Interim Report Q3 2020

# The new future starts to take shape

## Q3 2020 highlights

- Total net revenues of SEK 150.3 m (231.2), 189.7 excluding Abstral® EU and US
- Net earnings of SEK -84.9 m (111.7), net earnings of SEK -22.4 m excluding DTx launch. Net earnings also impacted by a material one-time tax adjustment of SEK -43.5 m.
- EBITDA of SEK -12.2 m (114.1), EBITDA of SEK 50.3 m excluding DTx launch
- US Pharma segment (ZUBSOLV® US) net revenues of SEK 143.8 m (182.7), EBIT of SEK 72.4 m (90.9)
- DTx segment EBIT of SEK -62.5 m (-), including US launch of the scientifically proven digital therapies deprexis® and vorvida®
- Cash flow from operating activities of SEK -12.9 m (135.7), a cash balance of SEK 593.3 m (812.9)
- Orexo US received subpoenas to provide US authorities with certain information with regards to ZUBSOLV® and other buprenorphine products
- Infringement litigation against Sun Pharmaceutical was commenced in response to Sun Pharmaceutical, that has filed an Abbreviated New Drug Application with the US FDA for ZUBSOLV® in the US
- Finalized development of a scalable proprietary platform to manage payment and reimbursement processes for current and future DTx products

## Important events after the period

- Secured a preferred position for ZUBSOLV® as the only branded product on national commercial and Medicare Part D formularies of the largest PBM in the commercial segment in the US, Express Script, from January 1 2021
- Updated financial outlook 2020

**SEK 72.4 m**
US Pharma EBIT

**SEK -12.2 m**
EBITDA. Excl. DTx launch SEK 50.3 m.

**SEK 593.3 m**
Cash and cash equivalents

| SEK m, unless otherwise stated | 2020 Jul-Sep | 2019 Jul-Sep | 2020 Jan-Sep | 2019 Jan-Sep | 2019 Jan-Dec | 2019-2020 Jul-Sep Δ |
|---|---|---|---|---|---|---|
| Net revenues | 150.3 | 231.2 | 504.4 | 606.7 | 844.8 | -35% |
| Cost of goods sold | -14.5 | -25.9 | -54.3 | -82.5 | -105.6 | -44% |
| Operating expenses | -165.4 | -99.4 | -459.0 | -364.5 | -508.0 | 66% |
| EBIT | -29.6 | 105.9 | -8.9 | 159.7 | 231.2 | -128% |
| EBIT margin, % | -19.7 | 45.8 | -1.8 | 26.3 | 27.4 | -65,5 ppt |
| EBITDA | -12.2 | 114.1 | 17.9 | 186.3 | 272.1 | -111% |
| Earnings per share, before dilution, SEK | -2.45 | 3.22 | -1.00 | 5.21 | 6.33 | -137% |
| Earnings per share, after dilution, SEK | -2.45 | 3.16 | -1.00 | 5.10 | 6.20 | -138% |
| Cash flow from operating activities | -12.9 | 135.7 | 28.0 | 230.7 | 287.0 | -110% |
| Cash and cash equivalents | 593.3 | 812.9 | 593.3 | 812.9 | 816.8 | -27% |

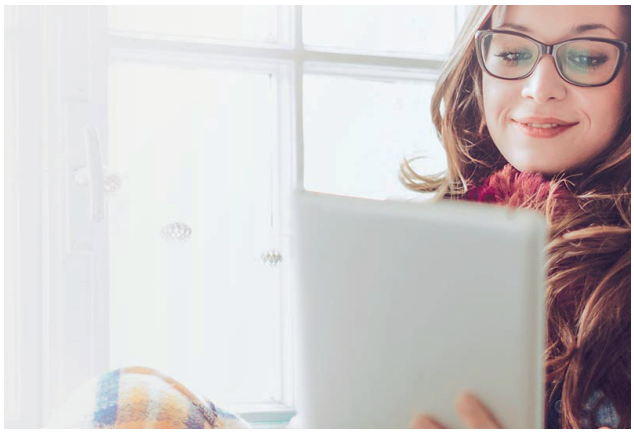
Unless otherwise stated in this report, all data refers to the Group, and numbers relate to the current quarter while numbers in parentheses relate to the corresponding period in 2019.

# Content



**About Orexo**

Orexo develops improved pharmaceuticals and digital therapies addressing unmet needs within the growing space of substance use disorders and mental health. The products are commercialized by Orexo in the US or via partners worldwide. The main market today is the American market for buprenorphine/naloxone products, where Orexo commercializes its lead product ZUBSOLV® for treatment of opioid use disorder. Total net sales for 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-q3-2020
Telephone: SE +46 8 56 642 706 UK +44 3 333 009 031 US +1 8 335 268 397
The presentation material will be available on Orexo´s website prior to the audiocast.

**Financial calendar**

Q4 incl. Full Year Report 2020 - January 28, 2020 at 8.00 am CET
Annual General Meeting 2021, April 13, 2021 at 4 pm CET
Interim Report Q1 2021 - April 29, 2021 at 8.00 am CET
Interim Report Q2 2021 - July 15, 2021 at 8.00 am CET

**For more information about Orexo**

Please visit, www.orexo.com. You can also follow Orexo on Twitter, @orexoabpubl, LinkedIn and YouTube.

# Keeping focus and maximizing business opportunities in a challenging environment

*It has been an eventful third quarter for Orexo, with good progress made in establishing our new business area in digital therapeutics. The quarter also brought some new challenges, primarily from new legal processes and impact from Covid-19. I am pleased that we have shown agility and determination in responding to these challenges, which I am certain we will manage with a limited impact on our core strategies and most importantly our future value drivers, Digital therapies and OX124. While Digital therapies and OX124 have significant future potential, ZUBSOLV® remains our main profit contributor and I am proud of the progress we have made with improving ZUBSOLV® market access and to announce we have secured a position for ZUBSOLV® as the only branded product on the preferred national Commercial and Medicare Part D formularies of the largest PBM in the Commercial segment in the US, Express Scripts, from January 1, 2021.*

## Focusing investments on main value drivers

During my nearly eight years as CEO of Orexo, strengthening our financial position has been and remains a key priority. A strong balance sheet enables investment when opportunities arise and ensures we can continue to pursue our long term goals, even when we are facing unexpected challenges. I am proud of what we have accomplished since we turned profitable in 2016, and with SEK 593 million in cash, we have the financial resources required to invest in developing digital therapies and to continue the prioritized development of the pharmaceutical pipeline.

During the quarter we conducted a strategic review of the business and decided to prioritize our efforts on the launch of our three digital therapies and our most advanced pharmaceutical pipeline project, OX124, a naloxone rescue medication for opioid overdose. We have already re-allocated resources from the ZUBSOLV® commercial team to Digital Therapeutics and will increase this re-allocation of resources and further investments in Digital Therapeutics as we secure market access and reimbursement by payors. In our pharmaceutical pipeline, therefore, we will focus most of our resources on the final stages of OX124 development and temporarily slow the development of OX125 and OX338. The development of our oral formulation of buprenorphine, OX382, will be put on hold while we continue to explore new formulation opportunities. These changes in prioritization have been made to ensure we have all the resources needed to secure a successful launch of the digital therapies and to ensure OX124 development is finalized and meet FDA's requirement. As a consequence of this prioritization, continuous prudent expense management, and a weakening US dollar, we reduce our full year OPEX guidance for 2020 to SEK 675-725 million from SEK 750-800 million and increase EBIT contribution margin guidance in US Pharma from 45-50 percent to exceeding 50 percent.

## Establishing Orexo as a leading player in Digital Therapeutics

Entering a new business arena is a major undertaking for Orexo, and we have invested significant resources both in terms of time and money into building the infrastructure needed to make our digital therapies accessible to patients. The launch of deprexis® and vorvida® in the US in July was fully focused on creating access and establishing a working payer model in dialog with insurance companies and institutional healthcare providers. Whilst we are making good progress, we continue to see that the market for digital therapies is in its infancy, despite the huge unmet need in this area.

