orexo

Stable commercial business in a volatile market

Interim Report Q1 2025

May 6, 2025

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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

Q1 2025 highlights

- Total net revenues of SEK 146.2 m (139.3)
- EBITDA of SEK 5.9 m (15.9)
- Net earnings of SEK -15.9 m (-8.9)
- US Commercial segment net revenues of SEK 133.0 m (129.3), in local currency USD 12.5 m (12.4)
- Cash flow from operating activities of SEK 32.9 m (-18.9), cash and cash equivalents of SEK 119.1 m (198.0)
- Earnings per share before and after dilution amounted to SEK -0.46 (-0.26)
- Positive topline data showed from clinical study of OX640, a nasal powder-based epinephrine 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.

Important events after the end of the period

- Orexo in collaboration with Abera Bioscience announced positive in-vivo data for powder-based intranasal vaccine formulated with the AmorphOX® technology.

SEK m unless otherwise stated	2025 Jan-Mar	2024 Jan-Mar	2024 Jan-Dec
Net revenues	146.2	139.3	590.0
Cost of goods sold	-20.7	-13.3	-72.1
Operating expenses	-130.7	-130.7	-658.2
EBIT	-5.2	-4.7	-140.3
EBIT margin %	neg.	neg.	neg.
EBITDA	5.9	15.9	48.9
Earnings per share, before dilution, SEK	-0.46	-0.26	-5.89
Earnings per share, after dilution, SEK	-0.46	-0.26	-5.89
Cash flow from operating activities	32.9	-18.9	-32.6
Cash and cash equivalents	119.1	198.0	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.

Group net revenues
146 SEK M

Group EBITDA
6 SEK M

Cash and cash equivalents
119 SEK M

SDG 3.5 net revenue ratio
91%

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.

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®								
OX390	overdose**	amorphOX®								
OX640	allergic reactions incl. anaphylaxis	amorphOX®								
Others	multiple***	amorphOX®								

* Digital Mental Health Programs, incl. MODIA® & Vorvida®
** OX124 incl naloxone, OX125 nalmefene, OX390 NCE
*** Multiple, incl. both small & large molecules

Contact persons quarterly report

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Presentation

On May 6, at 2 pm CEST 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://events.inderes.com/orexo/q1-report-2025/dial-in

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

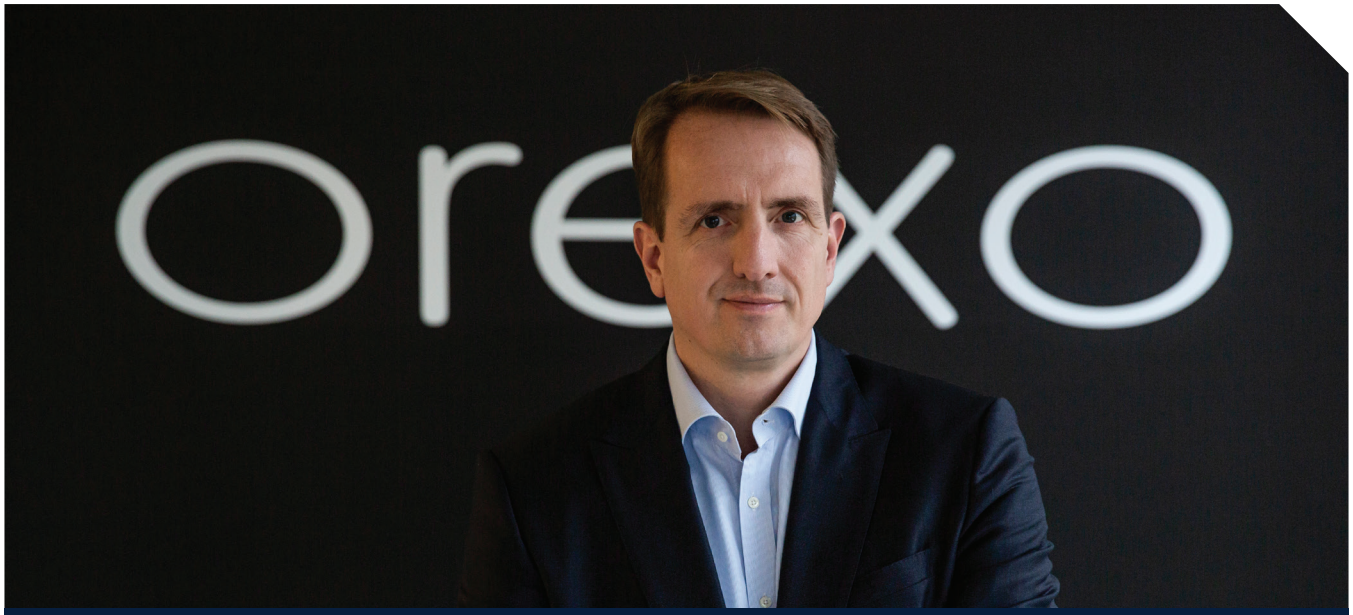
To attend via webcast:
https://orexo.events.inderes.com/q1-report-2025

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

Financial calendar

Annual General Meeting 2025 - May 8, at 4 pm
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

Stable commercial business in a volatile market



CEO Comments in brief

I'm pleased to report a stable start to 2025 from financial and product development perspectives. Our financial results in the quarter are in line with our expectations, including a positive EBITDA and only a slight decline in our cash position, caused solely by a weakening of the USD in March. Cash flow from operations is positive and have improved since last year. This is pleasing given that the first quarter can often be a challenging period, characterised by inventory reductions at wholesalers and a recurring seasonal decline in market demand due to resetting of deductibles, and formulary changes.

We're continuing to work with our nasal device supplier. As we're yet to have a firm delivery date for the device, we're now looking to resubmit OX124 to the FDA in mid-2026. Interest in OX640 from potential partners has increased since we in January reported positive results from our second OX640 clinical study, where we showed strong potential for a differentiated product.

Mitigating uncertainties from regulatory and geopolitical risks

Our main product, Zubsolv®, is for the treatment of patients living with opioid dependence, a disease space with significant political interest from the new US administration. On this basis our core business with Zubsolv is largely insulated from volatility in trade policies and changes at the FDA, and having a US manufacturing could be an advantage.

As a company with global reach, potential pharmaceutical tariffs may impact the products we are currently developing, where we're more dependent on international supply chains across Europe and Canada. We are currently experiencing delays in interactions with the FDA. These are giving rise to some concerns regarding timelines for our development programs, although we hope these will be resolved over the coming months. In the meantime, we're working through mitigation plans for various scenarios that may require us to rethink some of our supply chain plans.

