



Develops and commercializes improved pharmaceuticals and digital therapies in the growing space of substance use disorders and mental health



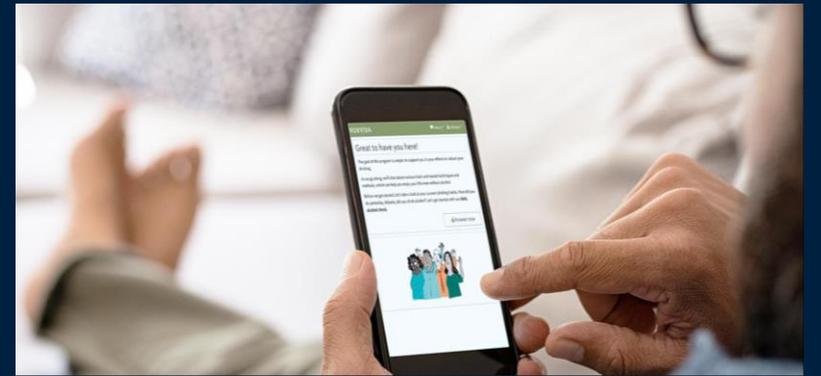
## Handelsbanken Mid/Small Cap Seminar

Nikolaj Sørensen, President and CEO, June 4, 2020

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# Overview & strategic agenda



# Orexo develops and commercializes pharmaceuticals and digital therapies

- Addresses unmet needs within the growing space of **substance use disorders (SUD)** and **mental health**
- Broad product portfolio and development pipeline of traditional **pharma products** and **digital therapies**
- Developed **four commercial products** with worldwide approval
- Direct presence in the **US**, with a **fully-owned commercial platform**
- 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, LTM<sup>2</sup> Q120

**846** m

**EBITDA**  
SEK, LTM Q120

**299** m

**Cash position**  
SEK, Q120

**861** m

<sup>1</sup> As of April 30, 2020

<sup>2</sup> Last Twelve Months

# 2012 – 2019 successful strategic focus on building a solid foundation

EBITDA SEK m 2012-2019



- ✓ Launch Zubsolv® in the US
- ✓ First actions taken to broaden the US commercial platform
- ✓ Secure profitability
- ✓ Ensure a sustainable business model

# 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

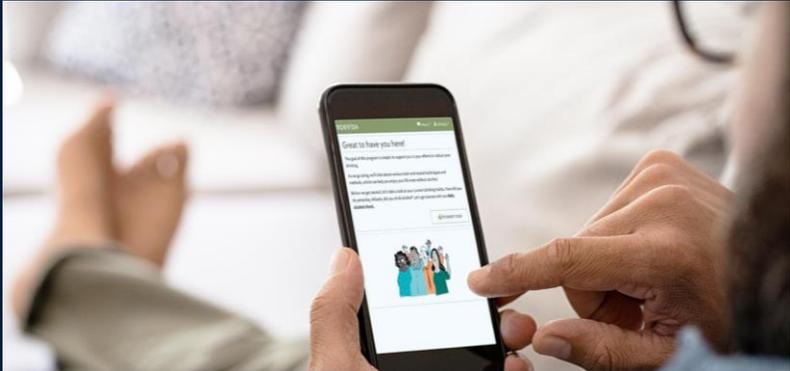
.. Zubsolv® profit contribution in 2020 and ensure it is sustainable and growing over time

## Launch

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



# Product portfolio



# Product portfolio including 3 upcoming US launches in 2020

Product	Zubsolv® 	deprexis® 	vorvida® 	Abstral® 	Edluar® 
Indication	Opioid use disorder (OUD)	Symptoms of mild to severe depression	Alcohol misuse incl. alcohol use disorder (AUD)	Breakthrough cancer pain	Sleeping disorder
Key market	US	US	US	Asia, the Middle East, Australia	US
Net sales/royalty 2019	SEK 719 m	<b>US launch in summer 2020</b>	<b>US launch in summer 2020</b>	SEK 113 m <sup>1</sup>	SEK 12 m
Potential annual net sales		USD >150 – 225 m	USD 120 – 200 m		
Partner					

Development project OXD01 (OUD) expected ready for **US launch in Q4 2020** – potential annual net sales USD 150 – 225 m

<sup>1</sup> Effective January 1, 2020, Orexo will not receive any royalty for sales in the EU and the US as the patents on corresponding markets expired in 2019

# 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](mailto: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 partner GAIA is a world leader in developing digital therapies

