orexo

Q4 Interim Report 2021, incl. Full Year Report

Ready to capitalize on a strong foundation

Q4 2021 highlights

- Total net revenues of SEK 144.0 m (159.2)
- Net earnings of SEK -66.0 m (-49.6)
- EBITDA of SEK -48.5 m (1.0)
- US Pharma segment (ZUBSOLV® US) net revenues of SEK 133.6 m (143.1), in local currency USD 15.1 m (16.7), US Pharma EBIT of SEK 72.2 m (94.4)
- Cash flow from operating activities of SEK -80.6 m (-11.2), cash balance of SEK 504.1 m (505.3)
- Earnings per share before and after dilution amounted to -1.92 (-1.45)
- Positive outcome announced for the pivotal trial for the lead pharmaceutical pipeline asset OX124, a high-dose overdose rescue medication
- Information was provided about amorphOX™, a novel drug delivery platform
- A new pharmaceutical development project, OX640, was initiated with the aim to develop a nasal adrenaline rescue medication
- Financial outlook for 2022 is presented on page 12

Important events after the period

- In collaboration with Sober Grid, VORVIDA® and DEPREXIS® will be made available on Walgreens Find Care® during Q1

SEK 72 m
US Pharma EBIT

54%
US Pharma EBIT margin

SEK 504 m
Cash and cash equivalents

SEK m, unless otherwise stated	2021 Oct-Dec	2020 Oct-Dec	2021 Jan-Dec	2020 Jan-Dec
Net revenues	144.0	159.2	565.0	663.6
Cost of goods sold	-20.3	-11.3	-78.9	-65.6
Operating expenses	-187.8	-158.9	-700.2	-617.9
EBIT	-64.1	-11.0	-214.1	-19.9
EBIT margin, %	-44.5%	-6.9%	-37.9%	-3.0%
EBITDA	-48.5	1.0	-161.0	19.0
Earnings per share, before dilution, SEK	-1.92	-1.45	-6.51	-2.45
Earnings per share, after dilution, SEK	-1.92	-1.45	-6.51	-2.45
Cash flow from operating activities	-80.6	-11.2	-229.0	16.8
Cash and cash equivalents	504.1	505.3	504.1	505.3

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 2020.

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 121. 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.

For further information, please contact
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Presentation

At 2 pm CET, the same day as the announcement of the report, Orexo invites analysts, investors and media to attend a presentation where Nikolaj Sørensen, CEO, Joseph DeFeo, CFO, and Robert Rönn, SVP and Head of R&D, will present the report and host a Q&A.
Questions can also be sent in advance to ir@orexo.com, no later than 11 am CET.
Please view the instructions below on how to participate.
Internet: https://tv.streamfabriken.com/orexo-q4-2021
Telephone: SE +46 8 50 55 83 74 UK +44 33 33 00 92 63 US +1 64 67 22 49 02
The presentation material will be available on Orexo´s website prior to the audiocast, view Investors/Reports, presentations.

Financial calendar

Annual Report 2021 - in the week beginning March 28, 2022
Annual General Meeting 2022 - April 21, 2022 at 4 pm CET
Interim Report Q1 2022 - April 28, 2022 at 8.00 am CET
Interim Report Q2 2022 - July 14, 2022 at 8.00 am CET
Interim Report Q3 2022 - November 3, 2022 at 8.00 am CET
Interim Report Q4 2022 - January 26, 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.

Expanding the business

I am pleased to report that the fourth quarter of 2021 saw a continued strong profit contribution from ZUBSOLV® and sales nearly in line with Q3. The financial contribution from ZUBSOLV® is important to maintain pace and enable us to continue building on the highlights of the quarter. During Q4 we showed a positive outcome for the OX124 pivotal trial, we informed about our new drug delivery platform amorphOX™, and expanded our pipeline with a new pharmaceutical project OX640 (nasal epinephrine). Additionally, we initiated the launch of MODIA™ and after the end of the period, our partnership with Sober Grid reached a significant milestone establishing an agreement with Walgreens to make our collaborative services available on their Find Care® digital market place during the first quarter.

ZUBSOLV® - Continued strong profit contribution
ZUBSOLV® is competing in a market dominated by generic alternatives and significant price competition. In this environment I am pleased to see we have stabilized net sales and we are entering 2022 with a broader reimbursement than the beginning of 2021. A continued broad reimbursement is critical to take advantage of future market growth and maintain the profit contribution from ZUBSOLV®, with an EBIT margin exceeding 50 percent. Overall market growth continues to be slow compared with 2020, as Covid-19 still holding society in a tight grip. However, we are optimistic that the increased focus and attention on opioid use disorder will continue driving positive market growth, but due to the pandemic we conservatively expect the market growth to be in the range of 5-8 percent in 2022.

"A continued broad reimbursement is critical to take advantage of future market growth and maintain the profit contribution from ZUBSOLV®

During 2021, Kentucky decided to expand Medicaid coverage to all buprenorphine products, which gave ZUBSOLV® access to this market for the first time since the launch in 2013. We saw a positive impact during 2021 with a 45 percent increase in Q4 compared with Q3. In light of the significant death toll from opioid overdoses we know other states in the US also are considering similar initiatives, to reduce treatment barriers for patients.

Looking beyond the US borders, we have finally completed the supply chain for other markets and we are now looking to initiate sales in Europe, along with Accord Healthcare, during the first half of 2022, potentially with some sales in the first quarter.

Digital Therapeutics – A collaboration was initiated with Walgreens
The Covid-19 pandemic has shown how fragile the healthcare systems are and the need for new, innovative solutions to ensure availability of care. Digital therapeutics were recognized by the FDA early in the pandemic as a valuable complement to existing care, and they opened up a temporary regulatory route to market, Emergency Use Authorization. Orexo, like most of our peers, saw the opportunity and accelerated our digital therapies launch, however the lack of commercial traction of digital therapeutic solutions made it clear the general market has not been ready to implement these tools more broadly.

The main concern is around the lack of reimbursement processes. On a national level in the US, intensive work is ongoing to establish reimbursement codes applicable to digital therapeutic solutions. These nation wide solutions will be a major trigger of these new groundbreaking treatments, and I am pleased to report the first national reimbursement code was approved in Q4 and will be ready for implementation in January 2023.

While waiting for the necessary reimbursement processes to be established, and for the market to gain momentum, we continue our strategic focus to build partnerships and establish a scalable full-service technical platform. Together with evidence-based digital therapies, commercial excellence and employees with extensive medical experience in treating mental illness, Orexo is well placed to take a leading position when the market starts to take off.

