orexo

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

October 2025

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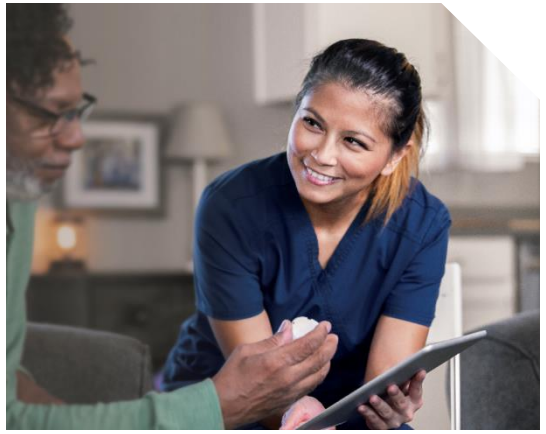
Orexo in brief

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

USD m

622.3

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

Note: Total net revenue converted from SEK to USD using USD/SEK rate as end of the period: 0625;9,4.

Commercial products and development pipeline

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

NCE – New Chemical Entity
IRM – Intranasal Rescue Medication

Commercial

Robust US commercial platform addressing the opioid crisis

Supporting people with OUD and saving lives in overdose crises

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.

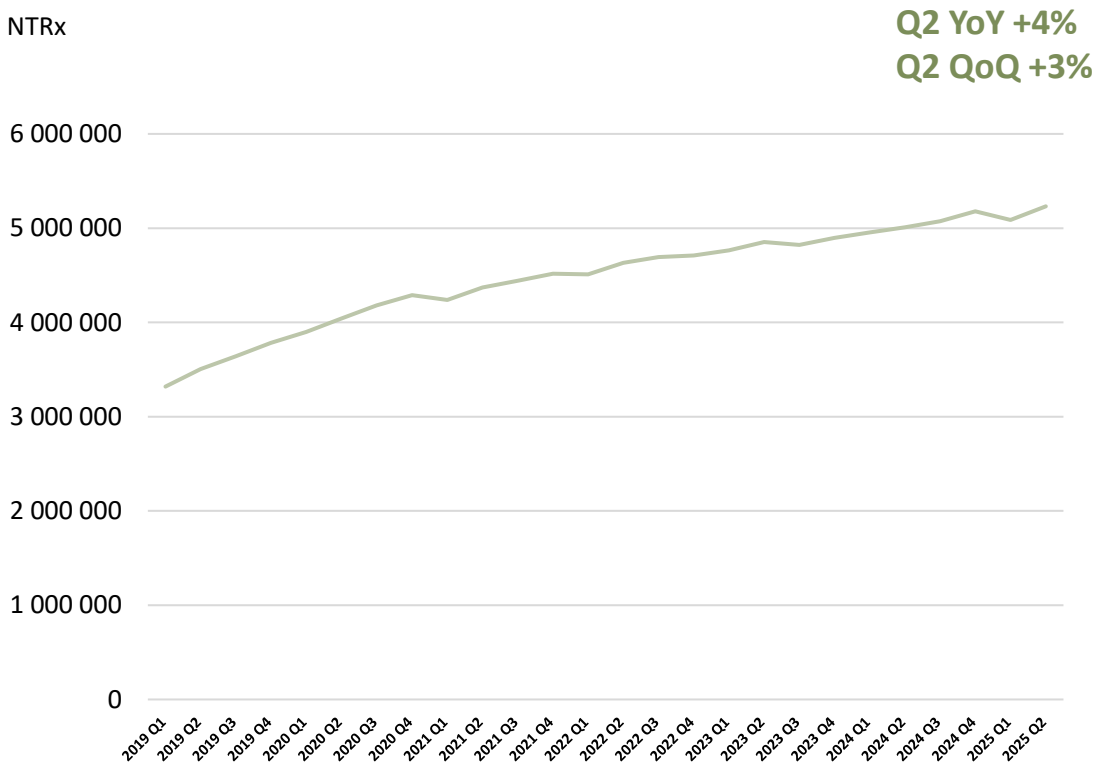
BARDA — Biomedical Advanced Research and Development Authority

ASPR — Administration for Strategic Preparedness and Response

NEWS: Orexo US to partnering with BARDA for development of OX390 for adulterated opioid overdoses.

