



Develops and commercializes improved pharmaceuticals and digital therapies – with the aim of becoming a leader within the treatment of addiction



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

**Redeye Digital Investor Forum,  
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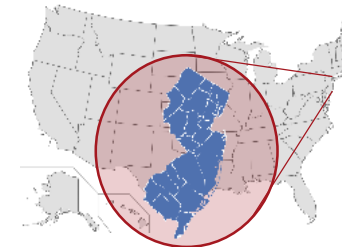
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# Orexo develops and commercializes pharmaceuticals and digital therapies

- Focuses on **treatment of addiction** in all phases, from prevention to treatment
- Broad pipeline with multiple assets based on innovative **drug delivery technologies** or **digital therapeutics (DTx)**
- Developed **four commercial products** with worldwide approval
- Direct presence in the **US opioid dependence market**, one of the largest health crises in US history, with lead asset **Zubsolv®**
- Strategic focus on **portfolio expansion** through development and licensing/M&A
- **Profitable** company with **strong financial position** to support future growth
- Top two largest shareholders<sup>1</sup>: **Novo Holdings** (27.7%) 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, 2019

**845** m

**EBITDA**  
SEK, 2019

**272** m

**Cash position**  
SEK, Dec. 31, 2019

**817** m

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

## 2019 delivered the strongest financial results ever

Group net revenues <b>SEK 845 m</b> <i>85% from Zubsolv®</i>	Growth <b>8%</b> <i>(Zubsolv® 16%)</i>
Group EBITDA <b>SEK 272 m</b>	Growth <b>133%</b>
US EBIT <b>SEK 351 m</b>	Growth <b>77%</b>
Cash position <b>SEK 817 m</b>	Positive net cash position <b>SEK 527 m</b>

# The profit contributions from Zubsolv® enables 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

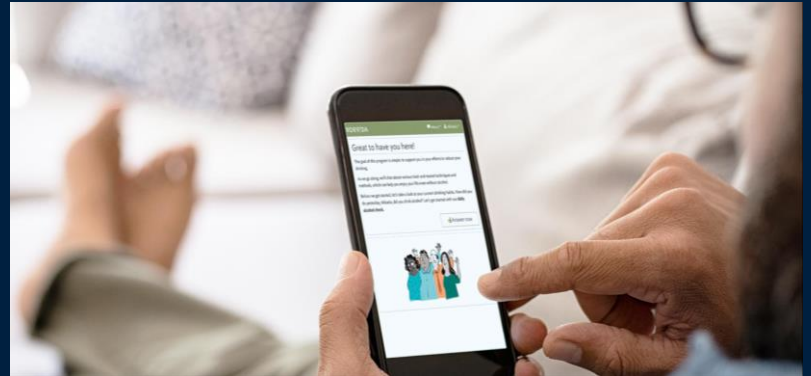
..a new pharmaceutical product from Orexo's development pipeline within the next two years





# Growing the Zubsolv® franchise

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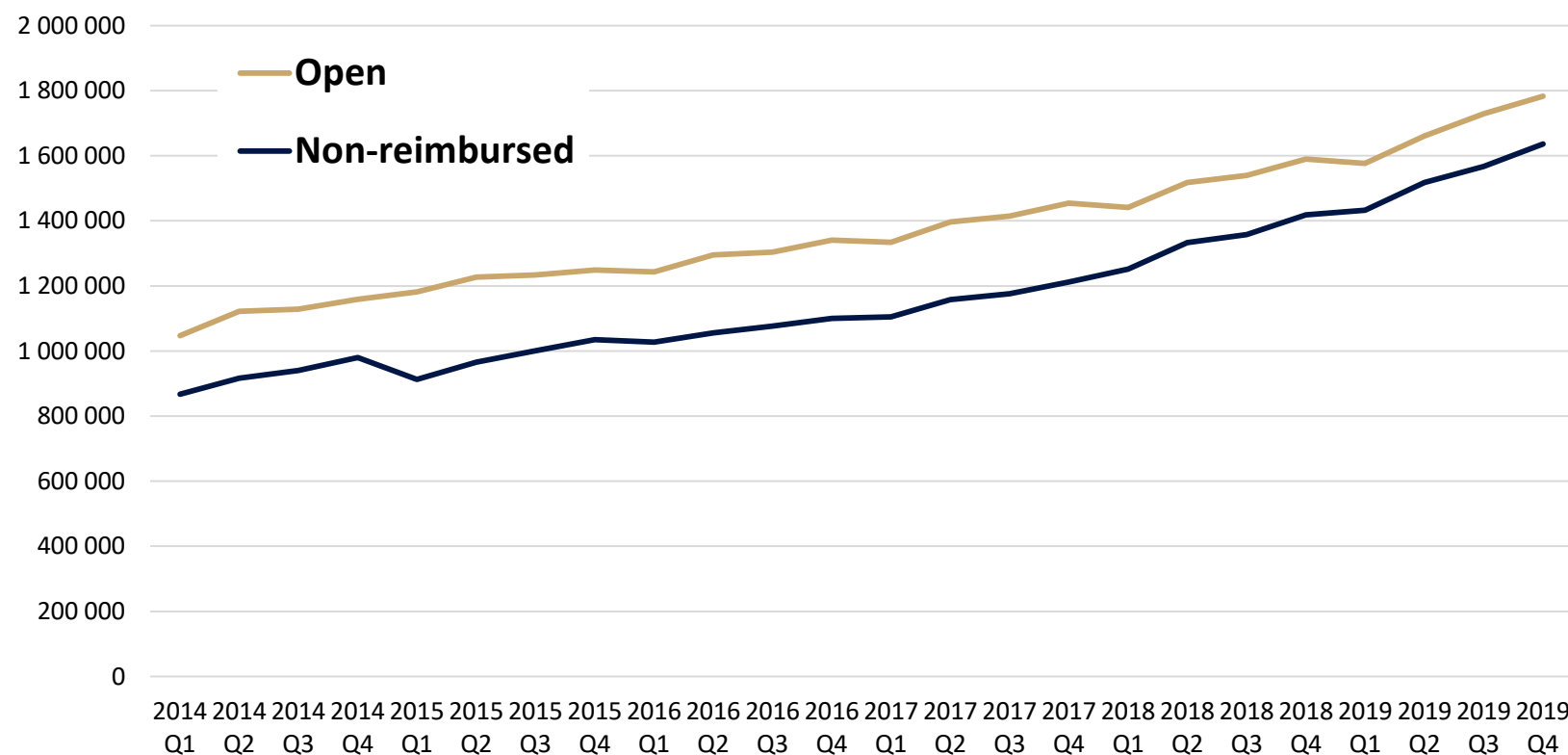


