orexo

Q1 Interim Report 2022

Promising start to 2022

Q1 2022 highlights

- Total net revenues of SEK 159.4 m (132.3)
- EBITDA of SEK 2.8 m (-23.9)
- Net earnings of SEK -23.6 m (-31.5)
- US Pharma segment (ZUBSOLV® US) net revenues of SEK 139.1 m (126.8), in local currency USD 14.8 m (15.1), US Pharma EBIT of SEK 84.0 m (66.1)
- Cash flow from operating activities of SEK -61.6 m (-47.8), cash balance of SEK 437.8 m (725.5)
- Earnings per share before and after dilution amounted to -0.69 (-0.92)
- Lead product ZUBSOLV® added to NY State Medicaid MAT Preferred Drug List as of March 22
- First sale of ZUBSOLV® to Accord Healthcare in the EU of SEK 4.6 m, incl. a small milestone payment
- Fredrik Järrsten appointed as new CFO, starting at latest in early September

Important events after the period

- Christine Rankin and Michael J Matly were elected as Board members at the Annual General Meeting. They replace David Colpman and Kirsten Detrick who have declined re-election.
- Orexo´s partner Gesynta Pharma's drug candidate GS-248 (OX-MPI) granted Orphan Drug Designation in the US by the FDA for the treatment of systemic sclerosis
- Financial outlook 2022 updated, view page 11

SEK 159 m
Group revenues

SEK 84 m
US Pharma EBIT

SEK 3 m
Group EBITDA

SEK m, unless otherwise stated	2022 Jan-Mar	2021 Jan-Mar	% change	2021 Jan-Dec
Net revenues	159.4	132.3	20.5%	565.0
Cost of goods sold	-27.5	-19.2	43.8%	-78.9
Operating expenses	-145.1	-149.9	-3.2%	-700.2
EBIT	-13.2	-36.8	64.2%	-214.1
EBIT margin	-8.3%	-27.8%	19.6%	-37.9%
EBITDA	2.8	-23.9	111.7%	-161.0
Earnings per share, before dilution, SEK	-0.69	-0.92	25.0%	-6.51
Earnings per share, after dilution, SEK	-0.69	-0.92	25.0%	-6.51
Cash flow from operating activities	-61.6	-47.8	-28.9%	-229.0
Cash and cash equivalents	437.8	725.5	-39.7%	504.1

Unless otherwise stated in this report, all data refers to the Group, and numbers relate to the current quarter while numbers in parentheses relate to the corresponding period in 2021.

Content

About Orexo
Orexo develops improved pharmaceuticals and digital therapies addressing unmet needs within the growing space of substance use disorders and mental health. The products are commercialized by Orexo in the US or via partners worldwide. The main market today is the American market for buprenorphine/naloxone products, where Orexo commercializes its lead product ZUBSOLV® for treatment of opioid use disorder. Total net sales for 2021 amounted to SEK 565 million and the number of employees was 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, and Joseph DeFeo, CFO, will present the report and host a Q&A.

Please view the instructions below on how to participate.
Internet: https://tv.streamfabriken.com/orexo-q1-2022
Telephone: SE: +46 851 99 93 83 UK: +44 33 33 00 92 60 US: +1 64 67 22 49 56
Prior to the call presentation material will be available on Orexo´s website Investors/Reports, presentations, audiocasts.

Financial calendar
Interim Report Q2 2022 - July 14, 2022 at 8.00 am CET
Interim Report Q3 2022 - November 3, 2022 at 8.00 am CET
Full Year Report 2022, incl. Q4 - January 26, 2023 at 8.00 am CET
Interim Report Q1 2023 - April 27, 2023 at 8.00 am CET

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

Making progress

The primary value drivers for Orexo are our ability to maintain our solid financial position, based on strong profit contributions from ZUBSOLV®, establishing a new profitable business segment in digital therapeutics and develop new pharmaceuticals. I am pleased to report we have made good progress in all of these areas in the first quarter. To maintain a strong financial base is essential for Orexo and we have had a strong focus on cost efficiency in the quarter. This prudent financial management has led to a positive EBITDA of SEK 2.8 million for the quarter and good financial results compared to last year.

ZUBSOLV® – continued strong profit contribution
The revenues in SEK for ZUBSOLV® increased during the quarter, and can be explained by the strengthening of the USD in combination with favourable price development. As expected we have seen a decline in demand of ZUBSOLV® in the first quarter in line with the seasonal effect seen nearly every year for ZUBSOLV® but also from a slight negative market growth. The highlight of the first quarter is the announcement of ZUBSOLV® receiving "preferred status" and reimbursement by all Medicaid payers in New York from March 22. ZUBSOLV® has performed well in the Commercial segment in NY, but has never been reimbursed by all Medicaid payers in NY. The success to gain preferred status is one of the greatest market access developments for ZUBSOLV® in years and is destined to be a strong growth contributor in the coming quarters and years for ZUBSOLV®.

"The highlight is the announcement of ZUBSOLV® receiving "preferred status" and reimbursement by all Medicaid payers in New York from March 22

The general market development for the treatment of Opioid Use Disorder continues to be slower than expected with a flat developement versus the last quarter. The feedback we get from our field force is several clinics continue to be affected by Covid-19 and have slowed down operations and moved more activities to tele medicine. However, we continue to see improvements and expect this will improve access to treatment and support an accelerated market growth in line with our expectation of 5-8 percent on a full year basis.

