



Develops improved pharmaceuticals and digital therapies addressing unmet needs within the growing space of substance use disorders and mental health



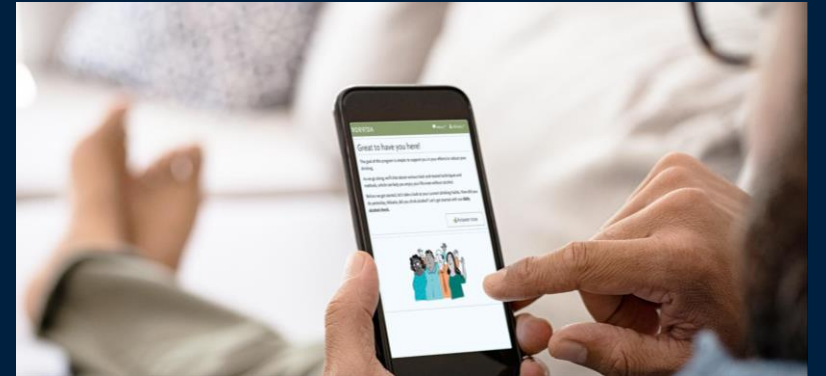
Interim Report Q3 2020, November 4th 2020

Nasdaq Stockholm: ORX US OTC Market: ORXOY (ADR)

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Quarterly overview & strategic agenda



Keeping focus and maximizing business opportunities in a challenging environment

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

- ZUBSOLV® only branded products on ESI & Cigna preferred national commercial and Medicare 2021 formularies
- Net revenues of SEK 150.3 m impacted by lower Abstral® royalties, currency effects and ZUBSOLV® demand
- ZUBSOLV® demand showed slight decline of 4% explained by Covid-19 and UHC/Humana vs Q2
- US Pharma continue with strong EBIT contribution from ZUBSOLV® with SEK 72.3 m and 50.3% margin
- Continued positive strong EBITDA of SEK 50.3 m when excluding DTx, despite loss of Abstral® royalties (SEK -12.2 m, reported)

Establishing Orexo as a leader in Digital Therapeutics

- Payment and reimbursement processing systems for vorvida® ready in late September, deprexis® will be added later in Q4
- Feedback from customers show a need for Orexo to have a comprehensive customer support system in place to process payments and reimbursement
- The investment in the customer support systems will become an important competitive advantage
- Modia™ technical development finalized and will move into final technical testing before commercial launch.

Focusing the investments on main value drivers

- Company prioritize investments in the launch of the three digital therapies and OX124
- OX125 and OX338 development will be slowed down to enable full focus on most important near term value drivers
- OX124 timelines have been impacted by new policies from FDA on devices delivering rescue medication and by difficulties to travel due to Covid-19
- OX124 pivotal trial moved to Q2 2021, but this has no impact on overall timelines, which are dependent on possible fast track designation from FDA and manufacturing

Existing net cash position and continuing profit from ZUBSOLV® enables continued investments in building a broader and stronger Orexo

Broadening...

..the portfolio of commercial products to be promoted by our existing US organization in 2020

Establishing...

..a new revenue generating business area within Digital Therapeutics (DTx) and launch first new product in 2020

Maintaining...

..ZUBSOLV® profit contribution in 2020 and ensure it is sustainable and growing over time

Launching...

..a new pharmaceutical product from Orexo's development pipeline within the next two years

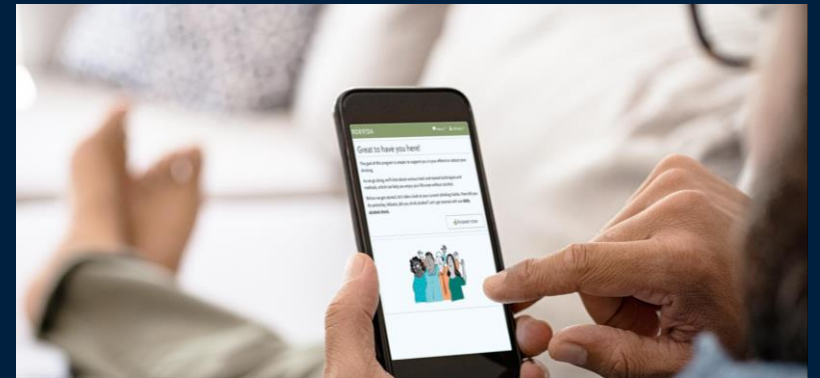


DTx: a new evidence-based
frontier in patient care

VORV!DA[®]

deprexis[®]

modia



Our ambition is to become a leader in digital therapeutics, leveraging our existing commercial infrastructure and new technical platforms to scale up

Enter DTx

deprexis[®]
VORV!DA[®]
modia[™]

orexo

Establish the platform

The image displays two screenshots of digital therapeutic platforms. The top screenshot is the VORV!DA website, featuring a green header with the text 'Here to help you get the most out of vorvida®'. Below this, there are sections for 'Get access through your insurance' and 'Get access through your employer', each with a 'Get access now' button. A 'Here to help' section with contact information is at the bottom. The bottom screenshot is the orexo 'Review & Sign Electronically' form, powered by Adobe Sign. It contains fields for 'Program User Information (All information required)' including First Name, Middle Initial, Last Name, Date of Birth, Gender, Street Address, City, State, Zip Code, Mobile Phone, Alternate Phone, and Email Address. It also has a section for 'Program User Health Insurance Information (All available information)'.

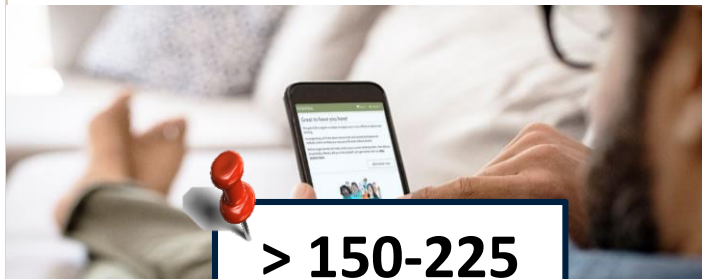
Expand presence and portfolio

The image shows a banner for the 'LYFEBULB AND OREXO INNOVATION CHALLENGE: SOLUTIONS FOR SUBSTANCE USE DISORDERS'. The banner includes the LYFEBULB logo, the challenge title, and a description: 'The goal of the initiative is to seek new solutions to unmet needs in supporting successful, long-term recovery from alcohol and opioid use disorders'. It also mentions the dates 'OCTOBER 14 & 15, 2020 VIRTUAL SUMMIT' and the 'Deadline for applications was Friday, August 14, 2020'. Below the banner is a blue box with the text 'Digital therapeutic quality, access, and appropriate utilization matter.' and a list of three bullet points: 'Are safe, effective, and ensure patient privacy', 'Demonstrate positive clinical and economic outcomes', and 'Influence the delivery of healthcare in a meaningful way'.

