orexo

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

March 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

5.600

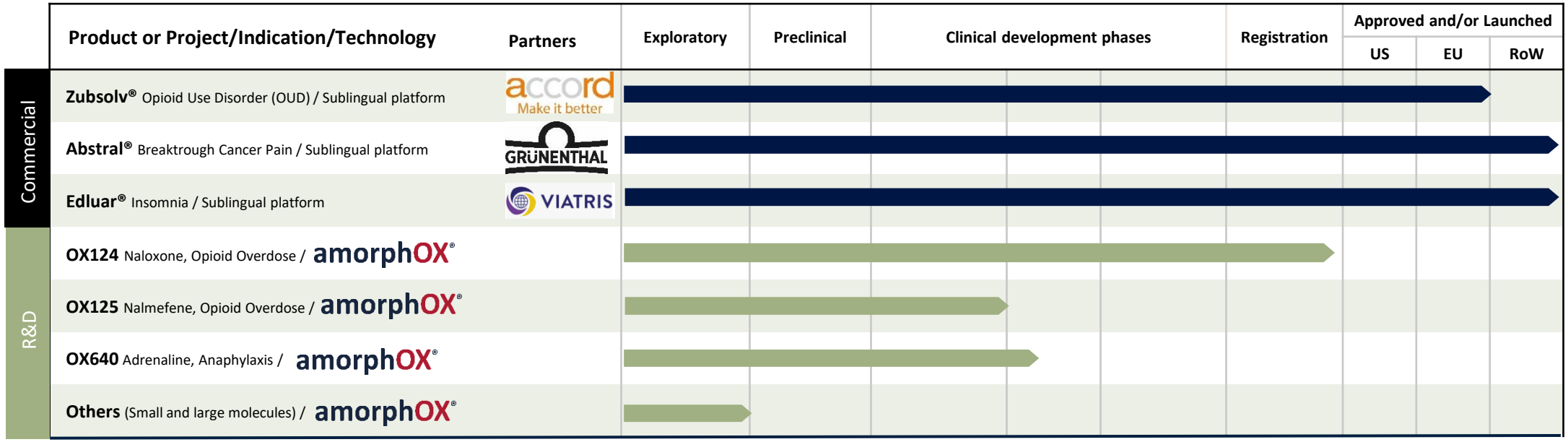
Total net revenue since US launch in 2013

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® & 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

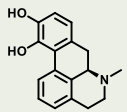


The scalable AmorphOX® platform takes Orexo beyond the OUD treatment area

Examples of both internal and partnered projects

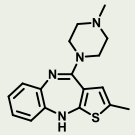
Small molecules

Apomorphine



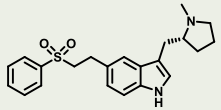
0.2% after 24 months

Olanzapine



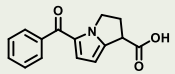
0.2% after 6 months

Eletriptan



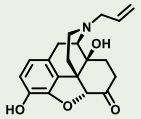
0.5% after 12 months

Ketorolac



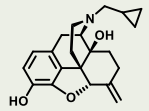
0.8% after 6 months

Naloxone



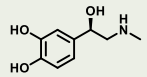
≤0.1% after 24 months

Nalmefene



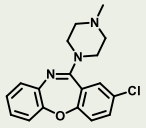
≤0.1% after 15 months

Epinephrine



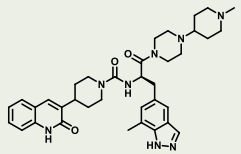
0.1% after 24 months

Loxapine



0.3% after 24 months

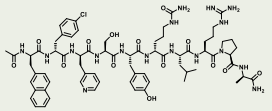
Zavegepant



≤0.1% after 9 months

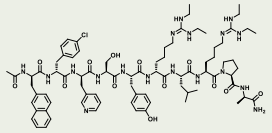
Peptides

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**

Commercial

Robust commercial platform targeting OUD regions

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.