Looking beyond the US borders, we have made our first shipment of ZUBSOLV® to our partner Accord Healthcare and registered the first revenue of SEK 4.6 million in the quarter. The majority of this revenue is associated with sale of ZUBSOLV®, but also includes a smaller milestone payment triggered by the first supply of the product. We expect continued shipment during the next quarters as they build their inventory in preparation for launch and when Accord Healthcare start to record sales we will also receive a double digit royalty.

Digital Therapeutics – full focus on reimbursement
Finally I start to see some light in the tunnel by concrete progress establishing reimbursement pathways for digital health solutions. During the quarter we have seen new legislation approved and additional legislative actions taken on a federal level to establish viable reimbursement pathways for digital health solutions. During the last year we have seen a hesitancy among payers to make individual solutions for suppliers and national initiatives are needed for the market to reach its full potential.

"Finally I start to see some light in the tunnel by concrete progress establishing reimbursement pathways for digital health solutions

For Orexo the partnership with Trinity Health in North Dakota is finally reaching implementation stage and in Q2 2022 we expect the first patients will get access to DEPREXIS® or VORVIDA®. We are certain we have managed to overcome the administrative hurdles to establish a reimbursement pathway together with Trinity Health. The next step is now to see actual reimbursement requests being processed and paid by the insurance companies as anticipated for the initial group of patients. With our presence and persistence in the digital health market in the US, I am also pleased to see health care providers now reaching out to Orexo to discuss our digital therapies. With our experience from Trinity Health and the interest from health care providers we are confident we can shorten the timeline from interest to implementation dramatically going forward.

As previously announced we have moved away from direct to consumer promotion and will rely on partnerships to reach the end customers. Our partnership with SoberGrid has resulted in our digital therapies are now accessible together with SoberGrids peer coaches on Walgreens Find Care® platform. Walgreens Find Care® serves as a digital marketplace that helps connect customers to a network of local and national health providers and healthcare services. This is a major accomplishment for the partnership and add both credibility to the products from the association and approval by a well known and leading player in US healthcare as well as access to the millions of users of Walgreens Find Care® services.

The reliance on partnerships has dramatically reduced our direct spending on digital therapies and the majority of expenses are now from shared expenses with our US Pharma business, e.g. field force and market access. The shared expenses are from the ZUBSOLV® sales team for the launch of our MODIA™ early access program for opioid dependence, modiaONE, among ZUBSOLV® prescribers. Meanwhile we allow engaged health care professionals to try the product on a limited number of patients for free and we also work with selected clinics to test various reimbursement pathways. Since the start in late February we have reached more than 250 users of MODIA™ and for our full DTx portfolio we now have over 1,800 users across early access commercial programs and clinical trials.

R&D – expanding amorphOX™

Our leading pipeline products are all based on our new innovative drug delivery platform amorphOX™ and the progress in each of the projects are valuable for all current and future projects based on this technology. Our most advanced project, OX124, is continuing to progress towards filing with the FDA late this year and basically all current activities are relevant for future nasal pipeline projects using amorphOX™ as well, from formulation, packaging and usability of the device.

The most important feature of amorphOX™ is the ability to deliver the drug efficiently. This has been proven in clinical trials for both OX124 and OX125, which makes us optimistic regarding the results for OX640, where the first clinical trial is planned for the third quarter. With positive clinical results for OX640, this will be great progress to enable a shift from the current expensive autoinjectors of epinephrine to a nasal formulation. In addition to superior stability of the product we are confident we have a product with significant benefits for the millions of patients at risk of severe allergic reactions.

In addition to our existing internal pipeline projects we are testing several new drugs in amorphOX™ and we have initiated collaboration with other pharmaceutical companies to test amorphOX™ on their pipeline projects. With positive results of the ongoing tests, amorphOX™ has the potential to expand our pipeline considerably with both internal and externally funded pipeline projects.

"With positive results of the ongoing tests, amorphOX™ has the potential to expand our pipeline considerably with both internal and externally funded pipeline projects

Summary and outlook

The first quarter of 2022 has shown our ability to control our costs, without slowing down our development programs or establishing a new business segment in digital therapeutics. With the launch of MODIA™ we are now able to fully exploit the cost and sales synergies of our pharmaceutical business and the digital therapeutics. With the Covid-19 impact diminishing and improved market access for both ZUBSOLV® and our digital therapies, in combination with good progress in our R&D pipeline we are well positioned to reinvigorate the growth of the company and create value for our shareholders.

Uppsala, Sweden, April 28, 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.

The overall market growth was slight negative versus Q4 2021. The quarterly year over year growth amounted to 6 percent. This slowdown from previous double-digit growth can be attributed to limited access to treatment during Covid-19. The pandemic has and continues to impact access to care thereby advancing the scourge of the opioid epidemic driving the number of fatal overdoses to record-high levels. As the Covid-19 pandemic wanes it is expected that the buprenorphine/naloxone market growth will be positively impacted by multiple initiatives underway to improve access to medication assisted treatment.

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

ZUBSOLV's Q1 2022 overall prescription volume is down 5 percent versus Q4 2021 of which 1.4 percent is due to less days in Q1. Our core segment, the open segment, declined 3 percent versus Q4 2021. Within the open segment, commercial declined, Medicaid (the largest market segment) volume was stable, and Medicare volume grew 7 percent.

On a year over year basis, Q1 2022 compared to Q1 2021 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.

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. Q1 2022 saw a decrease in access to prescribers versus Q4 2021. ZUBSOLV® is the only actively promoted daily treatment and less access to physicians has disproportional effect on ZUBSOLV® compared to generic competitors.

ZUBSOLV's market access in the public payer segment increased to 48 percent of patients having 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 maintained at 98 percent.

