orexo

Q3 2021 Interim Report

Steady progression on our journey to build a broader and stronger Orexo

Q3 2021 highlights

- Total net revenues of SEK 145.9 m (150.3)
- Net earnings of -52.0 SEK m (-84.9)
- EBITDA of SEK -47.4 m (-20.9)
- US Pharma segment (ZUBSOLV® US) net revenues of SEK 136.4 m (143.8), in local currency USD 15.8 m (16.2), US Pharma EBIT of SEK 78.5 m (72.4)
- Cash flow from operating activities of SEK -79.7 m (-12.9), cash balance of SEK 588.1 m (593.3)
- Earnings per share before dilution amounted to -1.51 (-2.45)
- Commercial partnership agreement signed with Sober Grid, the largest global social media network for people in addiction recovery, giving a large group of users access to VORVIDA® and DEPREXIS®
- Lead pharmaceutical pipeline asset, OX124 - a rescue medication for overdoses, entered pivotal trial
- Commercial agreement for VORVIDA® and DEPREXIS® signed with Benefis Health System, a leading regional health network

Important events after the period

- MODIA™ paper published in the Journal of Medical Internet Research Mental Health
- Updated financial outlook, FY 2021

SEK 78 m
US Pharma EBIT

58%
US Pharma EBIT margin

SEK 588 m
Cash and cash equivalents

SEK m, unless otherwise stated	2021 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Jan-Dec
Net revenues	145.9	150.3	421.0	504.4	663.6
Cost of goods sold	-21.3	-14.5	-58.6	-54.3	-65.6
Operating expenses	-183.7	-165.4	-512.4	-459.0	-617.9
EBIT	-59.0	-29.6	-150.0	-8.9	-19.9
EBIT margin, %	-40.5	-19.7	-35.6	-1.8	-3.0
EBITDA	-47.4	-20.9	-112.6	17.9	19.0
Earnings per share, before dilution, SEK	-1.51	-2.45	-4.59	-1.00	-2.45
Earnings per share, after dilution, SEK	-1.51	-2.45	-4.59	-1.00	-2.45
Cash flow from operating activities	-79.7	-12.9	-148.4	28.0	16.8
Cash and cash equivalents	588.1	593.3	588.1	593.3	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 2020 amounted to SEK 664 million and the number of employees was 138. 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 1.00 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, Dennis Urbaniak, EVP Digital Therapeutics and Joseph DeFeo, CFO, will present the report and host a Q&A.
Questions can also be sent in advance to ir@orexo.com, no later than 11.00 am CET.
Please view the instructions below on how to participate.
Internet: https://tv.streamfabriken.com/orexo-q3-2021
Telephone: SE +46 8 50 55 83 56 UK +44 33 33 00 92 70 US +1 64 67 22 49 56
The presentation material will be available on Orexo´s website prior to the audiocast, view Investors/Reports, presentations and audicasts

Financial calendar
Interim Report Q4 2021 - January 27, 2022 at 8.00 am CET
Annual General Meeting 2021, April 21, 2022 at 4 pm CET
Interim Report Q1 2022 - April 28, 2022 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.

Good third quarter for ZUBSOLV®

I am pleased to report that the third quarter showed continued stabilization and for the first time since 2019, ZUBSOLV® grew both revenues and profit from the previous quarter. The development of ZUBSOLV® is important to enable the continued investments in establishing our digital therapeutics (DTx) business and advancing our pharma pipeline. Mental health issues have grown significantly during Covid-19, which will inevitably lead to a significant increase in patients needing treatment. However, while demand has sharply increased, healthcare providers have been severely impacted by Covid-19 during 2021, resulting in patients suffering from reduced access to treatment, and healthcare providers' ability to assess and implement new innovative treatment methods like DTx has been limited. Fortunately, as the impact from Covid-19 diminishes, the priority and attention to address the significant rise in mental illnesses is increasing. This has led to improvements in our progress with new healthcare providers to test and implement our digital therapies, such as a new agreement with a leading regional health network, Benefis Health System.

ZUBSOLV® - Rebound to revenue and profit growth from previous quarter

While ZUBSOLV´s revenue as expected declined from 2020, I am pleased to see that ZUBSOLV's revenues after two years of decline had a positive growth from previous quarter. Revenues were supported by additional selling days, diminishing negative impact from the previous exclusive contracts with Humana and United Health Group and growth in other accounts such as Kentucky Medicaid. In addition, the EBIT margin improved this quarter to 58 percent, resulting in an increase in EBIT from Q3 2020 (50 percent). With the launch of MODIA™ I expect significant commercial and cost synergies which will contribute to the continued profit contribution from US Pharma.

"With the launch of MODIA™ I expect significant commercial and cost synergies with our DTx business which will contribute to the continued profit contribution from US Pharma.

While the issues with opioid use disorder continue to escalate in the wake of Covid-19, the overall market growth for buprenorphine/naloxone treatments has slowed down. The main driver is likely to be a combination of reduced access to treatment and fewer patients seeking treatment during the lockdown. With multiple federal and state initiatives to mitigate the escalating increase in opioid use disorder, I am convinced the overall market is destined to increase when the effects of Covid-19 vanish. As ZUBSOLV's market share is stable, our market access position continues to strengthen and with the launch of MODIA™ resulting in a new and broader value proposition for our customers, there are good opportunities for ZUBSOLV® to grow.

Digital Therapeutics – New partners being onboarded and increased focus on B2B

I am pleased to see our efforts to expand partnerships with healthcare providers and health networks are making good progress.

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Similar to the agreement with Trinity Health, Benefis Health System has made VORVIDA® and DEPREXIS® available for their staff and in parallel started to prepare implementation of the DTx in their treatment programs for alcohol misuse and depression. We have also signed an agreement with a healthcare provider in Chicago,

Justmiine, who is building a telemedicine and virtual care model for mental health where our DTx will be important elements.

