Interim Report Q2 2020

Investing in diversification to drive future growth

Q2 2020 highlights

- Total net revenues of SEK 179.1 m (201.2)
- EBITDA of SEK -9.0 m (60.4), positive EBITDA of SEK 26.5 m (60.4) excluding accelerated DTx US launch
- Net earnings of SEK -32.5 m (54.6), positive net earnings SEK 3.0 m (54.6) excluding accelerated DTx US launch
- US Pharma (ZUBSOLV® US) net revenues of SEK 172.5 m (184.4), EBIT of SEK 88.8 m (83.8)
- DTx EBIT of SEK -35.5 m (-)
- Cash flow from operating activities of SEK -7.2 m (46.1), a cash balance of SEK 677.2 m (697.0)
- Completed the program to repurchase 500,000 of the company´s ordinary shares
- James Noble elected Chairman of the Board and Charlotte Hansson elected as Board member at the Annual General Meeting. They replace Martin Nicklasson and Kristina Schauman who have declined re-election.
- Global IP protection granted for the novel intranasal drug delivery platform until 2039
- Aquired exclusive US rights from GAIA to commercialize deprexis®, a world-leading digital therapy to help patients manage the symptoms of depression
- Positive results from human PK-study for OX125 assessing the novel intranasal nalmefene formulations for opioid overdose reversal

Important events after the end of the period

- US launch of the scientifically proven digital therapies deprexis® July 1 and forthcoming launch of vorvida® July 20
- Updated financial outlook 2020 as OPEX expects to reach a level of SEK 750-800 m for FY 2020 due to establishment of DTx business and accelerated US launch of digital therapies
- Orexo US received subpoenas on July 14 to provide US authorities with certain information with regards to ZUBSOLV® and other buprenorphine products. Orexo has no knowledge of the background to the requests (for more information see note 8).

SEK 172.5 m
US Pharma net revenues

SEK 88.8 m
US Pharma EBIT

SEK -35.5 m
DTx EBIT due to launch preparations

SEK m, unless otherwise stated	2020 Apr-Jun	2019 Apr-Jun	2020 Jan-Jun	2019 Jan-Jun	2019 Jan-Dec	2019-2020 Apr-Jun Δ
Net revenues	179.1	201.2	354.2	375.5	844.8	-11%
Cost of goods sold	-19.9	-31.3	-39.9	-56.6	-105.6	-36%
Operating expenses	-172.5	-117.1	-293.6	-265.1	-508.0	47%
EBIT	-13.3	52.8	20.7	53.8	231.2	-125%
EBIT margin, %	-7,4	26.2	5.8	14.3	27.4	-33.7 ppt
EBITDA	-9.0	60.4	30.1	72.3	272.1	-115%
Earnings per share, before dilution, SEK	-0.94	1.54	1.44	1.93	6.33	-161%
Earnings per share, after dilution, SEK	-0.94	1.51	1.44	1.90	6.20	-162%
Cash flow from operating activities	-7.2	46.1	40.9	97.1	287.0	-116%
Cash and cash equivalents	677.2	697.0	677.2	697.0	816.8	-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 2019.

Content

About 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 2019 amounted to SEK 845 m and the number of employees was 127. 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 3.00 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-q2-2020
Telephone: SE +46 8 56 64 27 06 UK +44 33 33 00 90 32 US + 1 83 35 26 83 47
The presentation material will be available on Orexo´s website prior to the audiocast.

Financial calendar
Interim Report Q3 2020 - November 4, 2020 at 8.00 am CET
Q4 incl. Full Year Report 2020 - January 28, 2020 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.

Accelerated US launch of digital therapies as a response to Covid-19

This quarter will forever be associated with a pandemic causing countries across the world to lockdown societies and impose restrictions which would have been unimaginable just a few months ago. The key priorities for 2020 have proceeded according to plan and to respond to the pressing need for clinically validated digital therapies we accelerated the launch of our digital therapies.

Disciplined investment sets stage for future growth
Since 2015 we have continuously strengthened the company´s financial position to ensure we have sufficient resources to invest for future growth. Entering the digital therapeutics space, which is set to become an integral part of the global healthcare landscape, was an important strategic decision to ensure the longer-term growth of the business. The Covid-19 pandemic, subsequent social distancing and wider economic impact, has accelerated Orexo's launch plans for its digital offering, designed to address the surge in associated mental health issues, such as depression and substance misuse, many of which have resulted in an increased number of deaths caused by overdoses.

The launch of our three new digital therapies during the next six months will require significant investment, the benefits of which will be seen longer-term, in line with increased adoption of digital therapeutics. As a result, Orexo has increased OPEX guidance to SEK 750-800 million in 2020 to finance the commercial launch and associated costs of establishing the company's new DTx venture. We estimate combined sales potential of our three digital products of USD 420-650 million five years post launch. Notwithstanding the investment required, Orexo is confident that digital health presents a compelling commercial opportunity, one in which Orexo is well placed to become a leading player in the key US market, and where sales of digital therapeutics are expected to vastly exceed existing revenues from ZUBSOLV®.

While we remain confident about the commercial potential of our DTx offering, we also realize the market for digital therapies is in its infancy. As such the company will maintain a flexible business model, adapting as required to ensure the new digital treatments are adopted and used optimally by patients. The move into the digital therapeutics market will benefit from our existing US infrastructure for our profitable pharmaceutical business, in addition to significant commercial synergies from the commercialization of ZUBSOLV®.

ZUBSOLV® resilience during Covid-19
We responded swiftly to the lock-down imposed in several states in the US and the entire field force has worked from home since mid March. We are pleased to report limited impact due to remote working but saw a slight loss of market share and volume in this period due to the continued decline in demand from United Health Group (UHG), following their decision to reimburse generics in July last year. The wider market for ZUBSOLV® showed an accelerated growth and ZUBSOLV® continued to grow in the "open business" segment year over year, but showed a minimal decline from last quarter of one percent. From July 1 the "open business" is expected to increase as ZUBSOLV® will be reimbursed by Medicaid Louisiana and we are confident the "open business" part of the market will grow when the payers finalize their formularies of reimbursed products for 2021. With the field force slowly returning to pre-Covid-19 working practices, improved market access and the decline in demand from UHG diminishing, we expect ZUBSOLV® to return to growth in the second half of the year. We see an increased uncertainty in the market and for ZUBSOLV® the development of the commercial segment is important

and here increased unemployment due to Covid-19 might continue to have negative impact on growth in this segment which will impact our opportunity to grow ZUBSOLV®.