Ongoing geopolitical uncertainty has also resulted in volatile exchange rates. With a significant portion of sales, but also operations in the USA, both our revenues and costs are affected by changes in the USD/SEK exchange rate. In a scenario with a strengthened Swedish krona by 10 percent, revenues in USD would be correspondingly affected. The impact on EBIT level is expected to be dampened by a natural hedge on the cost side, amounting to about 80 percent of the lower revenues.

Zubsolv financials on a steady course

During Q1, we saw a small decline in market volume compared to the last quarter and a slowdown in the overall market growth for buprenorphine/naloxone products in the US with a low single-digit growth rate of 2 percent. Zubsolv sales in USD were similar to Q1 last year, supported by a price increase at the beginning of the year and lower inventory reductions. The increased price compensates for higher rebates and lower demand in the Commercial segment and in Medicare, where the new pricing and rebate system was implemented from January 1, 2025.

In the Commercial segment, the decline during Q1 followed a similar pattern to previous years, where patients required

to pay the full list price opt for cheaper generic alternatives when their deductible is reset. In addition, wholesalers reduced their inventory levels which also is a seasonal impact of the new year. In Q2 we anticipate the inventory levels to

> **Zubsolv sales in USD were similar to Q1 last year, supported by a price increase at the beginning of the year and lower inventory reductions.**

normalize, which will have a positive impact on sales. We're working intensively to optimize the profit contribution from our US commercial operations, and we're pleased to see a significant improvement in EBIT margin to 33 percent (25). We're also expecting additional improvements in COGS during 2025 and in the years ahead, which, in combination with other cost optimizations, will support improved profit contributions from Zubsolv®.

We're continuing to work with our legal advisors to find a resolution to the subpoena and the Department of Justice (DOJ) investigation that was initiated in 2020. We maintain the position that Zubsolv has been promoted in a compliant and responsible manner, but due to the associated uncertainty we are seeking a resolution. However, the recent change in the US administration may delay the process.

OX124 timeline remains uncertain

For OX124, our rescue medication for opioid overdose with naloxone, we have worked extensively to address the issues raised by the FDA. Unfortunately, we have not yet received the necessary components of the nasal device from one of our suppliers to start the commercial manufacturing and initiate the necessary testing. After the initiation of the development of OX124 a new version of the device has been developed, which is used for our epinephrine product, OX640. The new device is easier for patients to use due to its improved handling and it is available today. To mitigate future supply issues, we intend to move OX124 to the new device, and in combination with the review of the supply chain due to trade policy changes, this might cause some additional delay. Any device change will be discussed with the FDA to determine the best approach for transitioning to the new device.

AmorphOX® continues to deliver results

The quarter started with the announcement of positive results from the second clinical trial in healthy volunteers with OX640, our AmorphOX-based development program of a new nasal epinephrine product for the treatment of anaphylaxis. The study strengthened the evidence for the impact of epinephrine bioavailability in OX640 in patients with allergic rhinitis. In addition, data also provided more information about the dose required to ensure we have a competitive product. I'm delighted that these results confirm OX640 has the potential to be the gold standard for nasal treatment of anaphylaxis and it's encouraging to see increased interest from potential partners.

Turning to our collaboration with Abera Bioscience to develop nasal powder vaccines based on the AmorphOX technology, I'm pleased to report that we reached the first important scientific milestone right after the quarter closed when we announced positive in-vivo proof-of-concept data.

> **The quarter started with the announcement of positive results from the second clinical trial in healthy volunteers with OX640, our AmorphOX-based development program of a new nasal epinephrine product for the treatment of anaphylaxis.**

The results highlight how our proprietary powder-based drug delivery technology, AmorphOX, can be used to formulate powder-based vaccines with transformational potential for patients and healthcare providers worldwide.

Expanding the potential applications of our AmorphOX technology is integral to our strategy and we're already moving into a new pre-clinical project, OX390, where we're exploring the development of a rescue medication to treat patients overdosing with a certain combination of illicit drugs. We're communicating closely with the US authorities on this project, and we'll seek a development collaboration with these authorities should the pre-clinical project meet the expected requirements.

Summary and outlook

Except for the positive results from the OX640 study, 2025 started without any significant events. However, our financial results are in line with our plan of reaching a positive EBITDA, for the full year. Zubsolv continues to show stable financial development, and our R&D projects are making some progress. The main operational setback is the continued timeline uncertainty in the OX124 project due to issues with the nasal device.

For our current operations in the US, we have no impact from potential tariffs, due to manufacturing in the US and continued dedication by the new administration to address the opioid epidemic. We continue to assess our business to determine the best strategic path forward to optimize the value to our shareholders. The market environment is a factor in this assessment and in an environment with high uncertainty we have significant focus on cost optimization and how to improve cash flow over time.

Finally, a reasonable start to 2025 from a financial perspective, despite a volatile market environment. We anticipate stronger results in the coming quarters as the effects of inventory reductions are reversed and as we expect to see improved market development for Zubsolv.

Uppsala, Sweden, May 6, 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 and market development

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.[1] Of these, around 5.7 million are dependent on opioids, and approx. 2.3 million are receiving medication-assisted treatment (MAT).[2] Latest available data is showing predicted number of reported fatal opioid overdoses of more than 58,000 annually.[3] Nine out of ten of these involve synthetic illicitly manufactured opioids, such as fentanyl.[4] 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 alarmingly high.

In Q1, the buprenorphine/naloxone market declined 2 percent versus Q4 2024 and grew 2 percent versus Q1 2024, the decline was across all business segments and follows a similar pattern as previous years. 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 in recent years shifted from growth in Medicaid to the Commercial segment. In Medicaid, the market declined 3 percent vs Q1 2024, while the Commercial segment increased 9 percent. The decline in Medicaid is associated with removal of different emergency legislations enacted during Covid-19 leading to a disenrollment in Medicaid to the benefit of Commercial insurance.

Developments during the quarter

The first quarter is traditionally challenging to Zubsolv due to formulary changes and reset of patients deductibles[5] and this is also the situation this year when volume declined 7 percent versus Q4 2024 and 6 percent versus Q1 2024.

Resetting patients' deductibles means that patients must pay the difference between the list price and generic alternatives. This is mainly an issue in the commercial payer segment, where the volume for Zubsolv decreased by 7 percent compared to Q4 2024 and by 8 percent compared to Q1 2024.