**Customer Focus**
I am proud we have managed to build a customer support system capable of managing the entire payment and reimbursement process, particularly in light of the accelerated launch of vorvida®. We finalized the development of Orexo's proprietary system as planned at the end of Q3 and are now ready to manage the payment processing for all patients, independent of our financing model, i.e. from cash to insurance coverage. Orexo will launch an opportunity for patients to make payments in monthly installments, and we are establishing partnerships with healthcare providers who can take responsibility for the treatment if patients want to combine digital therapy with access to a healthcare provider. We believe this investment in a customer support system will be a significant competitive advantage for our current products and when we expand our Digital Therapeutics business.

**Partnerships**
Our first two partnership agreements, with GoGoMeds and Trinity Health ND (North Dakota), were announced during the quarter. GoGoMeds will make our digital therapies available to their clients in their system, which will go live during Q4 2020, initially with a focus on the court system in the US and people with a DUI (Driving Under the Influence) offense. Trinity Health ND will initially make products available to their employees, which Orexo is proud to sponsor, as a response to the Covid-19 crisis. We will continue to work with Trinity Health ND to broaden the commercial partnership. In addition to these frontrunners, we have several ongoing discussions with other payors and distribution partners, which we expect will result in additional agreements being signed during Q4 2020.

When we entered digital therapeutics, the foundation for this decision was the ability to leverage our existing commercial organization to promote these products. We continue to see significant synergies between our digital therapies and the customers for ZUBSOLV® and the re-allocation of resources is reflecting how our entire customer facing organization from October 2020 will promote the digital therapies in parallel with ZUBSOLV®. With a successful launch of the digital therapies and reimbursement of the products, we intend to increase our commercial organization which will benefit both ZUBSOLV® and Digital Therapeutics.

## ZUBSOLV® demonstrated resilience, but is impacted by Covid-19

During the Covid-19 pandemic, we have seen a surge in all issues related to opioid addiction as more patients are relapsing and overdosing, which in turn has increased the number of patients seeking treatment. In the quarter, the number of prescriptions in the market increased by 13 percent, the highest actual increase since the launch of ZUBSOLV® in September 2013. However, the increase is solely in the cash paying and Public segment i.e. Medicaid and Medicare. The Commercial segment, where ZUBSOLV® is nearly fully reimbursed and less rebated, declined during Q2 and Q3, which partly explain the modest 4 percent decline in ZUBSOLV® demand from Q2. The Commercial segment development is explained by increased unemployment in the US as a result of Covid-19. We expect the Commercial segment's share of the total market to normalize and show growth, as unemployment rates improve again, and as a result of the significant rise in opioid addication in the wake of the pandemic. With ZUBSOLV® as the only preferred branded product on the top three commercial PBMs' (ESI, Caremark & Optum) national formularies as of January 1, 2021, we expect sales to regain momentum as the Commercial segment grows again.

Our field force has and continues to play an important role in capturing the new improved market access position, and while we continue to have reduced access to the physicians/prescribers, we have seen a gradual improvement during Q3 2020. However, access to physicians remains tightly correlated with the development of the Covid-19 pandemic and the situation remains uncertain. Promoting the only branded daily buprenorphine/naloxone treatment, the continuous relationship, and dialogue with the customers is critical to maintaining the market position and we remain optimistic about the role ZUBSOLV® can play when the situation normalizes.

## Summary and Outlook

The global crisis presented by Covid-19 has continued and we are now experiencing how it impacts dynamics in the opioid addiction market and the subsequent significant rise in patients suffering from mental illness such as opioid addiction, alcohol misuse, and depression. These are all indications where Orexo is uniquely positioned to help with both pharmaceuticals and new innovative digital therapies. While the effect of the pandemic on global economics and unemployment is unlikely to diminish in the short term, the need and access to treatment for patients with mental illness will remain long term. With ZUBSOLV's significantly improved market access, our progressing pipeline, and launch of three digital therapies in the US, I am very excited about our future journey.

Uppsala, Sweden, November 4, 2020

Nikolaj Sørensen
President and CEO

# Financial information

## Revenues

Total revenues for the quarter amounted to SEK 150.3 m (231.2), of which ZUBSOLV® US revenues of SEK 143.8 m (182.7) while revenues, related to partner products, amounted to SEK 6.5 m (48.6).

The decrease in ZUBSOLV® US revenues for the quarter is driven by lower demand due to competition in previously exclusive plans, declining Commercial segment due to increased unemployment as a result of Covid-19, lower adjustments of accrued product returns and by unfavorable exchange-rates, this is partly offset by increased wholesaler stocking levels and improved pricing.

Abstral® royalty amounted to SEK 2.5 m (42.4) for the quarter explained by the previously communicated expiration of the contracts for the US and European markets.

Total revenues amounted to SEK 504.4 m (606.7) for the first nine months, corresponding to 16.9 percent decrease.

## Costs of goods sold

Cost of goods sold (COGS) amounted to SEK 14.5 m (25.9) for the quarter, explained by ZUBSOLV® US of SEK 12.6 m (25.9) and technical infrastructure costs of SEK 1.8 m ( - ) for deprexis® and vorvida®. The decrease in COGS vs Q3 is explained by efficiency improvements in the supply chain, exchange rate changes and reduced demand. For the first nine months COGS amounted to SEK 54.3 m (82.5), explained by ZUBSOLV® US of SEK 51.9 m (82.5) and technical infrastructure costs of SEK 2.5 m ( - ) for deprexis® and vorvida®.

## Operating expenses

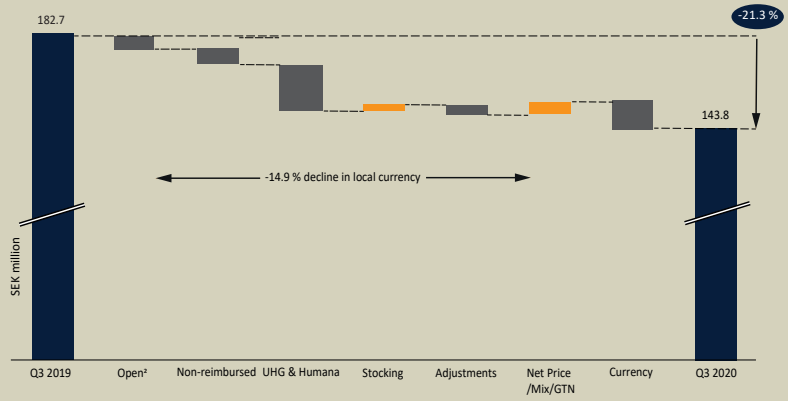
Selling expenses amounted to SEK 83.3 m (45.0) for the quarter. The increase over the same period last year is mainly explained by costs related to launch preparations for deprexis® and vorvida® in the US of SEK 53.5 m ( - ). This was partially offset with lower selling expenses in US Pharma of SEK 29.3 m (44.6). Selling expenses amounted to SEK 207.7 m (141.3) for the first nine months.

Administrative expenses amounted to SEK 26.4 m (18.1) for the quarter. The increase versus the prior year is mainly explained by higher legal costs in the US related to the FDA subpoena partly offset by lower costs for the long-term incentive programs following negative share price development and fair value adjustment versus prior quarter. The group also launched a new management long term incentive program during the quarter. Administrative expenses amounted to SEK 83.0 m (112.7) for the first nine months.

Research and development costs amounted to SEK 50.3 m (41.6) for the quarter. The increase is explained by the clinical trial of OX125 and final development of OX124 towards registration in 2021 partly offset by lower internal costs. Research and

US Pharma EBIT contribution amounted to SEK 72.4 m (90.9), equal to an EBIT margin of 50.3 percent (49.8).

ZUBSOLV® US NET REVENUES GROWTH BY KEY DRIVERS, Q3 2020 VERSUS Q3 2019[1]




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

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

development costs amounted to SEK 165.9 m (122.7) for the first nine months.

