Q1 2021 Interim Report

Investing in future growth drivers

Q1 2021 summary

- Total net revenues of SEK 132.3 m (175.0)
- Net earnings of SEK -31.5 m (82.6)
- EBITDA of SEK -23.9 m (39.1)
- US Pharma segment (ZUBSOLV® US) net revenues of SEK 126.8 m (163.9), EBIT of SEK 66.1 m (75.9)
- Cash flow from operating activities of SEK -47.8 m (48.1), cash balance of SEK 725.5 m (861.4)
- A new patent for OX124, overdose rescue medication, was issued by the US Patent and Trademark Office (USPTO), protecting the technology until 2039
- Issued a new corporate bond amounting to a nominal value of SEK 500 m and redemption of the corporate bond issued in 2017
- A partnership agreement was reached with Magellan Rx, the third largest payor for treatment of opioid dependence in the US, to test modia™ with patients and other payors in their network
- A new patent for ZUBSOLV®, with protection until 2032, was issued by the USPTO

No important events after the period

SEK 66 m
US Pharma EBIT

52%
US Pharma EBIT margin

SEK 726 m
Cash and cash equivalents

SEK m, unless otherwise stated	2021 Jan-Mar	2020 Jan-Mar	2020 Jan-Dec	2020-2021 Jan-Mar Δ
Net revenues	132.3	175.0	663.6	-24%
Cost of goods sold	-19.2	-20.0	-65.6	-4%
Operating expenses	-149.9	-121.1	-617.9	24%
EBIT	-36.8	34.0	-19.9	-208%
EBIT margin, %	-27.8	19.4	-3.0	-47.2 ppt
EBITDA	-23.9	39.1	19.0	-161%
Earnings per share, before dilution, SEK	-0.92	2.38	-2.45	-139%
Earnings per share, after dilution, SEK	-0.92	2.34	-2.45	-139%
Cash flow from operating activities	-47.8	48.1	16.8	-199%
Cash and cash equivalents	725.5	861.4	505.3	-16%

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 2.00 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 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-q1-2021
Telephone: SE + 46 8 505 583 56 UK + 44 333 300 92 61 US + 1 833 823 05 90
The presentation material will be available on Orexo´s website prior to the audiocast, view Investors/Reports, presentations and audicasts

Financial calendar
Interim Report Q2 2021 - July 15, 2021 at 8.00 am CET
Interim Report Q3 2021 - November 3, 2021 at 8.00 am CET
Interim Report Q4 2021 - January 27, 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.

ZUBSOLV® demand will contribute to a solid foundation for future growth

During the first quarter of 2021, we made good progress on multiple fronts. I am pleased to see that ZUBSOLV® demand has stabilized compared to the previous quarter, alongside the refinancing of the corporate bond, which has further strengthened Orexo´s opportunity to grow. Within our innovative digital therapeutic venture, several important steps have been taken to encourage growth in this new market and for our sales to start gaining momentum. As US society is moving to post-pandemic conditions, access to our customers is also increasing. This will be an important driver for ZUBSOLV® to return to growth and for the launch of our clinically proven digital therapies.

ZUBSOLV® - continued strong EBIT contribution from US Pharma

We have seen a decline in ZUBSOLV® net sales in Q1 as expected, following the seasonal patterns for Q1 seen since the launch of the product. This year we have fewer shipping days in Q1 compared to Q4, leading to an overall decline in the market despite a positive weekly trend. For ZUBSOLV®, wholesalers and pharmacies traditionally build inventory in Q4 in anticipation of price increases in January. Patients in the commercial payer segment also have their co-pay reset at the start of a new calendar year, which leads to a slow down in this part of the market. Overall, I have been pleased to see the weekly demand, i.e. prescriptions of ZUBSOLV®, stabilizing over the quarter,[1] and in particular to see a couple percent growth in weekly prescriptions in the Open segment, despite the difficulties for our sales representatives to access their customers due to Covid-19.

"Overall, I have been pleased to see the weekly demand, i.e. prescriptions of ZUBSOLV®, stabilizing over the quarter,[1] and in particular to see a couple percent growth in weekly prescriptions in the Open segment"

I am also proud we have maintained a strong EBIT contribution of 52 percent in the quarter, which should be seen in light of increased legal expenses. A stable sales and EBIT contribution from ZUBSOLV®, together with the refinancing of the corporate bond, enable us to invest in establishing Orexo as a leading player in digital health, without impacting the development of our pharmaceutical pipeline.

Digital therapeutics - a high-potential market in its infancy

We have made important progress over the quarter to expand the market for digital therapeutics. We signed an agreement with Magellan Rx, one of the largest Pharmacy Benefit Managers (PBMs) in the US, to conduct a real world evidence study with modia™, to demonstrate its potential as a valuable treatment option in opioid use disorder. modia™ was the reason we entered digital therapies and we continue to see significant value in the combination with primarily ZUBSOLV®, but also other buprenorphine products for patients, physicians and payers, such as Magellan Rx. We have also initiated a pilot of vorvida® and deprexis® with a leading US tech company, and two larger healthcare providers are preparing an integration of vorvida® and deprexis® into their treatment programs during Q2. The latter are leveraging a similar insurance pathway as the one Orexo recently tested with vorvida® in Pennsylvania. The test in Pennsylvania will now expand into new geographies and the insurance pathway will be the basis of the launch of deprexis® to health care providers which has started in April.