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.

USD 26.2m

YTD 2025 (Q2): US Commercial Net Revenues

USD 8.5m

YTD 2025 (Q2): US Commercial EBIT. *EBIT margin 33%*

Note: All numbers converted from SEK to USD using USD/SEK rate as end of each period: 0625;9,4.

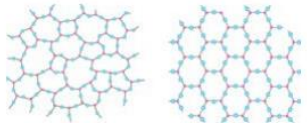
AmorphOX®

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

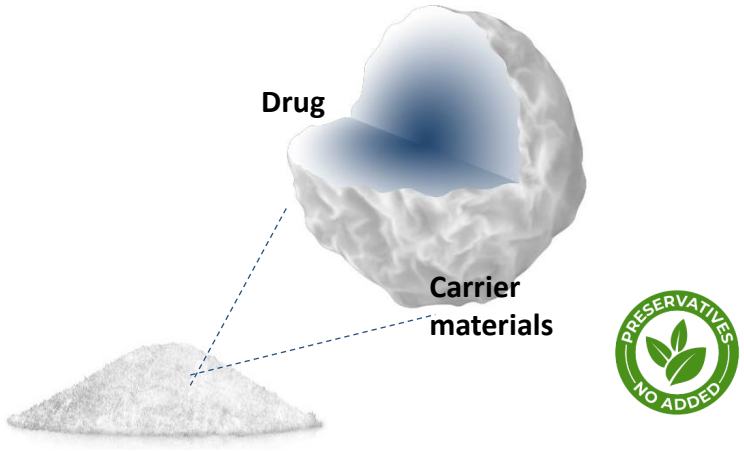
AmorphOX® is a unique drug delivery technology

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

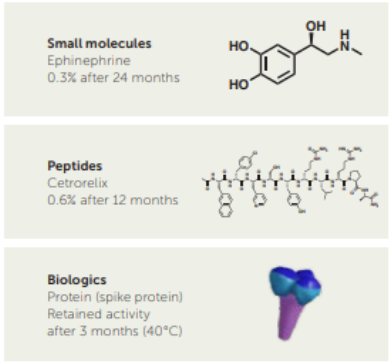


AmorphOX unique strengths

1 AmorphOX unique properties ensure physical and chemical stability

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

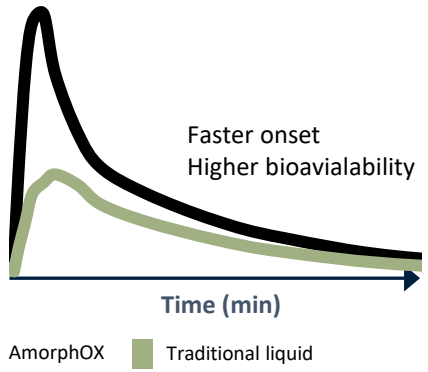
Examples **Chemical degradation after accelerated stability studies at 40°C/75% RH**



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:

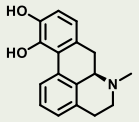
- ✓ Small molecules
- ✓ Peptides
- ✓ Biologics

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

Small — Molecular weight (Mw) — Large

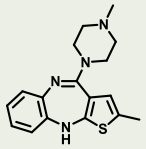
Small molecules | Peptides | Biologics

Apomorphine



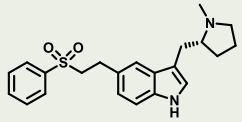
0.2% after 24 months

Olanzapine



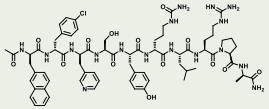
0.2% after 6 months

Eletriptan



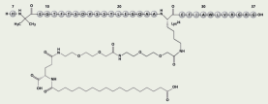
0.5% after 12 months

Cetrorelix



0.6% after 12 months

Semaglutide



0.1% after 6 months

Enzyme

Retained activity after 1 month (40°C)

