orexo

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

Sep. 16th, 2025

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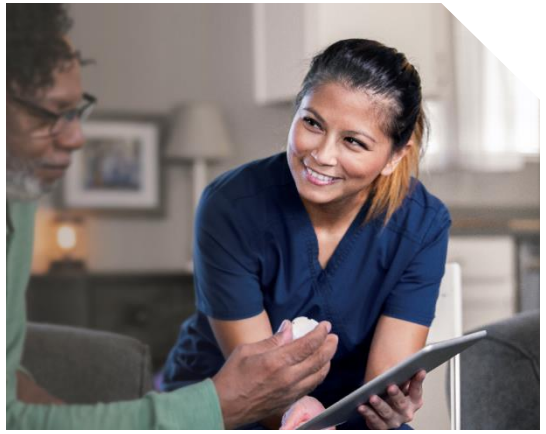
Orexo in brief

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 lead product

SEK m

5.850

Total net revenue since US launch in 2013

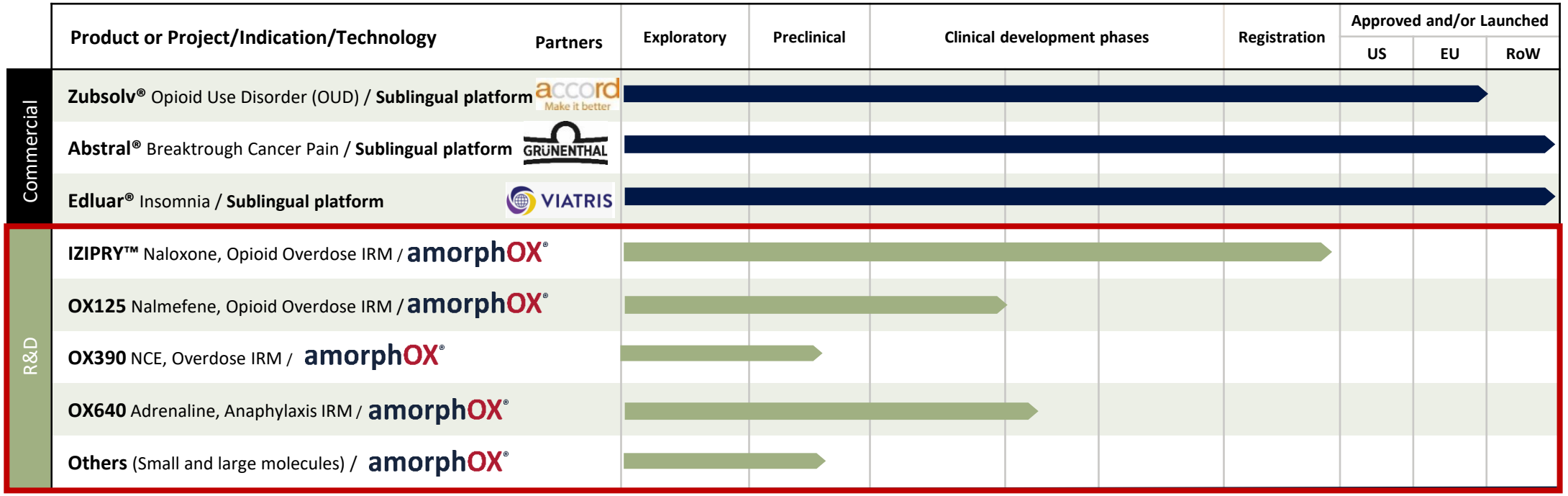
The next-generation drug delivery technology, AmorphOX,[1] provides improved stability and prolonged shelf-life for sensitive small and large molecules.