I am pleased to see our US Pharma business continue to show strong profitability with the EBIT margin reaching 52 percent and a total EBIT contribution of SEK 89 m. The continued strong cash flow contribution from ZUBSOLV® is critical to ensure a strong financial base and continued investment in the business to drive future growth.

Positive results from OX125 study demonstrates value of proprietary nasal drug delivery platform
We continued to see pipeline progress, most recently with the announcement of positive results from the human pharmacokinetic (PK) study of OX125. Preliminary results indicate extensive and rapid absorption across all three OX125 formulations as well as good tolerability, supporting the viability of OX125 as a rescue medication for opioid overdose. The results again underline the applicability of Orexo's novel nasal delivery platform and I am pleased to report the first patent has been granted for this platform, strengthening our IP position and extending patent protection until 2039.

Investment in the pipeline increased as anticipated, as we progressed establishing a commercial supply chain for OX124, our rescue medication for opioid overdose, and the clinical study of OX125.

Summary and Outlook
The global crisis presented by Covid-19 has forced many businesses to significantly change the way they operate. At Orexo we have adapted our business model with agility, embracing the "new normal". With a foundation in our profitable pharmaceutical business, Orexo has been able to invest and act on opportunities where we are uniquely positioned to help millions of people suffering from mental illness, whether caused by depression, problematic alcohol misuse or opioid dependence. With our pipeline progressing and the launch our DTx offering I am very excited about our future journey.

Uppsala, Sweden, July 16, 2020

Nikolaj Sørensen
President and CEO

Financial information

Revenues

Total revenues amounted to SEK 179.1 m (201.2), of which ZUBSOLV® US revenues of SEK 172.5 m (184.4) while revenues, related to partner products, amounted to SEK 6.6 m (16.8). The decrease in ZUBSOLV® US revenues is driven by lower demand due to previously exclusive plans partly offset by increased wholesaler stocking levels, adjustment of lower product returns, improved pricing and favorable exchange rates.

Costs of goods sold

Cost of goods sold (COGS) amounted to SEK 19.9 m (31.3), explained by ZUBSOLV® US of SEK 19.3 m (31.3) and technical infrastructure costs of SEK 0.6 m (-) for deprexis® and vorvida®. The decrease in COGS versus Q2 2019 is explained by efficiency improvements in the supply chain.

Operating expenses

Selling expenses amounted to SEK 70.0 m (49.0). The increase over the same period last year is mainly explained by costs related to launch preparations for deprexis® and vorvida® in the US, in H2 2020.

Administrative expenses amounted to SEK 32.7 m (24.5). The increase versus the prior year is mainly explained by higher costs for the long-term incentive programs following positive share price development and fair value adjustment versus prior quarter. In the quarter Orexo converted earlier equity-settled long-term incentive programs to be cash-settled, based on changes in group policy for how such instruments are to be settled. This change in classification causes fair value changes of affected program instruments, driven mainly by changes in value of the underlying Orexo stock, to be reported through the income statement. The group also launched the new year of the incentive program.

Research and development costs amounted to SEK 62.6 m (43.5) for the quarter. The increase is explained by the clinical trial of OX125 and final development of OX124 towards registration in 2021.

Other operating income and expenses amounted to SEK -7.1 m (-0.1) for the quarter and are mainly explained by exchange-rate losses derived from revaluations of parent company balance sheet items in foreign currency, predominantly in USD.

Operating profit

Orexo's profitability reflects planned investments in digital therapeutics and in pipeline and EBITDA amounted to SEK -9.0 m (60.4).

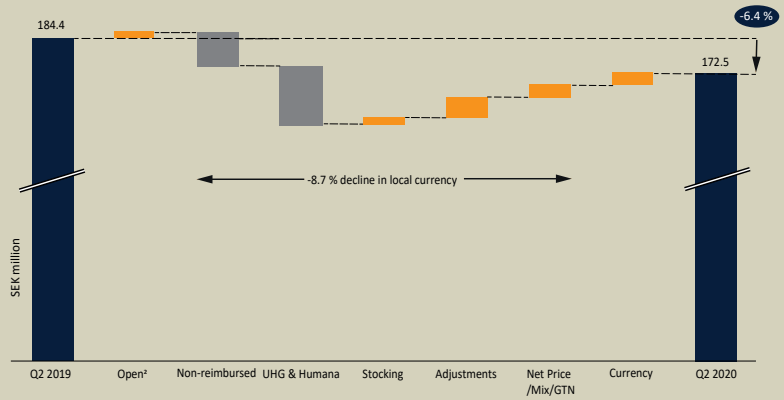
The EBIT contribution from US Pharma continued to grow and contributed to an EBIT improvement to SEK 88.8 m (83.8), equal to an EBIT margin of 51.5 percent (45.4).

Net financial items and tax

Net financial items amounted to SEK -22.2 m (5.7) mainly explained by negative unrealized exchange rate impact of SEK 18.2 m derived from the parent company's foreign currency bank accounts mainly in USD and by costs for corporate bonds of SEK 3.5 m.

US Pharma contributed with an EBIT improvement to SEK 88.8 m (83.8), equal to an EBIT margin of 51.5 percent (45.4).

ZUBSOLV® US NET REVENUES GROWTH BY KEY DRIVERS, Q2 2020 VERSUS Q2 2019[1]



[1] Orexo analysis using IMS demand data plus institutional sales
[2] Excluding cash segment and formulary changes (Wellcare, UHG and Humana)

Total tax expenses amounted to SEK 3.0 m (-3.9). Tax was positively impacted by a SEK 5.1 m (-2.4) adjustment to deferred tax assets related to temporary differences.

Orexo performs regular assessments of its deferred tax asset and makes adjustments according to the recognition requirements of IAS 12. No such adjustment was made for the quarter.

Net earnings

Net earnings amounted to SEK -32.5 m (54.6).

IFRS 16 Leases had a negative impact on net earnings of SEK -0.2 m (-0.3).

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 and HQ & Pipeline.[1]

US Pharma

ZUBSOLV® US net revenues amounted to SEK 172.5 m (184.4), corresponding to -6.4 percent decline in SEK and in local currency (USD) to -8.7 percent, equal to sales of USD 17.8 m (19.5).

