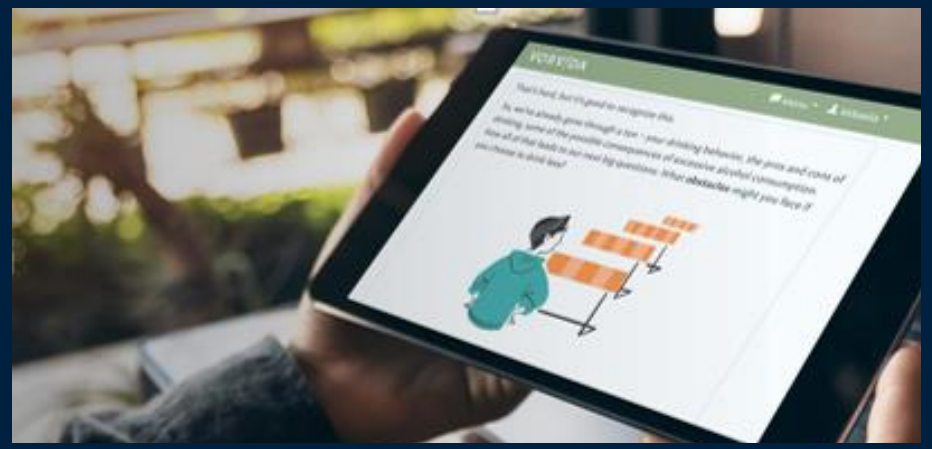
Develops improved pharmaceuticals and digital therapies addressing unmet needs within the growing space of substance use disorders and mental health



Interim Report Q1 April 29th 2021

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

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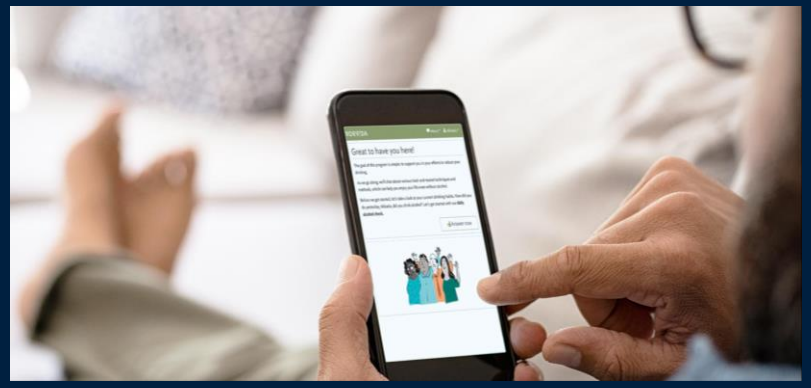
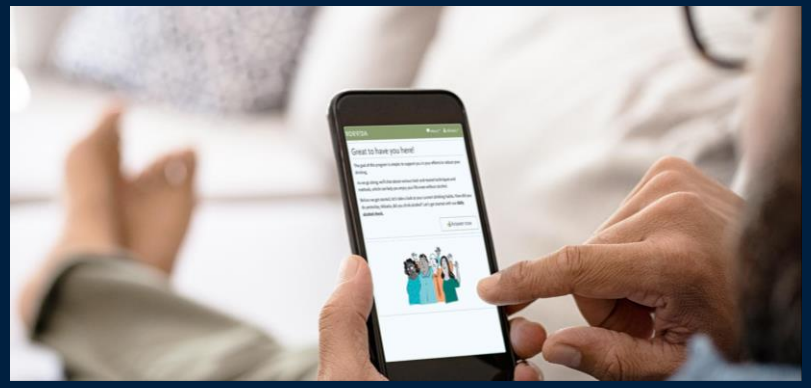
Quarterly highlights & strategic agenda



Progress while adjusting to new market dynamics following Covid-19

US Pharma	**ZUBSOLV® maintained stable weekly demand QoQ, while Net Sales is hit by less shipping days and inventory reductions at wholesalers**
Digital Therapeutics	**New partnerships for RWE of modia™, pilot test with large US employer and positive confirmation on reimbursement pathway**
HQ and Pipeline	**OX124 continue to progress towards filing mid-2022 filing. New ZUBSOLV® patent and European launch on track for H2 2021**

OX124 on track to file mid-2022



OX124 - a new stronger rescue medication with naloxone

Expected launch in 2023

The unmet need

Available rescue medications have been developed for heroin overdoses, but most patients are today dying from synthetic opioids like fentanyl. 87.000 deaths from overdose Oct. 2019 - Sep. 2020

Our aim

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

The potential

70-110 million USD net sales (US market)

Continued good progress with the aim to file with the FDA in the US mid-2022

Q1 progress	2021-2022
✓ Continue testing commercial supply chain to meet FDA reliability demands	Q2-Q3 Commence the pivotal bridging study
✓ Establish quality system and testing methods to monitor product quality	Mid-22 File the new drug application with FDA
X Fast track designation in the US	'23 Launch in the US

