

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

June 10, 2025

amorphOX[®]



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Orexo – rooted in science, proven in market



Orexo develops and commercializes improved pharmaceuticals based on proprietary drug delivery technologies, with a strong US presence and global partnerships across multiple therapeutic areas.

Commitment

- Tackling opioid misuse
- Advancing drug delivery innovation
- Expanding global therapeutic impact.

Approach

- Commercializing OUD¹ treatments in the US
- Enhancing known APIs with proprietary drug delivery technologies
- Partnering globally for development & commercialization in other areas.

Team

- Home to highly skilled scientists & researchers
- Energizing & collaborative workplace
- Inclusive & respectful culture for growth.

¹ Opioid use disorder

30 yrs

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

novo holdings
Investing to benefit people and the planet

- largest shareholder at 28 %



Orexo facts & figures

Financial backbone

Strong cash generation from US Commercial

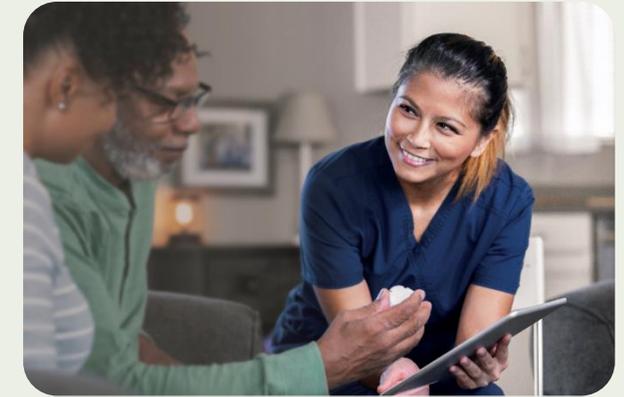
SEK m
5.750
Accrued Net Sales since 2013 from lead product

Q1 2025: Stable Zubsolv sales & positive EBITDA

P&L SEK m	Q125	Q124	FY24	FY23
Net revenues (NR)	146.2	139.3	590.0	638.8
<i>of which US Comm.</i>	133.0	129.3	560.3	677.7
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

Solid financial position

SEK m
119
+ SEK 30 m invested in own corporate social bond



Innovation by numbers



4
Innovated products of which 3 based on the sublingual platform

> 25
Approved markets

5
Clinical trials conducted with **amorphOX[®]**

Long experience from partnering

Key milestones

- 1995**: Founded as a drug delivery Co. in Uppsala, Sweden
- 2000**: **Diabact[®] UBT** (helicobacter pylori) reach 1st market approval
- 2008**: **EDLUAR[®]** (insomnia) 1st market approval
- 2009**: **ABSTRAL[®]** (breakthrough cancer) pain reach 1st market approval
- 2013**: **zubsolv** for OUD FDA approved and Orexo sets up a US subsidiary
- 2021**: **amorphOX[®]** launch of next-generation technology
- 2025**: **amorphOX[®]** 1 reg. phase & 2 clinical phase rescue medications in pipeline

Commercial products and development pipeline

	Product or Project/Indication/Technology	Partners	Exploratory	Preclinical	Clinical development phases	Registration	Approved and/or Launched			
							US	EU	RoW	
Commercial	Zubsolv® Opioid Use Disorder (OUD) / Sublingual platform ¹	accord Make it better	[Progress bar: Exploratory, Preclinical, Clinical development phases, Registration]							
	Abstral® Breakthrough Cancer Pain / Sublingual platform	GRÜNENTHAL	[Progress bar: Exploratory, Preclinical, Clinical development phases, Registration]							
	Edluar® Insomnia / Sublingual platform	VIATRIS	[Progress bar: Exploratory, Preclinical, Clinical development phases, Registration]							
R&D	OX124 Naloxone, Opioid Overdose / amorphOX®		[Progress bar: Exploratory, Preclinical, Clinical development phases]							
	OX125 Nalmefene, Opioid Overdose / amorphOX®		[Progress bar: Exploratory, Preclinical]							
	OX390 NCE, Overdose / amorphOX®		[Progress bar: Exploratory]							
	OX640 Adrenaline, Anaphylaxis / amorphOX®		[Progress bar: Exploratory, Preclinical, Clinical development phases]							
	Others (Small and large molecules) / amorphOX®		[Progress bar: Exploratory]							

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 opioids¹

2.3 m

are undergoing treatment¹

58,000

the number of fatal overdoses
caused by opioids annually²

USD 1,500 bn

The societal cost of the US opioid crisis³

Our approach

Medication-Assisted treatment (MAT)



Digital support program



Rescue medication



OX124 in registration phase (FDA)

