



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



DTx commercialization plan

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

Nikolaj Sørensen, CEO, & Dennis Urbaniak, EVP Digital Therapeutics, July 2 2020

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COVID-19 has significantly raised awareness and demand for digital therapies, particularly in certain conditions such as SUD and mental health issues

March 2020

Patients are flooding to virtual clinics and online medical councils

Companies are boosting their digital strategy on the back of the coronavirus

Digital and delivery services thrive on the coronavirus outbreak

Patienter strömmar till nätläkarna efter corona

Av JOHANNES KARLSSON | onsdag 11 mars 2020 kl. 20:19 | johannes.karlsson@di.se | [@Karlsson_J](https://twitter.com/Karlsson_J)



As Italy's Hospitals Overwhelmed by Coronavirus, Top Health Official Says 'Worst Is Yet Come' for US

"We will see more cases and things will get worse than they are right now."

Coronavirus' biggest winners: From Netflix to fitness bike maker Peloton

The COVID-19 virus has battered global markets and threatens to worsen the global economic slowdown. But not everyone is losing money even as the fast-spreading epidemic wipes out trillions from global markets.

Stay home, stay connected

Shares in teleconferencing startup Zoom Video have soared nearly 50% since February as investors bet on a rise in remote workplaces amid fears of the coronavirus spreading further. The company has already added more active users this year — 2.22 million — than it did in all of 2019, Bernstein Research analysts said.

April 2020

US outbreak surges,

Isolation consequences appearing as jobless claims skyrocket

Burden in psychiatric conditions intensifies

Emergency policy issued to address demand

Contains Nonbinding Recommendations

Enforcement Policy for Digital Health Devices For Treating Psychiatric Disorders During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

Guidance for Industry and Food and Drug Administration Staff

April 2020

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-14-26
Baltimore, Maryland 21244-1850



CMCS Informational Bulletin

DATE: April 2, 2020

FROM: Calder Lynch, Deputy Administrator and Director

SUBJECT: Rural Health Care and Medicaid Telehealth Flexibilities, and Guidance Regarding Section 1009 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (Pub. L. 115-271), entitled Medicaid Substance Use Disorder Treatment via Telehealth

Orexo's pharma and DTx products and our R&D pipeline are uniquely positioned to address the need arising from COVID-19

Deaths from opioid overdose increase



Opioid-related deaths make a disappointing uptick in early 2020, possibly related to coronavirus

By Meredith Cohn, The Baltimore Sun · 23 hrs ago



Alcohol misuse increase

Drug and Alcohol Use Increase During COVID-19

Our recent survey shows more people are using drugs and alcohol to cope with stress, boredom and mental health issues.



THE RECOVERY VILLAGE

Opioid misuse increase

Alexander Caudarella: The pandemic is making the opioid crisis worse

Escalating numbers of overdoses and deaths are being reported in many parts of the country. In Toronto in both April and May, there were more suspected opioid deaths than any month since September 2017

NATIONAL POST

Depression increase

Payer

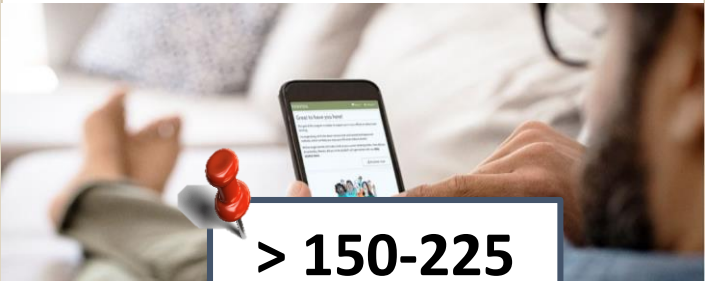
Prescriptions for antidepressants, anti-anxiety, anti-insomnia drugs jumps 21% post COVID-19



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 and is one of the most researched such in the world



> 150-225

MUSD net sales potential in the US

vorvida®

A fully automated digital therapy scientifically proven to reduce trouble-some drinking patterns in adults suffering from alcohol misuse incl. alcohol use disorder (AUD)



