A pharma-ceutical & digital therapeutics company

MAY 19 2022

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

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Orexo in brief

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.

HQ & Pipeline

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

Digital Therapeutics

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

US Pharma

ZUBSOLV® for the treatment of opioid use disorder

ZUBSOLV® short facts

Technology	Sublingual
Indication	Opioid use disorder
Market approvals	US, EU and Australia
US launch	2013
Commercial rights	Orexo owns global rights, ex EU
Partner EU	Accord Healthcare (accord Make it better)
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® sublingual tablets (buprenorphine and naloxone) ©

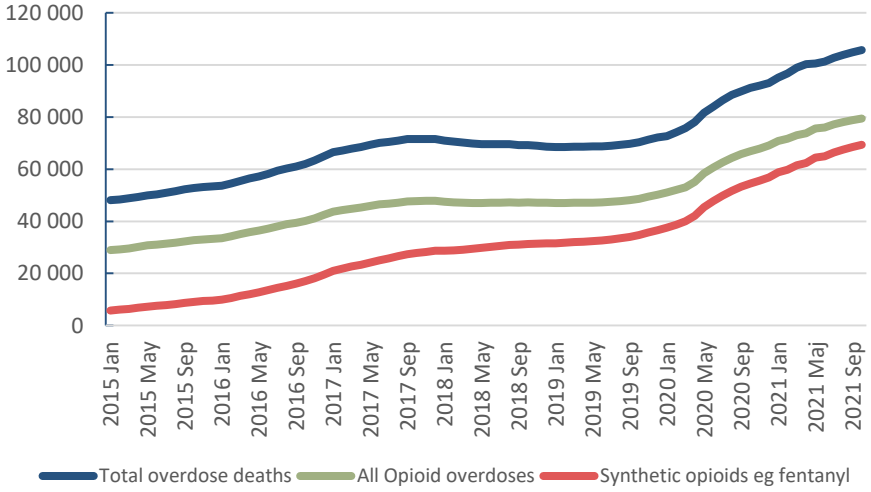
The opioid crisis - one of the largest health crises ever in the US

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

ZUBSOLV® is an important cash generator

Accumulated net revenues

4.2 SEK billion

Since US launch 2013 – Q1 2022

US Pharma net revenues[2]

