orexo

Q3 2023 Interim Report

November 2, 2023

Big step forward in launching OX124 in the US

Orexo supports the UN's Agenda 2030 with a focus on:

Q3 2023 highlights

- Total net revenues of SEK 156.1 m (161.0)
- EBITDA of SEK -9.5 m (-32.4), EBITDA excluding costs for legal processes and external non-repeating clinical trials, SEK 13.3 m (14.3)
- Net earnings of SEK -33.3 m (-26.5)
- US Pharma segment (ZUBSOLV® US) net revenues of SEK 140.4 m (150.1), in local currency USD 13.0 m (14.2), US Pharma EBIT of SEK 62.3 m (70.2)
- Cash flow from operating activities of SEK -21.9 m (-60.7), cash and invested funds of SEK 184.2 m (443.9)
- Earnings per share before and after dilution amounted to -0.97 (-0.77)
- ZUBSOLV reimbursed by Medicaid in Indiana state as of July 1
- The patent win announced in the end of Q2 was appealed by Sun Pharmaceuticals
- The first patent issued in the US for OX640, epinephrine rescue medication for allergic reactions
- OX124, high-dose rescue medication for opioid overdose, refiled with the FDA

Important events after the end of the period

- The MODIA® study didn't meet the primary end-points, but showed high rates of treatment response in both study arms, with no adverse events associated with the use of MODIA
- Robin Evers elected as board member at the Extraordinary General Meeting. He replaces Henrik Kjaer Hansen who has announced he will resign. Kjaer Hansen, has instead been appointed chairman of the Nomination Committee, representing Novo Holdings A/S.

SEK m unless otherwise stated	2023 Jul-Sep	2022 Jul-Sep	2023 Jan-Sep	2022 Jan-Sep	2022 Jan-Dec
Net revenues	156.1	161.0	472.8	468.3	624.3
Cost of goods sold	-22.8	-28.0	-68.8	-76.7	-102.6
Operating expenses	-161.9	-182.8	-505.0	-504.3	-705.6
EBIT	-28.6	-49.8	-100.9	-112.8	-183.9
EBIT margin	-18.4%	-31.0%	-21.3%	-24.1%	-29.5%
EBITDA	-9.5	-32.4	-44.8	-62.1	-115.2
Earnings per share. before dilution. SEK	-0.97	-0.77	-3.19	-2.50	-5.17
Earnings per share. after dilution. SEK	-0.97	-0.77	-3.19	-2.50	-5.17
Cash flow from operating activities	-21.9	-60.7	-92.4	-107.8	-156.6
Cash and invested funds	184.2	443.9	184.2	443.9	351.9

Unless otherwise stated in this report, alla data refers to the Group, and numbers relate to the current quarter while numbers in parantheses relate to the corresponding period in 2022

Group revenues
156 SEK M

Group EBITDA
-10 SEK M

Cash and cash equivalents
184 SEK M

Content

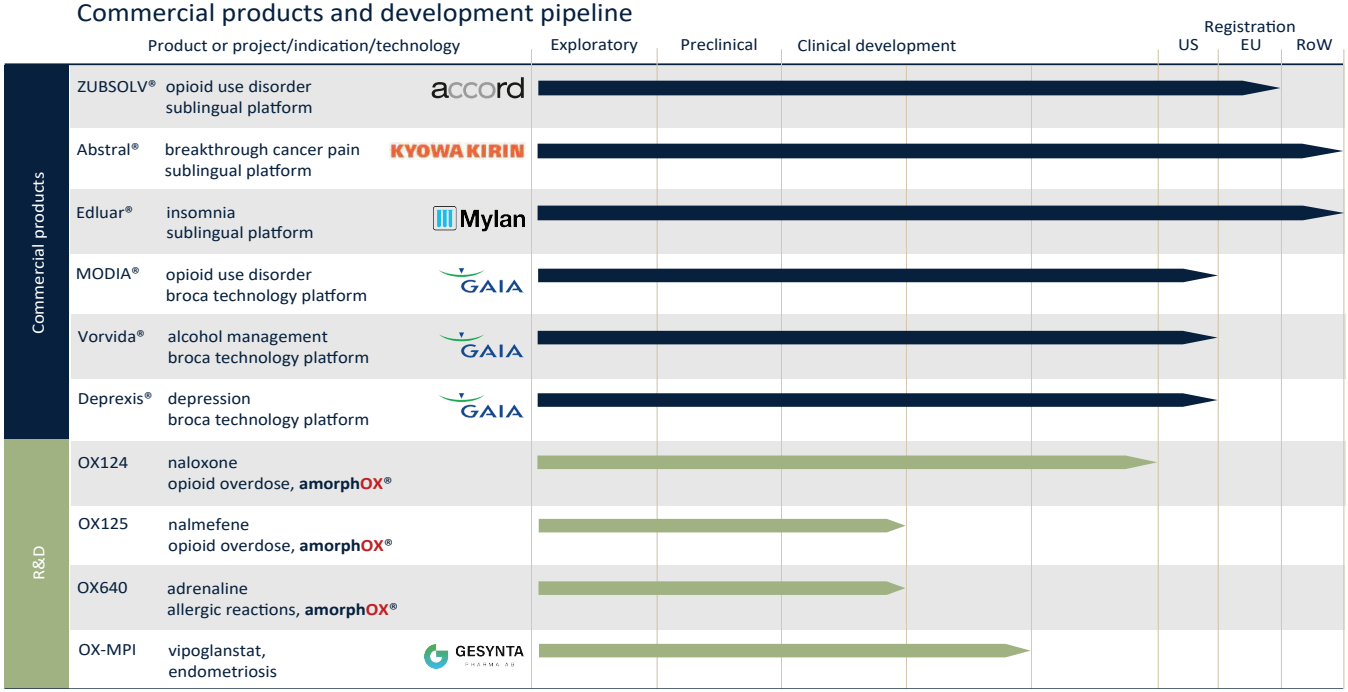
About Orexo

A commercial stage pharmaceutical company with three revenue generating pharmaceutical products

Profitable US commercial operations with a focus on one of the largest health crises in the US – opioid dependence

AmorphOX® - a world-class drug delivery platform leading to a new wave of products

Commercial products and development pipeline



Contact persons quarterly report

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Presentation

On Nov. 2, at 2 pm CET analysts, investors and media are invited to attend a presentation, incl. a Q&A.

To attend via teleconference where you can ask questions verbally:

https://conference.financialhearings.com/teleconference/?id=2001503

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

To attend via webcast:

https://ir.financialhearings.com/orexo-q3-2023/register

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

Financial calendar 2024

Interim Report Q4 2023, incl. Full Year Report, February 8, at 8 am
Annual Report - March 28
Annual General Meeting 2024 - April 26, at 4 pm
Interim Report Q1 2024 - May 8, at 8 am
Interim Report Q2 2024 - July 17, at 8 am
Interim Report Q3 2024 - November 14, at 8 am

Approaching EBITDA in balance H2

CEO Comments in brief

Prevailing in the patent litigation against Sun Pharmaceutical was a positive start to the quarter and strengthened our long-term ability to expand our US Commercial presence and product portfolio. The next product for commercialization in the US, the high-dose rescue medication for opioid overdose, OX124, was filed again with the FDA in September. With approval, we will launch our second pharmaceutical product in the US late 2024 or early 2025. Orexo's treatments of opioid use disorder (OUD) range from maintenance treatment with ZUBSOLV®, digital psychosocial support through MODIA® and soon, the rescue medication with OX124.

I am pleased to announce we reiterate our guidance to reach EBITDA in balance for H2 2023, despite the EBITDA for Q3 coming in at SEK -10 million. The negative result is explained by the SEK 18 million fee paid to the FDA for filing of OX124. In the current financial environment, improving financial results is important, and I am pleased to see we continue to reduce expenses.

Improved access to treatment crucial to combat the overdose epidemic

We continue to see relatively low growth in the daily US buprenorphine/naloxone market of 2.7 percent in Q3 and this equals a slight negative development in Q3 compared to Q2. Despite multiple federal and state initiatives to expand access to treatment as a result of the Biden administration´s 'Mainstreaming Addiction Treatment Act', among others, the expansion in treatment providers is still limited. Yearly market growth remains in line with the lower end of our guidance for 2023 of 4-7 percent. We have seen a small improvement in the last weeks of Q3 and continuing into Q4, which is needed to meet the guidance for the full year.

The low market growth in Q3 and lower sales to wholesalers in the beginning of the quarter, due to higher inventory stocking ahead of July 4th holiday than usual, caused a slight decline in ZUBSOLV sales compared to Q2 and last year. Most of the variation from Q2 is explained by normal quarterly variations in selling days and wholesalers inventory. We expect the overall market growth to rebound and support a continued stabilization of ZUBSOLV sales, which in the quarter landed at SEK 140 million in Q3 and EBIT contribution of SEK 62 million. Market access continues to be an important driver for growth and in Indiana, where ZUBSOLV gained significantly broader reimbursement in July, the sales in the quarter increased with 112 percent.

We are optimistic that the market for the treatment of OUD will grow to meet the significant unmet need in the US. With our complete product portfolio, ranging from maintenance treatment with ZUBSOLV, a digital psychosocial support program through MODIA, and soon a unique high-dose rescue medication for opioid overdose, OX124, we are well positioned to support more patients in their recovery journey while we are strengthening our competitiveness on the market. We are pleased to see several states initiating a process to allocate the USD 54 billion in abatement funds from the opioid settlements to combat the opioid crisis. However, we are somewhat concerned with the slow pace in many states to start investing in innovative concepts to improve access to, and expansion of, treatments to reduce the growing overdose death rates. Orexo is actively collaborating with leading local healthcare providers to develop

concepts that could be funded by the abatement funds to improve access to, and quality of, treatment. This is done under the MATCore® umbrella concept, where we combine the full breadth of our product portfolio and integrate it with the local healthcare providers' overall patient responsibilities.

