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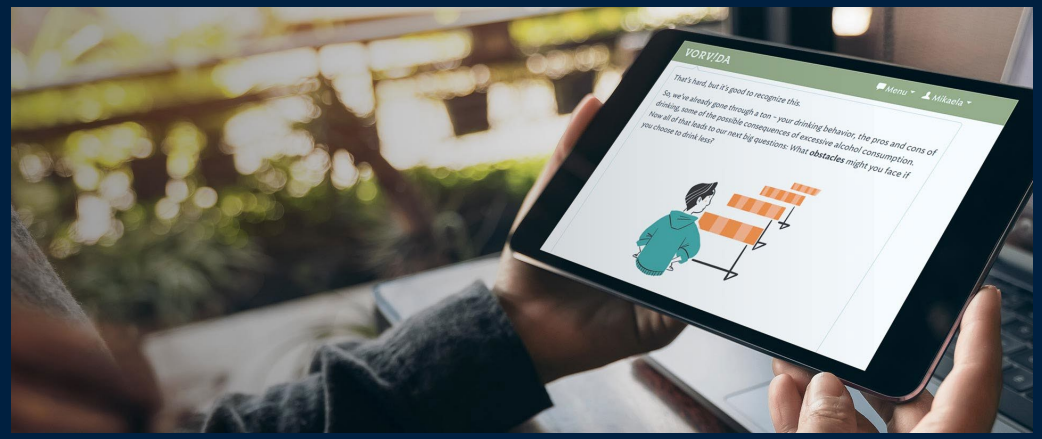
Improving the lives of people suffering from mental illness and substance use disorders



Interim Report Q2 2021 July 15, 2021

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

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Quarterly highlights

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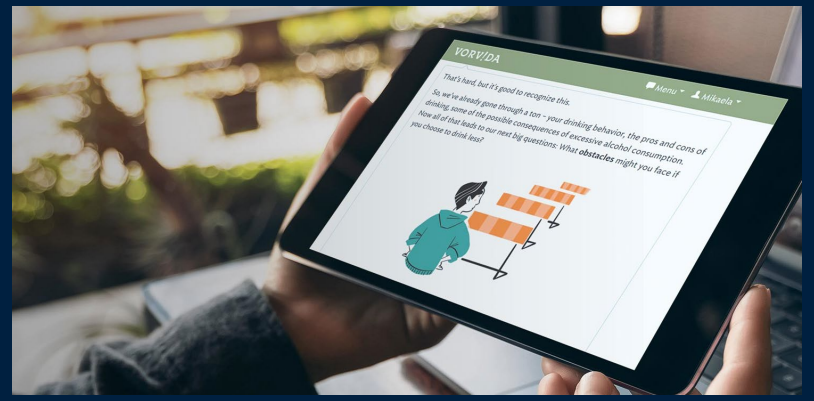
First commercial DTx contract signed with a large HCP and stable ZUBSOLV® sales from Q1

US Pharma	**ZUBSOLV® stable QoQ sales with slight increase in open commercial segment. Market access in Kentucky, confirmed**
Digital Therapeutics	**First commercial contract signed with large healthcare provider and with a clinic in NYC and St Louis. Continuous increased number of partnership discussions. modia™ RCT initiated.**
HQ and Pipeline	**OX124 continues to progress towards NDA filing and pivotal study will start shortly. New patents issued for ZUBSOLV®**

OX124 – towards NDA filing with the FDA in H2 2022



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OX124 - a new stronger rescue medication with naloxone

Expected launch in 2023

The unmet need

In the 12 months leading up to November 2020, the number of drug-related overdose deaths has surpassed 90,000 for the first time in history, an increase of 29%. 74% of these deaths were caused by opioids and within the opioid-related deaths synthetic opioids accounted for the vast majority (81%)[1]

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)

[1] Center of Disease Control

OX124 continued good progress with the aim to file in the US H2 2022

H1 progress	2021-2023
✓ Commercial supply chain established	H2 Perform the pivotal bridging study
✓ All preparation for pivotal study in the US are complete and study will start shortly	H2-22 File the New Drug Application with the FDA
✓ 12 month stability study initiated	'23 Launch in the US

The technology developed for OX124 and all learnings from the development process are now being applied on new APIs and tested *in vitro*

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Expanding the commercialization model in DTx

VORV!DA®

deprexis®

modia™

Multiple commercial contracts signed with healthcare providers…

……of which one with a Integrated Health Distribution Network – Trinity Health North Dakota

