



# **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:



# Agenda

**1**

Introduction  
& strategic  
priorities

**2**

Business  
segments

- US Pharma
- Pipeline & HQ
- Digital Therapeutics

**3**

Financial  
overview

- Legal update

**4**

Future  
value drivers



Lena Wange  
IR & Communications Director

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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

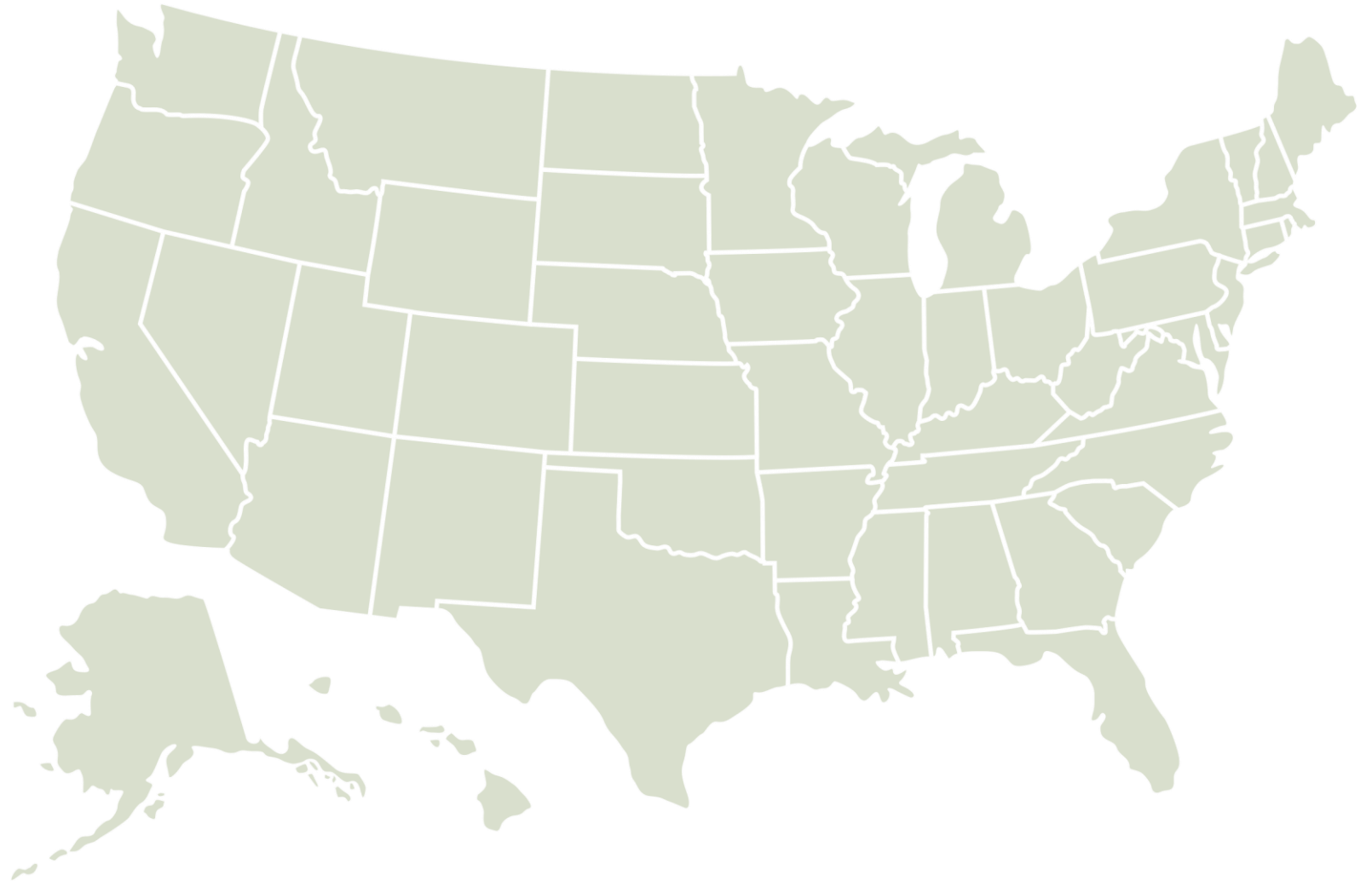
**5**

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





## Own commercial platform in the US



  
zubsolv

modia

VORV!DA

deprexis

# Strategic priorities with the ultimate goal to build a stronger and broader Orexo

**1**

**Broadening** the portfolio of commercial products to be promoted by our US Pharma and Digital Therapeutics businesses

**2**

**Maintaining** ZUBSOLV® profit contribution and ensure it is sustainable and growing over time.

**3**

**Establishing** a business area within Digital Therapeutics and expand into the next great growth area in life science

**4**

**Enhancing** the development pipeline in pharma, led by OX124, an opioid overdose rescue medication, in the US

A middle-aged man with grey hair is smiling and looking off to the side. He is wearing a dark blue quilted