Other operating income and expenses amounted to SEK -5.4 m (5.3) for the quarter and to SEK -2.5 m (12.3) for the first nine months 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 -12.2 m (114.1) for the quarter and to SEK 17.9 m (186.3) for the first nine months.

The EBIT contribution from US Pharma amounted to SEK 72.4 m (90.9) for the quarter, equal to an EBIT margin of 50.3 percent (49.8). The decline is explained by lower sales and higher legal costs for the FDA subpoena partly offset by lower operating costs. The EBIT contribution from US Pharma amounted to SEK 237.2 m (242.6) for the first nine months, equal to an EBIT margin of 49.4 percent (45.9).

## Net financial items and tax

Net financial items amounted to SEK -10.8 m (8.7) for the quarter mainly explained by negative unrealized exchange rate impact of SEK 7.1 m derived from the parent company's foreign currency bank accounts mainly in USD and by costs for corporate bonds of SEK 3.0 m.
Net financial items amounted to SEK 10.9 m (19.2) for the first nine months.

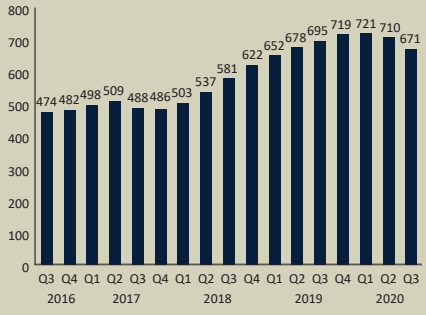
Total tax expenses amounted to SEK -44.4 m (-3.0) for the quarter, negatively impacted by decreased parent company tax asset of SEK 43.5 m ( - ) due to lower expected profits following continued investment into DTx segment. Adjustment to deferred tax assets related to temporary differences had a positive impact of SEK 0.6 m ( -1.9 ). Total tax expenses amounted to SEK -36.8 m (1.3) for the first nine months and was negatively impacted by decreased parent company tax asset of SEK -43.5 m ( - ) and positively impacted by adjustment to deferred tax assets of SEK 4.0 m ( 5.0 ) related to temporary differences.

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

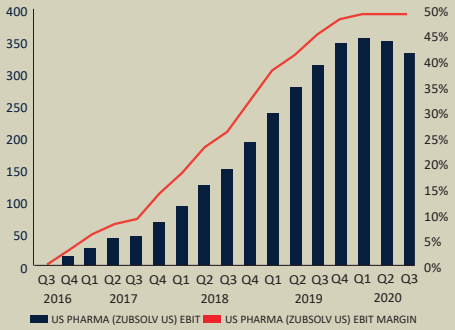
**NET REVENUES AND OPERATING EARNINGS PER SEGMENT**

| SEK m | Net Revenues | | | | | EBIT | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | 2020 Jul-Sep | 2019 Jul-Sep | 2020 Jan-Sep | 2019 Jan-Sep | 2019 Jan-Dec | 2020 Jul-Sep | 2019 Jul-Sep | 2020 Jan-Sep | 2019 Jan-Sep | 2019 Jan-Dec |
| ZUBSOLV® US | 143.8 | 182.7 | 480.2 | 528.7 | 719.2 | - | - | - | - | - |
| **US Pharma – total** | **143.8** | **182.7** | **480.2** | **528.7** | **719.2** | **72.4** | **90.9** | **237.2** | **242.6** | **347.1** |
| Digital Therapeutics | - | - | - | - | - | -62.5 | - | -110.1 | - | -0.9 |
| **Digital Therapeutics– total** | - | - | - | - | - | **-62.5** | **-** | **-110.1** | **-** | **-0.9** |
| Abstral® royalties | 2.5 | 42.4 | 14.6 | 66.3 | 112.6 | - | - | - | - | - |
| Edluar® royalties | 4.0 | 6.1 | 9.5 | 10.2 | 11.6 | - | - | - | - | - |
| ZUBSOLV® - ex US | - | - | 0.1 | 0.1 | 0.1 | - | - | - | - | - |
| OX-MPI | - | 0.1 | - | 1.4 | 1.4 | - | - | - | - | - |
| **HQ & Pipeline segment – total** | **6.5** | **48.6** | **24.2** | **78.0** | **125.6** | **-39.5** | **15.0** | **-136.0** | **-82.9** | **-115.0** |
| **Total** | **150.3** | **231.2** | **504.4** | **606.7** | **844.8** | **-29.6** | **105.9** | **-8.9** | **159.7** | **231.2** |

US PHARMA (ZUBSOLV® US) NET REVENUES (LTM[1], SEK m)




US PHARMA (ZUBSOLV® US) EBIT AND EBIT MARGIN (LTM[1], SEK m)




[1] LTM, Last Twelve Months

## Net earnings

Net earnings amounted to SEK -84.9 m (111.7) for the quarter and to SEK -34.8 m (180.3) for the first nine months.

## 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] See Note 2.

### US Pharma

ZUBSOLV® US net revenues amounted to SEK 143.8 m (182.7) for the quarter, corresponding to -21.3 percent decline in SEK and in local currency (USD) to -14.9 percent, equal to sales of USD 16.2 m (19.1).

Net revenues for the quarter were negatively impacted by lower demand, a weaker USD and lower reversal of accrued product returns. This was partly offset by improved prices and increased wholesaler stocking compared to Q3 2019. Wholesaler stocking was reduced compared to Q2 2020.

Net revenues amounted to SEK 480.2 m (528.7) for the first nine months, corresponding to 9.2 percent decrease.

EBIT amounted to SEK 72.4 m (90.9) for the quarter explained by lower revenues and higher legal costs for the FDA subpoena partly offset by lower Cost of goods sold and lower operating expenses versus Q3 2019. EBIT amounted to SEK 237.2 m (242.6) for the first nine months.

### Digital Therapeutics

EBIT amounted to SEK -62.5 m (-) for the quarter and to SEK -110.1 m (-) for the first nine months, mainly explained by initial costs related to building up of an organization and enterprise platform and the initiation of the launch of deprexis® and vorvida®. First revenues are expected in Q4 2020.

### HQ & Pipeline

Partner revenues amounted to SEK 6.5 m (48.6) for the quarter mainly explained by reduced Abstral® royalties of SEK 2.5 m (42.4). Abstral® royalty for sales in Europe was 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 the market. Edluar® royalties amounted to SEK 4.0 m (6.1). Total partner revenues amounted to SEK 24.2 m (78.0) for the first nine months.

EBIT amounted to SEK -39.5 m (15.0) for the quarter and to SEK -136.0 m (-82.9) for the first nine months, mainly explained by lower Abstral® royalties and lower other operating income and expenses of SEK -5.5 m (5.4) mainly explained by exchange-rate losses derived from revaluations of parent company balance sheet items in foreign currency, predominantly in USD.

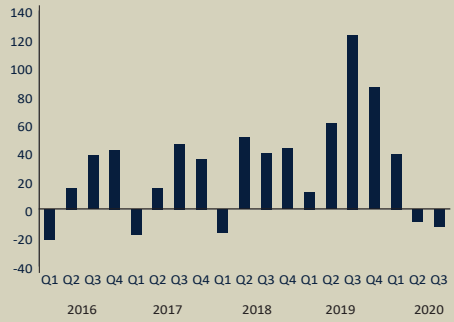
## Cash, cash flow and net cash/debt

As of September 30, 2020, cash and cash equivalents amounted to SEK 593.3 m (812.9) and interest-bearing liabilities to SEK 224.1 m (289.2), i.e. a positive net cash position of SEK 369.1 m (523.7). In the quarter Orexo paid a non-refundable milestone to its partner GAIA AG for vorvida® and made investments in Digital Therapeutic enterprise platform and equipment for development organization. During the nine months period Orexo has bought back bonds equal to SEK 66.6 m.

