Interim Report Q1 2020

A good start to the year despite COVID-19

Q1 2020 highlights

- Total net revenues of SEK 175.0 m (174.3), up 0.4 percent
- EBITDA of SEK 39.1 m (12.0), up 225.8 percent
- Net earnings of SEK 82.6 m (14.1), up 485.8 percent
- US Pharma (Zubsolv® US) net revenues of SEK 163.9 m (161.7), up 1.3 percent in SEK and -4.0 percent in local currency. HQ & Pipeline net revenues of SEK 11.1 m (12.6).
- US Pharma (Zubsolv US) EBIT of SEK 75.9 m (68.2), up 11.2 percent, Digital Therapeutics EBIT of SEK -12.0 m (-) and HQ & Pipeline EBIT of SEK -29.9 m (-67.1)
- Cash flow from operating activities of SEK 48.1 m (50.9), building a cash balance of SEK 861.4 m (647.4)
- OX338 showed promising results from the human PK-study, assessing novel ketorolac formulations for treatment of pain
- Application for vorvida® submitted to FDA to enable commercialization in the US
- Net sales potential for the development projects were communicated in connection to the company´s Capital Markets Day, see Operations/pharmaceuticals and digital therapies
- Repurchased 14 percent of the company´s outstanding corporate bonds with a nominal value of SEK 40.5 m

Important events after the end of the period

- Completed the program to repurchase 500,000 of the company´s ordinary shares, equalling to approx. 1.4 percent of the total issued ordinary shares in the company
- 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.
- Financial outlook 2020 is reiterated

SEK 82.6 m
Net earnings

46%
EBIT margin from Zubsolv® US

SEK 861.4 m
Cash and cash equivalents (SEK 48.1 m from operating activities in Q1)

SEK m, unless otherwise stated	2020 Jan-Mar	2019 Jan-Mar	2019 Jan-Dec	Δ 2019-2020
Net revenues	175.0	174.3	844.8	0.4%
Cost of goods sold	-20.0	-25.3	-105.6	-21%
Operating expenses	-121.1	-147.9	-508.0	-18%
EBIT	34.0	1.1	231.2	2991%
EBIT margin, %	19.4	0.6	27.4	18.8 ppt
EBITDA	39.1	12.0	272.1	226%
Earnings per share, before dilution, SEK	2.38	0.41	6.33	483%
Earnings per share, after dilution, SEK	2.34	0.40	6.20	484%
Cash flow from operating activities	48.1	50.9	287.0	-5.6%
Cash and cash equivalents	861.4	647.4	816.8	33%

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 mainly within the growing space of addiction. 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
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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-q1-2020
Telephone: SE +46 8 50 55 83 55 UK +44 33 33 00 92 73 US +1 83 38 23 05 89
The presentation material will be available on Orexo´s website prior to the audiocast.

Financial calendar
Interim Report Q2 2020 - July 16, 2020 at 8.00 am CET
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.

Resilient business driving continued growth in challenging times

I am pleased to report a solid financial performance for the first quarter with both profitability and cash improving. This reflects the progress at our US Pharma operations with an EBIT contribution margin of 46 percent. The impact of COVID-19 has, both operationally and financially, been limited at this stage. Longer-term we anticipate demand for addiction treatments will increase alongside accelerated adoption of digital therapies as a consequence of the COVID-19 pandemic.

Significant continued improvement in cash position – SEK 39 m in EBITDA and SEK 861 m in cash

Our Q1 performance is in line with expectations, with a decline in the demand for Zubsolv® due to generic competition in some previously exclusive contracts with United Health Group and Humana. The reduction in sales volume has been offset by higher average net prices, a reduction in product returns and improved gross margins. Early indicators suggest COVID-19 is impacting market dynamics, resulting in an increase in the average prescription size and an uptick in demand for Zubsolv® was seen during March. This partially reflects increased inventory build but feedback from the market also indicates a higher demand for treatment as access to illegal drugs declines. Longer-term the COVID-19 pandemic is expected to increase demand for addiction treatment, in line with previously challenging economic market conditions, which saw an increase in substance misuse.

One effect of the uncertainty caused by COVID-19 has been a weakening of the SEK. With all of our revenues and EBIT contribution from our US operations being USD denominated this translates into a positive impact on Orexo's financial results. We have leveraged this opportunity to reduce exposure to USD, through repurchasing of our corporate bond and of 500,000 shares, and realizing an exchange rate gain of SEK 29 m.

Digital Therapies – high growth opportunity with potential to increase access to treatment

The impact from COVID-19 is already being felt by most businesses but for some it presents an opportunity to accelerate the adoption of new technologies including video conferencing and digital health. Orexo, with its increasing focus on digital therapeutics, could play an important role in providing treatments for patients at a time when COVID-19 is severely impacting access to treatment. Subject to receiving FDA clearance for vorvida®, a digital therapy designed to offer patients high quality psychotherapy to treat harmful alcohol misuse, Orexo will review opportunities for an accelerated launch.