MODIA® is one of the core elements of MATCore, and after the quarter we reported the results from the clinical trial. I am disappointed the MODIA study, as previously commmunicated, didn't meet the primary end-points. However, I was encouraged to see that patients completing all of the MODIA modules reported better outcomes than those who only completed a few. The positive outcome for individuals who completed all modules corresponds well with the qualitative feedback we have from patients and healthcare providers engaged in the clinical trial and our earlier experience program modiaONE™. However, a digital health solution is not the right choice for all patients as it requires a level of self-motivation to achieve optimal outcomes. We have a viable regulatory pathway and positioning of MODIA and, after updating the program to the new regulatory status, we will "re-launch" MODIA to a selected group of customers under the FDA's enforcement discretion for medical device apps.

Orexo's second pharmaceutical OX124 resubmitted with the FDA

In line with our expectations we resubmitted OX124 with the FDA during Q3. We expect the review time to be ten to thirteen months, and if it is approved we will initate a launch in the US late next year or early 2025. OX124 is also the first product based on our amorphOX® technology. Therefore, an FDA approval will pave the way for future products based on the same technology.

The market of OX124 is highly dynamic with significant recent changes. We have seen the market leader moving from a prescription-only to an over-the-counter (OTC) product. This unique change was driven by the US government with the goal to improve access to rescue medications. The impact on the market is difficult to predict as the process has only just begun. Historically in the US, OTC products have limited third party reimbursement and we expect this will also be the case in the market for OX124. This will be a clear advantage for high-dose prescription medications such as OX124. In addition, we unfortunately continue to see a significant increase of overdoses with potent synthetic opioids where the low-dose alternatives often do not provide sufficient medication to reverse the overdose or sustain consciousness.

Unexpected CRL to a competing product will cause a delay in partnership discussions for OX640

Our second project built on the amorphOX technology OX640 is making good development progress. OX640 is a nasal powder solution with epinephrine to be used as a rescue medication for allergic reactions. During the summer we have made intense business development efforts. A significant focus for the interested companies has been the success of a competing liquid nasal epinephrine product to get FDA approval. After a positive advisory committee vote in June, the competing product received a Complete Response Letter (CRL) from the FDA. The CRL, a rejection of approval, was explained by the FDA's requirement for additional clinical documentation. This unexpected CRL, has had an impact on the ongoing business development discussions. The CRL does not undermine OX640 as long as we complete the additional studies required by the FDA and our view is the regulatory risk has reduced as the FDA has clearified the regulatory route. In light of this we are planning to consult with the FDA to gain full clarity in the additional requirement(s) needed for the clinical development program for OX640 which will be important input to the finalization of the business development process. Meanwhile, we continue the upscaling of the manufacturing process to commercial scale, leveraging the established supply chain for OX124.

Summary and outlook

The third quarter marked a significant milestone with the submission of the application to the FDA for approval of OX124 and the progress towards launching our second commercial pharmaceutical product. We continue to get new, encouraging data from our pipeline and we are in multiple discussions with potential partners to leverage our unique powder technology, amorphOX, to develop new products. ZUBSOLV sales still demonstrate resilience and stability, despite a small decline in Q3 and we continue to strengthen our EBITDA result in the quarter. With these results, we maintain our guidance for the year, but note some increased uncertainty for the growth in the buprenorphine/naloxone market.

We are confident in our ability to finance our development from the continued contributions from ZUBSOLV, revenues from out-licensed products, and business development. During the quarter, we have leveraged the benefit from the strong USD to repurchase SEK 33 million of the corporate bond at a favorable rate. As we have seen with the resubmission of OX124, and the unexpected CRL to a competing nasal liquid epinephrine product, progress in the pharmaceutical industry is rarely linear and we are measured by our ability to address these unexpected events. I am pleased to have incredibly dedicated and talented employees, who keep their motivation high and address setbacks and delays with continued engagement.

Uppsala, Sweden, November 2, 2023

Nikolaj Sørensen
President and CEO

Commercial products

Opioid use disorder

ZUBSOLV® (buprenorphine and naloxone) sublingual tablet (CIII)

ZUBSOLV is indicated for the maintenance treatment of 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.

MODIA® digital therapeutic support program

MODIA is a web-based software program intended to help OUD patients develop behavioral coping skills and provide educational information, reminders, and motivational guidance. MODIA is intended for use, over a period of six months, by patients engaged in a clinician directed medication-assisted treatment (MAT) plan for OUD.

Unmet need and market development

Misuse of opioids is a global problem but is of epidemic proportions in the US where an estimated 9.2 million people are misusing opioids.[1] Approximately 5.6 million people are dependent on opioids[2] and of these, around 1.8 million are undergoing treatment, with the most common being MAT.[3] The opioid crisis in the US has continued to accelerate mainly due to the Covid-19 pandemic and the prevalence of synthetic opioids, especially illicit fentanyl. Fatal opioid overdoses have reached record-high levels and according to latest available data the number exceeded 85,000 annually.[4] Nine out of ten opioid overdoses involve synthetic opioids, such as fentanyl.[5]

In Q3, the buprenorphine/naloxone market declined 1 percent versus Q2 2023 and grew 3 percent versus Q3 2022. Expectations are that the buprenorphine/naloxone market growth will be positively impacted over the long-term by the new law, the 'Mainstreaming Addiction Treatment Act', passed late in December 2022. The new law, effective January 1, 2023, eliminates the DATA 2000 requirements for waiver and patient caps. Now all physicians and nonphysician prescribers with a license to prescribe controlled drug substances can prescribe buprenorphine/naloxone for OUD. All prescribers of controlled drug substances are now required to complete a shorter training session when they renew this license. This is part of the Biden administration's strategy to expand treatment for OUD by giving all HCPs an incentive to adopt MAT into their practice. In addition, the opioid litigation settlements, of approx. USD 54 billion, are also expected to accelerate access to treatment.

Developments during the quarter

ZUBSOLV volume declined 3 percent vs Q2 2023 and declined 6 percent vs Q3 2022. ZUBSOLV declined quarter over quarter in each of the three segments: the open segment where ZUBSOLV is reimbursed, the non-reimbursed segment, and the formerly exclusive payers United Health Group and Humana. Despite the quarter over quarter Medicaid market decline of 3 percent, ZUBSOLV declined less, at 2 percent. ZUBSOLV outpaced the market in year over year Medicaid growth, growing 6 percent vs Q3 2022, compared to the market growing 1 percent. ZUBSOLV's growth is supported by the most recently accessed states; Kentucky growing 26 percent, New York growing 52 percent, and Indiana growing 112 percent after gaining broader access in July. The second and third largest ZUBSOLV Medicaid states of Michigan and Ohio experienced growth of 2 percent and 7 percent, respectively.

ZUBSOLV's best in class market access in the Commercial payer segment is maintained at 98 percent. ZUBSOLV public payer segment access increased from 47 percent to 50 percent with the addition of Indiana Medicaid. Indiana is the 5th largest buprenorphine/naloxone Medicaid state, securing ZUBSOLV access in 4 of the 5 largest Medicaid states.

The pivotal MODIA study was completed and enrolled 437 patients at 35 centers across the US. The study evaluated whether the use of MODIA in combination with sublingual/naloxone treatment is better than care as usual to reduce use of illicit opioids. Data did not demonstrated any statistically significant difference between both study groups when measuring intake of illicit opioids, but showed high completion response in both arms (55% BSC, 31% MODIA). Also treatment response rates were high (32% BSC, 31% MODIA). These unexpectedly high treatment response rates exceeded those of similarly designed trials of long-acting injectable buprenorphine, which had 18 and 24 study visits (17% and 29%, respectively). An exploratory analysis of the 219 patients randomized to MODIA who

subsequently completed the entire study (n=114), found that the 61 patients that completed all 24 modules of MODIA had a significantly higher treatment response rate of 61 percent than those that did not complete the entire program (n=53), who had a treatment response rate of 38% (p=0.0146). The difference in treatment response rate emerged after completion of 12 modules. In addition, the study showed indications of improved psychosocial outcome for those who completed MODIA which will be explored further in continued post-hoc analysis.

The company will continue to commercialize MODIA with limited changes as a mobile medical device subject to FDA enforcement discretion following the expected expiration of the Covid Public Health Emergency Guidance in November 2023. Under enforcement discretion MODIA will be positioned as a supportive resource for patients undergoing a clinician-directed treatment, rather than as a physician-prescribed treatment regimen. The study results indicate there is a high value of the combination of high frequency interactions with health care providers and completion of the MODIA program, as well as MODIA's strong safety profile. The company is continuing to analyse the study data and will continue to collect data to show the value of MODIA in supporting the patients with OUD.

ZUBSOLV – sublingual tablet for the treatment of OUD in the EU

There are estimated to be 1.3 million high risk opioid users in Europe, yet treatment rates are low.[6] Approximately 50 percent of people with OUD are receiving some form of substitution treatment across Europe, although this varies greatly between countries.[7]

ZUBSOLV is available in eleven European countries, commercialized by Orexo´s European partner Accord Healthcare.

