

# Q2 2021 Interim Report

"First commercial DTx contract signed with a large healthcare provider"

## Summary

- › Total net revenues of SEK 142.8 m (179.1)
- › Net earnings of SEK -73.7 m (-32.5)
- › EBITDA of SEK -41.1 m (-9.0)
- › US Pharma segment (ZUBSOLV® US) net revenues of SEK 126.0 m (172.5), in local currency USD 15.0 m (17.8), EBIT of SEK 61.6 m (88.8)
- › Cash flow from operating activities of SEK -20.9 m (-7.2), cash balance of SEK 679.7 m (677.2)
- › Two patents for ZUBSOLV®, with protection until 2032, were issued by the US Patent and Trademark Office
- › First patient enrolled in pivotal study evaluating the efficacy of modia™ in combination with sublingual buprenorphine/naloxone for the treatment of opioid use disorder
- › Commercial agreement for vorvida® and deprexis® signed with Trinity Health North Dakota

## Important events after the period

- › Commercial partnership agreement signed with Sober Grid, the largest global social media network for people in addiction recovery, giving a large group of users access to vorvida® and deprexis®

**SEK 62 m**  
US Pharma EBIT

**49%**  
US Pharma EBIT margin

**SEK 680 m**  
Cash and cash equivalents

SEK m, unless otherwise stated	2021 Apr-Jun	2020 Apr-Jun	2021 Jan-Jun	2020 Jan-Jun	2020 Jan-Dec
Net revenues	142.8	179.1	275.1	354.2	663.6
Cost of goods sold	-18.1	-19.9	-37.4	-39.9	-65.6
Operating expenses	-178.7	-172.5	-328.7	-293.6	-617.9
EBIT	-54.0	-13.3	-90.9	20.7	-19.9
EBIT margin, %	-37.8	-7.4	-33.1	5.8	-3.0
EBITDA	-41.1	-9.0	-65.2	30.1	19.0
Earnings per share, before dilution, SEK	-2.15	-0.94	-3.07	1.44	-2.45
Earnings per share, after dilution, SEK	-2.15	-0.94	-3.07	1.44	-2.45
Cash flow from operating activities	-20.9	-7.2	-68.7	40.9	16.8
Cash and cash equivalents	679.7	677.2	679.7	677.2	505.3

Unless otherwise stated in this report, all data refers to the Group, and numbers relate to the current quarter while numbers in parentheses relate to the corresponding period in 2020.

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## About Orexo

Orexo develops improved pharmaceuticals and digital therapies addressing unmet needs within the growing space of substance use disorders and mental health. The products are commercialized by Orexo in the US or via partners worldwide. The main market today is the American market for buprenorphine/naloxone products, where Orexo commercializes its lead product ZUBSOLV® for treatment of opioid use disorder. Total net sales for 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 3.00 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](mailto: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-q2-2021>

Telephone: SE + 46 8 50 55 83 50 UK + 44 33 33 00 92 70 US + 1 64 67 22 49 04

The presentation material will be available on Orexo's website prior to the audiocast, view Investors/Reports, presentations and audiocasts

## Financial calendar

Interim Report Q3 2021 - November 3, 2021 at 8.00 am CET

Interim Report Q4 2021 - January 27, 2022 at 8.00 am CET

Annual General Meeting 2021, April 21, 2022 at 4 pm CET

Interim Report Q1 2022 - April 28, 2022 at 8.00 am CET

## For more information about Orexo

Please visit, [www.orexo.com](http://www.orexo.com). You can also follow Orexo on Twitter, @orexoabpubl, LinkedIn and YouTube.



# First commercial DTx contract signed with a large healthcare provider

*The second quarter of 2021 showed some positive operational highlights in both our Digital Therapeutics (DTx) business and US Pharma. In DTx, I'm pleased to announce we've among others reached a commercial agreement with Trinity Health North Dakota. As a result, vorvida® and deprexis® are now also available for patients at their healthcare centers and hospitals. This is a major milestone and is already now an inspiring model for other healthcare providers in the US. In our US Pharma business, it was confirmed that ZUBSOLV® is available for patients within Medicaid in Kentucky since July 1, representing a growth opportunity for our lead pharma product.*

## **DTx – Commercial progress, but new marketing hurdles in consumer sales**

Orexo's response to the growth in mental health issues among healthcare workers during the Covid-19 pandemic was to make our digital therapies vorvida® and deprexis®, for alcohol misuse and depression respectively, available to them free of charge. One example is Trinity Health North Dakota, and on the basis of positive feedback from their healthcare workers, we have signed a commercial agreement also giving their patients access to vorvida® and deprexis®. The agreement is an important milestone for Orexo and I'm impressed by all the work Trinity Health has spent over the last eight months establishing new internal processes to implement our DTx with their existing treatment plans and obtain reimbursement from their largest insurance partners. The success with Trinity Health has led to additional contracts in NYC and St Louis and helped advancing discussions with much larger health care providers in the US.

During the start of the quarter we adjusted our marketing activities and targeted social media promotion, which led to some increase in sales. However, new guidelines from the social media platforms, effective in April, made targeted promotion of products associated with substance use disorder and mental health more difficult due to ethical and stigma concerns. This has limited our ability to expand these efforts and we're now developing new cost efficient promotional concepts to reach people suffering from alcohol misuse or depression. One of these new concepts is our partnership with Sober Grid announced this week enabling us to better reach our target groups.

At the centre of the DTx strategy is obtaining evidence of the efficacy of our digital therapies in comparison with other treatments. This requires us to apply similar scientific rigor to digital therapies as we do to our



pharmaceuticals which will be essential to differentiate our digital therapies enabling market access and appropriate regulatory classification by the FDA. This makes the real world evidence study in collaboration with Magellan Rx and the extensive pivotal study for modia™, our digital therapy for opioid use disorder, central to our long-term commercialization strategy. The real world evidence study will start to include patients early in Q3 while the pivotal trial started enrolling patients in the quarter. The pivotal trial will run into H2 2022 and we expect the total investment will reach a level of approximately USD 9 million.

**"At the centre of the DTx strategy is obtaining evidence of the efficacy of our digital therapies in comparison with other treatments. This requires us to apply similar scientific rigor to digital therapies as we do to our pharmaceuticals"**

**ZUBSOLV® - US Pharma's EBIT contribution maintained on a high level**

We're convinced the market for buprenorphine/naloxone treatment will continue growing with the US economy recovering, easing of Covid-19 restrictions and federal initiatives to expand access to treatment. The overall market growth was 8 percent with the Public market being the main growth driver. In Q2 the core market for ZUBSOLV®, the commercial segment, saw low single digit growth and is yet to recover as we had anticipated. One explanation is probably people with opioid dependence are a further away from the labor market than the average American and the effect will come with a delay. With a continuous increase in patients suffering from opioid use disorder we expect the commercial segment to show accelerated growth.