In addition to the traditional healthcare providers and health networks, digital therapies enable new innovative partnerships with non traditional partners, such as Sober Grid. The partnership is off to an excellent start and the combination of their more traditional offering with "peer coaches" for alcohol misuse and our novel digital therapies has turned out to be attractive to new groups of customers. Led by Sober Grid we are in advanced discussions with new partners and only two months into the parthership we have made good progress in broadening the distribution of the combined products to new channels.

Our expectations of the commercialization of DTx since the launch have been that the main revenue potential for our DTx will come from healthcare providers integrating our DTx in their treatment programs. This will offer patients a mix of digital intervention and care as usual from established healthcare providers, removing some of the natural hesitance to test novel treatment tools. During Covid-19 access to healthcare providers has been severely limited and I am pleased to see how it's improving as the extreme burden caused by Covid-19 declines. The agreements with Trinity Health and Benefis Health Systems are very important references and provide Orexo with credibility which is already opening access to new healthcare providers and health networks. In addition they provide important insights into the reimbursement and administrative hurdles we need to address when implementing digital therapies, which will shorten the time it takes to establish new partnerships and reduce customer's burden. With improving access to healthcare providers and networks, and the significant potential with this customer group, we will prioritize these customers and limit the direct to consumer activities.

R&D – Expanding the platform

In the quarter we initiated the pivotal trial for OX124, which is designed to reverse overdoses caused by the most powerful synthetic opioids, such as fentanyl. According to new data from the Center of Disease Control, fatal opioid overdoses continue to reach record-high levels and 84 percent of these can be referred to misuse of synthetic alternatives. The results from the pivotal trial for OX124 are expected in Q4 and if approved by the FDA the plan is to initiate US launch in 2023.

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We are continuing the development of our novel technology with some promising new product candidates and expect to announce the next development program later in Q4. OX124 is a combination product with a nasal device and a patented formulation. We have invested significant resources and learned a lot from this development program which will be valuable in future projects. These learnings are likely to shorten the development timeline, lower project risks and the overall costs.

Summary and outlook

The development and profitability of ZUBSOLV® is the cornerstone for Orexo and our ability to continue to invest in new growth opportunities, like DTx and our pharmaceutical pipeline. The growth in both revenues and profit over the last quarter was important evidence that ZUBSOLV® is competitive and has the ability to grow with favourable market conditions.

With the launch of MODIA™ and later OX124, Orexo will be the company offering the the most comprehensive range of treatment options for patients suffering from opioid addiction in the US.

Our commitment is to fiercely continue addressing the hurdles limiting patients' access to products and services that have the potential to improve their treatment outcome. Our DTx position Orexo as a frontrunner in creating a paradigm shift in the treatment of mental illness, but like all disruptive technologies we need to establish a functioning distribution and payment model to flourish. We are making good progress, but we are still in the early days of a long exciting journey.

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Uppsala, Sweden, November 3, 2021

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 been stable for the last two quarters, while the non-reimbursed segment and the previous exclusive contracts with Humana and United Health Group showed mild declines.

The overall market grew 2 percent over Q2 2021. The year over year growth amounted to 6 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, some physicians were prioritising acute care and thirdly some physicians limited acceptance of new patients. The opioid epidemic has accelerated during Covid-19 and market growth is predicted to be positively impacted by multiple initiatives underway to improve access to medication assisted treatment (MAT) in the wake of Covid-19. At the federal level multiple bills have been introduced and are progressing, with a focus to reduce overdose deaths and expand MAT on a nationwide basis. On a state level, many states are reviewing the opioid use disorder (OUD) treatment landscape as opioid settlement funds become available. One example is Kentucky, which passed legislation earlier this year 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. To capitalize the growth opportunities in Kentucky, starting at the beginning of the quarter, the sales activities have been scaled up. In Q3 we saw the first positive effects through a volume increase of 85 percent from previous quarter. More state and local level OUD treatment delivery activities, along with national level legislation are expected to be initiated in the near future, which can benefit all treatment options including the MAT market.

ZUBSOLV's Q3 2021 overall prescription volume is down 2 percent versus Q2 2021. Our core segment, the open segment, is stable with no change versus Q2 2021, making it the second consecutive quarter with stable open volume. Within the open segment, Commercial has declined slightly by 1 percent, and Medicaid and Medicare D grew slightly by 1 percent. The demand in former exclusive plans, Humana and United Health Group, showed mild decline from previous quarter which also refers to the non-reimbursed segment.

On a year over year basis, Q3 2021 compared to Q3 2020 ZUBSOLV® demand declined 11 percent. This is mainly due to the continued impact from changed formulary status at Humana and United Health Group.

ZUBSOLV® overall sales force activities continue to be negatively 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 shorter than pre-Covid times. While individual state mandates continue to fluctuate, we are gradually seeing an overall improvement in access to the prescribers during Q3. However, we are continuously reviewing the effectiveness of the sales force and have consolidated some sales districts reflecting the reduced access to healthcare providers.

The work to outline the commercial strategy for ZUBSOLV® used along with the digital therapy MODIA™, for opioid use disorder, was finalized and is expected to give Orexo's MAT portfolio access to new market segments.

With the legislative changes in Kentucky, market access in the public payer segment increased as of July 1, from 34 to 42 percent. ZUBSOLV's market access in the Commercial payer segment declined from 99 to 98 percent as BCBS Massachusetts moved ZUBSOLV® to not covered. The impact was minimal as this payer made up only 0.3 percent of ZUBSOLV's volume in it's final quarter of access.