During the quarter we hosted a Capital Markets Day and provided some additional insights on the market potential and initial investment required to develop our digital therapeutics offering. Digital therapies are still in their infancy in terms of market adoption but present an attractive market opportunity. Based on Orexo's conservative estimates we believe vorvida® and OXD01, for the treatment of opioid use disorder, have a combined revenue potential which could exceed USD 400 m.

In light of COVID-19 and changes to market access for digital therapies, we will consider investing in an earlier and broader launch, if the opportunity exists for both vorvida® and OXD01.

R&D – promising pipeline of next wave therapeutics to address growing market opportunity

Our pipeline development remains on track at present and we plan to initiate the first exploratory study for OX125 in H1 2020 and the pivotal trial for OX124 late in H2 this year. Both projects are rescue medications for the treatment of opioid overdose and are based on new and unique technologies involving partners in different geographies. If COVID-19 continues indefinitely and travel restrictions remain in place, this could impact trial timelines.

During the Capital Markets Day we also provided analysis of the revenue potential of our pipeline, including the combined potential of OX124 and OX125, estimated at USD 110-170 m in the current market environment. The market opportunity for OX338, our phase I candidate for the treatment of pain without using opioids, is harder to estimate as it applies to a very broad market, but is conservatively valued at USD 100 m. I am pleased with our pipeline development to date and expect to file for regulatory approval of OX124 as early as next year, a product which has the potential to exceed Zubsolv® revenues and could become an important growth driver for Orexo.

Summary and Outlook

I am very proud of how the Orexo team has responded to the global crisis presented by COVID-19, minimizing to date any material negative impact on our business whilst also ensuring the safety of our employees and partners. We will continue to monitor government guidance including US lockdown measures, which may impact our financial outlook if they continue into H2 2020. That said Orexo is a profitable and well-funded business with a promising pipeline of next-generation treatments, including innovative digital therapies, and is well placed to weather the current challenges posed by COVID-19.

Uppsala, Sweden, April 28, 2020

Nikolaj Sørensen
President and CEO

Financial information

Revenues

Total revenues amounted to SEK 175.0 m (174.3) for the quarter, of which Zubsolv® US revenues of SEK 163.9 m (161.7) while revenues, related to partner products, amounted to SEK 11.1 m (12.6). The minor increase in Zubsolv US revenues is driven by improved pricing, by adjustment of lower product returns and by favorable exchange rates.

Costs of goods sold

Cost of goods sold (COGS) amounted to SEK 20.0 m (25.3) for the quarter, all related to Zubsolv US.

Operating expenses

Selling expenses amounted to SEK 54.6 m (47.2) for the quarter. The increase over the same period last year is mainly explained by costs related to preparations to launch vorvida® in the US, in H2 2020.

Administrative expenses amounted to SEK 23.7 m (70.1). The decrease versus the prior year is explained by lower legal expenses. Legal expenses for IP litigations reached SEK 0.1 m (48.8) for the quarter.

Research and development costs amounted to SEK 52.9 m (37.6) for the quarter. The increase is mainly related to development projects.

Other operating income and expenses amounted to SEK 10.1 m (7.0) for the quarter and are mainly explained by exchange-rate gains derived from revaluations of parent company balance sheet items in foreign currency, predominantly in USD.

Operating profit

Orexo's profitability remained strong and EBITDA amounted to SEK 39.1 m (12.0) for the quarter due to growing contribution from the Zubsolv US, supported by lower COGS and no spending on IP litigations.

The EBIT contribution continued to grow, driven by Zubsolv US growth and reduction of COGS. Zubsolv US contributed to an EBIT improvement to SEK 75.9 m (68.2), equal to an EBIT margin of 46.3 percent (42.2).

Net financial items and tax

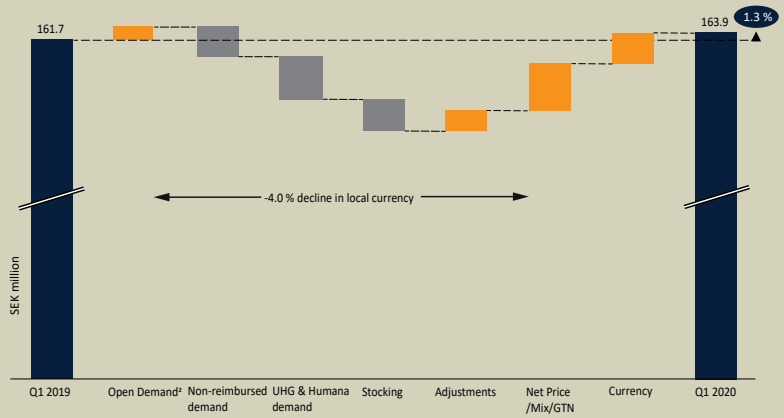
Net financial items amounted to SEK 44.0 m (4.8) for the quarter mainly explained by realised exchange-rate gain of SEK 29.0 m from converting funds from USD to SEK and by positive unrealized exchange rate impact of SEK 12.3 m derived from the parent company's foreign currency bank accounts mainly in USD. Earned interest contributed with SEK 1.6 m and the buyback of corporate bonds had a positive impact of SEK 1.1 m.

