orexo

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

November, 2025

amorphOX®

WE SUPPORT UN GLOBAL COMPACT

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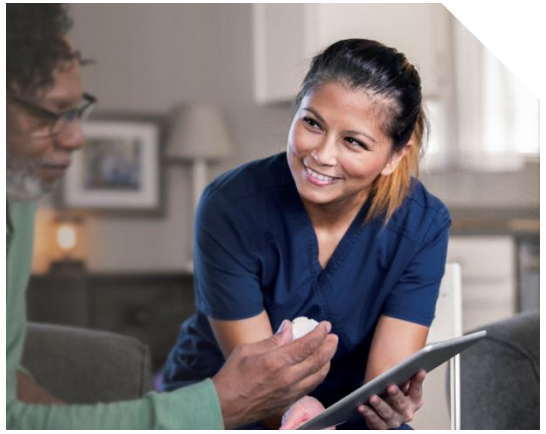
Orexo in brief

30 years of experience developing improved pharmaceuticals based on proprietary drug delivery technologies.

my green lab certification.

Addresses unmet needs within **opioid use disorder (OUD)** and other areas where our **technologies can contribute to improving drugs.**



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.

Strong cash generation from Zubsolv® in the US

SEK m

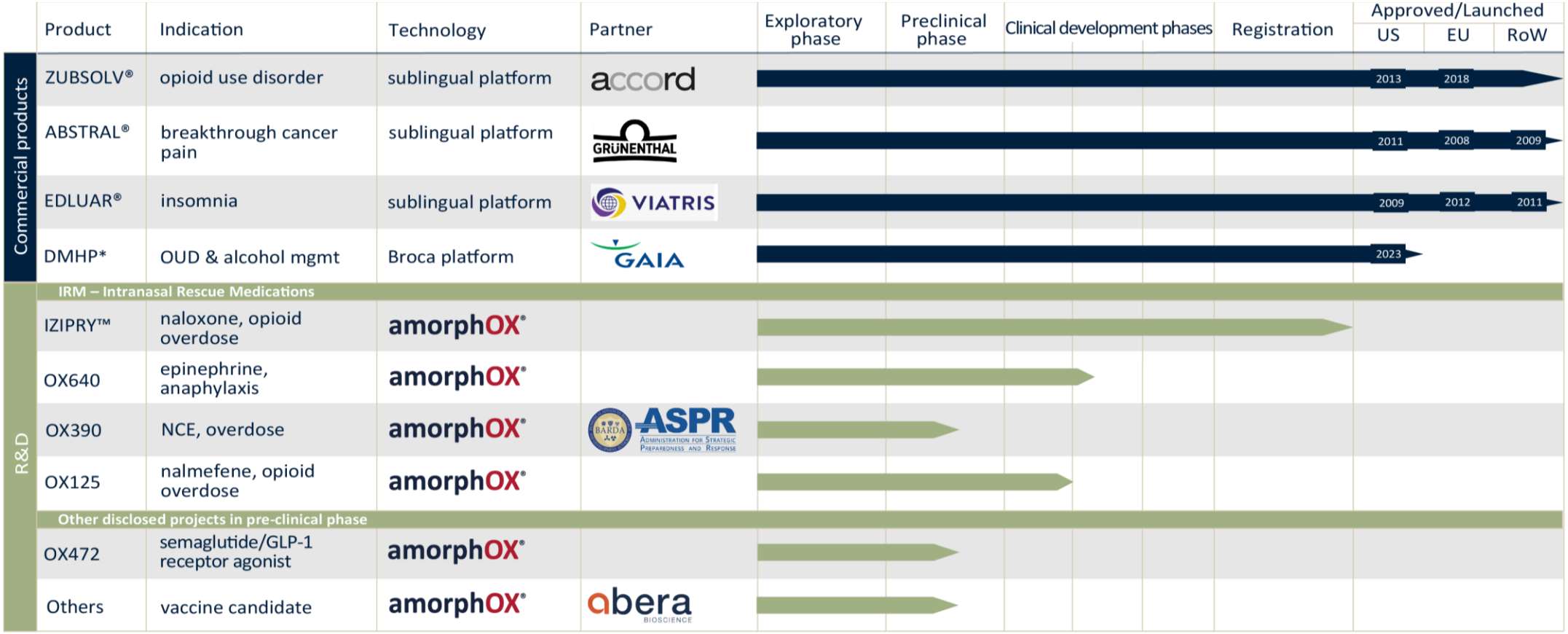
5.970

Total net revenue since US launch in 2013

[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: Product images, except for Zubsolv marketed in the US and EU, are prototypes

