orexo

Q2 2023 Interim Report

18 July 2023

The patent win critical enabler for future growth

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

Q2 2023 highlights

- Total net revenues of SEK 157.7 m (147.8)
- EBITDA of SEK 5.6 m (-32.5), EBITDA excluding legal costs and costs for non-repeating clinical trials, SEK 30.3 m (11.4)
- Net earnings of SEK -12.6 m (-35.8)
- US Pharma segment (ZUBSOLV® US) net revenues of SEK 145.4 m (139.6), in local currency USD 13.8 m (14.2), US Pharma EBIT of SEK 71.2 m (77.2)
- Cash flow from operating activities of SEK -12.7 m (14.5), cash and invested funds of SEK 251.1 m (467.7)
- Earnings per share before and after dilution amounted to -0.37 (-1.04)
- Due to issues in the outsourced packaging line FDA has requested Orexo to resubmit the NDA, which is planned to take place in Q3, 2023
- US District Court for the District of New Jersey ruled in favor of Orexo in the patent litigation against Sun Pharmaceutical
- Updated financial outlook, view page 15

Important events after the end of the period

- ZUBSOLV® reimbursed by Medicaid in Indiana state as of July 1, 2023

SEK m unless otherwise stated	2023 Apr-Jun	2022 Apr-Jun	2023 Jan-Jun	2022 Jan-Jun	% change quarter	2022 Jan-Dec
Net revenues	157.7	147.8	316.8	307.3	6.6%	624.3
Cost of goods sold	-17.2	-21.2	-46.0	-48.7	-19.1%	-102.6
Operating expenses	-153.4	-176.4	-343.0	-321.5	-13.0%	-705.6
EBIT	-12.9	-49.7	-72.3	-62.9	-74.0%	-183.9
EBIT margin	-8.2%	-33.6%	-22.8%	-20.5%	-25.4%	-29.5%
EBITDA	5.6	-32.5	-35.4	-29.7	-117.2%	-115.2
Earnings per share. before dilution. SEK	-0.37	-1.04	-2.22	-1.73	-64.4%	-5.17
Earnings per share. after dilution. SEK	-0.37	-1.04	-2.22	-1.73	-64.4%	-5.17
Cash flow from operating activities	-12.7	14.5	-70.5	-47.1	-187.1%	-156.6
Cash and invested funds	251.1	467.7	251.1	467.7	-46.3%	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
158 SEK M

Group EBITDA
6 SEK M

Cash and cash equivalents
251 SEK M

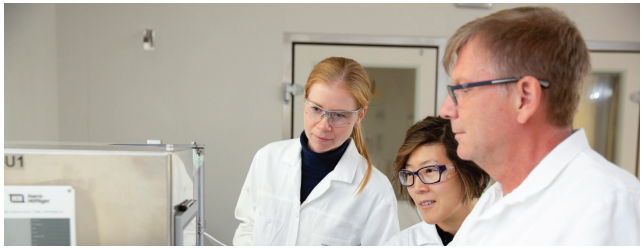
Content

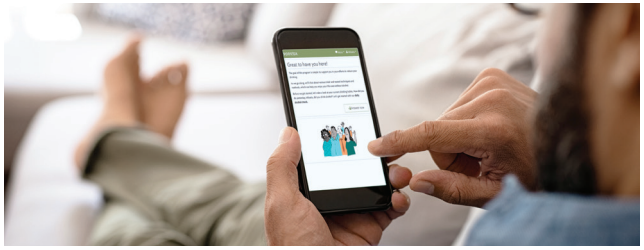
About Orexo

A commercial stage pharmaceutical company with three revenue generating pharmaceutical products

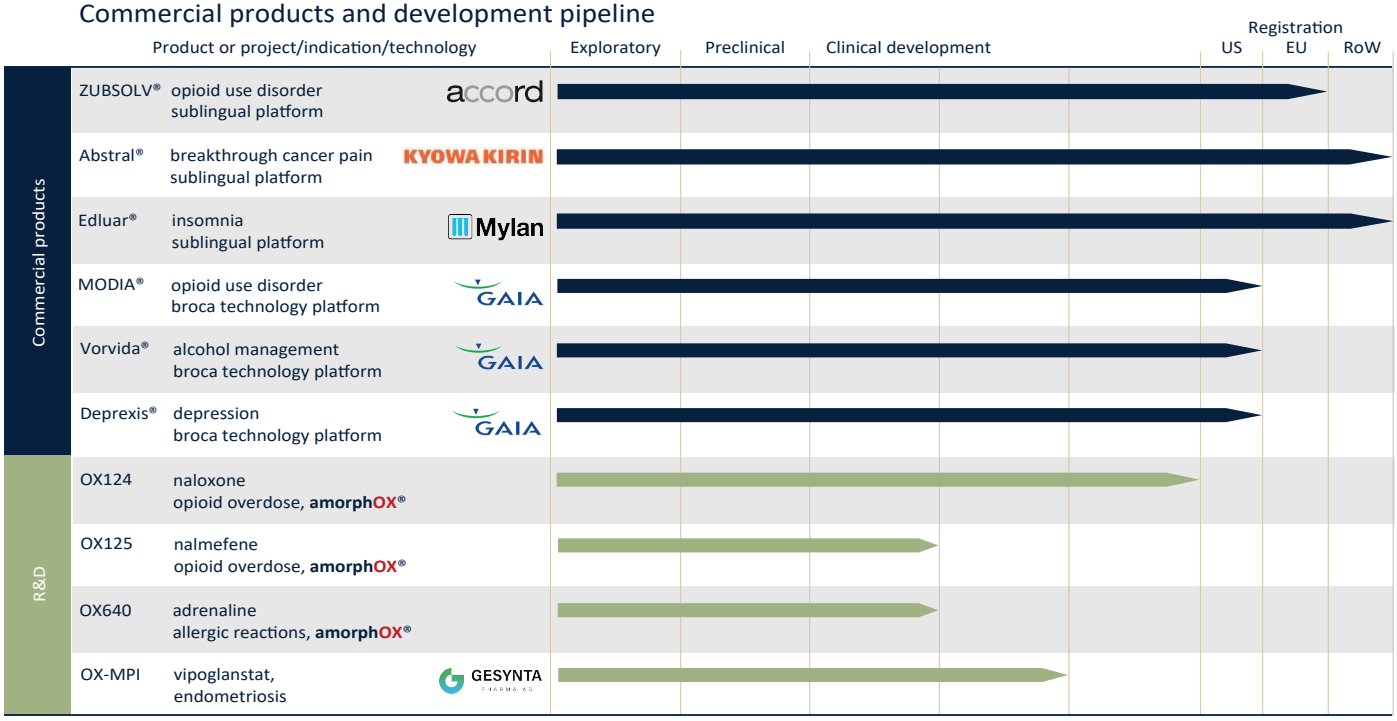
Profitable US commercial operations with a focus on one of the largest health crises in the US – opioid dependence

AmorphOX® - a novel world leading nasal delivery technology leading to a new wave of products





Commercial products and development pipeline



Contact persons quarterly report

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Presentation

At 3 pm CET the same day as the announcement of the report, Orexo invites analysts, investors and media to attend a presentation where Nikolaj Sørensen, CEO and Fredrik Järrsten, CFO, will present the report and host a Q&A.