New Commercial agreements signed in Q2

- Trinity Health North Dakota
- NYC clinic
- Mental health hospital in St Louis
- Start-up company providing telemedicine to health care professionals

Agreements are an inspiring model for other commercial leads

- Advanced discussions with two additional larger health care providers with multi-state operations in the US
- Advanced discussions with a large industrial company and their insurance company of a pilot test
- Advanced discussions with leading telemedicine company within mental health in the US
- Advanced discussion with several additional smaller healthcare providers

Pilot with Trinity Health (ND) provide important insights into future partnerships

Q3 2020 Pilot	Q4 2020 Model	H1 2021 Anchoring	Late Q2 Agreement	Q3-> Implemen-tation
• deprexis® and vorvida® made available for all 2300 employees at Trinity Health free of charge as a response to Covid-19	• Very positive feedback from employees at Trinity Health • Discussion initiated about models for a commercial agreement	• Treatment plans including vorvida ® and deprexis® developed • New treatment plans accepted by top payers for reimbursement • Clinical staff approves new treatment plans • Internal processes established to manage billing processes etc	• Commercial agreement signed to start making the new treatment plans available to patients within the Trinity Health (ND) network	• Continued education of clinical staff • Information campaigns to patients in ND • Media outreach to highlight new innovative treatments

The Sober Grid partnership will reach 300 000 individuals struggling with mental health issues

- Sober Grid is the **largest global digital network** for people trying to reach, or that are in, recovery from addiction

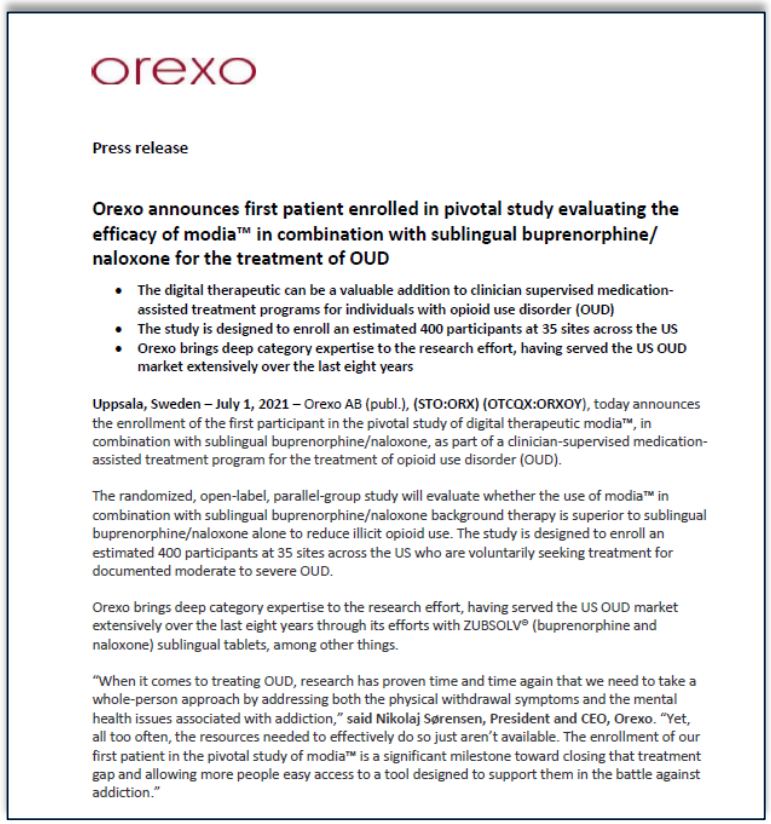
- **The partnership will evolve in three phases**
  - Phase 1: deprexis® and vorvida® will be made available through Sober Grid's certified peer coaches *(Q3 2021)*
  - Phase 2: deprexis® and vorvida® will be made available to the full Sober Grid network of 300 000 users *(Q4 2021)*
  - Phase 3: Orexo and Sober Grid will offer deprexis® and vorvida® together with Sober Grid's coaching services to other customers (H1 2022)

- The partnership will **kick-off in August 2021**

Sober Grid

modia™ randomized clinical trial initiated in 400 patients

Outcome essential for differentiation enabling market access and appropriate regulatory FDA classification



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Press release

Orexo announces first patient enrolled in pivotal study evaluating the efficacy of modia™ in combination with sublingual buprenorphine/ naloxone for the treatment of OUD