Commercial products and development pipeline



* Digital Mental Health Programs, incl. MODIA® & Vorvida®
OUD – Opioid Use Disorder
NCE – New Chemical Entity

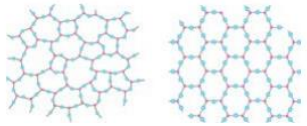
AmorphOX®

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

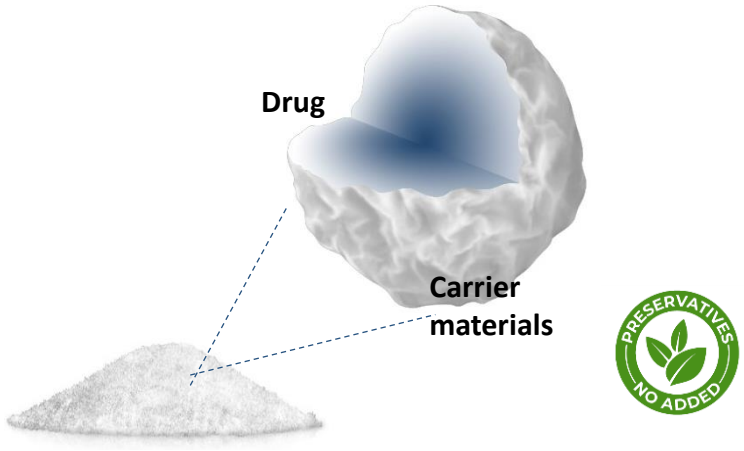
AmorphOX® is a unique drug delivery technology

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

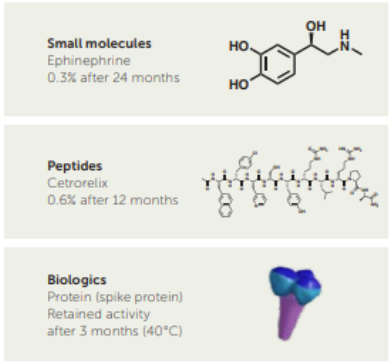


AmorphOX unique strengths

1 AmorphOX unique properties ensure physical and chemical stability

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

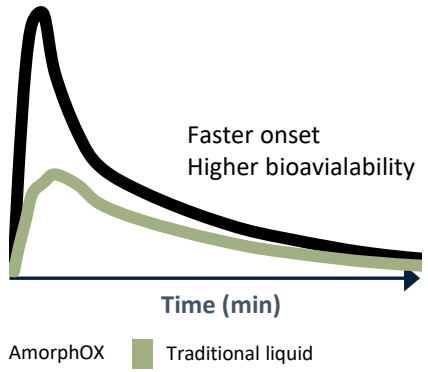
Examples **Chemical degradation after accelerated stability studies at 40°C/75% RH**



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:

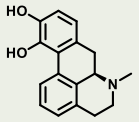
- ✓ Small molecules
- ✓ Peptides
- ✓ Biologics

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

Small — Molecular weight (Mw) — Large

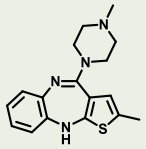
Small molecules | Peptides | Biologics

Apomorphine



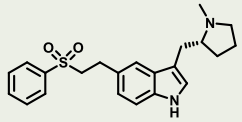
0.2% after 24 months

Olanzapine



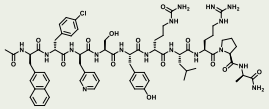
0.2% after 6 months

Eletriptan



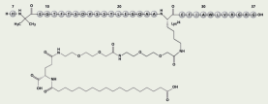
0.5% after 12 months

Cetrorelix



0.6% after 12 months

Semaglutide



0.1% after 62 months

Enzyme

Retained activity after 1 month (40°C)

