

A commercial stage pharma company with an exciting pipeline

June 2024

Orexo supports the UN's Agenda 2030 with a focus on:



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Orexo in brief

Orexo is a Swedish pharmaceutical company with over **25 years of experience** developing improved pharmaceuticals based on proprietary drug delivery technologies.

Addresses unmet needs among patients and healthcare systems with a focus on **opioid use disorder (OUD) and adjacent diseases**



Net Revenues LTM¹

USD 58.7 m

EBITDA LTM

USD 2.3 m

*Of which US Commercial
USD 18.3 m*

Liquid funds

USD 19.1 m

Own commercial platform in the US, incl the lead pharma product Zubsolv® for OUD & complementary digital mental health programs.

R&D pipeline based on the **AmorphOX®** - a drug delivery platform tested on a broad range of small & large molecules showing:






1. Improved stability
2. Reduced sensitivity to temperature changes
3. Superior bio-availability.



Note: OX124, high dose overdose rescue medication filed with the FDA in Q4 2023. prototype photo used. Conversion rate USD/SEK 10.39.

¹ Last Twelve Months.

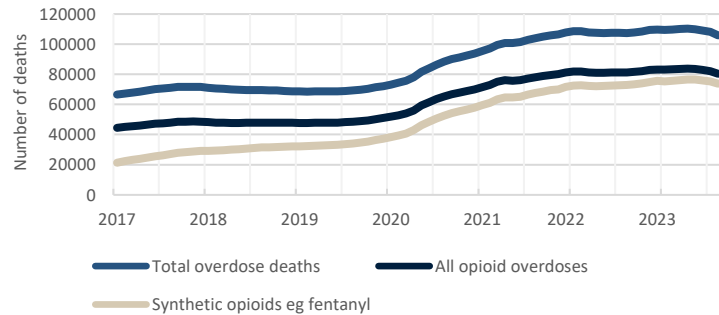
Commercial products and development pipeline

	Product or Project/Indication/Technology	Partners	Exploratory	Preclinical	Clinical development phases	Registration	Approved and/or Launched		
							US	EU	RoW
Commercial products	Zubsolv® Opioid Use Disorder (OUD) / Sublingual platform		[Progress bar]						
	Abstral® Breakthrough Cancer Pain / Sublingual platform		[Progress bar]						
	Edluar® Insomnia / Sublingual platform		[Progress bar]						
	DMHP ¹ OUD, alcohol mgmt, depression / Broca technology platform		[Progress bar]						
R&D	OX124 Naloxone, Opioid Overdose / AmorphOX ®		[Progress bar]						
	OX125 Nalmefene, Opioid Overdose / AmorphOX		[Progress bar]						
	OX640 Adrenaline, allergic reactions / AmorphOX		[Progress bar]						
	Others (small and large molecules) AmorphOX		[Progress bar]						
	OX-MPI Vipoglanstat, Endometriosis		[Progress bar]						

¹. Digital Mental Health Programs, incl. MODIA®, Vorvida® and Deprexis®

US market: Commercial products targeting a large unmet need

Fatal overdoses have surged due to synthetic opioids¹



Maintenance treatment



Digital mental health program



Rescue medication



Launch expected late 2024

8,900,000
are misusing opioids²

6,100,000
are dependent on opioids³

2,400,000
are undergoing treatment⁴



“Giana made the switch to heroin, and it was all downhill from there.”



Elise discovered her daughter’s opioid dependence months before she died from an overdose.

Read more at the [Orexo blog](#)

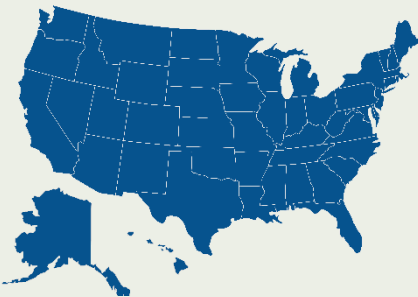
¹ Center of Disease Control. ^{2,3,4} Substance Abuse and Mental Health Services Administration

Zubsolv[®] an important cash generator

Net revenues since launch 2013

USD m

510



Sales and market dynamic in Q1

- 4% price increase from Jan. 1, stable Zubsolv sales to pharmacies, but the sector saw significant drop in wholesaler inventory in Feb./Mar. Expected to normalize in Q2.
- Low market growth in prescriptions of 3% vs Q1 2023 and 1% vs Q4 2023. Significant decline in Medicaid with minus 9% YoY following Medicaid disenrollment. Commercial growth of 9% YoY.
- Zubsolv declined slightly with 4% versus Q1 2023 and 2% vs Q4, explained by United Health Group/Humana and Medicaid market decline.
- Zubsolv outperformed the Medicaid segment both YoY +0% and QoQ -2%. Continued double-digit growth in new Medicaid contracts YoY.

