

A commercial stage pharma company with an exciting pipeline

Sep. 2023

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



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Orexo – a commercial stage pharmaceutical company with an exciting pipeline

A commercial stage pharmaceutical company with three revenue generating pharmaceutical products

Group revenues (LTM)

634 SEK M

Profitable US commercial operations with a strong focus on one of the largest health crises in the US – opioid dependence

US Pharma EBIT (LTM)

293 SEK M

New world leading nasal delivery technology - amorphOX[®] is leading to a new wave of products

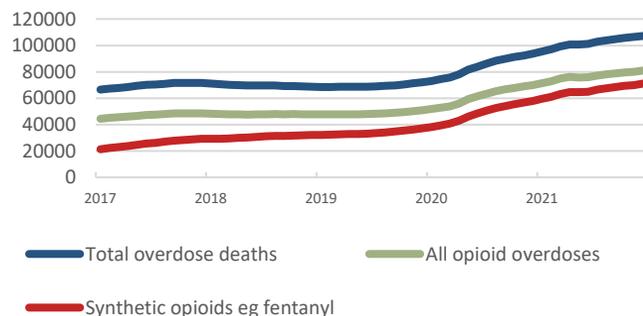


Commercial products and development pipeline

	Product or Project/Indication/Technology	Exploratory	Preclinical	Clinical development phases	Registration	Approved and/or Launched		
						US	EU	RoW
Commercial products	ZUBSOLV® Opioid Use Disorder / Sublingual platform 							
	Abstral® Breakthrough Cancer Pain / Sublingual platform 							
	Edluar® Insomnia / Sublingual platform 							
	Modia® Opioid Use Disorder / Broca technology platform 							
	Vorvida® Alcohol management / Broca technology platform 							
	Deprexis® Depression / Broca technology platform 							
R&D	OX124 Naloxone, Opioid Overdose / amorphOX®							
	OX125 Nalmefene, Opioid Overdose / amorphOX®							
	OX640 Adrenaline, allergic reactions / amorphOX®					2025		
	OX-MPI Vipoglanstat, Endometriosis 							

US market: Commercial products targeting a large unmet need

Fatal overdoses have surged due to synthetic opioids¹



Buprenorphine /Naloxone

Digital Therapy

Rescue Medication

Launch expected H2 2024

9,200,000
are misusing opioids²

5,600,000
are dependent on opioids³

1,800,000
are undergoing treatment⁴

Commercial DTx products targeting adjacent disease areas:
[deprexis](#)® for depression & [VORV!DA](#) for alcohol management



“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](#)

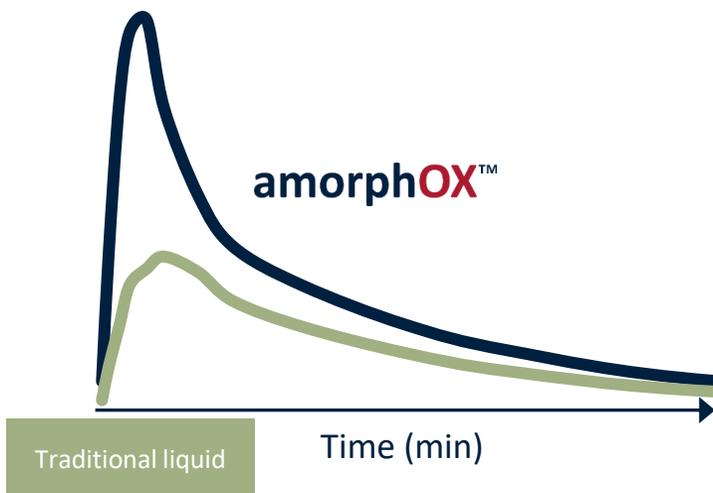
¹Center of Disease Control. ^{2,3} Substance Abuse and Mental Health Services Administration, 2021 NSDUH report. ⁴ Orexo data

Orexo's development pipeline building on the proprietary amorphOX[®] powder technology

