orexo

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


Sep. 1st, 2025

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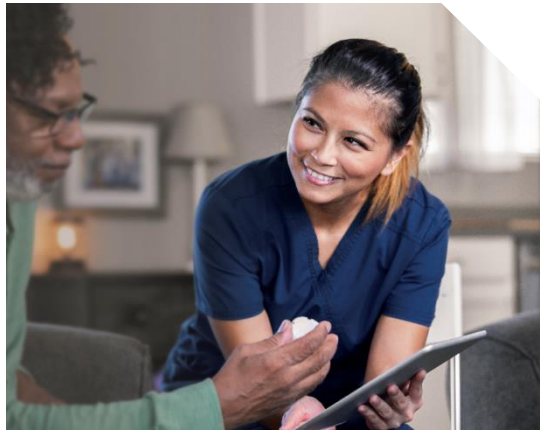
# Orexo in brief

**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

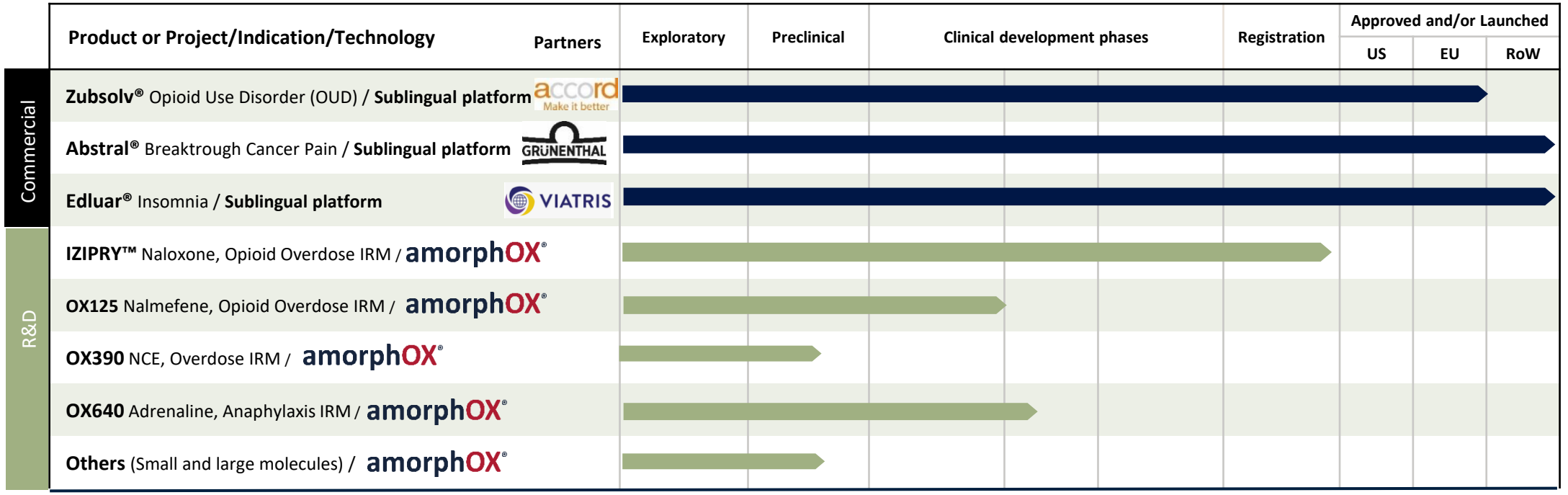
**The next-generation drug delivery technology, AmorphOX**,[1] provides improved stability and prolonged shelf live for sensitive small and large molecules.

