

A commercial-stage pharma company, developing drugs through cutting-edge drug delivery technologies

Sep. 23rd, 2025

amorphOX[®]

WE SUPPORT



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Orexo in brief

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

Addresses unmet needs within **opioid use disorder (OUD)** and other areas where our **technologies** can contribute to improving drugs.

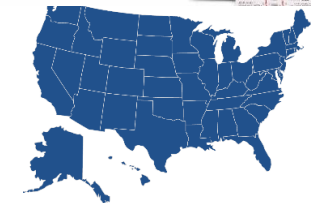


Strong cash generation from Zubsolv® in the US

SEK m

5.850

Total net revenue since US launch in 2013



The next-generation drug delivery technology, **AmorphOX¹**, provides improved stability and prolonged shelf-life for sensitive small and large molecules.

amorphOX®

Own commercial platform in the US, incl. the lead pharma product Zubsolv® and the digital support program MODIA® – both for patients suffering from OUD.

¹ AmorphOX follows the first-generation drug delivery technology – the sublingual, which is the backbone in the commercial stage drugs Abstral®, Edluar® and Zubsolv®

Commercial products and development pipeline

	Product or Project/Indication/Technology	Partners	Exploratory	Preclinical	Clinical development phases	Registration	Approved and/or Launched		
							US	EU	RoW
Commercial	Zubsolv® Opioid Use Disorder (OUD) / Sublingual platform								
	Abstral® Breakthrough Cancer Pain / Sublingual platform								
	Edluar® Insomnia / Sublingual platform								
R&D	IZIPRY™ Naloxone, Opioid Overdose IRM / amorphOX®		FDA resubmission expected mid 2026						
	OX125 Nalmefene, Opioid Overdose IRM / amorphOX®								
	OX390 NCE, Overdose IRM / amorphOX®								
	OX640 Adrenaline, Anaphylaxis IRM / amorphOX®								
	Others (Small and large molecules) / amorphOX®								





NCE – New Chemical Entity
IRM – Intranasal Rescue Medication



AmorphOX[®]

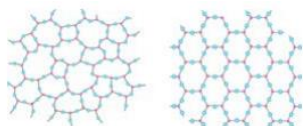
The next-generation
drug delivery technology
unlocks a broad range
of new opportunities in
the development of
innovative drugs



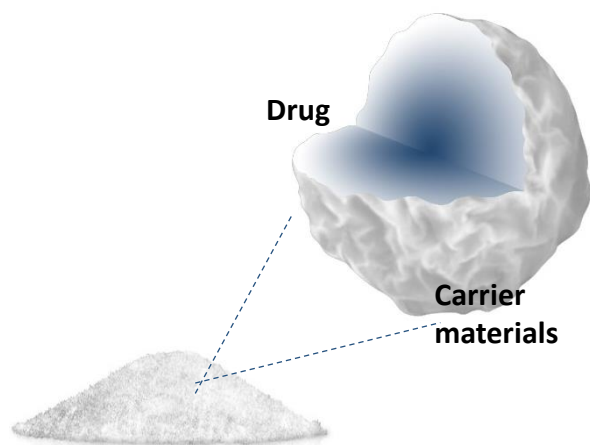
AmorphOX[®] is a unique drug delivery technology

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



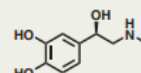
AmorphOX unique strengths

1 AmorphOX unique properties ensure physical and chemical stability

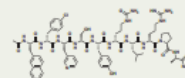
- ✓ Withstands high and low temperatures
- ✓ Stability maintained over time

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

Small molecules
Ephedrine
0.3% after 24 months



Peptides
Cetorelix
0.6% after 12 months



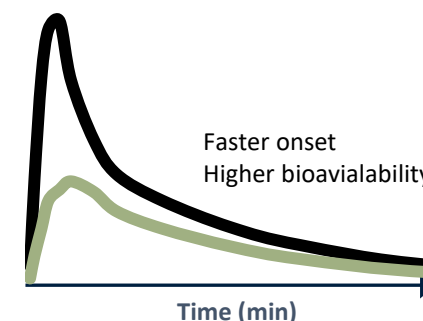
Biologics
Protein (spike protein)
Retained activity after 3 months (40°C)



