

Growing into a broader and stronger Orexo



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2022 – advancing in a challenging environment

- EU launch of ZUBSOLV® initiated by Accord Healthcare and
- ZUBSOLV® was added to NY Medicaid MAT Preferred Drug formulary
- R&D pipeline making strong progress
 - OX124 ready for FDA filing
 - Positive data from the 1st clinical study for OX640
 - AmorphOX® show strong results in broad range of molecules
- A ten-year contract signed with Veterans Affairs, providing access to deprexis® among 15 million Americans suffering from depression

Strengthened the social & environmental responsibilities based on stakeholder dialogue & materiality assessment



Business Update

US Commercial



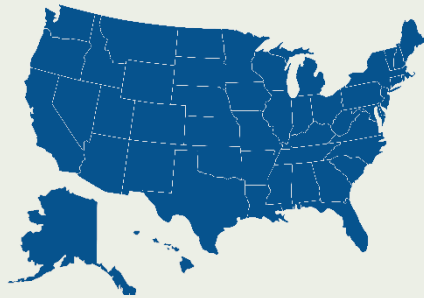
US market: Commercial products targeting large unmet needs

Opioid dependence	Alcohol management	Depression	
<p>Overdose deaths surpassed 107 000 in 2021, fueled by use of synthetic opioids such as fentanyl</p> <p>2017 2018 2019 2020 2021</p> <ul style="list-style-type: none"> Total overdose deaths All opioid overdoses Synthetic opioids eg fentanyl 	<p>9m are misusing opioids</p>	<p>17m are heavy alcohol users</p>	<p>20m are suffering from at least one major depression annually</p>
	<p>1.8m in treatment</p>	<p>1.5m in treatment</p>	<p>10m in treatment</p>
	<p>OX124, launch expected late H2 2024</p>		

ZUBSOLV[®] an important foundation to Orexo's commercial operations

Net revenues since launch 2013 (SEK m)

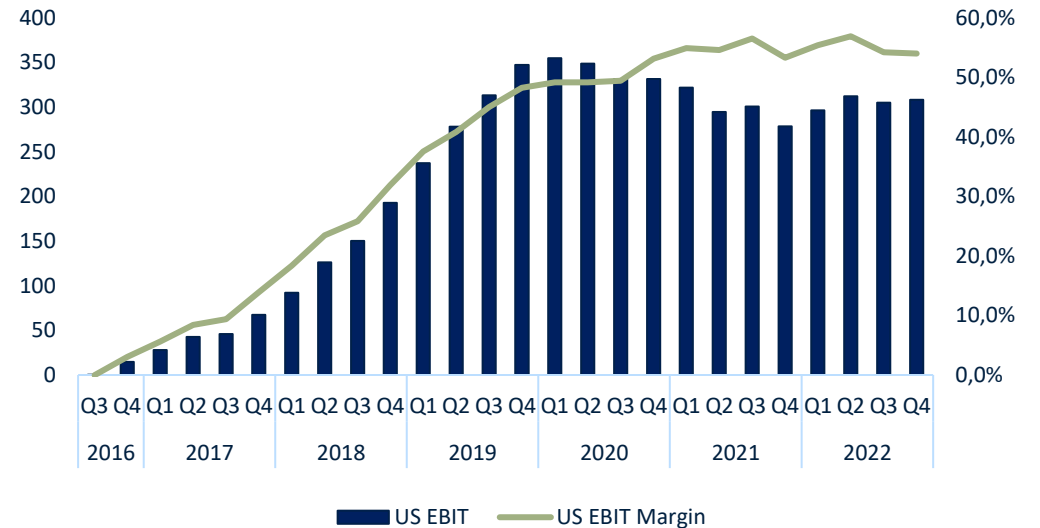
4,500
m



Market dynamic

- New legislation from Dec 28th removing hurdles to prescribe Bup/Nal products
- Increased funding from \$54B settlements in opioid litigation
- Market growth expected to accelerate from current low single digit
- Market access changes in Kentucky and NY main growth drivers in 2022 partly compensating continued decline in UHG and Humana