Digital Therapeutics

VORVIDA® deprexis® modia

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

The first quarter of 2022 brought advances in DTx industry reimbursement policy opportunities, continued growth in the Orexo DTx portfolio user base, and the launch of our MODIA™ early access program for OUD, modiaONE, among ZUBSOLV® prescribers. Following the approval of the first remote therapeutic monitoring code (RTM code) for digital cognitive behavioral therapy in Q4 2021, the first HCPCS (Healthcare Common Procedure Coding System) code for FDA cleared prescription digital therapy was approved and a bipartisan bill, The Access to Prescription Digital Therapeutics Act of 2022, was introduced by both chambers of the US congress, setting the future stage for Medicare and Medicaid coverage of FDA cleared or approved digital therapeutics.

While the RTM code and the HCPCS code represent small tangible opportunities for DTx companies, the bipartisan bill represents a potentially significant future pathway for coverage. The recent advancement of all three policy updates demonstrates a recognition of the importance of DTx as a foundational category in US healthcare and the need to provide DTx coverage going forward. As policy efforts progress, the focus for Orexo has been to expand the user base across our DTx portfolio to help providers, patients, and payers experience the benefits and ease of use associated with our three therapies.

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

Through Q1 2022, the Orexo DTx portfolio now has over 1,800 users across early access commercial programs and clinical trials. With the recent launch of modiaONE, we have seen over 250 users started on therapy in just a few weeks, offering important real world experience for providers and patients with MODIA™.

In the first quarter the majority of the promotional expenses in DTx are associated with the modiaONE campaign and cost allocated from US Pharma related to their field force. For VORVIDA® and DEPREXIS® the focus is on establishing reimbursed access through larger healthcare providers which limited the direct expenses in the quarter

The focus going forward is to grow the user base of commercial customers for our full DTx portfolio. This development will primarily be driven by two main factors. Firstly, more large healthcare providers are adding Orexo´s digital therapies to existing treatments programs, such as Trinity Health in North Dakota, where the first patients are expected to be treated with Orexo´s digital therapies in Q2 2022. Secondly, the billable market access for the full DTx portfolio starts to grow as broader reimbursement efforts progress.

HQ & Pipeline

amorphOX™ – a new proprietary drug delivery platform

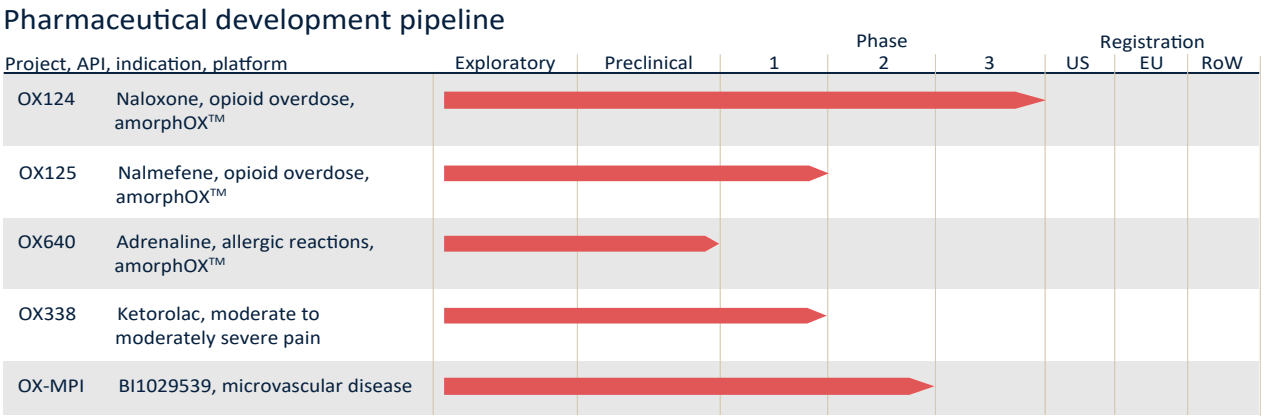
In Q4, information was provided about the new scalable drug delivery platform, amorphOX™. The platform comprises an innovative powder-based technology that can be used to develop highly differentiated drugs with various active ingredients and administration routes. amorphOX™, whose particles are presented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

amorphOX™ has been validated in various in vivo studies, including human clinical trials, demonstrating rapid and extensive absorption. Furthermore the platform is well tolerated and shows a low degree of inter-patient variability. amorphOX™ works with different APIs, dosage forms and administration routes. It is a versatile platform with significant potential that will serve as the backbone of Orexo´s future drugs.

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

The commercial supply chain has been established for Orexo´s fully developed pharmaceutical candidate OX124. This will contribute to shorter timelines, reduce costs and limit risks in the development of future products based on the amorphOX™ platform that use 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.

Pharmaceutical development pipeline



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 shown more rapid absorption, substantially higher plasma concentrations of naloxone, and sustained duration of elevated plasma concentrations when compared to the current market leader.

A launch of OX124 in the US is planned to be initiated in late 2023 and Orexo is targeting a market for overdose rescue medications today amounting to more than USD 450 million. The market is expected to continue growing, not only as an effect of the record-high level of fatal overdoses but also as multiple federal initiatives are ongoing to expand access to life-saving naloxone medications. Examples include mandatory co-prescription legislation when patients are being treated for pain, and standing orders at the pharmacy. According to Orexo´s estimates, the market size could reach a level of USD 1.5 – 2 billion if this mandatory co-prescription legislation is implemented nationwide and the pricing in the market is sustained at current levels. Today, the market is fully dominated by low-dose products including two generic versions of the branded market leader which have been launched with a price nearly in line with the branded product.

