.

Its enhanced stability allows Izipry to be stored at sub-zero temperatures until above room-temperatures without loss of efficacy.

Unlike OTC naloxone products, which are often not covered by insurance, Izipry, as a prescription medicine, is expected to be reimbursed by insurers. It may also have potential to be co-prescribed with prescription opioids for pain management.

To support individuals with financial difficulties, Izipry will be included in Orexo's patient assistance programs.

OX640 – for allergic reactions with powder-based epinephrine

The project in brief

The aim with OX640 is to develop a powder-based intranasal 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, particularly when exposed to elevated temperatures, which is the reason why the vast majority of today's commercial epinephrine products have limited shelf-life and restrictive and storage conditions.

Differentiation & IP

OX640 is a needle-free epinephrine treatment based on the AmorphOX technology. Using this platform, the epinephrine has been formulated with certain carrier materials and then spray dried to create a powder suitable for intranasal administration. Unlike liquid-based drugs, AmorphOX® powder formulations can better preserve the chemical and heat stability of the active substance, thereby extending shelf life, maintaining therapeutic efficacy over time, increasing flexibility in storage, and avoiding use of preservatives. These qualities offer important advantages for both patients and healthcare systems globally.

OX640 is protected by patents and patent applications until 2044.

Developments during the quarter

As part of the preparations for manufacturing in commercial scale, several batches at commercial scale of the spray-dried powder were manufactured. Scientific advice meetings were held with European regulatory authorities in order to get confirmation of the remaining development program, including the pivotal registration studies.

In parallel, discussions are held with potential partners for continued development and commercialization in global markets.

OX390 – for adulterated opioid overdoses

The project in brief

Anchored by the AmorphOX technology platform, a new rescue medication, OX390, is in development. Intended to complement the existing rescue treatments Izipry and OX125, OX390 addresses the growing adulteration of synthetic opioids, which complicates the management of accidental overdoses. It has the potential to rescue patients intoxicated with adulterated fentanyl who have not responded to naloxone or nalmefene alone.

Differentiation & IP

There are no known competitor products on the market. OX390 is protected by the AmorphOX patent portfolio.

Developments during the quarter

At the end of the quarter, Orexo US Inc. initiated a partnership with BARDA[7] for the development of OX390. Under the collaboration, BARDA will contribute with expertise and funding up to USD 51 million, covering non-clinical toxicology studies, human clinical trials, drug and device manufacturing, and regulatory filing activities. The funding will be provided based on the achievement of specific milestones and deliverables. Upon completion of the project and FDA approval of the product, Orexo will retain all commercial rights to OX390.

Following completed analyses and evaluations of several powder-based formulations developed using the AmorphOX technology, the development will be accelerated with a selected number of formulations. The next step is to assess the pharmacokinetics and tolerability of these candidate formulations in an in-vivo proof-of-concept study. Orexo has already met with the FDA regarding the investigational new drug (IND) requirements for OX390 and held initial discussions on the regulatory pathway toward a potential approval.

OX125 – for opioid overdose with powder-based nalmefene

Activities within the project have been paused due to internal resource prioritisation and headwinds for the first approved nalmefene nasal product for opioid overdose rescue on the US market.

Other disclosed projects in preclinical phase

OX472 – intranasal semaglutide/GLP-1 receptor agonist

Developments during the quarter

A pre-clinical in vivo study was conducted in which the AmorphOX technology was used to develop three powder-based intranasal formulations of semaglutide. The formulations were compared with a semaglutide tablet administered orally, Rybelsus®, and an injectable semaglutide administered subcutaneously, Wegovy®.

Data showed that two of the AmorphOX formulations provided up to seven times higher plasma concentrations than the oral tablet and, also lower variation in plasma levels. As expected, the plasma levels were lower than with subcutaneous injection.

The study reinforces the potential of the AmorphOX technology to enable effective intranasal administration of larger molecules, such as peptides. An intranasal semaglutide formulation can offer needle-free dosing, improved ease of use, and potentially better compliance. The ability of the AmorphOX technology to stabilize peptides means that the substance can maintain its effectiveness in varying temperature ranges and therefore does not require refrigerated storage, which applies to subcutaneous injections.

In parallel, stability studies were ongoing, with the most recent available data showing minimal degradation of the active substance, at elevated temperature (40°C) after 6 months.

The next step is to evaluate potential development pathways and the value that intranasal administration of semaglutide and other GLP-1 agonists may offer in various indications. Also potential development partnerships will be assesed.

Vaccine candidate

Together with Abera Bioscience, a proof-of-concept in-vivo study was conducted in Q1 2025. The aim was to assess how Abera's mucosal influenza vaccine platform performs in combination with the AmorphOX technology, which enables a stable and user-friendly powder formulation.

Data demonstrated that both the liquid and powder formulations generated strong systemic antibody response in serum (IgG) as well as locally in the nose and lungs (IgA). No difference in immune response was seen between the liquid intranasal solution and the intranasal powder.

An intranasal influenza vaccine has the potential to easily and effectively help reduce the spread of infections and prevent disease, which could play an important role in a potential future pandemic. Formulating vaccines in powder form using the AmorphOX technology provides the potential to develop cost-efficient, thermostable vaccines with no need for cold chain requirements.

Data from a stability study, in which the core component of Abera's vaccine platform was formulated as a powder using the AmorphOX technology, showed that after six months of storage at temperatures between -20 and +40 °C, the component retained its functionality very well across the entire range.

Orexo is in discussions with Abera regarding a potential continued collaboration.

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.

The sustainability strategy involves 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 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 2024 Sustainability Report.

