

# Important steps forward in a challenging environment

March, 2023

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 mental illness and substance use disorders, or other areas where our technologies can create values

**3**

Expanding pipeline based on the novel proprietary technology platform **amorphOX®**

**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 2022, SEK 308 m)

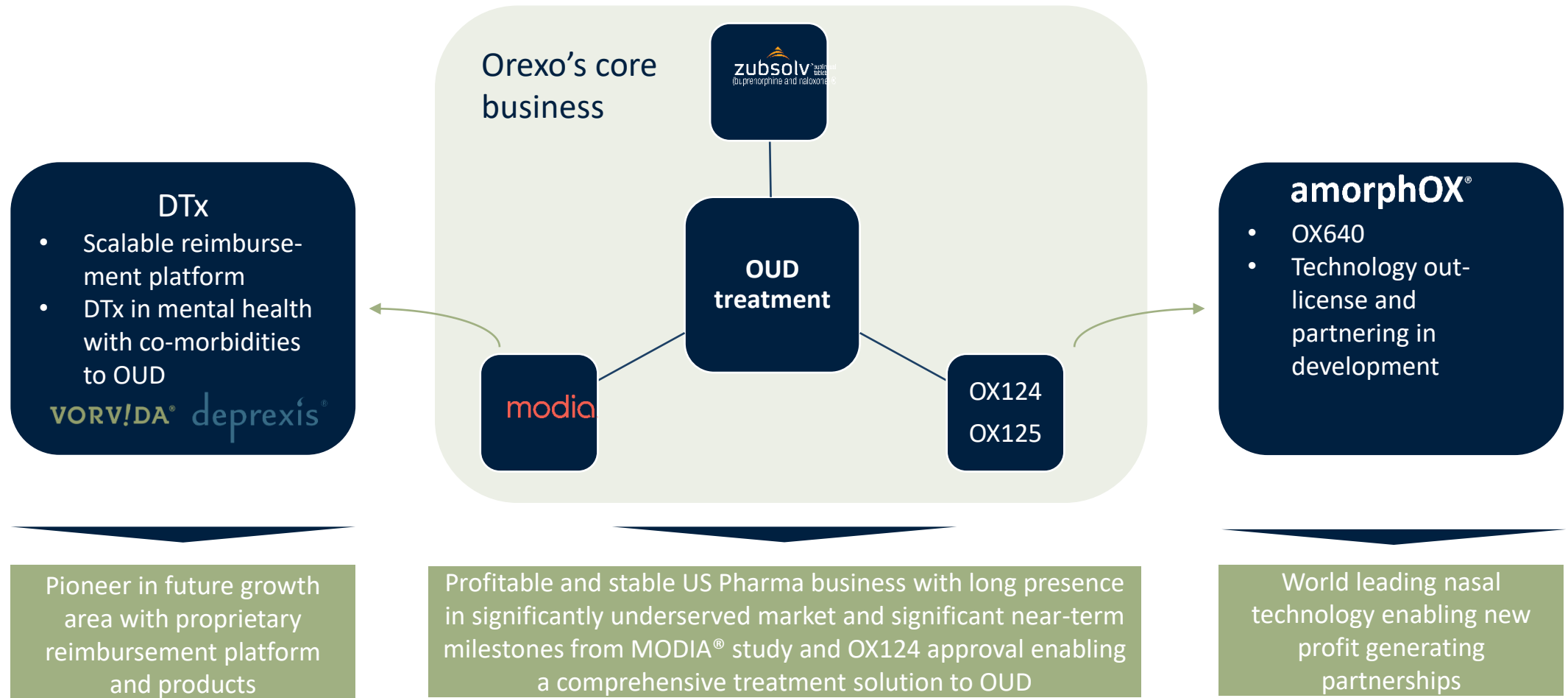


# Commercial products and development pipeline

Pharmaceuticals												
Product or project/ indication/technology		Exploratory	Preclinical	Clinical development phases				Registration	Approved and/or Launched			
									US	EU	RoW	
<b>ZUBSOLV®</b> Opioid Use Disorder/ <b>sublingual platform</b>												
<b>Abstral®</b> Breakthrough Cancer Pain/ <b>sublingual platform</b>												
<b>Edluar®</b> Insomnia/ <b>sublingual platform</b>												
<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>												
<b>OX-MPI</b> Endometriosis												
Digital Therapeutics												
		Exploratory	Development				Registration					
 <b>modia</b> Opioid Use Disorder												
 <b>VORV!DA®</b> Alcohol management												
 <b>deprexis®</b> Depression												