# Full year market growth of 14% 2019 vs 2018 continues in Q1

New market definitions to be applied by Orexo

## Market Volume Sales

Quarterly NTRx



## Q1 YTD Growth

Total Market: +14%

## By Segment

+14%

+13%

## 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

Note: NTRx = Total prescriptions adjusted to 30 tablet/film scripts  
Source: IQVIA XPO

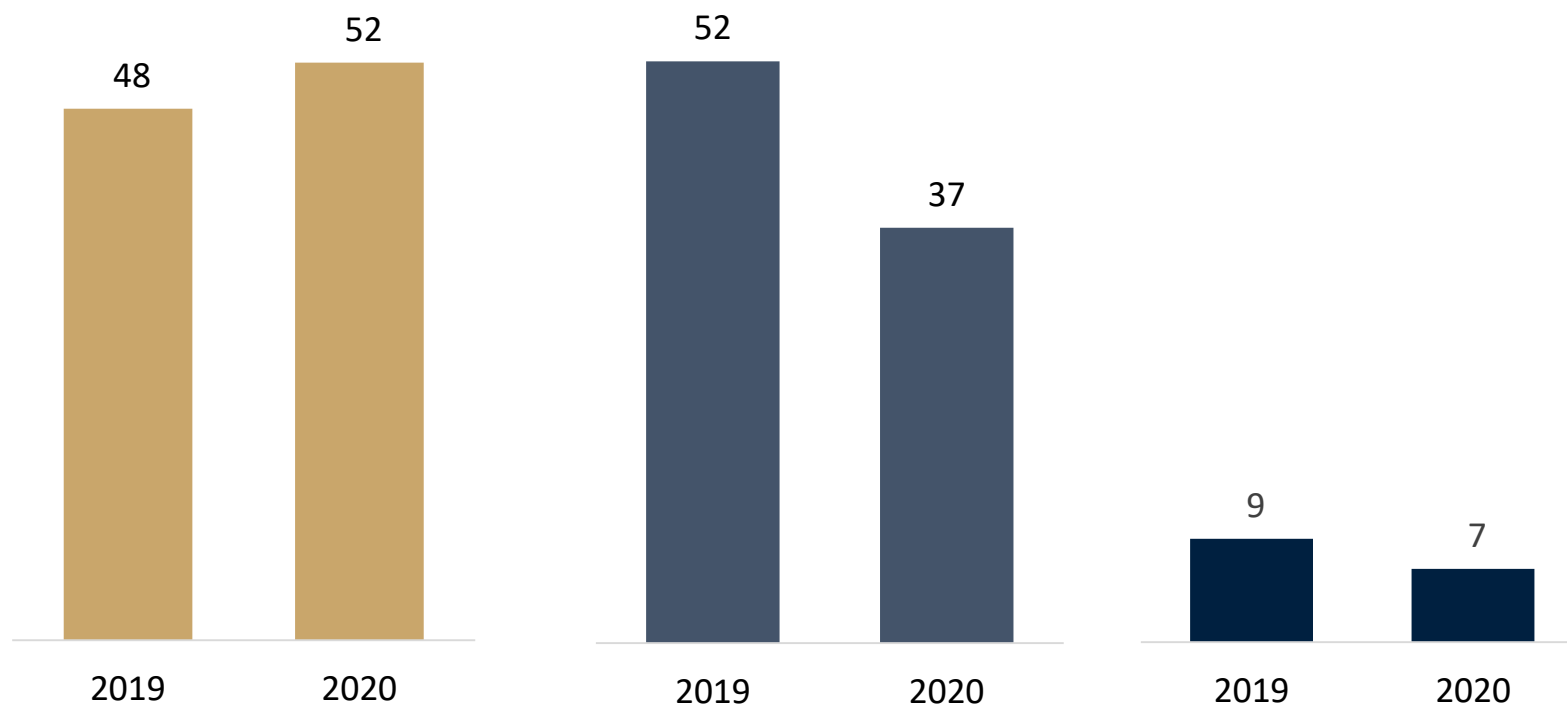
# Zubsolv® growing in the open business, but overall volume declining from competition in former exclusive contracts