vest over a blue and white plaid shirt. He has a black backpack on his shoulders and is holding the straps. The background is a blurred desert landscape with dry bushes and hills under a bright, hazy sky.

# 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



# Stable development in Q3 when impact from formulary changes in 2019 decelerated

## Operational update

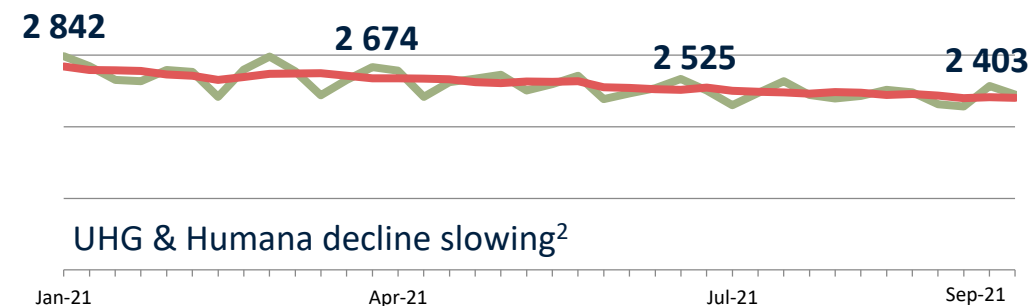
- ✓ Overall market access improved especially in Medicaid
- ✓ ZUBSOLV® reimbursed by Kentucky Medicaid as of 7.1.2021
- ✓ Field force will start promotion of modia™ and Zubsolv® from November
- ✓ Sales force access to prescribers continues to improve, but not yet on pre-Covid levels

## Development NTRx QoQ

Overall -2%  
Open segment<sup>1</sup> 0%  
UHG & Humana -4%  
Non-reimbursed -1%

## High level comments +/-

- + 85% growth in Kentucky during Q3
- + Good QoQ growth in several Medicaid accounts
- + YoY growth in large PBMs (CVS, ESI)
- Continued slow market growth especially in commercial segment



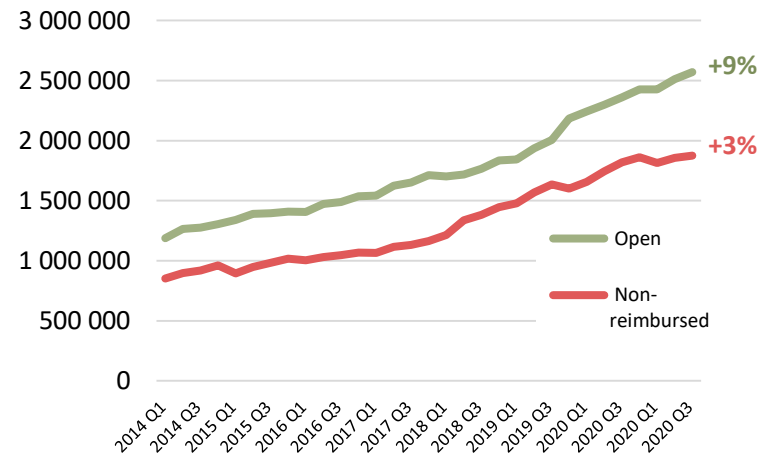
<sup>1</sup> Where ZUBSOLV® is reimbursed and competes on equal terms with both branded products and/or generics

<sup>2</sup> R4W Average NTRx in Bold Color; Single Week NTRx in Lighter Shade. Period 01.08.21-09.24.21