US Pharma EBIT (SEK m) and EBIT margin (%) LTM¹



SEK 571 m revenues in 2022

¹ Last Twelve Months

DTx comes with a lot of promise and potential, but yet to materialize

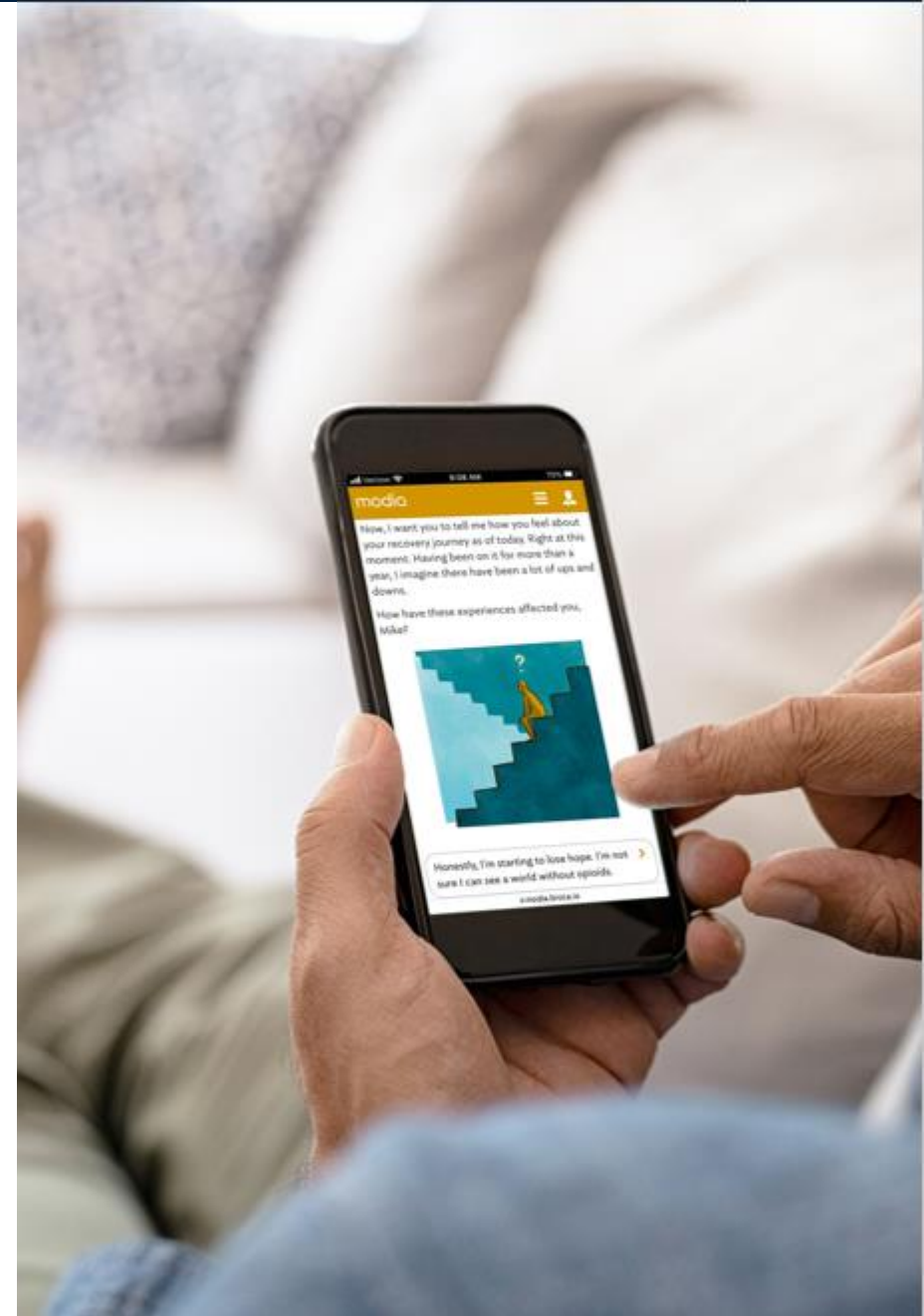
MODIA® focusing on gaining acceptance in OUD clinics

- >2000 patients received MODIA® in 2022
- Good progress in gaining reimbursement through medical benefits
- MODIA® is included in the MATCore™ platform to be implemented in Arizona

Large health care provider networks and Veterans Affairs main channels for vorvida® and deprexis® in 2023

- 10 year contract signed with Veterans Affairs in 2022
- Contract with Trinity Health and first patients received a DTx

Slow start of DTx lead to a review of the business and integration into US Pharma by Feb 1, 2023