In parallel, and in an effort to accelerate reimbursement opportunities by referring to already existing alternative reimbursement routes, we have been working with Trinity Health in North Dakota to develop an efficient and viable reimbursement process. This is possible when they integrate our digital therapies into existing reimbursed treatment programs. After solving several administrative hurdles, we expect this to become a benchmark for other large healthcare providers when it is implemented over the next few months.

In November, the ZUBSOLV® sales team started an educational and awareness campaign about MODIA™ for their ZUBSOLV® customers. We will expand this campaign to allow engaged healthcare professionals to try the product with a limited number of patients early in 2022, before expanding into broader commercialization mid-2022.

The ongoing work with Sober Grid, the world's largest online addiction community, and with other healthcare providers and employers is making good progress and we expect to see continuous growth during 2022 from these partnerships. The Sober Grid partnership has opened new distribution channels and I am proud that our combined solution met the high standards to be included on Walgreens Find Care® digital market place for healthcare services, providing VORVIDA® and DEPREXIS® with a new but well-established distribution channel to reach the millions of patients seeking care through Walgreens Find Care® online platform.

R&D – Important steps taken in the development of new innovative pharmaceuticals

In Q4 we took several significant steps forward with our development pipeline. Firstly, we reported a positive outcome of the pivotal trial for OX124. Upon approval by the FDA, the plan is to initiate the US launch late in 2023. With the significant rise in people overdosing with fentanyl and similar substances, the need for new and more powerful treatment options has never been greater.

Secondly, I am very pleased that in Q4 we could share more information about amorphOX™, our new drug delivery platform. amorphOX™ has been developed along with our nasal overdose medications, OX124 and OX125. The platform has several significant advantages to a broad range of products, such as rapid dissolve time and excellent stability. It is a very dynamic platform which will form the backbone of Orexo's pharmaceutical developments in the coming years.

"The amorphOX™ technology has several significant advantages to a broad range of products, such as rapid dissolve time and excellent stability.

First out is OX640, a nasal rescue medication for allergic reactions. OX640 will provide important benefits to patients and health care systems ensuring the correct adrenaline dose is both reliably and conveniently available when needed. The first clinical study is planned for the end of 2022. We can see strong synergies with OX124 and OX125, both in terms of clinical development and commercial supply.

Summary and outlook

The fourth quarter was eventful for Orexo and we took significant steps to broaden our business. While ZUBSOLV® continues to be a valuable profit contributor and has the potential to over time add additional revenue growth, the long term growth of the company depends on our ability to broaden our pharmaceutical product portfolio and the success in establishing a new business area within digtal therapeutics. 2021 was successful in expanding our pharmaceutical development platform and we expect to see revenue growth from digital therapies in 2022.

Uppsala, Sweden, January 27, 2022

Nikolaj Sørensen
President and CEO

Business update

US Pharma

zubsolv

Sublingual tablet for treatment of opioid use disorder

The ZUBSOLV® business is divided into three distinct segments with partly opposing drivers. ZUBSOLV´s sales development is most reliant on the open segment[1], where ZUBSOLV® demand comparing to the previous period has had a slight decline after being stable for two quarters.

The overall market grew 2 percent over Q3 2021. The year over year growth amounted to 5 percent. This slowdown from previous double-digit growth can be attributed to limited access to treatment during the Covid-19 pandemic caused by three main factors. Firstly, fewer patients were actively seeking treatment during the lockdown, secondly, less access to HCP's overall, and thirdly some physicians limited acceptance of new patients. The opioid epidemic has accelerated during the Covid-19 pandemic, and among others the number of fatal overdoses has reached record-high levels. In the wake of Covid-19 the buprenorphine/naloxone market growth is predicted to be positively impacted by multiple initiatives underway to improve access to medication assisted treatment. In 2021 Kentucky passed legislation to improve access to all opioid dependence treatment medications, including ZUBSOLV®, effective July 1, 2021. As Kentucky is the fourth largest volume Medicaid state in this treatment area this is an important growth opportunity. In Q4 we saw continued positive effects of the improved access with a volume increase of 45 percent from previous quarter in Kentucky.

ZUBSOLV's Q4 2021 overall prescription volume is down 4 percent versus Q3 2021. Our core segment, the open segment, declined slightly with 2 percent versus Q3 2021. Within the open segment, commercial showed a mild decline while Medicaid volume was stable Q4 versus Q3. The demand in former exclusive plans, Humana and United Health Group, showed 5 percent decline from previous quarter. The non-reimbursed segment declined 9 percent driven by two small New York based payers, IHA and CDPHP, who moved ZUBSOLV® to a non-preferred formulary position in Q4.

On a year over year basis, Q4 2021 compared to Q4 2020 ZUBSOLV® demand declined 12 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 to compensate due to Covid-19.

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. Q4 2021 saw a decrease in access to prescribers versus Q3 2021. This impact is mainly due to obstacles associated with new waves of Covid-19 infections and to some extent a seasonal effect of holiday office closure. ZUBSOLV® is the only actively promoted daily treatment and less access to physicians has disproportional effect on ZUBSOLV® compared to generic competitors.

For 2022 ZUBSOLV's market access in the public payer segment will be 42 percent of the patients have unrestricted access to ZUBSOLV®, an increase from 34 percent in January 2021. ZUBSOLV's best in class market access in the Commercial payer segment will be 98 percent, a minimal decline from 99 percent due to the loss of access in the small payers IHA and CDPHP.

Digital Therapeutics

VORVIDA® deprexis® modia

VORVIDA® - for heavy alcohol misuse
DEPREXIS® - for managing symptoms of depression
MODIA™ - for opioid use disorder

During Q4, Sober Grid has made VORVIDA® and DEPREXIS® available through their peer coaches and we have approached new potential customer and partners with our solution. The first major accomplishment was reached very recently in January, with an agreement with Walgreens Find Care® to make our collaborative services available on Walgreens Find Care® online platform. Walgreens Find Care® is one of the leading online digital healthcare marketplaces in the US dedicated to help patients find and connect with healthcare providers and services both physically and virtually.