With 3 digital therapies, Orexo is well positioned to take a leading role addressing unmet needs within SUD and mental health issues

deprexis®

deprexis® is a fully automated digital therapy to help patients manage their symptoms of mild to severe depression with extensive clinical evidence

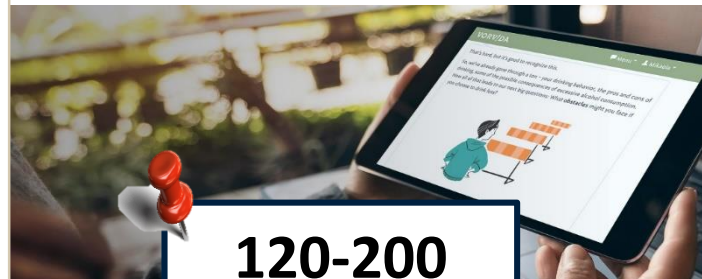


> 150-225

MUSD net sales potential in the US

vorvida®

A fully automated digital therapy scientifically proven to reduce troublesome drinking patterns in adults suffering from alcohol misuse incl. alcohol use disorder (AUD)



120-200

MUSD net sales potential in the US

OXD01/modia™

“Digitizing” counselling at scale to offer with ZUBSOLV®, a full medication assisted therapy (MAT) solution for opioid use disorder (OUD) patients in need



150-225

MUSD net sales potential in the US

Feedback from payors show a need and value from a comprehensive customer support system to process payments, reimbursement and insurance claims

Alternative Payor Models

Orexo see several alternatives for future payor models and will not apply a traditional one-fits-all Rx model

Pharmaceutical Model

- Reimbursement similar to pharmaceuticals or other medical benefits by insurance companies and employers

Framework agreement models

- Agreements with specific insurance companies to cover all customers
- Agreement with institutional health care providers

Patient model

- Patients paying for the therapy out-of-pocket

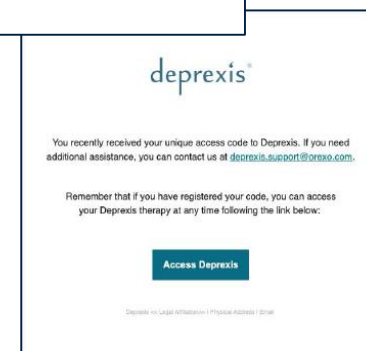
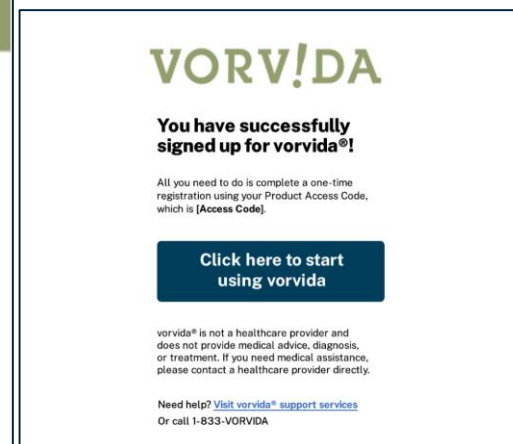
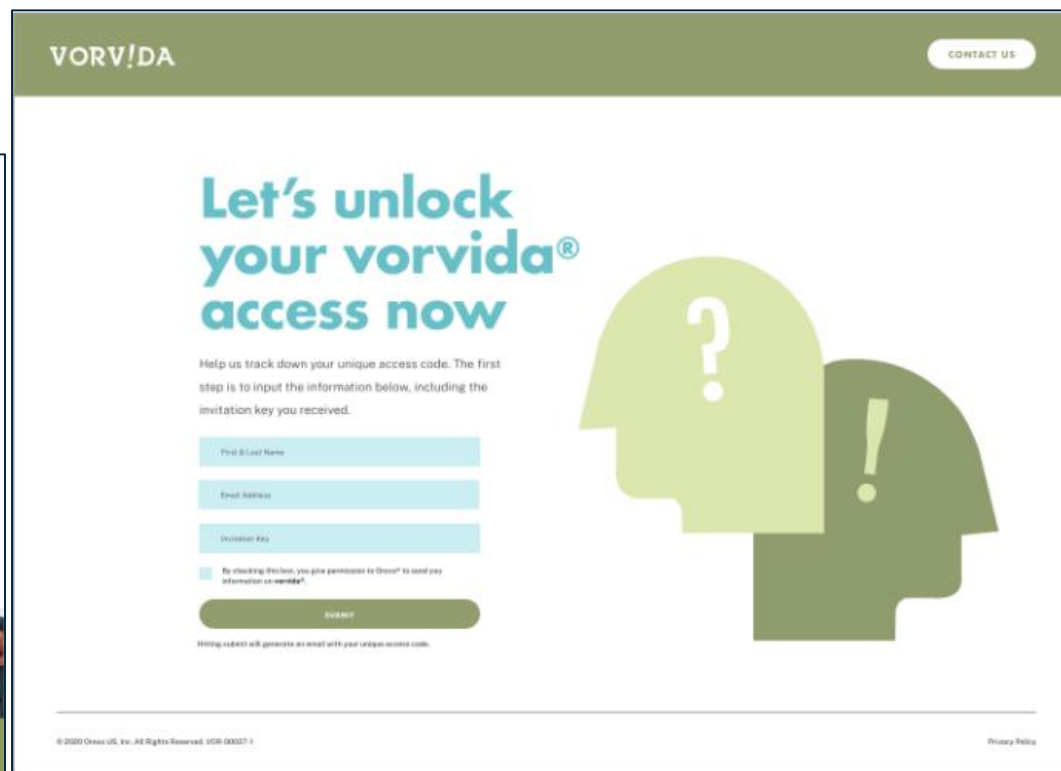
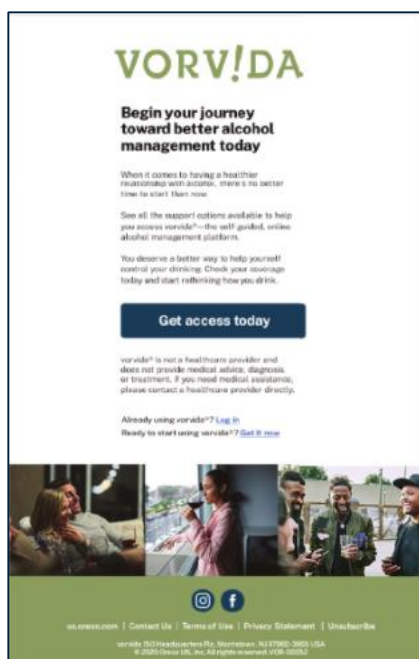
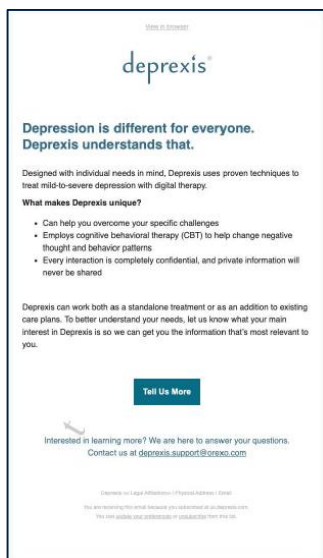
Focus on Q3

