

A commercial stage pharma company with an exciting pipeline

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WE SUPPORT



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Orexo in brief

Orexo is a Swedish pharmaceutical company with nearly **30 years of experience developing improved pharmaceuticals** based on proprietary drug delivery technologies.

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

Wholly owned commercial operations in the **US**, incl. the lead pharma product Zubsolv® for OUD & complementary digital mental health programs.

Strong cash generation from lead product

USD m

540

Total net revenue since US launch in 2013¹



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

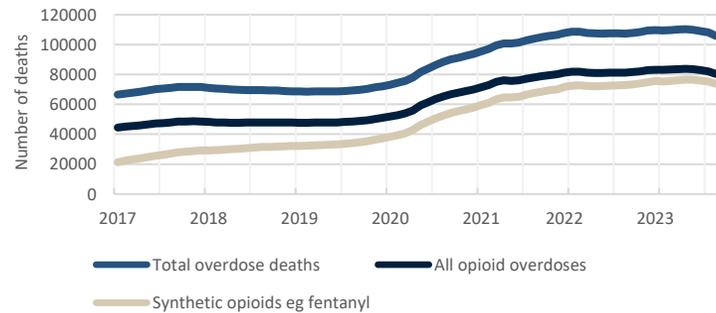
- ✓ Superior bio-availability
- ✓ Reduced sensitivity to temperature changes
- ✓ Highly stable.



¹ Converted from SEK to USD as of Q3 2024 (USD/SEK 10.42)

Orexo addressing OUD with a growing product offering

Fatal overdoses have surged due to synthetic opioids¹



8,900,000
are misusing opioids²

6,100,000
are dependent on opioids²

2,400,000
are undergoing treatment²

Maintenance treatment

This is for example only. Not actual barcode.

Digital mental health program

Rescue medication

Registration Phase (FDA)



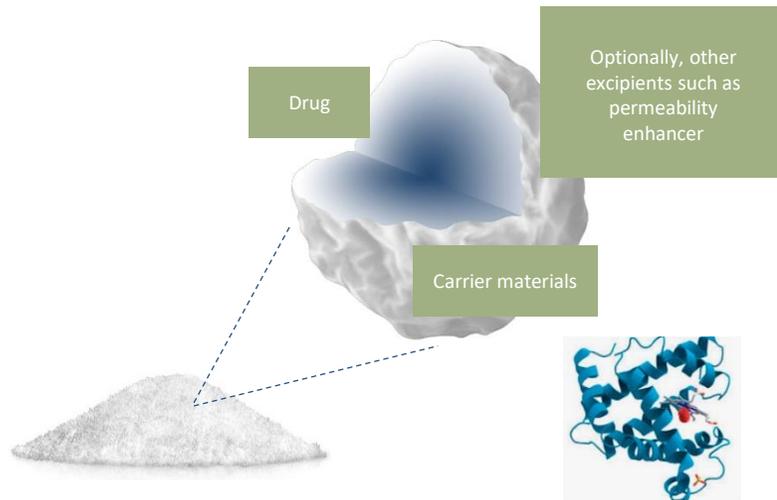
¹ Center of Disease Control. ² Substance Abuse and Mental Health Services Administration

Orexo's development pipeline building on the proprietary AmorphOX[®] drug delivery technology



Wide applicability

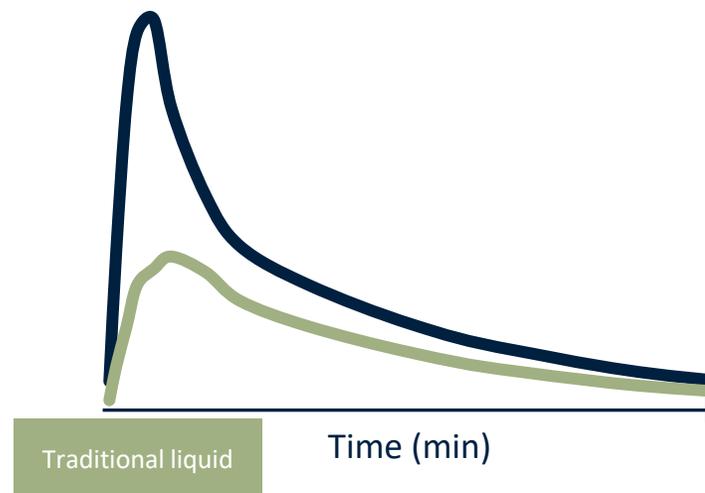
- ✓ Powder technology that works with a broad scope of small and large molecules, such as peptides and proteins