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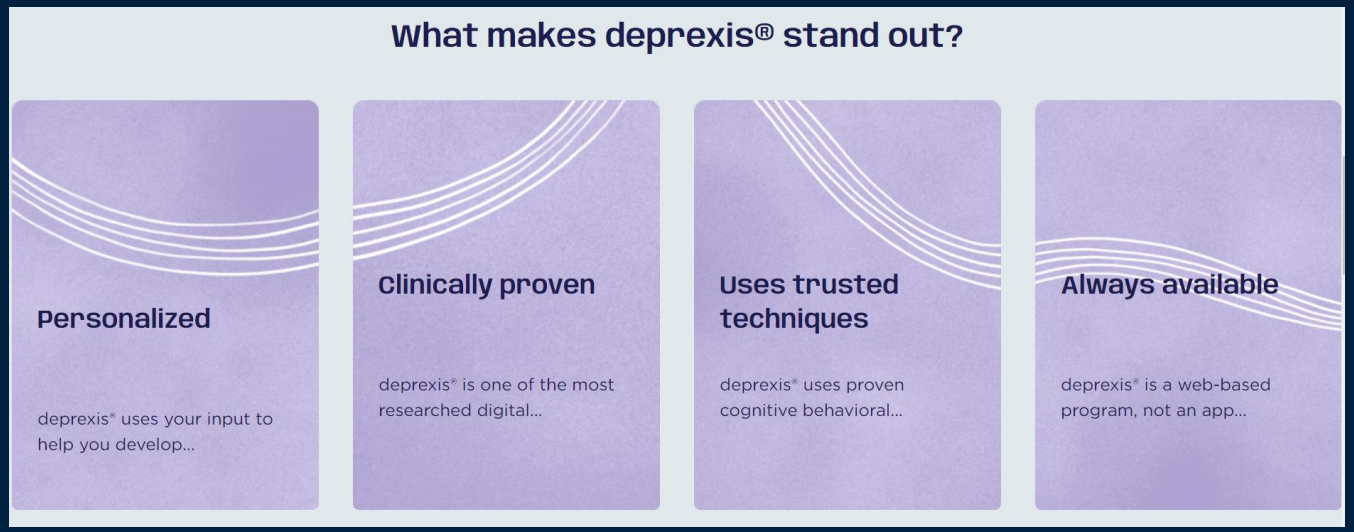
Expanding the commercialization model in DTx

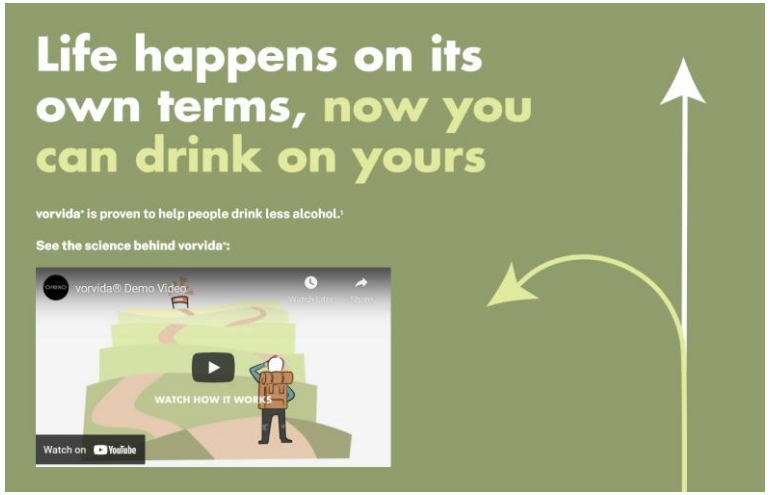
VORV!DA®

deprexis®

modia™



Q1 DTx sales still to accelerate, some preliminary drivers developing



Several important milestones reached during the quarter

- Agreement with Magellan Rx and two additional insurance companies to collect real world evidence (RWE) for modia™
- Large US Tech company is testing the vorvida® and deprexis® with their employees
- Several healthcare providers are in the process of including vorvida® and deprexis® in their treatment programs
- Pennsylvania test will be expanded to include three more states and deprexis®

Sales is improving, but remains limited in Q1

- Covid-19 has made sales processes more complex and time consuming
- Pilot test with direct to consumer promotion of vorvida® with mixed results
  - Upfront cost of $750 too high. Now reduced to $599
  - To drive adoption Orexo introduced a “money back guarantee”
  - Large variance in conversion rates between different marketing channels and focus will be on social media moving forward
- Sales of vorvida® in April exceed the full Q1 sales

Commercial activities remain focused on specific target groups in anticipation of reimbursement

	FDA approval/access	Product available	Pilot/trial	Targeted launch	Reimburse-ment	Broad launch
VORV!DA®	EUA ✓	us.vorvida.com ✓	multiple ✓	From Q3, 2020 ✓	Pennsylvania test expanded	Subject to reimbursement
deprexis®	513G (GAIA) ✓	us.deprexis.com ✓	multiple ✓	From April 2021	Test same route as vorvida®	
modia™	EUA ✓	-	Magellan Rx et al from late Q2	H2 2021		

Magellan Rx is a PBM and the 3rd largest payer within OUD managing the OUD reimbursement for multiple insurance companies in the US

Distribution and commercial partnerships

Several negotiations on-going for pilots and commercial partnerships e.g. telemedicine providers

GoGo meds ✓

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Strategy moved to employers and partnerships, while launching deprexis® with fully dedicated sales team in selected regions

Create a path forward with an online therapy proven to help with depression[1]

deprexis® is a web-based software for depression that uses proven techniques, similar to what you'd experience with your healthcare provider.[1]