## Open Market Access

## UHC/Humana/Cash

## Non-Reimbursed

Zubsolv® NTRx YoY Q1TD (thousands)



## Market Changes

From year 2019 to 2020

- **Generic film introduced late Feb 2019**
  - UHC/Humana add generics
- **2020 Public access lower by 3 %-point vs 2019**
- **2020 Commercial access increased 1 %-point vs 2019**

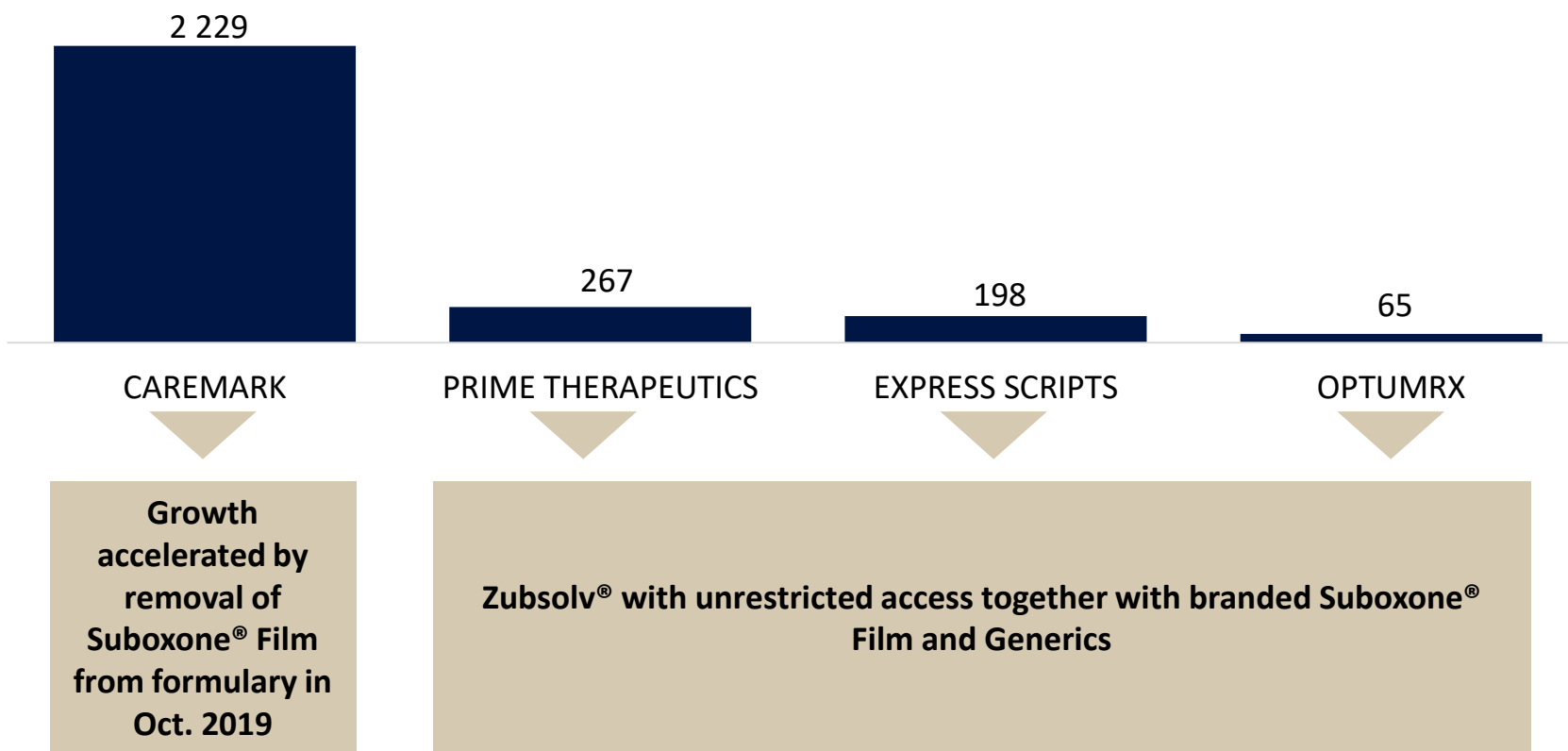
Note: NTRx = Total prescriptions adjusted to 30 tablet/film scripts  
Source: IQVIA XPO



# Zubsolv® growth in open business explained by unrestricted access to all large national commercial PBMs

## Prescription incremental growth to major national PBMs

Zubsolv® NTRx YoY Q1TD (thousands)



**Total increase of 2,759 NTRx year-to-date**

**Opportunity to continue to grow business and to translate successes to other payers as well**

**Additional removal of Suboxone® Film from formularies likely to drive additional growth**

**Growth in commercial formularies expected to increase after Q1 due to declining deductibles**

Note: NTRx = Total prescriptions adjusted to 30 tablet/film scripts  
Source: IQVIA XPO

# Several possible triggers for Zubsolv® growth in 2020 and beyond



## **Continued improved market access**

- ...Orexo continues to aggressively pursue expanding market access in Medicare and Medicaid
- ...Largest branded competitor likely to lose reimbursement over time