# 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 Parner: 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</b>									



**A new, stronger rescue medication (OX124) designed to reverse the effect of overdoses caused by the most powerful synthetic opioids**

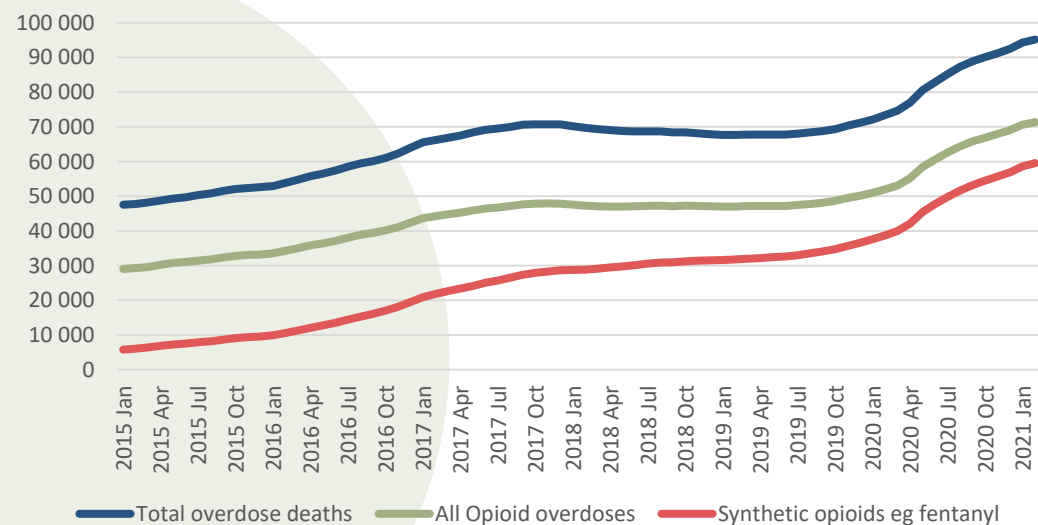


# In the US overdose deaths annually are approaching 100 000

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

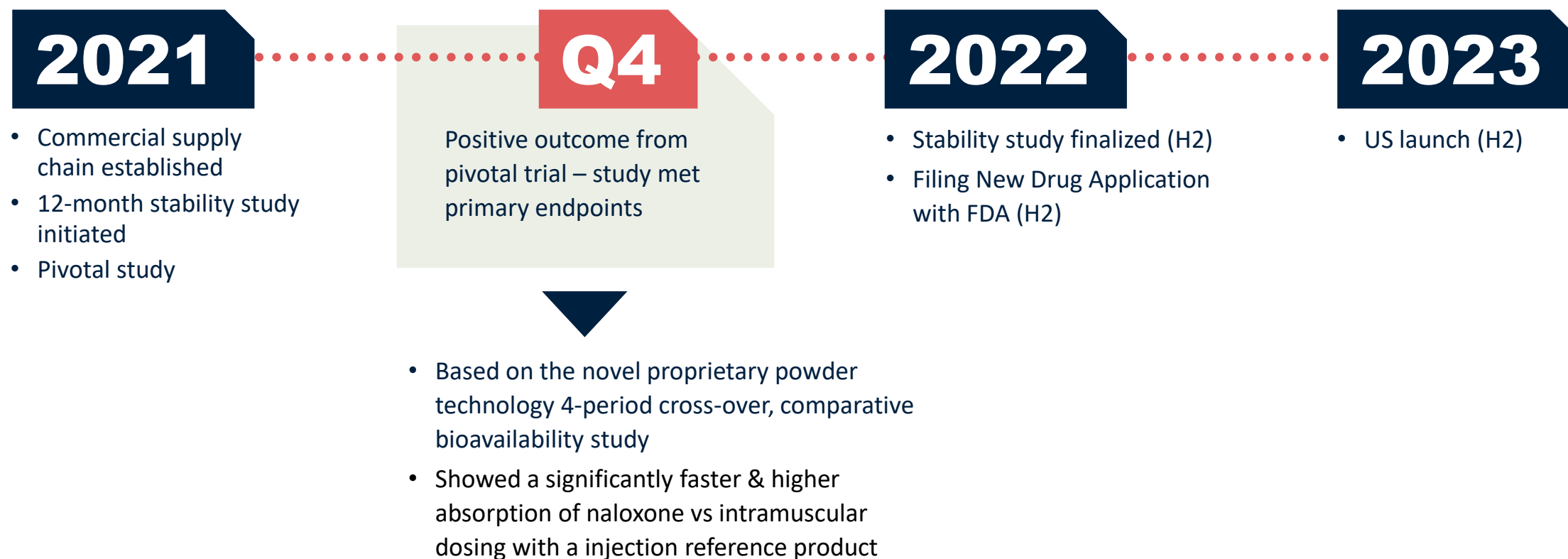
**“Giana made the switch to heroin, and it was all downhill from there.”**