Visit: us.deprexis.com

Team focus (time, $$, resources) prioritized to the following:		
Accelerating employer leads and reimbursement discussions with payers	Targeted deprexis commercial launch hiring a dedicated deprexis® sales team in selected regions	Partnerships with healthcare providers to integrate Orexo DTx in their treatment programs

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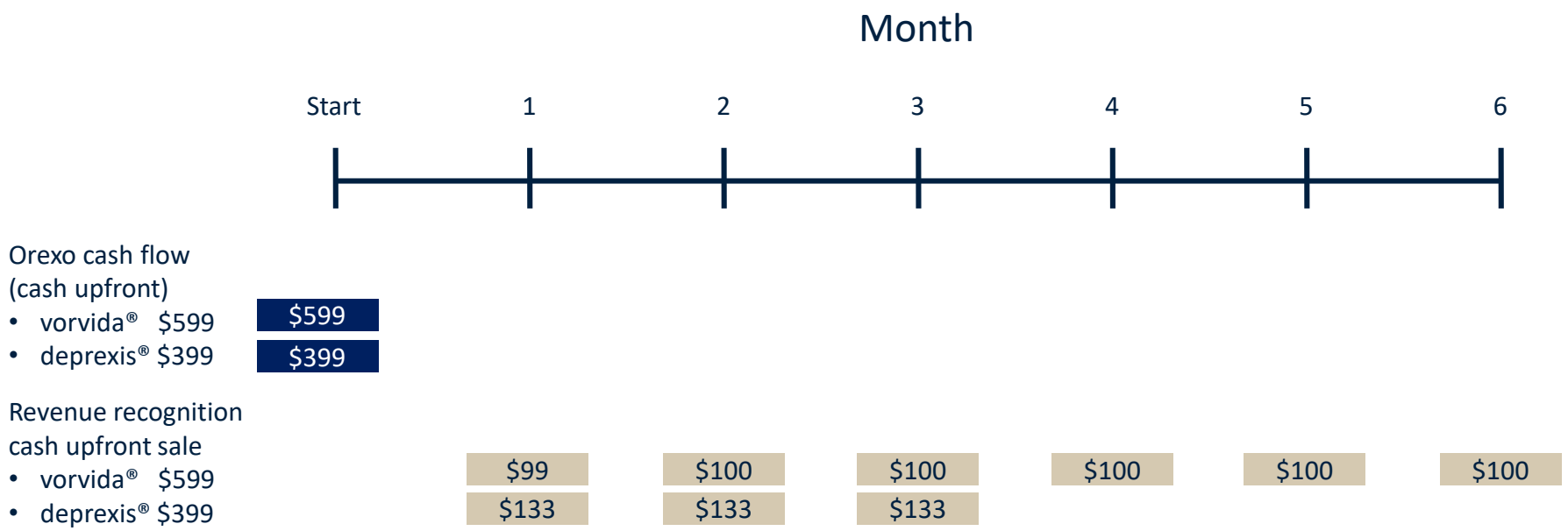
DTx revenue recognition

DTx revenues to be recognized throughout the validity of the license fee

- **vorvida®, modia™ are valid 6 months**
- **deprexis® 3 months**

Revenues of outcome based contracts/sales will be recognized when outcome is known

- **Including current money-back guarantee campaign on vorvida®**



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

zubsolv® sublingual tablets
(buprenorphine and naloxone) CII

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

2021 market volume growth lower than in recent years

- Market +9% YoY, driven by the Public segment
- ZUBSOLV´s core segment - the Commercial segment - +1% YoY due to Covid-19 and the fluctuating employment rate
- New US federal policy will significantly increase access to MAT

Access to physicians improved in Q1…..