Ready September 25th

Payor models are evolving continuously, but no established standard has emerged

vorvida® customer support services launched September 25th

The customer support system is scalable to other DTx products and will become an important driver of sales



vorvida® patient services, available from September include specialty hub services for insurance reimbursement, customer service, e-commerce storefronts, and on-going customer relationship management tools. deprexis® equivalents will start going live in Q4

Several important milestones have been reached and a broader commercialization is about to start

Good progress in the launch of the first two DTx..



Medical need and treatment value of our DTxs is established and well received in early customer discussions



Several discussion with national and regional payers, health care providers and distributors entering final stages



vorvida® website with online purchasing, reimbursement and customer support functionality went live September 25th



modia™ technical development completed

..but we are still in early stages



No established reimbursement and distribution process exist for DTx, slowing down implementation



Promotion to patients and physicians to create demand was initiated in October



deprexis® website allowing online purchasing and reimbursement functionality will be launched later in Q4



modia™ will need to be tested from both a technical and clinical perspective before broad launch in H2 2021

Examples of agreements are GoGoMeds and Trinity Health (ND)

Both agreements are good stepping stones to larger opportunities within their networks



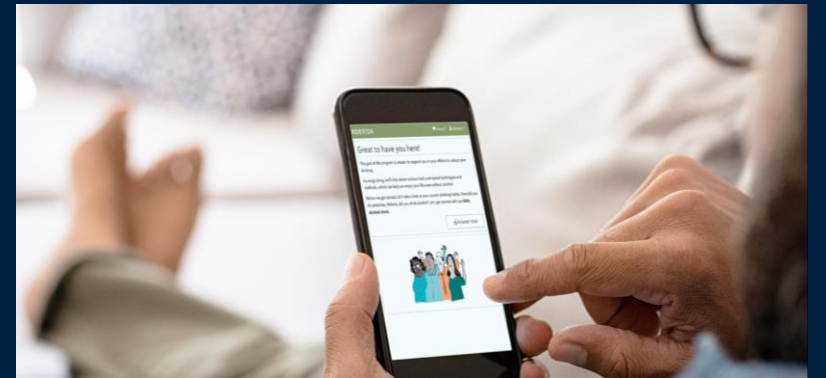
- Partnership to make deprexis® and vorvida® available for adjunctive treatment of depression and management of problematic alcohol misuse respectively
- GoGoMeds is a fully licensed pharmacy and authorized to do business in all 50 states and Washington, D.C.
- GoGoMeds services telemed companies, drug manufacturers, self-insured companies and directly to patients
- The partnership GoGoMeds will focus on making Orexo's DTx available through addiction services at the state level, including court systems, as well as through the private sector



- Trinity Health is a large network of non-profit healthcare providers and the agreement signed refers to Trinity Health in North Dakota and surrounding areas
- During Covid-19 their co-workers have been in the frontline relentlessly serving patients need in the wake of the pandemic
- To address issues of depression and alcohol abuse among employers (approx. 3000) they are offered Orexo's scientifically proven digital therapies deprexis® and vorvida®

Resilience in a challenging market environment


zubsolv[®] sublingual
tablets
(buprenorphine and naloxone) 



Continued impact from Covid-19 has created a challenging market for ZUBSOLV[®], but ZUBSOLV[®] has shown resilience

Strong market growth in Public segment, but decline in Commercial segment

- Strong overall market growth with 13%, but growth solely in Public segments and Cash, where generics have a favorable position
- Commercial segment is slightly declining due to Covid-19 and the increasing unemployment in the US
- Commercial segment remains the most important for ZUBSOLV[®] due to excellent reimbursement and less rebates than Public segment, but segment decline has direct impact on ZUBSOLV's ability to grow

Access to physicians improving, but is a challenge

- Entire field force returned to physical meetings in July 1
- Covid-19 restrictions have reduced access to clinics and to a greater extent the prescribers
- Access to prescribers is gradually improving during Q3, but continue to be significantly below pre-Covid-19 levels