"When regulation supports sustainability, capital follows. When compliance outweighs impact, the opportunity to do good at scale is lost.

Nikolaj Sørensen, CEO and President of Orexo, in the 2025 UN Global Compact CEO Survey by Accenture, published in September 2025.

Developments during the quarter

For the second consecutive year, Orexo AB's sustainability work was ranked among the top 5 percent of the 75,000 companies assessed annually by EcoVadis.

Orexo updated its sustainability strategy based on the results of the double materiality analysis conducted in the second half of 2024, in accordance with the CSRD directive and the Omnibus package. The proposed strategy will be reviewed and decided by the management team in the fourth quarter of 2025.

In line with the objective to expand access to treatment for those affected by opioid dependence, Orexo US entered into a partnership with BARDA[8]. Through this collaboration, BARDA will provide conditional funding for the development of OX390, a new rescue medication targeting adulterated overdoses. This growing challenge in the US impacts individuals, families, and communities, and poses increasing difficulties for emergency services and voluntary organizations nationwide.

A decision was made to relocate Orexo's head office to new premises in Uppsala Science Park in H2 2026. The new facility will be developed with a strong focus on sustainability, incorporating recycled and sustainable materials, using energy-efficient technologies, and the location offer excellent public transport connections for employees and visitors alike.

The laboratory in Uppsala, Sweden, was certified according to My Green Lab, which means that the adjustments required to meet specific environmental standards have been successfully implemented.

my green lab certification.

Financial development

Net revenues

Total net revenues amounted to SEK 118.7 m (136.5) for Q3 and to SEK 383.2 m (429.7) for the first nine months. The decrease is mainly explained by a weaker USD and lower net revenues in US Commercial.

Revenues by segment

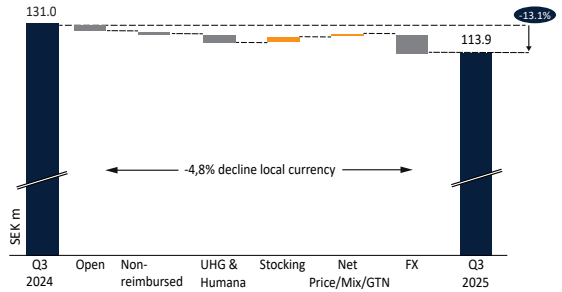
US Commercial revenues amounted to SEK 113.9 m (131.0) for Q3. The decrease compared to Q3 last year is driven by product sales of Zubsolv® in the US, primarily affected by a weaker USD reducing revenues by SEK 10.9 m. Lower demand especially from the previous exclusive contract within United Health Group and Humana also contributed negatively while a lower decrease in wholesaler inventories compared to the decrease last year, contributed positively by SEK 2.3 m. US Commercial revenues amounted to SEK 360.4 m (408.2) for the first nine months. In local currency US Commercial net revenues for Q3 amounted to USD 12.0 m (12.6) and for the first nine months to USD 36.2 m (38.9).

HQ & Pipeline partner product related revenues for Q3 amounted to SEK 4.8 m (5.5). The decrease is mainly explained by lower Zubsolv ex-US revenues of SEK 0.6 m (3.8) and lower Edluar royalties of SEK 2.9 m (3.0) partly offset by higher Abstral royalties of SEK 1.3 m (-1.4). HQ & Pipeline partner product related revenues amounted to SEK 22.8 m (21.5) for the first nine months.

Cost of goods sold

Cost of goods sold (COGS) amounted to SEK 7.1 m (20.1) for Q3. US Commercial amounted to SEK 7.0 m (17.8), the decrease is mainly explained by a positive FX impact of SEK 6.3 m vs prior year, favorable production costs for Zubsolv US and lower technical infrastructure costs for Digital Mental Health Programs (DMHP). HQ & Pipeline amounted to SEK 0.1 m (2.3) for Q3 where the decrease is due to absence of Zubsolv ex-US tablet sales to Orexo's partner Accord Healthcare. Cost of goods sold (COGS) amounted to SEK 36.3 m (49.7) for the first nine months.

ZUBSOLV US NET REVENUES DEVELOPMENT



Operating expenses

Total operating expenses were 3.9 percent lower compared to the same period last year and amounted to SEK 132.7 m (138.1) for Q3. Higher costs for long-term incentive programs mainly related to provisions for social security fees following a significantly higher share price at the end of the quarter of SEK 33.10 (14.20) contributed negatively in all functions with SEK -12.9 m (5.4) during the quarter. Weaker USD contributed positively with SEK 11.5 m vs prior year.

Selling expenses amounted to SEK 40.0 m (47.2) for Q3. The decrease is mainly explained by lower marketing-related costs for Izipry™ and lower staff-related expenses. Selling expenses amounted to SEK 122.6 m (142.8) for the first nine months.

Administrative expenses amounted to SEK 31.9 m (32.2) for Q3. The decrease is mainly explained by lower legal expenses for DOJ investigation in US Commercial partly offset by higher legal expenses in HQ & Pipeline. Administrative expenses amounted to SEK 93.9 m (109.3) for the first nine months.