As expected and foremost as an effect of high comparison numbers due to former exclusive accounts with Humana and United Health Group the sales of ZUBSOLV® versus Q2 2020 has declined. However, when comparing to Q1 2021 the sales are stable and we have maintained a good EBIT contribution. To accelerate the development of ZUBSOLV® and see growth, we'll need to see the commercial segment recover to stronger growth numbers, and we need to see positive impact from the market access improvement in Kentucky.

We're looking forward to launching modia™ in the US during the fall, enabling commercial synergies by designing a new product offering that compliments ZUBSOLV® with modia™. I believe this will be welcomed among existing and potential customers and opens new avenues for new creative types of commercial agreements.

**"We're looking forward to launching modia™ in the US during the fall, enabling commercial synergies by designing a new product offering that compliments ZUBSOLV® with modia™"**

**OX124 – based on a novel scalable intranasal formulation technology**

When starting the development of our lead pharmaceutical project, OX124, a rescue medication for opioid overdoses containing naloxone, the target product profile was a product which was faster than the existing alternatives, more powerful and with a longer duration. Solving this equation led to the development of a completely novel and unique intranasal formulation technology that today is the backbone for both OX124 and OX125, our rescue medication containing nalmeferene. At the announcement of the Q2 Interim Report we are days from starting the pivotal study for OX124. We're also analysing other active ingredients that may benefit from this novel intranasal formulation technology and we've initiated in vitro testing of some of the most promising. Positive results will provide Orexo with opportunities for new development projects.

**"We're also analysing other active ingredients that may benefit from this novel intranasal formulation technology and we've initiated in vitro testing of some of the most promising"**

**Summary and outlook**

The multiple operational milestones we've reached during Q2 pave the way for new income streams and growth opportunities. Developing agreements with large and established healthcare providers for our digital therapies is fundamental for Orexo's growth, equipping us with the reference cases we need to expand the business. For ZUBSOLV®, the market access win in Kentucky is the first in Medicaid for a while and, together with the commercial synergies from modia™, brings the potential to set ZUBSOLV® apart from competitors.

My colleagues and I are looking forward to the second half of 2021 where we expect to see even more progresses for Orexo that enable us to make a difference to patients.

Uppsala, Sweden, July 15, 2021

Nikolaj Sørensen  
President and CEO



# Business update

## US Pharma



### Sublingual tablet for treatment of opioid use disorder

The market for ZUBSOLV® consists of several distinct segments with partly opposing drivers. ZUBSOLV's sales development is most reliant on the open commercial segment<sup>1</sup>, where ZUBSOLV® demand had a slight upward development versus Q1 2021, while the non-reimbursed segment and the previous exclusive contracts with Humana and United Health Group showed minor declines. Overall ZUBSOLV® sales remained stable comparing to the same period.

The overall market grew 3 percent over Q1 2021. The year over year growth amounted to 8 percent. Over the long term, the market growth is likely to be positively impacted by several efforts to improve access to medication assisted treatment (MAT) 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 the fourth largest volume Medicaid state in this treatment area, a legislation has passed to improve access to all opioid dependence treatment medications, including ZUBSOLV®. With the legislation being fully implemented, effective July 1, ZUBSOLV® will be on the formulary and reimbursed for Medicaid patients. This is an important growth opportunity and we have scaled up activities in this state.

Compared to Q2 2020 ZUBSOLV® demand declined 12 percent mainly due to the continued impact from changed formulary status at Humana and United Health Group, in addition to a small decline in the Commercial payer segment business during the Covid-19 pandemic.

ZUBSOLV's Q2 2021 overall prescription volume is stable, down 1 percent versus Q1 2021. Our core segment, the open segment, is completely stable with no change versus Q1 2021. Within the open segment, Commercial has grown 1 percent, Medicaid remained stable, and Medicare D declined slightly by 1 percent. The major Commercial PBMs (Caremark, Express Scripts, and OptumRx) all had slight increases in open ZUBSOLV® volume. The demand in former exclusive plans, Humana and United Health Group, declined over previous quarter, but at the slowest pace since the formulary changes, down 3 percent. Non-reimbursed business has declined 3 percent, mainly due to a decline in Cash in January but Q2 monthly volume remains stable versus February and March.

With the legislative changes in Kentucky, market access in public payer segment increased as of July 1, from 34 to 42 percent. This change complements ZUBSOLV's market access in the Commercial payer segment, which is unchanged at 99 percent.

The ZUBSOLV® sales force activity continues to be negatively impacted by the Covid-19 pandemic versus pre-pandemic activity. The number of calls per day and the amount of direct time the sales representatives have in front of the physician and healthcare providers 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 Q2.

The work to outline the commercial strategy for ZUBSOLV® used along with the digital therapy modia™, for opioid use disorder, continues and expects to give Orexo's MAT portfolio 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, we have reached commercial agreement with health care providers who will now start offering our digital therapies as an integrated solution in their treatment programs for depression and alcohol misuse. In addition we have made good progress initiating new pilot tests with larger employers and health care providers.

During the last eight months we have worked intensively with Trinity Health North Dakota (ND) to integrate our digital therapies into their treatment plans. This work has included securing reimbursement of the treatment solution with the largest payers in ND, educating the health care professionals and for Trinity Health to establish internal processes to manage this new category of treatment. Treatment with vorvida® or deprexis® will include both the digital therapies and counselling by health care professionals from Trinity Health. We will now initiate targeted promotion and PR efforts in ND to make patients aware of this new innovative option. The collaboration with Trinity Health will be the model for similar agreements in the future, e.g. it has led to advanced discussions with two large integrated health delivery networks and a leading telemedicine provider. In addition to Trinity Health we have commercial agreements in place with a clinic in NYC and in St Louis, in

<sup>1</sup> ZUBSOLV® is reimbursed and competes on equal terms with both branded products and/or generics

parallel with several on-going pilot tests with other local health care providers. Without any established reimbursement pathways and digital therapies being a new tool for the health care providers, it is evident that successful implementations by first movers are critical for our possibilities to get broader traction with health care providers. The learnings from Trinity Health, the clinics in NYC and St Louis will be important in our efforts to reach agreements with more and larger health care providers.

Targeted efforts were made towards employers and we are in the implementation phase of the agreement announced with one of the large tech companies in the US, communicated in the Q1 2021 Interim Report. We have continued targeting employers and are in advanced discussion with a large industrial group and their health insurance company with the ambition to initiate a pilot in H2 2021. In addition we have targeted providers of health care services to employers and have during the quarter reached an agreement with a start-up offering tele-medicine services to health care professionals and are in advanced discussions with another provider of health care services to employees.

