Q4 2020, incl. Full Year Report

ZUBSOLV® stable and strong EBIT, despite challenging market due to Covid-19

Q4 2020 highlights

- Total net revenues of SEK 159.2 m (238.1 last year, 196.2 m excl. Abstral® EU and US)
- Net earnings of SEK -49.6 m (38.9)
- EBITDA of SEK 1.0 m (85.8)
- US Pharma segment (ZUBSOLV® US) net revenues of SEK 143.1 m (190.5), EBIT of SEK 94.4 m (95.5)
- Cash flow from operating activities of SEK -11.2 m (60.2), cash balance of SEK 505.3 m (816.8)
- Secured a preferred position for ZUBSOLV® as the only branded product on national commercial and Medicare Part D formularies of the largest PBM in the commercial segment in the US, Express Script, from January 1, 2021
- Finalized the technical development of modia™, a digital therapy for opioid use disorder, for which Orexo owns the exclusive global rights
- Entered an exclusive license and supply agreement with Accord Healthcare for ZUBSOLV® covering 29 European countries
- A new patent for ZUBSOLV®, with protection until 2032, was issued by the US Patent and Trademark Office (USPTO)
- Financial outlook provided for 2021, see page 14

Important events after the period

- A new patent for OX124, overdose rescue medication, was issued by the USPTO protecting the technology until 2039

SEK 94.4 m
US Pharma EBIT

66%
US Pharma EBIT margin

SEK 505.3 m
Cash and cash equivalents

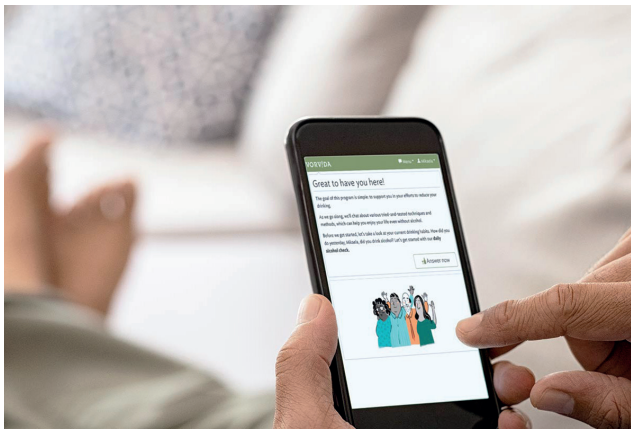
SEK m, unless otherwise stated	2020 Oct-Dec	2019 Oct-Dec	2020 Jan-Dec	2019 Jan-Dec	2019-2020 Oct-Dec Δ
Net revenues	159.2	238.1	663.6	844.8	-33%
Cost of goods sold	-11.3	-23.0	-65.6	-105.6	-51%
Operating expenses	-158.9	-143.5	-617.9	-508.0	11%
EBIT	-11.0	71.5	-19.9	231.2	-115%
EBIT margin, %	-6.9	30.0	-3.0	27.4	-36.9 ppt
EBITDA	1.0	85.8	19.0	272.1	-99%
Earnings per share, before dilution, SEK	-1.45	1.12	-2.45	6.33	-230%
Earnings per share, after dilution, SEK	-1.45	1.10	-2.45	6.20	-232%
Cash flow from operating activities	-11.2	60.2	16.8	287.0	-119%
Cash and cash equivalents	505.3	816.8	505.3	816.8	-38%

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 2019.

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 m 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
Nikolaj Sørensen, President and CEO, Joseph DeFeo, EVP and CFO, or Lena Wange, IR & Communications Director
Tel: +46 18 780 88 00, +1 855 982 7658, Email: ir@orexo.com

Presentation

At 2.00 pm CET, the same day as the announcement of the report, Orexo invites analysts, investors and media to attend an audiocast with a web presentation where Nikolaj Sørensen, CEO, and Joseph DeFeo, CFO, will present the report. After the presentation a Q&A will be held. 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-q4-2020
Telephone: SE +46 8 50 558 358 UK +44 333 300 9267 US +1 833 249 8403
The presentation material will be available on Orexo´s website prior to the audiocast, view Investors/Reports, presentations and audicasts

Financial calendar

Annual Report 2020, week 12, 2021
Annual General Meeting 2021, April 13, 2021 at 4 pm CET
Interim Report Q1 2021 - April 29, 2021 at 8.00 am CET
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.

Progress while adjusting to new market dynamics

From a management perspective, the most important factor for success is to be an agile company, ready to accelerate development and to capture opportunities when they arise, but also be prepared to shift priorities when the market requires it. The quarter has seen progress on many fronts, with US Pharma showing net revenue growth in local currency comparing to last quarter and improved EBIT margin, Digital Therapeutics (DTx) testing new reimbursement routes and launching new commercialization concepts. Our lead pipeline project, a rescue medication for opioid overdose, OX124, received positive feedback from the FDA[1] on the IND[2] application enabling a request for Fast Track Designation of the product and we also reported an exclusive license and supply agreement for ZUBSOLV® in Europe.

Strong financial base to enable investments in DTx and launch of OX124

Our full year OPEX was SEK 617 million, which is significantly less than the guidance of SEK 750-800 million communicated in our Q2 report. The guidance in Q2 was based on the significant interest in DTx in the beginning of the Covid-19 pandemic and our expectation that payers and healthcare providers would follow the FDA´s decision to include digital therapies under the Public Health Emergency Policy and find pragmatic routes for reimbursement. While the interest in Orexo's digital therapies remains high, building a new market requires patience. We start to see concrete and promising development with regards to DTx reimbursement, which is a cornerstone to accelerate growth.

Looking ahead, we expect to increase the investment in DTx as we see a progression in sales and a clearer picture emerges regarding the multiple routes to reimbursement. 2021 will also require significant investments in OX124, as we enter the pivotal trial starting in the summer this year. To ensure we have financial headroom to invest in opportunities when they arise, both internally in our products and our pipeline and through business development, we intend to refinance our existing corporate bond during Q1 2021 with a new corporate bond issue.

"Looking ahead, we expect to increase the investment in DTx as we see a progression in sales and a clearer picture emerges regarding the multiple routes to reimbursement.

Expanding the commercialization model in DTx

The expectations of our DTx portfolio in 2020 were boosted by the FDA's decision to implement a Public Health Emergency Policy allowing commercialization of digital therapies within the CNS[3] space without the ordinary approval process. We anticipated that the payers would adopt similar pragmatism to the reimbursement processes as a response to the Public Health Emergency Policy, but the reimbursement process is following the pattern we anticipated before Covid-19, i.e. a new disruptive treatment will take time to review and implement. As a result, we are testing several new concepts for reimbursement of our digital therapies in parallel, while making the DTx available through direct purchase for patients. The lead concept is a treatment program where we, in collaboration with selected healthcare providers, offer patients treatment under the supervision of a physician. Provided the physicians and the patients follow certain guidelines, this treatment program is currently available for reimbursement for a large portion of the US population. The program is being tested in Pennsylvania to a limited number of patients to ensure the reimbursement will follow the expected

[1] US Food and Drug Administration
[2] Investigational New Drug
[3] Central Nervous System

path before we launch nationwide. The same program will also be available for individual physicians to treat patients under a direct contract with Orexo. In addition to this program, we are finalizing a program for employers, working with patient to patient communication, and continue our work with payers to drive reimbursement.

ZUBSOLV® decline diminishing while impact of Covid-19 continues

With bipartisan support for the ongoing opioid crisis in the US, I am pleased to see politicians returning their attention to the opioid crisis. The former US administration recently paved the way for all US physicians to prescribe medical-assisted treatment (MAT) for opioid dependence, and we are confident that in the event of changes under the new administration, addressing the opioid crisis will remain a key priority. With the ongoing Covid-19 pandemic having significantly worsened this crisis, there is a pressing need increase access to treatment. Such a change will likely drive a sustained strong market growth, which will benefit Orexo and ZUBSOLV®.

