

# A commercial stage pharma company

May 2023

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)

**624** 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)

**299** SEK M

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



# Business model covering the full value chain....

1

## Develops new world leading drug delivery technologies

Developed four commercial pharmaceuticals generating **> SEK 10 billion in global sales**

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

- OX124, OX125, OX640
- Patent and patent applications covering a broad range of molecules until 2039-2042

2

## Commercial operations in the US since 2013 fighting the opioid use disorder (OUD) epidemic

### Significant value contribution from ZUBSOLV®

- >SEK 4.7 billion in sales since launch (SEK ~571 million 2022)

### Pipeline of synergistic overdose rescue medications

- High-dose naloxone - OX124, Fast acting nalmefene - OX125

### New complementary digital health solutions in OUD



3

## Value creating partnerships

### History of partnering with significant value contributions

- Royalties and milestones from partnership for sublingual platform **> SEK 2.3 billion**

### Partner opportunities emerging

- OX640 (epinephrine)
- AmorphOX® technology in biomolecules



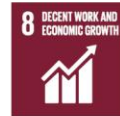


# .... grounded in sustainability

**At the core of a sustainable society are health and well-being, areas where Orexo makes significant impact**

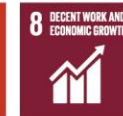
## ■ Responsible business

Responsible business based on trust, transparency, integrity and no tolerance for corruption is central to all our activities and a foundation for our sustainability work



## ■ Sustainable employees

In all our teams, create a healthy working climate where inclusion and diversity are a matter of course



## ■ Access to healthcare

Increase access to healthcare by patient support and strengthening knowledge of substance abuse and mental illness



## ■ Environment and Climate change

Our ambition is to reduce our impact on environment and climate change across all our activities and our products

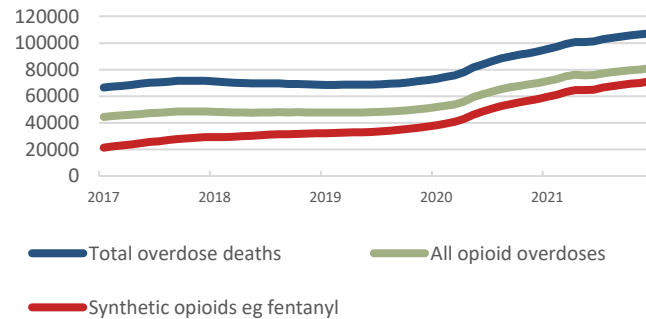


A middle-aged man with grey hair is smiling and looking off to the side. He is wearing a dark blue quilted vest over a blue and white plaid shirt. He has a black backpack on, and his hands are resting on the straps. The background is a blurred desert landscape with dry bushes and hills under a bright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

# US Commercial

# 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.”**



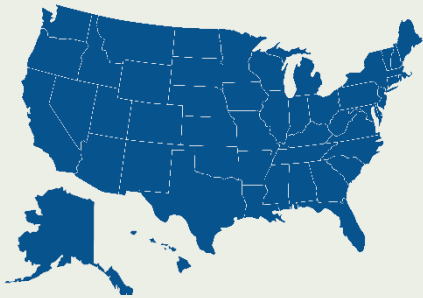
Elise discovered her daughter's opioid dependence months before she died from an overdose.

Read more at the **Orexo** blog

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

## Net revenues since launch 2013 (SEK m)

4,700  
m



## Market & Sales dynamic

### Market growth of 6%

- Expected to increase with improved access and financing

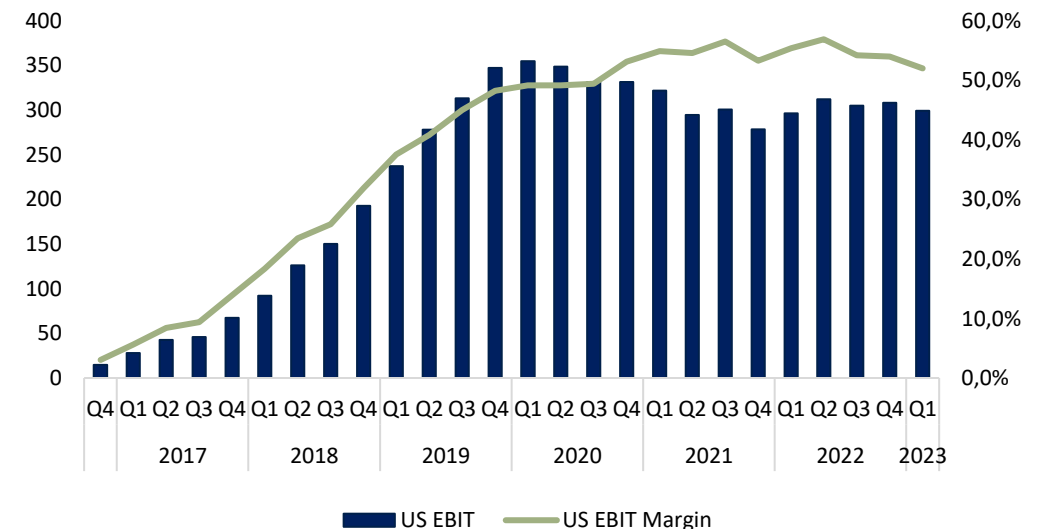
**ZUBSOLV® demand stabilizing** with with -2% versus Q4 2022 and -4% versus Q1 2022

