

A pharmaceutical & digital therapeutics company

August. 31, 2022

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



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Orexo in brief



HQ & Pipeline

Development of improved drugs based on well-known substances combined with innovative proprietary Drug Delivery technologies, such as amorphOX®.

US Pharma

Commercial US Pharma platform since 2013, incl. market access team and sales representatives who on a daily basis visit physicians, medical clinics and minor hospitals.



Digital Therapeutics

Evidence-based digital therapies grounded in cognitive behavioral therapy techniques, offer better treatment access for patients and improve their outcomes.



The opioid crisis - one of the largest health crises ever in the US

10
million

Americans
misusing
opioids

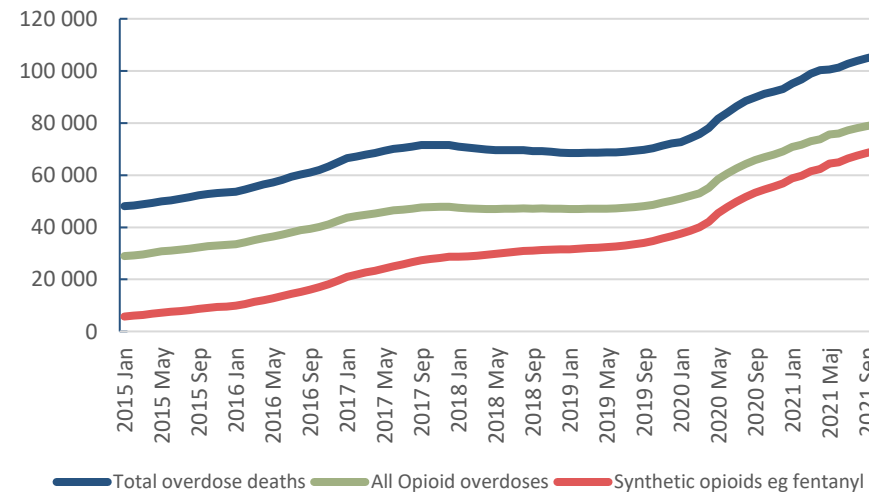
4
million

In need of
treatment

1.4
million

Under
treatment

Overdose deaths have surpassed **107 000** in 2021, fueled by use of synthetic opioids such as fentanyl



Sources: Substance Abuse and Mental Health Services Administration, Clarion Healthcare, Center of Disease Control



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



Elise discovered her daughter's opioid addiction months before she died from an overdose.

Read more at the [Orexo blog](#)

Orexo is building a unique portfolio of innovative treatment solutions for patients suffering from opioid dependence

Bup/nal medication

- Higher bioavailability
- Fast dissolve time
- Preferred menthol flavor
- Broadest range of dose strengths

zubsolv[®] sublingual tablets
(buprenorphine and naloxone) ©

modia



Digital therapy to support patients' long-term recovery enabling

- Improved treatment outcome
- Adherence to treatment
- Outcomes data

A rescue medication

- Stronger and longer-acting
- Potential to be effective in reversing overdoses caused by synthetic opioids

US Pharma

ZUBSOLV® for treatment of opioid use disorder

>4 BSEK in net revenues since launch

ZUBSOLV® short facts

Technology	Sublingual
Indication	Opioid use disorder
Market approvals	US, EU and Australia
Commercial rights	Orexo owns global rights, ex EU
Partner EU	Accord Healthcare 
Accumulated net revenues	SEK 4.3 billion
Patent protection	US, EU, Australia and New Zealand until 2032

Product advantages include:

- Higher bioavailability
- Fast dissolve time
- Preferred menthol flavor
- Broadest range of dose strengths



ZUBSOLV® resilience in a competitive market

Zubsolv making progress

- ✓ ZUBSOLV® with 98% access with commercial and 48% with public payers
- ✓ New agreement with NY Medicaid from March 2022
- ✓ To date access maintained in all published formularies for H2 2022 and 2023
- ✓ Field force initiated MODIA® awareness campaign to ZUBSOLV® customers
- ✓ Continued limitations in access to physicians compared with pre-covid levels