NET REVENUES AND EBIT PER SEGMENT

SEK m	Net revenue					EBIT				
	2025 Jul-Sep	2024 Jul-Sep	2025 Jan-Sep	2024 Jan-Sep	2024 Jan-Dec	2025 Jul-Sep	2024 Jul-Sep	2025 Jan-Sep	2024 Jan-Sep	2024 Jan-Dec
Zubsolv US product sales	113.9	131.0	360.4	408.2	560.3	–	–	–	–	–
Digital Mental Health Programs (DMHP) product sales	0.0	–	0.0	0.0	0.0	–	–	–	–	–
US Commercial – total	**113.9**	**131.0**	**360.4**	**408.2**	**560.3**	**38.2**	**25.3**	**117.8**	**93.3**	**27.9**
Abstral® royalty	1.3	-1.4	3.7	7.0	8.2	–	–	–	–	–
Edluar® royalty	2.9	3.0	9.9	9.0	12.5	–	–	–	–	–
Zubsolv – ex-US	0.6	3.8	9.2	5.5	8.9	–	–	–	–	–
HQ & Pipeline – total	**4.8**	**5.5**	**22.8**	**21.5**	**29.7**	**-59.3**	**-47.0**	**-165.5**	**-135.5**	**-168.3**
Total	**118.7**	**136.5**	**383.2**	**429.7**	**590.0**	**-21.1**	**-21.7**	**-47.8**	**-42.2**	**-140.3**

Research and development costs amounted to SEK 61.7 m (56.2) for Q3. The increase is mainly explained by higher costs for OX640 and higher internal costs partly offset by lower amortization costs for DMHP and Zubsolv® intangible assets. Research and development costs amounted to SEK 170.5 m (177.1) for the first nine months.

Other operating income and expenses amounted to SEK 0.9 m (-2.5) for Q3. This is explained by exchange rate losses derived from revaluations of parent company balance sheet items in foreign currency, predominantly in USD, amounting to SEK -0.2 m (-5.3), lower received insurance reimbursement of SEK 0.1 m (2.6), lower partner reimbursement of development costs of SEK 0.0 m (1.1), higher MATCore® grants of SEK 0.7 m (-0.2) and sublease income of SEK 0.3 m (0.3). Other operating income and expenses amounted to SEK -7.6 m (7.0) for the first nine months.

Operating profit

EBITDA amounted to SEK -9.8 m (-0.7) for Q3, including a negative impact from costs associated with LTIP programs of SEK -12.9 m (5.4). For the first nine months EBITDA amounted to SEK -14.0 m (20.2).

The EBITDA contribution from US Commercial amounted to SEK 39.3 m (36.1) for Q3 and to SEK 121.0 m (125.7) for the first nine months.

Total EBIT amounted to SEK -21.1 m (-21.7) for Q3 and to SEK -47.8 m (-42.2) for the first nine months.

EBIT contribution from US Commercial amounted to SEK 38.2 m (25.3) for Q3, equal to an EBIT margin of 33.6 percent (19.3). EBIT contribution from US Commercial amounted to SEK 117.8 m (93.3) for the first nine months, equal to an EBIT margin of 32.7 percent (22.9).

Net financial items and tax

Net financial items for Q3 amounted to SEK -11.6 m (-15.4) and are mainly explained by lower bond loan costs of SEK -11.3 m (-13.0), negative unrealized exchange rate impact of SEK -0.9 m (-2.9) derived from the parent company's foreign currency bank accounts in USD and lower interest income from bank accounts of SEK 0.8 m (0.9). Net financial items amounted to SEK -38.0 m (-42.0) for the first nine months.

Total tax expenses amounted to SEK 2.9 m (-4.8) for Q3. The decrease is mainly explained by higher positive adjustment of SEK 4.0 m (-3.6) to deferred tax assets related to temporary differences. Total tax expenses amounted to SEK 0.3 m (-2.5) 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 -29.8 m (-41.9) for Q3 and to SEK -85.5 m (-86.7) for the first nine months.

Cash and cash flow

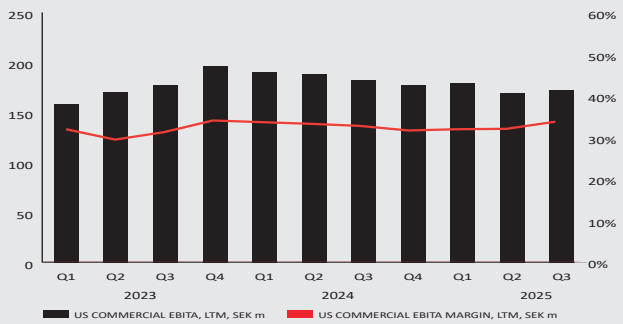
Cash flow from operating activities amounted to SEK -10.3 m (-13.4) for Q3 and was negatively impacted primarily by negative operating earnings, interest paid and changes in working capital partly offset by adjustment for non-cash items. Cash flow from operating activities amounted to SEK 21.9 m (-38.8) for the first nine months.

Total cash flow for the period amounted to SEK-14.9 m (-20.0) excluding a negative USD currency effect of SEK -0,8 m (-4.7). Total cash flow for the first nine months amounted to SEK -4.4 m (-54.0) excluding a negative USD currency effect of SEK -13,2 m (-2.1).

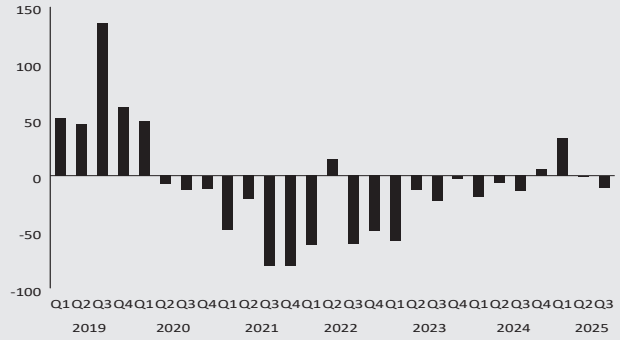
As of September 30, 2025, cash and cash equivalents amounted to SEK 105.6 m (114.9) and interest-bearing liabilities to SEK 472.3 m (459.3), i.e. a negative net cash position of SEK -366.7 m (-344.4). Cash and cash equivalents decreased by SEK 15.7 m from Q2 2025.

