



Improving lives of people suffering from mental illness and addiction disorders



## Introduction to Orexo

Nasdaq Stockholm: ORX, US OTC Market: ORXOY (ADR)

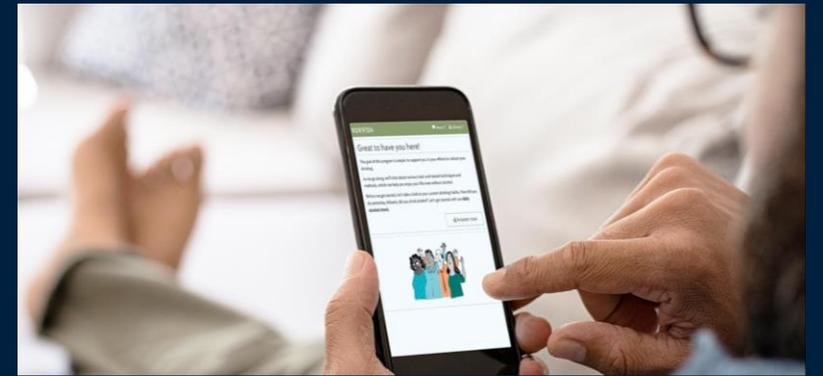
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# Introduction & strategic agenda



# Orexo in brief

- Developed **four commercial pharmaceutical products** with worldwide approval
- Addresses **unmet need** within the growing space of **mental illness** and **addiction disorders**
- Broad product portfolio and development pipeline of traditional **pharma products** and **digital therapies**
- Strategic focus on **portfolio expansion** through development and licensing/M&A
- **Strong financial position** enables investment in future growth
- Top two largest shareholders<sup>1</sup>: **Novo Holdings** (27.8%) and **HealthCap** (10.2%)



**Corporate Headquarters**  
(Uppsala, Sweden)  
Corporate functions and Development



**US Headquarters**  
(Morristown, New Jersey)  
Commercial subsidiary

**Net revenues**  
LTM<sup>2</sup> Q320

SEK **742** m

**EBITDA**  
LTM<sup>2</sup> Q320

SEK **104** m

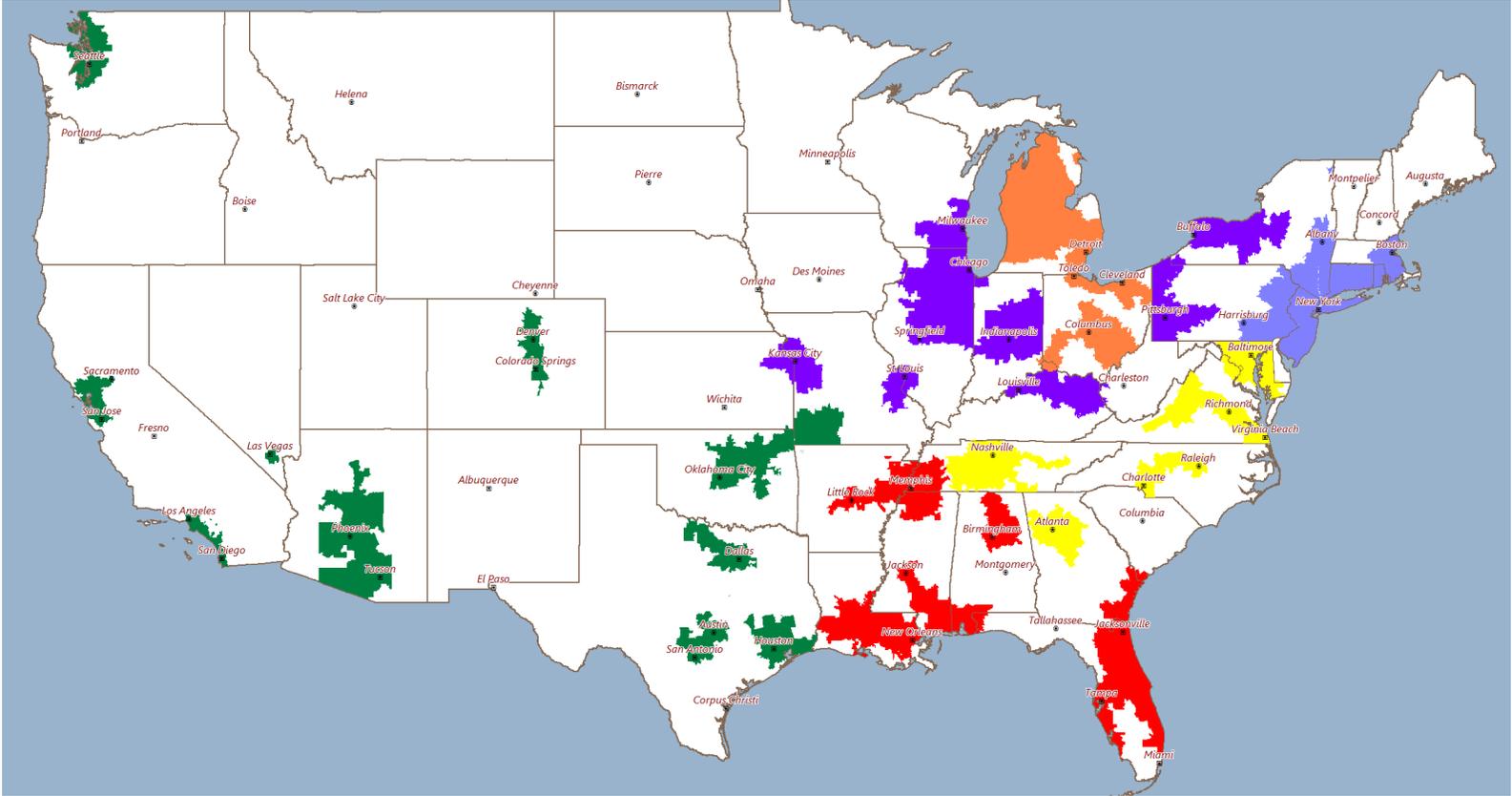
**Cash position**  
Q320

SEK **593** m

<sup>1</sup> As of October 30, 2020

<sup>2</sup> Last Twelve Months

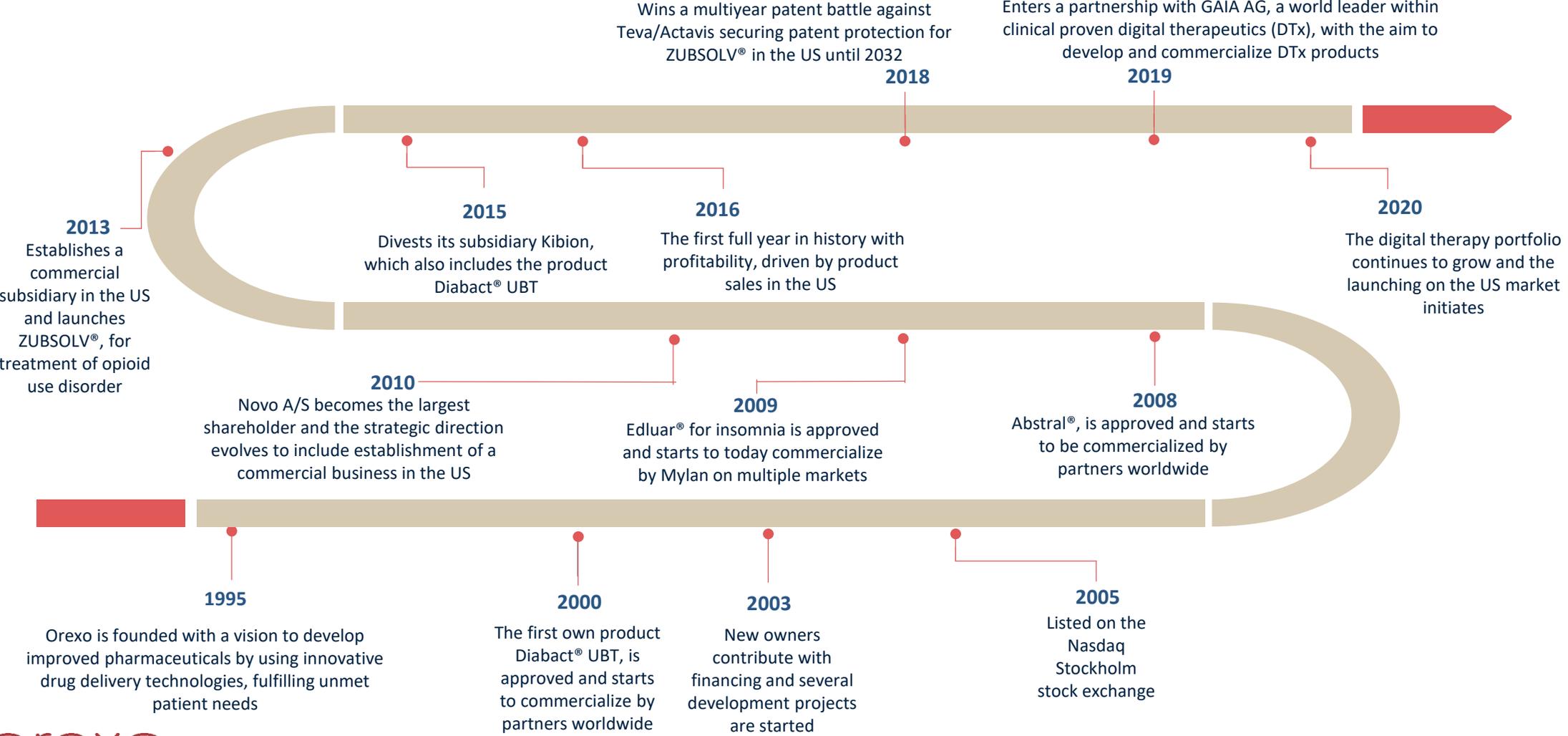
# Own commercial platform in the US



- Direct presence in the US since 2013
- Strong market access network
- Fully-owned field force covering most relevant geographies in the US
- Currently 51 sales territories organized in various regions

The colors represents the company's various sales regions

# Strong history paving the way for the future



# Highly qualified management building a strong team



**Nikolaj Sørensen**  
President and CEO

Holds current position since February 2013, employed since 2011.

B.Sc., and M.Sc., Copenhagen Business School, Denmark.

**Other appointments:**  
Member of the Board, Bioservo Technologies AB.

**Previous appointments:**  
Senior management positions at Pfizer Inc. with a focus on commercialization in Europe and Chairman of the Board and Managing Director at Pfizer AB. Prior to Pfizer Nikolaj Sørensen served as a management consultant at Boston Consulting Group (BCG), leading several projects within M&A, commercial transformation, and turnarounds.



**Robert A. DeLuca**  
President Orexo US Inc.

Has held current position since 2013.

R.Ph.

**Previous appointments:**  
Extensive experience establishing commercial operations in the US with a combined background in market access, marketing, and sales. Has held leadership positions at multinational pharmaceutical companies including Sanofi-Aventis, ScheringPlough, Berlex and Pharmacia, and most recently served as Chief Commercial Officer at Archimedes Pharmaceuticals.



**Joseph DeFeo**  
EVP and CFO

EVP and Chief Financial Officer since November 1, 2018. Joined Orexo US Inc. in 2013 as VP, Finance & Adm.

Bachelor degree in accounting from Clarion University, US, and a MBA in finance from St. Joseph's University, US.

**Previous appointments:**  
Joseph DeFeo has worked in several senior finance positions among others establishing of a US operations for a large Italian pharmaceutical company, Head of International Treasury and led finance for the commercial operations in the US for two major pharmaceutical companies.



**Johannes Doll**  
EVP and Chief Commercial Officer

EVP and CCO since October 2019, employed since 2016.

MBA, University of Texas, and Dipl. Kaufmann, WHU Otto Beisheim School of Management, Germany.

Johannes Doll worked as an advisor to Orexo during the period 2013-2016 when he was recruited as the EVP and Head of Corporate Development. Since October 2019, Johannes Doll is the company's Chief Commercial Officer.

**Previous appointments:**  
Johannes Doll has worked with McKinsey & Company from 2004 to 2013, advising clients in the global pharmaceutical and private equity industry.



**Dennis Urbaniak**  
EVP Digital Therapeutics

Has held the position as EVP Digital Therapeutics since December, 2019.

Monmouth University, US, BS Business Administration/Marketing/English

**Other appointments:**  
Member of HIMSS

**Previous appointments:**  
Chief Digital Officer, Havas Health & You, Chief Executive Officer, Havas Health Plus. Prior to Havas Health & You, Managing Director Accenture Digital Life Sciences Analytics and Janssen Client Account Lead. Before joining Accenture, twenty years at Sanofi in various sales and marketing roles.



**Michael Sumner**  
Chief Medical Officer

Had held current position since 2013.

MB BS, MRCP (UK), MBA.

**Previous appointments:**  
Extensive experience within the pharmaceutical industry from Novartis Pharmaceuticals, Aventis Behring and Novo Nordisk and most recently held the position of Vice President Clinical and Medical Affairs at Shire.

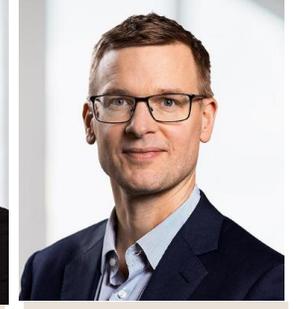


**Cecilia Coupland**  
VP and Head of Operations

VP and Head of Operations as of January 2019, employed since 2006.

MSc in Chemical Engineering, Uppsala University, Sweden.

**Previous appointments:**  
Head of Supply Chain & Planning at Orexo since 2014 and prior to that extensive experience of global pharmaceutical manufacturing and supply chain management, as well as drug development and project management, from various key positions at AstraZeneca and Orexo AB.



**Robert Rönner**  
VP and Head of R&D

VP and Head of R&D as of January 2019, employed since 2007.

MSc in Chemical Engineering and PhD in Medicinal Chemistry, Uppsala University, Sweden.

**Previous appointments:**  
Head of Pharmaceutical Development & IP at Orexo AB since 2016 and prior to that extensive experience of drug discovery and development, as well as patent prosecution and litigation, from various key positions at Biolipox AB and Orexo AB.

# 2012 – 2019 successful strategic focus on building a solid foundation

EBITDA SEK m 2012-2019



Launch ZUBSOLV® in the US



First actions taken to broaden the US commercial platform



Secure profitability



Ensure a sustainable business model

# Strong financial position to drive future growth

Numbers reflects loss in Abstral royalty due to patent expiration and investments in the build-up of DTx venture

Group net revenues LTM <sup>1,2</sup> <b>SEK 742 m</b> (USD 83 m)	Growth YoY <b>-11%</b>
Group EBITDA LTM <sup>1,2</sup> <b>SEK 104 m</b> (USD 12 m)	<b>-55%</b>
US Pharma EBIT (ZUBSOLV <sup>®</sup> US) LTM <sup>1</sup> <b>SEK 331 m</b> (USD 37 m)	<b>6%</b>
Cash position Q3 2020 <sup>2</sup> <b>SEK 593 m</b> (USD 67 m)	Positive net cash position <sup>2</sup> <b>SEK 369 m</b> (USD 41 m)

Denomination currency is SEK

<sup>1</sup> Last Twelve Months <sup>2</sup> 8.9 USD/SEK, Q3 average

# The profit and cash contributions from ZUBSOLV® enables continued investments in building a broader and stronger Orexo

## Broaden...

..the portfolio of commercial products to be promoted by our existing US organization in 2020

## Establish

..a new revenue generating business area within Digital Therapeutics (DTx) and launch first new product in 2020

## Maintain

..ZUBSOLV® profit contribution in 2020 and ensure it is sustainable and growing over time

## Launch

..a new pharmaceutical product from Orexo's development pipeline within the next two years



# Investment thesis



# Value drivers for long-term growth 1 - 5

## 1 Product portfolio addressing large and growing markets

Focusing on becoming a leader in the large and growing space of substance use disorders and mental health. In parallel, Orexo is also addressing the ongoing opioid epidemic, one of the largest health crises to take place in the US and increasingly a growing global concern.

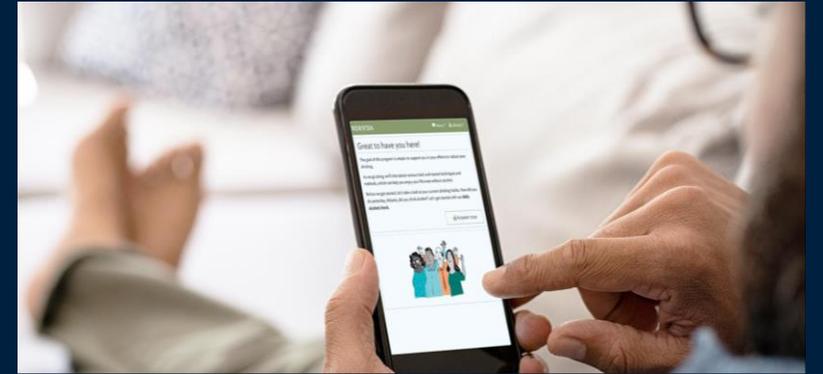
## 2 Entering digital therapeutics, a new evidence-based frontier in patient care

Digital therapeutics can increase access to treatment and improve treatment outcomes and is set to become an integral part of the global healthcare landscape. Substance use disorder and mental health are areas where it is most needed.