[1] Average weekly prescriptions for ZUBSOLV®, where all prescriptions are normalized to a size of 30 tablets

Despite the obvious patient need for these ground-breaking treatments, the implementation of digital therapies takes time and we need more awareness and evidence for the therapies before we can expect the market to accelerate. We are therefore focusing our efforts on setting up pilots and trials with well known health care providers, employers and payers to receive their endorsements and recommendations. So far I am encouraged by the positive feedback we are receiving and in particular their compliments to the products when comparing to other digital therapies they have assessed and look forward seeing this translate into a revenue contribution as the pilots transform into commercial contracts.

"Despite the obvious patient need for these ground-breaking treatments (DTx), the implementation of digital therapies takes time and we need more awareness and evidence for the therapies before we can expect the market to accelerate"

OX124 - urgent need for new treatment of opioid overdose

New preliminary yearly data[1] from Center of Disease Control indicates an increase in overdoses by 27 percent, where the portion caused by synthetic opioids, such as fentanyl, rose by 49 percent. Thus the need for our most advanced development project, OX124, a rescue medication for opioid overdose, is increasing everyday. We continue to make good progress towards initiating the final clinical study according to plan in late Q2. In parallel, minor adjustments were made to build up the supply chain in preparation to launch in the US market in 2023. With the differentiation shown in the first clinical study, versus the leading product on the market, we are confident the commercial potential for the product in the US is substantial.

Summary and outlook

Social responsibility in the pharmaceutical industry is becoming increasingly important, especially in the wake of Covid-19. The number of people suffering from mental illness and substance use disorders is growing rapidly. Orexo's ongoing transformation journey, from a one-product company to a company offering both pharmaceuticals and clinically proven digital therapies, means that we will be able to help many more people in urgent need of help. This mission is fully embraced by my excellent staff in both Sweden and the US, and is underpinned by our solid financial position.

Uppsala, Sweden, April 29, 2021

Nikolaj Sørensen
President and CEO

[1] Oct. 2019 - Sep. 2020

Business update

US Pharma

zubsolv

Sublingual tablet for treatment of opioid use disorder

Starting 2021, ZUBSOLV® demand continued to stabilize when looking at the weekly average prescriptions. The stabilization is explained by the Open segment showing a slight upward trend, several key accounts, such as CVS Caremark and Express Script (Medicare) are growing and the decline from previous exclusive contracts is diminishing.

The overall market grew 9 percent versus Q1 2020 and declined 1 percent over Q4 2020. The decline versus previous quarter is mainly caused by less sales days in Q1. The market growth is likely to be positively impacted by several efforts to improve access to medication assisted treatment (MAT) in the US which are showing signs of increased activity levels. At the federal level multiple bills have been introduced with a focus to reduce overdose deaths and greatly expand MAT. On a state level, in Kentucky, which is one of the largest volume states, a legislation has passed to improve access to all opioid dependence treatment medications, including ZUBSOLV®. Currently, Orexo has very limited commercial activities in Kentucky, due to lack of payer coverage. With the legislation being fully implemented, this will be an important growth opportunity and we are preparing to scale up activities in this state.

Compared to Q1 2020 demand declined 15 percent mainly due to the continued impact from changed formulary status at United Health Group and Humana, in addition to a small decline in the commercial segment business during the Covid-19 pandemic.

ZUBSOLV's Q1 2021 overall prescription volume is stable when looking at weekly averages, although the full quarter demand is down due to two less selling days in Q1 2021 compared to Q4 2020. Our core segment, the open formulary business showed a mild decline by 3 percent over Q4 2020 whereas the weekly average shows a slight increase. The demand on former exclusive plans, United Health Group and Humana, declined over previous quarter, but at a slower pace and adjusted for seasonal patterns the decline has diminished. The same pattern applies for non-reimbursed businesses.

Market access to the public segment increased from 34 to 36 percent during the period primarily due to ESI Med D and individual managed Medcaid plans in Indiana starting to reimburse ZUBSOLV®. With the legislative changes in one of the largest volume states, Kentucky, we are optimistic ZUBSOLV® will continue to improve access during 2021. ZUBSOLV's best-in-class Commercial access is unchanged at 99 percent.

The ZUBSOLV® sales force activity continues to be downwardly impacted by the Covid-19 pandemic. The number of calls per day and the amount of direct time the sales representatives have in front of the physician and healthcare providers is 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 Q1.

The work to outline the commercial strategy for ZUBSOLV® used along with the digital therapy modia™, for opioid use disorder, continued and expects to give access to new market segments.