Validated in humans

- ✓ Superior pharmacokinetic properties with more rapid onset, higher peak and overall exposure, lower variability

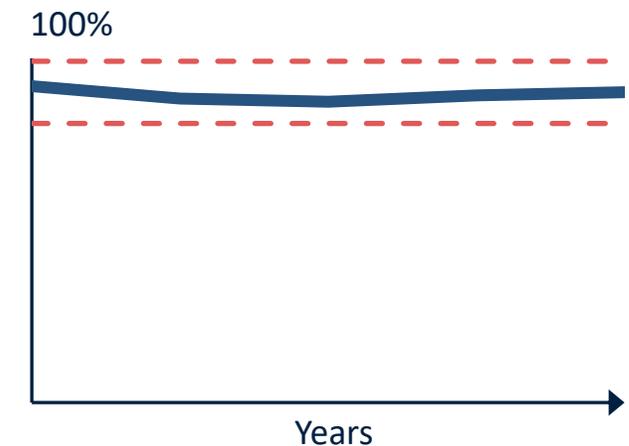
Plasma concentration from clinical trial



Excellent stability

- ✓ Excellent stability even under accelerated conditions and proven to work on a broad scope of API's

Amount of API



OX124 - a high-dose naloxone rescue medication designed to reverse the most powerful synthetic opioids

Intranasal powder delivery of naloxone built on AmorphOX®



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**

Approval has been delayed as a CRL was received from FDA on July 15 2024 due to:

1. the need for an additional Human Factors (HF) study (expected and a NEW HF study was successfully completed in Q2)
2. additional technical data on the final commercial product was requested
3. the CRL does not indicate a need for additional clinical or non-clinical studies.

► Orexo is planning to submit complementary data to the agency mid 2025.

if approved, OX124 could 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.**

Naloxone market has grown significantly and there is a need for a product like OX124

~25-40 M Doses Distributed (2024 estimate) Up From ~17 M Doses (2021 estimate) OTC Drives Wider Distribution

2024 Estimated Market Size: ~ USD >USD 550 M – with Narcan OTC being a clear market leader

	Retail Market	Hospitals/ Clinics	First Responders	Community/ Public Service	All
Estimated number of Naloxone Doses Distributed/ Purchased	~ 10-15 M (~40%)		~15-25 M (~60%)		~25-40 M (~100%)

"I would prescribe a high-dose option to ~30% of patients, as they are exposed to synthetic opioids." – Addiction Medicine Specialist

"We use high doses of naloxone, but never intranasal." – Emergency Medicine Specialist

"We consistently have to give patients multiple doses of Narcan because they may have residual overdoses." – Firefighter

"Our inmates bring in strong synthetic opioids, so we are usually giving multiple doses of Narcan." – Correctional Facility

OX640 – an intranasal powder-based epinephrine treatment of allergic reactions, incl. anaphylaxis