Net revenues were negatively impacted by lower demand partly offset by improved pricing, adjustment of lower product returns and positive impact from stronger USD vs Q2 2019. Wholesaler inventory levels increased.

EBIT amounted to SEK 88.8 m (83.8) supported by lower Cost of goods sold and lower operating expenses versus Q2 2019.

Digital Therapeutics

EBIT amounted to SEK -35.5 m (0.0), mainly explained by initial costs related to building up of an organization and enterprise platform and to prepare for the launch of deprexis® and vorvida®.

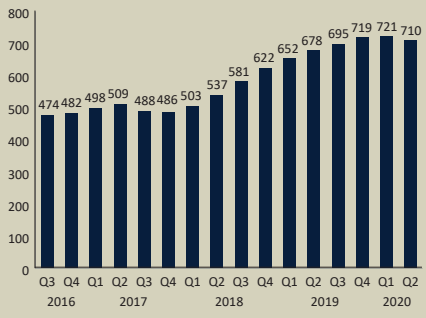
HQ & Pipeline

Partner revenues amounted to SEK 6.6 m (16.8) mainly explained by Abstral® royalties of SEK 3.5 m (13.1). Abstral® royalty for sales in Europe were received until December 31, 2019, when the European contract with Kyowa Kirin expired. Abstral® royalties for sales in the US were received until October 31, 2019, when Orexo's

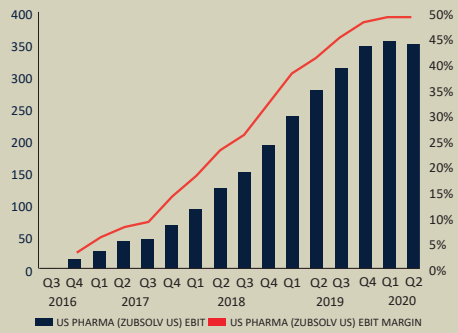
NET REVENUES AND OPERATING EARNINGS PER SEGMENT

SEK m	Net Revenues					EBIT				
	2020 Apr-Jun	2019 Apr-Jun	2020 Jan-Jun	2019 Jan-Jun	2019 Jan-Dec	2020 Apr-Jun	2019 Apr-Jun	2020 Jan-Jun	2019 Jan-Jun	2019 Jan-Dec
ZUBSOLV® US	172.5	184.4	336.4	346.1	719.2	-	-	-	-	-
US Pharma – total	**172.5**	**184.4**	**336.4**	**346.1**	**719.2**	**88.8**	**83.8**	**164.5**	**152.0**	**347.1**
Digital Therapeutics	-	-	-	-	-	-35.5	-	-47.6	-	-0.9
Digital Therapeutics– total	-	-	-	-	-	**-35.5**	**-**	**-47.6**	**-**	**-0.9**
Abstral® royalties	3.5	13.1	12.2	24.0	112.6	-	-	-	-	-
Edluar® royalties	3.1	2.4	5.5	4.2	11.6	-	-	-	-	-
ZUBSOLV® - ex US	-	-	0.1	-	0.1	**-**	-	-	-	**-**
OX-MPI	-	1.3	-	1.3	1.4	**-**	-	-	-	**-**
HQ & Pipeline segment – total	**6.6**	**16.8**	**17.8**	**29.4**	**125.6**	**-66.6**	**-31.0**	**-96.2**	**-98.1**	**-115.0**
Total	**179.1**	**201.2**	**354.2**	**375.5**	**844.8**	**-13.3**	**52.8**	**20.7**	**53.8**	**231.2**

US PHARMA (ZUBSOLV® US) NET REVENUES (LTM², SEK m)



US PHARMA (ZUBSOLV® US) EBIT AND EBIT MARGIN (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

partner Sentynl withdrew Abstral® from sale. Edluar® royalties of SEK 3.1 m (2.4).

EBIT amounted to SEK -66.6 m (-31.0) mainly explained by lower Abstral® royalties and higher development costs.

Cash, cash flow and net cash/debt

As of June 30, 2020, cash and cash equivalents amounted to SEK 677.2 m (697.0) and interest-bearing liabilities to SEK 223.8 m (321.3), i.e. a positive net cash position of SEK 453.4 m (375.7). In the quarter Orexo paid a non-refundable milestone to its partner GAIA AG for deprexis® and made a buyback of the corporate bond. The strong cash position enables Orexo to continue to pursue its strategy to progress the development pipeline and to pursue business development opportunities with the aim of adding more commercial stage products to the US commercial infrastructure.

Cash flow from operating activities amounted to SEK -7.2 m (46.1).

Investments

Gross investments in tangible and intangible fixed assets amounted to SEK 106.6 m (0.8). Higher investment is mainly explained by a payment of non-refundable milestone for deprexis® and by purchase of equipment for the development organization.

Equity

Shareholders' equity at June 30, 2020, was SEK 735.5 m (552.9). The equity/asset ratio was 50.3 percent (38.4).

Parent company

Net revenues amounted to SEK 131.4 m (101.2) for the quarter of which SEK 124.7 m (84.4) was related to sales to Group companies.

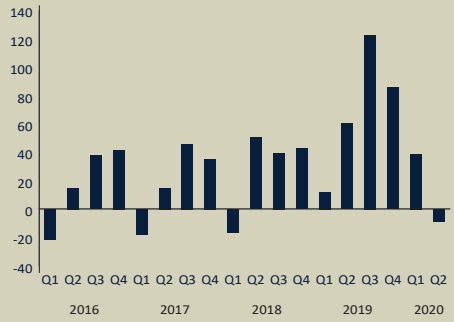
Earnings before tax were SEK -18.0 m (41.6).

Investments amounted to SEK 106.6 m (0.8).

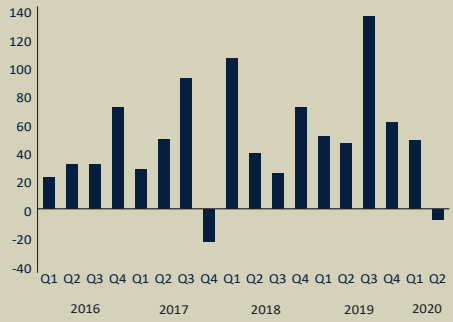
As of June 30, 2020, cash and cash equivalents in the parent company amounted to SEK 440.3 m (391.8).

Cash and cash equivalents amounted to SEK 677.2 m (697.0).

