orexo

Q3 Interim Report 2022

Advancing the pipeline facilitating future growth

Q3 2022 highlights

- Total net revenues of SEK 161.0 m (145.9)
- EBITDA of SEK -32.4 m (-47.4), EBITDA excluding legal costs and costs for non-repeating clinical trials, SEK 14.3 m (-13.4)
- Net earnings of SEK -26.5 m (-52.0)
- US Pharma segment (ZUBSOLV® US) net revenues of SEK 150.1 m (136.4), in local currency USD 14.2 m (15.8), US Pharma EBIT of SEK 70.2 m (78.5)
- Cash flow from operating activities of SEK -60.7 m (-79.7), cash and invested funds of SEK 443.9 m (588.1) a reduction of SEK 23,8 m from SEK 467.7 m in Q2
- Earnings per share before and after dilution amounted to -0.77 (-1.51)
- Phase 1 clinical study initiated for OX640, a nasal epinephrine rescue medication for allergic reactions
- The digital therapy deprexis®, for depression, reimbursed within the US Veterans Affairs Federal Supply Schedule
- First patent granted for OX640
- Orexo's partner Trinity Health gives patients within their healthcare network access to vorvida® and deprexis®, the digital therapies for alcohol misuse and depression respectively

Important events after the period

- Positive data announced from phase 1 clinical study for OX640
- Ed Kim, M.D., appointed as Chief Medical Officer, replacing Michael Sumner, M.D.
- Last patient enrolled in the clinical trial of MODIA®, the digital therapy for opioid use disorder

SEK 161 m
Group revenues

SEK 70 m
US Pharma EBIT

SEK 444 m
Cash and invested funds

SEK m, unless otherwise stated	2022 Jul-Sep	2021 Jul-Sep	2022 Jan-Sep	2021 Jan-Sep	% change	2021 Jan-Dec
Net revenues	161.0	145.9	468.3	421.0	10.3%	565.0
Cost of goods sold	-28.0	-21.3	-76.7	-58.6	31.6%	-78.9
Operating expenses	-182.8	-183.7	-504.3	-512.4	-0.5%	-700.2
EBIT	-49.8	-59.0	-112.8	-150.0	15.6%	-214.1
EBIT margin	-31.0%	-40.5%	-24.1%	-35.6%	9.5%	-37.9%
EBITDA	-32.4	-47.4	-62.1	-112.6	31.6%	-161.0
Earnings per share, before dilution, SEK	-0.77	-1.51	-2.50	-4.59	49.0%	-6.51
Earnings per share, after dilution, SEK	-0.77	-1.51	-2.50	-4.59	49.0%	-6.51
Cash flow from operating activities	-60.7	-79.7	-107.8	-148.4	23.8%	-229.0
Cash and invested funds	443.9	588.1	443.9	588.1	-24.5%	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.

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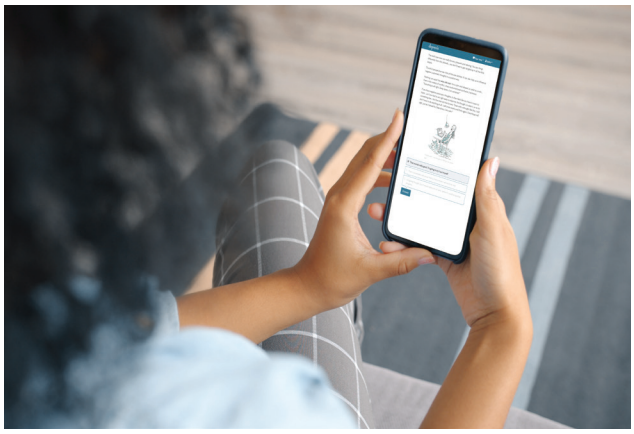
About Orexo
Orexo develops improved pharmaceuticals and digital therapies addressing unmet needs within the growing space of substance use disorders and mental health. The products are commercialized by Orexo in the US or via partners worldwide. The main market today is the American market for buprenorphine/naloxone 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, Fredrik Järrsten, CFO, and Robert Rönn, SVP and Head of R&D will present the report and host a Q&A.

Please view the instructions below on how to participate.
Internet: https://ir.financialhearings.com/orexo-q3-2022
Telephone: SE: +46 8 50 55 83 53 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/Audiocasts.

Financial calendar 2023
Full Year Report 2022, incl. Q4 - January 26, at 8 am CET
Annual General Meeting 2023 - April 18, at 4 pm CET
Interim Report Q1 2023 - April 27, at 8 am CET
Interim Report Q2 2023 - July 18, at 8 am CET
Interim Report Q3 2023 - November 2 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.

Aiming at profitability

Returning to profitability is a prime objective for Orexo and today's financial environment accentuates the need to secure our ability to finance investments in future growth drivers with contributions from our commercial assets and R&D partnerships based on our pipeline and the amorphOX® platform. As a first step we have set a key objective for 2022 to become profitable on an EBITDA level, when removing non-repeating external expenses. We have defined these as external expenses related to clinical studies and legal processes. In the third quarter these expenses exceeded SEK 45 million and the EBITDA result was minus SEK 32 million. This makes me comfortable that we have EBITDA profitability in sight.

Securing ZUBSOLV® profit contribution
In our US Pharma operation, ZUBSOLV® sales shows growth in SEK of 10 percent explained by the strengthened USD. Excluding the exchange rate exposure, I am pleased to see ZUBSOLV® sales in USD has stabilized during 2022, and Q3 net revenues very close to the second quarter. On a full year basis, we still believe the objective of increased ZUBSOLV® sales in the second half is feasible, but the trajectory of the current trend indicates sales in line with the first half in USD, while growing in SEK.

Q3 is the first quarter with a fully staffed sales organization in New York. With the increased investment in this state, I am pleased to see ZUBSOLV® outperforming the market growth in the state with an increase of 16 percent in prescription volume comparing to Q2 in 2022. The expansion in NY is an investment in future growth, short term this has a slight negative impact on the EBIT margin for our US Pharma business reaching 47 percent in Q3 compared to 54 percent year to date. We continue to monitor the performance to ensure return on this investment turns positive in 2023.

On a market growth level, we expected treatment of OUD (opioid use disorder) patients would accelerate post Covid-19, but market growth rates still remain below pre-Covid levels. Together with expected continued growth in NY, accelerating market growth is an important driver to grow ZUBSOLV® sales, provided ZUBSOLV® is reimbursed i.e., has market access. Looking into 2023, I am pleased to report we have maintained our market access and reimbursement from 2022 on all published reimbursement formularies.

