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

Interim Report Q4 2020, January 28 2021

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

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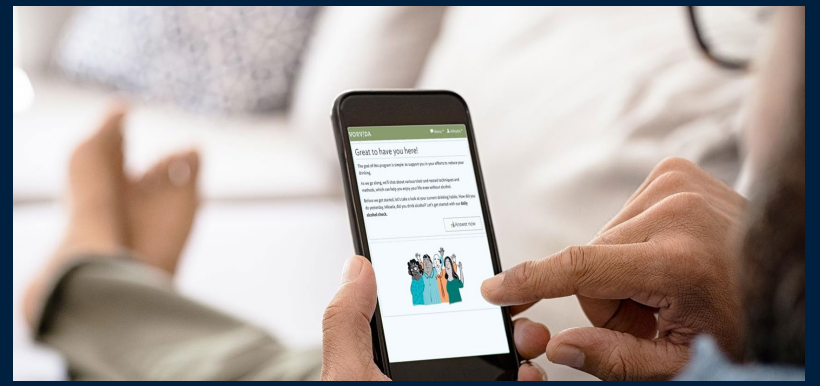
Quarterly highlights & strategic agenda



Progress while adjusting to new market dynamics following Covid-19 pandemic

US Pharma	**ZUBSOLV® stable and strong EBIT, despite challenging market due to Covid-19**
Digital Therapeutics	**Expanding the commercialization model in DTx and good progress in test of innovative reimbursement pathway**
HQ and Pipeline	**OX124 on track to file in Q1 2022, if fast track is approved. Agreement in place for ZUBSOLV® Europe**

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Strategic agenda to drive long-term growth

Broadening…

…the portfolio of commercial products to be promoted by our US Pharma and Digital Therapeutics businesses

Establishing…

…. a new revenue generating business area within DTx with three revenue generating products in the US market in 2021

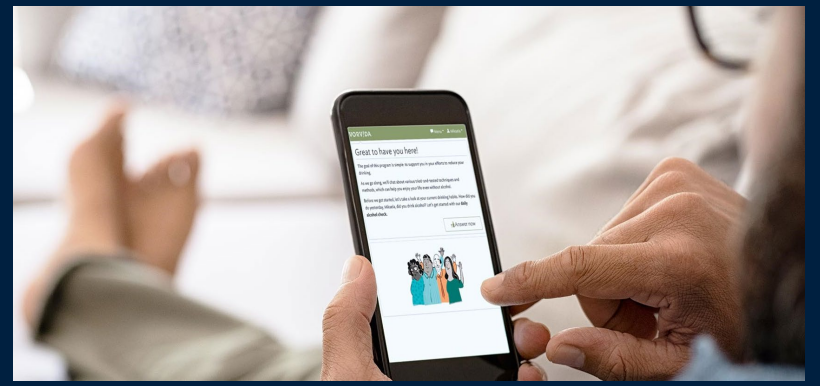
Maintaining…

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

Launching…

….OX124, opioid overdose rescue medication in the US

OX124 on track to file in Q1 2022, if fast track is approved



OX124 - a new stronger rescue medication with naloxone

Expected launch in late 2022

The unmet need

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

Our aim

A rescue medication that is stronger and longer-acting, and thus effective in reversing overdoses caused by synthetic opioids

The potential

70-110 million USD net sales (US market)

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OX124 will enter a >USD 300 million market

Recent market development

- **Covid-19 making the unmet need even more severe**:
  - According to estimated numbers 83,000 Americans died of an overdose in 2020, an increase of 21 percent[1]
  - Synthetic opioids are now representing 76 percent of opioid related deaths[1]
- **US market leader Narcan® sales at record level[2]**:
  - USD 234 m for first nine months 2020
  - 2020 Guidance: USD 295-315 m
  - Co-prescription legislation and standing orders at pharmacys will fuel growth going forward
- **New FDA requirements increase hurdle for new entrants**:
  - Competitor with high dose auto-injector received complete response letter and other competitors appear to be delayed

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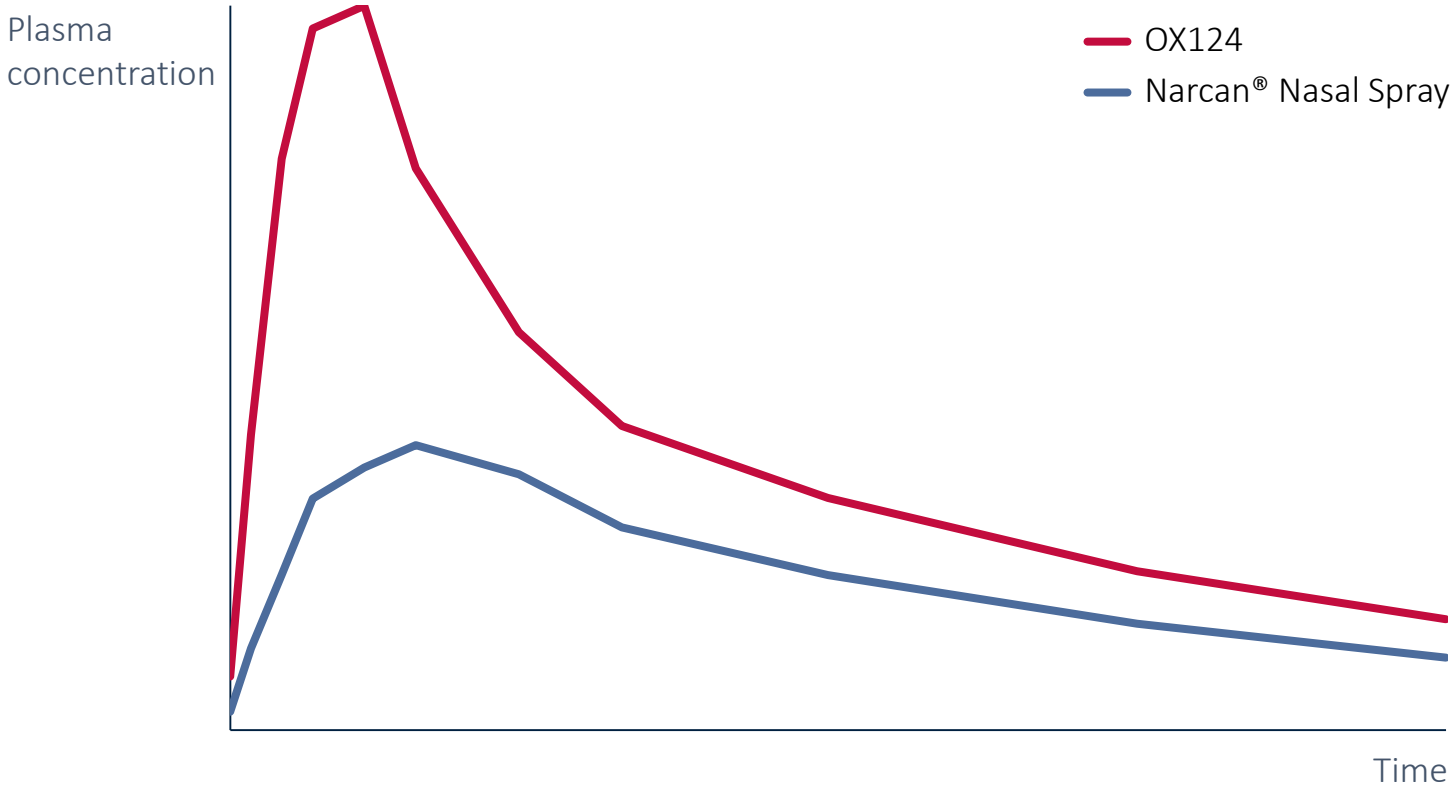
[1] June 2019 – June 2020 vs. June 2018 – June 2019 (https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm#dashboard)
[2] Emergent BioSolutions Q3 2020 Report