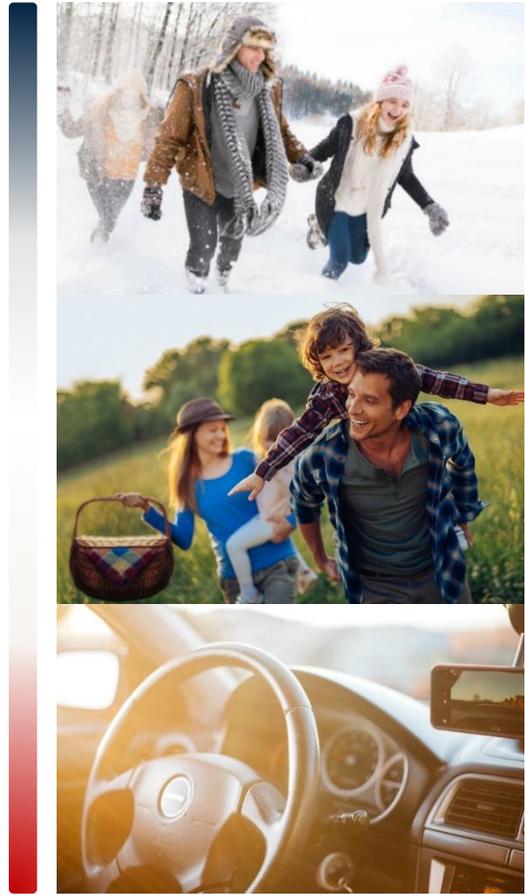
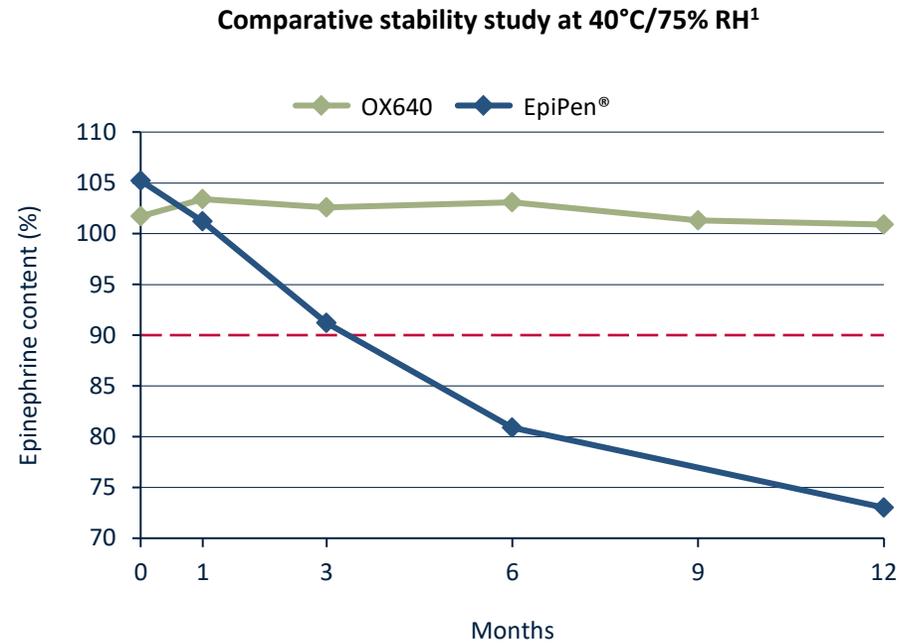
Improved stability and a more sustainable product

-  Needle-free and easy-to-use
-  Manufacturing without precaution for light or need for protective gas
-  Highly improved stability versus any available liquid formulation

-  Preservative-free (which may cause allergic reactions)
-  More convenient storage and longer shelf life

OX640: Intranasal epinephrine enabled by AmorphOX® remains stable in any life situation

First clinical trial indicates a superior bioavailability of OX640 compared to other liquid based nasal epinephrine products²



Source: Company information

Notes: ¹ Relative humidity. ² First OX640 clinical study used EpiPen as comparator, and comparisons with other liquid based nasal products are cross-study comparisons and not head-to-head studies.

Strategic initiatives based on a sustainable foundation

Growing revenues and profit contributions	Improving access to treatment	Capitalizing on the AmorphOX® drug delivery technology
<i>Key milestones and focus areas going forward</i>		
<ul style="list-style-type: none"> • Maintain Zubsolv® revenues • Approval and launch of OX124 • Milestones and royalties from current and future partnered products. 	<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 (collecting Orexo’s full OUD offering). 	<ul style="list-style-type: none"> • 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.



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

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APPENDIX

Q3 2024 legal update

Zubsolv® patent dispute vs Sun Pharmaceuticals

- ✓ In Q1 2023 the trial was conducted in the US District Court for the District of New Jersey.
- ✓ On June 30 (US Time Zone) the District Court for the District of New Jersey ruled in favor of Orexo against Sun. The district court found that Orexo's patents are valid and infringed by Sun
- ✓ In July 2023, Sun appealed the District Court decision to the US Court of Appeals for the Federal Circuit. A briefing schedule has been set by the Federal Circuit and an oral hearing is expected to take place during 2024

Overall strong IP rights for Zubsolv:

- In total 10 patents listed in the Orange Book
- Patent expiring dates Dec 2027 – Sep 2032
- Previously successfully managed to defend Zubsolv IP rights in the US appeal court

US government agency investigation related to Zubsolv

- ✓ 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'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.