# A strong focus on opioid misuse






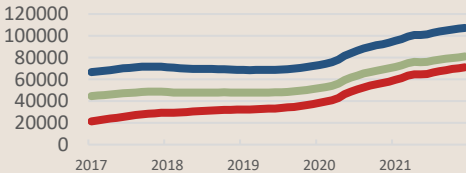


# US Commercial





# US market: Commercial products targeting a large unmet need

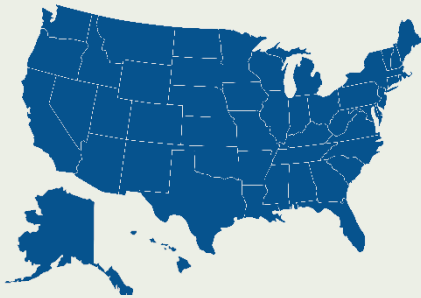
Opioid dependence		Alcohol management	Depression
   OX124 (expected H1 2024)		VORV!DA	deprexis®
Overdose deaths surpassed <b>107 000</b> in 2021, fueled by use of synthetic opioids such as fentanyl		<b>10m</b> are misusing opioids	<b>17m</b> are heavy alcohol users
 <p>             — Total overdose deaths              — All opioid overdoses              — Synthetic opioids eg fentanyl           </p>		<b>20m</b> are suffering from at least one major depression annually	
		<b>1.8</b> in treatment	<b>1.5m</b> in treatment
			<b>10m</b> in treatment



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

## Net revenues since launch 2013 (SEK m)

**4,500**  
m



## Market dynamic

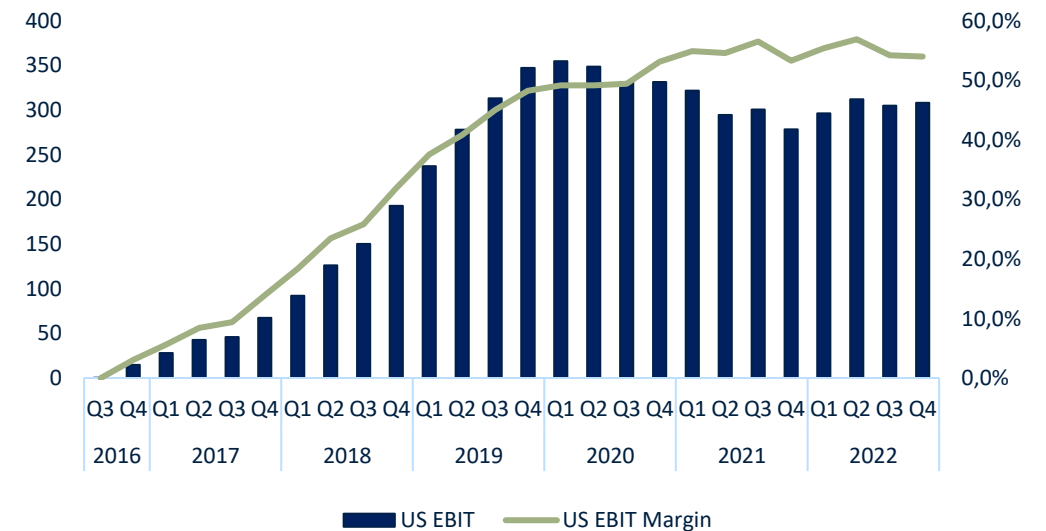
Sales volume stabilizing during 2022

- 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

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



**SEK 571 m revenues in 2022**

<sup>1</sup> Last Twelve Months



# Market is likely to expand due to legislative changes and access to financing

## New legislation approved by US Congress December 28<sup>th</sup>

- Market 2002-2022 limited prescription to “DATA-2000” waived physician and had significant administrative requirements
- Market 2023- allow nearly all physicians to prescribe

## USD 54 billion from settlements in opioid litigations in the US

- Money started to be paid late 2022 and will continue in the years to come with significant sums earmarked to OUD treatment and prevention
- In collaboration with Alay Psychiatry in Arizona Orexo received first grant for implementation of a solution combining DTx, patient information and medication in December 2022 (MATCore™)