Total tax expenses amounted to SEK 4.6 m (8.2) for the quarter. Tax for the quarter was positively impacted by a SEK 7.2 m (9.3) 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.

Zubsolv US contributed with an EBIT improvement to SEK 75.9 m (68.2), equal to an EBIT margin of 46.3 percent (42.2).

ZUBSOLV US NET REVENUES GROWTH BY KEY DRIVERS, Q1 2020 VERSUS Q1 2019[1]



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

Net earnings

Net earnings for the quarter amounted to SEK 82.6 m (14.1).

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

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 for the quarter amounted to SEK 163.9 m (161.7), corresponding to 1.3 percent growth in SEK. In local currency (USD) the equivalent growth rate was -4.0 percent, equal to sales of USD 16.9 m (17.6).

Net revenues for the quarter were positively impacted by improved pricing, by a SEK 6.8 m adjustment of lower product returns and by a SEK 8.7 m positive impact from stronger USD vs Q1 2019. Wholesaler inventory levels decreased by SEK 9.1 m during the quarter.

EBIT amounted to SEK 75.9 m (68.2) supported by lower Cost of goods sold and stronger USD vs Q1 2019.

Digital Therapeutics

EBIT amounted to SEK -12.1 m (0.0) during the quarter, explained by initial costs related to building up of an organization and enterprise platform for the segment.

HQ & Pipeline

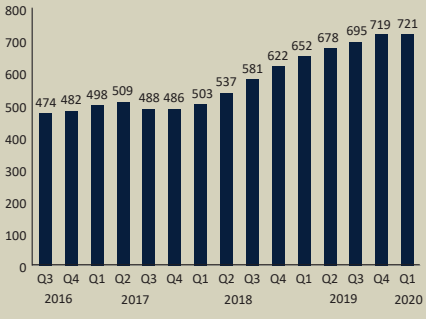
Partner revenues for the quarter amounted to SEK 11.1 m (12.6) explained by Abstral® royalties of SEK 8.6 m (10.9). Abstral royalty for sales in Europe were received until December 31, 2019, when the European contract with Kyowa Kirin expired. Abstral royalties for sales in the US were received until October 31, 2019, when Orexo's partner Sentynl withdrew Abstral from sale. Edluar® royalties of SEK 2.4 m (1.7)

EBIT for the quarter amounted to SEK -29.9 m (-67.1) mainly explained by lower legal expenses for IP litigations of SEK 0.1 m (48.8) while research and development costs amounted to SEK 38.4 m (23.3).

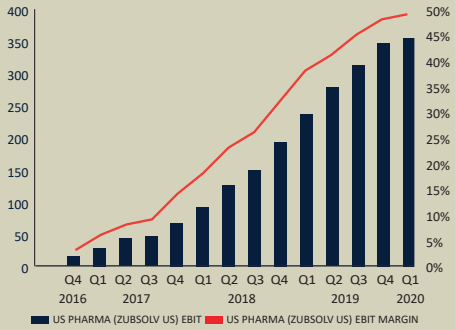
NET REVENUES AND OPERATING EARNINGS PER SEGMENT

SEK m	Net Revenues			EBIT		
	2020 Jan-Mar	2019 Jan-Mar	2019 Jan-Dec	2020 Jan-Mar	2019 Jan-Mar	2019 Jan-Dec
Zubsolv® US	163.9	161.7	719.2	75.9	68.2	347.1
US Pharma – total	**163.9**	**161.7**	**719.2**	**75.9**	**68.2**	**347.1**
Digital Therapeutics	-	-	-	-12.1	-	-0.9
Digital Therapeutics– total	-	-	-	**-12.1**	**-**	**-0.9**
Abstral® royalties	8.6	10.9	112.6	-	-	-
Edluar® royalties	2.4	1.7	11.6	-	-	-
Zubsolv - ex US	0.1	0.0	0.1	-	-	-
OX-MPI	-	-	1.4	-	-	-
HQ & Pipeline segment – total	**11.1**	**12.6**	**125.6**	**-29.9**	**-67.1**	**-115.0**
Total	**175.0**	**174.3**	**844.8**	**34.0**	**1.1**	**231.2**

US PHARMA (ZUBSOLV US) NET REVENUES (LTM[2], SEK m)



US PHARMA (ZUBSOLV US) EBIT AND EBIT MARGIN (LTM[2], 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

Cash, cash flow and net cash/debt

As of March 31, 2020, cash and cash equivalents amounted to SEK 861.4 m (647.4) and interest-bearing liabilities to SEK 249.5 m (321.0), i.e. a positive net cash position of SEK 611.9 m (326.4). During the quarter Orexo repurchased 464,035 of its ordinary shares for SEK 24.4 m and made a buyback of the corporate bond of SEK 40.5 m. 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 for the quarter amounted to SEK 48.1 m (50.9).