120-200

MUSD net sales potential in the US

OXD01

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



150-225

MUSD net sales potential in the US

Digital therapy is in its infancy and as the business model evolves and the commercialization advances Orexo can provide more firm guidance to the revenue potential

Commercialization

- Optimal pathways to commercialize and scale DTx are still uncharted

Pricing

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

Reimbursement

- Many payers 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 to be able to invest to capture new opportunities or slow down investments if needed

To enable accelerated launch of all three products investments will increase and OPEX guidance for FY 2020 will increase with approximately SEK 200 million

- Previous OPEX guidance excluded launch expenses for vorvida®, all expenses for deprexis® and launch of OXD01 ahead of original plan in 2022
- New guidance includes all expenses related to commercialization e.g.
 - Expanding "digital therapy engine" to cover three products to enable e-commerce, payer support, data warehousing etc
 - Launch preparations for three products to develop marketing material, OXD01 branding, customer insight generation, field force preparation etc
 - Launch* of three products during 2020 including non-personal promotion, field force activities
- The increased investment will impact all remaining quarters including Q2
- Investments will be monitored closely and adjusted pending our success in securing reimbursement during 2020
- Except for depreciation, the guidance does not include capitalized investments, such as milestone payments to GAIA AG and some limited infrastructure investments

We are building a business anchored on three core fundamental capabilities

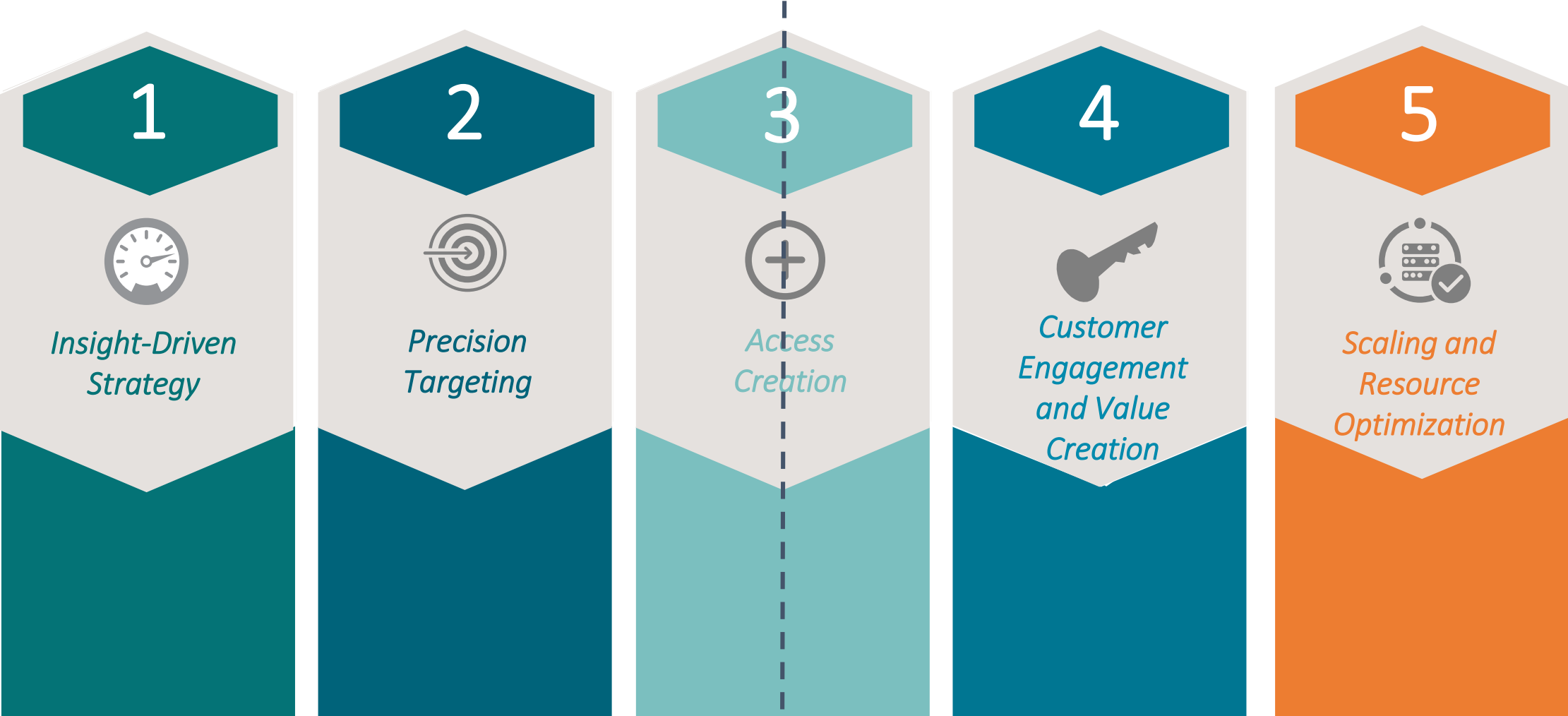


**Advanced
Data and
Analytics**

**Experience
Design and
Execution**

**Novel
Business
Models**

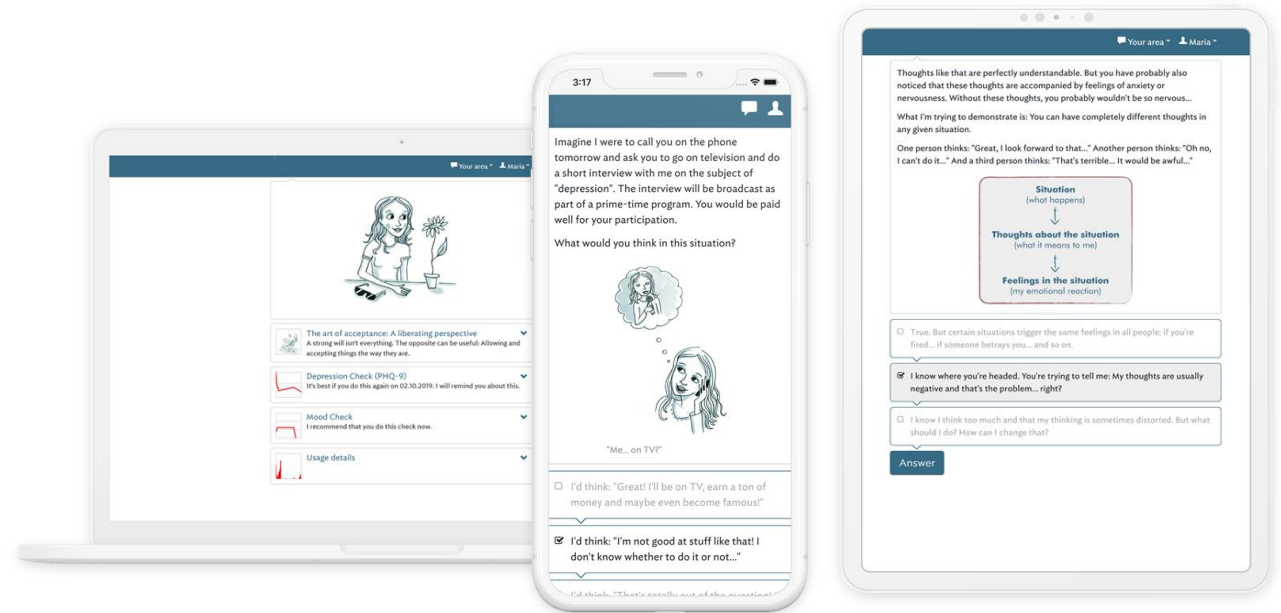
Our investment and go to market strategy is highly targeted and will scale as access is created in high need markets



Overview of deprexis®

- deprexis® is a clinically-proven online therapeutic support program, rooted in evidence-based, cognitive behavioral therapy (CBT) and other psychological approaches such as psychodynamic theory, designed to offer tailored, interactive psychotherapy interventions via their mobile device or computer.
- Comprised of 10 modules, deprexis® provides a series of customized exercises including information about the clinical situation of depression and proposed techniques to monitor and improve mood. The content is delivered to end-users via audio recordings, succinct text, embedded video, animations and illustrations.