## **Competition from “the preferred” authorized generic of Suboxone® Film will end**

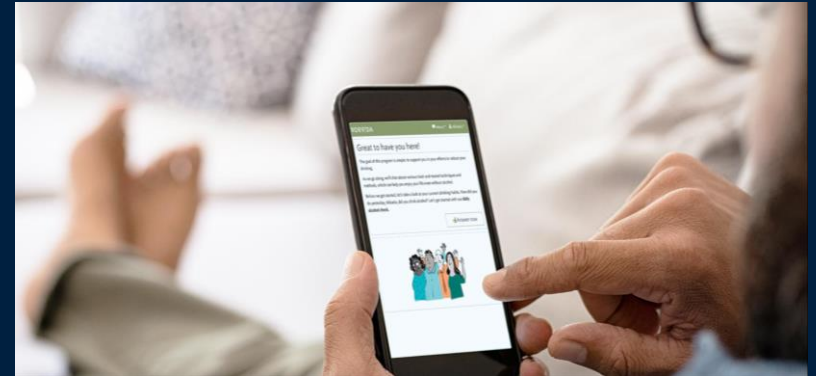
- ...Supply of authorized generic has ceased from the manufacturer (Indivior) and product will disappear when inventories are depleted
- ...Market share of authorized generic has dropped from >50% to 28% last week

## **Orexo will be the only pharmaceutical company promoting a Buprenorphine product to most prescribers**

- ...Sublocade® and other depot formulations primarily promoted to larger institutions
- ...Orexo has an expanding pipeline addressing the most urgent concerns in the industry

A pipeline with significant  
future potential

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# Pipeline addressing large markets with significant patient needs

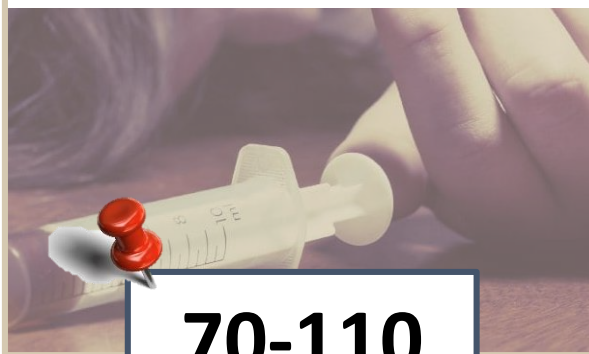
			Exploratory	Preclinical	Phase			Registration	Approved/Launched		
					1	2	3		US	EU	RoW
<b>Commercial products</b>											
	<b>Zubsolv®</b>	Opioid Use Disorder									▲
	<b>Abstral®</b>	Breakthrough Cancer Pain, <i>Kyowa Kirin</i>									
	<b>Edluar®</b>	Insomnia <i>Mylan Worldwide</i>									
<b>Development projects</b>											
Pharmaceuticals	<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									
	<b>OX-MPI</b>	BI1029539 – Microvascular Disease <i>Gesynta Pharma</i>									
Digital Therapies			Preclinical		Phase 3			Registration	Approved/Launched		
									US	EU	RoW
	<b>OXD01</b>	Opioid Use Disorder <i>GAIA AG</i>									
	<b>OXD02/vorvida®</b>	Heavy alcohol use, incl. Alcohol Use Disorder <i>GAIA AG</i>								●	



# 3 convincing development assets addressing critical unmet needs

## OX124 – opioid overdose

A powerful rescue medication, designed to reverse opioid overdoses, including those from synthetic opioids like fentanyl



**70-110**

MUSD net sales potential (US)

## OX125 – opioid overdose

A rescue medication to reverse opioid overdoses, developed for situations where very long-lasting effect is required



**40-60**

MUSD net sales potential (US)

## OX338 – non-opioid pain

A non-opioid pain killer with opioid-level efficacy for short-term pain (up to 5 days), but without the risk of addiction

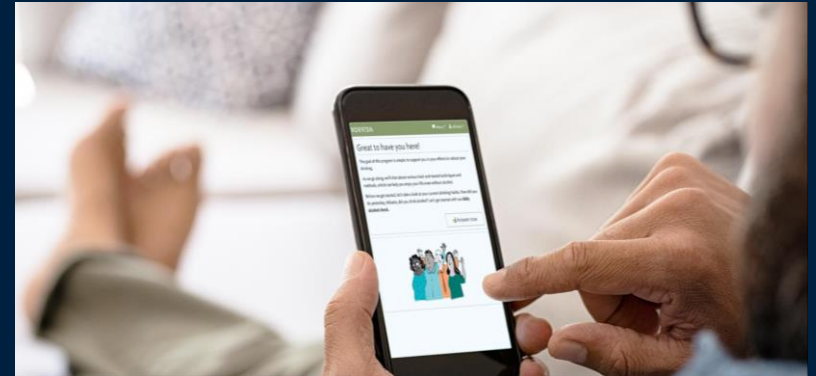


**>100**

MUSD net sales potential (US)

# DTx – new frontiers in patient care

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# In a few months....

