



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



Erik Penser Bank May 6, 2021

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

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Orexo – focusing on the large and growing space of treatment of mental illness

- Strong financial position
- International experienced management team and board
- Commercial presence in the US with own field force since 2013
- Active and leading life science investors as main shareholders: **Novo Holdings** (28%) and **HealthCap** (10%)

Profitable US Pharma operations

- Net revenues SEK 623 million
- EBITDA SEK 347 million
- EBIT Margin 53 percent

Three digital therapies for treatment of AUD, OUD and depression

- > 40 million potential patients (pre-Covid)
- Strong scientific evidence of clinical effect
- New frontier in patient care and following a mega-trend in health care

Lead pipeline product OX124 a new rescue medication for opioid overdose

- > USD 300 million market
- 49 % increase of OD with synthetic opioids
- Positive results from first clinical trial
- Expected US launch 2023

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



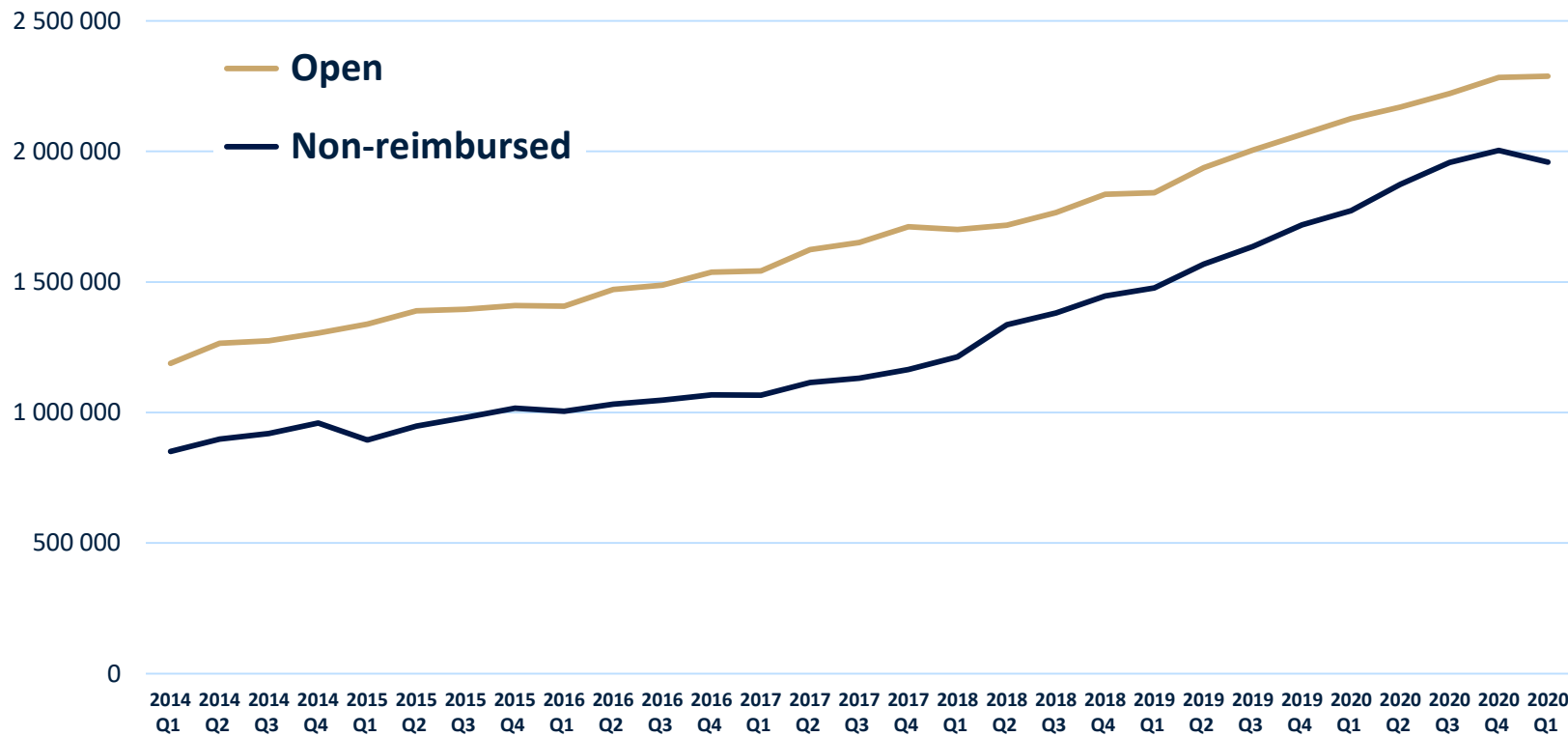
**ZUBSOLV® - contributing to
a solid foundation for future
growth**



