



# **We improve the lives of people suffering from mental illness and substance use disorders**

Orexo supports the UN's  
Agenda 2030 with a focus on:



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## Orexo in brief

**1**

Headquartered in Uppsala, Sweden, with own commercial platform in the US

**2**

Addresses unmet needs within fast growing therapeutic areas

**3**

Developed four commercial pharmaceutical products with worldwide approval

**4**

A pioneer in adding evidence-based digital therapies to improve pharma treatment results

**5**

Strong cash contribution from a profitable US Pharma segment (EBIT 2020, SEK 331 m)





# US Pharma



## ZUBSOLV® continues to be a strong cash contributor

- ✓ MAT<sup>1</sup> treatment for opioid use disorder containing buprenorphine/naloxone
- ✓ Should be used along with psychosocial support, such as MODIA™
- ✓ Launched in the US 2013 and commercialized by Orexo's field force
- ✓ The only branded & marketed buprenorphine/naloxone product on a generic market
- ✓ Patent protection until 2032

### Q3 ZUBSOLV® net revenues

**136** SEK M

### Q3 ZUBSOLV® net revenues ▲

**+8** %  
QoQ

### Q3 ZUBSOLV® EBIT

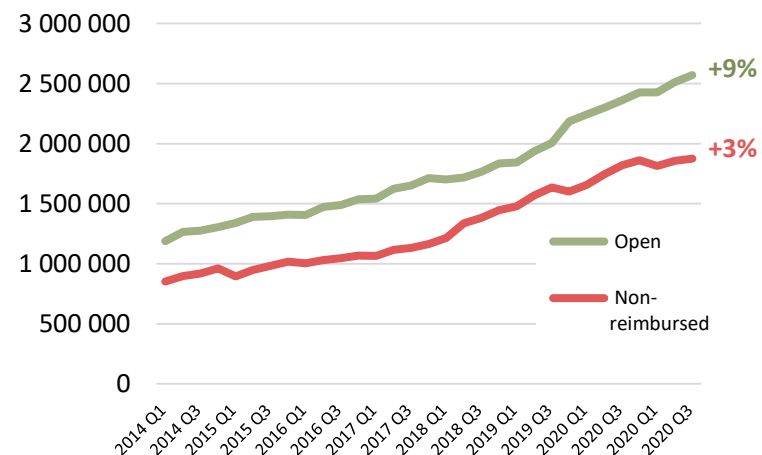
**78** SEK M

<sup>1</sup> Medication Assisted Treatment

# Multiple drivers for future growth

## 6% total market growth Q321 vs Q320

Driven primarily by Public payer segment, although the growth is lower than recent years, and Commercial payer segment also contributing



Market volume sales development<sup>1</sup>

<sup>1</sup> Volume sales, quarterly NTRx

1

Covid-19 effects likely to diminish improving patient access to care and Orexo access to customers

2

Multiple comprehensive activities on-going on federal and state levels will increase access to treatment

3

Overall improved market access for ZUBSOLV® with Public payer access improving from 34% to 42% and Commercial declining slightly from 99% to 98%

4

The launch of MODIA™ as a treatment complement to ZUBSOLV® will open up for new sales routes and market segments



# Pipeline & HQ



## Product portfolio and development pipeline

Pharmaceuticals									
Product/ Project	Exploratory	Preclinical	Phase			Registration	Approved and/or Launched		
			1	2	3		US	EU	RoW
<b>ZUBSOLV®</b> Opioid Use Disorder Partner: Accord Healthcare									
<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>OX-MPI</b> BI1029539, Microvascular Disease Partner: Gesynta Pharma									
<b>Early non-disclosed projects /amorphOX™</b>									