Business Update

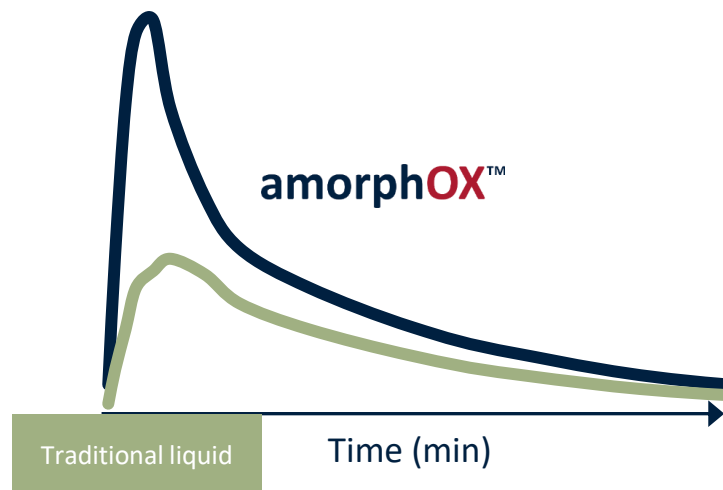
HQ & Pipeline

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

Validated in humans

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

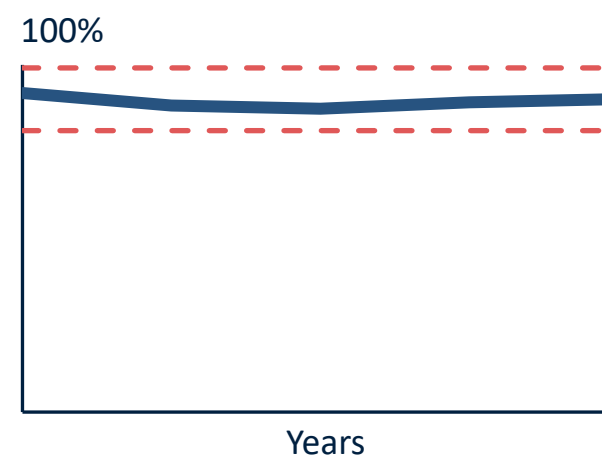
Plasma concentration from clinical trial



Excellent stability

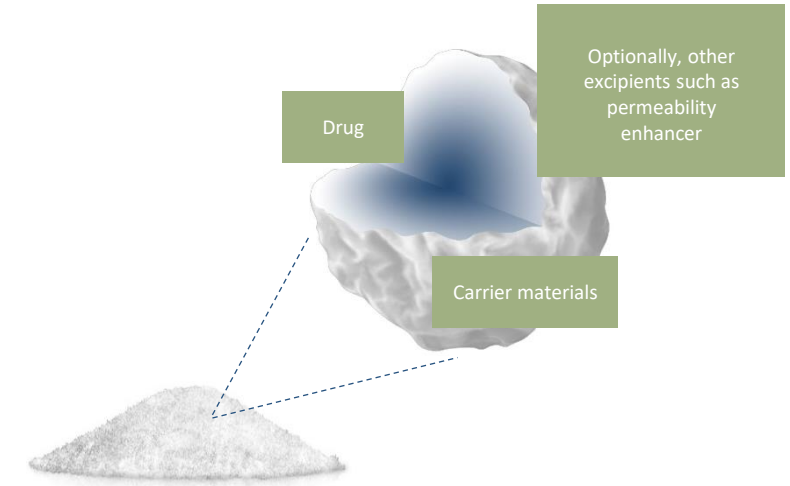
- ✓ Excellent stability even under accelerated conditions and proven to work on a broad scope of API's

Amount of API



Wide applicability

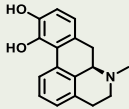
- ✓ Powder technology that works with a broad scope of small and large molecules, such as peptides and proteins



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

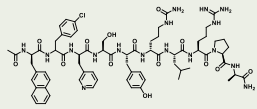
Chemical degradation after accelerated stability studies at 40°C/75% RH

Apomorphine



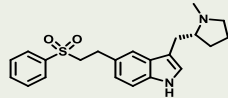
0.3% after 18 months

Cetrorelix



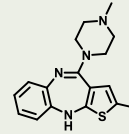
0.4% after 3 months

Eletriptan



0.5% after 3 months

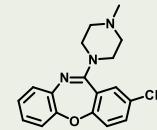
Olanzapine



Enzyme

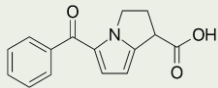


Loxapine



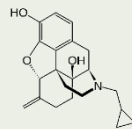
0.3% after 6 months

Ketorolac



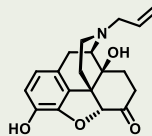
0.8% after 6 months

Nalmefene



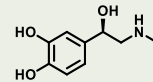
≤0.1% after 15 months

Naloxone



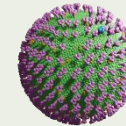
≤0.1% after 12 months

Epinephrine



0.5% after 6 months

Spike protein



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 study ongoing with two leading biopharmaceutical companies of amorphOX[®] applied to their proprietary API

OX124 & OX125 – overdose rescue medications

- Significant health issue in the US with >107,000 deaths from overdoses in 2021
- Based on amorphOX® and designed to treat overdoses caused by synthetic opioids, such as fentanyl
- OX124 clinically differentiated to market leader and GX of market leader
- OX124 filed with FDA in Feb. 3 2023, but due to equipment issues in the secondary packaging of the supply chain a new NDA is expected to be filed in Q3 2023