In Q4 an awareness and educational campaign for MODIA™ was initiated focusing on our existing ZUBSOLV® customers. Insights from our launch of VORVIDA® and DEPREXIS® have taught us to ensure the healthcare professionals fully understand and appreciate the treatment value of the digital therapies before asking them to start implement MODIA™ in their treatment programs. The awareness campaign will move into a trial phase in Q1 2022 to allow physicians to test MODIA™ with a limited number of patients before broadening the offer to all patients. We expect these programs to move into actual commercial utilization during the summer of 2022 when the physicians have established the reimbursement processes for MODIA™.

[1] ZUBSOLV® is reimbursed and competes on equal terms with both branded products and/or generics.

For VORVIDA® and DEPREXIS®, we have as previously announced moved away from direct media promotion to patients. This has resulted in reduced spending in Q4 compared to Q3, despite the additional expenses required to launch the awareness and educational campaign for MODIA™. The commercialization of VORVIDA® and DEPREXIS® is now focused on three customer segments:

• *Sales direct to patients*. This segment will be managed through partnerships with established and well known distributors, such as Sober Grid and the recently announced partnership with Walgreen's Find Care. Patients will be able to purchase VORVIDA® and DEPREXIS® directly through these channels or be redirected to the dedicated websites for the two digital therapies. Sober Grid has started sales of VORVIDA® through their peer coaches and will during the first half of 2022 expand to new groups of users of their online community

• *Sales to employers.* This segment will be managed through our partners Sober Grid, Just Miine and E-HBS. All of these partners have the capability of providing complementary services to the employers including access to healthcare professionals as needed. All three have advanced discussions with several employers and we expect to close the first contracts during H1. The assessment of the digital therapies with a leading US tech company has continued throughout 2021, with an expectations to reach a commercial agreement during H1 2022.

• *Sales to large healthcare providers.* This segment is the segment with the highest sales potential over time, but it is also the most complex segment for a new treatment due to the inherent bureaucracy in healthcare reimbursement, billing and monitoring. We have continued the collaboration with Trinity Health in North Dakota during the quarter to build a treatment program covered through their existing reimbursement channels. This work has been delayed several times due to new waves of Covid-19, but we expect first patients to be included during H1 2022. Benefis Health System is following the work at Trinity Health and will implement a similar reimbursement set up when ready. Discussion proceed with several other large healthcare providers and solving the reimbursement processes together with Trinity Health is expected to have positive effect on these discussions as well.

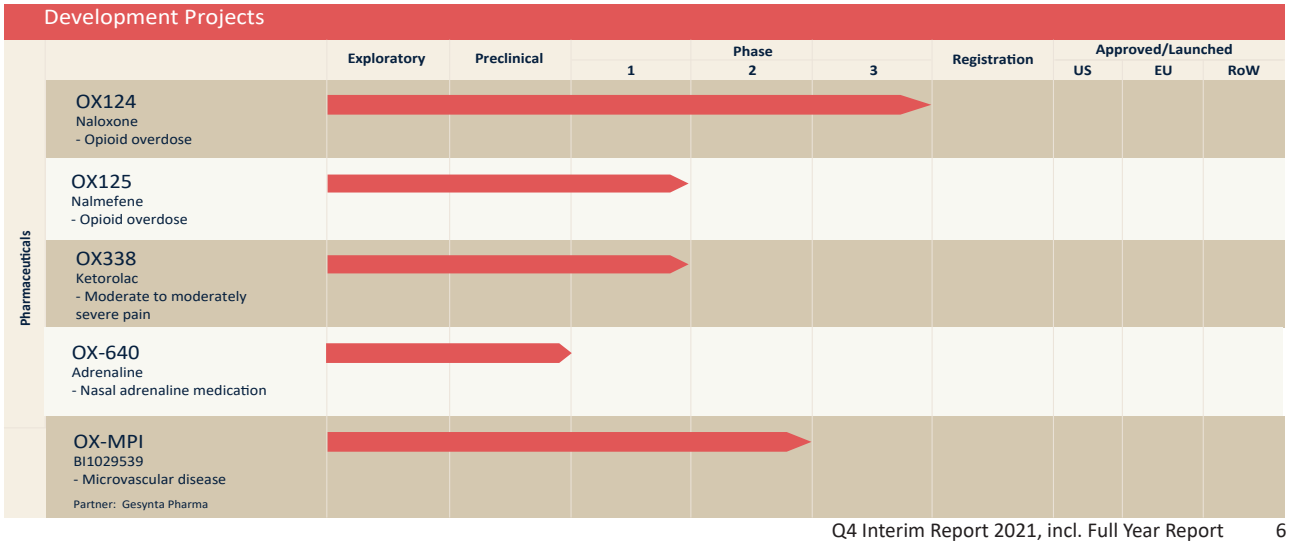
HQ & Pipeline

amorphOX™ – a new proprietary drug delivery platform

In Q4, information was provided about the new scalable drug delivery platform, amorphOX™. The platform comprises an innovative powder-based technology that can be used to develop highly differentiated drugs with various active ingredients and administration routes. amorphOX™, whose particles are presented as an amorphous composite, has shown to be both chemically and physically stable, commonly a significant problem for amorphous drug compositions.

In addition to provide improved stability and shelf-life, it displays nearly instant dissolution even in very limited amounts of liquids, making it an ideal choice for the development of drugs targeting administration sites such as the nasal and sublingual cavities. amorphOX™ has been validated in various in vivo studies, including human clinical trials, demonstrating rapid and extensive absorption of various drugs. The platform is well tolerated and shows a low degree of inter-patient variability. Several new patent applications directed to amorphOX™ have been filed, which should serve to protect the technology until 2042.

Today the amorphOX™ platform is the backbone in the development of the powerful rescue medications for opioid overdoses, OX124 and OX125, and additionally in the new pharma development project, OX640, where the aim is to develop an adrenaline rescue medication to treat allergic reactions. All using the nasal route of administration.



As the commercial supply chain has been established for OX124, it will contribute to shorten timelines, reduce costs and limit risks in the development of future products based on the amorphOX™ platform and using nasal delivery, including OX125 and OX640. Development of products based on this technology will be conducted by Orexo or in partnership with other pharmaceutical companies.

Most advanced fully-owned pipeline asset

OX124 – naloxone opioid overdose rescue medication with nasal delivery
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 showed more rapid absorption, substantially higher plasma concentrations of naloxone, and sustained duration of elevated plasma concentrations when compared to the current market leader.[1] Successful study result from the pivotal trial OX124-002 (view below) communicated in Q4, along with data from the on-going stability study, will be the primary support for the new drug application that is expected to be filed with the FDA in H2 2022. Following FDA approval, a US launch will be initiated in H2 2023. OX124 has patents protecting the product until 2039.