Digital Therapeutics

VORVIDA® deprexis® modia

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

In April 2020 the FDA declared Covid-19 a national health emergency and as a response to the expected surge in mental health issues they created an accelerated regulatory pathway via an emergency use authorization (EAU) for digital health solutions used in certain psychiatric conditions. Orexo responded to this urgency by making VORVIDA® available on-line during the summer of 2020 and DEPREXIS® on-line during the late fall of 2020. While working to develop broader reimbursement pathways, our initial focus was direct to consumer promotion of VORVIDA® in September 2020 followed by DEPREXIS® in April 2021. As executed our direct to

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

consumer efforts, we have applied a "test & learn" approach, to pilot and measure the impact of smaller targeted initiatives.

The initial direct to consumer strategy was to commercialize through a combination of targeted programmatic digital advertising along with social media paid and organic posts on Facebook and Instagram. We started to see positive signs of traction in April 2021 focusing on people with increased potential for harmful or problematic drinking. However, in the summer of 2021, updated policies at Facebook constrained our ability to execute and measure targeted promotion due to sensitivity of the disease. Following this change, we have made the decision to stop direct media promotion to consumers via these channels, since the return of investment of untargeted campaigns is negative in the current format. The effect of these changes will be visible in Q4 where marketing expenses will be reduced.

The main customer targets for DTx are health networks and insurance companies. The health networks have more than any been impacted by the waves of Covid-19 and rise in patients needing intensive care. While we have seen great interest from several of the leading players, new waves of Covid-19 have impacted their ability to make progress in the assessment, negotiation and implementation of new innovative solutions like our DTx. During Q2 the access to health networks improved considerably, but in late July and August the resurgence of Covid-19 temporarily slowed down progression in Q3, but we have regained momentum in these discussions late Q3 and Q4 as impact from Covid-19 diminishes.

Apart from some smaller independent healthcare providers, Trinity Health North Dakota is the first larger health network to integrate our DTx in their treatment programs. Trinity Health has worked intensively to establish the internal processes to enable the DTx to be integrated and covered under existing reimbursed treatment programs. The implementation is still on-going and we expect the first patients to be enrolled shortly. With the reference from Trinity Health, and their openness to share learnings from integrating the DTx into existing treatment programs, we have reached agreement with Benefis Health System, a Montana based health network of similar size as Trinity Health and yet another is about to test our DTx with their staff. Benefis Health System will start making our DTx available for their employees, while we finalize the commercial agreement and implementation plan.

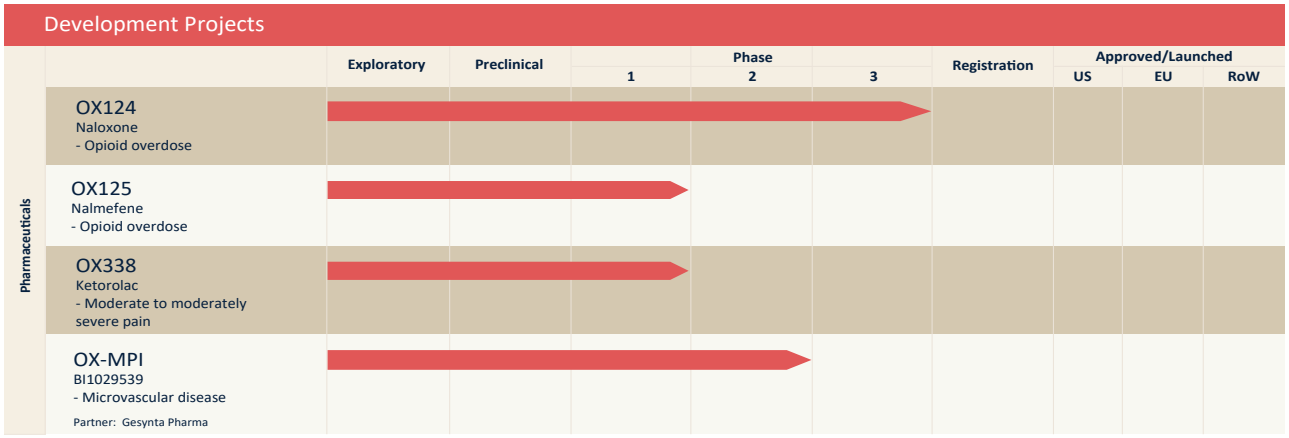
The partnership with Sober Grid has made good progress and we have seen the first patient referrals from their peer coaches. Even more importantly, Sober Grid and Orexo have through a combined offering, made good progress with selected employers and are collaborating to expand the distribution to new channels. Sober Grid's online community and availability of peer coaches, combined with Orexo's novel and scientifically proven digital therapies is clearly more attractive for some customers than each organizations products individually.

Due to limited access to healthcare providers during Covid-19, we decided to delay our launch of MODIA™ with the ZUBSOLV® field force to November. MODIA™ will initially be launched under FDAs Public Health Emergency Policy and when the ongoing clinical trial with MODIA™ is complete late 2022 we will apply for a 510K registration with FDA. This will broaden the medical claims we can make for the product and enhance the ability to gain reimbursement. The ambition for the initial launch is focused on OUD clinics to gain experience of using MODIA™, and as we establish valid reimbursement pathways we will move into more commercial relationships.

HQ & Pipeline

Most advanced fully-owned pipeline asset

OX124 - opioid overdose rescue medication containing naloxone
With the pharmaceutical project OX124 Orexo aims to develop a rescue medication designed to reverse opioid overdoses, including those from highly potent synthetic opioids. Results from Orexo's first PK study showed a significantly better PK profile compared to the market-



leading product, demonstrating OX124's potential to improve the ability to reverse the effect of the most powerful synthetic opioids, such as fentanyl.

