Interim Report Q1 2023

Focusing operations on Orexo´s strengths

Q1 2023 highlights

- Total net revenues of SEK 158.8 m (159.4)
- EBITDA of SEK -41.1 m (2.8), EBITDA excluding legal costs and costs for non-repeating clinical trials, SEK 20.9 m (32.2)
- Net earnings of SEK -63.9 m (-23.6)
- US Pharma segment (ZUBSOLV® US) net revenues of SEK 140.3 m (139.1), in local currency USD 13.5 m (14.8), US Pharma EBIT of SEK 74.3 m (84.0)
- Cash flow from operating activities of SEK -61.6 m (-61.6), cash and invested funds of SEK 278.9 m (437.8)
- Earnings per share before and after dilution amounted to -1.86 (-0.69)
- Exploratory feasibility studies of amorphOX® initiated in collaboration with two international biopharmaceutical and vaccine companies
- New Drug Application (NDA) submitted with the FDA for OX124, high-dose rescue medication for opioid overdose

Important events after the end of the period

- 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

SEK 159 m
Group revenues

SEK 74 m
US Pharma EBIT

SEK 279 m
Cash and invested funds

SEK m, unless otherwise stated	2023 Jan-Mar	2022 Jan-Mar	% change quarter	2022 Jan-Dec
Net revenues	158.8	159.4	-0.4%	624.3
Cost of goods sold	-28.7	-27.5	4.2%	-102.6
Operating expenses	-189.4	-145.1	30.6%	-705.6
EBIT	-59.3	-13.2	350.0%	-183.9
EBIT margin	-37.4%	-8.3%	29.1%	-29.5%
EBITDA	-41.1	2.8	-1,567.9%	-115.2
Earnings per share, before dilution, SEK	-1.86	-0.69	169.6%	-5.17
Earnings per share, after dilution, SEK	-1.86	-0.69	169.6%	-5.17
Cash flow from operating activities	-61.6	-61.6	0.0%	-156.6
Cash and invested funds	278.9	437.8	-36.3%	351.9

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

Content

About Orexo
Orexo develops improved pharmaceuticals and digital therapies addressing unmet needs within the growing space of substance use disorders and mental health. The products are commercialized by Orexo in the US or via partners worldwide. The main market today is the American market for buprenorphine/naloxone products, where Orexo commercializes its lead product ZUBSOLV® for treatment of opioid use disorder. Total net sales for 2022 amounted to SEK 624 million and the number of employees was 126. Orexo is listed on the Nasdaq Stockholm Main Market (ORX) and is available as ADRs on OTCQX (ORXOY) in the US. The company is headquartered in Uppsala, Sweden, where research and development activities are performed.

For further information, please contact
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Presentation
At 2 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 use this link:
https://conference.financialhearings.com/teleconference/?id=200679
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-q1-2023

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

Financial calendar 2023
Interim Report Q2 2023 - July 18, at 8 am
Interim Report Q3 2023 - November 2, at 8 am
Interim Report Q4 2023, incl. Full Year Report, January 25, at 8 am

For more information about Orexo
Please visit, www.orexo.com. You can also follow Orexo on Twitter, @orexoabpubl, LinkedIn and YouTube.

Navigating troubled waters

As expected, the first quarter has been intensive for Orexo with submission of the of OX124 file to the FDA, completion of the District Court Hearing in the patent litigation and integration of the DTx team into the US Pharma organization. ZUBSOLV® sales in SEK was in line with last year, supported by currency tailwinds, and ZUBSOLV® US sales have stabilized comparing to Q4 in USD. As expected, EBITDA compared to last year is lower explained by the increase in non-repeating expenses. These expenses will decline in the next quarters as we approach the critical milestones for the company with the decision in the District Court and the completion of the MODIA® clinical trial. Removing these non-repeating expenses from the P&L, EBITDA would have been positive in the quarter. I am disappointed with the news right after the quarter ended, that we had issues with the packaging line for OX124 and need to make a new submission to FDA later this year. If the final tests at our contract manufacturing partner are successful, we are expecting to resubmit the OX124 file with the FDA in Q3.

The Opioid Use Disorder treatment in transformation
Opioid Use Disorder (OUD) has for many years been stigmatized and access to treatment limited. Patients have been forced to approach clinics with sub-optimal medical standards and access to life saving overdose drugs were limited to prescriptions to the patient with OUD and not concerned relatives. Important steps have now been made to change this.

Legislative changes removing the DATA2000 certification requirement to prescribe medication, such as ZUBSOLV®, will improve access to treatment over time. The changes were implemented during the quarter, but physicians are still required to complete a training program in addiction and misuse before being allowed to prescribe. The new system covers all controlled substances and when fully implemented, a large share of the physicians in the US are likely to be able to treat patients suffering from OUD and prescribe ZUBSOLV®. The effect of this change is not visible yet, and we continue to see low market growth of 6 percent. Currently we lack clarity in the requirements for new physicians to start treatment of OUD. This problem will be solved, and the new legislation should be an important growth factor in the years to come.

Another important change is the decision by the FDA to approve NARCAN® 4 mg naloxone nasal spray as an OTC product i.e., no need for prescription. This is an important step to increase access to life saving naloxone, but most opioid overdoses in the US today are caused by strong synthetic opioids like fentanyl and an increasing amount of data points toward the standard dose of NARCAN® or the pre-filled syringes is not strong enough to completely reverse an overdose caused by a synthetic opioid. To survive an overdose two things matter, speed of onset of the naloxone product and amount of naloxone you get in the body. In our first study, all formulations of OX124 were faster and showed stronger bioavailability, even with the same dose naloxone as NARCAN®. If you overdose with a synthetic opioid this can be the difference between life and death. For OX124 an advantage from this change will be the clear separation of the low-dose OTC rescue medications and the high-dose prescription products, such as OX124. In the reimbursement system in the US today, most insurance companies often require a prescription to reimburse a product and rarely reimburse OTC products.