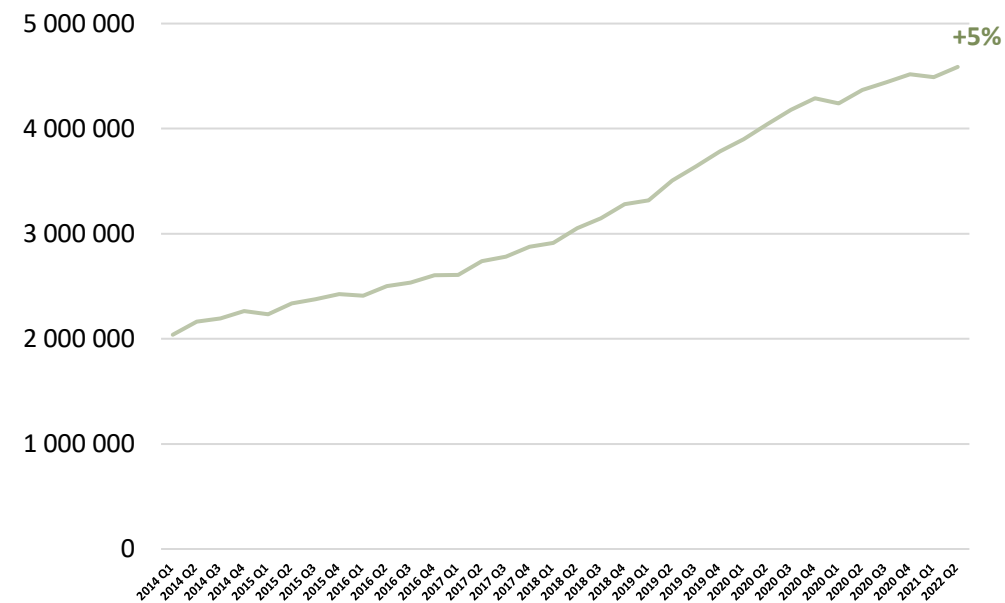
High level comments Q2+/-

- + 1% growth QoQ in ZUBSOLV's two largest Open Commercial and Medicaid Payers
- + 18% growth QoQ in Kentucky Medicaid
- + 22% growth QoQ in NY Medicaid
- Former exclusive payers, UHG & Humana slight negative although flattening
- Continued low market growth

¹ Where ZUBSOLV® is reimbursed and competes on equal terms with both branded products and/or generics

Multiple drivers for future growth

5% total market growth Q222 vs Q221¹



¹ Volume sales, quarterly NTRx

1

Covid-19 expected to diminish, improving patient access to care and Orexo access to customers

2

Multiple comprehensive activities on-going on federal and state levels to enable more patients access to treatment

3

Overall market access for ZUBSOLV® stable with Public payer access at 48% and Commercial at 98%

4

The launch of MODIA® will open up new market segments and is highly complementary to ZUBSOLV®

A female scientist with dark hair and glasses, wearing a white lab coat, is focused on her work in a laboratory. She is using a blue and white pipette to transfer liquid into a clear container. In the background, another person in a lab coat is visible, also working. The lab is filled with various pieces of equipment, including racks of test tubes and beakers.