- Continued stabilization in Q2
- Partly compensated by price increase in January

**ZUBSOLV® maintain & strengthen reimbursement** in competitive market

- Commercial access of 98%
- Public access of 47%

## US Pharma EBIT (SEK m) and EBIT margin (%) LTM<sup>1</sup>



**SEK 571 m in net revenues in 2022**

<sup>1</sup> Last Twelve Months



A female scientist with dark hair and glasses, wearing a white lab coat, is focused on her work. She is using a blue and white pipette to transfer liquid into a small vial. In the background, another person in a lab coat is visible, also working. The laboratory is filled with various glassware, including test tubes and beakers, some containing liquids. The overall atmosphere is professional and scientific.

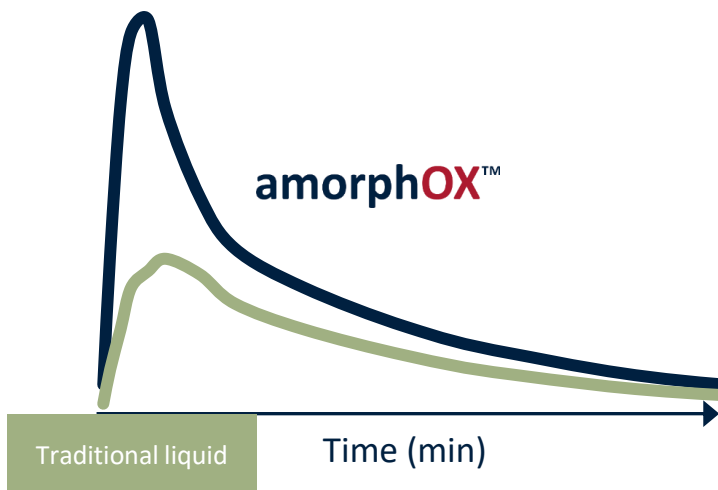
**Products under  
development**

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

## Validated in humans

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

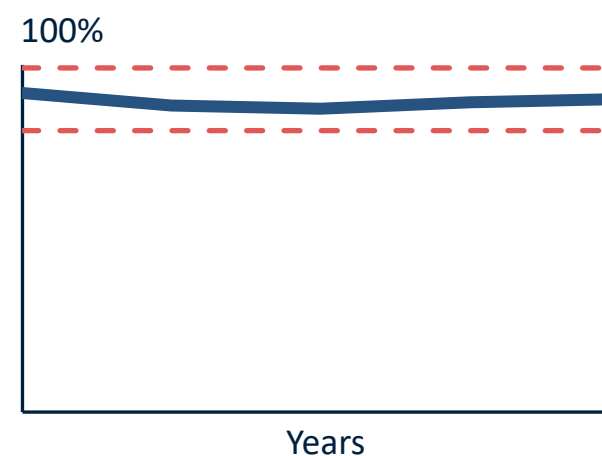
Plasma concentration from clinical trial