An important, but costly, activity is to protect our business with a successful outcome of the ongoing legal processes. The main legal activity is the ZUBSOLV® patent litigation against Sun Pharmaceuticals. The District Court hearing was scheduled in early November but

has now been postponed to the first quarter 2023. The preparation for the court hearing will be associated with increasing expenses in the two coming quarters as both parties are expected to finalize their arguments and associated evidence. We remain confident in the strength of our intellectual property rights and our ability to prevail in this process.

Strong belief in digital therapeutics (DTx), but adopting expenses to slow pace of implementation
When listening to key stakeholders in healthcare, digitalization is top on the list when it comes to the solution of the lack of resources to meet the growing demand of healthcare. We are encouraged by the feedback received from the more than 2000 patients who have tested our DTx and hundreds of healthcare providers who have tested our digital therapies with their patients. We are confident we have DTx that can help patients to improve treatment outcome, healthcare providers to treat more patients more efficiently with less resources and for payers to reduce the expenses for each patient. However, we are also facing the reality of lack of adequate reimbursement processes and inherent inertia in the introduction of new tools and methods of treatments in healthcare. Therefore, we have reduced our direct expenses for digital therapies with approx. 75 percent versus Q3 2021, through reduction of staff and focusing on fewer customer segments. Most of the spending in DTx is now allocations of shared expenses with US Pharma e.g., sales representatives promoting MODIA®.

I was pleased with the announcement by Trinity Health regarding the implementation of vorvida® and deprexis® in their healthcare programs for treatment of alcohol misuse and depression, following successful tests of the reimbursement processes in Q3. With this collaboration we collectively address the significant challenges with mental health in rural areas in the US and through an intensive innovation process ensured patients can receive our DTx with reimbursement. Following the announcement, we have allocated resources to ensure we have local representation in North Dakota to support a successful implementation together with Trinity Health from October. The first patients have received our DTx through Trinity Health and with a confirmation of the reimbursement from insurance providers, the first revenue from Trinity Health will be recognized in the Q4 report. We are also making good progress within Veterans Affairs (VA) and will start active promotion when the necessary administrative processes are in place late this year. Finally, in October, the first patients received MODIA® using existing reimbursement opportunities within OUD treatment. This is an important step to transition the clinics who have integrated MODIA® into their treatment programs for OUD during the free trial period with modiaOne into commercial customers.

The main strategic focus in the DTx team is to get traction within Trinity Health, prepare the commercial launch in VA and convert OUD clinics from the modiaOne program to commercial customers. We will expand the DTx team and resources when new hospital systems like Trinity Health are contracted and as we see commercial progress in VA. The MODIA® implementation is very synergistic with the US Pharma business as the same sales resources can be used for both ZUBSOLV® and MODIA® and from 2024 also for OX124. Investments in other customer segments will be minimal, reflecting the slow adoption seen in 2022.

Significant progress in the R&D pipeline

We continue with a high pace towards the objective of filing OX124, our opioid overdose rescue medication, with the FDA in the fourth quarter, which would give us a potential approval during the second half of 2023. The final development stage leading up to the filing with the FDA is intensive and requires significant external support. Thus, the investments in OX124 will peak in the fourth quarter. To maintain a prudent expense management, Orexo will hold back some activities needed to prepare for the commercial launch of OX124 until approval. This includes manufacturing of commercial launch material since any changes by the FDA to the package and label would force Orexo to write-off the finished goods. Delaying this process and other preparations will delay the launch until early 2024 but reduce the financial risk in 2023.

Shortly after the end of the third quarter we received the strong results from the first human trial for OX640, our rescue medication for allergic reactions. The strength of the data (for more detailed information view page 8) significantly reduces the clinical risk in the project, the time to market and improve the chances to have differentiation to some other non-injectable products under development. Based on the current feedback from FDA, Orexo will need to complete additional studies in healthy volunteers and in participants known to have a history of seasonal allergies with the final OX640 product, which can be manufactured in the supply chain for OX124. Orexo expects filing with the FDA is possible in 2025 and together with the strong stability data in a broad range of temperatures, the convenience of a small nasal spray and an established supply chain, OX640 should be an attractive product for potential partners.

We continue to test amorphOX® in a range of various molecules and have excellent stability data in both small and large molecules, such as peptides and proteins. We have also seen large biomolecules maintaining their activity level after the manufacturing process with amorphOX®, which potentially would enable Orexo to solve storage and shelf-life challenges for products such as vaccines. To reduce risk and expenses, Orexo's strategy is to work with partners where amorphOX® can add value. With the positive results from OX640 and strong interest from other companies to work with Orexo to test their API in our amorphOX® platform, we have decided to stop the OX338 project, a non-opioid pain medication, and maintain a low activity level of OX125, an overdose rescue medication with nalmefene.

Summary and outlook

Orexo is in a solid financial position with an ability to reach profitability through prioritization and slowdown of investments. With SEK 444 million in cash and invested funds, we will be able to continue the development of OX124 towards filing with the FDA later this year and to vigorously defend our intellectual property rights. These activities will continue to require investments short term and due to the strength of the USD we expect our operating expenses to slightly exceed the guidance of SEK 650-700 million in 2022. This will be compensated by an improved SEK value of the ZUBSOLV® revenues on an EBIT level. In 2023, the expenses for the SUN litigation will decrease significantly after the trial in Q1, the OX640 expenses are likely to be covered through partnerships, the OX124 development expenses will decrease and the MODIA® study will be finalized - all supporting Orexo to return to profitability.

Finally, I will welcome our new Chief Medical Officer, Ed Kim, M.D., to Orexo. Ed has many years of experience as clinician in psychiatry, from executive positions with leading healthcare systems and in the pharmaceutical industry. Key for our success is to ensure we have the right people in place and I am sure he will be an important contributor to strenghten our insights and network within treatment of mental health in the US.

Uppsala, Sweden, November 3, 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, where ZUBSOLV® demand comparing to the previous period was stable.

The overall market growth was 1 percent versus Q2 2022. The quarterly year over year growth was 5 percent, prior to 2020, market growth was in the mid-teens. This slowdown from previous double-digit growth can be attributed to limited access to treatment due to Covid-19 and also the broad availability of illicit fentanyl across the US. Fentanyl causes a significant increase in overdose and according to doctors also makes the patients more difficult to treat with increased rate of relapse during the induction of treatment. The pandemic continues to negatively impact access to OUD treatment thereby advancing the scourge of the opioid epidemic driving the number of fatal overdoses to record-high levels. Expectations are that the buprenorphine naloxone market growth will be positively impacted as the Covid-19 pandemic wanes and by the multiple initiatives underway to improve access to medication assisted treatment.

On a year over year basis, Q3 2022 compared to Q3 2021, ZUBSOLV® demand declined 11 percent. This is mainly due to the continued, but slowing erosion of ZUBSOLV® volume due the addition of generic Suboxone® at Humana and United Health Group. During Q3 ZUBSOLV's overall prescription volume declined 1 percent versus Q2 2022. Our core segment, the open segment, was stable versus Q2 2022.