Within the framework of the collaboration with Accord Healthcare, Orexo is responsible for product supply and will receive double digit royalty on net sales.

Revenues from ZUBSOLV ex-US are recognized in the HQ & Pipeline segment.

VORVIDA deprexis

Mental illness and substance use disorder, ex OUD

Vorvida® – evidence based digital therapy for alcohol management

Vorvida is a 6-month online program that can break negative thought patterns and responses to change behavior around alcohol. The therapy is developed in consultation with psychologists, physicians and patients and is based on cognitive behavioural therapy techniques. The effectiveness of vorvida is evaluated in a randomized clinical trial, including approximately 600 patients.[8]

Deprexis® – evidence based digital therapy for depression

Deprexis is a 3-month online program that can help people create more positive thoughts and behaviors. The therapy is developed in consultation with psychologists, physicians and patients and is based on cognitive behavioural therapy techniques. Its effectiveness has been evaluated and published in twelve randomized clinical trials including more than 2,800 patients. Deprexis can be used as a standalone treatment or alongside traditional pharmaceuticals.[9]

Developments during the quarter

The move of the administrative systems to a new vendor in the US was completed and will significantly lowering the fixed maintenance cost of the system. Without efficient reimbursement and distribution pathways, Orexo has been forced to reduce the fixed cost and staffing to support our digital health products. The company will focuses on selected customers to secure an efficient process exist before considering to expand the business and operations again.

Short term, the company primarily focus commercial efforts for deprexis and vorvida on opportunities within the Veterans Affairs (VA). Efforts to establish efficient processes for administration and distribution within the VA continued. To facilitate this work, discussions were initiated with a potential partner specialized in distribution of medical devices to the VA.

Longer term, progress is being made on a federal level in the US to establish a national reimbursement system for digital health solutions and therapies. An efficient reimbursement and distribution system is essential for Orexo's digital products to reach their full potential and the company is actively engaging with government representatives to ensure an efficient system to the benefit of patients and the healthcare providers.

Financial results for MODIA, vorvida and deprexis are recorded in the Digital Therapeutics segment.

amorphOX® – a versatile drug delivery platform

Identified need

Amorphous materials are becoming more and more common in drug development and can be of great importance for the properties of the drug product. Amorphous materials are non-crystalline and possess no long-range order, giving them unique and highly sought-after properties, such as very rapid dissolution in water. Historically however, amorphous drug compositions were found to degrade during storage due to chemical and physical instability. Orexo has a solution to this problem

The solution

Orexo's proprietary drug delivery platform, amorphOX, is a powder-based technology made up of particles that are built using the unique combination of a drug, carrier materials and, optionally, other excipients such as a permeability enhancer. The particles are presented as an amorphous composite of the various ingredients providing for excellent chemical and physical stability in both low and high temperatures, meanwhile the rapidly dissolving property is maintained. The platform is protected by patents and patent applications until 2039-2044.

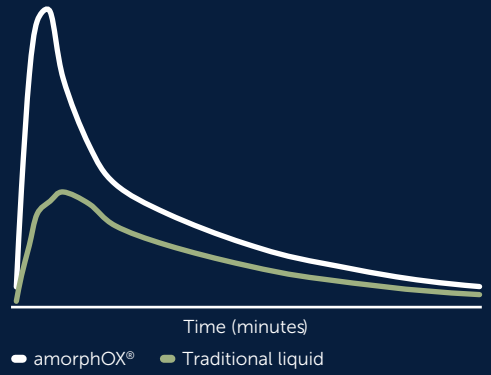
Clinically validated

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

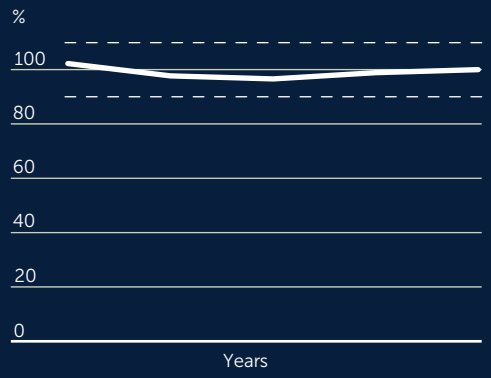
Wide applicability

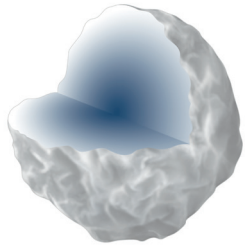
The technology works with a broad spectrum of active chemical substances, including small and large molecules,[10] and the properties of the powder can be tailored to meet specific needs such as particle size, dissolution, and mucosal retention. This makes it a versatile technology with broad applicability in pharmaceutical development across multiple therapeutic areas.

Plasma concentration



Amount of API





Successful clinical trials

Well tolerated
Higher exposure
Faster Onset
Lower variability

PRESERVATIVES NO ADDED

amorphOX®

Products under development

Development projects based on the amorphOX® drug delivery platform

OX124 – high-dose rescue medication for opioid overdose with naloxone

Project in brief

Opioid overdose is a life-threatening condition, characterized by loss of consciousness and respiratory depression. Based on the proprietary drug delivery platform amorphOX, Orexo has developed a high-dose naloxone rescue medication, OX124, designed to reverse opioid overdoses, including those from highly potent synthetic opioids.

Developments during the quarter

According to plan OX124 was resubmitted with the FDA.The technical issues with the packaging process, which earlier this year gave rise to FDA's request for refiling, have been solved in partnership with the contract manufacturer. To ensure the manufacturing process meets the highest reliability requirements, also tests and qualifications have successfully been conducted at the contract manufacturers site. FDA´s review process is expected to take 10 to 13 months.

Differentiation

Formulations of OX124 have shown more rapid absorption and substantially higher plasma concentrations of naloxone compared to the current market leader. All these properties can be critical in avoiding brain damages and saving lives as well as preventing re-intoxification during the revival process. In addition, OX124 has unique properties compared with existing products, which is related to its being a powder-based product while other products are liquid-based. The amorphOX powder-based technology provides for longer shelf-life and makes it less vulnerable to temperature changes. If approved, OX124 will be the only product on the market that does not freeze at temperatures below zero degrees. Except for having the potential to become the most reliable product for users and lay-people[11] it is easy to carry as OX124 comes in a unique device that is less bulky. OX124 has patents protecting the product until 2039.

Market and commercialization

Upon approval, Orexo will meet an increased need of a powerful overdose rescue medications, where most overdoses today are caused by misuse of synthetic opioids, such as illegal fentanyl. During the latest 12-month period, ending May 2023, the predicted annual number of fatal opioid overdoses in the US counted for more than 85,000.[12] Nine out of ten opioid overdoses involve synthetic opioids, such as fentanyl.[13]

The market for overdose rescue medications is continuously evolving, and it´s closely monitored by Orexo. Low-dose products, including the market leading product, NARCAN® and its generics, have become available at pharmacies (OTC product). These products are expected to have limited reimbursement, in contrast to the differentiated high-dose products, such as OX124, that will have access to reimbursement by insurance companies. The increased availability of naloxone products is expected to continue to grow the total market, while the large need for potent and longer-lasting overdose rescue medications will most likely also propel the prescription market, as well as the continued expansion of mandatory co-prescription of naloxone.

If the FDA approves OX124 as planned next year, Orexo's sales force will initiate the launch in late 2024 or early 2025. When launching the product, Orexo will benefit from its well-established network among insurance companies, its long experience and knowledge of treating patients with OUD, and particularly from its sales force covering large parts of the US, including twelve of the seventeen states with mandatory co-prescribing of naloxone with an opioid. To reach first responders, such as police and firefighters, which is made through centralized procurement, some minor reinforcement of the sales force will be necessary.

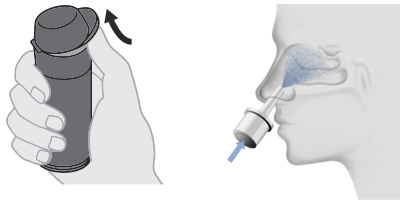
The device

OX124 can follow you anywhere: **small** in size, **easy to carry**

Moist-protection

Built-in desiccant to protect the powder from any moisture

Easy to use, nasal spray application



The **usage and application** of a potentially lifesaving dose of naloxone in case of an accidental opioid overdose event is **simple, fast, and** most of all: **high-dose**

OX125 – high-dose rescue medication for opioid overdose with nalmefene

Project in brief

The widespread use of synthetic opioids, such as illicit fentanyl, also increases the need for effective and long-lasting rescue medications for use in rural areas where it takes long time for patients to reach emergency care units. With OX125, the aim is to develop an overdose rescue medication for situations where the treatment effect needs to be long-lasting while also being powerful and fast-acting. Nalmefene has a half-life of 8-11 hours in the body versus 1-2 hours for naloxone.

OX125, also based on the proprietary drug delivery platform amorphOX®, has shown positive results from a human pharmacokinetic study. The study was a cross-over, comparative bioavailability study in healthy volunteers to assess nalmefene absorption from three development formulations of OX125, compared to a nalmefene intramuscular injection. Data demonstrated extensive and rapid absorption across all three OX125 formulations as well as good tolerability.

Developments during the quarter

A dialogue was initiated with the FDA to determine the continued development program. Remaining time for development is relatively short since the synergies between OX124 and OX125 are significant in terms of development and product supply.