## Excellent stability

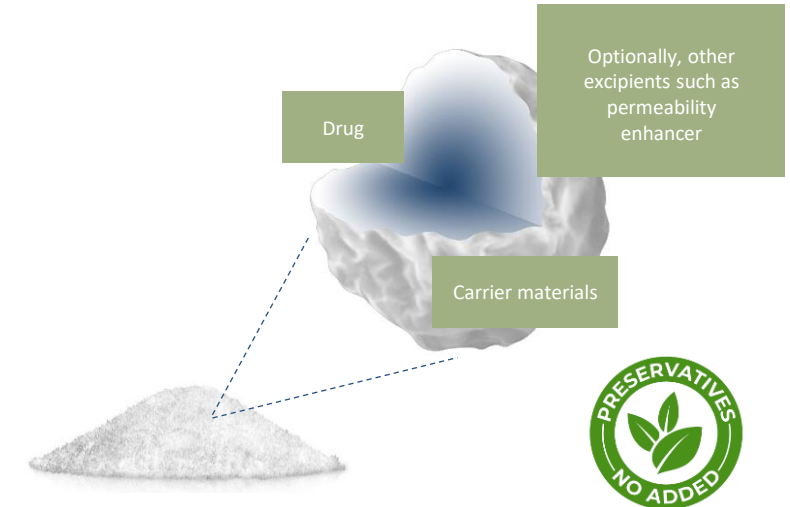
- ✓ Excellent stability even under accelerated conditions and proven to work on a broad scope of API's

Amount of API



## Wide applicability

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



## Feasibility study ongoing with two leading biopharmaceutical companies of amorphOX<sup>®</sup> 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 (USD)<sup>1</sup>**

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

*of which 450 m refers to US*

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

**10**  
**%**

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

Auto-injector global market size (USD)

4,000  
m

*of which 2,200 m refers to US*

Projected global annual growth

9  
%

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

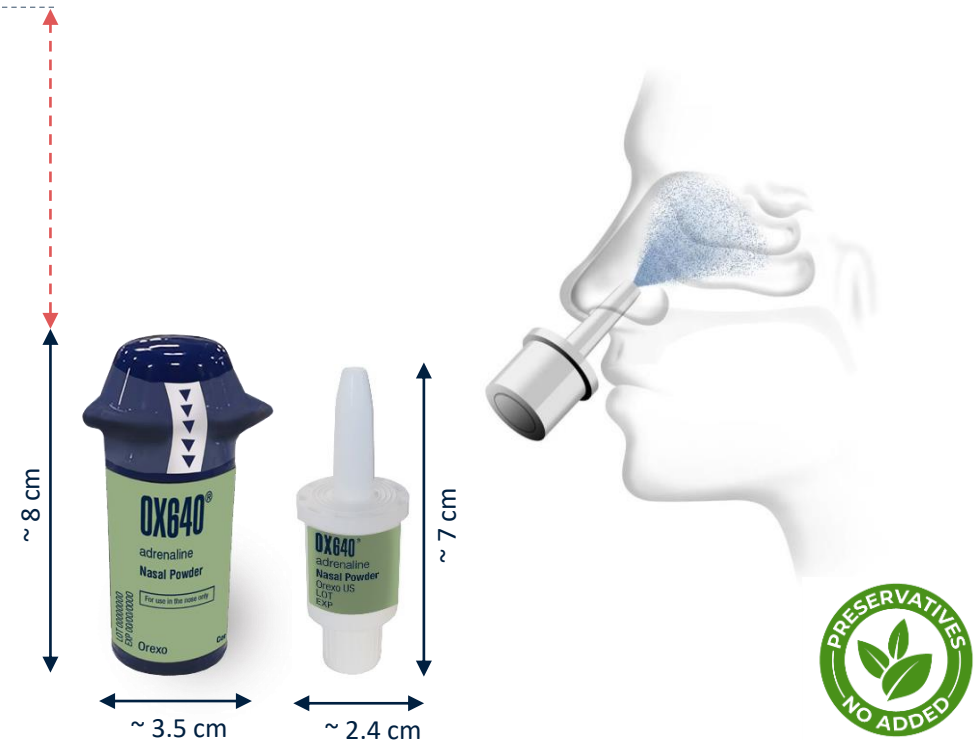


# OX640: The power to transform emergency treatment of allergic reactions

Going from this...