As previously reported, New York State's MAT Open Access law has been implemented by all Medicaid plans in the state effective March 22, 2022. This law requires all Medicaid plans reimburse all MAT products including ZUBSOLV® as preferred without any restrictions. Also, 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 16 percent in Q3 2022 over Q2 2022. ZUBSOLV® Kentucky Medicaid volume has grown 18 percent in Q3 2022 over Q2 2022.

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. No changes are expected to the market access for 2023 and ZUBSOLV® reimbursement has been confirmed by all large payers in the US.

Digital Therapeutics

VORVIDA® deprexis® modia

vorvida® – digital therapy for alcohol management
deprexis® – digital therapy for depression
MODIA® – digital therapy for opioid use disorder

The most significant progress in Q3 was the confirmation of the deprexis® Veterans Affairs (VA) contract award. This multi-year contract provides reimbursed access to deprexis® at the Department of Veterans Affairs, the Department of Defense, and Indian Health Services covering 15 million US citizens. Additional opportunities exist within the VA for vorvida® and MODIA®, but they require formal FDA registration before negotiations can advance. Following the contract award, the DTx team is executing a phased, prioritized approach to establish a deprexis® sales base within the federal government initially focusing on 3 out of 18 regions within the VA. The VA system is complex to navigate and has regulations and processes in terms of suppliers' opportunity to operate. Implementation within the VA following a contract award follows a defined process and requires local agreements within each of the 18 regions, known as VISN's (Veterans Integrated Service Networks) in terms of distribution process and Orexo's possibilities to promote the product. The expectations is Orexo will be ready to start commercialization late 2022.

The implementation of vorvida® and deprexis® within Trinity Health has made good progress and all focus will now be on creating demand and ensure frontline healthcare workers are ready to use these products. In mid-September Trinity Health publicly announced the the new service line availability of both deprexis® and vorvida®. To support Trinity Health during the start-up phase, Orexo will have physical representation in North Dakota to support the implementation, starting October. A training program has been developed in collaboration with Trinity Health and has been provided to several

[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.

primary care units within Trinity Health. Billing tests, i.e. testing the reimbursement process from patient initiation to payment from insurance companies, have been completed successfully during the quarter and the first real patients have received deprexis® with revenue recognition in Q4.

Our strategy for MODIA® is to create awareness, then confirm interest, then let the clinician try MODIA® through modiaONE for early access and then move to contracting and reimbursement, with a customized pathway in each state. We currently have over 2,000 patients enrolled from over 130 providers with several practices in active dialogue on contracting. With over 2,000 ZUBSOLV® target physicians, our focus will be on growing the base of providers trying MODIA® and moving to contracts. In parallel with the commercial launch of MODIA® the last patient has been recruited in October for the MODIA® trial (437 patients for 6 months). The recruitment has been negatively affected by Covid-19 and the result from the trial is expected in the summer of 2023 which will enable an application with the FDA for a 510 K approval.

With the progress at Trinity Health and VA, 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®. In addition, the development of systems and processes to support the reimbursement pathway required significant expenses in 2021 and first half of 2022. With the prioritization and finalization of the system support implemented at Trinity Health and with MODIA® customers, the direct expenses related to all DTx is reduced with nearly 75 percent compared to Q3 last year. The allocated expenses from US Pharma has increased due to the launch of MODIA® with the US Pharma sales team. In Q3, the total expenses for vorvida® and deprexis® accounted for about 40 percent of the DTx expenses, compared to nearly all during 2021. 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.

Through Q3 2022, the Orexo DTx portfolio now has over 3,700 patients across early access commercial programs and clinical trials. During Q3 the launch of modiaONE, our early access program for MODIA®, have seen more than 1,200 patients started on therapy, an increase of more than 130 percent from Q2.

The revenue recognition of the digital therapies will be phased based on the duration of the treatment i.e. three months for deprexis® and six months for vorvida® and MODIA®.

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.

A 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 the amorphOX® platform have been filed or approved, 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
Good progress towards filing with the FDA in the end of 2022 following a successful pre-NDA meeting earlier this year and positive outcome of the on-going activities. With the excellent stability from the amorphOX® platform we aim at, at least 24 months of stability for OX124. Other critical activities such as reliability testing and usability studies (human factor studies) are making good progress as well. Furthermore, the work continued with conducting the stability studies aiming to collect data supporting at least 24 months shelf life. The ongoing usability studies (human factor studies), which are in its final stage, also made progress during the quarter Data from these studies will along with the successful data from the pivotal trial, OX124-002, be the primary support to get the product approved in the US. The first brand names suggested to the FDA have not been approved and new brand names are currently being evaluated by the FDA. The NDA application is expected to be filed with the FDA in the end of 2022.

Project in brief
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. 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. OX124 has patents protecting the product until 2039.

The US overdose medication market
Orexo is targeting a market for overdose rescue medications today amounting to approx. 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
A launch of OX124 in the US is planned to be initiated early in 2024. With a continued high level of 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.

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. Project activities will be kept on a low level going forward, as resources related to pharmaceutical development will be allocated to the OX640 project and to further explore projects based on the amorphOX® platform.

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.

OX338 – acute moderate to moderately severe pain

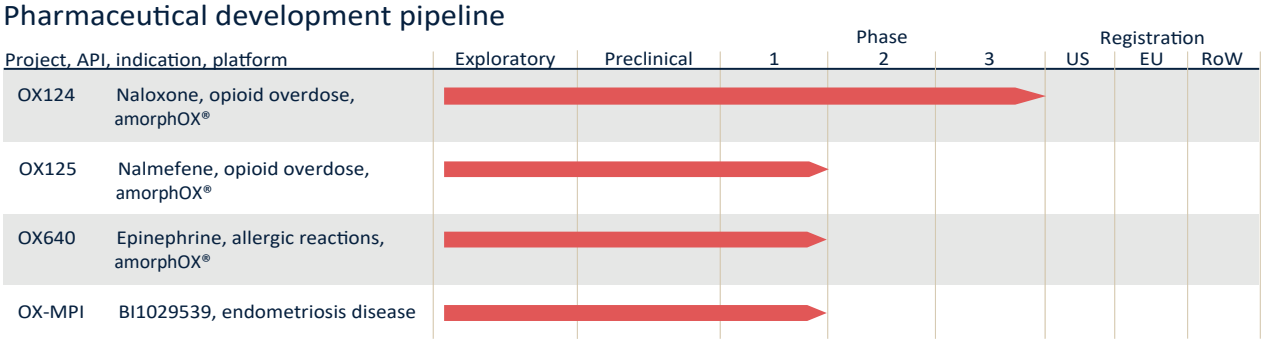
In the quarter a decision was taken to focus resources on the OX640 project and to further explore projects based on the drug delivery platform amorphOX®. Due to that a decision was taken to stop the OX338 project.