Validated in humans

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

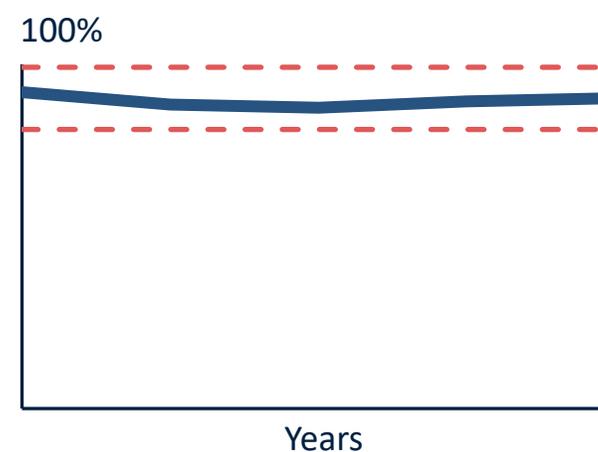
Plasma concentration from clinical trial



Excellent stability

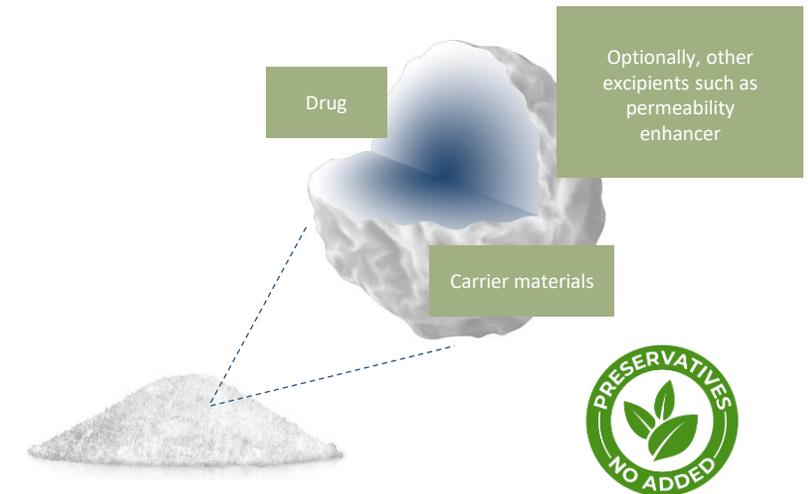
- ✓ Excellent stability even under accelerated conditions and proven to work on a broad scope of API's

Amount of API



Wide applicability

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

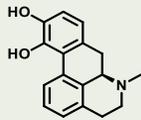


AmorphOX[®] – a versatile, world-class platform for nasal drug delivery



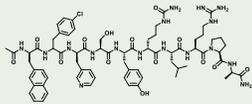
Chemical degradation after accelerated stability studies at 40°C/75% RH

Apomorphine



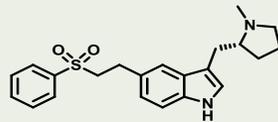
0.4% after 24 months

Cetrorelix



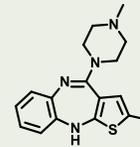
0.5% after 6 months

Eletriptan



0.5% after 12 months

Olanzapine



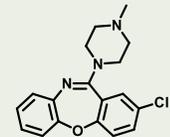
0.2% after 6 months

Enzyme



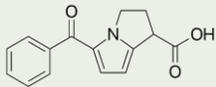
Retained activity after
1 month

Loxapine



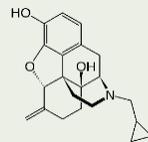
0.3% after 24 months

Ketorolac



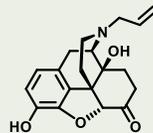
0.8% after 6 months

Nalmefene



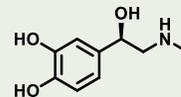
≤0.1% after 15 months

Naloxone



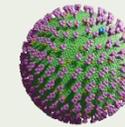
≤0.1% after 24 months

Epinephrine



1.8% after 18 months

Spike protein



Retained activity after
3 months

SARS-CoV-2 Spike Protein

- ✓ Successfully formulated in the **amorphOX[®]** platform
- ✓ High production recovery
- ✓ Free-flowing powder
- ✓ Retained activity after formulation and manufacturing
 - Confirmed by binding assay
 - Stability studies ongoing

