Q2 Interim Report 2022

Good tailwind in the financial development

Q2 2022 highlights

- Total net revenues of SEK 147.8 m (142.8)
- EBITDA of SEK -32.5 m (-41.1)
- Net earnings of SEK -35.8 m (-73.7)
- US Pharma segment (ZUBSOLV® US) net revenues of SEK 139.6 m (126.0), in local currency USD 14.2 m (15.0), US Pharma EBIT of SEK 77.2 m (61.6)
- Cash flow from operating activities of SEK 14.5 m (-20.9), cash and invested funds of SEK 467.7 m (679.7)
- Earnings per share before and after dilution amounted to -1.04 (-2.15)
- Christine Rankin and Michael J Matly were elected as Board members at the Annual General Meeting. They replace David Colpman and Kirsten Detrick who have declined re-election.
- Orexo´s partner Gesynta Pharma's drug candidate GS-248 (OX-MPI) granted Orphan Drug Designation in the US by the FDA for the treatment of systemic sclerosis

Important events after the period

- First clinical study initiated for OX640, a nasal adrenaline rescue medication for allergic reactions
- The digital therapy deprexis® reimbursed within the US Veterans Affairs Federal Supply Schedule
- Financial outlook 2022 reiterated

SEK 148 m
Group revenues

SEK 77 m
US Pharma EBIT

SEK 468 m
Cash and invested funds

SEK m, unless otherwise stated	2022 Apr-Jun	2021 Apr-Jun	2022 Jan-Jun	2021 Jan-Jun	% change	2021 Jan-Dec
Net revenues	147.8	142.8	307.3	275.1	3.5%	565.0
Cost of goods sold	-21.2	-18.1	-48.7	-37.4	17.5%	-78.9
Operating expenses	-176.4	-178.7	-321.5	-328.7	-1.3%	-700.2
EBIT	-49.7	-54.0	-62.9	-90.9	7.9%	-214.1
EBIT margin	-33.6%	-37.8%	-20.5%	-33.1%	4.2%	-37.9%
EBITDA	-32.5	-41.1	-29.7	-65.2	20.9%	-161.0
Earnings per share, before dilution, SEK	-1.04	-2.15	-1.73	-3.07	51.6%	-6.51
Earnings per share, after dilution, SEK	-1.04	-2.15	-1.73	-3.07	51.6%	-6.51
Cash flow from operating activities	14.5	-20.9	-47.1	-68.7	169.5%	-229.0
Cash and invested funds	467.7	679.7	467.7	679.7	-31.2%	504.1

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 2021.

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 2021 amounted to SEK 565 million and the number of employees was 123. Orexo is listed on the Nasdaq Stockholm Mid Cap (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.

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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, Joseph DeFeo, CFO, and Dennis Urbaniak, SVP Digital Therapeutics, will present the report and host a Q&A.

Please view the instructions below on how to participate.
Internet: https://tv.streamfabriken.com/orexo-q2-2022
Telephone: SE: +46 8 56 64 27 04 UK: +44 33 33 00 92 63 US: +1 64 67 22 49 56
Prior to the call presentation material will be available on Orexo´s website Investors/Reports, presentations, audiocasts.

Financial calendar
Interim Report Q3 2022 - November 3, 2022 at 8.00 am CET
Full Year Report 2022, incl. Q4 - January 26, 2023 at 8.00 am CET
Interim Report Q1 2023 - April 27, 2023 at 8.00 am CET
Interim Report Q2 2023 - July 18, 2023 at 8.00 am CET

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

A leader in providing new innovative treatment solutions for patients suffering from opioid dependence

I am pleased to report ZUBSOLV® demand fully stabilized versus Q1, contributing to an improved development for our main business, US Pharma. Comparing to last year US Pharma net revenues increased by 11 percent driven by a strong USD and a favorable payer mix, offsetting a negative development in ZUBSOLV® demand. With a significant exposure to the US dollar also in our expenses, I am particularly pleased to see a continued improved EBITDA compared to last year, which supports an increase in our cash position of 30 million. The financial development should be seen in the light of our continued investment in future growth drivers, in particular the finalizing of OX124, our opioid overdose rescue medication, for registration in the US later this year. Additionally, we are launching and in parallel running a large clinical trial for MODIA®, our digital therapy for opioid use disorder (OUD), also in the US. These investments are all important elements in a comprehensive solution to improve access to treatment and outcome for patients suffering from OUD.

Improving treatment of opioid use disorder
Orexo is a leading provider of treatment for OUD patients and our core mission during the last ten years has been to strive to improve the treatment outcome and survival of patients suffering from OUD. ZUBSOLV® has been an important contribution to the drug treatment choice for patients, but many patients in the US have limited access to psychological support and therapy. With the development of the digital therapy MODIA®, Orexo is now able to offer two unique treatment options to support OUD patients which are both central elements of medication assisted treatment (MAT). I am pleased to see how MODIA® is positively impacting our access to waivered healthcare providers as they are open to dialogue about new OUD treatment options, and we have more than 50 percent improved access to these healthcare providers when including both MODIA® and ZUBSOLV® in the dialogue compared to solely focusing on medication. Together with a good start in NY Medicaid, where ZUBSOLV® gained reimbursement as of late March, growing 22 percent versus Q1, I expect this to continue to have a growing positive impact on our sales in H2 and the coming years.

Our ambition is to have a dialogue with larger healthcare providers and payers on how we can improve patient access to MAT through a concept of treatment around medication and digital therapy. We aim to utilize our extensive customer network to establish more efficient treatment programs among waivered physicians and providers of OUD counselling to enable them to potentially reach many more patients than possible using traditional OUD methods. We are also talking to states and municipalities who are seeking a solution to expand treatment of OUD using MAT. Orexo's proprietary OUD product offerings have a unique opportunity to collaborate with multiple entities, e.g., health care professionals, states, municipalities, to offer new and innovative treatment options for their patient populations. These processes are slow, due to their disruptive nature, but Orexo is well placed to play a leading role in developing a new approach to treatment in the US. The most important element in this new business concept is MODIA® and to create an awareness and comfort among physicians and patients about the clinical effect of digital therapeutics on OUD patients.

I am pleased to report about 500 patients have received MODIA® during the quarter as part of our modiaONE test program. The MODIA® randomized clinical trial, which is designed to show a reduction of illicit drug use in OUD patients, is making good progress, but, like many clinical trials during this time, patient enrollment has been negatively impacted by Covid-19 and we now expect the last patient to be recruited in the fourth quarter.

The opioid crisis in the US is worsening due to record high overdose deaths fueled primarily by the prevalence of illicit fentanyl. Our pharmaceutical candidate OX124 is designed to reverse the effect of the most powerful synthetic opioids, such as fentanyl, and will provide us the opportunity to participate in reducing the rising overdose death toll. OX124 will be another important product in the portfolio in our ambitions of providing a comprehensive range of treatment options for OUD. I am pleased to report we are continuing to make good progress towards filing with the FDA in the fourth quarter.