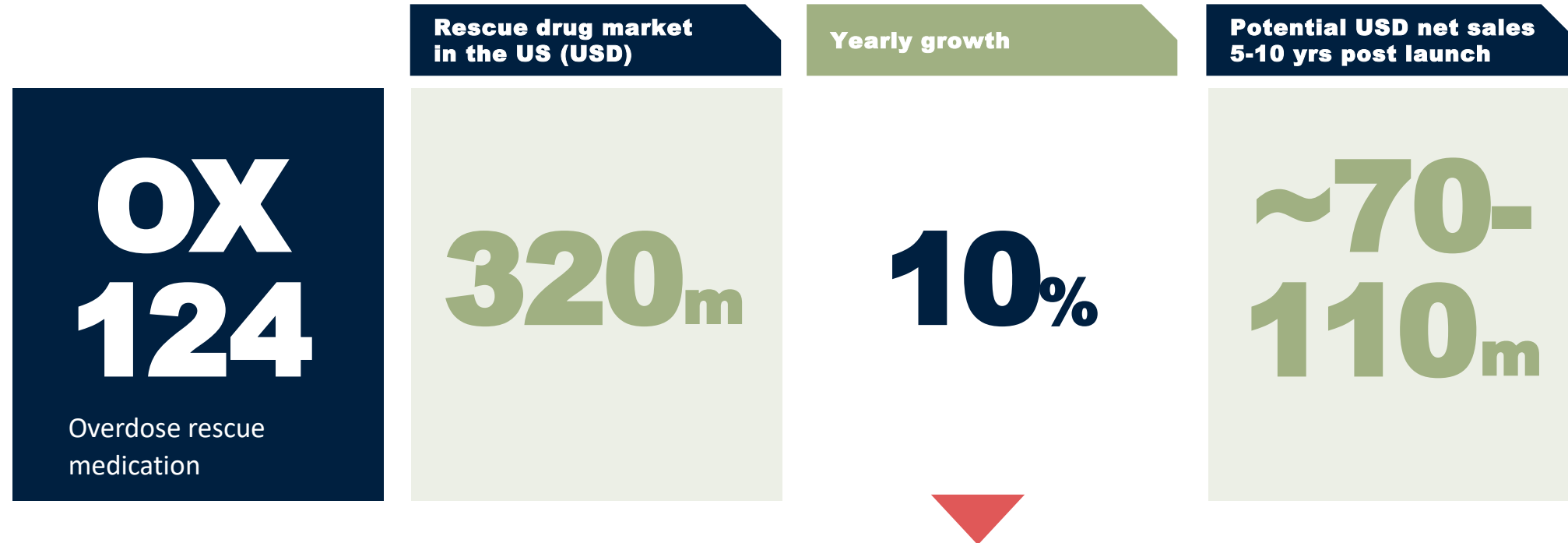
Elise discovered her daughter's opioid addiction months before she died from an overdose.