OX640 – epinephrine rescue medication based on amorphOX®

Progress during the quarter
In Q3 the phase 1 clinical study was successfully performed. The study primarily aimed to determine the relative bioavailability and absorption characteristics of investigational OX640 formulations versus an intramuscular epinephrine auto-injector (EpiPen®) in healthy volunteers.

The study result, announced in October, showed all four investigational OX640 formulations were extensively

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%.

absorbed and rapidly achieved clinically relevant plasma levels of epinephrine. In comparison to EpiPen®, and to other approved epinephrine injection products, the OX640 formulations displayed comparable or higher; (i) total epinephrine exposure, (ii) peak epinephrine exposure, (iii) epinephrine exposure during the first 20 minutes after administration, and (iv) proportion of subjects reaching clinically effective plasma levels of epinephrine during the first 20 minutes after administration.

Furthermore, the OX640 formulations displayed concentration dependent effects on blood pressure and heart rate, parameters used as surrogate markers for clinical efficacy.

Local and systemic safety findings were generally consistent with known effects of epinephrine and there were no findings that raised any safety concerns.

In Q3 the first patent was granted for OX640, covering the European market and will expire in 2041. Orexo has multiple patent applications filed in other territories and expect to continuously strengthen the patent portfolio for OX640.

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 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 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, ensuring the correct epinephrine dose is available when needed.

The next step in the development will be to finalize the formulation for large scale commercial manufacturing and establish the commercial supply chain leveraging the supply chain in place for OX124. Based on current feedback from the FDA and with availability of final commercial product, the final step is to conduct additional studies in healthy volunteers and in participants known to have a history of seasonal allergies. Orexo expects filing with the FDA is possible in 2025.

OX-MPI – endometriosis disease

Progress during the quarter
After the end of the quarter Orexo´s partner Gesynta Pharma, which owns all the rights to OX-MP, (GS-248) announced it has taken a strategic decision to develop a pharmaceutical for the treatment of endometriosis, a chronic inflammatory condition affecting approx. 10 percent of all women of reproductive age. The decision is based on strong positive data from a recently conducted preclinical proof-of-concept study with OX-MPI, in an advanced model of endometriosis, where disease-modifying properties of the drug candidate were firmly established. The new direction is based on that Gesynta Pharma in Q3 announced data from the phase 2 study where OX-MPI was tested among patients with systemic sclerosis. Data showed a good safety profile while no significant effects on symptoms could be demonstrated.

Instead of developing a drug for the treatment of systemic sclerosis, Gesynta Pharma will in Q4 continue preparations for a new phase 2 study in patients with endometriosis, capitalizing on the positive safety data displayed in the former clinical study.

Project in brief
OM-MPI is a non-hormonal clinical-stage drug candidate targeting the pro-inflammatory enzyme mPGES-1, which via its product prostaglandin E2 plays a key role in inducing and maintaining endometriosis lesions.

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

In Q3 Orexo´s partner Accord Healthcare continued to launch ZUBSOLV® in the EU. Except from Spain and Sweden where launch took place last quarter, ZUBSOLV® is now also available on markets such as, the UK, the Baltic States, the Czech Republic and Slovenia.

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,[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

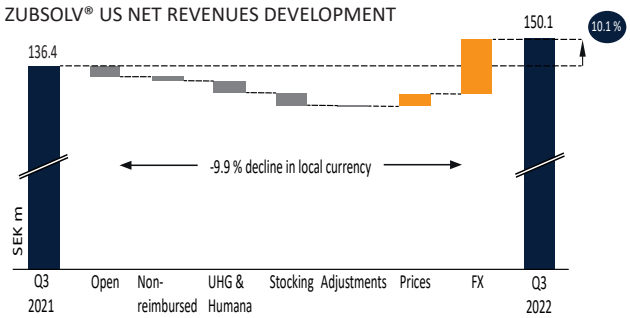
Financial overview

Revenues

Total revenues amounted to SEK 161.0 m (145.9) for Q3 and to SEK 468.3 m (421.0) for the first nine months. The increase is mainly explained by higher US Pharma revenues, driven by stronger USD exchage rate.

Revenues by segment

US Pharma revenues amounted to SEK 150.1 m (136.4) for Q3. 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 mainly due to overall market growth rates, which still remain below pre-Covid levels and due to competition in the previously exclusive plans United Health Group and Humana.



In local currency US Pharma net revenues for Q3 amounted to USD 14.2 m (15.8) while net revenues were flat vs Q2 2022.
US Pharma revenue amounted to SEK 428.8 m (389.2) for the first nine months.

Digital Therapeutics (DTx) recognized net revenues for Q3 amounting to SEK 0.0 m (0.4) and to SEK 0.3 m (0.8) for the first nine months. Sales efforts during the quarter have focused on implementation of vorvida® and deprexis® in Trinity Health healthcare programs and on preparation for active promotion within Veterans Affairs.

HQ & Pipeline partner product related revenues for Q3 amounted to SEK 10.8 m (9.2). The increase is mainly explained by higher Abstral® and Edluar® royalty.
HQ & Pipeline partner product amounted to SEK 39.1 m (31.0) for the first nine months.

Costs of goods sold

Cost of goods sold (COGS) amounted to SEK 28.0 m (21.3) for Q3. US Pharma amounted to SEK 24.4 m (18.3) mainly due to unfavorable exchange-rate impact vs prior year partly offset by lower negative production variances. Royalty and technical infrastructure costs for DTx amounted to SEK 2.7 m (2.9). HQ & Pipeline amounted to SEK 0.9 m (-) for ZUBSOLV® ex-US sales in the EU by Orexo's partner Accord Healthcare. Cost of goods sold (COGS) amounted to SEK 76.7 m (58.6) for the first nine months.

Operating expenses

Selling expenses amounted to SEK 54.7 m (79.0) for Q3. The decrease over the same period last year is mainly explained by significantly lower selling expenses in DTx. This is partly offset by negative impact of stronger USD exchange rate. Selling expenses amounted to SEK 146.8 m (209.5) for the first nine months.

Administrative expenses amounted to SEK 54.2 m (42.4) for Q3 and to SEK 138.5 m (112.4) for the first nine months. The increase is mainly explained by negative impact of stronger USD exchange rate and by higher legal expenses for IP litigation.

Research and development costs amounted to SEK 76.5 m (63.5) for Q3. The increase is mainly explained by costs related to OX124 and OX640 development projects. Research and development costs amounted to SEK 229.8 m (192.4) for the first nine months.

