# orexo

Develops and commercializes improved pharmaceuticals and digital therapies in the growing space of substance use disorders and mental health



### **ABG Sundal Collier Healthcare Seminar**

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# Overview & strategic agenda







## Orexo develops and commercializes pharmaceuticals and digital therapies

- Addresses unmet needs within the growing space of substance use disorders (SUD) and mental health
- Broad product portfolio and development pipeline of traditional pharma products and digital therapies
- Developed **four commercial products** with worldwide approval
- Direct presence in the US, with a fully-owned commercial platform
- Strategic focus on **portfolio expansion** through development and licensing/M&A
- Profitable company with strong financial position to support future growth
- Top two largest shareholders<sup>1</sup>: **Novo Holdings** (27.7%) and **HealthCap** (10.2%)



Corporate Headquarters (Uppsala, Sweden) Corporate functions and Development



US Headquarters
(Morristown, New Jersey)
Commercial subsidiary incl.
fully owned field force

**Net revenues** SEK, LTM<sup>2</sup> Q120

EBITDA SEK, LTM Q120 Cash position SEK, Q120

846 m

299<sub>m</sub>

861<sub>m</sub>

<sup>&</sup>lt;sup>2</sup> Last Twelve Months



<sup>&</sup>lt;sup>1</sup> As of April 30, 2020

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

**Orexo objectives** 

### Broaden...

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

### Maintain

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

### Establish

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

### Launch

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



# **Product portfolio**







### Product portfolio including 3 upcoming US launches in 2020

Product	Zubsolv®	deprexis®	vorvida®	Abstral®  Abstral  Ab	Edluar®
Indication	Opioid use disorder (OUD)	Symptoms of mild to severe depression	Alcohol misuse incl. alcohol use disorder (AUD)	Breakthrough cancer pain	Sleeping disorder
Key market	US	US	US	Asia, the Middle East, Australia	US
Net sales/ royalty 2019	SEK 719 m	US launch in summer 2020	US launch in summer 2020	SEK 113 m <sup>1</sup>	SEK 12 m
Potential annual net sales		USD >150 – 225 m	USD 120 – 200 m		
Partner	mundipharma	GAIA	GAIA	KYOWA KIRIN	<b>Mylan</b>

Development project OXD01 (OUD) expected ready for (US launch in Q4 2020)— potential annual net sales USD 150 – 225 m

<sup>&</sup>lt;sup>1</sup> Effective January 1, 2020, Orexo will not receive any royalty for sales in the EU and the US as the patents on corresponding markets expired in 2019



# COVID-19 has significantly raised awareness and demand for digital therapies, particularly in certain conditions such as SUD and mental health issues

#### March 2020

Patients are flooding to virtual clinics and online medical councils

Companies are boosting their digital strategy on the back of the coronavirus

Digital and delivery services thrive on the coronavirus outbreak

#### Patienter strömmar till nätläkarna efter corona



As Italy's Hospitals Overwhelmed by Coronavirus, Top Health Official Says 'Worst Is Yet Come' for US

"We will see more cases and things will get worse than they are right now."

Coronavirus' biggest winners: From Netflix to fitness bike maker Peloton

The COVID-19 virus has battered global markets and threatens to worsen the global economic slowdown. But not everyone is losing money even as the fast-spreading epidemic wipes out trillions from global markets.

#### Stay home, stay connected

Shares in teleconferencing startup Zoom Video have soared nearly 50% since February as investors bet on a rise in remote workplaces amid fears of the coronavirus spreading further. The company has already added more active users this year — 2.22 million — than it did in all of 2019, Bernstein Research analysts said.