2 AmorphOX is validated in multiple clinical trials

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

Plasma concentration from clinical trial

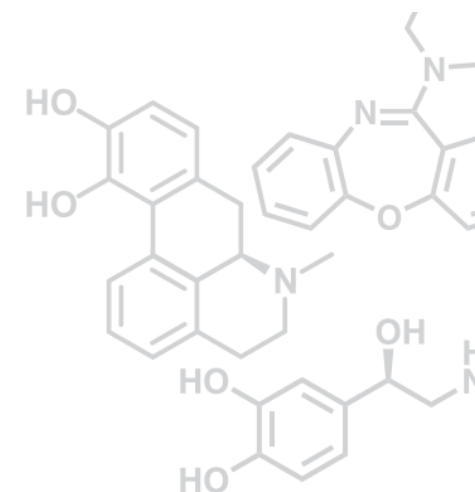


■ AmorphOX ■ Traditional liquid

3 AmorphOX is a versatile platform

Improves:

- ✓ Small molecules
- ✓ Peptides
- ✓ Biologics



The scalable AmorphOX[®] platform takes Orexo beyond the OUD treatment area

Small

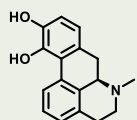
Molecular weight (Mw)

Large

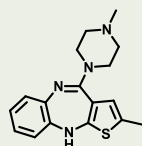
Small molecules

Peptides

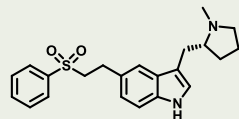
Biologics

Apomorphine

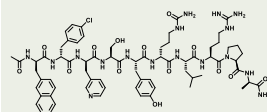
0.2% after 24 months

Olanzapine

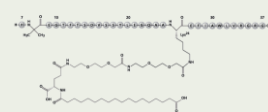
0.2% after 6 months

Eletriptan

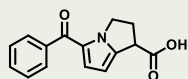
0.5% after 12 months

Cetrorelix

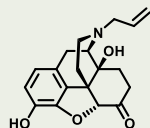
0.6% after 12 months

Semaglutide

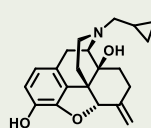
0.1% after 6 months

EnzymeRetained 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**

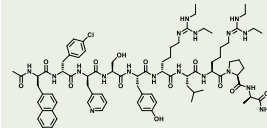
0.8% after 6 months

Naloxone

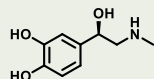
≤0.1% after 24 months

Nalmefene

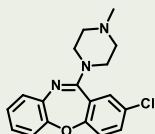
≤0.1% after 15 months

Ganirelix

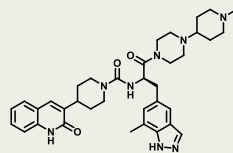
0.7% after 12 months

**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

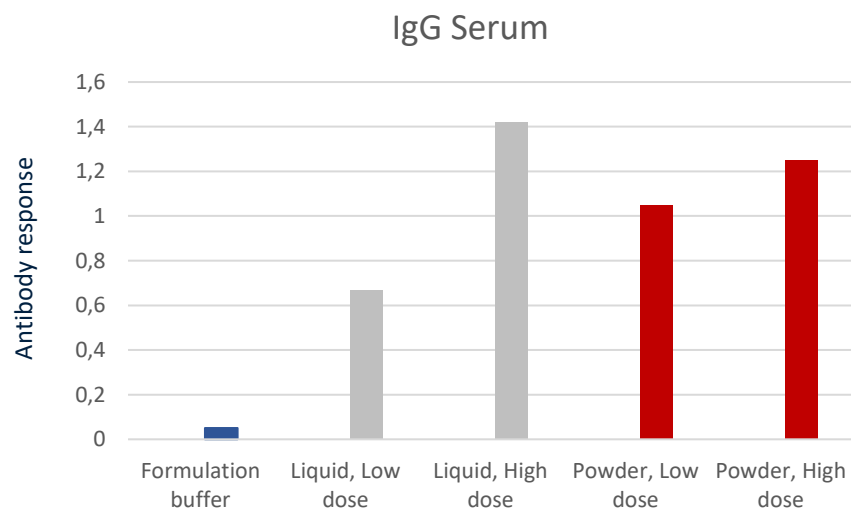
**Immuno-
modulator**99% purity after
1 month (50°C)