Additionally, and after the end of the period, a commercial partnership agreement was signed with Sober Grid, the largest global social media network for people in addiction recovery. This online community with approximately 300,000 users will be a new sales channel for vorvida® and deprexis®.

The current revenues from digital therapies is primarily from direct to end-users through our websites us.vorvida.com and us.deprexis.com. We have reviewed our promotional efforts in this channel and launched a new targeted campaign through social media in late March, which resulted in increased sales in April. However, during May our possibilities to promote vorvida® through targeted promotion in social media was constrained by new guidelines from the leading social media platforms

restricting the ability to target advertisement of treatments for substance misuse, explained by the stigma associated with the disease. This has reduced our ability to expand the campaign in April to a broader audience. We are now working with other content providers, such as Sober Grid and will launch new campaigns in Q3.

The work to promote deprexis® to healthcare professionals with a small dedicated sales team started. Initially to test different commercialization concepts with the ambition to expand this effort after the summer holidays. In parallel we are planning to initiate the launch of modia™ in H2 2021 with our existing ZUBSOLV® field force.

The modia™ clinical trial was initiated and expects to continue into H2 2022 and include 400 patients. In addition to the real world evidence study we are running with several payers in the US, among others Magellan Rx which is one of the largest payers for the treatment of opioid dependence. The clinical trial is important to gain the appropriate regulatory classification, to get reimbursement and to differentiate towards other digital therapies for treatment of opioid use disorder. The real world evidence study is on track and will start collecting data from the first patients using modia™ during the summer, the focus to date has been to analyse existing real world evidence data as a reference to the actual study.

## HQ & Pipeline

### Most advanced fully-owned pipeline asset

*OX124 - opioid overdose rescue medication containing naloxone*

With the pharmaceutical project OX124 Orexo aims to develop a rescue medication designed to reverse opioid overdoses, including those from highly potent

Development Projects										
Pharmaceuticals		Exploratory	Preclinical	1	Phase 2	3	Registration	Approved/Launched		
								US	EU	RoW
	OX124 Naloxone - Opioid overdose									
	OX125 Nalmefene - Opioid overdose									
	OX338 Ketorolac - Moderate to moderately severe pain									
	OX-MPI BI1029539 - Microvascular disease Partner: Gesynta Pharma									

synthetic opioids. 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.

Currently available rescue medications have been developed for heroin overdoses, but today most people are dying from accidental overdoses with synthetic opioids, such as fentanyl. In the 12 months leading up to November 2020, the number of drug-related overdose deaths has surpassed 90,000 for the first time in history, an increase of 29 percent versus the previous year. 74 percent of these deaths were caused by opioids and within the opioid-related deaths synthetic opioids accounted for the vast majority (81 percent),<sup>1</sup> underlining the need for more powerful and faster-acting rescue medications.<sup>2</sup>

To meet the target profile for more potent rescue medications, Orexo has developed a novel and unique intranasal formulation technology that allows for rapid and efficient delivery of active ingredients through the intranasal route. Nasal administration is a viable route for many different active pharmaceutical ingredients offering significant advantages compared with other administration routes, even parenteral injections. For example, delivering drugs through the intranasal route avoids first pass metabolism of the active ingredient allowing for rapid and potentially extensive exposure of the drug. This novel proprietary drug delivery technology, which is the foundation for OX124, has patent protection until 2039 and potential product net sales have been estimated to be between USD 70-110 million in the US market.

#### Status:

In Q2 the work continued to prepare for the pivotal study in healthy volunteers and to ensure the manufacturing and supply chain can provide the capacity and redundancy as needed by preparing for a pilot scale production of the final pharmaceutical product including the device. The regulatory stability study was initiated which will provide data to establish product storage requirements and expiration dating and to determine the impact of environmental conditions on product quality a reliability study was commenced.

As the external suppliers have taken slightly longer time to set up the commercial manufacturing the study is a few weeks behind the initial timeline but will start shortly. Preliminary timing for filing a new drug application with FDA is H2 2022.

## 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. The launch is expected to begin in late H2 2021, as the Romanian packaging plant's GMP permission is delayed due to Covid-19 but is expected to be granted in the coming weeks. Orexo will be responsible for product supply and double-digit royalty will be received on future net sales.

There are estimated to be 1.3 million high-risk opioid users in Europe,<sup>3</sup> 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.<sup>4</sup>

<sup>1</sup> All numbers taken from <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm> <sup>2</sup> N Volkow "Scientific Solutions for the Opioid Crisis" (2018) [https://www.nichd.nih.gov/sites/default/files/2018-01/201801\\_volkow\\_nichd\\_opioids.pdf](https://www.nichd.nih.gov/sites/default/files/2018-01/201801_volkow_nichd_opioids.pdf) <sup>3</sup> European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) 2019 <sup>4</sup> EMCDDA – Tackling Opioid Dependence 2019

# Financial overview

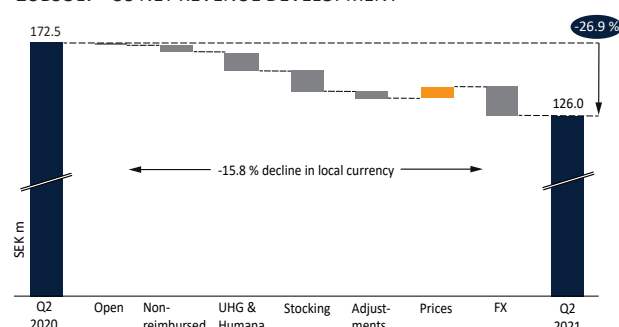
## Revenues

Total revenues for Q2 amounted to SEK 142.8 m (179.1) and for H1 to SEK 275.1 m (354.2).

## Revenues by segment

US Pharma revenues amounted to SEK 126.0 m (172.5). 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 15.0 m (17.8) and vs Q1 2021 US Pharma net revenues decreased by USD 0.1 m, while the drop in demand stabilized and a positive payer mix together with increased wholesaler inventory levels impacted positively. The negative revenue impact can mainly be referred to lower positive adjustment of product returns. US Pharma revenue for H1 amounted to SEK 252.8 m (336.4).

DTx recognized net revenues for Q2 amounted to SEK 0.3 m (-) and deferred revenues to SEK 0.3 m (-) as sales efforts during Q2 have focused on piloting

different reimbursement pathways and commercial concepts. DTx recognized net revenue amounted to SEK 0.4 m (-) and deferred revenues to SEK 0.4 m (-) for H1. 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 for Q2 amounted to SEK 16.5 m (6.6) and for H1 to SEK 21.9 m (17.8).

## Costs of goods sold

Cost of goods sold (COGS) amounted to SEK 18.1 m (19.9) for Q2, explained by US Pharma of SEK 15.4 m (19.3) and technical infrastructure costs of SEK 2.6 m (0.6) for vorvida® and deprexis®. Cost of goods sold (COGS) for H1 amounted to SEK 37.4 m (39.9).