- …….but continue to be significantly below pre-Covid-19 levels

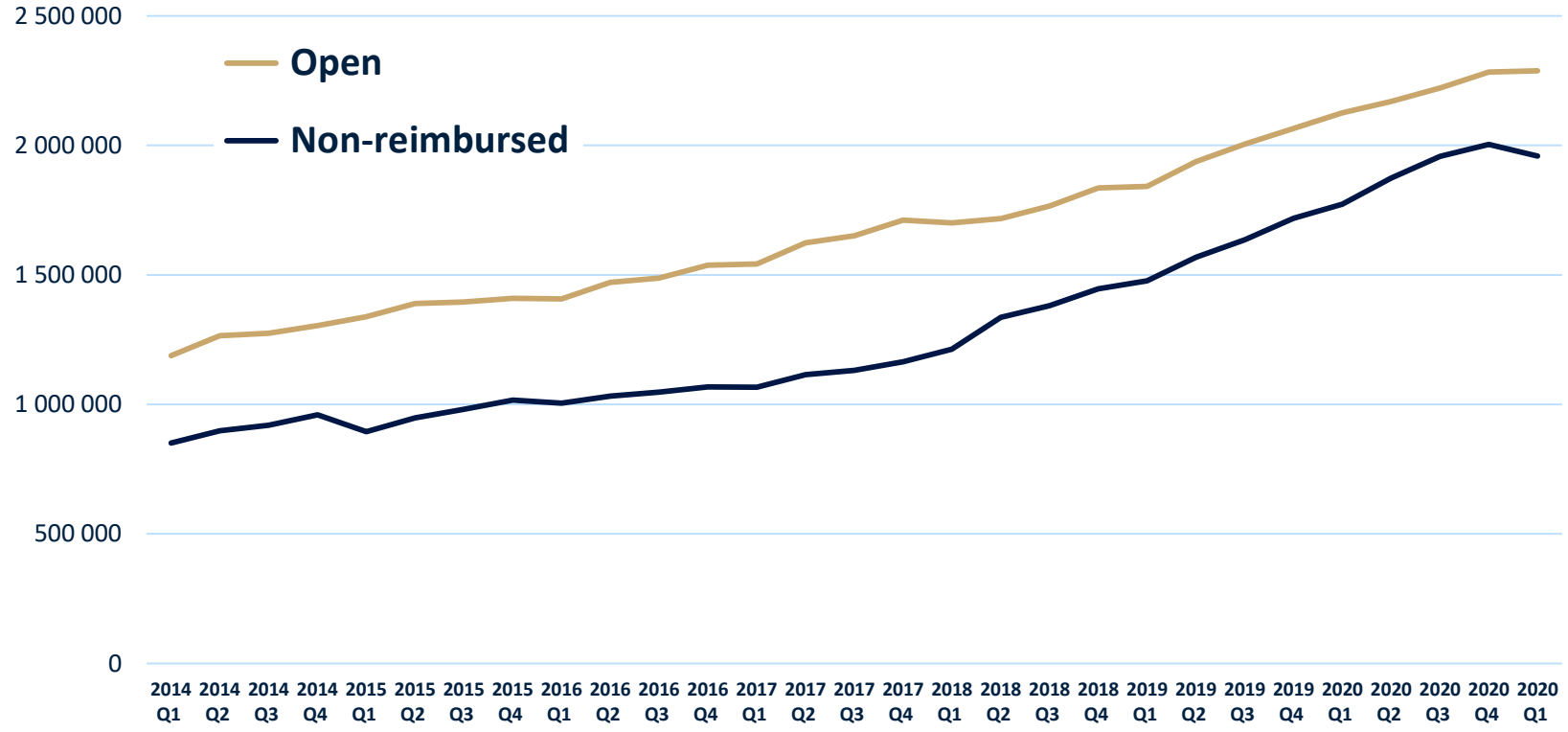
ZUBSOLV® access expands despite market challenges

- Only preferred branded product on ESI & Cigna Commercial and Medicare National formularies
- Only branded product on top three US PBMs for 2021, covering 58% of the commercial market
- New legislation in Kentucky could drive increase access in H2 2021

2021 market volume growth with a slight decline QoQ and slowing down YoY

Decline partly explained by less selling days in Q1 2021

Market Volume Sales, Quarterly NTRx



Q1'21 vs Q1'20 Growth

Total Market: +9%

By Segment

+8%

+10%

Definitions

Payers / Market Access

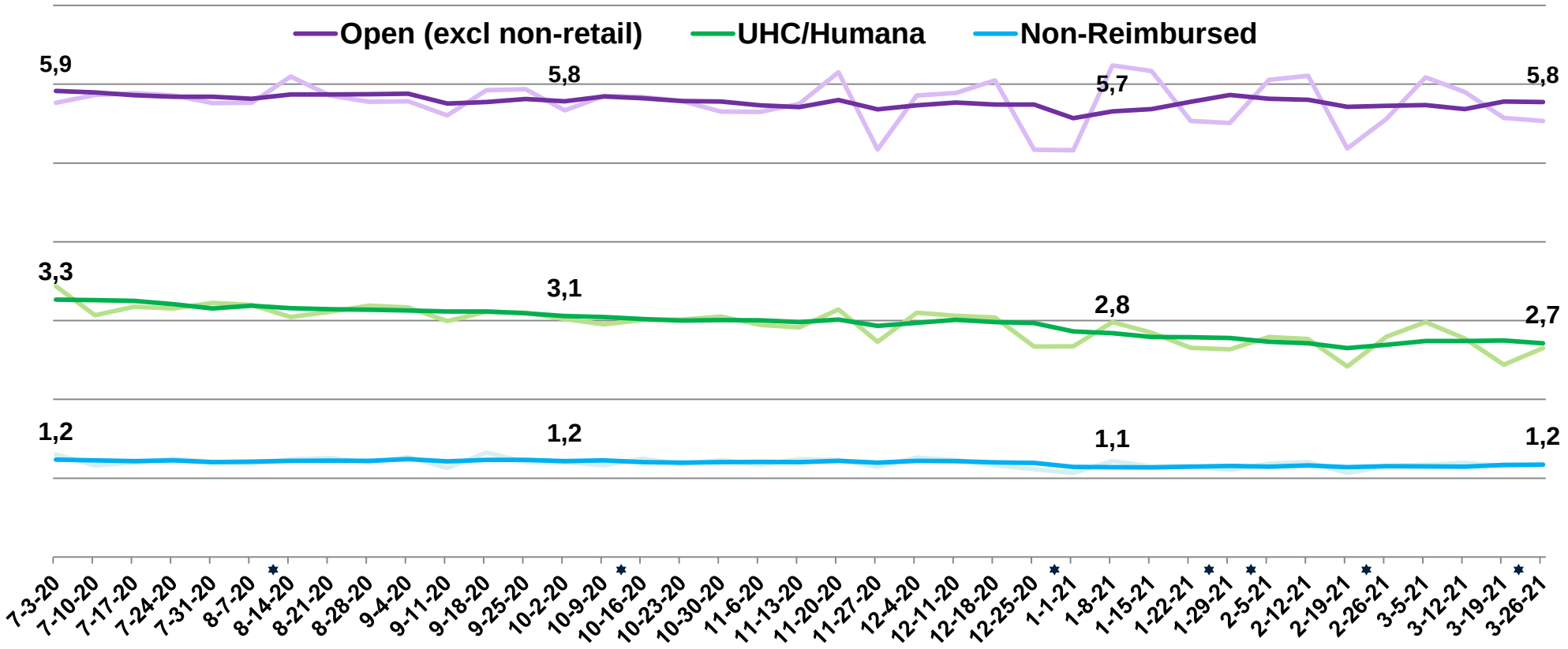
- **"Open"**
  - Market segments where ZUBSOLV® is currently reimbursed either exclusively or non-exclusively
- **"Non-Reimbursed"**
  - Market segments where ZUBSOLV® is currently not reimbursed