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

# Commercial

## Robust US commercial platform addressing the opioid crisis

# Committed to improve the life of patients suffering from OUD

## The unmet need in the US

**5.9 m**
are dependent on opioids[1]

**2.3 m**
are undergoing treatment[1]

**51,000**
the number of fatal overdoses caused by opioids annually[2]

**USD 1,500 bn**
The societal cost of the US opioid crisis[3]

## Our approach

**Medication-Assisted treatment (MAT)**


**Digital support program**

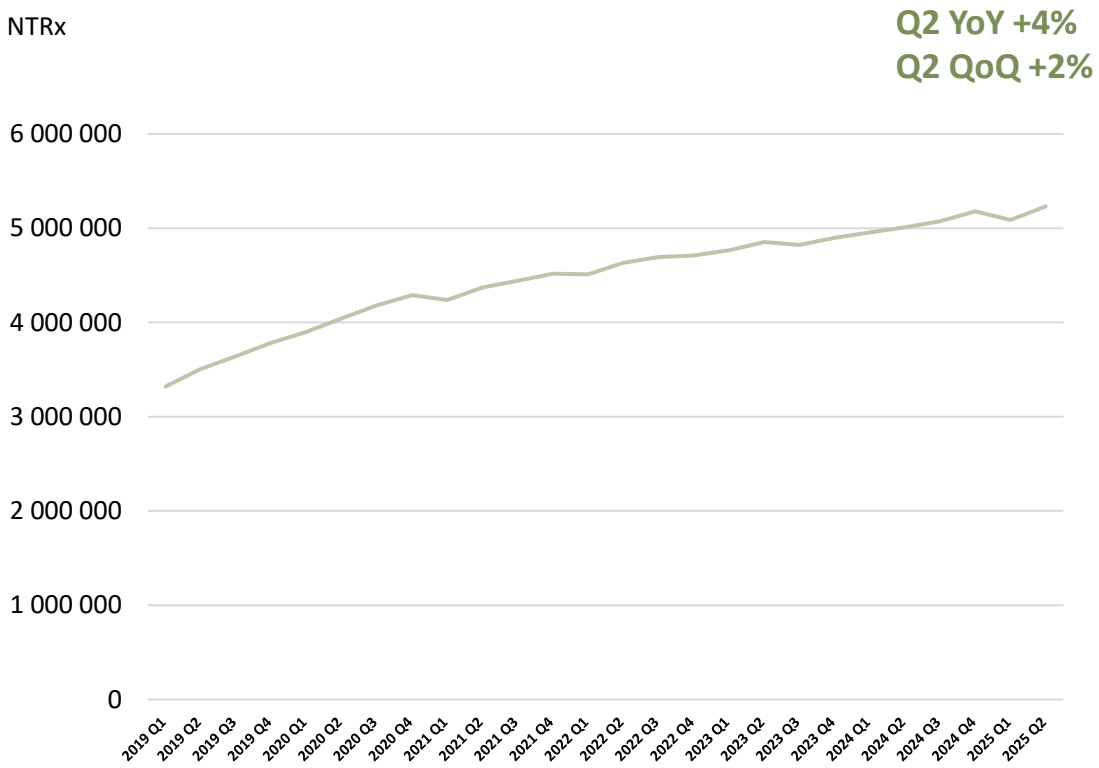

**Rescue medication**

Izipry™ in registration phase (FDA)

[1] SAMHSA Key Substance Use and Mental Health Indicators in the United States: Results from the 2023 National Survey on Drug Use and Health.
[2] Center of Disease Control and Prevention, predicted data March 2025. [3] US Joint Economic Committee, data refers to 2020.

# Q2 2025: Improved growth in the bup/nal market

### Buprenorphine/naloxone market development[1]




[1] Based on IQVIA prescription data and include both retail and non-retail volumes. Note weekly prescription data is volatile and is influenced by public holidays, weather and changes to reimbursement.

### Market development by payer segment YoY

- Medicaid segment growth stagnating at +1% following Medicaid disenrollment
- Commercial segment growth of +11% as patients switched from Medicaid
- Decline in Cash segment of -11%.

### Zubsolv® development

- **QoQ:** flat development, driven by growth in Medicaid and maintained volume in Commercial. UHG & Humana impacted negatively.
- **YoY**: -6%, mainly explained by lower volume at UHG and Humana Medicare D (new rebate system). Medicaid & Commercial showed flat development.