Medicare was a significant driver of the development due to the new rebate policy implemented January 1, 2025. The new rebate policy is favorable to Zubsolv from a net pricing perspective but has led to some formulary changes from large Medicare payors to favor generics for certain patient groups e.g., Humana Medicare D driving Zubsolv volume in the plan down 23 percent with this payor. Medicare is today 17 percent of the total Zubsolv volumes, but less in terms of net sales due to high rebates with some payers.

Zubsolv declined in Medicaid 4 percent versus Q4 2024 and 2 percent versus Q1 2024. Within Medicaid Zubsolv declined versus Q4 in Maryland and Michigan but grew in New York and Wisconsin.

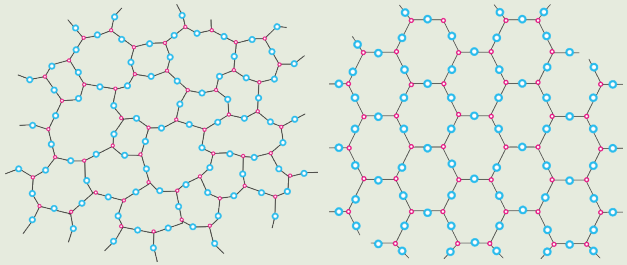
Zubsolv's best in class market access in the commercial payer segment grew to 99 percent due to shifts relative market volume declines in the non-accessible plans. In the Public segment market access declined from 51 to 49 percent due to changes in one Medicare payer.

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 **Crystalline materials**

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

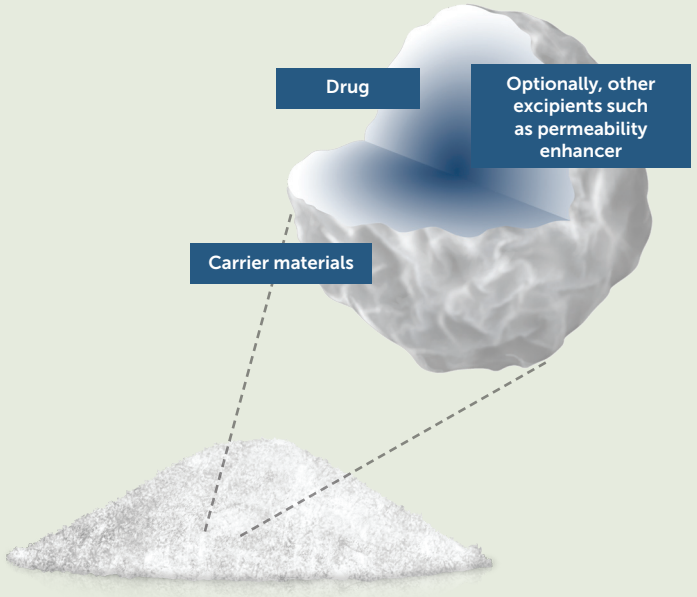
The challenge

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.



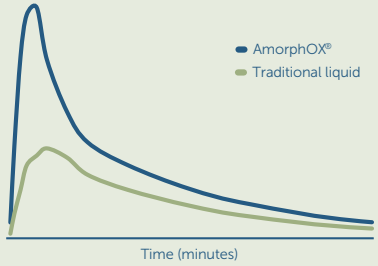
The unique strengths

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 pharmacokinetic (PK) properties with more rapid onset, higher peak and overall exposure.



PRESERVATIVES NO ADDED

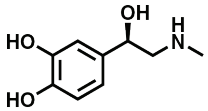
AmorphOX's unique properties ensure physical and chemical stability

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 dissolving property is maintained.

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

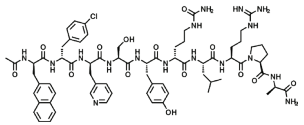
Small molecules

Ephinephrine
0,3% after 24 months



Peptides

Cetrorelix
0,6% after 12 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®

Leveraging strategic partnerships to maximize the potential of AmorphOX®

A key part of Orexo's strategy to expand the use of AmorphOX is to enter strategic partnerships with both large pharmaceutical companies and smaller, research-focused businesses. By testing AmorphOX in combination with molecules controlled by these partners, we aim to develop new and improved medicines, while also gathering valuable data to enhance the technology.

Unlocking significant opportunities for partnerships

Partnerships can create significant opportunities for partner companies:

- New product opportunities by improving existing medicines
- Expanded indications to target additional therapeutic areas
- Improved speed of onset for faster therapeutic action
- Increased patient convenience through more accessible delivery options
- Prolonged intellectual property (IP) protection as part of lifecycle management[6]
- Enhanced stability, which can streamline supply and distribution chains by eliminating the need for cold chains.

By leveraging the strengths of AmorphOX, our partners can unlock the full potential of their molecules, bringing innovative treatments to market faster and more efficiently.

Streamlining nasal drug delivery

Thanks to the powder-based technology, the drug can be adapted to be absorbed by the body through different routes of administration. For intranasal delivery, which applies for Orexo's rescue medications a supply chain has been developed, ensuring cost-efficiency and reliability. This strengthens the ability to scale up future intranasal product developments, both internally and in collaboration with other pharmaceutical companies.

Strong patent strategy

The in-house IP department works closely with the R&D team to ensure robust protection throughout the development process securing technologies and pipeline projects are supported by a comprehensive patent strategy. Orexo's strong patent portfolio, including enforceable patents listed in the FDA's 'Orange Book', safeguards the products in key markets.

Partner opportunity examples

Partner	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

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

The project

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, saving lives and preventing renarcotization during the revival process. In addition, studies have demonstrated, that the AmorphOX technology, 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 of 2024, the work continued preparing to generate updated technical data from commercial manufacturing as required by the agency. The New Drug Application previously submitted to the agency is based on data from pilot-scale manufacturing, which has long been a standard practice in the pharmaceutical industry. Preparations for generating new technical data are being adjusted in response to the FDA's feedback on the company's proposed process. This work encompasses not only the manufacturing process but also aspects to the device´s reliability and stability.

To provide the new technical data Orexo is dependent on external parties. During the quarter, several discussions were held with a supplier who has reported delays in delivering components critical for collecting the new data. Delays in delivery continues to impact the timeline for when production and testing on a commercial scale can be initiated. The timing of a potential approval of OX124 will also be dependent on FDA's time for reviewing the resubmission.