Digital therapeutics a continued concern
Starting the quarter, we took the decision to restructure our organisation for digital therapies and integrating this into the US Pharma organisation, although keeping our current segment reporting. The change was completed stepwise during Q1 and costs associated with the change were included in the Q1 result. The processes for reimbursement and distribution have been identified as a main issue for commercial traction and the pharma team has made a complete overhaul of this process.

The initial reimbursement pathways required significant administration of both Orexo and the healthcare providers. For example, with MODIA® we are now implementing a streamlined process which is expected to improve efficiency for both Orexo and the providers. In parallel we have discontinued the modiaONE™ trial program and are surveying participating HCP's for additional feedback to optimize our MODIA® offering. Also, we are now focusing our efforts on clinics with a genuine interest and capability to enter into a MODIA® commercial contract. Similar efficiencies and efforts are being addressed with deprexis® and vorvida®.

As a consequence of the change our direct operating expenses for digital therapies have declined with about 50 percent in the quarter and expect OPEX to continue to decline in Q2 when the full effect of the restructuring materializes. The vast majority of reported expenses in Digital Therapeutics is allocation of resources from US Pharma, such as the field force to promote MODIA®. We know efficiencies and access to physicians improves when the sales representatives present two products, in this case, MODIA® and ZUBSOLV®, to the providers which gives strong synergies for both revenues and expenses.

A cornerstone in the strategy for DTx moving forward is to make a collective offer of both digital therapies and pharmaceuticals under the brand name MATCore™. First step is the implementation in Arizona among patients, starting late April, and in Q1 this generated SEK 0,5 million in income to support the implementation (recognized under Other Income in Digital Therapeutics). Additional discussions exist in several states, both in terms of grants and a more traditional sales model. The recent Chapter 11 filing of a competitor has created interest from some of their customers and we are investigating how to proceed with MODIA®, which right now is commercialized under a different regulatory pathway than the competitor´s product. With a successful clinical trial for MODIA® we intend to upgrade the product to a prescription digital therapy.

R&D taking two steps forward and one step back

The highlight of the quarter was intended to be the filing of OX124 for approval in the US in February. However, issues in the packaging line force us to resubmit the file to FDA. We expect our manufacturing partners have the new packaging process ready for FDA inspection in Q3, which will trigger a new filing of OX124. In parallel with the OX124 filing, we continue to test amorphOX® in new APIs and continue to see positive results both in vitro and in vivo of all the APIs tested. The data from APIs tested in our drug delivery platform amorphOX®, the established supply chain for OX124 and the excellent data on OX640 have created a strong interest in OX640, where we are aiming to develop a needle-free rescue medication for allergic reactions. Our business model for amorphOX® is to find development partners for most projects, but also to leverage our supply chain and commercial organization in the US to promote some of the future products either independently or in partnership with other companies.

Summary and outlook

We knew the first quarter for 2023 was going to be a difficult quarter, with high expenses and some critical activities both in the pipeline and in the organization. I am pleased with our ability to control and reduce expenses and ZUBSOLV® continue to show resilience in a very competitive market. The company and our share price are suffering from the legal uncertainties associated with the patent litigation and the investigation by the authorities of the ZUBSOLV® promotion. This creates operational complexity and overshadows the significant progress we are making in our pipeline and our success in maintaining ZUBSOLV´s profitability and sales. I am optimistic that we can have a resolution of the legal processes during the summer. This will enable Orexo to fully focus on advancing the pipeline, enter the first partnership agreement of an amorphOX® product, resubmission of OX124 to FDA and develop new treatment solutions to patients suffering from opioid use disorder. All based on the strong foundation of continued financial contributions from ZUBSOLV® many years ahead.

Uppsala, Sweden, April 27, 2023

Nikolaj Sørensen
President and CEO

Business update

Commercial products

Opioid Use disorder

zubsolv

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

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 81,000 annually.[4] Nine out of ten opioid overdoses involve synthetic opioids, such as fentanyl.[5]

In Q1, the buprenorphine/naloxone market grew 1 percent versus Q4 2022 and grew 6 percent versus Q1 2022. This lower growth, compared to the double-digit market growth prior to 2020, can be attributed to limited access to treatment during Covid-19, which has continued in the aftermath of the pandemic. Also, according to physicians, the broad availability of illicit fentanyl analogues makes it more difficult to treat patients due to increased rate of relapse during the challenging induction treatment phase. This decreases the average treatment length and impact the market growth negatively. 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 non-physician prescribers of buprenorphine/naloxone of any controlled drug substance (incl. pain meds, ADHD meds etc.) will be required to complete a shorter training session of 8-hours when they renew their treatment license to prescribe these controlled substances (DEA-license). Details for practical implementation are still being worked out by US government agencies. 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 2 percent vs Q4 2022 and 4 percent vs Q1 2022. This is a slowing decline compared to the prior quarter's year over year decline of 9 percent. The development is explained by flat market development within the open segment where ZUBSOLV® is reimbursed, continued negative impact from the addition of generics on Humana and United Health Groups formulary lists, but this is increasingly compensated by continued strong growth from Medicaid in New York and Kentucky. ZUBSOLV's best in class market access in the Commercial payer segment maintained at 98 percent. Access to the Public payer segment was changed from 48 to 47 percent, due to shifting of market volumes in the segment.

The pivotal MODIA® study, including 437 participants at 35 sites across the US reached its final phase. 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. Data from the study is expected in mid-2023, if successful it will serve as a base for a 510k filing with the FDA to have MODIA® classified as a prescription DTx.

MODIA® has been well received by many physicians and patients, and the plan was to move away from the free trial of modiaONE™ and to start commercial roll-out during Q1. However, after integrating the digital therapy organization under the US Pharma organization, the new team has identified a need to revisit the reimbursement process. The aim is to reduce complexity and increase the responsibility of the healthcare provider for reimbursement and monitoring patient progress.