Q1'21: The US opioid crisis fuels a market characterized by strong growth

Market Q1: YoY growth impacted negatively by Covid-19 build-up in Q1'20 and QoQ by less selling days in Q1'21

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”**

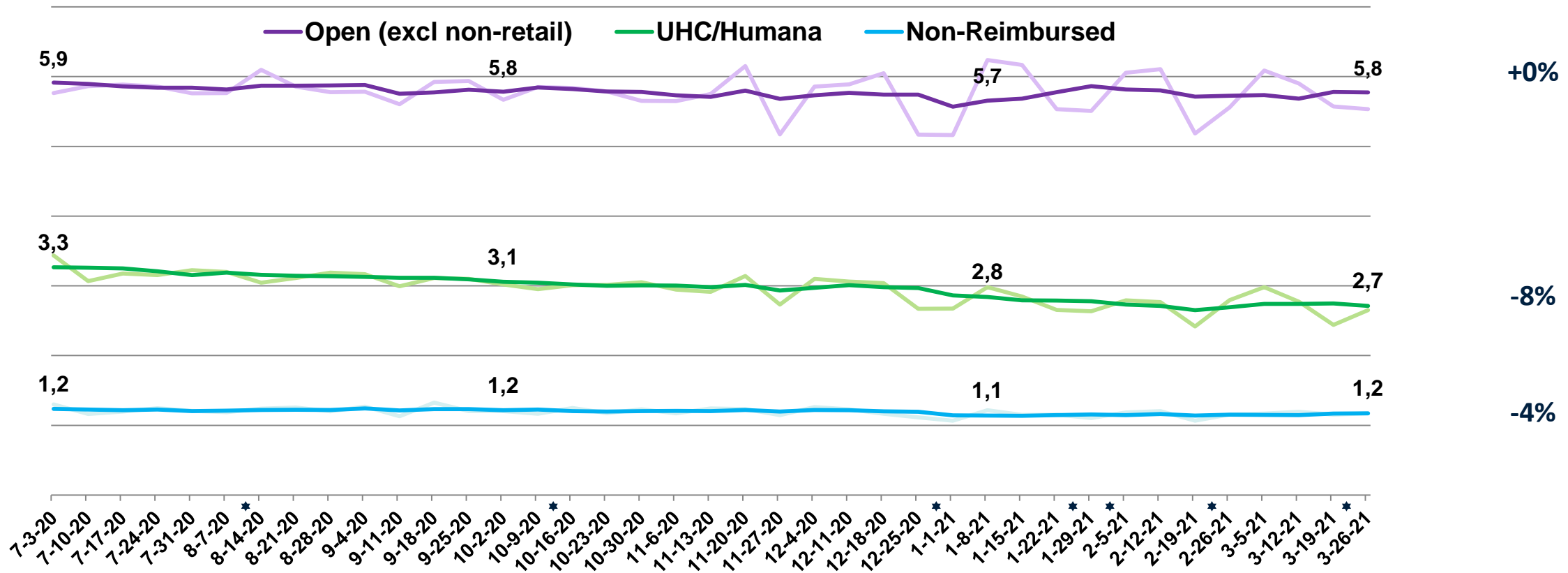
- Market segments where ZUBSOLV® is currently not reimbursed

Q1'21: ZUBSOLV® stable in open segment QoQ, despite less selling days

The negative impact from formulary changes at UHC/Humana is decelerating

ZUBSOLV® growth
(Q1 2021 vs Q4 2020)

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



*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

Several possible triggers for ZUBSOLV® to return to 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 buprenorphine¹, 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 2020¹

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

Expanding the commercialization model in DTx

VORV!DA[®]
deprexis[®]
modiaTM

What makes deprexis[®] stand out?