EBITDA, SEK m



CASH FLOW FROM OPERATING ACTIVITIES, SEK m



Operations

Commercial business

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

The Covid-19 lockdown in the US has had significant impact on sales force accessibility to waivered healthcare providers. The negative effect on operations has only had a limited negative impact on ZUBSOLV's existing sales. However, while the market demonstrated strong growth, ZUBSOLV's participation was limited due to the decreased access to healthcare providers and thereby inability to message on ZUBSOLV's advantages, to capitalize on the growth and the withdrawal of Sandoz authorized generic film from the market, which we had identified as an opportunity. Starting on March 16, Orexo ordered the discontinuation of all office-based field activity and initiated a virtual sales model, in which our sales representatives contacted customers via audio and video calls. As the states began to open for business post-lockdown Orexo gradually began to allow office based selling activities, beginning on June 1. As of the publishing of this report, all of our sales force is in the field and have physical meetings with healthcare providers, while continuing to conduct virtual sales calls to the large share of healthcare providers where access remains limited.

Sales development
Despite the Covid-19 lockdown ZUBSOLV® net revenues grew 5 percent over Q1 2020. Q2 2020 declined 9 percent over Q2 2019 in USD due mainly due to the formulary change impact at United Healthcare and Humana. Unit demand volume declined 4 percent over Q1 2020 and 18 percent over Q2 2019 respectively. Revenue growth in Q2 outpaced volume growth due to inventory adjustments in Q1 versus Q2 by the wholesalers. Additionally, Covid-19 had significant negative impact on US employment during the quarter resulting in flat volume in the commercial segment of the payer market versus last quarter thus impacting ZUBSOLV´s commercial volumes along with continued declines in the cash segment. Conversely, during Covid-19 lockdown period, the Medicaid segment of the market demonstrated greater growth than previous already strong growth trends. ZUBSOLV® did participate in this segment's growth, but not sufficient to cover the shortfall in the commercial and cash segments.

Market development
The market demonstrated strong growth of 15 percent in unit volume compared to Q2 2019, and 4 percent growth over Q1 2020. This year is the fastest market growth recorded thus far since the launch of ZUBSOLV® in September 2013. Relative to market unit volume growth, market prescription volume (total prescriptions) has remained almost flat with only 1 percent growth compared to Q2 2019. There are two reasons for this variance, one is a more recent phenomenon seen during Covid-19 related lockdowns, where patients received larger prescription sizes across all payer types to compensate for lack of accessibility to HCP office and pharmacy visits. The other reason, which has been highlighted for multiple quarters, is that in the cash segment of the market, prescription volume has not kept pace with unit volume growth as patients get larger script script sizes.

Open formulary business[1]
ZUBSOLV's open formulary business declined slightly by 1 percent over Q1 2020 and grew 2 percent over Q2 2019. Of the three open market segments, ZUBSOLV® grew in Medicaid in Q2 2020 versus Q1 2020, and declined in Commercial and Medicare D. Covid-19's impact on Commercial volumes created a more challenging environment for ZUBSOLV® to generate commercial growth. ZUBSOLV's growth over Q2 2019 is being driven by strong growth in the Public market segments with open Medicaid growing 7 percent and open Medicare D growing 8 percent, while the open Commercial segment remains flat. Within Commercial, Caremark and many regional payers had positive growth over Q2 2019. Within Medicaid, ZUBSOLV® continues to grow in the states it gained access to in 2019; Ohio, Texas,

ZUBSOLV®: of the publishing of this report, all of our sales force is in the field and have physical meetings with healthcare providers, while continuing to conduct virtual sales calls to the large share of healthcare providers where access remain limited.

[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.

Florida and Alabama. Within those states, ZUBSOLV® has grown Medicaid volume by 13 percent over Q1 2020, and 45 percent over of Q2 2019. ZUBSOLV® also continues to demonstrate strong growth over both Q1 2020 and Q2 2019 in some of the largest Medicaid states by ZUBSOLV® volume, such as Michigan and Illinois.

Earlier exclusive plans and non-reimbursed businesses
ZUBSOLV® volume in United Health Group and Humana has decreased 7 percent versus Q1 2020 and 35 percent versus Q2 2019. ZUBSOLV® volume in the non-reimbursed business, which includes WellCare and Pennsylvania Medicaid, has decreased 11 percent versus Q1 2020 and 34 percent versus Q2 2019. Humana Medicare D ZUBSOLV® volume has largely stabilized with its smallest quarter over quarter decline of 2 percent between Q2 2020 and Q1 2020.

Market access
ZUBSOLV® maintained its best-in-class coverage in the commercial segment at 98 percent. ZUBSOLV® coverage in the public segment had remained at 35 percent for Q2 and is increasing to 37 percent in Q3 due to the win in Louisiana Medicaid.

ZUBSOLV® in geographies outside the US
Due to Mundipharma Pty. Ltd has not succeeded in achieving reimbursement and listing of ZUBSOLV® on the Pharmaceutical Benefit Scheme (PBS) in Australia the commercial rights for ZUBSOLV® in Australia and New Zealand will be regained to Orexo.

For the EU market the ability to close collaborations with new potential partners will be dependent on the outcome of pricing discussions which are ongoing with authorities in multiple European countries.

Orexo has continued to work intensively to establish a streamlined supply chain outside the US as low cost of goods will be essential in response to the increasing price pressure from generics characterizing, foremost the EU market.

deprexis® US - digital therapy to manage symtoms of depression
vorvida® US - digital therapy for heavy alcohol use, incl. alcohol use disorder (AUD)

The Covid-19 pandemic, with social distancing and economic weakness, is expected to lead to a significant increase in mental health issues and substance use disorders. Recognizing the need for additional treatment solutions for rising mental health conditions during the pandemic, the FDA introduced an ”Enforcement Policy” in April 2020 with the aim of increasing access to digital therapies within the area of psychiatric disorders. Due to the vast patient need for access to low-risk clinically-validated digital health devices, the decision was taken to accelerate the launch of the DTx offering.