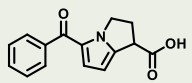
Virus like particle

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

Attenuated Virus

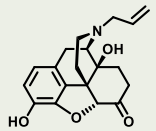
Retained titer levels, resilient to freeze thaw cycles

Ketorolac



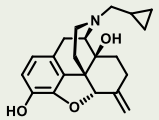
0.8% after 6 months

Naloxone



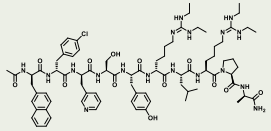
≤0.1% after 24 months

Nalmefene



≤0.1% after 15 months

Ganirelix

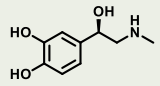


0.7% after 12 months

Covid Spike protein

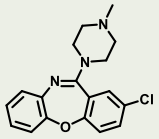
Retained activity after 3 months (40°C)

Epinephrine



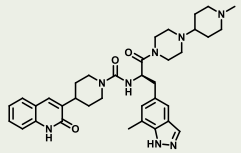
0.3% after 24 months

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**

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

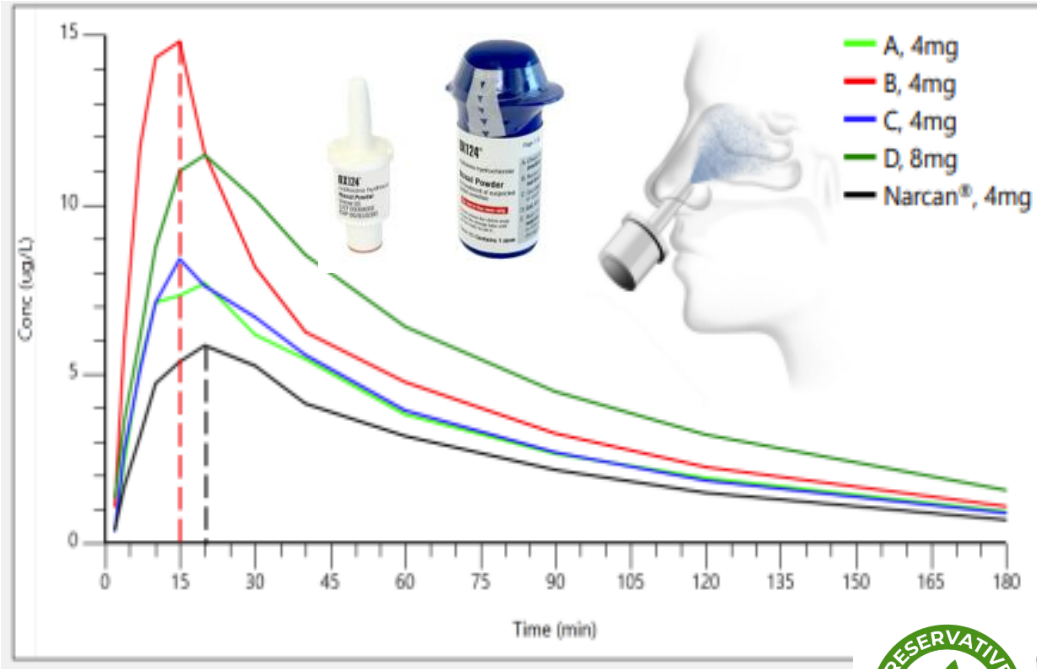


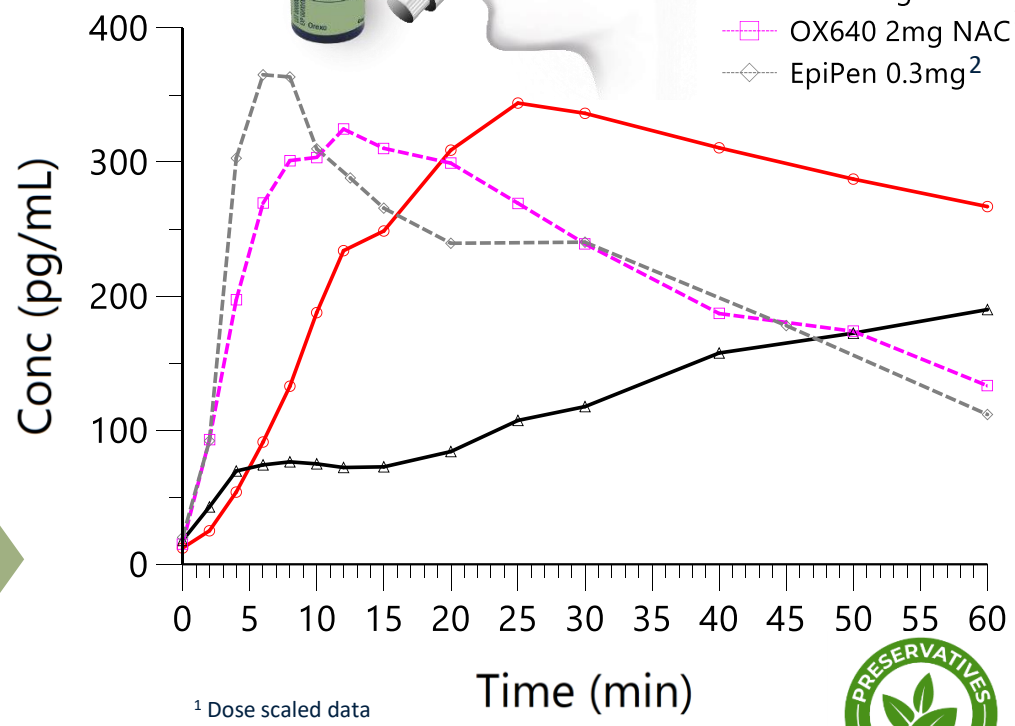
Figure 1: Naloxone plasma concentration vs time

Note: images are prototypes and not final packages

PRESERVATIVES NO ADDED

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**
- Differentiating properties
  - Superior absorption and exposure
  - No preservatives
  - Fast acting &
  - Less restrictive storage requirements & longer shelf life
  - Improved dose conformity.
- 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.
- **Partnering process ongoing for global commercialization.**



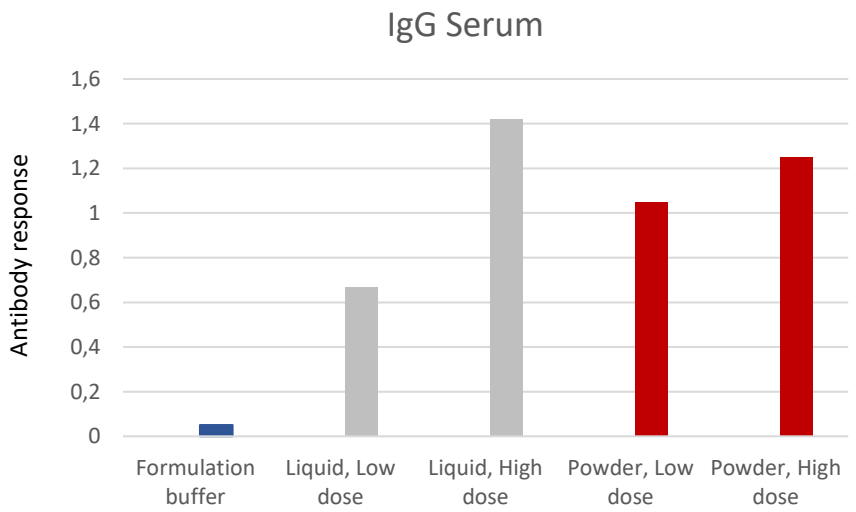
[1] Dose scaled data
[2] Cross-study comparison (Study EPI-15, FDA AC Briefing book)