NET REVENUES AND OPERATING EARNINGS PER SEGMENT

SEK m	Net Revenues					EBIT				
	2022 Jul-Sep	2021 Jul-Sep	2022 Jan-Sep	2021 Jan-Sep	2021 Jan-Dec	2022 Jul-Sep	2021 Jul-Sep	2022 Jan-Sep	2021 Jan-Sep	2021 Jan-Dec
ZUBSOLV® US product sales	150.1	136.4	428.8	389.2	522.7	—	—	—	—	—
US Pharma – total	**150.1**	**136.4**	**428.8**	**389.2**	**522.7**	**70.2**	**78.5**	**231.4**	**206.1**	**278.2**
Digital Therapeutics (DTx) product sales	0.0	0.4	0.3	0.8	1.1	—	—	—	—	—
Digital Therapeutics (DTx) – total	**0.0**	**0.4**	**0.3**	**0.8**	**1.1**	**-48.9**	**-76.4**	**-140.1**	**-186.7**	**-249.7**
Abstral® royalty	7.5	6.8	24.9	23.8	32.1	—	—	—	—	—
Edluar® royalty	2.9	2.4	7.7	7.2	9.1	—	—	—	—	—
ZUBSOLV® - ex US	0.4	—	6.5	—	—	—	—	—	—	—
HQ & Pipeline segment – total	**10.8**	**9.2**	**39.1**	**31.0**	**41.2**	**-71.2**	**-61.2**	**-204.0**	**-169.3**	**-242.6**
Total	**161.0**	**145.9**	**468.3**	**421.0**	**565.0**	**-49.8**	**-59.1**	**-112.8**	**-150.0**	**-214.1**

Other operating income and expenses amounted to SEK 2.5 m (1.3) for Q3, 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 amounted to SEK 10.7 m (1.9) for the first nine months.

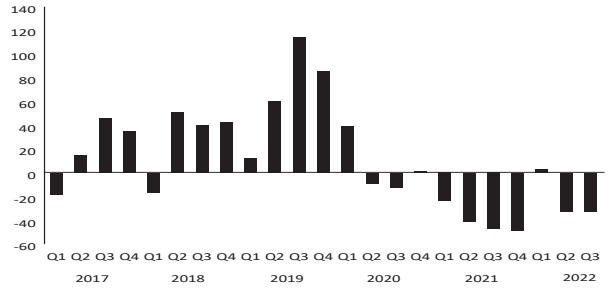
Operating profit

EBITDA amounted to SEK -32.4 m (-47.4) for Q3 and reflects foremost lower operating costs for DTx and higher gross profit. EBITDA amounted to SEK -62.1 m (-112.6) for the first nine months. Exclusion of costs for legal processes and external non-repeating costs for clinical studies, would result in a positive EBITDA of SEK 14.3 m (-13.4) for Q3 and SEK 57.9 m (-27.5) for the first nine months.

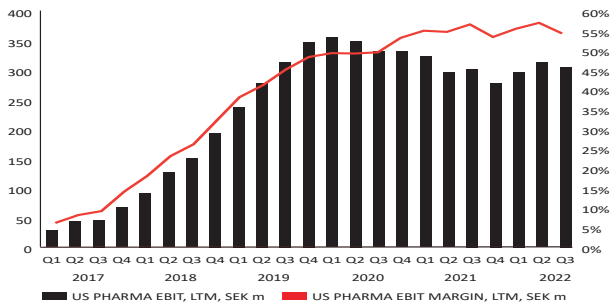
The EBIT contribution from US Pharma amounted to SEK 70.2 m (78.5) for Q3, equal to an EBIT margin of 46.8 percent (57.6). EBIT contribution from US Pharma amounted to SEK 231.4 m (206.1) for the first nine months, equal to an EBIT margin of 54.0 percent (52.9).

Total EBIT amounted to -49.8 m (-59.0) for Q3 and due to nearly perfect balance between USD based revenues and costs, stronger USD exchange rate had only a limited positive impact. Total EBIT amounted to -112.8 m (-150.0) for the first nine months.

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 Q3 amounted to SEK 27.4 m (-0.1) and is mainly explained by positive unrealized exchange rate impact of SEK 33.2 m (6.5) derived from the parent company's foreign currency bank accounts mainly in USD and by earned interest on short-term investments of SEK 1.4 m (-), partly offset by higher costs for corporate bonds of SEK 6.6 m (5.8). Net financial items amounted to SEK 37.8 m (-6.3) for the first nine months.

Total tax expenses amounted to SEK -4.1 m (7.1) for Q3. The increase is explained by negative adjustment to deferred tax assets related to temporary differences. Total tax expenses amounted to SEK -10.9 m (-1.3) for the first nine months. Orexo performs regular assessments of its deferred tax asset and makes adjustments according to the recognition requirements of IAS 12.

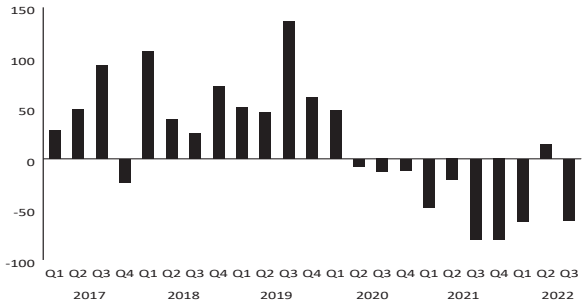
Net earnings

Net earnings amounted to SEK -26.5 m (-52.0) for Q3 and to SEK -85.8 (-157.6) for the first nine months.

Cash and cash flow

Cash flow from operating activities amounted to SEK -60.7 m (-79.7) for Q3 and was primarily impacted by negative operating earnings. Cash flow from operating activities amounted to SEK -107.8 m (-148.4) for the first nine months.

CASH FLOW FROM OPERATING ACTIVITIES, SEK m



During the quarter the company 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 September 30, 2022, cash and cash equivalents amounted to SEK 122.4 m (588.1) and short-term investments amounted to SEK 321.5 m (-). Cash and invested funds in total amounted to SEK 443.9 m (588.1) and interest-bearing liabilities to SEK 494.2 m (491.7), i.e. a negative net cash position including short-term investments of SEK -50.3 m (96.3). Cash and invested funds were reduced by SEK 23.8 m from Q2.

[1] Last Twelve Months

Investments

Gross investments in tangible and intangible fixed assets amounted to SEK 1.6 m (20.7) for Q3 and to SEK 11.7 m (50.0) for for the first nine months. Lower investment is mainly explained by investments in the DTx enterprise platform, in equipment for the development organization and by a payment of non-refundable milestone for MODIA® in Q3 2021.

Equity

Shareholders' equity at September 30, 2022, was SEK 298.4 m (411.7). The equity/asset ratio was 24.8 percent (31.4).