OX124 has shown better PK profile than Narcan® Nasal Spray

Faster, stronger and longer-acting vs Narcan® Nasal Spray

Results from exploratory PK study in healthy volunteers, 2019



Expected patient benefit

- Rescue more patients with the first dose (~34% of overdose patients require more than one dose of Narcan)
- Avoid ”second overdoses” thanks to longer duration (Fentanyl has a half life of 8-10 hours vs. 2 hours for naloxone)

Strong progress with the aim to launch in the US in late 2022

Q4 progress	2021-2022
✓ Established the full commercial supply chain of both devices and the API (Naloxone)	Q1 Receive a decision on the Fast Track Designation
✓ Received positive feedback from FDA on the investigational new drug (IND) application	Q2-Q3 Perform the pivotal bridging study
✓ Filed a Fast Track Designation with FDA	Q1,22 File the New Drug Application with FDA*
✓ Improved IP protection	Q4,22 Launch in the US*

* Assumes Fast Track Designation, without fast track designation, the filing will be delayed 6 months

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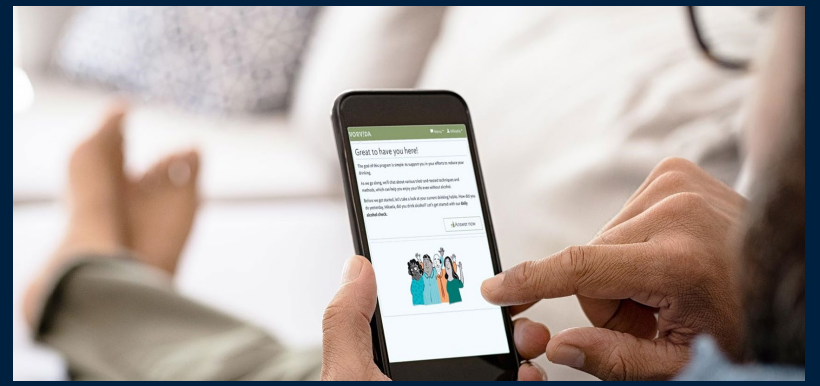
Expanding the commercialization model in DTx

VORV!DA®

deprexis®

modia



Digital Therapies is making progress, but Covid-19 is a short term challenge

- **While the interest in Orexo's digital therapies remains high, building a new market requires patience.**
- **We start to see several concrete and promising development with regards to DTx reimbursement, which is a cornerstone to accelerate growth.**
  - Reimbursement requests to >10 payers for named patients have been approved, although some difference in coverage
- **The expectations of our DTx portfolio in 2020 were boosted by the FDA's decision to implement a public health emergency policy allowing commercialization of digital therapies**
  - Payer response to Covid-19 has been less agile for new disruptive treatment and it takes time to review and decide on implementation pathways
  - Several payers have appointed dedicated people during Q4 on executive level to manage these processes e.g. United Health Group
- **Orexo response has time consuming pathway to reimbursement has been to pilot feasibility of reimbursement pathways and promotional concepts before moving to full scale commercial investment to ensure attractive ROI**
  - Covid-19 has made access to customers in all categories more challenging and some commercial investment have been delayed e.g. expansion of sales force outside ZUBSOLV® target group.
- **Direct to patient promotion intensified around the holidays end of 2020 and gained some traction**
  - New payment methods, including installments made available in December, New Years resolution rebate campaign

Learnings from the market response to date lead to continuous evolution of the commercial approach

We thought…

- Certain payers would **adopt fast** due to COVID and our flexible offers
- Medical benefit is the **optimal reimbursement** path
- **Regional** commercial insurers, Integrated delivery networks, and **"high liability"** employers are the best launch targets
- Educating on **evidence** and **experience** will drive differentiation
- Consumers can be **activated** on highly **confidential** issues

So far…

- Payer reaction **positive**, but process is not, need to **drive specific offers**
- Medical benefit remains the **optimal payer intro** path
- Target criteria still holds, however **complexity** of each needs a more **focused** approach
- **Orexo is a new player** in the field and needs to **build credibility**
- We are learning **early** signs of the activation journey and the value of peer recommendations

Our actions…

- **Integrate DTx into existing reimbursement categories** and test feasibility of reimbursement pathways.
- Requires **adaptation of payment** process e.g. monthly installments
- Hire **dedicated** new key account managers with strong networks, launch employer initiatives leveraging **business coalitions,**
- **Make product available to credible partner** for real world testing e.g. Trinity Health (ND) Texas Nurse Association and payers
- **Test consumer concepts** such as **campaign offerings**, and peer to peer information through **engagement of mentors**