In Q4 2022 Alay Psychiatry in Arizona was awarded a state grant with the purpose to implement MATCore™, a digital platform that are collecting Orexo´s offering within OUD along with education and support. Alay Psychiatry is an outpatient clinic with offices in Arizona that is dedicated

[1] Substance Abuse and Mental Health Services Administration 2021 NSDUH report
[2] Substance Abuse and Mental Health Services Administration 2021 NSDUH report
[3] Orexo data
[4] Center of Disease Control and Prevention, predicted numbers as of October 2022
[5] Center of Disease Control and Prevention, predicted numbers as of October 2022

to implementing innovative technologies to extend and improve treatment and access for OUD patients. The implementation of MATCore™ at Alay Psychiatry was initiated in Q1 2023 and the first income was 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
During the quarter Orexo´s partner Accord Healthcare continued to launch ZUBSOLV® on markets where the drug has been approved and got reimbursed. Since the initiation of the launch in Q2 2022 the drug is available in nine European countries, such as Sweden, UK, Spain, Romania, the Czech Republic, Slovenia and the three Baltic states.

The commercialization of ZUBSOLV® in the EU has the potential to cover 29 European countries and are fully managed by Accord Healthcare which has in-licensed the rights from Orexo. Orexo is responsible for product supply and will receive double digit royalty on net sales.

There are estimated to be 1.3 million high-risk opioid users in Europe, yet treatment rates are low.[1] Approximately 50 percent of people with opioid dependence are receiving some form of substitution treatment across Europe, although this varies greatly between countries.[2]

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

Mental Illness and Substance Use Disorder, ex OUD

VORV!DA®

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, incl. approx. 600 patients.[3]

deprexis®

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.[4]

Developments during the quarter
Following the reorganization of the DTx responsibilities during the quarter the new team has been tasked with a complete review of the causes of the lack of business progress and to improve cost efficiencies. The main hurdle is lack of efficient reimbursement and distributions processes, and the team has made a review aiming at reducing complexity in the system. The reimbursement pathways pursued by the previous team were viable and confirmed for individual patients, but complex for both Orexo and the healthcare provider to manage at scale. This slowed down implementation, increased expenses and made it difficult to sustain on a broader scale.

With the 10-year contract with Veterans Affairs (VA) this opportunity has been prioritized and is now led by the Market Access account team to establish an efficient ordering and invoicing process. The VA ordering process for a digital therapeutic such as deprexis® is new to the VA organization and Orexo works with the national VA contracting contacts to establish the processes and to initiate the implementation with the regional VA Network Contracting Offices. A prerequisite for commercial success is the availability of a streamlined process to insure that deprexis® can be easily ordered and accessed by VA. Once an ordering and invoicing process is determined, Orexo will be able to actively promote deprexis® within the VA system.

During the quarter vorvida® was registered under the registration pathway Enforcement Descretion, and has now the same classification as deprexis®. With the new registration it is now possible to start the process to include vorvida® under the contract with the VA for deprexis®.

Trinity Health has during the quarter moved their main facilities to new buildings and have asked for a restart of the implementation to be initiated after the move is completed, i.e., during Q2 2023.

Revenues and costs for vorvida® and deprexis® are recorded in the Digital Therapeutics segment.

[1] European Monitoring Centre for Drugs and Drugs Addiction (EMCDDA)
[2] EMCDDA - Tackling Opioid Dependence
[3] 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
[4] 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)

Products under development

amorphOX® – a scalable drug delivery platform central to new pharmaceuticals

Orexo's proprietary drug delivery platform, amorphOX®, is a powder using a unique combination of a drug, carrier materials and other ingredients. The particles are presented as an amorphous composite of the various ingredients providing for excellent chemical and physical stability, as well as rapid dissolution. The technology works for a broad scope of active ingredients, including both small and large molecules. amorphOX®, has been validated in several human clinical studies showing rapid and extensive drug exposure. In addition, studies have demonstrated outstanding stability of the substances after long period of storage in both low and high temperatures.

A commercial supply chain has been established for OX124. This will contribute to shorter timelines, reduced costs, and limit risks in the development of future products based on the amorphOX® platform using nasal delivery. Development of products based on the technology will be conducted by Orexo and in partnership with other pharmaceutical companies. Several patent applications directed to the amorphOX® platform have been filed or approved, which should serve to protect the technology until 2042.

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. Also, stability studies are performed. Orexo is aiming to continue to seek partnership 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.

In beginning of the quarter, two exploratory feasibility studies were initiated applying amorphOX® to a protein based pharmaceutical and a vaccine. The studies are conducted in collaboration with international biopharmaceutical and vaccine companies. In addition, Orexo has successfully tested amorphOX® in a new molecule from a US biotech company and in collaboration with them Orexo is discussing potential continued development pathways.

Development projects based on the amorphOX® platform

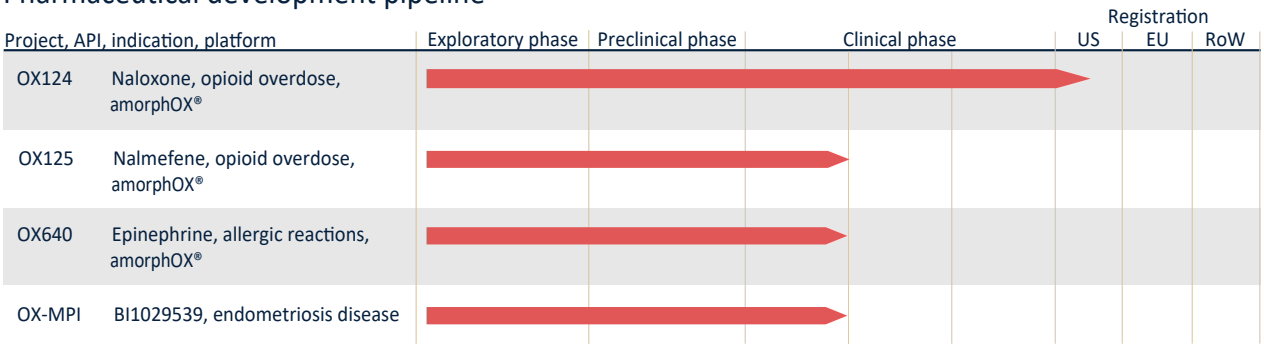
OX124 – high-dose medication for opioid overdose containing naloxone