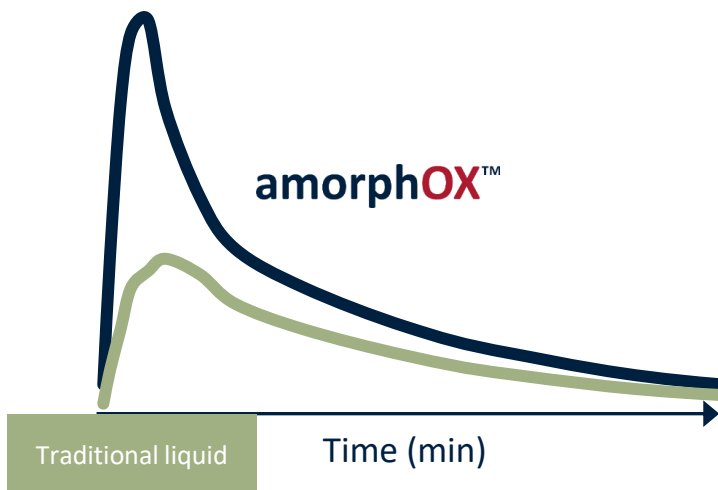
HQ & Pipeline

Orexo internal platform building on the amorphOX[®] technology

Validated in humans

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

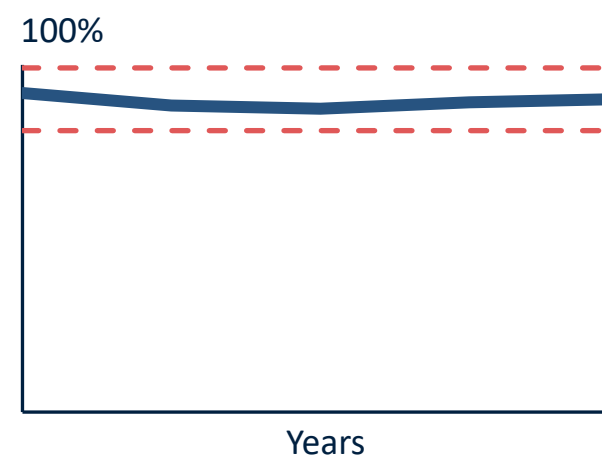
Plasma concentration from clinical trial



Excellent stability

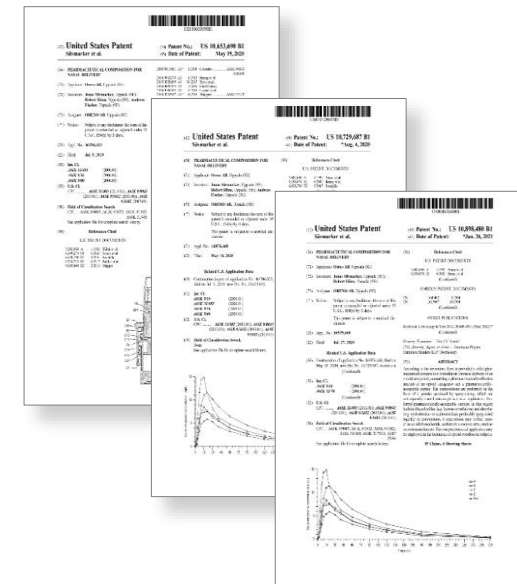
- ✓ Excellent stability even under accelerated conditions and proven to work on a broad scope of API's

Amount of API



Patent protected

- ✓ Three granted US patents and several patent applications have been filed with potential protection until 2042



OX124 & OX125 – overdose rescue medications

- Significant health issue in the US with >107.000 deaths from overdose in 2021
- Current US market exceeding **USD 400 million**
- 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 on track to be filed with FDA in Q4 2022**



Note: product image for OX125 is a prototype

OX640 – emergency treatment of allergic reactions

- First line treatment today: intramuscular auto-injectors
- Current global market exceeding **USD 2 billion** and growing
- OX640 offers:
 - Needle free alternative based on amorphOX®
 - Improved handling and storage (doubling shelf life of existing products)
 - No bisulfite antioxidant and preservative free
 - Improved convenience and acceptability vs injection products increases likelihood of timely use
- OX640 with excellent stability data compared to other products¹
- **First clinical trial initiated early Q3 2022 with results anticipated in Q4 2022**



¹ Based on publicly available data



Business update

Digital

Therapeutics (DTx)

Clinically proven DTx in collaboration with GAIA AG

Rooted in cognitive behavioral therapy techniques and based on AI technology offering a highly individualized intervention.