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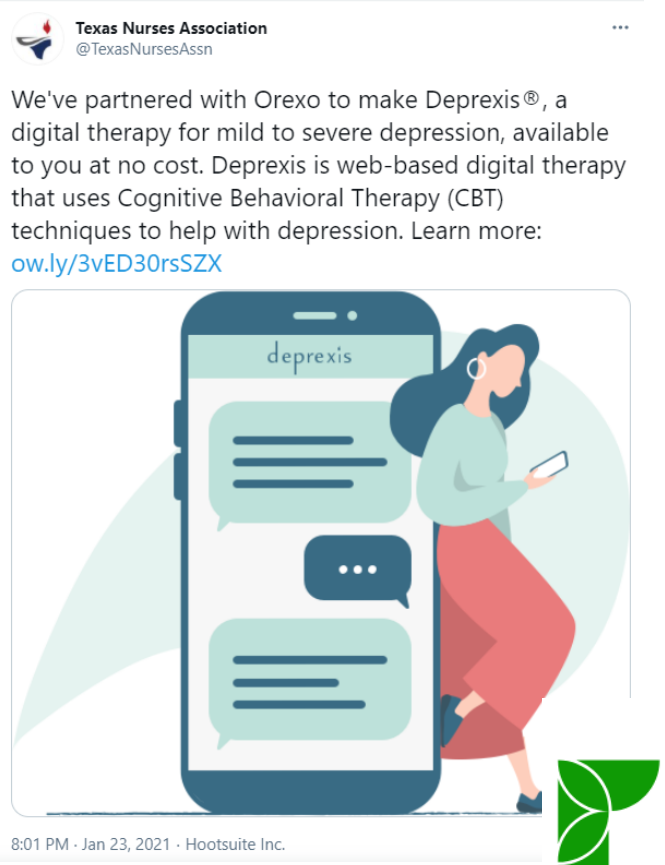
Partnering with healthcare providers during Covid-19 will present the value of the products while helping people in need



- Healthcare workers are working under extraordinary conditions during Covid-19 and Orexo is proud to support them with deprexis® and vorvida®
- Both have excellent scientific evidence, but lack strong reference cases from the US and positive experience from healthcare workers will help building credibility
- Based on expected prevalence of depression and alcohol misuse, a large share of the expected patients have decided to test the product(s) and the feedback is overwhelmingly positive
- Cases show the significant commercial potential when large employers decide to offer the product to their employees under commercial terms
- Both partners are used as references in discussions with commercial partners

TRINITY HEALTH

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modia™ technical development complete and is now ready to start real world testing in collaboration with payers

Bonding

modia — Menu — Mike

That sounds great, Mike. I'll do my best! I'll promise to listen to you, and to gently support you along our journey together. And even though I can't give you the hug you deserve, I really wish I could.

Now, the way we'll "talk" with each other here is a little unusual. Because I'm a computer program, I can't see you or hear you. I won't be able to hear the tone of your voice or see the expression on your face, but that doesn't mean we can't still communicate on a deeper level.

All you need to do is let me know what you think selecting one of the response options. Don't overthink it.

Even though some options might not exactly match how you're feeling, we'll still be able to dig in and make some real progress together.

Sounds pretty easy. ›

Diagnosing

modia — Menu — Mike

Okay, you've been traveling this road for a pretty long time. I'll keep that in mind as we move forward.

Now, I want you to tell me how you feel about your recovery journey as of today. Right at this moment. Having been on it for more than a year, I imagine there have been a lot of ups and downs.

How have these experiences affected you, Mike?

Honestly, I'm starting to lose hope. I'm not sure I can see a world without opioids. ›

I'm feeling optimistic. I know I can do this. ›

Education

modia — Menu — Mike

What I really want us to delve into is: **How opioids affect our brains.**

I know how they make me feel, but I'm not sure what they do in there. ›

I already know most of it. ›

Continue ›

Examples and dialog reduced for illustrative purposes

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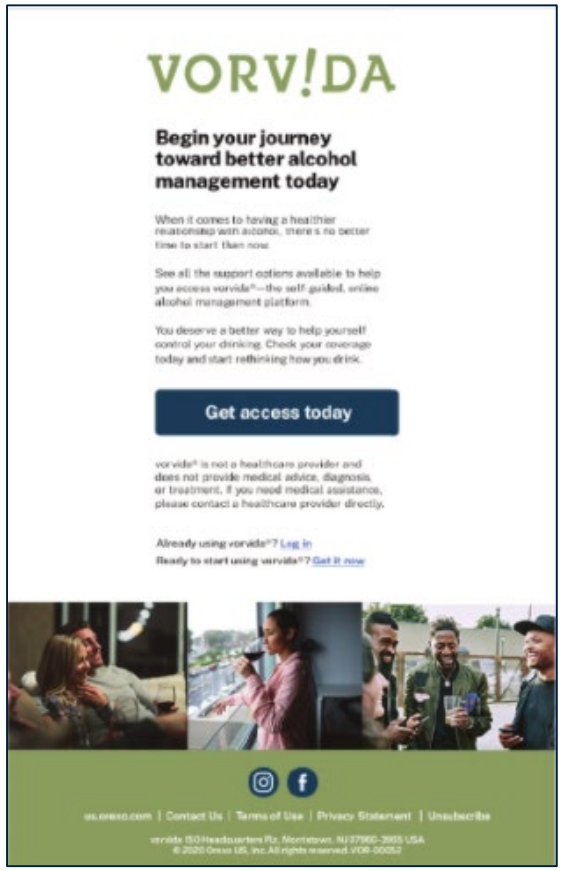
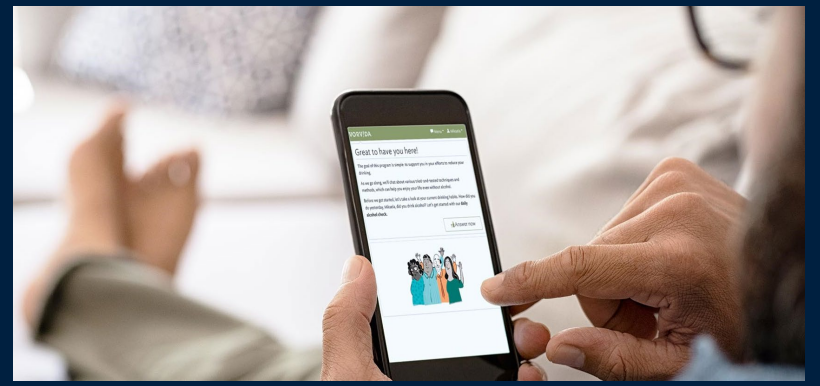
High expectations to 2021 for the Digital Therapeutics business