To attend via teleconference where you can ask questions verbally:
https://conference.financialhearings.com/teleconference/?id=5007950

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-q2-2023

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

Financial calendar 2023

Interim Report Q3 2023 - Nov. 2, 8 am
Interim Report Q4 2023, incl. Full Year Report, Jan. 25, 8 am

Good progress towards profitability

CEO Comments in brief

During the last three years the uncertainty from the patent litigation against Sun Pharmaceutical to protect the innovation and exclusivity of ZUBSOLV®, has had significant negative impact on all areas of the Orexo business. To prevail in the patent litigation is similar to a new beginning for the company, foremost as it removes a lot of uncertainty around our main product. However, our ability to grow is equally dependent on our financial strength and our ability to innovate. I am pleased to report a considerable improvement in our financial result from Q1 2023 with a positive EBITDA of SEK 5.6 million in Q2 (SEK -32,5 million Q2, 2022, and SEK -41.1 million Q1, 2023).

The improvement is a result of strengthened revenues explained by slightly increased ZUBSOLV® sales in USD and some tailwind from exchange rate effects in combination with significantly reduced expenses primarily related to the patent litigation process. I am pleased to see this financial development to be in line with our communication during the first half of 2023 and it shows how Orexo, when excluding sizeable non-recurring expenses, is approaching profitability. In addition we also see potential for income from business development in the second half of the year where we continue to see strong interest and progress from potential partners in our pipeline and technology.

Multiple iniatiatives will spark access to OUD treatment

The year started with a dramatic change and improvement in the conditions for providing treatment for opioid use disorder (OUD) with new legislation enabling more physicians to treat OUD with buprenorphine/naloxone products such as ZUBSOLV®. This change has resulted in an expansion of the number of healthcare providers prescribing buprenorphine/naloxone, but so far with limited impact in the overall prescription pattern and market growth remains in the mid-single digit, which is in line with our guidance for 2023.

ZUBSOLV® demand showed a minor growth comparing to previous quarter. I am also pleased to report net revenues of SEK 145.4 million, an increase of 3.6 percent from Q1 2023 and the corresponding growth number versus last year was 4.2 percent. The positive development is foremost driven by a stronger USD. Stable ZUBSOLV® sales is important for the financial stability of the company and with a strong EBIT contribution of SEK 71.2 million in the quarter, ZUBSOLV® enables investments in new products and creates a solid foundation for growth. ZUBSOLV® competes in a market dominated by generic versions of our main competitor and ZUBSOLV's stability and continued ability to grow depends primarily on our market access. During the quarter, our market access team in the US managed to further strengthen our access in the fast growing public segment with an agreement where ZUBSOLV® will be reimbursed for all patients within Medicaid in Indiana. The new position are improving our access in the public segment from 47 to 50 percent of the market volume starting July 1, 2023.

During the first half of 2023 we have worked to make an integrated approach to OUD combining all our tools and knowledge under an umbrella concept branded MATCore®. Under this umbrella, we are testing the concept in Arizona and have made several additional grant applications to test and develop the concept on a broader scale in other states.

The concept is designed to meet the demand of many states to test new approaches to OUD treatment and to enable Orexo to receive financing of these new concepts through the billions of US-dollars allocated to the states from the US opioid litigation settlements. MODIA®, the digital therapy for OUD, is a cornerstone in the concept and we are looking forward to finalize the analysis of the clinical study in cooperation with our partner GAIA.

For OX640 the main focus is on upscaling the manufacturing process to commercial scale and the first tests have been successfully completed

Due to lack of success in the commercialization of the digital therapies, we have made a complete overhaul of the reimbursement and distribution processes and associated IT systems, to simplify the process and to reduce expenses. As reported in Q1, this has delayed the commercialization of MODIA® and the other two digital therapies, deprexis® for depression and vorvida® for alcohol misuse. There is no doubt the reimbursement and distribution processes in the US for any digital health product is a major hurdle for the entire industry and several players have closed down during the first half of this year. Orexo continues to evaluate the business opportunities, but with a ten year contract with the Veterans Affairs for deprexis®, positive feedback from many physicians and patients using MODIA® and the opportunity to combine our digital therapies with ZUBSOLV®, we continue to see value potential in digital therapies. However, to reflect the increased uncertainty we have reduced the direct costs and expect continued reductions in the second half of 2023 in administrative expenses, when the new streamlined reimbursement systems and processes are implemented.

OX124 on track to be resubmitted with the FDA in Q3

The unexpected issue in our packaging of OX124, our high-dose rescue medication for opioid overdoses, seems to be resolved. The issue was of a purely technical character and was associated with one step of the fully automated and integrated packaging process, where a plastic foil in some test runs was misplaced. With the high quality requirement of any rescue medication in the US, the entire packaging line has to be retested at full scale before resubmission is possible. The tests are being finalized during July and if successful it will enable a resubmission with the FDA in Q3 as expected.

Our development using amorphOX® with other APIs is progressing well. For OX640, our epinephrine product intended for the emergency treatment of allergic reactions including anaphylaxis, the main focus is on upscaling the manufacturing process to commercial scale and the first tests have been successfully completed. We are also pleased to see a nasal liquid spray receiving strong support from the FDA advisory board. This provides important input to the development program and reduce the overall regulatory risk. The outcome of the advisory board increased the interest from potential partners in the project and their due diligence is in the final stages. Finally, the testing of amorphOX® with biomolecules is generating strong results, where highly instable and sensitive biomolecules retain full activity following formulation with amorphOX®.

Reduced risk after winning the patent litigation

The highlight of the quarter was the decision by the District Court of New Jersey on June 30 (US time zone) and the significant reduction of the risk in the company with reconfirmed validity of our ten patents for ZUBSOLV® and more than 9 years left before patent expiry in September 2032. This is the second win and confirmation of the ZUBSOLV® patents and even with the risk that the decision will be appealed, we find our position is considerably strengthened. The decision from the District Court was completely in Orexo's favor on both infringement and validity. Of similar importance is the opinion by the Judge, which we find is very comprehensive, and the decision is well motivated by facts and references to the evidence provided to the court by experts and test results. This collectively strengthens Orexos position substantially in a potential appeal process and should further discourage future potential generic entrants prior to patent expiry. Defending our intellectual properties is critical to the company, but it has been associated with substantial expenses since the start of the process in August 2020, these expenses declined significantly during Q2 and even in the event the decision is appealed, the expenses will be substantially lower going forward.

On the basis of this optimism we reiterate our financial guidance for H2 and expect an EBITDA in balance, while OPEX in H2 will decline comparing to H1

Summary and outlook

With the significant risk of the patent litigation being removed, we are now looking forward to fully focus on growing our business. I remain very optimistic that we can continue to deliver stable sales and strong profit contribution from ZUBSOLV®, finalize the business development negotiations for OX640, establish new partnerships for amorphOX®, resubmit OX124 in Q3 and we will present the results of the MODIA® study during the summer. On the basis of this optimism we reiterate our financial guidance for H2 and expect an EBITDA in balance, while OPEX in H2 will decline comparing to H1 (SEK 343 million including depreciation of SEK 37 million). I want to thank our shareholders, employees and partners for their patience since we initiated the litigation process three years ago, and I look forward to share our continued progress in the second half of 2023.

Uppsala, Sweden, July 18, 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 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.

MODIA® digital therapy

MODIA® is a 6-month therapy based on cognitive behavioral therapy techniques and should be used as part of a supervised medication-assisted treatment program for OUD. The therapy helps users develop a customized relapse prevention plan based on the responses collected from the exercises throughout the program.