GROUP EBITDA, SEK m

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



CASH FLOW FROM OPERATING ACTIVITIES, SEK m



Investments

Gross investments in tangible and intangible fixed assets amounted to SEK 0.0 m (0.0) for Q3 and to SEK 0.0 m (3.8) for the first nine months.

Equity

Shareholders' equity on September 30, 2025, was SEK -224.3 m (-27.2).

Parent company

Net revenues for Q3 amounted to SEK 4.8 m (63.1) of which SEK 0.0 m (57.6) was related to sales to Group companies, the decrease is explained by sale of assets related to the US Zubsolv business to the wholly owned subsidiary Biolipox AB in Q4 2024. Net revenues amounted to SEK 22.8 m (269.4) for the first nine months, of which SEK 0.0 m (247.9) was related to sales to Group companies.

Total EBIT amounted to SEK -62.3 m (-43.2) for Q3 and to SEK -174.9 m (-48.3) for the first nine months.

Earnings before tax amounted to SEK -48.6 m (-57.5) for Q3 and to SEK -134.0 m (-88.4) for the first nine months.

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

As of September 30, 2025, cash and cash equivalents in the parent company amounted to SEK 21.6 m (76.5).

Parent company shareholders' equity at September 30, 2025, was SEK 911.8 m (73.6). 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 in Q4 2024.

Other information

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 EBITDA forecast remains unchanged, driven by expectations of a positive inventory impact for Zubsolv in Q4 as well as stable demand. Continued strong cost control is also expected to have a positive effect. However, the EBITDA outlook is related to some increased risk due to impact from non-budgeted one-time items such as the non-recurring rebate payment of SEK 9 m recorded in Q2, provisions associated with the LTIP program and significant exchange rate fluctuations.

The financial outlook 2025 is based on a forward-looking assumption of a USD/SEK exchange rate of 10.50. The average USD/SEK exchange rate during Q3 was 9.51 and 9.41 at the end of the quarter.

From a currency sensitivity perspective, a 10 percent depreciation in the USD/SEK exchange rate would affect EBIT by approximately 20 percent of the corresponding change in net revenues, since the majority of costs are denominated in USD.

Forward-looking statements

This report contains forward-looking statements that reflect the company's current expectations. Although the company believes that the expectations reflected in such forward-looking statements are reasonable, no assurance can be given that such expectations prove to be correct as they are subject to risks and uncertainties that could cause actual results to differ materially due to a variety of factors.

Forward-looking statements speak only as of the date they were made, and, other than as required by applicable law, the company undertakes no obligation to update any of them considering new information or future events.

Risks and uncertainty factors

Orexo is exposed to external risks such as geopolitical conflicts and political and regulatory changes. Other risks that can have an impact on the company´s business are operational and sustainability risks as well as financial risks that can impact the financial development and position. The company continuously works to proactively identify, analyze, and mitigate both known and emerging risks.

Significant risks and uncertainties are presented in the Annual and Sustainability Report for 2024 and in the Interim Report Note 4, Dispute.

The recently approved (July 4) law, known as the Big Beautiful Bill, will result in reductions to Medicaid funding. The implications of these changes for access to care among individuals with OUD are not yet clear, but the developments are being closely monitored.

In relation to the potential imposed tariffs on global trade, potential tariffs on pharmaceuticals and manufacturing materials could affect the development projects, which are more dependent on an international supply chain. The current level of uncertainty makes it challenging to take immediate action, but the company is actively engaged in mitigation planning for various scenarios, which may require reconsideration of some elements of the planned supply chain.

Glossary

View https://orexo.com/glossary/

Uppsala, Sweden, October 23, 2025

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, 2025 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, Sweden, October 23, 2025

Ernst & Young AB

Oskar Wall
Authorized Public Accountant

References

1 Page 4, Biomedical Advanced Research and Development Authority (BARDA) is part of the Administration for Strategic Preparedness and Response in the US Department of Health and Human Services.

2 Page 4, Acosta-Mares P, Violante-Soria V, Browne T Jr, Cruz SL. Xylazine potentiates the lethal but not the rewarding effects of fentanyl in mice. Drug Alcohol Depend. 2023 Dec 1;253:110993. Page 6, Substance Abuse and Mental Health Services Administration

3 Page 6, Substance Abuse and Mental Health Services Administration

4 Page 6, Substance Abuse and Mental Health Services Administration

5 Page 6, Center of Disease Control and Prevention

6 Page 6, Center of Disease Control and Prevention

7 Page 10, Biomedical Advanced Research and Development Authority (BARDA) is part of the Administration for Strategic Preparedness and Response in the US Department of Health and Human Services.

8 Page 12, Biomedical Advanced Research and Development Authority (BARDA) is part of the Administration for Strategic Preparedness and Response in the US Department of Health and Human Services.