Digital Therapeutics

VORV!DA® deprexis® modia

vorvida® - for heavy alcohol misuse
deprexis® - for managing symptoms of depression
modia™ - for opioid use disorder

During the quarter, Orexo continued to explore the best commercialization pathways, ranging from direct to consumer activities, leveraging synergies with the ZUBSOLV® sales force, to establishing pilots with payors, employers and healthcare providers. In parallel, the company continues to develop selling techniques to overcome the restrictions imposed as a consequence of Covid-19. While virtual selling can work, face to face meetings are more effective, in particular when launching a new type of product to new customers. During the quarter access to all categories of customers improved.

An important milestone for Orexo's digital therapies was reached during the quarter, when a partnership agreement was reached with Magellan Rx, the third largest payor for treatment of opioid dependence in the US. Orexo will together with Magellan Rx and payors in their network, test modia™ in combination with buprenorphine treatment and collect real world evidence for the effectiveness and value of modia™. With this partnership agreement with Magellan Rx, Orexo has a unique opportunity to learn how the payors will assess the value of digital therapies in terms of effectiveness and cost.

While individual plan benefits are quite variable, we are seeing significant potential for this platform and are expanding to two additional states for evaluation in Q2. We are also in several partnering discussions to take the service national based on the existence of broad behavioral health coverage as a medical benefit.

Another interesting customer group is employers and Orexo has initiated a pilot program with one of the largest tech companies in the US. This partner will test vorvida® and deprexis® in a select group of employees and if successful, offer access to the programs as a benefit to all employees in the US. Based on this example, along with the interest that we have seen from other self-insured employers, Orexo will now increase the focus on this market segment.

When launching, the smallest expected target group has been consumers purchasing the product without any reimbursement. However, while working for broader reimbursement from payers, the majority of the revenues to date are from consumers buying access to the products directly from our e-commerce websites, us.vorvida.com and us.deprexis.com. Orexo has tested different marketing concepts since the launch of the products and has found use of social media and customers recommending the products in their social media channels to be the most cost-efficient. The consumers who have tested the products during Q1, are a mix of full-paying customers, customers with rebate vouchers and customers offered a free trial license.

The focus in Q2 will be launching deprexis® to healthcare professionals with a small dedicated sales team, who will test different commercialization concepts during the quarter. Also the promotion of deprexis® will be significantly broadened to other customers. In parallel the work to gain reimbursement by payers and employers will continue for our full DTx portfolio.

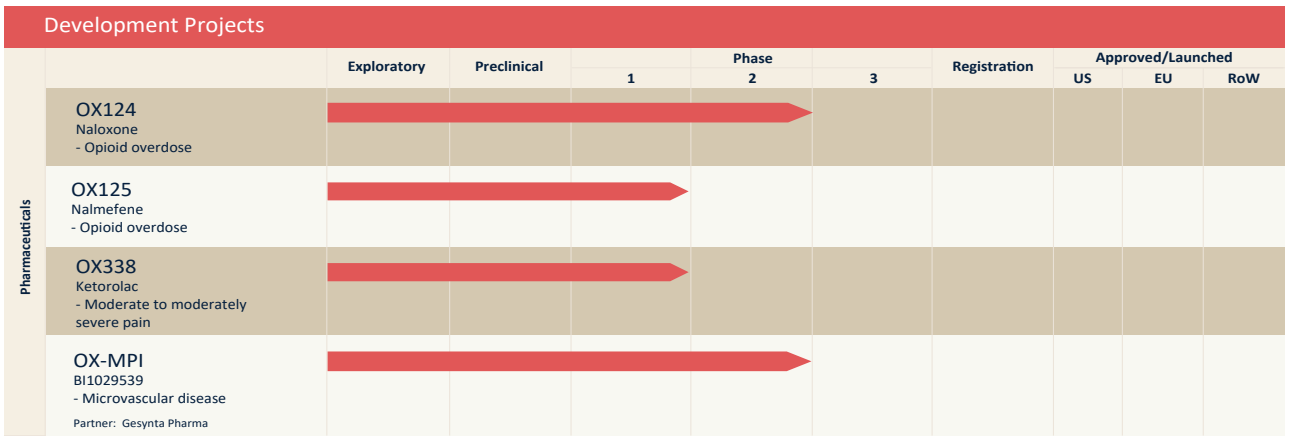
HQ & Pipeline

Most advanced fully-owned pipeline asset

OX124 - opioid overdose rescue medication containing naloxone
OX124 is based on Orexo´s novel intranasal formulation technology aimed to develop a medication that is more powerful, faster and longer-acting than the current market-leading product. Results from Orexo's 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. This ovel, proprietary drug delivery technology has patent protection until 2039 and potential net sales have been estimated to be between USD 70-110 million in the US market.

Currently available rescue medications have been developed for heroin overdoses, but today most people are dying from accidental overdose with synthetic opioids such as fentanyl. According to preliminary 12-month data, more than 87,000 Americans died of an drug overdose in the US, an increase of over 27 percent.[1] The majority of these overdoses were caused by synthetic opioids, which saw an increase of 49 percent.[1] Our primary aim with our pipeline is to develop a rescue solution to this fatal problem.