Investments

Gross investments in tangible and intangible fixed assets amounted to SEK 3.9 m (0.1) for the quarter. Higher investment is mainly explained by purchase of equipment for the development organization.

Equity

Shareholders' equity at March 31, 2020, was SEK 775.3 m (496.6). The equity/asset ratio was 50.0 percent (36.3).

Parent company

Net revenues amounted to SEK 137.6 m (116.8) for the quarter of which SEK 126.4 m (104.2) was related to sales to Group companies.

Earnings before tax were SEK 105.7 m (19.6) for the quarter.

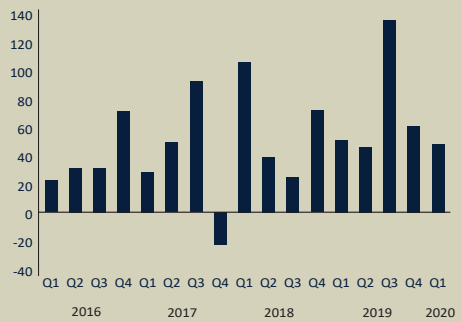
Investments for the quarter amounted to SEK 3.9 m (0.1).

As of March 31, 2020, cash and cash equivalents in the parent company amounted to SEK 575.2 m (346.5).

Cash and cash equivalents amounted to SEK 861.4 m (647.4).

EBITDA, SEK m

CASH FLOW FROM OPERATING ACTIVITIES, SEK m



Operations

Commercial business

Zubsolv® US - treatment of opioid use disorder (OUD) in the US

While Orexo has not seen any impact on the sales of Zubsolv in the quarter from COVID-19, the impact on operations has been severe as all face to face field force activities have been temporarily stopped. The field force continues its promotional efforts through other channels and to prepare for the launch of Orexo´s first digital therapy, vorvida®, during the summer. Orexo believe the impact on Zubsolv will be limited if travel restrictions are lifted during the coming months, but if continued into second half of 2020 there can be an impact on the growth trajectory of Zubsolv. Long term, COVID-19 is likely to lead to increased need for the treatment of OUD, since experience from previous crises and recessions have shown an increase in substance misuse, including opioids.

Sales development
Zubsolv net revenues declined 15 percent over Q4 2019 and 4 percent over Q1 2019 in USD, with a decline in unit volume of 8 percent versus Q4 2019 and 13 percent versus Q1 2019. This development was expected due to the changes in market access in 2019 and the seasonality we have seen every year with a weaker Q1 than Q4.

Both Zubsolv and market volumes demonstrated higher volumes in March as patients began to receive larger prescription sizes to prepare for fewer office and pharmacy visits during the COVID-19 lockdown.

The decline in total volume is primarily due to formulary additions of generics in specific payers (United Health Group and Humana) and formulary change to generic tablets only in Pennsylvania Medicaid. These adjustments, coupled with a continued decline of Zubsolv in cash volume as low cost generics take from all branded products in the category, had a negative impact on volume.

Market development
The market demonstrated strong growth of 17 percent in unit volume compared to Q1 2019, and 2 percent growth over Q4 2019. Relative to market unit volume growth, market prescription volume (total prescriptions) has grown less equating to only 8 percent compared to Q1 2019. There are two reasons for this difference, one is a more recent phenomenon seen during COVID-19 related lockdowns, where patients have begun to receive larger script sizes across all payer types. The other reason, which has been highlighted in prior quarters, is that in the cash segment of the market prescription volume has not kept pace with unit volume growth. Analyzing market dynamics excluding the cash segment demonstrates retail market prescription growth and unit growth are within 3 percent of each other, at 13 and 16 percent, respectively. The majority of the remaining variance is due to COVID-19 related larger script sizes.

Open formulary business[1]
Zubsolv's open formulary business declined by 2 percent over Q4 2019 and grew 8 percent over Q1 2019. The growth over Q1 2019 is being driven by strong growth in every insured market segment; open Commercial grew 7 percent, open Medicaid grew 10 percent, and open Medicare D grew 19 percent. The performance of Zubsolv over Q4 2019 was impacted by less growth in the open Commercial segment of -1 percent which is the most important for Zubsolv. On Caremark's national formulary, which makes up the majority of Caremark's market volume, Zubsolv grew 38 percent over Q1 2019.

Within Medicaid, Zubsolv continues to grow in the states it gained access to in 2019; Ohio, Texas, Florida and Alabama. Within those states, Zubsolv has grown Medicaid volume by an estimated 15 percent over Q4 2019, and doubled the volume of Q1 2019.