- **The digital therapeutic can be a valuable addition to clinician supervised medication-assisted treatment programs for individuals with opioid use disorder (OUD)**
- **The study is designed to enroll an estimated 400 participants at 35 sites across the US**
- **Orexo brings deep category expertise to the research effort, having served the US OUD market extensively over the last eight years**

Uppsala, Sweden – July 1, 2021 – Orexo AB (publ.), **(STO:ORX) (OTCQX:ORXOY)**, today announces the enrollment of the first participant in the pivotal study of digital therapeutic modia™, in combination with sublingual buprenorphine/naloxone, as part of a clinician-supervised medication-assisted treatment program for the treatment of opioid use disorder (OUD).

The randomized, open-label, parallel-group study will evaluate whether the use of modia™ in combination with sublingual buprenorphine/naloxone background therapy is superior to sublingual buprenorphine/naloxone alone to reduce illicit opioid use. The study is designed to enroll an estimated 400 participants at 35 sites across the US who are voluntarily seeking treatment for documented moderate to severe OUD.

Orexo brings deep category expertise to the research effort, having served the US OUD market extensively over the last eight years through its efforts with ZUBSOLV® (buprenorphine and naloxone) sublingual tablets, among other things.

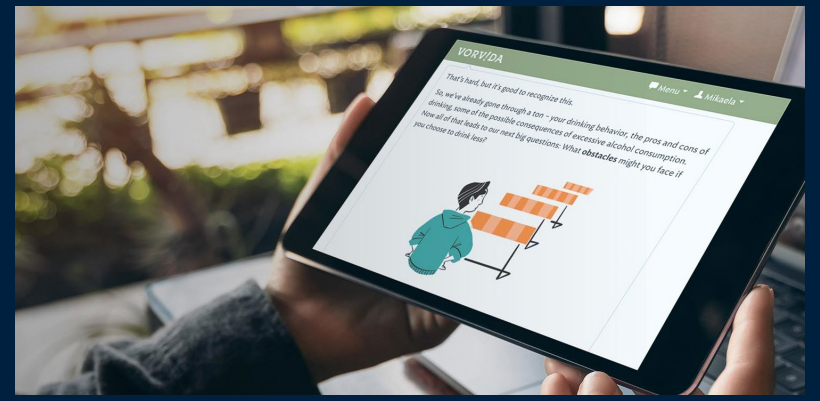
"When it comes to treating OUD, research has proven time and time again that we need to take a whole-person approach by addressing both the physical withdrawal symptoms and the mental health issues associated with addiction," **said Nikolaj Sørensen, President and CEO, Orexo**. "Yet, all too often, the resources needed to effectively do so just aren't available. The enrollment of our first patient in the pivotal study of modia™ is a significant milestone toward closing that treatment gap and allowing more people easy access to a tool designed to support them in the battle against addiction."

The study is designed to enroll an estimated 400 participants at 35 sites across the US

The randomized, open-label, parallel-group study will evaluate whether the use of modia™ in combination with sublingual buprenorphine/naloxone background therapy is **superior to sublingual buprenorphine/naloxone alone to reduce illicit opioid use**

The RCT is expected to end H2 2022 and reach a total investment of USD 9 million during H2 2021-2022

ZUBSOLV® stable from Q1 despite remnants of Covid-19 continuing to challenge HCP access. Kentucky open access confirmed



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

2021 YTD market volume growth lower than in recent years

- Market +8% YTD YoY, driven by the Public segment, although Public growth is lower than recent years
- ZUBSOLV´s core payer segment, the Commercial segment, +3% YoY due to Covid-19 and the fluctuating unemployment rate
- New US federal policy and state initiatives expected to significantly increase access to MAT