# **DTx comes with a lot of promise and potential, but yet to materialize**

**MODIA® focusing on gaining acceptance in OUD clinics**

- >2000 patients received MODIA® in 2022
- Good progress in gaining reimbursement through medical benefits
- MODIA® is included in the MATCore™ platform to be implemented in Arizona

**Large health care provider networks and Veterans Affairs main channels for vorvida® and deprexis® in 2023**

- 10 year contract signed with VA in 2022
- Contract with Trinity Health and first patients received a DTx

**Slow start of DTx lead to a review of the business and integration into US Pharma by Feb 1, 2023**







# Research & Development

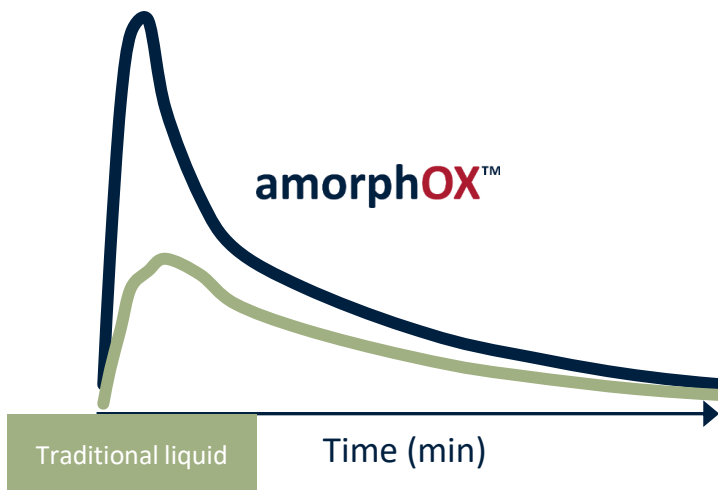


# Orexo's development platform building on the proprietary amorphOX<sup>®</sup> technology

## Validated in humans

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

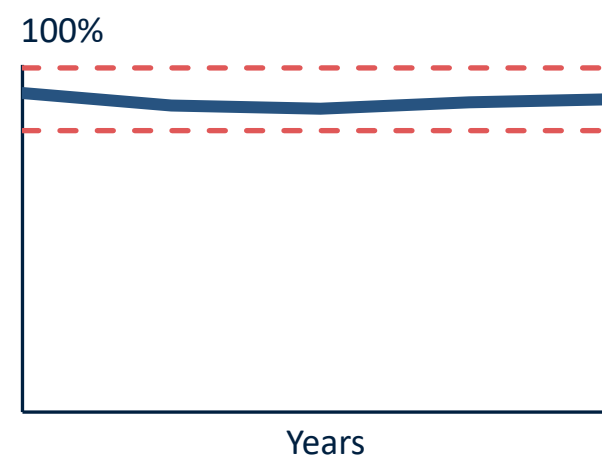
Plasma concentration from clinical trial



## Excellent stability

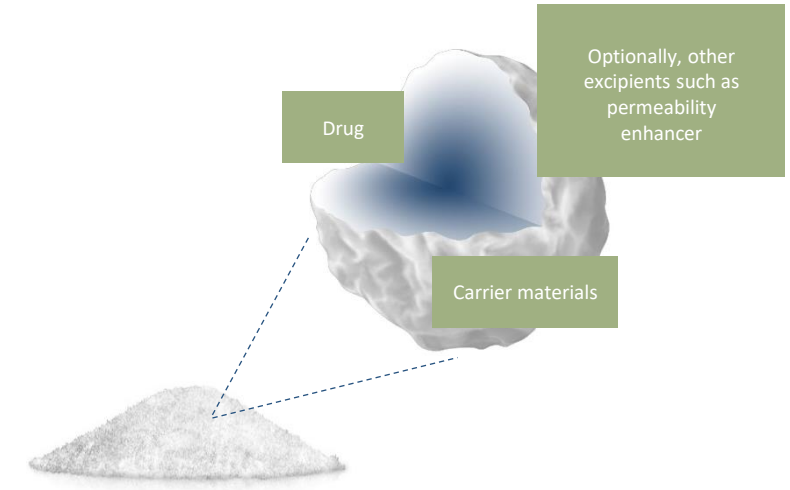
- ✓ Excellent stability even under accelerated conditions and proven to work on a broad scope of API's