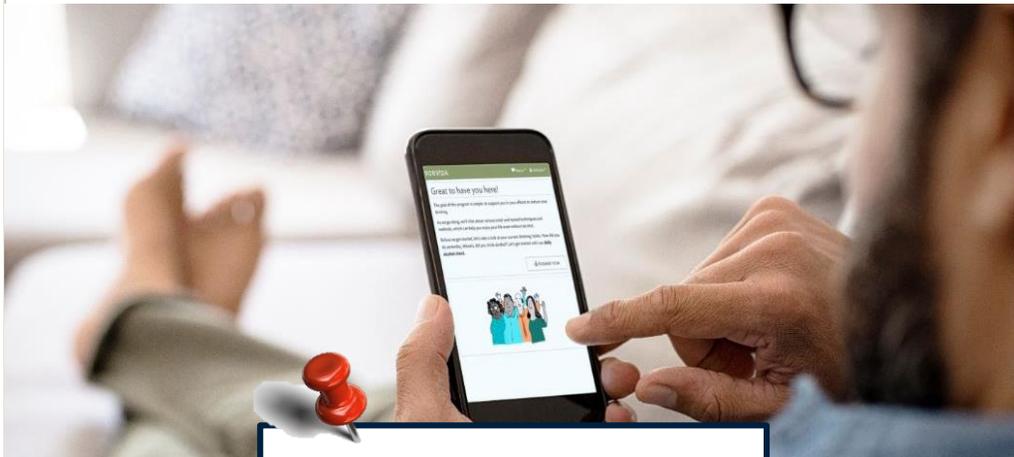
**” GAIA is a global pioneer in digital therapeutics, successfully launching its first product in 2001**

- GAIA has demonstrated digital therapies can have impressive improvement in treatment outcomes from supporting behavioral change and adherence to treatment – both critical for addiction treatment outcome
- GAIA's platform has proven effectiveness in numerous RCTs (Random Clinical Trials) with over 9,000 patients
- GAIA has 12+ years R&D experience, 20+ CE & FDA compliant products
- GAIA's products use artificial intelligence and offer unique individualization of the treatment

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

orexo

### One of the most researched digital therapies in the world

- Effectiveness in managing the symptoms of depression has proven in 13 randomized clinical trials (RCTs) including more than 2,500 patients
- In a 2017 study conducted by Beevers et al. in the US, the patient group utilizing deprexis® (n=285) were 12 times more likely to experience a +50 percent improvement to symptoms when compared to the control group (n=91)

WHO: "Depression is a leading cause of disability around the world and contributes greatly to the global burden of mental health illness"

.....offering digital therapies with **scientifically proven** efficacy enabling patients to receive help while maintaining social distancing