ZUBSOLV[®] has showed resilience despite market challenges

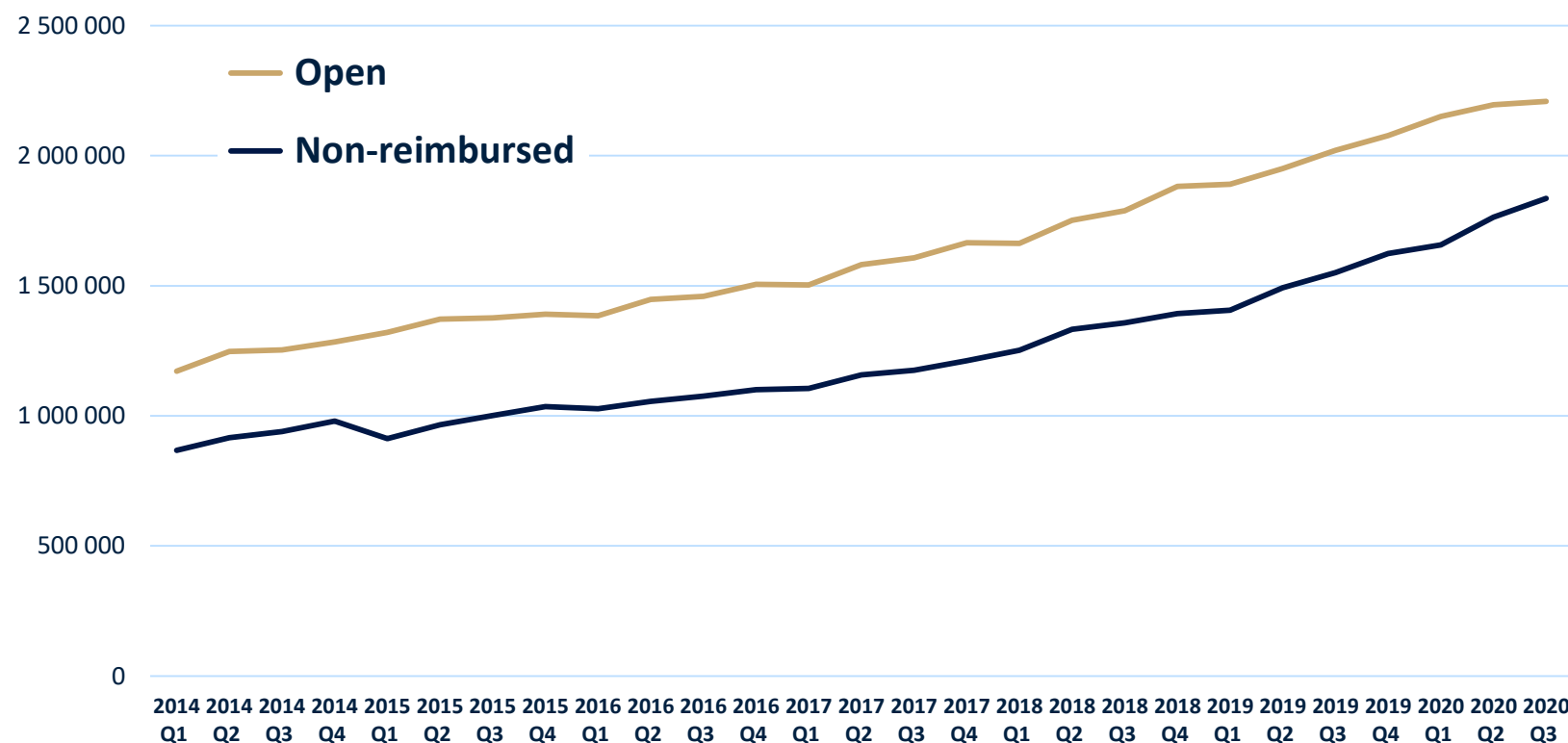
- Significant market access win in ESI & CIGNA, where is ZUBSOLV[®] now the **only preferred branded product on their 2021 Commercial and Medicare National formularies**
- ZUBSOLV[®] remains the **only branded product on top three US PBMs in 2021**, covering 59% of the commercial market
- **No loss of reimbursement for 2021**
- ZUBSOLV[®] dropped 4% in demand, but most of the drop is explained by decline in UHC
- Decline in UHC and Humana following Gx being added to formulary in 2019 has diminished to the lowest level since the changes were made

2020 market volume continues to have the strongest growth rate since ZUBSOLV launch