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

OX124 has patents protecting the product until 2039.

Successful data from the pivotal trial OX124-002 communicated in Q4, along with data from the on-going stability and usability studies, will be our 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 late H2 2023.

Other pipeline assets

OX125 – nalmefene opioid overdose rescue medication with nasal delivery
The widespread use of synthetic opioids, such as fentanyl, also increases the need for rescue medicines that are effective in rural areas where distance to emergency units require more potent and longer lasting overdose treatment. With OX125, the aim is to develop an overdose rescue medication for situations where powerful, rapid and long-lasting effects are required. OX125 is built on the amorphOX™ platform and its performance has been proven in an exploratory PK study in healthy volunteers which showed extensive and rapid absorption of nalmefene across all formulations included in the trial. The market potential for OX125 is highly dependent on the general guidelines of opioid overdose rescue medications in the US and whether nalmefene will become the primary API or naloxone will continue as the first line treatment. Assuming a market development as described above under OX124 and nalmefene staying a complement to naloxone, the potential net sales could be in the range of USD 40-60 million in the US market.

The innovative OX125 product has patent protection until 2039.

In Q1, the pharmaceutical development work continued, primarily focusing on evaluating 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 being closely monitored. Orexo is progressing towards a time when OX125 could meet an unmet medical need for an overdose medication, which in addition to having a rapid absorption and being powerful, also remains in the body for a much longer time.

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 earlier conducted exploratory PK study showed a significantly better PK profile with faster uptake and higher peak when compared to available nasal sprays on the market. Net sales are estimated to be more than USD 100 million in the US market. Current focus for Orexo is on OX124 and OX640, and activities on OX338 is limited.

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

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

OX640 is based on Orexo's proprietary drug delivery platform amorphOX™, and has shown promising chemical and physical stability data. In addition to providing allergic patients with a more convenient, needle-free alternative to auto-injectors currently on the market, an adrenaline product that provides greater flexibility in relation to how it can be handled and stored should provide significant benefits to patients and healthcare systems, ensuring the correct adrenaline dose is available when needed.

In Q1 the work preparing for the first exploratory clinical phase 1 trial during H2 2022 continued. Among others, preparations were made for the manufacturing of clinical trial material and for the submission of a Clinical Trial Application with the Swedish Medical Products Agency and the Ethical Review Board. Clinical trial data, expected to be available in late 2022, will guide the continued development and strategic decision on when to involve a partner in the development and future commercialization. Regarding the supply chain large synergies are expected with the manufacturing process built up for the nasal overdose rescue medications.

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 Q1 the first batches of ZUBSOLV® were delivered to Accord Healthcare ahead of the EU launch planned to be initiated in some selected markets shortly.
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

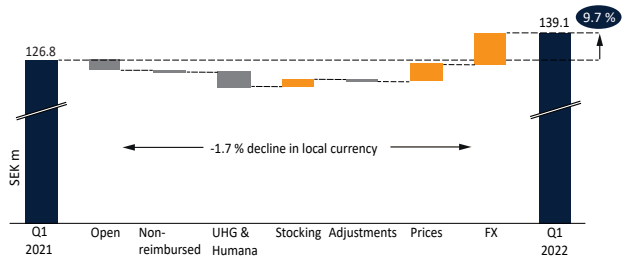
Revenues

Total revenues amounted to SEK 159.4 m (132.3) for the quarter. The increase is mainly explained by higher US Pharma and HQ & Pipeline revenues.

Revenues by segment

US Pharma revenues amounted to SEK 139.1 m (126.8) for the quarter. The increase in US Pharma revenues is mainly driven by favorable payer mix and favorable GTN supported by stronger USD exchange rate. This was partly offset by lower ZUBSOLV® demand due to competition in previously exclusive plans and a weaker overall market growth pace due to Covid-19.

ZUBSOLV® US NET REVENUES DEVELOPMENT



In local currency US Pharma net revenues for the quarter amounted to USD 14.8 m (15.1). Net revenues decreased by USD 0.3 m vs Q4 2021 mainly due to higher wholesaler destocking while demand declined.

Digital Therapeutics (DTx) recognized net revenues for the quarter amounted to SEK 0.2 m (0.2). Sales efforts during the quarter have focused on piloting different reimbursement pathways and commercial concepts.

HQ & Pipeline partner product related revenues for the quarter amounted to SEK 20.1 m (5.3). Explained by a positive adjustment for Abstral® royalty from Q4 2021 and the first sale of ZUBSOLV® in the EU to Accord Healthcare, where the delivery of the first batches ahead of the launch also triggered a minor milestone.

Costs of goods sold

Cost of goods sold (COGS) amounted to SEK 27.5 m (19.2) for the quarter. US Pharma amounted to SEK 22.6 m (16.4) mainly due to unfavorable exchange-rate impact vs prior year along with cyclical production pattern and variable scale. Royalties and technical infrastructure costs for DTx amounted to SEK 2.7 m (2.8). HQ & Pipeline amounted to to SEK 2.3 m (-) due to launch preparations for ZUBSOLV® ex-US sales in EU by Orexo's partner Accord Healthcare.

Operating expenses

Selling expenses amounted to SEK 41.6 m (68.7) for the quarter. The decrease over the same period last year is mainly explained by lower selling expenses in US Pharma and in DTx.

Administrative expenses amounted to SEK 33.0 m (28.6) for the quarter mainly explained by higher legal expenses for IP litigation.

Research and development costs amounted to SEK 72.0 m (55.6) for the quarter. The increase is mainly explained by costs related to MODIA™ study and to OX124 development project.