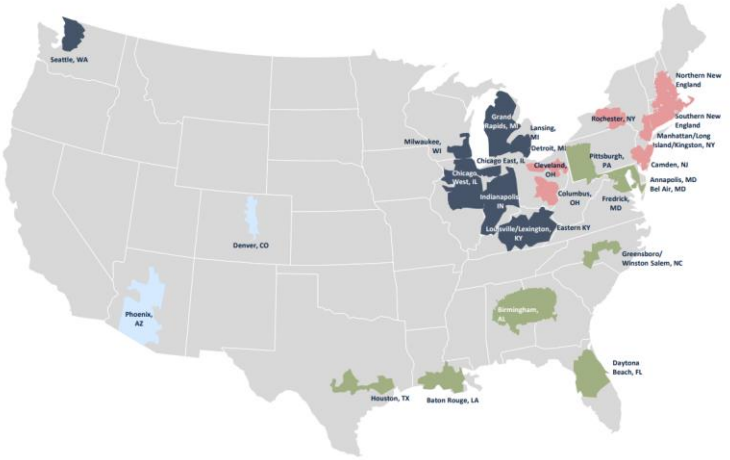
Zubsolv® with a robust commercial platform targeting OUD regions

Differentiated position

- ✓ Broadest range of doses allowing precise titration & individualized dosing
- ✓ Sole promoted daily MAT brand with no generic alternatives
- ✓ Treatment consistency and dose range appeal to physicians
- ✓ Patient preference vs Suboxone tablet and film formulations.[1]

Broad commercial infrastructure

- ✓ Sales territories in nearly all large metropolitan areas
- ✓ Sales territories optimized based on market size, growth and market access
- ✓ Market access team covering all established payers
- ✓ Medical Affairs team of experienced physician, pharmacist and psychologist.



98 %

Ratio of patients in the **Commercial payer segment** that can get Zubsolv reimbursed

50 %

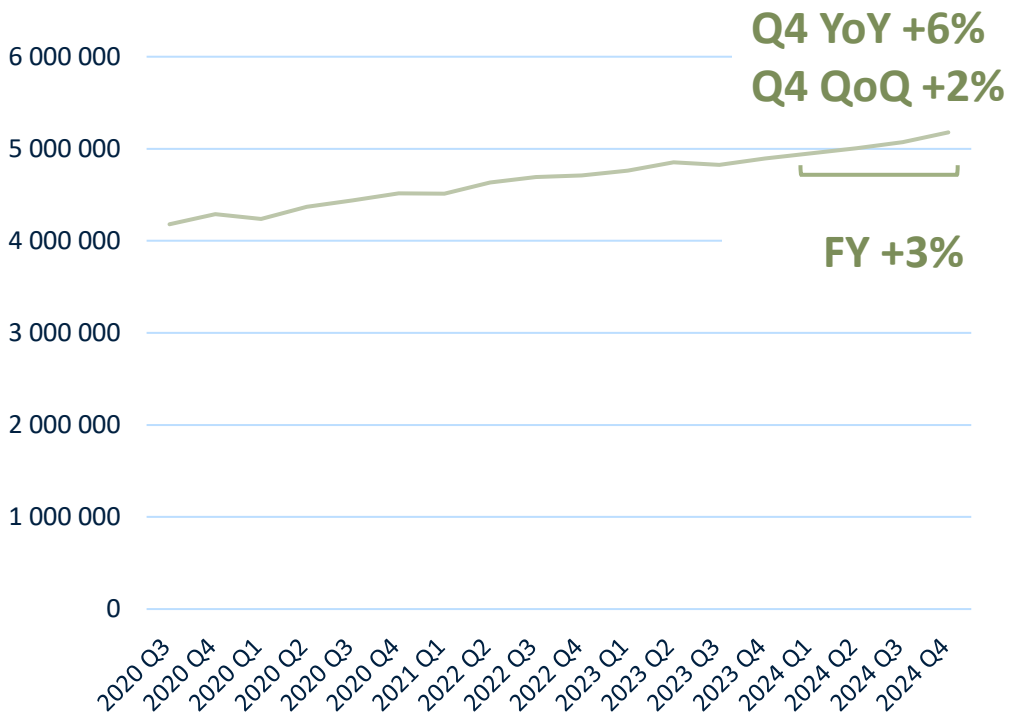
Ratio of patients in the **Public payer segment** that can get Zubsolv reimbursed

aetna · Blue Cross Blue Shield Blue Care Network of Michigan · cigna healthcare · CVS caremark · Elevance Health · Express Scripts By EVERNORTH · NAVITUS PHARMACY BENEFITS REINVENTED · Optum Rx · NEW YORK STATE The Empire Plan · United Healthcare

[1] Orexo ISTART study comparing Zubsolv to Suboxone tablets

Slightly accelerating market growth & stabilized Zubsolv® development

Market development (NTRx)



[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.