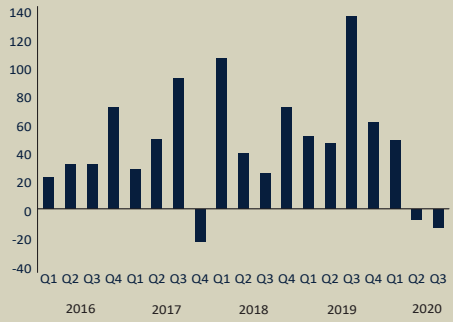
The net cash position enables Orexo to pursue its strategy to launch the digital therapies in the US, to

Cash and cash equivalents amounted to SEK 593.3 m (812.9).

EBITDA, SEK m




CASH FLOW FROM OPERATING ACTIVITIES, 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®.

progress the development pipeline and to launch OX124. In addition the cash from the corporate bond enables Orexo to continue to pursue business development opportunities to add new commercial stage products to the US commercial organization.

Cash flow from operating activities amounted to SEK -12.9 m (135.7) for the quarter and to SEK 28.0 m (230.7) for the first nine months.

## Investments

Gross investments in tangible and intangible fixed assets amounted to SEK 50.2 m (13.6). Higher investment is mainly explained by a payment of non-refundable milestone for vorvida®, investments in Digital Therapeutic enterprise platform and by purchase of equipment for the development organization.

## Equity

Shareholders' equity at September 30, 2020, was SEK 619.4 m (671.7). The equity/asset ratio was 46.6 percent (43.5).

## Parent company

Net revenues amounted to SEK 97.4 m (128.6) for the quarter of which SEK 91.0 m (80.2) was related to sales to Group companies. Net revenues amounted to SEK 366.4 m (346.7) for the first nine months of which SEK 342.1 m (268.4) was related to sales to Group companies.

Earnings before tax were SEK -43.9 m (100.8) mainly explained by investment into DTx.

Investments amounted to SEK 40.2 m (13.6).

As of September 30, 2020, cash and cash equivalents in the parent company amounted to SEK 439.0 m (411.2).

# Operations

## Commercial business

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

Throughout Q3 the Covid-19 pandemic continued to have significant impact on the sales force's ability to access healthcare providers. The fluctuating state by state mandates along with clinics changing hours of operation and staffing, has reduced the efficiency of reach and frequency requirements for ZUBSOLV®. Adding to the above is the significant change in the US unemployment rate. This has resulted in less new patient starts and patients switching to cash or public coverage, where generics have the greatest market access coverage versus branded competitors. Therefore, while the market demonstrated strong growth, ZUBSOLV's participation was limited and due to the low access to prescribers, thereby limited our ability to message on ZUBSOLV's advantages and market opportunities, e.g. withdrawal of authorized generic of Suboxone® Film.

*Sales development*
In Q3 2020 ZUBSOLV® net sales in USD declined 9 percent versus Q2 2020 mainly due to wholesaler destocking and a slight decrease in demand. Compared to Q3 2019 net sales declined with 15 percent mainly due to the formulary change impact at United Healthcare and Humana coupled with smaller declines in open and non-reimbursed business. Unit demand volume declined 4 percent over Q2 2020 and 18 percent over Q3 2019. Revenue decline over Q2 2020 significantly outpaced unit demand volume decline due to high stocking in Q2 and destocking in Q3. Additionally, Covid-19 had significant negative impact on US employment during the quarter resulting in volume decline of 1 percent in the commercial segment of the payer market versus last quarter, thus impacting ZUBSOLV® commercial volumes. The Public segment of the market demonstrated continued growth and, excluding Humana Medicare D, ZUBSOLV® maintained its volume in this segment versus last quarter.

*Market development*
The market demonstrated strong growth of 13 percent in unit volume compared to Q3 2019, and 2 percent growth over Q2 2020. This year is the fastest actual market growth recorded thus far since the launch of ZUBSOLV® in September 2013.

*Open formulary business[1]*
ZUBSOLV's open formulary business declined by 3 percent over Q2 2020 and declined by 4 percent over Q3 2019, excluding institutional non-retail business Open grew 1 percent over Q3 2019. ZUBSOLV® was flat in Medicaid in Q3 2020 versus Q2 2020, but declined slightly in Commercial, Medicare and non-retail. Covid-19's impact on Commercial, Medicare and non-retail in this period resulted in flat market volumes, creating a challenging environment for ZUBSOLV® to generate growth. 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 5 percent over Q2 2020, and 37 percent over Q3 2019. ZUBSOLV® is growing in its largest Medicaid payer, Michigan, versus Q3 2019 and its second largest Medicaid payer, Maryland, versus Q2 2020.

*Earlier exclusive plans and non-reimbursed businesses*
ZUBSOLV´s volume in United Health Group and Humana has decreased 7 percent versus Q2 2020 and 33 percent versus Q3 2019. ZUBSOLV® business in the non-reimbursed volume, which includes WellCare and Pennsylvania Medicaid, has decreased 2 percent versus Q2 2020 and 29 percent versus Q3 2019. United Commercial ZUBSOLV® volume decline is slowing, with Q3 over Q2 2020 showing the lowest quarterly ZUBSOLV® volume decline since generic film was added to formulary, despite United´s total market volume declined due to Covid-19.

Throughout Q3 the Covid-19 pandemic continued to have significant impact on the sales force's ability to access healthcare providers.

[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® maintained its best-in-class coverage in the commercial segment at 98 percent. The largest payer in the commercial segment is ESI & CIGNA with 22 percent of the commercial market, from January 1, 2021, ZUBSOLV® will be the only preferred branded product on ESI and CIGNA´s national commercial and Medicare Part D formularies. Therefore, effective January 1, 2021, ZUBSOLV® will be the only preferred branded product on the top three Commercial PBM (ESI, Caremark & Optum) national formularies which totals 59 percent of the commercial buprenorphine/naloxone market.
ZUBSOLV® coverage in the public segment increased to 37 percent due to the win in Louisiana Medicaid.

*ZUBSOLV® in geographies outside the US*
Orexo has managed to establish a streamlined supply chain also outside the US. A low Cost of goods sold will be essential in response to the increasing price pressure from generics characterizing foremost the EU market. However, the packaging supplier has not been able to have its plant inspected during the Covid-19 pandemic, which is required to handle ZUBSOLV®. The delay has from a timing perspective affected the negotiation process with a potential EU partner.

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

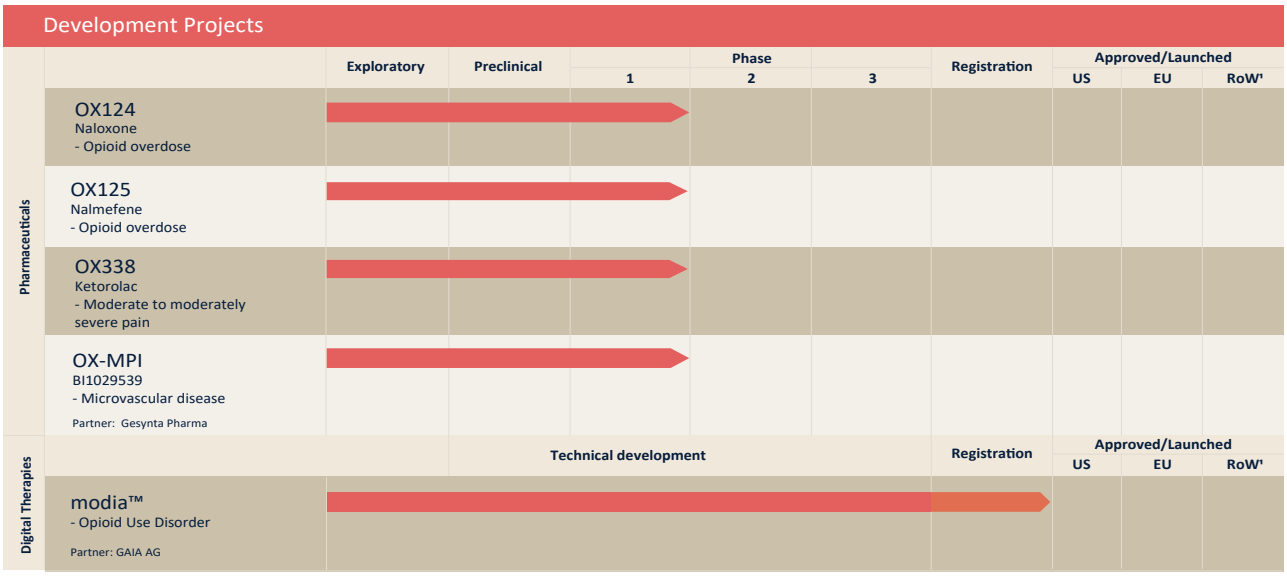
As a result of FDA´s Enforcement Policy, providing a fast track to market for digital therapies targeting psychiatric disorders the launch of the company´s digital therapies accelerated. In July both deprexis® and vorvida® were launched to payers and institutional healthcare providers to initiate the process to gain market access. In late September, the complete technical infrastructure was launched with adaptation to vorvida® with functionalities such as e-commerce, customer support and a service hub for insurance reimbursement. This novel ecosystem is fully scalable and the work to adapt it to deprexis® was initiated and a launch is planned in Q4.