Parent company

Net revenues for Q3 amounted to SEK 64.2 m (139.4) of which SEK 53.4 m (130.3) was related to sales to Group companies. Net revenues amounted to SEK 220.0 m (274.4) for the nine first months of which SEK 180.9 m (243.4) was related to sales to Group companies.

Earnings before tax amounted to SEK -42.9 m (-22.6) for Q3 and to SEK -121.2 m (-153.2) for the first nine months. The decrease is mainly explained by lower gross profit partly offset by lower selling expenses and higher net financial items. Investments in equipment for the development organization for Q3 amounted to SEK 0.3 m (15.1) and to SEK 7.8 m (28.9) for the nine first months.

As of September 30, 2022, cash and cash equivalents in the parent company amounted to SEK 78.7 m (462.0) and short-term investments amounted to SEK 255.5 m (-) i.e. companys cash and invested funds amounted to SEK 334.2 m (462.0).

Parent company shareholders' equity at September 30, 2022, was SEK 184.8 m (372.6).

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 be SEK 700-725 m based on the appreciation of the USD in Q3
- US Pharma EBIT margin will exceed 50 percent on a full year basis

All numbers are based on exchange rates in September 2022, if based on previous exchange rates, OPEX estimate from Q2 would still be valid.

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 2021 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.

Glossary

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

Uppsala, Sweden, November 3, 2022

Nikolaj Sørensen
President and CEO

Review report

Orexo AB, corporate identity number 556500-0600.

Introduction

We have reviewed the condensed interim report for Orexo AB as at September 30, 2022 and for the nine months period then ended. The Board of Directors and the Managing Director are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of review

We conducted our review in accordance with the International Standard on Review Engagements, ISRE 2410 Review of Interim Financial Statements Performed by the Independent Auditor of the Entity. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and other generally accepted auditing standards in Sweden. The procedures performed in a review do not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material respects, in accordance with IAS 34 and the Swedish Annual Accounts Act regarding the Group, and in accordance with the Swedish Annual Accounts Act regarding the Parent Company.

Stockholm, Sweden, November 3, 2022
Ernst & Young AB

Anna Svanberg
Authorized Public Accountant

Financial reports, notes and key figures

CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS

SEK m	Notes	2022 Jul-Sep	2021 Jul-Sep	2022 Jan-Sep	2021 Jan-Sep	2021 Jan-Dec
Net revenues	9	161.0	145.9	468.3	421.0	565.0
Cost of goods sold		-28.0	-21.3	-76.7	-58.6	-78.9
Gross profit		**133.0**	**124.7**	**391.5**	**362.4**	**486.1**
Selling expenses		-54.7	-79.0	-146.8	-209.5	-280.4
Administrative expenses		-54.2	-42.4	-138.5	-112.4	-151.5
Research and development expenses		-76.5	-63.5	-229.8	-192.4	-272.3
Other operating income and expenses		2.5	1.3	10.7	1.9	4.0
Operating earnings (EBIT)		**-49.8**	**-59.0**	**-112.8**	**-150.0**	**-214.1**
Net financial items		27.4	-0.1	37.8	-6.3	-8.4
Earnings before tax		**-22.4**	**-59.1**	**-74.9**	**-156.3**	**-222.5**
Tax	5	-4.1	7.1	-10.9	-1.3	-1.0
Net earnings for the period[1]		**-26.5**	**-52.0**	**-85.8**	**-157.6**	**-223.5**
Earnings per share, before dilution, SEK		-0.77	-1.51	-2.50	-4.59	-6.51
Earnings per share, after dilution, SEK		-0.77	-1.51	-2.50	-4.59	-6.51

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

SEK m	2022 Jul-Sep	2021 Jul-Sep	2022 Jan-Sep	2021 Jan-Sep	2021 Jan-Dec
Earnings for the period	**-26.5**	**-52.0**	**-85.8**	**-157.6**	**-223.5**
Other comprehensive income	—	—	—	—	—
Items that may subsequently be reversed to the statement of operations:					
Exchange-rate differences	16.1	4.4	34.8	9.1	13.0
Other comprehensive earnings for the period, net after tax	**16.1**	**4.4**	**34.8**	**9.1**	**13.0**
Total comprehensive earnings for the period [1]	**-10.4**	**-47.6**	**-51.0**	**-148.5**	**-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 Sep 30	2021 Sep 30	2021 Dec 31
ASSETS				
Fixed assets				
Tangible fixed assets		68.4	61.4	65.9
Intangible fixed assets		229.6	260.6	248.9
Right-of-use assets		48.5	62.2	59.2
Deferred tax assets	5	28.3	34.2	33.4
Other financial assets		1.0	0.8	0.8
Total fixed assets		**375.8**	**419.2**	**408.2**
Current assets				
Inventories		88.7	93.4	92.3
Accounts receivable and other receivables		295.1	211.5	269.2
Short-term investments		321.5	—	—
Cash and cash equivalents		122.4	588.1	504.1
Total current assets		**827.7**	**892.9**	**865.5**
Total assets		**1,203.5**	**1,312.1**	**1,273.7**
SHAREHOLDERS' EQUITY AND LIABILITIES				
Total shareholders' equity		**298.4**	**411.7**	**349.6**
Long-term liabilities				
Provisions		9.0	10.8	13.5
Long-term liabilities, interest bearing		494.2	491.7	492.3
Lease liabilities, long-term		26.6	41.3	38.0
Total long-term liabilities		**529.8**	**543.8**	**543.9**
Current liabilities and provisions				
Provisions		161.1	144.3	160.1
Current liabilities, non-interest bearing		193.0	192.4	199.9
Lease liabilities, current		21.2	19.8	20.2
Total current liabilities and provisions		**375.3**	**356.6**	**380.2**
Total liabilities		**905.1**	**900.4**	**924.1**
Total shareholders' equity and liabilities		**1,203.5**	**1,312.1**	**1,273.7**

CONSOLIDATED CHANGES IN SHAREHOLDERS' EQUITY

SEK m	2022 Sep 30	2021 Sep 30	2021 Dec 31
Opening balance, shareholders' equity	**349.6**	**558.5**	**558.5**
Total comprehensive earnings for the period	-51.0	-148.5	-210.5
Share-based payments	-0.1	1.5	1.5
Closing balance, shareholders' equity	**298.4**	**411.7**	**349.6**

