orexo

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

May 13, 2025

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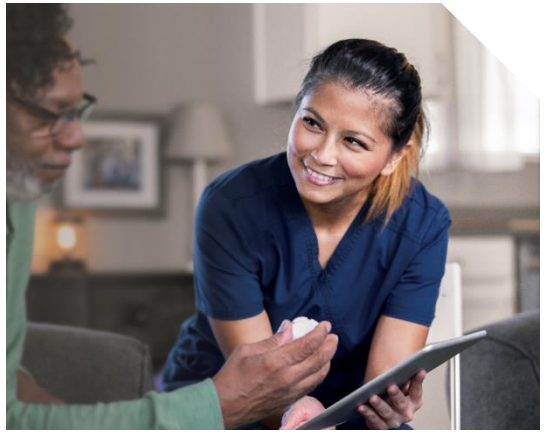
Orexo in brief

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

5.750

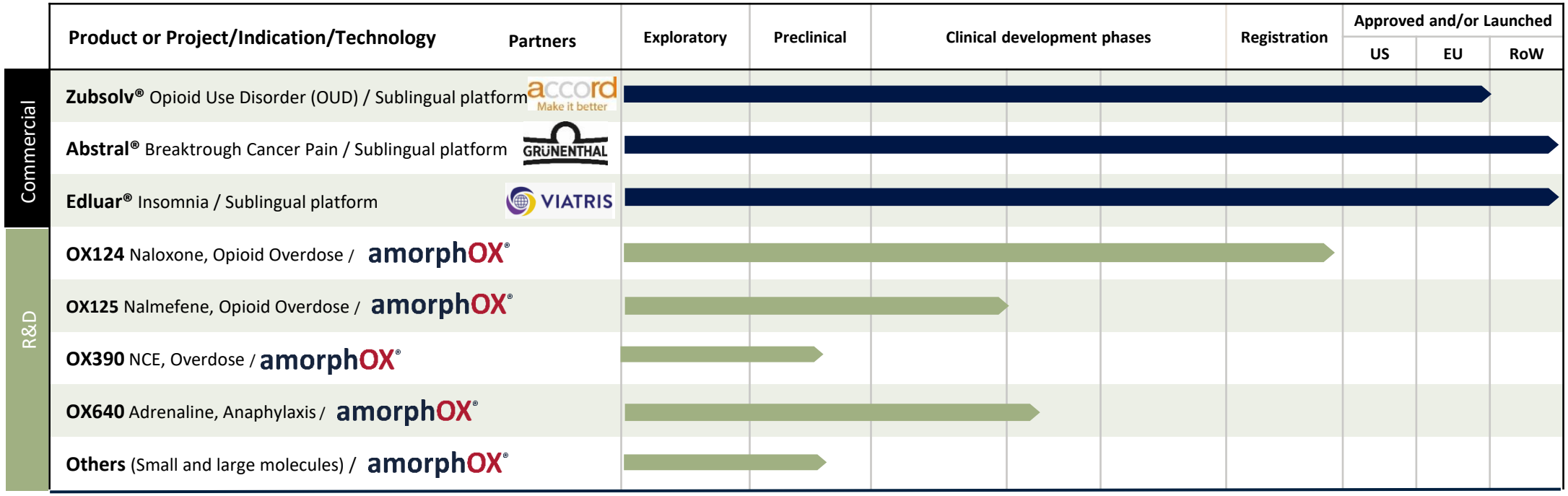
Total net revenue since US launch in 2013

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

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



Commercial

Robust US commercial platform fighting 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]