Access to physicians improved during Q2

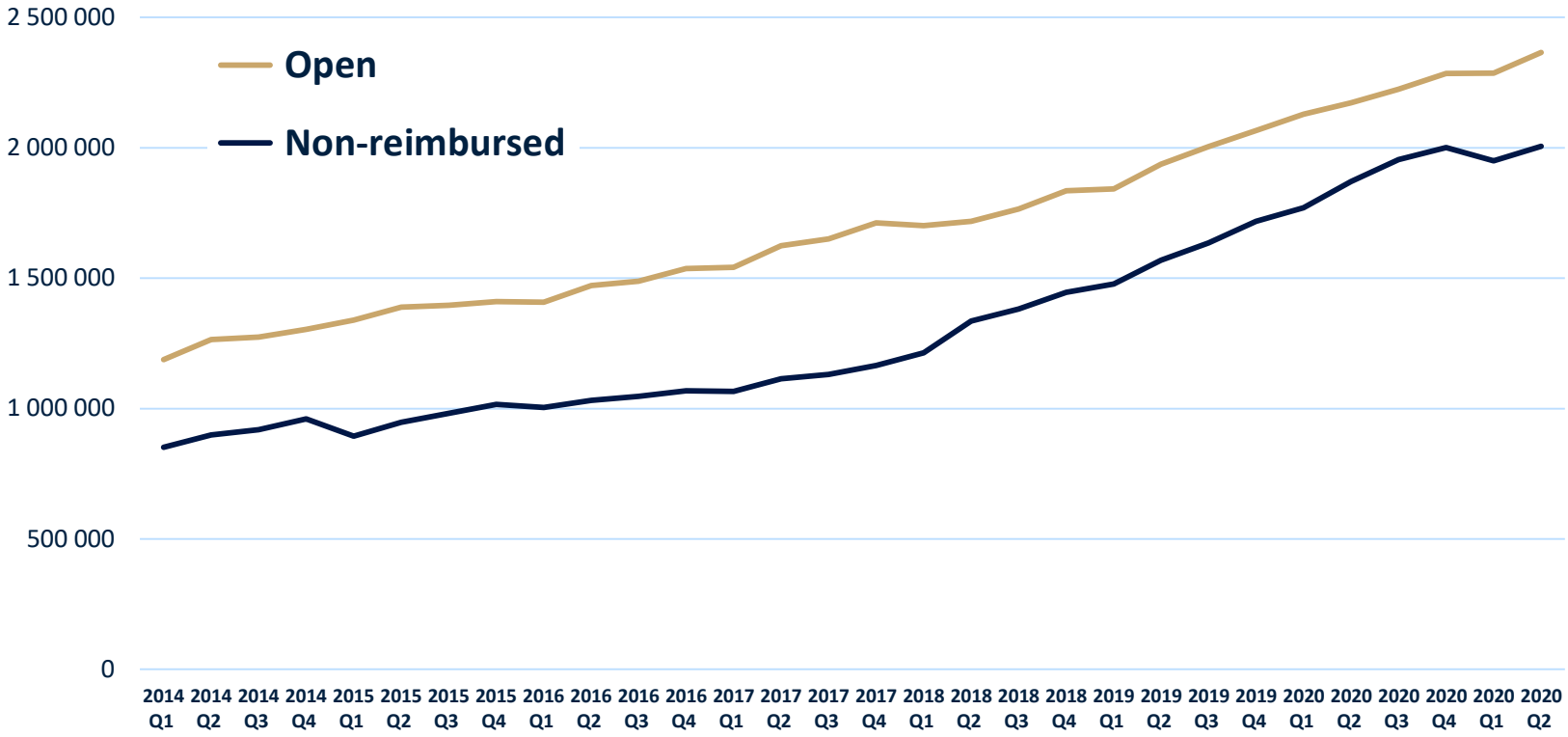
- Access to clinics and healthcare facilities approach pre-covid levels
- Prescribers are more restrictive and many have increased utilization of tele-medicine reducing accessibility in the office
- Access has been variable during the quarter and is expected to continue with local outbreaks of Covid-19
- Orexo field force is fully vaccinated

ZUBSOLV® access expands despite market challenges

- **Coverage in Kentucky Medicaid brings Public access from 34% to 42%**
- Only branded product on top three US PBMs for 2021, covering 58% of the commercial market
- Current market access confirmed for H2 2021
- 2022 market access so far unchanged to our knowledge, but many formularies yet to be published

Market volume reaching new highs in Q2 2021, with YoY growth rate decelerating due to drop in Q1 2021

