



**Rooted  
in science,  
proven in  
market**

**amorphOX<sup>®</sup>**



my green lab  
certification.

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# This is Orexo



Orexo is a pharmaceutical company dedicated to developing innovative medicines that save lives and address severe diseases.

## Our heritage

Founded in Uppsala, Sweden, with the vision to improve drugs, by combining well-known substances with proprietary drug delivery technologies.

**30** yrs

of experience developing improved pharmaceuticals based on proprietary drug delivery technologies.

## amorphOX® - next-generation technology

AmorphOX® is a powder-based drug delivery technology that improves bioavailability and stability for small and large molecules, unlocking new administration and manufacturing options.

**novo holdings**  
Investing to benefit people and the planet

- largest shareholder at 26 %

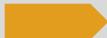
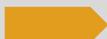
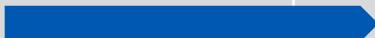
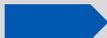
## Development pipeline

The pipeline spans multiple therapeutic areas and delivery routes, accelerating the development of new pharmaceuticals.

**SEK 912 m**

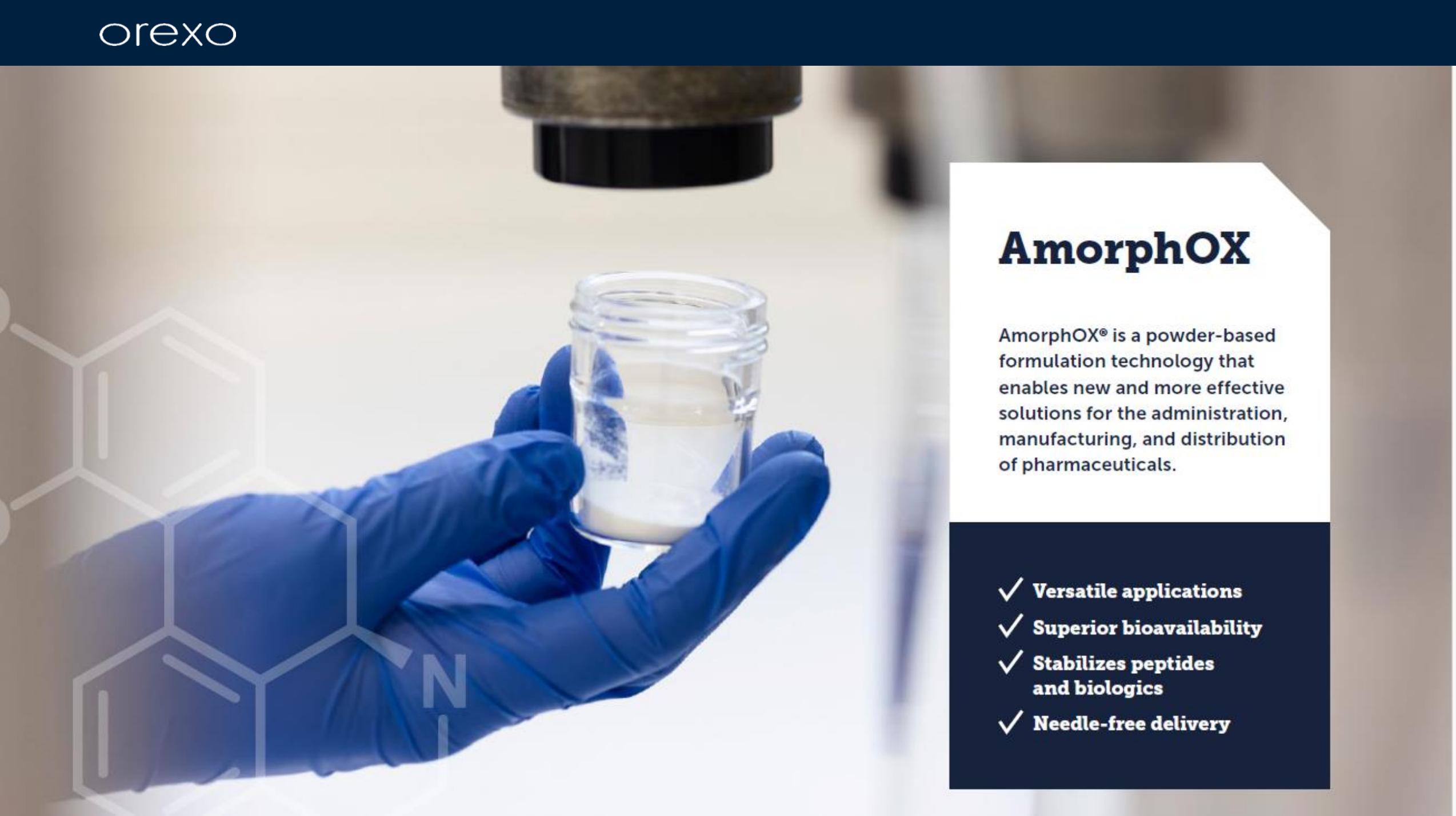
Cash position Dec. 31 2025

# Development pipeline and approved products<sup>1</sup>

		Technology	Partnership	Preclinical	Clinical	Registration	Approved	
	<b>Development program</b>							