Amount of API



## Wide applicability

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

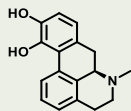




# amorphOX<sup>®</sup> – a versatile, world-class platform for intranasal drug delivery

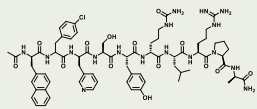
Chemical degradation after accelerated stability studies at 40°C/75% RH

## Apomorphine



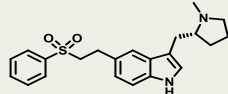
0.3% after 18 months

## Cetrorelix



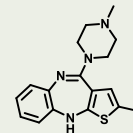
0.4% after 3 months

## Eletriptan



0.5% after 3 months

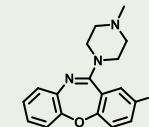
## Olanzapine



## Enzyme

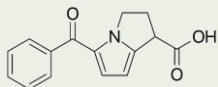


## Loxapine



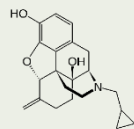
0.3% after 6 months

## Ketorolac



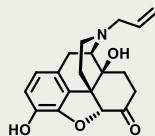
0.8% after 6 months

## Nalmefene



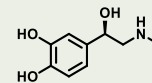
≤0.1% after 15 months

## Naloxone



≤0.1% after 12 months

## Epinephrine



0.5% after 6 months

## Spike protein



## 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 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
- OX124 clinically differentiated to market leader and GX of market leader
- **OX124 filed with FDA in February 6<sup>th</sup> 2023**



Naloxone

Nalmefene

<sup>1</sup> <https://www.coherentmarketinsights.com/market-insight/naloxone-market-1804>  
Note images are prototypes and not final packages

**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**  
**%**



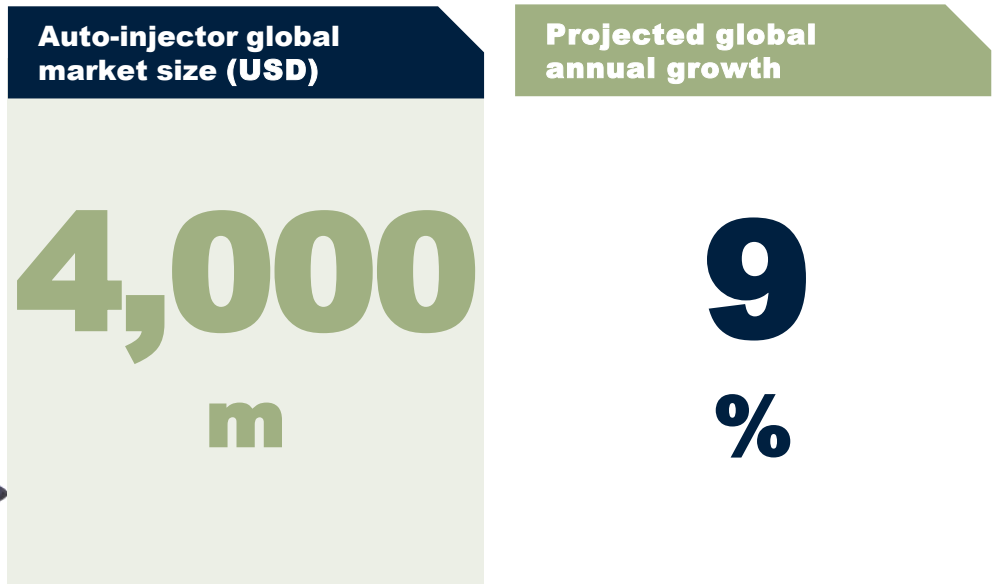
# OX640 – emergency treatment of allergic reactions

