

# A commercial stage pharma company

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



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# Orexo – a commercial stage pharmaceutical company with an exciting pipeline

A commercial stage pharmaceutical company with three revenue generating pharmaceutical products

Group revenues (LTM)

**634** SEK M

Profitable US commercial operations with a strong focus on one of the largest health crises in the US – opioid dependence








US Pharma EBIT (LTM)

**293** SEK M

New world leading nasal delivery technology - amorphOX® is leading to a new wave of products



# Commercial products and development pipeline

	Product or Project/Indication/Technology		Exploratory	Preclinical	Clinical development phases	Registration	Approved and/or Launched		
							US	EU	RoW
Commercial products	<b>ZUBSOLV®</b> Opioid Use Disorder / Sublingual platform								
	<b>Abstral®</b> Breakthrough Cancer Pain / Sublingual platform								
	<b>Edluar®</b> Insomnia / Sublingual platform								
	<b>Modia®</b> Opioid Use Disorder / Broca technology platform								
	<b>Vorvida®</b> Alcohol management / Broca technology platform								
	<b>Deprexis®</b> Depression / Broca technology platform								
R&D	<b>OX124</b> Naloxone, Opioid Overdose / <b>amorphOX®</b>								
	<b>OX125</b> Nalmefene, Opioid Overdose / <b>amorphOX®</b>								
	<b>OX640</b> Adrenaline, allergic reactions / <b>amorphOX®</b>					2025			
	<b>OX-MPI</b> Vipoglanstat, Endometriosis								

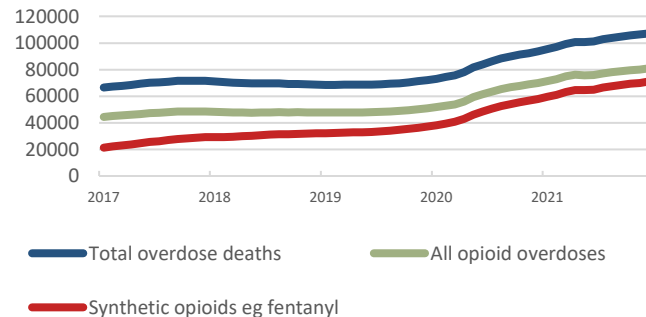


A middle-aged man with grey hair is smiling and looking off to the side. He is wearing a dark blue quilted vest over a plaid shirt and has a backpack on. The background is a blurred natural landscape with trees and a bright sky.

# US Commercial Products

# US market: Commercial products targeting a large unmet need

## Fatal overdoses have surged due to synthetic opioids<sup>1</sup>



**Buprenorphine  
/Naloxone**



**Digital  
Therapy**



**Rescue  
Medication**



Launch expected  
H2 2024

**9,200,000**  
are misusing opioids<sup>2</sup>

**5,600,000**  
are dependent on opioids<sup>3</sup>

**1,800,000**  
are undergoing treatment<sup>4</sup>

Commercial DTx products targeting adjacent disease areas:  
**deprexis®** for depression & **VORV!DA** for alcohol management



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



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

Read more at the **Orexo** blog



A female scientist with dark hair and glasses, wearing a white lab coat, is focused on her work in a laboratory. She is using a blue and white pipette to transfer liquid into a small vial. In the background, other lab equipment and another person in a lab coat are visible, though out of focus. The overall scene conveys a professional and scientific environment.