64,000
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

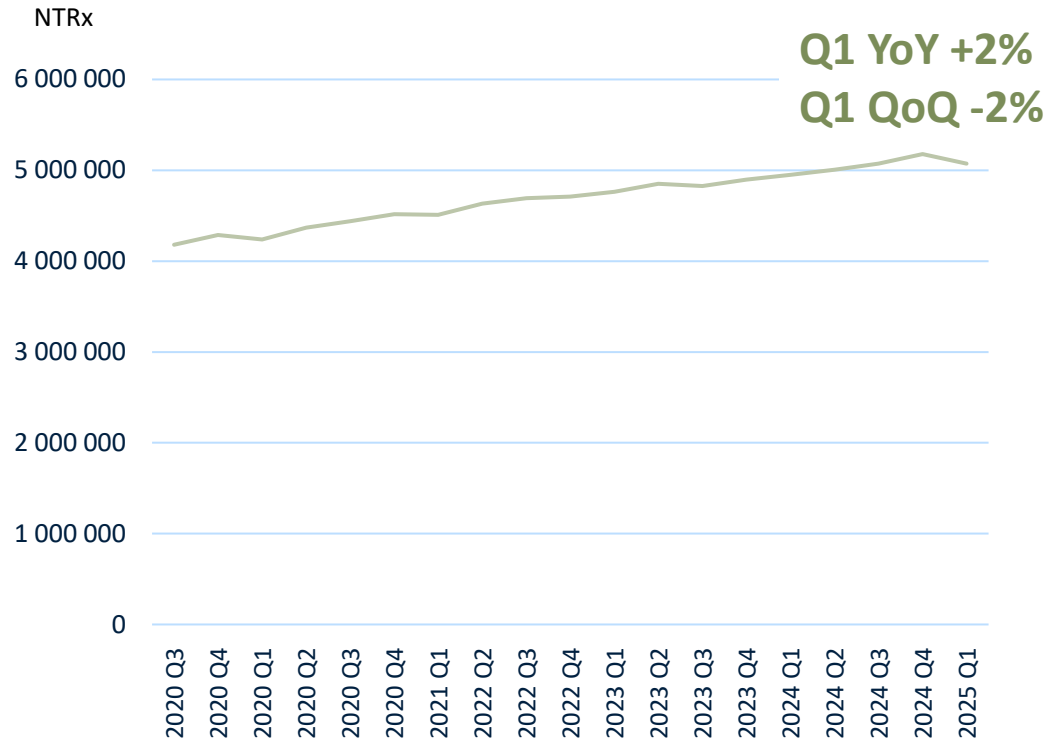
Rescue medication

OX124 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. [3] US Joint Economic Committee, data refers to 2020.

Q1 2025: Slightly lower bup/nal market growth

Market development



Market development by segment (across retail)

- YoY: Commercial +9%, Medicare +4%; Medicaid -3%
- QoQ: Commercial -3%, Medicare -4%, Medicaid -2%
- Market Share: Commercial 34%, Medicaid 37%, Medicare 14%

Zubsolv® development

- Overall: Weak quarter due to deductible resets and new Medicare rebate rules
- QoQ / YoY: -8% / -6%
- Across retail: Commercial -8% (mainly UHG), Medicaid -2%, with growth in NY and Wisconsin offsetting decline, Medicare -14% (Humana D and rebate policy impact)

SEK 133m

Q1 2025: Zubsolv Net Revenues

SEK 44m

Q1 2025: US Commercial EBIT. EBIT margin 33%

[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.

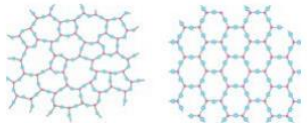
AmorphOX®

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

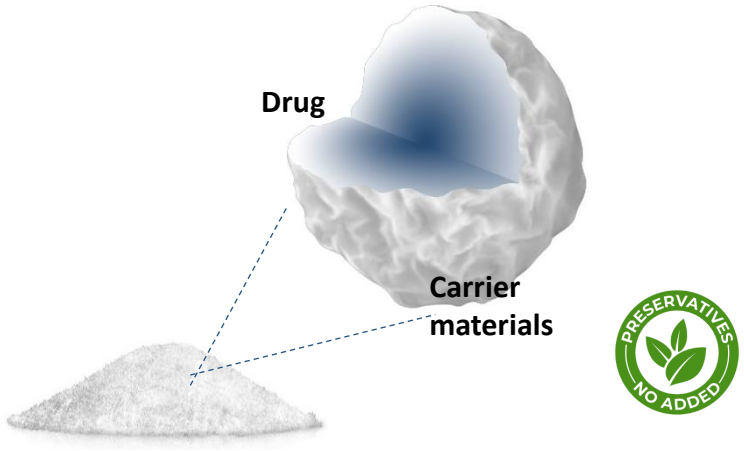
AmorphOX® is a unique drug delivery technology