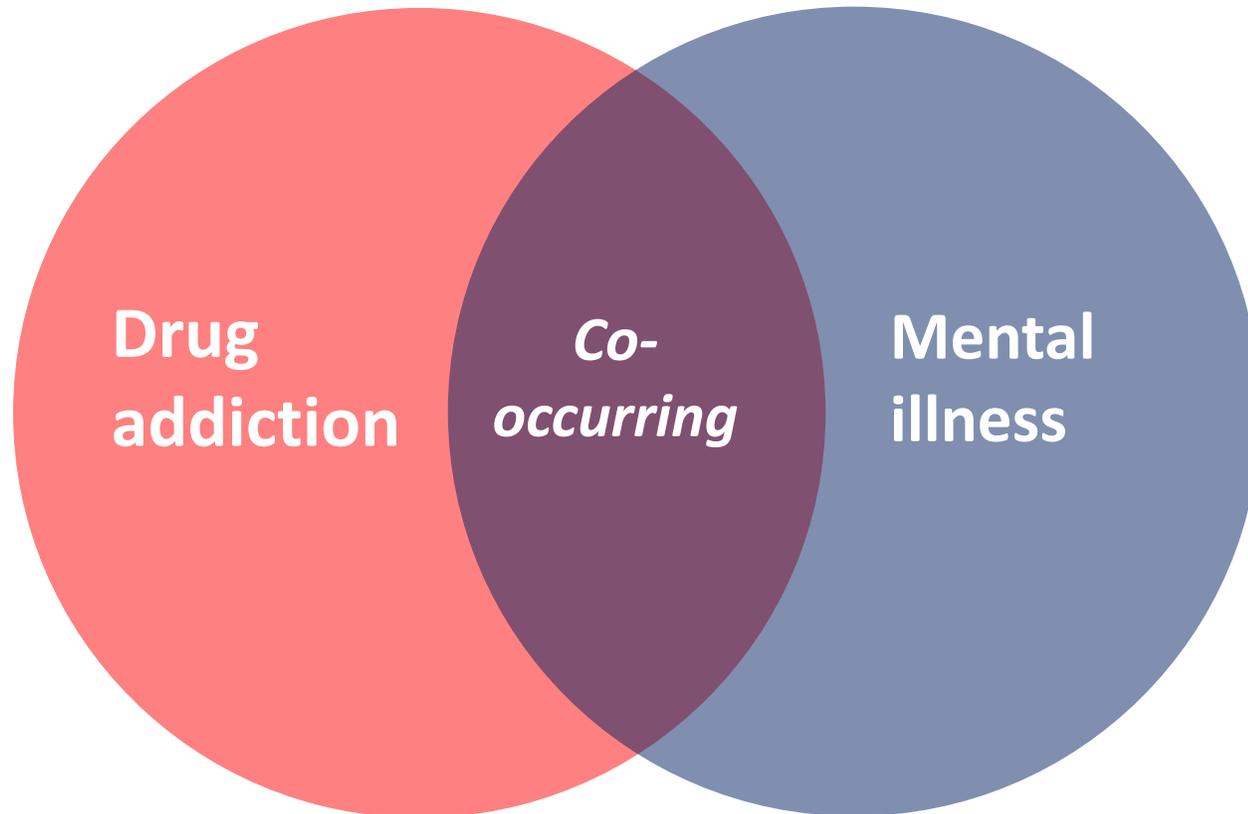
# Value drivers for long-term growth 1 - 5

- 3 Strong cash conversion to support growth**  
Lead product ZUBSOLV®, for the treatment of opioid use disorder, is a strong cash and profit contributor, enabling continued investment in on-market products and R&D.
- 4 Leveraging our US commercial excellence**  
Strategic focus on leveraging its commercial excellence and strong market access network in the US, by adding more products to the US commercial platform.
- 5 Expanding pipeline targeting unmet medical needs**  
Continue to build on the strong experience of developing products with worldwide approval by expanding the pipeline with multiple short-time to market assets based on innovative drug delivery technologies and digital therapies, addressing unmet medical needs in our key therapeutic areas.

# Unmet needs & key therapeutic areas



# Drug addiction - a chronic medical condition highly correlated with mental illness



- **Drug addiction**, also called **substance use disorder**, is a disease that affects a person's brain and behavior and leads to an inability to control the use of a drug
- Drug addiction is a **chronic medical condition** which often requires **life-long treatment**
- In 2018 approx. **50 percent** of the individuals suffering from drug addiction also reported having a **mental health illness**<sup>1</sup>
- Only about **half** of individuals with co-occurring mental health and drug addiction **received treatment in 2018**<sup>1</sup>

<sup>1</sup> Substance Abuse and Mental Health Services Administration

# Opioid addiction - one of largest health crises ever in the US

- Growing global concern with 53 million using opioids worldwide<sup>1</sup>
- Globally opioids continue to cause the most harm, accounting for two-thirds of the deaths attributed to drug use disorders<sup>1</sup>
- The problem in the US has reached epidemic proportions where approx. 4-5 million are dependent opioid users and in 2019 approx. 72,000 died of an overdose<sup>2</sup>
- In the US two out of three overdose deaths involved an opioid like prescription opioids, heroin, or synthetic opioids (e.g. fentanyl)<sup>2</sup>
- To die from an overdose is the leading cause of injury-related death in the US

<sup>1</sup> World Drug Report

<sup>2</sup> Center of Disease Control

<sup>3</sup> White House Council of Economic Advisors

<sup>4</sup> Centers for Disease Control and Prevention (CDC). Alcohol and Public Health: Alcohol-Related Disease Impact (ARDI). Average for United States 2006–2010 Alcohol-Attributable Deaths Due to Excessive Alcohol Use. <https://go.usa.gov/xKBjQ>

Large society burden

USD **696** billion

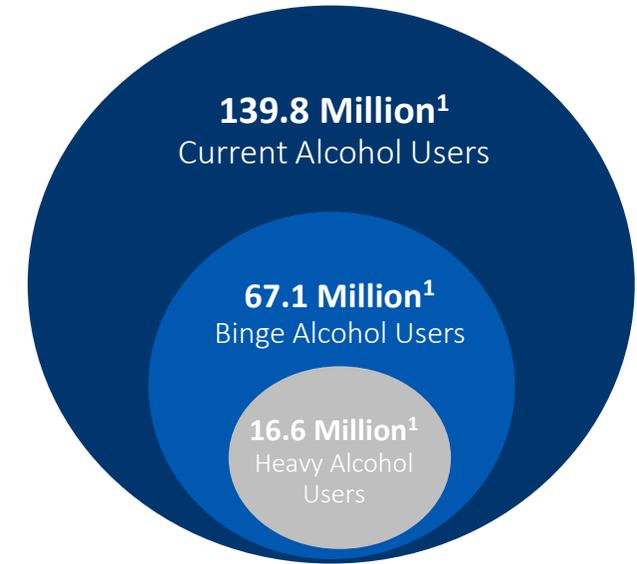
Opioid epidemic cost for the US society in 2018<sup>3</sup>

**8-10** %

...of people prescribed opioids for longer use develop an addiction<sup>4</sup>

# Alcohol misuse - another major health issue in the US

- In the US approximately 16.6 million are heavy alcohol users<sup>1</sup>
- Each year, more than 88,000 people die from alcohol-related causes,<sup>2</sup> making it the third leading preventable cause of death in the country
- Alcoholism is highly stigmatized, preventing patients from seeking treatment
- Approx. 20% of those diagnosed with alcohol use disorder (AUD) received treatment, of which 60% attended Self-Help Groups<sup>3</sup>
- Abstinence is often the only goal, and current therapies require abstinence prior to initiating therapy
- Current therapy solutions are ineffective and 85% of patients do not achieve long term abstinence



Large societal burden

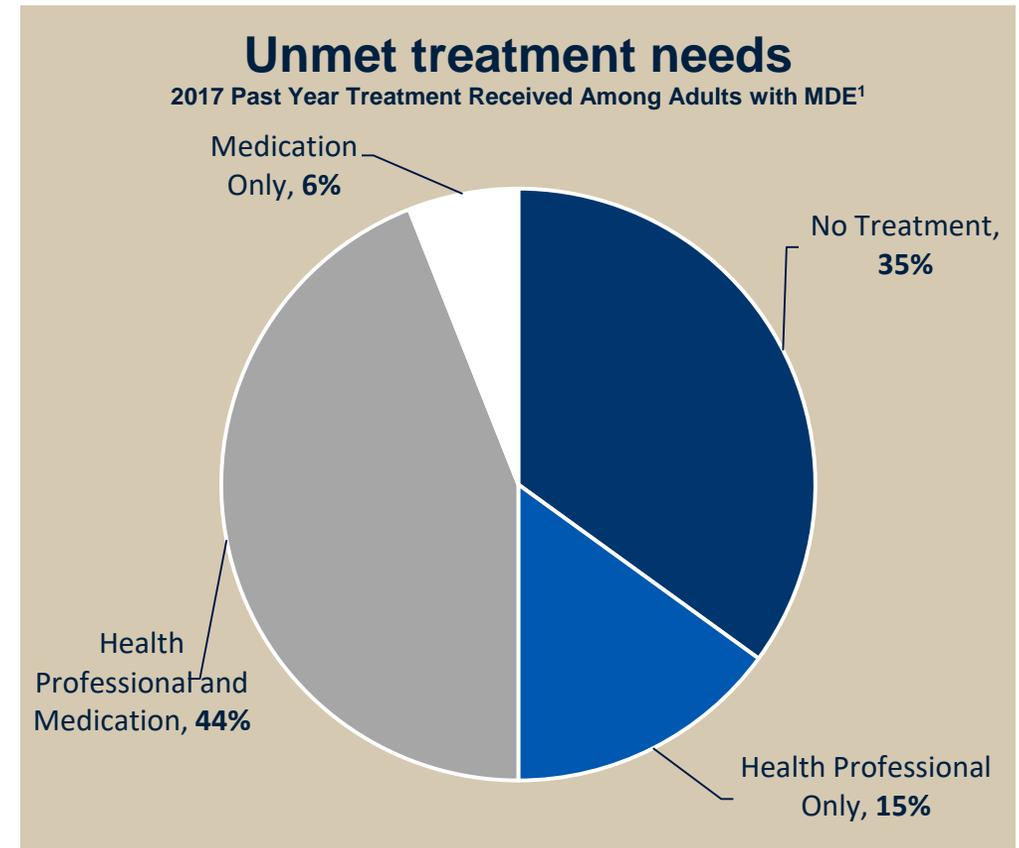
**USD 249 billion**

US society costs in 2010 for problematic drinking<sup>1</sup>

<sup>1</sup> Substance Abuse and Mental Health Services Administration <sup>2</sup> Sacks, J.J.; Gonzales, K.R.; Bouchery, E.E.; Tomedi, L.E.; and Brewer, R.D. 2010 National and state costs of excessive alcohol consumption. American Journal of Preventive Medicine 49(5):e73–e79, 2015. <sup>3</sup> SAMHSA 2017 NSDUH Tables 5.2A & 5.16A, 1) SAMHSA 2017 NSDUH Table 5.19A

# Depression - the leading cause of disability worldwide

- In 2017, an estimated 17.3 million US adults (7.1% of all adults) in had at least one Major Depressive Episode (MDE)<sup>1</sup>
- Major depression is highly recurrent: Risk of recurrence increases ~16% with each successive episode & estimated recurrence rate is ~20% over 6mo & >40% over 2 years<sup>2</sup>
- Despite the availability of effective interventions for depression, delays in initial treatment contact remain problematic<sup>3</sup>
- In 2017, approximately 35% of the 17.3 million US adults who experienced MDE did not receive treatment<sup>1</sup>



<sup>1</sup> National Institute of Mental Health. Major Depression. Retrieved from: <https://www.nimh.nih.gov/health/statistics/major-depression.shtml>

<sup>2</sup> UpToDate "Unipolar depression in adults and initial treatment: General principles & prognosis" (2018, lit review current thru Feb 2019); <sup>3</sup> American Psychiatric Association (APA) "Practice guideline for treatment of patients with MDD" (2010);

<sup>3</sup> Yoshikawa E, et al. *BMC Res Notes*. 2017; 10: 673.

# Covid-19 will create a tsunami of mental health issues and significantly increase the need for Orexo's products

## Deaths from opioid overdose increase

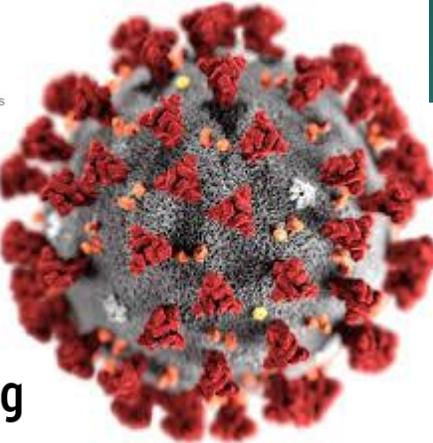
**The Washington Post**  
*Democracy Dies in Darkness*

Coronavirus Latest news U.S. map World map Reopening tracker Lives lost Your life at home Extraordinary people

Health

### 'Cries for help': Drug overdoses are soaring during the coronavirus pandemic

Suspected overdoses nationally jumped 18 percent in March, 29 percent in April and 42 percent in May, data from ambulance teams, hospitals and police shows.



## Alcohol misuse increase

### Drug and Alcohol Use Increase During COVID-19

Our recent survey shows more people are using drugs and alcohol to cope with stress, boredom and mental health issues.



## Opioid misuse increase

### Alexander Caudarella: The pandemic is making the opioid crisis worse

*Escalating numbers of overdoses and deaths are being reported in many parts of the country. In Toronto in both April and May, there were more suspected opioid deaths than any month since September 2017*



## Depression increase

**EdSurge** News Research Events Jobs Board More

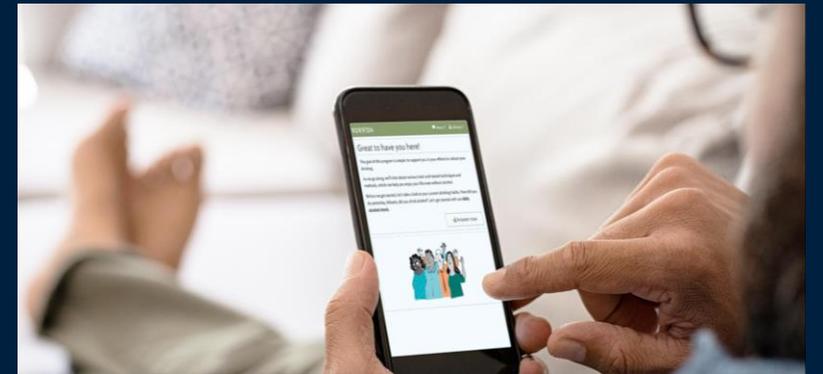
VOICES LEADERSHIP

### The Next Pandemic: Mental Health

By Cindy Mee and Isabelle Hsu May 20, 2020



# Pharma product and projects under development



# Our drug delivery technologies improve pharmaceuticals

*In our efforts to address unmet needs Orexo develops improved specialty pharma treatments – at a lower cost, in a shorter period of time and at a lower risk – by combining known pharmaceutical substances with its patented proprietary **drug delivery technologies***





# ZUBSOLV<sup>®</sup> for treatment of opioid use disorder

## ZUBSOLV<sup>®</sup> short facts

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<b>Technology</b>	Sublingual
<b>Indication</b>	Opioid use disorder
<b>Market approvals</b>	US, EU and Australia
<b>Commercial rights</b>	Orexo owns global rights
<b>Net revenue in 2019</b>	SEK 719.2 million
<b>Partner</b>	Orexo seeks partners ex US
<b>Patent protection</b>	US, EU, Australia and New Zealand until 2032

### Product advantages include:

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



# Edluar® & Abstral® for treatment of insomnia and breakthrough cancer repectively

## Edluar® short facts

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<b>Technology</b>	Sublingual
<b>Indication</b>	Insomnia
<b>Market approvals</b>	Worldwide
<b>Commercial rights</b>	Mylan worldwide
<b>Royalty in 2019</b>	SEK 11.6 million
<b>Partner</b>	 <b>Mylan</b>
<b>Patent protection</b>	US until 2031, EU until 2025



## Abstral® shorts facts

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<b>Technology</b>	Sublingual
<b>Indication</b>	Breakthrough cancer pain
<b>Market approvals</b>	Worldwide
<b>Commercial rights</b>	Kyowa Kirin worldwide
<b>Royalty in 2019</b>	SEK 112.6 million
<b>Partner</b>	<b>KYOWA KIRIN</b>
<b>Patent protection</b>	Most markets ex-US and the EU, until 2024



# OX124 - a new stronger rescue medication with naloxone

Expected launch in 2022

## The unmet need

Available rescue medications have been developed for heroin overdoses, but most patients are dying from synthetic opioids like fentanyl today

## Our aim

A rescue medication that is stronger and longer-acting, and thus effective in reversing overdoses caused by synthetic opioids

