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

ABGSC Life Science Summit

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

May 25, 2021

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

- Developed four commercial pharmaceutical products with worldwide approval
- Commercial presence in the US with own field force
- Strong financial position
- Strategic focus on portfolio expansion through R&D and licensing/M&A
- International experienced management team and board of directors

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[1] with synthetic opioids
- Positive results from first clinical trial
- Expected US launch 2023

[1] Overdoses

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

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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. The use of Fentanyl and death from overdose has accelerated during Covid-19.

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	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

DTx – a high-potential market in its infancy

VORVIDA®

deprexis®

modia™

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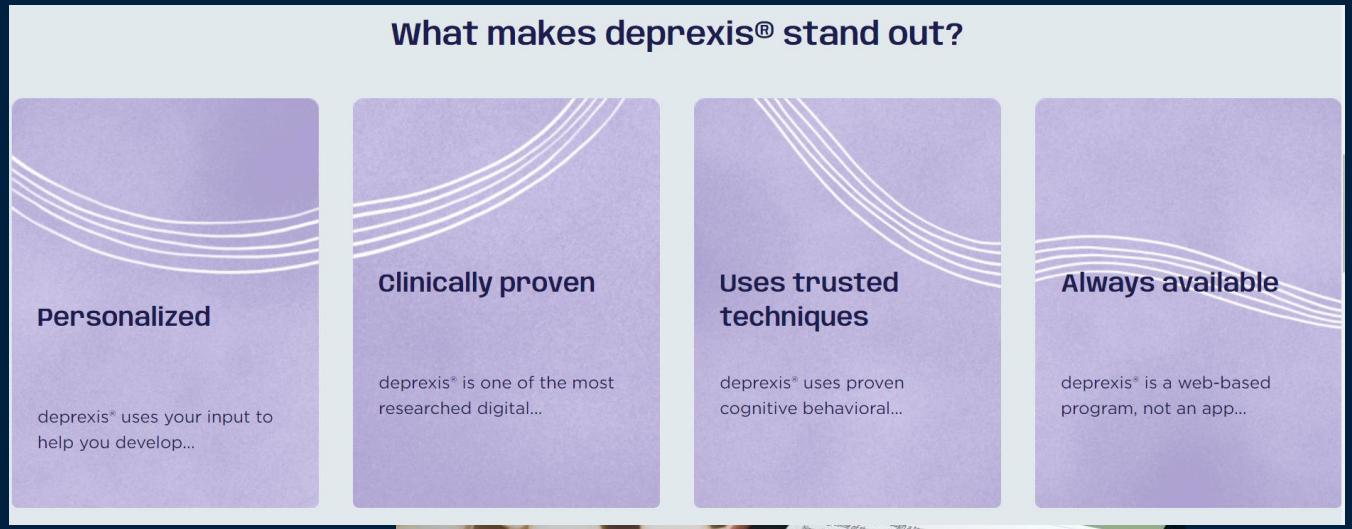