- 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**



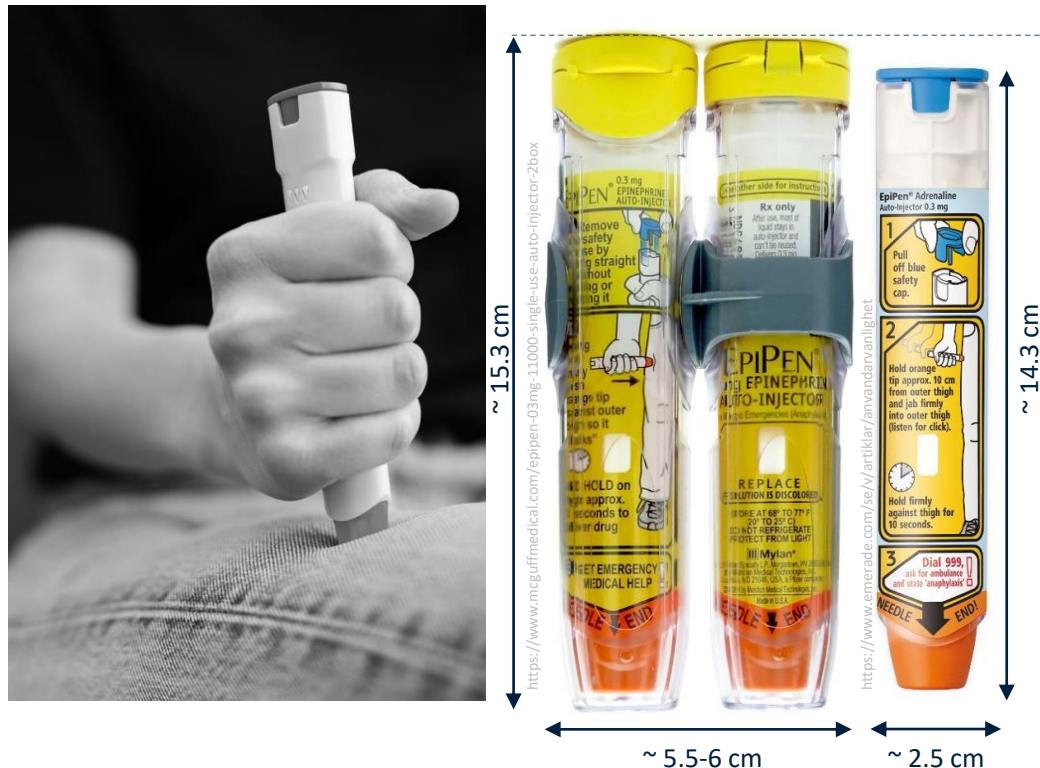
Epinephrine





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

Going from this...