This quarter we had a small net sales increase compared to Q3 and a strong EBIT margin of 66 percent. Apart from some one-time adjustments, this result is explained by minimal decline from former exclusive contracts and stable development in the open segment. When Covid-19 is behind us, we expect a stabilization of the business and growth. ZUBSOLV® is the only promoted daily treatment in opioid dependence in the US, and Covid-19 restrictions have had a severe impact on our ability to promote the product. In combination with our core market segment, the commercial segment, being stagnant due to the unemployment caused by Covid-19, it is a challenging market place during the pandemic. However, the Covid-19 challenges also provides learning of how to be more efficient in the sales process, which will benefit us long term. We expect ZUBSOLV® will continue to be an important EBIT contributor in the years to come and with the broad launch of modia™, our digital therapy for opioid use disorder, in the second half of 2021 we will see increased commercial synergies between our digital therapies and ZUBSOLV®, both from a cost and revenue perspective.

OX124 development progressing to plan

As the US death tolls associated with overdose of fentanyl continue, we are confident OX124 is urgently needed, with the promise of being the most powerful nasal delivery of naloxone in the market. I am very pleased with the progress we have made during the quarter. With continued progress according to plan, in Q1 2021 we will receive a decision on the Fast Track application, continue to establish a commercial supply chain, improve the IP protection and register the brand name for OX124. In Q2 2021 we will manufacture the batches required for regulatory stability data and we will start the pivotal clinical trial. If the Fast Track application is approved we will be ready to submit an application for approval in Q1 2022. Without Fast Track the process will be delayed as we expect the FDA will require additional stability data to support proposed shelf life of the commercial product.

"As the US death tolls associated with overdose of fentanyl continue, I am confident OX124 is urgently needed, with the promise of being the most powerful nasal delivery of naloxone in the market.

Summary and Outlook

In the last quarterly report I highlighted the pressing need for Orexo's products as a result of the Covid-19 pandemic. The Covid-19 pandemic has unfortunately escalated, and the need for our products is even greater than before. The delays to get the DTx products reimbursement is certainly frustrating, especially given the clear demand for such products in the current climate. However, I also have to respect that Covid-19 has had a severe impact on many organizations and their ability to operate as normal. This aside, we are encouraged by the positive feedback we receive from customers and the steady progression we see in the number of patients testing and buying our DTx products in January. I remain confident that 2021 will show the commercial potential of these products, while we continue to enjoy strong and stable EBIT contribution from ZUBSOLV® and prepare the new drug application for OX124.

Uppsala, Sweden, January 28, 2021

Nikolaj Sørensen
President and CEO

Financial information

Revenues

Total revenues for the quarter amounted to SEK 159.2 m (238.1), of which US Pharma revenues of SEK 143.1 m (190.5) while revenues, related to partner products, amounted to SEK 16.0 m (47.6).

The decrease in US Pharma revenues for the quarter is driven by lower demand due to competition in previously exclusive plans, declining Commercial segment due to increased unemployment as a result of Covid-19 and lower adjustments of accrued product returns, partly offset by improved pricing. Also unfavourable exchange rates had a negative impact. In local currency US Pharma net revenues amounted to USD 16.7 m (19.8) and vs Q3 2020 US Pharma net revenues increased by USD 0.5 m, a growth of 3 percent.

Abstral® royalty amounted to SEK 15.1 m (46.2) for the quarter explained by the previously communicated expiration of the contracts for the US and European markets.

Total revenues amounted to SEK 663.6 m (844.8) for the full year.

Costs of goods sold

Cost of goods sold (COGS) amounted to SEK 11.3 m (23.0) for the quarter, explained by US Pharma of SEK 9.1 m (23.0) and technical infrastructure costs of SEK 2.1 m (-) for deprexis® and vorvida®. The decrease in COGS is explained by efficiency improvements in the supply chain, exchange rate changes and reduced demand. For the full year COGS amounted to SEK 65.6 m (105.6), explained by US Pharma of SEK 61.0 m (105.6) and technical infrastructure costs of SEK 4.6 m (-) for deprexis® and vorvida®.

Operating expenses

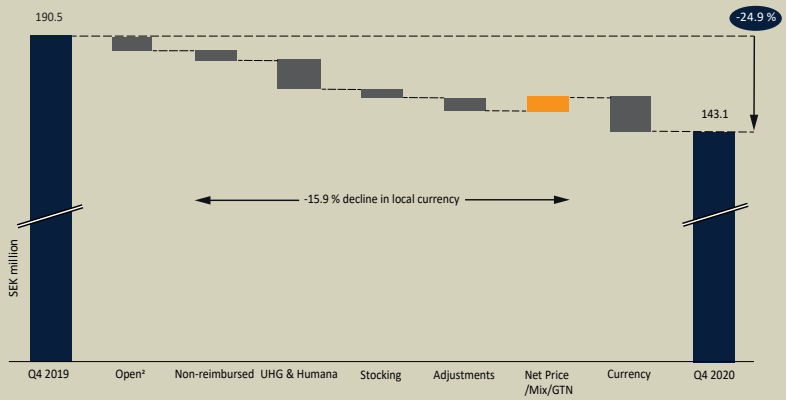
Selling expenses amounted to SEK 79.0 m (50.6) for the quarter. The increase over the same period last year is mainly explained by costs related to launch preparations for vorvida® and deprexis® and in the US of SEK 54.5 m (0.9). This was partially offset by lower selling expenses in US Pharma of SEK 24.5 m (49.4). Selling expenses amounted to SEK 286.6 m (191.9) for the full year.

Administrative expenses amounted to SEK 19.8 m (26.9) for the quarter. The decrease versus the same period last year is mainly explained by lower costs for the long-term incentive programs following negative share price development and fair value adjustment versus prior quarter. Administrative expenses amounted to SEK 102.8 m (139.6) for the full year. The decrease versus the prior year is mainly explained by lower legal expenses for IP litigations SEK 2.6 million (49.4) partly offset by higher legal costs in the US related to the FDA subpoena.

Research and development costs amounted to SEK 59.0 m (58.6) for the quarter and to SEK 224.9 m (181.3) for the full year. The increase is explained by the clinical trial of OX125 and as OX124 is approaching final clinical development, partly offset by lower internal costs.

Other operating income and expenses amounted to SEK -1.1 m (-7.4) for the quarter and to SEK -3.6 m (4.8) for the full year mainly explained by exchange-rate losses derived from revaluations of parent company balance sheet items in foreign currency, predominantly in USD.

ZUBSOLV® US NET REVENUES GROWTH BY KEY DRIVERS, Q4 2020 VERSUS Q4 2019[1]



[1] Orexo analysis using IMS demand data plus institutional sales

² Excluding cash segment and formulary changes (Wellcare, UHG and Humana)

Operating profit

Orexo's profitability reflects investments in DTx and in pipeline and EBITDA amounted to SEK 1.0 m (85.8) for the quarter and to SEK 19.0 m (272.1) for the full year.

The EBIT contribution from US Pharma amounted to SEK 94.4 m (95.5) for the quarter, equal to an EBIT margin of 65.9 percent (50.1). The increase is explained by lower operating costs partly offset by lower sales and gross profit. The EBIT contribution from US Pharma amounted to SEK 331.2 m (347.1) for the full year, equal to an EBIT margin of 53.1 percent (48.3).

US Pharma EBIT contribution amounted to SEK 94.4 m (95.5), equal to an EBIT margin of 65.9 percent (50.1).

