A commercial stage pharma company with an exciting pipeline

March 2024

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 net revenues 2023

639 SEK M

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

US Pharma EBIT 2023

283 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	Partner	Exploratory	Preclinical	Clinical development phases	Registration	Approved and/or Launched		
							US	EU	RoW
Commercial products	**Zubsolv®** Opioid Use Disorder (OUD) / Sublingual platform	accord Make it better							
	Abstral® Breaktrough Cancer Pain / Sublingual platform	KYOWA KIRIN							
	Edluar® Insomnia / Sublingual platform	VIATRIS							
	MODIA® OUD / Broca technology platform	GAIA							
	Vorvida® Alcohol management / Broca technology platform	GAIA							
	Deprexis® Depression / Broca technology platform	GAIA							
R&D	**OX124** Naloxone, Opioid Overdose / **AmorphOX®**								
	OX125 Nalmefene, Opioid Overdose / **AmorphOX**								
	OX640 Adrenaline, allergic reactions / **AmorphOX**					2025			
	OX-MPI Vipoglanstat, Endometriosis	GESYNTA PHARMA AB							

Strong track record developing revenue generating products based on drug delivery technologies

Drug delivery technologies: Global differentiations

SEK 10 billion

Global sales revenue from Orexo´s four[1] commercial pharmaceuticals, of which a large majority refers to products based on the sublingual platform

AmorphOX®

Pioneering nasal delivery technology backbone of new products OX124, OX125, OX640. Patent & patent applications cover range of molecules until 2039-2042

Commercial US operations: Tackling the opioid epidemic since 2013

Significant value contribution from Zubsolv®, a maintenance treatment for OUD
>SEK 5.2 billion in sales since launch, of which SEK 578 million in 2023

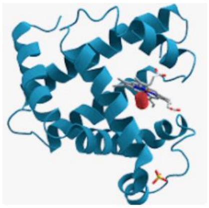
Pipeline of synergistic overdose rescue medications
High-dose naloxone, OX124, and fast-acting nalmefene, OX125

MODIA® a new complementary digital health program for OUD
For patients engaged in a clinical directed medication assisted treatment (MAT) plan

Capitalizing on partnership for development and commercialization

Driving revenue to execute our strategy
- Sublingual platform >SEK 2.3 billion

Emerging partnership opportunities
- Epinephrine products, OX640
- AmorphOX technology in biomolecules



[1] Of which one product, Diabact, was divested at the time of the sale of the subsidiary Kibion in 2015

Q4 2023 – improved performance on nearly all financial KPIs

Income statement SEK m	Q4 2023	Q4 2022	▲	FY 2023	FY 2022	▲
Net revenues (NR)	**166**	**156**	**6%**	**639**	**624**	**2%**
of which Zubsolv	*151*	*143*	*6%*	*578*	*571*	*1%*
Gross Profit	**146**	**130**	**12%**	**550**	**523**	**5%**
OPEX	**-154**	**-201**	**23%**	**-659**	**-706**	**7%**
EBIT	**-9**	**-71**	**87%**	**-109**	**-184**	**40%**
EBITDA	**12**	**-53**	**123%**	**-32**	**-115**	**72%**
Liquid funds	**171**	**352**	**-51%**	**171**	**352**	**-51%**

[1] Digital mental health programs, previously Digital therapies

Q4 2023 comments

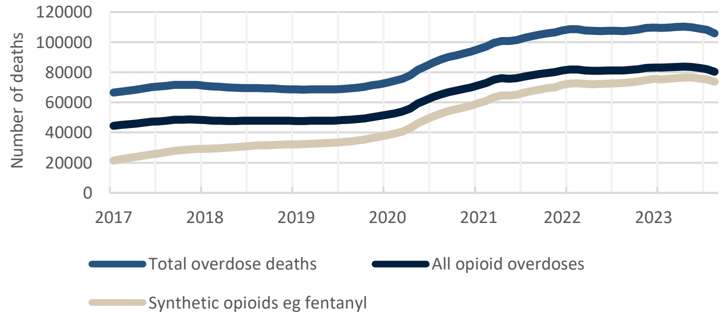
- ✓ NR supported by increased royalty from out-licensed products and growing Zubsolv sales (US Pharma) due to higher wholesaler stocking & favorable payer mix while FX and lower demand impacted negatively
- ✓ OPEX decline mainly due to lower costs for IP litigation, DHMP[1] and OX124
- ✓ Positive EBITDA of SEK 12 m led to reaching EBITDA guidance of EBITDA in balance H2 2023 (SEK 3 m)

➢ **EBITDA guidance FY 2024 – <u>positive</u> EBITDA**

Commercial Products

US market: Commercial products targeting a large unmet need

Fatal overdoses have surged due to synthetic opioids[1]



Maintenance treatment	Digital mental health program	Rescue medication
		 Launch expected late 2024

8,900,000
are misusing opioids[2]

6,100,000
are dependent on opioids[3]

2,400,000
are undergoing treatment[4]

Commercial digital mental health 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.