Q4 2024: Market development by segment

- Commercial growth YoY +19% and Medicare +9%
- Continued but slowing decline in Medicaid -2% YoY
- Medicaid remain the largest market segment with 37% of patients followed by Commercial with 34%

Q4 2024: Zubsolv development

- QoQ +1% and 0% YoY
- Growth in Public segment, both Medicaid & Medicare

SEK 578m

Net revenues 2024
Zubsolv

SEK 177m

EBITDA 2024
US Commercial

US market drivers support continued growth for Zubsolv® and upcoming OX124 launch

- New legislation (Mainstreaming Addiction Treatment Act, 2023) aimed to increase access to treatment long-term removing restrictions for prescription of MAT
- New funding from opioid litigation of an accumulated value of USD 57 billion to curb the opioid crisis.
- Strong growth in the profitable Commercial payer segment improve access to branded products like Zubsolv where 98 % of patients with a private insurance can get Zubsolv® reimbursed.
- Continued focus on improving access to opioid overdose rescue medication and need for new alternatives to curb high number for deaths due to fentanyl.

2-5 %

US bup/nal market
expected growth in 2025[1]

10 %

US naloxone market
expected growth (CAGR) 2023–2032[2]

[1] Orexo financial outlook 2025. [2] Spherical insights.

Settlement reached with Sun Pharmaceuticals after over 4 years of Zubsolv® IP litigation

- The agreement resolves the patent litigation initiated by Orexo in 2020 after Sun filed an ANDA to market generic Zubsolv in the US before Orexo's patent expiration.
  - ➢ Allows Sun to enter the US market with its generic versions of Zubsolv in September 2030.
  - ➢ Does not implicate Zubsolv´s patent protection incl. ten US patents ranging from 2027 to 2032.
- Eliminated the short-term risk of failing in the Federal Court of Appeals and losing Zubsolv exclusivity.

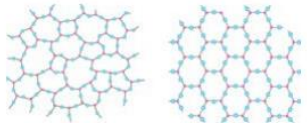
AmorphOX®

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

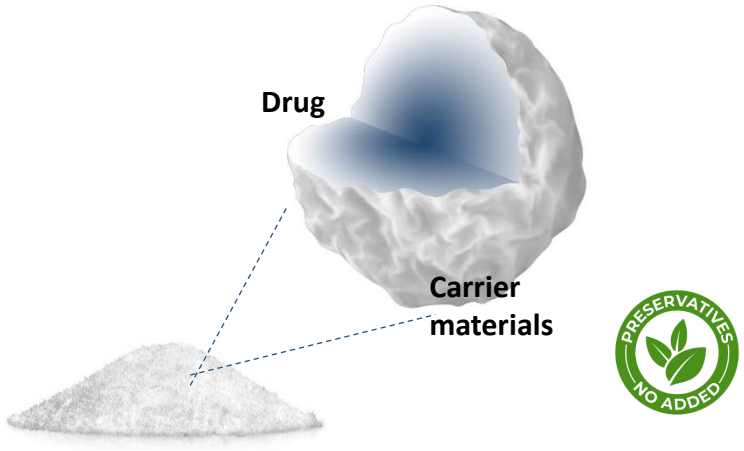
AmorphOX® is a unique drug delivery technology

The challenge

Amorphous materials, commonly used in drug development, are rapidly absorbed but tend to be **unstable limiting routes of administration, distribution and storage**



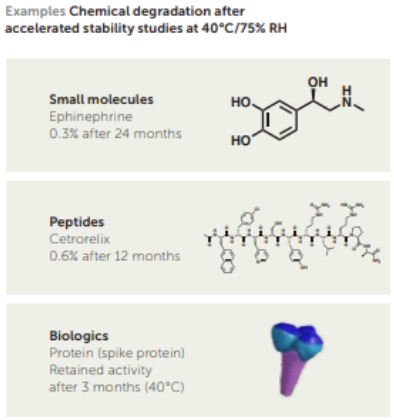
The solution – AmorphOX, a powder-based technology