Status:
OX124 is Orexo's prioritised pipeline project and a commercial supply chain has been established for the naloxone powder and administration device. Orexo's investigational new drug (IND) application was cleared by the US FDA in Q3 2020 and a pivotal clinical study is scheduled in Q2 2021. Preliminary timing for filing a new drug application is in mid-2022, a few months behind the initial time table, as the FDA did not granted fast track designation.



[1] Oct. 2019 – Sep. 2020, Center of Disease Control and Prevention

Other pipeline assets

OX125 - opioid overdose rescue medication containing nalmefene
OX125 is in development as 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 where it 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 have been estimated to be between 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 have been estimated to be > 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 late 2021.

ZUBSOLV® for treatment of opioid use disorder in geographies outside the US
The partnership with Accord Healthcare, which has licensed the exclusive commercial rights to ZUBSOLV® in 29 European countries, is ramping up and the first launches are scheduled to take place in H2 2021. Orexo will be responsible for product supply and double-digit royalites will be received on future net sales.

There are estimated to be 1.3 million high-risk opioid users in Europe,[1] yet treatment rates are low with around 50 percent of people with opioid dependence receiving some form of substitution treatment and this can vary greatly between countries.[2]

[1] European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) 2019
[2] EMCDDA – Tackling Opioid Dependence 2019

Financial overview

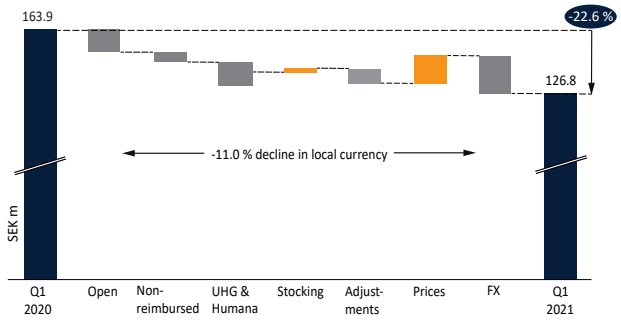
Revenues

Total revenues for the quarter amounted to SEK 132.3 m (175.0).

Revenues by segment

US Pharma revenues amounted to SEK 126.8 m (163.9). The decrease in US Pharma revenues year over year is mainly driven by lower ZUBSOLV® demand due to competition in previously exclusive plans and a declining Commercial segment as a result of increased unemployment. Also a weaker USD exchange rate impacted negatively while increased prices and a favourable product mix had a positive impact.

ZUBSOLV® US NET REVENUE DEVELOPMENT



In local currency US Pharma net revenues amounted to USD 15.1 (16.9) and vs Q4 2020 US Pharma net revenues decreased by USD 1.6 m, while the drop in demand stabilized and increase prices impacted positively the negative revenue impact can mainly be referred to seasonal adjustments due to inventory build-up among wholesalers in Q4 2020 and fewer shipping days in Q1 2021.

DTx recognized net revenues of SEK 0.2 m (-) and deferred revenues of SEK 0.2 m (-) as sales efforts during the quarter have focused on piloting different reimbursement pathways and commercial concepts. In accordance with IFRS 15 standard for revenue recognition the revenues are recognized throughout the validity of the license.

HQ and Pipeline partner product related revenues amounted to SEK 5.3 m (11.1).

Costs of goods sold

Cost of goods sold (COGS) amounted to SEK 19.2 m (20.0) for the quarter, explained by US Pharma of SEK 16.4 m (20.0) and technical infrastructure costs of SEK 2.8 m (-) for vorvida® and deprexis®

Operating expenses

Selling expenses amounted to SEK 68.7 m (54.6) for the quarter. The increase over the same period last year is mainly explained by costs related to launch preparations for vorvida® and deprexis®. This was partially offset by lower selling expenses in US Pharma.

Administrative expenses amounted to SEK 28.6 m (23.7) for the quarter. The increase is mainly explained by higher legal expenses for IP litigations partly offset by lower costs for the long-term incentive programs.

Research and development costs amounted to SEK 55.6 m (52.9) for the quarter. The increase is explained by costs related to launch preparations for vorvida® and deprexis®.

Other operating income and expenses amounted to SEK 3.0 m (10.1) for the quarter mainly explained by exchange-rate gains derived from revaluations of parent company balance sheet items in foreign currency, predominantly in USD.

