



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



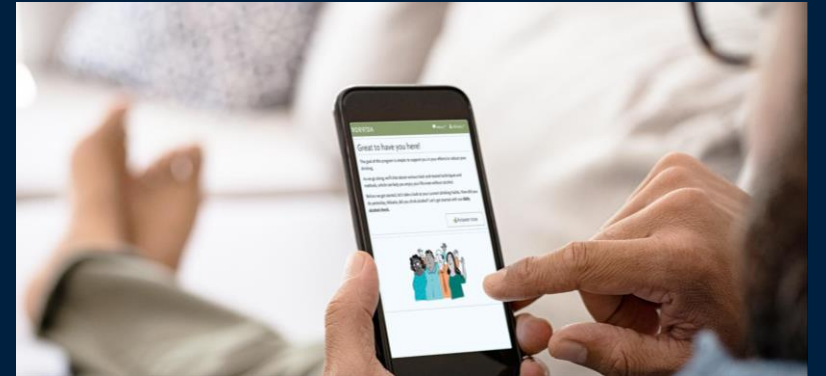
## Nordea Small Cap Days, August 13 2020

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

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# Overview & strategic agenda

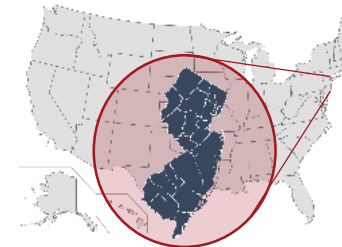


# Addresses unmet needs within the growing space of substance use disorders (SUD) and mental health

- Direct presence in the **US**, with a **fully-owned commercial platform**
- Developed **four commercial products** with worldwide approval
- Broad product portfolio and development pipeline of traditional **pharma products** and **digital therapies**
- Strategic focus on **portfolio expansion** through development and licensing/M&A
- **Strong financial position** enables investment in future growth
- Top two largest shareholders<sup>1</sup>: **Novo Holdings** (27.8%) and **HealthCap** (10.2%)



**Corporate Headquarters**  
(Uppsala, Sweden)  
Corporate functions and Development



**US Headquarters**  
(Morristown, New Jersey)  
Commercial subsidiary incl. fully owned field force

**Net revenues**  
SEK, LTM<sup>2</sup> Q220

**823** m

**EBITDA**  
SEK, LTM Q220

**239** m

**Cash position**  
SEK, Q220

**677** m

<sup>1</sup> As of July 31, 2020

<sup>2</sup> Last Twelve Months



The profit and cash contributions from ZUBSOLV® enables continued investments in building a broader and stronger Orexo

### Broaden...

..the portfolio of commercial products to be promoted by our existing US organization in 2020

### Establish

..a new revenue generating business area within Digital Therapeutics (DTx) and launch first new product in 2020

### Maintain

..ZUBSOLV® profit contribution in 2020 and ensure it is sustainable and growing over time

### Launch

..a new pharmaceutical product from Orexo's development pipeline within the next two years



# Covid-19 will create a tsunami of mental health issues and significantly increase the need for Orexo's products

## Deaths from opioid overdose increase



## 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.



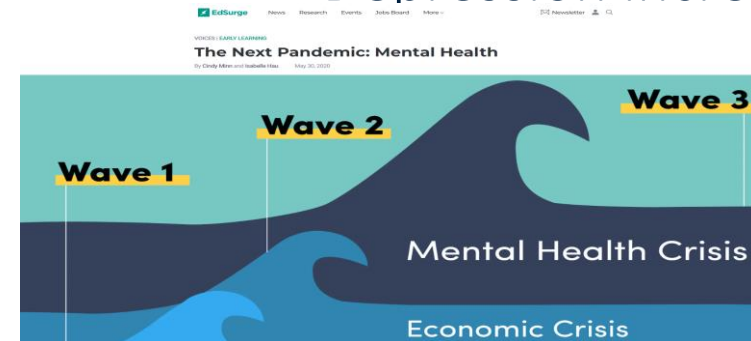
## Opioid misuse increase

### 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

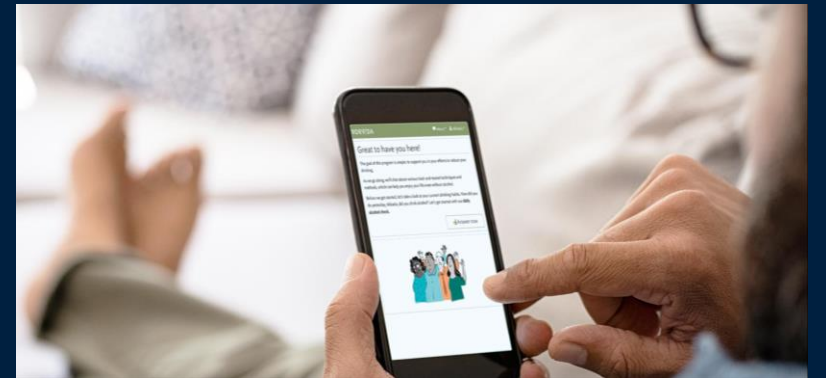
## Depression increase



# Pharmaceuticals

- Pipeline
- ZUBSOLV®
- OX124

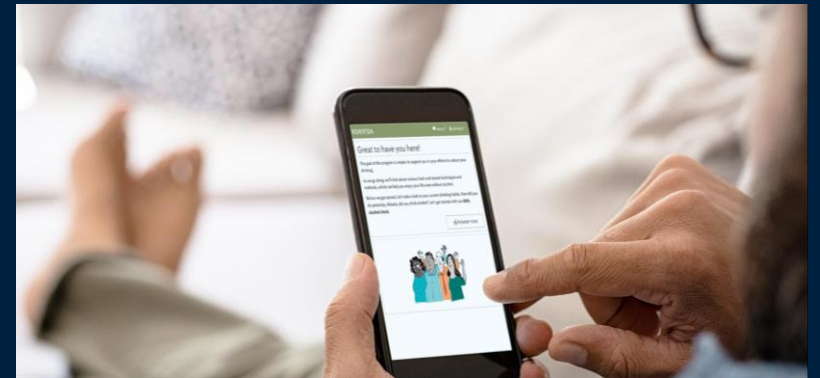
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# Pharmaceuticals

- Pipeline
- ZUBSOLV®
- OX124

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# Pharmaceutical products and pipeline addressing large markets with significant patient needs