Feasibility studies ongoing with two leading biopharmaceutical companies where **amorphOX[®]** is applied to their proprietary API

Nasal rescue medications targeting large and growing markets

- **OX124**, high-dose rescue medication incl. **naloxone**, designed to reverse the effect of the most powerful synthetic opioids, such as fentanyl. Filed with the FDA in Q3 2023. Based on **amorphOX**[®]
- **OX125**, overdose rescue medication incl. **nalmefene**. To be used in acute situations where the treatment effect needs to be long-lasting while also being powerful and fast-acting. Based on **amorphOX**[®]
- **OX640**, a nasally delivered powder formulation of epinephrine for the acute treatment of anaphylaxis (treatment of acute, potentially life-threatening, allergic reactions). Based on **amorphOX**[®]



Global overdose rescue medication market size 2022 (USD)¹

1,100 m

of which approx 650 m refers to the US²

Projected global annual growth¹

10 %

Epinephrine global market size 2022 (USD)³

2,100 m

Growth rate CAGR 2023-2032³

10 %

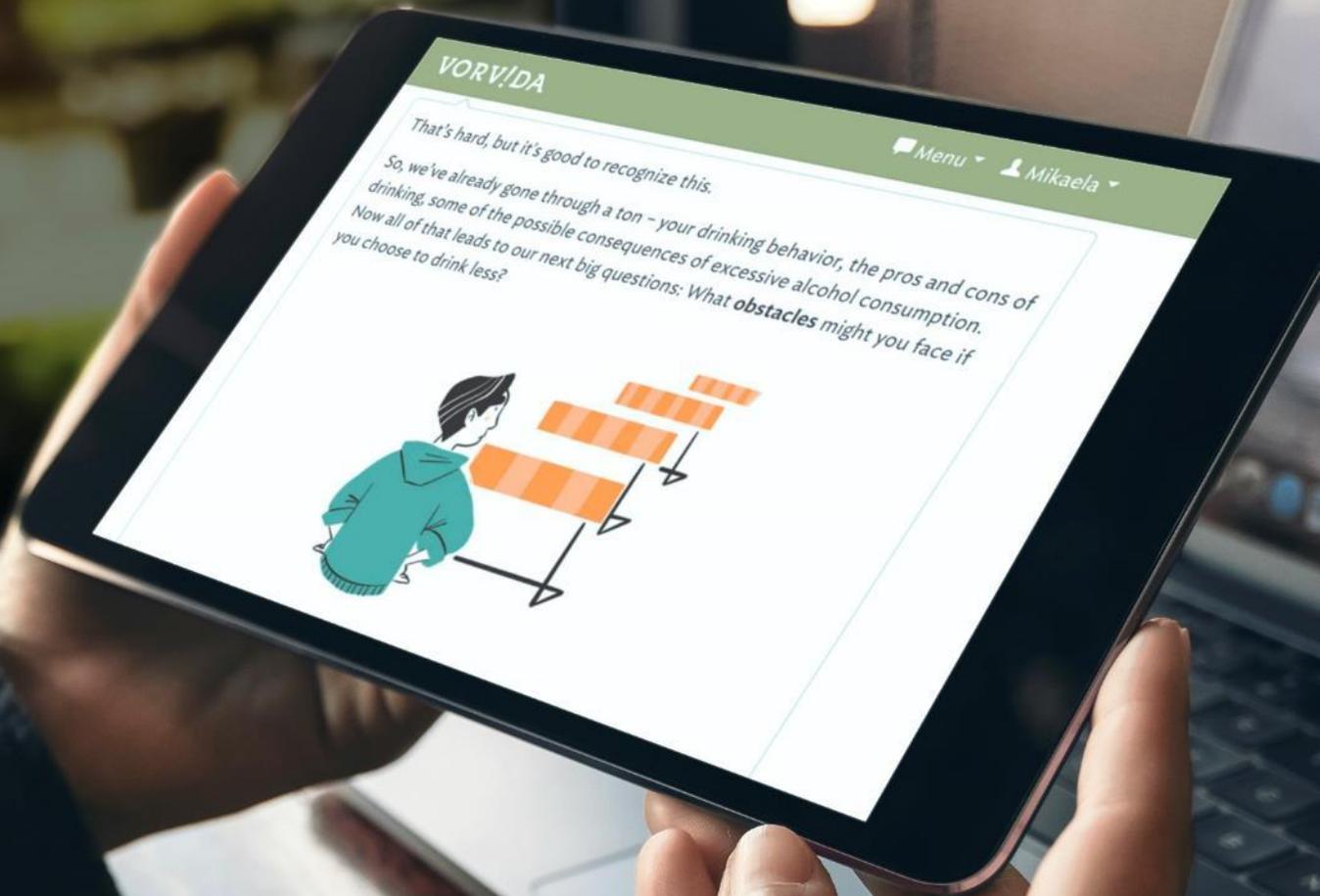
¹ <https://www.coherentmarketinsights.com/market-insight/naloxone-market-1804>