NET REVENUES AND OPERATING EARNINGS PER SEGMENT

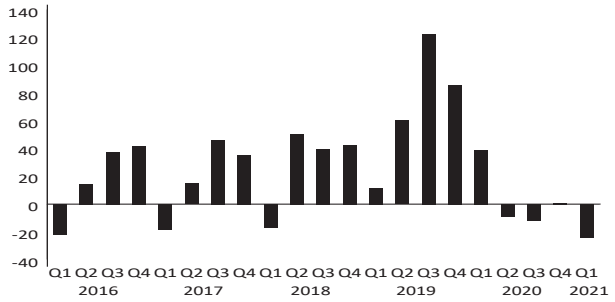
SEK m	Net Revenues			EBIT		
	2021 Jan-Mar	2020 Jan-Mar	2020 Jan-Dec	2021 Jan-Mar	2020 Jan-Mar	2020 Jan-Dec
ZUBSOLV® US product sales	126.8	163.9	623.3	-	-	-
US Pharma – total	**126.8**	**163.9**	**623.3**	**66.1**	**75.9**	**331.2**
Digital Therapeutics (DTx) product sales	0.2	-	0.0	-	-	-
Digital Therapeutics (DTx) – total	**0.2**	-	**0.0**	**-58.7**	**-12.1**	**-175.4**
Abstral® royalty	2.7	8.6	29.7	-	-	-
Edluar® royalty	2.6	2.4	10.4	-	-	-
ZUBSOLV® - ex US	-	0.1	0.1	-	-	-
OX-MPI	-	-	-	-	-	-
HQ & Pipeline segment – total	**5.3**	**11.1**	**40.2**	**-44.2**	**-29.9**	**-175.8**
Total	**132.3**	**175.0**	**663.6**	**-36.8**	**34.0**	**-19.9**

Operating profit

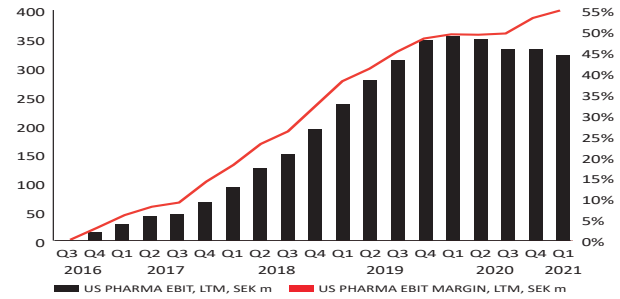
Orexo's profitability reflects investments in DTx and in pipeline and EBITDA amounted to SEK -23.9 m (39.1) for the quarter.

The EBIT contribution from US Pharma amounted to SEK 66.1 m (75.9) for the quarter, equal to an EBIT margin of 52.2 percent (46.3). 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 amounted to SEK 4.7 m (44.0) for the quarter mainly explained by a lower positive unrealized exchange rate impact of SEK 31.1 m derived from the parent company's foreign currency bank accounts mainly in USD, by costs for corporate bonds of SEK 5.4 m and by lower earned interest of SEK 1.6 m.

Total tax expenses amounted to SEK 0.6 m (4.6) for the quarter, negatively impacted by lower positive adjustment to deferred tax assets related to temporary differences of SEK 0.6 m (4.6).

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 -31.5 m (82.6) for the quarter.

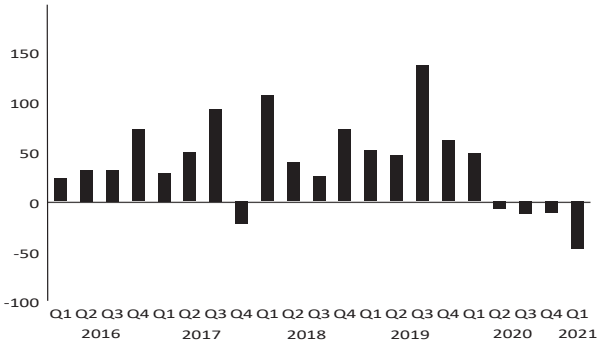
Cash and cash flow

As of March 31 2021, cash and cash equivalents amounted to SEK 725.5 m (861.4) and interest-bearing liabilities to SEK 490.5 m (249.5), i.e. a positive net cash position of SEK 235.0 m (611.9). In the quarter Orexo exercised its option for early redemption of the bonds 2017/2021 in full and issued senior unsecured callable floating rate bonds in the amount of SEK 500 million, under a framework of SEK 1,000 m with final maturity in February 2025 (the "New Bonds"). The New Bonds carry a floating rate interest of 3-month Stibor + 375 bps per annum.

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 -47.8 m (48.1) for the quarter.

CASH FLOW FROM OPERATING ACTIVITIES, SEK m



Investments

Gross investments in tangible and intangible fixed assets amounted to SEK 16.2 m (3.9) for the quarter. Higher investment is explained by investments in the DTx enterprise platform and in equipment for the development organization.

Equity

Shareholders' equity at March 31, 2021, was SEK 534.8 m (775.3). The equity/asset ratio was 37.3 percent (50.0).

Parent company

Net revenues amounted to SEK 89.4 m (137.6) for the quarter of which SEK 83.9 m (126.4) was related to sales to Group companies.

Earnings before tax were SEK -25.5 m (105.7) for the quarter mainly explained by investment in DTx and development projects. Investments amounted to SEK 8.2 m (3.9) for the quarter.

As of March 31, 2021, cash and cash equivalents in the parent company amounted to SEK 598.7 m (575.2).