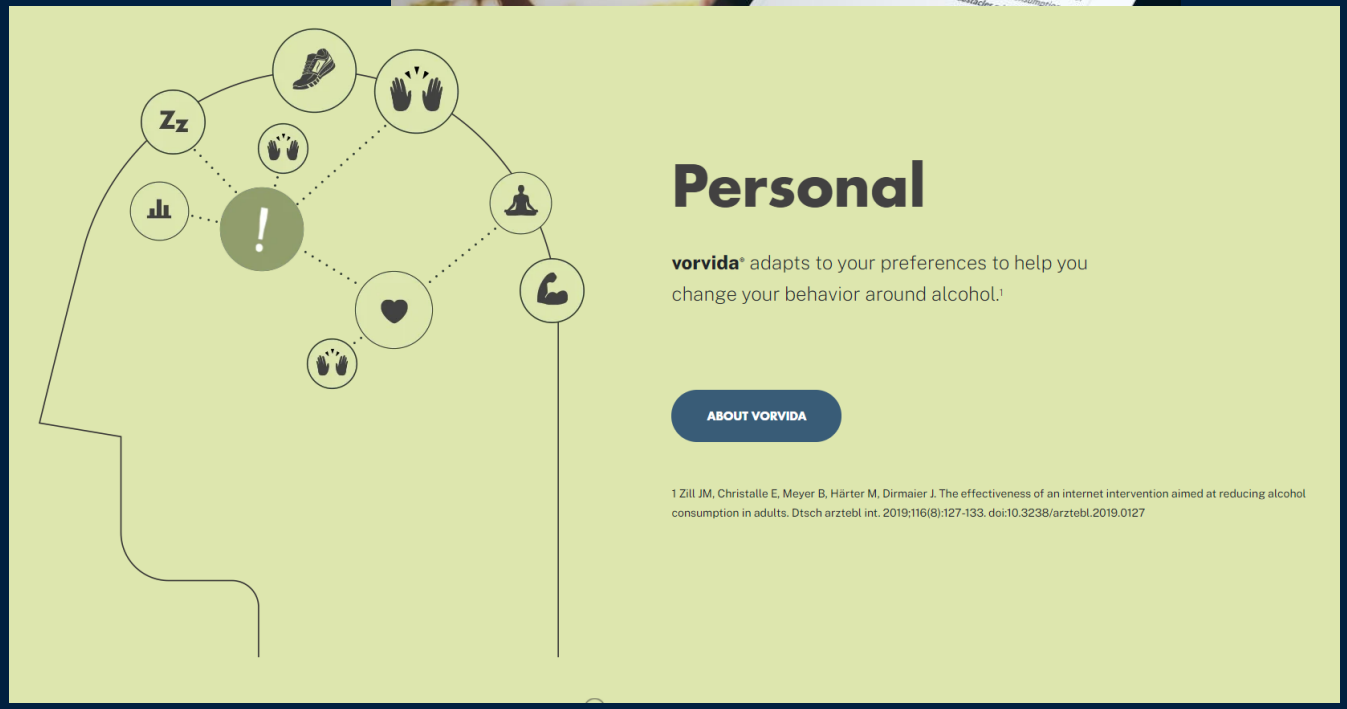

Orexo Digital Therapeutics (DTx)

17 million patients in the US suffered from depression pre-Covid

16 million Americans who are heavy drinkers and should be treated

Of the 10 million people misusing opiods and 2 million diagnosed only few have access to the psychosocial support they need as part of their recovery

deprexis®	Twelve weeks of digital cognitive behavioral therapy for mild to moderate to severe depression One of the most studied digital therapies in depression with 11+ original trials in over 2,800 patients
VORV!DA®	Twenty-four week duration digital cognitive behavioral therapy for problematic drinking Launching under Enforcement Policy for Digital Health Devices for treating psychiatric disorders during Covid-19 Public Health Emergency
modia™	Twenty-four week digital therapy to provide support for patients with opioid use disorder Launching in 2021 under US FDA Enforcement Policy for Digital Health Devices for treating psychiatric disorders during Covid-19 Public Health Emergency