Deprexis® reimbursed by US Veterans Affairs
I am delighted to highlight the great news we shared yesterday about deprexis® being granted reimbursement by the US Veterans Affairs. It is a true milestone as it is the first payer providing nationwide access to one of our digital therapies providing us with a huge potential to reach out to million veterans and their family members suffering from depression. We have been granted a 10-year contract and we expect the first patients to be treated in late 2022.

I am also pleased to report the first patients have been identified to receive vorvida® or deprexis® through Trinity Health in North Dakota (ND). This follows the final implementation of the necessary administrative procedures and when the reimbursement pathway is confirmed, it will be a major step forward to expand the concept to other healthcare provider. This is a major milestone for Orexo since the reimbursement pathway and collaboration set up at Trinity Health ND is the concept we will expand to other healthcare providers. The process with Trinity Health has been a true innovation process where Orexo has developed proprietary solutions to solve the administrative and operational issues identified by Trinity Health during the process. The main objective is to ensure Orexo has an efficient process and system in place to manage the requirements of the health care provider (Trinity Health) to receive reimbursement through a collaborative care model. We are now monitoring the reimbursement claims of the first patients being processed and paid by the insurance companies. With the expected successful outcome Trinity Health is ready to expand these programs across their network in ND and in collaboration with Orexo make pro-active outreach to patients to make them aware of the new innovative treatment offering.

With the progress from Trinity Health, we will now fully focus our commercial resources on larger healthcare providers for these products. The return on investment from working directly to consumers and even employers has not been attractive and any activities towards these customers will be nearly solely through partners, such as Sober Grid, Walgreens and Justmiine. The total Digital Therapeutics expenses are expected to remain at current level in the second half of 2022, but with the majority associated with the MODIA® commercial launch and more than half of the total expenses being shared expenses with US Pharma due to the synergies between ZUBSOLV® and MODIA®.

R&D – OX124 the trigger of serendipity
Many great innovations are results of unexpected findings and our amorphOX® platform is in this category. The technology was designed to improve speed of absorption of naloxone and nalmefene in the development of the opioid overdose rescue medications OX124 and OX125. When reading the ordinary stability data, we got extraordinary results. These results led to broader testing of our technology along with other molecules where significant drug formulation issues existed.

One good example is epinephrine, which is a molecule known to be inherently instable. As the data coming out from the stability studies were excellent we initiated the OX640 project, which is outside our core focus on OUD and mental illness but where the product profile is truly differentiating and has the potential to revolutionize the treatment of allergic reactions, including anaphylaxis. During the quarter we have prepared the first clinical trial of OX640, and I am pleased to report the first test persons received the product in the first week of July. OX640 is in a disease space where Orexo is not commercially present, and the plan is to find a partner who can work with us during the development program and commercialization.

Summary and outlook
The second quarter we continued to solidify our financial position, with positive cash flow and reduced profit loss. 2022, remain an investment year and non-recurring expenses in 2022 fully explain the negative result. We reiterate our guidance for the year, despite we expect to see increased legal expenses in the second half of 2022 as the litigation process against Sun Pharmaceuticals is now scheduled in November, which is earlier than anticipated. However, the outcome of the trial is still expected late in Q1 or early Q2 in 2023.

We are looking forward to an exciting second half of 2022. A period when we expect ZUBSOLV® to grow versus H1, Trinity Health ND to implement vorvida® and deprexis® across their network, new partnerships arising from the combination of ZUBSOLV® and MODIA® and we look forward to the data from the OX640 study.

I wish all of you a good summer.

Uppsala, Sweden, July 14, 2022

Nikolaj Sørensen
President and CEO

Business update

US Pharma

zubsolv

ZUBSOLV® - sublingual tablet for treatment of opioid use disorder

The ZUBSOLV® business is divided into three distinct segments[1] with partly opposing drivers.

1. Open
2. Non-reimbursed
3. United Health Group (UHG) and Humana

ZUBSOLV´s sales development is most reliant on the open segment[1], where ZUBSOLV® demand comparing to the previous period has grown.

The overall market growth was 2 percent versus Q1 2022. The quarterly year over year growth amounted to 5 percent. This slowdown from previous double-digit growth can be attributed to limited access to treatment during Covid-19. The pandemic has and continues to impact access to care thereby advancing the scourge of the opioid epidemic driving the number of fatal overdoses to record-high levels. As the Covid-19 pandemic wanes it is expected that the buprenorphine/naloxone market growth will be positively impacted by multiple initiatives underway to improve access to medication assisted treatment.

The recently passed New York State MAT Open Access law was implemented by all Medicaid plans in the state on March 22, 2022. This law requires all Medicaid plans reimburse all MAT products including ZUBSOLV® as preferred without any restrictions. Similar legislation was previously passed in Kentucky in 2021. New York State and Kentucky are the second and fourth, respectively, largest volume Medicaid states in this treatment area creating an important treatment growth opportunity. ZUBSOLV® New York State Medicaid volume has grown 22 percent in Q2 2022 over Q1 2022. ZUBSOLV® Kentucky Medicaid volume has grown 18 percent in Q2 2022 over Q1 2022.

ZUBSOLV's Q2 2022 overall prescription volume is flat versus Q1 2022. Our core segment, the open segment, grew 1 percent versus Q1 2022. Within the open segment, Medicaid (the largest market segment) grew 2 percent, while Commercial and Medicare volume was flat. Our two largest Open Commercial (CVS Caremark and ESI) and Open Medicaid payers (Maryland and Michigan) grew 1 percent versus Q1 2022.

ZUBSOLV® non-reimbursed volume grew 1 percent, while combined Humana and UHG volume declined 2 percent. In recent weeks Humana and UHG volumes have been flattening.

On a year over year basis, Q2 2022 compared to Q2 2021 ZUBSOLV® demand declined 11 percent. This is mainly due to the continued impact from addition of generics to the formulary status at Humana and United Health Group and lack of strong market growth.

ZUBSOLV® overall sales force activities continue to be impacted by the Covid-19 pandemic versus pre-pandemic activity. The number of calls per day and the amount of direct time the sales representatives have in front of the physician and healthcare providers are less than the pre-Covid period. This impact is industry wide in the US. Q2 2022 saw a decrease in access to prescribers versus Q1 2022. ZUBSOLV® is the only actively promoted daily treatment and less access to physicians has a disproportional effect on ZUBSOLV® compared to generic competitors.

ZUBSOLV's market access in the public payer segment maintained at 48 percent of patients having unrestricted access to ZUBSOLV®. ZUBSOLV's best in class market access in the Commercial payer segment maintained at 98 percent.

Digital Therapeutics

VORV!DA® deprexis® modia

Vorvida® – digital therapy for heavy alcohol misuse
Deprexis® – digital therapy for managing symptoms of depression
MODIA® – digital therapy for opioid use disorder

The main priority to establish a long-term viable business and ensure patients get access to clinically validated digital therapies, is access to reimbursement. In Q1 several advances were made on a federal policy driven opportunities to establish a reimbursement pathway. However, Orexo has continued to work intensively to leverage existing reimbursement pathways to accelerate the development. A major milestone was met in the end of Q2, when Trinity Health (North Dakota) started the process to initiate the first patients on vorvida® and deprexis®. Together with Trinity Health we have established a system to secure reimbursement of vorvida® and deprexis® when integrated into a collaborative care model, involving both the primary care physicians, continuous monitoring of patient progress and oversight of a psychiatrist of the program.