[1] Last Twelve Months

Other information

Financial outlook 2021

• With the Covid-19 pandemic continuing, the financial outlook is associated with significant uncertainties in 2021. Orexo will continue to conservatively manage the cost base to reflect the market environment.
• The buprenorphine/naloxone market will continue to show a double-digit growth
• Normal seasonal decline for ZUBSOLV® US in Q1 2021 from Q4 2020, then a stabilization and growth of ZUBSOLV® US quarterly net sales when the impact of Covid-19 has disappeared
• Total OPEX will increase in 2021 from 2020, with OX124 driving increased R&D expenses and DTx investments will increase, but the increase will depend on DTx sales progression and market environment
• US Pharma EBIT expected to be around 50 percent
• The financial outlook is based on exchange rates in December 2020

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 2020. 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 29, 2021

Nikolaj Sørensen
President and CEO

Financial reports, notes and key figures

CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS

SEK m	Notes	2021 Jan-Mar	2020 Jan-Mar	2020 Jan-Dec
Net revenues	9	132.3	175.0	663.6
Cost of goods sold		-19.2	-20.0	-65.6
Gross profit		**113.1**	**155.1**	**598.0**
Selling expenses		-68.7	-54.6	-286.6
Administrative expenses		-28.6	-23.7	-102.8
Research and development expenses		-55.6	-52.9	-224.9
Other operating income and expenses		3.0	10.1	-3.6
Operating earnings (EBIT)		**-36.8**	**34.0**	**-19.9**
Net financial items		4.7	44.0	-18.4
Earnings before tax		**-32.1**	**78.0**	**-38.3**
Tax	5	0.6	4.6	-46.1
Net earnings for the period[1]		**-31.5**	**82.6**	**-84.4**
Earnings per share, before dilution, SEK		-0.92	2.38	-2.45
Earnings per share, after dilution, SEK		-0.92	2.34	-2.45

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

SEK m	2021 Jan-Mar	2020 Jan-Mar	2020 Jan-Dec
Earnings for the period	**-31.5**	**82.6**	**-84.4**
Other comprehensive income			
Items that may subsequently be reversed to the statement of operations:			
Exchange-rate differences	7.8	9.3	-16.5
Other comprehensive earnings for the period, net after tax	**7.8**	**9.3**	**-16.5**
Total comprehensive earnings for the period[1]	**-23.7**	**91.9**	**-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	2021 Mar 31	2020 Mar 31	2020 Dec 31
ASSETS			
Fixed assets			
Tangible fixed assets	54.9	24.9	47.3
Intangible fixed assets	253.2	109.9	252.8
Right-of-use assets	64.3	76.1	67.8
Deferred tax assets	35.9	94.9	32.7
Other financial assets	0.8	1.5	0.7
Total fixed assets	**409.0**	**307.3**	**401.3**
Current assets			
Inventories	108.8	140.1	108.4
Accounts receivable and other receivables	190.2	241.6	217.9
Cash and cash equivalents	725.5	861.4	505.3
Total current assets	**1,024.5**	**1,243.0**	**831.6**
Total assets	**1,433.5**	**1,550.4**	**1,232.9**
SHAREHOLDERS' EQUITY AND LIABILITIES			
Total shareholders' equity	**534.8**	**775.3**	**558.5**
Long-term liabilities			
Provisions	19.0	10.2	25.7
Long-term liabilities, interest bearing	490.5	249.5	—
Lease liabilities, long-term	44.5	53.8	47.4
Total long-term liabilities	**554.0**	**313.5**	**73.1**
Current liabilities and provisions			
Provisions	171.0	283.5	197.3
Current liabilities, interest bearing	—	—	224.5
Current liabilities, non-interest bearing	154.9	157.7	160.4
Lease liabilities, current	18.7	20.6	19.1
Total current liabilities and provisions	**344.6**	**461.6**	**601.3**
Total liabilities	**898.6**	**775.1**	**674.4**
Total shareholders' equity and liabilities	**1,433.5**	**1,550.4**	**1,232.9**

CONSOLIDATED CHANGES IN SHAREHOLDERS' EQUITY

SEK m	2021 Mar 31	2020 Mar 31	2020 Dec 31
Opening balance, shareholders' equity	**558.5**	**706.4**	**706.4**
Total comprehensive earnings for the period	-23.7	91.9	-100.9
Share-based payments	0.0	1.4	-19.7
Buy back of shares	—	-24.4	-27.3
New share issue	—	—	—
Closing balance, shareholders' equity	**534.8**	**775.3**	**558.5**