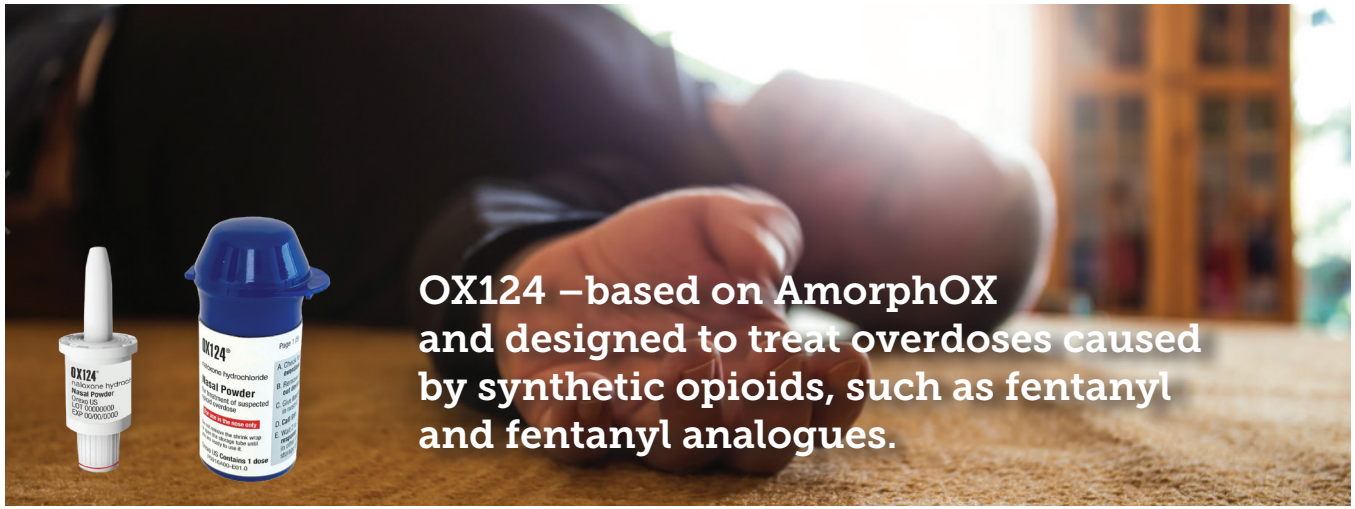
Market and commercialization

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.

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. Another advantage with OX124 is its low sensitivity to temperature fluctuations, made possible by reformulating naloxone from a liquid to a powder. This enhanced stability allows the drug to be stored at sub-zero temperatures without compromising its effectiveness, which is an important advantage for emergency responders operating in colder climates.

Driven by the need to increase access to overdose medication, low-dose naloxone products, including the market leader, have 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

The project

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.

OX390 – an intranasal rescue medication for overdoses caused by a combination of life-threatening illicit drugs

The project

Orexo is developing a new product, OX390, a rescue medication to address the growing adulteration of potent synthetic opioids like fentanyl, complicating the management of accidental overdoses. OX390 will be a complement to naloxone or nalmefene (used in the OX124 and OX125 rescue medications) to address the growing adulteration of synthetic opioids like fentanyl, which can prevent patients intoxicated with adulterated fentanyl from responding to naloxone or nalmefene alone. We are in the pre-clinical stage developing OX390 to address this emerging threat in the Opioid Public Health Emergency and have ongoing discussions with US health authorities to collaborate in development of OX390. OX390 uses our proprietary AmorphOX® technology.

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

The project

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 the vast majority of 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. A needle-free epinephrine product that's easier to handle and store offers a more convenient alternative to current auto-injectors, benefiting both allergic patients and healthcare systems globally.

In the third quarter, 2024, 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.

Developments during the quarter

In the beginning of 2025, positive topline data was communicated for the second clinical study with OX640. The study was conducted in Q4 2024, and the result was also communicated in the 2024 Full Year Report. One major study finding was related to absorption under allergic rhinitis conditions, which was significantly faster than under normal conditions, supporting rapid onset of effect also in patients with significant airway symptoms. During the quarter, progress was made in defining the final commercial formulation and dose which is an important step toward advancing the project to regulatory approval. Interactions have also taken place with the FDA for discussion and agreement on the continued development program for OX640.

Preparations for establishment of the commercial manufacturing process progressed according to plan and discussions continued with potential partners for further development and global commercialization.

OX640 is protected by patents and patent applications until 2044.

Early stage projects

Orexo has tested enzymes, peptides, and proteins with the drug delivery platform AmorphOX® and seen retained activity and significant improvement in stability compared to other formulations in a wide range of storage temperatures.
A core strategy to expand the use of the technology is to test AmorphOX in combination with molecules controlled by other companies, 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.

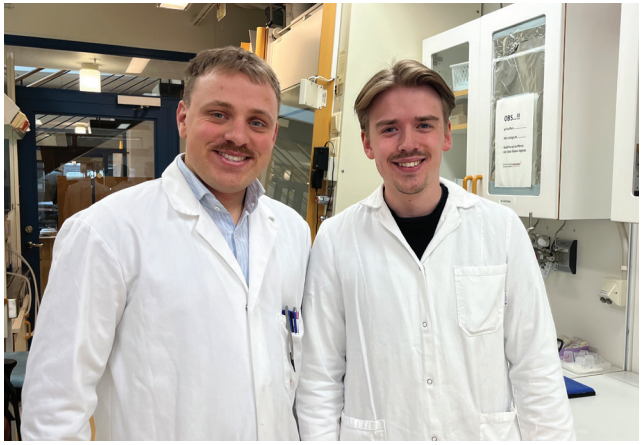
During the quarter, and together with Orexo's partner Abera Bioscience (Abera), a proof-of-concept study in rats was conducted to test the efficacy of Abera's intranasal vaccine candidate for influenza, both as a liquid and as a powder. The aim was to evaluate the performance of Abera's mucosal influenza vaccine platform in combination with Orexo's AmorphOX technology, which enables a stable and user-friendly powder formulation. After the end of the quarter, results from the study were communicated, showing 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 nasal 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.

The project was funded by grants received by Abera, mainly from CEPI (the Coalition for Epidemic Preparedness Innovation).

The collaboration with Sobi, where one of the company's biomolecules was tested with AmorphOX, has demonstrated excellent results regarding the ability to maintain activity over time. Orexo has been compensated for the work done with Sobi and the decision when to proceed with the project is fully with Sobi. The current status is AmorphOX has met all the required end-points, but Sobi is not ready to engage in a full development program due to internal prioritization, but the collaboration will continue on an exploratory basis.