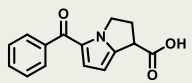
Virus like particle

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

Attenuated Virus

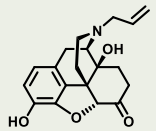
Retained titer levels, resilient to freeze thaw cycles

Ketorolac



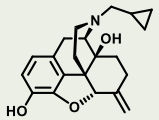
0.8% after 6 months

Naloxone



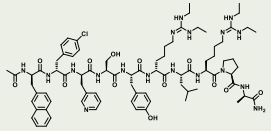
≤0.1% after 24 months

Nalmefene



≤0.1% after 15 months

Ganirelix

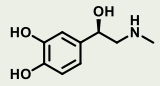


0.7% after 12 months

Covid Spike protein

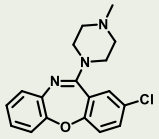
Retained activity after 3 months (40°C)

Epinephrine



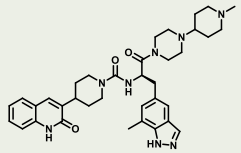
0.3% after 24 months

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) batches ready for stability and reliability studies

Manufacturing of required batches at commercial scale initiated in Q3 and completed in Q4

- Process initiated to complete the FDA required testing with expected filing mid-2026
- Stability data is the main driver of the timeline and Orexo has to balance time-to-market, shelf life at launch and risk of approval.

Market for Izipry increasingly competitive

- Orexo monitor development closely with commercial team in the US
- Launch strategy will be reviewed to limit financial risk of the company

Significant value for the AmorphOX® platform to have an approved product

- Availability of FDA approved supply chain and FDA approved product based on the AmorphOX technology is valuable in partner discussions and based on feedback from regulatory agencies also in the assessment of future AmorphOX products

FDA resubmission expected mid 2026

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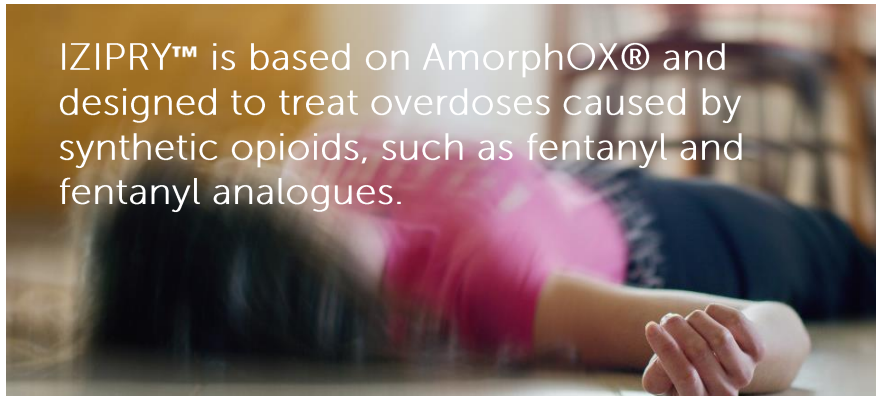
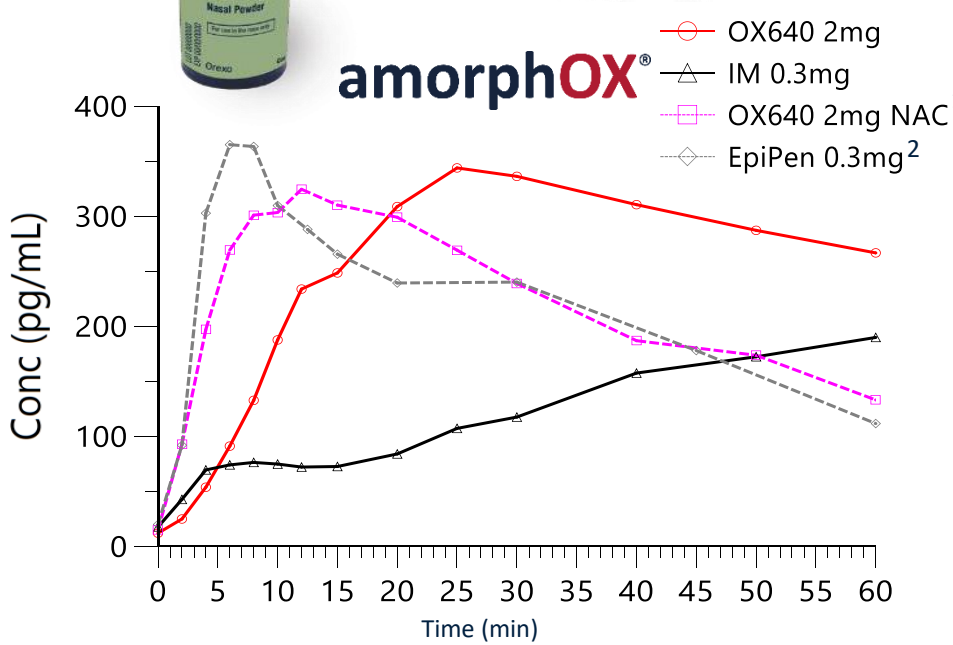