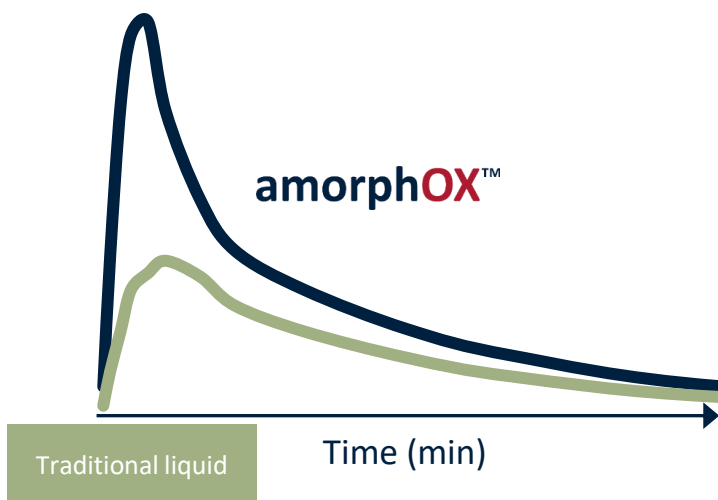
**Products under  
development**

# Orexo's development platform building on the proprietary amorphOX<sup>®</sup> powder technology

## Validated in humans

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

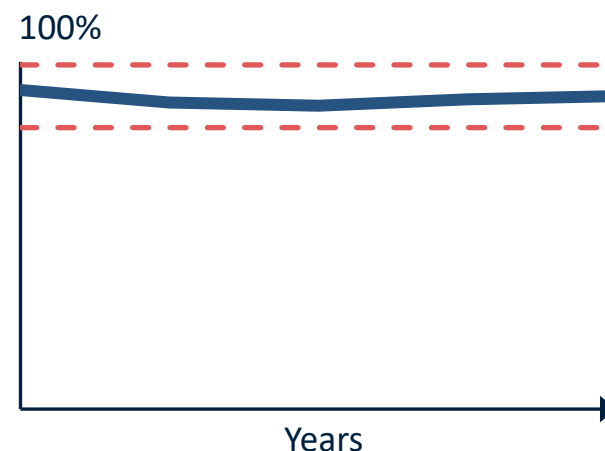
Plasma concentration from clinical trial



## Excellent stability

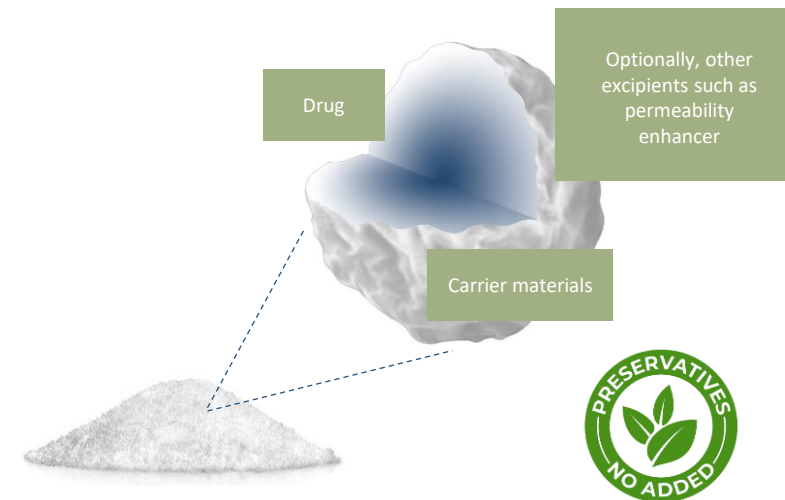
- ✓ Excellent stability even under accelerated conditions and proven to work on a broad scope of API's

Amount of API



## Wide applicability

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



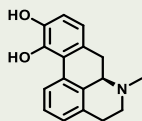


# AmorphOX<sup>®</sup> – a versatile, world-class platform for intranasal drug delivery



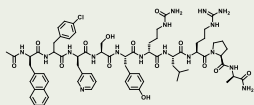
Chemical degradation after accelerated stability studies at 40°C/75% RH

## Apomorphine



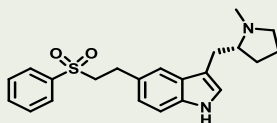
0.4% after 24 months

## Cetrorelix



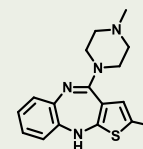
0.5% after 6 months

## Eletriptan



0.5% after 12 months

## Olanzapine



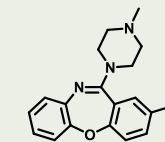
0.2% after 6 months

## Enzyme



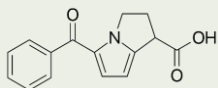
Retained activity after  
1 month

## Loxapine



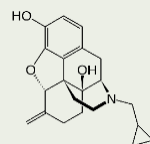
0.3% after 24 months

## Ketorolac



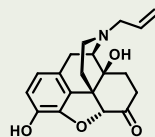
0.8% after 6 months

## Nalmefene



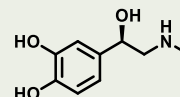
≤0.1% after 15 months

## Naloxone



≤0.1% after 24 months

## Epinephrine



1.8% after 18 months

## Spike protein



Retained activity after  
3 months

## SARS-CoV-2 Spike Protein

- ✓ Successfully formulated in the **amorphOX<sup>®</sup>** platform
- ✓ High production recovery
- ✓ Free-flowing powder
- ✓ Retained activity after formulation and manufacturing
  - Confirmed by binding assay
  - Stability studies ongoing

Feasibility studies ongoing with two leading biopharmaceutical companies where amorphOX<sup>®</sup> is applied to their proprietary API