Exploratory/ Large molecules	OX472 GLP-1 agonist, semaglutide	<b>amorphOX<sup>®</sup></b>	–					
	Vaccine, influenza	<b>amorphOX<sup>®</sup></b>	–					
Own projects/ Small molecules	OX640, epinephrine, incl. anaphylaxis	<b>amorphOX<sup>®</sup></b>	–					
	OX390, NCE, overdose caused by adulterated drugs	<b>amorphOX<sup>®</sup></b>						
	Izipry™, naloxone, overdose caused by opioids	<b>amorphOX<sup>®</sup></b>	–					
	<b>Launched products<sup>1</sup></b>							
	Zubsolv <sup>®</sup> US, opioid dependence	Sublingual platform						US
	Zubsolv EU, opioid dependence	Sublingual platform	<b>accord</b>					EU
	Abstral <sup>®</sup> , breakthrough cancer pain	Sublingual platform						EU, US, RoW
	Edluar <sup>®</sup> , insomnia	Sublingual platform						EU, US, RoW

 targeting serious diseases or pathogens       rescue medications

<sup>1</sup>. Products based on first-generation drug delivery technology – the sublingual platform. Approved markets are all markets, also where patents have expired. For Zubsolv US, Dexcel Pharma USA acquired all rights as of December 31, 2025.



## **AmorphOX**

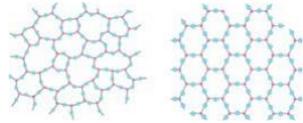
AmorphOX® is a powder-based formulation technology that enables new and more effective solutions for the administration, manufacturing, and distribution of pharmaceuticals.

- ✓ **Versatile applications**
- ✓ **Superior bioavailability**
- ✓ **Stabilizes peptides and biologics**
- ✓ **Needle-free delivery**

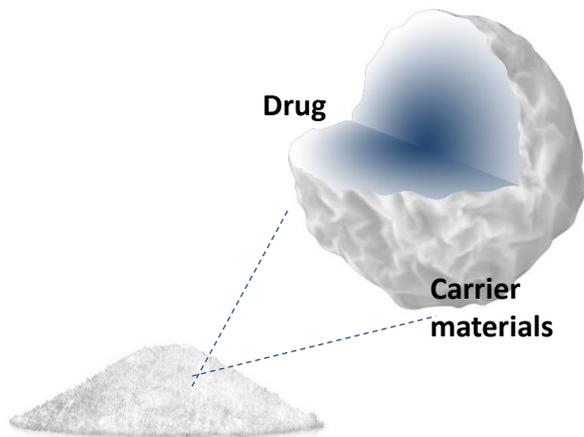
# AmorphOX<sup>®</sup> is a unique drug delivery technology