Pharmaceuticals									
Product/ Project	Exploratory	Preclinical	Phase			Registration	Approved and/or Launched		
			1	2	3		US	EU	RoW
<b>ZUBSOLV®</b> Opioid Use Disorder									
<b>Abstral®</b> Breakthrough Cancer Pain Partner: Kyowa Kirin									
<b>Edluar®</b> Insomnia Partner: Mylan									
<b>OX124</b> Naloxone, Opioid Overdose									
<b>OX125</b> Nalmefene, Opioid Overdose									
<b>OX338</b> Ketorolac, Moderate to moderately severe pain									
<b>OX382</b> Buprenorphine, Opioid Use Disorder/Pain									
<b>OX-MPI</b> BI1029539, Microvascular Disease Partner: Gesynta Pharma									

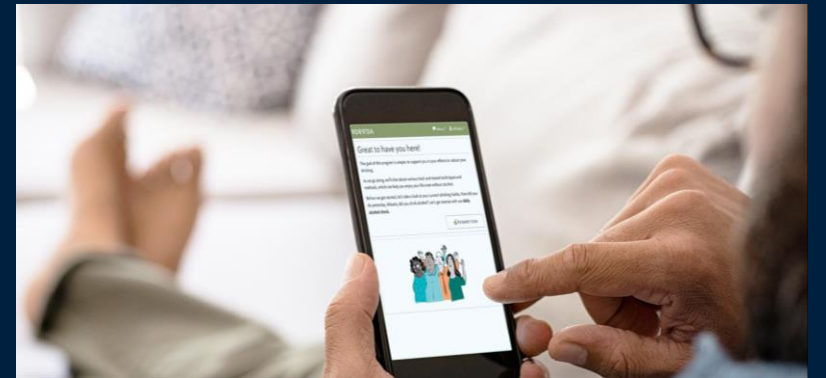
# Pharmaceuticals

- Pipeline

  
**zubsolv**<sup>®</sup> sublingual  
tablets  
(buprenorphine and naloxone) 

- OX124

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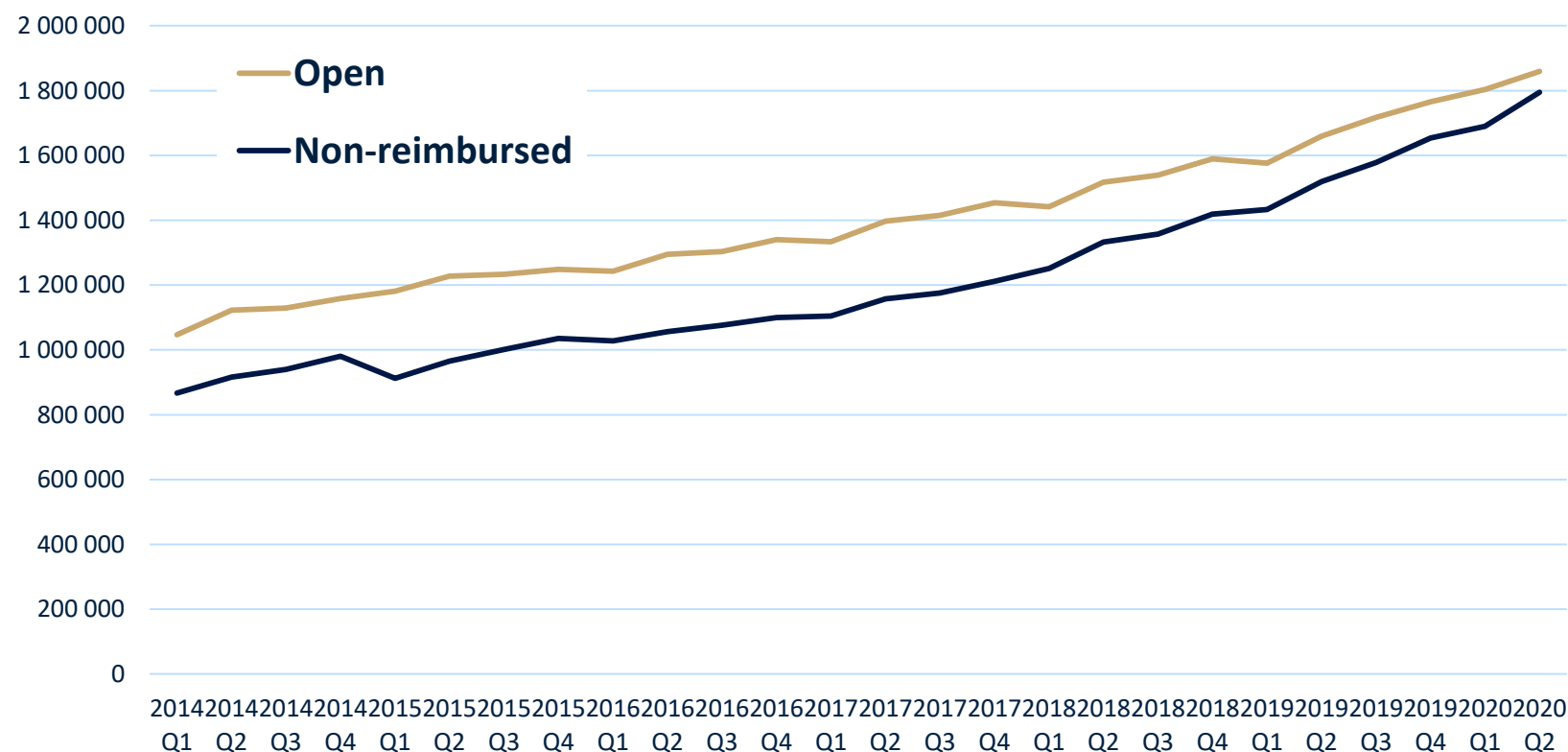


# ZUBSOLV®- 2020 market volume have strongest growth rate since launch

Market growth solely driven by the “Public Segment”