### 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



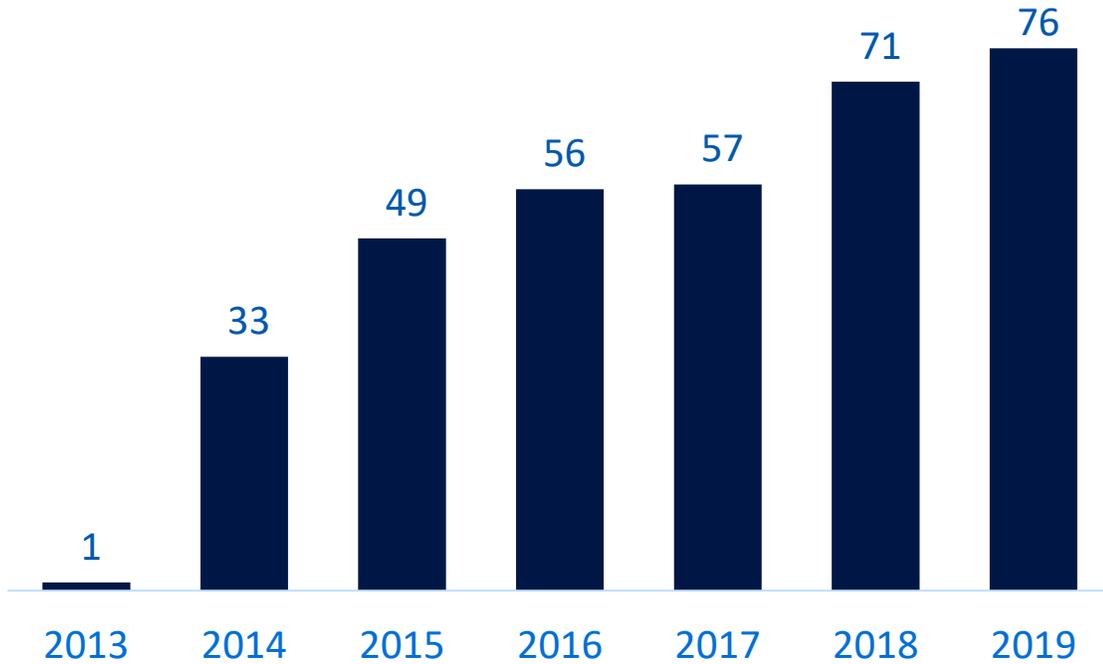
**150-225**

MUSD net sales potential in the US

# Zubsolv<sup>®</sup> has grown YoY despite increasing competition

## US Net Revenues

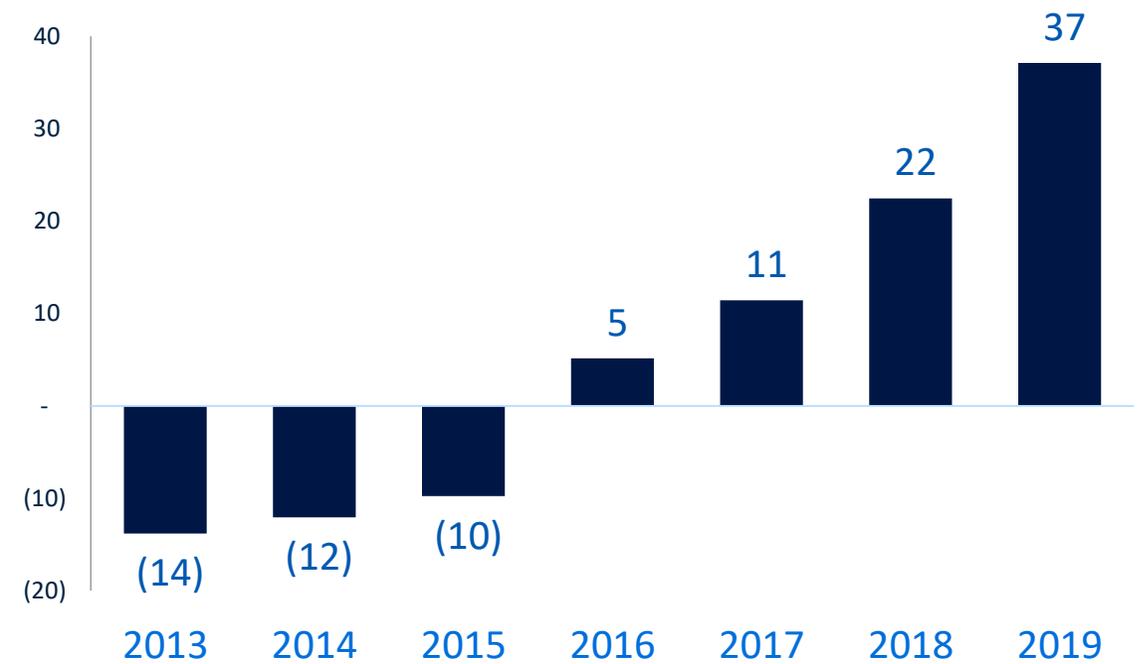
USD million



← Number of Gx competitors →

## US Operating Profit

USD million



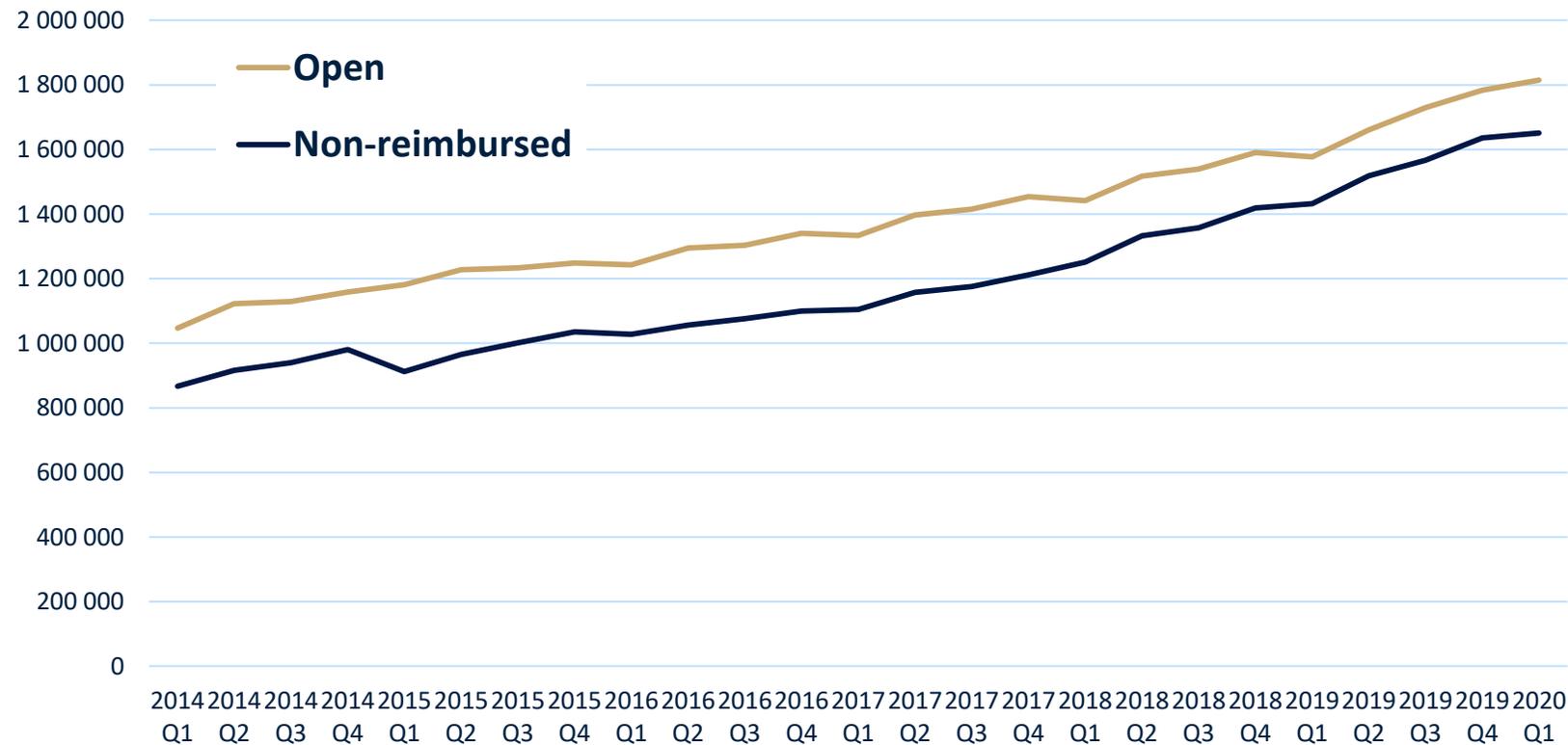
← Accumulated Operating Profit →

Source: Orexo Finance