OX640 (clinical phase) – emergency treatment of anaphylaxis

- 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.
- Partnering discussions ongoing in parallel with upscaling
  - Partnering discussions closely connected to performance of first nasal product and some increased uncertainty of commercial risk is being reflected in discussions
  - Continued negotiations, but confirmation of market potential important to reach a balanced financial agreement.

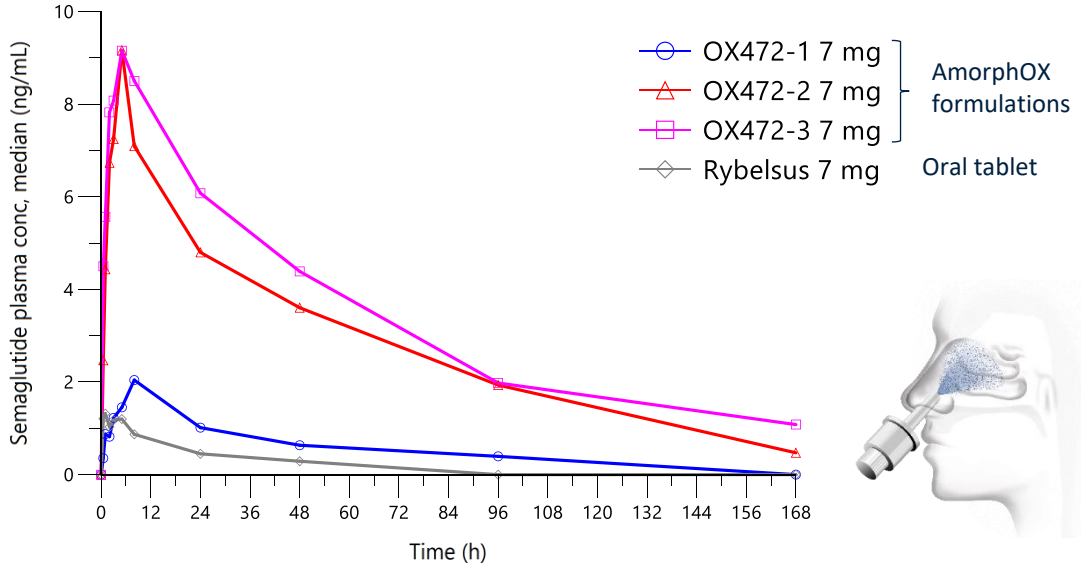


Positive data from two clinical studies. For OX640-002 also incl. patients with allergic rhinitis OX640 showed rapid absorption and sustained epinephrine levels during allergic rhinitis conditions, see data in the graph.