Unmet need and market development

Misuse of opioids is a global problem but is most prevalent 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 Medication Assisted Treatment (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, such as fentanyl. Fatal opioid overdoses have reached record-high levels and according to latest available data the number exceeded 83,000 annually.[4] Nine out of ten opioid overdoses involve synthetic opioids, such as fentanyl.[5]

In Q2, the buprenorphine/naloxone market grew 2 percent versus Q1 2023 and grew 5 percent versus Q2 2022. Expectations are that the buprenorphine/naloxone market growth will be positively impacted by the new law 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 opioid use disorder. 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 grew 1 percent vs Q1 2023 and declined 4 percent vs Q2 2022. ZUBSOLV's year over year decline is slowing. ZUBSOLV® achieved quarter over quarter growth in each of the three segments: the open segment where ZUBSOLV® is reimbursed, the non-reimbursed segment, and the formerly exclusive payers UHC and Humana. ZUBSOLV® continues to see strong growth in the states where it most recently received access, with New York Medicaid growing 64 percent and Kentucky Medicaid growing 46 percent over prior year. ZUBSOLV's best in class market access in the Commercial payer segment is maintained at 98 percent. As of July 1, ZUBSOLV® gained 100 percent access in Indiana Medicaid, increasing ZUBSOLV's Public payer segment from 47 percent to 50 percent. Indiana is the 5th largest Medicaid state, securing ZUBSOLV® access in 4 of the 5 largest Medicaid states.

The pivotal MODIA® study, including 437 participants at 35 sites across the US was finalized and the data is being analyzed in cooperation with GAIA, to leverage the opportunity to combine the data collected from the clinical trial sites with utilization data from MODIA®. As previously guided a result is expected to be announced during the summer. The study evaluates whether the use of MODIA® in combination with sublingual buprenorphine/naloxone treatment is better than sublingual buprenorphine/naloxone alone in reducing illicit opioid misuse.

During the quarter the modiaONE™ program has been stopped and field force involvement has been reduced to a few targeted clinics. A broader implementation of MODIA® requires a solid reimbursement and distribution process, and as outlined below the existing system and processes have been reviewed and a new more cost and time efficient system is being implemented.

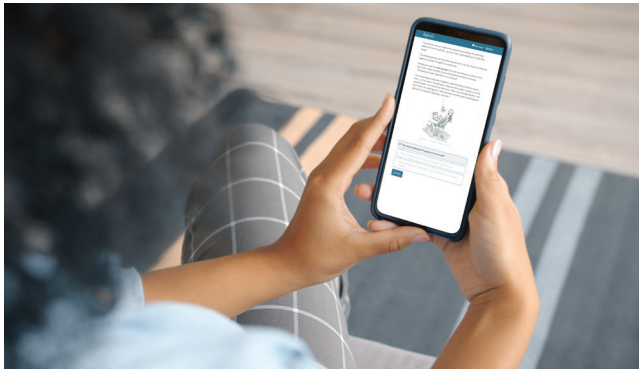
Orexo continues to develop MATCore™ and implement the program together with Alay Psychiatry in Arizona. MATCore™ is a digital platform that are collecting Orexo´s offering within OUD along with education and support. During the quarter additional grant applications have been submitted to expand the offering to new states.

The income from grants is recorded under Other Income in the P&L. Revenues and costs for ZUBSOLV® in the US are recorded in the US Pharma segment, while revenues and costs for MODIA® and MATCore™ can be find in the Digital Therapeutics segment.

ZUBSOLV® – sublingual tablet for the treatment of opioid use disorder in the EU

ZUBSOLV® is available in nine European countries, commercialized by our European partner Accord Healthcare. 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 opioid dependence are receiving some form of substitution treatment across Europe, although this varies greatly between countries.[7]

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 segment, HQ & Pipeline.



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 randomized clinical trial, including approximately 600 patients.[8]

Deprexis® – evidence 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 12 randomized clinical trials (RCTs) including more than 2,800 patients. Deprexis® can be used as a standalone treatment or alongside traditional pharmaceuticals.[9]

Developments during the quarter

In the review of the reimbursement and distribution process initiated during the last quarter and reviewing the failure of other companies in digital therapies to establish an efficient process at scale, the US commercial team has paused all new commercial activities to establish a new and more cost-efficient process, including relevant system support. The effect of the cost efficiencies will start in Q3 and the move to new systems and vendors during Q2 has caused a slight increase in administrative expenses.

The overall cost, excluding depreciation and allocated costs, in DTx has decreased with 40 percent since last year. Most OPEX from DTx are allocated costs and depreciation.

The 10-year contract with Veterans Affairs (VA) is prioritized and Orexo has in collaboration with a large region in the VA identified a process for ordering and invoicing, which is planned to get finalized during the summer. The VA ordering process will work nationally for all VA regions. Discussions with Trinity Health has restarted during the quarter but has been negatively impacted by the move of their main facilities to new buildings and change of staff involved in the discussions.

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

amorphOX® – a versatile drug delivery platform

Identified need

Amorphous compounds are common in drug development and can be of great importance for the properties of the drug substance. Amorphous solids 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 2042.

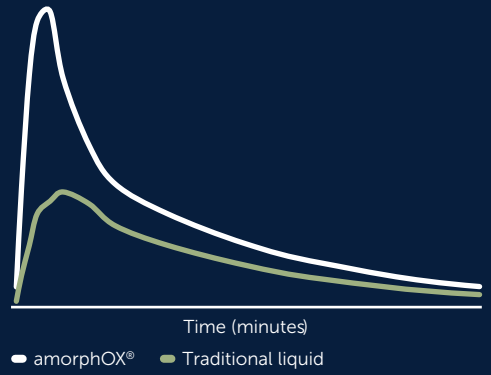
Clinically validated

The technology has successfully been proven in multiple clinical studies. It is validated in the development of various rescues medications including naloxone (OX124), nalmefene (OX125) and epinephrine (OX640), a treatment for allergic reactions. All use nasal delivery. Data has demonstrated qualities such as rapid dissolution, excellent bioavailability and both chemical and physical stability.

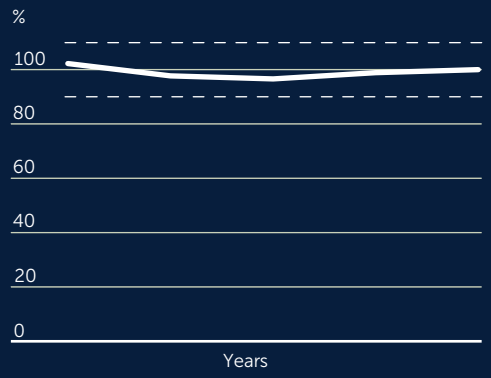
Wide applicability

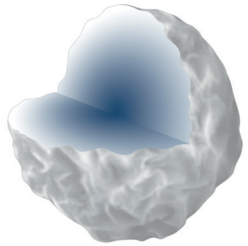
The technology works with a broad spectrum of active chemical substances, including small and large molecules,[10] and the properties of the powder can be tailored to meet specific needs such as particle size, dissolution, and mucosal retention. This makes it a versatile technology with broad applicability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

Plasma concentration



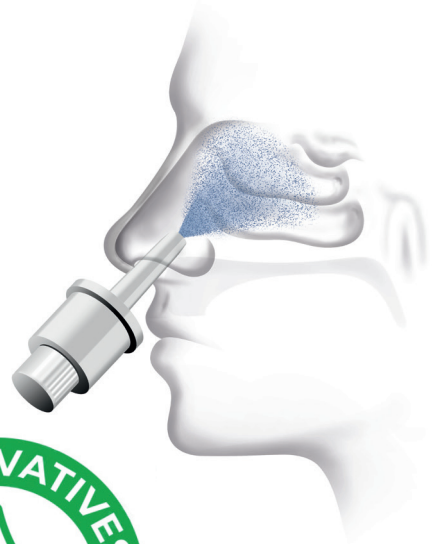
Amount of API





Successful clinical trials

Well tolerated
Higher exposure
Faster Onset
Lower variability



amorphOX®

Products under development

Development projects based on the amorphOX® platform

OX124 – high-dose medication for opioid overdose containing 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. 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 damage and saving lives as well as preventing re-intoxification during the revival process. OX124 has patents protecting the product until 2039.