The number of drug-related overdose deaths continue to be on a record-high level. The vast majority of these deaths, 76 percent, were caused by opioids and within the opioid-related deaths synthetic opioids accounted for 85 percent,[2] underlining the need for more powerful and faster-acting rescue medications.

Orexo is targeting a market today amounting to approximately USD 300-500 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, 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. Two generic versions of the branded leader have been launched with a price nearly in line with the branded product. Under these market conditions. With the current pricing and the market reaching its full potential, potential product net sales of OX124 in the US market could be in the range of USD 70-110 million.

In Q4, the pivotal trial OX124-002, successfully met the primary endpoints in a 4-period crossover, comparative bioavailability study in healthy volunteers. The study compared two dose regimens of OX124 to two dose regimens of an injection reference product. OX124 showed a significantly faster and higher absorption of naloxone compared to intramuscular dosing with the injection reference product and furthermore, OX124 was found to be well tolerated. In parallel to finalizing the clinical development, the work continued to ensure that the manufacturing and supply chain can provide the capacity and redundancy needed for commercial supply.

Other pipeline assets

OX125 – nalmefene opioid overdose rescue medication with nasal delivery
With OX125, Orexo is developing an overdose rescue medication for situations where powerful and long-lasting effects are required, e.g. in remote areas, as response to misuse of long-acting opioids or for anti-terror stockpiling. 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 innovation related to OX125 has patent protection until 2039. 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.

In Q4, the pharmaceutical development work continued, foremost focusing on formulation optimization and evaluation of stability data. Most of the current development activities for OX124 are also applicable to OX125 and apart from the formulation work next steps in the development of OX125 will be initiated after filing of OX124. In parallel, the increasing prevalence of new synthetic opioids and its impact on societies globally are closely monitored. A progress where OX125 could meet an unmet medical need for an overdose medication, which in addition to having a rapid absorption and being powerful, also remaining in the body for a much longer time.

[1] Press release communicating the results from the exploratory clinical study OX124-001: https://orexo.com/investors/regulatory-press-releases/2019-01-07-positive-results-from-human-pk-study-assessing-orexo-s-new-intranasal-naloxone-formulations-for-opioid-overdose-reversal
[2] Center of Disease Control, predicted data ending June 30, 2021

OX338 - acute moderate to moderately severe pain with oral delivery
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 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 with nasal delivery
In Q4 the work to develop a nasal adrenaline product for the emergency treatment of allergic reactions was initiated. 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 showed 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.

Orexo will initiate the first exploratory clinical phase 1 trial for OX640 during H2 and the result of this study will guide the continued development and strategic decision on when to involve a partner in the development and future commercialization.
OX-MPI – microvascular diseases
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. A clinical Phase 2 study in patients suffering from systemic sclerosis is underway and study results are expected in H2 2022.

ZUBSOLV® for treatment of opioid use disorder in geographies outside the US

In Q4 the collaboration with the commercialization partner Accord Healthcare ramped up preparing for launch in the EU that is expected to be initiated on some selected markets in H1 2022. All permissions and equipment material are in place for the supply chain and the work in Q4 was primarily directed at validation of the packaging process.

The commercialization of ZUBSOLV® has the potential to cover 29 European countries and will be 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 future 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

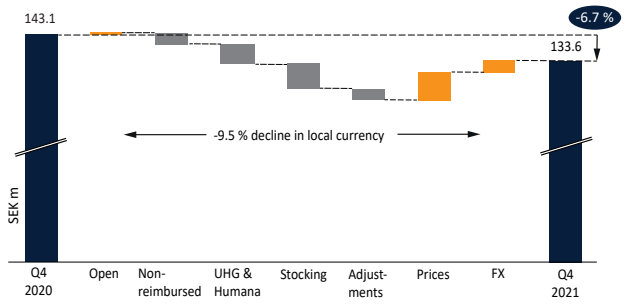
Revenues

Total revenues amounted to SEK 144.0 m (159.2) for the quarter and to SEK 565.0 m (663.6) for the full year. The decrease is mainly explained by lower US Pharma revenues.

Revenues by segment

US Pharma revenues amounted to SEK 133.6 m (143.1) for the quarter. The decrease in US Pharma revenues is mainly driven by lower ZUBSOLV® demand due to competition in previously exclusive plans and a weaker overall market growth pace due to Covid-19. Stronger USD exchange rate together with increased prices and a favorable product mix had a positive impact.

ZUBSOLV® US NET REVENUE DEVELOPMENT



In local currency US Pharma net revenues for the quarter amounted to USD 15.1 m (16.7) while vs Q3 2021 US Pharma net revenues decreased by USD 0.7 m mainly due to no adjustments of accrued product returns and less wholesaler stocking while demand continued to stabilize. US Pharma revenues amounted to SEK 522.7 m (623.3) for the full year.

Digital Therapeutics (DTx) recognized net revenues for the quarter amounted to SEK 0.3 m (0.0) as sales efforts during the quarter have focused on piloting different reimbursement pathways and commercial concepts. DTx recognized net revenue amounted to SEK 1.1 m (0.03) and deferred revenues to SEK 0.2 m (0.1) for the full year.

HQ and Pipeline partner product related revenues for the quarter amounted to SEK 10.1 m (16.0) and to SEK 41.2 m (40.2) for the full year.

Costs of goods sold

Cost of goods sold (COGS) amounted to SEK 20.3 m (11.3) for the quarter. US Pharma amounted to SEK 17.2 m (9.1) mainly due to cyclical production pattern and variable scale together with unfavorable exchange-rate impact vs prior year. Royalties and technical infrastructure costs for DTx amounted to SEK 2.7 m (2.1) explained by adding MODIA™ to the DTx product portfolio. Cost of goods sold (COGS) for the full year amounted to SEK 78.9 m (65.6). US Pharma amounted to SEK 67.5 m (61.0) mainly due to cyclical production pattern and variable scale. Royalties and technical infrastructure costs for DTx amounted to SEK 11.0 m (4.6) explained by full year impact.

Operating expenses

Selling expenses amounted to SEK 70.9 m (79.0) for the quarter. The decrease over the same period last year is mainly explained by lower selling expenses in US Pharma and in DTx. Selling expenses amounted to SEK 280.4 m (286.6) for the full year.