OX640 – epinephrine rescue medication for allergic reactions

Project in brief

The aim with OX640 is to develop a powder-based nasal epinephrine product for the emergency treatment of allergic reactions. Epinephrine is commonly used for the emergency treatment of allergic reactions, including anaphylaxis. Epinephrine is a very unstable active ingredient sensitive to chemical degradation, which is the reason why today's commercial epinephrine products have limited shelf-life with restrictive handling and storage.

OX640 is based on amorphOX and its powder-based technology provides excellent chemical and physical stability. In addition to providing allergic patients with a more convenient, needle-free alternative to auto-injectors currently on the market, an epinephrine product that provides greater flexibility in relation to how it can be handled and stored should provide significant benefits to patients and healthcare systems.

OX640 is protected by granted patents both on the US and European markets. Furthermore, multiple patent applications have been filed protecting OX640 on a global basis until 2044.

Developments during the quarter

The work to upscale the manufacturing process continued together with the establishment of a commercial supply chain, which will leverage on the existing supply chain for OX124. Stability studies continue to showcase great stability of OX640 and its ability to withstand large changes in temperature. In the quarter the first patent was granted protecting OX640 in the US until 2041.

A competing liquid nasal epinephrine product unexpectedly received a complete response letter (CRL/rejection of approval) by the FDA in September. The FDA was requiring additional clinical data to validate the effect of nasal administration of epinephrine. Although the rejection letter confirmed nasal administration is acceptable to the FDA, it created uncertainty around the clinical development program needed. Orexo will seek additional advice from the FDA to the clinical development program for OX640, and this has proven to be important to reach a final partnership agreement for the continued clinical development and commercialization of the product globally.

Early stage projects

The wide applications of the drug delivery platform amorphOX entail Orexo to continuously conduct tests of the platform with new APIs, including both small and large molecules, and to perform stability studies. Currently three exploratory feasibility studies are on-going in collaboration with international pharmaceutical companies, of which two of these companies are working with biological drugs or vaccines. The first results of the exploratory feasibility studies are promising, and large biomolecules maintain activity after formulation with the amorphOX platform. Orexo continues to work with the potential partner companies to explore the value of the amorphOX platform to their proprietary technology and as the development advance Orexo will receive compensation for specific development activities.

Orexo is aiming to continue to seek partnerships with other pharmaceutical and biotech companies to leverage the unique properties of amorphOX to improve the formulation of their products, while in parallel advance other projects to feed Orexo's US commercial organization with more products.

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

Other development projects

OX-MPI – endometriosis, BI1029539

OX-MPI (vipoglanstat, GS-248) is a drug candidate in clinical development. OX-MPI inhibits the proinflammatory enzyme mPGES-1, which via its product, prostaglandin E2, plays a key role in the chronic inflammatory disease endometriosis. This disease affects approximately 10 percent of women of reproductive age. Main symptoms of endometriosis are severe pain and reduced fertility, and there is a high need for nonhormonal treatment options.

Orexo's partner Gesynta Pharma owns all rights to the drug candidate.

Sustainability

Orexo supports Agenda 2030 and the Sustainable Development Goals (SDGs). The company has also been a participant in the UN Global Compact since 2017, and its strategy aligns with both this and the SDGs. SDG 3: "Good health and well-being", and in particular target 3.5: "Strengthen the prevention and treatment of substance abuse, including narcotic drug abuse and harmful use of alcohol" continue to be core to Orexo's business.

In 2022 the sustainability strategy was updated based on e.g., stakeholder dialogues and a materiality assessment and involves today four focus areas:

1. Responsible business

Responsible business based on trust, transparency, integrity, and no tolerance for corruption are central to all our activities and a foundation for our sustainability work.

2. Sustainable employees

In all our teams, create a healthy working climate where inclusion and diversity are a matter of course.

3. Access to healthcare

Increase access to healthcare by patient support and strengthening knowledge of substance abuse and mental illness.

4. Environment and Climate change

The ambition is to reduce our 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 2022 Sustainability Report.

Developments during the quarter

Progress was made to map the climate impact within Scope 3, in accordance with the GHG Protocol, and to conduct sustainability assessments of the suppliers for the OX124 product. In addition, a partnership was initiated with Agerus, which offers a platform of services to help companies develop and systematize a sustainable performance culture. During Q3, monthly pulse measurements of the organizational and social environment were conducted. These show that employees feel they have a good work-life balance, and that Orexo supports their well-being.

Financial development

Revenues

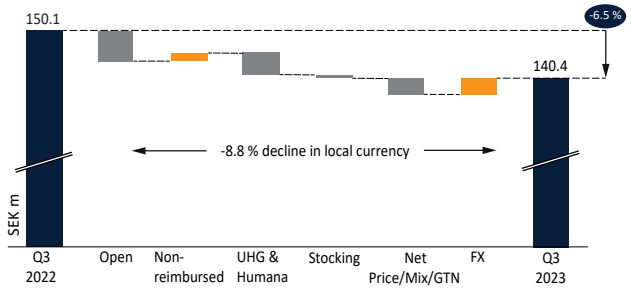
Total revenues amounted to SEK 156.1 m (161.0) for Q3. The decrease is mainly explained by lower US Pharma revenues partly offset by higher HQ & Pipeline partner product related revenues and the stronger USD exchange rate. For the first nine months total revenues amounted to SEK 472.8 m (468.3).

Revenues by segment

US Pharma revenues amounted to SEK 140.4 m (150.1) for Q3. The decrease in US Pharma revenues is mainly driven by lower demand and unfavorable payer mix partly offset by a positive impact of SEK 3.5 m from stronger USD exchange rate. ZUBSOLV® experienced lower demand mainly as a result of lower market growth, especially in the higher priced commercial segment. The demand in the previously exclusive plans United Health Group and Humana is lower year over year, but the decline has slowed down considerably in Q3. US Pharma revenues amounted to SEK 426.3 m (428.8) for the first nine months. In local currency US Pharma net revenues for Q3 amounted to USD 13.0 m (14.2) and for the first nine months to USD 40.2 m (43.2).

Digital Therapeutics (DTx) recognized net revenues for Q3 amounting to SEK 0.0 m (0.0) and to SEK 0.1 m (0.3) for the first nine months.

ZUBSOLV® US NET REVENUES DEVELOPMENT



HQ & Pipeline partner product related revenues for Q3 amounted to SEK 15.7 m (10.8). The increase is mainly explained by higher ZUBSOLV ex-US revenues related to sales of tablets to Orexo's partner Accord Healthcare and positive adjustments of Abstral® and Edluar® royalties from Q2 2023. HQ & Pipeline partner product related revenues amounted to SEK 46.4 m (39.1) for the first nine months.

Costs of goods sold

Cost of goods sold (COGS) amounted to SEK 22.8 m (28.0) for Q3. US Pharma amounted to SEK 16.1 m (24.4), the decrease is mainly due to favorable production costs. Royalty and technical infrastructure costs for DTx amounted to SEK 3.0 m (2.7). HQ & Pipeline amounted to SEK 3.7 m (0.9) for ZUBSOLV ex-US due to sale of tablets to Orexo's partner Accord. Cost of goods sold (COGS) amounted to SEK 68.8 m (76.7) for the first nine months.

NET REVENUES AND OPERATING EARNINGS PER SEGMENT

SEK m	Net Revenues					EBIT				
	2023 Jul-Sep	2022 Jul-Sep	2023 Jan-Sep	2022 Jan-Sep	2022 Jan-Dec	2023 Jul-Sep	2022 Jul-Sep	2023 Jan-Sep	2022 Jan-Sep	2022 Jan-Dec
ZUBSOLV US product sales	140.4	150.1	426.3	428.8	571.4	–	–	–	–	–
US Pharma – total	**140.4**	**150.1**	**426.3**	**428.8**	**571.4**	**62.3**	**70.2**	**207.7**	**231.4**	**308.4**
Digital Therapeutics (DTx) product sales	0.0	0.0	0.1	0.3	0.4	–	–	–	–	–
Digital Therapeutics (DTx) – total	**0.0**	**0.0**	**0.1**	**0.3**	**0.4**	**-31.6**	**-48.9**	**-101.8**	**-140.1**	**-189.1**
Abstral® royalty	7.7	7.5	21.9	24.9	30.4	–	–	–	–	–
Edluar® royalty	3.5	2.9	8.8	7.7	10.4	–	–	–	–	–
ZUBSOLV® – ex-US	4.5	0.4	15.6	6.5	11.8	–	–	–	–	–
HQ & Pipeline segment – total	**15.7**	**10.8**	**46.4**	**39.1**	**52.6**	**-59.3**	**-71.2**	**-206.9**	**-204.0**	**-303.2**
Total	**156.1**	**161.0**	**472.8**	**468.3**	**624.3**	**-28.6**	**-49.8**	**-100.9**	**-112.8**	**-183.9**

Operating expenses

Selling expenses amounted to SEK 44.7 m (54.7) for Q3. The decrease over the same period last year is mainly explained by significantly lower selling expenses in DTx. This is partly offset by negative impact of stronger USD exchange rate. Selling expenses amounted to SEK 138.7 m (146.8) for the first nine months.

Administrative expenses amounted to SEK 45.4 m (54.2) for Q3. The decrease is mainly explained by lower legal expenses for IP litigation partly offset by personnel-related non-recurring costs within US pharma and DTx as a result of organizational changes and negative impact of stronger USD exchange rate. Administrative expenses amounted to SEK 150.1 m (138.5) for the first nine months.