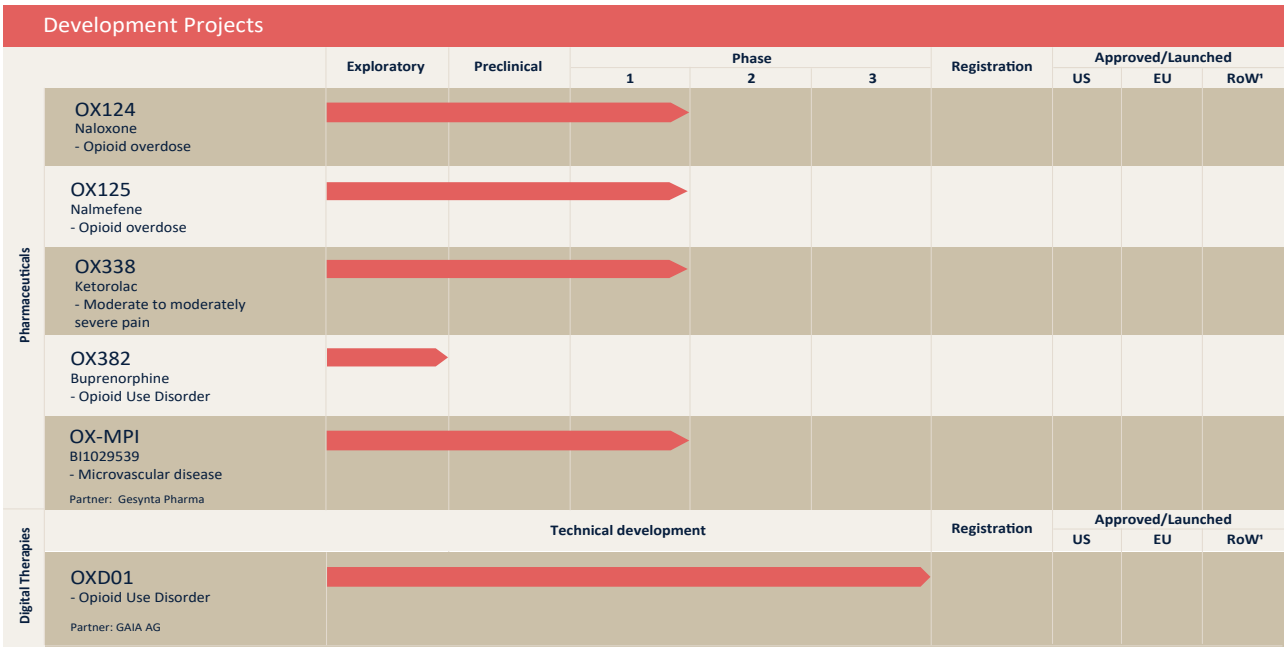
After the end of the period, on July 1, the scientifically proven digital therapy deprexis®, for the treatment of depression, was available for patients and vorvida®, to manage alcohol misuse, will be on July 20. Orexo’s development project OXD01, for the treatment of opioid use disorder, will be accelerated and tested in collaboration with selected customers in Q4 2020, in preparation for a broad launch in Q2, 2021, a year ahead of the original plan.

In the quarter all marketing and communication materials started to take shape. In order to deliver an optimal patient and customer experience, the work to build up several platforms and tools were initiated. Among others a specialty service hub for insurance reimbursement, e-commerce storefronts, and a tool for customer relationship management. These will be available in September when the broad launch of the first two digital therapies will take place. To facilitate promotion to eligible patients, providers, and payers the product information website meetdeprexis.com has been launched and meetvorvida.com will be available on July 20.

To leverage Orexo´s strong relationship with payers, negotiations were initiated to secure access and reimbursement with a selected group of payers. As access and reimbursement are established, Orexo will increase its sales force and marketing efforts to promote the products directly to relevant healthcare professionals.

DTx: To leverage Orexo´s strong relationship with payers, negotiations were initiated to secure access and reimbursement with a selected group of payers.

PIPELINE OF PHARMA AND DIGITAL THERAPY DEVELOPMENT PROJECTS



Development

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.

Our aim
Based on Orexo´s novel intranasal formulation technology, the aim is to develop a rescue medication that is faster and longer-acting, 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.

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

Changes during the quarter
In consultation with FDA, the work to prepare for the pivotal PK-bridging study in Q4 2020 is ongoing.

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.

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

Results from the exploratory PK-study in healthy volunteers showed extensive and rapid absorption of nalmefene across all three OX125 formulations.

[1] Rest of the World, excluding US and Europe

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.

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

Changes during the quarter
The results from the PK-study were delivered and showed extensive and rapid absorption across all three OX125 formulations as well as good tolerability, supporting the viability of OX125 as a rescue medication for opioid overdose. The study was a cross-over, comparative bioavailability study in healthy volunteers to assess nalmefene absorption from three development formulations, compared to a nalmefene intramuscular injection.

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
To ensure optimal product properties before progressing to the next stage of development the formulation work continued.

OX382 – opioid use disorder (OUD)

Unmet need
Today, buprenorphine products to treat OUD are only available in sublingual/buccal tablets and film formulations.

Our aim
Develop a formulation offering several advantages over currently available administrations routes for certain patient groups and treatment settings.

Financial potential
-

Differentiation
-

Changes during the quarter
Results from the in-vivo animal Proof of Concept study conducted in Q1 2019 did not support progressing the current oral formulation into clinical phase. Options for continued development, assessing other formulation options, are ongoing.

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
The study results from the first human PK-study showed OX-MPI was safe and well tolerated with a pharmacokinetic profile supporting once daily dosing and with potent and durable effects on relevant anti-inflammatory and vasoprotective biomarkers.
The study was designed to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of single oral doses up to 300 mg and multiple once daily doses up to 180 mg for 10 days in healthy male and female subjects.
After the end of the quarter Gesynta communicated the finalization of a new funding round enabling to enter a phase 2 study in patients suffering from systemic sclerosis in Q4 2020.

OX-MPI: After the end of the quarter Gesynta communicated the finalization of a new funding round enabling to enter a phase 2 study in patients suffering from systemic sclerosis in Q4 2020.

OXD01 – opioid use disorder (OUD)

Unmet need
Access to consistent high-quality counselling is a growing bottleneck in treatment of OUD. Medical assisted treatment should be complemented with psychosocial support.

Our aim
Develop the first digital therapy showing significant sustainable positive outcome on patients' treatment of OUD and make it available globally.

Differentiation
A fully automated digital therapy scientifically proven to improve treatment of OUD, alongside traditional medication treatments.

Financial potential
Net sales USD 150-225 m (US market).

Changes during the quarter
The product development of the new digital therapy continued and among others a first testing with a group of patients in recovery from opioids was conducted with first product compounds. The outcome reported strong results on all measures such as program design, language and understandability, as well as media and length of the interactions.