² Bloomberg

³ <https://www.precedenceresearch.com/epinephrine-market#:~:text=The%20global%20epinephrine%20market%20size,forecast%20period>

Note: images are prototypes and not final packages

Financial overview



Q2 2023 – improved performance on nearly all financial KPIs

Income statement SEK m	Q2 2023	Q2 2022	H1 2023	H1 2022	FY 2022
Net revenues	158	148	317	307	624
<i>of which US Pharma</i>	145	140	286	279	571
Gross Profit	140	127	271	258	522
OPEX	-153	-176	-343	-322	-706
EBIT	-12	-50	-72	-63	-184
EBITDA	6	-32	-35	-30	-115
Liquid funds	251	468	251	468	352

Q2 2023 comments

- ✓ Net revenues supported by FX tailwinds and slight ZUBSOLV® volume growth
- ✓ Significantly reduced OPEX despite FX headwinds
- ✓ Positive EBITDA

Financial outlook -> EBITDA expected to be in balance in H2 2023 driven by:

- Stabilized ZUBSOLV® sales, partner revenues and business development
- Lower OPEX from less legal expenses, R&D expenses from clinical trials (MODIA)



Future value drivers

Several significant milestones near term

- ✓ • **Corporate EBITDA profitability in sight¹**
 - Increased income from partners
 - Main current external cost drivers will diminish during H2 2023 and significant reduction in direct expenses for DTx
 - No new activities driving external expenses to be initiated without certainty of associated revenues
- ✓ • **ZUBSOLV[®] sales stabilized and improved access to patients**
 - Settlements providing approximately USD 54 billions announced and new legislation open up for all physician's to prescribe ZUBSOLV[®]
- **DTx progress with the potential to democratize access to psychosocial support**
 - MATCore[®] implementation in Arizona and potentially additional states providing grants or subsidies to improve treatment for patients in rural areas or with other hurdles to access OUD treatment
 - Veterans Affairs and restart of Trinity Health implementation
 - MODIA[®] study result during early autumn
- **R&D pipeline expected to result in revenue generating partnerships in 2023**
 - OX640 and amorphOX[®] partnering discussions on-going
 - NDA submission filed for OX124. If approved launch is expected in late H2 2024 or early 2025.
- ✓ • **Decision in SUN IP litigation during the summer of 2023**



¹ Assuming no unexpected events outside the control of Orexo e.g. legal expenses associated with the government investigation or new IP litigations



Thanks

www.orexo.com