Exclusive plans and non-reimbursed businesses
Zubsolv business in United Health Group and Humana has decreased 15 percent versus Q4 2019 and 28 percent versus Q1 2019. Zubsolv business in the non-reimbursed business, which includes WellCare and Pennsylvania Medicaid, has decreased 13 percent versus Q4 2019 and 33 percent versus Q1 2019. Humana volume grew within the quarter, and previous United Health Group volume declines are showing recent signs of stabilization.

Long term, COVID-19 is likely to lead to increased need for the treatment of OUD, since experience from previous crises and recessions have shown an increase in substance misuse, including opioids.

[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.

Market access
Zubsolv® increased its best-in-class coverage in the commercial segment to 98 percent with the addition of Florida Blue Cross Blue Shield. Zubsolv coverage in the public segment had decreased to 35 percent in the quarter due to Pennsylvania Medicaid payers starting to follow the generic tablet only fee for service formulary.

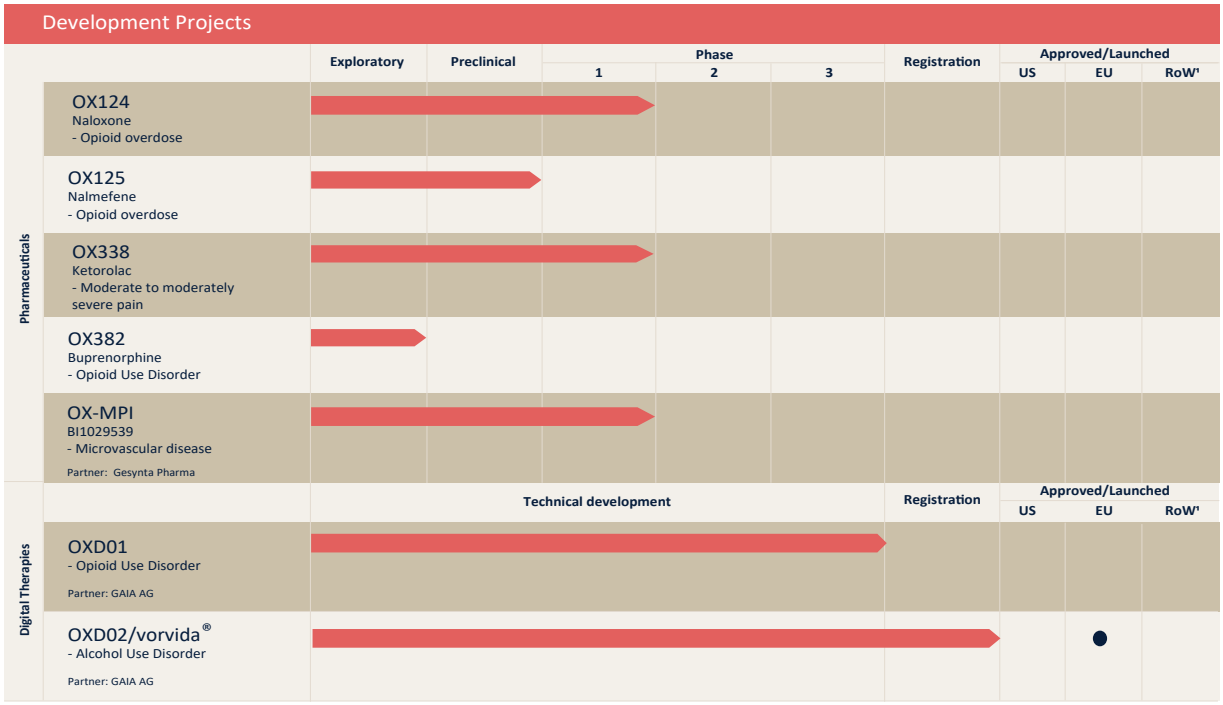
Zubsolv® in geographies outside the US – treatment of OUD

Orexo´s partner Mundipharma Pty. Ltd is in continued negotiations with the pricing authority in Australia. Subject to a price and reimbursement decision a launch is planned to take place earliest in 2020. Orexo will receive royalties on future net sales.

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.

PIPELINE OF PHARMA AND DIGITAL THERAPY DEVELOPMENT PROJECTS



Pharmaceuticals

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 stronger and longer-acting, and thus effective in reversing overdoses caused by synthetic opioids.

Differentiation
Results from the exploratory PK-study in healthy volunteers showed significant better PK-profile, such as, faster, stronger 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 H2 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 drugs or for anti-terror stockpiling.

Differentiation
Depending on the results from the first human PK-study that will take place in H1 2020.

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

Changes during the quarter
Continued preparations for the first human PK-study in the first half of 2020 are ongoing.

OX-124: Results from the exploratory PK-study in healthy volunteers showed significant better PK-profile.

[1] Rest of the World, excluding US and Europe
● vorvida® has been launched in Germany and Switzerland by GAIA

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
The study results from the first human PK-study was received, showed promising results, see differentiation above.

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
Depending on the results from the first in human PK-study that is ongoing.