Administrative expenses amounted to SEK 39.1 m (19.8) for the quarter explained by higher legal expenses for IP litigation and subpoena and by higher costs for the long-term incentive programs. Administrative expenses amounted to SEK 151.5 m (102.8) for the full year. The increase is mainly explained by higher legal expenses for IP litigation and subpoena partly offset by lower costs for

NET REVENUES AND OPERATING EARNINGS PER SEGMENT

SEK m	Net Revenues				EBIT			
	2021 Oct-Dec	2020 Oct-Dec	2021 Jan-Dec	2020 Jan-Dec	2021 Oct-Dec	2020 Oct-Dec	2021 Jan-Dec	2020 Jan-Dec
ZUBSOLV® US product sales	133.6	143.1	522.7	623.3	—	—	—	—
US Pharma – total	**133.6**	**143.1**	**522.7**	**623.3**	**72.2**	**94.4**	**278.2**	**331.2**
Digital Therapeutics (DTx) product sales	0.3	0.0	1.1	0.0	—	—	—	—
Digital Therapeutics (DTx) – total	**0.3**	**0.0**	**1.1**	**0.0**	**-63.8**	**-65.3**	**-249.7**	**-175.4**
Abstral® royalty	8.3	15.1	32.1	29.7	—	—	—	—
Edluar® royalty	1.8	0.9	9.1	10.4	—	—	—	—
ZUBSOLV® - ex US	—	—	—	0.1	—	—	—	—
HQ & Pipeline segment – total	**10.1**	**16.0**	**41.2**	**40.2**	**-72.5**	**-40.1**	**-242.6**	**-175.8**
Total	**144.0**	**159.2**	**565.0**	**663.6**	**-64.1**	**-11.0**	**-214.1**	**-19.9**

the long-term incentive programs.
Research and development costs amounted to SEK 80.0 m (59.0) for the quarter. The increase is mainly explained by costs related to MODIA™ study and higher internal costs. Research and development costs for the full year amounted to SEK 272.3 m (224.9).

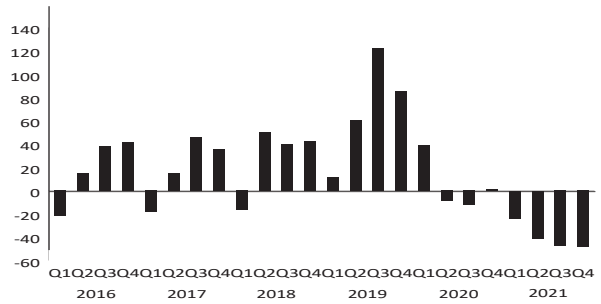
Other operating income and expenses amounted to SEK 2.1 m (-1.1) for the quarter, mainly explained by exchange-rate gains derived from revaluations of parent company balance sheet items in foreign currency, predominantly in USD. Other operating income and expenses for the full year amounted to SEK 4.0 m (-3.6).

Operating profit

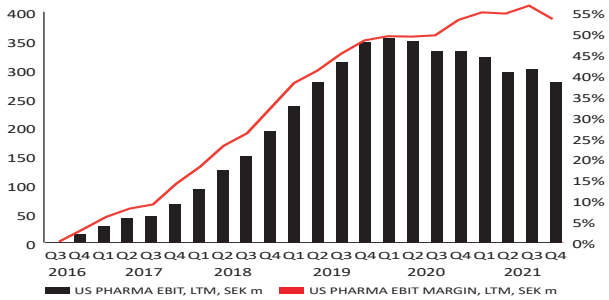
Orexo's profitability reflects costs in DTx and in pipeline and EBITDA amounted to SEK -48.5 m (1.0) for the quarter and to SEK -161.0 m (19.0) for the full year.

The EBIT contribution from US Pharma amounted to SEK 72.2 m (94.4) for the quarter, equal to an EBIT margin of 54.0 percent (65.9). The EBIT contribution from US Pharma amounted to SEK 278.2 m (331.2) for the full year, equal to an EBIT margin of 53.2 percent (53.1). The increase is explained by lower operating costs partly offset by lower sales and gross profit.

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 the quarter amounted to SEK -2.1 m (-29.3) and is mainly explained by positive unrealized exchange rate impact of SEK 4.0 m (-25.6) derived from the parent company's foreign currency bank accounts mainly in USD, partly offset by higher costs for corporate bonds of SEK -5.5 m (-3.0). Net financial items amounted to SEK -8.4 m (-18.4) for the full year.

Total tax expenses amounted to SEK 0.3 m (-9.2) for the quarter. The decrease is explained by absence of negative impact of SEK -5.5 m from decreased parent company tax asset in Q4 2020 and by positive adjustment to deferred tax assets related to temporary differences of SEK 0.2 m (-3.8). Total tax expenses amounted to SEK -1.0 m (-46.1) for the full year. The decrease is explained by absence of negative impact of SEK -49.0 m from decreased parent company tax asset in 2020 and by negative adjustment to deferred tax assets related to temporary differences of SEK -1.2 m (2.9).

Orexo performs regular assessments of its deferred tax asset and makes adjustments according to the recognition requirements of IAS 12.

Net earnings

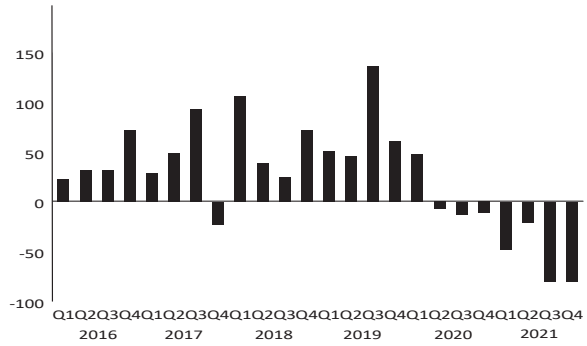
Net earnings amounted to SEK -66.0 m (-49.6) for the quarter and to SEK -223.5 m (-84.4) for the full year.

Cash and cash flow

As of December 31, 2021, cash and cash equivalents amounted to SEK 504.1 m (505.3) and interest-bearing liabilities to SEK 492.3 m (224.5), i.e. a positive net cash position of SEK 11.8 m (280.8).

Cash flow from operating activities amounted to SEK -80.6 m (-11.2) for the quarter and was negatively impacted by extended wholesaler payment terms in return of unchanged wholesaler fee. Cash flow from operating activities amounted to SEK -229.0 m (16.8) for the full year.