Research and development costs amounted to SEK 83.7 m (76.5) for Q3. The increase is mainly explained by external non-repeating costs for OX124 filing with the FDA, by higher internal costs and by negative impact of stronger USD exchange rate partly offset by lower costs related to MODIA® study that was finalized during the quarter. Research and development costs amounted to SEK 237.7 m (229.8) for the first nine months.

Other operating income and expenses amounted to SEK 11.9 m (2.5) for Q3. This is mainly explained by a received insurance reimbursement of SEK 7.3 m (0.0) for legal costs in the US, partner reimbursement of SEK 3.2 m (0.0) for R&D activities performed in relation to the amorphOX® platform, sublease of office space in US of SEK 0.2 m (0.0) and MATCore related income of SEK 0.4 m (0.0). This is partly offset by lower exchange-rate gains of SEK 0.7 m (3.5) derived from revaluations of parent company balance sheet items in foreign currency, predominantly in USD. Other operating income and expenses amounted to SEK 21.5 m (10.7) for the first nine months.

Operating profit

EBITDA amounted to SEK -9.5 m (-32.4) for Q3 and to SEK -44.8 m (-62.1) for the first nine months. Exclusion of costs for legal processes and external non-repeating costs for clinical studies, would result in an EBITDA of SEK 13.3 m (14.3) for Q3 and SEK 64.7 m (57.9) for the first nine months.

The EBIT contribution from US Pharma amounted to SEK 62.3 m (70.2) for Q3, equal to an EBIT margin of 44.4 percent (46.8). EBIT contribution from US Pharma amounted to SEK 207.7 m (231.4) for the first nine months, equal to an EBIT margin of 48.7 percent (54.0).

Total EBIT amounted to SEK -28.6 m (-49.8) for Q3 mainly explained by lower costs of goods sold and lower operating expenses. Total EBIT amounted to SEK -100.9 m (-112.8) for the first nine months.

Net financial items and tax

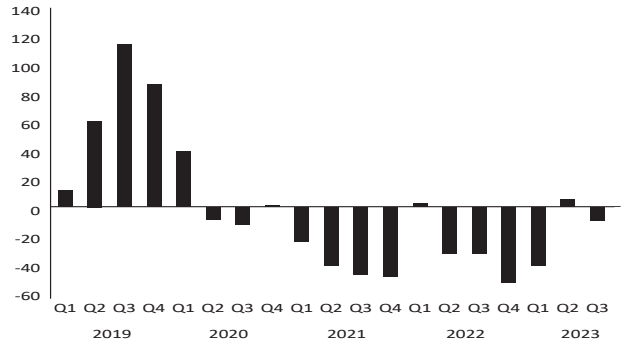
Net financial items for Q3 amounted to SEK -7.9 m (27.4) and is mainly explained by lower positive unrealized exchange rate impact of SEK 0.8 m (33.2) derived from the parent company's foreign currency bank accounts mainly in USD and is a result of absence of short-term investments of USD 0.0 m (20.1) as well as relatively stable USD exchange rate in Q3 2023. Higher interest rate had a negative impact on costs for corporate bonds of SEK -9.7 m (-6.7). This was partly offset by interest income of SEK 1.3 m (1.2) from bank accounts. Net financial items amounted to SEK -19.9 m (37.8) for the first nine months.

Total tax expenses amounted to SEK 3.3 m (-4.1) for Q3. The decrease is mainly explained by positive adjustment to deferred tax assets related to temporary differences. Total tax expenses amounted to SEK 11.1 m (-10.9) for the first nine months. Orexo performs regular assessments of its deferred tax asset and makes adjustments according to the recognition requirements of IAS 12.

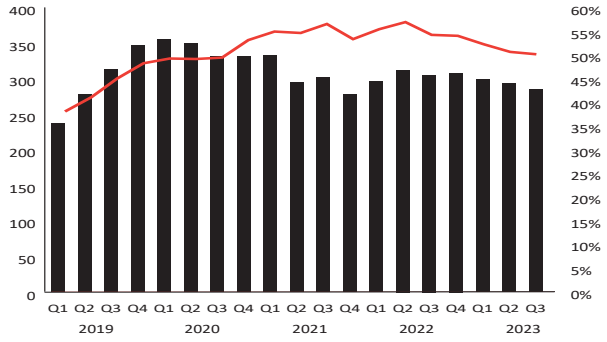
Net earnings

Net earnings amounted to SEK -33.3 m (-26.5) for Q3 and to SEK -109.7 m (-85.8) for the first nine months.

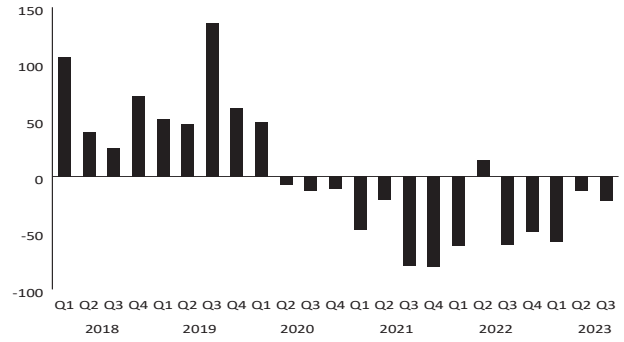
GROUP EBITDA, SEK m



US PHARMA EBIT MARGIN (LTM, SEK m) AND EBIT (LTM SEK m)[13]



CASH FLOW FROM OPERATING ACTIVITIES, SEK m



Cash and cash flow

Cash flow from operating activities amounted to SEK -21.9 m (-60.7) for Q3 and was primarily impacted by negative operating earnings. Cash flow from operating activities amounted to SEK -92.4 m (-107.8) for the first nine months. In the quarter Orexo made a buyback of the corporate bond with a nominal value of SEK 33.5 m and paid OX124 filing fee of SEK 18.0 m to the FDA. All invested surplus cash in certificates of deposits and in US treasuries matured in Q2. As of September 30, 2023, cash and cash equivalents amounted to SEK 184.2 m (122.4) and short-term investments amounted to SEK 0.0 m (321.5). Cash and invested funds in total amounted to SEK 184.2 m (443.9) and interest-bearing liabilities to SEK 447.8 m (494.2), i.e. a negative net cash position including short-term investments of SEK -263.6 m (-50.3). Cash and invested funds were reduced by SEK 66.9 m from Q2.

Investments

Gross investments in tangible and intangible fixed assets amounted to SEK 6.7 m (1.6) for Q3 and to SEK 18.3 m (11.7) for the first nine months. Higher investments for Q3 are mainly explained by investments in equipment for the development organisation.

Equity

Shareholders' equity at September 30, 2023, was SEK 92.0 m (298.4). The equity/asset ratio was 10.6 percent (24.8).

Parent company

Net revenues for Q3 amounted to SEK 122.0 m (64.2) of which SEK 106.3 m (53.4) was related to sales to Group companies. Net revenues amounted to SEK 379.9 m (220.0) for the first nine months of which SEK 332.9 m (180.9) was related to sales to Group companies.

Earnings before tax amounted to SEK -17.8 m (-42.9) for Q3. The development is mainly explained by higher gross profit and lower operating expenses partly offset by lower net financial items. Earnings before tax amounted to SEK -55.7 m (-121.2) for the first nine months.

Investments in equipment for the development organization for Q3 amounted to SEK 6.7 m (0.3) and to SEK 17.6 m (7.8) for the first nine months.

As of September 30, 2023, cash and cash equivalents in the parent company amounted to SEK 140.7 m (78.7) and short-term investments amounted to SEK 0.0 m (255.5) i.e. company's cash and invested funds amounted to SEK 140.7 m (334.2).

Parent company shareholders' equity at September 30, 2023, was SEK 53.4 m (184.8). See further risks and uncertainty factors under financial outlook.

Other information

Financial outlook 2023

- The buprenorphine/naloxone market will grow 4-7 percent. Due to the slowdown in the growth rate in Q3, the uncertainty in the full-year guidance has increased.
- Group revenues will increase, with ZUBSOLV® US revenues being in line with 2022.
- Reduced OPEX in H2 compared to H1, which amounted to SEK 343 million including depreciation of SEK 37 million.
- EBITDA in balance in H2.

Forward looking statements

This report includes forward-looking statements. Actual results may differ from those stated. Internal and external factors may affect Orexo's results.

Risks and uncertainty factors

Significant risks and uncertainties are presented in the Annual Report for 2022 and in the Interim Report Note 4, litigations. The continued commercialization of ZUBSOLV and digital therapies entails risk exposure of an operational nature. Orexo is continuously exposed to risks in relation to development projects, the intellectual property rights and changes related to commercialization and development partners. In addition, expanded geopolitical risk increases the risk of shortage of material in the product supply chain.

Going concern uncertainty factors

The shareholders' equity in the parent company decreased in Q3 and during the first nine months of 2023. It cannot be ruled out that it will decrease further. Reduced shareholders' equity to less than half of the registered share capital requires measures to be taken. To avoid such a situation following a potential continued negative development of the shareholders' equity, the company will take actions primarily through improved profitability, value-enhancing business development and cost savings and secondarily through a potential addition of external capital in some form. The board's assessment is that these actions are likely to be successful. However, if the actions are not successful, there are material uncertainty factors that may cast significant doubt regarding the entity's ability to continue as going concern. The group has sufficient funds for continued operations for at least the next twelve months. The interim report is prepared based on the assumption of going concern.

Glossary

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

Key near-term triggers

1. **Reach EBITDA profitability**
2. **ZUBSOLV sales stabilized and improved access to patients**
3. **Enter into partnership for one of the projects under development**
4. **DTx showing progress**

Review report

Orexo AB, corporate identity number 556500-0600.