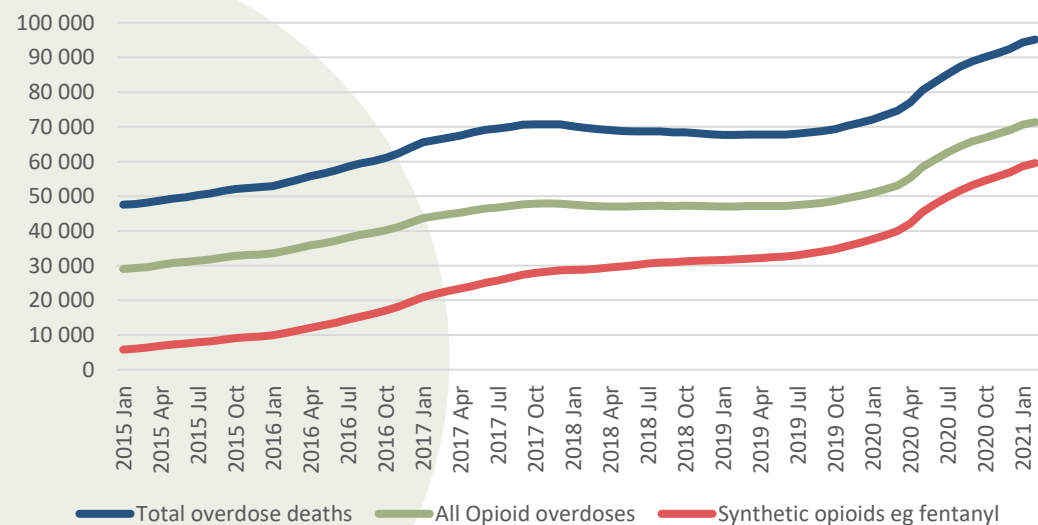


# In the US overdose deaths annually are approaching 100 000

75% are caused by opioids, of which 84% can be attributed to use of synthetic opioids such as fentanyl.



12-month ending provisional number of drug overdose deaths in the US<sup>1</sup>



<sup>1</sup> Center of Disease Control

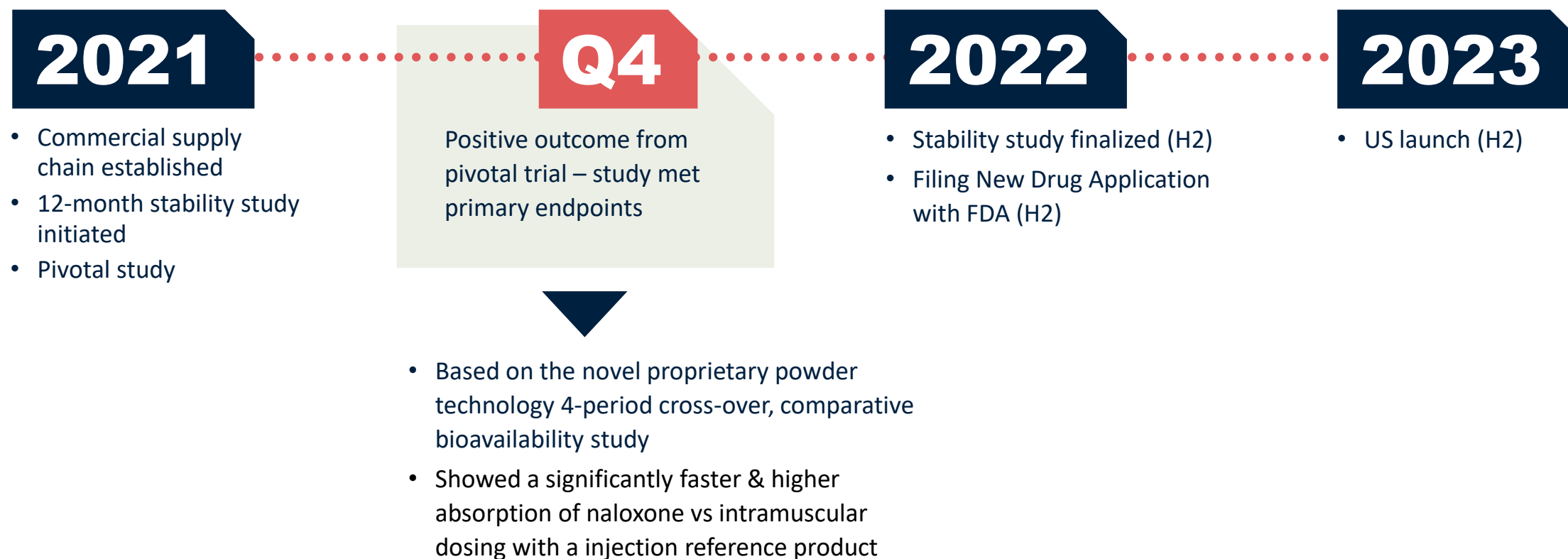
**“Giana made the switch to heroin, and it was all downhill from there.”**