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

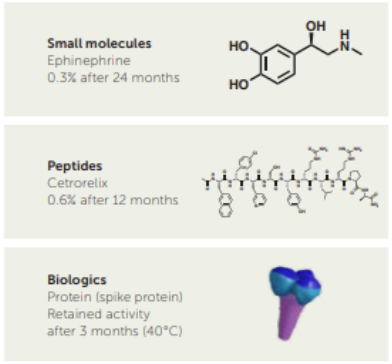


AmorphOX unique strengths

1 AmorphOX unique properties ensure physical and chemical stability

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

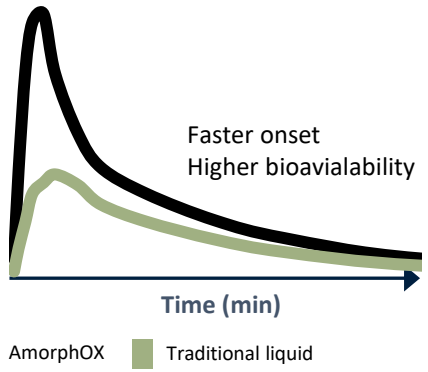
Examples **Chemical degradation after accelerated stability studies at 40°C/75% RH**



2 AmorphOX is validated in multiple clinical trials

- ✓ OX124 – high-dose rescue medication (naloxone)
- ✓ OX125 – overdose rescue medication (nalmefen)
- ✓ OX640 – adrenalinproduct for anaphylaxis

Plasma concentration from clinical trial



3 AmorphOX is a versatile platform

Improves:

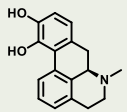
- ✓ Small molecules
- ✓ Peptides
- ✓ Biologics

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

Examples of both internal and partnered projects

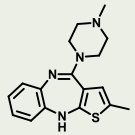
Small molecules

Apomorphine



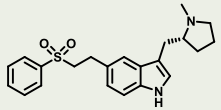
0.2% after 24 months

Olanzapine



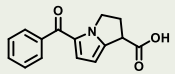
0.2% after 6 months

Eletriptan



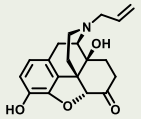
0.5% after 12 months

Ketorolac



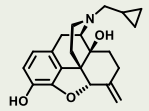
0.8% after 6 months

Naloxone



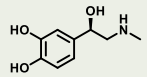
≤0.1% after 24 months

Nalmefene



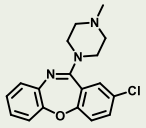
≤0.1% after 15 months

Epinephrine



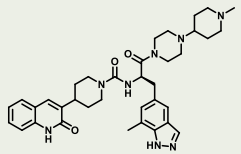
0.1% after 24 months

Loxapine



0.3% after 24 months

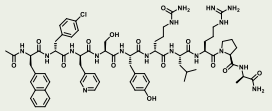
Zavegepant



≤0.1% after 9 months

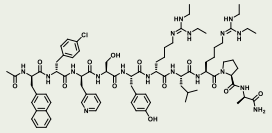
Peptides

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**

Maximize AmorphOX® potential through partnerships

From idea to commercial product

Orexo´s experts from R&D, Regulatory Affairs, Supply Chain & Market Access can support a partner´s innovative product development along the way

Get started with an MTA

Formulate and stability-test external APIs on AmorphOX within 3 months of receiving the API.

POC Study and Clinical Trials

Orexo performs feasibility and clinical trials to assess external APIs on AmorphOX.

GMP certified facilities & established Supply Chain

Orexo can manufacture (small[er] scale) clinical trial material for ph I trials in-house and leverage its established supply chain.

Lifecycle management / IP

License to AmorphOX IP ranging from currently 2039 to 2044 with the possibility for new, joint IP.

OX124 (registration phase) – high dose rescue medication for opioid overdose with naloxone

- Large health issue in the US with >58.000 deaths from opioid overdoses annually[1]
- OX124 is based on AmorphOX® and designed to treat overdoses caused by synthetic opioids representing >90% of the opioid overdoses
- Formulations of OX124 clinically differentiated to market leader and generic versions of market leader

Reduced uncertainty in FDA resubmission timeline

CRL received in mid-2024. Delivery of components to nasal device expected early Q3 2025 enabling initiation of commercial testing. Resubmission expected mid-2026.

Global overdose rescue market size 2022 (USD)[2]

1,483 m

Projected global annual growth[3]

11 %

[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 can have the following differentiating properties
  - Superior absorption and exposure
  - Fast acting
  - Longer shelf life
  - Less restrictive storage requirements
  - Improved dose conformity.
- Partnering process ongoing for global commercialization.