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, substantially higher plasma concentrations of naloxone, and sustained duration of elevated plasma concentrations when 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:
In beginning of February, a New Drug Application (NDA) was filed with the FDA. Due to identified technical issues in the equipment used in the secondary packaging in one of the production modules, the contract manufacturer is not ready for inspection by the FDA and Orexo was asked to resubmit the NDA when the manufacturer is ready for inspection, as communicated by Orexo in early April. The manufacturing team at Orexo is working intensively along with its partners to solve the problem and perform the equipment qualification to secure the production process meets the high requirements regarding reliability and quality. A new NDA is planned to be filed in Q3 2023 and an approval is expected in H2 2024.

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,

Pharmaceutical development pipeline



ending October 2022, the predicted annual number of fatal opioid overdoses in the US counted for more than 81,000[1]. Nine out of ten opioid overdoses involve synthetic opioids, such as fentanyl[2].

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 the 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.[3] 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 rescue medications that are effective in rural areas where distance to emergency units require more potent and longer lasting overdose treatment. With OX125, the aim is to develop an overdose rescue medication for situations where powerful, rapid, and long-lasting effects are required.

Developments during the quarter:
Orexo has during a long period closely monitored the development of nalmefene products on the market for opioid overdose medication. Today, no nalmefene products have yet been approved, but a product has been filed for approval by a leading player in the OUD treatment space. Orexo continues to assess the potential for OX125, which includes entering partnership to proceed with the clinical development or advance the project internally for US launch by Orexo. Upon a decision to accelerate the project, the development timeline is short as the synergies between OX124 and OX125 are significant.

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:
Following the promising results of the phase 1 study in Q4 2022, preparations for next round of communication with the FDA on the continued development program were initiated. Based on earlier feedback from the authority, the development program will include additional clinical studies in healthy volunteers and in participants known to have a history of seasonal allergies. In parallel, 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.

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 non-hormonal treatment options.

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

[1] Center of Disease Control and Prevention, predicted numbers
[2] Center of Disease Control and Prevention, predicted numbers
[3] Bloomberg and IQVIA

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:
Early in the quarter the updated sustainability strategy with long-term ambitions and measurable ESG targets was presented and anchored with the board. Based on the updated strategy an action plan was set for 2023, by the sustainability committee.

In addition, an extended sustainability evaluation including all suppliers in the commercial supply chain for OX124 was initiated. To ensure the suppliers have sustainability processes in place the assessment includes areas such as Management Systems, Ethics, Labour, Health & Safety Compliance, Risk Management and Environmental Compliance.

Financial overview

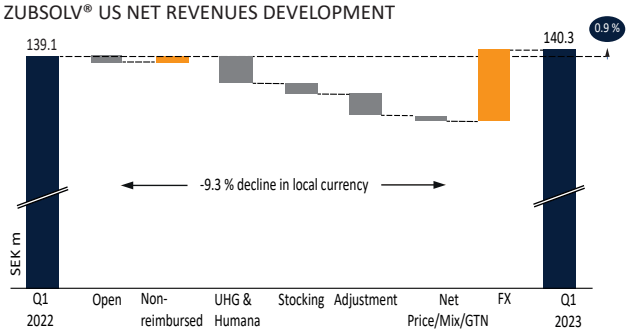
Revenues

Total revenues amounted to SEK 158.8 m (159.4) for Q1. The decrease is mainly explained by lower Abstral® and Edluar® royalties.

Revenues by segment

US Pharma revenues amounted to SEK 140.3 m (139.1) for Q1. The increase in US Pharma revenues is driven by stronger USD exchange rate. This was partly offset by lower ZUBSOLV® demand mainly due to overall market growth rates, which still remain below pre-Covid levels, and due to continued decline in the previously exclusive plans United Health Group and Humana. Net revenues were also affected negatively by higher wholesaler destocking and absence of positive return adjustment.

ZUBSOLV® US NET REVENUES DEVELOPMENT



In local currency US Pharma net revenues for Q1 amounted to USD 13.5 m (14.8).

Digital Therapeutics (DTx) recognized net revenues for Q1 amounting to SEK 0.0 m (0.2).

HQ & Pipeline partner product related revenues for Q1 amounted to SEK 18.5 m (20.1). The decrease is explained by lower Abstral® and Edluar® royalties, partly offset by higher ZUBSOLV® ex-US revenues related to sales of tablets to Orexo's partner Accord Healthcare.

Costs of goods sold

Cost of goods sold (COGS) amounted to SEK 28.7 m (27.5) for Q1. US Pharma amounted to SEK 11.6 m (22.6), the decrease is mainly due to change in product mix and positive production variances. Royalty and technical infrastructure costs for DTx amounted to SEK 2.8 m (2.7). HQ & Pipeline amounted to SEK 14.3 m (2.3) for ZUBSOLV® ex-US sales of tablets to Orexo's partner Accord Healthcare in the EU.

Operating expenses

Selling expenses amounted to SEK 45.5 m (41.6) for Q1. The increase over the same period last year is explained by negative impact of stronger USD exchange rate.

Administrative expenses amounted to SEK 66.5 m (33.0) for Q1. The increase is mainly explained by higher legal expenses for IP litigation and subpoena, in addition stronger USD exchange rate had a negative impact.

Research and development costs amounted to SEK 78.5 m (72.0) for Q1. The increase is mainly explained by higher internal costs in HQ & Pipeline related to preparation for OX124 filing with the FDA, and negative impact of stronger USD exchange rate.