Note: NTRx =Total prescriptions adjusted to 30 tablet/film scripts
Note: Historical quarters slightly restated due to IMS recategorization; LTC channel data available from Q2'18
Source: IQVIA XPO

ZUBSOLV® overall volume stable, supported by stability in Open Segment

UHC/Humana continue to decline, but the decline is decelerating

ZUBSOLV® by Access Segments, R4W Average NTRx in Bold Color; Single Week NTRx in Lighter Shade



ZUBSOLV® growth
(Q1 2021 vs Q4 2020)

+0%

-8%

-4%

*Holiday week
Source: IMS XPO
NTRx =Total prescriptions adjusted to 30 tablet/film scripts
Open: Market segments where ZUBSOLV® is reimbursed either exclusively or non-exclusively
Non-Reimbursed: Market segments where ZUBSOLV® is not reimbursed
Note: Historical figures may slightly vary due to IQVIA recategorization

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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%

…Legislative change in Kentucky, one of the largest states for MAT ,is likely to lead to further improvement in market access H2

Strong bi-partisan support to increase access to MAT

... Biden administration has on April 28th allowed nearly all providers to prescribe buprenorphine[1], which will be a strong driver of sustained market growth

…the opioid crisis is a key priority for the new Administration with more than 87.000 deaths from OD Sep 2019-Sep 2020[1]

Orexo Sales Force office access gradually improving

...Q1 2021 has had better office access than Q4 2020 and should continue to improve as restrictions begin to ease post-vaccine roll out

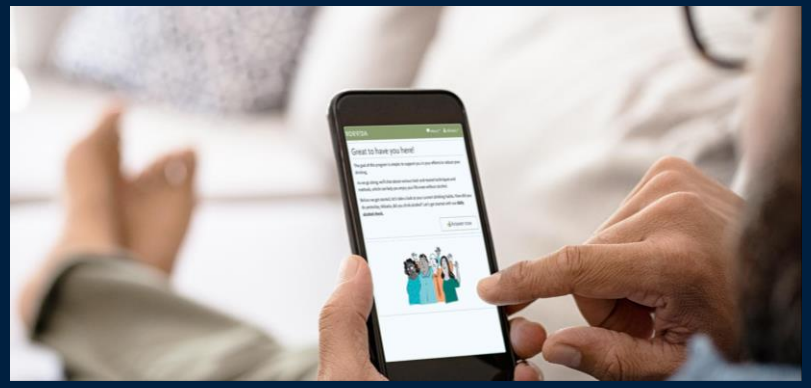
DTx offer new customer value proposition and synergies

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

…modia™ launch enable a complete offering to patients, physicians and payers of both medication and psychological support

(1): www.statnews.com April 27th, 2021

Financial information



Q121 - Lower ZUBSOLV® US net revenues

SEK m	Q1 2021	Q1 2020	Jan - Dec 2020
ZUBSOLV® US	126.8	163.9	623.3
US Pharma – Total	**126.8**	**163.9**	**623.3**
Digital Therapeutics (DTx)	0.2	-	0.0
Digital Therapeutics (DTx) – Total	**0.2**	**-**	**0.0**
Abstral® royalties	2.7	8.6	29.7
Edluar® royalties	2.6	2.4	10.4
ZUBSOLV® – ex US	-	0.1	0.1
OX-MPI	-	0.0	-
HQ & Pipeline – Total	**5.3**	**11.1**	**40.2**
TOTAL	**132.3**	**175.0**	**663.6**

- Net revenues for Q121 declined 24.4% mainly due to lower ZUBSOLV® US revenues
- ZUBSOLV® US revenues declined due to:
  - Declining demand during 2020 due to competition in previously exclusive plans and a declining Commercial segment due to Covid-19
  - Weaker USD exchange rate impacted negatively
  - Partly offset by increased prices and a favorable product mix.