April 2020

US outbreak surges,

Isolation consequences appearing as jobless claims skyrocket

Burden in psychiatric conditions intensifies

Emergency policy issued to address demand

Contains Nonbinding Recommendations

Enforcement Policy for Digital Health Devices For Treating Psychiatric Disorders During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

Guidance for Industry and Food and Drug Administration Staff

April 2020

DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services 7500 Security Boulevard, Mail Stop S2-14-26 Baltimore, Maryland 21244-1850



CMCS Informational Bulletin

**DATE:** April 2, 2020

FROM: Calder Lynch, Deputy Administrator and Director

SUBJECT: Rural Health Care and Medicaid Telehealth Flexibilities, and Guidance Regarding Section 1009 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (Pub. L. 115-271), entitled Medicaid Substance Use Disorder Treatment via Telehealth



With 3 digital therapies, Orexo is well positioned to take a leading role addressing unmet needs within SUD and mental health issues......

### deprexis®

deprexis<sup>®</sup> is a fully automated digital therapy to help patients manage their symptoms of mild to severe depression and is one of the most researched such in the world



## One of the most researched digital therapies in the world

- Effectiveness in managing the symptoms of depression has proven in 13 randomized clinical trials (RCTs) including more than 2,500 patients
- In a 2017 study conducted by Beevers et al. in the US, the patient group utilizing deprexis® (n=285) were 12 times more likely to experience a +50 percent improvement to symptoms when compared to the control group (n=91)

WHO: "Depression is a leading cause of disability around the world and contributes greatly to the global burden of mental health illness"

......offering digital therapies with scientifically proven efficacy enabling patients to receive help while maintaining social distancing

#### vorvida®

A fully automated digital therapy scientifically proven to reduce trouble-some drinking patterns in adults suffering from alcohol misuse incl. alcohol use disorder (AUD)



# OXD01 "Digitizing" counselling at scale to offer with Zubsolv<sup>®</sup>, a full medication assisted therapy (MAT) solution for so many opioid use disorder (OUD) patients in need 150-225 MUSD net sales potential in the US