Other operating income and expenses amounted to SEK 1.1 m (1.5) for Q1. This is mainly explained by implementation of MATCore™ in Arizona with income of SEK 0.5 m (-), partly offset by expenses of SEK 0.3 m (-) for setting up platform for patient usage and by exchange-rate gains of SEK 1.0 m (1.5) derived from revaluations of parent company balance sheet items in foreign currency, predominantly in USD.

NET REVENUES AND OPERATING EARNINGS PER SEGMENT

SEK m	Net Revenues			EBIT		
	2023 Jan-Mar	2022 Jan-Mar	2022 Jan-Dec	2023 Jan-Mar	2022 Jan-Mar	2022 Jan-Dec
ZUBSOLV® US product sales	140.3	139.1	571.4	—	—	—
US Pharma – total	**140.3**	**139.1**	**571.4**	**74.3**	**84.0**	**308.4**
Digital Therapeutics (DTx) product sales	0.0	0.2	0.4	—	—	—
Digital Therapeutics (DTx) – total	**0.0**	**0.2**	**0.4**	**-36.4**	**-43.4**	**-189.1**
Abstral® royalty	6.2	12.4	30.4	—	—	—
Edluar® royalty	1.3	3.2	10.4	—	—	—
ZUBSOLV® – ex US	10.9	4.6	11.8	—	—	—
HQ & Pipeline segment – total	**18.5**	**20.1**	**52.6**	**-97.2**	**-53.7**	**-303.2**
Total	**158.8**	**159.4**	**624.3**	**-59.3**	**-13.2**	**-183.9**

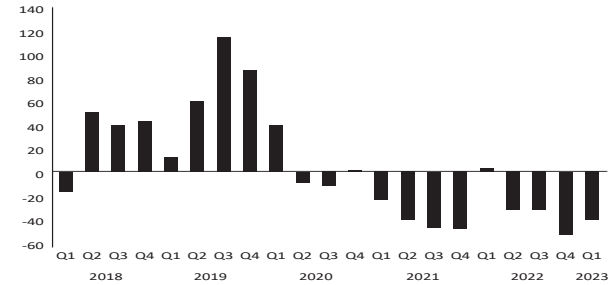
Operating profit

EBITDA amounted to SEK -41.1 m (2.8) for Q1. Exclusion of costs for legal processes and external non-repeating costs for clinical studies, would result in an EBITDA of SEK 20.9 m (32.2) for Q1.

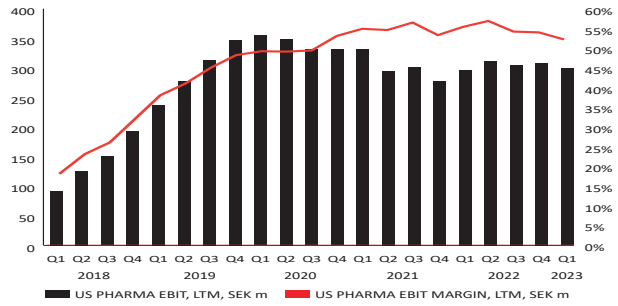
The EBIT contribution from US Pharma amounted to SEK 74.3 m (84.0) for Q1, equal to an EBIT margin of 53.0 percent (60.4).

Total EBIT amounted to -59.3 m (-13.2) for Q1 mainly explained by the increase in non-repeating expenses.

GROUP EBITDA, SEK m



US PHARMA EBIT MARGIN (LTM[1], SEK m) AND EBIT (LTM[1], SEK m)



Net financial items and tax

Net financial items for Q1 amounted to SEK -9.1 m (-1.9) and is mainly explained by negative unrealized exchange rate impact of SEK -1.5 m (4.0) derived from the parent company's foreign currency bank accounts mainly in USD. Higher interest expenses for corporate bonds amounted to SEK -8.0 m (-4.7). This was partly offset by interest income of SEK 1.6 m (-) from short-term cash investments.

Total tax expenses amounted to SEK 4.6 m (-8.5) for Q1. The decrease is mainly explained by positive adjustment to deferred tax assets related to temporary differences of SEK 5.8 million (-7.2). Orexo performs regular assessments of its deferred tax asset and makes adjustments according to the recognition requirements of IAS 12.

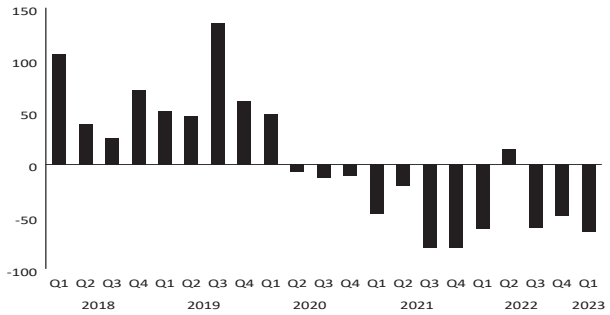
Net earnings

Net earnings amounted to SEK -63.9 m (-23.6) for Q1.

Cash and cash flow

Cash flow from operating activities amounted to SEK -61.6 m (-61.6) for Q1 and was primarily impacted by negative operating earnings. In the quarter Orexo made a buyback of the corporate bond with nominal value of SEK 6.25 m.

CASH FLOW FROM OPERATING ACTIVITIES, SEK m



The company has invested surplus cash in certificates of deposits and in US treasuries. Deposits with maturity from 6 months to 12 months are recorded as short-term investments. As of March 31, 2023, cash and cash equivalents amounted to SEK 142.4 m (437.8) and short-term investments amounted to SEK 136.5 m (-). Cash and invested funds in total amounted to SEK 278.9 m (437.8) and interest-bearing liabilities to SEK 489.1 m (492.9), i.e. a negative net cash position including short-term investments of SEK -210.2 m (-55.2). Cash and invested funds were reduced by SEK 73.0 m from Q4 2022.