[1] Open, where ZUBSOLV® is reimbursed and competes on equal terms with both branded products and/or generics. Non-reimbursed – formulary lists where ZUBSOLV® is not reimbursed. UHG and Humana - formulary lists where ZUBSOLV® had an exclusive position until 2019 when generics were added to the lists.

The partnership with Trinity Health will also be a test of our proprietary system and processes developed to support health care providers managing the documentation of patient progress and utilization of the digital therapy required under the collaborative care model by the payers. The system and processes are easily scalable and when proven to work as intended with Trinity Health, implementation with other large healthcare providers will be significantly easier.

With the progress at Trinity Health, interest from similar networks of health care providers and access to reimbursement, we have made the decision to focus our efforts on networks of healthcare providers and minimize our own activities to consumers and employers for vorvida® and deprexis®. The implication of this is a significant reduction in expenses related to vorvida® and deprexis®, and some restructuring of the organization. Future increases in expenses for these products will be associated with confirmed access to reimbursement and be directed to material and campaigns led by the partners to their customers. In Q2, the total vorvida® and deprexis® accounted for less the 50 percent of the DTx related commercial expenses, compared to nearly all during 2021.

The majority of our DTx expenses in Q2 have been related to the launch of MODIA® and the early access program modiaONE, which is a free trial program for a few patients offered to interested physicians. During the launch of MODIA® nearly all US Pharma sales representatives promote modiaONE to their ZUBSOLV customers.
A selected group of modiaONE customers are now in process of testing established reimbursement pathways. When reimbursement has been confirmed the modiaONE program will convert into commercialization of MODIA®, which is expected during H2 2022 in some selected states in the US with favorable reimbursement opportunities. In parallel with the commercial launch of MODIA® we are in the final stages of recruiting patients for the MODIA® trial (400 patients for 6 months). The recruitment has been negatively affected by Covid-19 and while we are mitigating some of the slow recruitment in 2021 and Q1 2022, the final patient recruited is now expected Q4.

Through Q2 2022, the Orexo DTx portfolio now has over 2410 patients across early access commercial programs and clinical trials. During Q2 the launch of modiaONE, our early access program for MODIA®, have seen more than 500 patients started on therapy and in total more than 650 patients since the start of the program in late February. Generally, with good feedback from patients and healthcare professionals.

HQ & Pipeline

amorphOX® – a new proprietary drug delivery platform

Orexo's proprietary drug delivery platform, amorphOX®, is a powder made up of particles which are built using a unique combination of a drug, carrier materials and, optionally, 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 and has been validated in several human clinical studies showing rapid and extensive drug exposure.

The commercial supply chain has been established for Orexo´s fully developed pharmaceutical candidate OX124. This will contribute to shorter timelines, reduce costs, and limit risks in the development of future products based on the amorphOX® platform using nasal delivery, today including OX125 and OX640. Development of products based on the technology will be conducted by Orexo or in partnership with other pharmaceutical companies.

Several patent applications directed to amorphOX® have been filed, which should serve to protect the technology until 2042.

OX124 – naloxone opioid overdose rescue medication based on amorphOX® - the most advanced pharma candidate

Progress during the quarter
In Q2 focus was directed to NDA preparations. To secure a smooth application process a pre-NDA meeting was conducted with FDA. Furthermore, the work continued with conducting the stability and usability studies. Data from these studies will along with the successful data from the pivotal trial, OX124-002, be the primary support to get the pharmaceutical approved in the US. The NDA application is expected to be filed in the end of 2022.

Project in brief
Based on the proprietary drug delivery platform, amorphOX®, Orexo has developed a high-dose rescue medication, OX124, designed to reverse opioid overdoses, including those from highly potent synthetic opioids. OX124 has shown more rapid absorption, substantially higher plasma concentrations of naloxone, and sustained duration of elevated plasma concentrations when compared to the current market leader.

The US overdose medication market
Orexo is targeting a market for overdose rescue medications today amounting to more than USD 450 million. The market is expected to continue growing, not only as an effect of the record-high level of fatal overdoses but also as multiple federal initiatives are

ongoing to expand access to life-saving naloxone medications. Examples include mandatory co-prescription legislation when patients are being treated for pain and standing orders at the pharmacy. According to Orexo´s estimates, the market size could reach a level of USD 1.5 – 2 billion if this mandatory co-prescription legislation is implemented nationwide and the pricing in the market is sustained at current levels. Today, the market is fully dominated by low-dose products including three generic versions of the branded market leader which have been launched with a price nearly in line with the branded product.

Commercialization and intellectual properties
A launch of OX124 in the US is planned to be initiated in late 2023. With a significant rise among people in the US that are overdosing, due to increased misuse of highly potent synthetic opioids, such as fentanyl, the need for new and more powerful rescue medications has never been greater.[1] With an own sales force in the US, covering most States, and with significant experience from treating patients suffering from opioid dependence, Orexo will be well positioned to compete on a market about to transform to offering high-dose products. With the current pricing and the market reaching its full potential, product net sales of OX124 in the US market could be in the range of USD 70-110 million.

OX124 has patents protecting the product until 2039.

OX125 – nalmefene opioid overdose rescue medication based on amorphOX®

Progress during the quarter
The synergies between OX124 and OX125 are comprehensive. Most of the current development activities for OX124 are also applicable to OX125. During the quarter, assessment of data relating to ongoing stability studies has continued.

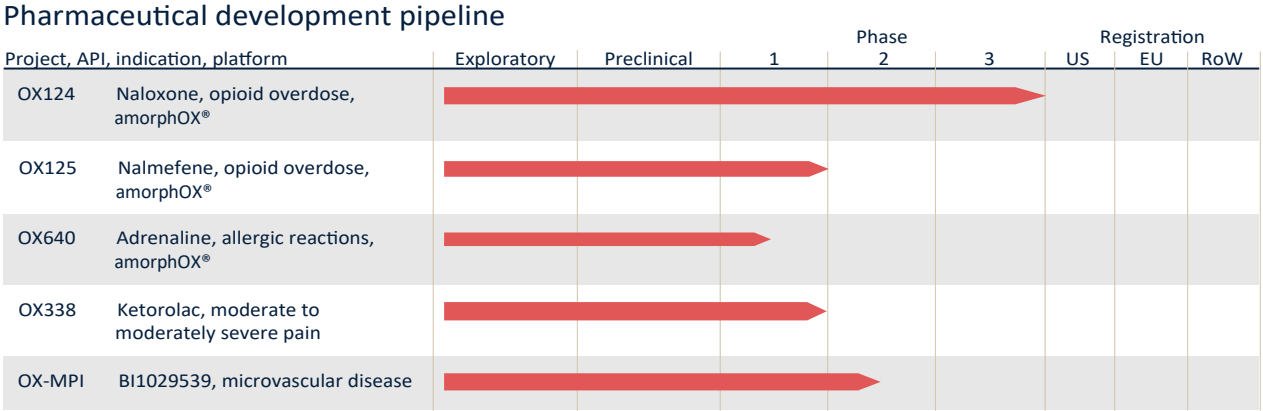
In parallel, the increasing prevalence of new synthetic opioids and its impact on societies globally are being closely monitored. OX125 could meet an unmet medical need for an overdose medication, which in addition to having a rapid absorption and being powerful, also remains in the body for a much longer time.