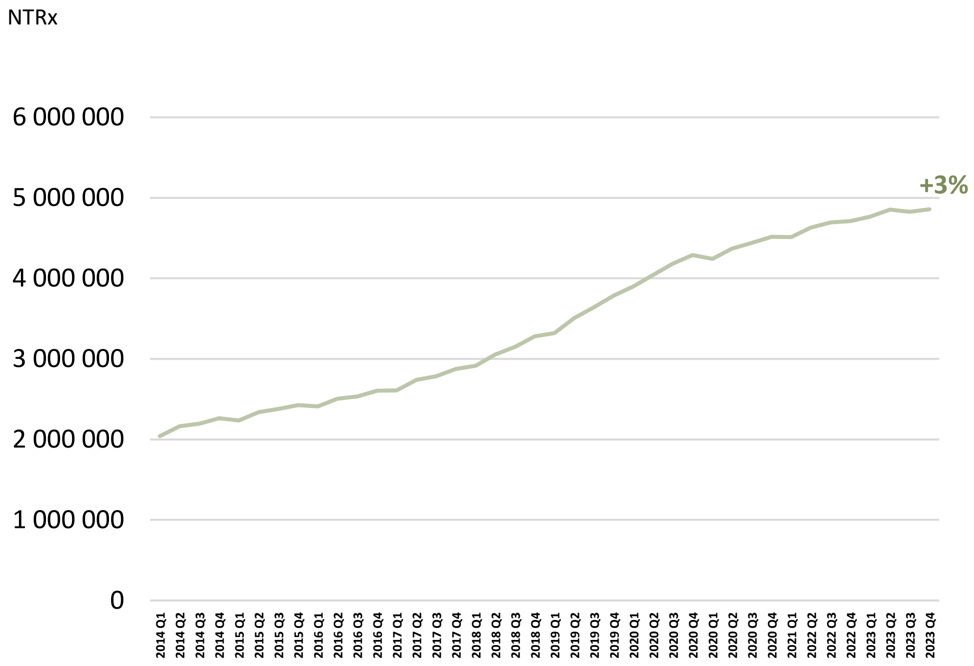
Read more at the Orexo blog

[1] Center of Disease Control. [2,3,4] Substance Abuse and Mental Health Services Administration

Zubsolv market: Triggers for acceleration in long term market growth

- The Mainstreaming Addiction Treatment Act, effective Jan. 1st, 2023, has removed the cap on how many patients a physician can treat at one time and reduced the MAT license requirements
- Significant inflow of new funds to finance treatment initiatives from USD 54 billion abatement funds, but the processes to allocate the funds are slow and bureaucratic
- Increase in fentanyl utilization makes treatment more difficult, but physicians are learning and refining their treatment approach e.g. different titration of medication

The buprenorphine/naloxone market grew 3 percent Q4 23 vs Q4 22[1]