Elise discovered her daughter's opioid addiction months before she died from an overdose.

Read more at the [Orexo blog](#)

# OX124 – positive results from pivotal trial



**DTx in brief**

- ✓ Subsection of digital health
- ✓ Evidence-based therapeutic intervention
- ✓ Prevent, manage, or treat a medical disorder or disease
- ✓ Particularly applicable in the mental illness & addiction space
- ✓ Standalone or along with pharma treatment
- ✓ Available 24/7



# Digital Therapeutics (DTx)

# Strong underlying trends will force the DTx market to gain traction

## Healthcare systems challenged

Aging population and sky-rocketing costs are forcing the healthcare providers to rethink how to deliver healthcare to increase efficiency and value.

## Consumers (patients) in the center

Patients want to be seen as consumers and requires holistic and customized treatments with access 24/7.



## Widespread technology acceptance

Covid-19 has further pushed forward the ongoing tech revolution and the use of telemedicine is pervasive.

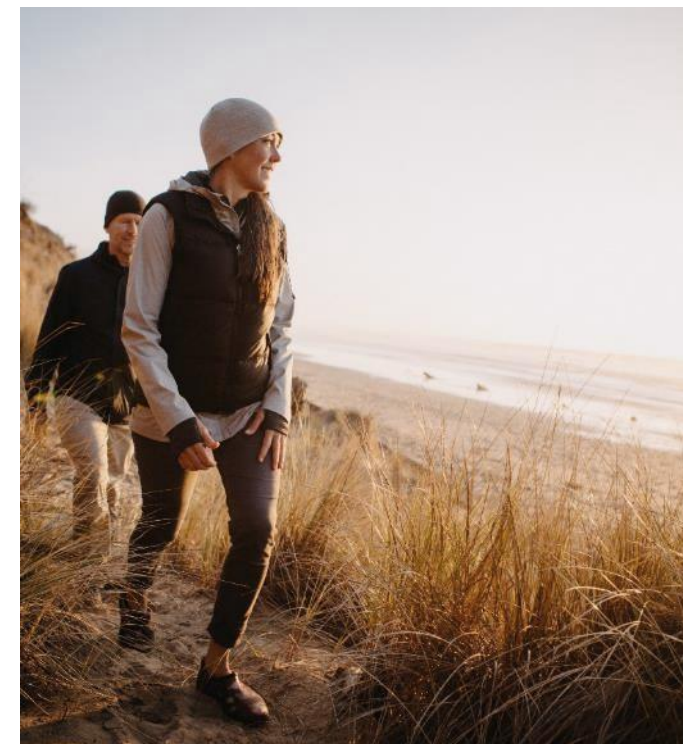
## Value-based care

Providers will be rewarded based on the ability to add patient value. Analyzing RWE data pave the way for efficient allocation of resources.