## Market Volume Sales

Quarterly NTRx



## Q2'20 vs Q2'19 Growth

Total Market: +15%

By Segment

+12%

+18%

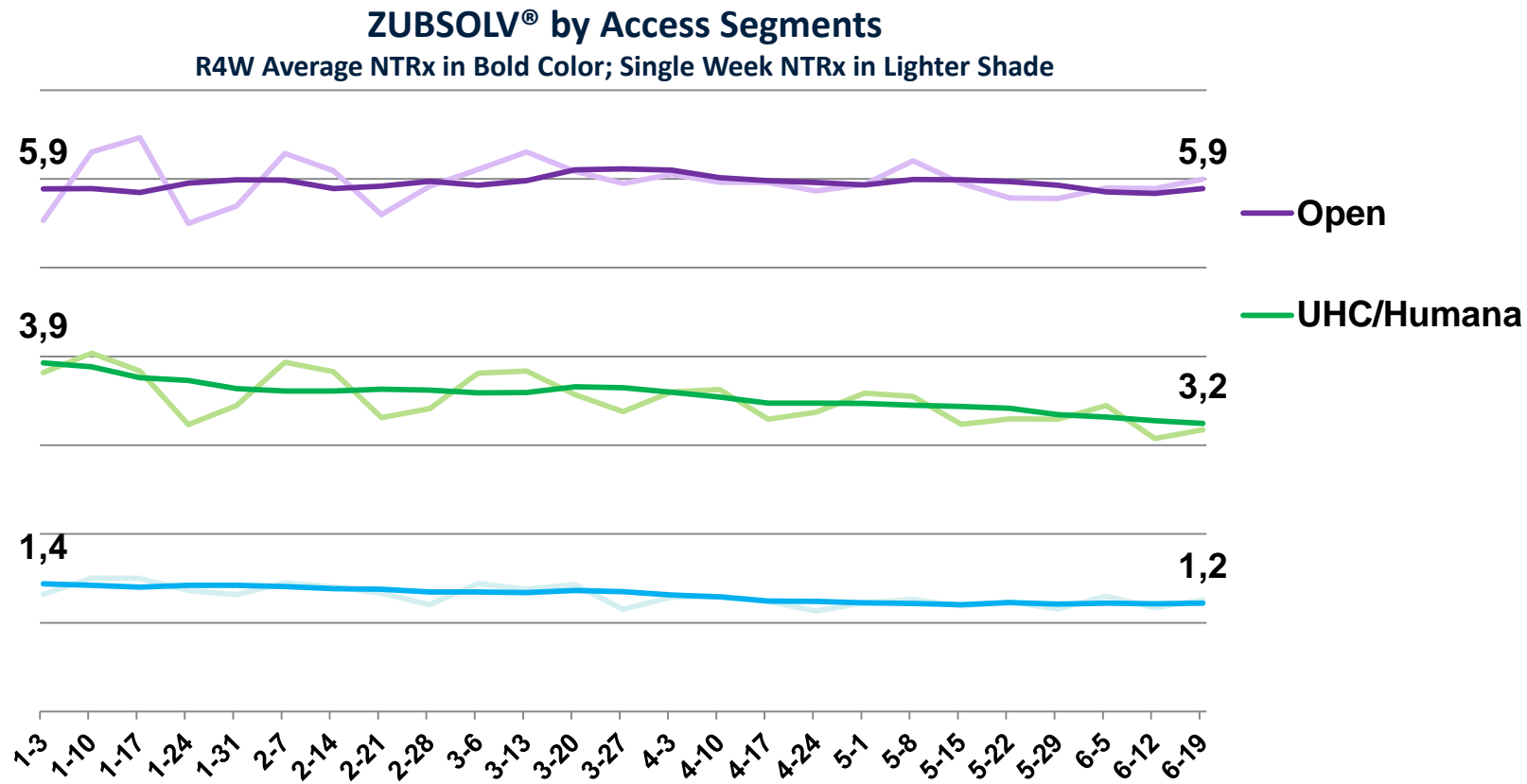
## Definitions

Payers / Market Access

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

# ZUBSOLV® - Mild negative impact from Covid-19 lockdown

Open segment stable, UHC/Humana segment declining due to increased competition from Gx



## ZUBSOLV® net sales up in Q2 vs Q1 despite a mild volume decline due to Covid-19 challenges during lockdown

... ZUBSOLV® grew net sales 5% though volume declined 4% QoQ

...Commercial segment showed a volume decline during Q2 due primarily to Covid related unemployment spike

...Main driver of market growth was Medicaid where ZUBSOLV® has limited access though ZUBSOLV® grew volume where it has “open” access in Medicaid



# ZUBSOLV®- Several possible triggers for growth in 2020 and beyond



## **Continued improvement in ZUBSOLV® market access**

- ...Louisiana Medicaid added ZUBSOLV® to preferred formulary increasing “public access” from 35% to 37% (effective July 1)
- ...Orexo continues to pursue expanding market access in Medicare and Medicaid while maintaining 98% commercial market access leadership position
- ...Generic Film availability pressuring access status of largest branded competitor

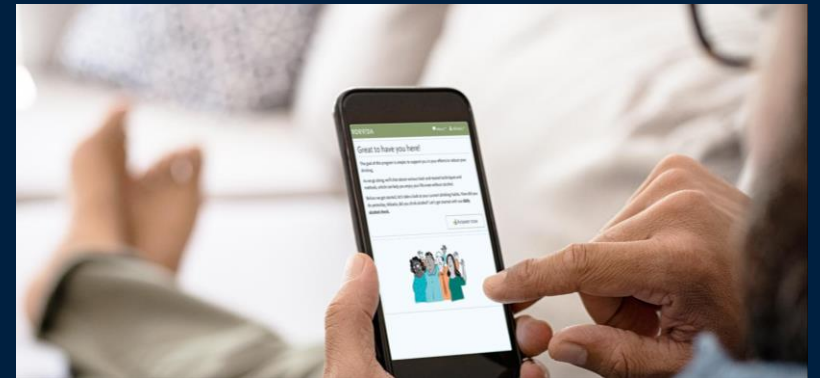
## **Orexo Sales Force now back to office-based selling after 3 months**

- ...Orexo stopped all office selling March 16<sup>th</sup> and the selling model was converted entirely to virtual setting (audio, video and e-mail) as necessitated by prescriber
- ...Currently entire team returning to office-based selling activities while continuing to use virtual selling as certain offices have entry restrictions based on policy & changing Covid environment

# Pharmaceuticals

- Pipeline
- ZUBSOLV®
- OX124

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# OX124 a new stronger rescue medication

Expected launch in H1 2022

## The unmet need

Available rescue medications have been developed for heroin overdoses, but most patients are dying from synthetic opioids like fentanyl today