Project in brief
The widespread use of synthetic opioids, such as fentanyl, also increases the need for rescue medicines 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.

OX125 is built on the amorphOX® platform and its performance has been proven in an exploratory PK study in healthy volunteers which showed extensive and rapid absorption of nalmefene across all formulations included in the trial. The market potential for OX125 is highly dependent on the general guidelines of opioid overdose rescue medications in the US and whether nalmefene will become the primary API or naloxone will continue as the first line treatment. Assuming a market development as described above under OX124 and nalmefene staying a complement to naloxone, the potential net sales could be in the range of USD 40-60 million in the US market.

The innovative OX125 product has patent protection until 2039.

Pharmaceutical development pipeline



[1] According to Center fo Disease Control 75% of fatal overdoses were caused by opioids and within the opioid related deaths synthetic opioids accounted for 86%.

OX338 – acute moderate to moderately severe pain

Progress during the quarter
As all R&D resources currently are prioritised to further develop the amorphOX® platform, including OX124, OX125 and OX640, no activities were performed.

Project in brief
OX338 is based on Orexo's novel oral formulation technology to develop an opioid-level pain relief treatment for short-term pain (up to 5 days) without the risk of addiction. Results from the earlier conducted exploratory PK study showed a significantly better PK profile with faster uptake and higher peak when compared to available nasal sprays on the market. Net sales are estimated to be more than USD 100 million in the US market.

OX640 – adrenaline rescue medication based on amorphOX®

Progress during the quarter
In Q2 work was conducted to prepare for the first clinical study which was initiated on July 4, 2022. The study aims to determine the relative bioavailability and absorption characteristics of investigational OX640 formulations versus an intramuscular adrenaline injection in healthy volunteers. Study data are expected in late 2022.

Project in brief
The aim with OX640 is to develop a nasal adrenaline product for the emergency treatment of allergic reactions. Adrenaline is commonly used for the emergency treatment of allergic reactions, including anaphylaxis. Adrenaline is a very unstable active ingredient sensitive to chemical degradation, which is the reason why today's commercial adrenaline products have limited shelf-life with restrictive storage conditions.

OX640 is based on Orexo's proprietary drug delivery platform 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 adrenaline product that provides greater flexibility in relation to how it can be handled and stored should provide significant benefits to patients and healthcare systems, ensuring the correct adrenaline dose is available when needed.

OX-MPI – microvascular diseases

Progress during the quarter
Orexo´s partner Gesynta Pharma which owns all the rights to OX-MPI, a drug candidate for the treatment of systemic sclerosis, was granted Orphan Drug Designation (ODD) in the US by the FDA. ODD is intended to encourage the development of drugs for the treatment of rare diseases. This exclusive classification provides up to seven years of market exclusivity and also gives some financial benefits during the development phase. If approved, Orexo will receive a tiered double-digit share of future revenues.
In parallel as being granted ODD the ongoing clinical phase 2 study continued. Data are expected in H2 2022.

Project in brief
Several severe microvascular complications face few or no approved pharmacological treatment options. Orexo´s partner Gesynta Pharma, which owns all the rights to OX-MPI (GS248), aims to develop a treatment that is more effective and/or safer than currently approved treatments for microvascular diseases in chronic inflammatory conditions.

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

In Q2 Orexo´s partner Accord Healthcare continued to build up inventories on multiple EU markets, such as Spain, France, UK, Sweden, Denmark, Norway, the Czech Republic, Romania, and the Baltic states. In June the first patients were treated with ZUBSOLV® in both Spain and Sweden.

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 are 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,[1] yet treatment rates are low. Approximately 50 percent of people with opioid dependence are receiving some form of substitution treatment across Europe, although this varies greatly between countries.[2]

[1] European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)
[2] EMCDDA – Tackling Opioid Dependence

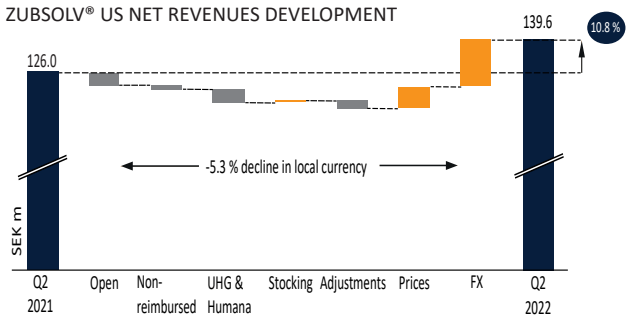
Financial overview

Revenues

Total revenues amounted to SEK 147.8 m (142.8) for Q2 and to SEK 307.3 m (275.1) for H1. The increase is mainly explained by higher US Pharma revenues.

Revenues by segment

US Pharma revenues amounted to SEK 139.6 m (126.0) for Q2. The increase in US Pharma revenues is mainly driven by stronger USD exchange rate and favorable payer mix. This was partly offset by lower ZUBSOLV® demand due to competition in previously exclusive plans and a weaker overall market growth pace due to Covid-19.



In local currency US Pharma net revenues for Q2 amounted to USD 14.2 m (15.0). Net revenues decreased by USD 0.6 m vs Q1 2022 mainly due to higher wholesaler destocking and absence of positive return adjustment while demand increased moderately. US Pharma revenue for H1 amounted to SEK 278.7 m (252.8).

Digital Therapeutics (DTx) recognized net revenues for Q2 amounted to SEK 0.1 m (0.3) and to SEK 0.3 m (0.4) for H1. Sales efforts during the quarter have focused on piloting different reimbursement pathways and commercial concepts.

HQ & Pipeline partner product related revenues for Q2 amounted to SEK 8.1 m (16.5). The decrease is explained by absence of a positive adjustment for Abstral® royalty from prior period partly offset by sales of ZUBSOLV® in the EU to Accord Healthcare, where the first sales also triggered a minor milestone. HQ & Pipeline partner product related revenues for H1 amounted to SEK 28.3 m (21.9).

Costs of goods sold

Cost of goods sold (COGS) amounted to SEK 21.2 m (18.1) for Q2. US Pharma amounted to SEK 17.7 m (15.4) mainly due to unfavorable exchange-rate impact vs prior year partly offset by positive production variances. Royalty and technical infrastructure costs for DTx amounted to SEK 2.7 m (2.6). HQ & Pipeline amounted to to SEK 0.8 m (-) for ZUBSOLV® ex-US sales in the EU by Orexo's partner Accord Healthcare. Cost of goods sold (COGS) for H1 amounted to SEK 48.7 m (37.4).

Operating expenses

Selling expenses amounted to SEK 50.5 m (61.8) for Q2. The decrease over the same period last year is mainly explained by lower selling expenses in DTx and synergies between US Pharma and DTx, offsetting the negative impact of stronger USD exchange rate. Selling expenses amounted to SEK 92.1 m (130.4) for H1.