Other exploratory feasibility studies conducted along with external parties have progressed as planned during the quarter. The ambition is to advance these exploratory collaborations to partnerships based on milestone payments, and royalty on future sales.



In the quarter the chemical engineering students at Uppsala University - Gustav Holmberg and Carl Lagergren - joined to conduct their master thesis linked to the powder-based technology, AmorphOX.

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.

Developments during the quarter

During the quarter, the European Commission proposed a relaxation of reporting requirements related to the CSRD and the EU Taxonomy through the Omnibus package. While the proposals are yet to be decided, it is unlikely that Orexo will be subject to the new reporting requirements. Potential impacts on the company's sustainability strategy and 2025 agenda will be discussed with management and the Board.

In addition, Orexo evaluated, summarized, and reported its 2024 sustainability performance in the Annual Sustainability Report. In line with the GHG Protocol, the evaluation showed a 32 percent reduction in total greenhouse gas emissions (Scope 1–3) compared to the 2022 base year, which is an important milestone toward the goal of reducing its climate impact by 50 percent in 2030.

Following the guidelines for issuance of social corporate bonds, an annual report was published outlining the allocation of capital across refinancing of previous social investments and new social investments. The report also presented several key performance indicators (KPI), including the number of patients treated with Zubsolv®, of which how many were supported by government funding or through patient support programs. For financial numbers and KPIs, read the report here:

https://orexo.com/media/inwd34w5/orexo-social-financing-report-2025.pdf

Financial development

Net revenues

Total net revenues amounted to SEK 146.2 m (139.3) for Q1. The increase is explained by higher net revenues in US Commercial and in HQ & Pipeline segment.

Revenues by segment

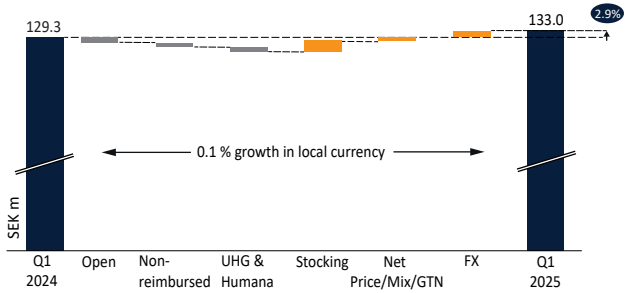
US Commercial revenues amounted to SEK 133.0 m (129.3) for Q1. The increase is driven by product sales of Zubsolv® in the US, primarily as a result of lower reduction of wholesaler inventories, a positive FX impact of SEK 3.6 m and price increase partly offset by lower demand and unfavorable payer mix. In local currency US Commercial net revenues for Q1 amounted to USD 12.5 m (12.4).

HQ & Pipeline partner product related revenues for Q1 amounted to SEK 13.2 m (10.0). The increase is mainly explained by higher Zubsolv ex-US revenues of SEK 8.1 m (0.2) related to higher sales of tablets to Orexo´s partner Accord Healthcare from a one-time build-up of inventory. Higher Edluar royalties of SEK 3.4 m (2.7) partly offset by lower Abstral royalties of SEK 1.7 m (7.1) following expiration of agreements for some individual countries.

Cost of goods sold

Cost of goods sold (COGS) amounted to SEK 20.7 m (13.3) for Q1. US Commercial amounted to SEK 16.0 m (12.7), the increase is mainly explained by a negative FX impact and unfavorable production costs for Zubsolv US partly offset by lower technical infrastructure costs for Digital Mental Health Programs (DMHP). HQ & Pipeline amounted to SEK 4.7 m (0.5) for Q1 where the increase is due to higher Zubsolv ex-US tablets sales to Orexo's partner Accord Healthcare.

ZUBSOLV US NET REVENUES DEVELOPMENT



NET REVENUES AND EBIT PER SEGMENT

SEK m	Net revenue			EBIT		
	2025 Jan-Mar	2024 Jan-Mar	2024 Jan-Dec	2025 Jan-Mar	2024 Jan-Mar	2024 Jan-Dec
Zubsolv US product sales	133.0	129.3	560.3	–	–	–
Digital Mental Health Programs (DMHP) product sales	–	–	0.0	–	–	–
US Commercial – total	**133.0**	**129.3**	**560.3**	**44.0**	**31.9**	**27.9**
Abstral® royalty	1.7	7.1	8.2	–	–	–
Edluar® royalty	3.4	2.7	12.5	–	–	–
Zubsolv – ex-US	8.1	0.2	8.9	–	–	–
HQ & Pipeline – total	**13.2**	**10.0**	**29.7**	**-49.1**	**-36.6**	**-168.3**
Total	**146.2**	**139.3**	**590.0**	**-5.2**	**-4.7**	**-140.3**

Operating expenses

Total operating expenses were stable compared to the same period last year and amounted to SEK 130.7 m (130.7). Lower costs for long-term incentive programs following a lower share price contributed positively in all functions with SEK 4.1 m (-1.8) during the quarter.

Selling expenses amounted to SEK 42.5 m (43.5) for Q1.

Administrative expenses amounted to SEK 31.0 m (34.9) for Q1. The decrease is mainly explained by lower costs for IP litigation in HQ & Pipeline partly offset by higher costs for legal expenses for DOJ investigation in US Commercial.

Research and development costs amounted to SEK 51.6 m (56.6) for Q1. The decrease is mainly explained by lower amortization costs for DMHP and Zubsolv intangible assets partly offset by higher costs for OX640 and AmorphOX.

Other operating income and expenses amounted to SEK -5.6 m (4.3) for Q1. This is mainly explained by exchange-rate losses derived from revaluations of parent company balance sheet items in foreign currency, predominantly in USD, amounted to SEK -7.1 m (3.5) partly offset by higher received insurance reimbursement of SEK 1.1 m (0.4) and higher partner reimbursement of ex-US Zubsolv costs of SEK 0.2 m (0.0).

Operating profit

EBITDA amounted to SEK 5.9 m (15.9) for Q1.

The EBITDA contribution from US Commercial amounted to SEK 45.1 m (42.6) for Q1.

Total EBIT amounted to SEK -5.2 m (-4.7) for Q1.

EBIT contribution from US Commercial amounted to SEK 44.0 m (31.9) for Q1, equal to an EBIT margin of 33.1 percent (24.6).

Net financial items and tax

Net financial items for Q1 amounted to SEK -14.1 m (-5.0) and is mainly explained by higher bond loan costs of SEK -11.5 m (-7.7), negative unrealized exchange rate impact of SEK -2.6 m (2.1) derived from the parent company's foreign currency bank accounts in USD and lower interest income from bank accounts of SEK 0.3 m (0.9).