Developments during the quarter

A New Drug Application (NDA) is planned to be filed in Q3 2023 and with an expected approval in H2 2024. The submission in Q3 follows a need to resubmit the NDA, due to identified technical issues in the equipment used in the secondary packaging in one of the production modules. The team at Orexo has successfully solved the problem along with the contract manufacturer and is conducting the final tests and qualification of the manufacturing process before resubmission in Q3.

The US overdose medication market

Upon approval, Orexo will meet a significant need of a powerful overdose rescue medications, where the overdose is caused by misuse of synthetic opioids, such as illegal fentanyl. During the latest 12-month period, ending January 2023, the predicted annual number of fatal opioid overdoses in the US counted for more than 83,000.[11] Nine out of ten opioid overdoses involve synthetic opioids, such as fentanyl.[12]

The market today is based on prescription products but according to the FDA the market leading product, NARCAN® 4 mg will become a non-prescription drug, available at pharmacies (OTC product). The decision will most likely result in the market converting into two segments, one for non-prescription low-dose products and the other will comprise differentiated high-dose products prescribed by physicians. The low-dose products available at the pharmacies are expected to have limited if any reimbursement, in contrast to the high-dose products, such as OX124, that will have access to reimbursement by the insurance companies. The increased availability of naloxone products is expected to grow the market from today's level of USD 400-500 million.[13] The large need for potent and longer-lasting overdose rescue medications will most likely propel the prescription market, as well as the continued expansion of mandatory co-prescription of naloxone.

OX125 – high-dose medication for opioid overdose containing 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.

Developments during the quarter

Orexo has during a long period closely monitored the development of nalmefene products on the market for opioid overdose medication. In the quarter, the first nasal nalmefene product was approved by the FDA, which will be marketed by a leading player in the OUD treatment space. Orexo continues to assess the most efficient roadmap bringing OX125 to market. 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 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 storage conditions.

OX640 is based on amorphOX® and has shown promising chemical and physical stability data. 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 has one granted patent protecting the product on the European market until 2041. Orexo has multiple patent applications filed in other territories and expect to continuously strengthen the patent portfolio for OX640.

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 display data showcasing great stability of OX640 and its ability to withstand large changes in temperature.

Orexo is in dialog with international pharmaceutical companies for potential partnership for the continued clinical development and for 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 leading pharmaceutical companies, of which two of these companies are working with biological drugs or vaccines. 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.

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 is 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

During the quarter, Orexo has continued to work on the action plan set for the year. In 2022, Orexo conducted a mapping of its climate impact within Scope 1 and 2 in accordance with the GHG Protocol. During the quarter, the mapping of Scope 3 was initiated. Furthermore, work continued with sustainability assessments of suppliers for OX124, including follow-up of selected sustainability questions through on-site audits. As a member of the UN Global Compact, Orexo has worked on answering the extensive battery of questions for "Communication on Progress". However, the UN Global Compact has encountered technical problems with the reporting platform and all companies will have to complete the reporting at the earliest in the fall. In addition, the development of the new Sustainability Reporting Directive (CSRD) is being closely monitored.

Financial development

Revenues

Total revenues amounted to SEK 157.7 m (147.8) for Q2 and to SEK 316.8 m (307.3) for H1. The increase is mainly explained by higher US Pharma revenues, driven by stronger USD exchange rate.

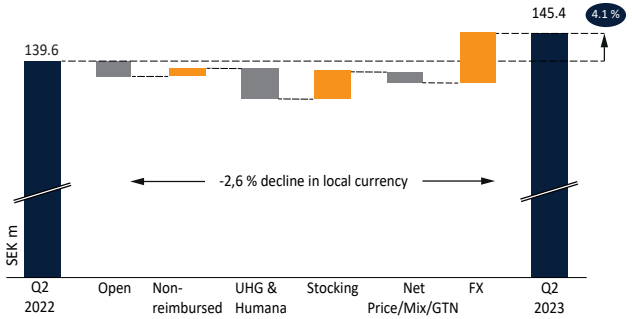
Revenues by segment

US Pharma revenues amounted to SEK 145.4 m (139.6) for Q2. The increase in US Pharma revenues is mainly driven by a positive impact of SEK 9.4 m from stronger USD exchange rate and lower wholesaler destocking. This was partly offset by lower ZUBSOLV® demand mainly as a result of lower market growth, especially in the higher priced commercial segment and due to competition in the previously exclusive plans United Health Group and Humana. US Pharma revenues amounted to SEK 286.0 m (278.7) for H1. In local currency US Pharma net revenues for Q2 amounted to USD 13.8 m (14.2) and for H1 to USD 27.3 m (29.0).

Digital Therapeutics (DTx) recognized net revenues for Q2 amounting to SEK 0.0 m (0.1) and to SEK 0.1 m (0.3) for H1.

HQ & Pipeline partner product related revenues for Q2 amounted to SEK 12.3 m (8.1). The increase is mainly explained by positive adjustments of Abstral® and Edluar® royalties from Q1 2023. HQ & Pipeline partner product related revenues amounted to SEK 30.8 m (28.3) for H1.

ZUBSOLV® US NET REVENUES DEVELOPMENT



Costs of goods sold

Cost of goods sold (COGS) amounted to SEK 17.2 m (21.2) for Q2. US Pharma amounted to SEK 14.8 m (17.7), the decrease is mainly due to favorable production costs. Royalty and technical infrastructure costs for DTx amounted to SEK 2.8 m (2.7). HQ & Pipeline amounted to SEK -0.5 m (0.8) for ZUBSOLV® ex US due to a positive true-up of accrued freight related costs. Cost of goods sold (COGS) amounted to SEK 46.0 m (48.7) for H1.

Operating expenses

Selling expenses amounted to SEK 48.2 m (50,5) for Q2. 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 94.0 m (92.1) for H1.

Administrative expenses amounted to SEK 38.3 m (51.2) for Q2. The decrease is mainly explained by lower legal expenses for IP litigation partly offset by negative impact of stronger USD exchange rate. Administrative expenses amounted to SEK 104.7 m (84.3) for H1.