Financial potential
-

Changes during the quarter
The first in human study is ongoing and proceeding according to plan. The results are expected in H1 2020.

Digital therapies

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
Prepare for finalizing the technical development of the new digital therapy.

OXD02/vorvida® - heavy alcohol use, incl. alcohol use disorder (AUD)

Unmet need
Alcohol misuse is a highly stigmatized, only few people seek professional help, and those who seek help will have issues finding quality support.

Our aim
Establish vorvida® as the leading digital therapy for people suffering from alcohol misuse

Differentiation
A fully automated digital therapy scientifically proven to reduce trouble-some drinking patterns in adults with AUD.

Financial potential
Net sales USD 120-200 m (US market).

Changes during the quarter
An application to the US Food and Drug Administration (FDA) for vorvida® to enable commercialization in the US was submitted. A clearance from FDA is anticipated in Q2 2020.

Our aim is to establish vorvida® as the leading digital therapy for people suffering from alcohol misuse.

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 OPEX will reach a level of SEK 550-600 m, excluding potential investments in an accelerated launch of digital therapies
• 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 investments in R&D, EBITDA will decrease
• US Pharma 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.

Uppsala, Sweden, April 28, 2020
Orexo AB (publ.)

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 Jan-Mar	2019 Jan-Mar	2019 Jan-Dec
Net revenues	9	175.0	174.3	844.8
Cost of goods sold		-20.0	-25.3	-105.6
Gross profit		**155.1**	**149.0**	**739.2**
Selling expenses		-54.6	-47.2	-191.9
Administrative expenses		-23.7	-70.1	-139.6
Research and development expenses		-52.9	-37.6	-181.3
Other operating income and expenses		10.1	7.0	4.8
Operating earnings (EBIT)		**34.0**	**1.1**	**231.2**
Net financial items		44.0	4.8	-3.3
Earnings before tax		**78.0**	**5.9**	**227.9**
Tax	5	4.6	8.2	-8.8
Net earnings for the period[1]		**82.6**	**14.1**	**219.1**
Earnings per share, before dilution, SEK		2.38	0.41	6.33
Earnings per share, after dilution, SEK		2.34	0.40	6.20

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

SEK m	2020 Jan-Mar	2019 Jan-Mar	2019 Jan-Dec
Earnings for the period	**82.6**	**14.1**	**219.1**
Other comprehensive income			
Items that may subsequently be reversed to the statement of operations:			
Exchange-rate differences	9.3	3.2	3.4
Other comprehensive earnings for the period, net after tax	**9.3**	**3.2**	**3.4**
Total comprehensive earnings for the period[1]	**91.9**	**17.3**	**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 Mar 31	2019 Mar 31	2019 Dec 31
ASSETS			
Fixed assets			
Tangible fixed assets	24.9	19.5	22.0
Intangible fixed assets	109.9	99.7	113.9
Right-of-use assets	76.1	68.2	57.0
Deferred tax assets	94.9	103.3	85.5
Other financial assets	1.5	10.8	1.4
Total fixed assets	**307.3**	**301.5**	**279.9**
Current assets			
Inventories	140.1	166.4	131.8
Accounts receivable and other receivables	241.6	252.2	272.6
Cash and cash equivalents	861.4	647.4	816.8
Total current assets	**1,243.0**	**1,065.9**	**1,221.2**
Total assets	**1,550.4**	**1,367.4**	**1,501.1**
SHAREHOLDERS' EQUITY AND LIABILITIES			
Total shareholders' equity	**775.3**	**496.6**	**706.4**
Long-term liabilities			
Provisions	10.2	7.7	10.7
Long-term liabilities, interest bearing	249.5	321.0	289.6
Lease liabilities, long-term	53.8	45.3	33.3
Total long-term liabilities	**313.5**	**373.9**	**333.6**
Current liabilities and provisions			
Provisions	283.5	286.5	269.3
Current liabilities, non-interest bearing	157.7	190.5	170.5
Lease liabilities, current	20.6	19.9	21.4
Total current liabilities and provisions	**461.6**	**496.9**	**461.1**
Total liabilities	**775.1**	**870.8**	**794.7**
Total shareholders' equity and liabilities	**1,550.4**	**1,367.4**	**1,501.1**

CONSOLIDATED CHANGES IN SHAREHOLDERS' EQUITY

SEK m	2020 Mar 31	2019 Mar 31	2019 Dec 31
Opening balance, shareholders' equity	**706.4**	**476.1**	**476.1**
Total comprehensive earnings for the period	91.9	17.3	222.5
Share-based payments	1.4	3.1	5.8
Buy back of shares	-24.4	—	—
New share issue	—	—	2.0
Closing balance, shareholders' equity	**775.3**	**496.6**	**706.4**