Personalized

deprexis[®] uses your input to help you develop...

Clinically proven

deprexis[®] is one of the most researched digital...

Uses trusted techniques

deprexis[®] uses proven cognitive behavioral...

Always available

deprexis[®] is a web-based program, not an app...



Personal

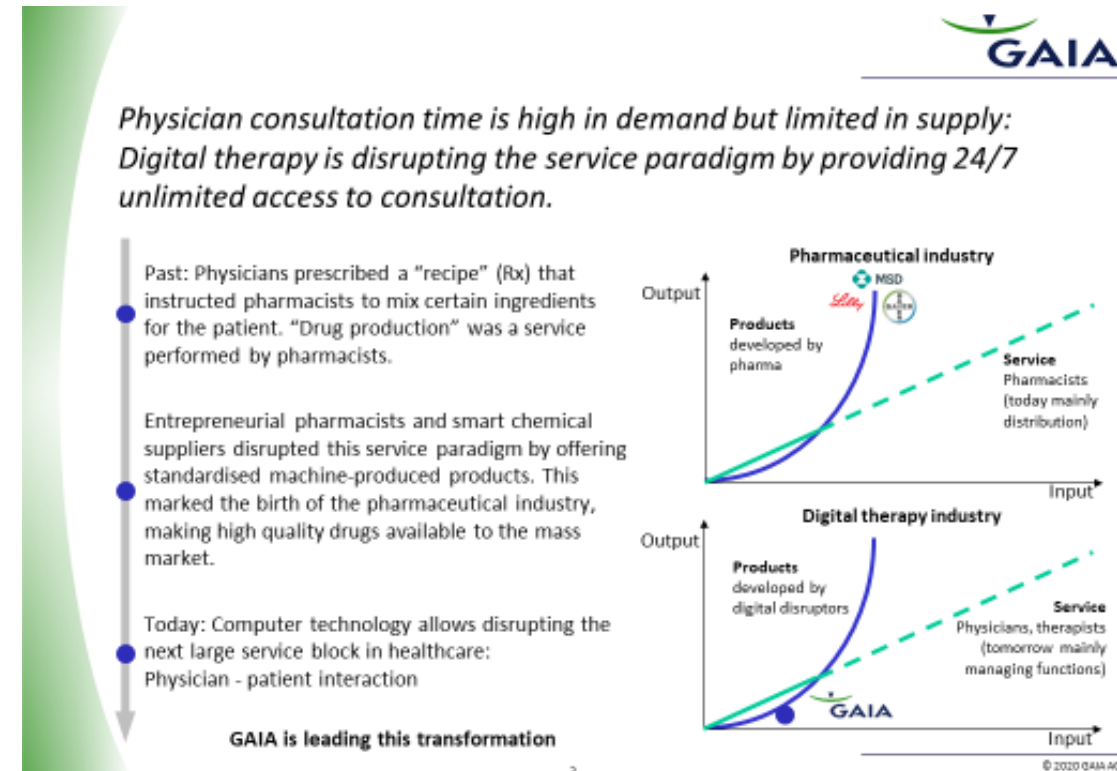
vorvida[®] adapts to your preferences to help you change your behavior around alcohol.¹

[ABOUT VORVIDA](#)

¹ Zill JM, Christalle E, Meyer B, Härter M, Dirmaier J. The effectiveness of an internet intervention aimed at reducing alcohol consumption in adults. Dtsch arztebl int. 2019;116(8):127-133. doi:10.3238/arztebl.2019.0127