Other operating income and expenses amounted to SEK 1.5 m (3.0) for the quarter, mainly explained by exchange-rate gains derived from revaluations of parent company balance sheet items in foreign currency, predominantly in USD.

NET REVENUES AND OPERATING EARNINGS PER SEGMENT

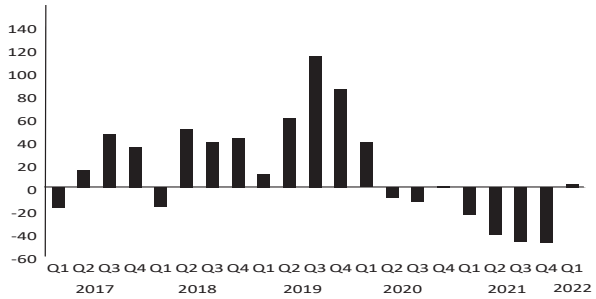
SEK m	Net Revenues			EBIT		
	2022 Jan-Mar	2021 Jan-Mar	2021 Jan-Dec	2022 Jan-Mar	2021 Jan-Mar	2021 Jan-Dec
ZUBSOLV® US product sales	139.1	126.8	522.7	—	—	—
US Pharma – total	**139.1**	**126.8**	**522.7**	**84.0**	**66.1**	**278.2**
Digital Therapeutics (DTx) product sales	0.2	0.2	1.1	—	—	—
Digital Therapeutics (DTx) – total	**0.2**	**0.2**	**1.1**	**-43.4**	**-58.7**	**-249.7**
Abstral® royalty	12.4	2.7	32.1	—	—	—
Edluar® royalty	3.2	2.6	9.1	—	—	—
ZUBSOLV® - ex US	4.6	—	—	—	—	—
HQ & Pipeline segment – total	**20.1**	**5.3**	**41.2**	**-53.7**	**-44.2**	**-242.6**
Total	**159.4**	**132.3**	**565.0**	**-13.2**	**-36.8**	**-214.1**

Operating profit

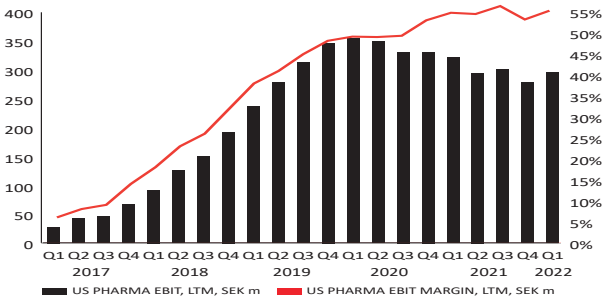
EBITDA amounted to SEK 2.8 m (-23.9) for the quarter and reflects foremost lower operating costs for US Pharma and DTx and higher gross profit.

The EBIT contribution from US Pharma amounted to SEK 84.0 m (66.1) for the quarter, equal to an EBIT margin of 60.4 percent (52.2).

GROUP EBITDA, SEK m



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



The increase in US Pharma EBIT margin is supported by increased allocations of commercial resources to DTx in relation to the launch of the modiaONE program.

Net financial items and tax

Net financial items for the quarter amounted to SEK -1.9 m (4.7) and is mainly explained by lower positive unrealized exchange rate impact of SEK 4.0 m (14.5) derived from the parent company's foreign currency bank accounts mainly in USD, more than completely offset by costs for corporate bonds of SEK 5.4 m (9.1).

Total tax expenses amounted to SEK -8.5 m (0.6) for the quarter. The increase is explained by negative adjustment to deferred tax assets related to temporary differences. Orexo performs regular assessments of its deferred tax asset and makes adjustments according to the recognition requirements of IAS 12.

Net earnings

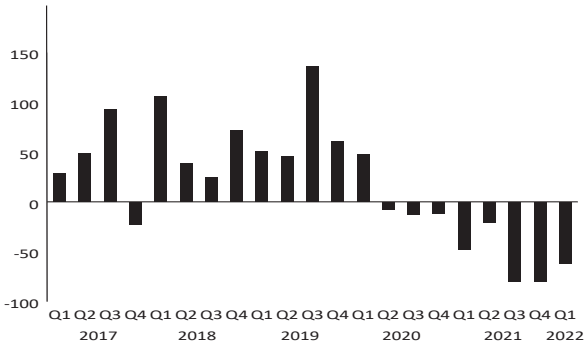
Net earnings amounted to SEK -23.6 m (-31.5) for the quarter.

Cash and cash flow

As of March 31, 2022, cash and cash equivalents amounted to SEK 437.8 m (725.5) and interest-bearing liabilities to SEK 492.9 m (490.5), i.e. a negative net cash position of SEK -55.1 m (235.0).

Cash flow from operating activities amounted to SEK -61.6 m (-47.8) for the quarter and was primarily impacted by changes in working capital and to a lesser extent from negative operating earnings.

CASH FLOW FROM OPERATING ACTIVITIES, SEK m



Investments

Gross investments in tangible and intangible fixed assets amounted to SEK 5.6 m (16.2) for the quarter mainly explained by investments in the DTx enterprise platform and in equipment for the development organization.

Equity

Shareholders' equity at March 31, 2022, was SEK 329.5 m (534.8). The equity/asset ratio was 27.3 percent (37.3).

Parent company

Net revenues for the quarter amounted to SEK 52.0 m (89.4) of which SEK 31.8 m (83.9) was related to sales to Group companies.