# OX124 & OX125 – overdose rescue medications

- Significant health issue in the US with >107.000 deaths from overdoses in 2021
- Based on amorphOX® and designed to treat overdoses caused by synthetic opioids, such as fentanyl
- Formulations of OX124 clinically differentiated to market leader and GX of market leader
- **OX124 filing with FDA expected in Q3 2023**



Naloxone

Nalmefene

**Global overdose rescue  
market size 2022 (USD)<sup>1</sup>**

**1,100**  
**m**

*of which approx 650 m refers  
to US<sup>2</sup>*

**Projected global  
annual growth<sup>1</sup>**

**10**  
**%**

<sup>1</sup> <https://www.coherentmarketinsights.com/market-insight/naloxone-market-1804>

<sup>2</sup> Bloomberg

Note: images are prototypes and not final packages



# OX640 – emergency treatment of allergic reactions

- First line treatment today: intramuscular auto-injectors
- OX640 offers clear differentiation to current market leader and products in development
  - Needle free alternative based on amorphOX®
  - Chemically stable and more robust formulation
  - Optimized manufacturing
  - Free of antioxidants and preservatives
- OX640 could be ready for FDA filing in 2025 based on initial FDA feedback on clinical evidence required
- Partnering process initiated for global commercialization



Epinephrine

Epinephrine global market size 2022 (USD)<sup>1</sup>

2,100  
m

Growth rate CAGR 2023-2032<sup>1</sup>

10  
%

**Positive data shown in the clinical phase 1 study**

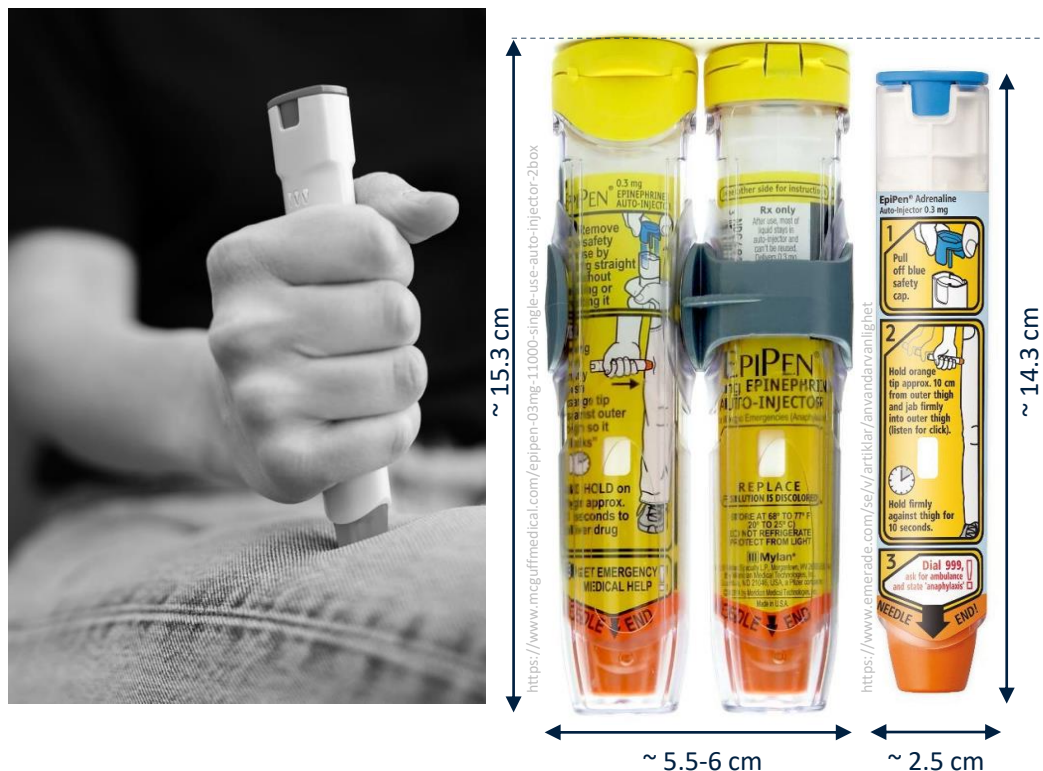


<sup>1</sup> <https://www.precedenceresearch.com/epinephrine-market#:~:text=The%20global%20epinephrine%20market%20size,forecast%20period>