CONDENSED CONSOLIDATED CASH FLOW STATEMENTS

SEK m	Notes	2021 Jan-Mar	2020 Jan-Mar	2020 Jan-Dec
Operating earnings (EBIT)		-36.8	34.0	-19.9
Interest received		0.0	2.7	3.0
Interest paid		-8.5	-3.4	-11.8
Income taxes paid		-1.8	-0.4	0.6
Adjustment for non-cash items	3	-34.7	-8.1	-7.1
Cash flow from operating activities before changes in working capital		**-81.7**	**24.9**	**-35.1**
Changes in working capital		**33.9**	**23.2**	**51.9**
Cash flow from operating activities		**-47.8**	**48.1**	**16.8**
Acquisition of tangible and intangible fixed assets		-16.2	-3.9	-189.8
Disposal of financial assets		—	—	0.6
Cash flow from investing activities		**-16.2**	**-3.9**	**-189.2**
Buy back shares		—	-24.4	-27.3
New loan		490.1	—	—
Repayment of loans		-228.4	-44.4	-84.0
Cash from financing activities		**261.7**	**-68.8**	**-111.3**
Cash flow for the period		**197.7**	**-24.6**	**-283.7**
Cash and cash equivalents at the beginning of the period		**505.3**	**816.8**	**816.8**
Exchange-rate differences in cash and cash equivalents		22.6	69.2	-27.8
Changes in cash and cash equivalents		220.2	44.7	-311.5
Cash and cash equivalents at the end of the period		**725.5**	**861.4**	**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 Jan-Mar	2020 Jan-Mar	2020 Jan-Dec
EBIT margin, %	-27.8	19.4	-3.0
Return on shareholder equity, %	-5.8	11.1	-13.3
Net debt, SEK m	-235.0	-611.9	-280.8
Debt/equity ratio, %	91.7	32.2	40.2
Equity/assets ratio, %	37.3	50.0	45.3
Number of shares, before dilution	34,294,873	34,710,639	34,398,815
Number of shares, after dilution	34,294,873	35,338,863	34,398,815
Earnings per share, before dilution, SEK	-0.92	2.38	-2.45
Earnings per share, after dilution, SEK	-0.92	2.34	-2.45
Number of employees at the end of the period	145	132	138
Shareholders' equity, SEK m	534.8	775.3	558.5
Capital employed, SEK m	1,025.3	1,024.8	783.0
Working capital, SEK m	-45.6	-79.9	-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 Jan-Mar	2020 Jan-Mar	2020 Jan-Dec
Net revenues		89.4	137.6	446.4
Cost of goods sold		-21.6	-19.7	-79.7
Gross profit		**67.8**	**117.9**	**366.7**
Selling expenses		-53.2	-23.9	-190.7
Administrative expenses		-15.4	-12.6	-51.1
Research and development costs		-44.9	-42.7	-180.1
Other operating income and expenses		14.8	23.2	50.0
Operating earnings (EBIT)		**-30.9**	**62.0**	**-7.2**
Interest income and expenses		-3.7	-2.6	-10.9
Other financial income and expenses		9.1	46.3	-5.4
Net financial items		**5.4**	**43.8**	**-16.3**
Earnings before tax		**-25.5**	**105.7**	**-23.4**
Tax	5	—	—	-49.0
Earnings for the period		**-25.5**	**105.7**	**-72.5**

PARENT COMPANY STATEMENT OF COMPREHENSIVE INCOME

SEK m	2021 Jan-Mar	2020 Jan-Mar	2020 Jan-Dec
Earnings for the period	**-25.5**	**105.7**	**-72.5**
Other comprehensive income	—	—	—
Total comprehensive earnings for the period	**-25.5**	**105.7**	**-72.5**

CONDENSED PARENT COMPANY BALANCE SHEET

SEK m	2021 Mar 31	2020 Mar 31	2020 Dec 31
ASSETS			
Fixed assets			
Intangible fixed assets	226.8	109.9	234.4
Tangible fixed assets	54.0	24.9	47.2
Deferred tax assets	—	49.0	—
Shares in subsidiaries	158.9	156.3	160.4
Total fixed assets	**439.7**	**340.1**	**442.0**
Current assets			
Inventories	79.5	113.3	90.9
Accounts receivable and other receivables	122.7	175.7	111.3
Cash and bank balances	598.7	575.2	361.3
Total current assets	**800.8**	**864.2**	**563.5**
Total assets	**1,240.5**	**1,204.4**	**1,005.5**
SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES			
Total shareholders' equity	**498.6**	**726.8**	**524.2**
Long-term liabilities			
Provisions	18.0	7.7	24.5
Bond loan	490.5	249.5	—
Total long-term liabilities	**508.5**	**257.2**	**24.5**
Current liabilities			
Accounts payable	12.1	29.3	17.3
Bond loan	—	—	224.5
Other liabilities	8.1	8.0	6.3
Liabilities to Group companies	191.5	163.2	187.3
Accrued expenses and deferred income	21.7	19.9	21.5
Total current liabilities	**233.3**	**220.4**	**456.8**
Total liabilities	**741.8**	**477.6**	**481.3**
Total shareholders' equity and liabilities	**1,240.5**	**1,204.4**	**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 Jan-Mar	2020 Jan-Mar	2020 Jan-Dec
US Pharma			
Net revenues	126.8	163.9	623.3
Operating earnings (EBIT)	66.1	75.9	331.2
Depreciation and amortization	-3.8	-3.8	-15.4
Digital Therapeutics			
Net revenues	0.2	0.0	0.0
Operating earnings (EBIT)	-58.7	-12.1	-175.4
Depreciation and amortization	-4.3	—	-3.2
HQ & Pipeline			
Net revenues	5.3	11.1	40.2
Operating earnings (EBIT)	-44.2	-29.9	-175.8
Depreciation and amortization	-4.8	-1.2	-20.3
Group			
Net revenues	132.3	175.0	663.6
Operating earnings (EBIT)	-36.8	34.0	-19.9
Depreciation and amortization	-12.9	-5.1	-38.9
Net financial items	4.7	44.0	-18.4
Earnings before tax	-32.1	78.0	-38.3