[1] Last Twelve Months

Investments

Gross investments in tangible and intangible fixed assets amounted to SEK 0.8 m (5.6) for Q1. Investments are mainly explained by investments in equipment for the development organization.

Equity

Shareholders' equity at March 31, 2023, was SEK 129.1 m (329.5). The equity/asset ratio was 13.6 percent (27.3).

Parent company

Net revenues for Q1 amounted to SEK 135.2 m (52.0) of which SEK 116.7 m (31.8) was related to sales to Group companies.

Earnings before tax amounted to SEK -40.6 m (-52.2) for Q1. The development is mainly explained by higher gross profit, partly offset by higher administrative expenses and lower net financial items. Investments in equipment for the development organization for Q1 amounted to SEK 0.1 m (4.0).

As of March 31, 2023, cash and cash equivalents in the parent company amounted to SEK 68.4 m (400.0) and short-term investments amounted to SEK 116.0 m (-) i.e. company's cash and invested funds amounted to SEK 184.4 m (400.0).

Parent company shareholders' equity at March 31, 2023, was SEK 68.6 m (253.8). 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
- OPEX H1 2023, slightly higher than H2 2022 (SEK 385 m), but H2 2023 will decline versus the same comparison period
- EBITDA will reach 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. The Covid-19 pandemic continues to drive uncertainty in the market and together with the war in Ukraine, this increase the risk for shortage of material in the supply chain.

Going concern uncertainty factors

The shareholders' equity in the parent company is expected to decrease during the first half of 2023 and it cannot be ruled out that the shareholders' equity in the parent company will be less than half of the registered share capital unless measures are 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 the expected 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/

Uppsala, Sweden, April 27, 2023

Nikolaj Sørensen
President and CEO

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

Financial reports, notes and key figures

CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS

SEK m	Notes	2023 Jan-Mar	2022 Jan-Mar	2022 Jan-Dec
Net revenues	9	158.8	159.4	624.3
Cost of goods sold		-28.7	-27.5	-102.6
Gross profit		**130.1**	**131.9**	**521.7**
Selling expenses		-45.5	-41.6	-199.0
Administrative expenses		-66.5	-33.0	-202.3
Research and development expenses		-78.5	-72.0	-318.0
Other operating income and expenses		1.1	1.5	13.7
Operating earnings (EBIT)		**-59.3**	**-13.2**	**-183.9**
Net financial items		-9.1	-1.9	13.5
Earnings before tax		**-68.5**	**-15.1**	**-170.4**
Tax	5	4.6	-8.5	-7.2
Net earnings for the period[1]		**-63.9**	**-23.6**	**-177.6**
Earnings per share, before dilution, SEK		-1.86	-0.69	-5.17
Earnings per share, after dilution, SEK		-1.86	-0.69	-5.17

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

SEK m	2023 Jan-Mar	2022 Jan-Mar	2022 Jan-Dec
Earnings for the period	**-63.9**	**-23.6**	**-177.6**
Other comprehensive income			
Items that may subsequently be reversed to the statement of operations:			
Exchange-rate differences	-0.9	3.5	22.1
Other comprehensive earnings for the period, net after tax	**-0.9**	**3.5**	**22.1**
Total comprehensive earnings for the period[1]	**-64.8**	**-20.1**	**-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 Mar 31	2022 Mar 31	2022 Dec 31
ASSETS				
Fixed assets				
Tangible fixed assets		73.3	68.3	76.1
Intangible fixed assets		207.2	241.7	217.4
Right-of-use assets		38.9	54.9	46.0
Deferred tax assets	5	39.6	26.5	33.1
Other financial assets		0.9	0.8	0.9
Total fixed assets		**360.0**	**392.2**	**373.5**
Current assets				
Inventories		64.7	77.6	74.6
Accounts receivable and other receivables		245.7	298.0	309.0
Short-term investments		136.5	—	219.6
Cash and cash equivalents		142.4	437.8	132.2
Total current assets		**589.3**	**813.4**	**735.5**
Total assets		**949.3**	**1,205.7**	**1,109.0**
SHAREHOLDERS' EQUITY AND LIABILITIES				
Total shareholders' equity		**129.1**	**329.5**	**193.9**
Long-term liabilities				
Provisions		6.1	9.9	10.2
Long-term liabilities, interest bearing		489.1	492.9	494.8
Lease liabilities, long-term		19.1	33.8	24.2
Total long-term liabilities		**514.4**	**536.7**	**529.2**
Current liabilities and provisions				
Provisions		127.4	146.9	121.5
Current liabilities, non-interest bearing		156.2	172.4	243.7
Lease liabilities, current		22.2	20.2	20.6
Total current liabilities and provisions		**305.7**	**339.5**	**385.9**
Total liabilities		**820.1**	**876.2**	**915.1**
Total shareholders' equity and liabilities		**949.3**	**1,205.7**	**1,109.0**

CONSOLIDATED CHANGES IN SHAREHOLDERS' EQUITY

SEK m	2023 Mar 31	2022 Mar 31	2022 Dec 31
Opening balance, shareholders' equity	**193.9**	**349.6**	**349.6**
Total comprehensive earnings for the period	-64.7	-20.1	-155.5
Share-based payments	0.0	0.0	-0.1
Closing balance, shareholders' equity	**129.1**	**329.5**	**193.9**