DTx - an attractive opportunity to diversify the company and drive future growth

- Continuous increase in scientific evidence of the value from digital health products
- Covid-19 has significantly accelerated the utilization of non face to face interactions between healthcare providers and patients
- Digital health solutions offer a superior monitoring of treatment outcome and enables value based solutions
- Most payers in the US are recognizing the value of digital health solutions and are assessing how to finance and implements these
- Patients are increasingly becoming comfortable with sharing sensitive information on-line



Strong synergies with the current US commercial platform with a focus on opioid use disorder and treatment with ZUBSOLV® (bup/nal) and R&D pipeline

Digital therapeutics is in its infancy - while the potential is significant, several hurdles need to be addressed before the market takes off

Commercialization

- Optimal pathways to commercialize and scale DTx are still uncharted

Pricing

- Entry barriers are low for offerings without clinical evidence, and thus payors need to establish appropriate assessment criteria to enable price differentiation

Reimbursement

- Many payors still to establish payment and reimbursement processes

Disruptive technology

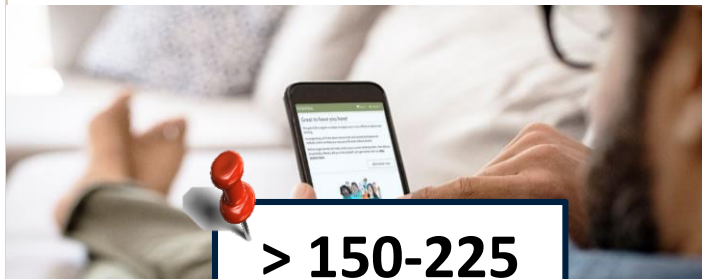
- While digital therapies have been proven clinically, speed of adoption is still unknown as for any new therapeutic approach

Orexo will continue to assess the business model, the potential and the investment levels required to capture new opportunities at the appropriate time