*Examples of both internal and
partnered projects*

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

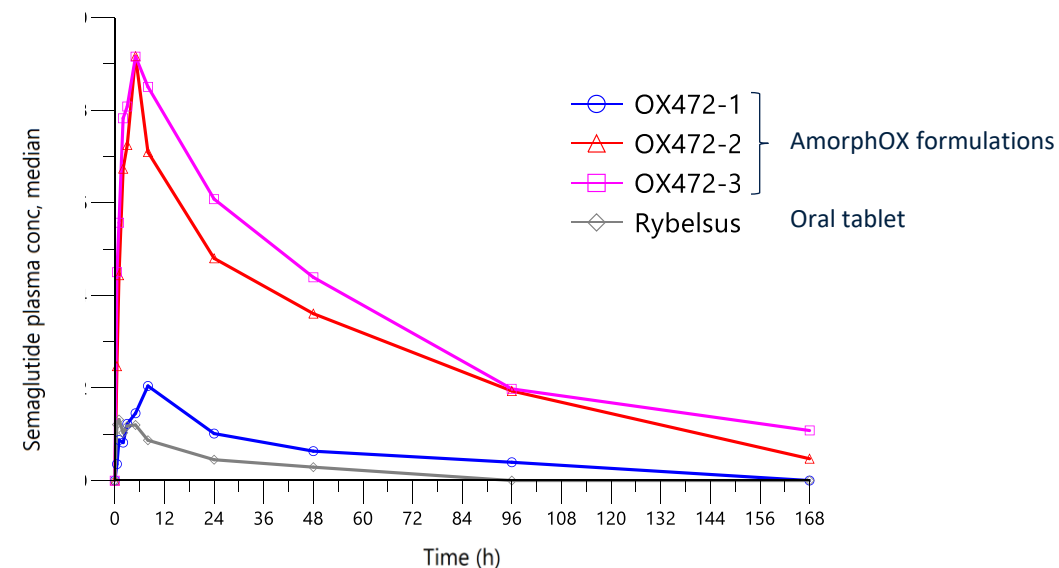
Early stage projects: AmorphOX[®] and large molecules

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



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

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



AmorphOX-formulated semaglutide nasal powders demonstrated 7-times higher exposure compared to Rybelsus[®] oral tablet (median values)¹

Rybelsus[®] is a registered trademark of Novo Nordisk A/S

¹ Exposure of AmorphOX formulations were lower than injectable reference

YTD 2025: Full-year financial forecast confirmed, incl. achieving positive EBITDA in 2025

Income statement SEK m	Jan-Jun 2025	Jan-Jun 2024	FY 2024	FY 2023
Net revenues (NR)	264.5	293.2	590.0	638.8
<i>of which US Commercial (Zubsolv®)</i>	246.5	277.2	560.3	577.7
Gross Profit	235.3	263.7	517.9	550.0
OPEX	-262.0	-284.2	-658.2	-659.5
EBIT	-26.7	-20.5	-140.3	-109.5
EBITDA	-4.2	20.9	48.9	-32.5
Cash position	121.3	139.7	123.3	171.0

YTD 2025 developments & legal update

- ✓ Zubsolv US NR impacted negatively by a non-recurring rebate payment of SEK 8.9 m and FX headwinds. Partly offset by higher wholesaler stocking. Flat volume development Q2 vs Q1 2025.
- ✓ Lower OPEX due to reduced SG&A- and R&D costs. FX had a positive impact on OPEX.
- ✓ Positive EBITDA of SEK 4.7 m when excl. non-recurring rebate.

Legal update – subpoena issued by US authorities in 2020: Orexo believes investigation relates to past marketing campaigns. The company is unaware of any filed cases & maintains the concerns are meritless, yet is negotiating resolution. A change in administration may delay the process due to politically appointed prosecutors.

Approach for expansion



Growing revenues & profit contributions

- ⇒ Maintain Zubsolv® revenue streams in USD
- ⇒ Obtain FDA approval and initiate US launch of Izipry™
- ⇒ Achieve milestones and receive royalties from existing and upcoming partnered products.



Improving access to treatment

- ⇒ Expand reimbursement of Zubsolv in the public payer segment and maintain access in the commercial payer segment
- ⇒ Secure reimbursement approval for the US launch of Izipry.



Capitalising the AmorphOX® technology

- ⇒ Advance internal rescue medications and out-license products based on the AmorphOX technology such as OX640
- ⇒ Expand into large molecules through partnership and improve scientific proof of concept
- ⇒ Partner with CDMO and other partners to expand reach of technology.



ESG

Responsible business

Access to healthcare

Environment & climate change

Sustainable employees



A man and a woman in white lab coats and safety glasses are working in a laboratory. The man is standing and looking down at something, while the woman is seated and also looking down. In the background, another person is visible working at a computer. The word "Thanks" is overlaid in large blue letters on the right side of the image.

Thanks

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