Introduction

We have reviewed the condensed interim report for Orexo AB as at September 30, 2023 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.

Material uncertainty related to going concern

We draw attention to the information on page 15, where it is stated that it cannot be ruled out that the shareholders' equity in the parent company may become less than half of the registered share capital unless measures are taken. To avoid this to happen the company will take actions primarily through improved profitability, value-enhancing business development and cost savings and secondarily through a potential addition of external capital in some form.

Should the planned measures not counteract the decline in equity to the extent expected by the Board of Directors, there is a material uncertainty that may cast significant doubt on the Company's ability to continue as a going concern.Our opinion is not modified in respect of this matter.

Uppsala, Sweden, November 2, 2023
Ernst & Young AB

Oskar Wall
Authorized Public Accountant

References

1 Page 6, Substance Abuse and Mental Health Services Administration 2021 NSDUH report

2 Page 6, Substance Abuse and Mental Health Services Administration 2021 NSDUH report

3 Page 6, Orexo data

4 Page 6, Center of Disease Control and Prevention, predicted numbers as of January 2023

5 Page 6, Center of Disease Control and Prevention, predicted numbers as of January 2023

6 Page 7, European Monitoring Centre for Drugs and Drugs Addiction (EMCDDA)

7 Page 7, EMCDDA - Tackling Opioid Dependence

8 Page 7, Jördis M. Zill, Eva Christalle, Björn Meyer, Martin Härter, and Jörg Dirmaier The Effectiveness of an Internet Intervention Aimed at Reducing Alcohol Consumption in Adults: Results of a Randomized Controlled Trial (Vorvida) Dtsch Arztebl Int 2019; 116: 127–33. DOI: 10.3238/arztebl.2019.0127

9 Page 7, Twomey et al. (2020), Zwerenz et al. (2017), Berger et al. (2018), Beevers et al. (2017), Klein et al. (2016), Meyer et al. (2015), Moritz et al. (2012), Berger et al. (2011), Meyer et al. (2009), Bücker et al. (2018), Fischer et al. (2015), Schröder et al. (2014)

10 Page 8, Enzymes, peptides and proteins

11 Page 9, E.g. police officers, prison personnel, family and relatives

12 Page 9, Center of Disease Control and Prevention, predicted numbers

13 Page 9, Center of Disease Control and Prevention, predicted numbers

14 Page 13, Last Twelve Months

Financial reports, notes and key figures

CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS

SEK m	Notes	2023 Jul-Sep	2022 Jul-Sep	2023 Jan-Sep	2022 Jan-Sep	2022 Jan-Dec
Net revenues	9	156.1	161.0	472.8	468.3	624.3
Cost of goods sold		-22.8	-28.0	-68.8	-76.7	-102.6
Gross profit		**133.3**	**133.0**	**404.1**	**391.5**	**521.7**
Selling expenses		-44.7	-54.7	-138.7	-146.8	-199.0
Administrative expenses		-45.4	-54.2	-150.1	-138.5	-202.3
Research and development expenses		-83.7	-76.5	-237.7	-229.8	-318.0
Other operating income and expenses		11.9	2.5	21.5	10.7	13.7
Operating earnings (EBIT)		**-28.6**	**-49.8**	**-100.9**	**-112.8**	**-183.9**
Net financial items		-7.9	27.4	-19.9	37.8	13.5
Earnings before tax		**-36.6**	**-22.4**	**-120.8**	**-74.9**	**-170.4**
Tax	5	3.3	-4.1	11.1	-10.9	-7.2
Net earnings for the period		**-33.3**	**-26.5**	**-109.7**	**-85.8**	**-177.6**
Earnings per share. before dilution. SEK		-0.97	-0.77	-3.19	-2.50	-5.17
Earnings per share. after dilution. SEK		-0.97	-0.77	-3.19	-2.50	-5.17

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

SEK m	2023 Jul-Sep	2022 Jul-Sep	2023 Jan-Sep	2022 Jan-Sep	2022 Jan-Dec
Earnings for the period	**-33.3**	**-26.5**	**-109.7**	**-85.8**	**-177.6**
Other comprehensive income	**—**	**—**	**—**	**—**	**—**
Items that may subsequently be reversed to the statement of operations:					
Exchange-rate differences	8.0	16.1	7.1	34.8	22.1
Other comprehensive earnings for the period, net after tax	**8.0**	**16.1**	**7.1**	**34.8**	**22.1**
Total comprehensive earnings for the period [1]	**-25.3**	**-10.4**	**-102.6**	**-51.0**	**-155.5**

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

CONDENSED CONSOLIDATED BALANCE SHEET

SEK m	Notes	2023 Sep 30	2022 Sep 30	2022 Dec 31
ASSETS				
Fixed assets				
Tangible fixed assets		85.4	68.4	76.1
Intangible fixed assets		186.4	229.6	217.4
Right-of-use assets		29.1	48.5	46.0
Deferred tax assets	5	49.2	28.3	33.1
Other financial assets		0.8	1.0	0.9
Total fixed assets		**350.9**	**375.8**	**373.5**
Current assets				
Inventories		64.6	88.7	74.6
Accounts receivable and other receivables		269.3	295.1	309.0
Short-term investments		0.0	321.5	219.6
Cash and cash equivalents		184.2	122.4	132.2
Total current assets		**518.1**	**827.7**	**735.5**
Total assets		**869.0**	**1,203.5**	**1,109.0**
SHAREHOLDERS' EQUITY AND LIABILITIES				
Total shareholders' equity		**92.0**	**298.4**	**193.9**
Long-term liabilities				
Provisions		10.0	9.0	10.2
Long-term liabilities, interest bearing		447.8	494.2	494.8
Lease liabilities, long-term		9.6	26.6	24.2
Total long-term liabilities		**467.3**	**529.8**	**529.2**
Current liabilities and provisions				
Provisions		131.4	161.1	121.5
Current liabilities, non-interest bearing		157.0	193.0	243.7
Lease liabilities, current		21.3	21.2	20.6
Total current liabilities and provisions		**309.7**	**375.3**	**385.9**
Total liabilities		**777.0**	**905.1**	**915.1**
Total shareholders' equity and liabilities		**869.0**	**1,203.5**	**1,109.0**

CONDENSED CONSOLIDATED CHANGES IN SHAREHOLDERS' EQUITY

SEK m	2023 Sep 30	2022 Sep 30	2022 Dec 31
Opening balance, shareholders' equity	**193.9**	**349.6**	**349.6**
Total comprehensive earnings for the period	-102.6	-51.0	-155.5
Share-based payments	-0.7	-0.1	-0.1
Closing balance, shareholders' equity	**92.0**	**298.4**	**193.9**

CONDENSED CONSOLIDATED CASH FLOW STATEMENTS

SEK m	Notes	2023 Jul-Sep	2022 Jul-Sep	2023 Jan-Sep	2022 Jan-Sep	2022 Jan-Dec
Operating earnings (EBIT)		-28.6	-49.8	-100.9	-112.8	-183.9
Interest received		1.2	-0.1	4.1	0.3	1.4
Interest paid		-10.1	-5.8	-27.1	-15.6	-22.4
Income taxes paid		-0.4	-1.4	-1.2	-2.1	1.5
Adjustment for non-cash items	3	11.9	0.9	56.7	0.9	-3.5
Cash flow from operating activities before changes in working capital		**-26.0**	**-56.3**	**-68.4**	**-129.2**	**-206.9**
Changes in working capital		**4.1**	**-4.4**	**-24.0**	**21.4**	**50.3**
Cash flow from operating activities		**-21.9**	**-60.7**	**-92.4**	**-107.8**	**-156.6**
Acquisition of tangible and intangible fixed assets		-6.7	-1.6	-18.3	-11.7	-23.9
Acquisition of short-term investments		0.1	-67.5	0.1	-289.2	-295.6
Disposal of short-term investments		—	—	219.9	—	84.0
Sales of tangible assets		—	—	0.0	—	0.8
Cash flow from investing activities		**-6.6**	**-69.0**	**201.7**	**-300.9**	**-234.7**
Repayment of loans and lease liabilities		-39.1	-5.0	-64.6	-15.6	-21.4
Cash from financing activities		**-39.1**	**-5.0**	**-64.6**	**-15.6**	**-21.4**
Cash flow for the period		**-67.6**	**-134.7**	**44.7**	**-424.3**	**-412.8**
Cash and cash equivalents at the beginning of the period		**251.1**	**244.2**	**132.2**	**504.1**	**504.1**
Exchange-rate differences in cash and cash equivalents		0.7	12.9	7.2	42.6	40.9
Changes in cash and cash equivalents		-66.9	-121.8	52.0	-381.7	-371.8
Cash and cash equivalents at the end of the period		**184.2**	**122.4**	**184.2**	**122.4**	**132.2**

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.