## The challenge

Amorphous materials, commonly used in drug development, are rapidly absorbed but tend to be unstable limiting routes of administration, distribution and storage



## The solution – AmorphOX, a powder-based technology



## AmorphOX unique strengths

### 1 AmorphOX unique properties ensure physical and chemical stability

- ✓ Withstands high and low temperatures
- ✓ Stability maintained over time

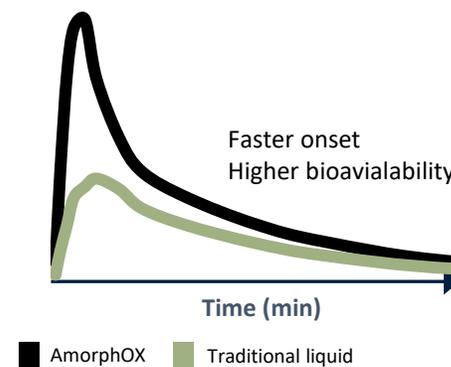
Examples: Chemical degradation after accelerated stability studies at 40°C/75% RH

<b>Small molecules</b> Ephinephrine 0.3% after 24 months	
<b>Peptides</b> Cetrorelix 0.6% after 12 months	
<b>Biologics</b> Protein (spike protein) Retained activity after 3 months (40°C)	

### 2 AmorphOX is validated in multiple clinical trials

- ✓ Izypry™ – high-dose rescue medication (naloxone)
- ✓ OX125 – overdose rescue medication (nalmefen)
- ✓ OX640 – adrenaline product for anaphylaxis

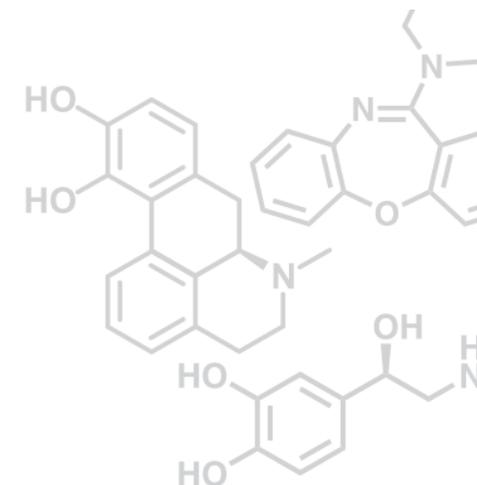
Plasma concentration from clinical trial



### 3 AmorphOX is a versatile platform

Improves:

- ✓ Small molecules
- ✓ Peptides
- ✓ Biologics



# The scalable AmorphOX<sup>®</sup> platform takes Orexo beyond the OUD treatment area

Small

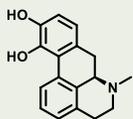
Molecular weight (Mw)

Large

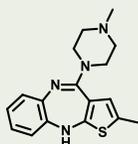
Small molecules

Peptides

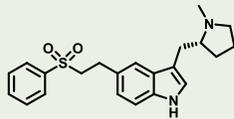
Biologics

**Apomorphine**

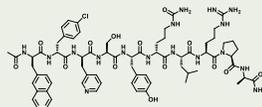
0.2% after 24 months

**Olanzapine**

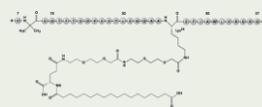
0.2% after 6 months

**Eletriptan**

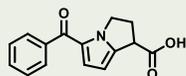
0.5% after 12 months

**Cetorelix**

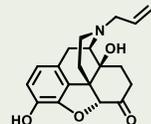
0.6% after 12 months

**Semaglutide**

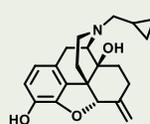
0.1% after 12 months

**Enzyme**Retained activity after  
1 month (40°C)**Virus like  
particle**Retained structure after  
processing and after  
3 months at 40°C**Attenuated  
Virus**Retained titer levels,  
resilient to freeze thaw  
cycles**Ketorolac**