9 Page 14, Last Twelve Months.

Financial reports, notes and key figures

CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS

SEK m	Notes	2025 Jul-Sep	2024 Jul-Sep	2025 Jan-Sep	2024 Jan-Sep	2024 Jan-Dec
Net revenues	9	118.7	136.5	383.2	429.7	590.0
Cost of goods sold		-7.1	-20.1	-36.3	-49.7	-72.1
Gross profit		**111.6**	**116.4**	**346.9**	**380.1**	**517.9**
Selling expenses		-40.0	-47.2	-122.6	-142.8	-191.3
Administrative expenses		-31.9	-32.2	-93.9	-109.3	-165.3
Research and development expenses		-61.7	-56.2	-170.5	-177.1	-340.0
Other operating income and expenses		0.9	-2.5	-7.6	7.0	38.4
Operating earnings (EBIT)		**-21.1**	**-21.7**	**-47.8**	**-42.2**	**-140.3**
Net financial items		-11.6	-15.4	-38.0	-42.0	-50.3
Earnings after financial items		**-32.7**	**-37.1**	**-85.8**	**-84.2**	**-190.6**
Income tax	5	2.9	-4.8	0.3	-2.5	-12.4
Net earnings for the period		**-29.8**	**-41.9**	**-85.5**	**-86.7**	**-203.0**
Earnings per share. before dilution. SEK		-0.86	-1.21	-2.47	-2.51	-5.89
Earnings per share. after dilution. SEK		-0.86	-1.21	-2.47	-2.51	-5.89

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

SEK m	2025 Jul-Sep	2024 Jul-Sep	2025 Jan-Sep	2024 Jan-Sep	2024 Jan-Dec
Earnings for the period	**-29.8**	**-41.9**	**-85.5**	**-86.7**	**-203.0**
Other comprehensive income					
Items that may subsequently be reversed to the statement of operations:					
Translation differences	-1.7	-9.3	-30.7	0.6	17.9
Other comprehensive earnings for the period. net after tax	**-1.7**	**-9.3**	**-30.7**	**0.6**	**17.9**
Total comprehensive earnings for the period [1]	**-31.5**	**-51.2**	**-116.2**	**-86.1**	**-185.1**

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

CONDENSED CONSOLIDATED BALANCE SHEET

SEK m	Notes	2025 Sep 30	2024 Sep 30	2024 Dec 31
ASSETS				
Fixed assets				
Tangible fixed assets		50.5	68.8	64.7
Intangible assets		23.2	142.6	26.9
Right-of-use assets		20.6	20.8	16.4
Deferred tax assets	5	40.2	48.9	38.9
Other financial assets		20.6	1.5	1.6
Total fixed assets		**155.0**	**282.6**	**148.4**
Current assets				
Inventories		42.5	54.3	60.1
Accounts receivable		159.3	187.8	198.5
Other receivables		16.0	15.0	35.2
Prepayment and accrued income		40.1	42.4	29.4
Cash and cash equivalents		105.6	114.9	123.3
Total current assets		**363.5**	**414.4**	**446.4**
TOTAL ASSETS		**518.6**	**697.0**	**594.8**
SHAREHOLDERS' EQUITY AND LIABILITIES				
Total shareholders' equity		**-224.3**	**-27.2**	**-126.3**
Long-term liabilities				
Provisions		13.0	13.5	24.0
Interest bearing liabilities	6	472.3	459.3	460.0
Lease liabilities, long-term		2.9	7.2	6.0
Total long-term liabilities		**488.3**	**480.0**	**490.0**
Current liabilities and provisions				
Accounts payable		68.1	54.7	41.5
Provisions		117.5	116.8	112.1
Other liabilities		11.1	11.1	9.1
Accrued expenses		41.7	48.7	58.2
Lease liabilities, current		16.1	12.9	10.0
Total current liabilities		**254.6**	**244.3**	**231.1**
Total liabilities		**742.9**	**724.3**	**721.1**
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		**518.6**	**697.0**	**594.8**

CONDENSED CONSOLIDATED CHANGES IN SHAREHOLDERS' EQUITY

SEK m	2025 Sep 30	2024 Sep 30	2024 Dec 31
Opening balance, shareholders' equity	**-126.3**	**58.9**	**58.9**
Total comprehensive earnings for the period	-116.2	-86.1	-185.1
Share-based payments[2]	18.2	—	—
Closing balance, shareholders' equity	**-224.3**	**-27.2**	**-126.3**

[2] The change compared with previous periods relates to the change in the option programs from cash-based to equity-based

CONDENSED CONSOLIDATED CASH FLOW STATEMENTS

SEK m	Notes	2025 Jul-Sep	2024 Jul-Sep	2025 Jan-Sep	2024 Jan-Sep	2024 Jan-Dec
Operating earnings (EBIT)		-21.1	-21.8	-47.8	-42.3	-140.3
Interest received		1.1	0.8	2.6	3.4	7.7
Interest paid		-11.3	-13.7	-35.3	-47.7	-60.2
Income taxes paid		-0.6	0.1	-1.3	-1.5	-1.5
Adjustment for non-cash items	3	36.7	12.9	75.8	49.2	163.7
Cash flow from operating activities before changes in working capital		**4.8**	**-21.8**	**-6.0**	**-38.9**	**-30.6**
Changes in working capital		**-15.1**	**8.4**	**27.8**	**0.1**	**-2.0**
Cash flow from operating activities		**-10.3**	**-13.4**	**21.9**	**-38.8**	**-32.6**
Acquisition of tangible and intangible fixed assets		—	—	—	-3.8	-4.6
Change in financial fixed assets		—	-0.7	-19.2	-0.7	-0.7
Cash flow from investing activities		**0.0**	**-0.7**	**-19.2**	**-4.5**	**-5.3**
Amortization of lease liability		-4.6	-5.9	-17.1	-17.1	-22.0
Change of repurchased part in bond		—	—	10.0	6.5	6.5
Cash from financing activities		**-4.6**	**-5.9**	**-7.1**	**-10.6**	**-15.5**
Cash flow for the period		**-14.9**	**-20.0**	**-4.4**	**-54.0**	**-53.5**
Cash and cash equivalents at the beginning of the period		**121.3**	**139.7**	**123.3**	**171.0**	**171.0**
Exchange-rate differences in cash and cash equivalents		-0.8	-4.7	-13.2	-2.1	5.8
Changes in cash and cash equivalents		-15.7	-24.8	-17.6	-56.1	-47.7
Cash and cash equivalents at the end of the period		**105.6**	**114.9**	**105.6**	**114.9**	**123.3**

Key Figures[3]

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.