Research and development costs amounted to SEK 75.6 m (81.3) for Q2. The decrease is mainly explained by lower development costs for OX124 and lower internal costs partly

NET REVENUES AND OPERATING EARNINGS PER SEGMENT

SEK m	Net Revenues					EBIT				
	2023 Apr-Jun	2022 Apr-Jun	2023 Jan-Jun	2022 Jan-Jun	2022 Jan-Dec	2023 Apr-Jun	2022 Apr-Jun	2023 Jan-Jun	2022 Jan-Jun	2022 Jan-Dec
ZUBSOLV® US product sales	145.4	139.6	286.0	278.7	571.4	–	–	–	–	–
US Pharma – total	**145.4**	**139.6**	**286.0**	**278.7**	**571.4**	**71.2**	**77.2**	**145.4**	**161.2**	**308.4**
Digital Therapeutics (DTx) product sales	0.0	0.1	0.1	0.3	0.4	–	–	–	–	–
Digital Therapeutics (DTx) – total	**0.0**	**0.1**	**0.1**	**0.3**	**0.4**	**-33.6**	**-47.9**	**-70.1**	**-91.3**	**-189.1**
Abstral® royalty	8.0	5.0	14.2	17.4	30.4	–	–	–	–	–
Edluar® royalty	4.0	1.6	5.3	4.8	10.4	–	–	–	–	–
ZUBSOLV® – ex US	0.2	1.5	11.2	6.1	11.8	–	–	–	–	–
HQ & Pipeline segment – total	**12.3**	**8.1**	**30.8**	**28.3**	**52.6**	**-50.5**	**-79.1**	**-147.5**	**-132.9**	**-303.2**
Total	**157.7**	**147.8**	**316.8**	**307.3**	**624.3**	**-12.9**	**-49.7**	**-72.3**	**-62.9**	**-183.9**

offset by negative impact of stronger USD exchange rate. Research and development costs amounted to SEK 154.0 m (153.3) for H1.

Other operating income and expenses amounted to SEK 8.6 m (6.7) for Q2. This is mainly explained by a received insurance reimbursement of SEK 4.2 m (0.0) for legal costs in the US partly offset by lower exchange-rate gains of SEK 4.8 m (6.8) derived from revaluations of parent company balance sheet items in foreign currency, predominantly in USD. Other operating income and expenses amounted to SEK 9.7 m (8.2) for H1.

Operating profit

EBITDA amounted to SEK 5.6 m (-32.5) for Q2 and to SEK -35.4 m (-29.7) for H1. Exclusion of costs for legal processes and external non-repeating costs for clinical studies, would result in an EBITDA of SEK 30.3 m (11.4) for Q2 and SEK 51.3 m (43.6) for H1.

The EBIT contribution from US Pharma amounted to SEK 71.2 m (77.2) for Q2, equal to an EBIT margin of 49.0 percent (55.3). EBIT contribution from US Pharma amounted to SEK 145.4 m (161.2) for H1, equal to an EBIT margin of 50.8 percent (57.8).

Total EBIT amounted to SEK -12.9 m (-49.7) for Q2 mainly explained by higher net revenues, lower cost of goods sold and lower operating expenses. Total EBIT amounted to SEK -72.3 m (-62.9) for H1.

Net financial items and tax

Net financial items for Q2 amounted to SEK -2.9 m (12.3) and is mainly explained by lower positive unrealized exchange rate impact of SEK 5.3 m (18.1) derived from the parent company's foreign currency bank accounts mainly in USD. Higher interest rate had a negative impact on costs for corporate bonds of SEK -9.3 m (-5.6). This was partly offset by interest income of SEK 1.5 m (0.4) from short-term cash investments and bank accounts. Net financial items amounted to SEK -12.0 m (10.4) for H1.

Total tax expenses amounted to SEK 3.2 m (1.7) for Q2. The increase is mainly explained by positive adjustment to deferred tax assets related to temporary differences. Total tax expenses amounted to SEK 7.8 m (-6.8) for H1. 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 -12.6 m (-35.8) for Q2 and to SEK -76.5 (-59.4) for H1.

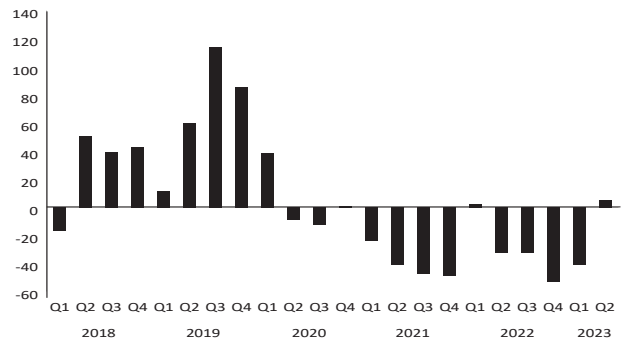
Cash and cash flow

Cash flow from operating activities amounted to SEK -12.7 m (14.5) for Q2 and was primarily impacted by negative changes in working capital. Cash flow from operating activities amounted to SEK -70.5 m (-47.1) for H1. In the quarter Orexo made a buyback of the corporate bond with a nominal value of SEK 8.75 m. All invested surplus cash in certificates of deposits and in US treasuries matured in Q2. As of June 30, 2023, cash and cash equivalents amounted to SEK 251.1 m (244.2) and short-term investments amounted to SEK 0.0 m (223.5). Cash and invested funds in total amounted to SEK 251.1 m (467.7) and interest-bearing liabilities to SEK 481.0 m (493.5), i.e. a negative net cash position including short-term investments of SEK -229.9 m (-25.9). Cash and invested funds were reduced by SEK 27.8 m from Q1.

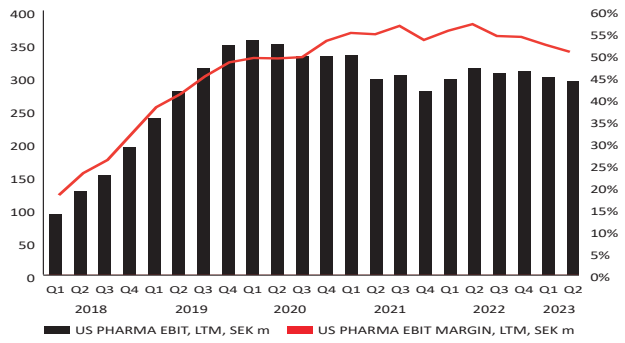
Investments

Gross investments in tangible and intangible fixed assets amounted to SEK 10.8 m (4.5) for Q2 and to SEK 11.6 m (10.1) for H1. Higher investments for Q2 are mainly explained by investments in equipment for the development organisation.

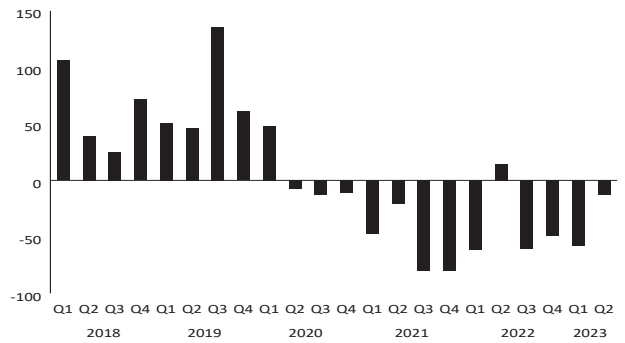
GROUP EBITDA, SEK m



US PHARMA EBIT MARGIN (LTM, SEK m) AND EBIT (LTM SEK m)[14]



CASH FLOW FROM OPERATING ACTIVITIES, SEK m



Equity

Shareholders' equity at June 30, 2023, was SEK 123.8 m (308.9). The equity/asset ratio was 13.4 percent (24.3).