Read more at the [Orexo blog](#)

# OX124 – positive results from pivotal trial



# OX124



Overdose rescue medication

## Initiatives for expanding access

- ✓ Mandatory co-prescription legislation when treated for pain
- ✓ Standing orders at the pharmacy
- ✓ Distribution of naloxone upon leaving emergency room
- ✓ Expand availability in communities

NOTE: The potential USD net sales is associated with significant uncertainties and is dependent on expansion of mandatory co-prescription and the competitive landscape



**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



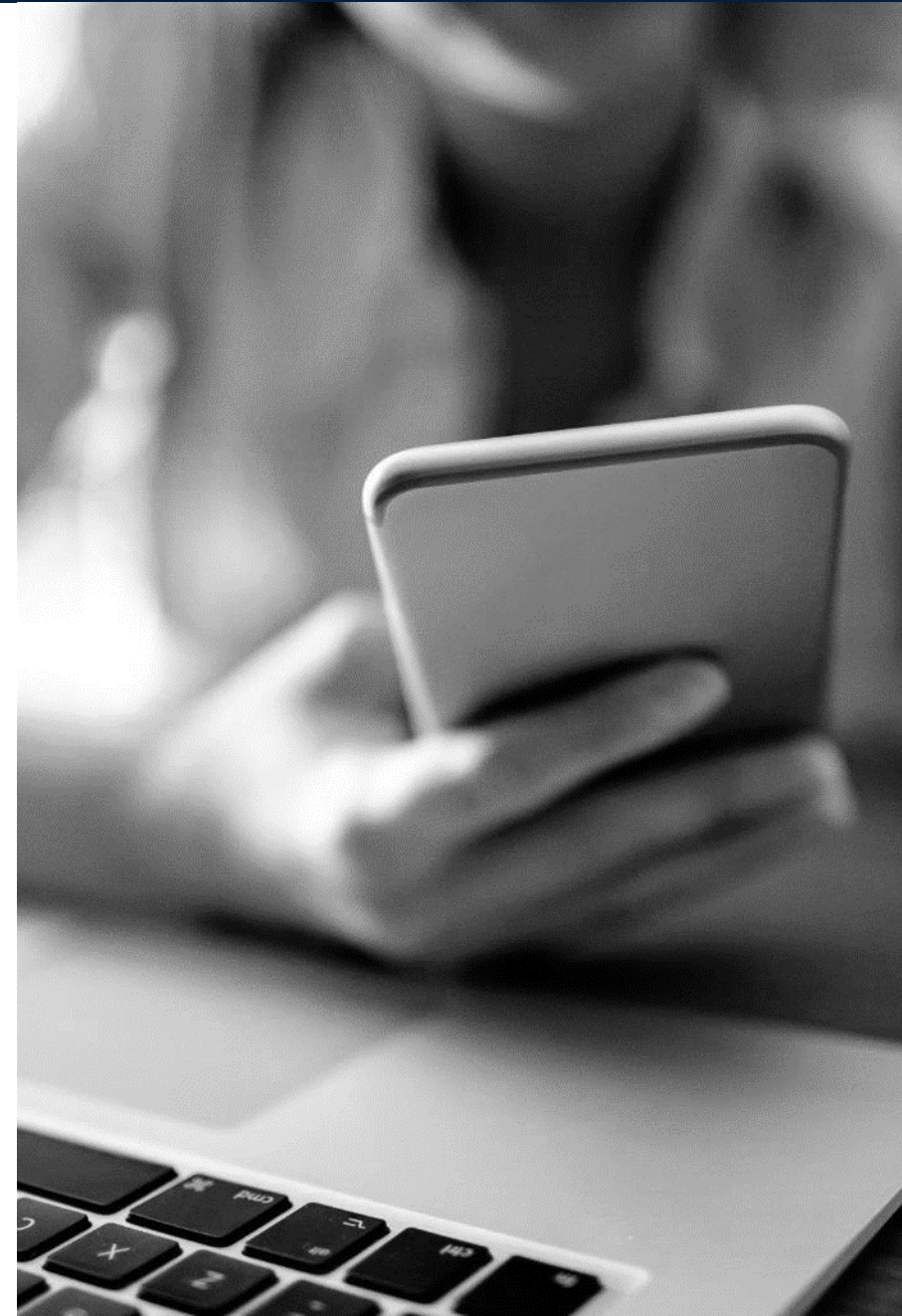
# Digital Therapeutics (DTx)

## 21.3 BUSD invested in digital health YTD 2021<sup>1</sup>

**“In sum, it is not hard to imagine the emergence of a very different healthcare system powered by digital technologies within ten years.”**

The promise of digital therapeutics, McKinsey & Co

<sup>1</sup> [www.rockhealth.com/insights/q3-2021-digital-health-funding-to-20b-and-beyond/](http://www.rockhealth.com/insights/q3-2021-digital-health-funding-to-20b-and-beyond/)