CONDENSED CONSOLIDATED CASH FLOW STATEMENTS

SEK m	Notes	2020 Jan-Mar	2019 Jan-Mar	2019 Jan-Dec
Operating earnings (EBIT)		34.0	1.1	231.2
Interest received		2.7	2.0	9.9
Interest paid		-3.4	-3.7	-17.7
Income taxes paid		-0.4	0.0	-12.2
Adjustment for non-cash items	3	-8.1	22.9	41.3
Cash flow from operating activities before changes in working capital		**24.9**	**22.3**	**252.5**
Changes in working capital		**23.2**	**28.6**	**34.5**
Cash flow from operating activities		**48.1**	**50.9**	**287.0**
Acquisition of tangible and intangible fixed assets		-3.9	-0.1	-32.0
Acquisition of financial assets		—	—	—
Disposal of financial assets		—	—	9.5
Cash flow from investing activities		**-3.9**	**-0.1**	**-22.4**
New share issue		—	—	2.0
Buy back shares		-24.4	—	—
Repayment of loans		-44.4	-10.7	-55.8
Cash from financing activities		**-68.8**	**-10.7**	**-53.7**
Cash flow for the period		**-24.6**	**40.2**	**210.8**
Cash and cash equivalents at the beginning of the period		**816.8**	**589.8**	**589.8**
Exchange-rate differences in cash and cash equivalents		69.2	17.3	16.1
Changes in cash and cash equivalents		44.7	57.4	227.0
Cash and cash equivalents at the end of the period		**861.4**	**647.4**	**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 Jan-Mar	2019 Jan-Mar	2019 Jan-Dec
EBIT margin, %	19.4	0.6	27.4
Return on shareholder equity, %	11.1	2.9	37.1
Net debt, SEK m	-611.9	-326.4	-527.2
Debt/equity ratio, %	32.2	64.6	41.0
Equity/assets ratio, %	50.0	36.3	47.1
Number of shares, before dilution	34,710,639	34,574,287	34,621,646
Number of shares, after dilution	35,338,863	35,223,304	35,348,484
Earnings per share, before dilution, SEK	2.38	0.41	6.33
Earnings per share, after dilution, SEK	2.34	0.40	6.20
Number of employees at the end of the period	132	131	127
Shareholders' equity, SEK m	775.3	496.6	706.4
Capital employed, SEK m	1,024.8	817.6	996.0
Working capital, SEK m	-79.9	-78.4	-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 Jan-Mar	2019 Jan-Mar	2019 Jan-Dec
Net revenues		137.6	116.8	534.0
Cost of goods sold		-19.7	-27.3	-98.6
Gross profit		**117.9**	**89.5**	**435.3**
Selling expenses		-23.9	-2.9	-6.6
Administrative expenses		-12.6	-62.5	-105.6
Research and development costs		-42.7	-30.5	-152.3
Other operating income and expenses		23.2	22.1	67.2
Operating earnings (EBIT)		**62.0**	**15.8**	**238.0**
Interest income and expenses		-2.6	-3.4	40.0
Other financial income and expenses		46.3	7.2	-46.9
Net financial items		**43.8**	**3.8**	**-6.9**
Earnings before tax		**105.7**	**19.6**	**231.1**
Tax	5	—	—	-11.8
Earnings for the period		**105.7**	**19.6**	**219.3**

PARENT COMPANY STATEMENT OF COMPREHENSIVE INCOME

SEK m	2020 Jan-Mar	2019 Jan-Mar	2019 Jan-Dec
Earnings for the period	**105.7**	**19.6**	**219.3**
Other comprehensive income	—	—	—
Total comprehensive earnings for the period	**105.7**	**19.6**	**219.3**

CONDENSED PARENT COMPANY BALANCE SHEET

SEK m	2020 Mar 31	2019 Mar 31	2019 Dec 31
ASSETS			
Fixed assets			
Intangible fixed assets	109.9	99.7	113.9
Tangible fixed assets	24.9	19.5	22.0
Deferred tax assets	49.0	60.9	49.0
Shares in subsidiaries	156.3	152.9	155.6
Total fixed assets	**340.1**	**332.9**	**340.6**
Current assets			
Inventories	113.3	142.5	113.4
Accounts receivable and other receivables	175.7	149.5	214.1
Cash and bank balances	575.2	346.5	469.0
Total current assets	**864.2**	**638.4**	**796.5**
Total assets	**1,204.4**	**971.3**	**1,137.1**
SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES			
Shareholders' equity	**726.8**	**439.6**	**644.0**
Long-term liabilities			
Other provisions	7.7	5.8	8.2
Bond loan	249.5	321.0	289.6
Total long-term liabilities	**257.2**	**326.7**	**297.8**
Current liabilities			
Accounts payable	29.3	20.1	22.8
Other liabilities	8.0	6.1	6.0
Liabilities to Group companies	163.2	136.8	144.7
Accrued expenses and deferred income	19.9	42.0	21.8
Total current liabilities	**220.4**	**205.0**	**195.3**
Total liabilities	**477.6**	**531.1**	**493.1**
Total shareholders' equity and liabilities	**1,204.4**	**971.3**	**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 Jan-Mar	2019 Jan-Mar	2019 Jan-Dec
US Pharma			
Net revenues	163.9	161.7	719.2
Operating earrnings (EBIT)	75.9	68.2	347.1
Digital Therapeutics			
Net revenues	0.0	0.0	0.0
Operating earrnings (EBIT)	-12.1	0.0	-0.9
HQ & Pipeline			
Net revenues	11.1	12.6	125.6
Operating earrnings (EBIT)	-29.9	-67.1	-115.0
Group			
Net revenues	175.0	174.3	844.8
Operating earrnings (EBIT)	34.0	1.1	231.2
Net financial items	44.0	4.8	-3.3
Earnings before tax	78.0	5.9	227.9