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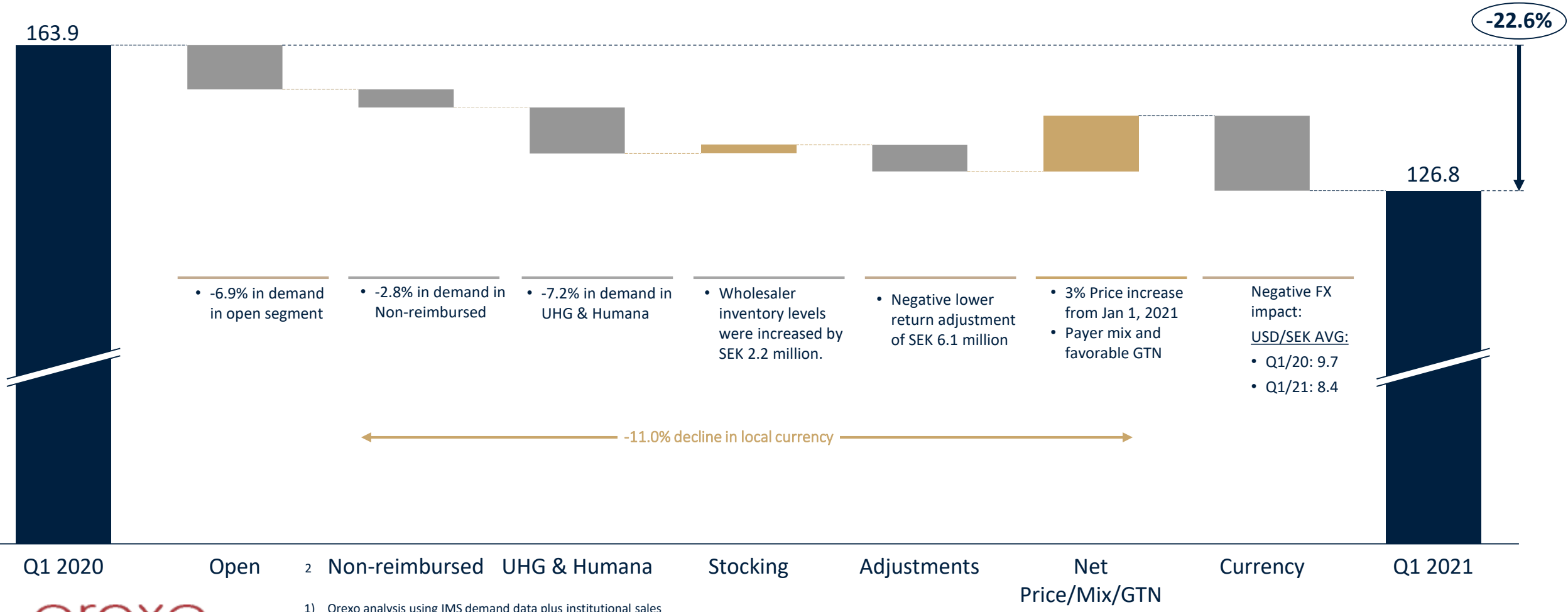
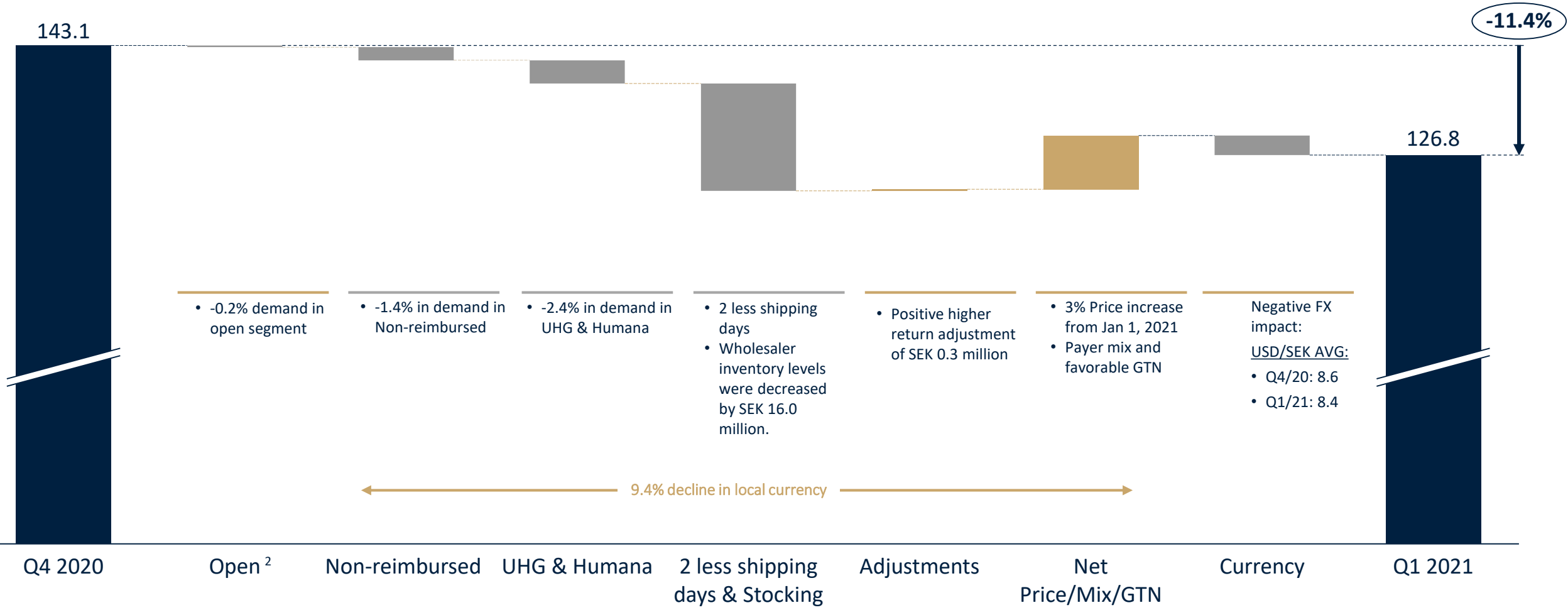
Demand reduction in first half of 2020 and currency driving the gap in net sales Q1 2021 vs Q1 2020