**SEK 246m**

**YTD 2025: US Commercial Net Revenues**

**SEK 80m**

**YTD 2025: US Commercial EBIT.** ***EBIT margin 33%***

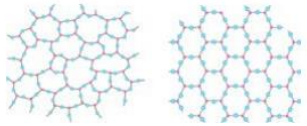
# AmorphOX®

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

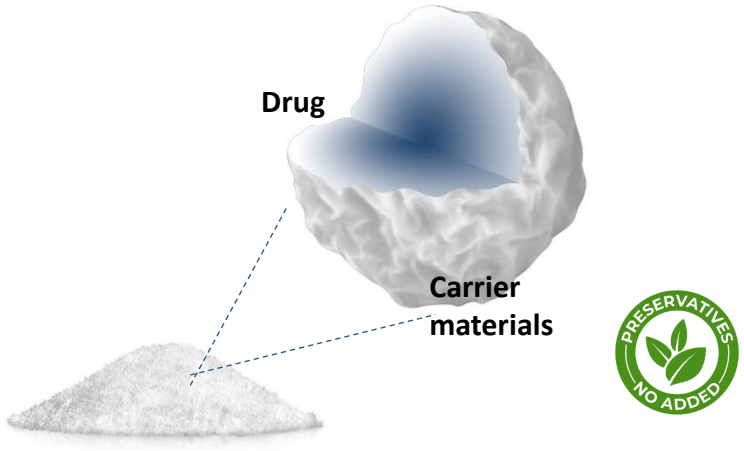
# AmorphOX® is a unique drug delivery technology

## 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

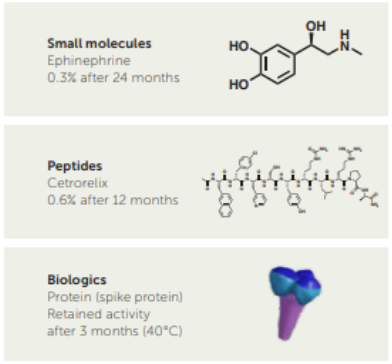



## AmorphOX unique strengths

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

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

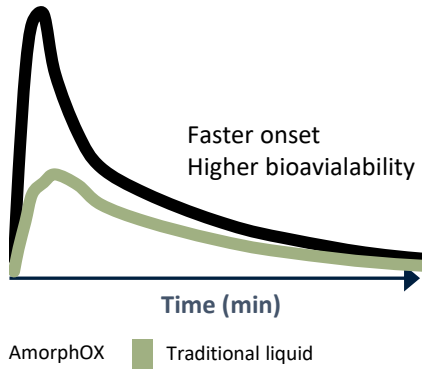
Examples **Chemical degradation after accelerated stability studies at 40°C/75% RH**




### 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:

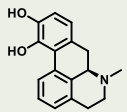
- ✓ Small molecules
- ✓ Peptides
- ✓ Biologics

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

*Examples of both internal and partnered projects*

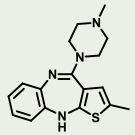
## Small molecules

**Apomorphine**



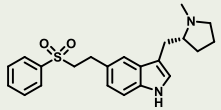
0.2% after 24 months

**Olanzapine**



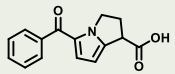
0.2% after 6 months

**Eletriptan**



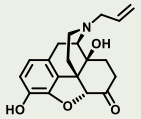
0.5% after 12 months

**Ketorolac**



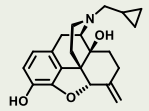
0.8% after 6 months

**Naloxone**



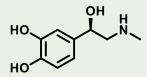
≤0.1% after 24 months

**Nalmefene**



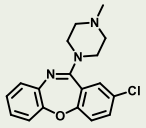
≤0.1% after 15 months

**Epinephrine**



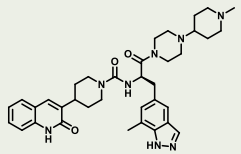
0.1% after 24 months

**Loxapine**



0.3% after 24 months

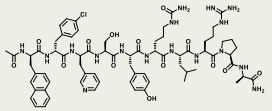
**Zavegepant**



≤0.1% after 9 months

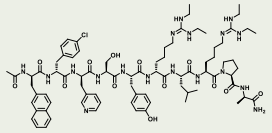
## Peptides

**Cetrorelix**



0.6% after 12 months

**Ganirelix**



0.74% after 12 months

## Biologics

**Enzyme**

Retained activity after 1 month (40°C)

**Virus like particle**

Retained activity after processing

**Attenuated Virus**

Retained titer levels, resilient to freeze thaw cycles

**Covid Spike protein**

Retained activity after 3 months (40°C)