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

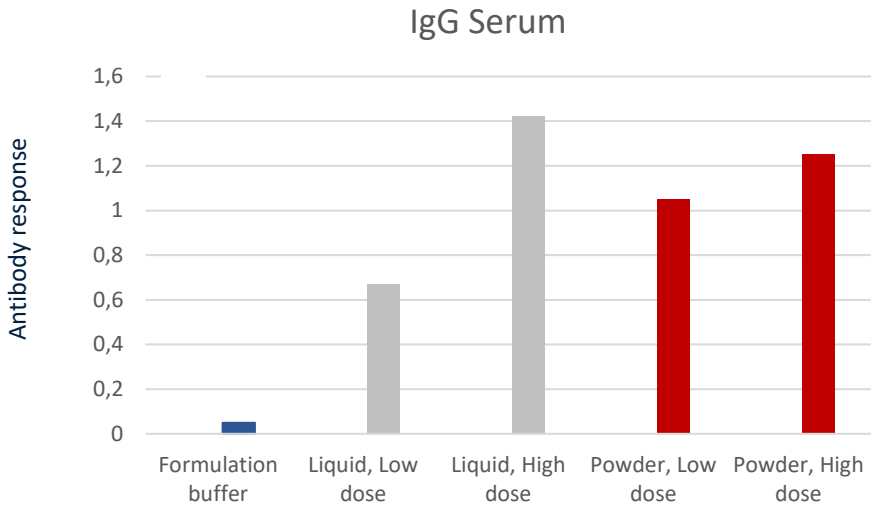
Early stage projects: AmorphOX® and large molecules

In-vivo proof-of-concept study of **nasal semaglutide powders**



AmorphOX-formulated semaglutide nasal powders demonstrated 7-times higher exposure compared to Rybelsus® oral tablet (median values)[1]

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

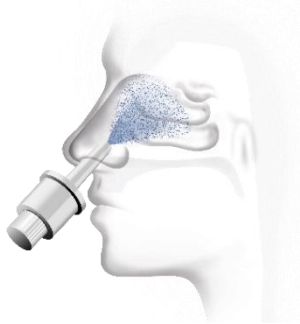
Rybelsus® is a registered trademark of Novo Nordisk A/S

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

NEWS: Orexo US awarded SEK 75 m by BARDA for OX390 development partnership[1]

Valued up to SEK 480 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.



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[1] In USD 8 m, valued up to USD 51 m

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

Income statement SEK m	Q3 2025	Q3 2024	FY 2024	FY 2023
Net revenues (NR)	**118.7**	**136.5**	**590.0**	**638.8**
of which US Commercial (Zubsolv®)	*113.9*	*131.0*	*560.3*	*577.7*
Gross Profit	**111.6**	**116.4**	**517.9**	**550.0**
OPEX	**-132.7**	**-138.1**	**-658.2**	**-659.5**
EBIT	**-21.1**	**-21.7**	**-140.3**	**-109.5**
EBITDA	**-9.8**	**-0.7**	**48.9**	**-32.5**
Cash position	**105.6**	**114.9**	**123.3**	**171.0**

YTD 2025 developments & legal update

- ✓ Zubsolv US NR impacted negatively by FX headwinds and lower demand. Partly offset by higher wholesaler stocking. Flat volume development Q3 vs Q2 2025.
- ✓ Lower OPEX due to reduced Sales and R&D costs. FX had a positive impact on OPEX.
- ✓ Cash position of SEK 125.6 m, when incl. holdings in Orexo´s corporate bond.

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.

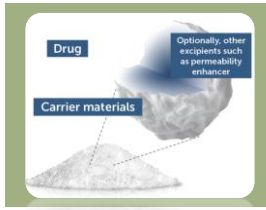
Approach for expansion

Advance value creation from commercial products

- Optimize value contribution from Zubsolv®
- Obtain FDA approval of Izipry™ and adapt go-to-market strategy to market potential

Develop products to meet patient needs

- OX390 development in partnership with BARDA to address growing issue with adulterated opioids
- OX472 to enter the sizable and growing market for AOM[1] and other GLP-1 agonists
- OX640 addressing the need for more convenient and stable formulation of epinephrine