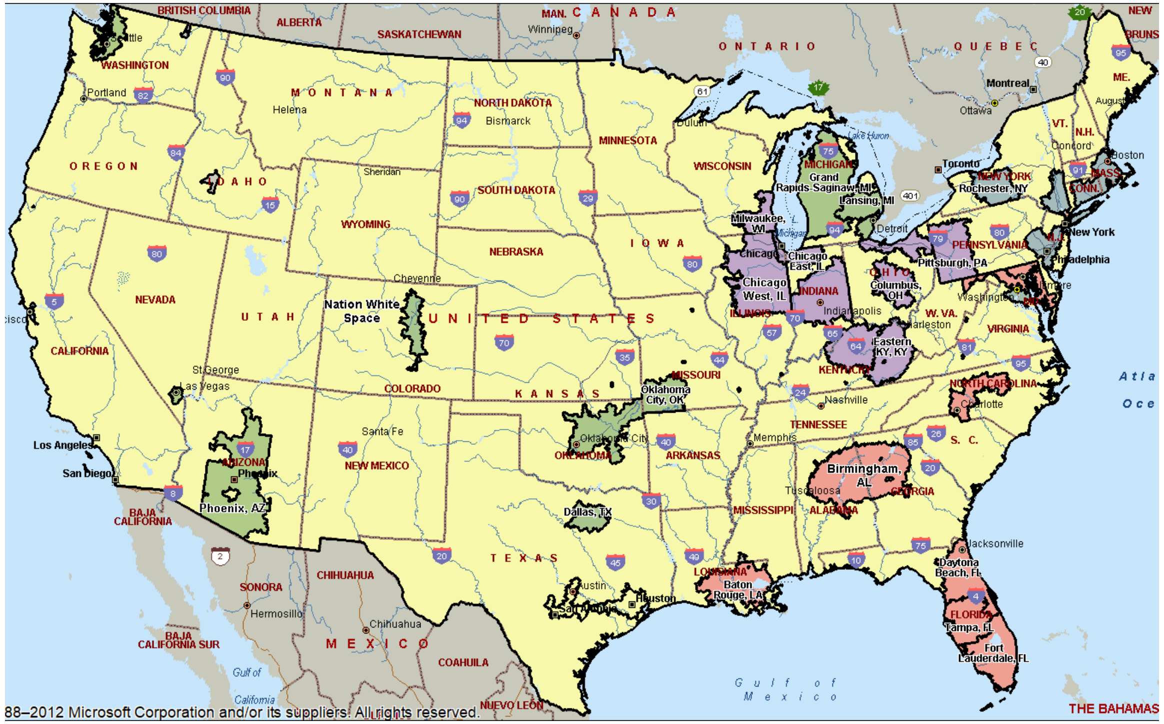


[1]Based on last 4w and 6w average NTRx volume. Note weekly prescription data is volatile and is influenced by public holidays, weather and changes to reimbursement.

Well positioned to treat more patients with OUD

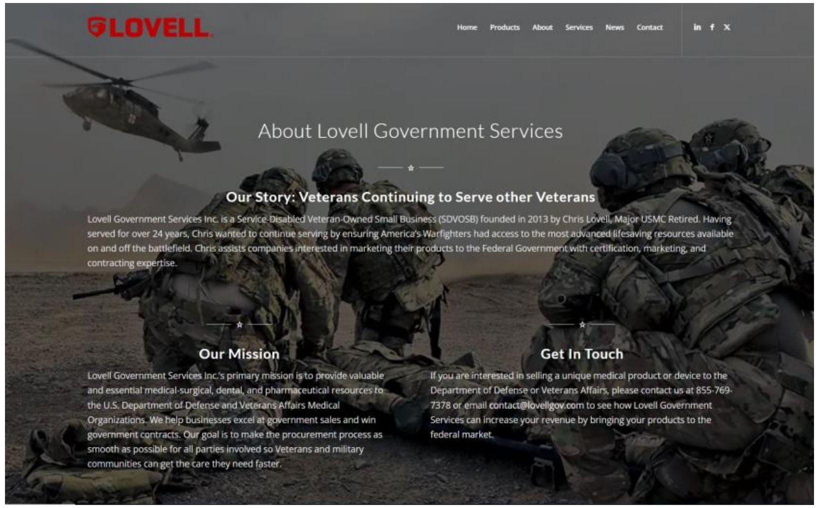
- More than a decade of experience and knowledge from treating OUD patients
- Sales force incl. 40 sales reps. covering approx. 50 percent of the market and approx. 70 percent of the Zubsolv current volume
- Record high reimbursement coverage within the commercial payer segment of 98 percent of patients
- Growing reimbursement coverage among patients within the public payer segment (e.g. Medicaid), from 48 to 50 percent in 2023
- Most comprehensive treatment offering for OUD patients, grounded in a holistic treatment approach

Orexo sales force coverage in 2023



Digital mental health programs: Focusing on growing within Veterans Affairs (VA)

- In Q4 2023 a distribution contract was signed with Lovell Government Services who will manage distribution and reimbursement within VA
- Vorvida® and MODIA® both added to the VA list from 2024
- Initial focus on on selected VA healthcare providers in the North East before expanding geographic reach and commercial resources.