OXD01: The outcome of the first formative study reported strong results on all measures such as program personality, language and understandability as well as media and length of the interactions.

Other information

Financial outlook 2020

• The buprenorphine/naloxone market will continue to show a double-digit growth
• ZUBSOLV® US net sales are expected to be in line with 2019. The open businesses will grow, whilst the previously highly rebated exclusive segments, including cash, will decrease.
• Due to increased R&D investments, establishment of DTx business and accelerated DTx US launch OPEX will reach a level of SEK 750-800 m
• Due to a decrease in Abstral® royalties 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
• US Pharma EBIT margin will be in the range of 45-50 percent
• Covid-19 has increased the uncertainty in the outlook
• The financial outlook is based on exchange rates in December 2019

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 development and ZUBSOLV® sales in 2020.

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 16, 2020
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 Coplman 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	2020 Apr-Jun	2019 Apr-Jun	2020 Jan-Jun	2019 Jan-Jun	2019 Jan-Dec
Net revenues	9	179.1	201.2	354.2	375.5	844.8
Cost of goods sold		-19.9	-31.3	-39.9	-56.6	-105.6
Gross profit		**159.2**	**169.9**	**314.3**	**318.9**	**739.2**
Selling expenses		-70.0	-49.0	-124.4	-96.3	-191.9
Administrative expenses		-32.7	-24.5	-56.5	-94.6	-139.6
Research and development expenses		-62.6	-43.5	-115.6	-81.2	-181.3
Other operating income and expenses		-7.1	-0.1	2.9	6.9	4.8
Operating earnings (EBIT)		**-13.3**	**52.8**	**20.7**	**53.8**	**231.2**
Net financial items		-22.2	5.7	21.8	10.5	-3.3
Earnings before tax		**-35.5**	**58.5**	**42.5**	**64.3**	**227.9**
Tax	5	3.0	-3.9	7.6	4.3	-8.8
Net earnings for the period[1]		**-32.5**	**54.6**	**50.1**	**68.6**	**219.1**
Earnings per share, before dilution, SEK		-0.94	1.54	1.44	1.93	6.33
Earnings per share, after dilution, SEK		-0.94	1.51	1.44	1.90	6.20

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

SEK m	2020 Apr-Jun	2019 Apr-jun	2020 Jan-Jun	2019 Jan-Jun	2019 Jan-Dec
Earnings for the period	**-32.5**	**54.6**	**50.1**	**68.6**	**219.1**
Other comprehensive income					
Items that may subsequently be reversed to the statement of operations:					
Exchange-rate differences	-9.4	0.5	-0.1	3.7	3.4
Other comprehensive earnings for the period, net after tax	**-9.4**	**0.5**	**-0.1**	**3.7**	**3.4**
Total comprehensive earnings for the period[1]	**-41.9**	**55.1**	**50.0**	**72.3**	**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 Jun 30	2019 Jun 30	2019 Dec 31
ASSETS			
Fixed assets			
Tangible fixed assets	23.3	19.4	22.0
Intangible fixed assets	213.5	95.5	113.9
Right-of-use assets	70.3	65.5	57.0
Deferred tax assets	98.1	110.2	85.5
Other financial assets	0.8	10.8	1.4
Total fixed assets	**406.0**	**301.4**	**279.9**
Current assets			
Inventories	126.2	150.6	131.8
Accounts receivable and other receivables	253.6	291.1	272.6
Cash and cash equivalents	677.2	697.0	816.8
Total current assets	**1,057.0**	**1,138.7**	**1,221.2**
Total assets	**1,463.0**	**1,440.1**	**1,501.1**
SHAREHOLDERS' EQUITY AND LIABILITIES			
Total shareholders' equity	**735.5**	**552.9**	**706.4**
Long-term liabilities			
Provisions	10.5	7.8	10.7
Long-term liabilities, interest bearing	223.8	321.3	289.6
Lease liabilities, long-term	48.8	42.0	33.3
Total long-term liabilities	**283.0**	**371.2**	**333.6**
Current liabilities and provisions			
Provisions	229.9	298.4	269.3
Current liabilities, non-interest bearing	194.8	196.9	170.5
Lease liabilities, current	19.8	20.8	21.4
Total current liabilities and provisions	**444.5**	**516.0**	**461.1**
Total liabilities	**727.5**	**887.2**	**794.7**
Total shareholders' equity and liabilities	**1,463.0**	**1,440.1**	**1,501.1**

CONSOLIDATED CHANGES IN SHAREHOLDERS' EQUITY

SEK m	2020 Jun 30	2019 Jun 30	2019 Dec 31
Opening balance, shareholders' equity	**706.4**	**476.1**	**476.1**
Total comprehensive earnings for the period	50.0	72.3	222.5
Share-based payments	6.4	4.4	5.8
Buy back of shares	-27.3	—	—
New share issue	—	—	2.0
Closing balance, shareholders' equity	**735.5**	**552.9**	**706.4**