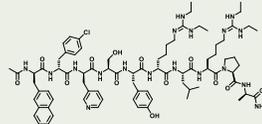
0.8% after 6 months

**Naloxone**

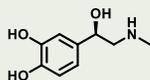
≤0.1% after 24 months

**Nalmefene**

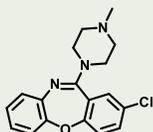
≤0.1% after 15 months

**Ganirelix**

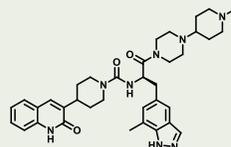
0.7% after 12 months

**Covid Spike  
protein**Retained activity after  
3 months (40°C)**Epinephrine**

0.3% after 24 months

**Loxapine**

0.3% after 24 months

**Zavegepant**

≤0.1% after 9 months

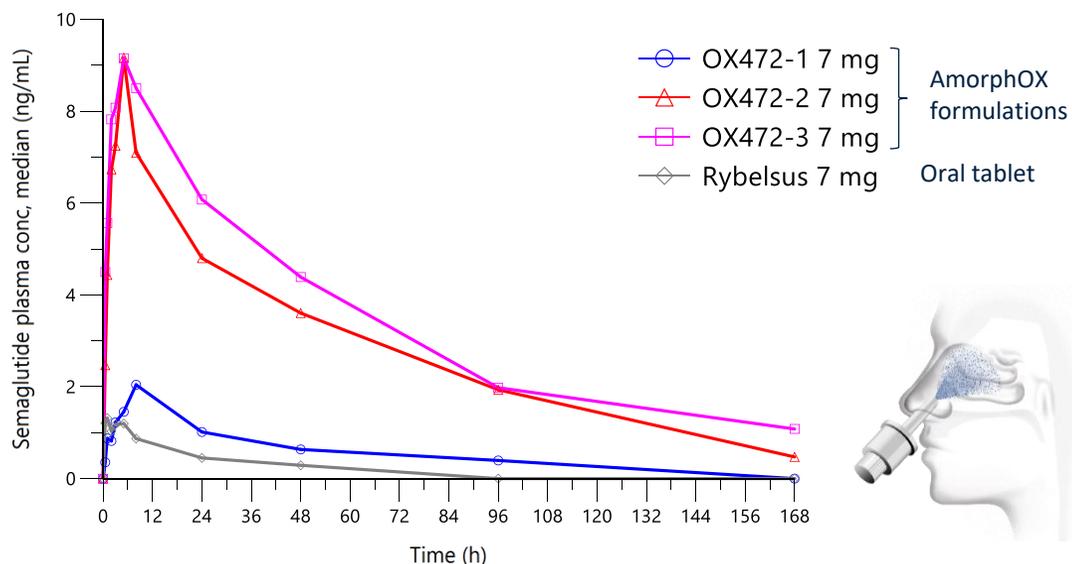
**Immuno-  
modulator**99% purity after  
1 month (50°C)