Net financial items and tax

Net financial items amounted to SEK -29.3 m (-22.5) for the quarter mainly explained by negative unrealized exchange rate impact of SEK 25.6 m derived from the parent company's foreign currency bank accounts mainly in USD and by costs for corporate bonds of SEK 3.0 m. Net financial items amounted to SEK -18.4 m (-3.3) for the full year.

Total tax expenses amounted to SEK -9.2 m (-10.1) for the quarter, negatively impacted by decreased parent company tax asset of SEK -5.5 m (-11.8) due to lower expected profits following continued investment in DTx. Adjustment to deferred tax assets related to temporary differences had a negative impact of SEK -3.8 m (1.7). Total tax expenses amounted to SEK -46.1 m (-8.8) for the full year and was negatively impacted by decreased parent company tax asset of SEK -49.0 m (-11.8) and positively impacted by adjustment to deferred tax assets of SEK 3.9 m (3.0) related to temporary differences.

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

Net earnings

Net earnings amounted to SEK -49.6 m (38.9) for the quarter and to SEK -84.4 m (219.1) for the full year.

Segment reporting

Orexo Group has its operations in Sweden and the US. With effect from Q1 2020, operations are monitored and presented in the segments US Pharma, Digital Therapeutics (DTx) and HQ & Pipeline.[1] See Note 2.

US Pharma

US Pharma net revenues amounted to SEK 143.1 m (190.5) for the quarter.

The decrease in US Pharma revenues for the quarter is driven by lower demand due to competition in previously exclusive plans, declining Commercial segment due to increased unemployment as a result of Covid-19 and lower adjustments of accrued product returns, partly offset by improved pricing. Also unfavourable exchange rates had a negative impact. In local currency US Pharma net revenues amounted to USD 16.7 m (19.8) and vs Q3 2020 US Pharma net revenues increased by USD 0.5 m, a growth of 3 percent.

The EBIT contribution from US Pharma amounted to SEK 94.4 m (95.5) for the quarter, equal to an EBIT margin of 65.9 percent (50.1). The increase is explained by lower operating costs partly offset by lower sales and gross profit.

US Pharma net revenues amounted to SEK 623.3 m (719.2) for the full year and EBIT to SEK 331.2 m.

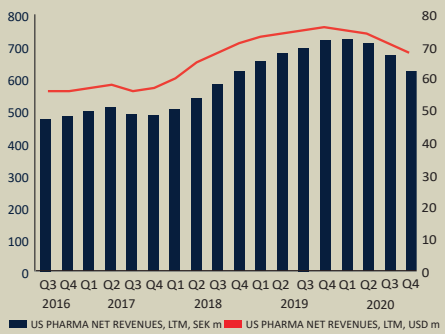
DTx

Sales efforts during the quarter have focused on piloting different reimbursement pathways and commercial concepts, this has been to ensure we maintain good cost control. Lack of broad scale commercial efforts have limited revenues from fully paid licenses during the quarter.

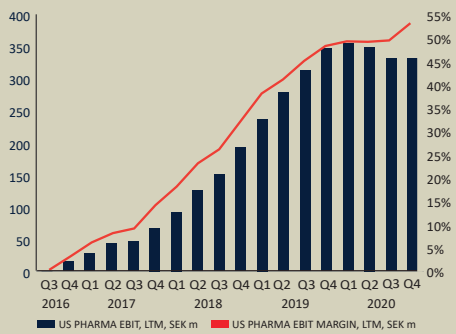
The recognized net revenues were SEK 30 k and deferred income SEK 100 k. In accordance with IFRS 15 standard for revenue recognition the revenues will be recognized throughout the validity of the license.

EBIT amounted to SEK -65.3 m (-0.9) for the quarter

US PHARMA NET REVENUES (LTM², SEK m & USD m)



US PHARMA EBIT MARGIN (LTM², USD m) AND EBIT (LTM², SEK m)



[1] HQ & Pipeline consists of the Group head quarter functions, R&D, Corporate Development, Global Regulatory and Supply Chain. Net revenues comprises all partner revenues for ZUBSOLV® – ex US, Abstral® and Edluar®.
[2] LTM, Last Twelve Months

and to SEK -175.4 m (-0.9) for the full year, mainly explained by initial costs related to building up the business and enterprise platform and the continued launch of vorvida® and deprexis®.

HQ & Pipeline

Partner revenues amounted to SEK 16.0 m (47.6) for the quarter mainly explained by reduced Abstral® royalty which amounted to SEK 15.1 m (46.2). Abstral® royalty for sales in Europe was received until December 31 2019, when the European contract with Kyowa Kirin expired. Abstral® royalty for sales in the US were received until October 31 2019, when Orexo's partner Sentynl withdrew Abstral® from the market. Edluar® royalty amounted to SEK 0.9 m (1.3). Total partner revenues amounted to SEK 40.2 m (125.6) for the full year.

EBIT amounted to SEK -40.1 m (-23.2) for the quarter and to SEK -175.8 m (-115.0) for the full year, mainly explained by lower Abstral® royalty and by costs for the clinical trial of OX125 and as OX124 is approaching final clinical development, partly offset by lower legal IP costs.

Cash, cash flow and net cash/debt

As of December 31 2020, cash and cash equivalents amounted to SEK 505.3 m (816.8) and interest-bearing liabilities to SEK 224.5 m (289.6), i.e. a positive net cash position of SEK 280.8 m (527.2). In the quarter Orexo paid a non-refundable milestone to its partner GAIA AG for modia™ and made investments in the DTx enterprise platform and in equipment for the development organization. During the year Orexo has bought back bonds equal to SEK 66.6 m and repurchased 500,000 of its ordinary shares for SEK 27.3 m.

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. Orexo intent to initiate a process during Q1 2021 to issue a new corporate bond and refinance the existing corporate bond expiring in November 2021.

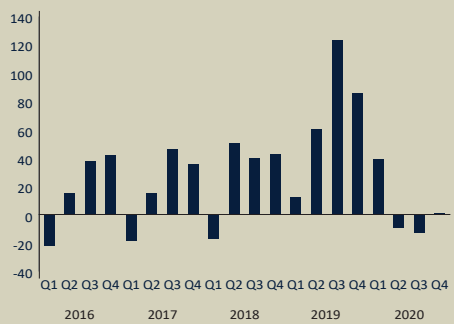
Cash flow from operating activities amounted to SEK -11.2 m (60.2) for the quarter and to SEK 16.8 m (287.0) for the full year.

Cash and cash equivalents amounted to SEK 505.3 m (816.8).

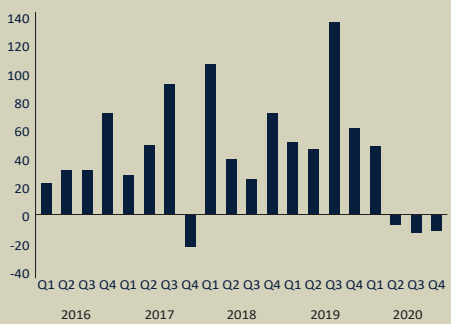
NET REVENUES AND OPERATING EARNINGS PER SEGMENT

SEK m	Net Revenues				EBIT			
	2020 Oct-Dec	2019 Oct-Dec	2020 Jan-Dec	2019 Jan-Dec	2020 Oct-Dec	2019 Oct-Dec	2020 Jan-Dec	2019 Jan-Dec
ZUBSOLV® US product sales	143.1	190.5	623.3	719.2	-	-	-	-
US Pharma – total	**143.1**	**190.5**	**623.3**	**719.2**	**94.4**	**95.5**	**331.2**	**347.1**
Digital Therapeutics (DTx) product sales	0.0	-	0.0	-	-	-	-	-
Digital Therapeutics (DTx) – total	**0.0**	-	**0.0**	-	**-65.3**	**-0.9**	**-175.4**	**-0.9**
Abstral® royalty	15.1	46.2	29.7	112.6	-	-	-	-
Edluar® royalty	0.9	1.3	10.4	11.6	-	-	-	-
ZUBSOLV® - ex US	-	-	0.1	0.1	-	-	-	-
OX-MPI	-	0.0	-	1.4	-	-	-	-
HQ & Pipeline segment – total	**16.0**	**47.5**	**40.2**	**125.6**	**-40.1**	**-23.2**	**-175.8**	**-115.0**
Total	**159.2**	**238.1**	**663.6**	**844.8**	**-11.0**	**71.5**	**-19.9**	**231.2**

EBITDA, SEK m



CASH FLOW FROM OPERATING ACTIVITIES, SEK m



Investments

Gross investments in tangible and intangible fixed assets amounted to SEK 29.0 m (21.4) for the quarter and to SEK 189.8 m (32.0) for the full year. Higher investment is mainly explained by a payment of non-refundable milestone for modia™, investments in the DTx enterprise platform and in equipment for the development organization.