- Piloting of reimbursement pathways and commercialization concepts continues during Q1
- With positive outcome, Orexo's financial strength enables rapid acceleration of commercial efforts
- Partnership with larger health care providers anticipated with positive outcome of pilot testing reimbursement pathways
- Expectations to announce partnership with payers for either reimbursement or pilot programs to test one or more of the products in real world settings during Q1
- Positive experience with Trinity Health as an employer has triggered increased focus on large employers in the US and partnership with employers is expected to be announced during Q1 or early Q2

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



Covid-19 continues to create a challenging environment for ZUBSOLV®, though the brand continues to demonstrate resilence

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

- Strong overall market growth with 13%, but growth mainly in Public segments and Cash, where generics have a favorable position
- Commercial segment only at 1% growth due to Covid-19 and the fluctuating employment rate
- Commercial segment remains the most critical for ZUBSOLV® due to its excellent reimbursement position, and lower rebates than Public segment, but segment volume stagnation has direct impact on ZUBSOLV´s ability to grow

Access to physicians improving, but is a challenge

- Access to prescribers is gradually improving during Q4, but continue to be significantly below pre-Covid-19 levels
- Covid-19 restrictions have reduced access to clinics and to a greater extent the prescribers

ZUBSOLV® has showed resilience despite market challenges

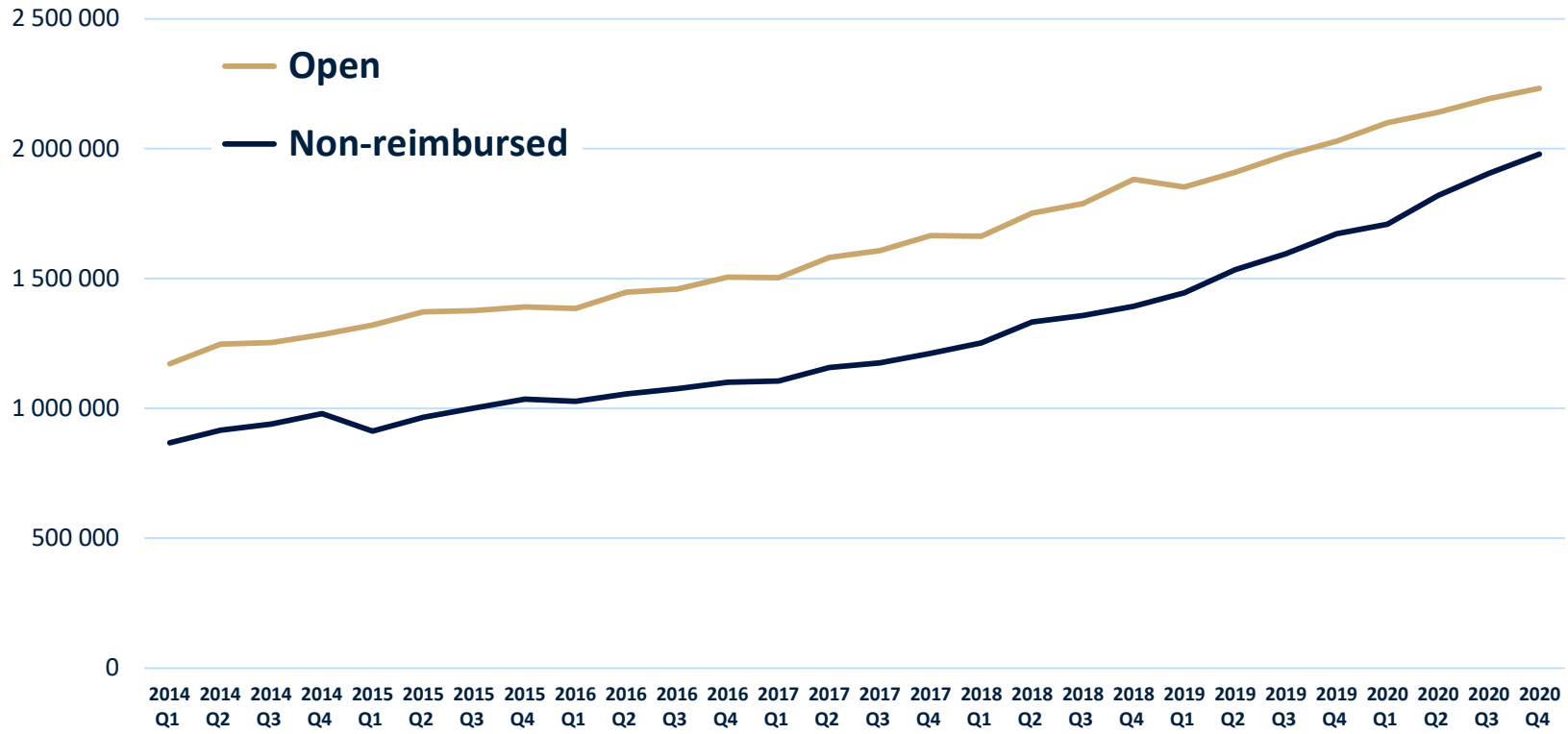
- **No loss of reimbursement for 2021**
- Significant market access formulary position improvement in ESI & Cigna, ZUBSOLV® is the **only preferred branded product on their Commercial and Medicare National formularies**
- ZUBSOLV® retains the **only branded product on top three US PBMs for 2021**, covering 57% of the commercial market
- ZUBSOLV® dropped 3% in demand, most of the drop is explained by decline in UHC and Humana
- 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 showed strongest growth rate since ZUBSOLV® launch