1) Orexo analysis using IMS demand data plus institutional sales

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

Demand stabilizing, with less shipping days and inventory driving the gap in net sales Q1 2021 vs Q4 2020

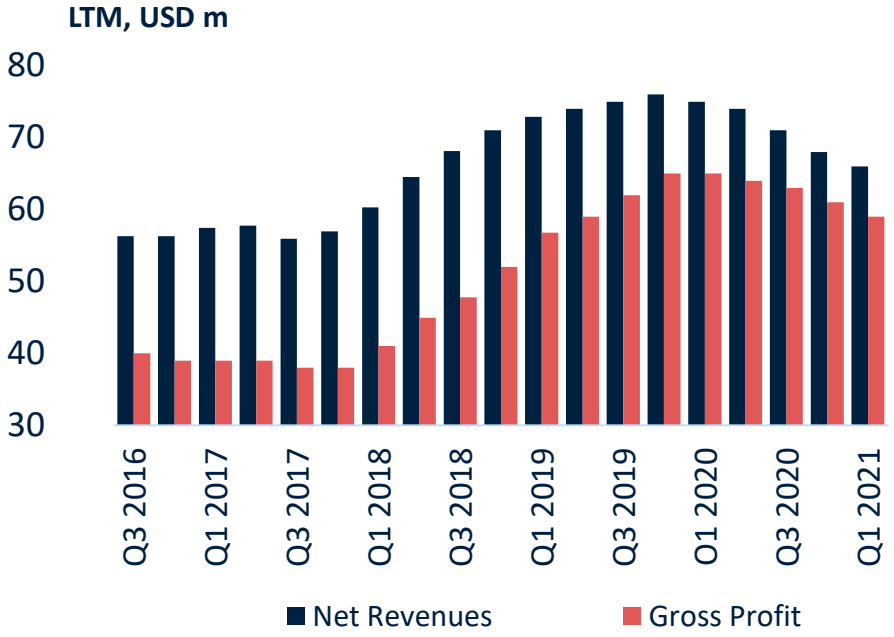


[1] Orexo analysis using IMS demand data plus institutional sales

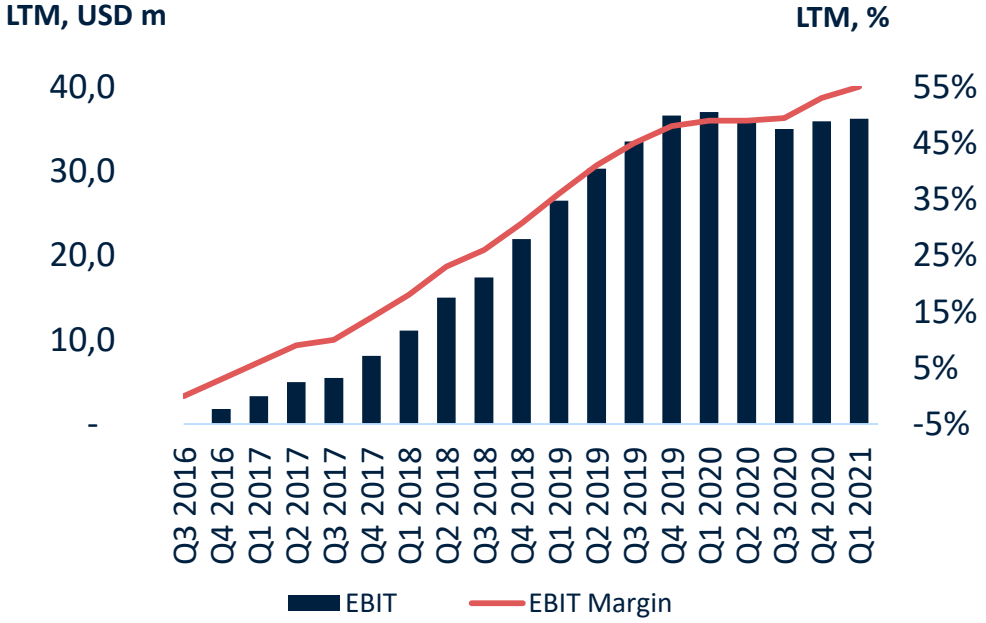
[2] Excluding Cash segment and formulary changes (Wellcare, UHG and Humana)

Q121 - US Pharma Operating Margin (LTM) grew to 55%

Sales and gross profit



EBIT



- ZUBSOLV® US net sales declined to USD 65.8 m from USD 75.3 m in Q120
- EBIT contribution of USD 36.2 m with slight decrease from USD 37.0 m in Q120 driven by lower sales
- US Pharma EBIT margin of 55.0% LTM in Q121 increasing from 49.1% in Q120, EBIT margin in Q1 2021 reached 52.2%

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

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Q121 - Investing in future growth drivers