Market Volume Sales, quarterly NTRx



Q2'21 vs Q2'20 Growth

Total Market: +8%

By Segment

+9%

+7%

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

2020 Q2 volume estimated
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

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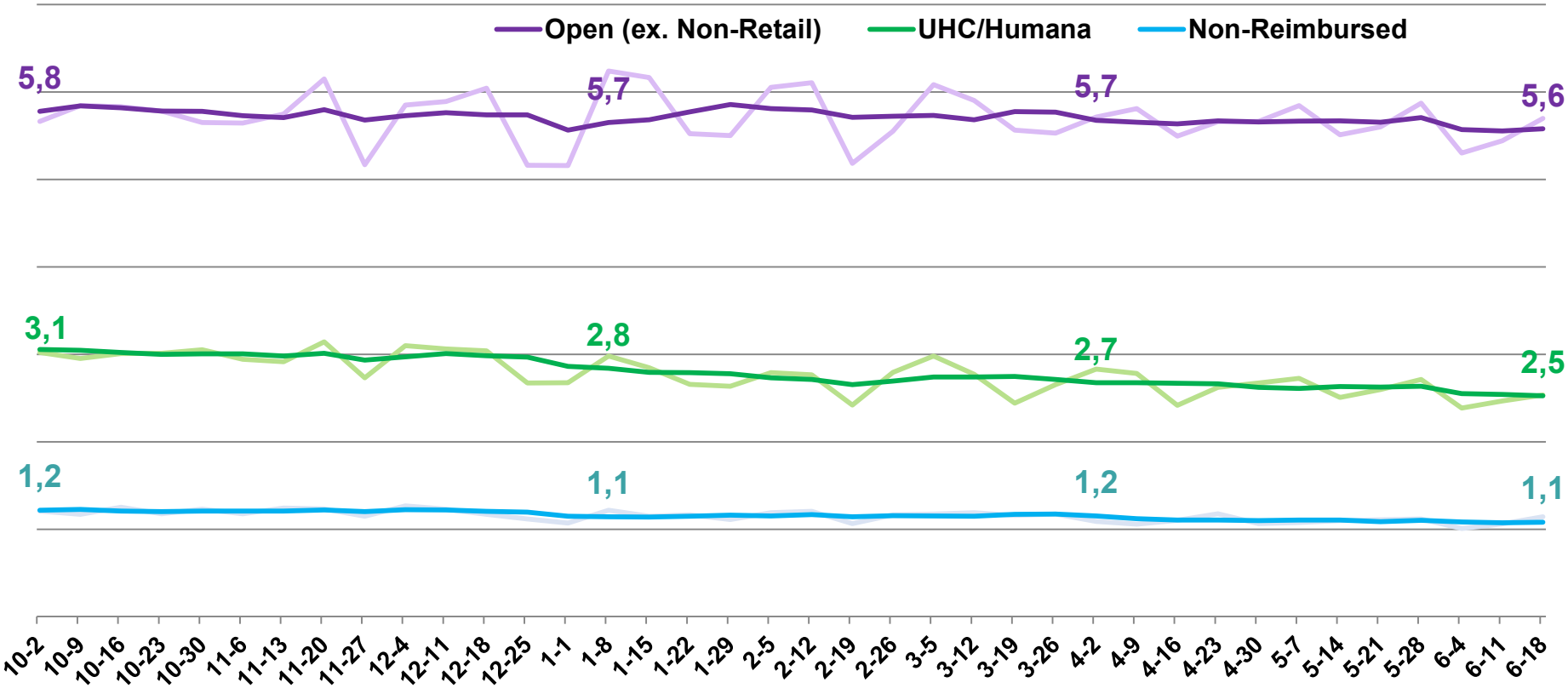
ZUBSOLV® overall volume stable supported by resilience in Open segment

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® change

(Q2 2021 vs Q1 2021)

+0%

-2%

-1%

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

Financial information

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Q221 - Lower ZUBSOLV® US net revenues but signs of stabilizing demand

SEK m	Q2 2021	Q2 2020	H1 2021	H1 2020	Jan - Dec 2020
ZUBSOLV® US	126.0	172.5	252.8	336.4	623.3
US Pharma – Total	**126.0**	**172.5**	**252.8**	**336.4**	**623.3**
Digital Therapeutics (DTx)	0.3	-	0.4	-	0.0
Digital Therapeutics (DTx) – Total	**0.3**	-	**0.4**	-	**0.0**
Abstral® royalties	14.3	3.5	17.0	12.2	29.7
Edluar® royalties	2.3	3.1	4.9	5.5	10.4
ZUBSOLV® – ex US	-	-	-	0.1	0.1
HQ & Pipeline – Total	**16.5**	**6.6**	**21.9**	**17.8**	**40.2**
TOTAL	**142.8**	**179.1**	**275.1**	**354.2**	**663.6**

- Net revenues for Q221 declined 20.3% from Q220 due to lower ZUBSOLV® US revenues
- ZUBSOLV® US revenues in local currency declined 15.8% in Q221 vs Q220 from USD 17.8 m to USD 15.0 m due to:
  - Lower demand due to competition in previously exclusive plans and a declining Commercial segment as a result of COVID-19 pandemic
  - Lower inventory with wholesalers and less positive return adjustment
  - Partly offset by increased prices and a favorable product mix.