Long-term growth drivers

- The Mainstreaming Addiction Treatment Act¹ effective Jan. 1, 2023, removes the cap on the numbers of patients HCP's can treat and reduce the requirements for prescribing medication assisted treatments (MAT)
- Significant inflow of new funds to finance treatment initiatives from USD 54 billion abatement funds
- IMPROVED POSITION - Orexo is about to become the player in the US market with the most comprehensive treatment solutions for people suffering with OUD.

Note: Conversion rate USD/SEK 10.39.

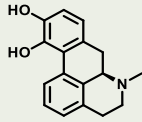
¹ Based on last 4w and 6w average NTRx volume. Note weekly prescription data is volatile and is influenced by public holidays, weather and changes to reimbursement

² Last Twelve Months

AmorphOX[®] – a versatile, world-class platform for intranasal drug delivery

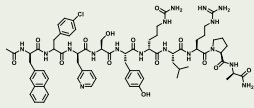
Chemical degradation after accelerated stability studies at 40°C/75% RH

Apomorphine



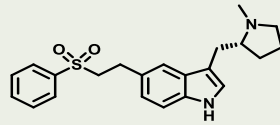
0.4% after 24 months

Cetrorelix



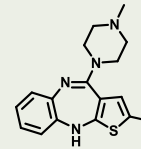
0.5% after 6 months

Eletriptan



0.5% after 12 months

Olanzapine



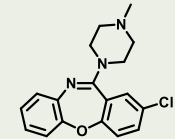
0.2% after 6 months

Enzyme



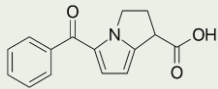
Retained activity after
1 month

Loxapine



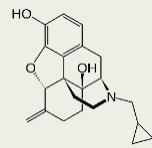
0.3% after 24 months

Ketorolac



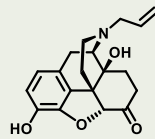
0.8% after 6 months

Nalmefene



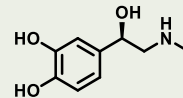
≤0.1% after 15 months

Naloxone



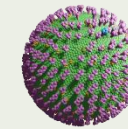
≤0.1% after 24 months

Epinephrine



1.8% after 18 months

Spike protein



Retained activity after
3 months



OX124 has unique properties and is progressing towards launch late 2024/early 2025

Intranasal powder delivery of naloxone & nalmefene

OX124 amorphOX®

High-dose rescue medication containing naloxone, **designed to reverse the effect of the most powerful synthetic opioids**, such as fentanyl

Filed with the FDA in Q3 2023



Small in size, easy to carry

Built-in desiccant to protect the powder from any moist exposure

The usage and application is simple, fast and most of all: high-dose

If approved, OX124 will be the only product on the market that does not freeze at temperatures below zero degrees

OX124 differentiation & competitive advantages



Rapid absorption and substantially higher plasma concentrations of naloxone compared to the current market leader – critical in avoiding brain damages, saving lives and preventing re-intoxification during the revival process



Unique properties compared with existing products i.e., **being a powder-based product** while other products are liquid-based



The amorphOX powder-based technology provides for **longer shelf-life and makes it less vulnerable to temperature changes**



Easy to carry as OX124 comes in a unique device that is less bulky



OX124 has **patents protecting the product until 2039**

OX640 a new treatment of allergic reactions

Improved stability as a more sustainable solutions



Preservative-free (which may cause allergic reactions)



No antioxidants, no chelating agent, no pH adjustment



Manufacturing without precaution for light or need for protective gas



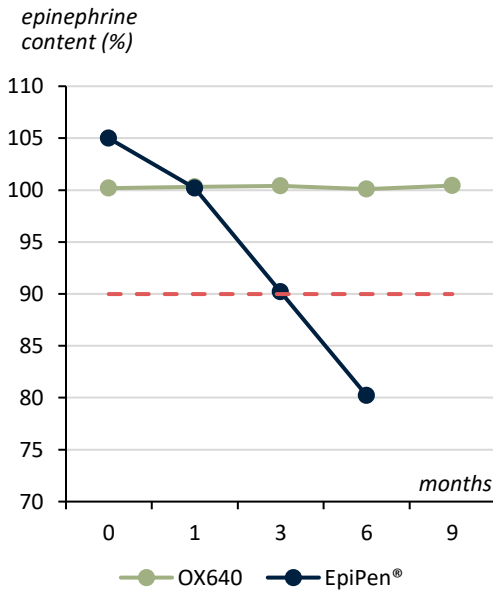
More convenient storage and longer shelf life