# Market growth of 15% YTD vs prior year is the strongest growth rate since Zubsolv<sup>®</sup> launch

## Market Volume Sales

Quarterly NTRx



## Q1 YTD Growth

Total Market: +15%

### By Segment

+15%

+15%

## Definitions

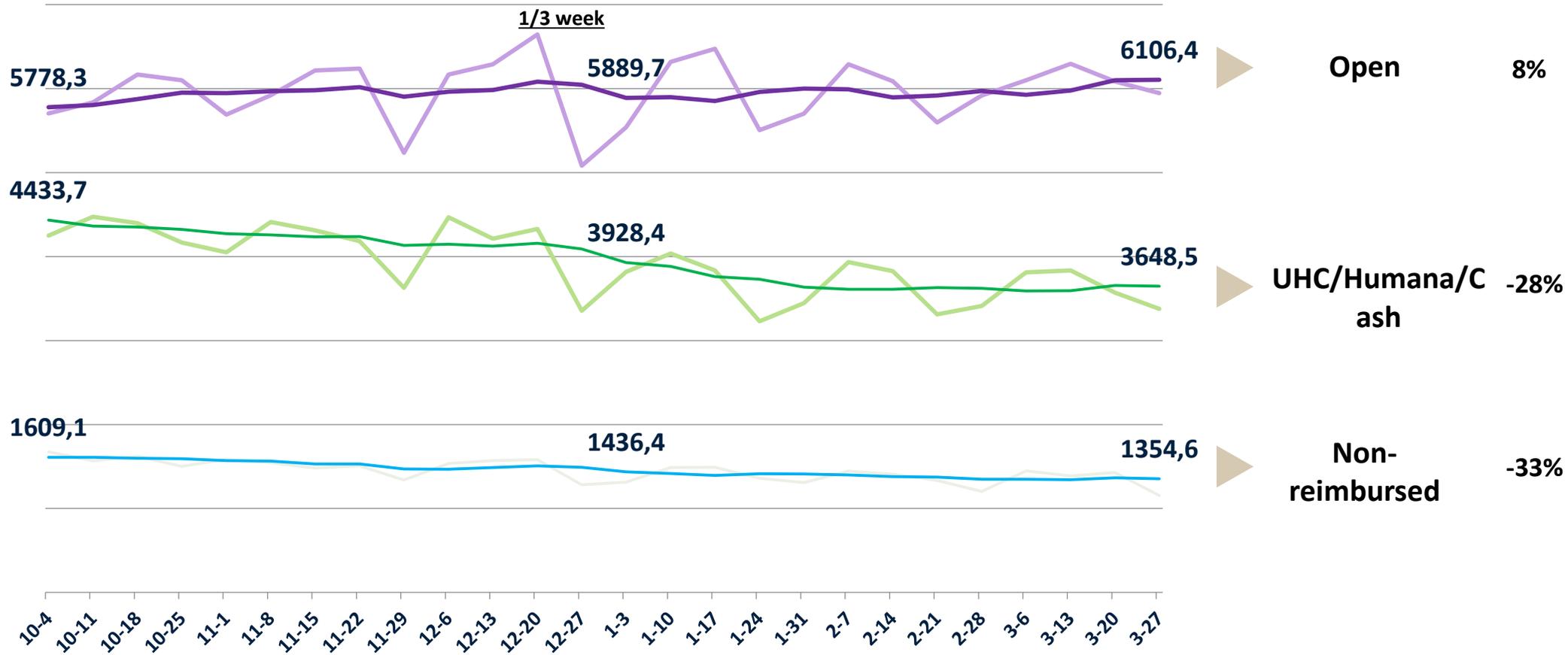
Payers / Market Access

- **“Open”**
  - Market segments where Zubsolv<sup>®</sup> is reimbursed either exclusively or non-exclusively
- **“Non-Reimbursed”**
  - Market segments where Zubsolv<sup>®</sup> is not reimbursed