3. Cash flow

ADJUSTMENT FOR NON-CASH ITEMS

SEK m	2021 Jan-Mar	2020 Jan-Mar	2020 Jan-Dec
Depreciation/amortization and impairment	12.9	8.7	38.9
Change in provisions	-44.6	-8.2	-28.5
Share based payments	0.0	1.4	-19.7
Exchange rate income and expenses	-3.0	-10.1	2.4
Total	**-34.7**	**-8.1**	**-7.1**

4. Litigations

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. Orexo has no knowledge of the background to the requests and is collaborating with the US authorities to ensure they receive the necessary information and to understand the scope of the investigations.

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.

Orexo currently has seven 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 and 10,946,010) with expiration dates ranging from December 2027 to September 2032. The latter, patent no. 10,946,010 with expiration date September 2032, was issued by the US Patent and Trademark Office and listed in the Orange book during the quarter.

As a respons 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.

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

No important events after the period.

9. Revenue from contracts with customers

SEK m				2021 Jan-Mar			
Segment	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**OX-MPI**	**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**	**0.0**	**0.1**	**0.0**	**132.3**
Geographical markets	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**OX-MPI**	**vorvida®**	**deprexis®**	**Total**
US	126.8	—	1.0	—	0.1	0.0	**127.9**
EU & UK	—	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**	**0.0**	**0.1**	**0.0**	**132.3**

SEK m				2020 Jan-Mar			
Segment	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**OX-MPI**	**vorvida®**	**deprexis®**	**Total**
US Pharma	163.9	—	—	—	—	—	**163.9**
Digital Therapeutics	—	—	—	—	—	—	**0.0**
HQ & Pipeline	0.1	8.6	2.4	—	—	—	**11.1**
Total revenue from contracts with customers	**164.0**	**8.6**	**2.4**	**0.0**	**0.0**	**0.0**	**175.0**
Geographical markets	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**OX-MPI**	**vorvida®**	**deprexis®**	**Total**
US	163.9	—	0.5	—	—	—	**164.4**
EU	—	8.6	1.1	—	—	—	**9.6**
Rest of the world	0.1	0.1	0.8	—	—	—	**1.0**
Total revenue from contracts with customers	**164.0**	**8.6**	**2.4**	**0.0**	**0.0**	**0.0**	**175.0**

9. Revenue from contracts with customers

SEK m	2020 Jan-Dec						
Segment	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**OX-MPI**	**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**	**0.0**	**663.6**
Geographical markets	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**OX-MPI**	**vorvida®**	**deprexis®**	**Total**
US	623.3	—	3.1	—	0.0	0.0	**626.4**
EU & UK	0.1	28.9	2.7	—	—	—	**31.7**
Rest of the world	—	0.8	4.7	—	—	—	**5.5**
Total revenue from contracts with customers	**623.4**	**29.7**	**10.4**	**0.0**	**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 Jan-Mar	2020 Jan-Mar	2020 Jan-Dec
EBIT	-36.8	34.0	-19.9
Depreciation and amortization	12.9	5.1	38.9
EBITDA	**-23.9**	**39.1**	**19.0**
DTx costs	58.7	0.1	175.4
EBITDA excluding DTx costs	**34.8**	**39.2**	**194.4**

RETURN ON SHAREHOLDERS' EQUITY	2021 Jan-Mar	2020 Jan-Mar	2020 Jan-Dec
Shareholders' equity beginning balance	558.5	706.4	706.4
Shareholders' equity ending balance	534.8	775.3	558.5
Average shareholders' equity	546.7	740.9	632.5
Net earnings	-31.5	82.6	-84.4
Return on shareholders' equity %	**-5.8**	**11.1**	**-13.3**

OPERATING EXPENSES SEK m	2021 Jan-Mar	2020 Jan-Mar	2020 Jan-Dec
Selling expenses	-68.7	-54.6	-286.6
Administrative expenses	-28.6	-23.7	-102.8
Research and development costs	-55.6	-52.9	-224.9
Other operating income and expenses	3.0	10.1	-3.6
Operating expenses	**-149.9**	**-121.1**	**-617.9**

GROSS INVESTMENTS SEK m	2021 Jan-Mar	2020 Jan-Mar	2020 Jan-Dec
Investments in tangible fixed assets	9.0	3.8	29.4
Investments in intangible fixed assets	7.2	0.1	160.3
Gross investments	**16.2**	**3.9**	**189.8**

This information is information that Orexo AB (publ.) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 8.00 am CET on April 29, 2021.