CONDENSED CONSOLIDATED CASH FLOW STATEMENTS

SEK m	Notes	2023 Jan-Mar	2022 Jan-Mar	2022 Jan-Dec
Operating earnings (EBIT)		-59.3	-13.2	-183.9
Interest received		0.4	0.0	1.4
Interest paid		-7.7	-4.7	-22.4
Income taxes paid		-1.1	1.9	1.5
Adjustment for non-cash items	3	19.6	-6.8	-3.5
Cash flow from operating activities before changes in working capital		**-48.2**	**-22.8**	**-206.9**
Changes in working capital		**-13.4**	**-38.8**	**50.3**
Cash flow from operating activities		**-61.6**	**-61.6**	**-156.6**
Acquisition of tangible and intangible fixed assets		-0.8	-5.6	-23.9
Acquisition of short-term investments		—	—	-295.6
Disposal of short-term investments		83.9	—	84.0
Sales of tangible assets		—	—	0.8
Cash flow from investing activities		**83.1**	**-5.6**	**-234.7**
Repayment of loans		-7.8	-5.3	-21.4
Cash from financing activities		**-7.8**	**-5.3**	**-21.4**
Cash flow for the period		**13.7**	**-72.5**	**-412.8**
Cash and cash equivalents at the beginning of the period		**132.2**	**504.1**	**504.1**
Exchange-rate differences in cash and cash equivalents		-3.6	6.3	40.9
Changes in cash and cash equivalents		10.2	-66.3	-371.8
Cash and cash equivalents at the end of the period		**142.4**[1]	**437.8**	**132.2**[1]

[1] Cash and cash equivalents excluding invested surplus cash of SEK 142.4 m in short-term assets, certificates of deposits and in US treasuries. As of March 31, 2023, cash and invested funds amounted to SEK 278.9 m (437.8)

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 Jan-Mar	2022 Jan-Mar	2022 Jan-Dec
EBIT margin, %	-37.4	-8.3	-29.5
Return on shareholder equity, %	-39.6	-6.4	-65.4
Net debt, SEK m	210.2	55.2	142.9
Debt/equity ratio, %	378.9	149.6	255.2
Equity/assets ratio, %	13.6	27.3	17.5
Number of shares, before dilution	34,367,616	34,327,907	34,351,732
Number of shares, after dilution	34,367,616	34,327,907	34,351,732
Earnings per share, before dilution, SEK	-1.86	-0.69	-5.17
Earnings per share, after dilution, SEK	-1.86	-0.69	-5.17
Number of employees at the end of the period	122	123	126
Shareholders' equity, SEK m	129.1	329.5	193.9
Capital employed, SEK m	618.3	822.4	688.7
Working capital, SEK m	141.2	36.1	217.4

[2] Definitions and reconcilliations of key figures are presented on page 22 of this report

CONDENSED PARENT COMPANY STATEMENT OF OPERATIONS

SEK m	Notes	2023 Jan-Mar	2022 Jan-Mar	2022 Jan-Dec
Net revenues		135.2	52.0	348.2
Cost of goods sold		-33.8	-14.9	-72.4
Gross profit		**101.4**	**37.1**	**275.8**
Selling expenses		-30.4	-37.5	-165.1
Administrative expenses		-46.5	-20.1	-123.1
Research and development costs		-61.9	-60.7	-266.9
Other operating income and expenses		5.8	29.4	65.4
Operating earnings (EBIT)		**-31.6**	**-51.8**	**-213.9**
Interest income and expenses		-7.0	-4.7	-19.6
Other financial income and expenses		-2.0	4.2	36.7
Net financial items		**-9.0**	**-0.4**	**17.1**
Earnings before tax		**-40.6**	**-52.2**	**-196.8**
Tax	5	—	—	—
Earnings for the period		**-40.6**	**-52.2**	**-196.8**

PARENT COMPANY STATEMENT OF COMPREHENSIVE INCOME

SEK m	2023 Jan-Mar	2022 Jan-Mar	2022 Jan-Dec
Earnings for the period	**-40.6**	**-52.2**	**-196.8**
Other comprehensive income	—	—	—
Total comprehensive earnings for the period	**-40.6**	**-52.2**	**-196.8**

CONDENSED PARENT COMPANY BALANCE SHEET

SEK m	2023 Mar 31	2022 Mar 31	2022 Dec 31
ASSETS			
Fixed assets			
Intangible fixed assets	173.1	206.6	181.4
Tangible fixed assets	73.3	68.3	76.1
Shares in subsidiaries	160.6	160.6	161.2
Total fixed assets	**407.0**	**435.6**	**418.7**
Current assets			
Inventories	45.0	61.4	60.2
Accounts receivable and other receivables	167.2	69.3	159.0
Short-term investments	116.0	—	178.6
Cash and cash equivalents	68.4	400.0	61.7
Total current assets	**396.5**	**530.7**	**459.5**
Total assets	**803.6**	**966.3**	**878.2**
SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES			
Total shareholders' equity	**68.6**	**253.8**	**109.2**
Long-term liabilities			
Provisions	5.8	9.5	9.8
Bond loan	489.1	492.9	494.8
Total long-term liabilities	**494.9**	**502.4**	**504.5**
Current liabilities			
Accounts payable	26.8	18.1	32.0
Other liabilities	11.5	8.4	8.8
Liabilities to Group companies	173.6	158.7	184.3
Accrued expenses and deferred income	28.1	24.9	39.3
Total current liabilities	**240.0**	**210.1**	**264.5**
Total liabilities	**735.0**	**712.5**	**769.0**
Total shareholders' equity and liabilities	**803.6**	**966.3**	**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 Jan-Mar	2022 Jan-Mar	2022 Jan-Dec
US Pharma			
Net revenues	140.3	139.1	571.4
Operating earnings (EBIT)	74.3	84.0	308.4
Depreciation and amortization	-3.8	-3.8	-15.4
Digital Therapeutics			
Net revenues	0.0	0.2	0.4
Operating earnings (EBIT)	-36.4	-43.4	-189.1
Depreciation and amortization	-6.8	-5.7	-25.7
HQ & Pipeline			
Net revenues	18.5	20.1	52.6
Operating earnings (EBIT)	-97.2	-53.7	-303.2
Depreciation and amortization	-7.6	-6.5	-27.7
Group			
Net revenues	158.8	159.4	624.3
Operating earnings (EBIT)	-59.3	-13.2	-183.9
Depreciation and amortization	-18.2	-16.0	-68.7
Net financial items	-9.1	-1.9	13.5
Earnings before tax	-68.5	-15.1	-170.4

