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# Orexo – our business areas



#### **US Pharma**

Commercial US Pharma platform since 2013, incl. market access team and sales representatives who on a daily basis visit physicians, medical clinics and minor hospitals.

### **HQ & Pipeline**

Development of improved drugs based on well-known substances combined with innovative proprietary Drug Delivery technologies, such as amorphOX<sup>®</sup>.



## Digital Therapeutics

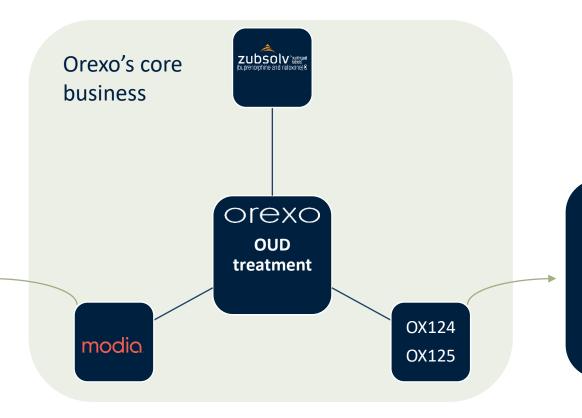
Evidence-based digital therapies grounded in cognitive behavioral therapy techniques, offer better treatment access for patients and improve their outcomes.

## A strong focus on opioid misuse

#### DTx

- Scalable reimbursement platform
- DTx in mental health with co-morbidities to OUD

vorv!da deprexis



Profitable and stable US Pharma business with long presence in significantly underserved market and significant near-term milestones from MODIA® study and OX124 approval enabling a comprehensive treatment solution to OUD

World leading technology enabling new profit

generating partnerships

amorphOX°

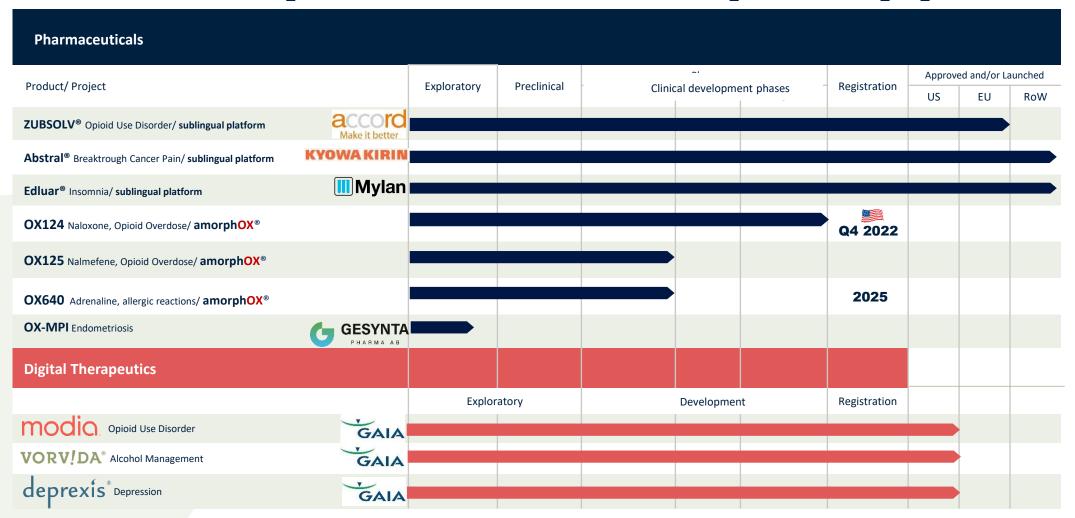
• OX640

 Technology outlicense and partnering in development

Pioneer in future growth area with proprietary reimbursement platform and products



## Commercial products and development pipeline



## US market: Commercial products targeting a large unmet need



Opioid dependence		Alcohol management	Depression
zubsolv modio ox124 (6	zubsolv modio OX124 (expected H1 2024)		deprexís®
Overdose deaths surpassed 107 000 in 2021, fueled by use of synthetic opioids such as fentanyl	10m are misusing opioids	17m are heavy alcohol users	20m  are suffering from at least one major depression annually
120000 100000 80000 60000 40000 2017 2018 2019 2020 2021 — Total overdose deaths — All opioid overdoses — Synthetic opioids eg fentanyl	1.4m in treatment	1.5m in treatment	10m in treatment

## ZUBSOLV® an important foundation to Orexo's commercial operations

**Net revenues** since launch 2013 (SEK m) <sup>1</sup> Last Twelve Months

#### Market dynamic

Sales volume stabilizing during 2022

- New reimbursement agreements in NY and Kentucky main growth drivers
- Decline in largest payers UHG and Humana after market leader lost exclusivity in 2019
- All market access maintained 2023

Market growth double digit pre-covid, but slowed down to 5% due to Covid-19 and Fentanyl crisis

 Significant increase in funding expected in 2023 and beyond





562 MSEK revenues LTM<sup>1</sup> (Q3 2022)

# Orexo is at the leading edge of digitalization in the pursuit to take DTx from its infancy to become a natural part of healthcare

"In less than a decade, DTx companies have completely disrupted the healthcare scene for the better."

The Future of Digital Therapeutics and The Impact On Care, The Linus Group, May 2021

- ✓ Establishing Reimbursement
  Orexo working in tight collaboration
  with world leaders in digital health to
  make DTx accessible to all patients.
  However, universal reimbursement
  processes still to be established
- ✓ **Disruptive technology**Through pilot programs, trials and real world evidence collection, Orexo is working with payers and leading healthcare organizations to build confidence in the value of our DTx to healthcare.