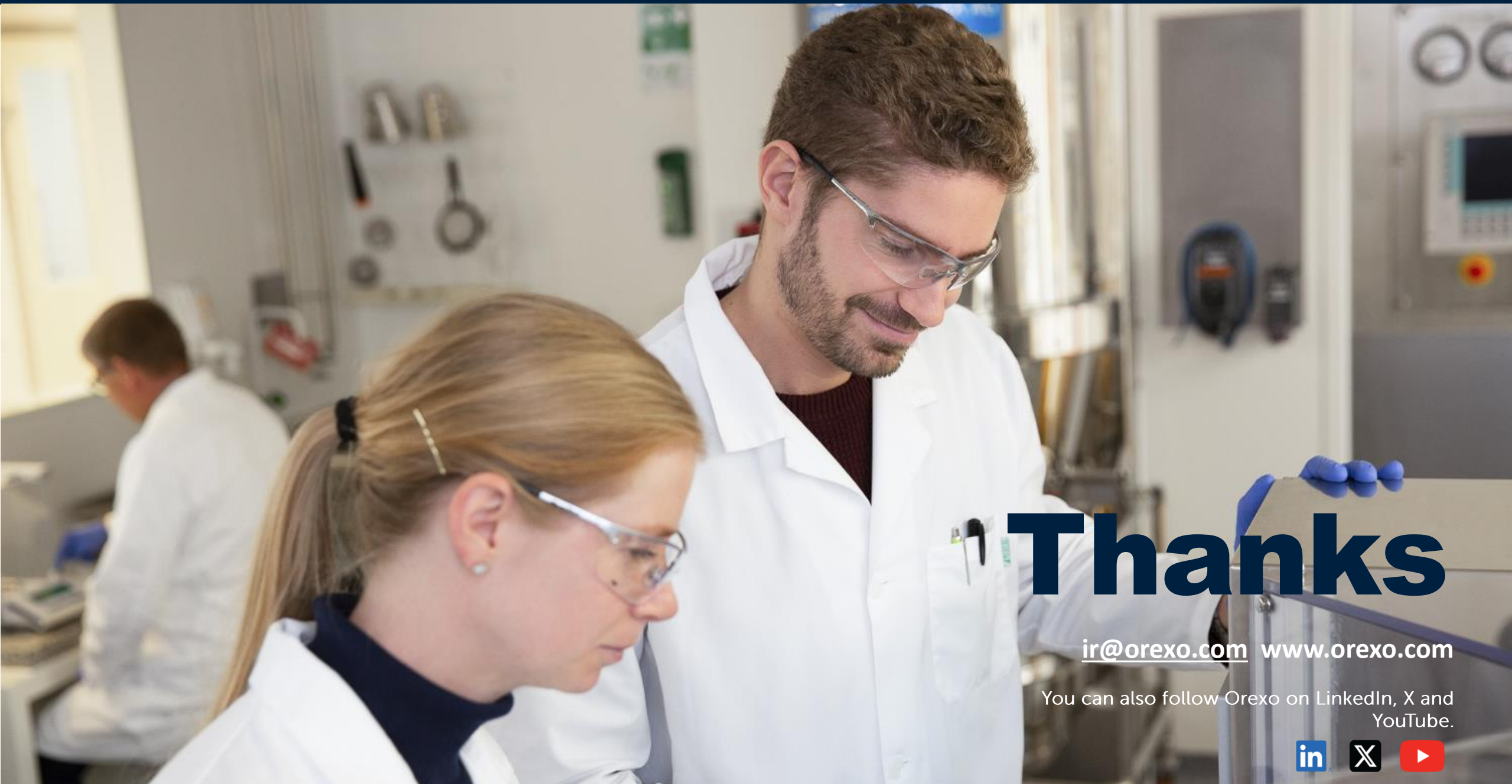
Capitalising the AmorphOX® technology

- Become the partner of choice for nasal powder delivery
- Partner internal projects to secure financing while maintain substantial value share e.g. OX640, OX390
- Expand into large molecules through partnership and improve scientific proof of concept e.g. Abera

ESG

Responsible business	Access to healthcare	Environment & climate change	Sustainable employees

[1] Anti-obesity medication



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