In the 12 months leading up to March 2021, the number of drug-related overdose deaths has surpassed 96,000 for the first time in history, an increase of 30 percent versus the previous year.[1] 75 percent of these deaths were caused by opioids and within the opioid-related deaths synthetic opioids accounted for the vast majority (84 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 potential product net sales on the US market are estimated to be in the range of USD 70-110 million.

To meet the target profile for more potent rescue medications, Orexo has developed a novel and unique intranasal formulation technology that allows for rapid and efficient delivery of active ingredients through the intranasal route. Nasal administration is a viable route for many different active pharmaceutical ingredients offering significant advantages compared with other administration routes, even parenteral injections. For example, delivering drugs through the intranasal route avoids first pass metabolism of the active ingredient allowing for rapid and potentially extensive exposure of the drug. This novel proprietary drug delivery technology, which is the foundation for OX124, has patent protection until 2039.

Status:
In Q3 the pivotal clinical trial, OX124-002, was initiated. The study is a 4-period cross-over, comparative bioavailability study in healthy volunteers, comparing two dose regimens of OX124 to two dose regimens of an injection reference product. Study results are expected in Q4 2021 and are intended to be the primary support for the new drug application that is expected to be filed with the FDA in H2 2022. Additionally, the work continued to ensure the manufacturing and supply chain can provide the capacity and redundancy as needed for the commercial supply of the final OX124 product.

Other pipeline assets

OX125 - opioid overdose rescue medication containing nalmefene
With OX125 Orexo is developing an overdose rescue medication for circumstances where very long-lasting effects of rescue medications are needed, such as in remote areas. 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. This novel, proprietary intranasal delivery technology has patent protection until 2039 and potential net sales are estimated to be in the range of USD 40-60 million in the US market.

OX338 - acute moderate to moderately severe pain
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.

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 H1 2022.

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

In Q3 the Romanian packaging plant was granted the updated GMP licence, but due to delays in delivery of equipment and material, foremost as an effect of Covid-19, the launch is postponed until H1 2022. The commercialization of ZUBSOLV® in 29 European countries 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,[3] 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.[4]

[1] Center of Disease Control
[2] Center of Disease Control
[3] European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) 2019
[4] EMCDDA – Tackling Opioid Dependence 2019

Financial overview

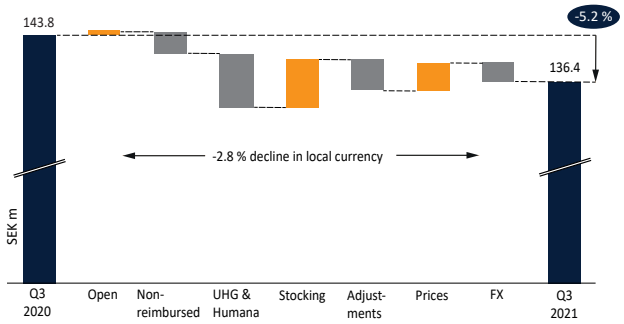
Revenues

Total revenues amounted to SEK 145.9 m (150.3) for the quarter and to SEK 421.0 m (504.4) for the first nine months.

Revenues by segment

US Pharma revenues amounted to SEK 136.4 m (143.8) 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. Also a weaker USD exchange rate impacted negatively while 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 15.8 m (16.2) while vs Q2 2021 US Pharma net revenues increased by USD 0.8 m as the drop in demand continued to stabilize and wholesaler inventory levels increased. The positive revenue impact can mainly be referred to extra shipping days. US Pharma revenues amounted to SEK 389.2 m (480.2) for the first nine months.

DTx recognized net revenues for the quarter amounted to SEK 0.4 m (-) and deferred revenues to SEK -0.1 m (-) as sales efforts during the quarter have focused on piloting different reimbursement pathways and commercial concepts. DTx recognized net revenue amounted to SEK 0.8 m (-) and deferred revenues to SEK 0.5 m (-) for the first nine months.

HQ and Pipeline partner product related revenues for the quarter amounted to SEK 9.2 m (6.5) and to SEK 31.0 m (24.2) for the first nine months.

Costs of goods sold

Cost of goods sold (COGS) amounted to SEK 21.3 m (14.5) for the quarter. US Pharma amounted to SEK 18.3 m (12.6) due to lower production of ZUBSOLV® tablets in the quarter and unfavorable production variances. Technical infrastructure costs amounted to SEK 2.9 m (1.8) explained by adding MODIA™ to the DTx product portfolio. Cost of goods sold (COGS) for the first nine months amounted to SEK 58.6 m (54.3).

Operating expenses

Selling expenses amounted to SEK 79.0 m (83.3) for the quarter. The decrease over the same period last year is mainly explained by lower selling expenses in US Pharma costs. This was partially offset by increased costs related to launch preparations for MODIA™. Selling expenses for the first nine months amounted to SEK 209.5 m (207.7).

Administrative expenses amounted to SEK 42.4 m (26.4) for the quarter and to SEK 112.4 m (83.0) for the first nine months. The increase is mainly explained by higher legal expenses for IP litigation and subpoena partly offset by lower costs for the long-term incentive programs.

Research and development costs amounted to SEK 63.5 m (50.3) for the quarter. The increase is mainly explained by costs related to MODIA™ study. Research and development costs for the first nine months amounted to SEK 192.4 m (165.9).

Other operating income and expenses amounted to SEK 1.3 m (-5.4) 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 first nine months amounted to SEK 1.9 m (-2.5).