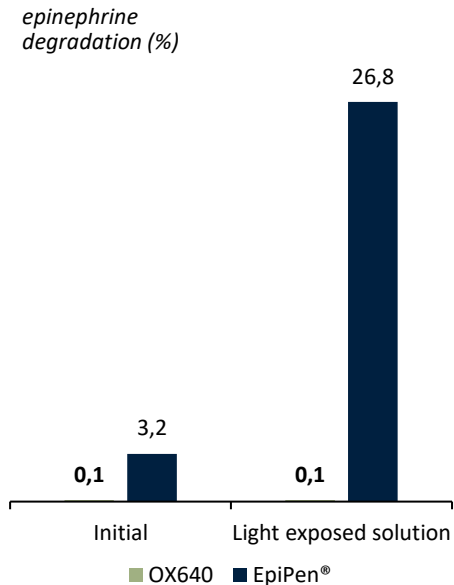
Highly improved stability versus any available liquid formulation

OX640: **Nasal epinephrine** enabled by **amorphOX** remains stable in any life situation

Comparative stability study at 40 Celsius/75% RH¹



Comparative light stability study at 1.2 M lux for 18h



First clinical trial indicates a superior bio-availability of OX640 compared to other liquid based nasal epinephrine products¹



Source: Company information. Notes: 1) Relative humidity.

¹ First OX640 clinical study compared to EpiPen and comparison with other liquid based nasal products in purely cross-over comparison and **not** head to head studies.

Q1 2024 – starting 2024 with a positive EBITDA

Income statement USD m	Q1 2024	Q1 2023	FY 2023
Net revenues (NR)	13.4	15.3	61.5
<i>of which US Pharma</i>	<i>12.4</i>	<i>13.5</i>	<i>55.6</i>
Gross Profit	12.1	12.5	52.9
OPEX	-12.6	-18.2	-63.4
EBIT	-0.5	-5.7	-10.5
EBITDA	1.5	-3.9	-3.1
Liquid funds	19.1	26.9	16.5

Q1 2024 comments

- ✓ NR decline primarily due to higher wholesaler destocking, slightly lower demand and FX headwind. Also, Zubsolv EU impacted negatively.
- ✓ Significantly reduced OPEX due to lower costs for IP, US Commercialization org., and R&D
- ✓ Positive EBITDA

Other financial highlights:

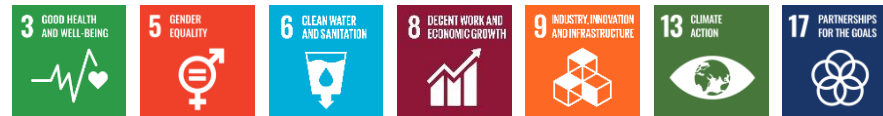
- Refinancing of the old bond by the issue of a 4 Y secured bond of SEK 500 m (USD 48.1) under a social financing framework.

Strategic initiatives going forward

Growing commercial revenues and profit contributions	Improving access to treatment	Capitalising on the amorphOX® drug delivery technology
<i>Key milestones and focus areas going forward</i>		
<ul style="list-style-type: none"> Stabilise Zubsolv® revenues and focus commercial investments in areas with growth opportunities Approval of OX124 by the FDA Hire experienced OX124 team Launch of OX124 in the US leveraging existing resources and focused investments into new areas 	<ul style="list-style-type: none"> Expand reimbursement of Zubsolv in the public segment and maintain access in the commercial segment Secure reimbursement for OX124 at launch Establish collaborations with healthcare providers under MatCore Establish patient support programs for all Orexo’s products Establish legislation and policies enabling access to all types of treatment of OUD and mental health 	<ul style="list-style-type: none"> Partnering with other pharmaceutical companies to co-develop new products based on AmorphOX® Out-license products based on the AmorphOX technology such as OX640 Develop new products for Orexo to commercialise primarily within OUD and mental health.



Responsible business	Access to healthcare	Environment & climate change	Sustainable employees
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Thanks

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