Administrative expenses amounted to SEK 51.2 m (41.4) for Q2 and to SEK 84.3 m (70.0) for H1. The increase is mainly explained by higher legal expenses for IP litigation and the ongoing global ERP project, a new platform for finance and supply chain management.

Research and development costs amounted to SEK 81.3 m (73.2) for Q2. The increase is mainly explained by costs related to MODIA® study and to OX640 development project. Research and development costs for H1 amounted to SEK 153.3 m (128.8).

NET REVENUES AND OPERATING EARNINGS PER SEGMENT

SEK m	Net Revenues					EBIT				
	2022 Apr-Jun	2021 Apr-Jun	2022 Jan-Jun	2021 Jan-Jun	2021 Jan-Dec	2022 Apr-Jun	2021 Apr-Jun	2022 Jan-Jun	2021 Jan-Jun	2021 Jan-Dec
ZUBSOLV® US product sales	139.6	126.0	278.7	252.8	522.7	—	—	—	—	—
US Pharma – total	**139.6**	**126.0**	**278.7**	**252.8**	**522.7**	**77.2**	**61.6**	**161.2**	**127.7**	**278.2**
Digital Therapeutics (DTx) product sales	0.1	0.3	0.3	0.4	1.1	—	—	—	—	—
Digital Therapeutics (DTx) – total	**0.1**	**0.3**	**0.3**	**0.4**	**1.1**	**-47.9**	**-51.6**	**-91.3**	**-110.5**	**-249.7**
Abstral® royalty	5.0	14.3	17.4	17.0	32.1	—	—	—	—	—
Edluar® royalty	1.6	2.3	4.8	4.9	9.1	—	—	—	—	—
ZUBSOLV® - ex US	1.5	—	6.1	—	—	—	—	—	—	—
HQ & Pipeline segment – total	**8.1**	**16.5**	**28.3**	**21.9**	**41.2**	**-79.1**	**-63.9**	**-132.9**	**-108.2**	**-242.6**
Total	**147.8**	**142.8**	**307.3**	**275.1**	**565.0**	**-49.7**	**-54.0**	**-62.9**	**-90.9**	**-214.1**

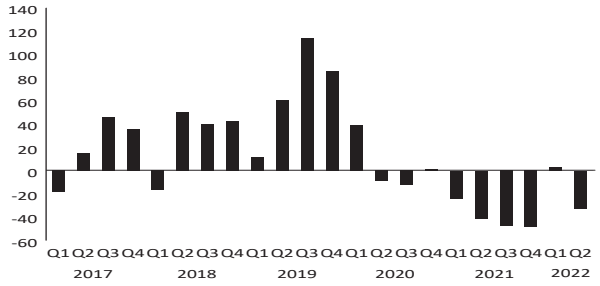
Other operating income and expenses amounted to SEK 6.7 m (-2.4) for Q2, mainly explained by exchange-rate gains derived from revaluations of parent company balance sheet items in foreign currency, predominantly in USD. Other operating income and expenses for H1 amounted to SEK 8.2 m (0.6).

Operating profit

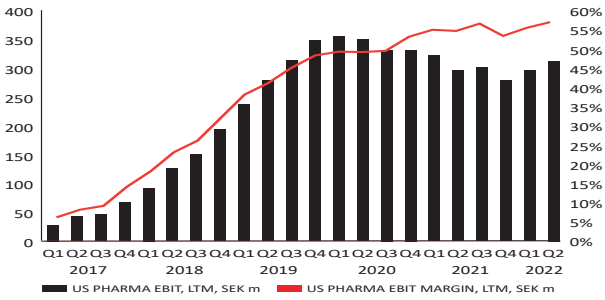
EBITDA amounted to SEK -32.5 m (-41.1) for Q2 and reflects foremost lower operating costs for US Pharma and DTx and higher gross profit. EBITDA amounted to SEK -29.7 m (-65.2) for H1.

The EBIT contribution from US Pharma amounted to SEK 77.2 m (61.6) for Q2, equal to an EBIT margin of 55.3 percent (48.9). H1 EBIT contribution from US Pharma amounted to SEK 161.2 m (127.7), equal to an EBIT margin of 57.8 percent (50.5).

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 Q2 amounted to SEK 12.3 m (-10.8) and is mainly explained by positive unrealized exchange rate impact of SEK 18.1 m (-5.2) derived from the parent company's foreign currency bank accounts mainly in USD and by earned interest on short-term investments of SEK 0.4 m (-), partly offset by higher costs for corporate bonds of SEK 5.6 m (5.0). Net financial items amounted to SEK 10.4 m (-6.2) for H1.

Total tax expenses amounted to SEK 1.7 m (-8.9) for Q2. The decrease is explained by positive adjustment to deferred tax assets related to temporary differences. Total tax expenses amounted to SEK -6.8 m (-8.3) for H1. Orexo performs regular assessments of its deferred tax asset and makes adjustments according to the recognition requirements of IAS 12.

Net earnings

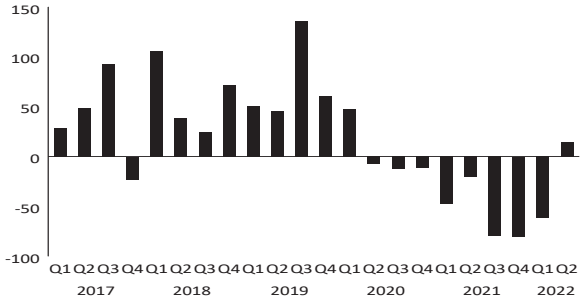
Net earnings amounted to SEK -35.8 m (-73.7) for Q2 and to SEK -59.4 (-105.4) for H1.

Cash and cash flow

During the quarter the company invested surplus cash in certificates of deposits and in US treasuries. Deposits with 3 months maturity are recorded as cash equivalents and deposits with maturity from 6 months to 12 months are recorded as short-term investments. As of June 30, 2022, cash and invested funds amounted to SEK 467.7 m (679.7) and interest-bearing liabilities to SEK 493.5 m (491.1), i.e. a negative net cash position including short-term investments of SEK -25.9 m (453.4).

Cash flow from operating activities amounted to SEK 14.5 m (-20.9) for Q2 and was primarily impacted by positive changes in working capital due to increased current liabilities and to a lesser extent from negative operating earnings. Cash flow from operating activities amounted to SEK -47.1 m (-68.7) for H1.

CASH FLOW FROM OPERATING ACTIVITIES, SEK m



[1] Last Twelve Months

Investments
Gross investments in tangible and intangible fixed assets amounted to SEK 4.5 m (13.1) for Q2 and to SEK 10.1 m (29.3) for H1. Lower investment is mainly explained by investments in the DTx enterprise platform and in equipment for the development organization.

Equity
Shareholders' equity at June 30, 2022, was SEK 308.9 m (459.4). The equity/asset ratio was 24.3 percent (34.2).

Parent company
Net revenues for Q2 amounted to SEK 103.8 m (45.5) of which SEK 95.6 m (29.0) was related to sales to Group companies. H1 net revenues amounted to SEK 155.8 m (135.0) of which SEK 127.5 m (113.1) was related to sales to Group companies.