CASH FLOW FROM OPERATING ACTIVITIES, SEK m



[1] Last Twelve Months

Investments

Gross investments in tangible and intangible fixed assets amounted to SEK 2.9 m (29.0) for the quarter, lower investment is mainly explained by a payment of non-refundable milestone for MODIA™, investments in the DTx enterprise platform and in equipment for the development organization in Q4 2020. Gross investments in tangible and intangible fixed assets amounted to SEK 52.9 m (189.8) for the full year, lower investment is mainly explained by a payment of non-refundable milestone for DEPREXIS® and MODIA™, investments in the DTx enterprise platform and in equipment for the development organization in 2020.

Equity

Shareholders' equity at December 31, 2021, was SEK 349.6 m (558.5). The equity/asset ratio was 27.4 percent (45.3).

Parent company

Net revenues for the quarter amounted to SEK 91.5 m (80.1) of which SEK 81.3 m (64.0) was related to sales to Group companies. Net revenues amounted to SEK 365.9 m (446.4) for the full year of which SEK 324.7 m (406.2) was related to sales to Group companies.

Earnings before tax were SEK -66.6 m (-67.2) for the quarter and to SEK -219.8 m (-23.4) for the full year mainly explained by investment in DTx and development projects. Investments for the quarter amounted to SEK 6.1 m (17.6) and to SEK 35.0 m (168.7) for the full year. Lower investment is mainly explained by a payment of non-refundable milestones for DEPREXIS® and MODIA™ and by investments in equipment for the development organization in 2020.

As of December 31, 2021, cash and cash equivalents in the parent company amounted to SEK 444.5 m (361.3).

Other information

Outcome financial outlook 2021

• Due to Covid-19 the buprenorphine/naloxone market will temporarily show a lower annual growth pace and reach a level of 5-8 percent
Outcome: 7.5 percent
• ZUBSOLV® US net sales in Q4 is expected to be in line with Q3, and net sales for 2021 will decline compared to 2020
Outcome: ZUBSOLV® net sales showed a mild decline QoQ of -2 percent, same direction was shown on an annual basis
• OPEX for Q4 will be in line with Q3
Outcome: mild increase of 2 percent
• US Pharma EBIT will exceed 50 percent
Outcome: 53 percent

With the Covid-19 pandemic continuing, the financial outlook is associated with increased uncertainties. The financial outlook is based on exchange rates in September 2021.

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
• ZUBSOLV® net sales will decline slightly in H1 2022 vs H2 2021. In H2 ZUBSOLV® net sales will increase comparing to H1.
• OPEX in line with 2021, with R&D expenses increasing and selling expenses declining
• US Pharma EBIT margin will exceed 50 percent

With the Covid-19 pandemic continuing, the financial outlook is associated with increased uncertainties. All numbers are based on exchange rates in December 2021.

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 2020 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, January 27, 2022

Nikolaj Sørensen
President and CEO

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

Financial reports, notes and key figures

CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS

SEK m	Notes	2021 Oct-Dec	2020 Oct-Dec	2021 Jan-Dec	2020 Jan-Dec
Net revenues	9	144.0	159.2	565.0	663.6
Cost of goods sold		-20.3	-11.3	-78.9	-65.6
Gross profit		**123.7**	**147.9**	**486.1**	**598.0**
Selling expenses		-70.9	-79.0	-280.4	-286.6
Administrative expenses		-39.1	-19.8	-151.5	-102.8
Research and development expenses		-80.0	-59.0	-272.3	-224.9
Other operating income and expenses		2.1	-1.1	4.0	-3.6
Operating earnings (EBIT)		**-64.1**	**-11.0**	**-214.1**	**-19.9**
Net financial items		-2.1	-29.3	-8.4	-18.4
Earnings before tax		**-66.2**	**-40.3**	**-222.5**	**-38.3**
Tax	5	0.3	-9.2	-1.0	-46.1
Net earnings for the period[1]		**-66.0**	**-49.6**	**-223.5**	**-84.4**
Earnings per share, before dilution, SEK		-1.92	-1.45	-6.51	-2.45
Earnings per share, after dilution, SEK		-1.92	-1.45	-6.51	-2.45

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

SEK m	2021 Oct-Dec	2020 Oct-Dec	2021 Jan-Dec	2020 Jan-Dec
Earnings for the period	**-66.0**	**-49.6**	**-223.5**	**-84.4**
Other comprehensive income				
Items that may subsequently be reversed to the statement of operations:				
Exchange-rate differences	3.9	-11.6	13.0	-16.5
Other comprehensive earnings for the period, net after tax	**3.9**	**-11.6**	**13.0**	**-16.5**
Total comprehensive earnings for the period[1]	**-62.1**	**-61.2**	**-210.5**	**-100.9**

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

CONDENSED CONSOLIDATED BALANCE SHEET

SEK m	Notes	2021 Dec 31	2020 Dec 31
ASSETS			
Fixed assets			
Tangible fixed assets		65.9	47.3
Intangible fixed assets		248.9	252.8
Right-of-use assets		59.2	67.8
Deferred tax assets	5	33.4	32.7
Other financial assets		0.8	0.7
Total fixed assets		**408.2**	**401.3**
Current assets			
Inventories		92.3	108.4
Accounts receivable and other receivables		269.2	217.9
Cash and cash equivalents		504.1	505.3
Total current assets		**865.5**	**831.6**
Total assets		**1,273.7**	**1,232.9**
SHAREHOLDERS' EQUITY AND LIABILITIES			
Total shareholders' equity		**349.6**	**558.5**
Long-term liabilities			
Provisions		13.5	25.7
Long-term liabilities, interest bearing		492.3	—
Lease liabilities, long-term		38.0	47.4
Total long-term liabilities		**543.9**	**73.1**
Current liabilities and provisions			
Provisions		160.1	197.3
Current liabilities, interest bearing		—	224.5
Current liabilities, non-interest bearing		199.9	160.4
Lease liabilities, current		20.2	19.1
Total current liabilities and provisions		**380.2**	**601.3**
Total liabilities		**924.1**	**674.4**
Total shareholders' equity and liabilities		**1,273.7**	**1,232.9**

CONSOLIDATED CHANGES IN SHAREHOLDERS' EQUITY

SEK m	2021 Dec 31	2020 Dec 31
Opening balance, shareholders' equity	**558.5**	**706.4**
Total comprehensive earnings for the period	-210.5	-100.9
Share-based payments	1.5	-19.7
Buy back of shares	—	-27.3
New share issue	—	—
Closing balance, shareholders' equity	**349.6**	**558.5**