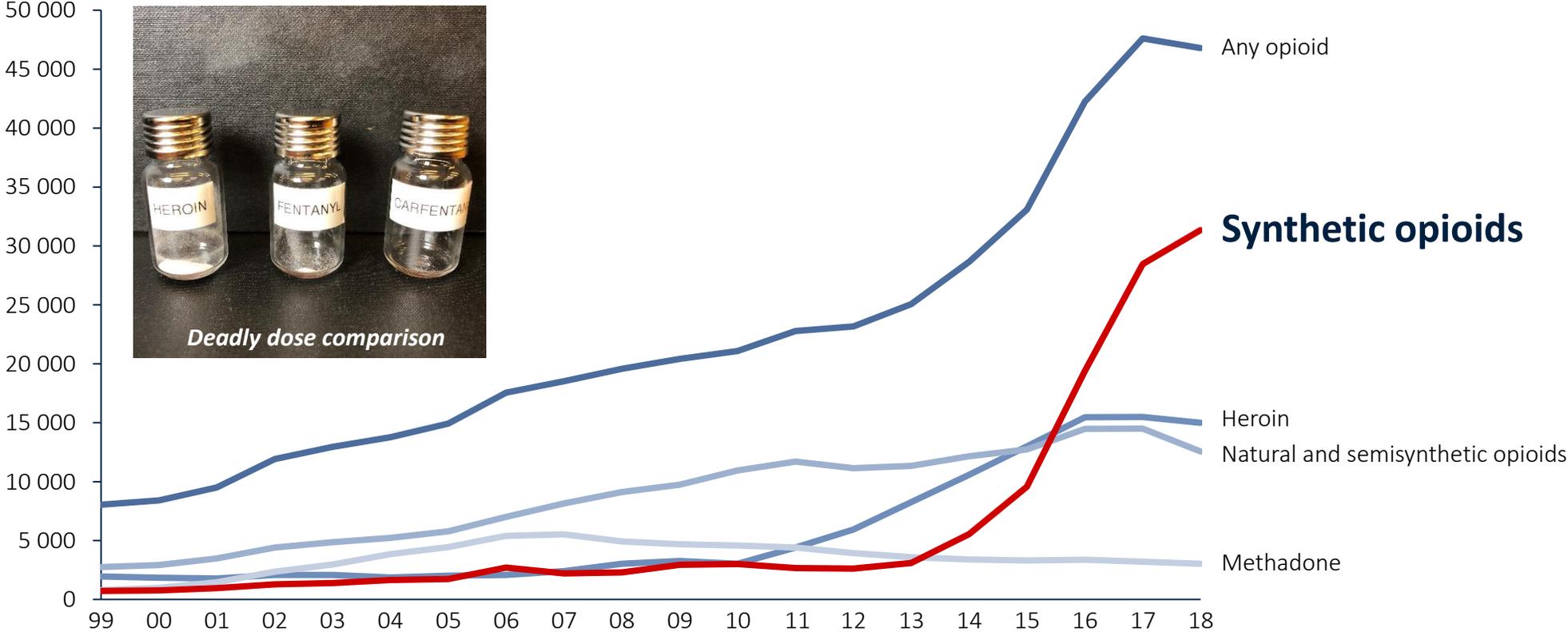
## The potential

**70-110** million USD net sales (US market)



# OX124 - While overall deaths from opioid overdoses showed a slight decline in 2018, deaths from synthetic opioids continue to rise

Deaths from opioid overdose, by type of opioid, United States

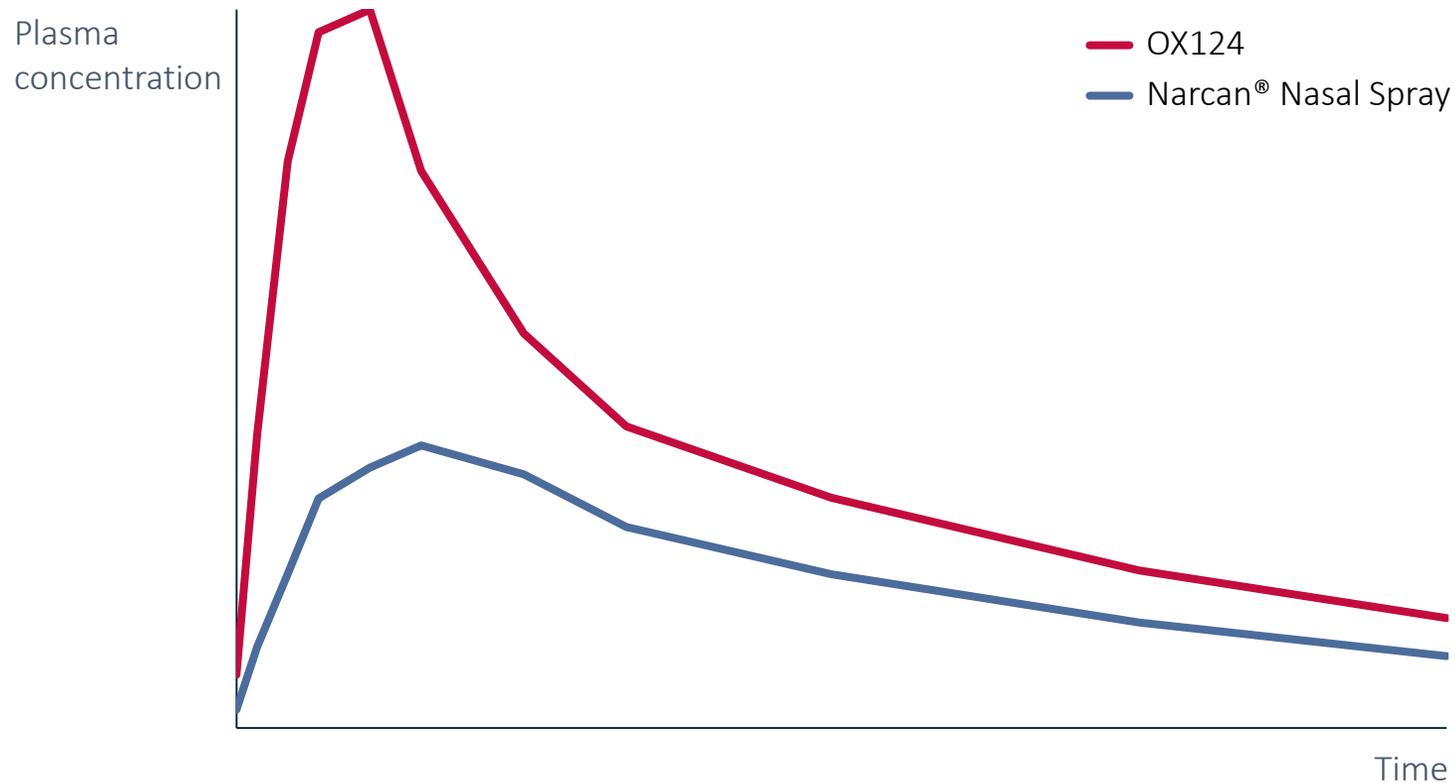


Source: Hedegaard H, et al. NCHS DATA Brief 356 - Drug Overdose Deaths in the United States, 1999-2018. NCHS, National Vital Statistics System, Mortality. Jan 2020.

# OX124 - We have shown better PK profile than Narcan<sup>®</sup> Nasal Spray

## Faster, stronger and longer-acting vs Narcan<sup>®</sup> Nasal Spray

Results from exploratory PK study in healthy volunteers, 2019



## Expected patient benefit

- Rescue more patients with the first dose (~34% of overdose patients require more than one dose of Narcan)
- Avoid "second overdoses" thanks to longer duration (Fentanyl has a half life of 8-10 hours vs. 2 hours for naloxone)

# OX125 - a new stronger rescue medication with nalmeffene

## The unmet need

Available rescue medications have been developed for heroin overdoses, but most patients are dying from synthetic opioids like fentanyl today

## Our aim

A powerful rescue medication for situations where very long-lasting effect is required, e.g., in remote areas, as response to long-acting drugs or for anti-terror stockpiling

## The potential

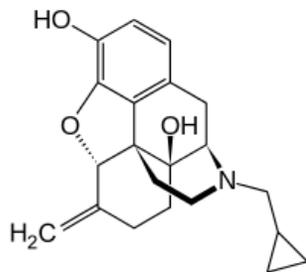
**40-60** million USD net sales (US market)



While we expect naloxone to remain the dominant rescue drug, there are distinct areas where nalmefene may be better suited

## Nalmefene

- Opioid antagonist (like naloxone)
- More potent than naloxone (higher mu receptor affinity)
- Longer half-life than naloxone (8 hours vs. 2 hours)



## Where it may be better suited than naloxone



### Rural areas

- Long acting rescue drug optimal for areas with long travel time to the closest hospital



### Response to long-acting illicit drugs

- Recent emergence of illicit oral fentanyl tablets with longer effect in Philadelphia



### Narco-terrorism

- Safety stock for potential terror attacks involving fentanyl or other synthetic opioids

# OX338 - a non-opioid for treatment of pain

## The unmet need

Opioids are still used unnecessarily in many situations, further fuelling the opioid crisis

## Our aim

Opioid-level pain relief for short-term pain (up to 5 days) without the risk of addiction

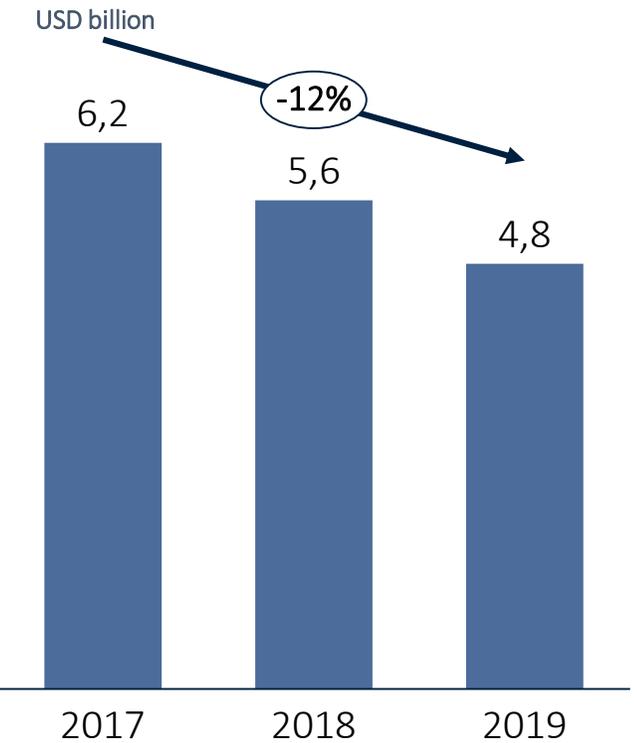
## The potential

**>100** million USD net sales (US market)



Despite some decline, the opioid market is still massive – and opioids continue to be used unnecessarily in many situations

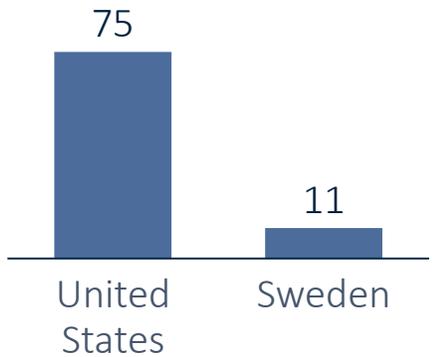
Opioid market United States<sup>1</sup>



Evidence of opioid over-prescribing, US



Share of patients with an opioid prescription upon discharge post-surgery<sup>2</sup>



~6% of adolescents and young adults who have received opioids after wisdom teeth removal were diagnosed with opioid abuse within 12 months<sup>3</sup>

<sup>1</sup> IQVIA National Sales Perspective (Average Selling Prices)

<sup>2</sup> JAMA Netw Open. 2019; 2(9): e1910734, based on four frequently performed procedures: surgery to remove the appendix, surgery to remove the gallbladder, a minimally invasive procedure to treat a torn meniscus cartilage in the knee and a procedure to remove a breast lump

<sup>3</sup> JAMA Intern Med. 2019: 145-152

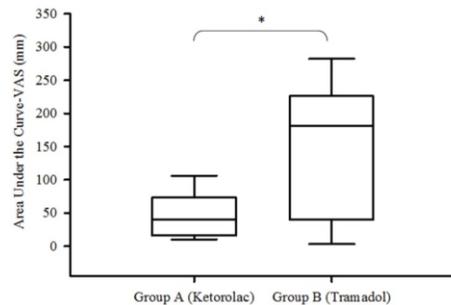
# Ketorolac is proven to be as effective as opioids

Examples for ketorolac's proven efficacy

MEDICINA ORAL  
PATOLOGIA ORAL  
Y CIRUGIA BUCAL



## Third Molar surgery



“...this study suggests that **10 mg of oral ketorolac had superior analgesic effect than 50 mg of tramadol** when administered before a mandibular third molar surgery.”

Isirdia-Espinoza et al. 2016. Med Oral Patol Oral Cir Bucal



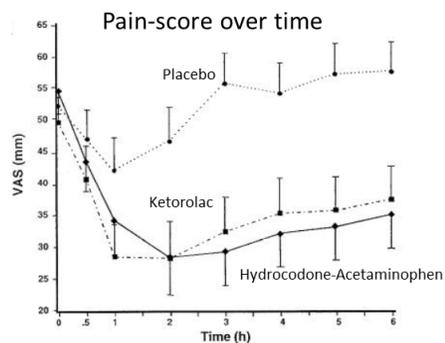
## Painful injuries

“Ketorolac proved to be **as effective as morphine in relieving pain and did so just as quickly**. It seemed to have advantages over morphine in relieving pain associated with activity.”

Jelinek. 2000. British Medical Journal  
(ER injuries included e.g., fractures of the femur, tibia, and fibula)

ANESTHESIA &  
ANALGESIA

## Arthroscopic surgery procedures



“In conclusion, there was **no difference in the efficacy between oral ketorolac and hydrocodone-acetaminophen combination** in controlling pain after outpatient arthroscopic surgery procedures.”

White et al. 1997. Anesthesia & Analgesia

PHARMACOTHERAPY  
The Journal of Human Pharmacology and Drug Therapy

## Surgeries

“Ketorolac 10 and 30 mg were **as effective as morphine 12 mg** during the entire 6-hour observation period, and ketorolac 90 mg was **more effective than morphine 12 mg** during the entire 6 hours.”

Yee et al. 1986. Pharmacotherapy  
(Surgeries included e.g., cholecystectomy and abdominal hysterectomy, tendon and ligament repairs)

# We are aiming at clearly differentiating OX338 vs. SPRIX and Generics

## SPRIX Nasal Spray

- Only branded product on the market
- Complicated storage and dosing instructions
- Administration site reactions/ discomfort and bad taste
- High \$1,600 list price



## **OX338** is expected to...

- ... be much easier to administer and have less patient discomfort
- ... not require the first dose to be given as an injection

## Ketorolac Generics

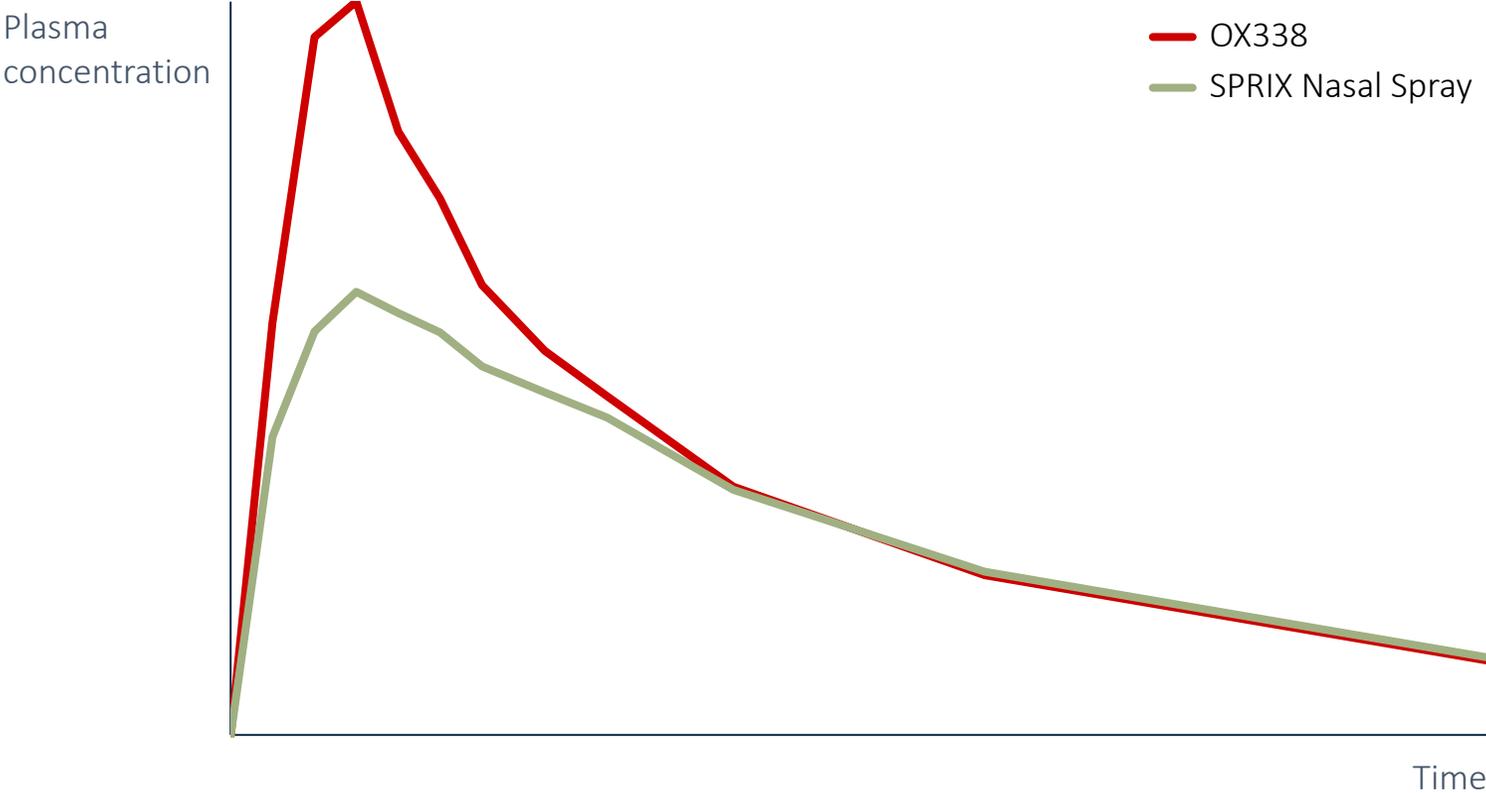
- First dose must be given as an IM or IV injection
- Oral Gx are only indicated for continuation therapy after the injection
- Complicated dosing