Equity

Shareholders' equity at December 31, 2020, was SEK 558.5 m (706.4). The equity/asset ratio was 45.3 percent (47.1).

Parent company

Net revenues amounted to SEK 80.1 m (187.3) for the quarter of which SEK 64.0 m (139.8) was related to sales to Group companies. Net revenues amounted to SEK 446.4 m (534.0) for the full year of which SEK 406.2 m (408.5) was related to sales to Group companies.

Earnings before tax were SEK -67.2 m (69.1) for the quarter and SEK -23.4 m (231.1) for the full year mainly explained by investment into DTx and development projects. Investments amounted to SEK 17.6 m (21.4) for the quarter and to SEK 168.7 m (35.9) for the full year.

As of December 31, 2020, cash and cash equivalents in the parent company amounted to SEK 361.3 m (469.0).

Higher investment is mainly explained by a payment of a non-refundable milestone for modia™, investments in the DTx enterprise platform and in equipment for the development organization.

Operations

US Pharma

ZUBSOLV® US - treatment of opioid use disorder (OUD)

During the fourth quarter sales force activity continued to be impacted by the Covid-19 pandemic, restricting face to face access by our field force to waivered healthcare providers. Individual state mandates continue to fluctuate, resulting in offices and clinics changing hours of operation and staffing to accommodate personnel and patient safety. This has resulted in a reduction of the efficiency of in-person customer interactions for ZUBSOLV®. Additionally, the ever-changing US employment rate has resulted in less new patient starts in commercial payers and patients switching to cash or public coverage, where generics have the greatest market access coverage versus branded competitors. Therefore, while the market demonstrated strong growth, ZUBSOLV's participation was limited and due to the low access to prescribers, thereby limited our ability to message on ZUBSOLV's advantages and market opportunities.

Sales development
In Q4 2020 ZUBSOLV® net sales in USD grew 3 percent versus Q3 2020 mainly due to positive adjustments to inventory stocking in Q4 and limited decline in demand. Compared to Q4 2019 net sales declined 16 percent mainly due to the continued impact of the formulary status of ZUBSOLV® at United Health Group and small declines in other open and non-reimbursed business during the Covid-19 pandemic. Unit demand volume declined 3 percent over Q3 2020 and 17 percent over Q4 2019. The demand volume decline is the lowest since United Health Group opened up for generic competition in Q3 2019 and the effect of this change is diminishing.

Market development
The market demonstrated strong growth of 13 percent in unit volume compared to Q4 2019, and 2 percent growth over Q3 2020. This year is the fastest market growth recorded thus far since the launch of ZUBSOLV® in September 2013.

Additionally, as Covid-19 had significant impact once again on US employment during the quarter resulting in market volume growth of only 1 percent in the Commercial segment versus last quarter, thus impacting ZUBSOLV® commercial volumes and ability to grow in this segment. The Public segment of the market demonstrated continued growth and excluding Humana Medicare D, ZUBSOLV® grew its volume by 1 percent in this segment versus last quarter.

Open formulary business[1]
Volumetrically, ZUBSOLV's open formulary business declined by 1 percent over Q3 2020 and declined by 7 percent over Q4 2019. ZUBSOLV® was flat in Medicaid and Medicare in Q4 2020 versus Q3 2020, but volume declined 2 percent in Commercial and 1 percent in non-retail. Covid-19's impact on Commercial market volume, slowing it to 1 percent growth, creates a challenging environment for ZUBSOLV® to generate growth, until unemployment in the US decline and the Commercial segment return to growth. ZUBSOLV® is stable in its largest Medicaid payer, Michigan, versus Q3 2020 and grew in its second largest Medicaid payer, Maryland, versus Q3 2020. ZUBSOLV® has grown 16 percent versus Q3 2020 on Louisiana Medicaid where it first became accessible on July 1, 2020.

Former exclusive plans and non-reimbursed businesses
ZUBSOLV´s volume in United Health Group and Humana has decreased 5 percent versus Q3 2020 and 29 percent versus Q4 2019. ZUBSOLV® business in the non-reimbursed volume has decreased 5 percent versus Q3 2020 and 26 percent versus Q4 2019. United Commercial ZUBSOLV® volume decline is slowing, with Q4 over Q3 2020 showing the lowest quarterly ZUBSOLV® volume decline since generics were added to the formulary in Q3 2019.

Market access
ZUBSOLV's best-in-class Commercial access has reached 99 percent.[2] The largest payer in the commercial segment is ESI & Cigna with 21 percent of the Commercial market, as earlier communicated ZUBSOLV® is now the only preferred branded product on ESI and Cigna´s national

The demand volume decline is the lowest since United Health Group opened up for generic competition in Q3 2019 and the effect of this change is diminishing.

[1] ZUBSOLV's open formulary business is total business where ZUBSOLV is reimbursed and competes with other products in the market both brand and/or generics. Open formulary business excludes recent formulary changes in United Health Group and Humana, the cash segment, and payers where it is not reimbursed. [2] IQVIA (formerly IMS) payer reconciliation shifted volumes to Medicaid

commercial and Medicare Part D formularies. This makes ZUBSOLV® the only preferred branded product on the top three Commercial PBM (ESI, Caremark & Optum) national formularies which will bring ZUBSOLV® preferred brand status to 60 percent of the commercial buprenorphine/naloxone market.

ZUBSOLV® coverage in the public segment decreased to 34 percent primarily due to Washington Medicaid tightening non-enforced restrictions on ZUBSOLV®, this change has marginal impact on ZUBSOLV® due to low volume and market share with Washington Medicaid.

DTx

vorvida® US - digital therapy for heavy alcohol use, incl. alcohol use disorder (AUD)
deprexis® US - digital therapy to manage symptoms of depression
modia™ US - digital therapy for opioid use disorder (OUD)

Based on the FDA´s Enforcement Policy from April 2020, our anticipation was that payers and IDNs[1] would respond with similar urgency. This has not been the case and the reimbursement process is following the pattern expected prior to the Covid-19 outbreak. Thus, to ensure a good Return on Investment from the commercialization efforts, the strategy for the DTx business is to test commercialization concepts, before making a broad investment in marketing and sales resources. This has resulted in a significant reduction in investments in Q4 2020. The sales of vorvida® has increased late in the quarter and we have continued to see positive development in beginning of 2021, as we in December made it possible to pay installments through our existing e-commerce platform. Due to accounting policies the revenues from the digital therapies will be recorded over the life time of the product (6 months for vorvida® and 3 months for deprexis®) and the reported revenues were low during the quarter.

To ensure a good Return on Investment from the commercialization efforts, the strategy for the DTx business is to test commercialization concepts, before making a broad investment in marketing and sales resources.