## Clinically proven DTx

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

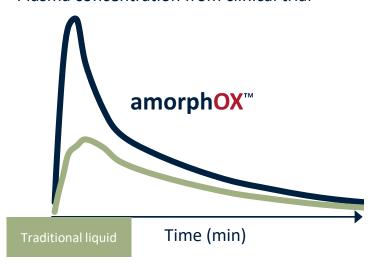
	modia	VORV!DA	deprexís®
Instructions for use	Opioid dependence	Alcohol management	Depression
Clinical evidence	Ongoing randomized clinical trial incl. 437 patients	Evaluated in 1 randomized clinical trial, > 600 patients	Evaluated in 13 randomized clinical trials, > 2.800 patients
Length of treatment	6 months	6 months	3 months
Treatment method	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
FDA clearance	Will apply for a 510 k clearance, meanwhile launched under FDA's Public Health Emergency Use Authorization (EUA)	FDA cleared under the EUA	FDA cleared under the enforcement discretion

## Orexo's development platform building on the proprietary amorphOX® technology

#### Validated in humans

✓ Superior pharmacokinetic properties with more rapid onset, higher peak and overall exposure, lower variability

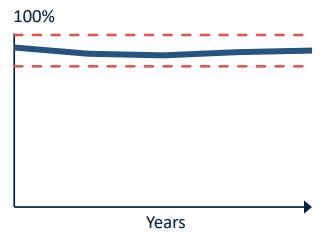
Plasma concentration from clinical trial



#### **Excellent stability**

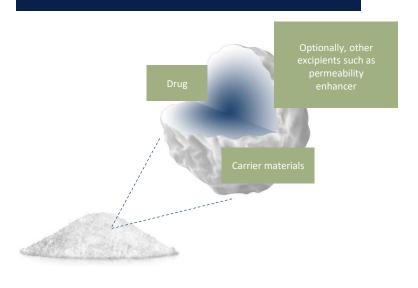
 Excellent stability even under accelerated conditions and proven to work on a broad scope of API's

#### **Amount of API**



#### Wide applicability

✓ Powder technology that works with a broad scope of small and large molecules, such as peptides and proteins



## OX124 & OX125 – overdose rescue medications

- Significant health issue in the US with >107.000 deaths from overdose in 2021
- Based on amorphOX® and designed to treat overdoses caused by synthetic opioids, such as fentanyl
- OX124 clinically differentiated to market leader and GX of market leader
- OX124 on track to be filed with FDA in Q4 2022



Global overdose rescue market size (USD)

1 1 1 0 0

M
of which 450 m refers to US

Projected global annual growth

10

%

## OX640 – emergency treatment of allergic reactions

- First line treatment today: intramuscular auto-injectors
- OX640 offers clear differentiation
  - Needle free alternative based on amorphOX®
  - Chemically stable and more robust formulation
  - Optimized manufacturing
  - Free of antioxidants or preservatives
- No meaningful innovation for decades
- OX640 could be ready for FDA filing in 2025 based on initial FDA feedback on clinical evidence required

Positive data showed in the clinical phase 1 study

Auto-injector global market size (USD)

Epinephrine

Projected global annual growth

4,000

9

%



## OX640: The power to transform emergency treatment of allergic reactions

Going from this...

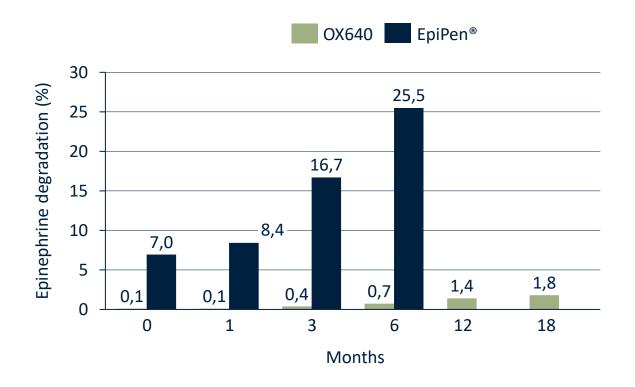


... to this





## OX640: Nasal epinephrine enabled by amorphOX® - remains stable in any life situation









OX640 will work indpendent on temperature, from a hot car in Texas to a winterday in Colorado

## Q3 2022 LTM<sup>1</sup> -**A transformative** period building for future growth

- **Significant investments in** establishing the DTx business, conducting clinical trials and to protect ZUBSOLV® **IP** rights
- **Recurring business is** financed from ZUBSOLV® profit and royalty contributions

**Group net revenues** 

**56** 

US Pharma net revenues

52

**EBITDA** 

**US Pharma EBIT** 

**US Pharma EBIT margin** 

**Cash position** 

<sup>1</sup> Last Twelve Months Q4 2021-Q3 2022 Note: USD/SEK conversion rate 10.86

## Why Orexo?

- Corporate profitability in sight
  - Main external cost drivers will diminish during H1 2023
  - No new activity driving external expenses to be initiated without certainty of associated revenues
  - Significant focus on cost efficiency
- **ZUBSOLV®** sales stabilized and opportunities to grow
  - Settlements providing USD 54 billions announced
- DTx revenues expected to build from Q4 and beyond
  - Reimbursement model confirmed
- **R&D pipeline** is expected to result in revenue generating partnerships 2023
  - OX124 filing with the FDA in Q4 2022 (to be commercialized by Orexo)
  - OX640 and amorphOX® partnering discussions on-going