	2025 Jul-Sep	2024 Jul-Sep	2025 Jan-Sep	2024 Jan-Sep	2024 Jan-Dec
EBIT margin, %	neg.	neg.	neg.	neg.	neg.
Return on shareholder equity, %	neg.	neg.	neg.	neg.	neg.
Net debt, SEK m	366.7	344.4	366.7	344.4	336.8
Debt/equity ratio, %	neg.	neg.	neg.	neg.	neg.
Equity/assets ratio, %	neg.	neg.	neg.	neg.	neg.
Number of shares, before dilution	34,705,306	34,505,226	34,585,957	34,477,143	34,491,050
Number of shares, after dilution	40,659,856	34,505,226	39,219,396	34,477,143	34,491,050
Earnings per share, before dilution, SEK	-0.86	-1.21	-2.47	-2.51	-5.89
Earnings per share, after dilution, SEK	-0.86	-1.21	-2.47	-2.51	-5.89
Number of employees at the end of the period	104	113	104	113	110
Shareholders' equity, SEK m	-224.3	-27.2	-224.3	-27.2	-126.3
Capital employed, SEK m	248.1	432.0	248.1	432.0	333.8
Working capital, SEK m	3.3	55.2	3.3	55.2	92.0

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

CONDENSED PARENT COMPANY STATEMENT OF OPERATIONS

SEK m	Notes	2025 Jul-Sep	2024 Jul-Sep	2025 Jan-Sep	2024 Jan-Sep	2024 Jan-Dec
Net revenues		4.8	63.1	22.8	269.4	303.8
Cost of goods sold		-2.4	-17.6	-11.9	-52.9	-63.2
Gross profit		**2.4**	**45.5**	**10.8**	**216.5**	**240.5**
Selling expenses		-3.2	-29.6	-11.1	-85.3	-124.9
Administrative expenses		-16.6	-9.8	-43.7	-40.9	-58.2
Research and development costs		-47.7	-44.1	-134.2	-138.6	-288.8
Other operating income and expenses	7	2.7	-5.2	3.3	0.0	1,143.1
Operating earnings (EBIT)		**-62.3**	**-43.2**	**-174.9**	**-48.3**	**911.7**
Interest income and expenses		15.0	-10.6	47.0	-30.6	-39.9
Other financial income and expenses		-1.3	-3.7	-6.2	-9.5	-6.5
Net financial items		**13.7**	**-14.3**	**40.8**	**-40.1**	**-46.4**
Earnings before tax		**-48.6**	**-57.5**	**-134.0**	**-88.4**	**865.3**
Income tax	5	—	—	—	—	—
Earnings for the period		**-48.6**	**-57.5**	**-134.0**	**-88.4**	**865.3**

PARENT COMPANY STATEMENT OF COMPREHENSIVE INCOME

SEK m	2025 Jul-Sep	2024 Jul-Sep	2025 Jan-Sep	2024 Jan-Sep	2024 Jan-Dec
Earnings for the period	**-48.6**	**-57.5**	**-134.0**	**-88.4**	**865.3**
Other comprehensive income	—	—	—	—	—
Total comprehensive earnings for the period	**-48.6**	**-57.5**	**-134.0**	**-88.4**	**865.3**

CONDENSED PARENT COMPANY BALANCE SHEET

SEK m	Notes	2025 Sep 30	2024 Sep 30	2024 Dec 31
ASSETS				
Fixed assets				
Patents, intellectual property rights, proprietary intangible assets and software		21.6	124.4	24.1
Equipment, machinery, renovation of the property of others		50.5	68.8	64.7
Shares and participations in group companies		292.9	287.7	291.8
Participations and securities in other companies		19.2	–	–
Total fixed assets		**384.2**	**480.9**	**380.6**
Current assets				
Inventories		0.0	30.9	6.8
Accounts receivable		8.6	14.6	6.8
Other receivables		11.3	10.0	30.3
Receivables from Group companies	7	985.0	90.1	1,049.4
Prepaid expenses and accrued income		21.6	24.1	15.1
Cash and cash equivalents		21.6	76.5	61.2
Total current assets		**1,048.2**	**246.1**	**1,169.6**
TOTAL ASSETS		**1,432.4**	**727.1**	**1,550.2**
SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES				
Total shareholders' equity		**911.8**	**73.6**	**1,027.4**
Long-term liabilities				
Other provisions		8.2	12.7	22.3
Interest bearing liabilities		472.3	459.3	460.0
Total long-term liabilities		**480.5**	**472.0**	**482.4**
Current liabilities				
Accounts payable		13.9	9.6	11.6
Other liabilities		8.4	8.5	7.6
Liabilities to Group companies		–	144.7	–
Accrued expenses and deferred income		17.7	18.7	21.2
Total current liabilities		**40.0**	**181.5**	**40.4**
Total liabilities		**520.6**	**653.5**	**522.8**
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		**1,432.4**	**727.1**	**1,550.2**

Notes

1. Accounting policies

This report was prepared pursuant to IAS 34. Orexo applies IFRS(R) Accounting Standards on its condensed consolidated financial statements.