From a commercialization perspective the DTx team is currently working through four main channels:

1. Payers and integrated health distribution networks (IDNs):
We have continued to work with payers to gain access and continue to receive encouraging feedback from the medical leadership of the payers. The main hurdle remains finding ways to ensure a smooth reimbursement process for the payer, the patient, the healthcare provider and for Orexo. The progress is continuing in several ongoing discussions and expect to close the first agreements in Q1 2021, either as a direct coverage of the products or as a collaboration model to test one or more of the products in the payer's customer base. We are processing reimbursement requests from patients in our reimbursement hub and we have reimbursement requests accepted from more than 10 payers, although with varying degree of co-pay and deductibles. The collaboration with Trinity Health in North Dakota has progressed well and discussions have started on the structure of a commercial partnership.

2. Sales force:
The sales force started promotion of vorvida® in October to healthcare providers. The main objectives have been to gain increased insight into the customer needs, get healthcare providers to refer patients to the service and to get healthcare providers to offer the service to their patients. As anticipated a robust route to reimbursement is a hygiene factor to gain broad traction through the sales force. Apart from the continued work with payers, we are running a test in Pennsylvania to enable healthcare providers to integrate vorvida® into an existing treatment pathway and get the product reimbursed through existing categories of medical benefits associated with that pathway. This test will run throughout Q1 2021 to ensure the process runs smoothly from a reimbursement perspective. This concept requires monthly installments and the testing was started in December when the system was ready. Covid-19 restrictions imposed during Q4 2020 have impacted the field force ability to reach the healthcare providers and we have delayed investments in expanding the sales force until the restrictions are lifted permanently.

[1] Payers and integrated health distribution networks

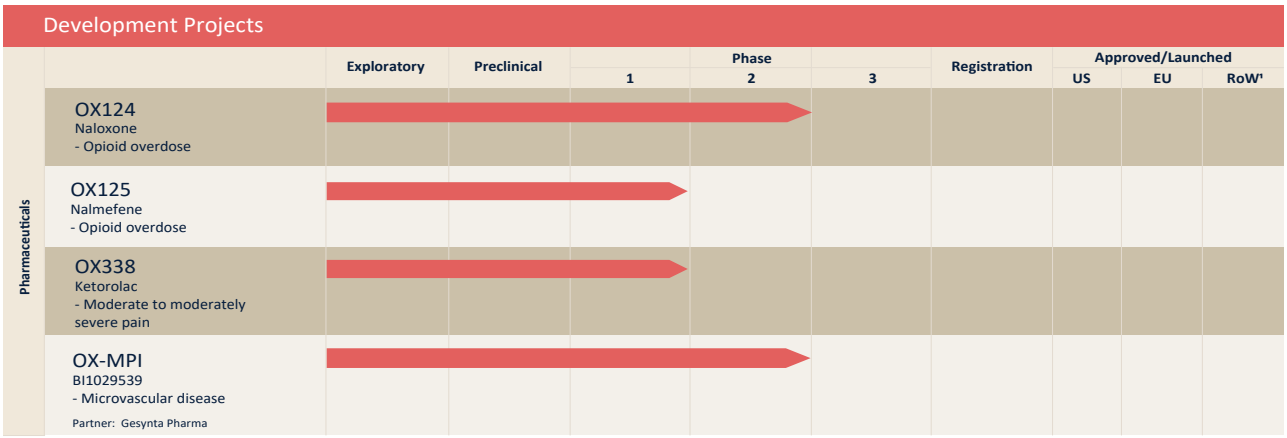
3. Direct to consumer selling:
The media activities for vorvida® have increased around the holiday season in the year-end and we have made certain direct offers to patients which have been well received. Monitoring the customer activities and listening to feedback, it is clear the one-time cost of vorvida® of USD 750 may be a cash purchase barrier for some and the availability of monthly installments from December has increased the sales conversion. We have established collaboration with healthcare providers and will be ready to offer a service from our online platform, with vorvida® or deprexis® treatment under a physician's supervision, which for many patients will be covered under their existing medical benefits. This service is based on the test in Pennsylvania mentioned above and will be launched broadly in H1 2021, subject to the outcome of the test. In addition to the direct advertisement we are testing models for promotion and mentorship through a group of people who are in recovery from alcohol misuse, this test started late December 2020.

4. Employers:
Mental health and substance abuse are priorities for employers and the issue is increasing due to Covid-19, these are recognized as an increasing cost driver and a retention problem. We have initiated a series of round-table discussions with large employers during Q4 2020 and we are ready to start testing the products together with some of these employers. The ambition is to create unique value arrangements for our DTx therapies which can be offered broadly. Our distribution partner GoGoMeds will also target specific categories of employers in the US during the first half of 2021. The feedback received from Trinity Health in North Dakota in their capacity as an employer and the Nurse Association in Texas has been overwhelmingly positive and will be good reference cases when expanding the offering.

Technical development
During the quarter deprexis® also became available with functionalities such as e-commerce, customer support and a service hub for insurance reimbursement. As we received feedback from customers and gain more insights into possible reimbursement routes we identified a need to add an option for monthly installments rather than a one-time payment. This option was operational from early December and is now the most popular acquisition route for cash paying customers. The technical development of modia™ is now complete and we are ready to start testing the therapy with patients and together with partners to collect real world evidence. This data is needed to sustain the market access under the FDA´s Enforcement Policy, providing a fast track to market for digital therapies within addiction. Several partners have been identified and are ready to be announced during H1 2021.

The feedback received from Trinity Health in North Dakota in their capacity as an employer and the Nurse Association in Texas has been overwhelmingly positive and will be good reference cases when expanding the offering.

PIPELINE OF PHARMA DEVELOPMENT PROJECTS



HQ & Pipeline

OX124 - opioid overdose rescue medication containing naloxone

Unmet need
Available rescue medications have been developed for heroin overdoses, but most patients are dying from synthetic opioids like fentanyl today. Due to Covid-19 the number of overdoses is expected to surge in 2020. According to 12 month data ending in June 2020 more than 83,000 Americans died of an overdose, corresponding to an increase of over 21 percent compared to the previous year.[2] The majority of the overdoses was caused by fentanyl.

Our aim
Based on Orexo´s novel intranasal formulation technology, the aim is to develop a rescue medication that is faster and longer-acting when compared to the market leading product, and thus effective in reversing overdoses caused by synthetic opioids.

Differentiation
Results from the exploratory pharmacokinetic study (PK-study) in healthy volunteers showed significantly better PK-profile, such as faster and longer-acting, when compared to the market leading product. This novel, proprietary drug delivery technology has patent protection until 2039.

Financial potential
Net sales USD 70-110 m (US market).

Changes during the quarter
Established the full commercial supply chain of both devices and the naloxone powder and the investigational new drug (IND) application, filed with FDA in Q3 was cleared, giving green light to proceed with the final clinical study, preliminarily scheduled in Q2 2021. An application for a fast track designation was submitted with the FDA and the work to prepare for a new drug application (NDA) continued. An NDA is expected to be filed in Q1 2022, which is based on the assumption that OX124 is granting fast track designation, which is expected to be granted in Q1 2021.

OX124: An application for a fast track designation was submitted with the FDA and the work to prepare for a new drug application continued.

OX125 - opioid overdose rescue drug containing nalmefene

Unmet need
Available rescue medications have been developed for heroin overdoses, but most patients are dying from synthetic opioids like fentanyl today.

Our aim
Based on Orexo´s novel intranasal formulation technology, the aim is to develop a powerful rescue medication for situations where very long-lasting effect is required, e.g. in remote areas, as response to long-acting opioids or for anti-terror stockpiling.