# Open segment becomes an important growth driver, when the decline in UHC and Humana diminish in 2020

## Zubsolv by Access Segments

R4W Average NTRx in Bold Color; Single Week NTRx in Lighter Shade



Source: IMS XPO

NTRx = Total prescriptions adjusted to 30 tablet/film scripts

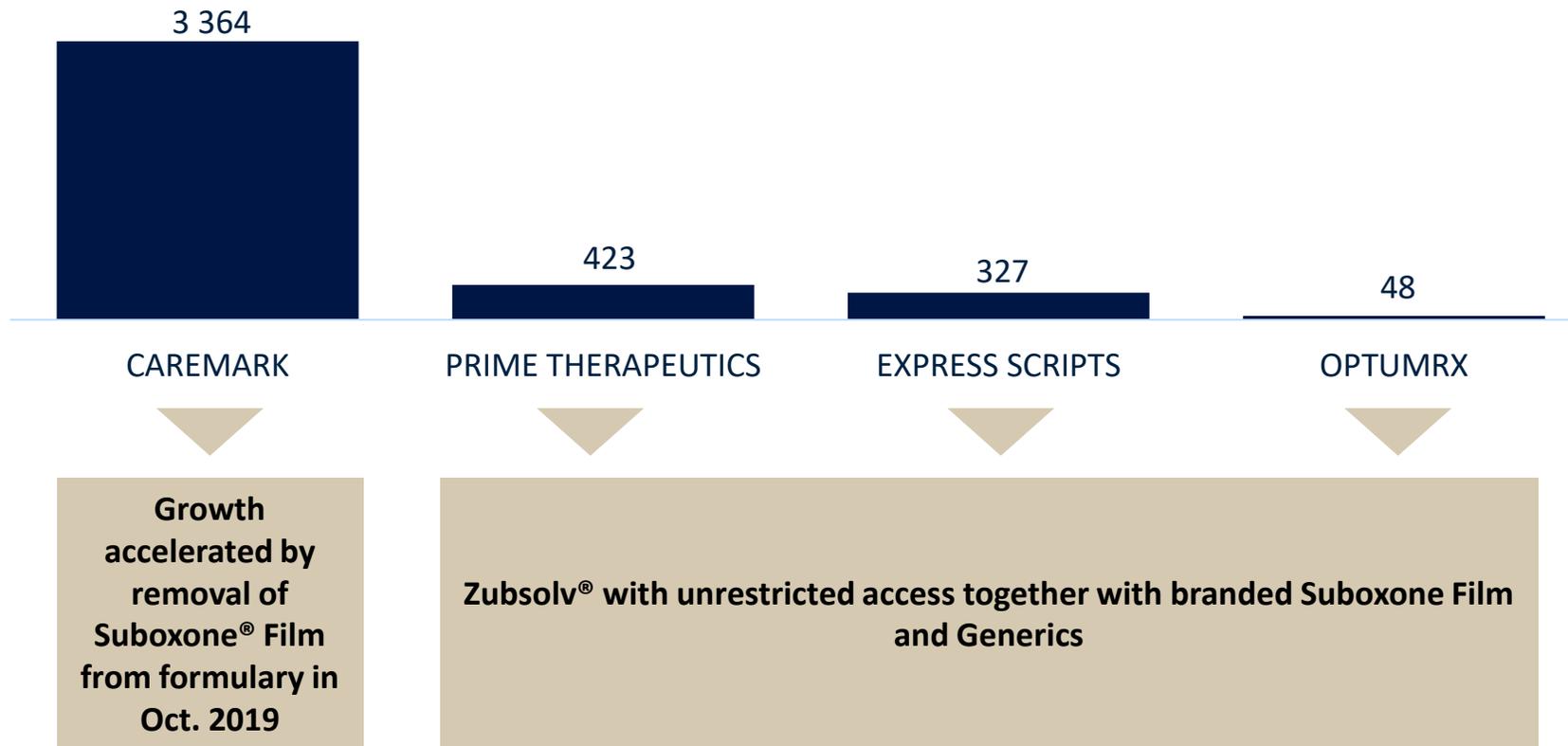
Open: Market segments where Zubsolv® is reimbursed either exclusively or non-exclusively

Non-Reimbursed: Market segments where Zubsolv® is not reimbursed

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

## Prescription incremental growth to major national PBMs

Zubsolv NTRx YoY Q1



**Total increase of 4,162 NTRx YoY**

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

**Additional removal of Suboxone<sup>®</sup> Film from formularies likely to drive additional growth**

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

# 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

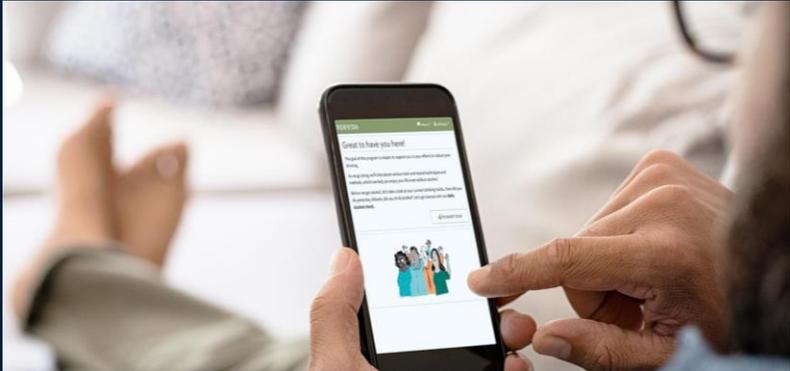
## **Competition from “the preferred” authorized generic of Suboxone® Film will end**