## Operating expenses

Selling expenses amounted to SEK 61.8 m (70.0) for Q2. The decrease over the same period last year is mainly explained by lower selling expenses in US Pharma costs. This was partially offset by increased costs related to launch preparations for vorvida® and deprexis®. Selling expenses for H1 amounted to SEK 130.4 m (124.4)

Administrative expenses amounted to SEK 41.4 m (32.7) for Q2 and to SEK 70.0 m (56.5) for H1. The increase is mainly explained by higher legal expenses for IP litigation and subpoena partly offset by lower costs for the long-term incentive programs.

Research and development costs amounted to SEK 73.2 m (62.6) for Q2. The increase is explained by costs related to development projects and to launch preparations for vorvida® and deprexis®. Research and development costs for H1 amounted to SEK 128.8 m (115.6)

Other operating income and expenses amounted to SEK -2.4 m (-7.1) for Q2 mainly explained by exchange-rate losses derived from revaluations of parent company

## NET REVENUES AND OPERATING EARNINGS PER SEGMENT

SEK m	Net Revenues					EBIT				
	2021 Apr-Jun	2020 Apr-Jun	2021 Jan-Jun	2020 Jan-Jun	2020 Jan-Dec	2021 Apr-Jun	2020 Apr-Jun	2021 Jan-Jun	2020 Jan-Jun	2020 Jan-Dec
ZUBSOLV® US product sales	126.0	172.5	252.8	336.4	623.3	-	-	-	-	-
<b>US Pharma – total</b>	<b>126.0</b>	<b>172.5</b>	<b>252.8</b>	<b>336.4</b>	<b>623.3</b>	<b>61.6</b>	<b>88.8</b>	<b>127.7</b>	<b>164.5</b>	<b>331.2</b>
Digital Therapeutics (DTx) product sales	0.3	-	0.4	-	0.0	-	-	-	-	-
<b>Digital Therapeutics (DTx) – total</b>	<b>0.3</b>	<b>-</b>	<b>0.4</b>	<b>-</b>	<b>0.0</b>	<b>-51.6</b>	<b>-35.5</b>	<b>-110.5</b>	<b>-47.6</b>	<b>-175.4</b>
Abstral® royalty	14.3	3.5	17.0	12.2	29.7	-	-	-	-	-
Edluar® royalty	2.3	3.1	4.9	5.5	10.4	-	-	-	-	-
ZUBSOLV® - ex US	-	-	-	0.1	0.1	-	-	-	-	-
<b>HQ &amp; Pipeline segment – total</b>	<b>16.5</b>	<b>6.6</b>	<b>21.9</b>	<b>17.8</b>	<b>40.2</b>	<b>-63.9</b>	<b>-66.6</b>	<b>-108.2</b>	<b>-96.2</b>	<b>-175.8</b>
<b>Total</b>	<b>142.8</b>	<b>179.1</b>	<b>275.1</b>	<b>354.2</b>	<b>663.6</b>	<b>-54.0</b>	<b>-13.3</b>	<b>-90.9</b>	<b>20.7</b>	<b>-19.9</b>



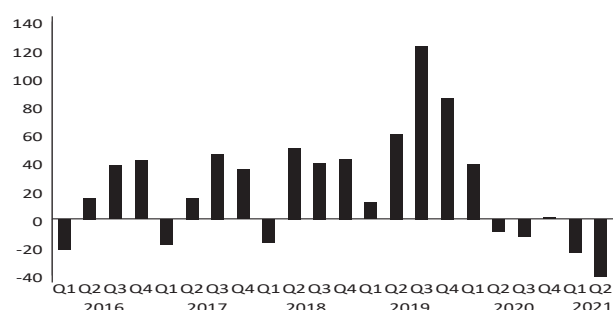
balance sheet items in foreign currency, predominantly in USD. Other operating income and expenses for H1 amounted to SEK 0.6 m (2.9)

## Operating profit

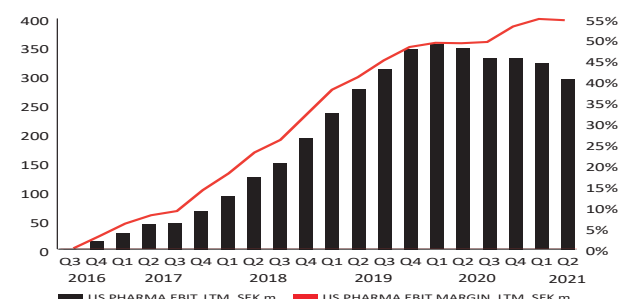
Orexo's profitability reflects costs in DTx and in pipeline and EBITDA amounted to SEK -41.1 m (-9.0) for Q2 and to SEK -65.2 m (30.1) for H1.

The EBIT contribution from US Pharma amounted to SEK 61.6 m (88.8) for Q2, equal to an EBIT margin of 48.9 percent (51.5). H1 EBIT contribution from US Pharma amounted to SEK 127.7 m (164.5), equal to an EBIT margin of 50.5 percent (48.9). 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<sup>1</sup>, SEK m) AND EBIT (LTM<sup>1</sup>, SEK m)



## Net financial items and tax

Net financial items amounted to SEK -10.8 m (-22.2) for the Q2 mainly explained by a lower negative unrealized exchange rate impact of SEK 13.0 m derived from the parent company's foreign currency bank accounts mainly in USD, partly offset by higher costs for corporate bonds of SEK 1.4 m and by lower earned interest of SEK 0.3 m. Net financial items amounted to SEK -6.2 m (21.8) for H1.

Total tax expenses amounted to SEK -8.9 m (3.0) for Q2, impacted by negative adjustment to deferred tax assets related to temporary differences of SEK -7.7 m (5.1). Total tax expenses amounted to SEK -8.3 m (7.6) for H1.

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 -73.7 m (-32.5) for Q2 and to SEK -105.4 m (50.1) for H1.

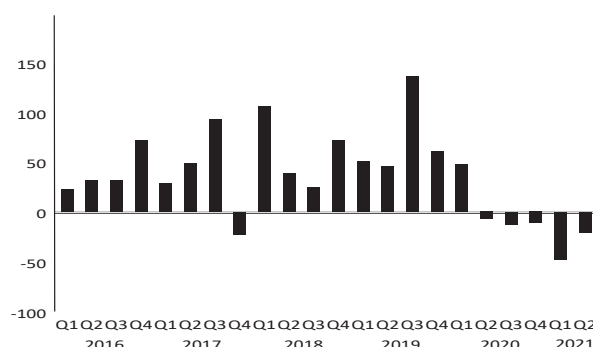
## Cash and cash flow

As of June 30, 2021, cash and cash equivalents amounted to SEK 679.7 m (677.2) and interest-bearing liabilities to SEK 491.1 m (223.8), i.e. a positive net cash position of SEK 188.6 m (453.4).