[1] Rest of the World, excluding US and Europe
[2] Centers for Disease Control and Prevention (CDC)

Differentiation
Results from the first exploratory human PK-study in healthy volunteers showed extensive and rapid absorption of nalmefene across all three OX125 formulations. As nalmefene has a longer half-life than naloxone, OX125 has the potential to be an effective response to the increased use of potent, long-acting synthetic opioids as well as protecting against renarcotization (second overdose) as the antagonist wears off. This novel, proprietary drug delivery technology has patent protection until 2039.

Financial potential
Net sales USD 40-60 m (US market).

Changes during the quarter
As mentioned in the Q3 report most development resources for OX125 were directed to OX124 as the project is approaching finalization. As OX125 is based on the same intranasal formulation technology used for OX124, progress made related to OX124, will also be applicable to OX125.

As OX125 is based on the same intranasal formulation technology used for OX124, progress made related to OX124, will also be applicable to OX125.

OX338 - acute moderate to moderately severe pain

Unmet need
Opioids are still used unnecessarily in many situations, further fueling the opioid crisis.

Our aim
Based on Orexo´s novel oral formulation technology, the aim is to develop an opioid-level pain relief treatment for short-term pain (up to 5 days) without the risk of addiction.

Differentiation
Results from the exploratory PK-study in healthy volunteers showed significant better PK-profile, such as faster uptake and higher peak, when compared to nasal spray available on the market.

Financial potential
Net sales > USD 100 m (US market).

Changes during the quarter
Based on the positive outcome of the first clinical trial, but need for further work of the formulation to ensure sufficient commercial differentiation, the formulation work has continued. Orexo has decided to focus most resources on OX124 during 2021, which will delay the development of OX338.

OX-MPI – microvascular diseases

Unmet need
Several severe microvascular complications currently have few or no approved pharmacological treatment options.

Our aim
Gesynta Pharma, who owns all the rights to OX-MPI (GS-248), aims to develop a treatment for the microvascular diseases in chronic inflammatory conditions.

Differentiation
More effective and/or safer than currently approved treatments.

Financial potential
Will depend on outcome of clinical program.

Changes during the quarter
Preparations ahead of the clinical phase 2 study, which was initiated in patients suffering from systemic sclerosis, after the end of the period, in beginning of 2021. The study results are expected in late 2021.

ZUBSOLV® in geographies outside the US
An exclusive licensing agreement was signed with Accord Healthcare, for the commercialization of ZUBSOLV® in 29 European countries, with the first launches expected to start in H2 2021. 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]

Orexo will be responsible for product supply and will receive double-digit royalties on future net sales.

An exclusive licensing agreement was signed with Accord Healthcare, for the commercialization of ZUBSOLV® in 29 European countries.

[1] European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) 2019, https://www.emcdda.europa.eu. Q4 2020, incl. Full Year Report
[2] EMCDDA – Tackling Opioid Dependence 2019, https://www.emcdda.europa.eu/best-practice/briefings/tackling-opioid-dependence_en

Other information

Financial outlook 2020 - outcome

• The buprenorphine/naloxone market will continue to show a double-digit growth
Outcome: 15 percent
• ZUBSOLV® US net sales in Q4 2020 is expected to be in line with Q3 2020, and net sales for 2020 will decline compared to 2019
Outcome: Net Sales increased 3 percent in local currency vs Q3 2020 and declined vs 2019
• Due to increased R&D investments, establishment of DTx business and accelerated DTx US launch OPEX will reach a level of SEK 675-725 m
Outcome: SEK 617 m
• Due to a decrease in Abstral® royalty of approx. SEK 85 m, as an effect of expiration of IP protection in the US and the EU, and increased OPEX, EBITDA will decrease
Outcome: Decreased
• US Pharma EBIT margin will exceed 50 percent
Outcome: 53.1 percent
• Covid-19 has increased the uncertainty in the outlook
• The financial outlook is based on exchange rates in September 2020

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 margin will be in the range of 45-50 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.

Risks and uncertainty factors

Significant risks and uncertainties are presented in the Annual Report for 2019. 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.

Uppsala, Sweden, January 28, 2021

Nikolaj Sørensen
President and CEO

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

Financial reports, notes and key figures

CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS

SEK m	Notes	2020 Oct-Dec	2019 Oct-Dec	2020 Jan-Dec	2019 Jan-Dec
Net revenues	9	159.2	238.1	663.6	844.8
Cost of goods sold		-11.3	-23.0	-65.6	-105.6
Gross profit		**147.9**	**215.0**	**598.0**	**739.2**
Selling expenses		-79.0	-50.6	-286.6	-191.9
Administrative expenses		-19.8	-26.9	-102.8	-139.6
Research and development expenses		-59.0	-58.6	-224.9	-181.3
Other operating income and expenses		-1.1	-7.4	-3.6	4.8
Operating earnings (EBIT)		**-11.0**	**71.5**	**-19.9**	**231.2**
Net financial items		-29.3	-22.5	-18.4	-3.3
Earnings before tax		**-40.3**	**49.0**	**-38.3**	**227.9**
Tax	5	-9.2	-10.1	-46.1	-8.8
Net earnings for the period[1]		**-49.6**	**38.9**	**-84.4**	**219.1**
Earnings per share, before dilution, SEK		-1.45	1.12	-2.45	6.33
Earnings per share, after dilution, SEK		-1.45	1.10	-2.45	6.20

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

SEK m	2020 Oct-Dec	2019 Oct-Dec	2020 Jan-Dec	2019 Jan-Dec
Earnings for the period	**-49.6**	**38.9**	**-84.4**	**219.1**
Other comprehensive income				
Items that may subsequently be reversed to the statement of operations:				
Exchange-rate differences	-11.6	-6.3	-16.5	3.4
Other comprehensive earnings for the period, net after tax	**-11.6**	**-6.3**	**-16.5**	**3.4**
Total comprehensive earnings for the period[1]	**-61.2**	**32.6**	**-100.9**	**222.5**

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

CONDENSED CONSOLIDATED BALANCE SHEET

SEK m	2020 Dec 31	2019 Dec 31
ASSETS		
Fixed assets		
Tangible fixed assets	47.3	22.0
Intangible fixed assets	252.8	113.9
Right-of-use assets	67.8	57.0
Deferred tax assets	32.7	85.5
Other financial assets	0.7	1.4
Total fixed assets	**401.3**	**279.9**
Current assets		
Inventories	108.4	131.8
Accounts receivable and other receivables	217.9	272.6
Cash and cash equivalents	505.3	816.8
Total current assets	**831.6**	**1,221.2**
Total assets	**1,232.9**	**1,501.1**
SHAREHOLDERS' EQUITY AND LIABILITIES		
Total shareholders' equity	**558.5**	**706.4**
Long-term liabilities		
Provisions	25.7	10.7
Long-term liabilities, interest bearing	—	289.6
Lease liabilities, long-term	47.4	33.3
Total long-term liabilities	**73.1**	**333.6**
Current liabilities and provisions		
Provisions	197.3	269.3
Current liabilities, interest bearing	224.5	—
Current liabilities, non-interest bearing	160.4	170.5
Lease liabilities, current	19.1	21.4
Total current liabilities and provisions	**601.3**	**461.1**
Total liabilities	**674.4**	**794.7**
Total shareholders' equity and liabilities	**1,232.9**	**1,501.1**

CONSOLIDATED CHANGES IN SHAREHOLDERS' EQUITY

SEK m	2020 Dec 31	2019 Dec 31
Opening balance, shareholders' equity	**706.4**	**476.1**
Total comprehensive earnings for the period	-100.9	222.5
Share-based payments	-19.7	5.8
Buy back of shares	-27.3	—
New share issue	—	2.0
Closing balance, shareholders' equity	**558.5**	**706.4**