# At the forefront of addressing hurdles for reimbursement and commercial sales

Reimbursement Route	Requirement	Orexo's Activities
The Prescription Model	<ul style="list-style-type: none"><li>FDA approval as a prescription digital therapy (PDT)</li><li>Pharmacy benefit coverage pathway</li></ul>	<ul style="list-style-type: none"><li>✓ Active member in the DTx alliance to enable change in Washington</li><li>✓ Randomized clinical trial for MODIA™ underway, early market entry via FDA EUA</li></ul>
The Medical Benefit Model	<ul style="list-style-type: none"><li>HCPs integrate DTx in treatment programs</li><li>CPT codes defined by AMA/CMS</li></ul>	<ul style="list-style-type: none"><li>✓ Partnership with IDNs such as Trinity Health and Benefis Health System</li><li>✓ Engagement of payers and generation of RWE e.g. Magellan</li></ul>



# Clinically proven DTx in collaboration with GAIA AG

Rooted in cognitive behavioral therapy techniques and based on AI technology offering a highly individualized intervention

	modia	VORV!DA	deprexis®
<b>Instructions for use</b>	Opioid dependence	Alcohol misuse	Depression
<b>Clinical evidence<sup>1</sup></b>	Ongoing randomized clinical trial, 400 patients	Evaluated in 1 randomized clinical trial, > 600 patients	Evaluated in 13 randomized clinical trials, > 2.800 patients
<b>Length of treatment</b>	6 months	6 months	3 months
<b>Treatment method</b>	Along with current standard of care including medication	Standalone or as a complement to current standard of care	Standalone or as a complement to current standard of care
<b>FDA clearance</b>	Will apply for a 510 k clearance, meanwhile launched under FDA's Public Health Emergency Use Authorization (EUA)	FDA cleared under the Emergency Use Authorization	FDA cleared under the enforcement discretion

<sup>1</sup> View study results in Appendix

# Partnering with health network systems and healthcare providers are expected to be the primary sales channel

## Examples of announced partnerships



~3,000 employees  
Serving residents in ND and Montana

- ✓ Magellan (RWE study)
- ✓ NYC clinic
- ✓ Mental health hospital in St Louis

## New partnerships evolving in Q3



Sober Grid

>300,000 users  
The largest global social media network for people in recovery from addiction