CONDENSED CONSOLIDATED CASH FLOW STATEMENTS

SEK m	Notes	2021 Oct-Dec	2020 Oct-Dec	2021 Jan-Dec	2020 Jan-Dec
Operating earnings (EBIT)		-64.1	-11.0	-214.1	-19.9
Interest received		0.0	0.0	0.0	3.0
Interest paid		-4.9	-2.6	-22.9	-11.8
Income taxes paid		5.1	1.5	5.1	0.6
Adjustment for non-cash items	3	26.4	23.2	-16.8	-7.1
Cash flow from operating activities before changes in working capital		**-37.5**	**11.1**	**-248.6**	**-35.1**
Changes in working capital		**-43.1**	**-22.3**	**19.6**	**51.9**
Cash flow from operating activities		**-80.6**	**-11.2**	**-229.0**	**16.8**
Acquisition of tangible and intangible fixed assets		-2.9	-29.0	-52.9	-189.8
Disposal of financial assets		—	—	—	0.6
Cash flow from investing activities		**-2.9**	**-29.0**	**-52.9**	**-189.2**
Buy back shares		—	—	—	-27.3
New loan		—	—	490.1	—
Repayment of loans		-5.5	-4.3	-239.5	-84.0
Cash from financing activities		**-5.5**	**-4.3**	**250.6**	**-111.3**
Cash flow for the period		**-89.0**	**-44.6**	**-31.2**	**-283.7**
Cash and cash equivalents at the beginning of the period		**588.1**	**593.3**	**505.3**	**816.8**
Exchange-rate differences in cash and cash equivalents		5.0	-43.4	30.0	-27.8
Changes in cash and cash equivalents		-84.0	-88.0	-1.2	-311.5
Cash and cash equivalents at the end of the period		**504.1**	**505.3**	**504.1**	**505.3**

Key Figures[1]

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.

	2021 Oct-Dec	2020 Oct-Dec	2021 Jan-Dec	2020 Jan-Dec
EBIT margin, %	-44.5	-6.9	-37.9	-3.0
Return on shareholder equity, %	-17.3	-8.4	-49.2	-13.3
Net debt, SEK m	-11.7	-280.8	-11.7	-280.8
Debt/equity ratio, %	140.8	40.2	140.8	40.2
Equity/assets ratio, %	27.4	45.3	27.4	45.3
Number of shares, before dilution	34,327,907	34,294,873	34,319,649	34,398,815
Number of shares, after dilution	34,327,907	34,294,873	34,319,649	34,398,815
Earnings per share, before dilution, SEK	-1.92	-1.45	-6.51	-2.45
Earnings per share, after dilution, SEK	-1.92	-1.45	-6.51	-2.45
Number of employees at the end of the period	121	138	121	138
Shareholders' equity, SEK m	349.6	558.5	349.6	558.5
Capital employed, SEK m	841.9	783.0	841.9	783.0
Working capital, SEK m	-18.8	-50.5	-18.8	-50.5

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

CONDENSED PARENT COMPANY STATEMENT OF OPERATIONS

SEK m	Notes	2021 Oct-Dec	2020 Oct-Dec	2021 Jan-Dec	2020 Jan-Dec
Net revenues		91.5	80.1	365.9	446.4
Cost of goods sold		-15.3	-13.2	-71.2	-79.7
Gross profit		**76.2**	**66.9**	**294.7**	**366.7**
Selling expenses		-57.6	-60.8	-227.3	-190.7
Administrative expenses		-24.2	-10.6	-92.3	-53.1
Research and development costs		-68.0	-51.3	-226.0	-180.1
Other operating income and expenses		8.5	17.1	36.8	50.0
Operating earnings (EBIT)		**-65.1**	**-38.7**	**-214.2**	**-7.2**
Interest income and expenses		-4.8	-2.6	-18.0	-10.9
Other financial income and expenses		3.4	-26.0	12.5	-5.4
Net financial items		**-1.5**	**-28.5**	**-5.6**	**-16.3**
Earnings before tax		**-66.6**	**-67.2**	**-219.8**	**-23.4**
Tax	5	—	-5.5	—	-49.0
Earnings for the period		**-66.6**	**-72.8**	**-219.8**	**-72.5**

PARENT COMPANY STATEMENT OF COMPREHENSIVE INCOME

SEK m	2021 Oct-Dec	2020 Oct-Dec	2021 Jan-Dec	2020 Jan-Dec
Earnings for the period	**-66.6**	**-72.8**	**-219.8**	**-72.5**
Other comprehensive income	—	—	—	—
Total comprehensive earnings for the period	**-66.6**	**-72.8**	**-219.8**	**-72.5**

CONDENSED PARENT COMPANY BALANCE SHEET

SEK m	2021 Dec 31	2020 Dec 31
ASSETS		
Fixed assets		
Intangible fixed assets	214.2	234.4
Tangible fixed assets	65.9	47.2
Shares in subsidiaries	162.5	160.4
Total fixed assets	**442.6**	**442.0**
Current assets		
Inventories	67.8	90.9
Accounts receivable and other receivables	115.4	111.3
Cash and bank balances	444.5	361.3
Total current assets	**627.7**	**563.5**
Total assets	**1,070.2**	**1,005.5**
SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES		
Total shareholders' equity	**306.0**	**524.2**
Long-term liabilities		
Provisions	12.8	24.5
Bond loan	492.3	—
Total long-term liabilities	**505.1**	**24.5**
Current liabilities		
Accounts payable	17.1	17.3
Bond loan	—	224.5
Other liabilities	9.1	6.3
Liabilities to Group companies	207.9	187.3
Accrued expenses and deferred income	25.0	21.5
Total current liabilities	**259.1**	**456.8**
Total liabilities	**764.2**	**481.3**
Total shareholders' equity and liabilities	**1,070.2**	**1,005.5**

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 2020 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	2021 Oct-Dec	2020 Oct-Dec	2021 Jan-Dec	2020 Jan-Dec
US Pharma				
Net revenues	133.6	143.1	522.7	623.3
Operating earnings (EBIT)	72.2	94.4	278.2	331.2
Depreciation and amortization	-3.8	-3.8	-15.4	-15.4
Digital Therapeutics				
Net revenues	0.3	0.0	1.1	0.0
Operating earnings (EBIT)	-63.8	-65.3	-249.7	-175.4
Depreciation and amortization	-5.1	-3.2	-18.6	-3.2
HQ & Pipeline				
Net revenues	10.1	16.0	41.2	40.2
Operating earnings (EBIT)	-72.5	-40.1	-242.6	-175.8
Depreciation and amortization	-6.7	-5.0	-19.1	-20.3
Group				
Net revenues	144.0	159.2	565.0	663.6
Operating earnings (EBIT)	-64.1	-11.0	-214.1	-19.9
Depreciation and amortization	-15.6	-12.0	-53.0	-38.9
Net financial items	-2.1	-29.3	-8.4	-18.4
Earnings before tax	-66.2	-40.3	-222.5	-38.3