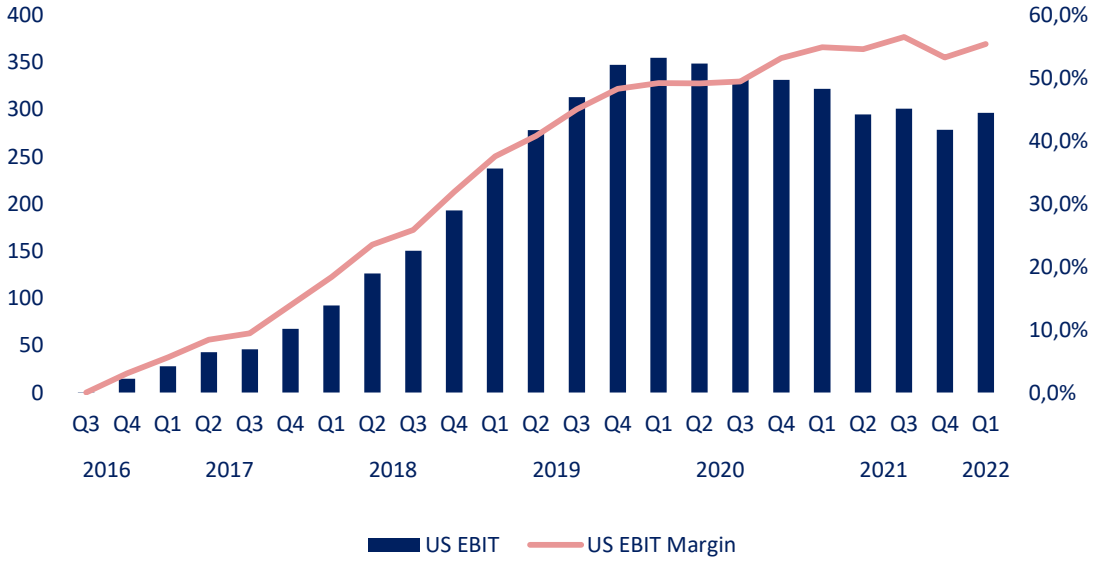
535 SEK M

LTM Q1 2022

Key operational highlights in Q1 2022

- ✓ ZUBSOLV® added to preferred NY Medicaid formulary from March 22
- ✓ Commercial market share in NY in Q1 was 10 percent[1] compared to Medicaid with ~0.5 percent
- ✓ Increased investment in field force from April in NY
- ✓ Field force continue with MODIA™ awareness campaign and initiated modiaONE trial campaign to ZUBSOLV® customers in February

ZUBSOLV® EBIT (SEK M) and EBIT margin, LTM Q1 2022



[1] Includes UHG and Humana, 7.2% marketshare if these are excluded
[2] LTM, Last Twelve Months (Q2 2021-Q1 2022)

HQ & Pipeline

Pharma products and development pipeline

Pharmaceuticals

Product/ Project	Exploratory	Preclinical	Phase 1	Phase 2	Phase 3	Registration	Approved and/or Launched US	Approved and/or Launched EU	Approved and/or Launched RoW
ZUBSOLV® Opioid Use Disorder/ **sublingual platform** (accord Make it better)									
Abstral® Breaktrough Cancer Pain/ **sublingual platform** (KYOWA KIRIN)									
Edluar® Insomnia/ **sublingual platform** (Mylan)									
OX124 Naloxone, Opioid Overdose/ **amorphOX™**									
OX125 Nalmefene, Opioid Overdose/ **amorphOX™**									
OX338 Ketorolac, Moderate to moderately severe pain									
OX640 Adrenaline, allergic reactions/ **amorphOX™**									
OX-MPI Microvascular Disease (GESYNTA PHARMA AB)						**Granted orphan drug designation in April 2022**			

OX124 & OX125 – overdose rescue medications

- Significant health issue in the US with >107.000 deaths from overdose last 12 months
- 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 H2 2022**

Note: product image for OX125 is a prototype

[1] Based on publicly available data

OX640 – emergency treatment of allergic reactions

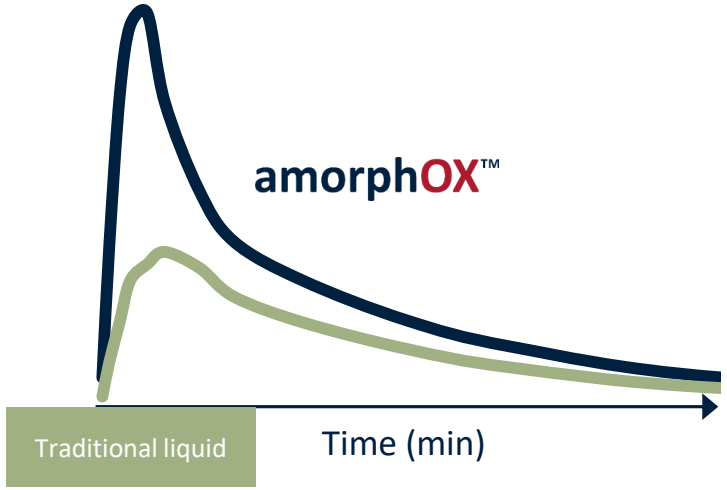
- Needle free and based on amorphOX™
- Improved handling and storage (doubling shelf life of existing products)
- No bisulfite antioxidant and preservative free
- Improved convenience and acceptability vs injection products increases likelihood of timely use
- OX640 with excellent stability data compared to other products[1]
- **First clinical trial on track to be initiated in Q3 2022**