Earnings before tax amounted to SEK -52.2 m (-25.5) for the quarter mainly explained by investment in DTx operating expenses and development projects. Investments in equipment for the development organization for the quarter amounted to SEK 4.0 m (8.2).

As of March 31, 2022, cash and cash equivalents in the parent company amounted to SEK 400.0 m (598.7).

[1] Last Twelve Months

Other information

Financial outlook 2022

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

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

Forward looking statements

This report includes forward-looking statements. Actual results may differ from those stated. Internal and external factors may affect Orexo's results.

Audit

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

Risks and uncertainty factors

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

Glossary

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

Uppsala, Sweden, April 28, 2022

Nikolaj Sørensen
President and CEO

Financial reports, notes and key figures

CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS

SEK m	Notes	2022 Jan-Mar	2021 Jan-Mar	2021 Jan-Dec
Net revenues	9	159.4	132.3	565.0
Cost of goods sold		-27.5	-19.2	-78.9
Gross profit		**131.9**	**113.1**	**486.1**
Selling expenses		-41.6	-68.7	-280.4
Administrative expenses		-33.0	-28.6	-151.5
Research and development expenses		-72.0	-55.6	-272.3
Other operating income and expenses		1.5	3.0	4.0
Operating earnings (EBIT)		**-13.2**	**-36.8**	**-214.1**
Net financial items		-1.9	4.7	-8.4
Earnings before tax		**-15.1**	**-32.1**	**-222.5**
Tax	5	-8.5	0.6	-1.0
Net earnings for the period[1]		**-23.6**	**-31.5**	**-223.5**
Earnings per share, before dilution, SEK		-0.69	-0.92	-6.51
Earnings per share, after dilution, SEK		-0.69	-0.92	-6.51

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

SEK m	2022 Jan-Mar	2021 Jan-Mar	2021 Jan-Dec
Earnings for the period	**-23.6**	**-31.5**	**-223.5**
Other comprehensive income			
Items that may subsequently be reversed to the statement of operations:			
Exchange-rate differences	3.5	7.8	13.0
Other comprehensive earnings for the period, net after tax	**3.5**	**7.8**	**13.0**
Total comprehensive earnings for the period[1]	**-20.1**	**-23.7**	**-210.5**

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

CONDENSED CONSOLIDATED BALANCE SHEET

SEK m	2022 Mar 31	2021 Mar 31	2021 Dec 31
ASSETS			
Fixed assets			
Tangible fixed assets	68.3	54.9	65.9
Intangible fixed assets	241.7	253.2	248.9
Right-of-use assets	54.9	64.3	59.2
Deferred tax assets	26.5	35.9	33.4
Other financial assets	0.8	0.8	0.8
Total fixed assets	**392.2**	**409.0**	**408.2**
Current assets			
Inventories	77.6	108.8	92.3
Accounts receivable and other receivables	298.0	190.2	269.2
Cash and cash equivalents	437.8	725.5	504.1
Total current assets	**813.4**	**1,024.5**	**865.5**
Total assets	**1,205.7**	**1,433.5**	**1,273.7**
SHAREHOLDERS' EQUITY AND LIABILITIES			
Total shareholders' equity	**329.5**	**534.8**	**349.6**
Long-term liabilities			
Provisions	9.9	19.0	13.5
Long-term liabilities, interest bearing	492.9	490.5	492.3
Lease liabilities, long-term	33.8	44.5	38.0
Total long-term liabilities	**536.7**	**554.0**	**543.9**
Current liabilities and provisions			
Provisions	146.9	171.0	160.1
Current liabilities, non-interest bearing	172.4	154.9	199.9
Lease liabilities, current	20.2	18.7	20.2
Total current liabilities and provisions	**339.5**	**344.6**	**380.2**
Total liabilities	**876.2**	**898.6**	**924.1**
Total shareholders' equity and liabilities	**1,205.7**	**1,433.5**	**1,273.7**

CONSOLIDATED CHANGES IN SHAREHOLDERS' EQUITY

SEK m	2022 Mar 31	2021 Mar 31	2021 Dec 31
Opening balance, shareholders' equity	**349.6**	**558.5**	**558.5**
Total comprehensive earnings for the period	-20.1	-23.7	-210.5
Share-based payments	0.0	0.0	1.5
Closing balance, shareholders' equity	**329.5**	**534.8**	**349.6**

CONDENSED CONSOLIDATED CASH FLOW STATEMENTS

SEK m	Notes	2022 Jan-Mar	2021 Jan-Mar	2021 Jan-Dec
Operating earnings (EBIT)		-13.2	-36.8	-214.1
Interest received		0.0	0.0	0.0
Interest paid		-4.7	-8.5	-22.9
Income taxes paid		1.9	-1.8	8.2
Adjustment for non-cash items	3	-6.8	-34.7	-16.8
Cash flow from operating activities before changes in working capital		**-22.8**	**-81.7**	**-245.5**
Changes in working capital		**-38.8**	**33.9**	**16.5**
Cash flow from operating activities		**-61.6**	**-47.8**	**-229.0**
Acquisition of tangible and intangible fixed assets		-5.6	-16.2	-52.9
Cash flow from investing activities		**-5.6**	**-16.2**	**-52.9**
New loan		—	490.1	490.1
Repayment of loans		-5.3	-228.4	-239.5
Cash from financing activities		**-5.3**	**261.7**	**250.6**
Cash flow for the period		**-72.5**	**197.7**	**-31.2**
Cash and cash equivalents at the beginning of the period		**504.1**	**505.3**	**505.3**
Exchange-rate differences in cash and cash equivalents		6.3	22.6	30.0
Changes in cash and cash equivalents		-66.3	220.2	-1.2
Cash and cash equivalents at the end of the period		**437.8**	**725.5**	**504.1**

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.