CONDENSED CONSOLIDATED CASH FLOW STATEMENTS

SEK m	Notes	2022 Jul-Sep	2021 Jul-Sep	2022 Jan-Sep	2021 Jan-Sep	2021 Jan-Dec
Operating earnings (EBIT)		-49.8	-59.0	-112.8	-150.0	-214.1
Interest received		-0.1	—	0.3	0.0	0.0
Interest paid		-5.8	-5.2	-15.6	-18.1	-22.9
Income taxes paid		-1.4	-1.0	-2.1	0.0	8.2
Adjustment for non-cash items	3	0.9	-24.1	0.9	-43.1	-16.8
Cash flow from operating activities before changes in working capital		**-56.3**	**-89.4**	**-129.2**	**-211.1**	**-245.5**
Changes in working capital		**-4.4**	**9.8**	**21.4**	**62.7**	**16.5**
Cash flow from operating activities		**-60.7**	**-79.7**	**-107.8**	**-148.4**	**-229.0**
Acquisition of tangible and intangible fixed assets		-1.6	-20.7	-11.7	-50.0	-52.9
Short-term investments		-67.5	—	-289.2	—	—
Cash flow from investing activities		**-69.0**	**-20.7**	**-300.9**	**-50.0**	**-52.9**
New loan		—	—	—	490.1	490.1
Repayment of loans		-5.0	-2.0	-15.6	-234.0	-239.5
Cash from financing activities		**-5.0**	**-2.0**	**-15.6**	**256.1**	**250.6**
Cash flow for the period		**-134.7**	**-102.4**	**-424.3**	**57.7**	**-31.2**
Cash and cash equivalents at the beginning of the period		**244.2**	**679.7**	**504.1**	**505.3**	**505.3**
Exchange-rate differences in cash and cash equivalents		12.9	10.7	42.6	25.1	30.0
Changes in cash and cash equivalents		-121.8	-91.6	-381.7	82.8	-1.2
Cash and cash equivalents at the end of the period		**122.4[1]**	**588.1**	**122.4[1]**	**588.1**	**504.1**

[1] Cash and cash equivalents excluding invested surplus cash of SEK 321.5 m in short-term assets, certificates of deposits and in US treasuries. As of September 30, 2022, cash and invested funds amounted to SEK 443.9 m (588.1)

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 Jul-Sep	2021 Jul-Sep	2022 Jan-Sep	2021 Jan-Sep	2021 Jan-Dec
EBIT margin, %	-31.0	-40.5	-24.1	-35.6	-37.9
Return on shareholder equity, %	-8.7	-11.9	-26.5	-32.5	-49.2
Net debt, SEK m	50.3	-96.3	50.3	-96.3	-11.7
Debt/equity ratio, %	165.6	119.4	165.6	119.4	140.8
Equity/assets ratio, %	24.8	31.4	24.8	31.4	27.4
Number of shares, before dilution	34,367,616	34,327,907	34,347,762	34,311,390	34,319,649
Number of shares, after dilution	34,367,616	34,327,907	34,347,762	34,311,390	34,319,649
Earnings per share, before dilution, SEK	-0.77	-1.51	-2.50	-4.59	-6.51
Earnings per share, after dilution, SEK	-0.77	-1.51	-2.50	-4.59	-6.51
Number of employees at the end of the period	126	128	126	128	121
Shareholders' equity, SEK m	298.4	411.7	298.4	411.7	349.6
Capital employed, SEK m	792.5	903.4	792.5	903.4	841.9
Working capital, SEK m	330.0	-51.8	330.0	-51.8	-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 Jul-Sep	2021 Jul-Sep	2022 Jan-Sep	2021 Jan-Sep	2021 Jan-Dec
Net revenues		64.2	139.4	220.0	274.4	365.9
Cost of goods sold		-12.2	-26.5	-46.6	-55.9	-71.2
Gross profit		**52.1**	**113.0**	**173.4**	**218.5**	**294.7**
Selling expenses		-44.8	-70.1	-123.6	-169.7	-227.3
Administrative expenses		-32.2	-27.9	-82.6	-68.1	-92.3
Research and development costs		-63.7	-51.8	-193.4	-158.0	-226.0
Other operating income and expenses		17.1	13.6	63.8	28.3	36.8
Operating earnings (EBIT)		**-71.6**	**-23.2**	**-162.4**	**-149.1**	**-214.2**
Interest income and expenses		-4.9	-5.2	-14.1	-13.2	-18.0
Other financial income and expenses		33.5	5.8	55.3	9.1	12.5
Net financial items		**28.7**	**0.6**	**41.2**	**-4.1**	**-5.6**
Earnings before tax		**-42.9**	**-22.6**	**-121.2**	**-153.2**	**-219.8**
Tax	5	—	—	—	—	—
Earnings for the period		**-42.9**	**-22.6**	**-121.2**	**-153.2**	**-219.8**

PARENT COMPANY STATEMENT OF COMPREHENSIVE INCOME

SEK m	2022 Jul-Sep	2021 Jul-Sep	2022 Jan-Sep	2021 Jan-Sep	2021 Jan-Dec
Earnings for the period	**-42.9**	**-22.6**	**-121.2**	**-153.2**	**-219.8**
Other comprehensive income	—	—	—	—	—
Total comprehensive earnings for the period	**-42.9**	**-22.6**	**-121.2**	**-153.2**	**-219.8**

CONDENSED PARENT COMPANY BALANCE SHEET

SEK m	2022 Sep 30	2021 Sep 30	2021 Dec 31
ASSETS			
Fixed assets			
Intangible fixed assets	189.8	221.8	214.2
Tangible fixed assets	68.4	61.4	65.9
Shares in subsidiaries	160.9	161.1	162.5
Total fixed assets	**419.0**	**444.2**	**442.6**
Current assets			
Inventories	65.3	68.3	67.8
Accounts receivable and other receivables	129.1	160.5	115.4
Short-term investments	255.5	—	—
Cash and cash equivalents	78.7	462.0	444.5
Total current assets	**528.5**	**690.8**	**627.7**
Total assets	**947.5**	**1,135.0**	**1,070.2**
SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES			
Total shareholders' equity	**184.8**	**372.6**	**306.0**
Long-term liabilities			
Provisions	8.6	10.3	12.8
Bond loan	494.2	491.7	492.3
Total long-term liabilities	**502.8**	**502.0**	**505.1**
Current liabilities			
Accounts payable	32.3	21.6	17.1
Other liabilities	9.4	6.9	9.1
Liabilities to Group companies	182.3	208.2	207.9
Accrued expenses and deferred income	36.0	23.7	25.0
Total current liabilities	**260.0**	**260.4**	**259.1**
Total liabilities	**762.7**	**762.4**	**764.2**
Total shareholders' equity and liabilities	**947.5**	**1,135.0**	**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 Jul-Sep	2021 Jul-Sep	2022 Jan-Sep	2021 Jan-Sep	2021 Jan-Dec
US Pharma					
Net revenues	150.1	136.4	428.8	389.2	522.7
Operating earnings (EBIT)	70.2	78.5	231.4	206.1	278.2
Depreciation and amortization	-6.4	-3.8	-11.5	-11.5	-15.4
Digital Therapeutics					
Net revenues	0.0	0.4	0.3	0.8	1.1
Operating earnings (EBIT)	-48.9	-76.4	-140.1	-186.7	-249.7
Depreciation and amortization	-6.7	-4.6	-19.0	-13.5	-18.6
HQ & Pipeline					
Net revenues	10.8	9.2	39.1	31.0	41.2
Operating earnings (EBIT)	-71.2	-61.2	-204.0	-169.3	-242.6
Depreciation and amortization	-4.4	-3.2	-20.2	-12.4	-19.1
Group					
Net revenues	161.0	145.9	468.3	421.0	565.0
Operating earnings (EBIT)	-49.8	-59.0	-112.8	-150.0	-214.1
Depreciation and amortization	-17.5	-11.6	-50.7	-37.4	-53.0
Net financial items	27.4	-0.1	37.8	-6.3	-8.4
Earnings before tax	-22.4	-59.1	-74.9	-156.3	-222.5