	2023 Jul-Sep	2022 Jul-Sep	2023 Jan-Sep	2022 Jan-Sep	2022 Jan-Dec
EBIT margin, %	-18.4	-31.0	-21.3	-24.1	-29.5
Return on shareholder equity, %	-30.1	-8.7	-76.7	-26.5	-65.4
Net debt, SEK m	263.6	50.3	263.6	50.3	143.1
Debt/equity ratio, %	486.8	165.6	486.8	165.6	255.2
Equity/assets ratio, %	10.6	24.8	10.6	24.8	17.5
Number of shares, before dilution	34,420,649	34,367,616	34,392,914	34,347,762	34,351,732
Number of shares, after dilution	34,420,649	34,367,616	34,392,914	34,347,762	34,351,732
Earnings per share, before dilution, SEK	-0.97	-0.77	-3.19	-2.50	-5.17
Earnings per share, after dilution, SEK	-0.97	-0.77	-3.19	-2.50	-5.17
Number of employees at the end of the period	118	126	118	126	126
Shareholders' equity, SEK m	92.0	298.4	92.0	298.4	193.9
Capital employed, SEK m	539.8	792.5	539.8	792.5	688.7
Working capital, SEK m	24.2	330.0	24.2	330.0	217.2

[2] Definitions and reconcilliations of key figures are presented on page 28 of this report

CONDENSED PARENT COMPANY STATEMENT OF OPERATIONS

SEK m	Notes	2023 Jul-Sep	2022 Jul-Sep	2023 Jan-Sep	2022 Jan-Sep	2022 Jan-Dec
Net revenues		122.0	64.2	379.9	220.0	348.2
Cost of goods sold		-22.4	-12.2	-73.7	-46.6	-72.4
Gross profit		**99.6**	**52.1**	**306.2**	**173.4**	**275.8**
Selling expenses		-33.2	-44.8	-95.4	-123.6	-165.1
Administrative expenses		-16.1	-32.2	-76.7	-82.6	-123.1
Research and development costs		-68.7	-63.7	-192.9	-193.4	-266.9
Other operating income and expenses		8.1	17.1	22.3	63.8	65.4
Operating earnings (EBIT)		**-10.3**	**-71.6**	**-36.4**	**-162.4**	**-213.9**
Interest income and expenses		-8.7	-4.9	-23.4	-14.1	-19.6
Other financial income and expenses		1.2	33.5	4.1	55.3	36.7
Net financial items		**-7.5**	**28.7**	**-19.3**	**41.2**	**17.1**
Earnings before tax		**-17.8**	**-42.9**	**-55.7**	**-121.2**	**-196.8**
Tax	5	—	—	—	—	—
Earnings for the period		**-17.8**	**-42.9**	**-55.7**	**-121.2**	**-196.8**

PARENT COMPANY STATEMENT OF COMPREHENSIVE INCOME

SEK m	2023 Jul-Sep	2022 Jul-Sep	2023 Jan-Sep	2022 Jan-Sep	2022 Jan-Dec
Earnings for the period	**-17.8**	**-42.9**	**-55.7**	**-121.2**	**-196.8**
Other comprehensive income	**—**	**—**	**—**	**—**	**—**
Total comprehensive earnings for the period	**-17.8**	**-42.9**	**-55.7**	**-121.2**	**-196.8**

CONDENSED PARENT COMPANY BALANCE SHEET

SEK m	2023 Sep 30	2022 Sep 30	2022 Dec 31
ASSETS			
Fixed assets			
Intangible fixed assets	155.9	189.8	181.4
Tangible fixed assets	85.4	68.4	76.1
Shares in subsidiaries	162.4	160.9	161.2
Total fixed assets	**403.6**	**419.0**	**418.7**
Current assets			
Inventories	33.9	65.3	60.2
Accounts receivable and other receivables	161.8	129.1	159.0
Short-term investments	0.0	255.5	178.6
Cash and cash equivalents	140.7	78.7	61.7
Total current assets	**336.4**	**528.5**	**459.5**
Total assets	**740.1**	**947.5**	**878.2**
SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES			
Total shareholders' equity	**53.4**	**184.8**	**109.2**
Long-term liabilities			
Provisions	9.3	8.6	9.8
Bond loan	447.8	494.2	494.8
Total long-term liabilities	**457.1**	**502.8**	**504.5**
Current liabilities			
Accounts payable	15.3	32.3	32.0
Other liabilities	12.3	9.4	8.8
Liabilities to Group companies	176.1	182.3	184.3
Accrued expenses and deferred income	25.8	36.0	39.3
Total current liabilities	**229.5**	**260.0**	**264.5**
Total liabilities	**686.6**	**762.7**	**769.0**
Total shareholders' equity and liabilities	**740.1**	**947.5**	**878.2**

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 2022 Annual Report. None of the amended standards and interpretations that became effective January 1, 2023 have had significant impact on the Group's financial reporting.

The Parent Company's financial statements were prepared in accordance with RFR 2 (Swedish Financial Reporting Board's recommendation) and Chapter 9 of the Swedish Annual Accounts Act.

2. Segment Reporting

Operations are monitored and presented in the segments US Pharma, Digital Therapeutics and HQ & Pipeline. US Pharma segment comprises the distribution and sale of ZUBSOLV® for treatment of opioid use disorder in the US.

Digital Therapeutics segment comprises the d-istribution and sale of digital therapies in the US. This is a complement to existing treatments and provide patients with access to highly sophisticated and individualized support when they need it most.

HQ & Pipeline consists of the Group head quarter functions, R&D, Business Development, Global Regulatory and Supply Chain. Net revenues comprises all partner revenues for ZUBSOLV – ex US, Abstral® and Edluar®.

No operating segments have been aggregated to form the above reportable operating segments. The President and CEO is the chief operating decision maker and monitors the operating results of the group's segments separately for the purpose of making decisions about resource allocation and performance assessment. Segment performance is evaluated based on EBIT and is measured consistently with EBIT in the consolidated financial statements.

DISTRIBUTION OF REVENUE AND EBIT PER SEGMENT

SEK m	2023 Jul-Sep	2022 Jul-Sep	2023 Jan-Sep	2022 Jan-Sep	2022 Jan-Dec
US Pharma					
Net revenues	140.4	150.1	426.3	428.8	571.4
Operating earnings (EBIT)	62.3	70.2	207.7	231.4	308.4
Depreciation and amortization	-4.1	-6.4	-11.8	-11.5	-15.4
Digital Therapeutics					
Net revenues	0.0	0.0	0.1	0.3	0.4
Operating earnings (EBIT)	-31.6	-48.9	-101.8	-140.1	-189.1
Depreciation and amortization	-7.3	-6.7	-21.1	-19.0	-25.7
HQ & Pipeline					
Net revenues	15.7	10.8	46.4	39.1	52.6
Operating earnings (EBIT)	-59.3	-71.2	-206.9	-204.0	-303.2
Depreciation and amortization	-7.8	-4.4	-23.2	-20.2	-27.7
Group					
Net revenues	156.1	161.0	472.8	468.3	624.3
Operating earnings (EBIT)	-28.6	-49.8	-100.9	-112.8	-183.9
Depreciation and amortization	-19.2	-17.5	-56.1	-50.7	-68.7
Net financial items	-7.9	27.4	-19.9	37.8	13.5
Earnings before tax	-36.6	-22.4	-120.8	-74.9	-170.4

3. Cash flow

ADJUSTMENT FOR NON-CASH ITEMS

SEK m	2023 Jul-Sep	2022 Jul-Sep	2023 Jan-Sep	2022 Jan-Sep	2022 Jan-Dec
Depreciation/amortization and impairment	19.2	17.5	56.1	50.7	68.7
Realization results	0.0	—	0.0	—	-0.2
Change in provisions	-6.6	-12.9	4.1	-37.9	-64.9
Share based payments	0.0	-0.1	0.0	-0.1	-0.1
Other non cash items	0.0	—	3.1	—	—
Exchange rate income and expenses	-0.7	-3.5	-6.5	-11.8	-7.0

4. Litigations

US government agency investigation related to ZUBSOLV® sales

On July 14, 2020, Orexo's US subsidiary received subpoenas for the purpose of enabling US authorities to obtain certain information in relation to sales and marketing of ZUBSOLV and other buprenorphine products. All information requested by the authorities have been delivered. Orexo will continue to cooperate with the US authorities to ensure they receive the necessary information and to understand the scope of the investigations.

Paragraph IV litigations against Sun Pharmaceutical Industries Ltd

On August 10, 2020, the company announced it has received a "Paragraph IV" patent certification notice from Sun Pharmaceutical Industries Limited ("Sun"). The Notice Letter advises Orexo of Sun's filing of an Abbreviated New Drug Application with the US Food and Drug Administration seeking approval of generic versions of ZUBSOLV before the expiration of Orexo's patents.

As a response to above notice Orexo on September 13, 2020, filed a patent infringement action in the US District Court for the District of New Jersey, against Sun.

The trial was conducted in January 2023 and was followed by closing arguments at the end of the same quarter. On June 30 (US Time Zone) the District Court for the District of New Jersey ruled in favor of Orexo against Sun. The district court found that Orexo´s patents are valid and infringed by Sun.

In July 2023, Sun appealed the District Court decision to the US Court of Appeals for the Federal Circuit. A briefing schedule has been set by the Federal Circuit and an oral hearing is expected to take place during 2024.

Orexo has in total ten patents listed in the Orange Book (US Patent Nos. 8,470,361; 8,658,198; 8,940,330; 9,259,421; 9,439,900; 10,874,661;10,946,010; 11,020,387; 11,020,388 and 11,433,066) with expiration dates ranging from December 2027 to September 2032.

5. Deferred tax

The tax effect of the Group's temporary differences are related to non-deductible current provisions for sales rebates, sales allowances, distribution, sales returns and other relevant deductions in the company's US operations.