Earnings before tax amounted to SEK -26.0 m (-105.1) for Q2 and to SEK -78.3 m (-130.6) for H1. The increase is mainly explained by higher gross profit and higher other operating income. Investments in equipment for the development organization for Q2 amounted to SEK 3.5 m (5.6) and to SEK 7.5 m (13.8) for H1.

As of June 30, 2022, cash and cash equivalents in the parent company amounted to SEK 177.9 m (568.6) and short-term investments amounted to SEK 183.5 m (-) i.e. companys cash and invested funds amounted to SEK 361.4 m (568.6).

Other information

Financial outlook 2022
- Due to the continuing pandemic the buprenorphine/naloxone market will show a growth pace in line with 2021, and reach a level of 5-8 percent
- In H2 ZUBSOLV® net sales in USD will increase comparing to H1
- OPEX will decline from 2021 to SEK 650-700 m with the current business plans and activity level in legal processes
- US Pharma EBIT will exceed 50 percent on a full year basis

With the Covid-19 pandemic continuing, the financial outlook is associated with increased uncertainties. All numbers are based on exchange rates in June 2022.

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.

Audit
This Report has not been reviewed by the company´s auditors.

Risks and uncertainty factors
Significant risks and uncertainties are presented in the Annual Report for 2021 and in the Interim Report Note 4, litigations. The continued commercialization of ZUBSOLV® entails risk exposure of an operational nature and Orexo is continuously exposed to risks in relation to development projects and the intellectual property rights. The Covid-19 pandemic has increased the uncertainty about the market and sales development.

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

Uppsala, Sweden, July 14, 2022

Nikolaj Sørensen
President and CEO

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 14, 2022
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 & CEO

Financial reports, notes and key figures

CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS

SEK m	Notes	2022 Apr-Jun	2021 Apr-Jun	2022 Jan-Jun	2021 Jan-Jun	2021 Jan-Dec
Net revenues	9	147.8	142.8	307.3	275.1	565.0
Cost of goods sold		-21.2	-18.1	-48.7	-37.4	-78.9
Gross profit		**126.6**	**124.8**	**258.5**	**237.7**	**486.1**
Selling expenses		-50.5	-61.8	-92.1	-130.4	-280.4
Administrative expenses		-51.2	-41.4	-84.3	-70.0	-151.5
Research and development expenses		-81.3	-73.2	-153.3	-128.8	-272.3
Other operating income and expenses		6.7	-2.4	8.2	0.6	4.0
Operating earnings (EBIT)		**-49.7**	**-54.0**	**-62.9**	**-90.9**	**-214.1**
Net financial items		12.3	-10.8	10.4	-6.2	-8.4
Earnings before tax		**-37.4**	**-64.8**	**-52.5**	**-97.1**	**-222.5**
Tax	5	1.7	-8.9	-6.8	-8.3	-1.0
Net earnings for the period[1]		**-35.8**	**-73.7**	**-59.4**	**-105.4**	**-223.5**
Earnings per share, before dilution, SEK		-1.04	-2.15	-1.73	-3.07	-6.51
Earnings per share, after dilution, SEK		-1.04	-2.15	-1.73	-3.07	-6.51

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

SEK m	2022 Apr-Jun	2021 Apr-Jun	2022 Jan-Jun	2021 Jan-Jun	2021 Jan-Dec
Earnings for the period	**-35.8**	**-73.7**	**-59.4**	**-105.4**	**-223.5**
Other comprehensive income	—	—	—	—	—
Items that may subsequently be reversed to the statement of operations:					
Exchange-rate differences	15.2	-3.1	18.7	4.8	13.0
Other comprehensive earnings for the period, net after tax	**15.2**	**-3.1**	**18.7**	**4.8**	**13.0**
Total comprehensive earnings for the period[1]	**-20.6**	**-76.8**	**-40.7**	**-100.6**	**-210.5**

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

CONDENSED CONSOLIDATED BALANCE SHEET

SEK m	Notes	2022 Jun 30	2021 Jun 30	2021 Dec 31
ASSETS				
Fixed assets				
Tangible fixed assets		70.1	59.7	65.9
Intangible fixed assets		235.5	250.7	248.9
Right-of-use assets		51.5	64.6	59.2
Deferred tax assets	5	31.0	25.2	33.4
Other financial assets		0.9	0.7	0.8
Total fixed assets		**389.0**	**401.0**	**408.2**
Current assets				
Inventories		84.4	95.7	92.3
Accounts receivable and other receivables		329.9	168.5	269.2
Short-term investments		223.5	—	—
Cash and cash equivalents		244.2	679.7	504.1
Total current assets		**882.0**	**943.9**	**865.5**
Total assets		**1,271.0**	**1,344.9**	**1,273.7**
SHAREHOLDERS' EQUITY AND LIABILITIES				
Total shareholders' equity		**308.9**	**459.4**	**349.6**
Long-term liabilities				
Provisions		7.3	10.4	13.5
Long-term liabilities, interest bearing		493.5	491.1	492.3
Lease liabilities, long-term		30.2	43.6	38.0
Total long-term liabilities		**531.1**	**545.1**	**543.9**
Current liabilities and provisions				
Provisions		161.3	174.3	160.1
Current liabilities, non-interest bearing		249.3	146.3	199.9
Lease liabilities, current		20.6	19.8	20.2
Total current liabilities and provisions		**431.1**	**340.3**	**380.2**
Total liabilities		**962.2**	**885.4**	**924.1**
Total shareholders' equity and liabilities		**1,271.0**	**1,344.9**	**1,273.7**

CONSOLIDATED CHANGES IN SHAREHOLDERS' EQUITY

SEK m	2022 Jun 30	2021 Jun 30	2021 Dec 31
Opening balance, shareholders' equity	**349.6**	**558.5**	**558.5**
Total comprehensive earnings for the period	-40.7	-100.6	-210.5
Share-based payments	-0.1	1.6	1.5
Closing balance, shareholders' equity	**308.9**	**459.4**	**349.6**

CONDENSED CONSOLIDATED CASH FLOW STATEMENTS

SEK m	Notes	2022 Apr-Jun	2021 Apr-Jun	2022 Jan-Jun	2021 Jan-Jun	2021 Jan-Dec
Operating earnings (EBIT)		-49.7	-54.0	-62.9	-90.9	-214.1
Interest received		0.4	—	0.4	—	0.0
Interest paid		-5.0	-4.4	-9.7	-12.8	-22.9
Income taxes paid		-2.6	2.8	-0.7	1.0	8.2
Adjustment for non-cash items	3	6.8	15.7	0.0	-19.0	-16.8
Cash flow from operating activities before changes in working capital		**-50.1**	**-40.0**	**-72.9**	**-121.7**	**-245.5**
Changes in working capital		**64.7**	**19.1**	**25.8**	**53.0**	**16.5**
Cash flow from operating activities		**14.5**	**-20.9**	**-47.1**	**-68.7**	**-229.0**
Acquisition of tangible and intangible fixed assets		-4.5	-13.1	-10.1	-29.3	-52.9
Short-term investments		-221.8	—	-221.8	—	—
Cash flow from investing activities		**-226.3**	**-13.1**	**-231.9**	**-29.3**	**-52.9**
New loan		—	—	—	490.1	490.1
Repayment of loans		-5.3	-3.5	-10.6	-231.9	-239.5
Cash from financing activities		**-5.3**	**-3.5**	**-10.6**	**258.2**	**250.6**
Cash flow for the period		**-217.0**	**-37.5**	**-289.6**	**160.1**	**-31.2**
Cash and cash equivalents at the beginning of the period		**437.8**	**725.5**	**504.1**	**505.3**	**505.3**
Exchange-rate differences in cash and cash equivalents		23.4	-8.2	29.7	14.3	30.0
Changes in cash and cash equivalents		-193.6	-45.8	-259.9	174.4	-1.2
Cash and cash equivalents at the end of the period		**244.2**[1]	**679.7**	**244.2**	**679.7**	**504.1**

[1] Cash and cash equivalents after the reclassification of cash into two parts due to invested surplus cash of SEK 223.5 m in certificates of deposits and in US treasuries in Q2 2022.