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



NCE – New Chemical Entity
IRM – Intranasal Rescue Medication

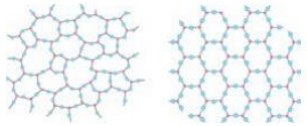
AmorphOX®

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

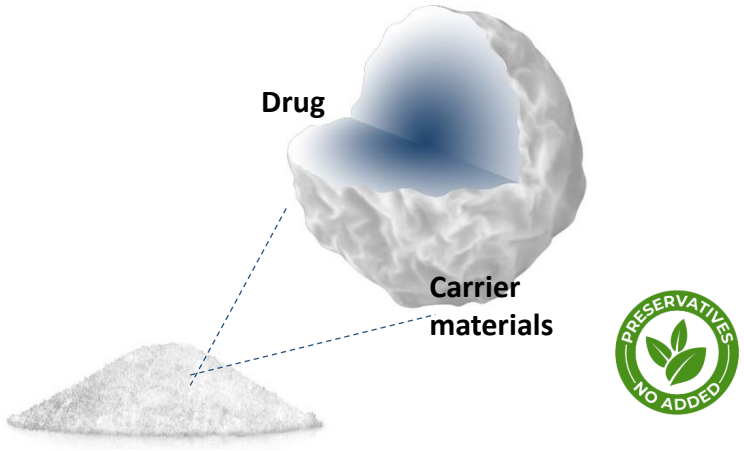
AmorphOX® is a unique drug delivery technology

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

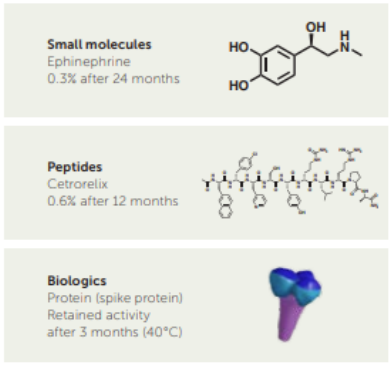


AmorphOX unique strengths

1 AmorphOX unique properties ensure physical and chemical stability

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

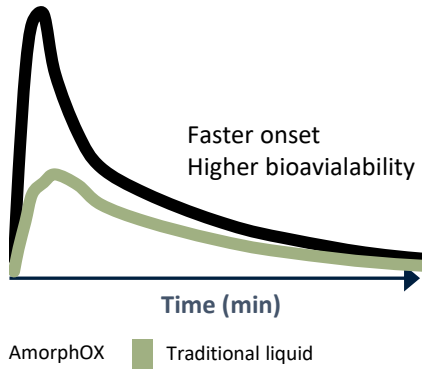
Examples **Chemical degradation after accelerated stability studies at 40°C/75% RH**



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:

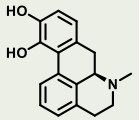
- ✓ Small molecules
- ✓ Peptides
- ✓ Biologics

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

Small — Molecular weight (Mw) — Large

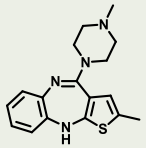
Small molecules | Peptides | Biologics

Apomorphine



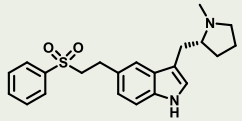
0.2% after 24 months

Olanzapine



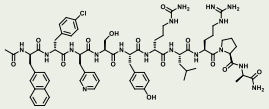
0.2% after 6 months

Eletriptan



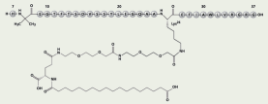
0.5% after 12 months

Cetrorelix



0.6% after 12 months

Semaglutide



0.1% after 6 months

Enzyme

Retained activity after 1 month (40°C)

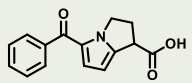
Virus like particle

Retained structure after processing and after 3 months at 40°C

Attenuated Virus

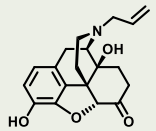
Retained titer levels, resilient to freeze thaw cycles

Ketorolac



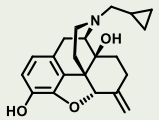
0.8% after 6 months

Naloxone



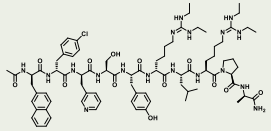
≤0.1% after 24 months

Nalmefene



≤0.1% after 15 months

Ganirelix

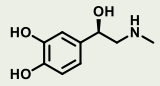


0.7% after 12 months

Covid Spike protein

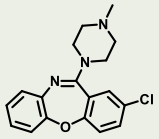
Retained activity after 3 months (40°C)