The tax-loss carry-forward in the Group amounts to SEK 1,540 m as of December 31, 2022 and refers to the 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 noninterest bearing liabilities, current interest-bearing liabilities and long-term interest-bearing liabilities. The financial instruments held by the group are recognized at amortized cost using the effective interest method. The group does not hold any financial instruments which are reported at fair value. The fair value of financial instruments held at the balance sheet date is significantly the same as the book value.

7. Related parties

There were no significant related parties transactions during the period.

8. Important events after the period

- The MODIA® didn't meet the primary end-points, but showed high rates of treatment response in both study arms, with no adverse events associated with the use of MODIA.
- Robin Evers elected as board member at the Extraordinary General Meeting. He replaces Henrik Kjaer Hansen who has announced he will resign. Kjaer Hansen, has instead been appointed chairman of the Nomination Committee, representing Novo Holdings A/S.

9. Revenue from contracts with customers

SEK m	2023 Jul-Sep					
Segment	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**vorvida®**	**deprexis®**	**Total**
US Pharma	140.4	–	–	–	–	**140.4**
Digital Therapeutics	–	–	–	0.0	0.0	**0.0**
HQ & Pipeline	4.5	7.7	3.5	–	–	**15.7**
Total revenue from contracts with customers	**144.9**	**7.7**	**3.5**	**0.0**	**0.0**	**156.1**
Geographical markets	**ZUBSOLV**	**Abstral**	**Edluar**	**vorvida**	**deprexis**	**Total**
US	140.4	–	0.4	0.0	0.0	**140.8**
EU & UK	4.5	7.5	2.3	–	–	**14.3**
Rest of the world	–	0.2	0.8	–	–	**1.0**
Total revenue from contracts with customers	**144.9**	**7.7**	**3.5**	**0.0**	**0.0**	**156.1**

SEK m	2023 Jan-Sep					
Segment	**ZUBSOLV**	**Abstral**	**Edluar**	**vorvida**	**deprexis**	**Total**
US Pharma	426.3	–	–	–	–	426.3
Digital Therapeutics	–	–	–	0.0	0.0	0.1
HQ & Pipeline	15.6	21.9	8.8	–	–	46.4
Total revenue from contracts with customers	**442.0**	**21.9**	**8.8**	**0.0**	**0.0**	**472.8**
Geographical markets	**ZUBSOLV**	**Abstral**	**Edluar**	**vorvida**	**deprexis**	**Total**
US	426.3	–	1.6	0.0	0.0	428.0
EU & UK	15.6	21.3	4.9	–	–	41.9
Rest of the world	–	0.6	2.3	–	–	2.9
Total revenue from contracts with customers	**442.0**	**21.9**	**8.8**	**0.0**	**0.0**	**472.8**

SEK m	2022 Jul-Sep					
Segment	**ZUBSOLV**	**Abstral**	**Edluar**	**vorvida**	**deprexis**	**Total**
US Pharma	150.1	–	–	–	–	150.1
Digital Therapeutics	–	–	–	0.0	0.0	0.0
HQ & Pipeline	0.4	7.5	2.9	–	–	10.8
Total revenue from contracts with customers	**150.5**	**7.5**	**2.9**	**0.0**	**0.0**	**161.0**
Geographical markets	**ZUBSOLV**	**Abstral**	**Edluar**	**vorvida**	**deprexis**	**Total**
US	150.1	–	0.7	0.0	0.0	150.8
EU	0.4	7.2	1.4	–	–	9.1
Rest of the world	–	0.3	0.8	–	–	1.1
Total revenue from contracts with customers	**150.5**	**7.5**	**2.9**	**0.0**	**0.0**	**161.0**

SEK m	2022 Jan-Sep					
Segment	**ZUBSOLV**	**Abstral**	**Edluar**	**vorvida**	**deprexis**	**Total**
US Pharma	428.8	–	–	–	–	**428.8**
Digital Therapeutics	–	–	–	0.3	0.0	**0.3**
HQ & Pipeline	6.5	24.9	7.7	–	–	**39.1**
Total revenue from contracts with customers	**435.3**	**24.9**	**7.7**	**0.3**	**0.0**	**468.3**
Geographical markets	**ZUBSOLV**	**Abstral**	**Edluar**	**vorvida**	**deprexis**	**Total**
US	428.8	0.0	1.7	0.3	0.0	**430.8**
EU & UK	6.5	24.0	3.4	–	–	**34.0**
Rest of the world	–	0.9	2.6	–	–	**3.5**
Total revenue from contracts with customers	**435.3**	**24.9**	**7.7**	**0.3**	**0.0**	**468.3**

SEK m	2022 Jan-Dec					
Segment	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**vorvida®**	**deprexis®**	**Total**
US Pharma	571.4	—	—	—	—	**571.4**
Digital Therapeutics	—	—	—	0.3	0.1	**0.4**
HQ & Pipeline	11.8	30.4	10.4	—	—	**52.6**
Total revenue from contracts with customers	**583.2**	**30.4**	**10.4**	**0.3**	**0.1**	**624.3**
Geographical markets	**ZUBSOLV**	**Abstral**	**Edluar**	**vorvida**	**deprexis**	**Total**
US	571.4	—	2.5	0.3	0.1	**574.2**
EU	11.8	29.3	4.5	—	—	**45.6**
Rest of the world	—	1.2	3.4	—	—	**4.5**
Total revenue from contracts with customers	**583.2**	**30.4**	**10.4**	**0.3**	**0.1**	**624.3**

Geographical distribution of royalties and milestones is based on the counterparts registered office

Definitions and reconciliations of key figures

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

Margins	Definition/calculation	Purpose
Gross margin	Gross profit divided by net revenues	Gross Margin is used to measure the relative direct profitabilityfrom sold products
Operating margin (EBITmargin)	Operating earnings as a percentage of net revenues	Operating profit margin is used for measuring the operational profitability
Return	**Definition/calculation**	**Purpose**
Return on equity	Net earnings for the period as a percentage of average shareholders' equity	Return on equity is used to measure profit generation, given the resources attributable to the owners of the Parent Company
Capital structure	**Definition/calculation**	**Purpose**
Cash and invested funds	Short-term investments plus cash and cash equivalents	Cash and invested funds is used to measure how much cash company has available in short-term from bank balances and invested funds
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	2023 Jul-Sep	2022 Jul-Sep	2023 Jan-Sep	2022 Jan-Sep	2022 Jan-Dec
EBIT	-28.6	-49.8	-100.9	-112.8	-183.9
Depreciation and amortization	19.2	17.5	56.1	50.7	68.7
EBITDA	**-9.5**	**-32.4**	**-44.8**	**-62.1**	**-115.2**
External costs for clinical studies	18.0	23.0	55.8	68.0	96.4
IP litigation and subpoena	4.9	23.7	53.7	52.0	76.6
EBITDA excluding external costs for clinical studies. IP litigation and subpoena	**13.3**	**14.3**	**64.7**	**57.9**	**57.8**

OPERATING EXPENSES SEK m	2023 Jul-Sep	2022 Jul-Sep	2023 Jan-Sep	2022 Jan-Sep	2022 Jan-Dec
Selling expenses	-44.7	-54.7	-138.7	-146.8	-199.0
Administrative expenses	-45.4	-54.2	-150.1	-138.5	-202.3
Research and development costs	-83.7	-76.5	-237.7	-229.8	-318.0
Other operating income and expenses	11.9	2.5	21.5	10.7	13.7
Operating expenses	**-161.9**	**-182.8**	**-505.0**	**-504.3**	**-705.6**

CASH AND INVESTED FUNDS	2023 Jul-Sep	2022 Jul-Sep	2023 Jan-Sep	2022 Jan-Sep	2022 Jan-Dec
Short-term investments	—	321.5	—	321.5	219.6
Cash and cash equivalents	184.2	122.4	184.2	122.4	132.2
Cash and invested funds	**184.2**	**443.9**	**184.2**	**443.9**	**351.9**

GROSS INVESTMENTS SEK m	2023 Jul-Sep	2022 Jul-Sep	2023 Jan-Sep	2022 Jan-Sep	2022 Jan-Dec
Investments in tangible fixed assets	6.7	0.3	17.6	7.8	18.8
Investments in intangible fixed assets	—	1.2	0.7	3.8	5.1
Gross investments	**6.7**	**1.6**	**18.3**	**11.7**	**23.9**

RETURN ON SHAREHOLDERS' EQUITY	2023 Jul-Sep	2022 Jul-Sep	2023 Jan-Sep	2022 Jan-Sep	2022 Jan-Dec
Shareholders' equity beginning balance	123.8	308.9	193.9	349.6	349.6
Shareholders' equity ending balance	92.0	298.4	92.0	298.4	193.9
Average shareholders' equity	107.9	303.6	142.9	324.0	271.8
Net earnings	-33.3	-26.5	-109.7	-85.8	-177.6
Return on shareholders' equity %	**-30.9**	**-8.7**	**-76.7**	**-26.5**	**-65.4**

Orexo is a Swedish pharmaceutical company with over 25 years of experience developing improved pharmaceuticals based on proprietary formulation technologies that meet large medical needs. On the US market, Orexo provides innovative treatment solutions for patients suffering from opioid use disorder and adjacent diseases. Products targeting other therapeutic areas are developed and commercialized worldwide with leading partners. Total net sales in 2022 amounted to SEK 624 million, and the number of employees to 126. Orexo is listed on Nasdaq Stockholm's main list and is available as an ADR on OTCQX (ORXOY) in the US.

For more information about Orexo please visit, www.orexo.com.
You can also follow Orexo on Linkedin, Twitter and YouTube and also read our blog.



blog.orexo.com

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