New market definitions applied by Orexo

Market Volume Sales

Quarterly NTRx



Q3'20 vs Q3'19 Growth

Total Market: +13%

By Segment

+9%

+18%

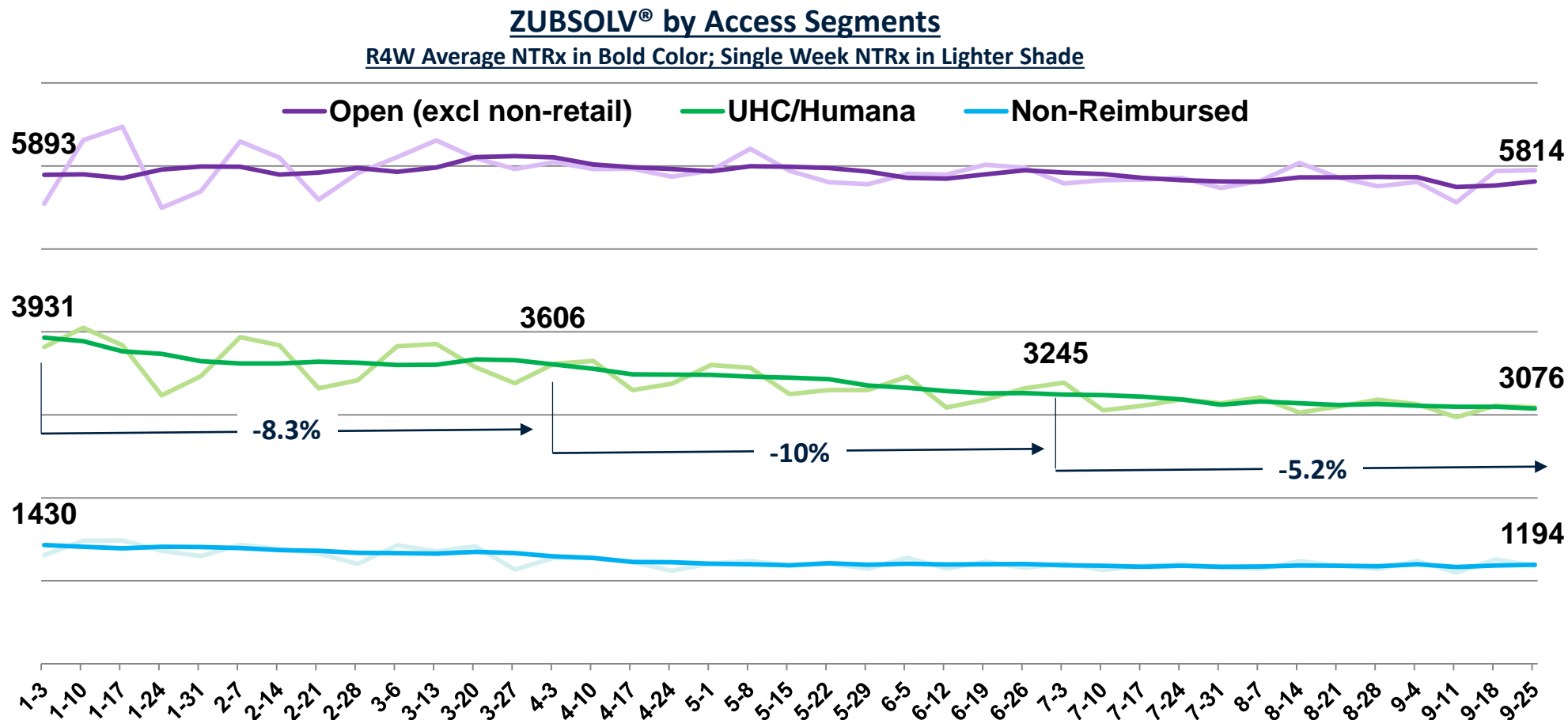
Definitions

Payers / Market Access

- **“Open”**
 - Market segments where Zubsolv® is reimbursed either exclusively or non-exclusively
- **“Non-Reimbursed”**
 - Market segments where Zubsolv® is not reimbursed

Open segment resilient throughout 2020 despite market challenges

UHC/Humana continue to decline, but the decline is fading during Q3



Source: IMS XPO

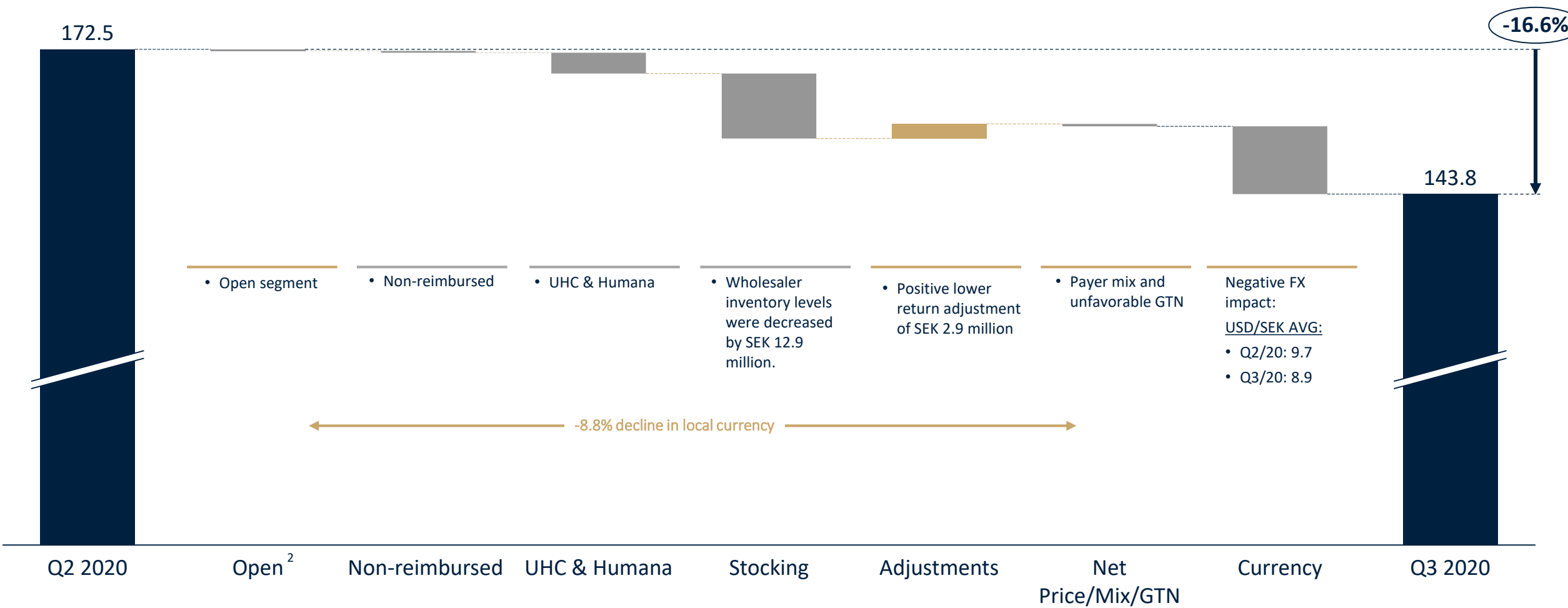
NTRx = Total prescriptions adjusted to 30 tablet/film scripts

Open: Market segments where Zubsolv® is reimbursed either exclusively or non-exclusively

Note: Historical figures may slightly vary due to IQVIA recategorization

Non-Reimbursed: Market segments where Zubsolv® is not reimbursed

ZUBSOLV® significant net Sales decline vs. Q2 2020 explained by isolated events and the continued decline in UHC/Humana