Positive data from two clinical studies

Epinephrine global market size 2023 (USD)[1]

2,800 m

Growth rate CAGR 2024-2033[1]

8 %

PRESERVATIVES NO ADDED

[1] https://www.precedenceresearch.com/epinephrine-market#:~:text=The%20global%20epinephrine%20market%20size,forecast%20period

Note: images are prototypes and not final packages

Collaboration between Abera and Orexo to develop nasal powder vaccines using AmorphOX®

abera BIOSCIENCE

Abera at a glance:

- Swedish vaccine and biotechnology company founded in 2012
- Development of innovative nasal vaccines based on proprietary and patented platform technologies

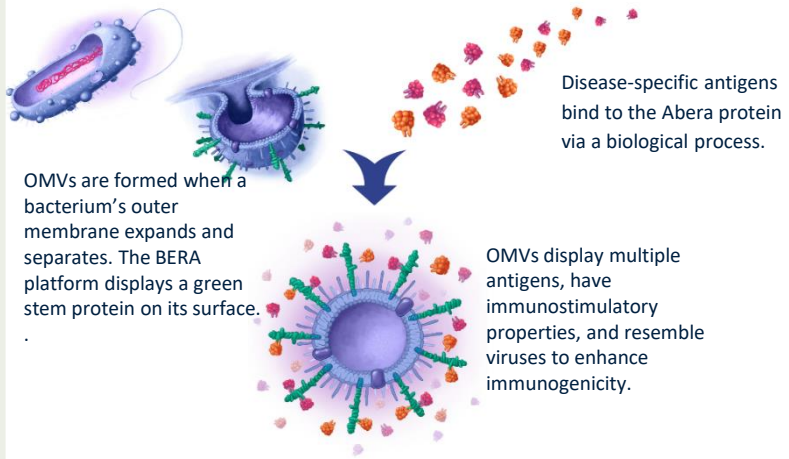
Candidate(s):

Influenza

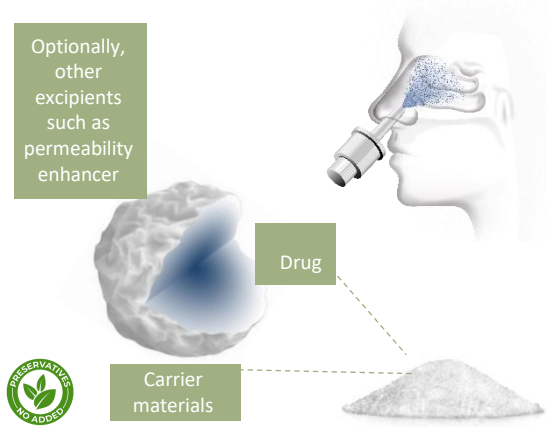
Funding:

CEPI

BERA™ vaccine platform



AmorphOX® technology



In vivo study results:

- Abera's influenza vaccine candidate was successfully formulated using AmorphOX.
- The AmorphOX® nasal powder vaccine elicited both systemic and local immune responses, potentially limiting infection spread.
- This vaccine may eliminate cold chain needs due to enhanced stability.

This slide uses publicly available information.
For more information on Abera, we refer to their website: https://aberabio.com/. For more information on CEPI, please visit: https://cepi.net/. For more information on Orexo, please visit: https://orexo.com/rd/the-amorphox-technology/

Financial & legal

Q1 2025: Stable Zubsolv® sales & continued positive EBITDA

Income statement SEK m	Jan-Mar 2025	Jan-Mar 2024	FY 2024	FY 2023
Net revenues (NR)	**146.2**	**139.3**	**590.0**	**638.8**
of which US Commercial (Zubsolv)	*133.0*	*129.3*	*560.3*	*577.7*
Gross Profit	**125.5**	**126.0**	**517.9**	**550.0**
OPEX	**-130.7**	**-130.7**	**-658.2**	**-659.5**
EBIT	**-5.2**	**-4.7**	**-140.3**	**-109.5**
EBITDA	**5.9**	**15.9**	**48.9**	**-32.5**
Cash position	**119.1**	**198.0**	**123.3**	**171.0**

Q1 2025 developments & legal update

- ✓ **Zubsolv US Net revenues grew 2.9%** due to lower reduction of wholesaler inventories, a positive FX impact, and price increase partly offset by lower demand. **Also stable in local currency.**
- ✓ **Positive EBITDA SEK 6 m despite** currency headwind and less royalty from Abstral®
- ✓ **Positive improvement in cash flow from operations QoQ** with SEK 33 m (-19), but negative impact from weaker USD.

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.