During the quarter several discussions were initiated with national and regional payers, health care providers and distributors, resulting in signed distribution agreements with GoGoMeds and Trinity Health North Dakota. GoGoMeds is a nationwide digital pharmacy in the US who serves multiple state-owned and private employers. Within the agreement deprexis® and vorvida® will be available within their network of clients. Trinity Health is a comprehensive delivery network serving the North Dakota, Montana, and Saskatchewan region with over 240 providers and over 2800 employees. The agreement was signed to offer the digital therapies to their front line healthcare workers free of charge during the Covid-19 pandemic in the areas they serve. Orexo will continue to work with Trinity Health to expand the collaboration to new patient groups within their network.

In parallel with starting the launch of vorvida® and deprexis® to payers, Orexo has built the organization to manage the future commercialization of digital therapies in the US, and prepared a broader promotion towards patients and healthcare providers starting in October 2020.

In late September, the complete technical infrastructure was launched with adaptation to vorvida® with functionalities such as e-commerce, customer support and a service hub for insurance reimbursement.

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. Novel, proprietary drug delivery technology with patent protection until 2039.

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

*Changes during the quarter*
Orexo has during the quarter intensified the dialog with the FDA since the FDA has changed the technical requirements to devices delivering rescue medications. As a consequence Orexo has to perform additional testing and development of the nasal device to ensure it comply with the FDA requirements. These new requirements in combination with difficulties to travel due to Covid-19, will cause a delay in the pivotal trial, and it has now been preliminary rescheduled to Q2 2021. The objective remain to file with the FDA H2 2021, but the risk for a delay into Q1 2022 has increased. Orexo has filed an IND (Investigational New Drug) application, which is a first step towards finalizing the design of the pivotal trial, the New Drug Application (NDA) and the process to apply for fast track designation, which is required for a 2021 and Q1 2022 FDA filing.

### 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.

OX124: Orexo has filed an Investigational New Drug application, which is a first step towards finalizing the design of the pivotal trial, the New Drug Application and the process to apply for fast track designation.

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

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

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

*Changes during the quarter*
The FDA requirements to OX124 are fully applicable on OX125 also and most development resources have been redirected to OX124. OX125 development will slow down during the finalization of OX124.

**OX338 - acute moderate to moderately severe pain**

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

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

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

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

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

**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.

*Changes during the quarter*
The company has decided to move OX382 from a formalized project, to a pre-project, not including in the company´s pipeline. The work to address the issues identified in the in-vivo trial, will continue but with less resources and be placed on hold during 2021.

**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*
Based on positive results from the first human PK study in Q2 Gesynta finalized a new funding round enabling to enter a phase 2 study in patients suffering from systemic sclerosis in Q4 2020.

**modia™ (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 technical development was finalized and testing of all product compounds was initiated. The aim is to make the therapy ready for US launch in Q4 2020 to a controlled group of patients under FDA´s enforcement policy for digital health devices targeting psychiatric disorders during the Covid-19 pandemic.

The work also began to assess optional routes for commercialization of modia™ outside the US.

The work also began to assess optional routes for commercialization of modia™ outside the US.

# Other information

## Financial outlook 2020

• The buprenorphine/naloxone market will continue to show a double-digit growth
• ZUBSOLV® US net sales in Q4 2020 is expected to be in line with Q3 2020, and net sales for 2020 will decline compared to 2019
• Due to increased R&D investments, establishment of DTx business and accelerated DTx US launch OPEX will reach a level of SEK 675-725 m
• 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 exceed 50 percent
• Covid-19 has increased the uncertainty in the outlook
• The financial outlook is based on exchange rates in September 2020

## Forward looking statements

This report includes forward-looking statements. Actual results may differ from those stated. Internal and external factors may affect Orexo's results.

## Risks and uncertainty factors

Significant risks and uncertainties are presented in the Annual Report for 2019. The continued commercialization of ZUBSOLV® entails risk exposure of an operational nature and Orexo is continuously exposed to risks in relation to development projects and the intellectual property rights. The Covid-19 pandemic has increased the uncertainty about the market development and ZUBSOLV® sales.

Uppsala, Sweden, November 4, 2020

Nikolaj Sørensen
President and CEO

# Review report

Orexo AB, corporate identity number 556500-0600.

## Introduction

We have reviewed the condensed interim report for Orexo AB as at September 30, 2020 and for the nine months period then ended. The Board of Directors and the Managing Director are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

## Scope of review

We conducted our review in accordance with the International Standard on Review Engagements, ISRE 2410 Review of Interim Financial Statements Performed by the Independent Auditor of the Entity. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and other generally accepted auditing standards in Sweden. The procedures performed in a review do not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

## Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material respects, in accordance with IAS 34 and the Swedish Annual Accounts Act regarding the Group, and in accordance with the Swedish Annual Accounts Act regarding the Parent Company.

Uppsala, Sweden, November 4, 2020
Ernst & Young AB

Anna Svanberg
Authorized Public Accountant

# Financial reports, notes and key figures

**CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS**

| SEK m | Notes | 2020 Jul-Sep | 2019 Jul-Sep | 2020 Jan-Sep | 2019 Jan-Sep | 2019 Jan-Dec |
|---|---|---|---|---|---|---|
| Net revenues | 9 | 150.3 | 231.2 | 504.4 | 606.7 | 844.8 |
| Cost of goods sold | | -14.5 | -25.9 | -54.3 | -82.5 | -105.6 |
| **Gross profit** | | **135.8** | **205.3** | **450.1** | **524.2** | **739.2** |
| Selling expenses | | -83.3 | -45.0 | -207.7 | -141.3 | -191.9 |
| Administrative expenses | | -26.4 | -18.1 | -83.0 | -112.7 | -139.6 |
| Research and development expenses | | -50.3 | -41.6 | -165.9 | -122.7 | -181.3 |
| Other operating income and expenses | | -5.4 | 5.3 | -2.5 | 12.3 | 4.8 |
| **Operating earnings (EBIT)** | | **-29.6** | **105.9** | **-8.9** | **159.7** | **231.2** |
| Net financial items | | -10.8 | 8.7 | 10.9 | 19.2 | -3.3 |
| **Earnings before tax** | | **-40.5** | **114.6** | **2.0** | **178.9** | **227.9** |
| Tax | 5 | -44.4 | -3.0 | -36.8 | 1.3 | -8.8 |
| **Net earnings for the period**[1] | | **-84.9** | **111.7** | **-34.8** | **180.3** | **219.1** |
| Earnings per share, before dilution, SEK | | -2.45 | 3.22 | -1.00 | 5.21 | 6.33 |
| Earnings per share, after dilution, SEK | | -2.45 | 3.16 | -1.00 | 5.10 | 6.20 |

**CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME**

| SEK m | 2020 Jul-Sep | 2019 Jul-Sep | 2020 Jan-Sep | 2019 Jan-Sep | 2019 Jan-Dec |
|---|---|---|---|---|---|
| **Earnings for the period** | **-84.9** | **111.7** | **-34.8** | **180.3** | **219.1** |
| **Other comprehensive income** | | | | | |
| **Items that may subsequently be reversed to the statement of operations:** | | | | | |
| Exchange-rate differences | -4.8 | 5.9 | -4.9 | 9.6 | 3.4 |
| **Other comprehensive earnings for the period, net after tax** | **-4.8** | **5.9** | **-4.9** | **9.6** | **3.4** |
| **Total comprehensive earnings for the period**[1] | **-89.7** | **117.6** | **-39.7** | **189.9** | **222.5** |

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

## CONDENSED CONSOLIDATED BALANCE SHEET

| SEK m | 2020 Sep 30 | 2019 Sep 30 | 2019 Dec 31 |
|---|---|---|---|
| **ASSETS** | | | |
| **Fixed assets** | | | |
| Tangible fixed assets | 41.5 | 21.8 | 22.0 |
| Intangible fixed assets | 239.6 | 101.9 | 113.9 |
| Right-of-use assets | 64.7 | 62.2 | 57.0 |
| Deferred tax assets | 54.4 | 110.8 | 85.5 |
| Other financial assets | 0.8 | 12.3 | 1.4 |
| **Total fixed assets** | **401.0** | **309.0** | **279.9** |
| **Current assets** | | | |
| Inventories | 120.7 | 137.0 | 131.8 |
| Accounts receivable and other receivables | 213.2 | 286.4 | 272.6 |
| Cash and cash equivalents | 593.3 | 812.9 | 816.8 |
| **Total current assets** | **927.2** | **1,236.4** | **1,221.2** |
| **Total assets** | **1,328.2** | **1,545.3** | **1,501.1** |
| **SHAREHOLDERS' EQUITY AND LIABILITIES** | | | |
| **Total shareholders' equity** | **619.4** | **671.7** | **706.4** |
| **Long-term liabilities** | | | |
| Provisions | 33.6 | 8.3 | 10.7 |
| Long-term liabilities, interest bearing | 224.1 | 289.2 | 289.6 |
| Lease liabilities, long-term | 44.1 | 38.2 | 33.3 |
| **Total long-term liabilities** | **301.9** | **335.7** | **333.6** |
| **Current liabilities and provisions** | | | |
| Provisions | 200.9 | 281.9 | 269.3 |
| Current liabilities, non-interest bearing | 186.9 | 234.5 | 170.5 |
| Lease liabilities, current | 19.2 | 21.6 | 21.4 |
| **Total current liabilities and provisions** | **407.0** | **537.9** | **461.1** |
| **Total liabilities** | **708.9** | **873.6** | **794.7** |
| **Total shareholders' equity and liabilities** | **1,328.2** | **1,545.3** | **1,501.1** |

## CONSOLIDATED CHANGES IN SHAREHOLDERS' EQUITY

| SEK m | 2020 Sep 30 | 2019 Sep 30 | 2019 Dec 31 |
|---|---|---|---|
| **Opening balance, shareholders' equity** | **706.4** | **476.1** | **476.1** |
| Total comprehensive earnings for the period | -39.7 | 189.9 | 222.5 |
| Share-based payments | -20.0 | 3.6 | 5.8 |
| Buy back of shares | -27.3 | — | — |
| New share issue | — | 2.0 | 2.0 |
| **Closing balance, shareholders' equity** | **619.4** | **671.7** | **706.4** |

## CONDENSED CONSOLIDATED CASH FLOW STATEMENTS

| SEK m | Notes | 2020 Jul-Sep | 2019 Jul-Sep | 2020 Jan-Sep | 2019 Jan-Sep | 2019 Jan-Dec |
|---|---|---|---|---|---|---|
| Operating earnings (EBIT) | | -29.6 | 105.9 | -8.9 | 159.7 | 231.2 |
| Interest received | | 0.8 | 2.5 | 4.6 | 7.2 | 9.9 |
| Interest paid | | -3.4 | -3.7 | -10.7 | -11.1 | -17.7 |
| Income taxes paid | | -0.2 | 0.1 | -1.0 | -9.1 | -12.2 |
| Adjustment for non-cash items | 3 | -9.1 | -29.1 | -30.3 | 15.0 | 41.3 |
| **Cash flow from operating activities before changes in working capital** | | **-41.5** | **75.7** | **-46.3** | **161.7** | **252.5** |
| **Changes in working capital** | | **28.6** | **-60.0** | **74.3** | **69.0** | **34.5** |
| **Cash flow from operating activities** | | **-12.9** | **135.7** | **28.0** | **230.7** | **287.0** |
| Acquisition of tangible and intangible fixed assets | | -50.2 | -13.7 | -160.7 | -14.5 | -32.0 |
| Acquisition of financial assets | | — | -0.8 | — | -0.8 | — |
| Disposal of financial assets | | — | — | 0.6 | — | 9.5 |
| **Cash flow from investing activities** | | **-50.2** | **-14.5** | **-160.1** | **-15.3** | **-22.4** |
| New share issue | | — | — | — | 2.0 | 2.0 |
| Buy back shares | | — | — | -27.3 | — | — |
| Repayment of loans | | -4.2 | -36.9 | -79.7 | -51.4 | -55.8 |
| **Cash from financing activities** | | **-4.2** | **-36.9** | **-106.9** | **-49.4** | **-53.7** |
| **Cash flow for the period** | | **-67.4** | **84.3** | **-239.1** | **166.0** | **210.8** |
| **Cash and cash equivalents at the beginning of the period** | | **677.2** | **697.0** | **816.8** | **589.8** | **589.8** |
| Exchange-rate differences in cash and cash equivalents | | -16.5 | 31.6 | 15.6 | 57.1 | 16.1 |
| Changes in cash and cash equivalents | | -83.9 | 115.9 | -223.5 | 223.1 | 227.0 |
| **Cash and cash equivalents at the end of the period** | | **593.3** | **812.9** | **593.3** | **812.9** | **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 Jul-Sep | 2019 Jul-Sep | 2020 Jan-Sep | 2019 Jan-Sep | 2019 Jan-Dec |
|---|---|---|---|---|---|
| EBIT margin, % | -19.7 | 45.8 | -1.8 | 26.3 | 27.4 |
| Return on shareholder equity, % | -12.5 | 18.2 | -5.2 | 31.4 | 37.1 |
| Net debt, SEK m | -369.1 | -523.7 | -369.1 | -523.7 | -527.2 |
| Debt/equity ratio, % | 36.2 | 43.1 | 36.2 | 43.1 | 41.0 |
| Equity/assets ratio, % | 46.6 | 43.5 | 46.6 | 43.5 | 47.1 |
| Number of shares, before dilution | 34,710,639 | 34,710,639 | 34,710,639 | 34,603,847 | 34,621,646 |
| Number of shares, after dilution | 34,710,639 | 35,370,992 | 34,710,639 | 35,322,129 | 35,348,484 |
| Earnings per share, before dilution, SEK | -2.45 | 3.22 | -1.00 | 5.21 | 6.33 |
| Earnings per share, after dilution, SEK | -2.45 | 3.16 | -1.00 | 5.10 | 6.20 |
| Number of employees at the end of the period | 136 | 130 | 136 | 130 | 127 |
| Shareholders' equity, SEK m | 619.4 | 671.7 | 619.4 | 671.7 | 706.4 |
| Capital employed, SEK m | 843.5 | 960.9 | 843.5 | 960.9 | 996.0 |
| Working capital, SEK m | -73.0 | -114.5 | -73.0 | -114.5 | -56.7 |