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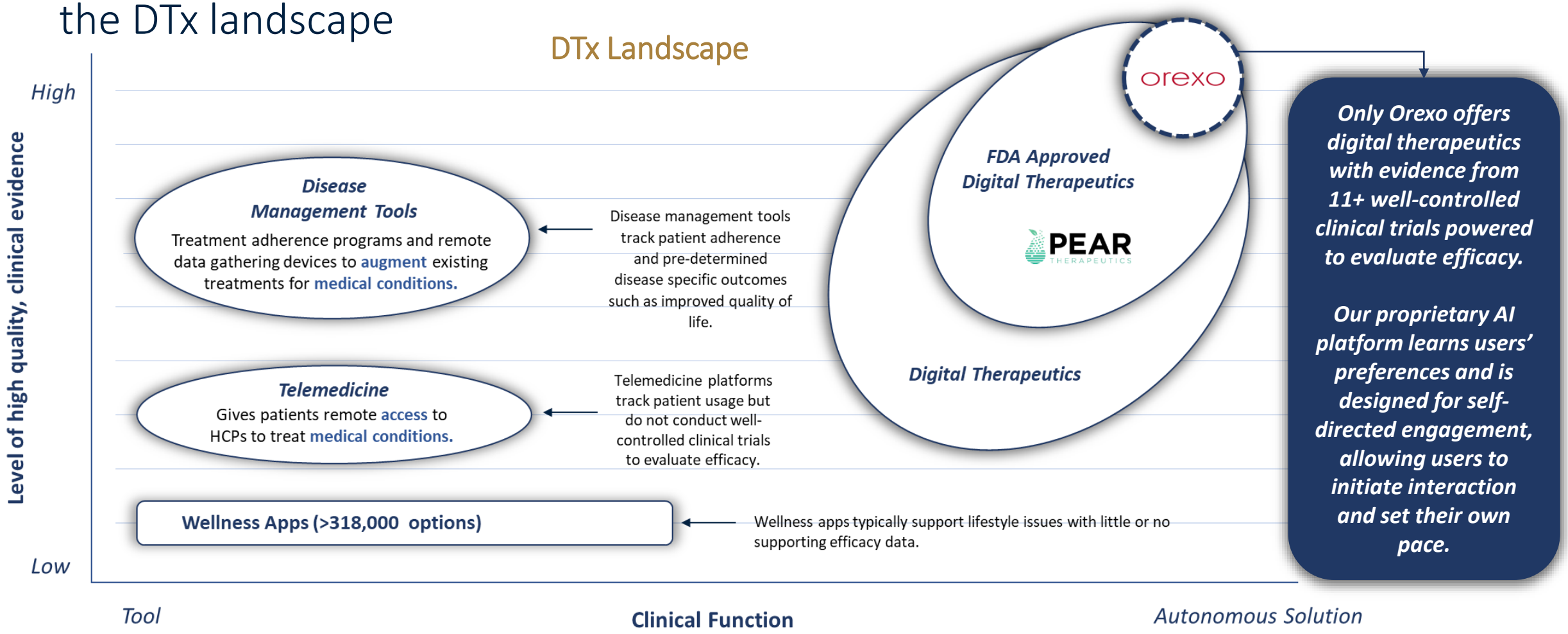
The Orexo portfolio has unparalleled clinical evidence and functionality in the DTx landscape



Only Orexo offers digital therapeutics with evidence from 11+ well-controlled clinical trials powered to evaluate efficacy.

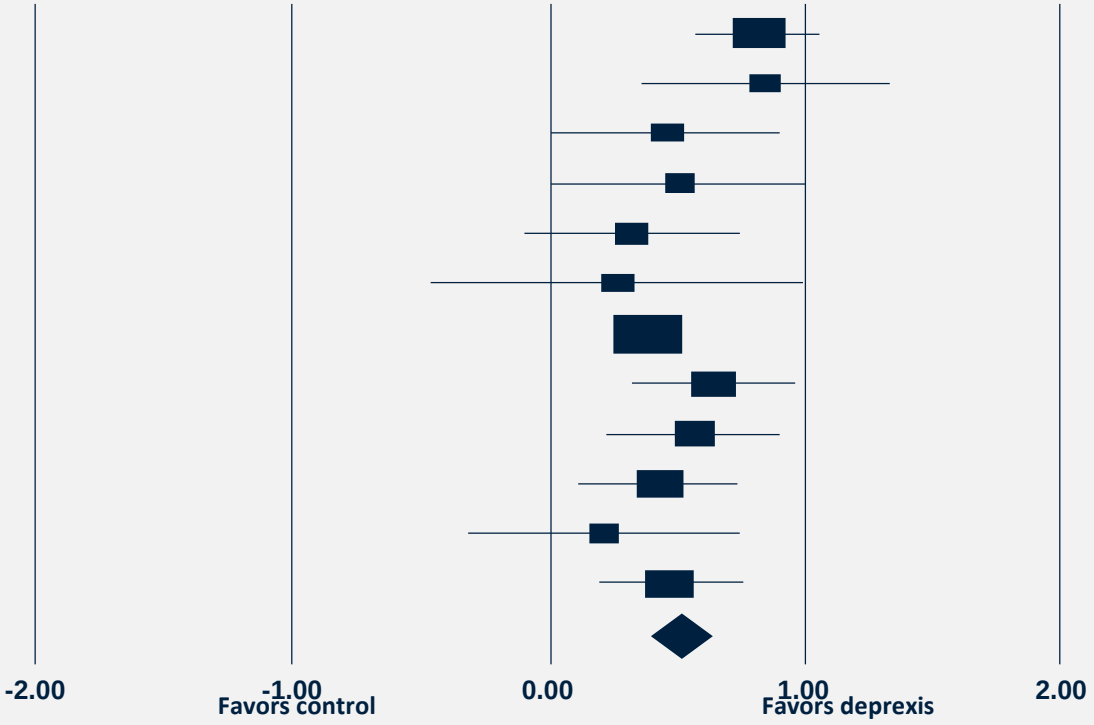
Our proprietary AI platform learns users' preferences and is designed for self-directed engagement, allowing users to initiate interaction and set their own pace.