Parent company

Net revenues for Q2 amounted to SEK 122.7 m (103.8) of which SEK 110.5 m (95.6) was related to sales to Group companies. Net revenues amounted to SEK 257.9 m (155.8) for H1 of which SEK 227.1 m (127.5) was related to sales to Group companies.

Earnings before tax amounted to SEK 2.6 m (-26.0) for Q2. The development is mainly explained by higher gross profit and lower operating expenses partly offset by lower net financial items. Earnings before tax SEK -37.9 m (-78.3) for H1.

Investments in equipment for the development organization for Q2 amounted to SEK 10.8 m (3.5) and to SEK 10.8 m (7.5) for H1.

As of June 30, 2023, cash and cash equivalents in the parent company amounted to SEK 180.5 m (177.9) and short-term investments amounted to SEK 0.0 m (183.5) i.e. company's cash and invested funds amounted to SEK 180.5 m (361.4).

Parent company shareholders' equity at June 30, 2023, was SEK 71.3 m (227.7). See further risks and uncertainty factors under financial outlook.

Other information

Financial outlook 2023

- The buprenorphine/naloxone market will grow 4-7 percent, based on current growth trajectory. The new legislation, effective January 1, 2023, will have a positive effect over time, but due to uncertainty related to timeline of the implementation its impact on market growth in 2023 is excluded.
- 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 the war in Ukraine increases the the risk for shortage of material in the supply chain.

Going concern uncertainty factors

The shareholders's equity in the parent company decreased during the first half of 2023. Even though shareholders´ equity increased in Q2, and overall risk reduced it cannot be ruled out that that it will decrease again in the second half of 2023. Reduced shareholders' equity to less than half of the registered share capital requires measures to be taken. This means that there are uncertainty factors that can give rise to doubts regarding the continued operation of the business. However, the group has sufficient funds for continued operations for at least the next twelve months and a potential continued negative development of the shareholders' equity in the parent company will be managed 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 and the CEO continuously assess the parent company's and the group's liquidity and financial resources in both the short and long term.

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. Publication of data from the MODIA® clinical study

5. DTx showing progress

Assurance by the Board of Directors and the CEO

The Board of Directors and the CEO give their assurance that the six-month report provides a fair and accurate view of the Company´s and the Group´s operations, financial positions and earnings and describes the significant risk and uncertainties facing the company and the companies included in the group.

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

Uppsala, Sweden, July 18, 2023
Orexo AB (publ)

James Noble
Chairman of the board

Henrik Kjaer Hansen
Board member

Staffan Lindstrand
Board member

Charlotte Hansson
Board member

Christine Rankin
Board member

Michael Matly
Board member

Mary-Pat Christie
Board member

Fred Wilkinson
Board member

Nikolaj Sørensen
President and CEO

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, Center of Disease Control and Prevention, predicted numbers

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

13 Page 9, Bloomberg and IQVIA

14 Page 13, Last Twelve Months

Financial reports, notes and key figures

CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS

SEK m	Notes	2023 Apr-Jun	2022 Apr-Jun	2023 Jan-Jun	2022 Jan-Jun	2022 Jan-Dec
Net revenues	9	157.7	147.8	316.8	307.3	624.3
Cost of goods sold		-17.2	-21.2	-46.0	-48.7	-102.6
Gross profit		**140.5**	**126.6**	**270.8**	**258.5**	**521.7**
Selling expenses		-48.2	-50.5	-94.0	-92.1	-199.0
Administrative expenses		-38.3	-51.2	-104.7	-84.3	-202.3
Research and development expenses		-75.6	-81.3	-154.0	-153.3	-318.0
Other operating income and expenses		8.6	6.7	9.7	8.2	13.7
Operating earnings (EBIT)		**-12.9**	**-49.7**	**-72.3**	**-62.9**	**-183.9**
Net financial items		-2.9	12.3	-12.0	10.4	13.5
Earnings before tax		**-15.8**	**-37.4**	**-84.3**	**-52.5**	**-170.4**
Tax	5	3.2	1.7	7.8	-6.8	-7.2
Net earnings for the period		**-12.6**	**-35.8**	**-76.5**	**-59.4**	**-177.6**
Earnings per share. before dilution. SEK		-0.37	-1.04	-2.22	-1.73	-5.17
Earnings per share. after dilution. SEK		-0.37	-1.04	-2.22	-1.73	-5.17

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

SEK m	2023 Apr-Jun	2022 Apr-Jun	2023 Jan-Jun	2022 Jan-Jun	2022 Jan-Dec
Earnings for the period	**-12.6**	**-35.8**	**-76.5**	**-59.4**	**-177.6**
Other comprehensive income	**—**	**—**	**—**	**—**	**—**
Items that may subsequently be reversed to the statement of operations:					
Exchange-rate differences	8.0	15.2	7.1	18.7	22.1
Other comprehensive earnings for the period, net after tax	**8.0**	**15.2**	**7.1**	**18.7**	**22.1**
Total comprehensive earnings for the period [1]	**-4.6**	**-20.6**	**-69.4**	**-40.7**	**-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 Jun 30	2022 Jun 30	2022 Dec 31
ASSETS				
Fixed assets				
Tangible fixed assets		81.4	70.1	76.1
Intangible fixed assets		197.8	235.5	217.4
Right-of-use assets		34.0	51.5	46.0
Deferred tax assets	5	44.8	31.0	33.1
Other financial assets		0.3	0.9	0.9
Total fixed assets		**358.2**	**389.0**	**373.5**
Current assets				
Inventories		67.1	84.4	74.6
Accounts receivable and other receivables		250.5	329.9	309.0
Short-term investments		—	223.5	219.6
Cash and cash equivalents		251.1	244.2	132.2
Total current assets		**568.7**	**882.0**	**735.5**
Total assets		**926.9**	**1,271.0**	**1,109.0**
SHAREHOLDERS' EQUITY AND LIABILITIES				
Total shareholders' equity		**123.8**	**308.9**	**193.9**
Long-term liabilities				
Provisions		3.8	7.3	10.2
Long-term liabilities, interest bearing		481.0	493.5	494.8
Lease liabilities, long-term		14.3	30.2	24.2
Total long-term liabilities		**499.1**	**531.1**	**529.2**
Current liabilities and provisions				
Provisions		144.1	161.3	121.5
Current liabilities, non-interest bearing		138.0	249.3	243.7
Lease liabilities, current		21.8	20.6	20.6
Total current liabilities and provisions		**304.0**	**431.1**	**385.9**
Total liabilities		**803.1**	**962.2**	**915.1**
Total shareholders' equity and liabilities		**926.9**	**1,271.0**	**1,109.0**

CONSOLIDATED CHANGES IN SHAREHOLDERS' EQUITY

SEK m	2023 Jun 30	2022 Jun 30	2022 Dec 31
Opening balance, shareholders' equity	**193.9**	**349.6**	**349.6**
Total comprehensive earnings for the period	-69.4	-40.7	-155.5
Share-based payments	-0.7	-0.1	-0.1
Closing balance, shareholders' equity	**123.8**	**308.9**	**193.9**