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

## CONDENSED PARENT COMPANY STATEMENT OF OPERATIONS

| SEK m | Notes | 2020 Jul-Sep | 2019 Jul-Sep | 2020 Jan-Sep | 2019 Jan-Sep | 2019 Jan-Dec |
|---|---|---|---|---|---|---|
| Net revenues | | 97.4 | 128.6 | 366.4 | 346.7 | 534.0 |
| Cost of goods sold | | -21.0 | -17.3 | -66.6 | -67.6 | -98.6 |
| **Gross profit** | | **76.4** | **111.3** | **299.8** | **279.0** | **435.3** |
| Selling expenses | | -67.4 | -0.4 | -129.9 | -5.4 | -6.6 |
| Administrative expenses | | -7.8 | -10.5 | -42.5 | -89.4 | -105.6 |
| Research and development costs | | -36.5 | -35.0 | -128.8 | -101.5 | -152.3 |
| Other operating income and expenses | | 1.5 | 27.7 | 32.9 | 63.3 | 67.2 |
| **Operating earnings (EBIT)** | | **-33.8** | **93.1** | **31.6** | **145.9** | **238.0** |
| Interest income and expenses | | -2.6 | -2.7 | -8.3 | -9.0 | 40.0 |
| Other financial income and expenses | | -7.5 | 10.4 | 20.6 | 25.1 | -46.9 |
| **Net financial items** | | **-10.1** | **7.7** | **12.2** | **16.1** | **-6.9** |
| **Earnings before tax** | | **-43.9** | **100.8** | **43.8** | **162.0** | **231.1** |
| Tax | 5 | -43.5 | 0.0 | -43.5 | 0.0 | -11.8 |
| **Earnings for the period** | | **-87.4** | **100.8** | **0.3** | **162.0** | **219.3** |

## PARENT COMPANY STATEMENT OF COMPREHENSIVE INCOME

| SEK m | 2020 Jul-Sep | 2019 Jul-Sep | 2020 Jan-Sep | 2019 Jan-Sep | 2019 Jan-Dec |
|---|---|---|---|---|---|
| **Earnings for the period** | **-87.4** | **100.8** | **0.3** | **162.0** | **219.3** |
| **Other comprehensive income** | — | — | — | — | — |
| **Total comprehensive earnings for the period** | **-87.4** | **100.8** | **0.3** | **162.0** | **219.3** |

## CONDENSED PARENT COMPANY BALANCE SHEET

| SEK m | 2020 Sep 30 | 2019 Sep 30 | 2019 Dec 31 |
|---|---|---|---|
| **ASSETS** | | | |
| **Fixed assets** | | | |
| Intangible fixed assets | 230.4 | 101.9 | 113.9 |
| Tangible fixed assets | 41.5 | 21.8 | 22.0 |
| Deferred tax assets | 5.5 | 60.9 | 49.0 |
| Shares in subsidiaries | 163.0 | 154.3 | 155.6 |
| **Total fixed assets** | **440.5** | **338.8** | **340.6** |
| | | | |
| **Current assets** | | | |
| Inventories | 94.4 | 124.1 | 113.4 |
| Accounts receivable and other receivables | 136.3 | 192.0 | 214.1 |
| Cash and bank balances | 439.0 | 411.2 | 469.0 |
| **Total current assets** | **669.7** | **727.3** | **796.5** |
| | | | |
| **Total assets** | **1,110.2** | **1,066.1** | **1,137.1** |
| | | | |
| **SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES** | | | |
| | | | |
| **Shareholders' equity** | **597.0** | **584.6** | **644.0** |
| | | | |
| **Long-term liabilities** | | | |
| Other provisions | 31.9 | 6.6 | 8.2 |
| Bond loan | 224.1 | 289.2 | 289.6 |
| **Total long-term liabilities** | **256.1** | **295.8** | **297.8** |
| | | | |
| **Current liabilities** | | | |
| Accounts payable | 16.7 | 14.4 | 22.8 |
| Other liabilities | 10.5 | 8.2 | 6.0 |
| Liabilities to Group companies | 210.1 | 145.1 | 144.7 |
| Accrued expenses and deferred income | 19.8 | 18.1 | 21.8 |
| **Total current liabilities** | **257.2** | **185.7** | **195.3** |
| | | | |
| **Total liabilities** | **513.3** | **481.5** | **493.1** |
| | | | |
| **Total shareholders' equity and liabilities** | **1,110.2** | **1,066.1** | **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®.

No operating segments have been aggregated to form the above reportable operating segments.
The President and CEO is the chief operating decision maker and monitors the operating results of the group's segments separately for the purpose of making decisions about resource allocation and performance assessment. Segment performance is evaluated based on EBIT and is measured consistently with EBIT in the consolidated financial statements.

Comparative figures have been presented retroactively.

**DISTRIBUTION OF REVENUE AND EBIT PER SEGMENT**

| SEK m | 2020 Jul-Sep | 2019 Jul-Sep | 2020 Jan-Sep | 2019 Jan-Sep | 2019 Jan-Dec |
|---|---|---|---|---|---|
| **US Pharma** | | | | | |
| Net revenues | 143.8 | 182.7 | 480.2 | 528.7 | 719.2 |
| Operating earnings (EBIT) | 72.4 | 90.9 | 237.2 | 242.6 | 347.1 |
| | | | | | |
| **Digital Therapeutics** | | | | | |
| Net revenues | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Operating earnings (EBIT) | -62.5 | 0.0 | -110.1 | 0.0 | -0.9 |
| | | | | | |
| **HQ & Pipeline** | | | | | |
| Net revenues | 6.5 | 48.6 | 24.2 | 78.0 | 125.6 |
| Operating earnings (EBIT) | -39.5 | 15.0 | -136.0 | -82.9 | -115.0 |
| | | | | | |
| **Group** | | | | | |
| Net revenues | 150.3 | 231.2 | 504.4 | 606.7 | 844.8 |
| Operating earnings (EBIT) | -29.6 | 105.9 | -8.9 | 159.7 | 231.2 |
| Net financial items | -10.8 | 8.7 | 10.9 | 19.2 | -3.3 |
| Earnings before tax | -40.5 | 114.6 | 2.0 | 178.9 | 227.9 |

## 3. Cash flow

**ADJUSTMENT FOR NON-CASH ITEMS**

| SEK m | 2020 Jul-Sep | 2019 Jul-Sep | 2020 Jan-Sep | 2019 Jan-Sep | 2019 Jan-Dec |
|---|---|---|---|---|---|
| Depreciation/amortization and impairment | 8.7 | 8.2 | 26.8 | 26.7 | 41.0 |
| Change in provisions | 3.6 | -31.1 | -38.2 | -6.6 | -2.7 |
| Share based payments | -26.4 | -0.8 | -20.0 | 3.6 | 5.8 |
| Exchange rate income and expenses | 5.0 | -5.3 | 1.1 | -8.7 | -2.7 |
| **Total** | **-9.1** | **-29.1** | **-30.3** | **15.0** | **41.3** |

## 4. Legal disputes

On July 14 Orexo's US subsidiary received subpoenas for the purpose of enabling US authorities to obtain certain information in relation to sales and marketing of ZUBSOLV® and other buprenorphine products. Orexo has no knowledge of the background to the requests and is collaborating with the US authorities to ensure they receive the necessary information and to understand the scope of the investigations.

On August 10 the company announced it has received a "paragraph IV" patent certification notice from Sun Pharmaceutical Industries Limited ("Sun"). The Notice Letter advises Orexo of Sun's filing of an Abbreviated New Drug Application ("ANDA") with the US Food and Drug Administration (FDA) seeking approval of generic versions of ZUBSOLV® before the expiration of Orexo's patents listed in the Orange Book.

Orexo currently has five patents listed in the Orange Book (US Patent Nos. 8,470,361; 8,658,198; 8,940,330; 9,259,421 and 9,439,900) with expiration dates ranging from December 2027 to September 2032.

As a respons to above notice Orexo on September 13 filed a patent infringement action in the US District Court for the District of New Jersey, against Sun. The filing statutorily precludes FDA from approving Sun's ANDA for 30 months, or until a district court decision finds the patents to be invalid or not infringed, whichever occurs first.