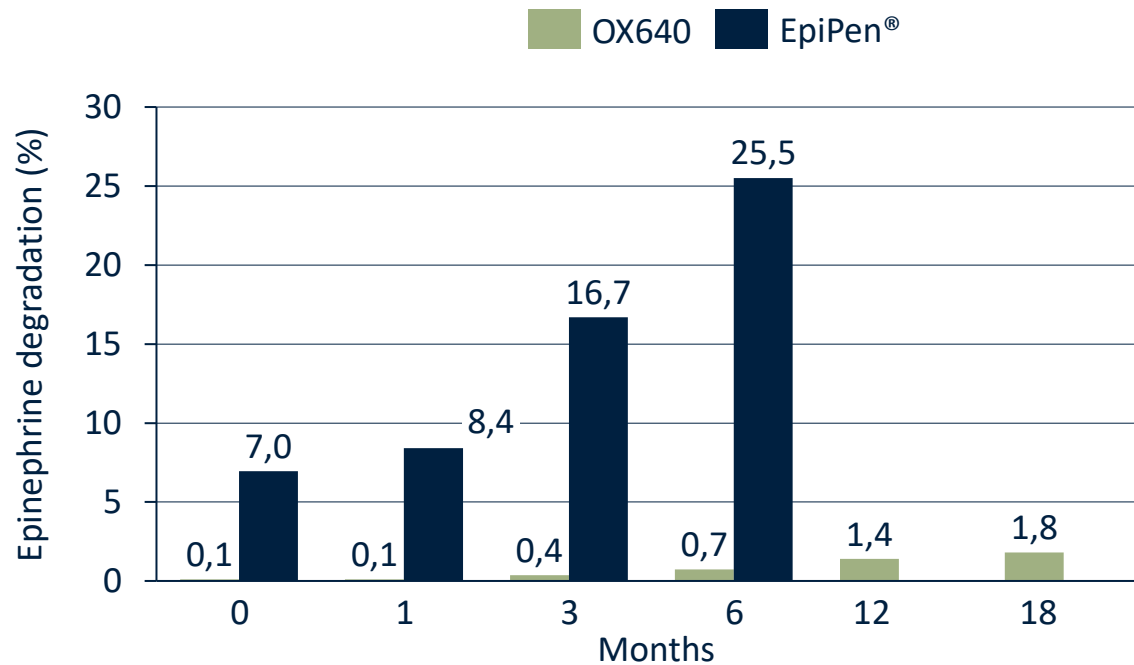


... to this



Images are for representative purpose only

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



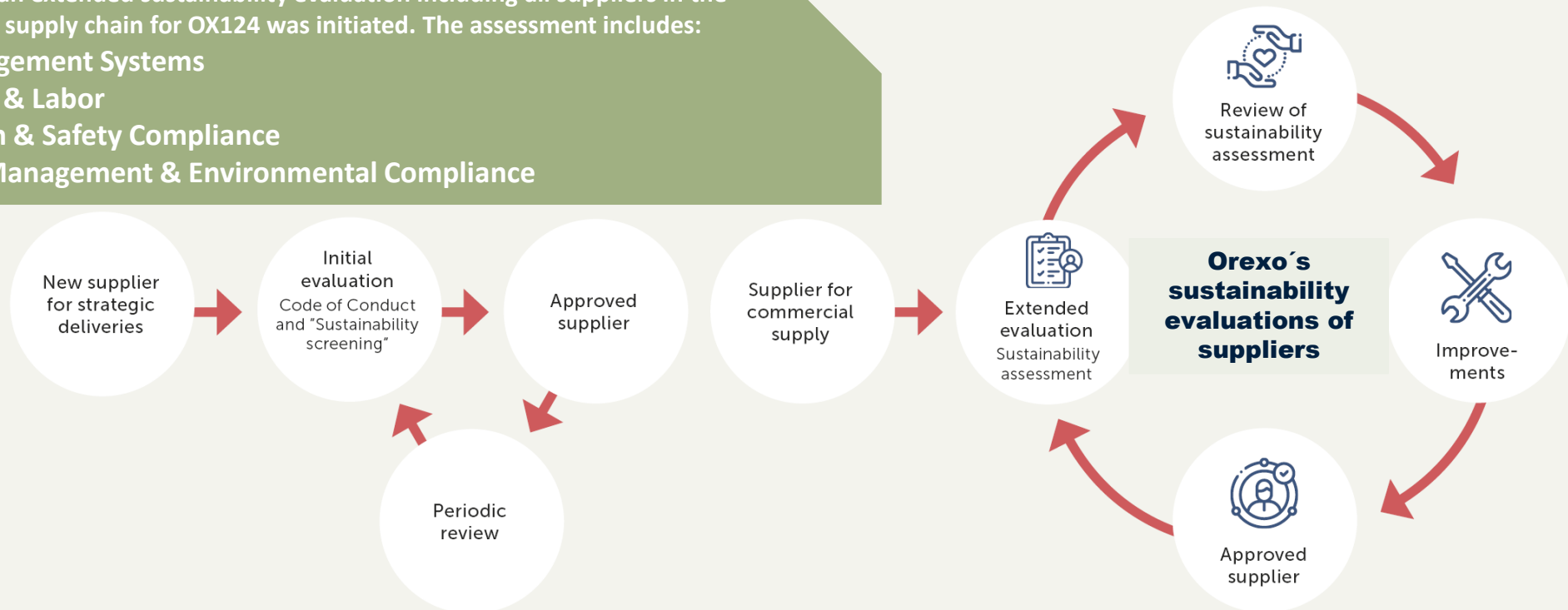
OX640 will work  
independent on  
temperature