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

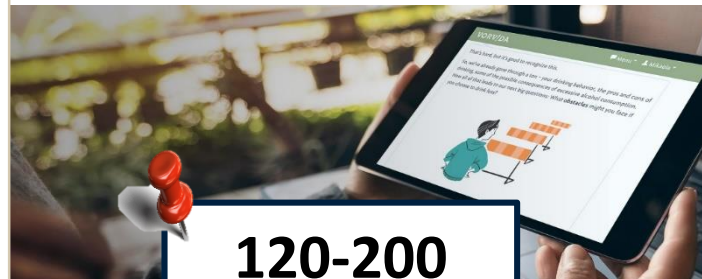


> 150-225

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

modia™

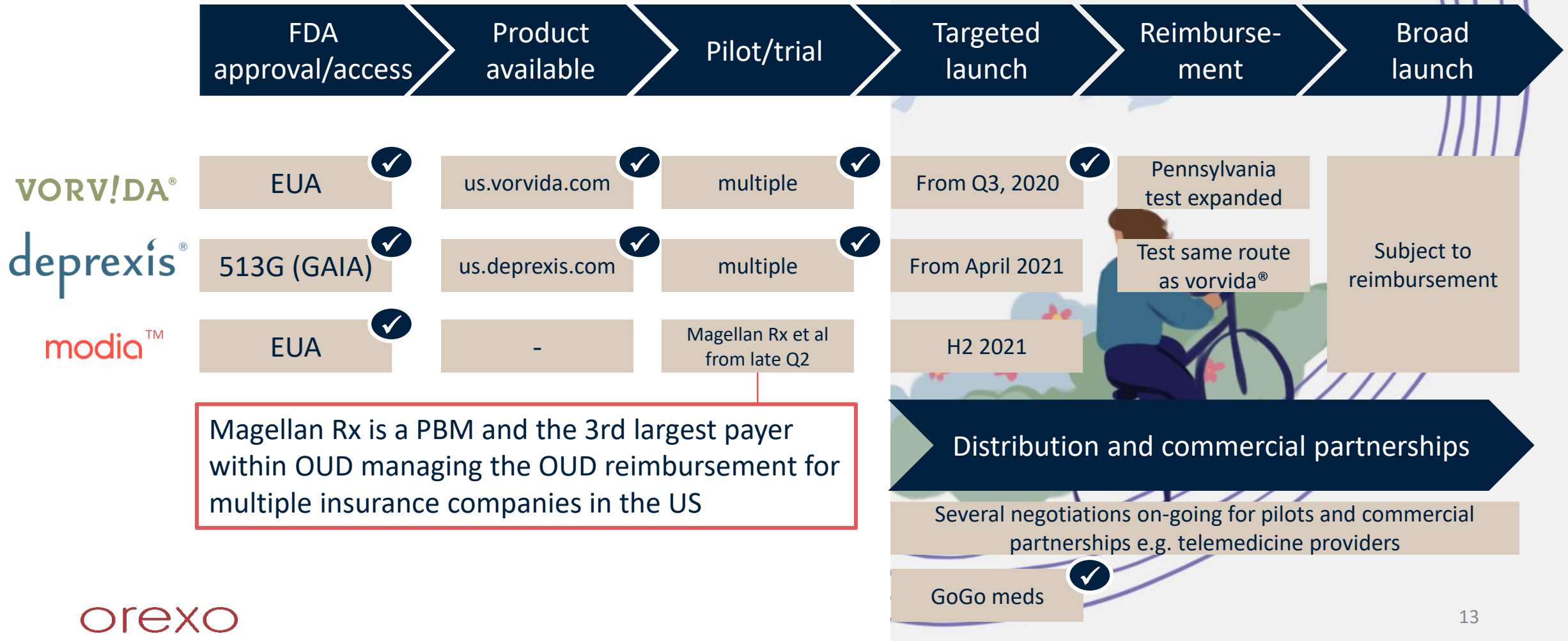
“Digitizing” counselling at scale to offer with ZUBSOLV®, a full medication assisted therapy (MAT) solution for opioid use disorder (OUD) patients in need



150-225

MUSD net sales potential in the US

Multiple commercial activities in anticipation of reimbursement



Several important milestones reached recently

Payers & IDNs

Agreement with Magellan Rx and two additional insurance companies to collect real world evidence (RWE) for modia™. Continued discussions with Trinity Health ND.



Employers

Large US Tech company is testing vorvida® and deprexis® with their employees



HCPs

Agreements signed with multiple regional and local HCPs which will integrate our DTx into their treatment program – **based on already established reimbursement routes (Pennsylvania model)**



US salesforce – increased access to all categories of customers as the US society is slowly returning to post-covid conditions.




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 USD 750 too high. Now reduced to USD 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

Life happens on its own terms, now you can drink on yours

vorvida® is proven to help people drink less alcohol.*

See the science behind vorvida®:



WATCH HOW IT WORKS

Watch on YouTube




In a recent survey, nearly 18 million adults in the United States reported having depression¹⁵

If you're feeling depressed, you are not alone.

Nearly 80% of people with depression say they experience challenges related to work, home, or social activities because of their depression. See how deprexis® can work to help you take on depression.¹⁶

[LEARN MORE](#)

NOW THERE'S A WAY TO TAKE CONTROL OF MY DRINKING BEFORE IT TAKES CONTROL OF ME.



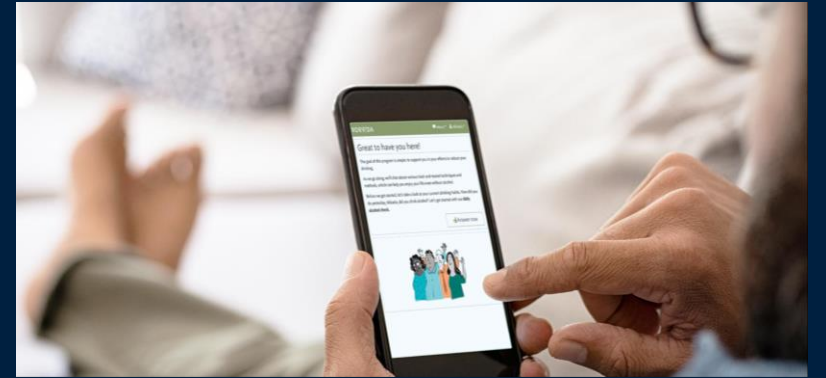
Introducing VORVIDA—the new way to manage drinking.