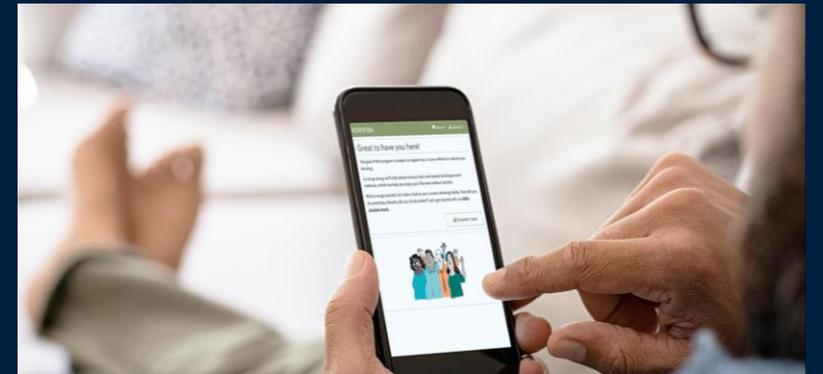
# We have shown better PK profile than SPRIX<sup>®</sup> Nasal Spray

## Faster uptake and higher peak vs. SPRIX<sup>®</sup> Nasal Spray

Results from exploratory PK study in healthy volunteers, 2019 (n=19)

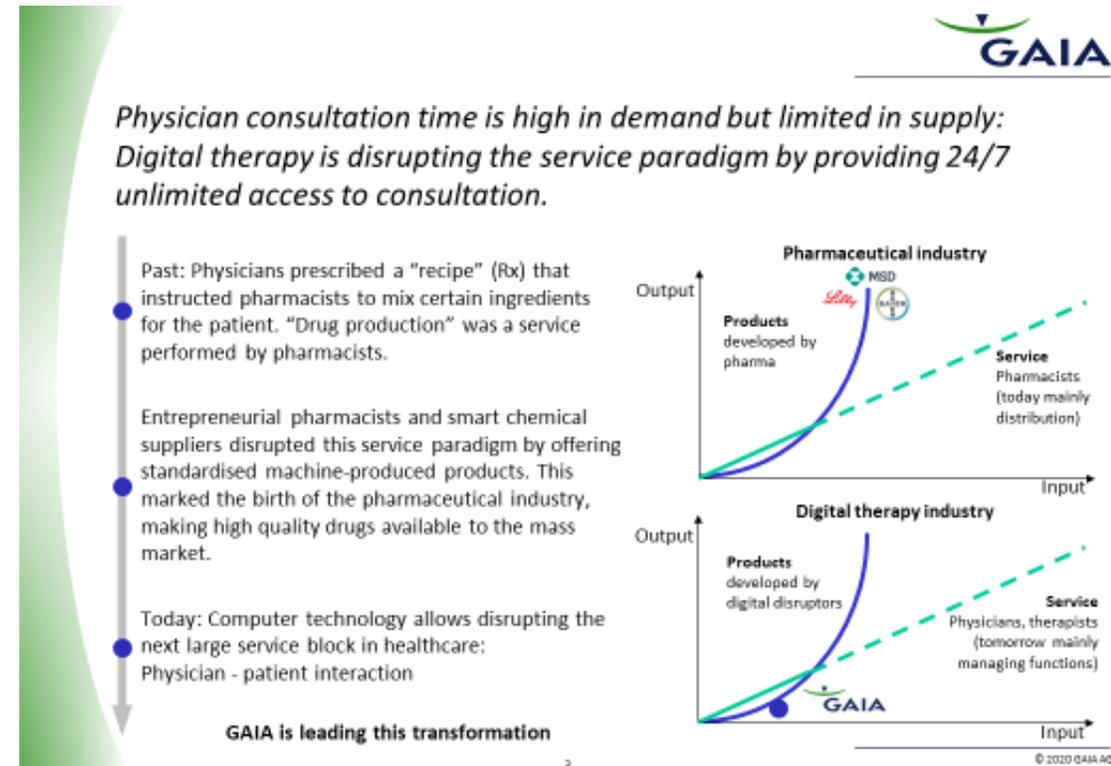


# Digital therapeutics branch out



# Leveraging our existing commercial pharma platform makes DTx an attractive opportunity to diversify the company and drive future growth

- Almost all industries have been transformed or are under transformation by digitalization; healthcare is not an exception
- To meet increased demand from an aging population, health care delivery needs to be transformed to drive efficiency
- Digital therapeutics have the potential to significantly improve the efficiency and quality of multiple disease spaces and in particular within mental health
- Quality of digital therapeutics are improving and payors are starting to finance digital therapies along with traditional treatments
- By entering a partnership with GAIA, Orexo has joined a world leading company in digital therapies
- **Strong synergies with the current US commercial platform with a focus on opioid use disorder and treatment with ZUBSOLV® (bup/nal) and R&D pipeline**



# Technology – In partnership with GAIA offering best in class products

GAIA's Artificial Intelligence (AI) software **broca**® simulates interaction between the patient and an empathetic physician/ therapist – highly individualized, fully automated and scalable

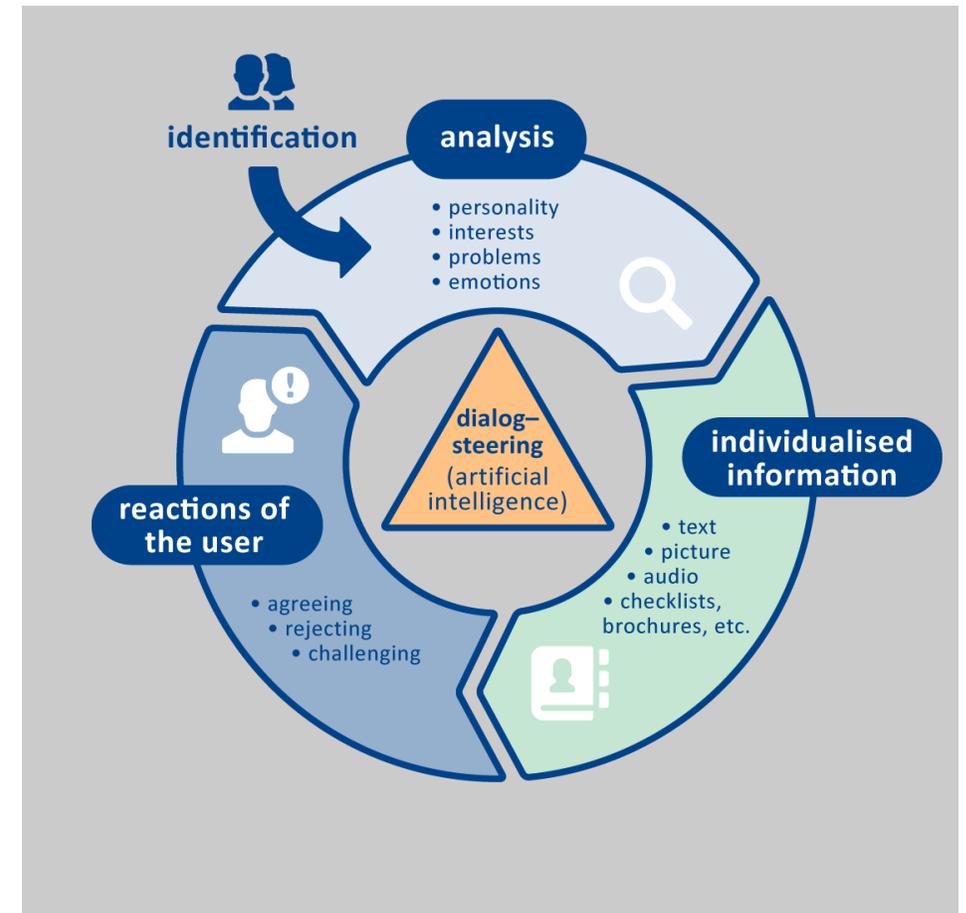
▶ **100% mobile and cloud-based:** for 24/7 usage on any mobile device (PC, tablet, smartphone)

▶ **Complex cognitive-functional interventions** to modulate brain functions and thought processes

▶ **Individualised:** Tailored provision of information and exercises based on continuous identification of the patient's needs and emotional situation

▶ **In-depth collection** of individual **patient data** to trigger further research and patient interaction

▶ **Input from wearables** used to drive further content and user interaction



Technologically supported by the Airbus Group **AIRBUS GROUP**

# Orexo aims to provide digital therapeutics (DTx).....

...with evidence-based therapeutic interventions that improve efficiency in the delivery of healthcare

## Orexo's rigorous approach to DTx:

- Digitized counseling designed on **best practice standards of delivering Cognitive Behavioral Therapy (CBT)**
- Products supported by published **peer reviewed clinical evidence**
- **Available in the privacy of the patient's home**, only a browser and registration key is needed, no apps to download or other steps for the end user
- Self directed engagement level set by the patient, **highly adaptable to their personal situation**
- **Individualized therapy** tailored by an artificial intelligence engine that targets content and exercises based on the patient's responses to questions and content

Digital therapeutics is in its infancy - while the potential is significant, several hurdles need to be addressed before the market takes off

### **Commercialization**

- Optimal pathways to commercialize and scale DTx are still uncharted

### **Pricing**

- Entry barriers are low for offerings without clinical evidence, and thus payors need to establish appropriate assessment criteria to enable price differentiation

### **Reimbursement**

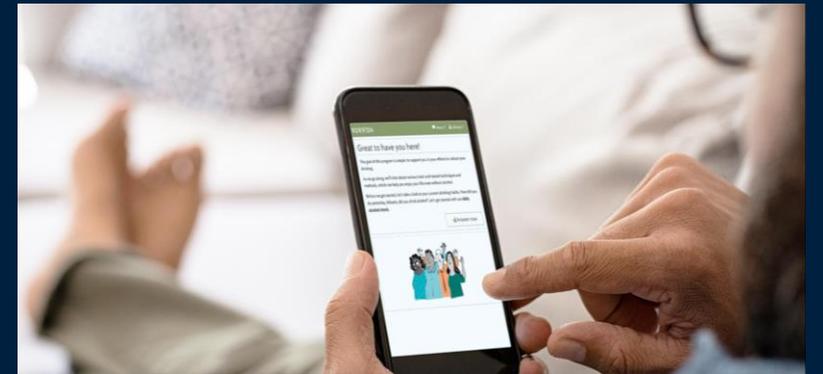
- Many payors still to establish payment and reimbursement processes

### **Disruptive technology**

- While digital therapies have been proven clinically, speed of adoption is still unknown as for any new therapeutic approach

**Orexo will continue to assess the business model, the potential and the investment levels required to capture new opportunities at the appropriate time**

# Digital therapies, clinical evidence & go to market strategy



# Digital therapeutics to become an integral part of the healthcare landscape

SUD and mental health issues are one of the main areas most in need of innovative ways to deliver treatment

Digital therapies										
	Technical Development					Registration	Approved and/or Launched			
							US	EU	RoW	
<b>deprexis</b> ® Depression Partner: GAIA AG	[Progress bar]									
<b>vorvida</b> ® Alcohol misuse, incl. alcohol use disorder Partner: GAIA AG	[Progress bar]									
<b>OXD01</b> Opioid Use Disorder Partner: GAIA AG	[Progress bar]									

# deprexis<sup>®</sup> for treatment of depression

## deprexis<sup>®</sup> short facts

---

<b>Technology</b>	The artificial intelligence (AI) system, broca <sup>®</sup>
<b>Indication</b>	Symptoms of mild to severe depression
<b>Treatment period</b>	3 months
<b>Commercial rights</b>	Orexo owns the US rights
<b>Potential Net Sales five years post launch</b>	USD 150-225 million
<b>Partner</b>	GAIA

- Product advantages include:**
- Based on Cognitive Behavioural Therapy
  - Strong clinical evidence
  - Highly individualized
  - Standalone treatment or as a complement to traditional pharma treatments

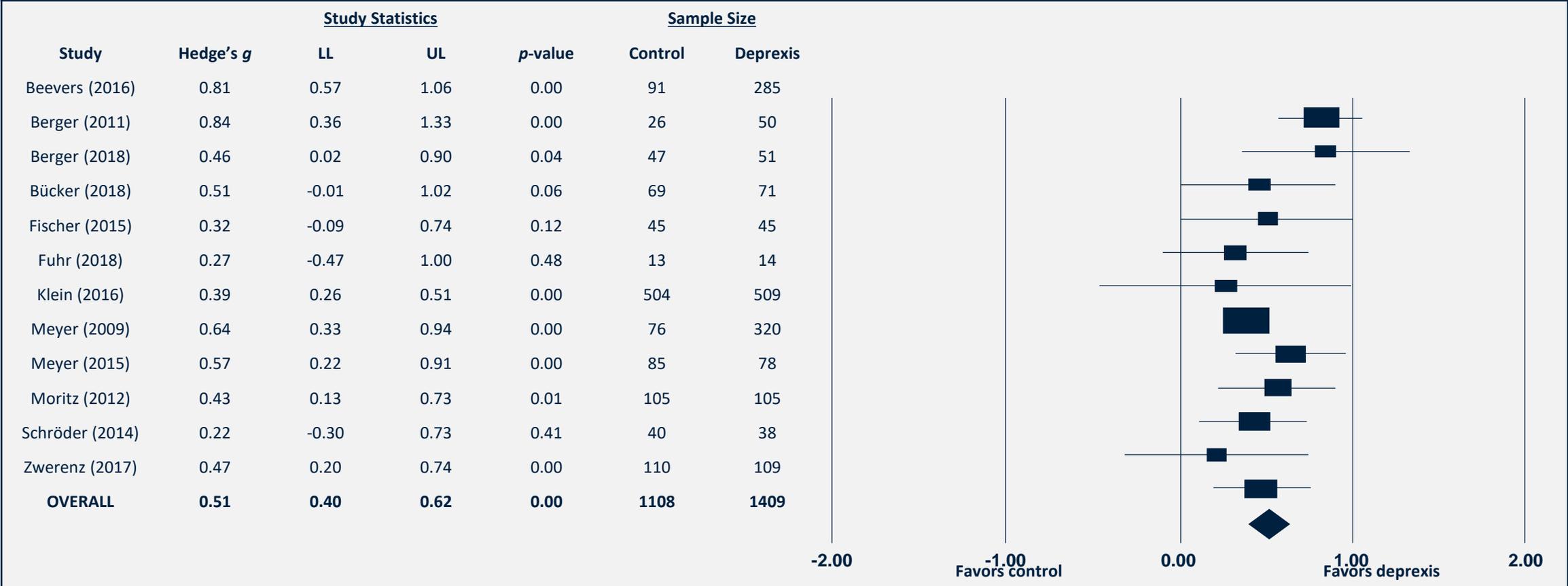
The logo for deprexis, featuring the word "deprexis" in a lowercase, blue, sans-serif font. A registered trademark symbol (®) is located to the upper right of the letter 'i'.