AmorphOX unique strengths

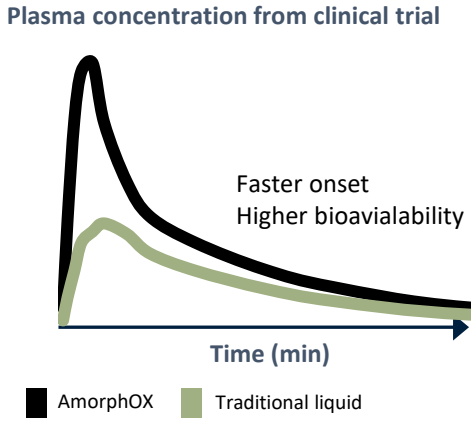
1 AmorphOX unique properties ensure physical and chemical stability

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



2 AmorphOX is validated in multiple clinical trials

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



3 AmorphOX is a versatile platform

Improves:

- ✓ Small molecules
- ✓ Peptides
- ✓ Biologics

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

- Large health issue in the US with >64.000 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
- **NDA filed with the FDA in 2023 and ongoing work to address FDA requests for additional data related to the commercial manufacturing and device.**

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 initiated 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 %

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

Note: images are prototypes and not final packages

Financial & legal

Improving profitability and removing uncertainties

Income statement SEK m	Oct-Dec 2024	Oct-Dec 2023	FY 2024	FY 2023
Net revenue (NR)	**160.3**	**166.0**	**590.0**	**638.8**
of which US Commercial (Zubsolv®)	*152.1*	*151.3*	*560.3*	*577.7*
Gross Profit	**138.0**	**145.9**	**517.9**	**550.0**
OPEX	**-235.9**	**-154.5**	**-658.2**	**-659.5**
EBIT	**-98.0**	**-8.6**	**-140.3**	**-109.5**
EBITDA	**28.9**	**12.4**	**48.9**	**-32.5**
Liquid funds	**123.3**	**171.0**	**123.3**	**171.0**

[1] Digital Mental Health Programs, Deprexis and Vorvida. [2] Mainly related to costs referring to the US government agency investigation.

2024 – the best EBITDA result since 2019

- ✓ **Positive EBITDA both full year, SEK +48.9 m (-32,5) and in Q4, SEK +28.9 m (12.4) explained by reduced OPEX**
- ✓ Zubsolv® revenue stable YoY in both SEK and USD, but significant growth from Q3 in line with expectations
- ✓ Lower Abstral® RoW royalties based on lower sales following agreements for individual countries expire
- ✓ **Non-recurring items affecting OPEX** mainly due to write-down of **SEK 99.2 m** DMHP[1] intangible assets
- ✓ Internal transaction between Orexo AB (parent company) and Biolipox (fully owned subsidiary) related to Zubsolv worth ~**SEK 1.1 b** in Q4

Legal update

Subpoena issued by the US authorities

- On July 14, 2020, Orexo became aware of an investigation by the US authorities which is ongoing
- Based on communications from the US authorities, the company believes it refers to certain historic marketing messaging campaigns
- Orexo, as of this date, is not aware of any filed civil or criminal case related to the investigation
- Orexo's position to the government has been that its investigation concerns have no merit, but Orexo is also seeking to negotiate a settlement of the matter.