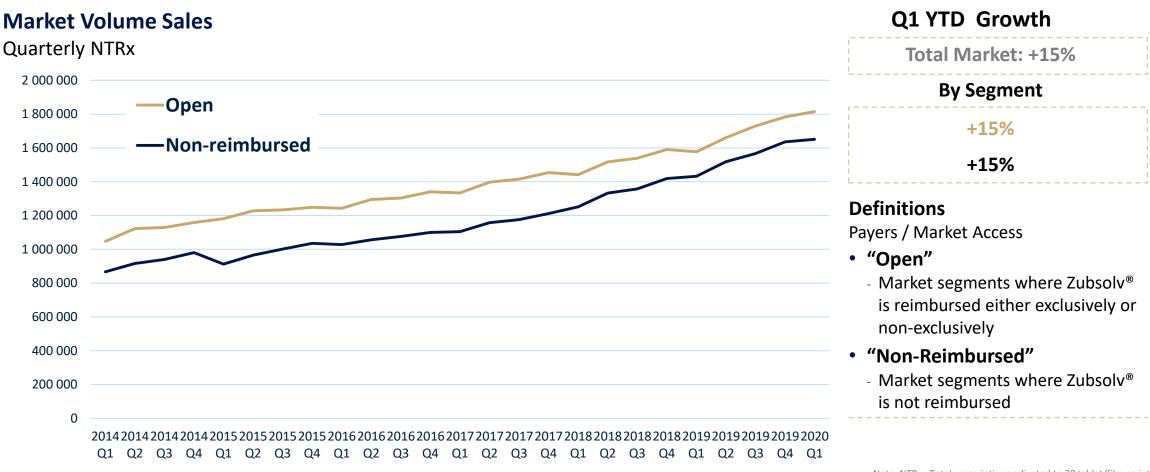


### Zubsolv® has grown YoY despite increasing competition





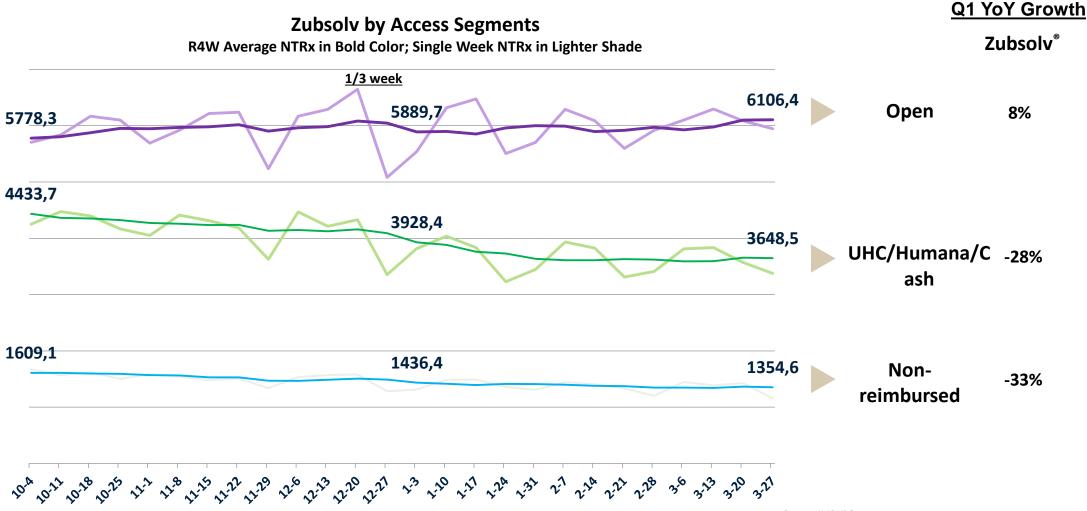
# Market growth of 15% YTD vs prior year is the strongest growth rate since Zubsolv® launch



orexo

Note: NTRx =Total prescriptions adjusted to 30 tablet/film scripts Source: IOVIA XPO

# Open segment becomes an important growth driver, when the decline in UHC and Humana diminish in 2020



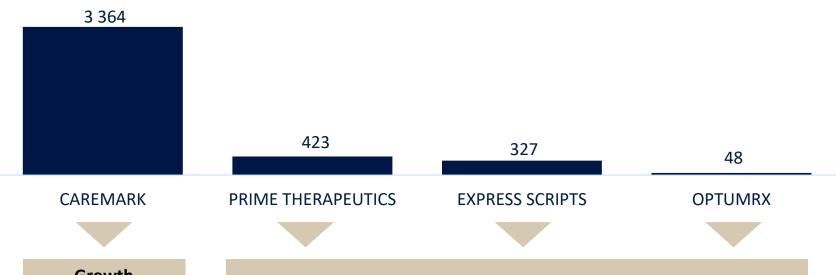


Source: IMS XPO

# Zubsolv® growth in open business explained by unrestricted access to all large national commercial PBMs

Prescription incremental growth to major national PBMs

**Zubsolv NTRx YoY Q1** 



Growth
accelerated by
removal of
Suboxone® Film
from formulary in
Oct. 2019

Zubsolv® with unrestricted access together with branded Suboxone Film and Generics

Total increase of 4,162 NTRx YoY

Opportunity to continue to grow business and to translate successes to other payers as well

Additional removal of Suboxone® Film from formularies likely to drive additional growth

Growth in commercial formularies expected to increase after Q1 due to declining deductibles



## Several possible triggers for Zubsolv® growth in 2020 and beyond



### **Continued improved market access**

- ...Orexo continues to aggressively pursue expanding market access in Medicare and Medicaid
- ...Largest branded competitor likely to lose reimbursement over time

# Competition from "the preferred" authorized generic of Suboxone® Film will end

- ...Supply of authorized generic has ceased from the manufacturer (Indivior) and product will disappear when inventories are depleted
- ...Market share of authorized generic has dropped from >50% to 9% last week