New market definitions applied by Orexo

Market Volume Sales

Quarterly NTRx



Q4 2020 vs Q4 2019 Growth

Total Market: +13%

By Segment

+10%

+18%

Definitions

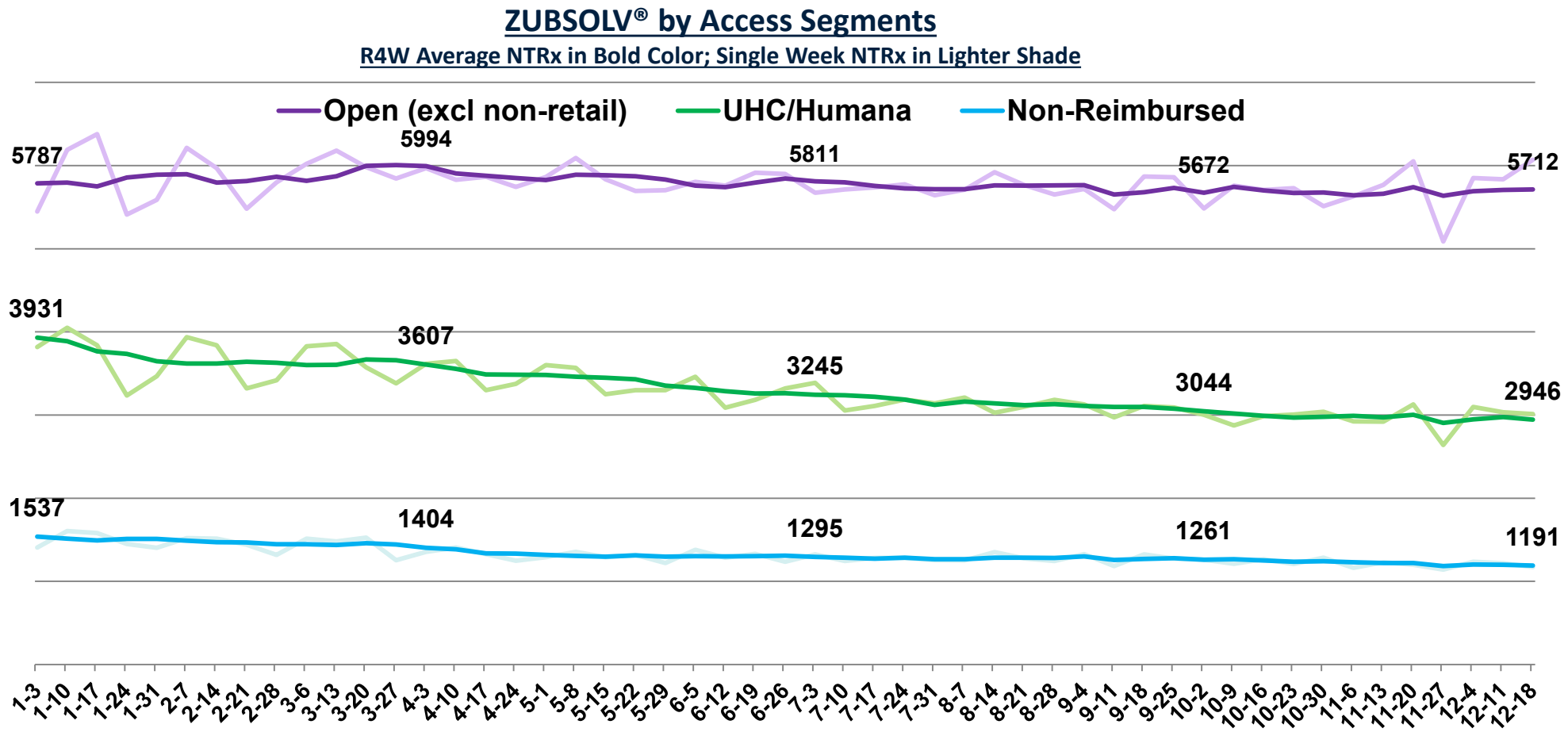
Payers / Market Access

- **"Open"**
  - Market segments where ZUBSOLV® is currently reimbursed either exclusively or non-exclusively
- **"Non-Reimbursed"**
  - Market segments where ZUBSOLV® is currently not reimbursed

Note: NTRx =Total prescriptions adjusted to 30 tablet/film scripts
Note: Historical figures may slightly vary due to IQVIA recategorization
Source: IQVIA XPO

Open segment resilient throughout 2020 despite market challenges

UHC/Humana continue to decline, but the decline is fading during Q4



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

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Several possible triggers for ZUBSOLV® growth in 2021

Continued improvement in ZUBSOLV® market access

…ESI & Cigna have now listed ZUBSOLV® as the only preferred branded product on their Commercial and Medicare formularies.

…Commercial access increased to 99%

Strong bi-partisan support to increase access to MAT

... The former US administration recently paved the way for all US physicians to prescribe medical-assisted treatment(MAT) for opioid dependence

…such a change will likely drive sustained strong market growth

…the opioid crisis will remain a key priority for the new Administration

Orexo Sales Force office access gradually improving

...Q4 2020 has had better office access than Q3 2020 and should continue to improve in 2021 as restrictions begin to ease post-vaccine roll out

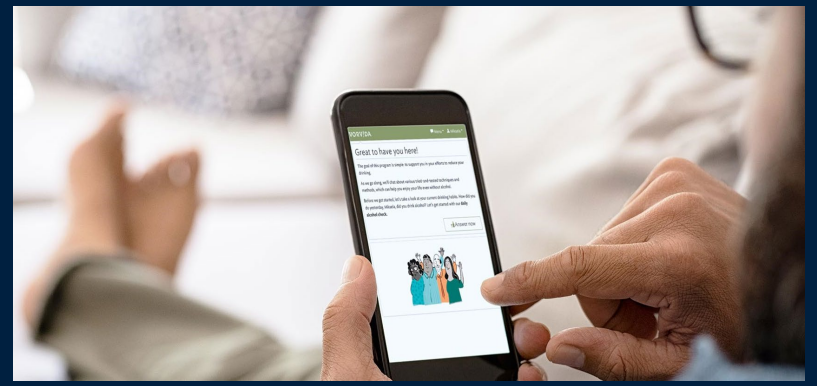
…Orexo to continue to develop new selling methods to overcome barriers

DTx offer new customer value proposition and synergies

...sales meetings including vorvida® get significantly more time from health care providers

…modia™ will provide patients, physicians and payers with a complete offering of both medication and psychological support

Financial information



Q420 - Lower ZUBSOLV® net revenues and ceased Abstral® royalties in the EU and the US