Examples of both internal and  
partnered projects

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

# Early stage projects: AmorphOX<sup>®</sup> in large molecules

## In-vivo proof-of-concept study of nasal semaglutide powders

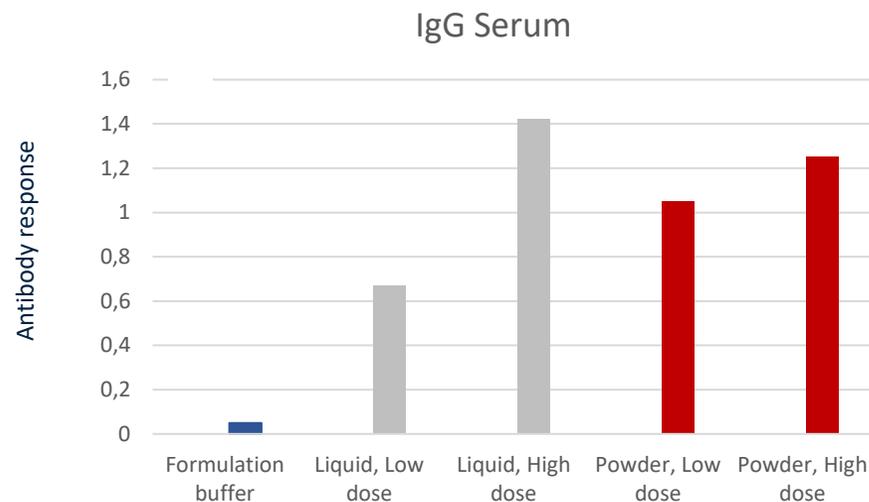


**AmorphOX**-formulated semaglutide nasal powders demonstrated 7-times higher exposure compared to Rybelsus<sup>®</sup> oral tablet (median values)<sup>1</sup>

Rybelsus<sup>®</sup> is a registered trademark of Novo Nordisk A/S

<sup>1</sup> Exposure of AmorphOX formulations were lower than injectable reference

## With Abera Bioscience an in-vivo proof-of-concept study was conducted for a nasal powder vaccine



abera  
BIOSCIENCE

Successful proof-of-concept for **AmorphOX**-formulated nasal powder vaccine with the potential to eliminate cold chain requirements thanks to improved stability

# OX640 (clinical phase) – emergency treatment of anaphylaxis



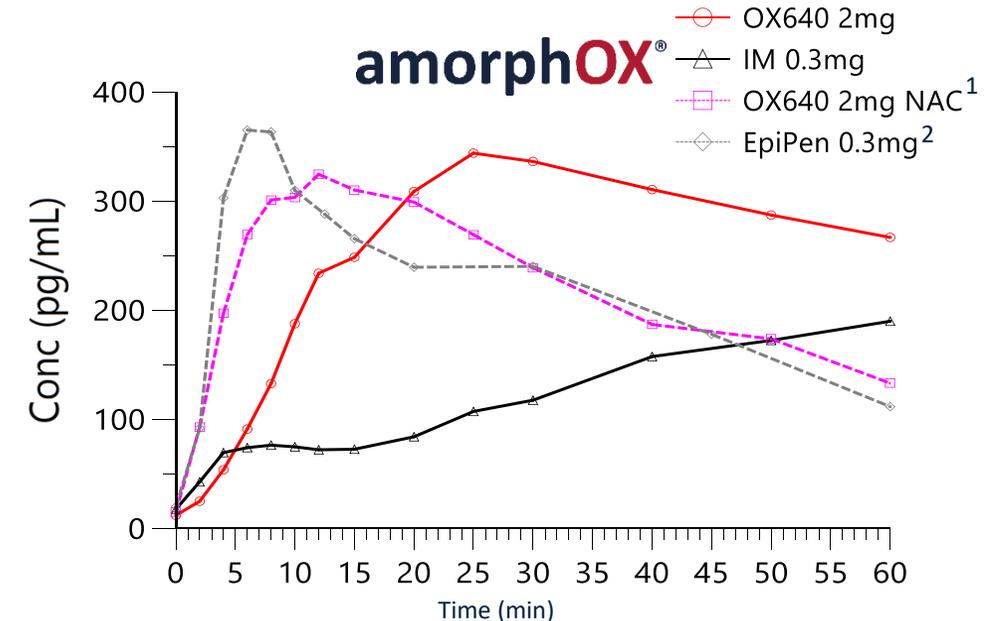
In 2024 the first nasal product was approved in the US and EU which can pave the way for transformative shift (intramuscular auto-injectors today's first line treatment)

## Differentiating properties

- Superior absorption and exposure
- No preservatives
- Fast acting
- Less restrictive storage requirements & longer shelf life
- Improved dose conformity.