CONDENSED CONSOLIDATED CASH FLOW STATEMENTS

SEK m	Notes	2023 Apr-Jun	2022 Apr-Jun	2023 Jan-Jun	2022 Jan-Jun	2022 Jan-Dec
Operating earnings (EBIT)		-12.9	-49.7	-72.3	-62.9	-183.9
Interest received		2.2	0.4	2.9	0.4	1.4
Interest paid		-8.6	-5.0	-17.0	-9.7	-22.4
Income taxes paid		-0.5	-2.6	-0.8	-0.7	1.5
Adjustment for non-cash items	3	21.9	6.8	44.8	0.0	-3.5
Cash flow from operating activities before changes in working capital		**2.0**	**-50.1**	**-42.4**	**-72.9**	**-206.9**
Changes in working capital		**-14.7**	**64.7**	**-28.1**	**25.8**	**50.3**
Cash flow from operating activities		**-12.7**	**14.5**	**-70.5**	**-47.1**	**-156.6**
Acquisition of tangible and intangible fixed assets		-10.8	-4.5	-11.6	-10.1	-23.9
Acquisition of short-term investments		-0.8	-221.8	0.0	-221.8	-295.6
Disposal of short-term investments		136.8	—	219.9	—	84.0
Sales of tangible assets		—	—	—	—	0.8
Cash flow from investing activities		**125.1**	**-226.3**	**208.3**	**-231.9**	**-234.7**
Repayment of loans		-14.0	-5.3	-25.5	-10.6	-21.4
Cash from financing activities		**-14.0**	**-5.3**	**-25.5**	**-10.6**	**-21.4**
Cash flow for the period		**98.5**	**-217.0**	**112.3**	**-289.6**	**-412.8**
Cash and cash equivalents at the beginning of the period		**142.4**	**437.8**	**132.2**	**504.1**	**504.1**
Exchange-rate differences in cash and cash equivalents		10.1	23.4	6.5	29.7	40.9
Changes in cash and cash equivalents		108.6	-193.6	118.8	-259.9	-371.8
Cash and cash equivalents at the end of the period		**251.1**	**244.2**	**251.1**	**244.2**	**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 Apr-Jun	2022 Apr-Jun	2023 Jan-Jun	2022 Jan-Jun	2022 Jan-Dec
EBIT margin, %	-8.2	-33.6	-22.8	-20.5	-29.5
Return on shareholder equity, %	-10.0	-11.2	-48.1	-18.0	-65.4
Net debt, SEK m	229.9	25.9	229.9	25.9	143.1
Debt/equity ratio, %	388.5	159.8	388.5	159.8	255.2
Equity/assets ratio, %	13.4	24.3	13.4	24.3	17.5
Number of shares, before dilution	34,415,773	34,367,616	34,383,668	34,341,143	34,351,732
Number of shares, after dilution	34,415,773	34,367,616	34,383,668	34,341,143	34,351,732
Earnings per share, before dilution, SEK	-0.37	-1.04	-2.22	-1.73	-5.17
Earnings per share, after dilution, SEK	-0.37	-1.04	-2.22	-1.73	-5.17
Number of employees at the end of the period	120	123	120	123	126
Shareholders' equity, SEK m	123.8	308.9	123.8	308.9	193.9
Capital employed, SEK m	604.8	802.4	604.8	802.4	688.7
Working capital, SEK m	13.6	206.8	13.6	206.8	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 Apr-Jun	2022 Apr-Jun	2023 Jan-Jun	2022 Jan-Jun	2022 Jan-Dec
Net revenues		122.7	103.8	257.9	155.8	348.2
Cost of goods sold		-17.5	-19.6	-51.3	-34.5	-72.4
Gross profit		**105.2**	**84.2**	**206.6**	**121.3**	**275.8**
Selling expenses		-31.7	-41.3	-62.2	-78.7	-165.1
Administrative expenses		-14.1	-30.2	-60.6	-50.4	-123.1
Research and development costs		-62.3	-68.9	-124.2	-129.7	-266.9
Other operating income and expenses		8.4	17.3	14.2	46.7	65.4
Operating earnings (EBIT)		**5.4**	**-39.0**	**-26.1**	**-90.7**	**-213.9**
Interest income and expenses		-7.8	-4.6	-14.7	-9.3	-19.6
Other financial income and expenses		5.0	17.5	3.0	21.7	36.7
Net financial items		**-2.8**	**12.9**	**-11.8**	**12.5**	**17.1**
Earnings before tax		**2.6**	**-26.0**	**-37.9**	**-78.3**	**-196.8**
Tax	5	—	—	—	—	—
Earnings for the period		**2.6**	**-26.0**	**-37.9**	**-78.3**	**-196.8**

PARENT COMPANY STATEMENT OF COMPREHENSIVE INCOME

SEK m	2023 Apr-Jun	2022 Apr-Jun	2023 Jan-Jun	2022 Jan-Jun	2022 Jan-Dec
Earnings for the period	**2.6**	**-26.0**	**-37.9**	**-78.3**	**-196.8**
Other comprehensive income	**—**	**—**	**—**	**—**	**—**
Total comprehensive earnings for the period	**2.6**	**-26.0**	**-37.9**	**-78.3**	**-196.8**

CONDENSED PARENT COMPANY BALANCE SHEET

SEK m	2023 Jun 30	2022 Jun 30	2022 Dec 31
ASSETS			
Fixed assets			
Intangible fixed assets	164.8	198.1	181.4
Tangible fixed assets	81.4	70.1	76.1
Shares in subsidiaries	159.8	160.1	161.2
Total fixed assets	**406.0**	**428.2**	**418.7**
Current assets			
Inventories	39.1	56.3	60.2
Accounts receivable and other receivables	171.9	144.6	159.0
Short-term investments	—	183.5	178.6
Cash and cash equivalents	180.5	177.9	61.7
Total current assets	**391.5**	**562.3**	**459.5**
Total assets	**797.5**	**990.5**	**878.2**
SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES			
Total shareholders' equity	**71.3**	**227.7**	**109.2**
Long-term liabilities			
Provisions	3.6	7.1	9.8
Bond loan	481.0	493.5	494.8
Total long-term liabilities	**484.6**	**500.6**	**504.5**
Current liabilities			
Accounts payable	26.9	39.7	32.0
Other liabilities	11.2	5.2	8.8
Liabilities to Group companies	174.8	183.5	184.3
Accrued expenses and deferred income	28.8	33.8	39.3
Total current liabilities	**241.6**	**262.2**	**264.5**
Total liabilities	**726.3**	**762.8**	**769.0**
Total shareholders' equity and liabilities	**797.5**	**990.5**	**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 distribution and sale of digital therapies which complement existing treatments and provide patients with access to highly sophisticated and individualized support when they need it most in the US.