Triggers for long term growth – digital mental health programs

➢ The healthcare sector globally is under pressure, driven by an aging population and sky-rocketing costs. In parallel more patients want to be seen as consumers and require holistic and customized treatments with access 24/7. These are examples of overarching forces that will propel the market for digital health programs.

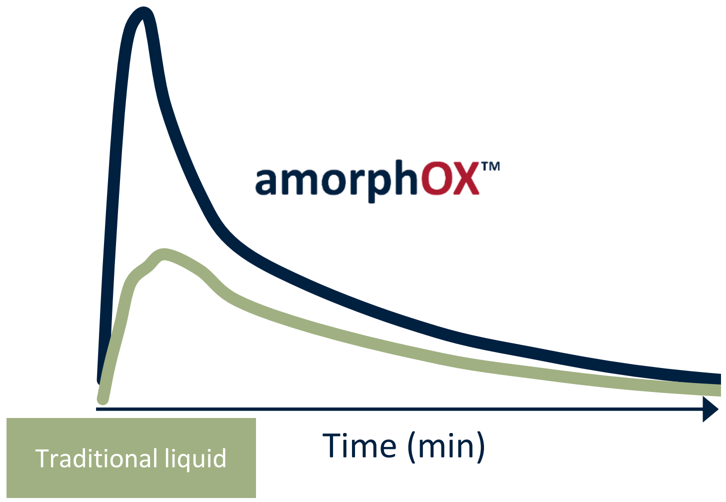
Products under development

Orexo´s development platform building on the proprietary AmorphOX® powder technology

Validated in humans

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

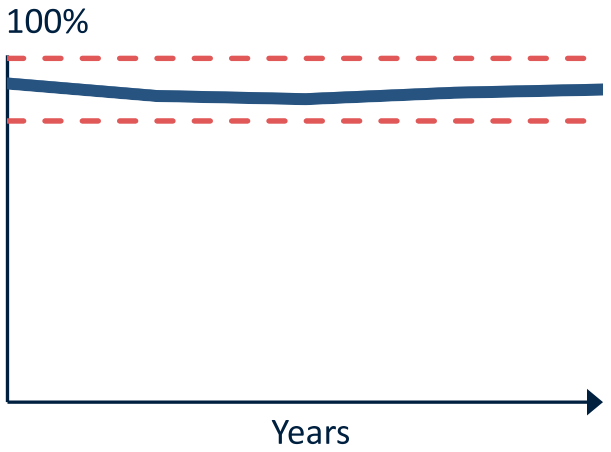
Plasma concentration from clinical trial



Excellent stability

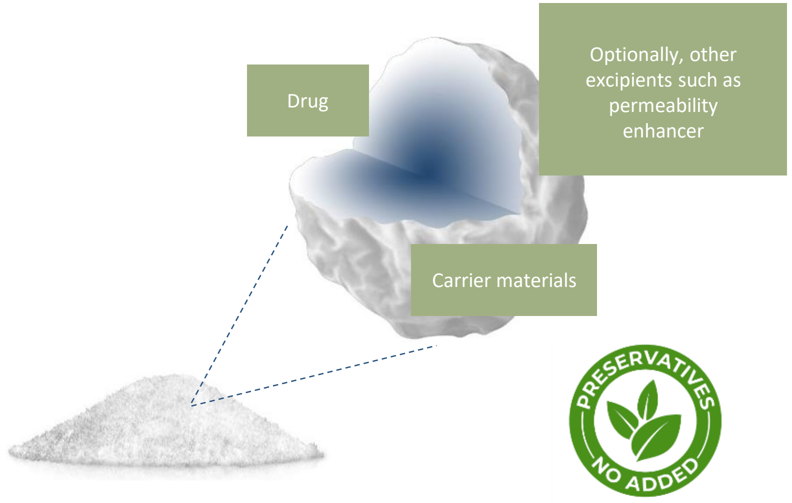
- ✓ Excellent stability even under accelerated conditions and proven to work on a broad scope of API's

Amount of API



Wide applicability

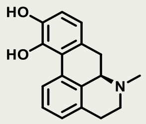
- ✓ Powder technology that works with a broad scope of small and large molecules, such as peptides and proteins



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

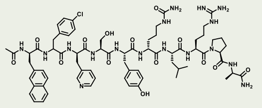
Chemical degradation after accelerated stability studies at 40°C/75% RH