- ...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 9% 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

# Development projects



# 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

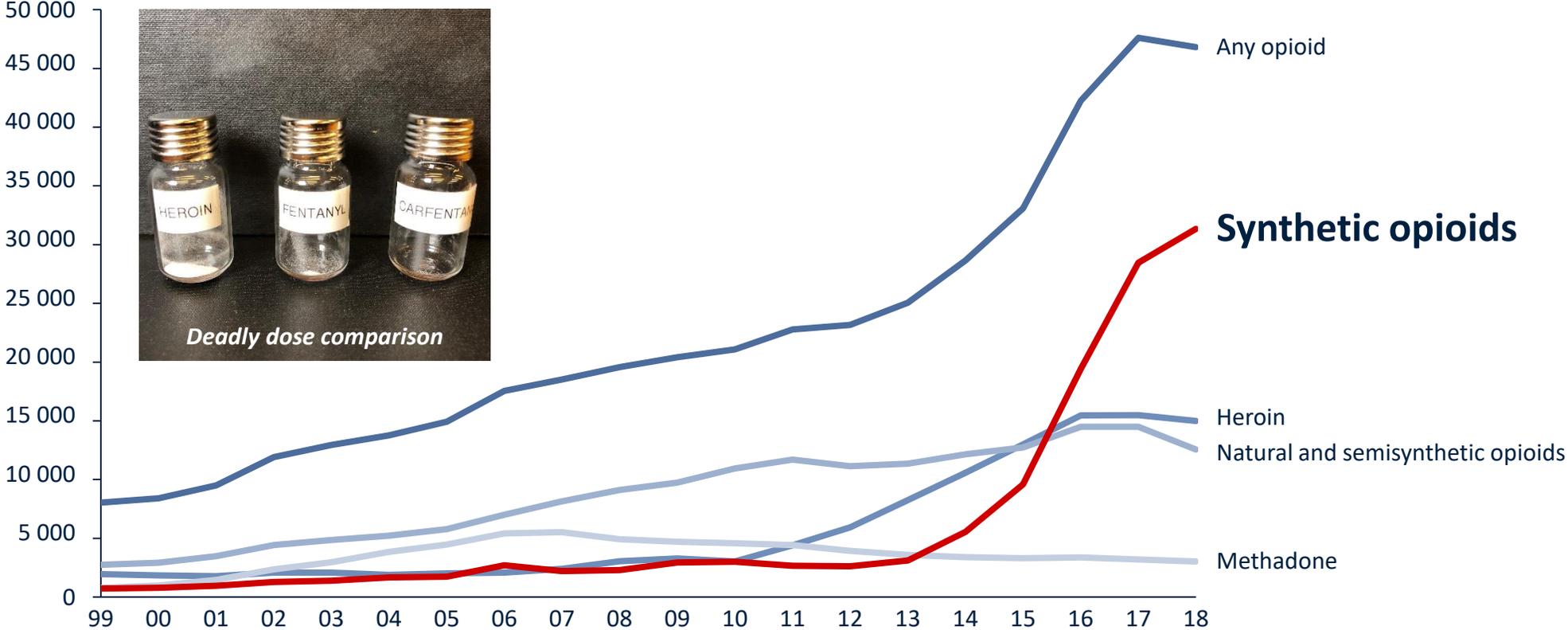


**>100**

MUSD net sales potential (US)