## 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

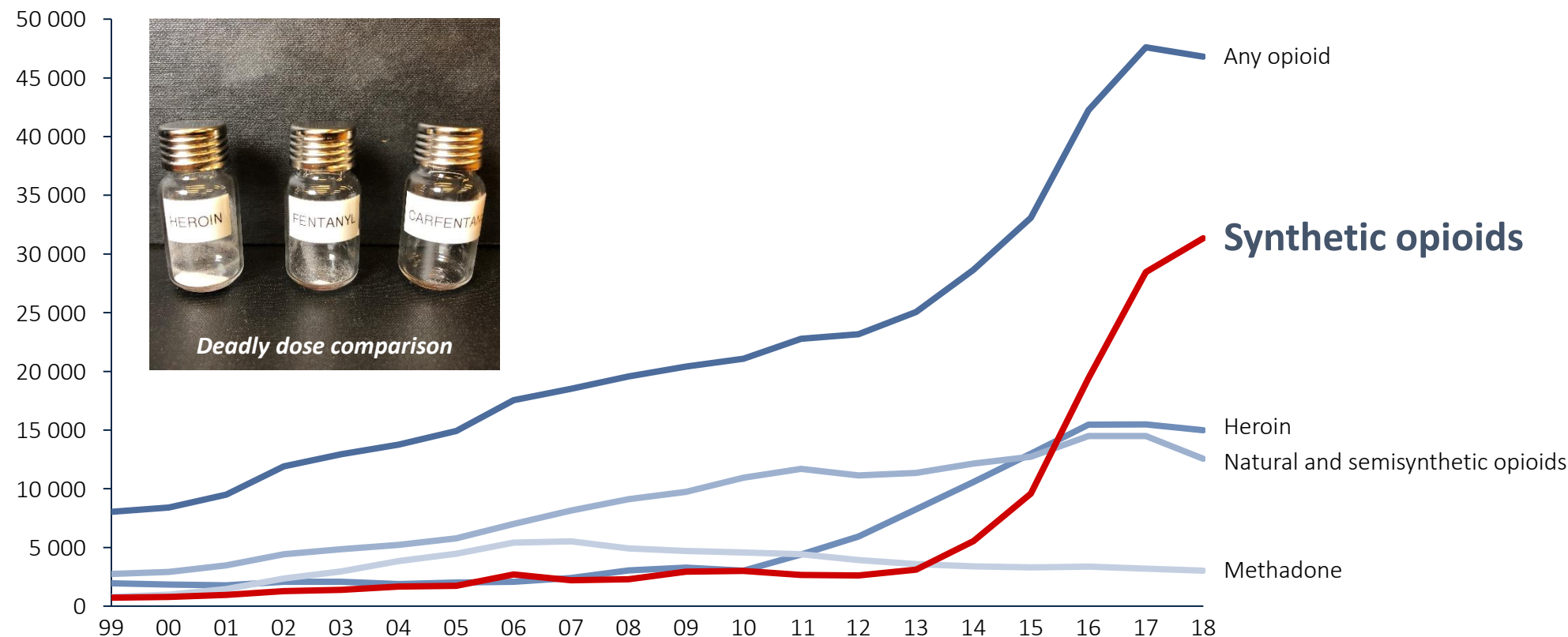
million USD net sales (US market)





# OX124 - While overall deaths from opioid overdoses showed a slight decline in 2018, deaths from synthetic opioids continue to rise

Deaths from opioid overdose  
By type of opioid, United States



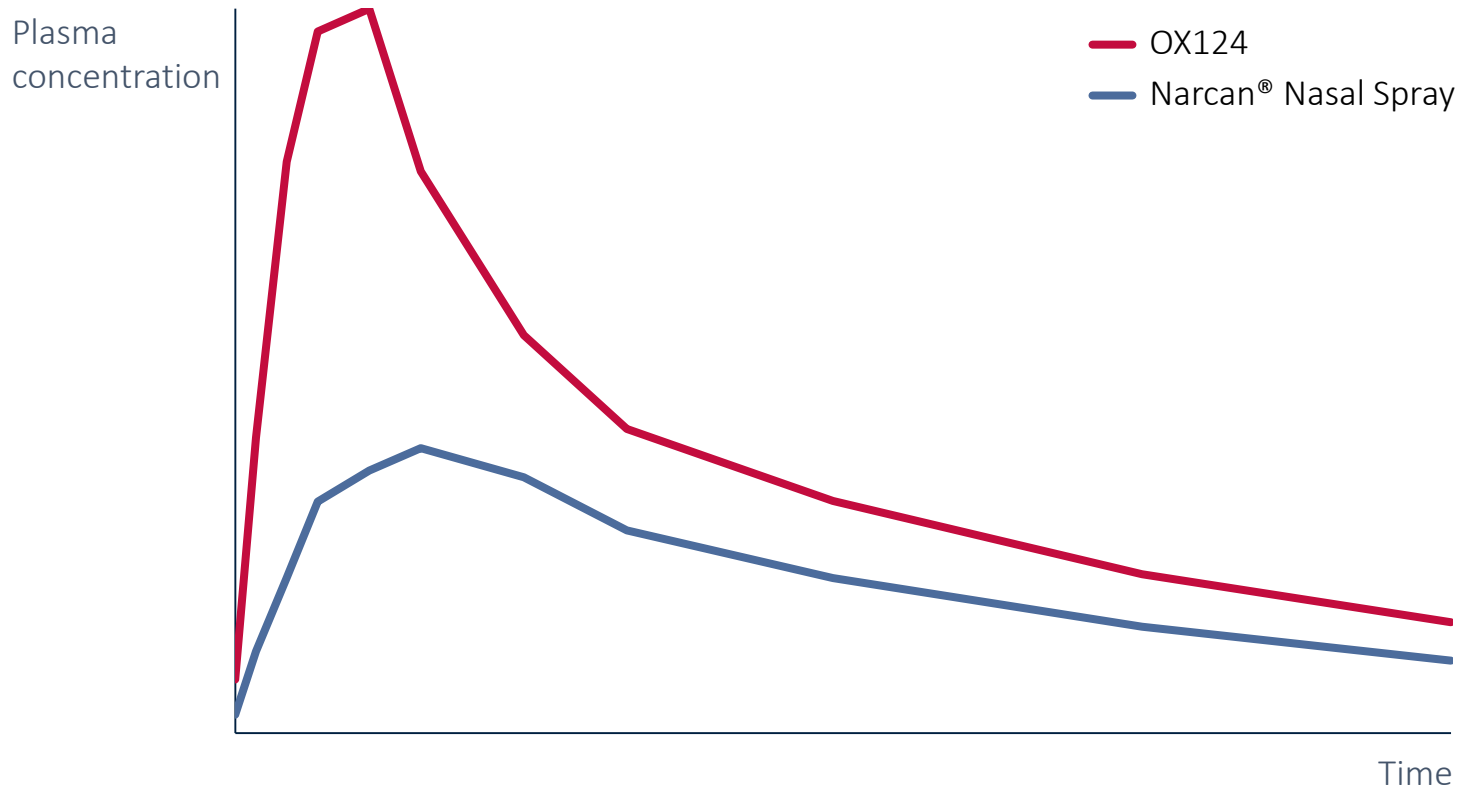
Source: Hedegaard H, et al. NCHS DATA Brief 356 - Drug Overdose Deaths in the United States, 1999-2018. NCHS, National Vital Statistics System, Mortality. Jan 2020.