Note: images are prototypes and not final packages

PRESERVATIVES NO ADDED

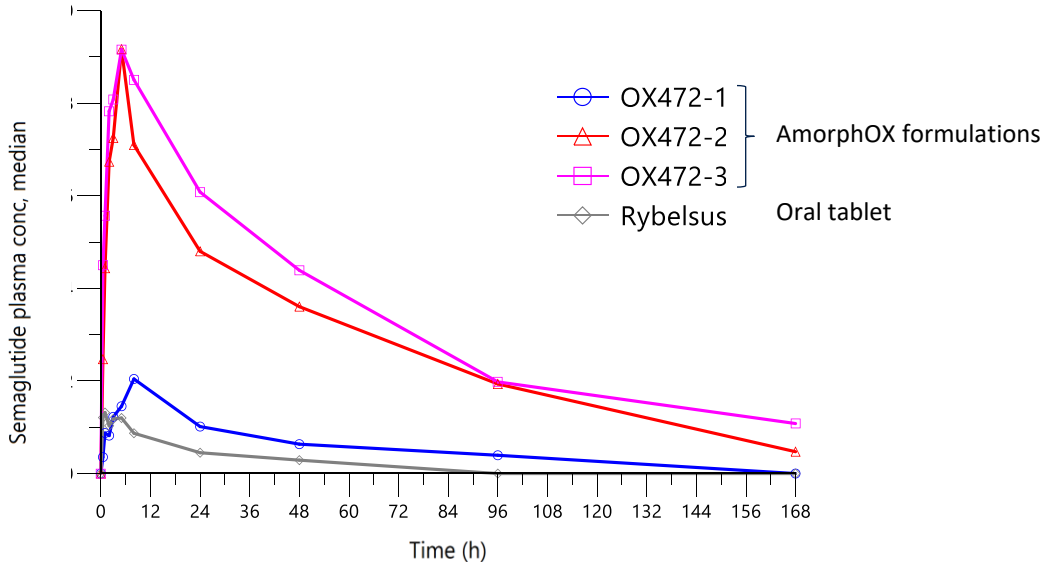
Early stage projects: AmorphOX® and large molecules

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]

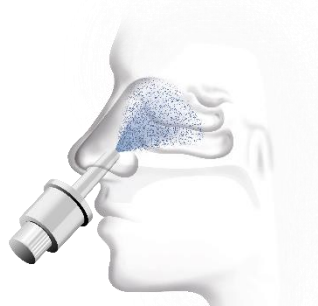
Rybelsus® is a registered trademark of Novo Nordisk A/S

[1] Exposure of AmorphOX formulations were lower than injectable reference

NEWS: Orexo US awarded USD 8 m by BARDA for OX390 development partnership

Valued up to USD 50 m and structured in five stages

- **OX390, today in pre-clinical 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®

Financial & legal

YTD 2025 (Q2): Full-year financial forecast confirmed, incl. achieving positive EBITDA in 2025

Income statement USD m	Jan-Jun 2025	Jan-Jun 2024	FY 2024	FY 2023
Net revenues (NR)	**28.1**	**27.7**	**53.3**	**63.3**
of which US Commercial (Zubsolv®)	*26.2*	*26.1*	*50.6*	*57.2*
Gross Profit	**25.03**	**24.9**	**46.8**	**54.5**
OPEX	**-27.9**	**-26.8**	**-59.4**	**-65.7**
EBIT	**-2.8**	**-20.5**	**-12.7**	**-10.8**
EBITDA	**-0.4**	**1.9**	**4.4**	**-3.2**
Cash position	**12.9**	**13.2**	**11.1**	**16.9**

Note: All numbers converted from SEK to USD using USD/SEK rate as end of each period: 0625;9,4, 0624; 10,06, 1224; 11,07, 1223; 10,09.

YTD 2025 developments & legal update

- ✓ Zubsolv US NR impacted negatively by a non-recurring rebate payment of USD 0.9 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 USD 0.5 m when excl. non-recurring rebate.

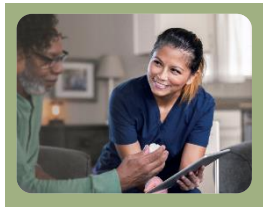
Legal update – subpoena issued by US authorities in 2020: Orexo believes investigation relates to past marketing campaigns. The company is unaware of any filed cases & maintains the concerns are meritless, yet is negotiating resolution. A change in administration may delay the process due to politically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

Future value drivers

Approach for expansion

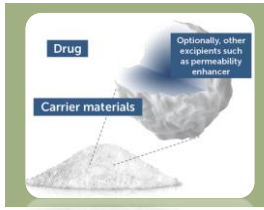
Growing revenues & profit contributions

- 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.