Clinical evidence is critical for DTx to gain traction in health care

deprexis® demonstrates consistent clinical effect across multiple settings

Meta-analysis of 12 RCTs demonstrated the effectiveness of deprexis for reducing depressive symptoms with a moderate effect size (g = 0.51, 95% CI: 0.40–0.62) and low heterogeneity (I^2= 26 %)

	Study Statistics				Sample Size	
Study	**Hedge's *g***	**LL**	**UL**	***p*-value**	**Control**	**Deprexis**
Beevers (2016)	0.81	0.57	1.06	0.00	91	285
Berger (2011)	0.84	0.36	1.33	0.00	26	50
Berger (2018)	0.46	0.02	0.90	0.04	47	51
Bücker (2018)	0.51	-0.01	1.02	0.06	69	71
Fischer (2015)	0.32	-0.09	0.74	0.12	45	45
Fuhr (2018)	0.27	-0.47	1.00	0.48	13	14
Klein (2016)	0.39	0.26	0.51	0.00	504	509
Meyer (2009)	0.64	0.33	0.94	0.00	76	320
Meyer (2015)	0.57	0.22	0.91	0.00	85	78
Moritz (2012)	0.43	0.13	0.73	0.01	105	105
Schröder (2014)	0.22	-0.30	0.73	0.41	40	38
Zwerenz (2017)	0.47	0.20	0.74	0.00	110	109
OVERALL	**0.51**	**0.40**	**0.62**	**0.00**	**1108**	**1409**