# 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.

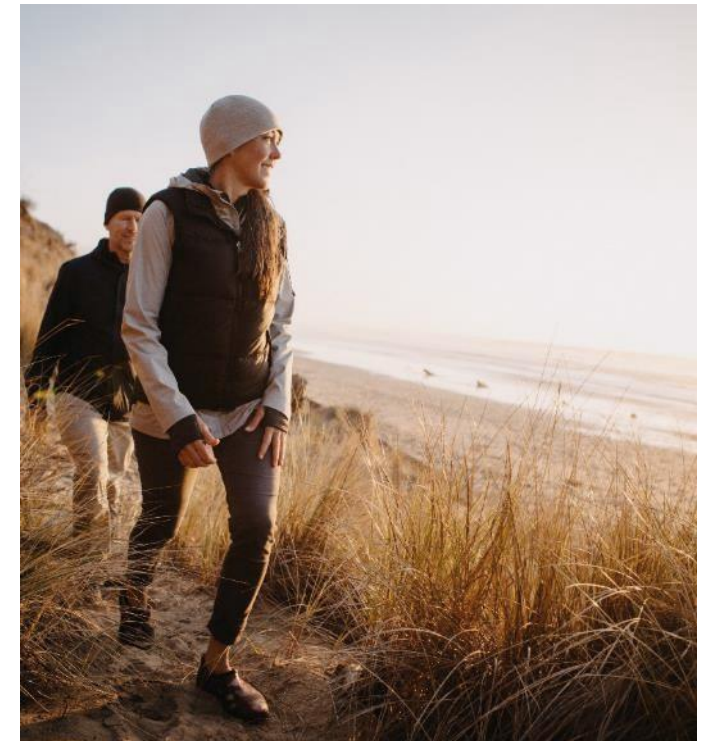
## Value-based care

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

	<b>modia</b>	<b>VORV!DA</b>	<b>deprexis®</b>
<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

## Many affected and few are treated

	US Market	Patients in treatment	Potential USD net sales 5–10 yrs post launch
 <b>modia</b> Opioid dependence	<b>10m</b> are misusing opioids	<b>1.3m</b>	<b>~150-225 m</b>
 <b>VORV!DA</b> Alcohol misuse	<b>17m</b> heavy alcohol users	<b>1.5m</b>	<b>~120-200 m</b>
 <b>deprexis</b> <sup>®</sup> Depression	<b>20m</b> are suffering from at least one major depression annually	<b>10m</b>	<b>&gt;150-225 m</b>

Note assumptions: MODIA™ – potential net sales based on a market share in the range of 10-15% among patients who are in treatment and that these measured in number are grow by 12% per year.

VORVIDA® – potential net sales based on a market share in the range of 8-12% among patients who are in treatment and 0.5–1.0% among non-treated heavy alcohol users.

DEPREXIS® – potential net sales based on a market share in the range of 3-8% among patients who are in treatment for depression

NOTE: The potential USD net sales is associated with significant uncertainties and is highly dependent on access to viable reimbursement pathways for digital therapies

# 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



# What to expect from DTx?

Digital Therapies are a new disruptive tool in healthcare and while significant interest exist and viable reimbursement pathways are evolving the development of the overall market is still in its infancy

## Continued focus on new partnerships

- ✓ Leveraging learnings from Trinity Health to expand number of partnerships
- ✓ Working with Sober Grid with an expanded offering combining our services to new distribution channels
- ✓ Additional partners expected every quarter from now

## Pull through existing partnerships

- ✓ Finalize internal administrative processes at Trinity Health and start promoting solution
- ✓ First commercial patients from Trinity Health are expected near term

## Launch of MODIA™

- ✓ MODIA™ launch initiated with Orexo field force in November
- ✓ Initial focus on gaining credibility and advocacy
- ✓ Revenues expected H1 2022



# 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



A photograph of a man with a beard and a young girl with curly hair, both smiling and laughing. The man is wearing a red jacket over a white shirt, and the girl is wearing a grey hoodie. They are outdoors in a park with green trees in the background. The man is carrying the girl on his shoulders, and they are both holding hands.

# Thanks