Naloxone



Nalmefene

Global overdose rescue market size (USD)¹

1,100
m

of which 450 m refers to US

Projected global annual growth¹

10
%

¹ <https://www.coherentmarketinsights.com/market-insight/naloxone-market-1804>
Note images are prototypes and not final packages

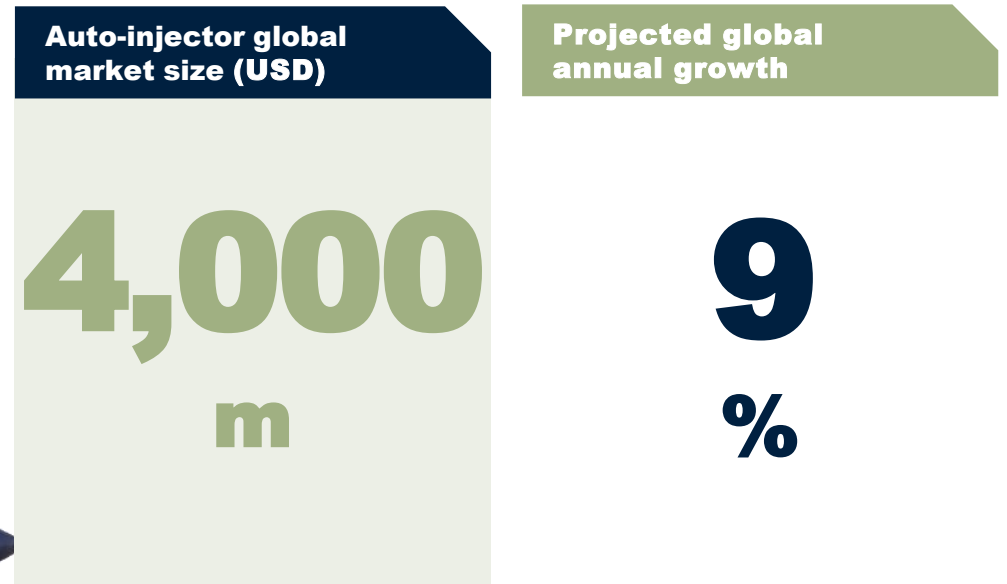
OX640 – emergency treatment of allergic reactions

- First line treatment today: intramuscular auto-injectors
- OX640 offers clear differentiation
 - Needle free alternative based on amorphOX®
 - Chemically stable and more robust formulation
 - Optimized manufacturing
 - Free of antioxidants or preservatives
- No meaningful innovation for decades
- OX640 could be ready for FDA filing in 2025 based on initial FDA feedback on clinical evidence required

Positive data showed in the clinical phase 1 study



Epinephrine



A woman with dark hair tied back, wearing a pink and white striped sweater, stands with her arms outstretched and her head tilted back, looking up at the sky. The background is a soft-focus green landscape, suggesting an outdoor setting. The word "Sustainability" is overlaid in large, bold, dark blue letters on the right side of the image.

Sustainability

Orexo improves the lives of people

Focus areas building a foundation for Orexo's contribution to a more sustainable world

Responsible business

Responsible business based on trust, transparency, integrity and no tolerance for corruption is central to all our activities and a foundation for our sustainability work



Sustainable employees

In all our teams, create a healthy working climate where inclusion and diversity are a matter of course



Access to healthcare

Increase access to healthcare by patient support and strengthening knowledge of substance abuse and mental illness



Environment and Climate change

Our ambition is to reduce our impact on environment and climate change across all our activities and our products



Financial & near time milestones



2022 – building for future growth

FY EBITDA positive excluding external non-repeating costs related to:

- **MODIA® study**
- **OX640 1st clinical study**
- **OX124 Human Factor study**
- **IP litigation**
- **Subpoena**

Group net revenues

624 SEK M

US Pharma net revenues

571 SEK M

EBITDA

-115 SEK M

US Pharma EBIT

308 SEK M

Cash position

352 SEK M

US Pharma EBIT margin

54 %

The financial development is monitored based on three segments, US Pharma, HQ & Pipeline and Digital Therapeutics. Due to US Pharma was merged with Digital Therapeutics in Q1 2023 Orexo is operationally managed built on two business areas US Commercial (former US Pharma & Digital Therapeutics) and HQ & Pipeline.

Potential milestones in near-term

- **District court decision in ZUBSOLV® patent litigation case**
- **AmorphOX® partnerships e.g. OX640**
- **Positive data from the MODIA® clinical study and FDA filing**
- **DTx turn around and new cost efficient business model to evolve while building revenues**
- **Refiling of OX124 in the US in Q3 and approval 2024**



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