SEK m	Q4 2020	Q4 2019	Jan - Dec 2020	Jan - Dec 2019
ZUBSOLV® US	143.1	190.5	623.3	719.2
US Pharma – Total	**143.1**	**190.5**	**623.3**	**719.2**
Digital Therapeutics (DTx)	0.0	-	0.0	-
Digital Therapeutics (DTx) – Total	**0.0**	**-**	**0.0**	**-**
Abstral® royalties	15.1	46.2	29.7	112.6
Edluar® royalties	0.9	1.3	10.4	11.6
ZUBSOLV® – ex US	-	-	0.1	0.1
OX-MPI	-	0.0	-	1.4
HQ & Pipeline – Total	**16.0**	**47.5**	**40.2**	**125.6**
TOTAL	**159.2**	**238.1**	**663.6**	**844.8**

- Net revenues for Q420 declined 33.2% due to lower ZUBSOLV® US revenues and due to absence of Abstral EU and US royalties
- In local currency Zubsolv net revenues amounted to USD 16.7 m (19.8) and vs Q3 2020 US Pharma net revenues increased by USD 0.5 m, a growth of 3 percent.
- Abstral declined YoY due to expiry of license agreement in Europe and the US, some increase from Q3 SEK 15.1m vs SEK 2.5m

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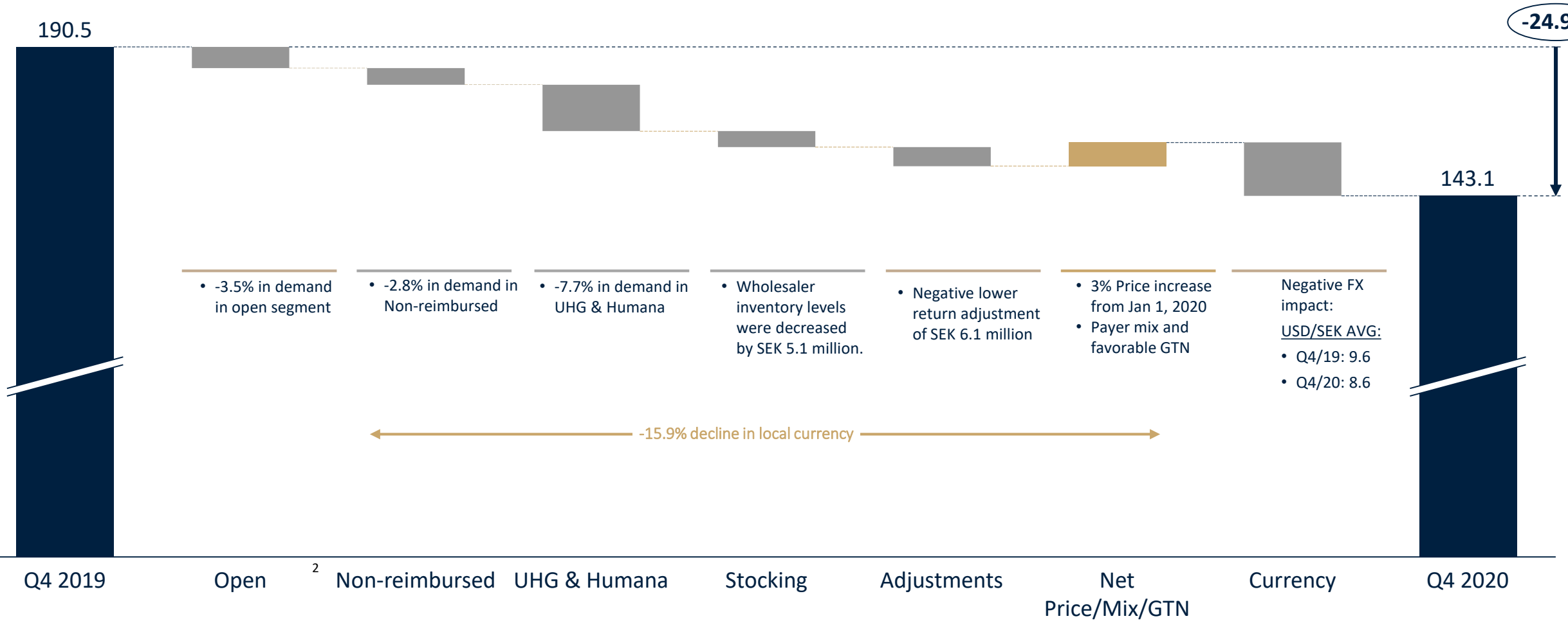
ZUBSOLV® US net revenues growth by key drivers, Q4 2020 vs Q4 2019