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 -20.9 m (-7.2) for Q2 and to SEK -68.7 m (40.9) for H1.

CASH FLOW FROM OPERATING ACTIVITIES, SEK m



## Investments

Gross investments in tangible and intangible fixed assets amounted to SEK 13.1 m (106.6) for Q2 and to SEK 29.3 m (110.5) for H1. Lower investment is mainly explained by a payment of non-refundable milestone for deprexis® in Q2 2020.

## Equity

Shareholders' equity at June 30, 2021, was SEK 459.4 m (735.5). The equity/asset ratio was 34.2 percent (50.3).

## Parent company

Net revenues amounted to SEK 45.5 m (131.4) for Q2 of which SEK 29.0 m (124.7) was related to sales to Group companies. H1 net revenues amounted to SEK 135.0 m (268.9) of which SEK 113.1 m (251.2) was related to sales to Group companies.

Earnings before tax were SEK -105.1 m (-18.0) for Q2 and to SEK -130.6 m (87.7) for H1 mainly explained by investment in DTx and development projects. Investments amounted to SEK 5.6 m (106.6) for Q2 and to SEK 13.8 m (110.5) for H1. Lower investment is mainly explained by a payment of non-refundable milestone for deprexis® in Q2 2020.

As of June 30, 2021, cash and cash equivalents in the parent company amounted to SEK 568.6 m (440.3).

<sup>1</sup> 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, July 15, 2021

Nikolaj Sørensen  
President and CEO

## Assurance by the Board of Directors

The Board of Directors and the CEO give their assurance that the six-month report provides a fair and accurate view of the Company's and the Group's operations, financial positions and earnings and describes the significant risk and uncertainties facing the company and the companies included in the group.

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

Uppsala, Sweden, July 15, 2021

Orexo AB (publ)

James Noble  
Chairman of the Board

Henrik Kjaer Hansen  
Board member

Staffan Lindstrand  
Board member

Charlotte Hansson  
Board member

Kirsten Detrick  
Board member

David Colpman  
Board member

Mary-Pat Christie  
Board member

Fred Wilkinson  
Board member

Nikolaj Sørensen  
President & CEO

# Financial reports, notes and key figures

## CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS

SEK m	Notes	2021 Apr-Jun	2020 Apr-Jun	2021 Jan-Jun	2020 Jan-Jun	2020 Jan-Dec
Net revenues	9	142.8	179.1	275.1	354.2	663.6
Cost of goods sold		-18.1	-19.9	-37.4	-39.9	-65.6
<b>Gross profit</b>		<b>124.8</b>	<b>159.2</b>	<b>237.7</b>	<b>314.3</b>	<b>598.0</b>
Selling expenses		-61.8	-70.0	-130.4	-124.4	-286.6
Administrative expenses		-41.4	-32.7	-70.0	-56.5	-102.8
Research and development expenses		-73.2	-62.6	-128.8	-115.6	-224.9
Other operating income and expenses		-2.4	-7.1	0.6	2.9	-3.6
<b>Operating earnings (EBIT)</b>		<b>-54.0</b>	<b>-13.3</b>	<b>-90.9</b>	<b>20.7</b>	<b>-19.9</b>
Net financial items		-10.8	-22.2	-6.2	21.8	-18.4
<b>Earnings before tax</b>		<b>-64.8</b>	<b>-35.5</b>	<b>-97.1</b>	<b>42.5</b>	<b>-38.3</b>
Tax	5	-8.9	3.0	-8.3	7.6	-46.1
<b>Net earnings for the period<sup>1</sup></b>		<b>-73.7</b>	<b>-32.5</b>	<b>-105.4</b>	<b>50.1</b>	<b>-84.4</b>
Earnings per share, before dilution, SEK		-2.15	-0.94	-3.07	1.44	-2.45
Earnings per share, after dilution, SEK		-2.15	-0.94	-3.07	1.44	-2.45

## CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

SEK m	2021 Apr-Jun	2020 Apr-Jun	2021 Jan-Jun	2020 Jan-Jun	2020 Jan-Dec
<b>Earnings for the period</b>	<b>-73.7</b>	<b>-32.5</b>	<b>-105.4</b>	<b>50.1</b>	<b>-84.4</b>
<b>Other comprehensive income</b>					
<b>Items that may subsequently be reversed to the statement of operations:</b>					
Exchange-rate differences	-3.1	-9.4	4.8	-0.1	-16.5
<b>Other comprehensive earnings for the period, net after tax</b>	<b>-3.1</b>	<b>-9.4</b>	<b>4.8</b>	<b>-0.1</b>	<b>-16.5</b>
<b>Total comprehensive earnings for the period<sup>1</sup></b>	<b>-76.8</b>	<b>-41.9</b>	<b>-100.6</b>	<b>50.0</b>	<b>-100.9</b>

<sup>1</sup> All equity and earnings for the respective period are attributable to the Parent Company's shareholders



## CONDENSED CONSOLIDATED BALANCE SHEET

SEK m	2021 Jun 30	2020 Jun 30	2020 Dec 31
<b>ASSETS</b>			
<b>Fixed assets</b>			
Tangible fixed assets	59.7	23.3	47.3
Intangible fixed assets	250.7	213.5	252.8
Right-of-use assets	64.6	70.3	67.8
Deferred tax assets	25.2	98.1	32.7
Other financial assets	0.7	0.8	0.7
<b>Total fixed assets</b>	<b>401.0</b>	<b>406.0</b>	<b>401.3</b>
<b>Current assets</b>			
Inventories	95.7	126.2	108.4
Accounts receivable and other receivables	168.5	253.6	217.9
Cash and cash equivalents	679.7	677.2	505.3
<b>Total current assets</b>	<b>943.9</b>	<b>1,057.0</b>	<b>831.6</b>
<b>Total assets</b>	<b>1,344.9</b>	<b>1,463.0</b>	<b>1,232.9</b>
<b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>			
<b>Total shareholders' equity</b>	<b>459.4</b>	<b>735.5</b>	<b>558.5</b>
<b>Long-term liabilities</b>			
Provisions	10.4	10.5	25.7
Long-term liabilities, interest bearing	491.1	223.8	—
Lease liabilities, long-term	43.6	48.8	47.4
<b>Total long-term liabilities</b>	<b>545.1</b>	<b>283.0</b>	<b>73.1</b>
<b>Current liabilities and provisions</b>			
Provisions	174.3	229.9	197.3
Current liabilities, interest bearing	—	—	224.5
Current liabilities, non-interest bearing	146.3	194.8	160.4
Lease liabilities, current	19.8	19.8	19.1
<b>Total current liabilities and provisions</b>	<b>340.3</b>	<b>444.5</b>	<b>601.3</b>
<b>Total liabilities</b>	<b>885.4</b>	<b>727.5</b>	<b>674.4</b>
<b>Total shareholders' equity and liabilities</b>	<b>1,344.9</b>	<b>1,463.0</b>	<b>1,232.9</b>