# 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

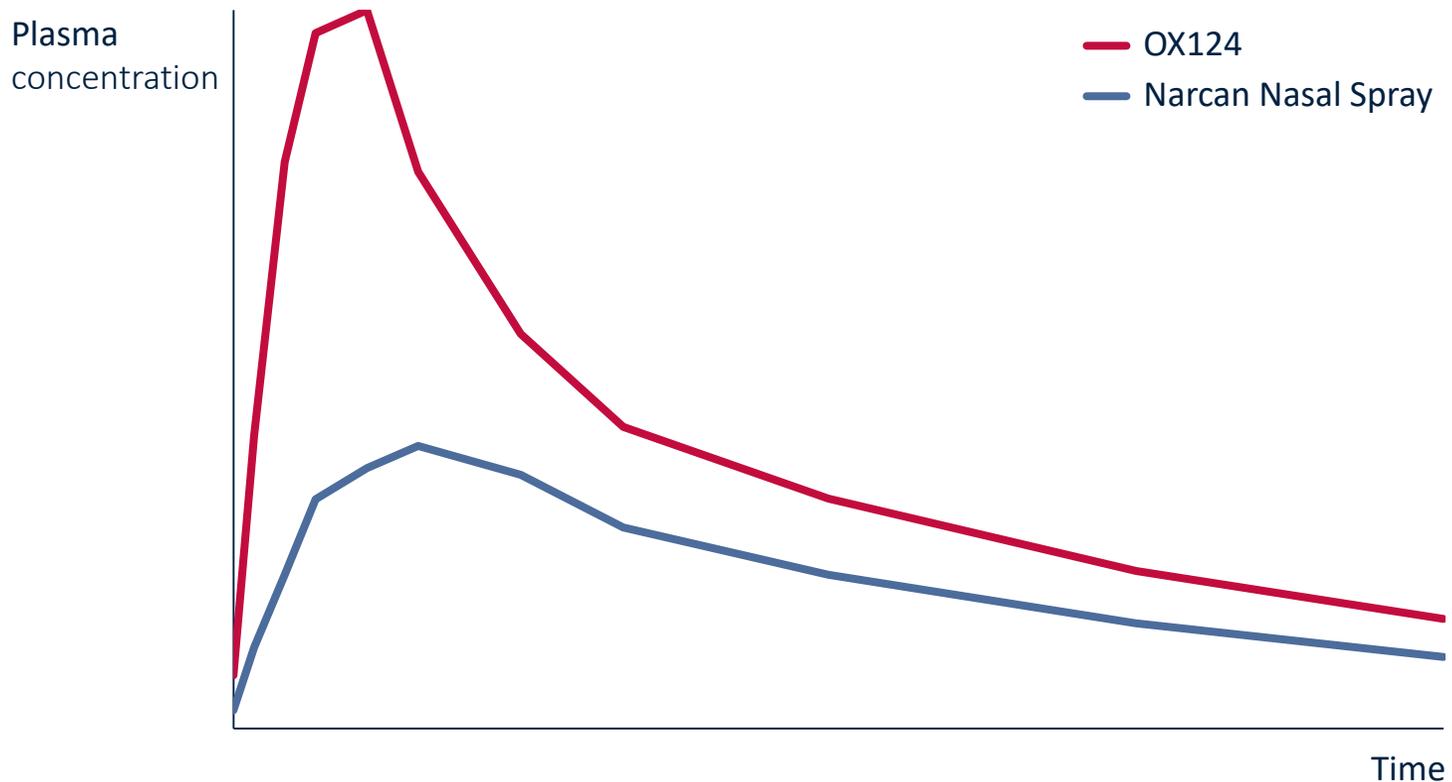


# OX124 - We have shown better PK profile than Narcan<sup>®</sup> Nasal Spray

Faster, stronger and longer-acting vs Narcan<sup>®</sup> Nasal Spray

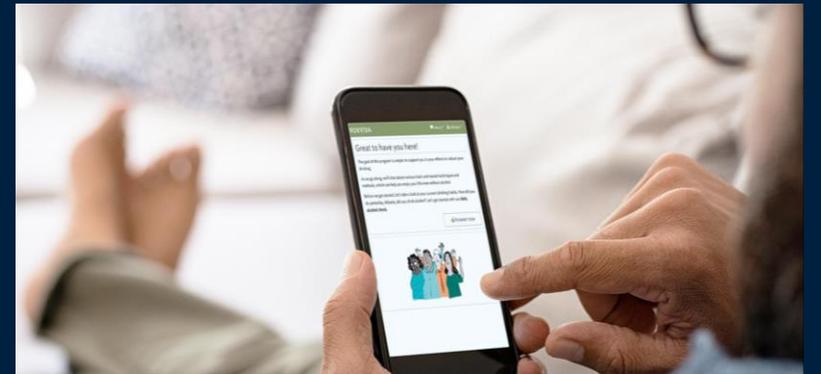
Expected patient benefit

Results from exploratory PK study in healthy volunteers, 2019



- 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)