# OX124 - We have shown better PK profile than Narcan® Nasal Spray

## Faster, stronger and longer-acting vs Narcan® Nasal Spray

Results from exploratory PK study in healthy volunteers, 2019



## Expected patient benefit

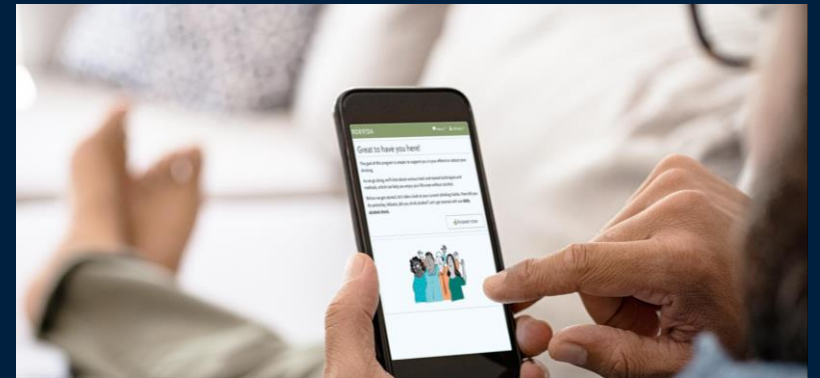
- Rescue more patients with the first dose (~34% of overdose patients require more than one dose of Narcan)
- Avoid "second overdoses" thanks to longer duration (Fentanyl has a half life of 8-10 hours vs. 2 hours for naloxone)

# Digital therapies

VORV!DA<sup>®</sup>

deprexis<sup>®</sup>

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# Digital therapeutics to become an integral part of the healthcare landscape

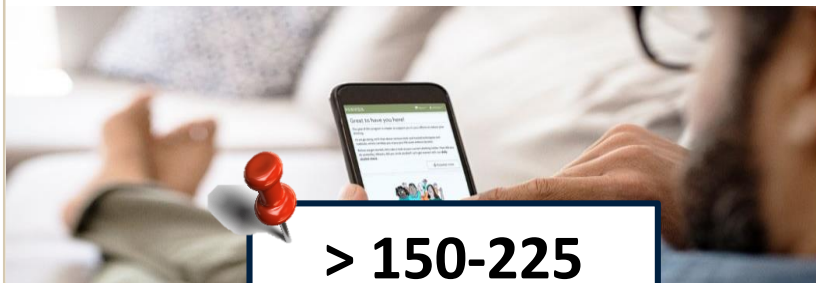
SUD and mental health issues are one of the main areas most in need of innovative ways to deliver treatment

Digital therapies									
	Technical Development					Registration	Approved and/or Launched		
							US	EU	RoW
<b>deprexis®</b> Depression Partner: GAIA AG									
<b>vorvida®</b> Alcohol misuse, incl. alcohol use disorder Partner: GAIA AG									
<b>OXD01</b> Opioid Use Disorder Partner: GAIA AG									

Launching two digital therapies, Orexo is well positioned to take a leading role addressing unmet needs within SUD and mental health issues