## CONSOLIDATED CHANGES IN SHAREHOLDERS' EQUITY

SEK m	2021 Jun 30	2020 Jun 30	2020 Dec 31
<b>Opening balance, shareholders' equity</b>	<b>558.5</b>	<b>706.4</b>	<b>706.4</b>
Total comprehensive earnings for the period	-100.6	50.0	-100.9
Share-based payments	1.6	6.4	-19.7
Buy back of shares	—	-27.3	-27.3
New share issue	—	—	—
<b>Closing balance, shareholders' equity</b>	<b>459.4</b>	<b>735.5</b>	<b>558.5</b>

## CONDENSED CONSOLIDATED CASH FLOW STATEMENTS

SEK m	Notes	2021 Apr-Jun	2020 Apr-Jun	2021 Jan-Jun	2020 Jan-Jun	2020 Jan-Dec
Operating earnings (EBIT)		-54.0	-13.3	-90.9	20.7	-19.9
Interest received		—	1.0	0.0	3.8	3.0
Interest paid		-4.4	-3.9	-12.8	-7.3	-11.8
Income taxes paid		2.8	-0.4	1.0	-0.8	0.6
Adjustment for non-cash items	3	15.7	-13.1	-19.0	-21.2	-7.1
<b>Cash flow from operating activities before changes in working capital</b>		<b>-40.0</b>	<b>-29.7</b>	<b>-121.7</b>	<b>-4.8</b>	<b>-35.1</b>
<b>Changes in working capital</b>		<b>19.1</b>	<b>22.5</b>	<b>53.0</b>	<b>45.7</b>	<b>51.9</b>
<b>Cash flow from operating activities</b>		<b>-20.9</b>	<b>-7.2</b>	<b>-68.7</b>	<b>40.9</b>	<b>16.8</b>
Acquisition of tangible and intangible fixed assets		-13.1	-106.6	-29.3	-110.5	-189.8
Disposal of financial assets		—	0.6	—	0.6	0.6
<b>Cash flow from investing activities</b>		<b>-13.1</b>	<b>-106.0</b>	<b>-29.3</b>	<b>-109.9</b>	<b>-189.2</b>
Buy back shares		—	-2.9	—	-27.3	-27.3
New loan		—	—	490.1	—	—
Repayment of loans		-3.5	-31.1	-231.9	-75.4	-84.0
<b>Cash from financing activities</b>		<b>-3.5</b>	<b>-33.9</b>	<b>258.2</b>	<b>-102.7</b>	<b>-111.3</b>
<b>Cash flow for the period</b>		<b>-37.5</b>	<b>-147.1</b>	<b>160.1</b>	<b>-171.7</b>	<b>-283.7</b>
<b>Cash and cash equivalents at the beginning of the period</b>		<b>725.5</b>	<b>861.4</b>	<b>505.3</b>	<b>816.8</b>	<b>816.8</b>
Exchange-rate differences in cash and cash equivalents		-8.2	-37.1	14.3	32.1	-27.8
Changes in cash and cash equivalents		-45.8	-184.2	174.4	-139.6	-311.5
<b>Cash and cash equivalents at the end of the period</b>		<b>679.7</b>	<b>677.2</b>	<b>679.7</b>	<b>677.2</b>	<b>505.3</b>

Key Figures<sup>1</sup>

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 Apr-Jun	2020 Apr-Jun	2021 Jan-Jun	2020 Jan-Jun	2020 Jan-Dec
EBIT margin, %	-37.8	-7.4	-33.1	5.8	-3.0
Return on shareholder equity, %	-14.8	31.0	-20.7	6.9	-13.3
Net debt, SEK m	-188.6	-453.4	-188.6	-453.4	-280.8
Debt/equity ratio, %	106.9	41.0	106.9	30.4	40.2
Equity/assets ratio, %	34.2	50.3	34.2	50.3	45.3
Number of shares, before dilution	34,327,907	34,710,639	34,305,884	34,710,639	34,398,815
Number of shares, after dilution	34,327,907	34,710,639	34,305,884	34,710,639	34,398,815
Earnings per share, before dilution, SEK	-2.15	-0.94	-3.07	1.44	-2.45
Earnings per share, after dilution, SEK	-2.15	-0.94	-3.07	1.44	-2.45
Number of employees at the end of the period	139	136	139	136	138
Shareholders' equity, SEK m	459.4	735.5	459.4	735.5	558.5
Capital employed, SEK m	950.6	959.2	950.6	959.2	783.0
Working capital, SEK m	-76.1	-64.7	-76.1	-64.7	-50.5

<sup>1</sup> Definitions and reconciliations of key figures are presented on page 20 of this report

## CONDENSED PARENT COMPANY STATEMENT OF OPERATIONS

SEK m	Notes	2021 Apr-Jun	2020 Apr-Jun	2021 Jan-Jun	2020 Jan-Jun	2020 Jan-Dec
Net revenues		45.5	131.4	135.0	268.9	446.4
Cost of goods sold		-7.8	-25.9	-29.4	-45.5	-79.7
<b>Gross profit</b>		<b>37.7</b>	<b>105.5</b>	<b>105.5</b>	<b>223.4</b>	<b>366.7</b>
Selling expenses		-46.4	-38.6	-99.6	-62.5	-190.7
Administrative expenses		-24.8	-22.0	-40.2	-34.6	-53.1
Research and development costs		-61.4	-49.6	-106.3	-92.3	-180.1
Other operating income and expenses		-0.1	8.1	14.7	31.4	50.0
<b>Operating earnings (EBIT)</b>		<b>-94.9</b>	<b>3.4</b>	<b>-125.9</b>	<b>65.4</b>	<b>-7.2</b>
Interest income and expenses		-4.3	-3.2	-8.0	-5.7	-10.9
Other financial income and expenses		-5.8	-18.3	3.2	28.0	-5.4
<b>Net financial items</b>		<b>-10.1</b>	<b>-21.5</b>	<b>-4.7</b>	<b>22.3</b>	<b>-16.3</b>
<b>Earnings before tax</b>		<b>-105.1</b>	<b>-18.0</b>	<b>-130.6</b>	<b>87.7</b>	<b>-23.4</b>
Tax	5	—	—	—	—	-49.0
<b>Earnings for the period</b>		<b>-105.1</b>	<b>-18.0</b>	<b>-130.6</b>	<b>87.7</b>	<b>-72.5</b>