## 5. Deferred tax

The current Swedish corporate tax rates have been announced with 21.4 percent from January 1, 2019, and 20.6 percent from January 1, 2021. In line with IFRS which on this area is based on a principle that changes in tax rates should be incorporated into the accounting for the relevant tax positions immediately upon enactment, the company has performed a tax analysis. The tax-loss carry-forward in the Group amounts to SEK 1,180 m as of December 31 2019 and refers to the Swedish companies. Deferred tax assets of SEK 5.5 m for tax-loss carry-forwards have been capitalized as per September 30, 2020, for the part of these tax-loss carry-forwards which the company has assessed as fulfilling the recognition requirements of IAS 12. There is no time limit for when the remaining loss carryforwards can be utilized. The rest of the tax effect of the Group's temporary differences are related to non-deductible current provisions for sales rebates, sales allowances, distribution, sales returns and other relevant deductions in the company's US operations.

## 6. Financial instruments

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

## 7. Related parties

There were no significant related parties transactions during the period.

## 8. Important events after the period

- ZUBSOLV®, the only branded product on the preferred national commercial and Medicare Part D formularies of the largest PBM in the Commercial segment in the US, Express Script
- Updated financial outlook 2020

## 9. Revenue from contracts with customers

| SEK m | | | 2020 Jul-Sep | | |
|---|---|---|---|---|---|
| **Segment** | **ZUBSOLV®** | **Abstral®** | **Edluar®** | **OX-MPI** | **Total** |
| US Pharma | 143.8 | — | — | — | **143.8** |
| Digital Therapeutics | — | — | — | — | **0.0** |
| HQ & Pipeline | — | 2.5 | 4.0 | — | **6.5** |
| **Total revenue from contracts with customers** | **143.8** | **2.5** | **4.0** | **0.0** | **150.3** |
| | | | | | |
| **Geographical markets** | **ZUBSOLV®** | **Abstral®** | **Edluar®** | **OX-MPI** | **Total** |
| US | 143.8 | — | 1.6 | — | **145.4** |
| EU & UK | — | 2.2 | 0.4 | — | **2.7** |
| Rest of the world | — | 0.2 | 2.0 | — | **2.2** |
| **Total revenue from contracts with customers** | **143.8** | **2.5** | **4.0** | **0.0** | **150.3** |

| SEK m | | | 2019 Jul-Sep | | |
|---|---|---|---|---|---|
| **Segment** | **ZUBSOLV®** | **Abstral®** | **Edluar®** | **OX-MPI** | **Total** |
| US Pharma | 182.7 | — | — | — | **182.7** |
| Digital Therapeutics | — | — | — | — | **0.0** |
| HQ & Pipeline | — | 42.4 | 6.1 | 0.1 | **48.6** |
| **Total revenue from contracts with customers** | **182.7** | **42.4** | **6.1** | **0.1** | **231.2** |
| | | | | | |
| **Geographical markets** | **ZUBSOLV®** | **Abstral®** | **Edluar®** | **OX-MPI** | **Total** |
| US | 182.7 | -0.3 | 2.7 | — | **185.1** |
| EU | — | 41.8 | 0.8 | 0.1 | **42.7** |
| Rest of the world | — | 0.9 | 2.6 | — | **3.5** |
| **Total revenue from contracts with customers** | **182.7** | **42.4** | **6.1** | **0.1** | **231.2** |

## 9. Revenue from contracts with customers

| SEK m | 2020 Jan-Sep | | | | |
|---|---|---|---|---|---|
| **Segment** | **ZUBSOLV®** | **Abstral®** | **Edluar®** | **OX-MPI** | **Total** |
| US Pharma | 480.2 | — | — | — | **480.2** |
| Digital Therapeutics | — | — | — | — | **0.0** |
| HQ & Pipeline | 0.1 | 14.6 | 9.5 | — | **24.2** |
| **Total revenue from contracts with customers** | **480.3** | **14.6** | **9.5** | **0.0** | **504.4** |
| | | | | | |
| **Geographical markets** | **ZUBSOLV®** | **Abstral®** | **Edluar®** | **OX-MPI** | **Total** |
| US | 480.2 | — | 3.0 | — | **483.2** |
| EU & UK | 0.1 | 14.1 | 2.1 | — | **16.3** |
| Rest of the world | — | 0.6 | 4.4 | — | **5.0** |
| **Total revenue from contracts with customers** | **480.3** | **14.6** | **9.5** | **0.0** | **504.4** |

| SEK m | 2019 Jan-Sep | | | | |
|---|---|---|---|---|---|
| **Segment** | **ZUBSOLV®** | **Abstral®** | **Edluar®** | **OX-MPI** | **Total** |
| US Pharma | 528.7 | — | — | — | **528.7** |
| Digital Therapeutics | — | — | — | — | **0.0** |
| HQ & Pipeline | 0.1 | 66.3 | 10.2 | 1.4 | **78.0** |
| **Total revenue from contracts with customers** | **528.8** | **66.3** | **10.2** | **1.4** | **606.7** |
| | | | | | |
| **Geographical markets** | **ZUBSOLV®** | **Abstral®** | **Edluar®** | **OX-MPI** | **Total** |
| US | 528.7 | 1.9 | 4.3 | — | **534.9** |
| EU | 0.1 | 62.2 | 1.6 | 1.4 | **65.3** |
| Rest of the world | — | 2.3 | 4.4 | — | **6.7** |
| **Total revenue from contracts with customers** | **528.8** | **66.3** | **10.2** | **1.4** | 606.7 |

| 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 Jul-Sep | 2019 Jul-Sep | 2020 Jan-Sep | 2019 Jan-Sep | 2019 Jan-Dec |
|---|---|---|---|---|---|
| EBIT | -29.6 | 105.9 | -8.9 | 159.7 | 231.2 |
| Depreciation and amortization | 17.4 | 8.2 | 26.8 | 26.6 | 40.9 |
| **EBITDA** | **-12.2** | **114.1** | **17.9** | **186.3** | **272.1** |
| DTx costs | 62.5 | — | 110.1 | — | 0.9 |
| **EBITDA excluding DTx costs** | **50.3** | **114.1** | **128.0** | **186.3** | **273.0** |

| RETURN ON SHAREHOLDERS' EQUITY | 2020 Jul-Sep | 2019 Jul-Sep | 2020 Jan-Sep | 2019 Jan-Sep | 2019 Jan-Dec |
|---|---|---|---|---|---|
| Shareholders' equity beginning balance | 735.5 | 552.9 | 706.4 | 476.1 | 476.1 |
| Shareholders' equity ending balance | 619.4 | 671.7 | 619.4 | 671.7 | 706.4 |
| Average shareholders' equity | 677.4 | 612.3 | 662.9 | 573.9 | 591.3 |
| Net earnings | -84.9 | 111.7 | -34.8 | 180.3 | 219.1 |
| **Return on shareholders' equity %** | **-12.5** | **18.2** | **-5.2** | **31.4** | **37.1** |

| OPERATING EXPENSES SEK m | 2020 Jul-Sep | 2019 Jul-Sep | 2020 Jan-Sep | 2019 Jan-Sep | 2019 Jan-Dec |
|---|---|---|---|---|---|
| Selling expenses | -83.3 | -45.0 | -207.7 | -141.3 | -191.9 |
| Administrative expenses | -26.4 | -18.1 | -83.0 | -112.7 | -139.6 |
| Research and development costs | -50.3 | -41.6 | -165.9 | -122.7 | -181.3 |
| Other operating income and expenses | -5.4 | 5.3 | -2.5 | 12.3 | 4.8 |
| **Operating expenses** | **-165.4** | **-99.4** | **-459.0** | **-364.5** | **-508.0** |

| GROSS INVESTMENTS SEK m | 2020 Jul-Sep | 2019 Jul-Sep | 2020 Jan-Sep | 2019 Jan-Sep | 2019 Jan-Dec |
|---|---|---|---|---|---|
| Investments in tangible fixed assets | 19.7 | 3.0 | 22.4 | 3.8 | 5.0 |
| Investments in intangible fixed assets | 30.5 | 10.7 | 138.3 | 10.7 | 27.0 |
| **Gross investments** | **50.2** | **13.6** | **160.7** | **14.5** | **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