3. Cash flow

ADJUSTMENT FOR NON-CASH ITEMS

SEK m	2021 Oct-Dec	2020 Oct-Dec	2021 Jan-Dec	2020 Jan-Dec
Depreciation/amortization and impairment	15.6	12.0	53.0	38.9
Change in provisions	12.7	9.7	-67.4	-28.5
Share based payments	0.0	0.3	1.5	-19.7
Exchange rate income and expenses	-2.0	1.2	-3.9	2.4
Total	**26.4**	**23.2**	**-16.8**	**-7.1**

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.

5. Deferred tax

The current Swedish corporate tax rates have been announced with 21.4 percent from January 1, 2019, and 20.6 percent from January 1, 2021. In line with IFRS which on this area is based on a principle that changes in tax rates should be incorporated into the accounting for the relevant tax positions immediately upon enactment, the company has performed a tax analysis. 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. The rest of 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.

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

In collaboration with Sober Grid, VORVIDA® and DEPREXIS® will be made available on Walgreens Find Care® during Q1

9. Revenue from contracts with customers

SEK m	2021 Oct-Dec					
Segment	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**VORVIDA®**	**DEPREXIS®**	**Total**
US Pharma	133.6	—	—	—	—	**133.6**
Digital Therapeutics	—	—	—	0.3	0.0	**0.3**
HQ & Pipeline	—	8.3	1.8	—	—	**10.1**
Total revenue from contracts with customers	**133.6**	**8.3**	**1.8**	**0.3**	**0.0**	**144.0**
Geographical markets	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**VORVIDA®**	**DEPREXIS®**	**Total**
US	133.6	—	0.7	0.3	0.0	**134.5**
EU & UK	—	8.0	0.9	—	—	**8.9**
Rest of the world	—	0.3	0.3	—	—	**0.6**
Total revenue from contracts with customers	**133.6**	**8.3**	**1.8**	**0.3**	**0.0**	**144.0**

SEK m	2020 Oct-Dec					
Segment	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**VORVIDA®**	**DEPREXIS®**	**Total**
US Pharma	143.1	—	—	—	—	**143.1**
Digital Therapeutics	—	—	—	0.0	0.0	**0.0**
HQ & Pipeline	—	15.1	0.9	—	—	**16.0**
Total revenue from contracts with customers	**143.1**	**15.1**	**0.9**	**0.0**	**0.0**	**159.2**
Geographical markets	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**VORVIDA®**	**DEPREXIS®**	**Total**
US	143.1	—	0.1	0.0	0.0	**143.2**
EU	—	14.8	0.6	—	—	**15.4**
Rest of the world	—	0.2	0.3	—	—	**0.5**
Total revenue from contracts with customers	**143.1**	**15.1**	**0.9**	**0.0**	**0.0**	159.2

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	0.0	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 & UK	—	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**

9. Revenue from contracts with customers

SEK m	2020 Jan-Dec					
Segment	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**VORVIDA®**	**DEPREXIS®**	**Total**
US Pharma	623.3	—	—	—	—	**623.3**
Digital Therapeutics	—	—	—	0.0	0.0	**0.0**
HQ & Pipeline	0.1	29.7	10.4	—	—	**40.2**
Total revenue from contracts with customers	**623.4**	**29.7**	**10.4**	**0.0**	**0.0**	**663.6**
Geographical markets	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**VORVIDA®**	**DEPREXIS®**	**Total**
US	623.3	—	3.1	0.0	0.0	**626.4**
EU & UK	—	28.9	2.7	—	—	**31.7**
Rest of the world	0.1	0.8	4.7	—	—	**5.5**
Total revenue from contracts with customers	**623.4**	**29.7**	**10.4**	**0.0**	**0.0**	**663.6**

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**
Net Debt	Current and long-term interest-bearing liabilities including pension liabilities, less 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 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	2021 Oct-Dec	2020 Oct-Dec	2021 Jan-Dec	2020 Jan-Dec
EBIT	-64.1	-11.0	-214.1	-19.9
Depreciation and amortization	15.6	12.0	53.0	38.9
EBITDA	**-48.5**	**1.0**	**-161.0**	**19.0**
DTx EBIT	63.8	65.3	249.7	175.4
IP litigation and subpoena costs	13.2	5.1	59.6	16.8
EBITDA excluding DTx, IP litigation and subpoena costs	**28.5**	**71.4**	**148.3**	**211.3**

RETURN ON SHAREHOLDERS' EQUITY	2021 Oct-Dec	2020 Oct-Dec	2021 Jan-Dec	2020 Jan-Dec
Shareholders' equity beginning balance	411.7	619.4	558.5	706.4
Shareholders' equity ending balance	349.6	558.5	349.6	558.5
Average shareholders' equity	380.6	589.0	454.1	632.5
Net earnings	-66.0	-49.6	-223.5	-84.4
Return on shareholders' equity %	**-17.3**	**-8.4**	**-49.2**	**-13.3**

OPERATING EXPENSES SEK m	2021 Oct-Dec	2020 Oct-Dec	2021 Jan-Dec	2020 Jan-Dec
Selling expenses	-70.9	-79.0	-280.4	-286.6
Administrative expenses	-39.1	-19.8	-151.5	-102.8
Research and development costs	-80.0	-59.0	-272.3	-224.9
Other operating income and expenses	2.1	-1.1	4.0	-3.6
Operating expenses	**-187.8**	**-158.9**	**-700.2**	**-617.9**

GROSS INVESTMENTS SEK m	2021 Oct-Dec	2020 Oct-Dec	2021 Jan-Dec	2020 Jan-Dec
Investments in tangible fixed assets	6.1	7.0	24.7	29.4
Investments in intangible fixed assets	-3.2	22.1	28.1	160.3
Gross investments	**2.9**	**29.0**	**52.9**	**189.8**

This information is information that Orexo AB (publ.) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 8.00 am CET on January 27, 2022.