3. Cash flow

ADJUSTMENT FOR NON-CASH ITEMS

SEK m	2023 Jan-Mar	2022 Jan-Mar	2022 Jan-Dec
Depreciation/amortization and impairment	18.2	16.0	68.7
Realization results	—	—	-0.2
Change in provisions	2.4	-21.3	-64.9
Share based payments	0.0	0.0	-0.1
Exchange rate income and expenses	-1.0	-1.5	-7.0
Total	**19.6**	**-6.8**	**-3.4**

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 and in Q1 2023 some additional documentation have been shared at the request. 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 ("ANDA") with the US Food and Drug Administration (FDA) seeking approval of generic versions of ZUBSOLV® before the expiration of Orexo's patents listed in the Orange Book.

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 filing statutorily precludes FDA from approving Sun's ANDA for 30 months, or until a district court decision finds the patents to be invalid or not infringed, whichever occurs first.

Orexo has currently 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.

The trial was conducted in the beginning of the quarter followed by closing arguments at the end of the quarter. A decision from the District Court is expected during the summer of 2023.

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 non-interest bearing liabilities, current interest-bearing liabilities and long-term interest-bearing liabilities. The financial instruments held by the group are recognized at amortized cost using the effective interest method. The group does not hold any financial instruments which are reported at fair value. The fair value of financial instruments held at the balance sheet date is significantly the same as the book value.

7. Related parties

There were no significant related parties transactions during the period.

8. Important events after the period

› Due to issues in the outsourced packaging line FDA has requeated Orexo to resubmit the NDA, which is planned to take place in Q3, 2023

9. Revenue from contracts with customers

SEK m	2023 Jan-Mar					
Segment	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**vorvida®**	**deprexis®**	**Total**
US Pharma	140.3	—	—	—	—	**140.3**
Digital Therapeutics	—	—	—	0.0	0.0	**0.0**
HQ & Pipeline	10.9	6.2	1.3	—	—	**18.5**
Total revenue from contracts with customers	**151.2**	**6.2**	**1.3**	**0.0**	**0.0**	**158.8**
Geographical markets	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**vorvida®**	**deprexis®**	**Total**
US	140.3	—	0.7	0.0	0.0	**141.0**
EU & UK	10.9	6.1	0.1	—	—	**17.2**
Rest of the world	—	0.1	0.5	—	—	**0.7**
Total revenue from contracts with customers	**151.2**	**6.2**	**1.3**	**0.0**	**0.0**	**158.8**

SEK m	2022 Jan-Mar					
Segment	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**vorvida®**	**deprexis®**	**Total**
US Pharma	139.1	—	—	—	—	**139.1**
Digital Therapeutics	—	—	—	0.2	0.0	**0.2**
HQ & Pipeline	4.6	12.4	3.2	—	—	**20.1**
Total revenue from contracts with customers	**143.7**	**12.4**	**3.2**	**0.2**	**0.0**	**159.4**
Geographical markets	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**vorvida®**	**deprexis®**	**Total**
US	139.1	—	0.8	0.2	0.0	**140.1**
EU	4.6	12.1	1.0	—	—	**17.7**
Rest of the world	—	0.3	1.3	—	—	**1.6**
Total revenue from contracts with customers	**143.7**	**12.4**	**3.2**	**0.2**	**0.0**	159.4

SEK m	2022 Jan-Dec					
Segment	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**vorvida®**	**deprexis®**	**Total**
US Pharma	571.4	—	—	—	—	**571.4**
Digital Therapeutics	—	—	—	0.3	0.0	**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**	**0.0**	**624.3**
Geographical markets	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**vorvida®**	**deprexis®**	**Total**
US	571.4	—	2.5	0.3	0.0	**574.2**
EU & UK	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**	**0.0**	**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 profitability from sold products
Operating margin (EBIT margin)	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 Jan-Mar	2022 Jan-Mar	2022 Jan-Dec
EBIT	-59.3	-13.2	-183.9
Depreciation and amortization	18.2	16.0	68.7
EBITDA	**-41.1**	**2.8**	**-115.2**
External costs for clinical studies	19.7	21.7	96.4
IP litigation and subpoena	42.3	7.7	76.6
EBITDA excluding external costs for clinical studies. IP litigation and subpoena	**20.9**	**32.2**	**57.8**

CASH AND INVESTED FUNDS	2023 Jan-Mar	2022 Jan-Mar	2022 Jan-Dec
Short-term investments	136.5	—	219.6
Cash and cash equivalents	142.4	437.8	132.2
Cash and invested funds	**278.9**	**437.8**	**351.9**

RETURN ON SHAREHOLDERS' EQUITY	2023 Jan-Mar	2022 Jan-Mar	2022 Jan-Dec
Shareholders' equity beginning balance	193.9	411.7	349.6
Shareholders' equity ending balance	129.1	329.5	193.9
Average shareholders' equity	161.5	370.6	271.8
Net earnings	-63.9	-23.6	-177.6
Return on shareholders' equity %	**-39.6**	**-6.4**	**-65.4**

OPERATING EXPENSES SEK m	2023 Jan-Mar	2022 Jan-Mar	2022 Jan-Dec
Selling expenses	-45.5	-41.6	-199.0
Administrative expenses	-66.5	-33.0	-202.3
Research and development costs	-78.5	-72.0	-318.0
Other operating income and expenses	1.1	1.5	13.7
Operating expenses	**-189.4**	**-145.1**	**-705.6**

GROSS INVESTMENTS SEK m	2023 Jan-Mar	2022 Jan-Mar	2022 Jan-Dec
Investments in tangible fixed assets	0.1	4.0	18.8
Investments in intangible fixed assets	0.7	1.6	5.1
Gross investments	**0.8**	**5.6**	**23.9**

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