Apomorphine



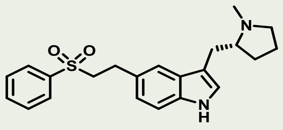
0.4% after 24 months

Cetrorelix



0.5% after 6 months

Eletriptan



0.5% after 12 months

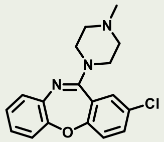
Olanzapine

0.2% after 6 months

Enzyme

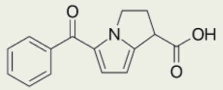
Retained activity after 1 month

Loxapine



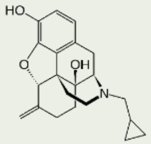
0.3% after 24 months

Ketorolac



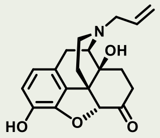
0.8% after 6 months

Nalmefene



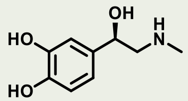
≤0.1% after 15 months

Naloxone



≤0.1% after 24 months

Epinephrine



1.8% after 18 months

Spike protein

Retained activity after 3 months

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

OX124 – high dose rescue medication for opioid overdose with naloxone

- Significant health issue in the US with >110.000 deaths from overdoses in 2022[1]
- Based on AmorphOX® and designed to treat overdoses caused by synthetic opioids, such as fentanyl
- Formulations of OX124 clinically differentiated to market leader and GX of market leader
- **OX124 filed with the FDA in Q3. PDUFA date set to July 15, 2024. US launch expected to be initiated in late 2024.**

Naloxone

Nalmefene

Global overdose rescue market size 2022 (USD)[2]

1,100 m

of which approx 650 m refers to US[3]

Projected global annual growth[3]

10 %

[1] Center of Disease Control, predicted numbers
[2] https://www.coherentmarketinsights.com/market-insight/naloxone-market-1804
[3] Bloomberg
Note: images are prototypes and not final packages