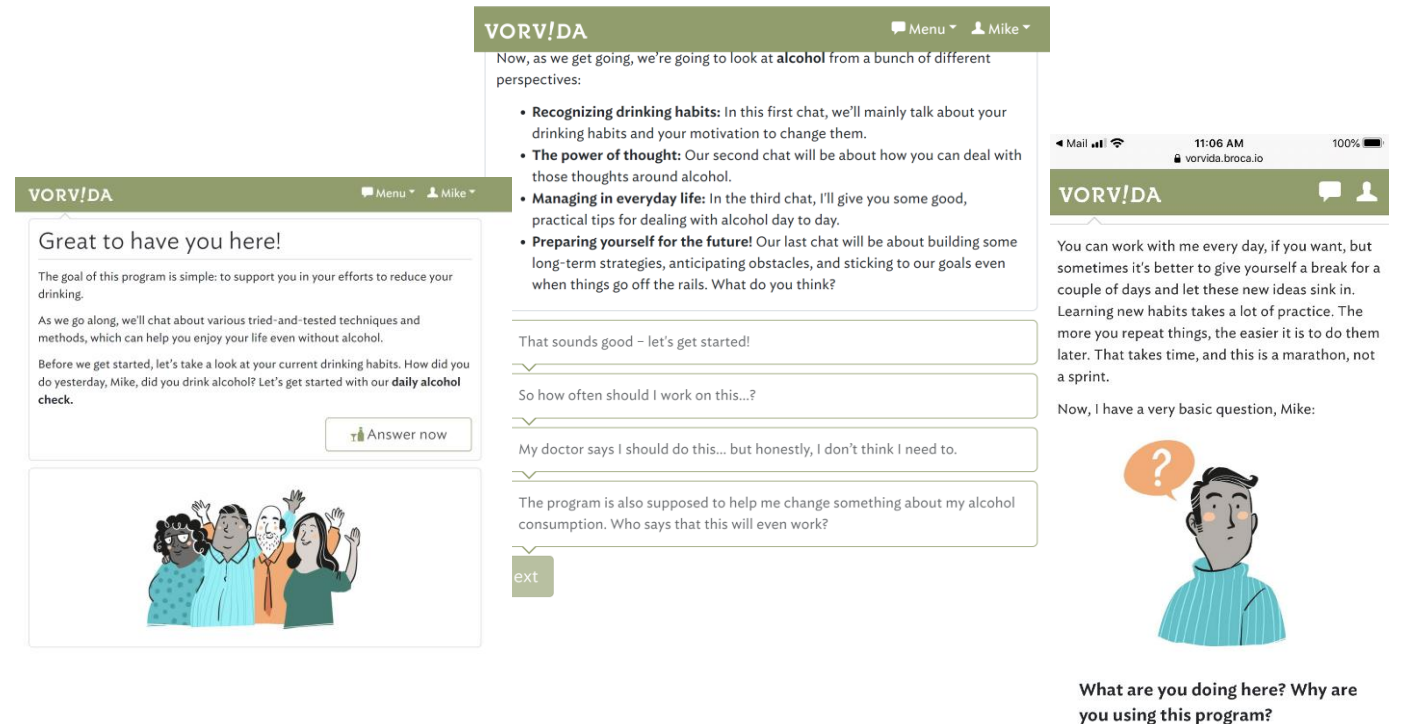
- **Self-directed engagement:** users initiate interaction and set their own pace
- **Discreet:** users can engage in a private setting, and there's no need to share anything publicly
- **Support and flexibility:** can be used independently or in conjunction with care as usual
- **Easily accessible:** the online intervention is always available when and where users need it



Overview of vorvida®

- vorvida® delivers evidence-based cognitive-behavioral therapy techniques via an internet-based intervention in order to reduce alcohol consumption among adults with problematic drinking behaviors
- vorvida® does not require human guidance or support; the program uses artificial intelligence software to tailor the program to the user in order to continually simulate a dialogue

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To complement the significant evidence supporting our products, we are developing user experience driven program content