deprexis<sup>®</sup>

deprexis<sup>®</sup> 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

VORV!DA<sup>®</sup>

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

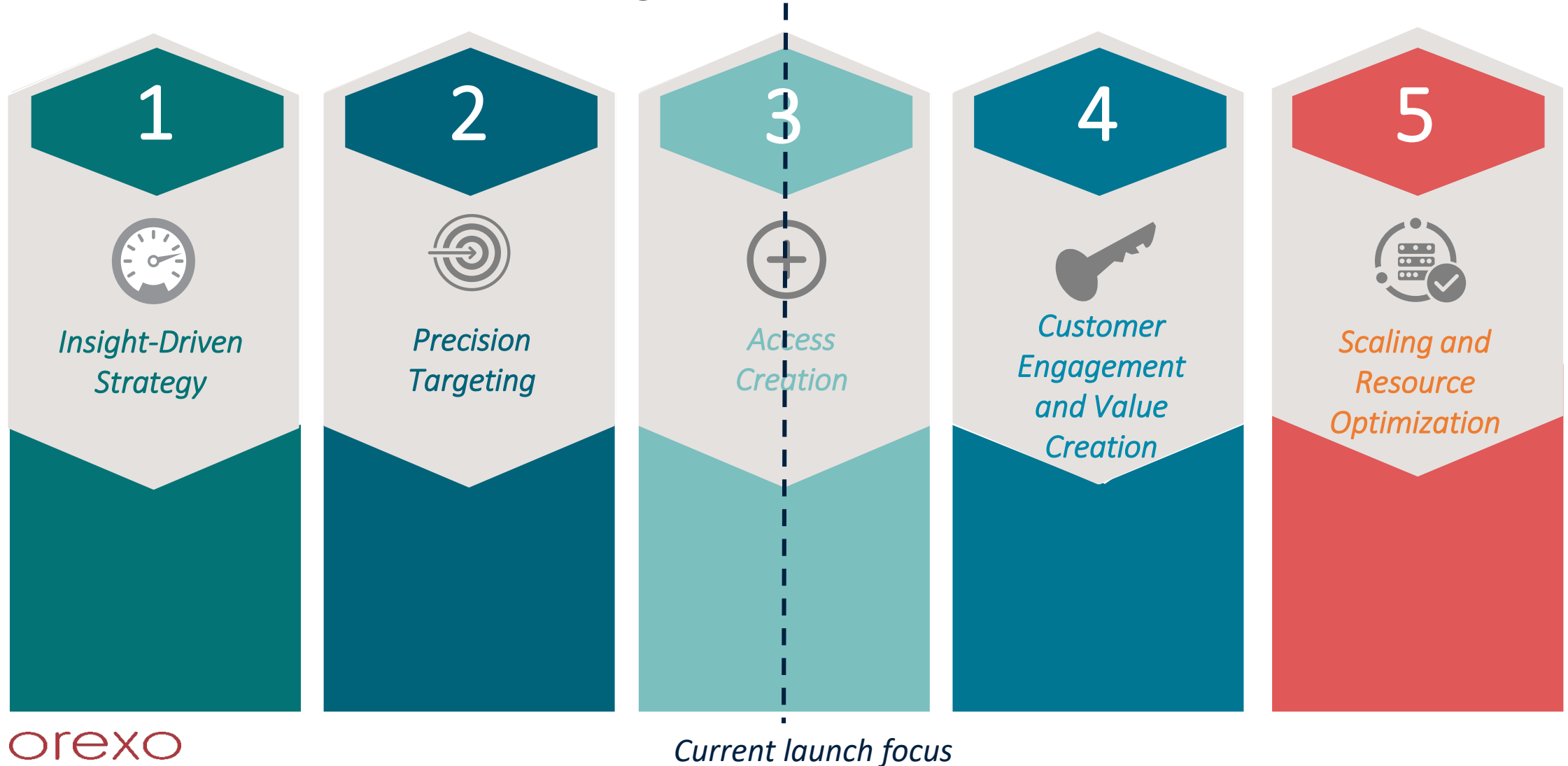


**120-200**

MUSD net sales potential in the US



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

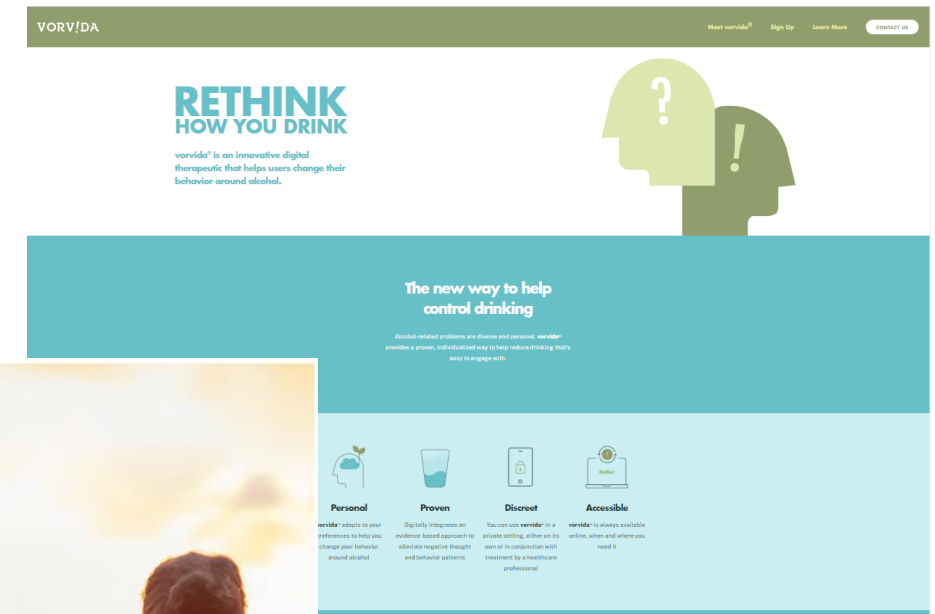


# To complement the significant evidence supporting our products, we are developing user experience driven program content

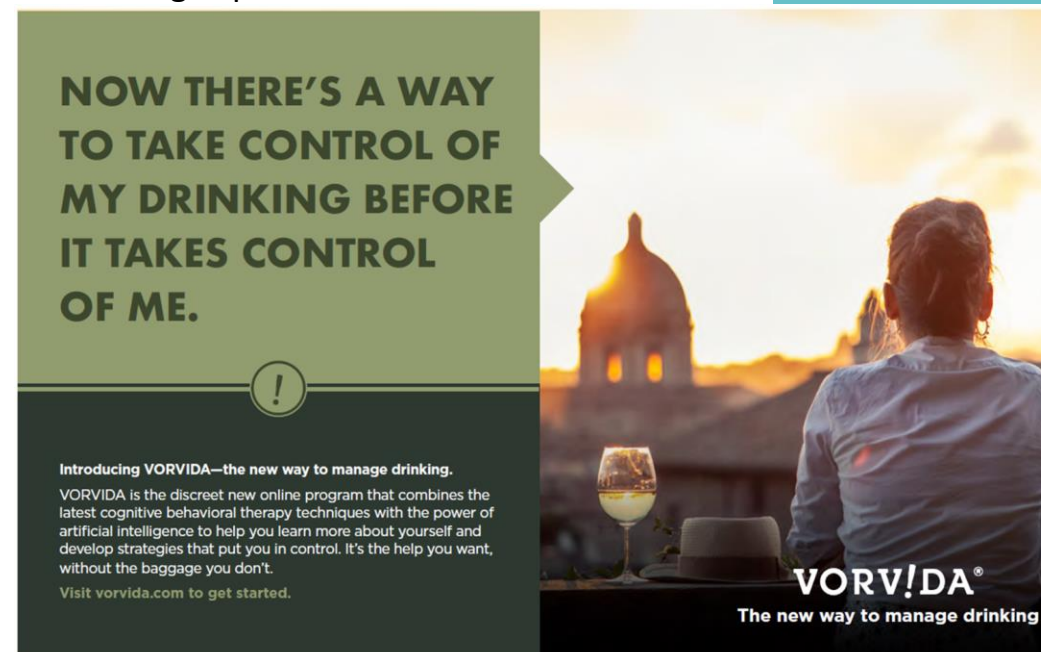
deprexis® “Day 1” site [meetdeprexis.com](https://meetdeprexis.com)



vorvida® “Day 1” site [us.vorvida.com](https://us.vorvida.com)



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

The collage displays five screenshots of the Deprexis website interface:

- Top Left:** A page titled "Depression is different for everyone. Deprexis understands that." It describes the digital therapy and includes a "Tell Us More" button.
- Middle Left:** A page showing a "Thank you for submitting your invitation code" message and a unique access code: **2XV8FGWMJ0V5**. It includes "Next Steps" and a "Register Access Code" button.
- Center:** A large registration form titled "Let's unlock your Deprexis access now!". It includes fields for "FIRST & LAST NAME", "EMAIL ADDRESS", and "INVITATION KEY", followed by a "SUBMIT" button. An illustration of a woman using a smartphone is shown to the right.
- Top Right:** A "Confirmed!" page stating that the subscription to the mailing list is confirmed and providing an "unsubscribe" link.
- Bottom Right:** A page stating "You recently received your unique access code to Deprexis" and providing an "Access Deprexis" button.