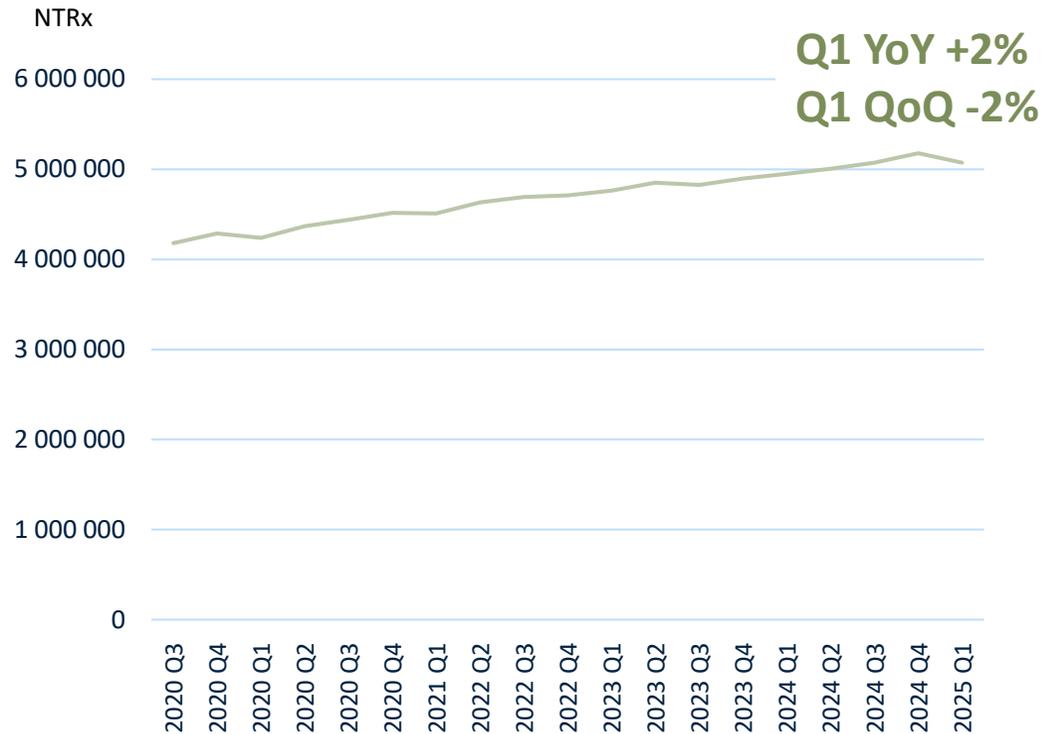


¹ SAMHSA Key Substance Use and Mental Health Indicators in the United States: Results from the 2023 National Survey on Drug Use and Health.

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 development¹



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 **133**_m

Q1 2025: Zubsolv Net Revenues

SEK **44**_m

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.
 NOTE: An ACTIVE SUBPOENA regarding Zubsolv US sales was issued by US authorities in July 2020. For further details, refer to note 4 in the quarterly reports.



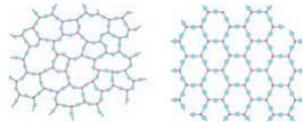
AmorphOX[®]

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

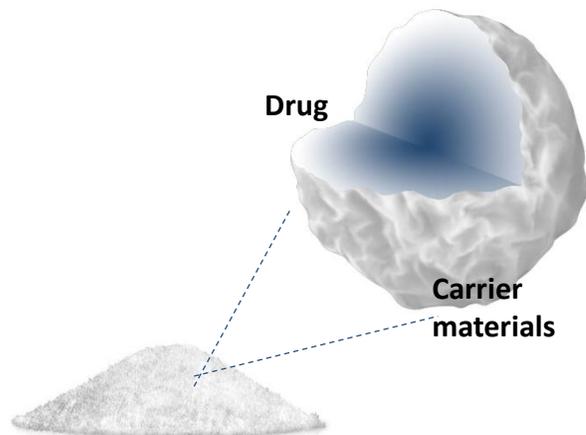
AmorphOX[®] is a unique drug delivery technology

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

Small molecules Ephinephrine 0.3% after 24 months	
Peptides Cetorelix 0.6% after 12 months	
Biologics Protein (spike protein) Retained activity after 3 months (40°C)	

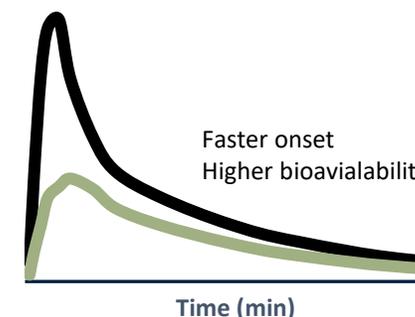
2 AmorphOX is validated in multiple clinical trials