NET REVENUES AND OPERATING EARNINGS PER SEGMENT

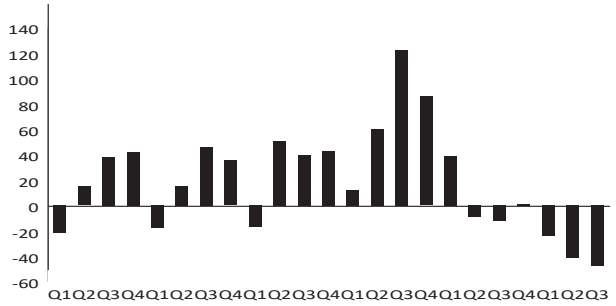
SEK m	Net Revenues					EBIT				
	2021 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Jan-Dec	2021 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Jan-Dec
ZUBSOLV® US product sales	136.4	143.8	389.2	480.2	623.3	-	-	-	-	-
US Pharma – total	**136.4**	**143.8**	**389.2**	**480.2**	**623.3**	**78.5**	**72.4**	**206.1**	**237.2**	**331.2**
Digital Therapeutics (DTx) product sales	0.4	-	0.8	-	0.0	-	-	-	-	-
Digital Therapeutics (DTx) – total	**0.4**	-	**0.8**	**-**	**0.0**	**-76.4**	**-62.5**	**-186.7**	**-110.1**	**-175.4**
Abstral® royalty	6.8	2.5	23.8	14.6	29.7	-	-	-	-	-
Edluar® royalty	2.4	4.0	7.2	9.5	10.4	-	-	-	-	-
ZUBSOLV® - ex US	-	-	-	0.1	0.1	-	-	-	-	-
HQ & Pipeline segment – total	**9.2**	**6.5**	**31.0**	**24.2**	**40.2**	**-61.2**	**-39.5**	**-169.3**	**-136.0**	**-175.8**
Total	**145.9**	**150.3**	**421.0**	**504.4**	**663.6**	**-59.1**	**-29.6**	**-150.0**	**-8.9**	**-19.9**

Operating profit

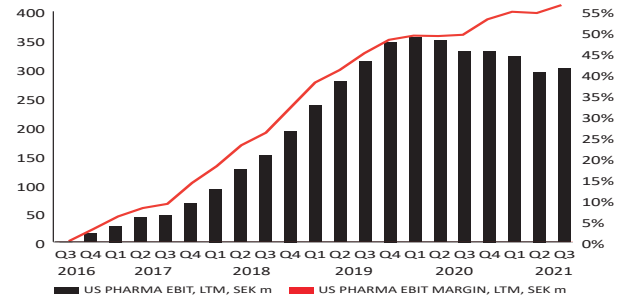
Orexo's profitability reflects costs in DTx and in pipeline and EBITDA amounted to SEK -47.4 m (-20.9) for the quarter and to SEK -112.5 m (17.9) for the first nine months.

The EBIT contribution from US Pharma amounted to SEK 78.5 m (72.4) for the quarter, equal to an EBIT margin of 57.6 percent (50.3). The EBIT contribution from US Pharma amounted to SEK 206.1 m (237.2) for the first nine months, equal to an EBIT margin of 52.9 percent (49.4). 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 -0.1 m (-10.8), mainly explained by positive unrealized exchange rate impact of SEK 13.5 m derived from the parent company's foreign currency bank accounts mainly in USD, partly offset by higher costs for corporate bonds of SEK 2.8 m. Net financial items amounted to SEK -6.3 m (10.9) for the first nine months.

Total tax expenses amounted to SEK 7.1 m (-44.4) for the quarter, impacted by positive adjustment to deferred tax assets related to temporary differences of SEK 8.5 m (0.6) while decreased parent company tax asset of SEK 43.5 m impacted negatively versus Q3 2020. Total tax expenses amounted to SEK -1.3 m (-36.8) 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 -52.0 m (-84.9) for the quarter, SEK -157.6 m (-34.8) for the first nine months.

[1] Last Twelve Months

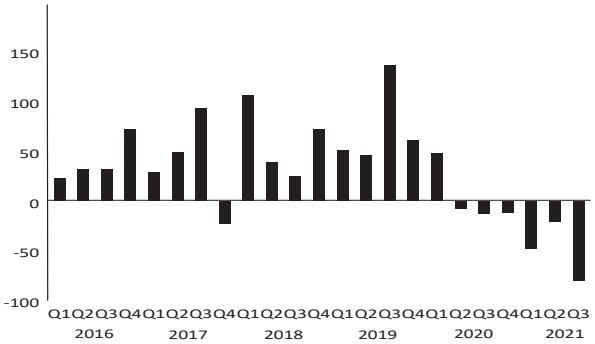
Cash and cash flow

As of September 30, 2021, cash and cash equivalents amounted to SEK 588.1 m (593.3) and interest-bearing liabilities to SEK 491.7 m (224.1), i.e. a positive net cash position of SEK 96.4 m (369.1).

The cash position enables Orexo to pursue its strategy to launch the digital therapies in the US, to progress the development pipeline and to launch OX124.

Cash flow from operating activities amounted to SEK -79.7 m (-12.9) for the quarter. The decrease is mainly expained by higher negative operating earnings and by lower positive changes in working capital. Cash flow from operating activities amounted to SEK -148.4 m (28.0) for the first nine months.

CASH FLOW FROM OPERATING ACTIVITIES, SEK m



Investments

Gross investments in tangible and intangible fixed assets amounted to SEK 20.7 m (50.2) and to SEK 50.0 m (160.7) for the first nine months. Lower investment is mainly explained by a payment of nonrefundable milestone for DEPREXIS® in Q2 2020.

Equity

Shareholders' equity at September 30, 2021, was SEK 411.7 m (619.4). The equity/asset ratio was 31.4 percent (46.6).

Parent company

Net revenues for the quarter amounted to SEK 139.4 m (97.4) of which SEK 130.3 m (91.0) was related to sales to Group companies. Net revenues amounted to SEK 274.4 m (366.4) for the first nine months of which SEK 243.4 m (342.1) was related to sales to Group companies.