## deprexis<sup>®</sup> has been studied in 11 RCTs including >2800 patients

Study	N	Evidence
Meyer (2009)	396	First RCT to demonstrate the effectiveness of deprexis vs care as usual (CAU)
Berger (2011)	76	Both guided and unguided use of deprexis were shown to be effective vs CAU
Moritz (2012)	210	Replicated results of previous studies across multiple clinical scales
Schröder (2014)	78	deprexis was effective for reducing depressive symptoms and improving quality of life among patients with epilepsy
Fischer (2015)	90	deprexis was effective for reducing depressive symptoms among patients with multiple sclerosis
Meyer (2015)	163	deprexis was effective among patients with severe depression; subgroup analysis revealed that concurrent antidepressant treatment augmented the treatment effect of deprexis
Klein (2016)	1013	EVIDENT trial; the largest trial of an Internet intervention for depression in which deprexis demonstrated effectiveness on both self-rated and clinician-rated scales
Beevers (2017)	376	First deprexis trial in the U.S.; replicated effectiveness results from European trials
Berger (2017)	98	deprexis added to face-to-face psychotherapy demonstrated greater effectiveness than face-to-face psychotherapy alone
Zwerenz (2017)	229	deprexis added to inpatient psychodynamic psychotherapy demonstrated greater effectiveness than inpatient psychodynamic psychotherapy alone
Bücker (2018)	140	deprexis was effective for reducing depressive and gambling-related symptoms

# deprexis<sup>®</sup> demonstrates consistent clinical effect across multiple settings

Meta-analysis of 12 RCTs demonstrated the effectiveness of deprexis for reducing depressive symptoms with a moderate effect size ( $g = 0.51$ , 95% CI: 0.40–0.62) and low heterogeneity ( $I^2 = 26\%$ )

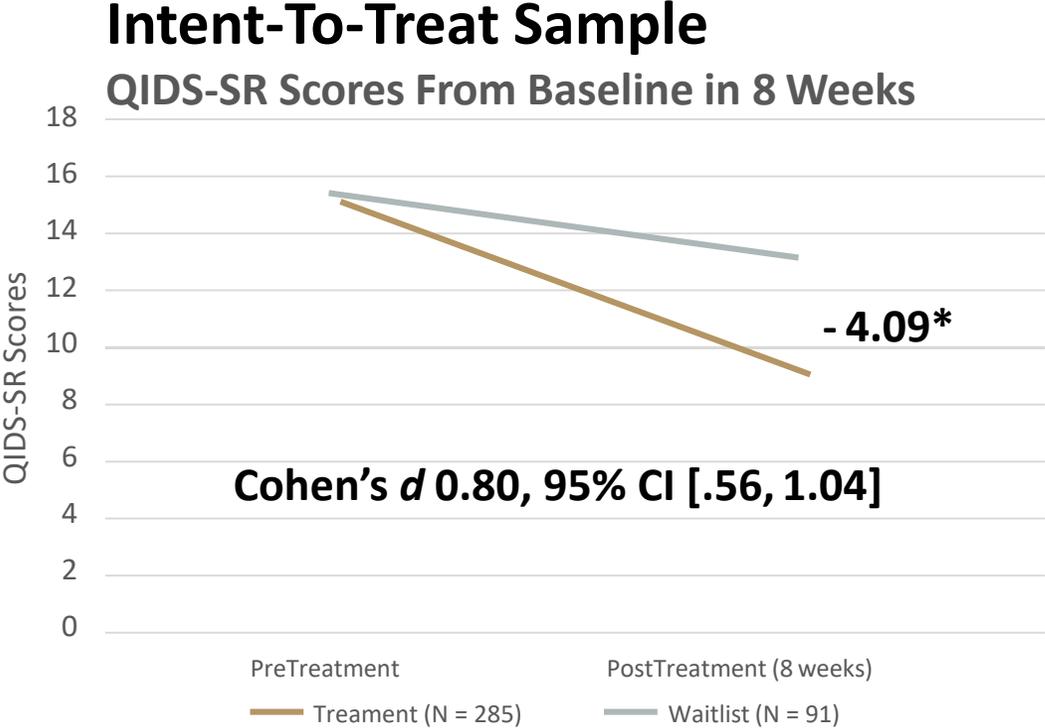


# Beevers (2017): Effectiveness of an internet intervention (deprexis®) for depression in a US adult sample

- A parallel-group, pragmatic randomized controlled trial in treatment-seeking adults with elevated depression
- Randomized to receive an 8-week course of treatment immediately or after an 8-week delay
- Inclusion criteria:
  - Ages between 18 and 55
  - English fluency
  - Reliable access to the Internet (i.e., dialup or broadband access)
  - Presence of moderate levels of depression or greater as measured by the Quick Inventory of Depressive Symptoms (QIDS) Self-Report (score  $\geq 10$ )
  - Treatment stability (no changes in psychotropic medication or psychosocial treatment in the 30 days before study entry)
  - Living in the United States of America
- Exclusion criteria:
  - Presence of psychotic or substance use symptoms
  - A diagnosis of bipolar disorder
  - Suicidal risk

1. Beevers, Effectiveness of an internet intervention (Deprexis) for depression in a united states adult sample: A parallel-group pragmatic randomized controlled trial. *J Consult Clin Psychol.* 2017;85(4):367-380. doi:10.1037/ccp0000171.

# deprexis<sup>®</sup> demonstrated significantly lower self-reported depression symptoms post-treatment



deprexis<sup>®</sup> was also associated with improvements in other facets of depression and anxiety:

- 5.8-point improvement on the HRSD ( $d = 0.68$ ; moderate to large effect)
- Significant improvements in ill temper, well-being, social anxiety, and panic symptoms on IDAS
- 55.75-point improvement on the SDS ( $d = 0.65$ ; moderate to large effect)

\*P value < 0.001

QIDS-SR Scores: Quick Inventory of Depressive Symptoms-Self-Report  
Total scores range from 0 to 27;  $\leq 5$  = no depression, 6 to 10 = mild depression, 11 to 15 = moderate depression, 16 to 20 = severe depression, and  $\geq 21$  = very severe depression

1. Beavers, Effectiveness of an internet intervention (Deprexis) for depression in a united states adult sample: A parallel-group pragmatic randomized controlled trial. J Consult Clin Psychol. 2017;85(4):367-380

# vorvida<sup>®</sup> for treatment of alcohol misuse

## vorvida<sup>®</sup> short facts

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<b>Technology</b>	The artificial intelligence (AI) system, broca <sup>®</sup>
<b>Indication</b>	Heavy alcohol misuse, incl. alcohol use disorder
<b>Treatment period</b>	6 months
<b>Commercial rights</b>	Orexo owns the US rights
<b>Launched</b>	July 2020
<b>Potential Net Sales five years post launch</b>	USD 120-200 million
<b>Partner</b>	GAIA

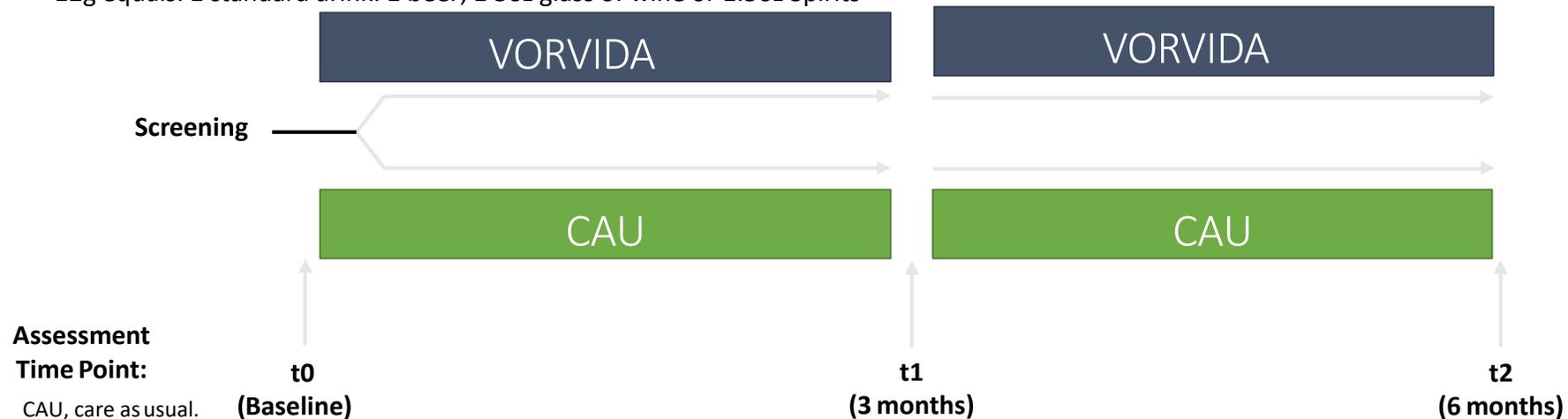
### **Product advantages include:**

- Based on Cognitive Behavioural Therapy
- Strong clinical evidence
- Highly individualized
- Standalone treatment or as a complement to traditional pharma treatments

**VORV!DA<sup>®</sup>**

# Zill study design<sup>1,2</sup>

- Parallel-group pragmatic randomized controlled trial conducted in Germany to test the effectiveness of vorvida<sup>®</sup> in reducing alcohol consumption versus Care As Usual (CAU)
- 608 patients completed the baseline questionnaire and were randomized 1:1 to receive vorvida<sup>®</sup> or CAU
- Inclusion criteria:
  - 18 years of age or older
  - Average consumption of >12/24 g (women/men) of pure alcohol per day and/or AUDIT-C score  $\geq 3$  indicating unhealthy alcohol use
    - 12g equals: 1 standard drink: 1 beer; 1 5oz glass of wine or 1.5oz Spirits



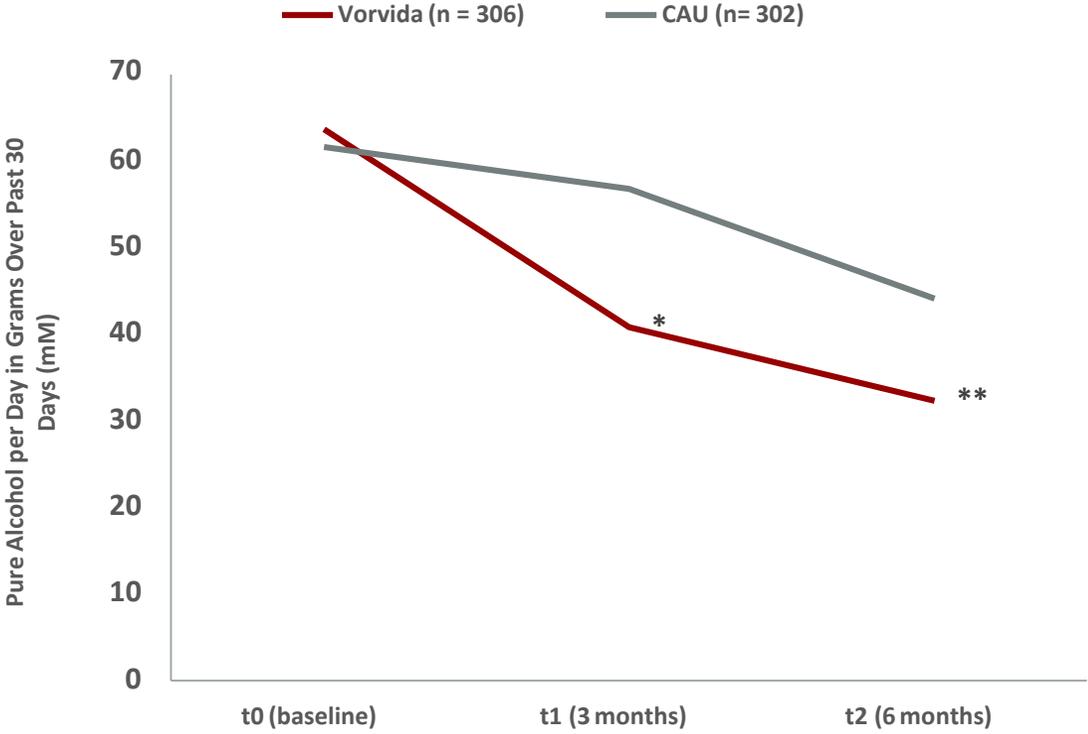
# Zill outcome measures<sup>1,2</sup>

- Primary outcome measure:
  - Average daily consumption of grams of pure alcohol determined by:
    - **Quantity-Frequency-Index (QFI)**: Measures self-reported alcohol consumption during past 30 days
    - **Timeline-Follow-Back (TFB)**: Measures self-reported beverage consumption during the past 7 days
- Secondary outcome measures:
  - Drinking behavior measured through patient-reported binge drinking and drunkenness:
    - **Binge drinking**: On how many days did you drink five or more drinks on one occasion, regardless of whether this was beer, wine/sparkling wine, spirits, or mixed drinks/cocktails containing alcohol?
    - **Drunkenness**: On how many days within the past 30 days did you feel drunk (e.g., unsteady on the feet, blurred vision, unclear speech)?
  - Patient satisfaction with Vorvida

1. Zill JM, et al. *BMC Psychiatry*. 2016; 16:19. 2. Zill JM, et al. *Dtsch Arztebl Int*. 2019; 116: 127-133

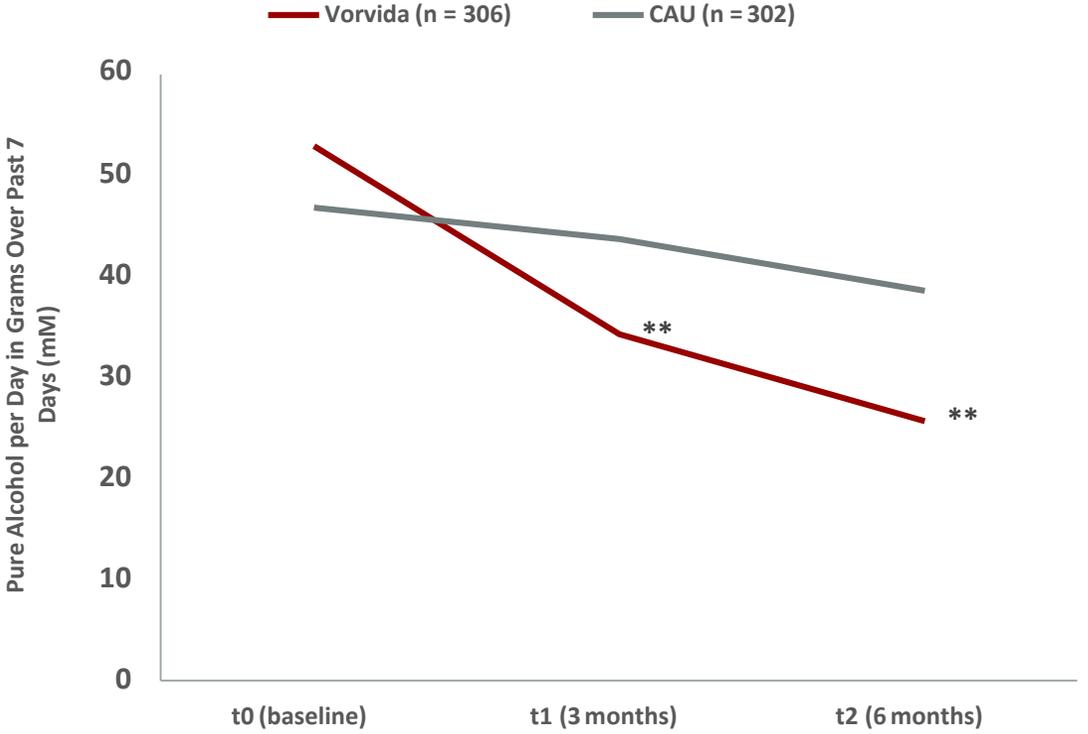
# vorvida<sup>®</sup> was associated with a reduction in average daily alcohol consumption

**Quantity-Frequency-Index (QFI)**



Effect Size (Cohen's d)	0.278	0.327
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**Timeline-Follow-Back (TFB)**

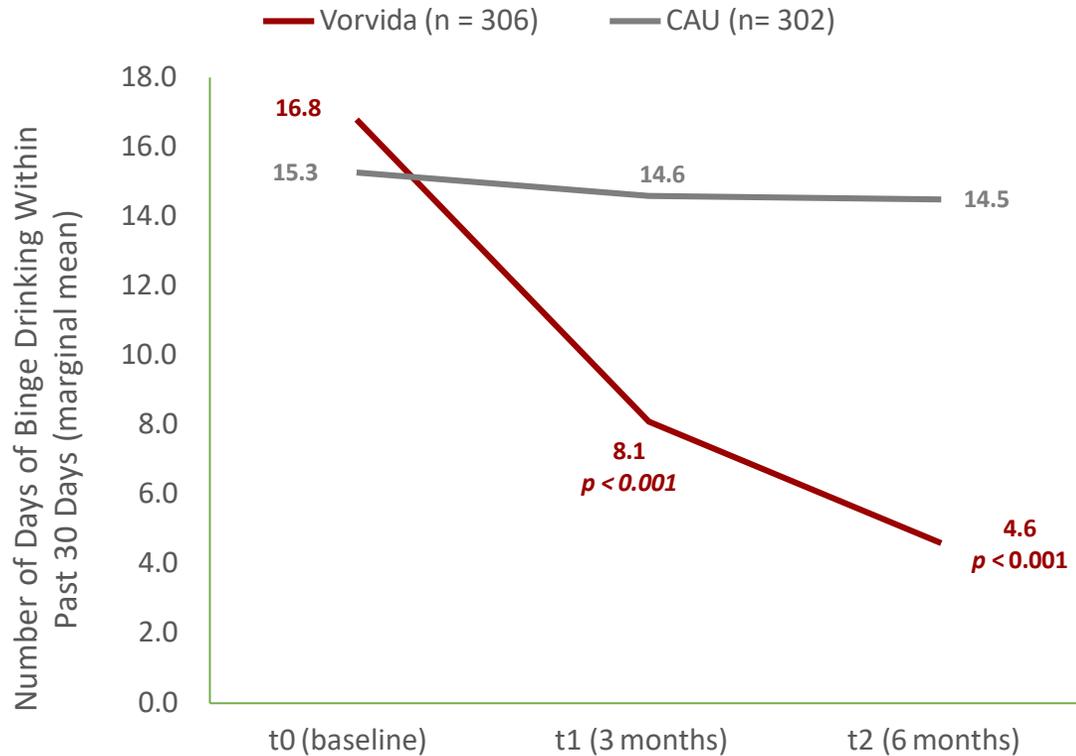


Effect Size (Cohen's d)	0.419	0.540
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\* Vorvida vs CAU  $p = 0.001$ ; \*\* Vorvida vs CAU  $p < 0.001$ ; CAU, care as usual. Zill JM, et al. *Dtsch Arztebl Int.* 2019; 116: 127-133.