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

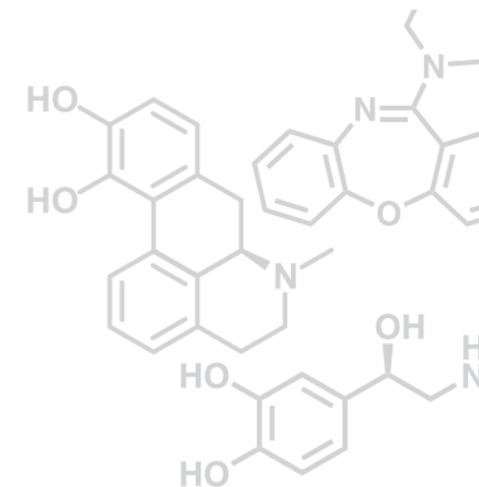
3 AmorphOX is a versatile platform

- Improves:
- ✓ Small molecules
 - ✓ Peptides
 - ✓ Biologics

Plasma concentration from clinical trial



■ AmorphOX ■ Traditional liquid

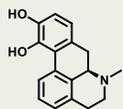


The scalable AmorphOX[®] platform takes Orexo beyond the OUD treatment area

Examples of both internal and partnered projects

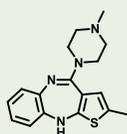
Small molecules

Apomorphine



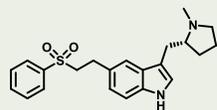
0.2% after 24 months

Olanzapine



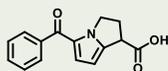
0.2% after 6 months

Eletriptan



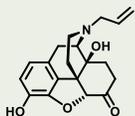
0.5% after 12 months

Ketorolac



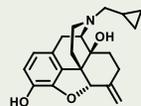
0.8% after 6 months

Naloxone



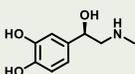
≤0.1% after 24 months

Nalmefene



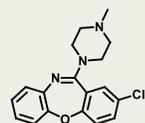
≤0.1% after 15 months

Epinephrine



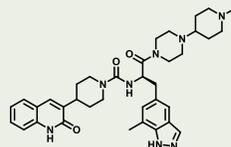
0.1% after 24 months

Loxapine



0.3% after 24 months

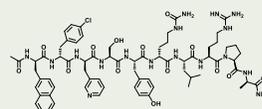
Zavegepant



≤0.1% after 9 months

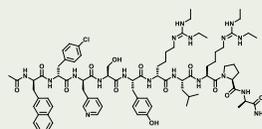
Peptides

Cetorelix



0.6% after 12 months

Ganirelix



0.74% after 12 months

Enzyme



Retained activity after 1 month (40°C)

Covid Spike protein



Retained activity after 3 months (40°C)

Immuno-modulator



99% purity after 1 month (50°C)

Biologics

Virus like particle



Retained activity after processing

Attenuated Virus



Retained titer levels, resilient to freeze thaw cycles



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

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 annually¹
- 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 growth²

11
%



¹ Center of Disease Control and prevention. ² [Naloxone Market Size, Share and Opportunities, 2025-2032](#).

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



¹ [Epinephrine Market Trends, Share and Forecast, 2025-2032](#)

Note: images are prototypes and not final packages

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



Abera at a glance:

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

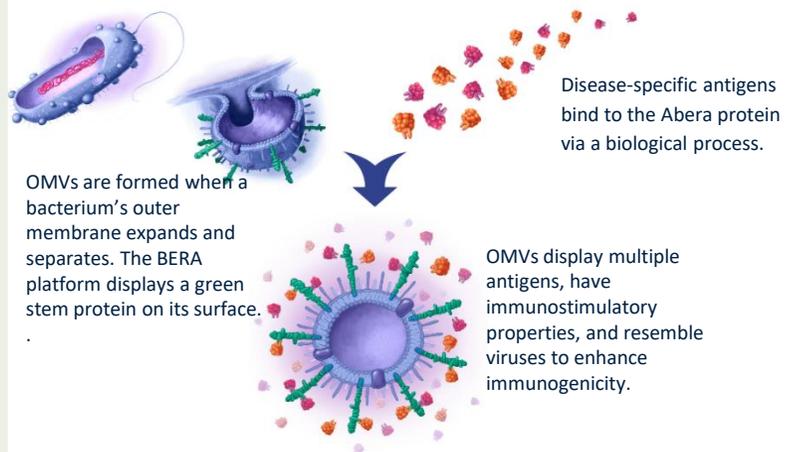
Candidate(s):

Influenza

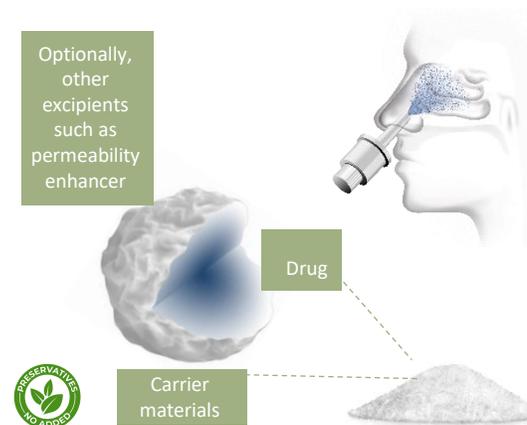
Funding:

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.



Future value drivers

Approach for expansion



Growing revenues & profit contributions

- ⇒ Maintain Zubsolv® revenue streams
- ⇒ Obtain FDA approval and initiate US launch of OX124
- ⇒ 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 for OX124 US launch.



Capitalising the AmorphOX® technology

- ⇒ Collaborating with other pharmaceutical companies to jointly create new products utilizing AmorphOX.
- ⇒ Out-licensing products that leverage the AmorphOX technology, including OX640
- ⇒ Develop new products for Orexo to commercialize primarily within OUD.



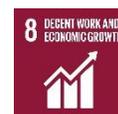
ESG

Responsible business

Access to healthcare

Environment & climate change

Sustainable employees



Thanks

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