# Sustainability at the core of establishing the supply chain for nasal delivery products

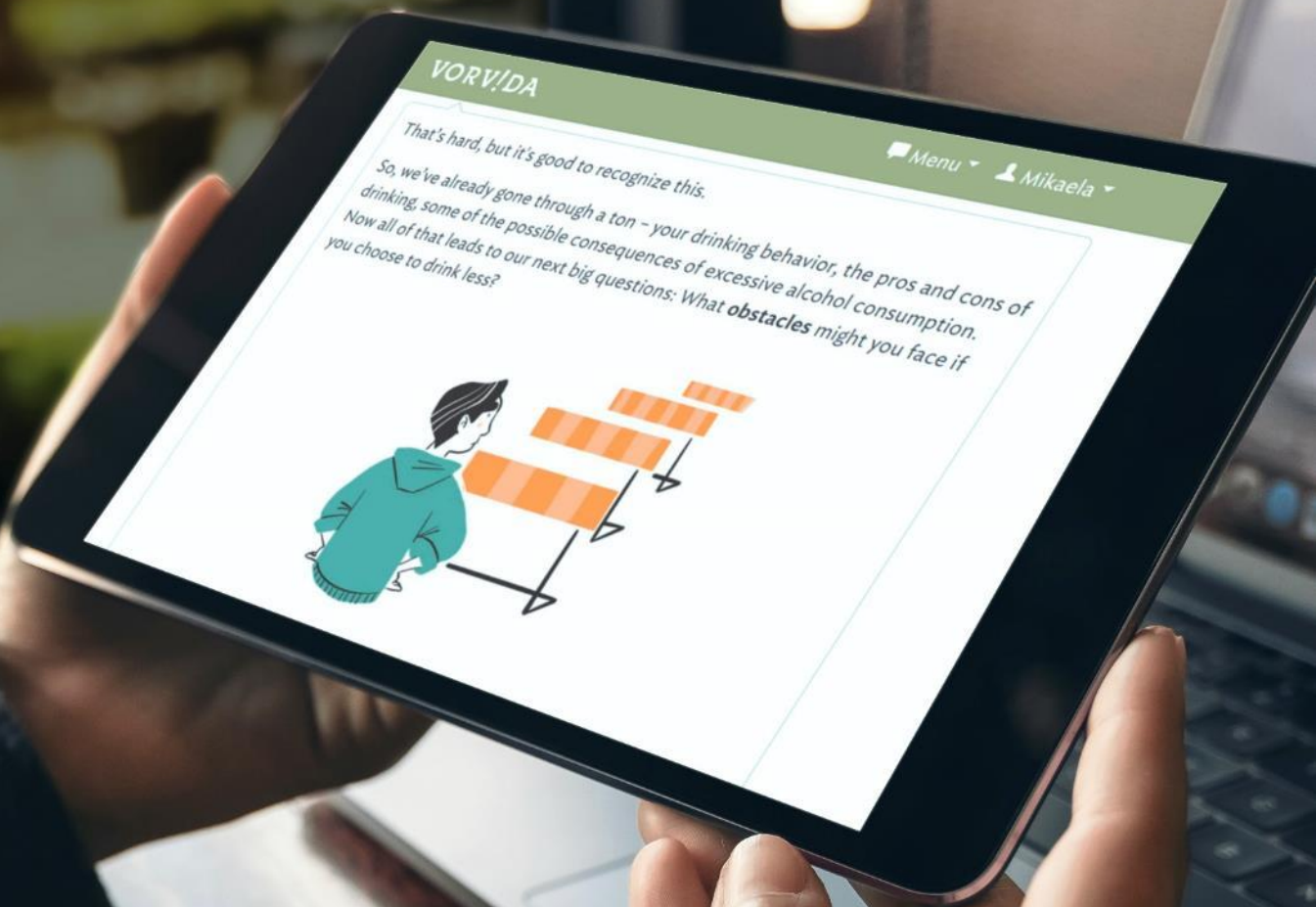
In Q1 2023 an extended sustainability evaluation including all suppliers in the commercial supply chain for OX124 was initiated. The assessment includes:

- Management Systems
- Ethics & Labor
- Health & Safety Compliance
- Risk Management & Environmental Compliance





# Financial & legal overview



## 2022/2023 - A transformative period building for future growth

- Significant investments in developing the pipeline, 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 LTM

**624** SEK M

US Pharma net revenues LTM

**572** SEK M

EBITDA LTM

**-159** SEK M

US Pharma EBITDA LTM

**299** SEK M

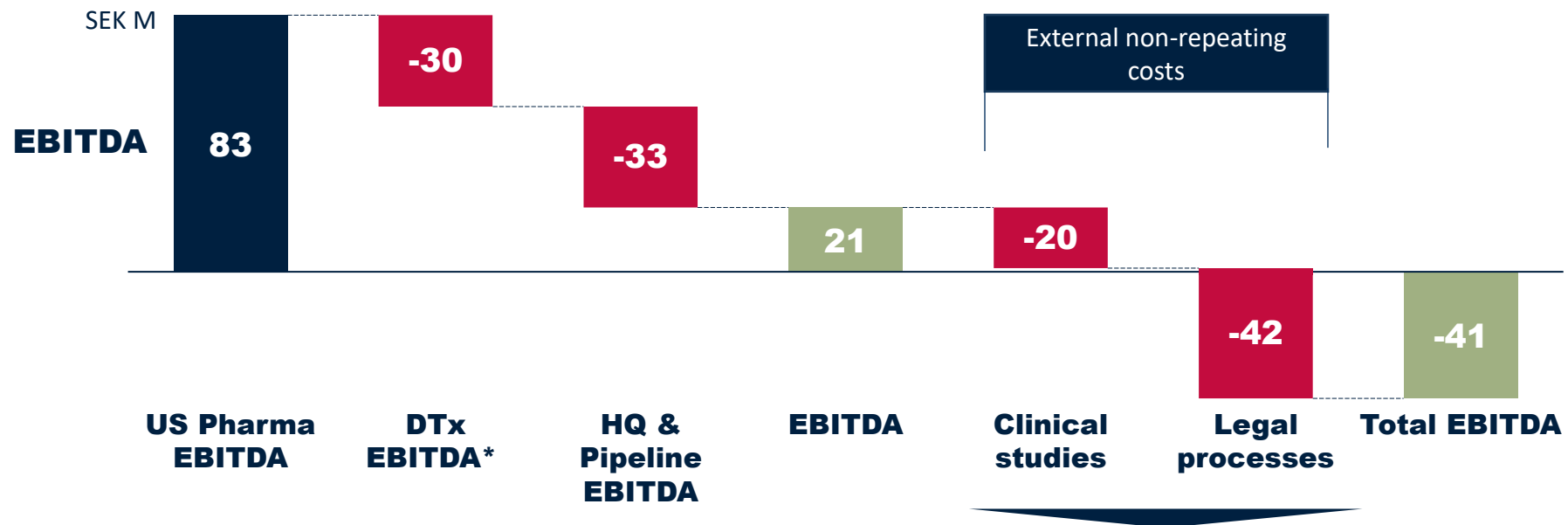
Cash position Q1 2023

**279** SEK M

US Pharma EBIT margin LTM

**52** %

# Q1 2023 EBITDA positive excluding external non-repeating costs



- MODIA® study
- OX640 project
- OX124 project
- Sun Litigation
- Subpoena

\* DTx EBITDA including internal allocations from US Pharma

# Legal update

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

- ✓ In Q1 2023 the trial was conducted in the US District Court for the District of New Jersey.

### **Overall strong IP rights for ZUBSOLV®:**

- In total 10 patents listed in the Orange Book
- Patent expiring dates Dec. 2027 – Sep. 2032
- Previously successfully managed to defend ZUBSOLV® IP rights in the US appeal court

**The outcome of the trial is expected during the summer of 2023**

## **US authorities' investigation with regards to ZUBSOLV® promotion**

- ✓ In Q1 2023 additional information have been shared at the request of the authorities
- ✓ Orexo continues to cooperate with the authorities and provide the requested documentation related to the promotion of ZUBSOLV®





# **Future value drivers**

# Several significant milestones near term

- **Corporate 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 approx. USD 54 billions announced and new legislation open up for all physician's to prescribe ZUBSOLV®
- **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
- **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 access OUD treatment
  - VA and restart of Trinity Health implementation
  - MODIA® study result during the summer
- **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

**The opioid crisis is one of the largest health crises in the US in modern times. Our core commitment is to improve these people's lives with pioneering and holistic treatment solutions.**

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