The value story

Several potential value triggers near term

1 Zubsolv® value potential after removing IP litigation threat

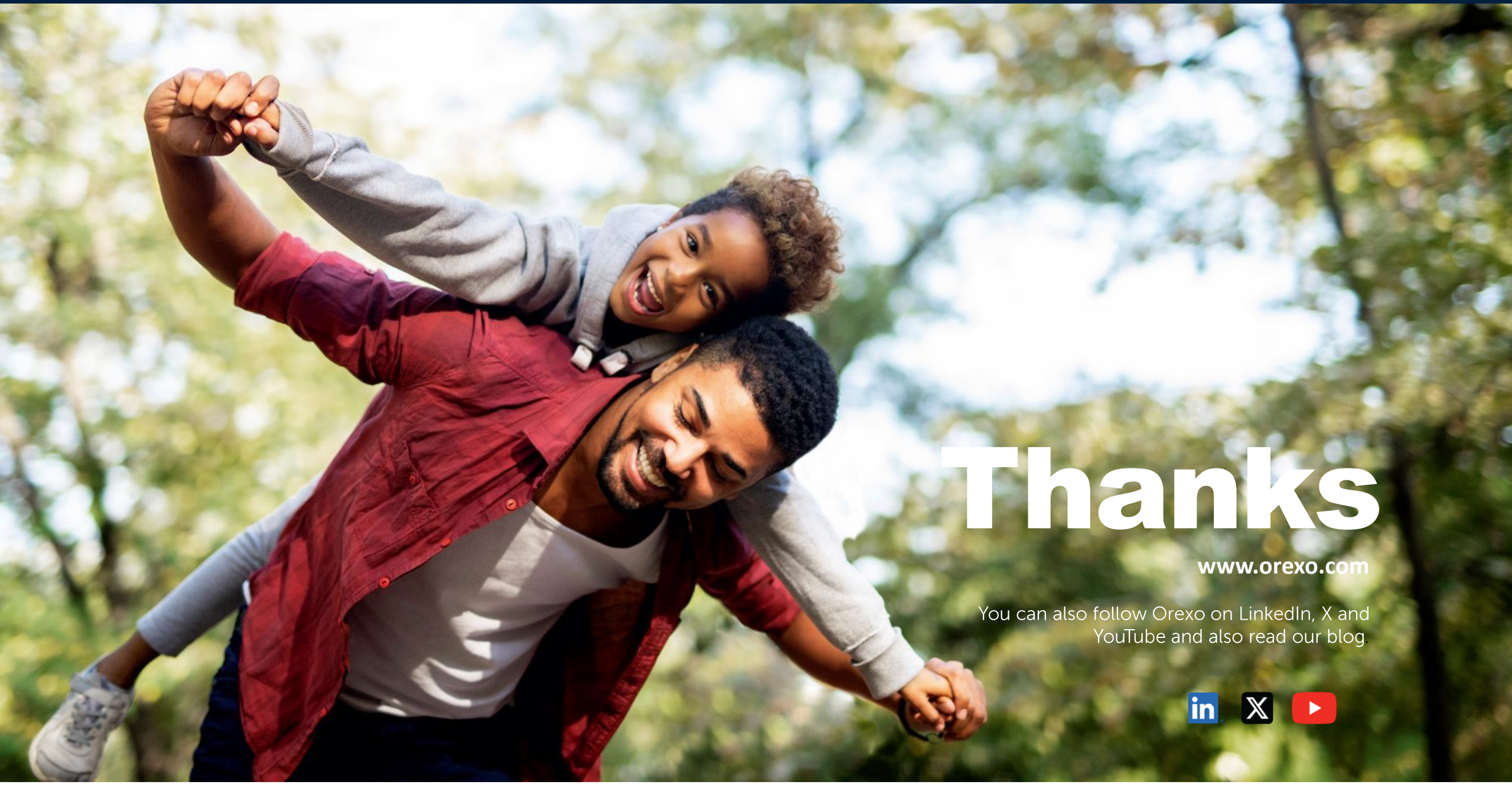
- Stabilizing sales and profit contributions from Orexo US
  - 2024: SEK 578 m net revenue and SEK 177 m EBITDA contribution
- Continued market growth and currently driven by the more attractive commercial segment
- IP maintained until September 2032, with first entrant potentially late 2030 following settlement with Sun
- Settlement with Sun increase strategic flexibility for US operations.

2 Partnering around AmorphOX® drug delivery technology

- OX640 for treatment of anaphylaxis is open for partnering now following two successful clinical trials
- On-going partnerships in exploratory phase in vaccines and protein-based products e.g. Abera
- Partnering with other pharma companies to co-develop new products based on AmorphOX.

3 OX124 resubmitted to FDA and launch in the US

- OX124 filing completed and accepted by FDA except for additional data requests related to the Instructions for Use and the final commercial product
  - New Instructions for Use successfully tested in July 2024
  - Additional testing of final commercial product prepared and waiting for delivery of critical component
- Low risk to the final approval since all questions are of technical nature and will be solved.



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