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.

	2022 Apr-Jun	2021 Apr-Jun	2022 Jan-Jun	2021 Jan-Jun	2021 Jan-Dec
EBIT margin, %	-33.6	-37.8	-20.5	-33.1	-37.9
Return on shareholder equity, %	-11.2	-14.8	-18.0	-20.7	-49.2
Net debt, SEK m	25.9	-188.6	25.9	-188.6	-11.7
Debt/equity ratio, %	159.8	106.9	159.8	106.9	140.8
Equity/assets ratio, %	24.3	34.2	24.3	34.2	27.4
Number of shares, before dilution	34,367,616	34,327,907	34,341,143	34,305,884	34,319,649
Number of shares, after dilution	34,367,616	34,327,907	34,341,143	34,305,884	34,319,649
Earnings per share, before dilution, SEK	-1.04	-2.15	-1.73	-3.07	-6.51
Earnings per share, after dilution, SEK	-1.04	-2.15	-1.73	-3.07	-6.51
Number of employees at the end of the period	123	139	123	139	121
Shareholders' equity, SEK m	308.9	459.4	308.9	459.4	349.6
Capital employed, SEK m	802.4	950.6	802.4	950.6	841.9
Working capital, SEK m	206.8	-76.1	206.8	-76.1	-18.8

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

CONDENSED PARENT COMPANY STATEMENT OF OPERATIONS

SEK m	Notes	2022 Apr-Jun	2021 Apr-Jun	2022 Jan-Jun	2021 Jan-Jun	2021 Jan-Dec
Net revenues		103.8	45.5	155.8	135.0	365.9
Cost of goods sold		-19.6	-7.8	-34.5	-29.4	-71.2
Gross profit		**84.2**	**37.7**	**121.3**	**105.5**	**294.7**
Selling expenses		-41.3	-46.4	-78.7	-99.6	-227.3
Administrative expenses		-30.2	-24.8	-50.4	-40.2	-92.3
Research and development costs		-68.9	-61.4	-129.7	-106.3	-226.0
Other operating income and expenses		17.3	-0.1	46.7	14.7	36.8
Operating earnings (EBIT)		**-39.0**	**-94.9**	**-90.7**	**-125.9**	**-214.2**
Interest income and expenses		-4.6	-4.3	-9.3	-8.0	-18.0
Other financial income and expenses		17.5	-5.8	21.7	3.2	12.5
Net financial items		**12.9**	**-10.1**	**12.5**	**-4.7**	**-5.6**
Earnings before tax		**-26.0**	**-105.1**	**-78.3**	**-130.6**	**-219.8**
Tax	5	—	—	—	—	—
Earnings for the period		**-26.0**	**-105.1**	**-78.3**	**-130.6**	**-219.8**

PARENT COMPANY STATEMENT OF COMPREHENSIVE INCOME

SEK m	2022 Apr-Jun	2021 Apr-Jun	2022 Jan-Jun	2021 Jan-Jun	2021 Jan-Dec
Earnings for the period	**-26.0**	**-105.1**	**-78.3**	**-130.6**	**-219.8**
Other comprehensive income	—	—	—	—	—
Total comprehensive earnings for the period	**-26.0**	**-105.1**	**-78.3**	**-130.6**	**-219.8**

CONDENSED PARENT COMPANY BALANCE SHEET

SEK m	2022 Jun 30	2021 Jun 30	2021 Dec 31
ASSETS			
Fixed assets			
Intangible fixed assets	198.1	219.2	214.2
Tangible fixed assets	70.1	58.0	65.9
Shares in subsidiaries	160.1	160.8	162.5
Total fixed assets	**428.2**	**438.0**	**442.6**
Current assets			
Inventories	56.3	80.6	67.8
Accounts receivable and other receivables	144.6	54.1	115.4
Short-term investments	183.5	—	—
Cash and cash equivalents	177.9	568.6	444.5
Total current assets	**562.3**	**703.4**	**627.7**
Total assets	**990.5**	**1,141.4**	**1,070.2**
SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES			
Total shareholders' equity	**227.7**	**395.1**	**306.0**
Long-term liabilities			
Provisions	7.1	10.0	12.8
Bond loan	493.5	491.1	492.3
Total long-term liabilities	**500.6**	**501.1**	**505.1**
Current liabilities			
Accounts payable	39.7	21.1	17.1
Other liabilities	5.2	6.4	9.1
Liabilities to Group companies	183.5	192.6	207.9
Accrued expenses and deferred income	33.8	25.1	25.0
Total current liabilities	**262.2**	**245.1**	**259.1**
Total liabilities	**762.8**	**746.2**	**764.2**
Total shareholders' equity and liabilities	**990.5**	**1,141.4**	**1,070.2**

Notes

1. Accounting policies
This report was prepared pursuant to IAS 34. Orexo applies IFRS as approved by the EU.

The accounting policies stated below are in line with those applied in the preparation of the 2021 Annual Report.

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	2022 Apr-Jun	2021 Apr-Jun	2022 Jan-Jun	2021 Jan-Jun	2021 Jan-Dec
US Pharma					
Net revenues	139.6	126.0	278.7	252.8	522.7
Operating earnings (EBIT)	77.2	61.6	161.2	127.7	278.2
Depreciation and amortization	-1.3	-3.8	-5.1	-7.7	-15.4
Digital Therapeutics					
Net revenues	0.1	0.3	0.3	0.4	1.1
Operating earnings (EBIT)	-47.9	-51.6	-91.3	-110.5	-249.7
Depreciation and amortization	-6.6	-4.6	-12.2	-8.9	-18.6
HQ & Pipeline					
Net revenues	8.1	16.5	28.3	21.9	41.2
Operating earnings (EBIT)	-79.1	-63.9	-132.9	-108.2	-242.6
Depreciation and amortization	-9.4	-4.4	-15.9	-9.2	-19.1
Group					
Net revenues	147.8	142.8	307.3	275.1	565.0
Operating earnings (EBIT)	-49.7	-54.0	-62.9	-90.9	-214.1
Depreciation and amortization	-17.2	-12.9	-33.2	-25.8	-53.0
Net financial items	12.3	-10.8	10.4	-6.2	-8.4
Earnings before tax	-37.4	-64.8	-52.5	-97.1	-222.5

3. Cash flow

ADJUSTMENT FOR NON-CASH ITEMS

SEK m	2022 Apr-Jun	2021 Apr-Jun	2022 Jan-Jun	2021 Jan-Jun	2021 Jan-Dec
Depreciation/amortization and impairment	17.2	12.8	33.2	25.8	53.0
Change in provisions	-3.6	-1.1	-24.9	-45.8	-67.4
Share based payments	-0.1	1.6	-0.1	1.6	1.5
Exchange rate income and expenses	-6.8	2.4	-8.2	-0.6	-3.9
Total	**6.8**	**15.7**	**0.0**	**-19.0**	**-16.8**

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 has no knowledge of the background to the requests and will continue to collaborate 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 currently has nine 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 and 11,020,388) with expiration dates ranging from December 2027 to September 2032. All nine listed patents have been asserted in patent infringement actions against Sun in the US District Court for the District of New Jersey.