## Patients

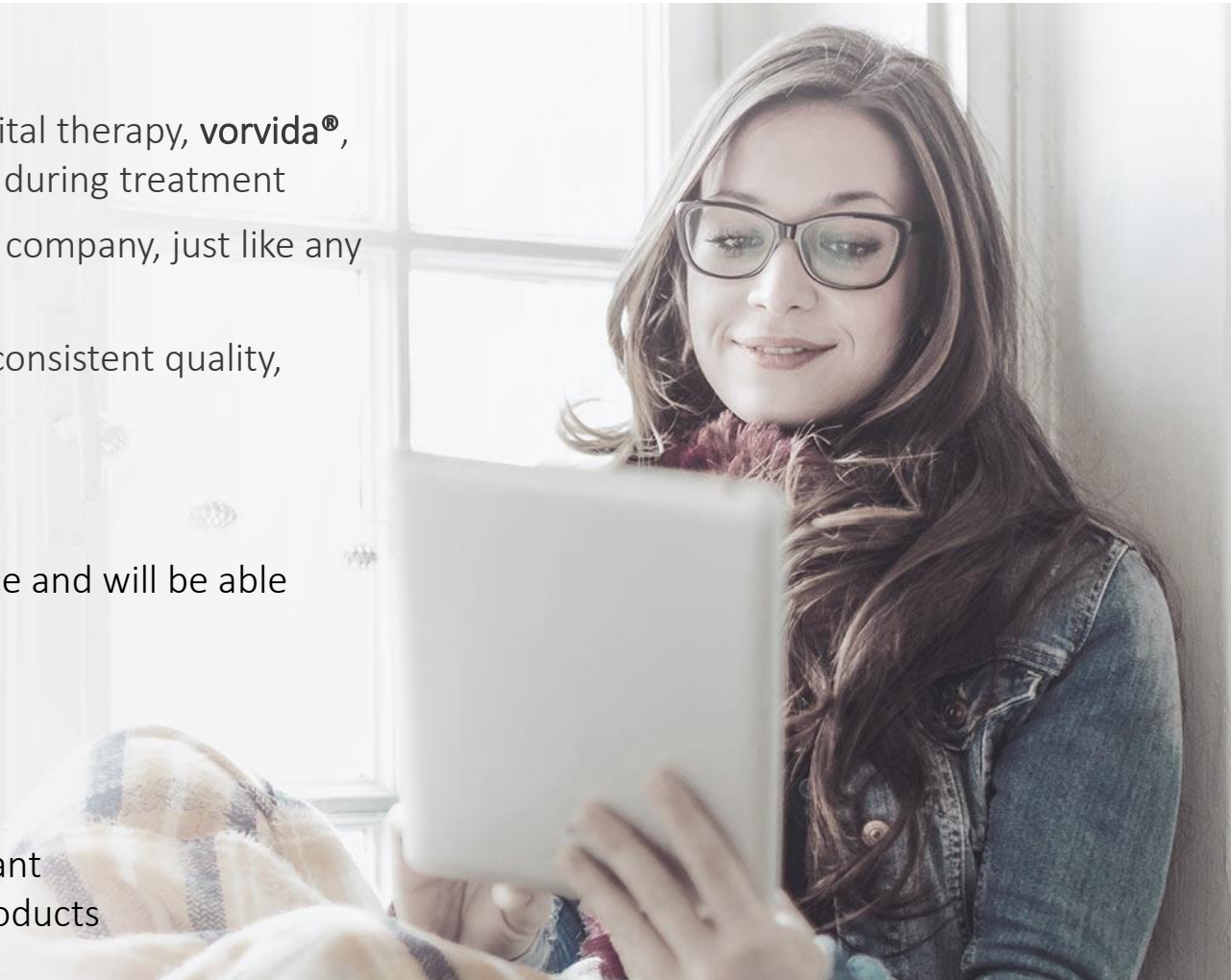
- ...suffering from alcohol misuse will have access to a new digital therapy, **vorvida**®, which replaces the need for frequent visits to a counsellor during treatment
- ...will get their digital therapy reimbursed by their insurance company, just like any other medical intervention
- ...will have access to gold standard behavioral therapy with consistent quality, when they have time and in their own privacy

## Healthcare Professionals

- ...will have access to a treatment with strong clinical evidence and will be able to prescribe **vorvida**® like any other treatment available
- ...will be able to treat more patients with less efforts

## Orexo

- ... will expand into a new adjacent disease area with significant unmet patient need and with a completely new type of products



# The regulatory and payer landscape is starting to adopt digital therapy ...

## Significant movement in both US and Europe



**The Digital Health Software Pre-certification (Pre-Cert) Program** is part of an effort by the FDA to develop a future regulatory model that will provide more streamlined and efficient regulatory oversight of software-based medical devices.<sup>2</sup>



**The Bundestag recently passed the German Digital Care Act (DVG)**, which requires public health insurance companies to cover the costs of certain health technology applications.<sup>1</sup>

## The two largest PBMs are reducing barriers for DTx



**Express Scripts** is placing companies, offering cutting-edge treatments, into a "formulary" of recommendations for insurance plans and doctors in order to ease commercial traction.<sup>3</sup>



**CVS Caremark** has launched a platform for digital therapies, enabling payers to formalize the reimbursement and distribution and allowing CVS to capitalize on booming interest in digital health treatments.<sup>4</sup>

Source: 1. Frontiers <https://www.frontiers.health/german-digital-healthcare-act/> 2. <https://www.fda.gov/medical-devices/digital-health/digital-health-software-precertification-pre-cert-program> 3. CNBC <https://www-cnbc-com.cdn.ampproject.org/c/s/www.cnn.com/amp/2019/12/12/express-scripts-to-add-digital-health-treatments-like-livongo-omada.html> 4. Business Insider <https://www.businessinsider.com/cvs-caremark-launches-digital-therapeutics-platform-2019-6?r=US&IR=T>