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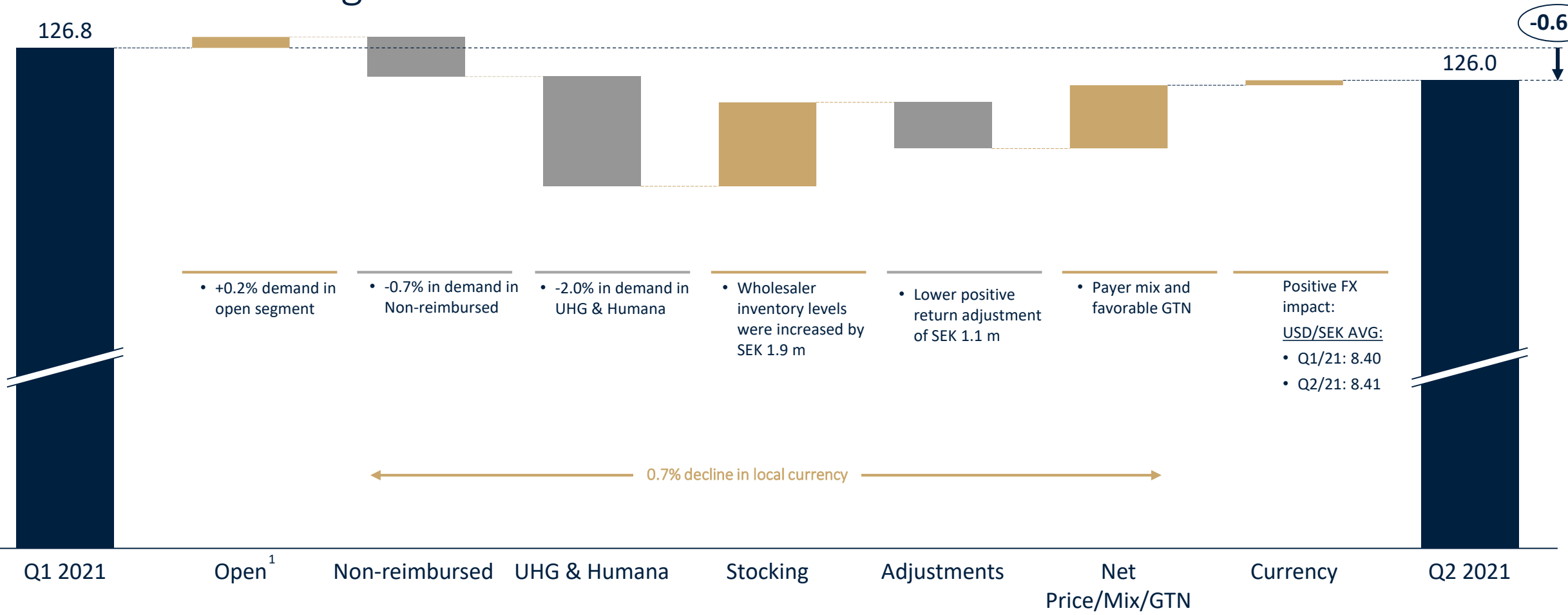
Demand stabilizing Q2 2021 vs Q1 2021 with increase in Open Segment and decreasing decline from UHG and Humana