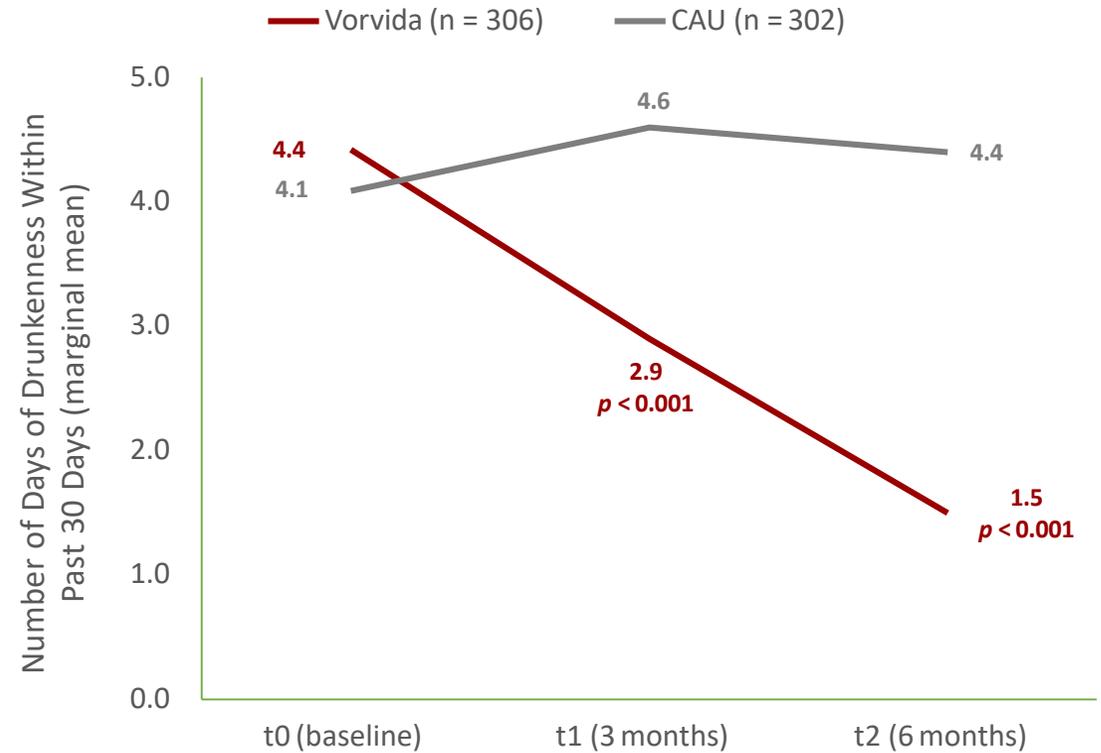
# Secondary Outcome: Change in drinking behaviors

## Binge Drinking



<b>Effect Size (Cohen's d)</b>	<b>0.873</b>	<b>1.400</b>
--------------------------------	--------------	--------------

## Drunkennes



<b>Effect Size (Cohen's d)</b>	<b>0.392</b>	<b>0.742</b>
--------------------------------	--------------	--------------

CAU, care as usual.

P-values denote statistical differences between Vorvida and CAU groups at each timepoint.

Zill JM, et al. *Dtsch Arztebl Int.* 2019; 116: 127-133.

# modia™ for treatment of opioid use disorder

## modia™ short facts

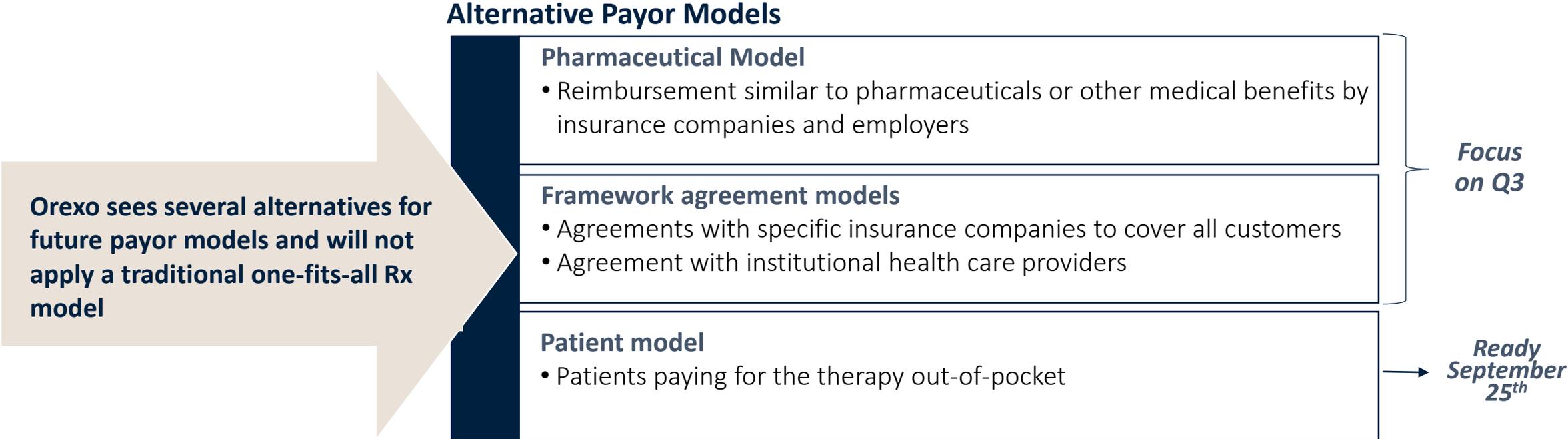
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<b>Technology</b>	The artificial intelligence (AI) system, broca®
<b>Indication</b>	Opioid use disorder
<b>Treatment period</b>	6 months
<b>Commercial rights</b>	Orexo owns the global rights
<b>Launched</b>	Launched together with some selected clients in Q4 2020. Accelerated launched planned in H2 2021
<b>Potential Net Sales five years post launch</b>	> USD 150-225 million
<b>Partner</b>	GAIA

- Product advantages include:**
- Based on Cognitive Behavioural Therapy
  - Highly individualized
  - Complement to traditional pharma treatments



Launch in July 2020 had a focus on payors and the optimal reimbursement model



*Payor models are evolving continuously, but no established standard has emerged*

# Examples of agreements are GoGoMeds and Trinity Health (ND)

Both agreements are stepping stones to larger opportunities within their networks

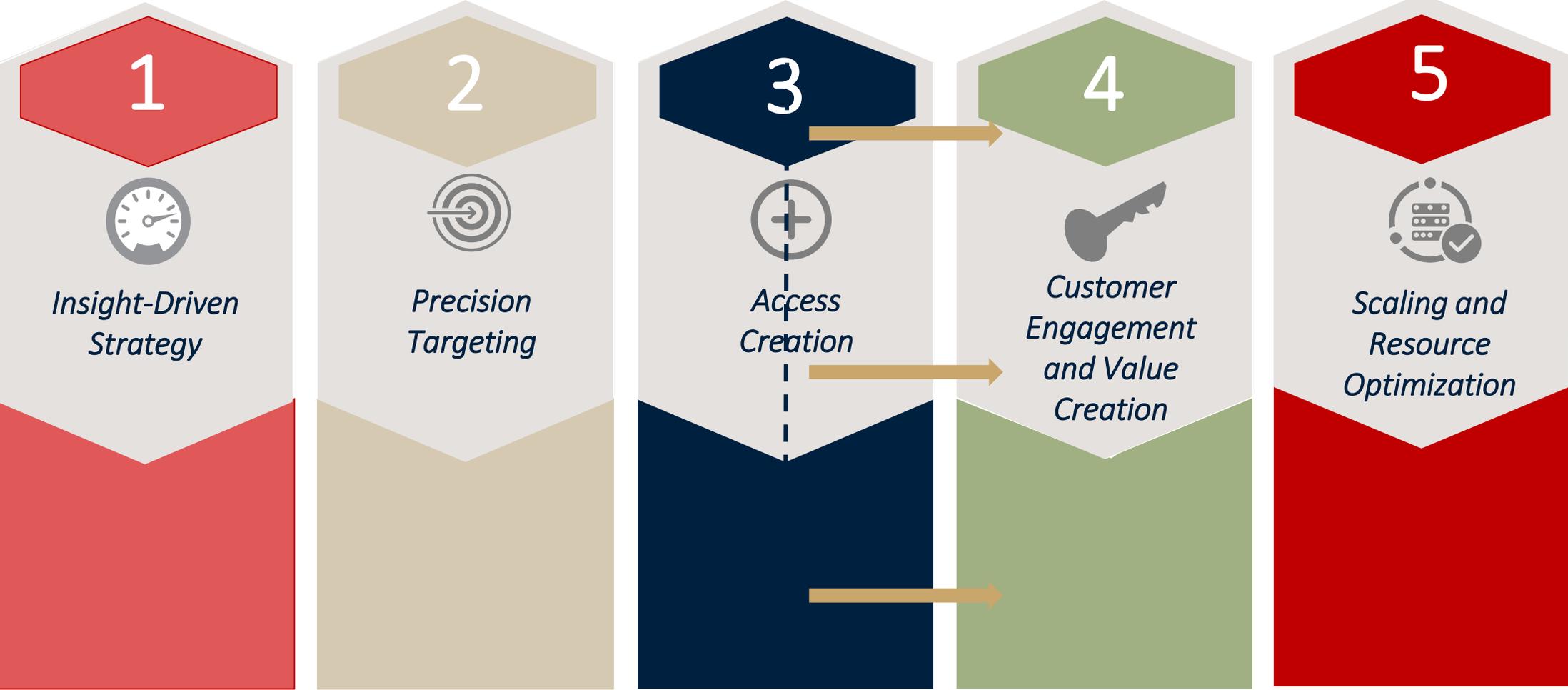


- Partnership to make deprexis® and vorvida® available for adjunctive treatment of depression and management of problematic alcohol misuse respectively
- GoGoMeds is a fully licensed pharmacy and authorized to do business in all 50 states and Washington, D.C.
- GoGoMeds services telemed companies, drug manufacturers, self-insured companies and directly to patients
- The partnership with GoGoMeds will focus on making Orexo's DTx available through addiction services at the state level, including court systems, as well as through the private sector



- Trinity Health is a large network of non-profit healthcare providers. The agreement signed refers to Trinity Health in North Dakota and surrounding areas
- During COVID-19 their co-workers have been in the frontline relentlessly serving patients need in the wake of the pandemic
- To address issues of depression and alcohol abuse among employers (approx. 3000) they will be offered Orexo's scientifically proven digital therapies deprexis® and vorvida®

Our investment and go to market strategy is highly targeted and will scale as access is created in high need markets



# To complement the significant evidence supporting our products, we are developing user experience driven program content

vorvida® website and online purchasing and reimbursement platform is now **LIVE!**

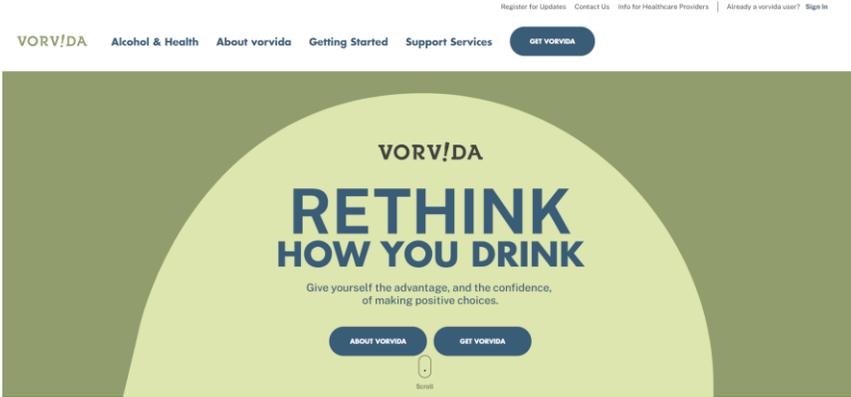
deprexis® “Day 1” site [meetdeprexis.com](https://meetdeprexis.com)



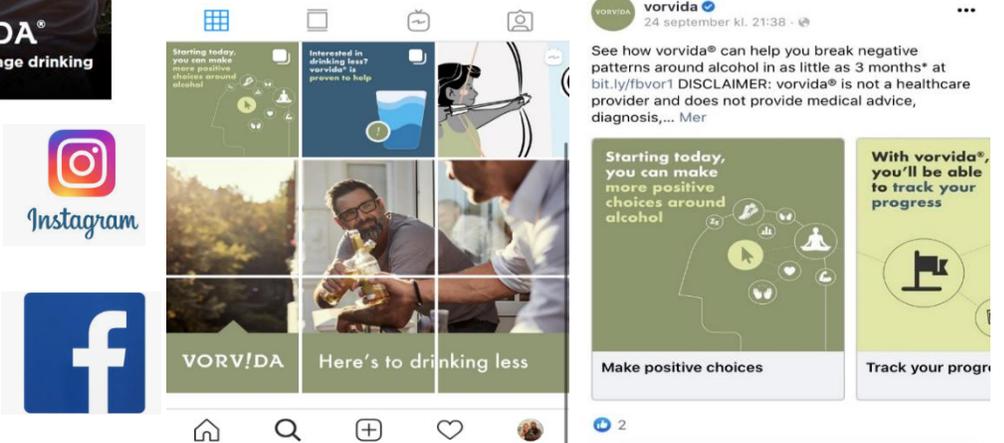
vorvida® marketing materials



vorvida® website [us.vorvida.com](https://us.vorvida.com)



vorvida® Instagram and Facebook



# Patient engagement - key to understanding the disease and optimising our products



## Latest blog posts



**Liv Pennelle**

Liv Pennelle Benefits of



**Jerry**

Jerry 1.) How long have you



**Jessica**

Jessica 1) How long have you



**Bobi Conn**

Bobi Conn I was born in

# Patients suffering from depression or alcohol misuse are vulnerable – Orexo offers a range of services to ensure patient engagement and support

deprexis®

Depression is different for everyone. Deprexis understands that.

Designed with individual needs in mind, Deprexis uses proven techniques to treat mild-to-severe depression with digital therapy.

**What makes Deprexis unique?**

- Can help you overcome your specific challenges
- Employs cognitive behavioral therapy (CBT) to help change negative thought and behavior patterns
- Every interaction is completely confidential, and private information will never be shared

Deprexis can work both as a standalone treatment or as an addition to existing care plans. To better understand your needs, let us know what your main interest in Deprexis is so we can get you the information that's most relevant to you.

[Tell Us More](#)

Interested in learning more? We are here to answer your questions. Contact us at [deprexis.support@orexo.com](mailto:deprexis.support@orexo.com)

Deprexis is a Legal Abbreviation of Physical Address Only  
We are not providing medical advice or information on our website. For more information, please contact your healthcare provider.  
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VORV!DA

**Begin your journey toward better alcohol management today**

When it comes to having a healthier relationship with alcohol, there's no better time to start than now.

See all the support options available to help you access vorvida®—the self-guided, online alcohol management platform.

You deserve a better way to help yourself control your drinking. Check your coverage today and start rethinking how you drink.

[Get access today](#)

vorvida® is not a healthcare provider and does not provide medical advice, diagnosis, or treatment. If you need medical assistance, please contact a healthcare provider directly.

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Ready to start using vorvida®? [Get It Now](#)



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VORV!DA [CONTACT US](#)

**Let's unlock your vorvida® access now**

Help us track down your unique access code. The first step is to input the information below, including the invitation key you received.

First & Last Name

Email Address

Invitation Key

By checking this box, you give permission to Orexo® to use your information on vorvida®.

[SUBMIT](#)

Submitting correct will generate an email with your unique access code.

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VORV!DA

**You have successfully signed up for vorvida®!**

All you need to do is complete a one-time registration using your Product Access Code, which is [Access Code].

[Click here to start using vorvida](#)

vorvida® is not a healthcare provider and does not provide medical advice, diagnosis, or treatment. If you need medical assistance, please contact a healthcare provider directly.

Need help? [Visit vorvida® support services](#)  
Or call 1-833-VORVIDA

deprexis®

You recently received your unique access code to Deprexis. If you need additional assistance, you can contact us at [deprexis.support@orexo.com](mailto:deprexis.support@orexo.com).