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

Several possible triggers for ZUBSOLV® growth in 2020 and beyond



Continued improvement in ZUBSOLV® market access

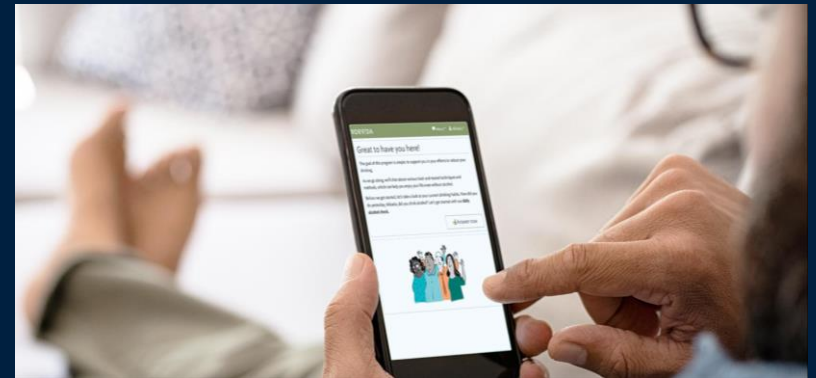
- ...ESI & Cigna have now listed ZUBSOLV® as the only preferred branded product on their 2021 Commercial and Medicare formularies. Confirming anticipated loss of access for leading branded competitor
- ...Louisiana Medicaid added ZUBSOLV® to preferred formulary increasing “public access” from 35% to 37% (effective July 1)
- ...Reimbursement coverage for ZUBSOLV® maintained for 2021

Orexo Sales Force now back to office-based selling after 3 months, but access to prescribers remain a challenge

- ... Currently entire team returning to office-based selling activities while continuing to use virtual selling as certain offices have entry restrictions based on policy & changing Covid-19 environment
- ...fluctuating restrictions and local outbreaks of Covid-19 will remain a challenge until the pandemic is under control, but Orexo continue to develop new selling methods to overcome barriers

Financials

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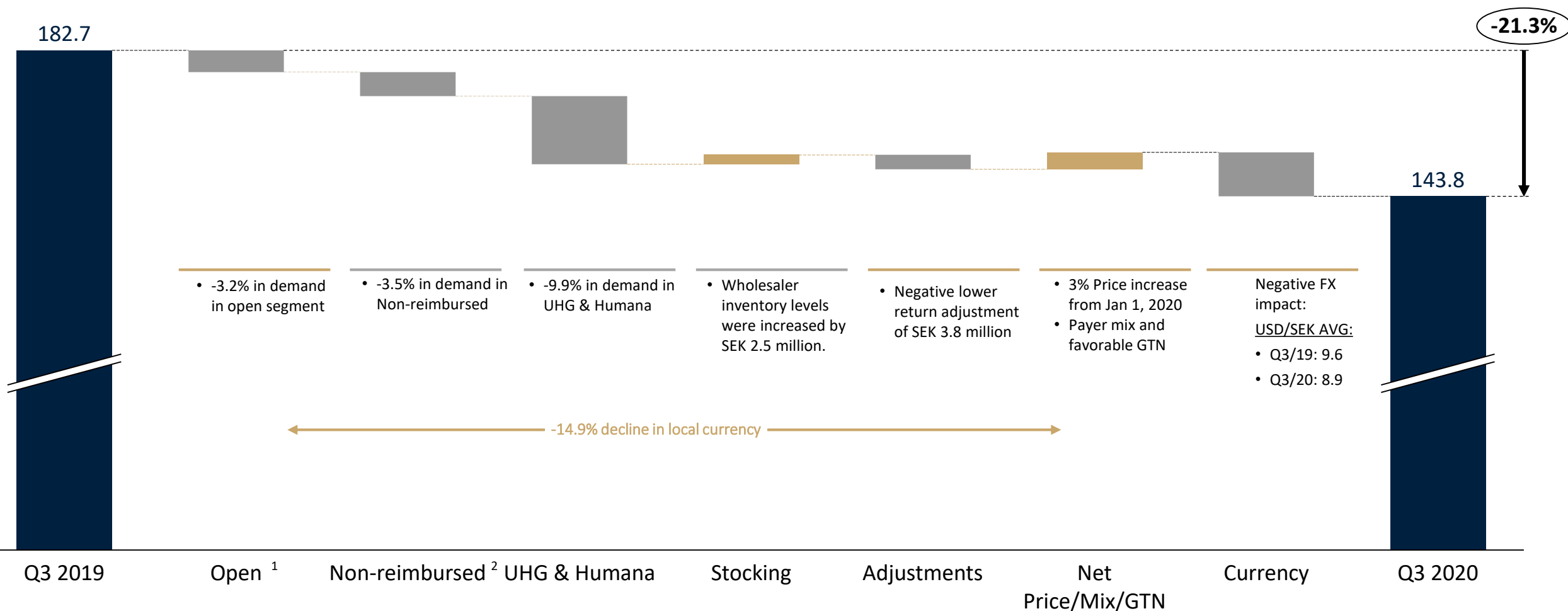


Q320 - Lower ZUBSOLV® net revenues and ceased Abstral® royalties in the EU and the US

SEK m	Q3 2020	Q3 2019	Jan - Sep 2020	Jan - Sep 2019	Jan - Dec 2019
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
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 – Total	6.5	48.6	24.2	77.9	125.6
TOTAL	150.3	231.2	504.4	606.7	844.8

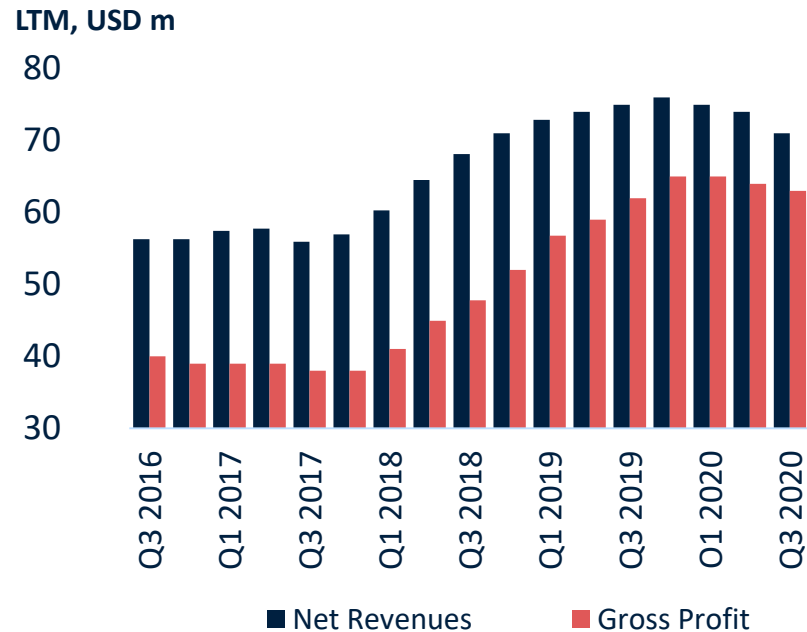
- Net revenues for Q320 declined 35.0% due to lower ZUBSOLV® US revenues and due to absence of Abstral EU and US royalties, ZUBSOLV® US revenues declined 21.3% in Q320 vs Q319 to SEK 143.8 m
- Abstral Q320 decline explained by expired agreement for EU royalties and by discontinued sales since October 31 2019 in the US following loss of patent protection and a slight decline in “rest of world”