SEK m	Q1 2021	Q1 2020	Jan - Dec 2020
Net revenues	132.3	175.0	663.6
Cost of goods sold (COGS)	-19.2	-20.0	-65.6
Gross Profit	**113.1**	**155.1**	**598.0**
Selling expenses	-68.7	-54.6	-286.6
Administrative expenses	-28.6	-23.7	-102.8
Research & development expenses	-55.6	-52.9	-224.9
Other operating income & expenses	3.0	10.1	-3.6
Operating Costs	**-149.9**	**-121.1**	**-617.9**
EBIT	**-36.8**	**34.0**	**-19.9**
Net financial items	4.7	44.0	-18.4
EBT	**-32.1**	**78.0**	**-38.3**
Tax	0.6	4.6	-46.1
Net profit/loss	**-31.5**	**82.6**	**-84.4**
EBITDA	**-23.9**	**39.1**	**19.0**

Q121 comments:

Cost of goods sold:

- ZUBSOLV® US COGS SEK 16.4 m (20.0) driven by lower sales partly offset by negative production variances ➔ gross margin 87% vs 88% prior year.
- DTx COGS SEK 2.8 m (0.0) driven by technical infrastructure costs for deprexis® and vorvida®.

▪ **Operating Costs** above prior year due to:

- Selling expenses increased explained by costs related to launch vorvida® and deprexis ® in the US of SEK 43.8 m (8.9) partly offset by lower selling expenses in US Pharma of SEK 24.6 m (45.7).
- Administrative expenses increased explained by higher legal expenses for IP litigations partly offset by lower costs for the long-term incentive programs.
- R&D expenses increased explained by costs related to launch preparations for vorvida® and deprexis®.
- Other operating income contributed positively due to exchange-rate gains derived from revaluations of parent company balance sheet items in foreign currency, predominantly in USD.

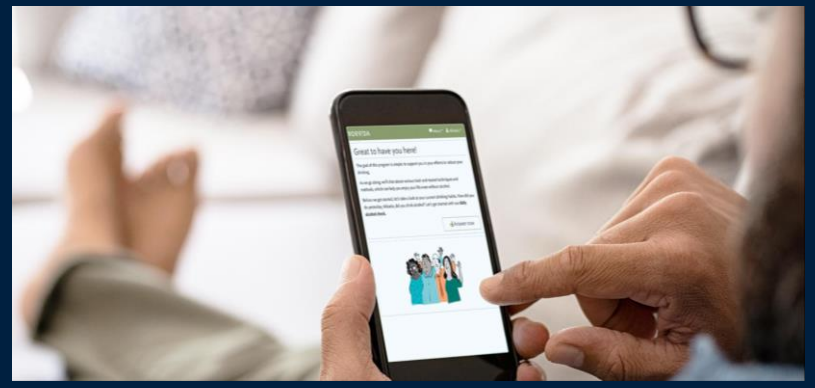
▪ **Net Financial items** had positive impact mainly explained by a lower positive unrealized exchange rate impact of SEK 31.1 m derived from the parent company's foreign currency bank accounts mainly in USD, by costs for corporate bonds of SEK 5.4 m and by lower earned interest of SEK 1.6 m.

Q121 – Redeemed the bonds 2017/2021 and issued corporate bond of SEK 500 m

Cash flow SEK m	Q1 2021	Q1 2020	Jan - Dec 2020
Cash flow from operating activities	-47.8	48.1	16.8
Investment activities	-16.2	-3.9	-189.2
Financing activities	261.7	-68.8	-111.3
Cash flow (excl exchange rate differences)	197.7	-24.6	-283.7
Liquid funds	**725.5**	**861.4**	**505.3**
Net cash position	235.0	611.9	280.8

- Negative cash flow from operating activities for the period Q121
  - SEK 47.8 m negative contribution from operating activities
  - Investment activities had a negative impact of SEK 16.2 m primarily due to purchase of equipment for the development organization and investments in DTx enterprise platform
  - Financing activities had a positive impact of SEK 261.7 m due to early redemption the bonds 2017/2021 and issuance of a senior unsecured callable floating rate bonds in the amount of SEK 500 m 2021/2025
  - SEK 22.6 m positive impact on cash position due to stronger USD in March 2021
- Cash position at the end of Q121 of SEK 725.5 m after refinancing of corporate bond loan of SEK 500 m

Outlook



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Q121 - 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 expected to be around 50 percent
- The outlook is based on exchange rates in December 2020

No changes in the two ongoing legal processes in Q1, except new patent issued for ZUBSOLV®

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 **seven** 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

Promising value triggers in 2021

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.

Magellan Rx and two BCBS insurance companies to conduct RWE testing

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.

Pilot test with large US tech company

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.

Several regional and local HCPs are in process to integrate our DTx into their treatment program

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

Q3

Results from pivotal trial for OX124

Orexo expects to initiate the pivotal trial in late Q2 and with the results expected in Q3. Based on the positive outcome of the first clinical trial, the pivotal trial has reduced risk.

H2

Launch of ZUBSOLV® in Europe by Accord Healthcare

Following final approval of the supply chain in Europe by the authorities we expect Accord Healthcare to launch 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

IR Contact: Lena Wange, IR & Communications Director, ir@orexo.com. For more information please visit www.orexo.com.
You can also follow Orexo at Twitter @orexoabpubl, LinkedIn and YouTube