## 1st pivotal clinical trial planned for Q4 2026

- Preparations ongoing for manufacturing in commercial scale at established site in Canada
- Data from the 1<sup>st</sup> pivotal clinical trial expected in Q1 2027
- Orexo will seek partnership for commercialization.

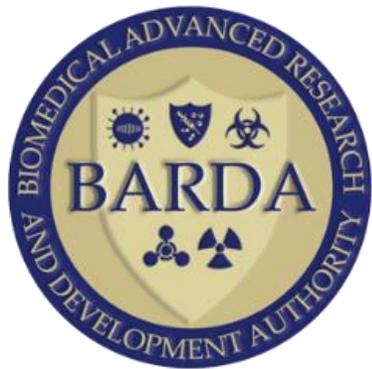


Positive data from two clinical studies. For OX640-002 also incl. patients with allergic rhinitis OX640 showed rapid absorption and sustained epinephrine levels during allergic rhinitis conditions, see data in the graph.

<sup>1</sup> Dose scaled data. <sup>2</sup> Cross-study comparison (Study EPI-15, FDA AC Briefing book)

# Orexo US awarded SEK 75 m by BARDA for OX390 development partnership<sup>1</sup>

Valued up to SEK 480 m and structured in six stages



- **OX390, today in preclinical stage, is specifically designed for adulterated overdoses** where current treatments like naloxone or nalmefene are less effective
- **Addresses a high-mortality patient group**, easing challenges faced by first responders and relatives
- **Preliminary development plan aligned with BARDA and FDA**, with toxicology studies underway before human trials (expected in just over two years)
- **Built on Orexo's AmorphOX technology platform**, consistent with Orexo's other development programs.



amorphOX<sup>®</sup>

<sup>1</sup> In USD 8 m, valued up to USD 51 m

# Izipry (registration phase) batches ready for stability and reliability studies

## Manufacturing of required batches at commercial scale initiated completed in Q4 2025

- Process initiated to complete the FDA required testing with expected resubmission in 2026
- Stability data is the main driver of the timeline and Orexo has to balance time-to-market, shelf life at launch and risk of approval.

## Market for Izipry™ increasingly competitive

- To limit financial risk of the company Orexo will seek partnership for commercialization.

## Having an approved product is highly valuable for the AmorphOX® platform

- Availability of FDA approved supply chain and FDA approved product based on the AmorphOX technology is valuable in partner discussions and based on feedback from regulatory agencies also in the assessment of future AmorphOX products.



amorphOX®

FDA resubmission expected in Q3 2026

IZIPRY™ is based on AmorphOX® and designed to treat overdoses caused by synthetic opioids, such as fentanyl and fentanyl analogues.



**Future value  
drivers**

# Approach for value growth



**Drive global leadership  
in amorphous powder  
for drug delivery.**

- Accelerate R&D and strengthen internal expertise to reinforce Orexo's leadership in drug delivery based on amorphous powder formulations.
- Strengthen the position within biomolecules advancing research into new areas specifically in peptides and proteins.
- Expand collaboration with academic institutions and key thought leaders to drive innovation and credibility.



**Advance projects  
to value  
inflection.**

- Leverage financial capacity to support proprietary project developments, until value inflection point.
- Implement clear go/no-go decision points to optimize resource allocation and accelerate timelines.
- Proactively identify and negotiate out-licensing opportunities with potential pharma partners.



**Expand partnerships  
for the AmorphOX®  
technology.**

- Establish partnerships, enabling them to benefit from the unique properties of AmorphOX.
- Reduce risk and cost in overall development through partner financed projects.
- Retain value from partnerships through royalties and milestones when co-developed projects reach commercial stage.

# Orexo R&D Day

- March 24, 2026
- 9.30 am – 12 pm (followed by lunch)
- IVA, Grev Turegatan 16
- Registration on the website

# Thanks

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