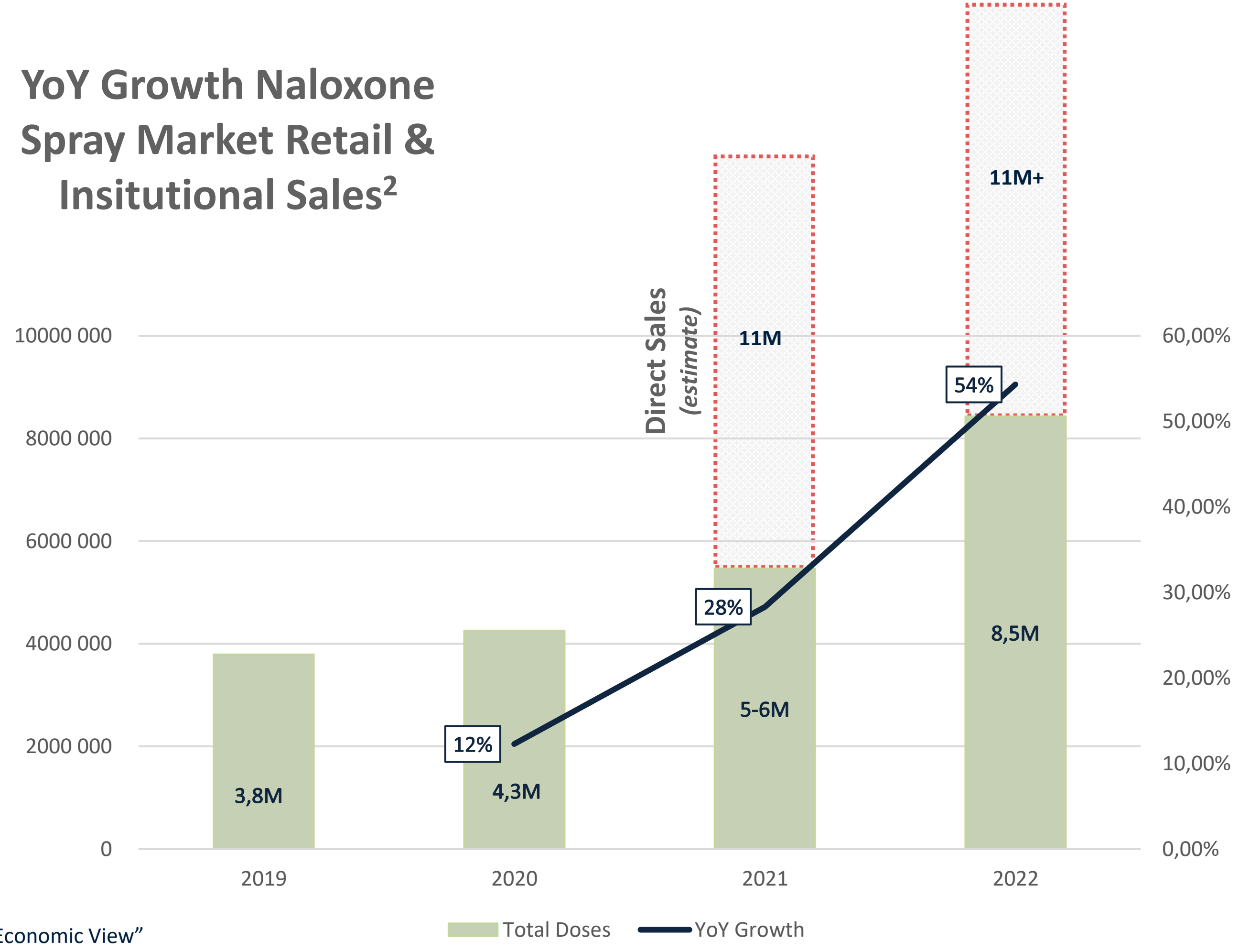
PRESERVATIVES NO ADDED

Significant need for rescue medication reflected in rapid market growth

Institutional sales i.e. hospital, medical college, corporate organisations, centralized institutions like group practices, integrated delivery networks (IDNs) and **market retail** i.e. pharmacy sales together cover the large majority of all sales of the naloxone spray market.

The total distribution is however, much larger with recorded figures around **17 million doses**[1] of naloxone distributed in 2021. Only ~5-6 million of which were distributed to retail pharmacies and other health care facilities, respectively, indicating **both stockpiling, direct sales (federal, hospitals etc.) and the effect of standing orders.**

YoY Growth Naloxone Spray Market Retail & Insitutional Sales[2]



[1] Regall Undall Foundation for the Food and Drug Aministration, 2023, "Summary Report Naloxone Economic View"
[2] Bloomberg

Attractive business case for OX124, but we enter a dynamic market

- **Significant market need** for more effective treatment of overdose
  - Low-dose OTC alternatives **not strong enough to sustain reversal** in many overdoses with fentanyl **(deaths are driven by synthetic opioids)**
  - 80 percent of all lethal overdoses are fentanyl related (synthetic opioids)
- **Commercial synergies** with existing organization and capabilities
  - **Orexo field force** in 12 out of 17 states with mandatory co-prescription of naloxone with an opioid (including Zubsolv)
  - **Long history with largest payers** in the OUD disease space
  - **Extensive knowledge of OUD** in all parts of the organization
  - Some new capabilities needed in marketing and institutional sales in 2024
- **A dynamic market** with several interesting market drivers to monitor
  - **Pricing dynamic** after launch of OTC products and lowering price to **USD 50 /2 pack**
  - **Traction for high-dose Kloxxado**
  - **Potential switch to Nalmefene** for high risk patients (fentanyls/synthetics)

	OX124 (High-dose naloxone)
Naloxone "Gold Standard"	✓
High-Dose Naloxone	✓
Powder	✓
Unique Device	✓
Does not freeze	✓
Long Shelf-Life	✓

OX640 – emergency treatment of allergic reactions

- First line treatment today: intramuscular auto-injectors
- OX640 offers clear differentiation to current market leader and products in development
    - Needle free alternative based on amorphOX®
    - Chemically stable and more robust formulation
    - Optimized manufacturing
    - Free of antioxidants and preservatives
- OX640 could be ready for FDA filing in 2025 based on initial FDA feedback on clinical evidence required
- Partnering process initiated for global commercialization

Epinephrine

Epinephrine global market size 2022 (USD)[1]

2,100 m

Growth rate CAGR 2023-2032[1]

10 %

Positive data shown in the clinical phase 1 study

[1] https://www.precedenceresearch.com/epinephrine-market#:~:text=The%20global%20epinephrine%20market%20size,forecast%20period

Future value drivers

Creating a solid ground for 2024 and beyond

- Strong focus on cost control and EBITDA balance
- Approval and launch of OX124
- Maintain Zubsolv as a strong cash contributor
- Partnering of pipeline projects and the AmorphOX® technology
- Focus digital health on Orexo´s strongholds in OUD and confirmed contracts such as the contract with Veterans Affairs
- Resolution of legal processes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