**Immuno-modulator**

99% purity after 1 month (50°C)


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**

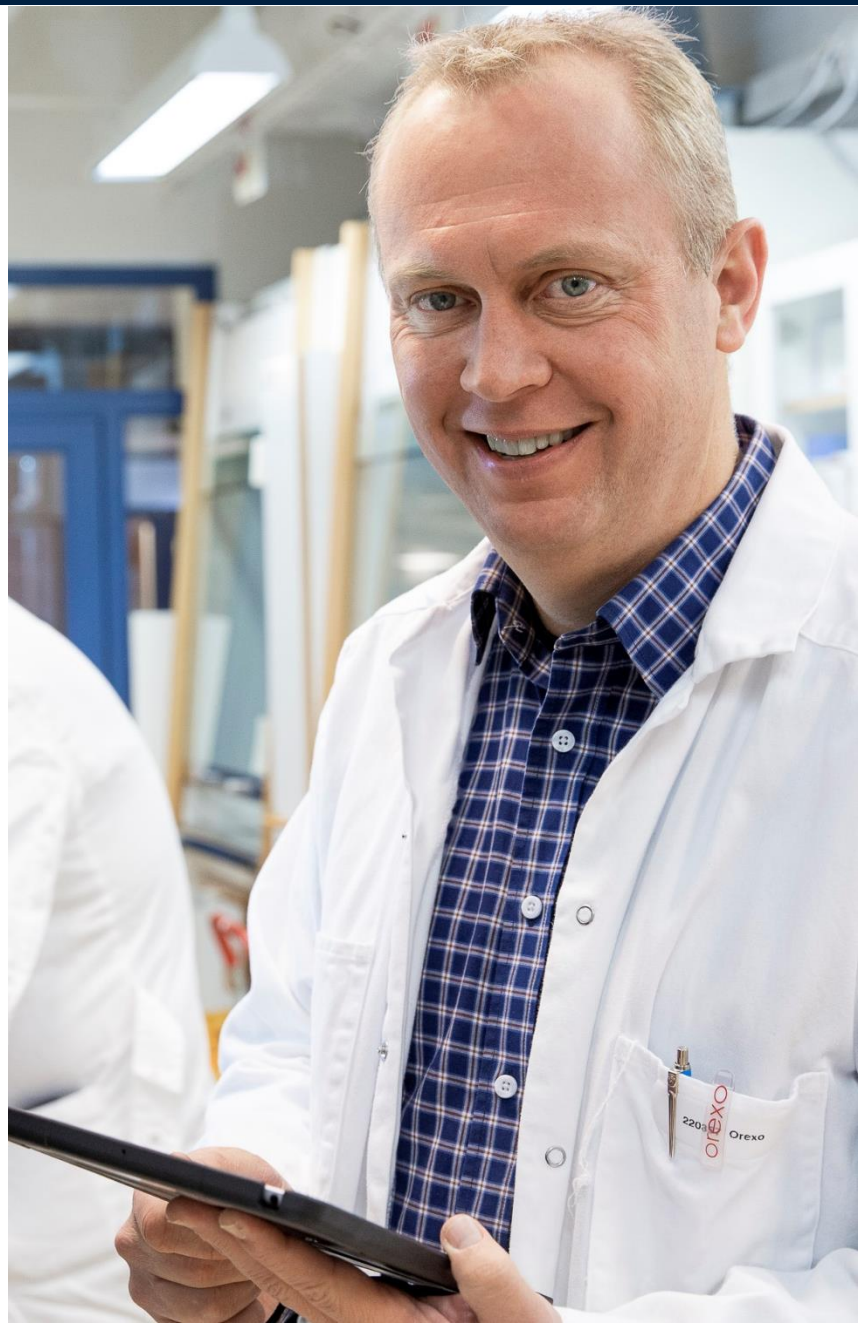
- Izipry® (OX124) targeting opioid overdose
- OX640 aimed at treating anaphylaxis
- OX390 focused on overdoses from illicit drugs
- OX125 for opioid overdose (currently paused).