CONDENSED CONSOLIDATED CASH FLOW STATEMENTS

SEK m	Notes	2020 Oct-Dec	2019 Oct-Dec	2020 Jan-Dec	2019 Jan-Dec
Operating earnings (EBIT)		-11.0	71.5	-19.9	231.2
Interest received		0.0	2.7	3.0	9.9
Interest paid		-2.6	-6.6	-11.8	-17.7
Income taxes paid		1.5	-3.2	0.6	-12.2
Adjustment for non-cash items	3	23.2	26.4	-7.1	41.3
Cash flow from operating activities before changes in working capital		**11.1**	**90.7**	**-35.1**	**252.5**
Changes in working capital		**-22.3**	**-30.6**	**51.9**	**34.5**
Cash flow from operating activities		**-11.2**	**60.2**	**16.8**	**287.0**
Acquisition of tangible and intangible fixed assets		-29.0	-21.4	-189.8	-32.0
Disposal of financial assets		—	10.4	0.6	9.5
Cash flow from investing activities		**-29.0**	**-11.0**	**-189.2**	**-22.4**
New share issue		—	—	—	2.0
Buy back shares		—	—	-27.3	—
Repayment of loans		-4.3	-4.3	-84.0	-55.8
Cash from financing activities		**-4.3**	**-4.3**	**-111.3**	**-53.7**
Cash flow for the period		**-44.6**	**44.8**	**-283.7**	**210.8**
Cash and cash equivalents at the beginning of the period		**593.3**	**812.9**	**816.8**	**589.8**
Exchange-rate differences in cash and cash equivalents		-43.4	-40.9	-27.8	16.1
Changes in cash and cash equivalents		-88.0	3.9	-311.5	227.0
Cash and cash equivalents at the end of the period		**505.3**	**816.8**	**505.3**	**816.8**

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.

	2020 Oct-Dec	2019 Oct-Dec	2020 Jan-Dec	2019 Jan-Dec
EBIT margin, %	-6.9	30.0	-3.0	27.4
Return on shareholder equity, %	-8.4	5.6	-13.3	37.1
Net debt, SEK m	-280.8	-527.2	-280.8	-527.2
Debt/equity ratio, %	40.2	41.0	40.2	41.0
Equity/assets ratio, %	45.3	47.1	45.3	47.1
Number of shares, before dilution	34,294,873	34,710,639	34,398,815	34,621,646
Number of shares, after dilution	34,294,873	35,360,829	34,398,815	35,348,484
Earnings per share, before dilution, SEK	-1.45	1.12	-2.45	6.33
Earnings per share, after dilution, SEK	-1.45	1.10	-2.45	6.20
Number of employees at the end of the period	138	127	138	127
Shareholders' equity, SEK m	558.5	706.4	558.5	706.4
Capital employed, SEK m	783.0	996.0	783.0	996.0
Working capital, SEK m	-50.5	-56.7	-50.5	-56.7

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

CONDENSED PARENT COMPANY STATEMENT OF OPERATIONS

SEK m	Notes	2020 Oct-Dec	2019 Oct-Dec	2020 Jan-Dec	2019 Jan-Dec
Net revenues		80.1	187.3	446.4	534.0
Cost of goods sold		-13.2	-31.0	-79.7	-98.6
Gross profit		**66.9**	**156.3**	**366.7**	**435.3**
Selling expenses		-60.8	-1.2	-190.7	-6.6
Administrative expenses		-10.6	-16.2	-51.1	-105.6
Research and development costs		-51.3	-50.7	-180.1	-152.3
Other operating income and expenses		17.1	3.9	50.0	67.2
Operating earnings (EBIT)		**-38.7**	**92.1**	**-7.2**	**238.0**
Interest income and expenses		-2.6	-1.9	-10.9	40.0
Other financial income and expenses		-26.0	-21.1	-5.4	-46.9
Net financial items		**-28.5**	**-23.0**	**-16.3**	**-6.9**
Earnings before tax		**-67.2**	**69.1**	**-23.4**	**231.1**
Tax	5	-5.5	-11.8	-49.0	-11.8
Earnings for the period		**-72.8**	**57.3**	**-72.5**	**219.3**

PARENT COMPANY STATEMENT OF COMPREHENSIVE INCOME

SEK m	2020 Oct-Dec	2019 Oct-Dec	2020 Jan-Dec	2019 Jan-Dec
Earnings for the period	**-72.8**	**57.3**	**-72.5**	**219.3**
Other comprehensive income	—	—	—	—
Total comprehensive earnings for the period	**-72.8**	**57.3**	**-72.5**	**219.3**

CONDENSED PARENT COMPANY BALANCE SHEET

SEK m	2020 Dec 31	2019 Dec 31
ASSETS		
Fixed assets		
Intangible fixed assets	234.4	113.9
Tangible fixed assets	47.2	22.0
Deferred tax assets	—	49.0
Shares in subsidiaries	160.4	155.6
Total fixed assets	**442.0**	**340.6**
Current assets		
Inventories	90.9	113.4
Accounts receivable and other receivables	111.3	214.1
Cash and bank balances	361.3	469.0
Total current assets	**563.5**	**796.5**
Total assets	**1,005.5**	**1,137.1**
SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES		
Shareholders' equity	**524.2**	**644.0**
Long-term liabilities		
Other provisions	24.5	8.2
Bond loan	—	289.6
Total long-term liabilities	**24.5**	**297.8**
Current liabilities		
Accounts payable	17.3	22.8
Bond loan	224.5	—
Other liabilities	6.3	6.0
Liabilities to Group companies	187.3	144.7
Accrued expenses and deferred income	21.5	21.8
Total current liabilities	**456.8**	**195.3**
Total liabilities	**481.3**	**493.1**
Total shareholders' equity and liabilities	**1,005.5**	**1,137.1**

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 2019 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
With effect from the first quarter 2020, 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.

Comparative figures have been presented retroactively.

DISTRIBUTION OF REVENUE AND EBIT PER SEGMENT

SEK m	2020 Oct-Dec	2019 Oct-Dec	2020 Jan-Dec	2019 Jan-Dec
US Pharma				
Net revenues	143.1	190.5	623.3	719.2
Operating earnings (EBIT)	94.4	95.5	331.2	347.1
Depreciation and amortization	-3.8	-3.8	-15.4	-15.4
Digital Therapeutics				
Net revenues	0.0	-	0.0	-
Operating earnings (EBIT)	-65.3	-0.9	-175.4	-0.9
Depreciation and amortization	-3.2	-	-3.2	-
HQ & Pipeline				
Net revenues	16.0	47.5	40.2	125.6
Operating earnings (EBIT)	-40.1	-23.2	-175.8	-115.0
Depreciation and amortization	-5.0	-10.5	-20.3	-25.6
Group				
Net revenues	159.2	238.1	663.6	844.8
Operating earnings (EBIT)	-11.0	71.5	-19.9	231.2
Depreciation and amortization	-12.0	-14.3	-38.9	-40.9
Net financial items	-29.3	-22.5	-18.4	-3.3
Earnings before tax	-40.3	49.0	-38.3	227.9

3. Cash flow

ADJUSTMENT FOR NON-CASH ITEMS

SEK m	2020 Oct-Dec	2019 Oct-Dec	2020 Jan-Dec	2019 Jan-Dec
Depreciation/amortization and impairment	12.0	14.3	38.9	41.0
Change in provisions	9.7	3.9	-28.5	-2.7
Share based payments	0.3	2.2	-19.7	5.8
Exchange rate income and expenses	1.2	6.0	2.4	-2.7
Total	**23.2**	**26.4**	**-7.1**	**41.3**

4. Legal disputes

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 five patents listed in the Orange Book (US Patent Nos. 8,470,361; 8,658,198; 8,940,330; 9,259,421 and 9,439,900) with expiration dates ranging from December 2027 to September 2032. In addition, a new ZUBSOLV® patent with expiration date September 2032, US Patent No. 10,874,661, was issued by the US Patent and Trademark Office on December 29, 2020.