Earnings before tax were SEK -22.6 m (-43.9) for the quarter and to SEK -153.2 m (43.8) for the first nine months mainly explained by investment in DTx and development projects. Investments for the quarter amounted to SEK 15.1 m (50.2) and to SEK 28.9 m (160.7) for the first nine months. Lower investment is mainly explained by a payment of non-refundable milestone for DEPREXIS® in Q2 2020.

As of September 30, 2021, cash and cash equivalents in the parent company amounted to SEK 462.0 m (439.0).

Other information

Financial outlook 2021

• With the Covid-19 pandemic continuing, the financial outlook is associated with increased uncertainties
• Due to Covid-19 the buprenorphine/naloxone market will temporarily show a lower annual growth pace and reach a level of 5-8 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
• OPEX for Q4 will be in line with Q3
• US Pharma EBIT will exceed 50 percent
• The financial outlook is based on exchange rates in September 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, November 3, 2021

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, 2021 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, 2021

Ernst & Young AB
Anna Svanberg
Authorized Public Accountant

Financial reports, notes and key figures

CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS

SEK m	Notes	2021 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Jan-Dec
Net revenues	9	145.9	150.3	421.0	504.4	663.6
Cost of goods sold		-21.3	-14.5	-58.6	-54.3	-65.6
Gross profit		**124.7**	**135.8**	**362.4**	**450.1**	**598.0**
Selling expenses		-79.0	-83.3	-209.5	-207.7	-286.6
Administrative expenses		-42.4	-26.4	-112.4	-83.0	-102.8
Research and development expenses		-63.5	-50.3	-192.4	-165.9	-224.9
Other operating income and expenses		1.3	-5.4	1.9	-2.5	-3.6
Operating earnings (EBIT)		**-59.0**	**-29.6**	**-150.0**	**-8.9**	**-19.9**
Net financial items		-0.1	-10.8	-6.3	10.9	-18.4
Earnings before tax		**-59.1**	**-40.5**	**-156.3**	**2.0**	**-38.3**
Tax	5	7.1	-44.4	-1.3	-36.8	-46.1
Net earnings for the period[1]		**-52.0**	**-84.9**	**-157.6**	**-34.8**	**-84.4**
Earnings per share, before dilution, SEK		-1.51	-2.45	-4.59	-1.00	-2.45
Earnings per share, after dilution, SEK		-1.51	-2.45	-4.59	-1.00	-2.45

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

SEK m	2021 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Jan-Dec
Earnings for the period	**-52.0**	**-84.9**	**-157.6**	**-34.8**	**-84.4**
Other comprehensive income					
Items that may subsequently be reversed to the statement of operations:					
Exchange-rate differences	4.4	-4.8	9.1	-4.9	-16.5
Other comprehensive earnings for the period, net after tax	**4.4**	**-4.8**	**9.1**	**-4.9**	**-16.5**
Total comprehensive earnings for the period [1]	**-47.6**	**-89.7**	**-148.5**	**-39.7**	**-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 Sep 30	2020 Sep 30	2020 Dec 31
ASSETS				
Fixed assets				
Tangible fixed assets		61.4	41.5	47.3
Intangible fixed assets		260.6	239.6	252.8
Right-of-use assets		62.2	64.7	67.8
Deferred tax assets	5	34.2	54.4	32.7
Other financial assets		0.8	0.8	0.7
Total fixed assets		**419.2**	**401.0**	**401.3**
Current assets				
Inventories		93.4	120.7	108.4
Accounts receivable and other receivables		211.5	213.2	217.9
Cash and cash equivalents		588.1	593.3	505.3
Total current assets		**892.9**	**927.2**	**831.6**
Total assets		**1,312.1**	**1,328.2**	**1,232.9**
SHAREHOLDERS' EQUITY AND LIABILITIES				
Total shareholders' equity		**411.7**	**619.4**	**558.5**
Long-term liabilities				
Provisions		10.8	33.6	25.7
Long-term liabilities, interest bearing		491.7	224.1	—
Lease liabilities, long-term		41.3	44.1	47.4
Total long-term liabilities		**543.8**	**301.9**	**73.1**
Current liabilities and provisions				
Provisions		144.3	200.9	197.3
Current liabilities, interest bearing		—	—	224.5
Current liabilities, non-interest bearing		192.4	186.9	160.4
Lease liabilities, current		19.8	19.2	19.1
Total current liabilities and provisions		**356.6**	**407.0**	**601.3**
Total liabilities		**900.4**	**708.9**	**674.4**
Total shareholders' equity and liabilities		**1,312.1**	**1,328.2**	**1,232.9**

CONSOLIDATED CHANGES IN SHAREHOLDERS' EQUITY

SEK m	2021 Sep 30	2020 Sep 30	2020 Dec 31
Opening balance, shareholders' equity	**558.5**	**706.4**	**706.4**
Total comprehensive earnings for the period	-148.5	-39.7	-100.9
Share-based payments	1.5	-20.0	-19.7
Buy back of shares	—	-27.3	-27.3
New share issue	—	—	—
Closing balance, shareholders' equity	**411.7**	**619.4**	**558.5**