ZUBSOLV® US net revenues growth by key drivers, Q3 2020 vs Q3 2019

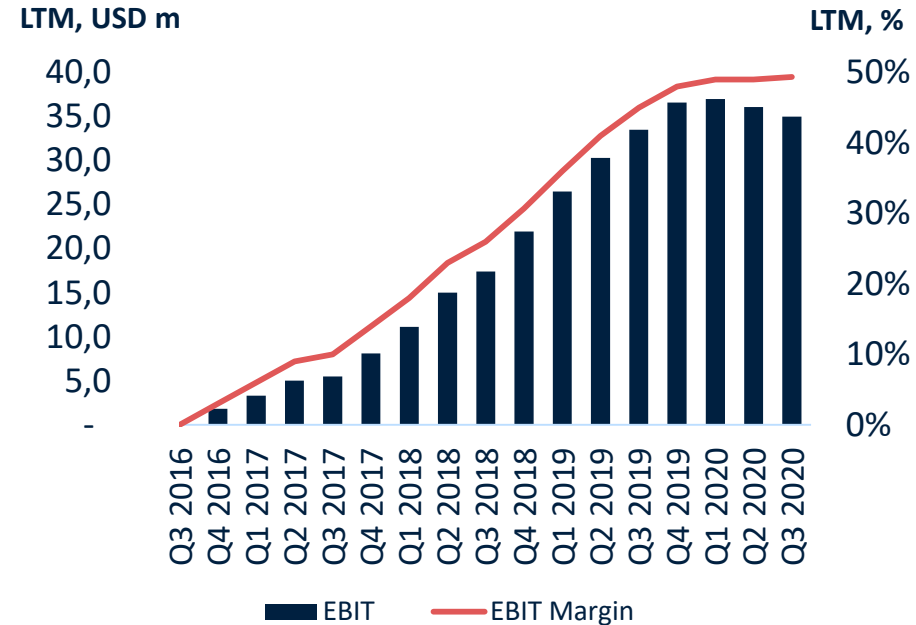


Q320 - US Pharma Operating Margin of 50.3%

Sales and gross profit



EBIT



- ZUBSOLV® US net sales LTM declined slightly to USD 70.8 m from USD 74.6 m in Q3 2019
- EBIT contribution of USD 35.0 m increasing from USD 33.5 m in Q319 driven by 39% lower COGS
- US Pharma EBIT margin of 49.4% LTM in Q320 increasing from 44.9% in Q319, EBIT margin in Q3 2020 reached 50.3%
- Full year US Pharma EBIT margin is expected to exceed 50% in 2020 and net sales for 2020 will decline compared to 2019.

Note: COGS converted from SEK to USD using monthly average exchange rates for the period.

Q320 - Increased investments in DTx and OX124

SEK m	Q3 2020	Q3 2019	Jan - Sep 2020	Jan - Sep 2019	Jan - Dec 2019
Net revenues	150.3	231.2	504.4	606.7	844.8
Cost of goods sold (COGS)	-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 & development expenses	-50.3	-41.6	-165.9	-122.7	-181.3
Other operating income & expenses	-5.4	5.3	-2.5	12.3	4.8
Operating Costs	-165.4	-99.4	-459.0	-364.5	-508.0
EBIT	-29.6	105.9	-8.9	159.7	231.2
Net financial items	-10.8	8.7	10.9	19.2	-3.3
EBT	-40.5	114.6	2.0	178.9	227.9
Tax	-44.4	-3.0	-36.8	1.3	-8.8
Net profit/loss	-84.9	111.7	-34.8	180.3	219.1
EBITDA	-12.2	114.1	17.9	186.3	272.1

Q320 comments:

- **COGS** for the quarter 44.0% lower vs prior year driven by manufacturing efficiency program and lower sales volumes
- **Operating Costs** above prior year due to:
 - Selling expenses increased explained by costs related to preparations to launch vorvida® and deprexis® in the US of SEK 53.5 m (-) partly offset by lower selling expenses in US Pharma of SEK 29.3 m (44.6).
 - Administrative expenses higher, 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.
 - R&D expenses higher due to the clinical trial of OX125 and final development of OX124 towards registration in 2021 partly offset by lower internal costs.
 - Other operating income contributed negatively due to exchange-rate losses derived from revaluations of parent company balance sheet items in foreign currency, predominantly in USD
- **Net Financial items** had negative impact mainly explained by negative unrealized exchange-rate impact of SEK 18.5 m derived from the parent company's foreign currency bank accounts mainly in USD.
- **Tax** negatively impacted by decreased parent company tax assets of SEK 43.5 m.