Total tax expenses amounted to SEK 3.3 m (0.9) for Q1. The increase is mainly explained by higher positive adjustment of SEK 4.4 m (2.2) to deferred tax assets related to temporary differences. 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 -15.9 m (-8.9) for Q1.

Cash and cash flow

Cash flow from operating activities amounted to SEK 32.9 m (-18.9) for Q1 and was positively impacted primarily by changes in working capital. The transaction signed in Q4 2024 to convert rights to future proceeds and royalties from vipoglanstat (OX-MPI) to shares in Gesynta AB, was closed in Q1 having a positive impact of SEK 19.2 m (0.0) on working capital offset by a negative SEK -19.2 m (0.0) impact on investment activities.

As of March 31, 2025, cash and cash equivalents amounted to SEK 119.1 m (198.0) and interest-bearing liabilities to SEK 460.8 m (497.8), i.e. a negative net cash position of SEK -341.7 m (-299.8). Cash and cash equivalents decreased by SEK 4.2 m from Q4 2024.

Investments

Gross investments in tangible and intangible fixed assets amounted to SEK 0.0 m (1.2) for Q1.

Equity

Shareholders' equity on March 31, 2025, was SEK -161.3 m (61.4).

Parent company

Net revenues for Q1 amounted to SEK 13.2 m (100.5) of which SEK 0.0 m (90.5) was related to sales to Group companies.

Total EBIT amounted to SEK -51.8 m (2.3) for Q1.

Earnings before tax amounted to SEK -38.5 m (-2.4) for Q1.

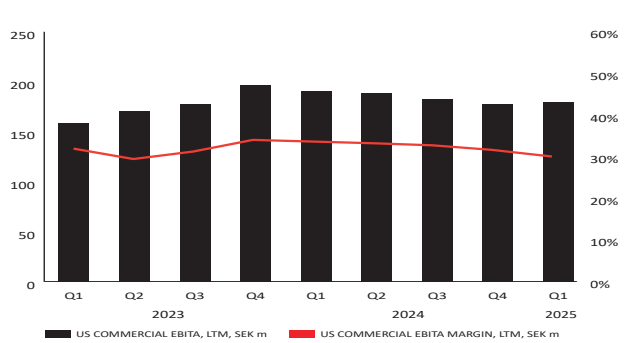
Investments in equipment for the development organization for Q1 amounted to SEK 0.0 m (1.2).

As of March 31, 2025, cash and cash equivalents in the parent company amounted to SEK 24.3 m (163.1).

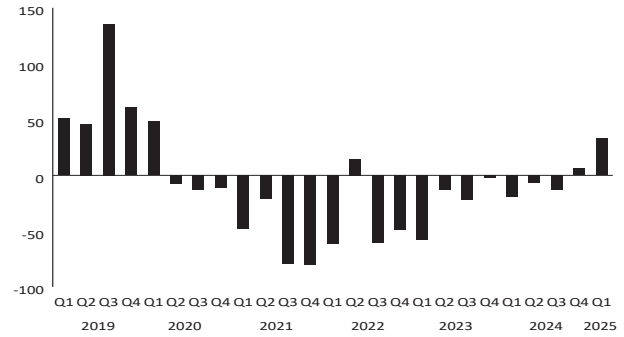
Parent company shareholders' equity at March 31, 2025, was SEK 998.9 m (159.7). The increase over the same period last year is mainly explained by the internal transaction with the sale of assets related to the US Zubsolv business to the wholly owned subsidiary Biolipox AB at a fair market value of SEK 1,138.9 m in Q4 2024.

GROUP EBITDA, SEK m

US COMMERCIAL EBITDA MARGIN AND EBITDA (LTM[7], SEK m)



CASH FLOW FROM OPERATING ACTIVITIES, SEK m



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 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 Q1 was 10.68. Going forward, a volatile market may lead to changes in the exchange rate. In a currency sensitivity analysis including a 10 percent decline in USD/SEK, the negative impact on US Commercial net sales will be dampened at the EBIT level due to a natural hedge on the cost side covering about 80 percent of the reduced net sales.

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.

These factors include, but are not limited to, changes in global economy, market and competitive conditions, changes in product demand, supply and production constraints, currency fluctuations, developments in product litigations, changes in the regulatory environment and other government actions.

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, Disputes.

In relation to the recently imposed tariffs on global trade, Orexo's Zubsolv business will not be impacted, as it relies on a domestic US supply chain. However, 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.

Annual General Meeting 2025

Shareholders are summoned to an annual general meeting, to be held on 8 May, 2025, at 4 pm at Rapsgatan 28 in Uppsala, Sweden. Further information regarding the AGM is available on www.orexo.com.

Glossary

View https://orexo.com/glossary/

Uppsala, Sweden, May 6, 2025

Nikolaj Sørensen
President and CEO

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

References

1 Page 6, Substance Abuse and Mental Health Services Administration

2 Page 6, Substance Abuse and Mental Health Services Administration

3 Page 6, Center of Disease Control and Prevention

4 Page 6, Center of Disease Control and Prevention

5 Page 6, A deductible is the amount of money you pay out of pocket for certain covered health care services before your health plan starts to pay

6 Page 9, The AmorphOX technology is protected by patents and patent applications until 2039–2044

7 Page 15, Last Twelve Months.

Financial reports, notes and key figures

CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS

SEK m	Notes	2025 Jan-Mar	2024 Jan-Mar	2024 Jan-Dec
Net revenues	9	146.2	139.3	590.0
Cost of goods sold		-20.7	-13.3	-72.1
Gross profit		**125.5**	**126.0**	**517.9**
Selling expenses		-42.5	-43.5	-191.3
Administrative expenses		-31.0	-34.9	-165.3
Research and development expenses		-51.6	-56.6	-340.0
Other operating income and expenses		-5.6	4.3	38.4
Operating earnings (EBIT)		**-5.2**	**-4.7**	**-140.3**
Net financial items		-14.1	-5.0	-50.3
Earnings after financial items		**-19.3**	**-9.8**	**-190.6**
Income tax	5	3.3	0.9	-12.4
Net earnings for the period		**-15.9**	**-8.9**	**-203.0**
Earnings per share. before dilution. SEK		-0.46	-0.26	-5.89
Earnings per share. after dilution. SEK		-0.46	-0.26	-5.89