## ... but digital therapy is in its infancy

### **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**

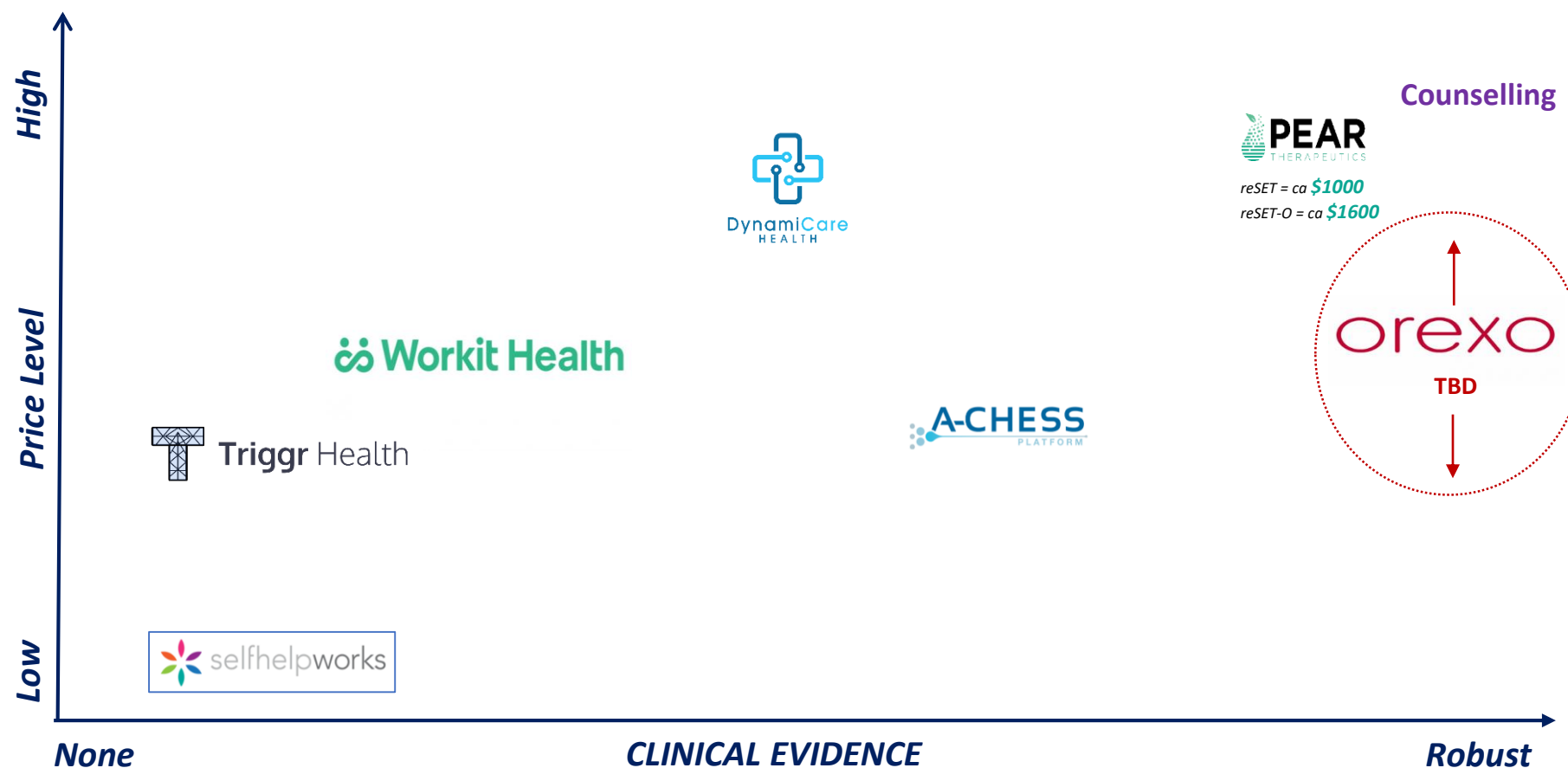
- Many payers still to establish payment and reimbursement processes

### **Disruptive technology**

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



The pricing of digital therapy is scattered, with significant differences driven by sophistication and clinical evidence

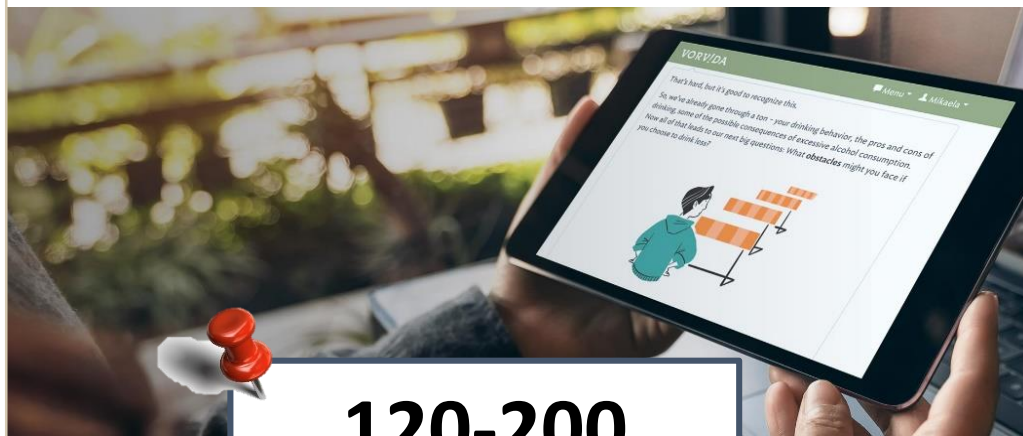


Pricing of Orexo DTx expected in the range of USD 600-1,000 per treatment

# Two digital therapies with the potential to disrupt the current treatment of substance use disorder in the US

## vorvida®

A fully automated digital therapy scientifically proven to reduce trouble-some drinking patterns in adults with AUD