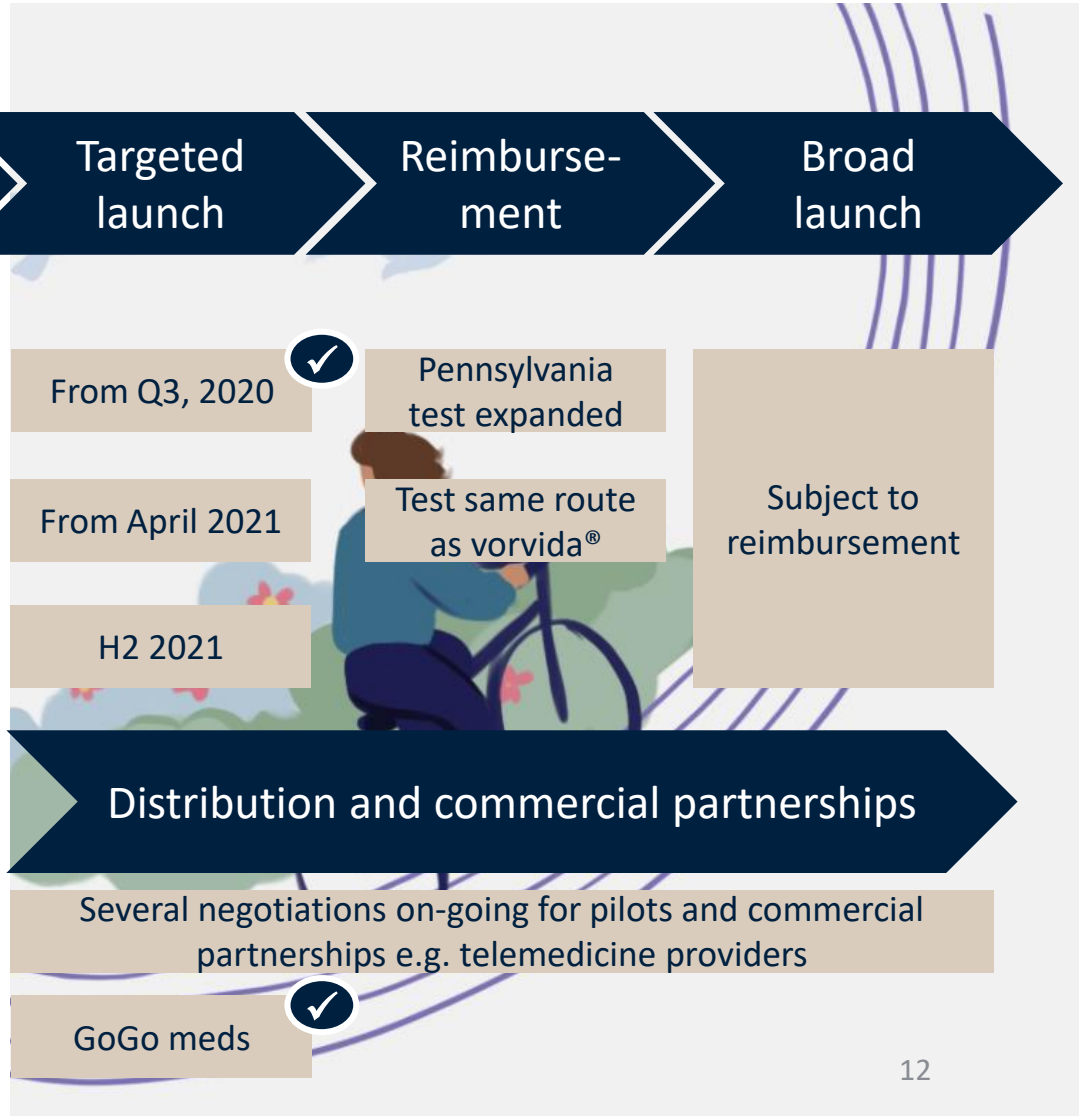


Twomey C, et al. PLoS One. 2020; 30;15(1): e0228100.

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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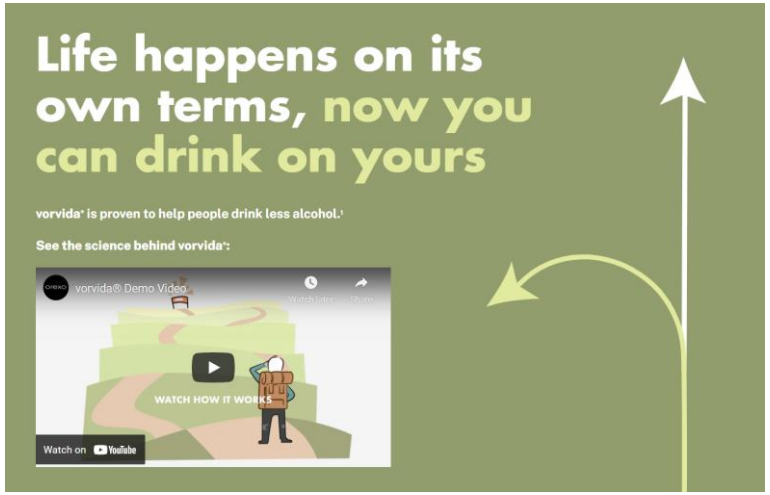
DTx sales still to accelerate, some preliminary drivers developing