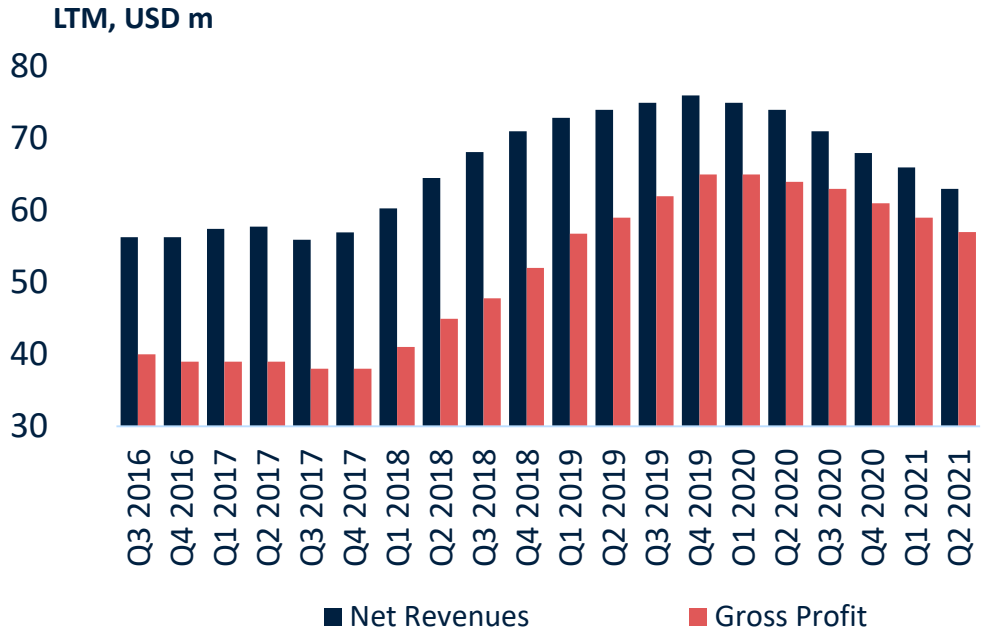


[1] Excluding Cash segment and formulary changes (Wellcare, UHG and Humana)

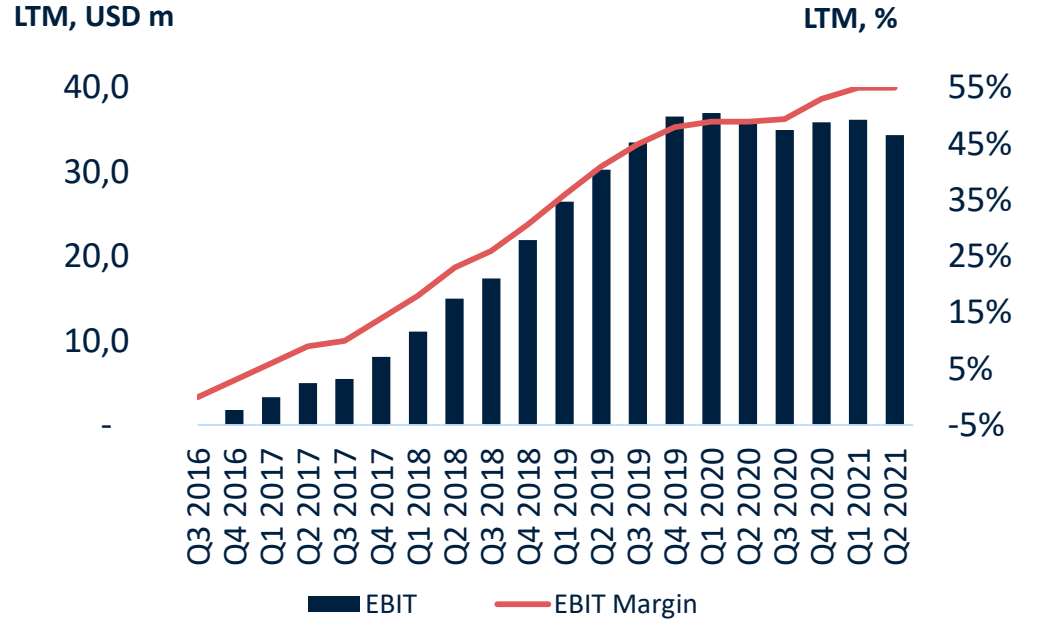
Source: Orexo analysis using IMS demand data plus institutional sales

Q221 - US Pharma Operating Margin (LTM) 54.6%

Sales and gross profit



EBIT



- ZUBSOLV® US net sales declined to USD 62.9 m from USD 73.6 m in Q220
- EBIT contribution of USD 34.4 m with slight decrease from USD 36.2 m in Q220 driven by lower sales and increased admin costs due to Subpoena
- US Pharma EBIT margin of 54.6% LTM in Q221 increasing from 49.1% in Q220, EBIT margin for H1 2021 reached 50.5%

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

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Q221 - Investing in future growth drivers