Epinephrine



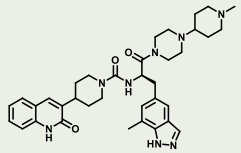
0.3% after 24 months

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**

AmorphOX® strategy focuses on large molecules and intranasal rescue medications

Progess internal rescue medication projects

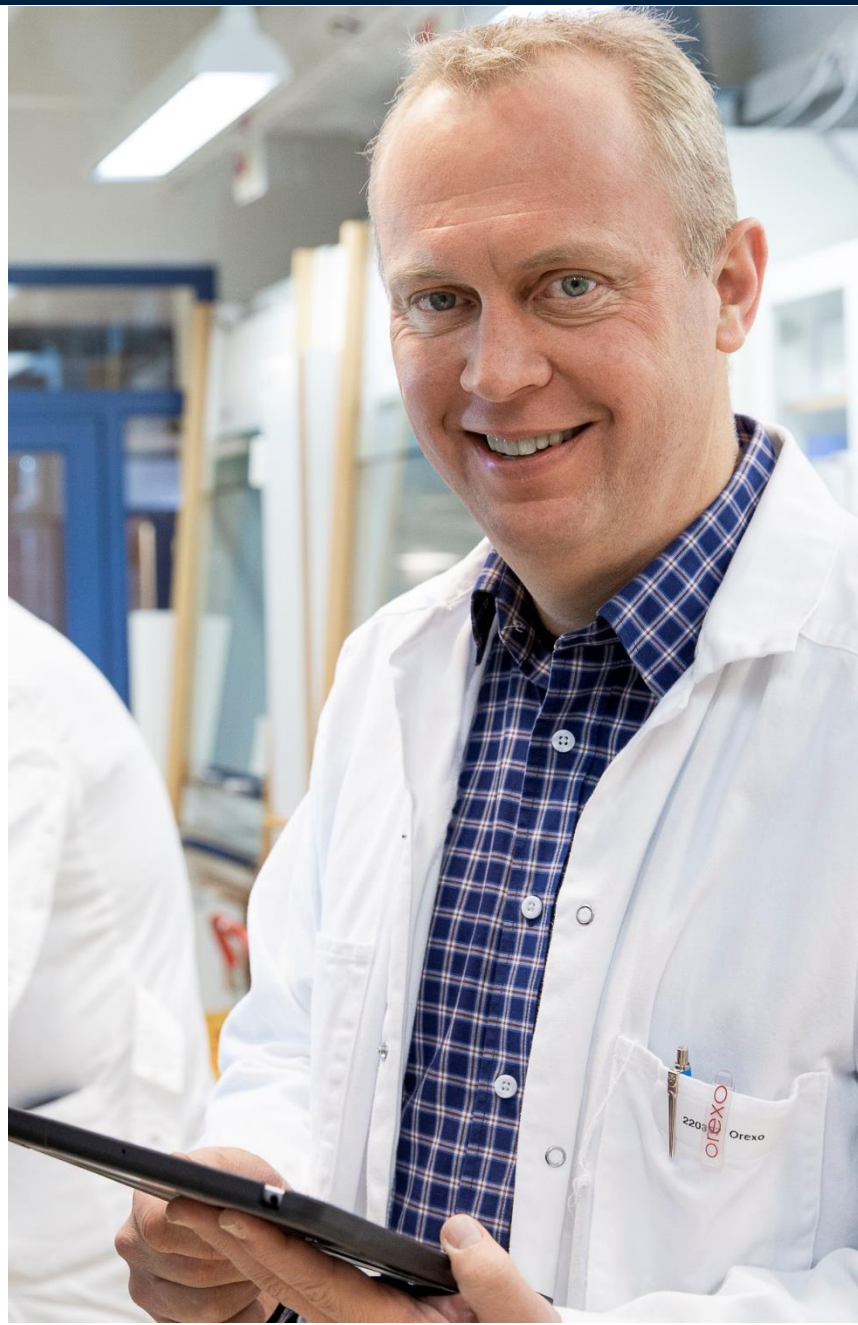
- Izipry™ (OX124) targeting opioid overdose
- OX640 aimed at treating anaphylaxis
- OX390 focused on overdoses from illicit drugs
- OX125 for opioid overdose (currently paused).