VORVIDA is the discreet new online program that combines the latest cognitive behavioral therapy techniques with the power of artificial intelligence to help you learn more about yourself and develop strategies that put you in control. It's the help you want, without the baggage you don't.

Visit vorvida.com to get started.

VORVIDA®
The new way to manage drinking

**OX124 - designed to reverse
the effect of the most
powerful synthetic opioids**



OX124 – targeting a > USD 300 million market

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)

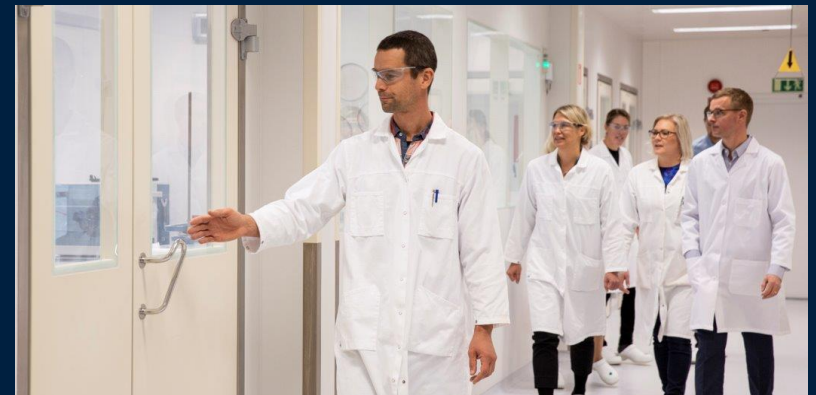
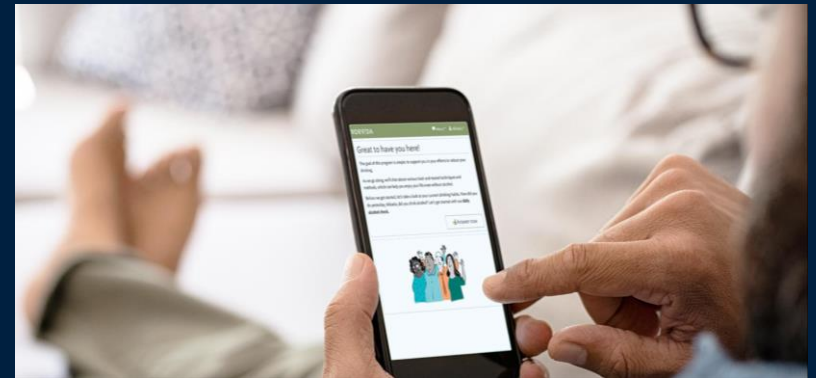


Continued good progress with the aim to file with the FDA in the US mid-2022

Q1 progress	2021-2023
 Continue testing commercial supply chain to meet FDA reliability demands	 Commence the pivotal bridging study
 Establish quality system and testing methods to monitor product quality	 File the new drug application with FDA
 Fast track designation in the US	 Launch in the US

Financial information

orexo



A transformative last 12 months building for future growth

Numbers reflects loss in Abstral® royalty due to patent expiration and investments in the build-up of DTx venture

Group net revenues LTM Q1'21 SEK 621 m	US Pharma net revenues LTM Q1'21 USD 66 m
Group EBITDA LTM Q1'21 SEK -44 m	US Pharma EBIT LTM Q1'21 USD 38 m
Cash position SEK 726 m	US Pharma EBIT Margin (SEK) 55 %
Net Cash position SEK 235 m	Investments in DTx LTM (OPEX) SEK ~175 m

LTM, Last Twelve Months

Denomination currency is SEK USD/SEK 8.4, Q1 2021 average

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 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 **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

H1

Agreements with payers 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.

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.

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

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