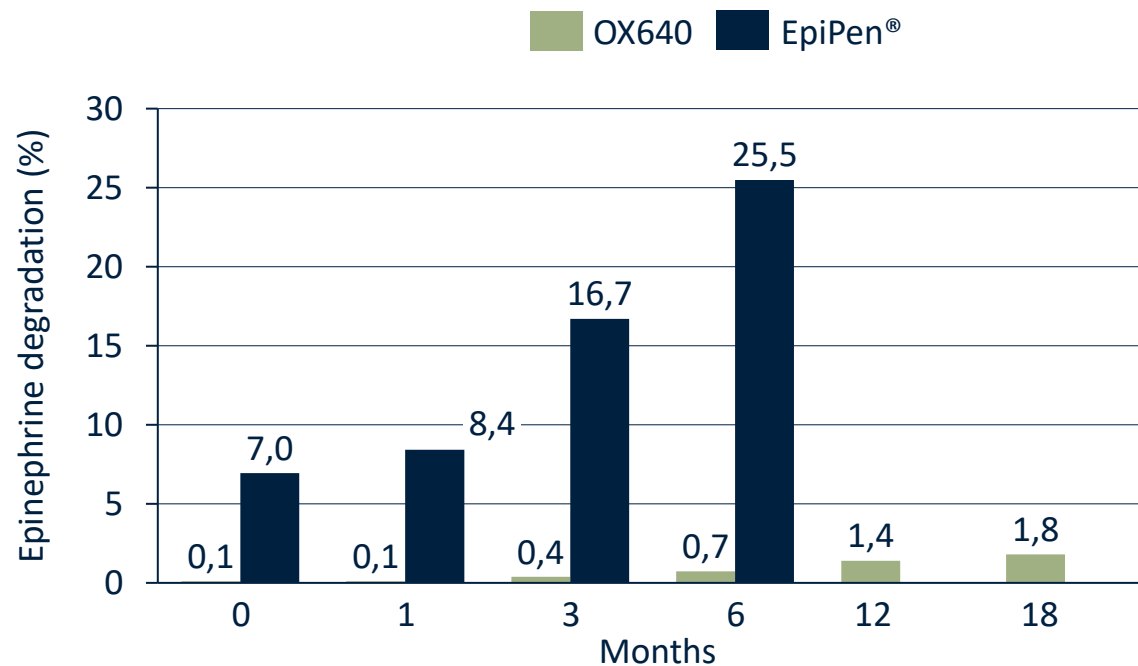
... to this



Images are for representative purpose only



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



Partnering process initiated for global commercialization



OX640 will work  
independent on  
temperature



# Financial & legal





## 2022 - 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

**624** SEK M

### US Pharma net revenues

**571** SEK M

### EBITDA

**-115** SEK M

### US Pharma EBITDA

**308** SEK M

### Cash position

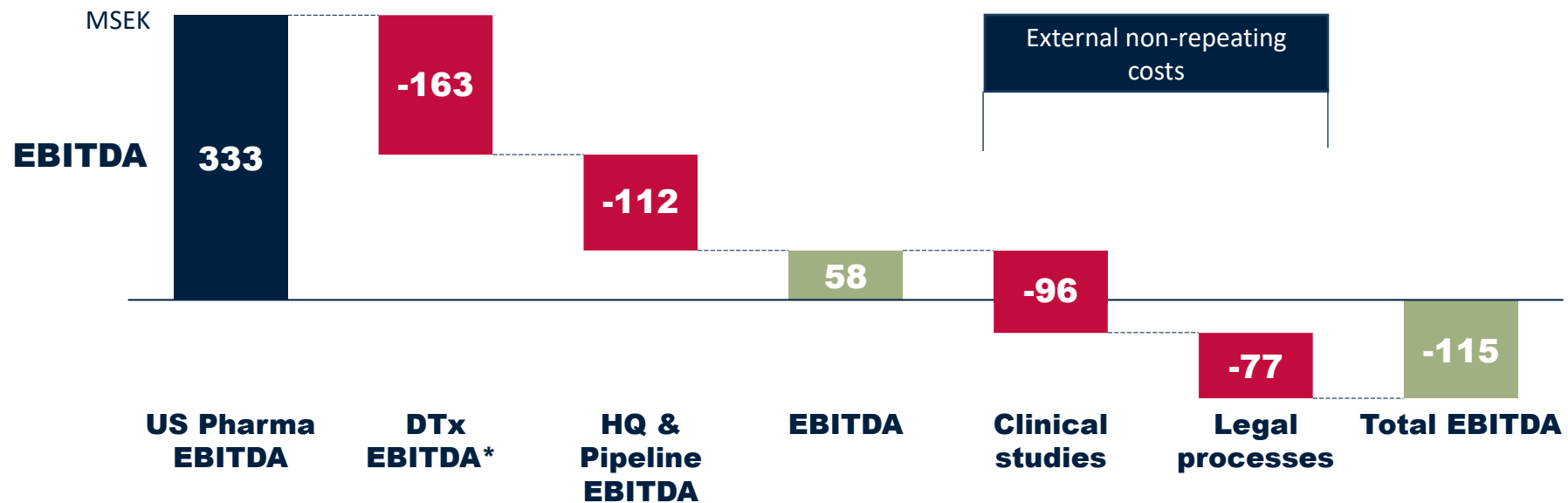
**352** SEK M

### US Pharma EBIT margin

**54** %



# Orexo core FY EBITDA positive excluding external non-repeating costs



## Completed

- MODIA® phase III Q2, 2023
- OX640 phase I Q4, 2022
- OX124 HF studies Q4, 2022
- Sun Litigation Q1, 2023 (District Court)
- Subpoena TBD

\* DTx EBITDA including internal allocations from US Pharma



## Q4 legal update

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

- ✓ Trial completed in the US District Court in the District of New Jersey, February 3<sup>rd</sup>

#### **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

30 month stay expires in February, but no generic expected prior to final court decision

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

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

- ✓ No material activities in Q4 and YTD 2023





# **Future value drivers**



# Why Orexo?

## ✓ **Corporate profitability** in sight<sup>1</sup>

- Main external cost drivers will diminish during H2 2023
- No new activity driving external expenses to be initiated without certainty of associated revenues
- Significant focus on cost efficiency

## ✓ **R&D pipeline** is expected to result in revenue generating partnerships during 2023

- OX124 filing with the FDA February 6<sup>th</sup>
- OX640 and amorphOX® partnering discussions on-going

## ✓ **DTx revenues** expected to build from Q1 2023 and beyond

- Reimbursement model confirmed

## ✓ **ZUBSOLV® sales** stabilized and opportunities to grow

- Settlements providing USD 54 billions announced
- New legislation open up for all physician's to prescribe ZUBSOLV®
- Decision in the patent litigation by the District Court of New Jersey

<sup>1</sup> Assuming no unexpected events outside the control of Orexo





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