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

› A new patent for OX124, overdose rescue medication, was issued by the US Patent and Trademark Office protecting the technology until 2039

9. Revenue from contracts with customers

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

SEK m	2019 Oct-Dec						
Segment	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**OX-MPI**	**Vorvida®**	**Deprexis®**	**Total**
US Pharma	190.5	—	—	—	—	—	**190.5**
Digital Therapeutics	—	—	—	—	—	—	**0.0**
HQ & Pipeline	—	46.2	1.3	—	—	—	**47.5**
Total revenue from contracts with customers	**190.5**	**46.2**	**1.3**	**0.0**	**0.0**	**0.0**	**238.1**
Geographical markets	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**OX-MPI**	**Vorvida®**	**Deprexis®**	**Total**
US	190.5	0.3	0.1	—	—	—	**190.9**
EU	—	41.6	0.6	—	—	—	**42.2**
Rest of the world	—	4.4	0.6	—	—	—	**4.9**
Total revenue from contracts with customers	**190.5**	**46.2**	**1.3**	**0.0**	**0.0**	**0.0**	**238.1**

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**

SEK m	2019 Jan-Dec						
Segment	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**OX-MPI**	**Vorvida®**	**Deprexis®**	**Total**
US Pharma	719.2	—	—	—	—	—	**719.2**
Digital Therapeutics	—	—	—	—	—	—	**0.0**
HQ & Pipeline	0.1	112.6	11.6	1.4	—	—	**125.6**
Total revenue from contracts with customers	**719.3**	**112.6**	**11.6**	**1.4**	**0.0**	**0.0**	**844.8**
Geographical markets	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**OX-MPI**	**Vorvida®**	**Deprexis®**	**Total**
US	719.2	2.2	4.4	—	—	—	**725.8**
EU	0.1	107.8	2.2	1.4	—	—	**111.5**
Rest of the world	—	2.5	4.9	—	—	—	**7.5**
Total revenue from contracts with customers	**719.3**	**112.6**	**11.6**	**1.4**	**0.0**	**0.0**	**844.8**

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	2020 Oct-Dec	2019 Oct-Dec	2020 Jan-Dec	2019 Jan-Dec
EBIT	-11.0	71.5	-19.9	231.2
Depreciation and amortization	12.0	14.3	38.4	40.9
EBITDA	**1.0**	**85.8**	**19.0**	**272.1**
DTx costs	65.3	0.9	175.4	0.9
EBITDA excluding DTx costs	**66.3**	**86.7**	**194.4**	**273.0**

RETURN ON SHAREHOLDERS' EQUITY	2020 Oct-Dec	2019 Oct-Dec	2020 Jan-Dec	2019 Jan-Dec
Shareholders' equity beginning balance	619.4	671.7	706.4	476.1
Shareholders' equity ending balance	558.5	706.4	558.5	706.4
Average shareholders' equity	589.0	689.1	632.5	591.3
Net earnings	-49.6	38.9	-84.4	219.1
Return on shareholders' equity %	**-8.4**	**5.6**	**-13.3**	**37.1**

OPERATING EXPENSES SEK m	2020 Oct-Dec	2019 Oct-Dec	2020 Jan-Dec	2019 Jan-Dec
Selling expenses	-79.0	-50.6	-286.6	-191.9
Administrative expenses	-19.8	-26.9	-102.8	-139.6
Research and development costs	-59.0	-58.6	-224.9	-181.3
Other operating income and expenses	-1.1	-7.4	-3.6	4.8
Operating expenses	**-158.9**	**-143.5**	**-617.9**	**-508.0**

GROSS INVESTMENTS SEK m	2020 Oct-Dec	2019 Oct-Dec	2020 Jan-Dec	2019 Jan-Dec
Investments in tangible fixed assets	7.0	5.1	29.4	5.0
Investments in intangible fixed assets	22.1	16.3	160.3	27.0
Gross investments	**29.0**	**21.4**	**189.8**	**32.0**

Glossary

American Depositary Receipt (ADR)
An instrument that is issued by a depositary bank that represents ownership of a company's underlying shares. ADR programs are created to facilitate US investors to hold shares in non-US companies and trade them in the same way as US securities.
ANDA
An Abbreviated New Drug Application (ANDA) is an application for a US generic drug approval for an existing licensed medication or approved drug
Anesthesia
Procedure for lowering a patient's consciousness to enable a Medical procedure to proceed without pain for the patient
Artificial intelligence
Artificial intelligence (AI) is the simulation of human intelligence processes by machines, especially computer systems
Broca®
GAIA's proprietary intelligence system, based on artificial intelligence, underpins the development of digital therapies targeting multiple therapy areas
Buprenorphine
A potent opioid partial agonist first used as a pain-relieving substance, but now most commonly used to help patients withdraw from more addictive opioid drugs such as morphine
Cash segment
One of the three distinct payer segments in the US market for treatment of opioid dependence. In this segment, the patient is paying for the prescriptions out of pocket
CHMP
The Committee for Medicinal Products for Human Use
Clinical studies/Clinical trials
Studies of the safety and efficacy of a drug in human beings
Commercial segment
One of the three distinct payer segments in the US market for treatment of opioid dependence. The commercial segment is funded by private insurances or employers
Digital therapeutics (DTx)
Digital therapeutics, a subset of digital health, are evidence-based therapeutic interventions driven by high quality software programs to prevent, manage, or treat a medical disorder or disease
Digital health
Digital health is the convergence of digital technologies with health and healthcare to enhance the efficiency of healthcare delivery and make medicine more personalized and precise
Drug delivery
The process through which a pharmaceutical may be introduced to the patient that enables the active compound to function as intended
EMA
The European Medicine Agency
FDA
The US Food and Drug Administration
Fentanyl
An opioid with a similar effect on human patients as morphine. Used mainly within anesthesia and analgesia
HHS
The US Department of Health and Human Services
In Vitro studies
In an in vitro study; living matter is examined outside of its natural context e.g. in a test-tube
IP
Intellectual Properties
Naloxone
An opioid antagonist used to counter the effects of opioids
LTM
Last Twelve Months
NSAID
Non-steroid anti-inflammatory drugs which are active against pain, inflammation and fever
NTRx
Tablets per prescription divided by 30
Opioids
Collective term for compounds that act via opioid receptors on nerve cells, mainly in the central nervous system
PBM (Pharmacy Benefit Manager)
Responsible for management of costs associated with prescription pharmaceuticals and recommendations on behalf of insurance companies and employers in the US
PGE
Prostaglandin (PG) E2 – biologically active mediator derived from arachidonic acid and involved in inflammatory conditions
Phase I studies
Studies mainly of the safety of a drug. Performed on healthy human volunteers
Phase II studies
Studies of the safety and efficacy of a drug in appropriate doses. Performed on a limited number of patients
Phase III studies
Studies of the safety and efficacy of a drug in a clinical setting. Performed on a large number of patients
Preclinical development/Preclinical studies
Studies of the safety and efficacy of a drug prior to evaluation in humans. Can be performed on animals and in various cell systems
Proof of Concept studies
A Proof of Concept study is performed to get a first indication of an idea's practical feasibility
Public segment
One of three distinct payer segments in the US market for treatment of opioid dependence. The public segment covers state and federal funded reimbursement programs i.e. Managed Medicaid, FFS Medicaid, Medicare Part D
Reimbursement
Contribution from the state or insurance company in order to reduce the price of drugs / treatment for the patient
Sublingual
Under the tongue