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

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

## Alternative Payer Models

Orexo sees several alternatives for future payer models and will not apply a traditional one-fits-all Rx model

### Pharmaceutical Model

- Reimbursement similar to pharmaceuticals or other medical benefits by insurance companies and employers

### Framework agreement models

- Agreements with specific insurance companies to cover all customers
- Agreement with institutional health care providers

### Patient model

- Patients paying for the therapy out-of-pocket

*Current focus*

*Starting September*

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

*Good launch progress with high interest from leading payers in the US, several advanced discussions on-going with concrete focus on how to integrate deprexis and vorvida in the established re-imburement processes. Sales team has expanded recently to include new hires with expertise in Integrated Health Providers and behavioral health*



# OXD01 at a glance

## The unmet need

Access to consistent high-quality counselling is a growing bottleneck in treatment of OUD. Medical assisted treatment should be complemented with psychosocial support

## Our aim

Develop the first digital therapy showing significant sustainable positive outcome on patients' treatment of OUD and make it available globally

## Launch

Will be accelerated and tested in collaboration with selected customers in Q4 2020, in preparation for a broad launch in Q2, 2021, a year ahead of the original plan.



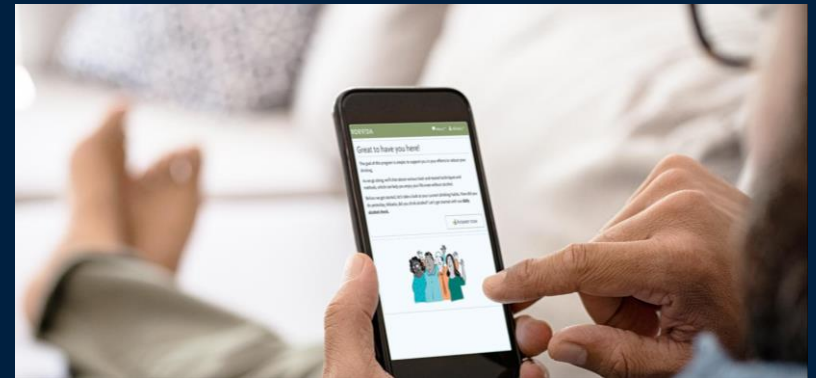
**150-225**

MUSD net sales potential in  
the US



# Financials and legal update

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# Strong financial position to drive future growth

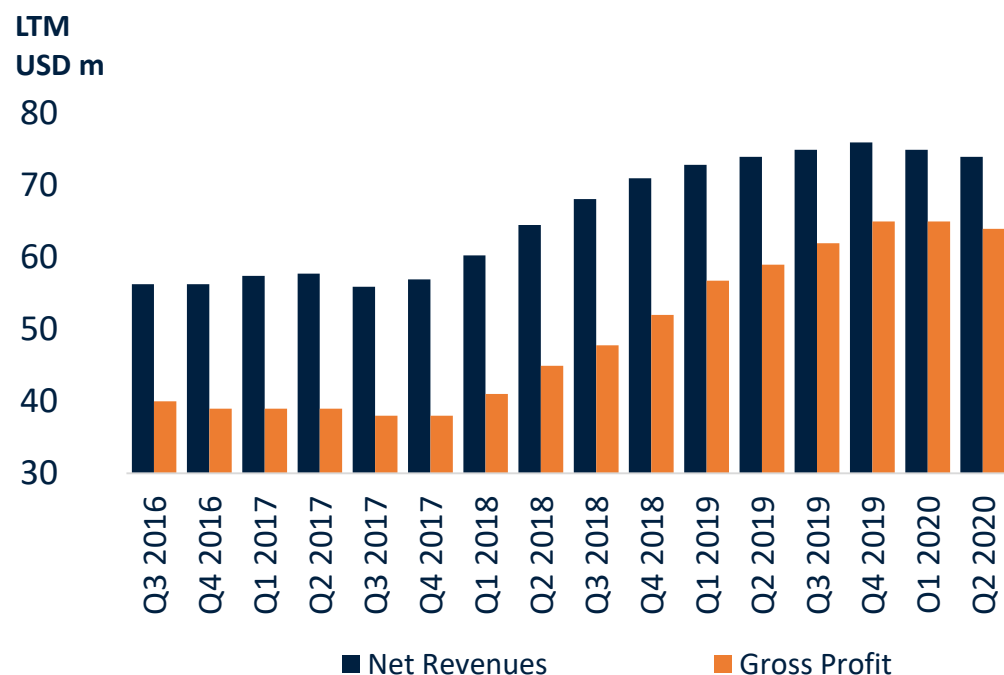
EBITDA and Cash position below impacted by increased investments in pipeline and DTx

Group net revenues LTM <sup>1</sup> <b>SEK 823 m</b> <i>Of which 86% from ZUBSOLV® US</i>	Growth <b>1%</b> <i>ZUBSOLV® US 5%</i>
Group EBITDA LTM <sup>1</sup> <b>SEK 239 m</b>	Growth <b>54%</b>
US Pharma EBIT (ZUBSOLV® US) LTM <sup>1</sup> <b>SEK 349 m</b>	Growth <b>26%</b>
Cash position Q2 2019 <b>SEK 677 m</b>	Positive net cash position <b>SEK 453 m</b>