CONDENSED CONSOLIDATED CASH FLOW STATEMENTS

SEK m	Notes	2020 Apr-Jun	2019 Apr-Jun	2020 Jan-Jun	2019 Jan-Jun	2019 Jan-Dec
Operating earnings (EBIT)		-13.3	52.7	20.7	53.8	231.2
Interest received		1.0	2.6	3.8	4.7	9.9
Interest paid		-3.9	-3.6	-7.3	-7.4	-17.7
Income taxes paid		-0.4	-9.2	-0.8	-9.2	-12.2
Adjustment for non-cash items	3	-13.1	21.2	-21.2	44.1	41.3
Cash flow from operating activities before changes in working capital		**-29.7**	**63.8**	**-4.8**	**86.1**	**252.5**
Changes in working capital		**22.5**	**-17.6**	**45.7**	**11.0**	**34.5**
Cash flow from operating activities		**-7.2**	**46.1**	**40.9**	**97.1**	**287.0**
Acquisition of tangible and intangible fixed assets		-106.6	-0.8	-110.5	-0.8	-32.0
Acquisition of financial assets		—	—	—	—	—
Disposal of financial assets		0,6	—	0.6	—	9.5
Cash flow from investing activities		**-106.0**	**-0.8**	**-109.9**	**-0.8**	**-22.4**
New share issue		—	—	—	—	2.0
Buy back shares		-2.9	—	-27.3	—	—
Repayment of loans		-31.1	-3.8	-75.4	-14.5	-55.8
Cash from financing activities		**-33.9**	**-3.8**	**-102.7**	**-14.5**	**-53.7**
Cash flow for the period		**-147.1**	**41.6**	**-171.7**	**81.7**	**210.8**
Cash and cash equivalents at the beginning of the period		**861.4**	**647.4**	**816.8**	**589.8**	**589.8**
Exchange-rate differences in cash and cash equivalents		-37.1	8.1	32.1	25.5	16.1
Changes in cash and cash equivalents		-184.2	49.7	-139.6	107.2	227.0
Cash and cash equivalents at the end of the period		**677.2**	**697.0**	**677.2**	**697.0**	**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 Apr-Jun	2019 Apr-Jun	2020 Jan-Jun	2019 Jan-Jun	2019 Jan-Dec
EBIT margin, %	-7.4	26.2	5.8	14.3	27.4
Return on shareholder equity, %	31.0	10.4	6.9	13.3	37.1
Net debt, SEK m	-527.2	-375.7	-453.4	-375.7	-527.2
Debt/equity ratio, %	41.0	58.1	30.4	58.1	41.0
Equity/assets ratio, %	50.3	38.4	50.3	38.4	47.1
Number of shares, before dilution	34 710 639	35 498 310	34 710 639	35 498 310	34,621,646
Number of shares, after dilution	34 710 639	36 153 872	34 710 639	36 153 872	35,348,484
Earnings per share, before dilution, SEK	-0.94	1.54	1.44	1.93	6.33
Earnings per share, after dilution, SEK	-0.94	1.51	1.44	1.90	6.20
Number of employees at the end of the period	136	130	136	130	127
Shareholders' equity, SEK m	735.5	552.9	735.5	552.9	706.4
Capital employed, SEK m	959.2	874.3	959.2	874.3	996.0
Working capital, SEK m	-64.7	-74.4	-64.7	-74.4	-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 Apr-Jun	2019 Apr-Jun	2020 Jan-Jun	2019 Jan-Jun	2019 Jan-Dec
Net revenues		131.4	101.2	268.9	218.0	534.0
Cost of goods sold		-25.9	-23.0	-45.5	-50.3	-98.6
Gross profit		**105.5**	**78.2**	**223.4**	**167.7**	**435.3**
Selling expenses		-38.6	-2.1	-62.5	-5.0	-6.6
Administrative expenses		-22.0	-16.4	-34.6	-78.9	-105.6
Research and development costs		-49.6	-36.1	-92.3	-66.5	-152.3
Other operating income and expenses		8.1	13.5	31.4	35.6	67.2
Operating earnings (EBIT)		**3.4**	**37.0**	**65.4**	**52.8**	**238.0**
Interest income and expenses		-3.2	-2.9	-5.7	-6.3	40.0
Other financial income and expenses		-18.3	7.5	28.0	14.7	-46.9
Net financial items		**-21.5**	**4.6**	**22.3**	**8.4**	**-6.9**
Earnings before tax		**-18.0**	**41.6**	**87.7**	**61.2**	**231.1**
Tax	5	0.0	0.0	0.0	0.0	-11.8
Earnings for the period		**-18.0**	**41.6**	**87.7**	**61.2**	**219.3**

PARENT COMPANY STATEMENT OF COMPREHENSIVE INCOME

SEK m	2020 Apr-Jun	2019 Apr-Jun	2020 Jan-Jun	2019 Jan-Jun	2019 Jan-Dec
Earnings for the period	**-18.0**	**41.6**	**87.7**	**61.2**	**219.3**
Other comprehensive income	—	—	—	—	—
Total comprehensive earnings for the period	**-18.0**	**41.6**	**87.7**	**61.2**	**219.3**

CONDENSED PARENT COMPANY BALANCE SHEET

SEK m	2020 Jun 30	2019 Jun 30	2019 Dec 31
ASSETS			
Fixed assets			
Intangible fixed assets	213.5	95.5	113.9
Tangible fixed assets	23.3	19.4	22.0
Deferred tax assets	49.0	60.9	49.0
Shares in subsidiaries	162.5	153.4	155.6
Total fixed assets	**448.4**	**329.2**	**340.6**
Current assets			
Inventories	101.8	133.7	113.4
Accounts receivable and other receivables	180.6	135.3	214.1
Cash and bank balances	440.3	391.8	469.0
Total current assets	**722.7**	**660.8**	**796.5**
Total assets	**1,171.1**	**990.0**	**1,137.1**
SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES			
Shareholders' equity	**710.8**	**482.7**	**644.0**
Long-term liabilities			
Other provisions	8.3	5.5	8.2
Bond loan	223.8	321.3	289.6
Total long-term liabilities	**232.0**	**326.8**	**297.8**
Current liabilities			
Accounts payable	25.4	12.1	22.8
Other liabilities	8.1	7.0	6.0
Liabilities to Group companies	171.6	137.6	144.7
Accrued expenses and deferred income	23.2	23.8	21.8
Total current liabilities	**228.3**	**180.5**	**195.3**
Total liabilities	**460.3**	**507.3**	**493.1**
Total shareholders' equity and liabilities	**1,171.1**	**990.0**	**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 with exception for new and updated standards and interpretations described below.

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, Corporate Development, Global Regulatory and Supply Chain. Net revenues comprises all partner revenues for ZUBSOLV® – ex US, Abstral® and Edluar®.

Comparative figures have been restated.

DISTRIBUTION OF REVENUE AND EBIT PER SEGMENT

SEK m	2020 Apr-Jun	2019 Apr-Jun	2020 Jan-Jun	2019 Jan-Jun	2019 Jan-Dec
US Pharma					
Net revenues	172.5	184.4	336.4	346.1	719.2
Operating earnings (EBIT)	88.8	83.8	164.5	152.0	347.1
Digital Therapeutics					
Net revenues	0.0	0.0	0.0	0.0	0.0
Operating earnings (EBIT)	-35.5	0.0	-47.6	0.0	-0.9
HQ & Pipeline					
Net revenues	6.6	16.8	17.8	29.4	125.6
Operating earnings (EBIT)	-66.6	-31.0	-96.2	-98.1	-115.0
Group					
Net revenues	179.1	201.2	354.2	375.5	844.8
Operating earnings (EBIT)	-13.3	52.8	20.7	53.8	231.2
Net financial items	-22.2	5.7	21.8	10.5	-3.3
Earnings before tax	-35.5	58.5	42.5	64.3	227.9

3. Cash flow

ADJUSTMENT FOR NON-CASH ITEMS

SEK m	2020 Apr-Jun	2019 Apr-Jun	2020 Jan-Jun	2019 Jan-Jun	2019 Jan-Dec
Depreciation/amortization and impairment	9.4	7.6	18.1	18.5	41.0
Change in provisions	-33.7	12.1	-41.9	24.6	-2.7
Share based payments	5.0	1.3	6.4	4.4	5.8
Exchange rate income and expenses	6.2	0.1	-3.9	-3.4	-2.7
Total	**-13.1**	**21.2**	**-21.2**	**44.1**	**41.3**

4. Legal disputes

No disputes as of June 30.