Expand into large molecules research

- Data contributions from multiple partnerships, including Abera, SOBI and other undisclosed agreements
- Continue generating data on selected large molecules.

Form partnerships to broaden scope and reduce risk

- Develop collaborations with contract development and manufacturing organisations to enhance reach.



Izipry™ (registration phase) – powder-based intranasal rescue medication for opioid overdose

- Izipry, formulated with AmorphOX®, is designed to combat overdoses from synthetic opioids, which make up more than 90% of opioid overdose incidents.
- Izipry includes naloxone in a powder form, enhancing its stability and shelf-life.
- Research indicates that nasal powders deliver higher naloxone plasma concentrations, offer longer-lasting effects, and absorb more rapidly than Narcan® liquid nasal spray.
- Commercial manufacturing initiated.

FDA resubmission expected mid 2026

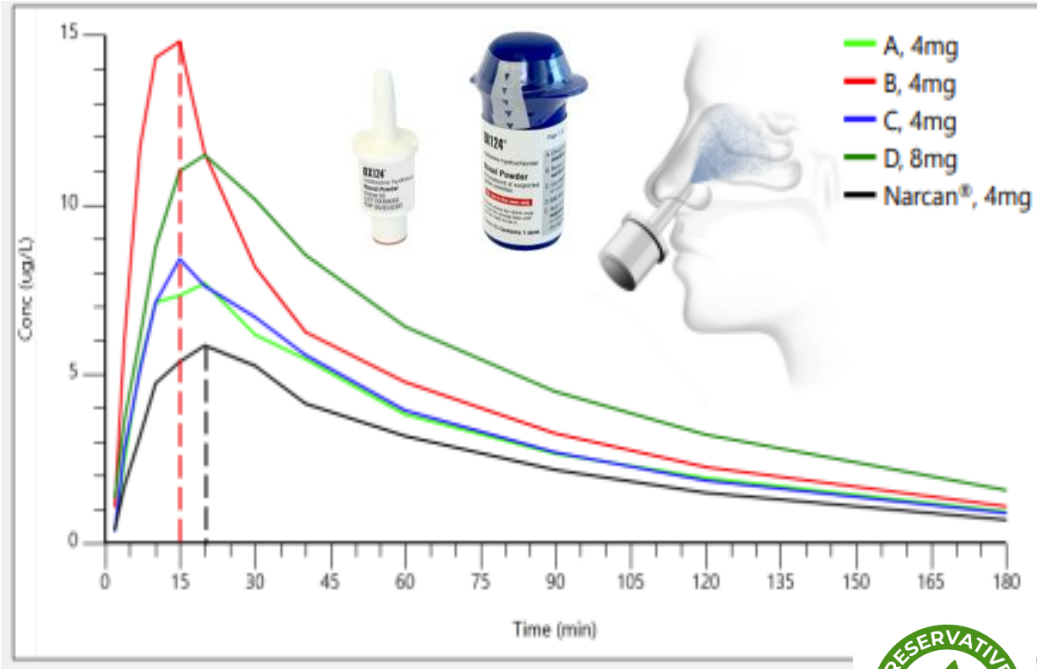


Figure 1: Naloxone plasma concentration vs time

[1] Center of Disease Control and prevention. [2] https://www.coherentmarketinsights.com/market-insight/naloxone-market-1804. [3] Custom market insights.
Note: images are prototypes and not final packages

OX640 (clinical phase) – emergency treatment of allergic reactions, incl. anaphylaxis

- First line treatment today: intramuscular auto-injectors. **In 2024 the first nasal product was approved in the US and EU which can pave the way for transformative shift**
- If approved OX640 nasal epinephrine powder can have the following differentiating properties:
  - Superior pharmacokinetic profile
  - No preservatives
  - Longer shelf-life
  - Less restrictive storage requirements
  - Improved dose conformity
- Partnering process ongoing

Positive data from two clinical studies

Epinephrine global market size 2024 (USD)[1]

2,300 m

Growth rate CAGR 2024-2032[1]