SEK m	Q2 2021	Q2 2020	H1 2021	H1 2020	Jan - Dec 2020
Net revenues	142.8	179.1	275.1	354.2	663.6
Cost of goods sold (COGS)	-18.1	-19.9	-37.4	-39.9	-65.6
Gross Profit	**124.8**	**159.2**	**237.7**	**314.3**	**598.0**
Selling expenses	-61.8	-70.0	-130.4	-124.4	-286.6
Administrative expenses	-41.4	-32.7	-70.0	-56.5	-102.8
Research & development expenses	-73.2	-62.6	-128.8	-115.6	-224.9
Other operating income & expenses	-2.4	-7.1	0.6	2.9	-3.6
Operating Costs	**-178.7**	**-172.5**	**-328.7**	**-293.6**	**-617.9**
EBIT	**-54.0**	**-13.3**	**-90.9**	**20.7**	**-19.9**
Net financial items	-10.8	-22.2	-6.2	21.8	-18.4
EBT	**-64.8**	**-35.5**	**-97.1**	**42.5**	**-38.3**
Tax	-8.9	3.0	-8.3	7.6	-46.1
Net profit/loss	**-73.7**	**-32.5**	**-105.4**	**50.1**	**-84.4**
EBITDA	**-41.1**	**-9.0**	**-65.2**	**30.1**	**19.0**

Q221 vs Q220 comments:

Cost of goods sold:

- ZUBSOLV® US COGS SEK 15.4 m (19.3) driven by lower sales partly offset by negative production variances ➔ gross margin 88% vs 89% prior year.
- DTx COGS SEK 2.6 m (0.6) driven by technical infrastructure costs for deprexis® and vorvida®.

- **Operating Costs** above prior year due to:
  - Selling expenses decrease explained by lower selling expenses in US Pharma of SEK 25.3 m (41.4) partly offset by costs related to launch of vorvida® and deprexis ® in the US of SEK 36.5 m (28.7).
  - Administrative expenses increase explained by higher legal expenses for IP litigation and subpoena partly offset by lower costs for the long-term incentive programs.
  - R&D expenses increase explained by costs related to OX124 and medical activities related to launch preparations for vorvida® and deprexis®.
  - 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 positive impact mainly explained by a lower negative unrealized exchange rate impact of SEK 13.0 m derived from the parent company's foreign currency bank accounts mainly in USD partly offset by higher costs for corporate bonds of SEK 1.4 m and by lower earned interest of SEK 0.3 m.

Q221 – Strong Cash Position enables continued investments in DTx, OX124 and new development programs

Cash flow SEK m	Q2 2021	Q2 2020	H1 2021	H1 2020	Jan - Dec 2020
Cash flow from operating activities	-20.9	-7.2	-68.7	40.9	16.8
Investment activities	-13.1	-106.0	-29.3	-109.9	-189.2
Financing activities	-3.5	-33.9	258.2	-102.7	-111.3
Cash flow (excl exchange rate differences)	-37.5	-147.1	160.1	-171.7	-283.7
Liquid funds	**679.7**	**677.2**	**679.7**	**677.2**	**505.3**
Net cash position	188.6	453.4	188.6	453.4	280.8

- Negative cash flow from operating activities for the period Q221
  - SEK 20.9 m negative contribution from operating activities
  - Investment activities had a negative impact of SEK 13.1 m primarily due to purchase of equipment for the development organization and investments in DTx enterprise platform
  - Financing activities had a negative impact of SEK 3.5 m due to amortization of leasing liability according to IFRS 16
  - SEK 8.2 m negative impact on cash position due to weaker USD in June 2021
- Cash position at the end of Q221 of SEK 679.7 m after refinancing of corporate bond loan of SEK 500 m

No changes in the two ongoing legal processes in Q2, except for **two new patents 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
- Two new patents issued for ZUBSOLV®
- Orexo currently has **nine** 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

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Outlook

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Q221 - Financial outlook 2021 reiterated

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

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
Trinity Health (ND) secured reimbursement from payers prior to commercial agreement in Q2

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 initiated
Advanced discussions with large industrial company and their insurance Co.
Agreement with start-up targeting HCPs with telemedicine health services

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.

Trinity Health ND, clinics in NYC & St Louis. Advanced discussions with additional providers

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 market growth in the commercial segment, we expect to see ZUBSOLV® stabilize and grow

Q4

Results from pivotal trial for OX124

Orexo expects to initiate the pivotal trial early Q3 and with the results expected in Q4. 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 late 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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