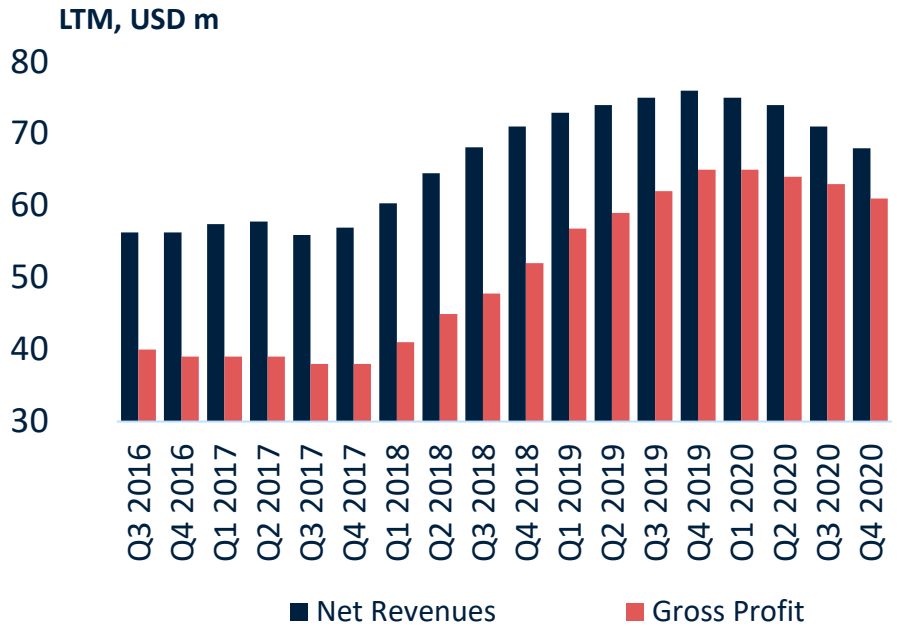


1) Orexo analysis using IMS demand data plus institutional sales

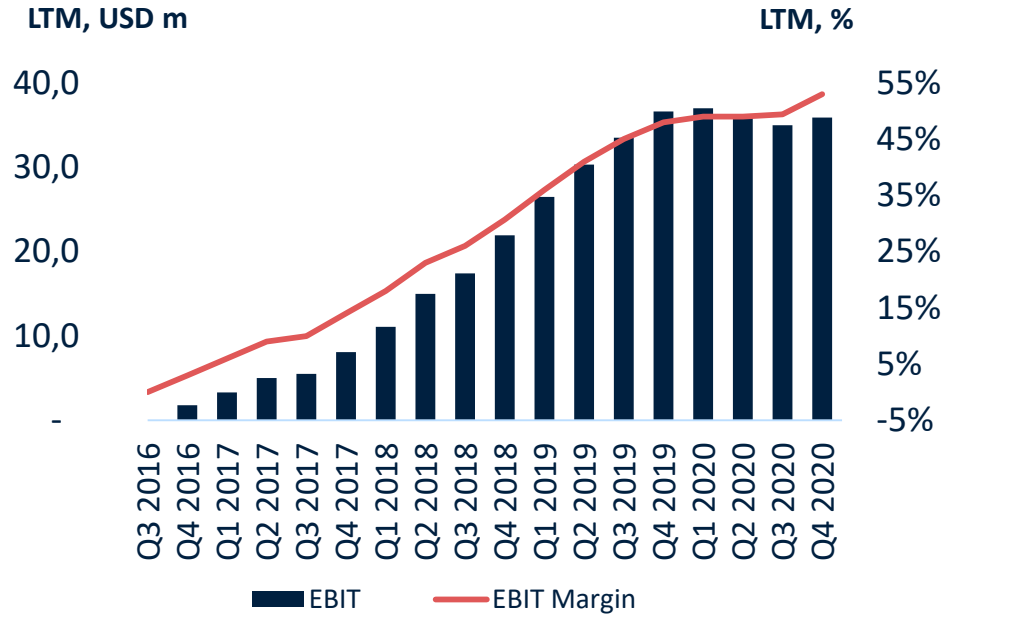
2) Excluding Cash segment and formulary changes (Wellcare, UHG and Humana)

Q420 - US Pharma Operating Margin (LTM) grew to 53.1%

Sales and gross profit



EBIT



- ZUBSOLV® US net sales declined to USD 67.6 m from USD 76.0 m in Q419
- EBIT contribution of USD 35.9 m with slight decrease from USD 36.6 m in Q419 driven by lower sales
- US Pharma EBIT margin of 53.1% LTM in Q420 increasing from 48.2% in Q419, EBIT margin in Q4 2020 reached 65.9%

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

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Q420 - Increased investments in DTx

SEK m	Q4 2020	Q4 2019	Jan - Dec 2020	Jan - Dec 2019
Net revenues	159.2	238.1	663.6	844.8
Cost of goods sold (COGS)	-11.3	-23.0	-65.6	-105.6
Gross Profit	**147.9**	**215.0**	**598.0**	**739.2**
Selling expenses	-79.0	-50.6	-286.6	-191.9
Administrative expenses	-19.8	-26.9	-102.8	-139.6
Research & development expenses	-59.0	-58.6	-224.9	-181.3
Other operating income & expenses	-1.1	-7.4	-3.6	4.8
Operating Costs	**-158.9**	**-143.5**	**-617.9**	**-508.0**
EBIT	**-11.0**	**71.5**	**-19.9**	**231.2**
Net financial items	-29.3	-22.5	-18.4	-3.3
EBT	**-40.3**	**49.0**	**-38.3**	**227.9**
Tax	-9.2	-10.1	-46.1	-8.8
Net profit/loss	**-49.6**	**38.9**	**-84.4**	**219.1**
EBITDA	**1.0**	**85.8**	**19.0**	**272.1**

Q420 comments:

- **COGS** for the quarter 50.9% 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 63.2 m (0.9) partly offset by lower selling expenses in US Pharma of SEK 24.5 m (49.4).
  - Administrative expenses decreased explained by lower costs for the long-term incentive programs following negative share price development and fair value adjustment versus prior quarter.
  - R&D expenses flat as higher costs for 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 5.5 m.

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Q420 - Financial performance per business segment

US Pharma SEK m	Q4 2020	Q4 2019	Jan - Dec 2020	Jan - Dec 2019
Net revenues	143.1	190.5	623.3	719.2
Cost of goods sold (COGS)	-9.1	-23.0	-61.0	-105.6
Gross Profit	**134.0**	**167.4**	**562.3**	**613.6**
Operating expenses	**-39.6**	**-71.9**	**-231.1**	**-266.5**
EBIT	**94.4**	**95.5**	**331.2**	**347.1**
EBITDA	**98.2**	**99.3**	**346.6**	**362.5**

Digital Therapeutics SEK m	Q4 2020	Q4 2019	Jan - Dec 2020	Jan - Dec 2019
Net revenues	0.0	-	0.0	-
Cost of goods sold (COGS)	-2.1	-	-4.6	-
Gross Profit	**-2.1**	**-**	**-4.6**	**-**
Operating expenses	**-63.2**	**-0.9**	**-170.8**	**-0.9**
EBIT	**-65.3**	**-0.9**	**-175.4**	**-0.9**
EBITDA	**-62.1**	**-0.9**	**-172.2**	**-0.9**

HQ & Pipeline SEK m	Q4 2020	Q4 2019	Jan - Dec 2020	Jan - Dec 2019
Net revenues	16.0	47.5	40.2	125.6
Cost of goods sold (COGS)	-	-	-	-
Gross Profit	**16.0**	**47.5**	**40.2**	**125.6**
Operating expenses	**-56.1**	**-70.7**	**-216.0**	**-240.6**
EBIT	**-40.1**	**-23.2**	**-175.8**	**-115.0**
EBITDA	**-35.1**	**-12.8**	**-155.5**	**-89.4**

US Pharma

- Lower revenue almost completely offset by reduced cost of goods and OPEX drive flat EBIT.
- EBIT increased significantly from Q3 (72.4) to SEK 94.4 m