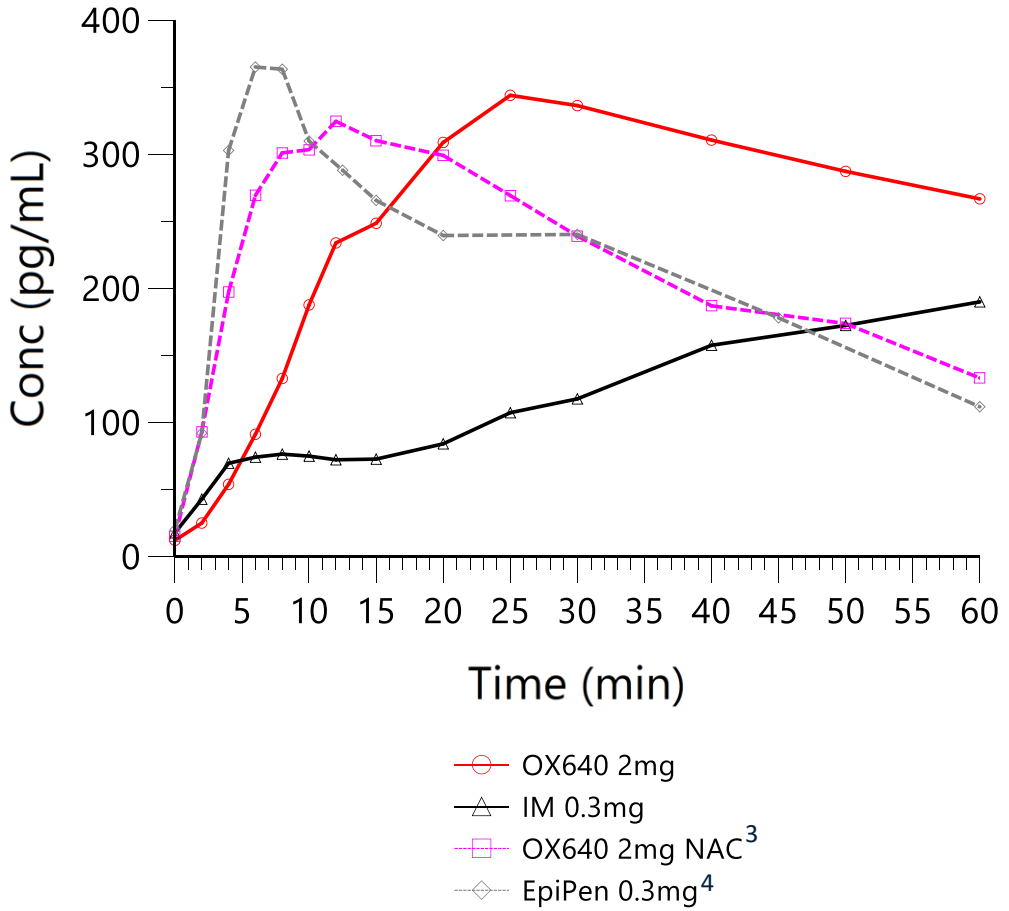
8.5 %

[1] https://www.fortunebusinessinsights.com/epinephrine-market-104291. Market size 2024 is a projected number based on market size in 2023, USD 2,170 m and a growth rate of 6.5%

Note: images are prototypes and not final packages

OX640-002: Clinical study in subjects with and without allergic rhinitis

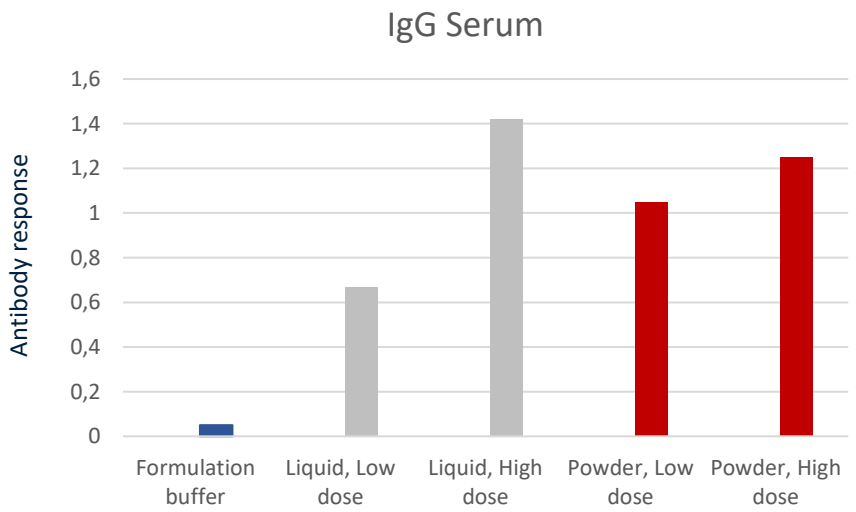
- Second clinical study with OX640, performed in subjects with and without allergic rhinitis (N=30)[1]
- The study suggest the following:
  - Commercial dose identified
  - Relevant plasma levels and pharmacodynamic effects[2] for treatment of anaphylaxis achieved
  - Epinephrine exposure within the clinical range of injection products
  - More rapid epinephrine absorption during allergic rhinitis conditions
  - More sustainable epinephrine levels during allergic rhinitis conditions when compared to competitors