The accounting policies are in line with those used in the preparation of the 2024 Annual Report. None of the amended standards and interpretations effective as of 1 January 2025 have had significant impact on the Group's financial reporting and have not been applied in the preparation of these financial statements.

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	2025 Jul-Sep	2024 Jul-Sep	2025 Jan-Sep	2024 Jan-Sep	2024 Jan-Dec
US Commercial					
Net revenues	113.9	131.0	360.4	408.2	560.3
Cost of goods sold	-7.0	-17.8	-31.4	-45.9	-66.3
Selling expenses	-40.0	-47.3	-122.6	-142.8	-191.3
Administrative expenses	-15.4	-22.5	-50.5	-68.5	-107.4
Research and development costs	-14.3	-20.9	-41.4	-65.2	-179.4
Other operating income and expenses	1.1	2.8	3.3	7.6	12.0
Operating earnings (EBIT)	**38.2**	**25.3**	**117.8**	**93.3**	**27.9**
Depreciation and amortization	-1.1	-10.8	-3.2	-32.4	-149.3
EBITDA	**39.3**	**36.1**	**121.0**	**125.7**	**177.2**
HQ & Pipeline					
Net revenues	4.8	5.5	22.8	21.5	29.7
Cost of goods sold	-0.1	-2.3	-4.9	-3.7	-5.8
Selling expenses	—	0.1	0.0	-0.1	0.0
Administrative expenses	-16.5	-9.7	-43.5	-40.8	-57.9
Research and development costs	-47.4	-35.3	-129.1	-111.9	-160.6
Other operating income and expenses	-0.2	-5.3	-10.9	-0.6	26.4
Operating earnings (EBIT)	**-59.3**	**-47.0**	**-165.5**	**-135.5**	**-168.3**
Depreciation and amortization	-10.2	-10.2	-30.6	-30.0	-39.9
EBITDA	**-49.1**	**-36.8**	**-135.0**	**-105.5**	**-128.3**
Group					
Net revenues	118.7	136.5	383.2	429.7	590.0
Cost of goods sold	-7.1	-20.1	-36.3	-49.7	-72.1
Selling expenses	-40.0	-47.2	-122.6	-142.8	-191.3
Administrative expenses	-31.9	-32.2	-93.9	-109.3	-165.3
Research and development costs	-61.7	-56.2	-170.5	-177.1	-340.0
Other operating income and expenses	0.9	-2.5	-7.6	7.0	38.4
Operating earnings (EBIT)	**-21.1**	**-21.7**	**-47.8**	**-42.2**	**-140.3**
Depreciation and amortization	-11.3	-21.0	-33.8	-62.4	-189.2
EBITDA	**-9.8**	**-0.7**	**-14.0**	**20.2**	**48.9**
Net financial items	-11.6	-15.4	-38.0	-42.0	-50.3
Earnings before tax	**-32.7**	**-37.1**	**-85.8**	**-84.2**	**-190.6**

3. Cash flow

ADJUSTMENT FOR NON-CASH ITEMS

SEK m	2025 Jul-Sep	2024 Jul-Sep	2025 Jan-Sep	2024 Jan-Sep	2024 Jan-Dec
Depreciation/amortization and impairment	11.3	21.0	33.8	62.4	189.2
Change in provisions	20.7	-13.6	12.6	-15.6	-20.3
Other non cash items	-0.1	0.2	-0.1	0.5	0.5
Exchange rate income and expenses	0.2	5.3	11.1	1.8	-5.8
Share-based payments	4.6	—	18.4	—	—
Total	**36.7**	**12.9**	**75.8**	**49.2**	**163.7**

4. Dispute

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 is that Zubsolv has been promoted in a compliant and responsible manner, but Orexo is seeking a resolution. Orexo as of this date is not aware of any filed civil or criminal case related to the investigation.

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. Deferred tax assets relates to intercompany profit in inventory, 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 Biolipox AB and Orexo Inc, remuneration to the board, president and senior executives. All transactions have been made at at arm's length.

8. Important events after the end of the period

› No important events after the end of the period.

9. Net revenue from contracts with customers

	2025 Jul-Sep					
SEK m	Zubsolv®	Abstral®	Edluar®	Vorvida®	MODIA®	Total
Segment						
US Commercial	113.9	—	—	0.0	—	**113.9**
HQ & Pipeline	0.6	1.3	2.9	—	—	**4.8**
Total revenue from contracts with customers	**114.5**	**1.3**	**2.9**	**0.0**	**0.0**	**118.7**
Geographical markets						
US	113.9	—	0.3	0.0	—	**114.2**
EU & UK	0.6	1.3	2.0	—	—	**3.9**
Rest of the world	—	0.0	0.6	—	—	**0.6**
Total revenue from contracts with customers	**114.5**	**1.3**	**2.9**	**0.0**	**0.0**	**118.7**

	2025 Jan–Sep					
SEK m	Zubsolv	Abstral	Edluar	Vorvida	MODIA	Total
Segment						
US Commercial	360.4	—	—	0.0	—	**360.4**
HQ & Pipeline	9.2	3.7	9.9	—	—	**22.8**
Total revenue from contracts with customers	**369.6**	**3.7**	**9.9**	**0.0**	**0.0**	**383.2**
Geographical markets						
US	360.4	—	0.7	0.0	—	**361.1**
EU & UK	9.2	3.9	7.1	—	—	**20.2**
Rest of the world	—	-0.2	2.1	—	—	**1.9**
Total revenue from contracts with customers	**369.6**	**3.7**	**9.9**	**0.0**	**0.0**	**383.2**