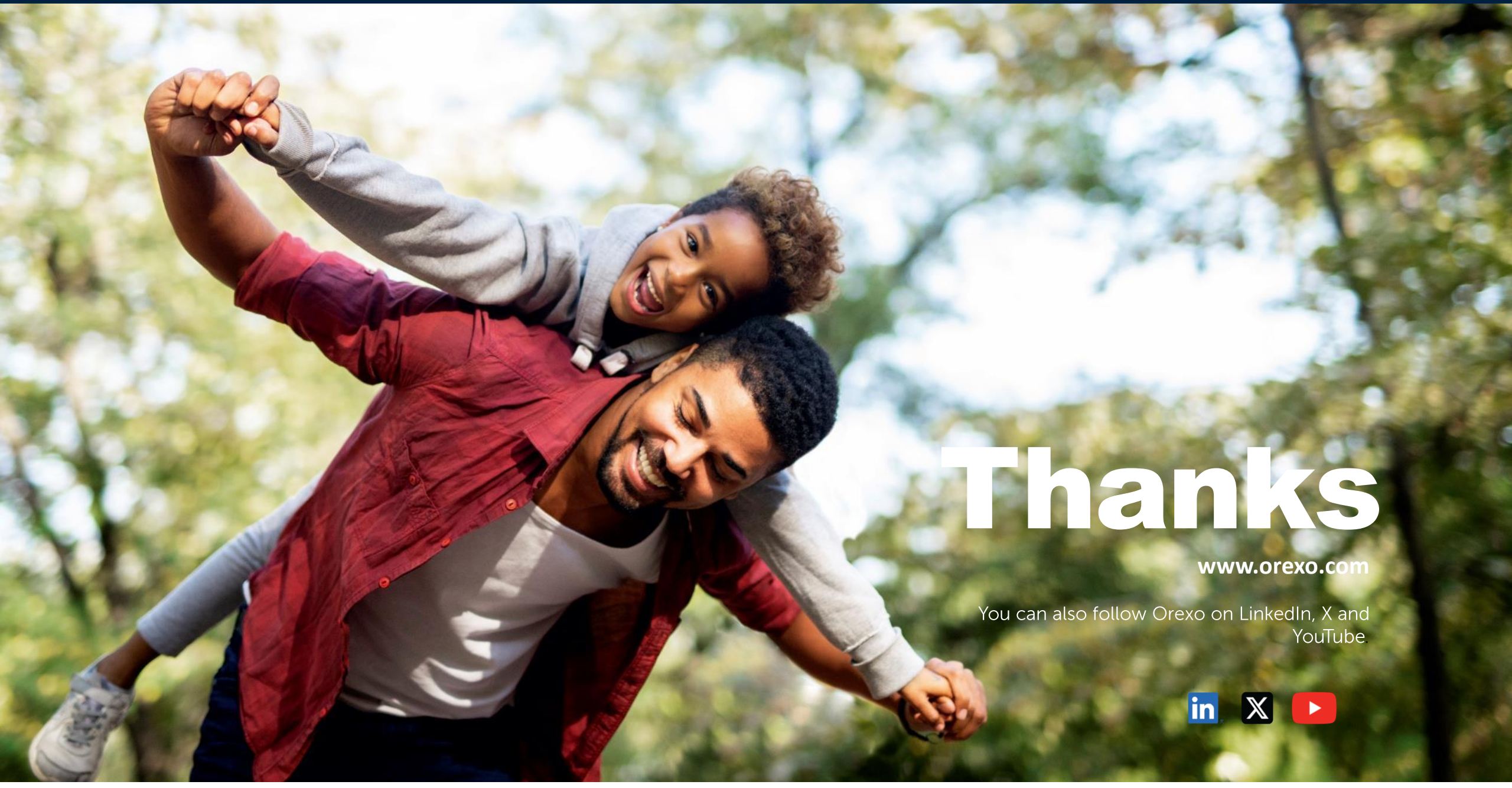
Future value drivers

Strategic initiatives based on a sustainable foundation

Growing revenues and profit contributions	Improving access to treatment	Capitalising on the AmorphOX® drug delivery technology
Key milestones and focus areas going forward		
• Maintain Zubsolv® revenues • Approval and launch of OX124 • Milestones and royalties from current and future partnered products.	• Expand reimbursement of Zubsolv in the public segment and maintain access in the commercial segment • Secure reimbursement for OX124 at launch.	• Partnering with other pharma companies to co-develop new products based on AmorphOX • Out-license products based on the AmorphOX technology such as OX640 • Develop new products to commercialise primarily within OUD and mental health.

orexo *Sustainability strategy*

Responsible business	Access to healthcare	Environment & climate change	Sustainable employees



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