~3,300 employees  
Serving residents in Montana



Telehealth and established clinic in Chicago

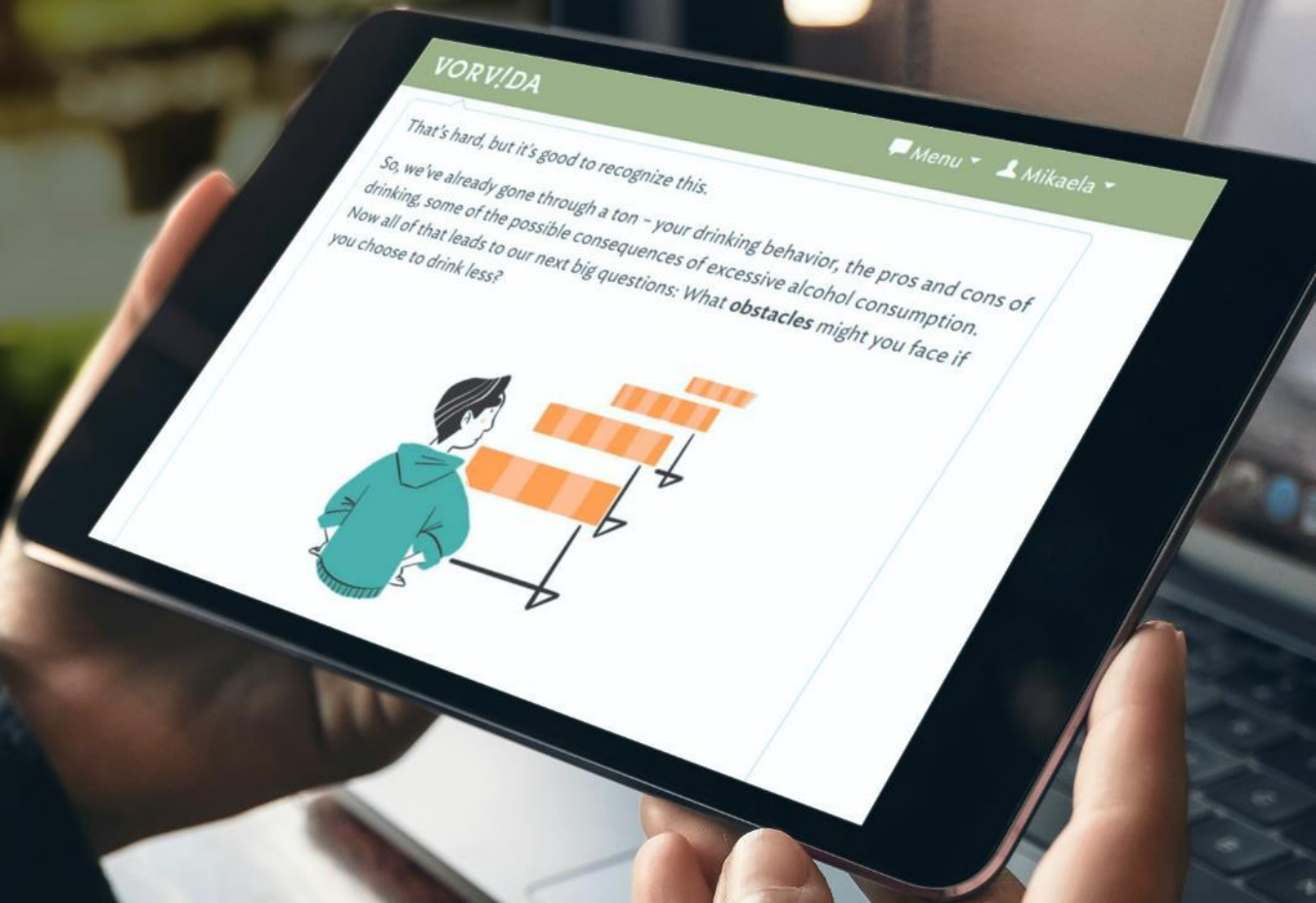


*Employer health Business Solutions  
Providing the Bridge to Employers*

Employer benefit solutions sales broker



# Financial & legal





# A transformative 12-month period building for future growth

- Significant investments in establishing digital therapeutics business and development of OX124
- Recurring business is well financed from ZUBSOLV® profit contribution

Group net revenues<sup>1</sup>

**580** SEK M

US Pharma net revenues<sup>1</sup>

**532** SEK M

EBITDA

**-112** SEK M

US Pharma EBIT<sup>1</sup>

**301** SEK M

Cash position

**588** SEK M

US Pharma EBIT margin

**57** %

<sup>1</sup> LTM, Last Twelve Months, Q4 2020-Q3 2021

# Legal update

## **ZUBSOLV® patent dispute vs Sun Therapeutics**

No changes in Q3

- ✓ 9 patents listed in the Orange Book
- ✓ Expiring dates Dec 2027 – Sep 2032
- ✓ Previously successfully managed to defend ZUBSOLV® IP rights in the US appeal court

## **Subpoena with regards to ZUBSOLV®**

No changes in Q3

- ✓ No additional information received since issuance of subpoena July 2020



# Future value drivers

# Strong value drivers for long-term growth

**1**

Product portfolio addressing large and growing markets

**2**

Leveraging our US commercial excellence

**3**

Pharma pipeline targeting unmet medical needs

**4**

Strong cash position  
cash flow from US  
Pharma to finance  
growth

**5**

Entering digital  
therapeutics, a new  
evidence-based  
frontier in patient  
care





# Thanks

Orexo is listed on the Nasdaq  
Stockholm Mid Cap (ORX) and is  
available as ADRs on OTCQX  
(ORXOY) in the US