**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 testing initiated of final product.

**FDA resubmission expected mid 2026**

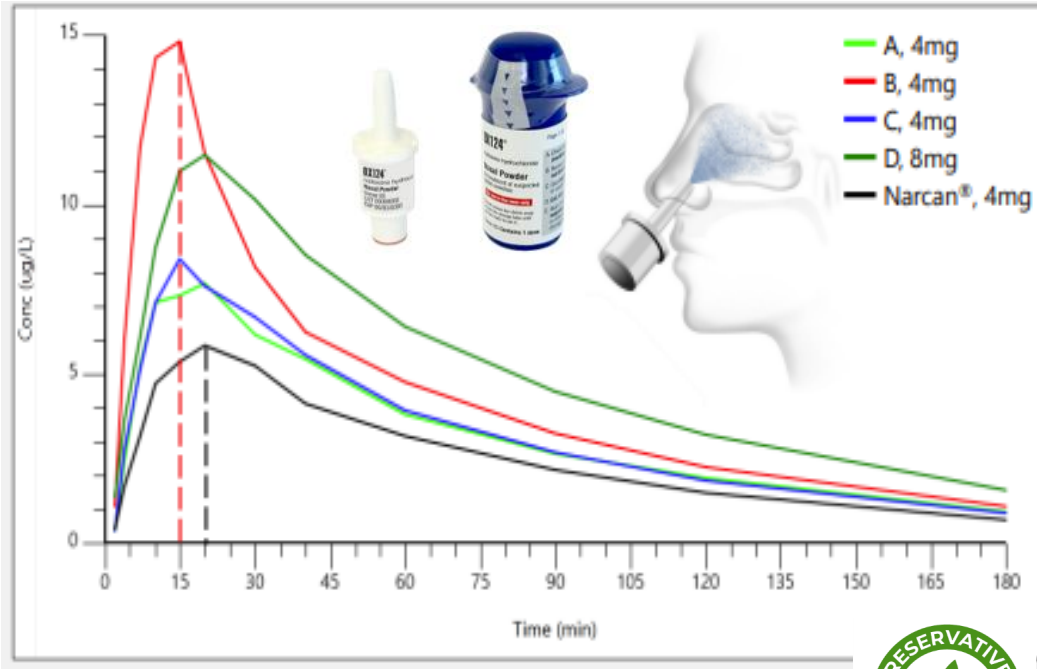



Figure 1: Naloxone plasma concentration vs time

[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

# Izipry™ differentiation and US market opportunity

**High-dose efficacy**

Designed to address overdoses from potent synthetic opioids where standard 4 mg naloxone may require multiple doses.

**Rescue reliability**

Provides an important tool for first responders and others managing severe overdoses.

**Temperature stability**

Low sensitivity to temperature fluctuations enables storage at sub-zero conditions, critical for emergency responders in colder climates.

**Insurance coverage**

As a prescription product, Izipry is more likely to be covered by public and private insurance, unlike OTC naloxone options.

**Clinical integration**

Potential for co-prescribing with prescription opioids, increasing access for at-risk patients.

**Global naloxone market size approx. USD 1,483 m. 2025-2032 projected CAGR 11%[1]**

[1] https://www.coherentmarketinsights.com/market-insight/naloxone-market-1804. US + Canada represent approx. 54% of the global market.

# 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 can have the following differentiating properties
  - Superior absorption and exposure
  - No preservatives
  - Fast acting
  - Longer shelf life
  - Less restrictive storage requirements
  - Improved dose conformity.
- Partnering process ongoing for global commercialization.

**Epinephrine global market size 2024 (USD)[1]**

**2,300 m**

**Growth rate CAGR 2024-2032[1]**

**8.5 %**

## Positive data from two clinical studies


[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

# 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.

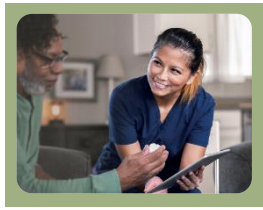
**Legal update – subpoena issued by US authorities in 2020:** Orexo believes investigation relates to past marketing campaigns. The company is unaware of any filed cases & maintains the concerns are meritless, yet is negotiating resolution. A change in administration may delay the process due to politically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

# Future value drivers

# Approach for expansion

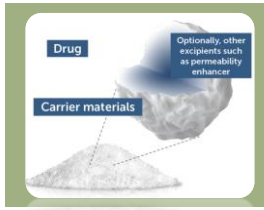
**Growing revenues & profit contributions**

- 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.