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 Apr-Jun	2022 Apr-Jun	2023 Jan-Jun	2022 Jan-Jun	2022 Jan-Dec
US Pharma					
Net revenues	145.4	139.6	286.0	278.7	571.4
Operating earnings (EBIT)	71.2	77.2	145.4	161.2	308.4
Depreciation and amortization	-3.8	-1.3	-7.7	-5.1	-15.4
Digital Therapeutics					
Net revenues	0.0	0.1	0.1	0.3	0.4
Operating earnings (EBIT)	-33.6	-47.9	-70.1	-91.3	-189.1
Depreciation and amortization	-7.0	-6.6	-13.8	-12.2	-25.7
HQ & Pipeline					
Net revenues	12.3	8.1	30.8	28.3	52.6
Operating earnings (EBIT)	-50.5	-79.1	-147.5	-132.9	-303.2
Depreciation and amortization	-7.7	-9.4	-15.4	-15.9	-27.7
Group					
Net revenues	157.7	147.8	316.8	307.3	624.3
Operating earnings (EBIT)	-12.9	-49.7	-72.3	-62.9	-183.9
Depreciation and amortization	-18.5	-17.2	-36.9	-33.2	-68.7
Net financial items	-2.9	12.3	-12.0	10.4	13.5
Earnings before tax	-15.8	-37.4	-84.3	-52.5	-170.4

3. Cash flow

ADJUSTMENT FOR NON-CASH ITEMS

SEK m	2023 Apr-Jun	2022 Apr-Jun	2023 Jan-Jun	2022 Jan-Jun	2022 Jan-Dec
Depreciation/amortization and impairment	18.5	17.2	36.9	33.2	68.7
Realization results	—	—	—	—	-0.2
Change in provisions	8.2	-3.6	10.7	-24.9	-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	-4.8	-6.8	-5.8	-8.2	-7.0
Total	**21.9**	**6.8**	**44.8**	**0.0**	**-3.5**

4. Litigations

Subpoena related to sales and marketing of ZUBSOLV®

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.

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, short-term investments, 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

- ZUBSOLV® reimbursed by Medicaid in Indiana state as of July 1, 2023

9. Revenue from contracts with customers

SEK m	2023 Apr-Jun					
Segment	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**vorvida®**	**deprexis®**	**Total**
US Pharma	145.4	–	–	–	–	**145.4**
Digital Therapeutics	–	–	–	0.0	0.0	**0.0**
HQ & Pipeline	0.2	8.0	4.0	–	–	**12.3**
Total revenue from contracts with customers	**145.6**	**8.0**	**4.0**	**0.0**	**0.0**	**157.7**
Geographical markets	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**vorvida®**	**deprexis®**	**Total**
US	145.4	–	0.6	0.0	0.0	**146.0**
EU & UK	0.2	7.8	2.4	–	–	**10.4**
Rest of the world	–	0.2	1.1	–	–	**1.3**
Total revenue from contracts with customers	**145.6**	**8.0**	**4.0**	**0.0**	**0.0**	**157.7**

SEK m	2023 Jan-Jun					
Segment	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**vorvida®**	**deprexis®**	**Total**
US Pharma	286.0	–	–	–	–	286.0
Digital Therapeutics	–	–	–	0.0	0.0	0.1
HQ & Pipeline	11.2	14.2	5.3	–	–	30.8
Total revenue from contracts with customers	**297.1**	**14.2**	**5.3**	**0.0**	**0.0**	**316.8**
Geographical markets	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**vorvida®**	**deprexis®**	**Total**
US	286.0	–	1.2	0.0	0.0	287.2
EU & UK	11.2	13.9	2.5	–	–	27.6
Rest of the world	–	0.4	1.6	–	–	1.9
Total revenue from contracts with customers	**297.1**	**14.2**	**5.3**	**0.0**	**0.0**	**316.8**

SEK m	2022 Apr-Jun					
Segment	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**vorvida®**	**deprexis®**	**Total**
US Pharma	139.6	–	–	–	–	139.6
Digital Therapeutics	–	–	–	0.1	0.0	0.1
HQ & Pipeline	1.5	5.0	1.6	–	–	8.1
Total revenue from contracts with customers	**141.1**	**5.0**	**1.6**	**0.1**	**0.0**	**147.8**
Geographical markets	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**vorvida®**	**deprexis®**	**Total**
US	139.6	–	0.2	0.1	0.0	139.9
EU	1.5	4.7	1.0	–	–	7.2
Rest of the world	–	0.3	0.5	–	–	0.8
Total revenue from contracts with customers	**141.1**	**5.0**	**1.6**	**0.1**	**0.0**	**147.8**

SEK m	2022 Jan-Jun					
Segment	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**vorvida®**	**deprexis®**	**Total**
US Pharma	278.7	–	–	–	–	**278.7**
Digital Therapeutics	–	–	–	0.3	0.0	**0.3**
HQ & Pipeline	6.1	17.4	4.8	–	–	**28.3**
Total revenue from contracts with customers	**284.8**	**17.4**	**4.8**	**0.3**	**0.0**	**307.3**
Geographical markets	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**vorvida®**	**deprexis®**	**Total**
US	278.7	–	1.0	0.3	0.0	**280.0**
EU & UK	6.1	16.8	2.0	–	–	**24.9**
Rest of the world	–	0.6	1.8	–	–	**2.4**
Total revenue from contracts with customers	**284.8**	**17.4**	**4.8**	**0.3**	**0.0**	**307.3**

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	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 Apr-Jun	2022 Apr-Jun	2023 Jan-Jun	2022 Jan-Jun	2022 Jan-Dec
EBIT	-12.9	-49.7	-72.3	-62.9	-183.9
Depreciation and amortization	18.5	17.2	36.9	33.2	68.7
EBITDA	**5.6**	**-32.5**	**-35.4**	**-29.7**	**-115.2**
External costs for clinical studies	18.1	23.3	37.8	45.0	96.4
IP litigation and subpoena	6.6	20.6	48.9	28.3	76.6
EBITDA excluding external costs for clinical studies. IP litigation and subpoena	**30.3**	**11.4**	**51.3**	**43.6**	**57.8**

OPERATING EXPENSES SEK m	2023 Apr-Jun	2022 Apr-Jun	2023 Jan-Jun	2022 Jan-Jun	2022 Jan-Dec
Selling expenses	-48.2	-50.5	-94.0	-92.1	-199.0
Administrative expenses	-38.3	-51.2	-104.7	-84.3	-202.3
Research and development costs	-75.6	-81.3	-154.0	-153.3	-318.0
Other operating income and expenses	8.6	6.7	9.7	8.2	13.7
Operating expenses	**-153.4**	**-176.4**	**-343.0**	**-321.5**	**-705.6**

CASH AND INVESTED FUNDS	2023 Apr-Jun	2022 Apr-Jun	2023 Jan-Jun	2022 Jan-Jun	2022 Jan-Dec
Short-term investments	—	223.5	—	223.5	219.6
Cash and cash equivalents	251.1	244.2	251.1	244.2	132.2
Cash and invested funds	**251.1**	**467.7**	**251.1**	**467.7**	**351.9**

GROSS INVESTMENTS SEK m	2023 Apr-Jun	2022 Apr-Jun	2023 Jan-Jun	2022 Jan-Jun	2022 Jan-Dec
Investments in tangible fixed assets	10.8	3.5	10.8	7.5	18.8
Investments in intangible fixed assets	0.0	1.0	0.7	2.6	5.1
Gross investments	**10.8**	**4.5**	**11.6**	**10.1**	**23.9**

RETURN ON SHAREHOLDERS' EQUITY	2023 Apr-Jun	2022 Apr-Jun	2023 Jan-Jun	2022 Jan-Jun	2022 Jan-Dec
Shareholders' equity beginning balance	129.1	329.5	193.9	349.6	349.6
Shareholders' equity ending balance	123.8	308.9	123.8	308.9	193.9
Average shareholders' equity	126.5	319.2	158.9	329.2	271.8
Net earnings	-12.6	-35.8	-76.5	-59.4	-177.6
Return on shareholders' equity %	**-10.0**	**-11.2**	**-48.1**	**-18.0**	**-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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