	2022 Jan-Mar	2021 Jan-Mar	2021 Jan-Dec
EBIT margin, %	-8.3	-27.8	-37.9
Return on shareholder equity, %	-6.4	-5.8	-49.2
Net debt, SEK m	55.2	-235.0	-11.7
Debt/equity ratio, %	149.6	91.7	140.8
Equity/assets ratio, %	27.3	37.3	27.4
Number of shares, before dilution	34,327,907	34,294,873	34,319,649
Number of shares, after dilution	34,327,907	34,294,873	34,319,649
Earnings per share, before dilution, SEK	-0.69	-0.92	-6.51
Earnings per share, after dilution, SEK	-0.69	-0.92	-6.51
Number of employees at the end of the period	123	145	121
Shareholders' equity, SEK m	329.5	534.8	349.6
Capital employed, SEK m	822.4	1,025.3	841.9
Working capital, SEK m	36.1	-45.6	-18.8

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

CONDENSED PARENT COMPANY STATEMENT OF OPERATIONS

SEK m	Notes	2022 Jan-Mar	2021 Jan-Mar	2021 Jan-Dec
Net revenues		52.0	89.4	365.9
Cost of goods sold		-14.9	-21.6	-71.2
Gross profit		**37.1**	**67.8**	**294.7**
Selling expenses		-37.5	-53.2	-227.3
Administrative expenses		-20.1	-15.4	-92.3
Research and development costs		-60.7	-44.9	-226.0
Other operating income and expenses		29.4	14.8	36.8
Operating earnings (EBIT)		**-51.8**	**-30.9**	**-214.2**
Interest income and expenses		-4.7	-3.7	-18.0
Other financial income and expenses		4.2	9.1	12.5
Net financial items		**-0.4**	**5.4**	**-5.6**
Earnings before tax		**-52.2**	**-25.5**	**-219.8**
Tax	5	—	—	—
Earnings for the period		**-52.2**	**-25.5**	**-219.8**

PARENT COMPANY STATEMENT OF COMPREHENSIVE INCOME

SEK m	2022 Jan-Mar	2021 Jan-Mar	2021 Jan-Dec
Earnings for the period	**-52.2**	**-25.5**	**-219.8**
Other comprehensive income	—	—	—
Total comprehensive earnings for the period	**-52.2**	**-25.5**	**-219.8**

CONDENSED PARENT COMPANY BALANCE SHEET

SEK m	2022 Mar 31	2021 Mar 31	2021 Dec 31
ASSETS			
Fixed assets			
Intangible fixed assets	206.6	226.8	214.2
Tangible fixed assets	68.3	54.0	65.9
Shares in subsidiaries	160.6	158.9	162.5
Total fixed assets	**435.6**	**439.7**	**442.6**
Current assets			
Inventories	61.4	79.5	67.8
Accounts receivable and other receivables	69.3	122.7	115.4
Cash and bank balances	400.0	598.7	444.5
Total current assets	**530.7**	**800.8**	**627.7**
Total assets	**966.3**	**1,240.5**	**1,070.2**
SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES			
Total shareholders' equity	**253.8**	**498.6**	**306.0**
Long-term liabilities			
Provisions	9.5	18.0	12.8
Bond loan	492.9	490.5	492.3
Total long-term liabilities	**502.4**	**508.5**	**505.1**
Current liabilities			
Accounts payable	18.1	12.1	17.1
Other liabilities	8.4	8.1	9.1
Liabilities to Group companies	158.7	191.5	207.9
Accrued expenses and deferred income	24.9	21.7	25.0
Total current liabilities	**210.1**	**233.3**	**259.1**
Total liabilities	**712.5**	**741.8**	**764.2**
Total shareholders' equity and liabilities	**966.3**	**1,240.5**	**1,070.2**

Notes

1. Accounting policies

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

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

The Parent Company's financial statements were prepared in accordance with RFR 2 (Swedish Financial Reporting Board's recommendation) and Chapter 9 of the Swedish Annual Accounts Act.

2. Segment Reporting

Operations are monitored and presented in the segments US Pharma, Digital Therapeutics and HQ & Pipeline.
US Pharma segment comprises the distribution and sale of ZUBSOLV® for treatment of opioid use disorder in the US.

Digital Therapeutics segment comprises the distribution and sale of digital therapies which complement existing treatments and provide patients with access to highly sophisticated and individualized support when they need it most in the US.

HQ & Pipeline consists of the Group head quarter functions, R&D, Business Development, Global Regulatory and Supply Chain. Net revenues comprises all partner revenues for ZUBSOLV® – ex US, Abstral® and Edluar®.

No operating segments have been aggregated to form the above reportable operating segments.
The President and CEO is the chief operating decision maker and monitors the operating results of the group's segments separately for the purpose of making decisions about resource allocation and performance assessment. Segment performance is evaluated based on EBIT and is measured consistently with EBIT in the consolidated financial statements.