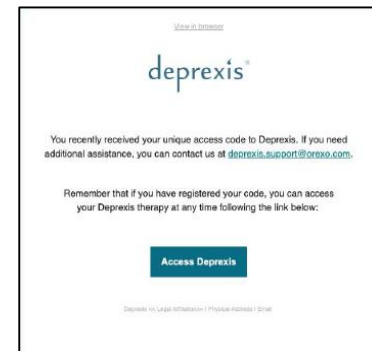
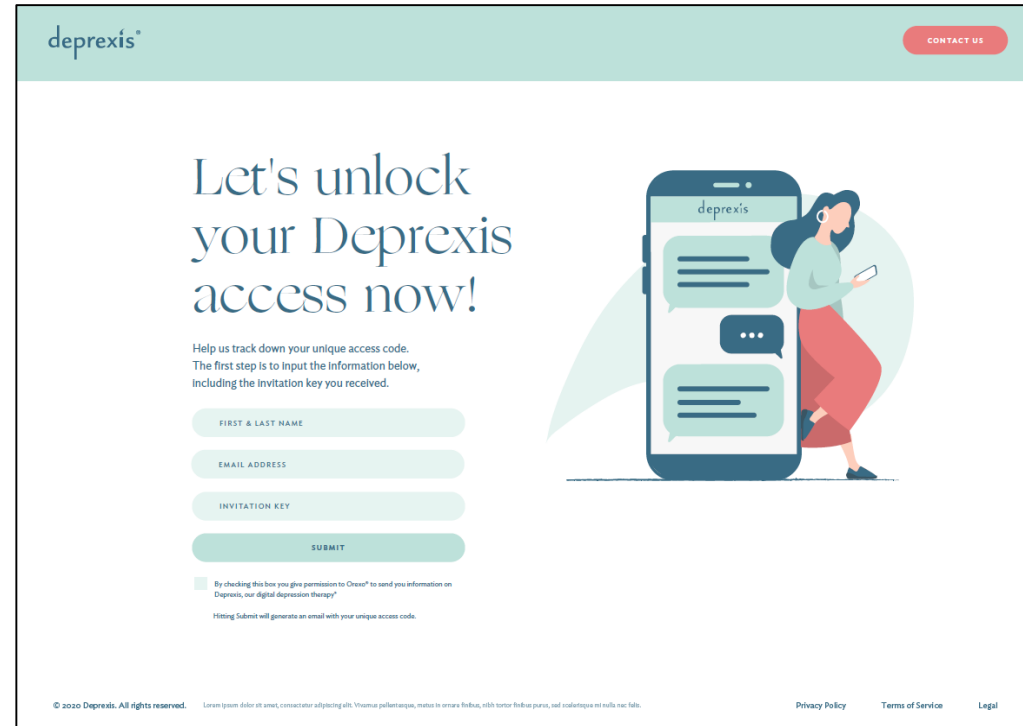
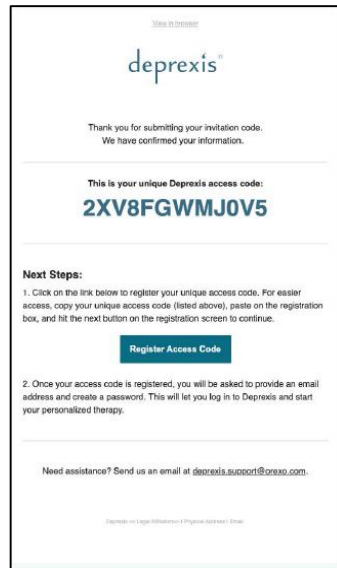
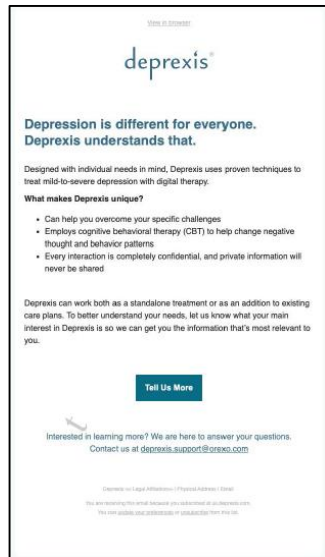
deprexis® “Day 1” site *meetdeprexis.com* live as of July 2nd, 2020



vorvida communication materials coming Sept. 2020



Patients suffering from depression or alcohol misuse are vulnerable and Orexo prepare a range of services to ensure patient engagement and support