3. Cash flow

ADJUSTMENT FOR NON-CASH ITEMS

SEK m	2020 Jan-Mar	2019 Jan-Mar	2019 Jan-Dec
Depreciation/amortization and impairment	8.7	10.9	41.0
Change in provisions	-8.2	12.4	-2.7
Share based payments	1.4	3.1	5.8
Exchange rate income and expenses	-10.1	-3.5	-2.7
Total	**-8.1**	**22.9**	**41.3**

4. Legal disputes

-

5. Deferred tax

New 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 December 31, 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

- Completed the program to repurchase 500,000 of the company´s ordinary shares, equalling to approx. 1.4 percent of the total issued ordinary shares in the company
- 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.
- Financial outlook 2020 is reiterated

9. Revenue from contracts with customers

SEK m	2020 Jan-Mar				
Segment	**Zubsolv®**	**Abstral®**	**Edluar®**	**OX-MPI**	**Total**
US Pharma	163.9	—	—	—	**163.9**
Digital Therapeutics	—	—	—	—	**0.0**
HQ & Pipeline	0.1	8.6	2.4	—	**11.1**
Total revenue from contracts with customers	**164.0**	**8.6**	**2.4**	**0.0**	**175.0**
Geographical markets	**Zubsolv**	**Abstral**	**Edluar**	**OX-MPI**	**Total**
US	163.9	—	0.5	—	**164.4**
EU & UK	—	8.6	1.1	—	**1.7**
Rest of the world	0.1	0.1	0.8	—	**8.9**
Total revenue from contracts with customers	**164.0**	**8.6**	**2.4**	**0.0**	**175.0**

SEK m	2019 Jan-Mar				
Segment	**Zubsolv**	**Abstral**	**Edluar**	**OX-MPI**	**Total**
US Pharma	161.7	—	—	—	**161.7**
Digital Therapeutics	—	—	—	—	**0.0**
HQ & Pipeline	—	10.9	1.7	—	**12.6**
Total revenue from contracts with customers	**161.7**	**10.9**	**1.7**	**0.0**	**174.3**
Geographical markets	**Zubsolv**	**Abstral**	**Edluar**	**OX-MPI**	**Total**
US	161.7	1.2	0.4	—	**163.3**
EU	—	6.0	0.6	—	**6.5**
Rest of the world	—	3.7	0.8	—	**4.5**
Total revenue from contracts with customers	**161.7**	**10.9**	**1.7**	**0.0**	**174.3**

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	87.3	2.2	1.4	**91.0**
Rest of the world	—	23.1	4.9	—	**28.0**
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 Jan-Mar	2019 Jan-Mar	2019 Jan-Dec
EBIT	34.0	1.1	231.2
Depreciation and amortization	5.1	10.9	40.9
EBITDA	**39.1**	**12.0**	**272.1**
IP litigation costs	0.1	48.8	49.4
EBITDA excluding IP litigation costs	**39.2**	**60.8**	**321.5**

RETURN ON SHAREHOLDERS' EQUITY	2020 Jan-Mar	2019 Jan-Mar	2019 Jan-Dec
Shareholders' equity beginning balance	706.4	476.1	476.1
Shareholders' equity ending balance	775.3	496.6	706.4
Average shareholders' equity	740.9	486.4	591.3
Net earnings	82.6	14.1	219.1
Return on shareholders' equity %	**11.1**	**2.9**	**37.1**

OPERATING EXPENSES SEK m	2020 Jan-Mar	2019 Jan-Mar	2019 Jan-Dec
Selling expenses	-54.6	-47.2	-191.9
Administrative expenses	-23.7	-70.1	-139.6
Research and development costs	-52.9	-37.6	-181.3
Other operating income and expenses	10.1	7.0	4.8
Operating expenses	**-121.1**	**-147.9**	**-508.0**

GROSS INVESTMENTS SEK m	2020 Jan-Mar	2019 Jan-Mar	2019 Jan-Dec
Investments in tangible fixed assets	3.8	0.1	5.0
Investments in intangible fixed assets	0.1	—	27.0
Gross investments	3.9	**0.1**	**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