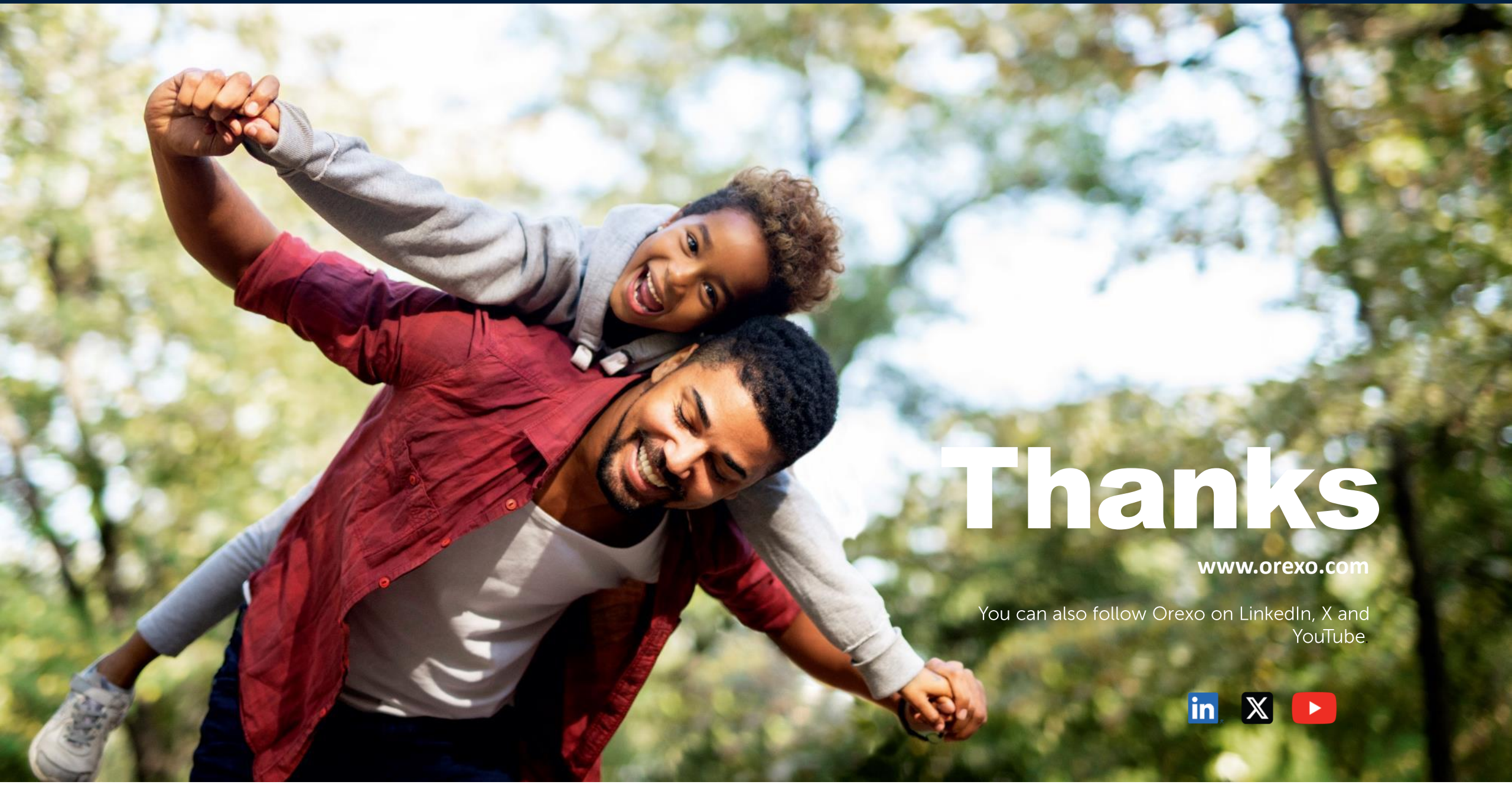


Capitalising the AmorphOX® technology

- 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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