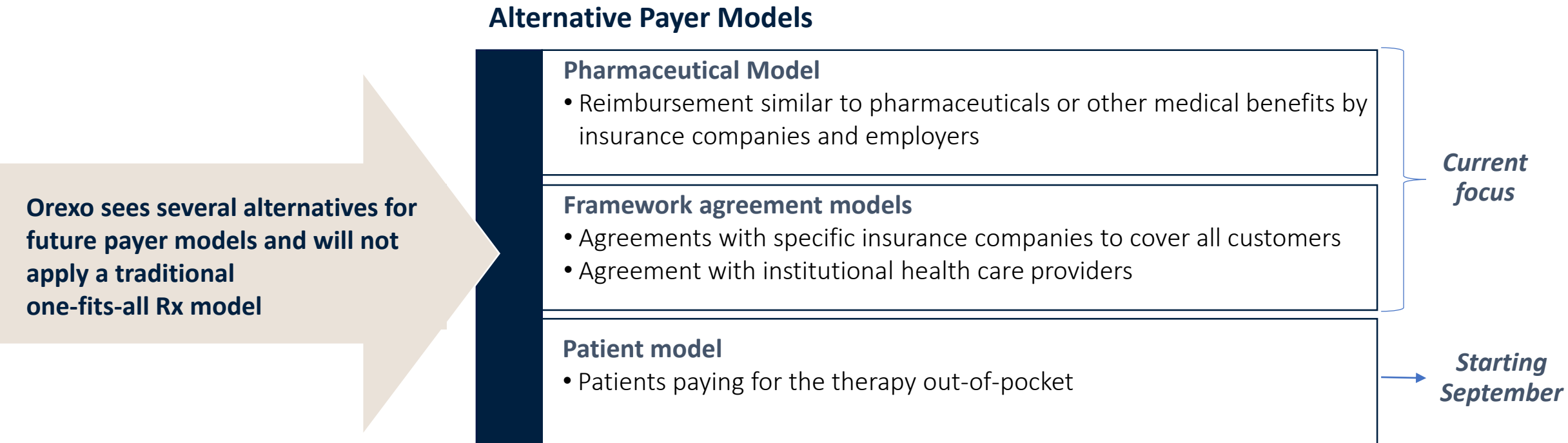
Patients services available from September include user friendly patient services spanning specialty hub services for insurance reimbursement, customer service, e-commerce storefronts, and on-going customer relationship management tools

Early customer feedback supports the market need and demonstrates a positive response to the products...

- *“I think that if it’s something that can be used in addition to therapy with a live therapist, it’s a good thing because it’s another tool that people can use to get through the process of depression.” – Patient*
- *“I think this is better than live therapy, actually. People sometimes don’t like to go in person or look at somebody and speak about their problems.” – Caregiver*
- *“The biggest advantage is that the product is available anytime, anywhere for individuals that can continue therapy outside of in-person sessions. I think that would be really helpful.” – Therapist*

- *“I think this is very relevant. I've been in meetings where there continues to be concern over excessive drinking by employees. It’s certainly something we want to find solutions for.” – Pharmacy Director*
- *“Alcohol dependence is something we don't talk about. As an employee, being able to do something digitally and in the privacy of my own home seems like a great opportunity.” – Employee Benefits Manager*
- *“I have a lot of confidence in CBT, there are a lot of ways to tailor it for different populations and patients. It tends to be one of those gold standard treatments. I love it as a treatment.” – Therapist*

Establishing a pricing and payer model is critical for future success in digital therapy



Payer models are evolving continuously, but no established standard has emerged

Digital therapy has the potential to become a very important tool in the treatment of addiction and mental health

The unmet need

Addiction and mental health are complex diseases requiring multi-faceted approaches, with both significantly increasing related to the COVID-19 situation

Our aim

Orexo will become the leading provider of clinically proven digital therapy for addiction/mental health treatment by leveraging our strong current US commercial organization

The value to patients

Patients can access a gold standard behavioral therapy, with a consistent and quality therapeutic intervention, when they need the interactions the most

The value to healthcare

Orexo enables physicians and counsellors to treat more patients, more efficiently, with significantly better monitoring of patient treatment progress



THANK YOU

IR Contact: Lena Wange, IR & Communications Director, ir@orexo.com. For more information please visit www.orexo.com.

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