CONDENSED CONSOLIDATED CASH FLOW STATEMENTS

SEK m	Notes	2021 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Jan-Dec
Operating earnings (EBIT)		-59.0	-29.6	-150.0	-8.9	-19.9
Interest received		—	0.8	—	4.6	3.0
Interest paid		-5.2	-3.4	-18.1	-10.7	-11.8
Income taxes paid		-1.0	-0.2	0.0	-1.0	0.6
Adjustment for non-cash items	3	-24.1	-9.1	-43.1	-30.3	-7.1
Cash flow from operating activities before changes in working capital		**-89.4**	**-41.5**	**-211.1**	**-46.3**	**-35.1**
Changes in working capital		**9.8**	**-28.6**	**62.7**	**74.3**	**51.9**
Cash flow from operating activities		**-79.7**	**-12.9**	**-148.4**	**28.0**	**16.8**
Acquisition of tangible and intangible fixed assets		-20.7	-50.2	-50.0	-160.7	-189.8
Disposal of financial assets		—	0.0	—	0.6	0.6
Cash flow from investing activities		**-20.7**	**-50.2**	**-50.0**	**-160.1**	**-189.2**
Buy back shares		—	—	—	-27.3	-27.3
New loan		—	—	490.1	—	—
Repayment of loans		-2.0	-4.2	-234.0	-79.7	-84.0
Cash from financing activities		**-2.0**	**-4.2**	**256.1**	**-106.9**	**-111.3**
Cash flow for the period		**-102.4**	**-67.4**	**57.7**	**-239.1**	**-283.7**
Cash and cash equivalents at the beginning of the period		**679.7**	**677.2**	**505.3**	**816.8**	**816.8**
Exchange-rate differences in cash and cash equivalents		10.7	-16.5	25.1	15.6	-27.8
Changes in cash and cash equivalents		-91.6	-83.9	82.8	-223.5	-311.5
Cash and cash equivalents at the end of the period		**588.1**	**593.3**	**588.1**	**593.3**	**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 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Jan-Dec
EBIT margin, %	-40.5	-19.7	-35.6	-1.8	-3.0
Return on shareholder equity, %	-11.9	-12.5	-32.5	-5.2	-13.3
Net debt, SEK m	-96.3	-369.1	-96.3	-369.1	-280.8
Debt/equity ratio, %	119.4	36.2	119.4	36.2	40.2
Equity/assets ratio, %	31.4	46.6	31.4	46.6	45.3
Number of shares, before dilution	34,327,907	34,710,639	34,311,390	34,710,639	34,398,815
Number of shares, after dilution	34,327,907	34,710,639	34,311,390	34,710,639	34,398,815
Earnings per share, before dilution, SEK	-1.51	-2.45	-4.59	-1.00	-2.45
Earnings per share, after dilution, SEK	-1.51	-2.45	-4.59	-1.00	-2.45
Number of employees at the end of the period	128	136	128	136	138
Shareholders' equity, SEK m	411.7	619.4	411.7	619.4	558.5
Capital employed, SEK m	903.4	843.5	903.4	843.5	783.0
Working capital, SEK m	-51.8	-73.0	-51.8	-73.0	-50.5

[1] Definitions and reconciliations of key figures are presented on page 20 of this report

CONDENSED PARENT COMPANY STATEMENT OF OPERATIONS

SEK m	Notes	2021 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Jan-Dec
Net revenues		139.4	97.4	274.4	366.4	446.4
Cost of goods sold		-26.5	-21.0	-55.9	-66.6	-79.7
Gross profit		**113.0**	**76.4**	**218.5**	**299.8**	**366.7**
Selling expenses		-70.1	-67.4	-169.7	-129.9	-190.7
Administrative expenses		-27.9	-7.8	-68.1	-42.5	-53.1
Research and development costs		-51.8	-36.5	-158.0	-128.8	-180.1
Other operating income and expenses		13.6	1.5	28.3	32.9	50.0
Operating earnings (EBIT)		**-23.2**	**-33.8**	**-149.1**	**31.6**	**-7.2**
Interest income and expenses		-5.2	-2.6	-13.2	-8.3	-10.9
Other financial income and expenses		5.8	-7.5	9.1	20.6	-5.4
Net financial items		**0.6**	**-10.1**	**-4.1**	**12.2**	**-16.3**
Earnings before tax		**-22.6**	**-43.9**	**-153.2**	**43.8**	**-23.4**
Tax	5	—	-43.5	—	-43.5	-49.0
Earnings for the period		**-22.6**	**-87.4**	**-153.2**	**0.3**	**-72.5**

PARENT COMPANY STATEMENT OF COMPREHENSIVE INCOME

SEK m	2021 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Jan-Dec
Earnings for the period	**-22.6**	**-87.4**	**-153.2**	**0.3**	**-72.5**
Other comprehensive income					
Total comprehensive earnings for the period	**-22.6**	**-87.4**	**-153.2**	**0.3**	**-72.5**

CONDENSED PARENT COMPANY BALANCE SHEET

SEK m	2021 Sep 30	2020 Sep 30	2020 Dec 31
ASSETS			
Fixed assets			
Intangible fixed assets	221.8	230.4	234.4
Tangible fixed assets	61.4	41.5	47.2
Deferred tax assets	—	5.5	—
Shares in subsidiaries	161.1	163.0	160.4
Total fixed assets	**444.2**	**440.5**	**442.0**
Current assets			
Inventories	68.3	94.4	90.9
Accounts receivable and other receivables	160.5	136.3	111.3
Cash and bank balances	462.0	439.0	361.3
Total current assets	**690.8**	**669.7**	**563.5**
Total assets	**1,135.0**	**1,110.2**	**1,005.5**
SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES			
Total shareholders' equity	**372.6**	**597.0**	**524.2**
Long-term liabilities			
Provisions	10.3	31.9	24.5
Bond loan	491.7	224.1	—
Total long-term liabilities	**502.0**	**256.1**	**24.5**
Current liabilities			
Accounts payable	21.6	16.7	17.3
Bond loan	—	—	224.5
Other liabilities	6.9	10.5	6.3
Liabilities to Group companies	208.2	210.1	187.3
Accrued expenses and deferred income	23.7	19.8	21.5
Total current liabilities	**260.4**	**257.2**	**456.8**
Total liabilities	**762.4**	**513.3**	**481.3**
Total shareholders' equity and liabilities	**1,135.0**	**1,110.2**	**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 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Jan-Dec
US Pharma					
Net revenues	136.4	143.8	389.2	480.2	623.3
Operating earnings (EBIT)	78.5	72.4	206.1	237.2	331.2
Depreciation and amortization	-3.8	-3.8	-11.5	-11.5	-15.4
Digital Therapeutics					
Net revenues	0.4	—	0.8	—	0.0
Operating earnings (EBIT)	-76.4	-62.5	-186.7	-110.1	-175.4
Depreciation and amortization	-4.6	—	-13.5	—	-3.2
HQ & Pipeline					
Net revenues	9.2	6.5	31.0	24.2	40.2
Operating earnings (EBIT)	-61.2	-39.5	-169.3	-136.0	-175.8
Depreciation and amortization	-3.2	-4.8	-12.4	-15.3	-20.3
Group					
Net revenues	145.9	150.3	421.0	504.4	663.6
Operating earnings (EBIT)	-59.0	-29.6	-150.0	-8.9	-19.9
Depreciation and amortization	-11.6	-8.7	-37.4	-26.8	-38.9
Net financial items	-0.1	-10.8	-6.3	10.9	-18.4
Earnings before tax	-59.1	-40.5	-156.3	2.0	-38.3