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

SEK m	2025 Jan-Mar	2024 Jan-Mar	2024 Jan-Dec
Earnings for the period	**-15.9**	**-8.9**	**-203.0**
Other comprehensive income			
Items that may subsequently be reversed to the statement of operations:			
Translation differences	-19.1	11.4	17.9
Other comprehensive earnings for the period. net after tax	**-19.1**	**11.4**	**17.9**
Total comprehensive earnings for the period [1]	**-35.0**	**2.5**	**-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 Mar 31	2024 Mar 31	2024 Dec 31
ASSETS				
Fixed assets				
Tangible fixed assets		59.6	76.1	64.7
Intangible assets		25.5	165.3	26.9
Right-of-use assets		25.7	23.8	16.4
Deferred tax assets	5	41.8	50.9	38.9
Other financial assets		20.7	0.8	1.6
Total fixed assets		**173.2**	**316.9**	**148.4**
Current assets				
Inventories		36.2	71.7	60.1
Accounts receivable		161.8	173.1	198.5
Other receivables		15.7	39.2	35.2
Prepayment and accrued income		23.0	31.0	29.4
Cash and cash equivalents		119.1	198.0	123.3
Total current assets		**355.8**	**513.0**	**446.4**
TOTAL ASSETS		**529.0**	**829.9**	**594.8**
SHAREHOLDERS' EQUITY AND LIABILITIES				
Total shareholders' equity		**-161.3**	**61.4**	**-126.3**
Long-term liabilities				
Provisions		19.8	13.4	24.0
Interest bearing liabilities	6	460.8	—	460.0
Lease liabilities, long-term		4.1	5.9	6.0
Total long-term liabilities		**484.7**	**19.3**	**490.0**
Current liabilities and provisions				
Accounts payable		39.9	37.9	41.5
Provisions		94.1	140.9	112.1
Current liabilities, interest bearing		—	497.8	—
Other liabilities		11.4	35.0	9.1
Accrued expenses		41.2	19.3	58.2
Lease liabilities, current		19.0	18.3	10.0
Total current liabilities		**205.6**	**749.2**	**231.1**
Total liabilities		**690.3**	**768.5**	**721.1**
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		**529.0**	**829.9**	**594.8**

CONDENSED CONSOLIDATED CHANGES IN SHAREHOLDERS' EQUITY

SEK m	2025 Mar 31	2024 Mar 31	2024 Dec 31
Opening balance, shareholders' equity	**-126.3**	**58.9**	**58.9**
Total comprehensive earnings for the period	-35.0	2.5	-185.1
Closing balance, shareholders' equity	**-161.3**	**61.4**	**-126.3**

CONDENSED CONSOLIDATED CASH FLOW STATEMENTS

SEK m	Notes	2025 Jan-Mar	2024 Jan-Mar	2024 Jan-Dec
Operating earnings (EBIT)		-5.2	-4.7	-140.3
Interest received		0.7	1.8	7.7
Interest paid		-11.5	-10.3	-60.2
Income taxes paid		-0.4	-0.5	-1.5
Adjustment for non-cash items	3	5.9	18.1	163.7
Cash flow from operating activities before changes in working capital		**-10.5**	**4.3**	**-30.6**
Changes in working capital		**43.4**	**-23.3**	**-2.0**
Cash flow from operating activities		**32.9**	**-18.9**	**-32.6**
Acquisition of tangible and intangible fixed assets		—	-1.2	-4.6
Change in financial fixed assets		-19.2	—	—
Disposal of short-term investments		—	—	-0.7
Cash flow from investing activities		**-19.2**	**-1.2**	**-5.3**
Amortization of lease liability		-7.0	-5.5	-22.0
Change of repurchased part in bond		—	48.8	6.5
Cash from financing activities		**-7.0**	**43.3**	**-15.5**
Cash flow for the period		**6.7**	**23.2**	**-53.5**
Cash and cash equivalents at the beginning of the period		**123.3**	**171.0**	**171.0**
Exchange-rate differences in cash and cash equivalents		-10.8	3.8	5.8
Changes in cash and cash equivalents		-4.2	27.0	-47.7
Cash and cash equivalents at the end of the period		**119.1**	**198.0**	**123.3**

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.

	2025 Jan-Mar	2024 Jan-Mar	2024 Jan-Dec
EBIT margin, %	neg.	neg.	neg.
Return on shareholder equity, %	neg.	neg.	neg.
Net debt, SEK m	341.7	299.8	336.8
Debt/equity ratio, %	neg.	810.7	neg.
Equity/assets ratio, %	neg.	7.4	neg.
Number of shares, before dilution	34,505,226	34,449,595	34,491,050
Number of shares, after dilution	34,505,226	34,449,595	34,491,050
Earnings per share, before dilution, SEK	-0.46	-0.26	-5.89
Earnings per share, after dilution, SEK	-0.46	-0.26	-5.89
Number of employees at the end of the period	104	113	110
Shareholders' equity, SEK m	-161.3	61.4	-126.3
Capital employed, SEK m	299.5	559.2	333.8
Working capital, SEK m	31.1	63.6	92.0

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

CONDENSED PARENT COMPANY STATEMENT OF OPERATIONS

SEK m	Notes	2025 Jan-Mar	2024 Jan-Mar	2024 Jan-Dec
Net revenues		13.2	100.5	303.8
Cost of goods sold		-20.4	-17.9	-63.2
Gross profit		**-7.2**	**82.6**	**240.5**
Selling expenses		-3.6	-25.4	-124.9
Administrative expenses		-12.8	-15.1	-58.2
Research and development costs		-41.0	-43.4	-288.8
Other operating income and expenses	7	12.8	3.7	1,143.1
Operating earnings (EBIT)		**-51.8**	**2.3**	**911.7**
Interest income and expenses		16.8	-6.5	-39.9
Other financial income and expenses		-3.4	1.8	-6.5
Net financial items		**13.4**	**-4.7**	**-46.4**
Earnings before tax		**-38.5**	**-2.4**	**865.3**
Income tax	5	—	—	—
Earnings for the period		**-38.5**	**-2.4**	**865.3**

PARENT COMPANY STATEMENT OF COMPREHENSIVE INCOME

SEK m	2025 Jan-Mar	2024 Jan-Mar	2024 Jan-Dec
Earnings for the period	**-38.5**	**-2.4**	**865.3**
Other comprehensive income	—	—	—
Total comprehensive earnings for the period	**-38.5**	**-2.4**	**865.3**