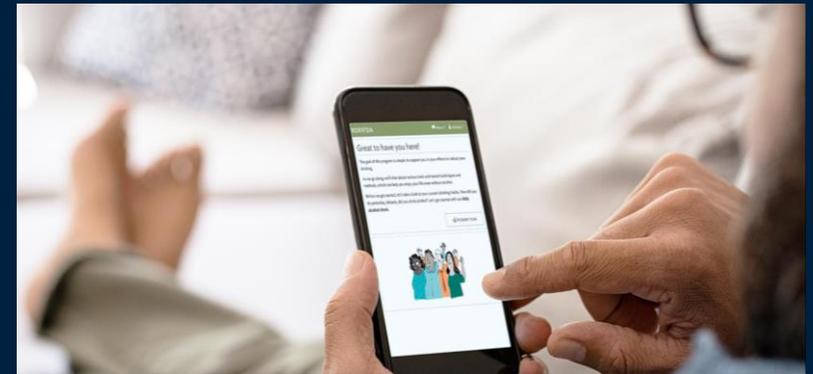
Remember that if you have registered your code, you can access your Deprexis therapy at any time following the link below:

[Access Deprexis](#)

Deprexis is a Legal Abbreviation of Physical Address Only

vorvida® patient services, available from September include specialty hub services for insurance reimbursement, customer service, e-commerce storefronts, and on-going customer relationship management tools. deprexis® equivalents will start going live in Q4

# Financial information and Outlook

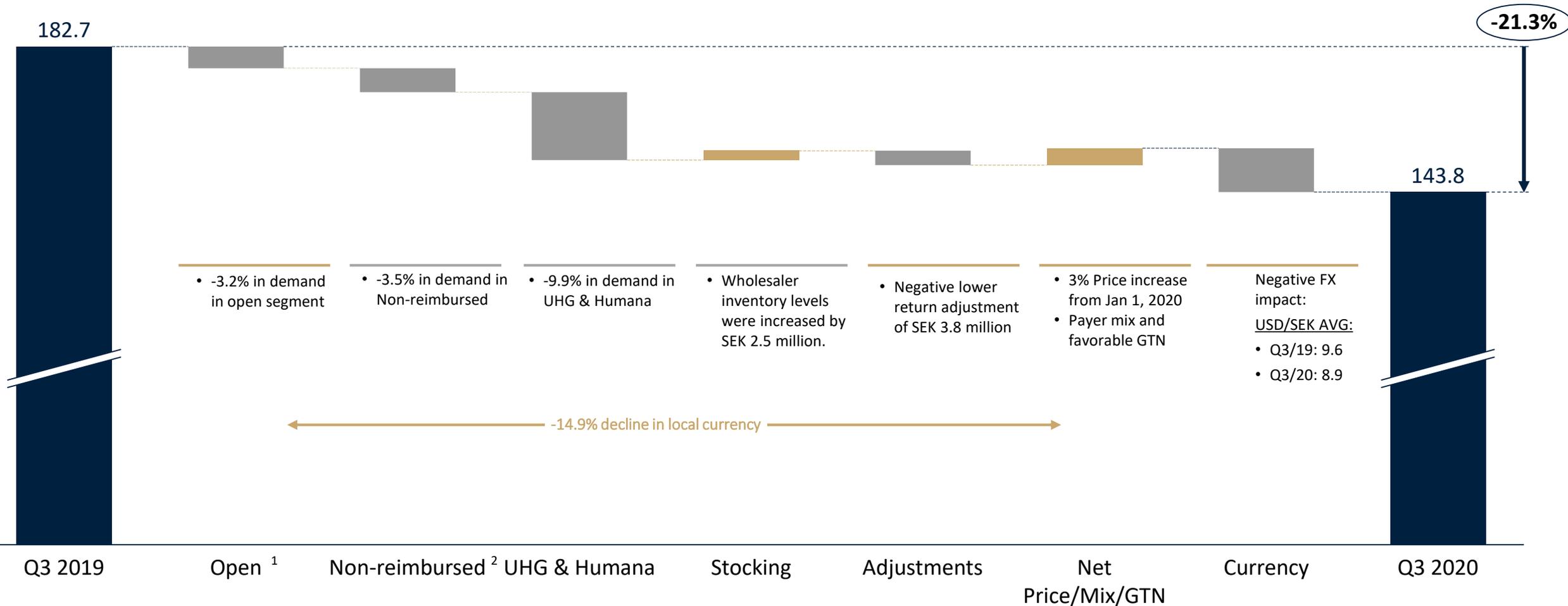


## Q320 - Lower ZUBSOLV<sup>®</sup> net revenues and ceased Abstral<sup>®</sup> royalties in the EU and the US

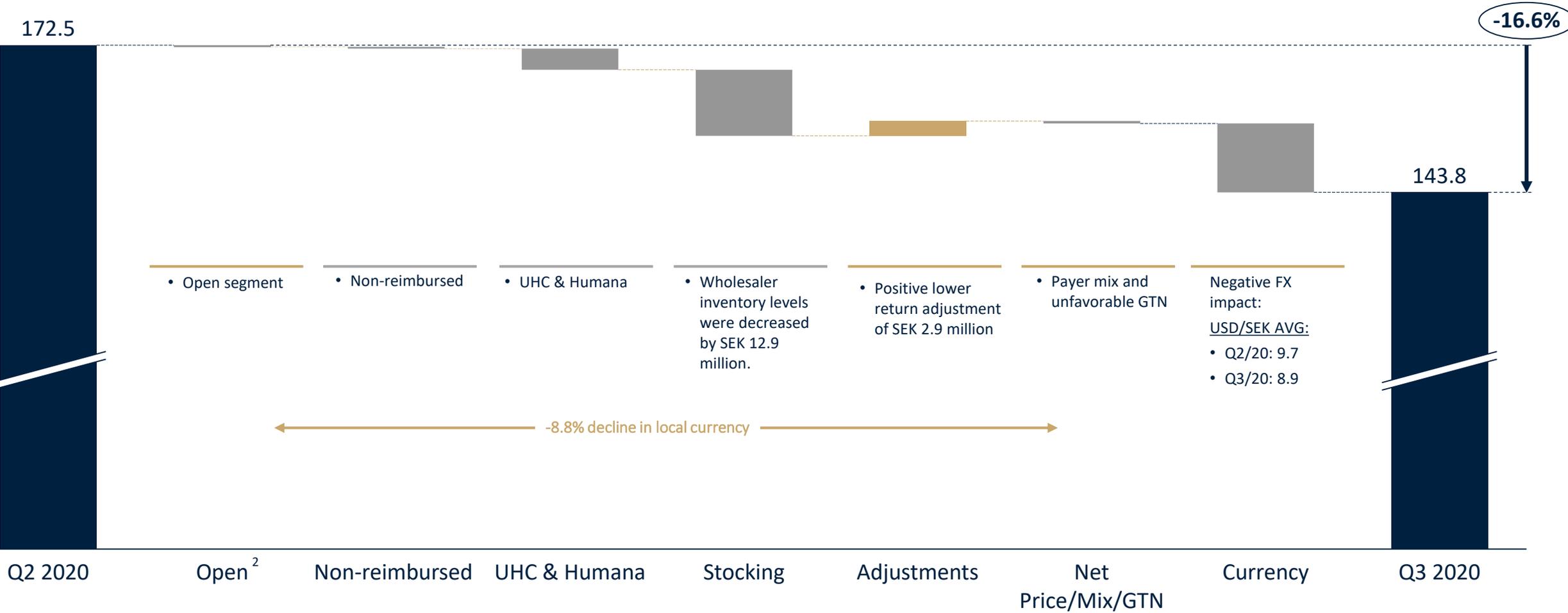
SEK m	Q3 2020	Q3 2019	Jan - Sep 2020	Jan - Sep 2019	Jan - Dec 2019
ZUBSOLV <sup>®</sup> US	143.8	182.7	480.2	528.7	719.2
<b>US Pharma - Total</b>	<b>143.8</b>	<b>182.7</b>	<b>480.2</b>	<b>528.7</b>	<b>719.2</b>
Abstral <sup>®</sup> royalties	2.5	42.4	14.6	66.3	112.6
Edluar <sup>®</sup> royalties	4.0	6.1	9.5	10.2	11.6
ZUBSOLV <sup>®</sup> – ex US	-	-	0.1	0.1	0.1
OX-MPI	-	0.1	-	1.4	1.4
<b>HQ &amp; Pipeline – Total</b>	<b>6.5</b>	<b>48.6</b>	<b>24.2</b>	<b>77.9</b>	<b>125.6</b>
<b>TOTAL</b>	<b>150.3</b>	<b>231.2</b>	<b>504.4</b>	<b>606.7</b>	<b>844.8</b>

- Net revenues for Q320 declined 35.0% due to lower ZUBSOLV<sup>®</sup> US revenues and due to absence of Abstral EU and US royalties, ZUBSOLV<sup>®</sup> US revenues declined 21.3% in Q320 vs Q319 to SEK 143.8 m
- Abstral Q320 decline explained by expired agreement for EU royalties and by discontinued sales since October 31 2019 in the US following loss of patent protection and a slight decline in “rest of world”

# ZUBSOLV<sup>®</sup> US net revenues growth by key drivers, Q3 2020 vs Q3 2019



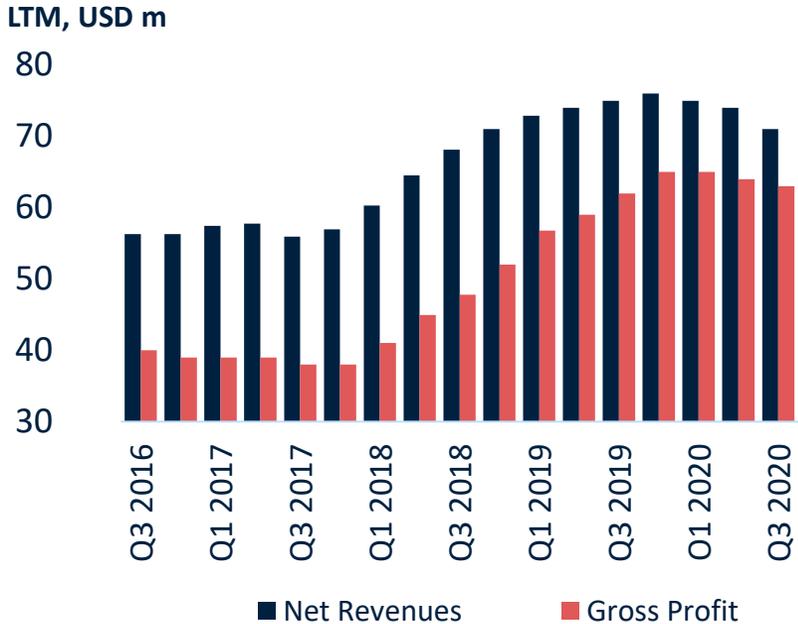
# ZUBSOLV® significant net Sales decline vs. Q2 2020 explained by isolated events and the continued decline in UHC/Humana



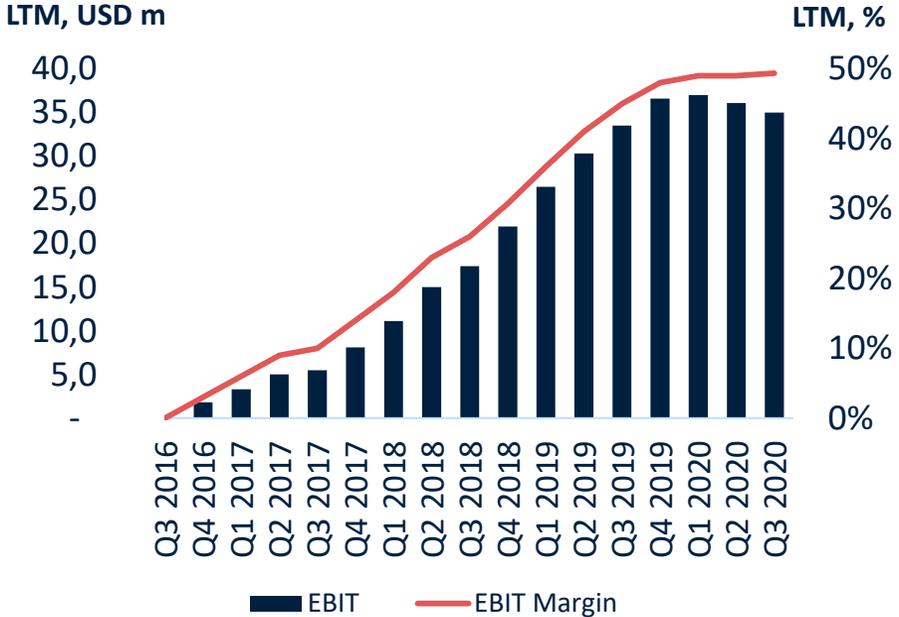
1) Orexo analysis using IMS demand data plus institutional sales  
 2) Excluding Cash segment and formulary changes ( Wellcare, UHG and Humana ), including institutional sales

# Q320 - US Pharma Operating Margin of 50.3%

## Sales and gross profit



## EBIT



- ZUBSOLV® US net sales LTM declined slightly to USD 70.8 m from USD 74.6 m in Q3 2019
- EBIT contribution of USD 35.0 m increasing from USD 33.5 m in Q319 driven by 39% lower COGS
- US Pharma EBIT margin of 49.4% LTM in Q320 increasing from 44.9% in Q319, EBIT margin in Q3 2020 reached 50.3%
- Full year US Pharma EBIT margin is expected to exceed 50% in 2020 and net sales for 2020 will decline compared to 2019.

Note: COGS converted from SEK to USD using monthly average exchange rates for the period.

## Q320 - Increased investments in DTx and OX124

SEK m	Q3 2020	Q3 2019	Jan - Sep 2020	Jan - Sep 2019	Jan - Dec 2019
Net revenues	150.3	231.2	504.4	606.7	844.8
Cost of goods sold (COGS)	-14.5	-25.9	-54.3	-82.5	-105.6
<b>Gross Profit</b>	<b>135.8</b>	<b>205.3</b>	<b>450.1</b>	<b>524.2</b>	<b>739.2</b>
Selling expenses	-83.3	-45.0	-207.7	-141.3	-191.9
Administrative expenses	-26.4	-18.1	-83.0	-112.7	-139.6
Research & development expenses	-50.3	-41.6	-165.9	-122.7	-181.3
Other operating income & expenses	-5.4	5.3	-2.5	12.3	4.8
<b>Operating Costs</b>	<b>-165.4</b>	<b>-99.4</b>	<b>-459.0</b>	<b>-364.5</b>	<b>-508.0</b>
<b>EBIT</b>	<b>-29.6</b>	<b>105.9</b>	<b>-8.9</b>	<b>159.7</b>	<b>231.2</b>
Net financial items	-10.8	8.7	10.9	19.2	-3.3
<b>EBT</b>	<b>-40.5</b>	<b>114.6</b>	<b>2.0</b>	<b>178.9</b>	<b>227.9</b>
Tax	-44.4	-3.0	-36.8	1.3	-8.8
<b>Net profit/loss</b>	<b>-84.9</b>	<b>111.7</b>	<b>-34.8</b>	<b>180.3</b>	<b>219.1</b>
<b>EBITDA</b>	<b>-12.2</b>	<b>114.1</b>	<b>17.9</b>	<b>186.3</b>	<b>272.1</b>

### Q320 comments:

- **COGS** for the quarter 44.0% lower vs prior year driven by manufacturing efficiency program and lower sales volumes
- **Operating Costs** above prior year due to:
  - Selling expenses increased explained by costs related to preparations to launch vorvida® and deprexis® in the US of SEK 53.5 m ( - ) partly offset by lower selling expenses in US Pharma of SEK 29.3 m (44.6).
  - Administrative expenses higher, explained by higher legal costs in the US related to the FDA subpoena partly offset by lower costs for the long-term incentive programs following negative share price development and fair value adjustment versus prior quarter.
  - R&D expenses higher due to the clinical trial of OX125 and final development of OX124 towards registration in 2021 partly offset by lower internal costs.
  - Other operating income contributed negatively due to exchange-rate losses derived from revaluations of parent company balance sheet items in foreign currency, predominantly in USD
- **Net Financial items** had negative impact mainly explained by negative unrealized exchange-rate impact of SEK 18.5 m derived from the parent company's foreign currency bank accounts mainly in USD.
- **Tax** negatively impacted by decreased parent company tax assets of SEK 43.5 m.

# Q320 - Financial performance per business segment

US Pharma SEK m	Q3 2020	Q3 2019	Jan - Sep 2020	Jan - Sep 2019	Jan - Dec 2019
Net revenues	143.8	182.7	480.2	528.7	719.2
Cost of goods sold (COGS)	-12.6	-25.9	-51.9	-82.5	-105.6
<b>Gross Profit</b>	<b>131.2</b>	<b>156.7</b>	<b>428.3</b>	<b>446.2</b>	<b>613.6</b>
<b>Operating expenses</b>	<b>-58.8</b>	<b>-65.9</b>	<b>-191.2</b>	<b>-203.5</b>	<b>-266.5</b>
<b>EBIT</b>	<b>72.4</b>	<b>90.9</b>	<b>237.2</b>	<b>242.6</b>	<b>347.1</b>

- **US Pharma** Continued strong EBIT margin of 50.3 percent due to reduced cost of goods and OPEX. Lower Zubolv revenues explains lower EBIT reduction.

Digital Therapeutics SEK m	Q3 2020	Q3 2019	Jan - Sep 2020	Jan - Sep 2019	Jan - Dec 2019
Net revenues	-	-	-	-	-
Cost of goods sold (COGS)	-1.8	-	-2.5	-	-
<b>Gross Profit</b>	<b>-1.8</b>	<b>-</b>	<b>-2.5</b>	<b>-</b>	<b>-</b>
<b>Operating expenses</b>	<b>-60.6</b>	<b>-</b>	<b>-107.6</b>	<b>-</b>	<b>-0.9</b>
<b>EBIT</b>	<b>-62.5</b>	<b>-</b>	<b>-110.1</b>	<b>-</b>	<b>-0.9</b>

- **Digital Therapeutics** Negative EBIT solely explained by investments in launch preparations of deprexis® and vorvida®.