Digital Therapeutics

- Negative EBIT explained by investments in launch activites of deprexis® and vorvida®
- SEK 30 k in revenues and SEK 0.1 m deferred revenues due to IFRS revenue recognition standards

HQ and Pipeline

- Investments in R&D and reduced royalties from Abstral explains negative EBIT contribution for the quarter.
- EBIT improved from Q3 (-39.5), explained by increased royalties from Abstral

Q420 - Financial position impacted by investment in DTx and in development projects

Cash position of SEK 505.3 m and a positive net cash position of SEK 280.8 m

Cash flow SEK m	Q4 2020	Q4 2019	Jan - Dec 2020	Jan - Dec 2019
Cash flow from operating activities	-11.2	60.2	16.8	287.0
Investment activities	-29.0	-11.0	-189.2	-22.4
Financing activities	-4.3	-4.3	-111.3	-53.7
Cash flow (excl exchange rate differences)	-44.6	44.8	-283.7	210.8
Liquid funds	**505.3**	**816.8**	**505.3**	**816.8**
Net cash position	280.8	527.2	280.8	527.2

Negative cash flow from operating activities for the period Q420

- SEK 11.2 m negative contribution from operating activities due to investments in DTx and OX124.
- Investment activities had a negative impact of SEK 29.0 m primarily due to payment of a non-refundable milestone to GAIA AG for modia™, purchase of equipment for the development organization and investments in DTx enterprise platform.
- SEK 43.4 m negative impact on cash position due to weaker USD in December 2020

Jan - Dec 2020 - Financial position adjusted with buyback of corporate bond loan and repurchase of 500,000 ordinary shares

Cash flow SEK m	Adjusted Jan - Dec 2020	Jan - Dec 2020
Cash flow from operating activities	16.8	16.8
Investment activities	-189.2	-189.2
Financing activities	-17.4	-111.3
Cash flow (excl exchange rate differences)	-189.8	-283.7
Liquid funds	**599.2**	**505.3**
Net cash position	308.1	280.8

- Cash flow impacted by SEK 93.9 m due to buyback of corporate bond loan and repurchase of ordinary shares
  - buyback of corporate bond loan of SEK 66.6 m
  - repurchase of 500,000 ordinary shares of SEK 27.3 m
- Net Cash position impacted by SEK 27.3 m due to repurchase of ordinary shares
- Orexo intent to initiate a process during Q1 2021 to issue a new corporate bond, refinancing the existing corporate bond expiring in November 2021

No changes in the two ongoing legal processes during Q4, except new patent issued for Zubsolv in December and listed in Orange book in January

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 advice 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.

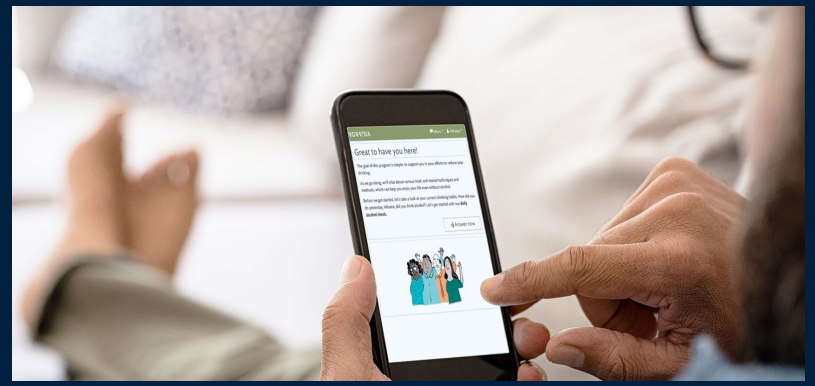
Patent infringement litigation against Sun Pharma

- 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 six 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

Outlook



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Q420 - Financial outlook 2021

- With the Covid-19 pandemic continuing, the financial outlook is associated with significant uncertainties in 2021. Orexo will continue to conservatively manage the cost base to reflect the market environment.
- The buprenorphine/naloxone market will continue to show a double-digit growth
- Normal seasonal decline for ZUBSOLV® US in Q1 2021 from Q4 2020, then a stabilization and growth of ZUBSOLV® US quarterly net sales when the impact of Covid-19 has disappeared
- Total OPEX will increase in 2021 from 2020, with OX124 driving increased R&D expenses and DTx investments will increase, but the increase will depend on DTx sales progression and market environment
- US Pharma EBIT margin will be in the range of 45-50 percent

The outlook is based on exchange rates in December 2020

Promising value triggers in 2021

Q1

Fast Track Designation for OX124

Orexo has applied for fast track designation at the FDA. With fast track designation FDA indicate the important contribution OX124 will have in the rescue of patients with opioid overdose. Fast track designation enable Orexo to file OX124 in Q1 2022, without fast track designation the FDA filing will be delayed ~6 months

Q1

Agreements with insurance companies for DTx products

Orexo is in concrete discussions with insurance companies, both with regards to reimbursement and pilot projects to test one or more of the DTx in a real world setting. Expectation is to announce agreements with insurance companies in Q1.

Promising value triggers in 2021

H1

Agreements with employers for DTx products

The positive outcome of the collaboration with Trinity Health and Texas nurse association, show the value to employers and for Orexo of these agreements. Increased efforts have been made towards employers in Q4 and we expect to have agreements in place during H1.

H1

Agreements with healthcare providers

Following positive outcome of the on-going reimbursement test in Pennsylvania, we expect to announce agreements with healthcare providers with broad reach in the US.

Q3

Results from pivotal trial for OX124

Orexo expect to initiate the pivotal trial in Q2 and the results will be ready early Q3. Based on the positive outcome of the first clinical trial, the pivotal trial has reduced risk.

Promising value triggers in 2021

H2

ZUBSOLV® stabilization and growth

With the expectation of Covid-19 to have significantly reduced impact on our ability to meet customers and on the unemployment in the US, we expect to see ZUBSOLV® stabilize and grow.

H2

Launch of ZUBSOLV® in Europe by Accord Healthcare

Following final approval of the supply chain in Europe by the authorities we expect launch of Zubsolv in Europe in H2

H2

Continued commercial progress of DTx and launch of modia™

The sales progress of DTx will be important to monitor and with successful pilots completed during H1, the broader roll-out of these concepts in combination with the launch of modia™ will be important long term value drivers.

Thank You

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