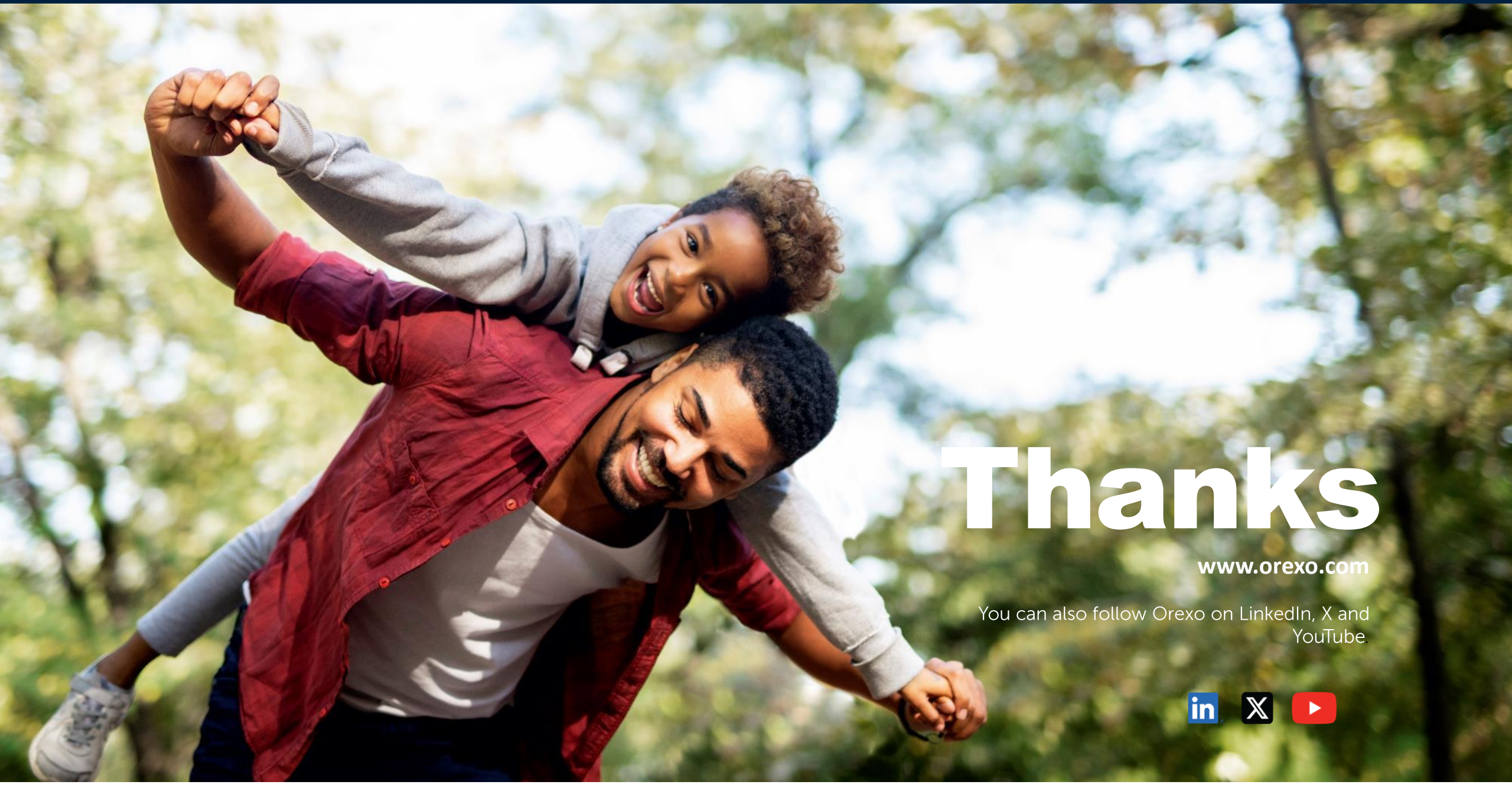



**Capitalising the AmorphOX® technology**

- 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 |
|---|---|---|---|



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