3. Cash flow

ADJUSTMENT FOR NON-CASH ITEMS

SEK m	2021 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Jan-Dec
Depreciation/amortization and impairment	11.6	8.7	37.4	26.8	38.9
Change in provisions	-34.4	3.6	-80.2	-38.2	-28.5
Share based payments	-0.1	-26.4	1.5	-20.0	-19.7
Exchange rate income and expenses	-1.3	5.0	-1.9	1.1	2.4
Total	**-24.1**	**-9.1**	**-43.1**	**-30.3**	**-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.

On August 18, Sun sent Orexo a "Paragraph IV" patent certification notice letter regarding US patents no 11,020,387 and 11,020,388, which were issued in June 2021. After the end of the period, Orexo filed an additional patent infringement action against Sun in the US District Court for the District of New Jersey, relating to these two new patents.

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 1,188 m as of December 31 2020 and refers to the Swedish companies. No deferred tax assets for tax-loss carry-forwards have been capitalized as per December 31, 2020, 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

- MODIA™ paper published in the Journal of Medical Internet Research Mental Health
- Updated financial outlook, FY 2021

9. Revenue from contracts with customers

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 & UK	—	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	2020 Jul-Sep					
Segment	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**VORVIDA®**	**DEPREXIS®**	**Total**
US Pharma	143.8	—	—	—	—	**143.8**
Digital Therapeutics	—	—	—	—	—	**0.0**
HQ & Pipeline	—	2.5	4.0	—	—	**6.5**
Total revenue from contracts with customers	**143.8**	**2.5**	**4.0**	**0.0**	**0.0**	**150.3**
Geographical markets	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**VORVIDA®**	**DEPREXIS®**	**Total**
US	143.8	—	1.6	—	—	**145.4**
EU	—	2.2	0.4	—	—	**2.7**
Rest of the world	—	0.2	2.0	—	—	**2.2**
Total revenue from contracts with customers	**143.8**	**2.5**	**4.0**	**0.0**	**0.0**	**150.3**

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**

9. Revenue from contracts with customers

SEK m	2020 Jan-Sep					
Segment	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**VORVIDA®**	**DEPREXIS®**	**Total**
US Pharma	480.2	—	—	—	—	**480.2**
Digital Therapeutics	—	—	—	—	—	**0.0**
HQ & Pipeline	0.1	14.6	9.5	—	—	**24.2**
Total revenue from contracts with customers	**480.3**	**14.6**	**9.5**	**0.0**	**0.0**	**504.4**
Geographical markets	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**VORVIDA®**	**DEPREXIS®**	**Total**
US	480.2	—	3.0	—	—	**483.2**
EU & UK	0.1	14.1	2.1	—	—	**16.3**
Rest of the world	—	0.6	4.4	—	—	**5.0**
Total revenue from contracts with customers	**480.3**	**14.7**	**9.5**	**0.0**	**0.0**	**504.4**

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 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Jan-Dec
EBIT	-59.0	-29.6	-150.0	-8.9	-19.9
Depreciation and amortization	11.6	8.7	37.4	26.8	38.9
EBITDA	**-47.4**	**-20.9**	**-112.6**	**17.9**	**19.0**
DTx costs	76.4	62.5	186.7	110.1	175.4
EBITDA excluding DTx costs	**29.0**	**41.6**	**74.1**	**128.0**	**194.4**

RETURN ON SHAREHOLDERS' EQUITY	2021 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Jan-Dec
Shareholders' equity beginning balance	459.4	735.5	558.5	706.4	706.4
Shareholders' equity ending balance	411.7	619.4	411.7	619.4	558.5
Average shareholders' equity	435.6	677.4	485.1	662.9	632.5
Net earnings	-52.0	-84.9	-157.6	-34.8	-84.4
Return on shareholders' equity %	**-11.9**	**-12.5**	**-32.5**	**-5.2**	**-13.3**

OPERATING EXPENSES SEK m	2021 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Jan-Dec
Selling expenses	-79.0	-83.3	-209.5	-207.7	-286.6
Administrative expenses	-42.4	-26.4	-112.4	-83.0	-102.8
Research and development costs	-63.5	-50.3	-192.4	-165.9	-224.9
Other operating income and expenses	1.3	-5.4	1.9	-2.5	-3.6
Operating expenses	**-183.7**	**-165.4**	**-512.4**	**-459.0**	**-617.9**

GROSS INVESTMENTS SEK m	2021 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Jan-Dec
Investments in tangible fixed assets	3.3	19.7	18.6	22.4	29.4
Investments in intangible fixed assets	17.4	30.5	31.4	138.3	160.3
Gross investments	**20.7**	**50.2**	**50.0**	**160.7**	**189.8**

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