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

ZUBSOLV® - contributing to a solid foundation for future growth

zubsolv® sublingual tablets
(buprenorphine and naloxone) C-III

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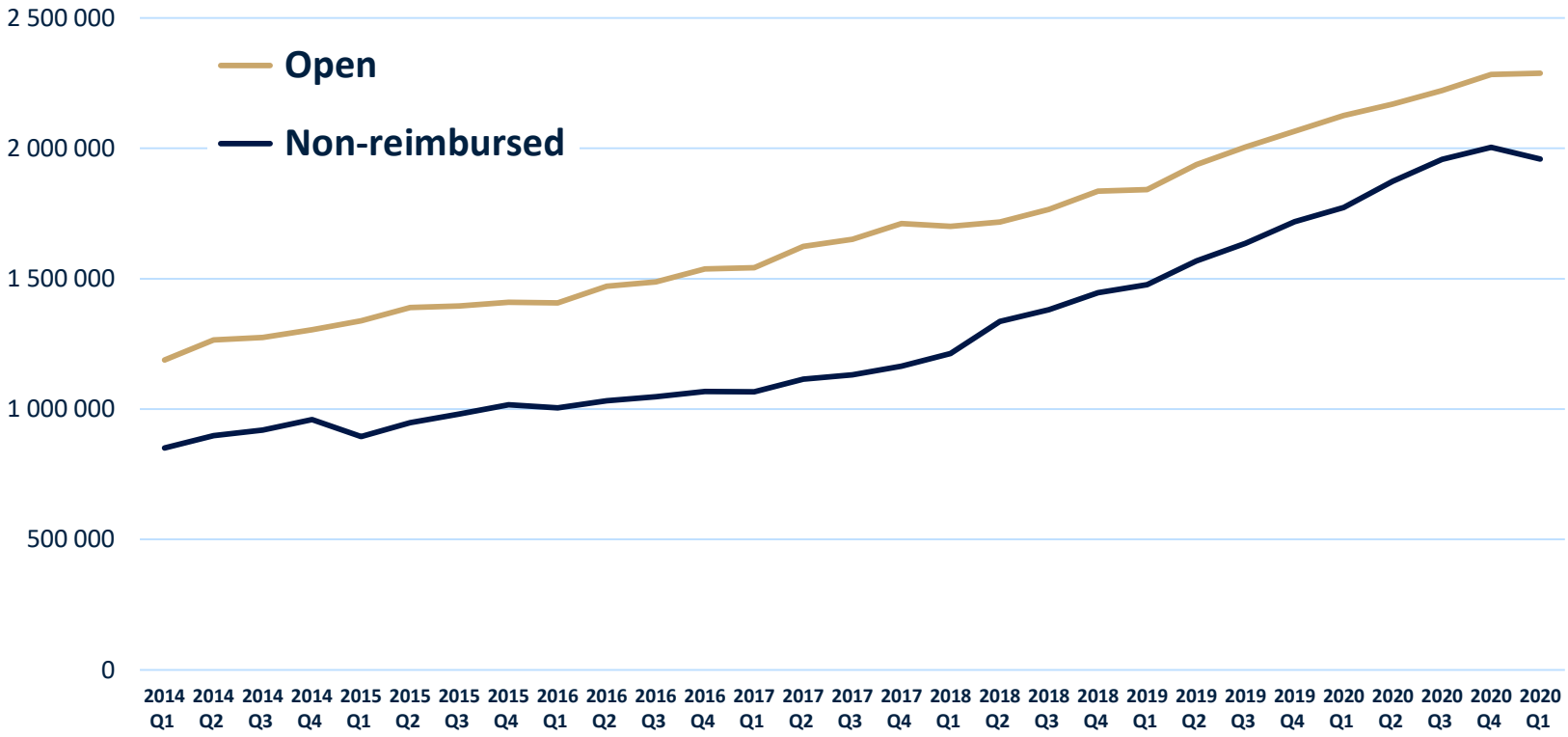
Q1´21: The US opioid crisis fuels a market characterized by strong growth