[1] Data presented at the EAACI Congress 2025, 13-16 June 2025, Glasgow, United Kingdom
[2] Data not shown
[3] Dose scaled data
[4] Cross-study comparison (Study EPI-15, FDA AC Briefing book)

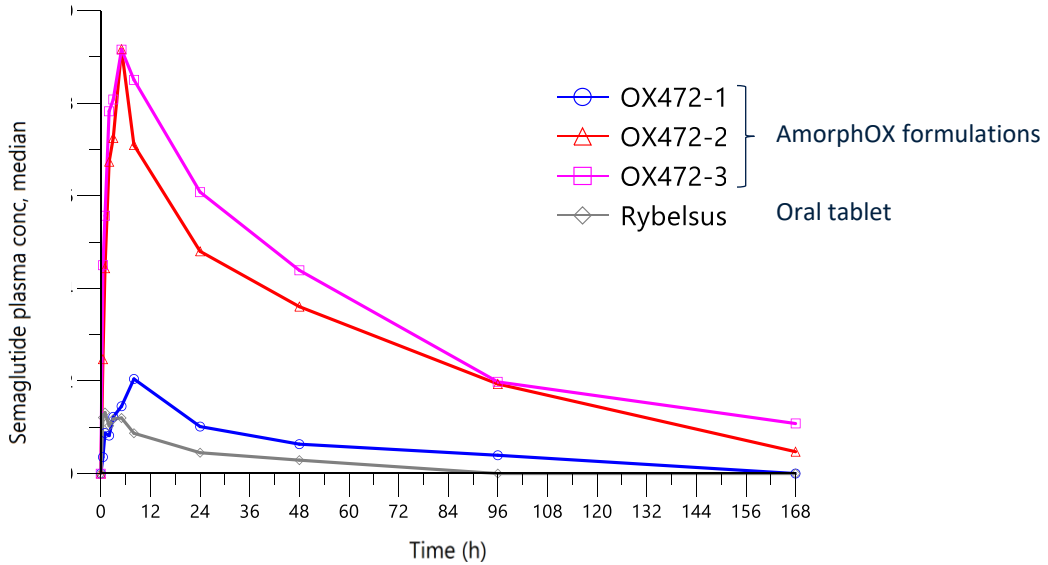
Early stage projects: AmorphOX® and large molecules

In-vivo proof-of-concept study of **nasal powder vaccine** performed in collab. with Abera Bioscience



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

Financial & legal

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**
of which US Commercial (Zubsolv®)	*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.

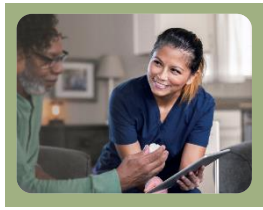
Legal update – subpoena issued by US authorities in 2020: Orexo believes investigation relates to past marketing campaigns. The company is unaware of any filed cases & maintains the concerns are meritless, yet is negotiating resolution. A change in administration may delay the process due to politically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

Future value drivers

Approach for expansion

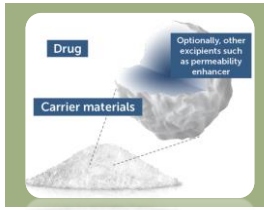
Growing revenues & profit contributions

- 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

Thanks

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