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 1,180 m as of December 31 2019 and refers to the Swedish companies. Deferred tax assets of SEK 49.0 m for tax-loss carry-forwards have been capitalized as per June 30, 2019, 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

- The US launch of the scientifically proven digital therapies deprexis® and vorvida® was initiated
- Updated financial outlook 2020 as OPEX expects to reach a level of SEK 750-800 m for FY 2020 due to establishment of DTx business and accelerated US launch of digital therapies
- 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.

9. Revenue from contracts with customers

SEK m	2020 Apr-Jun				
Segment	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**OX-MPI**	**Total**
US Pharma	172.5	—	—	—	**172.5**
Digital Therapeutics	—	—	—	—	**0.0**
HQ & Pipeline	—	3.5	3.1	—	**6.6**
Total revenue from contracts with customers	**172.5**	**3.5**	**3.1**	**0.0**	**179.1**
Geographical markets	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**OX-MPI**	**Total**
US	172.5	—	0.9	—	**173.4**
EU & UK	—	3.3	0.6	—	**3.9**
Rest of the world	—	0.3	1.6	—	**1.9**
Total revenue from contracts with customers	**172.5**	**3.5**	**3.1**	**0.0**	**179.1**

SEK m	2019 Apr-Jun				
Segment	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**OX-MPI**	**Total**
US Pharma	184.4	—	—	—	**184.4**
Digital Therapeutics	—	—	—	—	**0.0**
HQ & Pipeline	—	13.1	2.4	1.3	**16.8**
Total revenue from contracts with customers	**184.4**	**13.1**	**2.4**	**1.3**	**201.2**
Geographical markets	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**OX-MPI**	**Total**
US	184.4	1.0	1.2	—	**186.6**
EU	—	10.9	0.3	1.3	**12.5**
Rest of the world	—	1.1	1.0	—	**2.1**
Total revenue from contracts with customers	**184.4**	**13.1**	**2.4**	**1.3**	**201.2**

9. Revenue from contracts with customers

SEK m	2020 Jan-Jun				
Segment	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**OX-MPI**	**Total**
US Pharma	336.4	—	—	—	**336.4**
Digital Therapeutics	—	—	—	—	**0.0**
HQ & Pipeline	0.1	12.2	5.5	—	**17.8**
Total revenue from contracts with customers	**336.5**	**12.2**	**5.5**	**0.0**	**354.2**
Geographical markets	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**OX-MPI**	**Total**
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**
Total revenue from contracts with customers	**336.5**	**12.2**	**5.5**	**0.0**	**354.2**

SEK m	2019 Jan-Jun				
Segment	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**OX-MPI**	**Total**
US Pharma	346.1	—	—	—	**346.1**
Digital Therapeutics	—	—	—	—	**0.0**
HQ & Pipeline	—	24.0	4.2	1.3	**29.4**
Total revenue from contracts with customers	**346.1**	**24.0**	**4.2**	**1.3**	**375.5**
Geographical markets	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**OX-MPI**	**Total**
US	346.1	2.3	1.6	—	**350.0**
EU	—	20.3	0.8	1.3	**22.4**
Rest of the world	—	1.4	1.8	—	**3.2**
Total revenue from contracts with customers	**346.1**	**24.0**	**4.2**	**1.3**	**375.5**

SEK m	2019 Jan-Dec				
Segment	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**OX-MPI**	**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**	**844.8**
Geographical markets	**ZUBSOLV®**	**Abstral®**	**Edluar®**	**OX-MPI**	**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**	**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 Apr-Jun	2019 Apr-Jun	2020 Jan-Jun	2019 Jan-Jun	2019 Jan-Dec
EBIT	-13.3	52.8	20.7	53.8	231.2
Depreciation and amortization	4.3	7.6	9.4	18.5	40.9
EBITDA	**-9.0**	**60.4**	**30.1**	**72.3**	**272.1**
DTx costs	35.5	-	47.6	-	0.9
EBITDA excluding DTx costs	**26.5**	**60.4**	**77.7**	**72.3**	**273.0**

RETURN ON SHAREHOLDERS' EQUITY	2020 Apr-Jun	2019 Apr-Jun	2020 Jan-Jun	2019 Jan-Jun	2019 Jan-Dec
Shareholders' equity beginning balance	775.3	496.6	706.4	476.1	476.1
Shareholders' equity ending balance	735.5	552.9	735.5	552.9	706.4
Average shareholders' equity	755.4	524.8	721.0	514.5	591.3
Net earnings	-32.5	54.6	50.1	68.6	219.1
Return on shareholders' equity %	**-4.3**	**10.4**	**6.9**	**13.3**	**37.1**

OPERATING EXPENSES SEK m	2020 Apr-Jun	2019 Apr-Jun	2020 Jan-Jun	2019 Jan-Jun	2019 Jan-Dec
Selling expenses	-70.0	-49.0	-124.4	-96.3	-191.9
Administrative expenses	-32.7	-24.5	-56.5	-94.6	-139.6
Research and development costs	-62.6	-43.5	-115.6	-81.2	-181.3
Other operating income and expenses	-7.1	-0.1	2.9	6.9	4.8
Operating expenses	**-172.5**	**-117.1**	**-293.6**	**-265.1**	**-508.0**

GROSS INVESTMENTS SEK m	2020 Apr-Jun	2019 Apr-Jun	2020 Jan-Jun	2019 Jan-Jun	2019 Jan-Dec
Investments in tangible fixed assets	-1.0	0.7	2.8	0.7	5.0
Investments in intangible fixed assets	107.6	0.1	107.7	0.1	27.0
Gross investments	**106.6**	**0.8**	**110.5**	**0.8**	**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