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

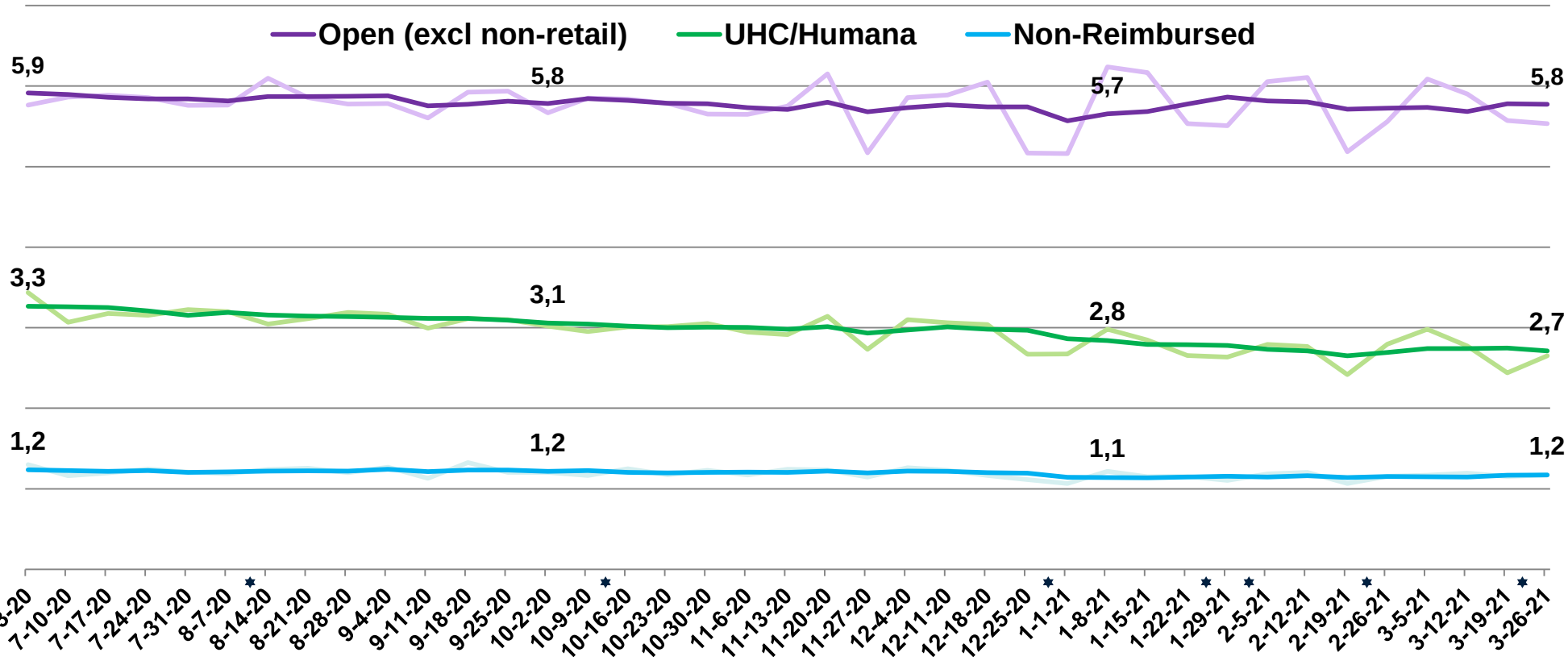
- **"Open"**
  - Market segments where ZUBSOLV® is currently reimbursed either exclusively or non-exclusively
- **"Non-Reimbursed"**
  - Market segments where ZUBSOLV® is currently not reimbursed

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

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

The negative impact from formulary changes at UHC/Humana 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® 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 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 & legal information

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A transformative last 12 month period 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

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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.
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