# OX640 - the power to transform emergency treatment of allergic reactions

## Going from this...

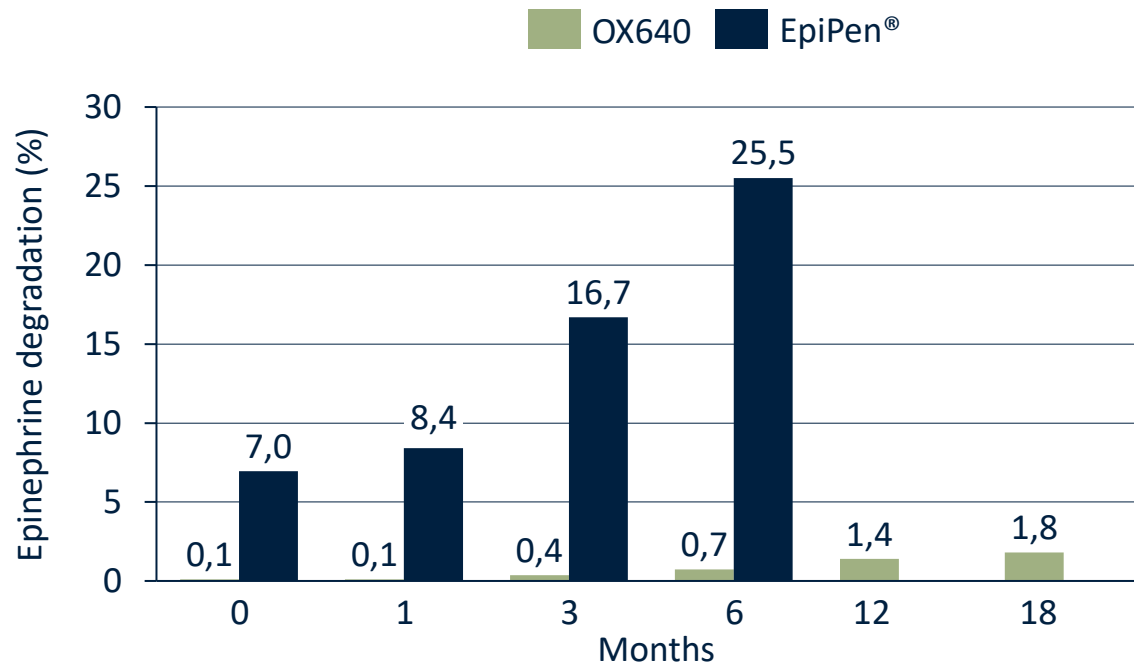


... to this



Images are for representative purpose only

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



OX640 will work  
independent on  
temperature



# Financial overview





## Q2 2023 – improved performance on nearly all financial KPIs

Income statement SEK m	Q2 2023	Q2 2022	H1 2023	H1 2022	FY 2022
Net revenues	158	148	317	307	624
<i>of which US Pharma</i>	145	140	286	279	571
Gross Profit	140	127	271	258	522
OPEX	-153	-176	-343	-322	-706
EBIT	-12	-50	-72	-63	-184
EBITDA	6	-32	-35	-30	-115
Liquid funds	251	468	251	468	352

### Q2 2023 comments

- ✓ Net revenues supported by FX tailwinds and slight ZUBSOLV volume growth
- ✓ Significantly reduced OPEX despite FX headwinds
- ✓ Positive EBITDA

**Financial outlook -> EBITDA expected to be in balance in H2 2023 driven by:**

- Stabilized ZUBSOLV sales, partner revenues and business development
- Lower OPEX from less legal expenses, R&D expenses from clinical trials (MODIA)



# **Future value drivers**

# Several significant milestones near term

- ✓ • **Corporate EBITDA profitability in sight<sup>1</sup>**
  - Increased income from partners
  - Main current external cost drivers will diminish during H2 2023 and significant reduction in direct expenses for DTx
  - No new activities driving external expenses to be initiated without certainty of associated revenues
- ✓ • **ZUBSOLV® sales stabilized and improved access to patients**
  - Settlements providing approximately USD 54 billions announced and new legislation open up for all physician's to prescribe ZUBSOLV®
- **DTx progress with the potential to democratize access to psychosocial support**
  - MATCore® implementation in Arizona and potentially additional states providing grants or subsidies to improve treatment for patients in rural areas or with other hurdles to access OUD treatment
  - Veterans Affairs and restart of Trinity Health implementation
  - MODIA® study result during early autumn
- **R&D pipeline expected to result in revenue generating partnerships in 2023**
  - OX640 and amorphOX® partnering discussions on-going
  - New OX124 FDA filing in Q3 2023 providing a new alternative to save patients with fentanyl overdose
- ✓ • **Decision in SUN IP litigation during the summer of 2023**

<sup>1</sup> Assuming no unexpected events outside the control of Orexo e.g. legal expenses associated with the government investigation or new IP litigations







# Thanks

[www.orexo.com](http://www.orexo.com)