HQ & Pipeline SEK m	Q3 2020	Q3 2019	Jan - Sep 2020	Jan - Sep 2019	Jan - Dec 2019
Net revenues	6.5	48.6	24.2	78.0	125.6
Cost of goods sold (COGS)	-	-	-	-	-
<b>Gross Profit</b>	<b>6.5</b>	<b>48.6</b>	<b>24.2</b>	<b>78.0</b>	<b>125.6</b>
<b>Operating expenses</b>	<b>-46.0</b>	<b>-33.6</b>	<b>-160.2</b>	<b>-160.9</b>	<b>-240.6</b>
<b>EBIT</b>	<b>-39.5</b>	<b>15.0</b>	<b>-136.0</b>	<b>-82.9</b>	<b>-115.0</b>

- **HQ and Pipeline** Investments in OX124 and OX124 explain increased OPEX. The expected reduction in royalties from Abstral EU and US, explains negative EBIT contribution for the quarter.

# Q320 - Strong financial position after investment in DTx

Cash position of SEK 593.3 m and a positive net cash position of SEK 369.1 m

Cash flow SEK m	Q3 2020	Q3 2019	Jan - Sep 2020	Jan - Sep 2019	Jan - Dec 2019
Cash flow from operating activities	-12.9	135.7	28.0	230.7	287.0
Investment activities	-50.2	-14.5	-160.1	-15.3	-22.4
Financing activities	-4.2	-36.9	-106.9	-49.4	-53.7
Cash flow (excl exchange rate differences)	-67.4	84.3	-239.1	166.0	210.8
<b>Liquid funds</b>	<b>593.3</b>	<b>812.9</b>	<b>593.3</b>	<b>812.9</b>	<b>816.8</b>
Net cash position	369.1	523.7	369.1	523.7	527.2

- Negative cash flow from operating activities for the period Q320
  - SEK 12.9 m negative contribution from operating activities.
- Investment activities had a negative impact of SEK 50.2 m primarily due to payment of a non-refundable milestone to GAIA AG for vorvida®, purchase of equipment for the development organization and investments in DTx enterprise platform.
  - Financing activities had a negative impact of SEK 4.2 m due to negative IFRS 16 impact
  - SEK 16.5 m negative impact on cash position due to weaker USD in September 2020
- Strong cash position at the end of Q320 with SEK 593.3 m despite large investments

# ZUBSOLV®- Several possible triggers for growth in 2020 and beyond

## **Continued improvement in ZUBSOLV® market access**

- ESI & Cigna make Zubsolv only preferred branded product on their national formularies from January 1, 2021. Confirming anticipated loss of access for leading branded competitor
- Louisiana Medicaid added ZUBSOLV® to preferred formulary increasing “public access” from 35% to 37% (effective July 1)
- All market access positions from 2020 maintained for 2021

## **Orexo Sales Force now back to office-based selling after 3 months, but access to prescribers remain a challenge**

- Currently entire team returning to office-based selling activities while continuing to use virtual selling as certain offices have entry restrictions based on policy & changing COVID environment
- Fluctuating restrictions and local outbreaks of Covid-19 will remain a challenge until the pandemic is under control, but Orexo continue to develop new selling methods to overcome barriers

## Q320 - Financial outlook 2020

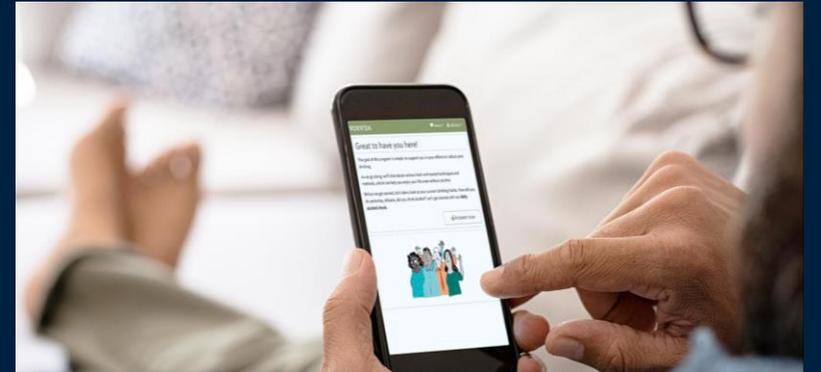
### Previous guidance

- › The buprenorphine/naloxone market will continue to show a double-digit growth
- › ZUBSOLV® net sales are expected to be in line with 2019. The open businesses will grow, whilst the previously highly rebated exclusive segments, including cash, will decrease.
- › Due to increased R&D investments, establishment of DTx business and accelerated DTx US launch OPEX will reach a level of SEK 750-800 m
- › Due to a decrease in Abstral® royalties of approx. SEK 85 m, as an effect of expiration of IP protection in the US and the EU, and increased OPEX, EBITDA will decrease
- › US Pharma EBIT margin will be in the range of 45-50 percent

### Revised guidance

- › No change
- › **ZUBSOLV® US net sales in Q4 2020 is expected to increase over Q3 2020, but net sales for 2020 will decline compared to 2019**
- › Due to increased R&D investments, establishment of DTx business and accelerated DTx US launch **OPEX will reach a level of SEK 675-725 m**
- › No change
- › US Pharma EBIT margin will **exceed 50 percent**

# Ownership



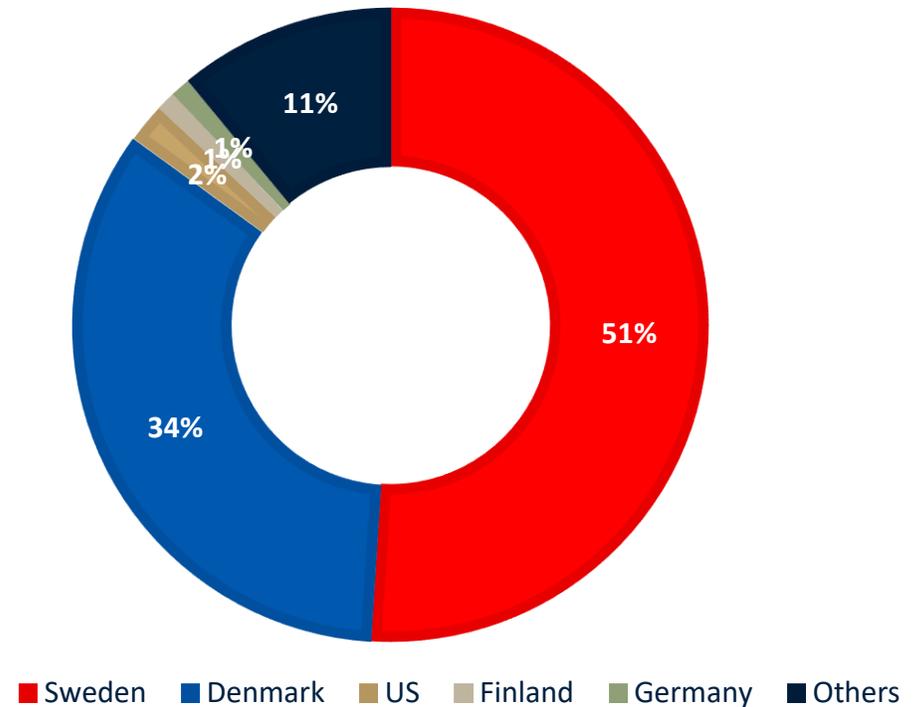
# Ownership distribution as of August 31, 2020

#	Owners	ORX	Capital	Votes
1	Novo Holdings A/S	9 643 184	27,8%	27,8%
2	HealthCap	3 556 334	10,2%	10,2%
3	Arbejdsmarkedets Tillægspension (ATP)	2 040 633	5,9%	5,9%
4	Avanza Pension	1 629 644	4,7%	4,7%
5	Brohuvudet/ Anders Walldov	1 580 000	4,6%	4,6%
6	Nordnet Pension Insurance	545 248	1,6%	1,6%
7	Lancelot Asset Management AB	500 000	1,4%	1,4%
8	Orexo AB	415 766	1,2%	1,2%
9	Evli Funds	344 599	1,0%	1,0%
10	Thomas Lundqvist	264 567	0,8%	0,8%
11	SEB Funds	246 931	0,7%	0,7%
12	Huber, Reuss & Kollegen Vermögensverwaltung	246 000	0,7%	0,7%
13	Swedbank Insurance	237 931	0,7%	0,7%
14	Kungl. Vetenskapsakademien (KVA)	220 000	0,6%	0,6%
15	Stiftelsen Vin & Sprithistoriska Muséet	200 000	0,6%	0,6%
Total top 15		21 670 837	62,4%	62,4%
Others		13 039 802	37,6%	37,6%
Total		34 710 639	100,0%	100,0%

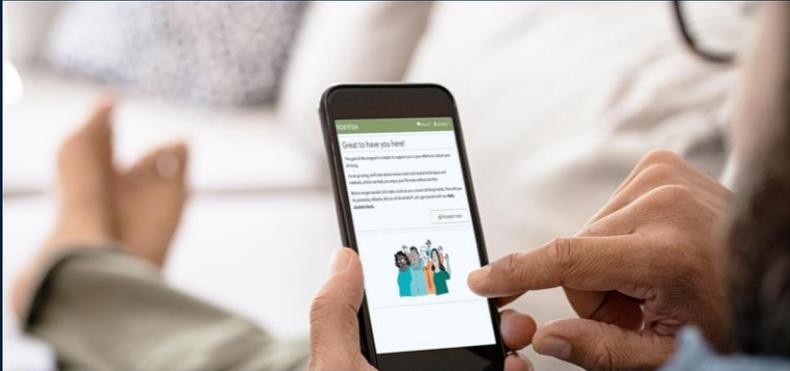
# Key share details

Orexo share	
Listing	Nasdaq Stockholm, Sweden Main list, mid cap
Numbers of share	34 710 639
Market capitalization, aug. 31 2020	SEK 1 752 million
ISIN code	SE0000736415
Ticker code	ORX
Orexo ADR	
Trading platform	OTC Market, tier ORXQX
Deposit bank	Citibank N.A.
ISIN code	US68616W1027
Ticker code	ORXOY
Ratio	1:1

Ownership distribution per country



# Legal



# Two legal processes emerged during July and August 2020

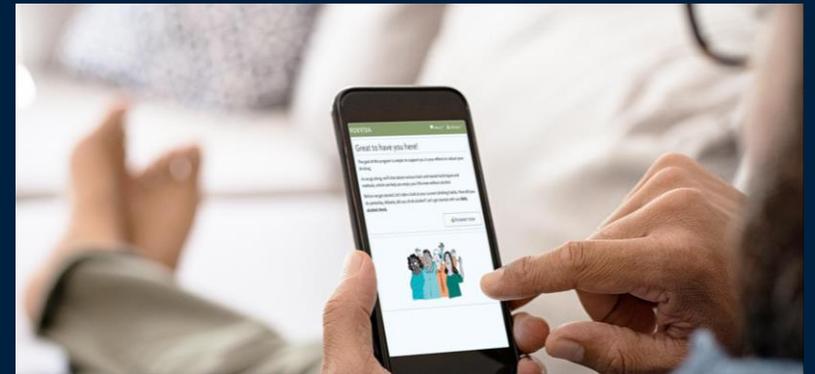
## Subpoena

- On July 14, 2020 Orexo US received subpoenas to provide US Authorities with certain information with regards to ZUBSOLV® and other buprenorphine products. Orexo has no knowledge of the background to the requests.
- No further information or requests have been received from the authorities after July 14<sup>th</sup> 2020.

## Paragraph IV notice from Sun Pharmaceutical Industries Ltd (“Sun”)

- The Notice Letter advises Orexo of Sun’s filing of an Abbreviated New Drug Application (“ANDA”) with the FDA seeking approval of generic versions of ZUBSOLV® before the expiration of Orexo’s patents listed in the Orange Book. Orexo currently has five patents listed in the Orange Book with expiration dates ranging from December 2027 to September 2032.
- Orexo has initiated a process to review the notice letter together with US legal counsel in preparation of legal actions to defend the exclusivity for ZUBSOLV®.
- Orexo has previously successfully defended the ZUBSOLV® patents and is well prepared for a new process with Sun.

# Sustainability



# Our sustainability agenda

Since 2018, Orexo supports the ten principles of the UN Global Compact in the areas of:

 Human Rights	 Labor
 Environment	 Anti-Corruption

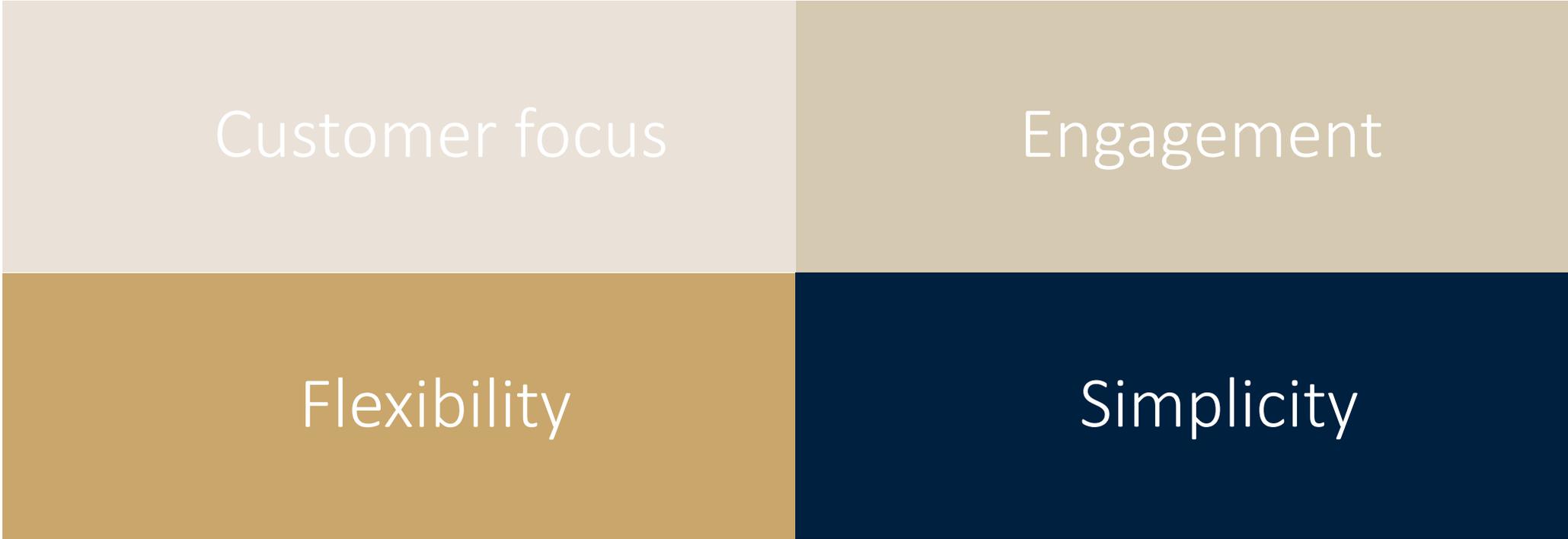


**3** GOOD HEALTH AND WELL-BEING

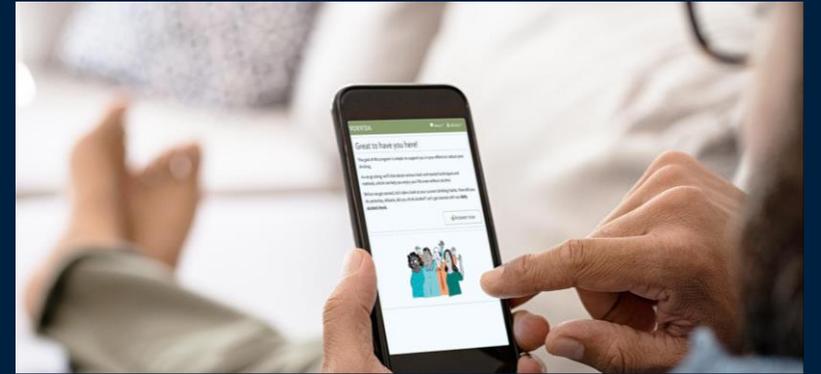


At Orexo, the sustainability work contributes to several of the UN’s Sustainable Development Goals (SDGs) with a primary focus on SDG3 “Good health and well-being”. This target is of especial importance as it is closely aligned with Orexo’s ambition to strengthen the prevention and treatment of substance abuse.

# Our core values



# Summary



## Summary - Strong value drivers for long-term growth

<b>Future value drivers</b>	<ul style="list-style-type: none"><li>➤ Product portfolio addressing large and growing markets</li></ul>	<ul style="list-style-type: none"><li>➤ Strong cash conversion to support growth</li></ul>
<ul style="list-style-type: none"><li>➤ Leveraging our US commercial excellence</li></ul>	<ul style="list-style-type: none"><li>➤ Expanding pipeline targeting unmet medical needs</li></ul>	<ul style="list-style-type: none"><li>➤ Entering digital therapeutics, a new evidence-based frontier in patient care</li></ul>

# Thank You

IR Contact: Lena Wange, IR & Communications Director, [ir@orexo.com](mailto:ir@orexo.com). For more information please visit [www.orexo.com](http://www.orexo.com).

You can also follow Orexo at Twitter [@orexoabpubl](https://twitter.com/orexoabpubl), LinkedIn and YouTube   