	2024 Jul-Sep						
SEK m	Zubsolv	Abstral	Edluar	Vorvida	Deprexis	MODIA	Total
Segment							
US Commercial	131.0	—	—	—	—	—	**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	—	—	—	—	—	**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	—	**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**

	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	—	1.4	—	0.0	—	**561.7**
EU & UK	8.9	7.5	8.1	—	—	—	**24.5**
Rest of the world	—	0.7	3.1	—	—	—	**3.8**
Total revenue from contracts with customers	**569.2**	**8.2**	**12.5**	**0.0**	**0.0**	**0.0**	**590.0**

Definitions and reconciliations of key figures

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

Margins	Definition/calculation	Purpose
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.
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. In the event of negative earnings per share, diluted earnings per share are reported as the same as earnings per share before dilution
Other definitions	**Definition/calculation**	**Purpose**
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

KEY FIGURES AND CERTAIN OTHER OPERATING INFORMATION ARE RECONCILED AS FOLLOWS

EBITDA SEK m	2025 Jul-Sep	2024 Jul-Sep	2025 Jan-Sep	2024 Jan-Sep	2024 Jan-Dec
EBIT	-21.1	-21.7	-47.8	-42.2	-140.3
Depreciation and amortization	11.3	21.0	33.8	62.4	189.2
EBITDA	**-9.8**	**-0.7**	**-14.0**	**20.2**	**48.9**

OPERATING EXPENSES SEK m	2025 Jul-Sep	2024 Jul-Sep	2025 Jan-Sep	2024 Jan-Sep	2024 Jan-Dec
Selling expenses	-40.0	-47.2	-122.6	-142.8	-191.3
Administrative expenses	-31.9	-32.2	-93.9	-109.3	-165.3
Research and development costs	-61.7	-56.2	-170.5	-177.1	-340.0
Other operating income and expenses	0.9	-2.5	-7.6	7.0	38.4
Operating expenses	**-132.7**	**-138.1**	**-394.7**	**-422.3**	**-658.2**

RETURN ON SHAREHOLDERS' EQUITY SEK m	2025 Jul-Sep	2024 Jul-Sep	2025 Jan-Sep	2024 Jan-Sep	2024 Jan-Dec
Shareholders' equity beginning balance	-197.0	24.2	-126.3	58.9	58.9
Shareholders' equity ending balance	-224.3	-27.2	-224.3	-27.2	-126.3
Average shareholders' equity	-210.7	-1.5	-175.3	15.8	-33.7
Net earnings	-29.8	-41.9	-85.5	-86.7	-203.0
Return on shareholders' equity %	**neg.**	**neg.**	**neg.**	**neg.**	**neg.**

GROSS INVESTMENTS SEK m	2025 Jul-Sep	2024 Jul-Sep	2025 Jan-Sep	2024 Jan-Sep	2024 Jan-Dec
Investments in tangible fixed assets	–	–	–	2.5	3.1
Investments in intangible fixed assets	–	–	–	1.4	1.6
Gross investments	**0.0**	**0.0**	**0.0**	**3.8**	**4.6**

KEY FIGURES AND CERTAIN OTHER OPERATING INFORMATION ARE RECONCILED AS FOLLOWS

Net debt SEK m	2025 Jul-Sep	2024 Jul-Sep	2025 Jan-Sep	2024 Jan-Sep	2024 Jan-Dec
Current and long-term interest-bearing liabilities including pension liabilities	472.3	459.3	472.3	459.3	460.0
Cash and cash equivalents.	105.6	114.9	105.6	114.9	123.3
Net debt	**366.7**	**344.4**	**366.7**	**344.4**	**336.8**

KEY FIGURES AND CERTAIN OTHER OPERATING INFORMATION ARE RECONCILED AS FOLLOWS

Debt/equity ratio	2025 Jul-Sep	2024 Jul-Sep	2025 Jan-Sep	2024 Jan-Sep	2024 Jan-Dec
Interest-bearing liabilities	472.3	459.3	472.3	459.3	460.0
Shareholders equity	-224.3	-27.2	-224.3	-27.2	-126.3
Debt/equity ratio %	**neg.**	**neg.**	**neg.**	**neg.**	**neg.**

KEY FIGURES AND CERTAIN OTHER OPERATING INFORMATION ARE RECONCILED AS FOLLOWS

Earnings per share. before dilution SEK	2025 Jul-Sep	2024 Jul-Sep	2025 Jan-Sep	2024 Jan-Sep	2024 Jan-Dec
Number of shares. before dilution	34,705,306	34,505,226	34,585,957	34,477,143	34,491,050
Net earnings for the period SEK m	-29.8	-41.9	-85.5	-86.7	-203.0
Earnings per share. before dilution	**-0.86**	**-1.21**	**-2.47**	**-2.51**	**-5.89**

KEY FIGURES AND CERTAIN OTHER OPERATING INFORMATION ARE RECONCILED AS FOLLOWS

Earnings per share, after dilution SEK	2025 Jul-Sep	2024 Jul-Sep	2025 Jan-Sep	2024 Jan-Sep	2024 Jan-Dec
Number of shares, after dilution	40,659,856	34,505,226	39,219,396	34,477,143	34,491,050
Net earnings for the period SEK m	-29.8	-41.9	-85.5	-86.7	-203.0
Earnings per share, after dilution[4]	**-0.73**	**-1.21**	**-2.18**	**-2.51**	**-5.89**

[4] Due to negative values, diluted earnings per share are reported using the same values as for earnings per share before dilution in other tables in the report.

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. 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 ADRs on OTCQX market (ORXOY) in the US.

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