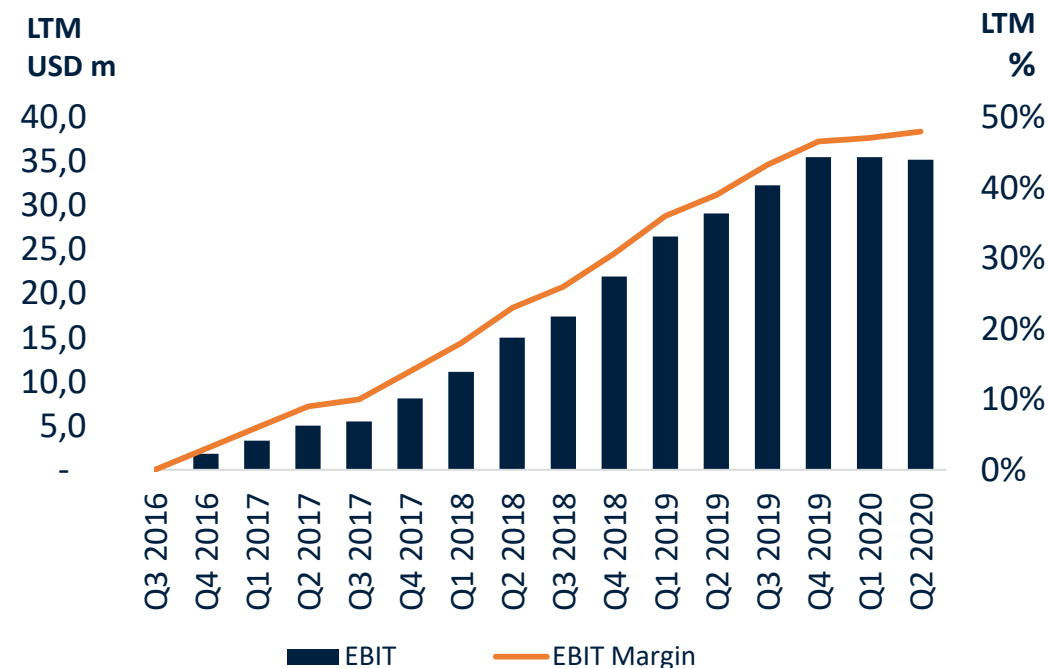
<sup>1</sup> Last Twelve Months

# US Pharma Operating Margin (LTM) grew to 47.8% in Q2 2020

## Sales and gross profit



## EBIT



- ZUBSOLV® US net sales declined slightly to USD 73.6 m from USD 74.1 m in Q219
- Strong growth in EBIT contribution to USD 35.2 m increasing from USD 29.1 m in Q219 driven by lower COGS and lower operating expenses
- US Pharma EBIT margin of 47.8% LTM in Q220 increasing from 39.3% in Q219, EBIT margin in Q2 2020 reached 51.5%
- Full year US Pharma EBIT margin of 45-50% is expected in 2020 and a short term flattening of the net sales due to volume decline in previously exclusive contracts. Price increase of 3% from January 2020.

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

# Two new legal processes emerging during July and August 2020

## 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.
- No further information or requests have been received from the authorities after July 14<sup>th</sup> 2020.

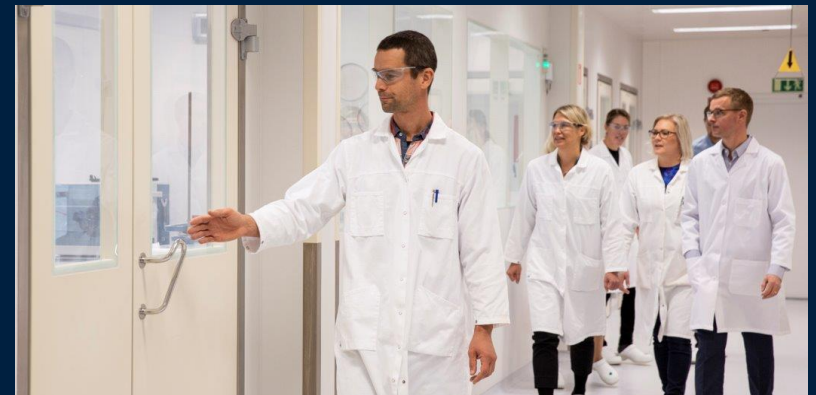
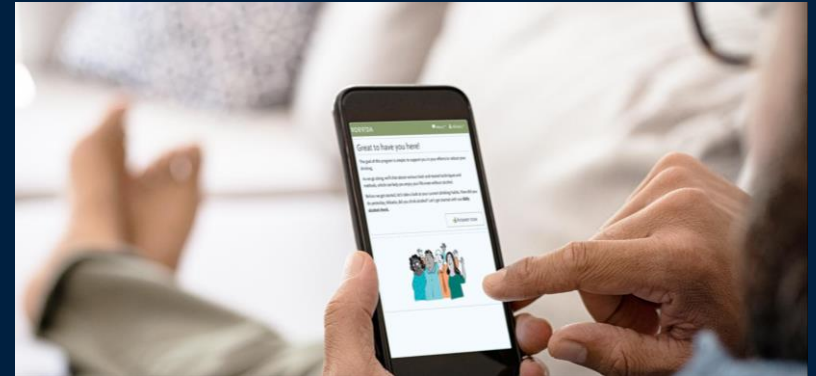
## Paragraph IV notice from Sun Pharmaceutical Industries Ltd (“Sun”)

- The Notice Letter advises Orexo of Sun’s filing of an Abbreviated New Drug Application (“ANDA”) with the FDA seeking approval of generic versions of ZUBSOLV® before the expiration of Orexo’s patents listed in the Orange Book. Orexo currently has five patents listed in the Orange Book with expiration dates ranging from December 2027 to September 2032.
- Orexo has initiated a process to review the notice letter together with US legal counsel in preparation of legal actions to defend the exclusivity for ZUBSOLV®.
- Orexo has previously successfully defended the ZUBSOLV® patents and is well prepared for a new process with Sun.



# Outlook

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# Financial outlook 2020

Increased uncertainty due to Covid-19 and exchange rate fluctuations

- › The buprenorphine/naloxone market will continue to show a double-digit growth
- › ZUBSOLV® net sales are expected to be in line with 2019. The open businesses will grow, whilst the previously highly rebated exclusive segments, including cash, will decrease.
- › Due to increased R&D investments, establishment of DTx business and accelerated DTx US launch OPEX will reach a level of SEK 750-800 m, **excluding legal expenses from new legal processes**
- › Due to a decrease in Abstral® royalties of approx. SEK 85 m, as an effect of expiration of IP protection in the US and the EU, and increased OPEX, EBITDA will decrease
- › US Pharma EBIT margin will be in the range of 45-50 percent

*The outlook is based on exchange rates in December 2019*

## Strong value drivers for long-term growth

<b>Future value drivers</b>	<ul style="list-style-type: none"><li>➤ <b>Product &amp; pipeline portfolio addressing large and growing markets</b></li></ul>	<ul style="list-style-type: none"><li>➤ <b>Strong cash conversion to support growth</b></li></ul>
<ul style="list-style-type: none"><li>➤ <b>Leveraging our US commercial excellence</b></li></ul>	<ul style="list-style-type: none"><li>➤ <b>Expanding pipeline targeting unmet medical needs</b></li></ul>	<ul style="list-style-type: none"><li>➤ <b>Entering digital therapeutics, a new evidence-based frontier in patient care</b></li></ul>

# Thank You

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