## PARENT COMPANY STATEMENT OF COMPREHENSIVE INCOME

SEK m	2021 Apr-Jun	2020 Apr-Jun	2021 Jan-Jun	2020 Jan-Jun	2020 Jan-Dec
<b>Earnings for the period</b>	<b>-105.1</b>	<b>-18.0</b>	<b>-130.6</b>	<b>87.7</b>	<b>-72.5</b>
<b>Other comprehensive income</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>
<b>Total comprehensive earnings for the period</b>	<b>-105.1</b>	<b>-18.0</b>	<b>-130.6</b>	<b>87.7</b>	<b>-72.5</b>

## CONDENSED PARENT COMPANY BALANCE SHEET

SEK m	2021 Jun 30	2020 Jun 30	2020 Dec 31
<b>ASSETS</b>			
<b>Fixed assets</b>			
Intangible fixed assets	219.2	213.5	234.4
Tangible fixed assets	58.0	23.3	47.2
Deferred tax assets	—	49.0	—
Shares in subsidiaries	160.8	162.5	160.4
<b>Total fixed assets</b>	<b>438.0</b>	<b>448.4</b>	<b>442.0</b>
<b>Current assets</b>			
Inventories	80.6	101.8	90.9
Accounts receivable and other receivables	54.1	180.6	111.3
Cash and bank balances	568.6	440.3	361.3
<b>Total current assets</b>	<b>703.4</b>	<b>722.7</b>	<b>563.5</b>
<b>Total assets</b>	<b>1,141.4</b>	<b>1,171.1</b>	<b>1,005.5</b>
<b>SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES</b>			
<b>Total shareholders' equity</b>	<b>395.1</b>	<b>710.8</b>	<b>524.2</b>
<b>Long-term liabilities</b>			
Provisions	10.0	8.3	24.5
Bond loan	491.1	223.8	—
<b>Total long-term liabilities</b>	<b>501.1</b>	<b>232.0</b>	<b>24.5</b>
<b>Current liabilities</b>			
Accounts payable	21.1	25.4	17.3
Bond loan	—	—	224.5
Other liabilities	6.4	8.1	6.3
Liabilities to Group companies	192.6	171.6	187.3
Accrued expenses and deferred income	25.1	23.2	21.5
<b>Total current liabilities</b>	<b>245.1</b>	<b>228.3</b>	<b>456.8</b>
<b>Total liabilities</b>	<b>746.2</b>	<b>460.3</b>	<b>481.3</b>
<b>Total shareholders' equity and liabilities</b>	<b>1,141.4</b>	<b>1,171.1</b>	<b>1,005.5</b>



## 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 Apr-Jun	2020 Apr-Jun	2021 Jan-Jun	2020 Jan-Jun	2020 Jan-Dec
<b>US Pharma</b>					
Net revenues	126.0	172.5	252.8	336.4	623.3
Operating earnings (EBIT)	61.6	88.8	127.7	164.5	331.2
Depreciation and amortization	-3.8	-3.8	-7.7	-7.7	-15.4
<b>Digital Therapeutics</b>					
Net revenues	0.3	—	0.4	—	0.0
Operating earnings (EBIT)	-51.6	-35.5	-110.5	-47.6	-175.4
Depreciation and amortization	-4.6	—	-8.9	—	-3.2
<b>HQ &amp; Pipeline</b>					
Net revenues	16.5	6.6	21.9	17.8	40.2
Operating earnings (EBIT)	-63.9	-66.6	-108.2	-96.2	-175.8
Depreciation and amortization	-4.4	-0.5	-9.2	-1.7	-20.3
<b>Group</b>					
Net revenues	142.8	179.1	275.1	354.2	663.6
Operating earnings (EBIT)	-54.0	-13.3	-90.9	20.7	-19.9
Depreciation and amortization	-12.9	-4.3	-25.8	-9.4	-38.9
Net financial items	-10.8	-22.2	-6.2	21.8	-18.4
Earnings before tax	-64.8	-35.5	-97.1	42.5	-38.3

### 3. Cash flow

#### ADJUSTMENT FOR NON-CASH ITEMS

SEK m	2021 Apr-Jun	2020 Apr-Jun	2021 Jan-Jun	2020 Jan-Jun	2020 Jan-Dec
Depreciation/amortization and impairment	12.8	9.4	25.8	18.1	38.9
Change in provisions	-1.1	-33.7	-45.8	-41.9	-28.5
Share based payments	1.6	5.0	1.6	6.4	-19.7
Exchange rate income and expenses	2.4	6.2	-0.6	-3.9	2.4
<b>Total</b>	<b>15.7</b>	<b>-13.1</b>	<b>-19.0</b>	<b>-21.2</b>	<b>-7.1</b>

### 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. The latter, patent nos. 11,020,387 and 11,020,388 with expiration date September 2032, was issued by the US Patent and Trademark Office and listed in the Orange book during the quarter.

On May 21, Orexo received a "Paragraph IV" patent certification notice letter from Sun regarding US patents no 10,874,661 and 10,946,010, which were issued in December 2020 and March 2021, respectively. After the end of the period Orexo filed an additional patent infringement action against Sun in the US District Court for the District of New Jersey, relating to these two new patents.

### 5. Deferred tax

The current Swedish corporate tax rates have been announced with 21.4 percent from January 1, 2019, and 20.6 percent from January 1, 2021. In line with IFRS which on this area is based on a principle that changes in tax rates should be incorporated into the accounting for the relevant tax positions immediately upon enactment, the company has performed a tax analysis. The tax-loss carry-forward in the Group amounts to SEK 1,188 m as of December 31 2020 and refers to the Swedish companies. No deferred tax assets for tax-loss carry-forwards have been capitalized as per December 31, 2020, for the part of these tax-loss carry-forwards which the company has assessed as fulfilling the recognition requirements of IAS 12. There is no time limit for when the remaining loss carryforwards can be utilized. The rest of the tax effect of the Group's temporary differences are related to non-deductible current provisions for sales rebates, sales allowances, distribution, sales returns and other relevant deductions in the company's US operations.

### 6. Financial instruments

The Group's financial instruments consists of current receivables, non-current receivables, cash and cash equivalents, current non-interest bearing liabilities, current interest-bearing liabilities and long-term interest-bearing liabilities. The financial instruments held by the group are recognized at amortized cost using the effective interest method. The group does not hold any financial instruments which are reported at fair value. The fair value of financial instruments held at the balance sheet date is significantly the same as the book value.

### 7. Related parties

There were no significant related parties transactions during the period.