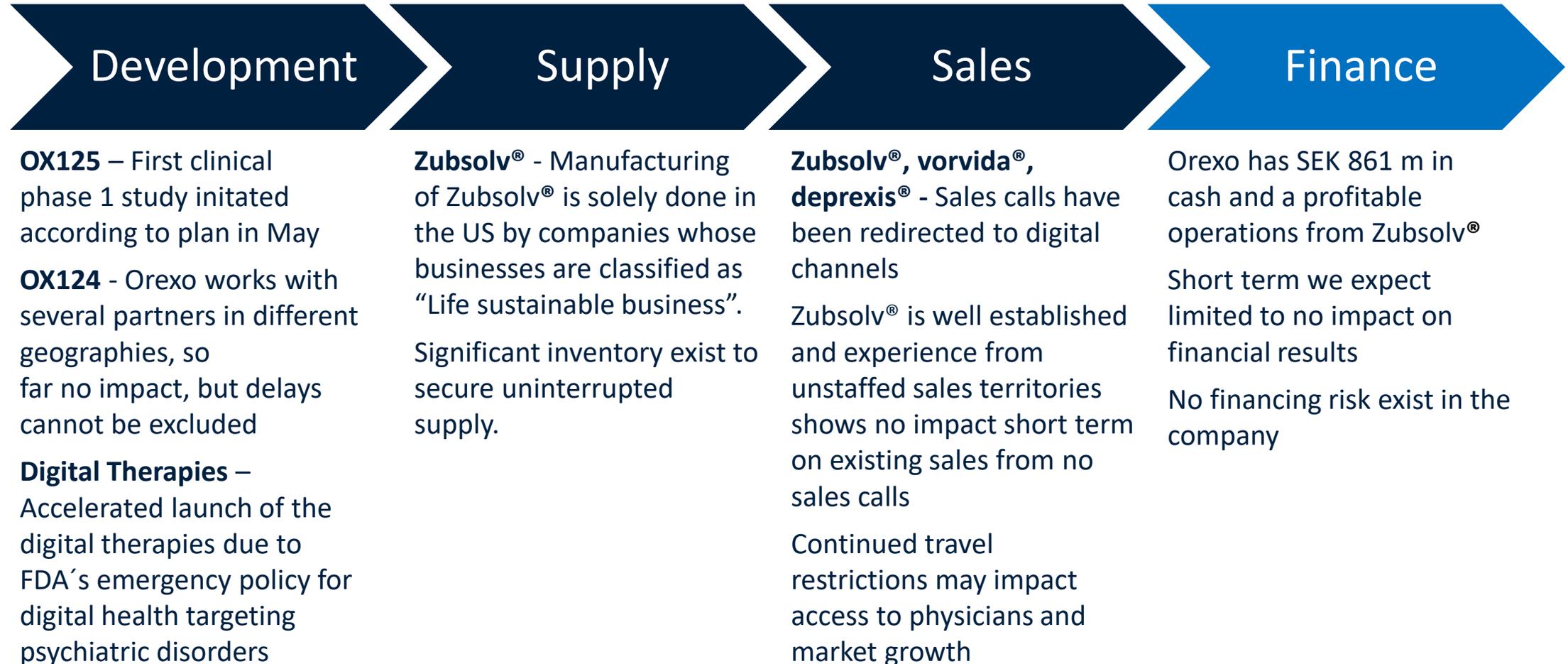
# Financials & outlook



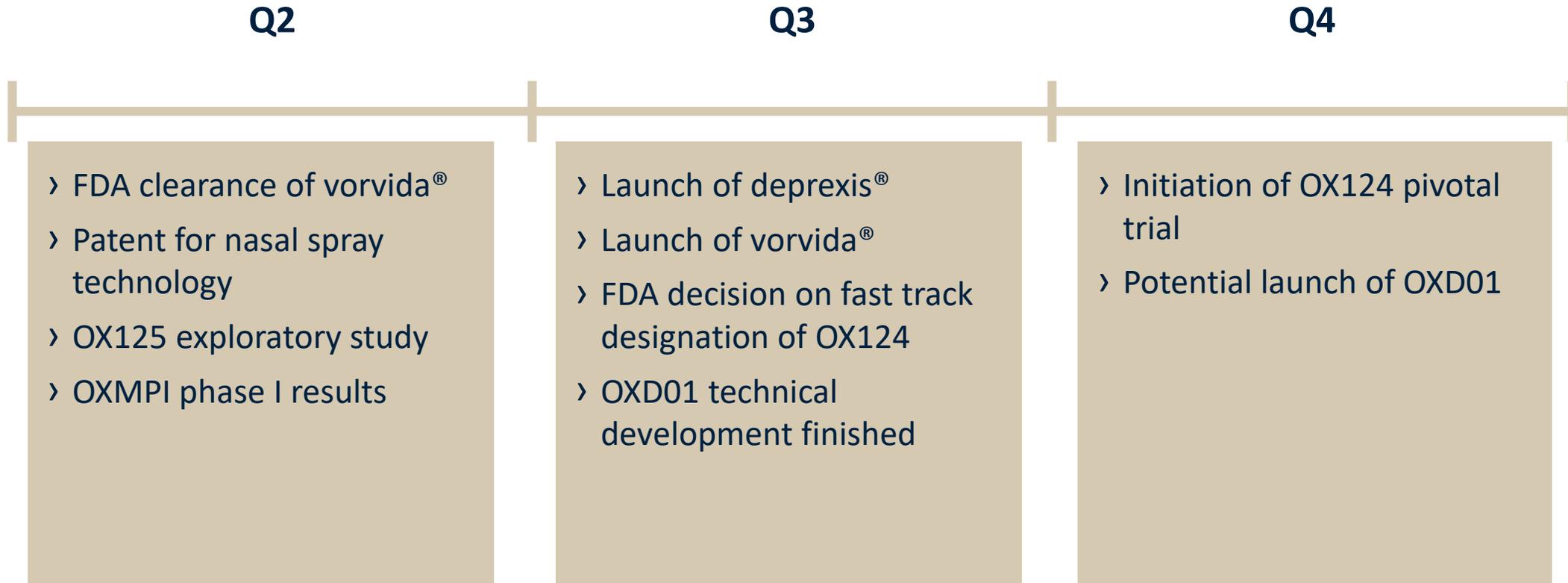
## Strong financial position enabling continued investments in future growth opportunities

Group net revenues LTM <b>SEK 846 m</b> <i>Of which 85% from Zubsolv® US</i>	Growth <b>3%</b> <i>Zubsolv® US 11%</i>
Group EBITDA LTM <b>SEK 299 m</b>	Growth <b>133%</b>
US Pharma EBIT (Zubsolv® US) LTM <b>SEK 355 m</b>	Growth <b>50%</b>
Cash position <b>SEK 861 m</b>	Positive net cash position <b>SEK 612 m</b>

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



## 2020 a year with a steady news flow expected



# THANK YOU!

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