3. Cash flow

ADJUSTMENT FOR NON-CASH ITEMS

SEK m	2022 Jul-Sep	2021 Jul-Sep	2022 Jan-Sep	2021 Jan-Sep	2021 Jan-Dec
Depreciation/amortization and impairment	17.5	11.6	50.7	37.4	53.0
Change in provisions	-12.9	-34.4	-37.9	-80.2	-67.4
Share based payments	-0.1	-0.1	-0.1	1.5	1.5
Exchange rate income and expenses	-3.5	-1.3	-11.8	-1.9	-3.9
Total	**0.9**	**-24.1**	**0.9**	**-43.1**	**-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.

In Q3 some legal work were conducted related to clarification and complements to the information previously shared with the US authorities.

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.

In Q3 2022 a new patent covering ZUBSOLV® was granted in the US meaning Orexo currently has 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. Seven of the listed patents are currently part of the patent infringement action against Sun in the US District Court for the District of New Jersey.

In Q3 2022 the date for trial was rescheduled and is now planned to take place in Q1, 2023. The outcome of the trial 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 1,364 m as of December 31, 2021 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

- Positive data announced from phase 1 clinical trial for OX640®, a nasal epinephrine rescue medication for allergic reactions
- Ed Kim, M.D., appointed as Chief Medical Officer, replacing Michael Sumner M.D.
- Last patient enrolled in the clinical trial of MODIA®, the digital therapy for opioid use disorder

9. Revenue from contracts with customers

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

SEK m	2021 Jul-Sep					
Segment	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**vorvida®**	**deprexis®**	**Total**
US Pharma	136.4	—	—	—	—	**136.4**
Digital Therapeutics	—	—	—	0.3	0.0	**0.4**
HQ & Pipeline	—	6.8	2.4	—	—	**9.2**
Total revenue from contracts with customers	**136.4**	**6.8**	**2.4**	**0.3**	**0.0**	**145.9**
Geographical markets	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**vorvida®**	**deprexis®**	**Total**
US	136.4	—	0.8	0.3	0.0	**137.5**
EU	—	6.5	0.9	—	—	**7.4**
Rest of the world	—	0.3	0.7	—	—	**1.0**
Total revenue from contracts with customers	**136.4**	**6.8**	**2.4**	**0.3**	**0.0**	**145.9**

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

SEK m	2021 Jan-Sep					
Segment	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**vorvida®**	**deprexis®**	**Total**
US Pharma	389.2	—	—	—	—	**389.2**
Digital Therapeutics	—	—	—	0.7	0.1	**0.8**
HQ & Pipeline	—	23.8	7.2	—	—	**31.0**
Total revenue from contracts with customers	**389.2**	**23.8**	**7.2**	**0.7**	**0.1**	**421.0**
Geographical markets	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**vorvida®**	**deprexis®**	**Total**
US	389.2	—	2.3	0.7	0.1	**392.2**
EU & UK	—	22.9	2.2	—	—	**25.2**
Rest of the world	—	0.9	2.7	—	—	**3.6**
Total revenue from contracts with customers	**389.2**	**23.8**	**7.2**	**0.7**	**0.1**	**421.0**

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 Jul-Sep	2021 Jul-Sep	2022 Jan-Sep	2021 Jan-Sep	2021 Jan-Dec
EBIT	-49.8	-59.0	-112.8	-150.0	-214.1
Depreciation and amortization	17.5	11.6	50.7	37.4	53.0
EBITDA	**-32.4**	**-47.4**	**-62.1**	**-112.6**	**-161.0**
External costs for clinical studies	23.0	17.3	68.0	38.7	63.5
IP litigation and subpoena	23.7	16.6	52.0	46.4	59.6
EBITDA excluding external costs for clinical studies, IP litigation and subpoena	**14.3**	**-13.4**	**57.9**	**-27.5**	**-37.9**

CASH AND INVESTED FUNDS	2022 Jul-Sep	2021 Jul-Sep	2022 Jan-Sep	2021 Jan-Sep	2021 Jan-Dec
Short-term investments	321.5	—	321.5	—	—
Cash and cash equivalents	122.4	588.1	122.4	588.1	504.1
Cash and invested funds	**443.9**	**588.1**	**443.9**	**588.1**	**504.1**

RETURN ON SHAREHOLDERS' EQUITY	2022 Jul-Sep	2021 Jul-Sep	2022 Jan-Sep	2021 Jan-Sep	2021 Jan-Dec
Shareholders' equity beginning balance	308.9	459.4	349.6	558.5	558.5
Shareholders' equity ending balance	298.4	411.7	298.4	411.7	349.6
Average shareholders' equity	303.6	435.6	324.0	485.1	454.1
Net earnings	-26.5	-52.0	-85.8	-157.6	-223.5
Return on shareholders' equity %	**-8.7**	**-11.9**	**-26.5**	**-32.5**	**-49.2**

OPERATING EXPENSES SEK m	2022 Jul-Sep	2021 Jul-Sep	2022 Jan-Sep	2021 Jan-Sep	2021 Jan-Dec
Selling expenses	-54.7	-79.0	-146.8	-209.5	-280.4
Administrative expenses	-54.2	-42.4	-138.5	-112.4	-151.5
Research and development costs	-76.5	-63.5	-229.8	-192.4	-272.3
Other operating income and expenses	2.5	1.3	10.7	1.9	4.0
Operating expenses	**-182.8**	**-183.7**	**-504.3**	**-512.4**	**-700.2**

GROSS INVESTMENTS SEK m	2022 Jul-Sep	2021 Jul-Sep	2022 Jan-Sep	2021 Jan-Sep	2021 Jan-Dec
Investments in tangible fixed assets	0.3	3.3	7.8	18.6	24.7
Investments in intangible fixed assets	1.2	17.4	3.8	31.4	28.1
Gross investments	**1.6**	**20.7**	**11.7**	**50.0**	**52.9**