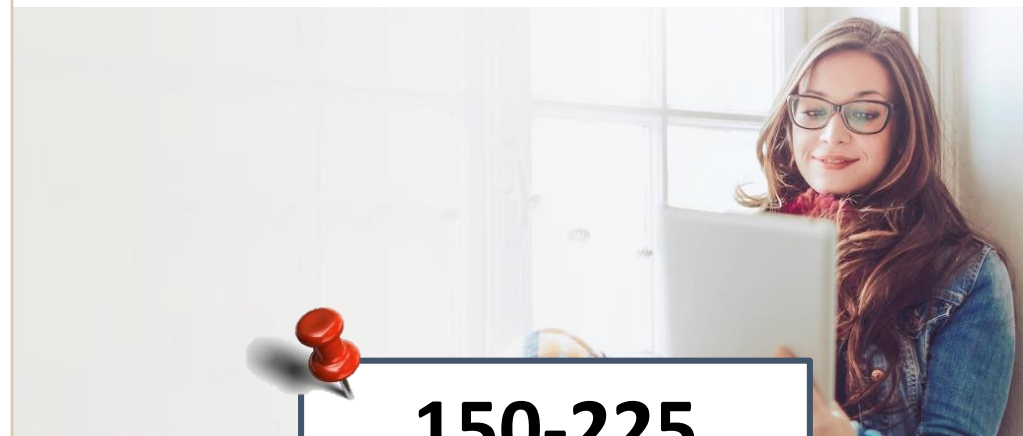


**120-200**

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.



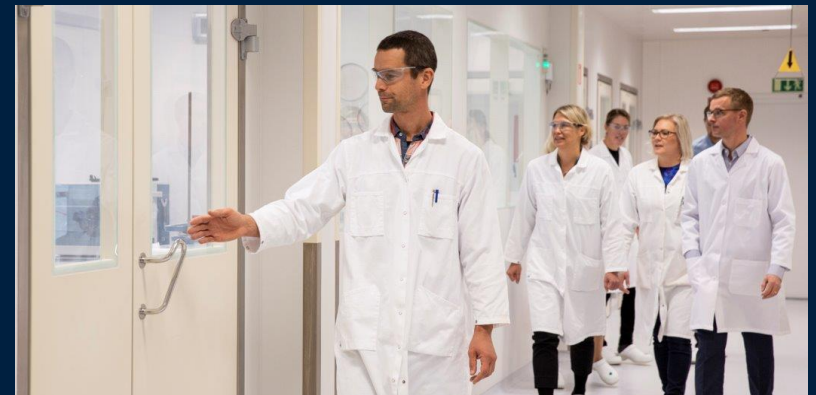
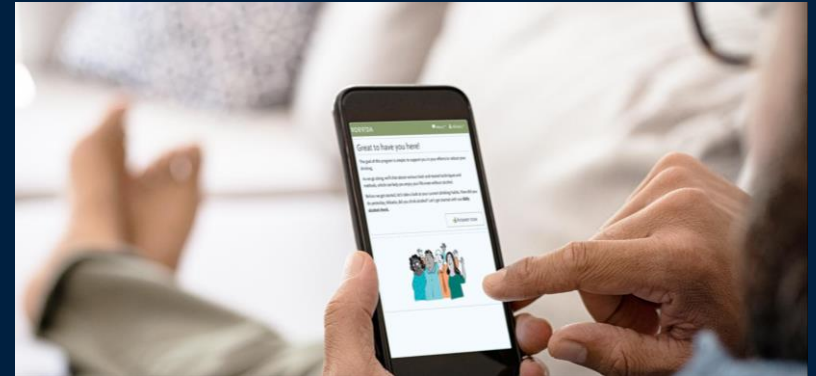
**150-225**