DISTRIBUTION OF REVENUE AND EBIT PER SEGMENT

SEK m	2022 Jan-Mar	2021 Jan-Mar	2021 Jan-Dec
US Pharma			
Net revenues	139.1	126.8	522.7
Operating earnings (EBIT)	84.0	66.1	278.2
Depreciation and amortization	-3.8	-3.8	-15.4
Digital Therapeutics			
Net revenues	0.2	0.2	1.1
Operating earnings (EBIT)	-43.4	-58.7	-249.7
Depreciation and amortization	-5.7	-4.3	-18.6
HQ & Pipeline			
Net revenues	20.1	5.3	41.2
Operating earnings (EBIT)	-53.7	-44.2	-242.6
Depreciation and amortization	-6.5	-4.8	-19.1
Group			
Net revenues	159.4	132.3	565.0
Operating earnings (EBIT)	-13.2	-36.8	-214.1
Depreciation and amortization	-16.0	-12.9	-53.0
Net financial items	-1.9	4.7	-8.4
Earnings before tax	-15.1	-32.1	-222.5

3. Cash flow

ADJUSTMENT FOR NON-CASH ITEMS

SEK m	2022 Jan-Mar	2021 Jan-Mar	2021 Jan-Dec
Depreciation/amortization and impairment	16.0	12.9	53.0
Change in provisions	-21.3	-44.6	-67.4
Share based payments	0.0	0.0	1.5
Exchange rate income and expenses	-1.5	-3.0	-3.9
Total	**-6.8**	**-34.7**	**-16.8**

4. Litigations

Subpoena related to sales and marketing of ZUBSOLV®
On July 14, 2020, Orexo's US subsidiary received subpoenas for the purpose of enabling US authorities to obtain certain information in relation to sales and marketing of ZUBSOLV® and other buprenorphine products. All information requested by the authorities have been delivered. Orexo has no knowledge of the background to the requests and will continue to collaborate with the US authorities to ensure they receive the necessary information and to understand the scope of the investigations.

Paragraph IV litigations against Sun Pharmaceutical Industries Ltd
On August 10, 2020, the company announced it has received a "paragraph IV" patent certification notice from Sun Pharmaceutical Industries Limited ("Sun"). The Notice Letter advises Orexo of Sun's filing of an Abbreviated New Drug Application ("ANDA") with the US Food and Drug Administration (FDA) seeking approval of generic versions of ZUBSOLV® before the expiration of Orexo's patents listed in the Orange Book.

As a response to above notice Orexo on September 13, 2020, filed a patent infringement action in the US District Court for the District of New Jersey, against Sun. The filing statutorily precludes FDA from approving Sun's ANDA for 30 months, or until a district court decision finds the patents to be invalid or not infringed, whichever occurs first.

Orexo currently has nine patents listed in the Orange Book (US Patent Nos. 8,470,361; 8,658,198; 8,940,330; 9,259,421; 9,439,900; 10,874,661;10,946,010; 11,020,387 and 11,020,388) with expiration dates ranging from December 2027 to September 2032. All nine listed patents have been asserted in patent infringement actions against Sun in the US District Court for the District of New Jersey.

5. Deferred tax

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

- Christine Rankin and Michael J Matly were elected as Board members at the Annual General Meeting. They replace David Colpman and Kirsten Detrick who have declined re-election.
- Orexo´s partner Gesynta Pharma's drug candidate GS-248 (OX-MPI) granted Orphan Drug Designation in the US by the FDA for the treatment of systemic sclerosis
- Financial outlook 2022 updated, view page 11

9. Revenue from contracts with customers

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

SEK m	2021 Jan-Mar					
Segment	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**VORVIDA®**	**DEPREXIS®**	**Total**
US Pharma	126.8	—	—	—	—	**126.8**
Digital Therapeutics	—	—	—	0.1	0.0	**0.2**
HQ & Pipeline	—	2.7	2.6	—	—	**5.3**
Total revenue from contracts with customers	**126.8**	**2.7**	**2.6**	**0.1**	**0.0**	**132.3**
Geographical markets	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**VORVIDA®**	**DEPREXIS®**	**Total**
US	126.8	—	1.0	0.1	0.0	**127.9**
EU	—	2.5	0.6	—	—	**3.0**
Rest of the world	—	0.3	1.1	—	—	**1.3**
Total revenue from contracts with customers	**126.8**	**2.7**	**2.6**	**0.1**	**0.0**	**132.3**

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**

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	2022 Jan-Mar	2021 Jan-Mar	2021 Jan-Dec
EBIT	-13.2	-36.8	-214.1
Depreciation and amortization	16.0	12.9	53.0
EBITDA	**2.8**	**-23.9**	**-161.0**
DTx EBIT	43.4	58.7	249.7
IP litigation and subpoena costs	7.7	11.3	59.6
EBITDA excluding DTx, IP litigation and subpoena costs	**53.9**	**46.1**	**148.3**

RETURN ON SHAREHOLDERS' EQUITY	2022 Jan-Mar	2021 Jan-Mar	2021 Jan-Dec
Shareholders' equity beginning balance	411.7	558.5	558.5
Shareholders' equity ending balance	329.5	534.8	349.6
Average shareholders' equity	370.6	546.7	454.1
Net earnings	-23.6	-31.5	-223.5
Return on shareholders' equity %	**-6.4**	**-5.8**	**-49.2**

OPERATING EXPENSES SEK m	2022 Jan-Mar	2021 Jan-Mar	2021 Jan-Dec
Selling expenses	-41.6	-68.7	-280.4
Administrative expenses	-33.0	-28.6	-151.5
Research and development costs	-72.0	-55.6	-272.3
Other operating income and expenses	1.5	3.0	4.0
Operating expenses	**-145.1**	**-149.9**	**-700.2**

GROSS INVESTMENTS SEK m	2022 Jan-Mar	2021 Jan-Mar	2021 Jan-Dec
Investments in tangible fixed assets	4.0	9.0	24.7
Investments in intangible fixed assets	1.6	7.2	28.1
Gross investments	**5.6**	**16.2**	**52.9**