[1] Based on publicly available data

Orexo internal platform building on the amorphOX™ technology

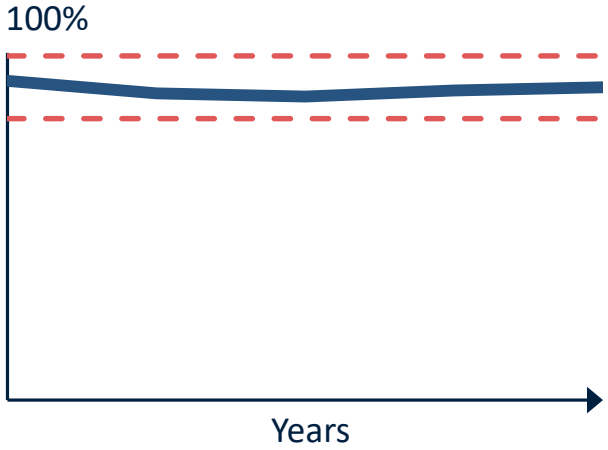
- ✓ Superior pharmacokinetic properties with more rapid onset, higher peak and overall exposure, lower variability

Plasma concentration from clinical trial

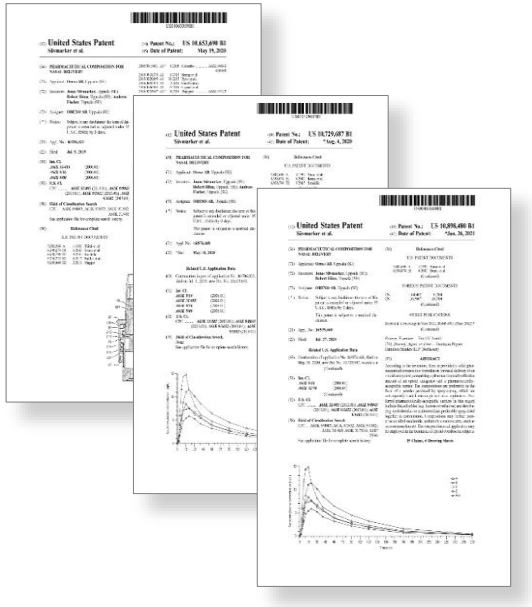


- ✓ Excellent stability even under accelerated conditions and proven to work on a broad scope of API's

Amount of API

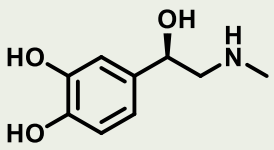


- ✓ Three granted US patents and several patent applications have been filed with potential protection until 2042



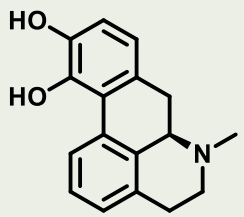
amorphOX™ works for a broad scope of drugs