	modia	VORV!DA	deprexis®
Instructions for use	Opioid dependence	Alcohol misuse	Depression
Clinical evidence	Ongoing randomized clinical trial, 400 patients	Evaluated in 1 randomized clinical trial, > 600 patients	Evaluated in 13 randomized clinical trials, > 2.800 patients
Length of treatment	6 months	6 months	3 months
Treatment method	Along with current standard of care including medication	Standalone or as a complement to current standard of care	Standalone or as a complement to current standard of care
FDA clearance	Will apply for a 510 k clearance, meanwhile launched under FDA's Public Health Emergency Use Authorization (EUA)	FDA cleared under the EUA	FDA cleared under the enforcement discretion

Orexo is at the leading edge of digitalization in the pursuit to take DTx from its infancy to become a natural part of healthcare

“In less than a decade, DTx companies have completely disrupted the healthcare scene for the better.”

The Future of Digital Therapeutics and The Impact On Care,
The Linus Group, May 2021

✓ Establishing Reimbursement

Orexo working in tight collaboration with world leaders in digital health to make DTx accessible to all patients. However, universal reimbursement processes still to be established

✓ Disruptive technology

Through pilot programs, trials and real world evidence collection, Orexo is working with payers and leading healthcare organizations to build confidence in the value of our DTx to healthcare.

Good progress to obtain reimbursement



TRINITY
HEALTH

All administrative processes in place to manage reimbursement process through the collaborative care model

Validation of reimbursement process and education of HCPs during the summer

Full commitment from Trinity Health to expand program to all relevant care units when reimbursement process has been confirmed



U.S. Department
of Veterans Affairs

Orexo granted a 10 year contract July 13th securing reimbursement for deprexis® reaching 15 million citizens

Main potential patient population within Veterans Affairs with 9 million, but also IHS and Department of Defence is covered with close to 6 million members

Financial information



H1 2022 – A transformative period building for future growth

- **Significant investments in establishing digital therapeutics business and development of OX124**
- **Recurring business is well financed from ZUBSOLV® profit contribution**

Note: LTM, Last Twelve Months

Group net revenues

307 SEK M

US Pharma net revenues

279 SEK M

EBITDA

-30 SEK M

US Pharma EBIT

161 SEK M

Cash position

468 SEK M

US Pharma EBIT margin

58 %



Future value drivers

Why Orexo?

Profitable US Pharma

- ✓ SEK 77 m in EBIT contribution Q2 2022 and 41 quarters left to patent expires for ZUBSOLV®
- ✓ Significantly strengthened market access last 12 month despite Gx competition
- ✓ Outstanding performance in securing market access in low priced Gx market, which is key to all future product launches

Unique pharmaceutical pipeline and technology

- ✓ Developed an entirely new and unique drug delivery technology, amorphOX™ attracting interest from leading biotech companies
- ✓ OX124, with a clearly differentiated profile to market leader in >450 MUSD market
- ✓ OX640 with a superior stability to any other epinephrine product¹ and soon clinical data
- ✓ Patent protection of amorphOX™ covering multiple other APIs

Pioneer in digital therapies

- ✓ Digital health market is in it's early stages, but significant progress in establishing reimbursement
- ✓ Established a proprietary technical infrastructure to manage reimbursement processes in the US for DTx
- ✓ Excellent customer feedback from the >2400 initial users of our DTx
- ✓ Good progress in obtaining reimbursement with VA contract and TH ready to start first patients

¹ Based on publicly available data

A photograph of a man and a young girl in a park. The man is carrying the girl on his shoulders. They are both smiling and looking towards the camera. The background is a blurred green forest. The word "Thanks" is written in large, bold, dark blue letters on the right side of the image.

Thanks

Orexo is listed on the Nasdaq
Stockholm Mid Cap (ORX) and is
available as ADRs on OTCQX
(ORXOY) in the US