Q320 - Financial performance per business segment

US Pharma SEK m	Q3 2020	Q3 2019	Jan - Sep 2020	Jan - Sep 2019	Jan - Dec 2019
Net revenues	143.8	182.7	480.2	528.7	719.2
Cost of goods sold (COGS)	-12.6	-25.9	-51.9	-82.5	-105.6
Gross Profit	131.2	156.7	428.3	446.2	613.6
Operating expenses	-58.8	-65.9	-191.2	-203.5	-266.5
EBIT	72.4	90.9	237.2	242.6	347.1
Digital Therapeutics SEK m	Q3 2020	Q3 2019	Jan - Sep 2020	Jan - Sep 2019	Jan - Dec 2019
Net revenues	-	-	-	-	-
Cost of goods sold (COGS)	-1.8	-	-2.5	-	-
Gross Profit	-1.8	-	-2.5	-	-
Operating expenses	-60.6	-	-107.6	-	-0.9
EBIT	-62.5	-	-110.1	-	-0.9
HQ & Pipeline SEK m	Q3 2020	Q3 2019	Jan - Sep 2020	Jan - Sep 2019	Jan - Dec 2019
Net revenues	6.5	48.6	24.2	78.0	125.6
Cost of goods sold (COGS)	-	-	-	-	-
Gross Profit	6.5	48.6	24.2	78.0	125.6
Operating expenses	-46.0	-33.6	-160.2	-160.9	-240.6
EBIT	-39.5	15.0	-136.0	-82.9	-115.0

▪ **US Pharma** Continued strong EBIT margin of 50.3 percent due to reduced cost of goods and OPEX. Lower Zubolv revenues explains lower EBIT reduction.

▪ **Digital Therapeutics** Negative EBIT solely explained by investments in launch preparations of depraxis® and vorvida®.

▪ **HQ and Pipeline** Investments in OX124 and OX124 explain increased OPEX. The expected reduction in royalties from Abstral EU and US, explains negative EBIT contribution for the quarter.

Q320 - Strong financial position after investment in DTx

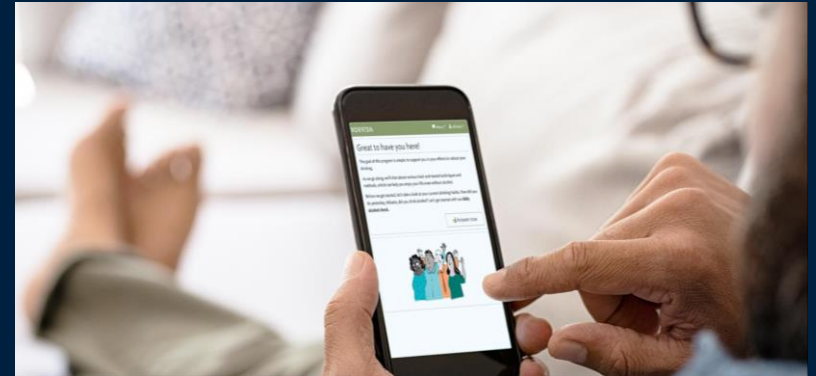
Cash position of SEK 593.3 m and a positive net cash position of SEK 369.1 m

Cash flow SEK m	Q3 2020	Q3 2019	Jan - Sep 2020	Jan - Sep 2019	Jan - Dec 2019
Cash flow from operating activities	-12.9	135.7	28.0	230.7	287.0
Investment activities	-50.2	-14.5	-160.1	-15.3	-22.4
Financing activities	-4.2	-36.9	-106.9	-49.4	-53.7
Cash flow (excl exchange rate differences)	-67.4	84.3	-239.1	166.0	210.8
Liquid funds	593.3	812.9	593.3	812.9	816.8
Net cash position	369.1	523.7	369.1	523.7	527.2

- Negative cash flow from operating activities for the period Q320
 - SEK 12.9 m negative contribution from operating activities.
- Investment activities had a negative impact of SEK 50.2 m primarily due to payment of a non-refundable milestone to GAIA AG for vorvida®, purchase of equipment for the development organization and investments in DTx enterprise platform.
 - Financing activities had a negative impact of SEK 4.2 m due to negative IFRS 16 impact
 - SEK 16.5 m negative impact on cash position due to weaker USD in September 2020
- Strong cash position at the end of Q320 with SEK 593.3 m despite large investments

Outlook

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Q320 - Financial outlook 2020

Previous guidance		Revised guidance
› The buprenorphine/naloxone market will continue to show a double-digit growth	➔	› No change
› ZUBSOLV® 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.	➔	› ZUBSOLV® US net sales in Q4 2020 is expected to increase over Q3 2020, but 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 750-800 m	➔	› 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	➔	› No change
› US Pharma EBIT margin will be in the range of 45-50 percent	➔	› US Pharma EBIT margin will exceed 50 percent

Two new legal processes emerging during July and August 2020

Subpoena

- On July 14, 2020 Orexo US received subpoenas to provide US Authorities with certain information with regards to ZUBSOLV® and other buprenorphine products. Orexo has no knowledge of the background to the requests.
- Orexo has engaged a US counsel to advise the company and prepare for any further requests or actions from the authorities

No further information or requests have been received from the authorities after July 14th 2020.

Patent infringement litigation against Sun Pharma

- Orexo on September 13 filed a patent infringement action in the US District Court for the District of New Jersey, against Sun Pharmaceuticals. The filing statutorily precludes FDA from approving Sun's ANDA for 30 months, or until a district court decision finds Zubsolv's patents to be invalid or not infringed, whichever occurs first
- Orexo currently has five patents listed in the Orange Book with expiration dates from Dec. 2027 to Sep. 2032

Orexo has previously successfully defended the ZUBSOLV® patents and is well prepared for a new process with Sun

1 Abbreviated New Drug Application

Value drivers for long-term growth 1 - 5

1

Product portfolio addressing large and growing markets

Focusing on becoming a leader in the large and growing space of substance use disorders and mental health. In parallel, Orexo is also addressing the ongoing opioid epidemic, one of the largest health crises to take place in the US and increasingly a growing global concern

2

Entering digital therapeutics, a new evidence-based frontier in patient care

Digital therapeutics can increase access to treatment and improve treatment outcomes, and is set to become an integral part of the global healthcare landscape. Substance use disorder and mental health are areas where it is most needed

Value drivers for long-term growth 1 - 5

3

Strong cash conversion to support growth

Lead product ZUBSOLV®, for the treatment of opioid use disorder, is a strong cash and profit contributor, enabling continued investment in on-market products, and R&D

4

Leveraging our US commercial excellence

Strategic focus on leveraging its commercial excellence and strong market access network in the US, by adding more products to the US commercial platform

5

Expanding pipeline targeting unmet medical needs

Continue to build on the strong experience of developing products with worldwide approval by expanding the pipeline with multiple short-time to market assets based on innovative drug delivery technologies and digital therapies, addressing unmet medical needs in our key therapeutic areas

Thank You

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