### 8. Important events after the period

- › Commercial partnership signed with Sober Grid, the largest global social media network for people in addiction recovery, giving a large group of users access to vorvida® and deprexis®

## 9. Revenue from contracts with customers

SEK m		2021 Apr-Jun				
Segment	ZUBSOLV®	Abstral®	Edluar®	vorvida®	deprexis®	Total
US Pharma	126.0	—	—	—	—	126.0
Digital Therapeutics	—	—	—	0.2	0.0	0.3
HQ & Pipeline	—	14.3	2.3	—	—	16.5
<b>Total revenue from contracts with customers</b>	<b>126.0</b>	<b>14.3</b>	<b>2.3</b>	<b>0.2</b>	<b>0.0</b>	<b>142.8</b>
Geographical markets	ZUBSOLV®	Abstral®	Edluar®	vorvida®	deprexis®	Total
US	126.0	—	0.5	0.2	0.0	126.8
EU & UK	—	14.0	0.8	—	—	14.8
Rest of the world	—	0.3	1.0	—	—	1.2
<b>Total revenue from contracts with customers</b>	<b>126.0</b>	<b>14.3</b>	<b>2.3</b>	<b>0.2</b>	<b>0.0</b>	<b>142.8</b>
SEK m		2020 Apr-Jun				
Segment	ZUBSOLV®	Abstral®	Edluar®	vorvida®	deprexis®	Total
US Pharma	172.5	—	—	—	—	172.5
Digital Therapeutics	—	—	—	—	—	0.0
HQ & Pipeline	—	3.5	3.1	—	—	6.6
<b>Total revenue from contracts with customers</b>	<b>172.5</b>	<b>3.5</b>	<b>3.1</b>	<b>0.0</b>	<b>0.0</b>	<b>179.1</b>
Geographical markets	ZUBSOLV®	Abstral®	Edluar®	vorvida®	deprexis®	Total
US	172.5	—	0.9	—	—	173.4
EU	—	3.3	0.6	—	—	3.9
Rest of the world	—	0.3	1.6	—	—	1.9
<b>Total revenue from contracts with customers</b>	<b>172.5</b>	<b>3.5</b>	<b>3.1</b>	<b>0.0</b>	<b>0.0</b>	<b>179.1</b>
SEK m		2021 Jan-Jun				
Segment	ZUBSOLV®	Abstral®	Edluar®	vorvida®	deprexis®	Total
US Pharma	252.8	—	—	—	—	252.8
Digital Therapeutics	—	—	—	0.4	0.1	0.4
HQ & Pipeline	—	17.0	4.9	—	—	21.9
<b>Total revenue from contracts with customers</b>	<b>252.8</b>	<b>17.0</b>	<b>4.9</b>	<b>0.4</b>	<b>0.1</b>	<b>275.1</b>
Geographical markets	ZUBSOLV®	Abstral®	Edluar®	vorvida®	deprexis®	Total
US	252.8	—	1.5	0.4	0.1	254.7
EU & UK	—	16.5	1.3	—	—	17.8
Rest of the world	—	0.6	2.0	—	—	2.6
<b>Total revenue from contracts with customers</b>	<b>252.8</b>	<b>17.0</b>	<b>4.9</b>	<b>0.4</b>	<b>0.1</b>	<b>275.1</b>

## 9. Revenue from contracts with customers

SEK m	2020 Jan-Jun					
Segment	ZUBSOLV®	Abstral®	Edluar®	vorvida®	deprexis®	Total
US Pharma	336.4	—	—	—	—	336.4
Digital Therapeutics	—	—	—	—	—	0.0
HQ & Pipeline	0.1	12.2	5.5	—	—	17.8
<b>Total revenue from contracts with customers</b>	<b>336.5</b>	<b>12.2</b>	<b>5.5</b>	<b>0.0</b>	<b>0.0</b>	<b>354.2</b>
<b>Geographical markets</b>	<b>ZUBSOLV®</b>	<b>Abstral®</b>	<b>Edluar®</b>	<b>vorvida®</b>	<b>deprexis®</b>	<b>Total</b>
US	336.4	—	1.4	—	—	337.8
EU & UK	—	11.9	1.7	—	—	13.7
Rest of the world	0.1	0.3	2.4	—	—	2.7
<b>Total revenue from contracts with customers</b>	<b>336.5</b>	<b>12.2</b>	<b>5.5</b>	<b>0.0</b>	<b>0.0</b>	<b>354.2</b>

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

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 Apr-Jun	2020 Apr-Jun	2021 Jan-Jun	2020 Jan-Jun	2020 Jan-Dec
EBIT	-54.0	-13.3	-90.9	20.7	-19.9
Depreciation and amortization	12.9	4.3	25.8	9.4	38.9
<b>EBITDA</b>	<b>-41.1</b>	<b>-9.0</b>	<b>-65.2</b>	<b>30.1</b>	<b>19.0</b>
DTx costs	51.6	35.5	110.5	47.6	175.4
<b>EBITDA excluding DTx costs</b>	<b>10.5</b>	<b>26.5</b>	<b>45.3</b>	<b>77.7</b>	<b>194.4</b>

RETURN ON SHAREHOLDERS' EQUITY	2021 Apr-Jun	2020 Apr-Jun	2021 Jan-Jun	2020 Jan-Jun	2020 Jan-Dec
Shareholders' equity beginning balance	534.8	775.3	558.5	706.4	706.4
Shareholders' equity ending balance	459.4	735.5	459.4	735.5	558.5
Average shareholders' equity	497.1	755.4	509.0	721.0	632.5
Net earnings	-73.7	-32.5	-105.4	50.1	-84.4
<b>Return on shareholders' equity %</b>	<b>-14.8</b>	<b>-4.3</b>	<b>-20.7</b>	<b>6.9</b>	<b>-13.3</b>

OPERATING EXPENSES SEK m	2021 Apr-Jun	2020 Apr-Jun	2021 Jan-Jun	2020 Jan-Jun	2020 Jan-Dec
Selling expenses	-61.8	-70.0	-130.4	-124.4	-286.6
Administrative expenses	-41.4	-32.7	-70.0	-56.5	-102.8
Research and development costs	-73.2	-62.6	-128.8	-115.6	-224.9
Other operating income and expenses	-2.4	-7.1	0.6	2.9	-3.6
<b>Operating expenses</b>	<b>-178.7</b>	<b>-172.5</b>	<b>-328.7</b>	<b>-293.6</b>	<b>-617.9</b>

GROSS INVESTMENTS SEK m	2021 Apr-Jun	2020 Apr-Jun	2021 Jan-Jun	2020 Jan-Jun	2020 Jan-Dec
Investments in tangible fixed assets	6.3	-1.0	15.4	2.8	29.4
Investments in intangible fixed assets	6.7	107.6	14.0	107.7	160.3
<b>Gross investments</b>	<b>13.1</b>	<b>106.6</b>	<b>29.3</b>	<b>110.5</b>	<b>189.8</b>

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 July 15, 2021.