MUSD net sales potential in the US



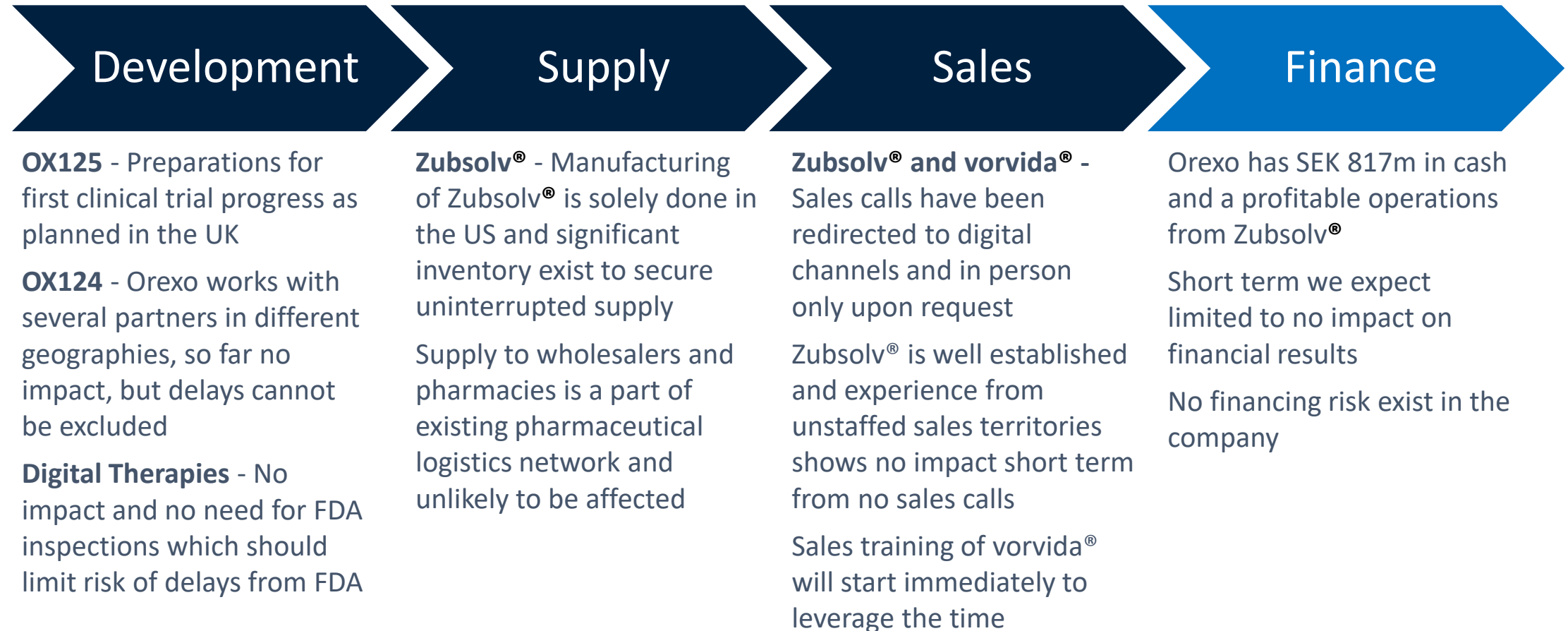
# Outlook

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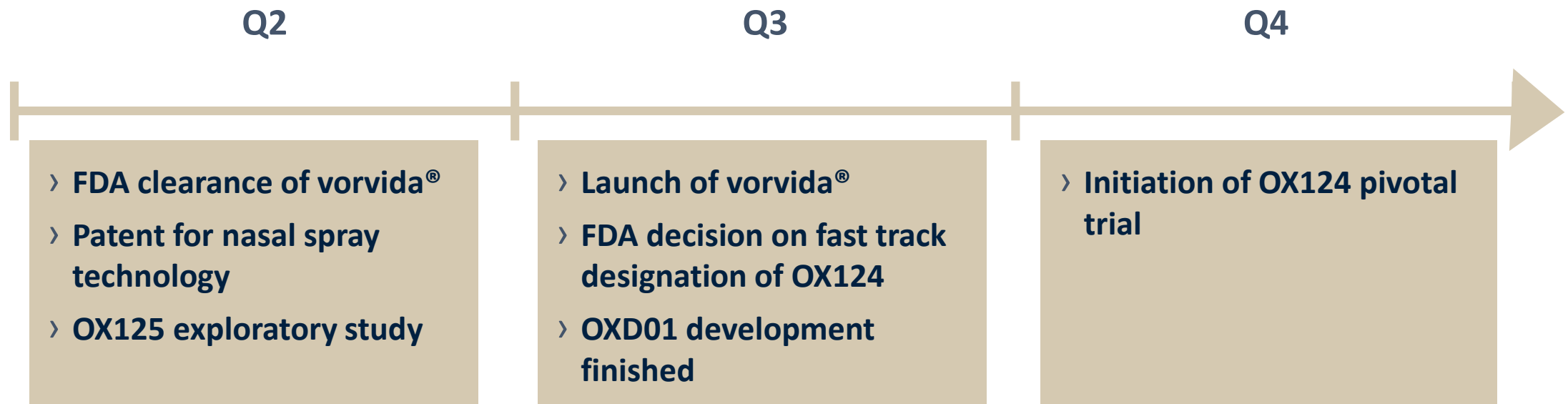


# Limited impact from the COVID-19 virus currently<sup>1</sup>



<sup>1</sup> This analysis assumes impact from COVID-19 is limited to H1 2020

2020 a year with a steady news flow expected



# Strong value drivers for long-term growth

## Investment thesis

### 1. Addressing large markets with significant patient needs

Focusing on becoming a leader within the large and growing space of addiction, alongside addressing the opioid epidemic, one of the largest health crises ever in America and a growing global concern

### 2. Strong financial position and profitability

Fueled by the sales of the lead product Zubsolv® which will continue to be an important cash and profitability contributor

### 3. Leverage the US commercial platform

Strategic focus on product portfolio expansion, through M&A and business development, to leverage the US commercial infrastructure

### 4. Expanding pipeline

Continues to build on the strong track record of developing products with worldwide approval by expanding the pipeline with multiple assets based on innovative drug delivery technologies and digital therapeutics addressing unmet medical need in addiction

### 5. Entering DTx, the new megatrend in life science

Digital therapeutics (DTx) will become an integral part of the healthcare landscape and addiction is one of the therapeutic areas where it is most needed

# Thank You!

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