CONDENSED PARENT COMPANY BALANCE SHEET

SEK m	Notes	2025 Mar 31	2024 Mar 31	2024 Dec 31
ASSETS				
Fixed assets				
Patents, intellectual property rights, proprietary intangible assets and software		23.2	140.7	24.1
Equipment, machinery, renovation of the property of others		59.6	76.1	64.7
Shares and participations in group companies		290.3	286.8	291.8
Participations and securities in other companies		19.2	–	–
Total fixed assets		**392.3**	**503.6**	**380.6**
Current assets				
Inventories		2.4	37.5	6.8
Accounts receivable		7.4	12.0	6.8
Other receivables		7.8	34.5	30.3
Receivables from Group companies	7	1,058.4	81.9	1,049.4
Prepaid expenses and accrued income		15.0	20.6	15.1
Cash and cash equivalents		24.3	163.1	61.2
Total current assets		**1,115.3**	**349.5**	**1,169.6**
TOTAL ASSETS		**1,507.5**	**853.1**	**1,550.2**
SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES				
Total shareholders' equity		**988.9**	**159.7**	**1,027.4**
Long-term liabilities				
Other provisions		18.6	12.5	22.3
Interest bearing liabilities		460.8	–	460.0
Total long-term liabilities		**479.4**	**12.5**	**482.4**
Current liabilities				
Accounts payable		11.2	11.4	11.6
Bond loan		–	497.8	–
Other liabilities		9.6	7.7	7.6
Liabilities to Group companies		–	144.7	–
Accrued expenses and deferred income		18.5	19.3	21.2
Total current liabilities		**39.2**	**680.9**	**40.4**
Total liabilities		**518.6**	**693.4**	**522.8**
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		**1,507.5**	**853.1**	**1,550.2**

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 2024 Annual Report. None of the amended standards and interpretations that became effective January 1, 2025 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	2025 Jan-Mar	2024 Jan-Mar	2024 Jan-Dec
US Commercial			
Net revenues	133.0	129.3	560.3
Cost of goods sold	-16.0	-12.7	-66.3
Selling expenses	-42.5	-43.5	-191.3
Administrative expenses	-18.2	-19.8	-107.4
Research and development costs	-13.7	-22.0	-179.4
Other operating income and expenses	1.4	0.7	12.0
Operating earnings (EBIT)	**44.0**	**31.9**	**27.9**
Depreciation and amortization	-1.1	-10.8	-149.3
EBITDA	**45.1**	**42.6**	**177.2**
HQ & Pipeline			
Net revenues	13.2	10.0	29.7
Cost of goods sold	-4.7	-0.5	-5.8
Selling expenses	0.0	0.0	0.0
Administrative expenses	-12.7	-15.1	-57.9
Research and development costs	-38.0	-34.6	-160.6
Other operating income and expenses	-6.9	3.6	26.4
Operating earnings (EBIT)	**-49.1**	**-36.6**	**-168.3**
Depreciation and amortization	-10.0	-9.9	-39.9
EBITDA	**-39.1**	**-26.7**	**-128.3**
Group			
Net revenues	146.2	139.3	590.0
Cost of goods sold	-20.7	-13.3	-72.1
Selling expenses	-42.5	-43.5	-191.3
Administrative expenses	-31.0	-34.9	-165.3
Research and development costs	-51.6	-56.6	-340.0
Other operating income and expenses	-5.6	4.3	38.4
Operating earnings (EBIT)	**-5.2**	**-4.7**	**-140.3**
Depreciation and amortization	-11.1	-20.6	-189.2
EBITDA	**5.9**	**15.9**	**48.9**
Net financial items	-14.1	-5.0	-50.3
Earnings before tax	**-19.3**	**-9.8**	**-190.6**

3. Cash flow

ADJUSTMENT FOR NON-CASH ITEMS

SEK m	2025 Jan-Mar	2024 Jan-Mar	2024 Jan-Dec
Depreciation/amortization and impairment	11.1	20.6	189.2
Change in provisions	-12.3	1.0	-20.3
Share based payments	—	—	—
Other non cash items	—	0.0	0.5
Exchange rate income and expenses	7.1	-3.5	-5.8
Total	**5.9**	**18.1**	**163.7**

4. Disputes

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.

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.

8. Important events after the end of the period

› Orexo in collaboration with Abera Bioscience announced positive in-vivo data for powder-based intranasal vaccine formulated with the AmorphOX technology.

9. Net revenue from contracts with customers

	2025 Jan-Mar					
SEK m	Zubsolv®	Abstral®	Edluar®	Vorvida®	MODIA®	Total
Segment						
US Commercial	133.0	—	—	—	—	**133.0**
HQ & Pipeline	8.1	1.7	3.4	—	—	**13.2**
Total revenue from contracts with customers	**141.1**	**1.7**	**3.4**	**0.0**	**0.0**	**146.2**
Geographical markets						
US	133.0	—	0.1	—	—	**133.2**
EU & UK	8.1	1.9	2.9	—	—	**12.9**
Rest of the world	—	-0.2	0.4	—	—	**0.2**
Total revenue from contracts with customers	**141.1**	**1.7**	**3.4**	**0.0**	**0.0**	**146.2**

	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**

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

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
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	2025 Jan-Mar	2024 Jan-Mar	2024 Jan-Dec
EBIT	-5.2	-4.7	-140.3
Depreciation and amortization	11.1	20.6	189.2
EBITDA	**5.9**	**15.9**	**48.9**

OPERATING EXPENSES SEK m	2025 Jan-Mar	2024 Jan-Mar	2024 Jan-Dec
Selling expenses	-42.5	-43.5	-191.3
Administrative expenses	-31.0	-34.9	-165.3
Research and development costs	-51.6	-56.6	-340.0
Other operating income and expenses	-5.6	4.3	38.4
Operating expenses	**-130.7**	**-130.7**	**-658.2**

RETURN ON SHAREHOLDERS' EQUITY SEK m	2025 Jan-Mar	2024 Jan-Mar	2024 Jan-Dec
Shareholders' equity beginning balance	-126.3	58.9	58.9
Shareholders' equity ending balance	-161.3	61.4	-126.3
Average shareholders' equity	-143.8	60.2	-33.7
Net earnings	-15.9	-8.9	-203.0
Return on shareholders' equity %	**neg.**	**neg.**	**neg.**

GROSS INVESTMENTS SEK m	2025 Jan-Mar	2024 Jan-Mar	2024 Jan-Dec
Investments in tangible fixed assets	—	—	3.1
Investments in intangible fixed assets	—	1.2	1.6
Gross investments	**0.0**	**1.2**	**4.6**

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.