Adrenaline



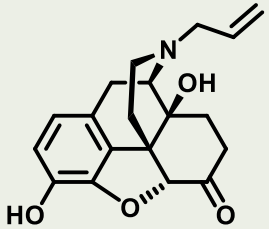
0.5% after 6 months

Apomorphine



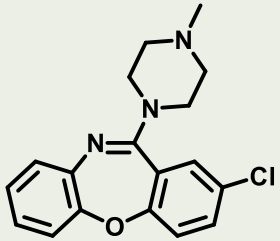
0.2% after 9 months

Naloxone



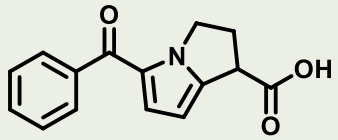
≤0.1% after 12 months

Loxapine



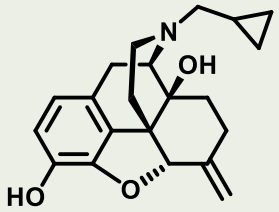
0.2% after 12 months

Ketorolac



0.8% after 6 months

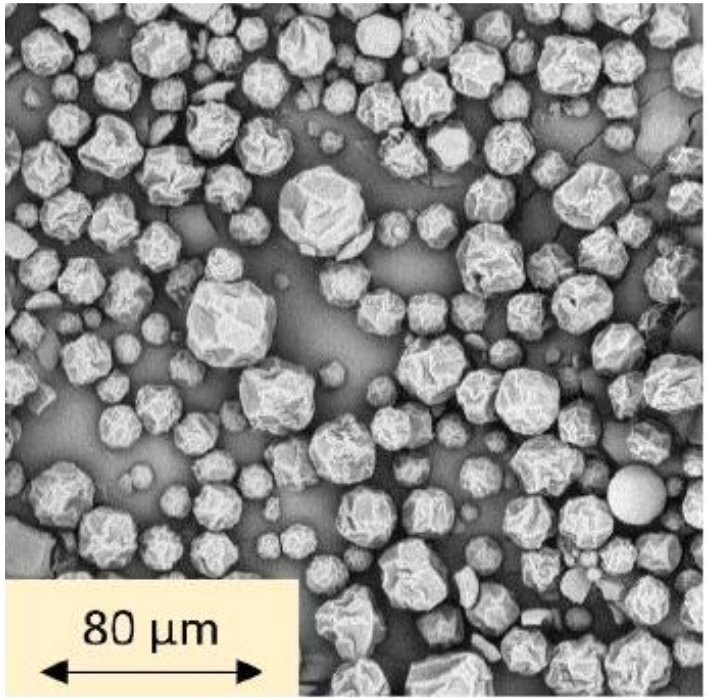
Nalmefene



≤0.1% after 15 months

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

amorphOX™ and macromolecules



Recent protein example

- ✓ Enzyme of 464 kDa (~1000 amino acids)
- ✓ Successfully formulated in the **amorphOX™** platform
- ✓ High yield
- ✓ Free-flowing powder
- ✓ Narrow particle size distribution
- ✓ Enzymatic activity fully retained after:
  - manufacturing
  - 1M storage @ 40°C/75%RH

Digital Therapeutics (DTx)

DTx in brief

- ✓ Subsection of digital health
- ✓ Evidence-based therapeutic intervention
- ✓ Prevent, manage, or treat a medical disorder or disease
- ✓ Particularly applicable in the mental illness & addiction space
- ✓ Standalone or along with pharma treatment
- ✓ Available 24/7

Strong underlying trends will force the DTx market to gain traction

Healthcare systems challenged
Aging population and sky-rocketing costs are forcing the healthcare providers to rethink how to deliver healthcare to increase efficiency and value.

Consumers (patients) in the center
Patients want to be seen as consumers and requires holistic and customized treatments with access 24/7.

Widespread technology acceptance
Covid-19 has further pushed forward the ongoing tech revolution and the use of telemedicine is pervasive.

Value-based care
Providers will be rewarded based on the ability to add patient value. Analyzing RWE data pave the way for efficient allocation of resources.

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. <u>However, universal reimbursement processes still to be established</u>

- ✓ **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.

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[1]	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 disctretion

[1] View study results in Appendix

Financial & legal

Q1 2022 LTM – 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
592 SEK M

US Pharma net revenues
535 SEK M

EBITDA
-134 SEK M

US Pharma EBIT
296 SEK M

Cash position
434 SEK M

US Pharma EBIT margin
55 %

Legal update – no changes in Q1 2022

ZUBSOLV® patent dispute vs Sun Therapueutics

No changes in Q1

- ✓ 9 patents listed in the Orange Book
- ✓ Expiring dates Dec 2027 – Sep 2032
- ✓ Previously successfully managed to defend ZUBSOLV® IP rights in the US appeal court

Subpoena with regards to ZUBSOLV®

No changes in Q1

- ✓ Very limited activities in Q1
- ✓ No additional information received since issuance of subpoena July 2020

Future value drivers

Why Orexo?

Profitable US Pharma

- ✓ SEK 84 m in EBIT contribution Q1 and 42 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 >440 MUSD opioid overdose rescue medication market
- ✓ OX640 with a superior stability to any other epinephrine product[1] 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 >1800 initial users of our DTx
- ✓ Intimate partnership with large healthcare provider to develop treatment program and reimbursement pathways

[1] Based on publicly available data

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Thanks

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