In Q2 2022 the date for rehearsal was scheduled and will take place during the period of November 4 - 11, 2022. The outcome of the trial is expected in late Q1 or in Q2, 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 1,364 m as of December 31, 2021 and refers to the Swedish companies. No deferred tax assets for tax-loss carry-forwards have been capitalized as per December 31, 2021, for the part of these tax-loss carry-forwards which the company has assessed as fulfilling the recognition requirements of IAS 12. There is no time limit for when the remaining loss carryforwards can be utilized.

6. Financial instruments

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

7. Related parties

There were no significant related parties transactions during the period.

8. Important events after the period

- First clinical study initiated for OX640, a nasal adrenaline rescue medication for allergic reactions
- The digital therapy deprexis® reimbursed within the US Veterans Affairs Federal Supply Schedule
- Financial outlook 2022 reiterated

9. Revenue from contracts with customers

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 & UK	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	2021 Apr-Jun					
Segment	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**vorvida®**	**deprexis®**	**Total**
US Pharma	126.0	—	—	—	—	**126.0**
Digital Therapeutics	—	—	—	0.2	0.0	**0.3**
HQ & Pipeline	—	14.3	2.3	—	—	**16.5**
Total revenue from contracts with customers	**126.0**	**14.3**	**2.3**	**0.2**	**0.0**	**142.8**
Geographical markets	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**vorvida®**	**deprexis®**	**Total**
US	126.0	—	0.5	0.2	0.0	**126.8**
EU	—	14.0	0.8	—	—	**14.8**
Rest of the world	—	0.3	1.0	—	—	**1.2**
Total revenue from contracts with customers	**126.0**	**14.3**	**2.3**	**0.2**	**0.0**	**142.8**

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	2021 Jan-Jun					
Segment	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**vorvida®**	**deprexis®**	**Total**
US Pharma	252.8	—	—	—	—	**252.8**
Digital Therapeutics	—	—	—	0.4	0.1	**0.4**
HQ & Pipeline	—	17.0	4.9	—	—	**21.9**
Total revenue from contracts with customers	**252.8**	**17.0**	**4.9**	**0.4**	**0.1**	**275.1**
Geographical markets	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**vorvida®**	**deprexis®**	**Total**
US	252.8	—	1.5	0.4	0.1	**254.7**
EU & UK	—	16.5	1.3	—	—	**17.8**
Rest of the world	—	0.6	2.0	—	—	**2.6**
Total revenue from contracts with customers	**252.8**	**17.0**	**4.9**	**0.4**	**0.1**	**275.1**

SEK m	2021 Jan-Dec					
Segment	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**vorvida®**	**deprexis®**	**Total**
US Pharma	522.7	—	—	—	—	**522.7**
Digital Therapeutics	—	—	—	1.0	0.1	**1.1**
HQ & Pipeline	—	32.1	9.1	—	—	**41.2**
Total revenue from contracts with customers	**522.7**	**32.1**	**9.1**	**1.0**	**0.1**	**565.0**
Geographical markets	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**vorvida®**	**deprexis®**	**Total**
US	522.7	—	2.9	1.0	0.1	**526.8**
EU	—	31.0	3.1	—	—	**34.1**
Rest of the world	—	1.1	3.0	—	—	**4.2**
Total revenue from contracts with customers	**522.7**	**32.1**	**9.1**	**1.0**	**0.1**	**565.0**

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	2022 Apr-Jun	2021 Apr-Jun	2022 Jan-Jun	2021 Jan-Jun	2021 Jan-Dec
EBIT	-49.7	-54.0	-62.9	-90.9	-214.1
Depreciation and amortization	17.2	12.9	33.2	25.8	53.0
EBITDA	**-32.5**	**-41.1**	**-29.7**	**-65.2**	**-161.0**
DTx EBIT	47.9	51.6	91.3	110.5	249.7
IP litigation and subpoena costs	5.9	18.5	4.2	29.7	59.6
EBITDA excluding DTx, IP litigation and subpoena costs	**21.2**	**29.0**	**65.8**	**75.1**	**148.3**

CASH AND INVESTED FUNDS	2022 Apr-Jun	2021 Apr-Jun	2022 Jan-Jun	2021 Jan-Jun	2021 Jan-Dec
Short-term investments	223.5	—	223.5	—	—
Cash and cash equivalents	244.2	679.7	244.2	679.7	504.1
Cash and invested funds	**467.7**	**679.7**	**467.7**	**679.7**	**504.1**

RETURN ON SHAREHOLDERS' EQUITY	2022 Apr-Jun	2021 Apr-Jun	2022 Jan-Jun	2021 Jan-Jun	2021 Jan-Dec
Shareholders' equity beginning balance	329.5	534.8	349.6	558.5	558.5
Shareholders' equity ending balance	308.9	459.4	308.9	459.4	349.6
Average shareholders' equity	319.2	497.1	329.2	509.0	454.1
Net earnings	-35.8	-73.7	-59.4	-105.4	-223.5
Return on shareholders' equity %	**-11.2**	**-14.8**	**-18.0**	**-20.7**	**-49.2**

OPERATING EXPENSES SEK m	2022 Apr-Jun	2021 Apr-Jun	2022 Jan-Jun	2021 Jan-Jun	2021 Jan-Dec
Selling expenses	-50.5	-61.8	-92.1	-130.4	-280.4
Administrative expenses	-51.2	-41.4	-84.3	-70.0	-151.5
Research and development costs	-81.3	-73.2	-153.3	-128.8	-272.3
Other operating income and expenses	6.7	-2.4	8.2	0.6	4.0
Operating expenses	**-176.4**	**-178.7**	**-321.5**	**-328.7**	**-700.2**

GROSS INVESTMENTS SEK m	2022 Apr-Jun	2021 Apr-Jun	2022 Jan-Jun	2021 Jan-Jun	2021 Jan-Dec
Investments in tangible fixed assets	3.5	6.3	7.5	15.4	24.7
Investments in intangible fixed assets	1.0	6.7	2.6	14.0	28.1
Gross investments	**4.5**	**13.1**	**10.1**	**29.3**	**52.9**