# Orexo will be the only pharmaceutical company promoting a Buprenorphine product to most prescribers

- ...Sublocade® and other depot formulations primarily promoted to larger institutions
- ...Orexo has an expanding pipeline addressing the most urgent concerns in the industry



# **Development projects**







### 3 convincing development assets addressing critical unmet needs

#### OX124 – opioid overdose

A powerful rescue medication, designed to reverse opioid overdoses, including those from synthetic opioids like fentanyl



#### OX125 – opioid overdose

A rescue medication to reverse opioid overdoses, developed for situations where very long-lasting effect is required



#### OX338 – non-opioid pain

A non-opioid pain killer with opioid-level efficacy for short-term pain (up to 5 days), but without the risk of addiction

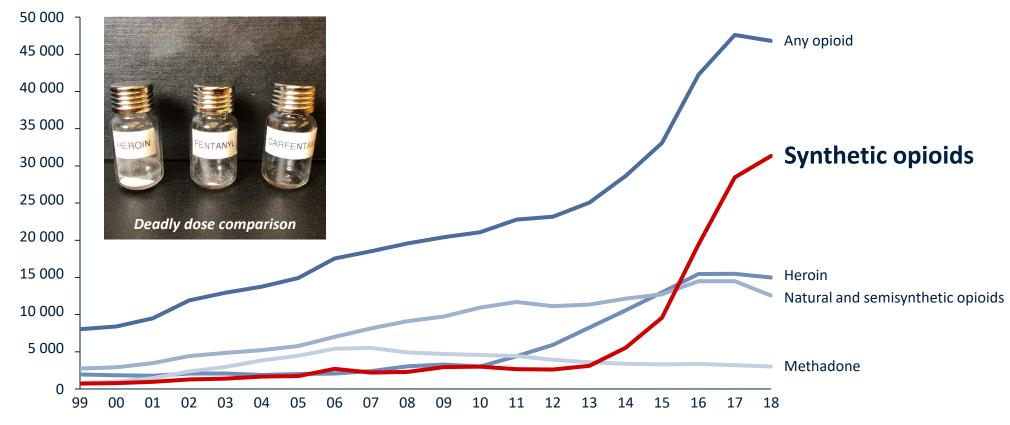




# OX124 - While overall deaths from opioid overdoses showed a slight decline in 2018, deaths from synthetic opioids continue to rise

### Deaths from opioid overdose



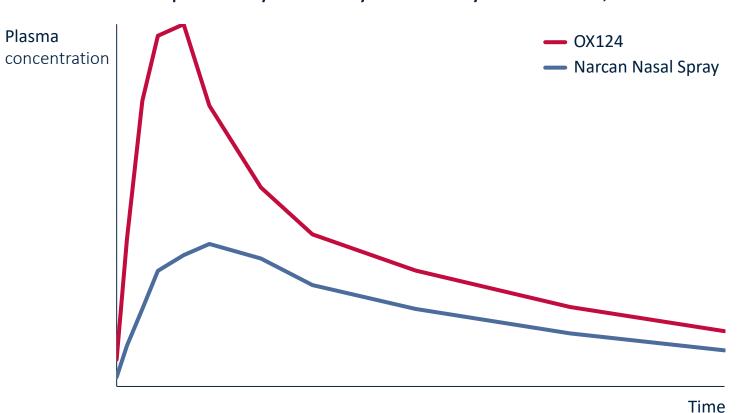




## OX124 - We have shown better PK profile than Narcan® Nasal Spray

### 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)



## Financials & outlook







# Strong financial position enabling continued investments in future growth opportunities

Group net revenues LTM	Growth	
SEK 846 m  Of which 85% from Zubsolv® US	3%	
Of Which 65% from Zubsolv 5 03	Zubsolv® US 11%	
Group EBITDA LTM	Growth	
SEK 299 m	133%	
US Pharma EBIT (Zubsolv® US) LTM	Growth	
SEK 355 m	50%	
Cash position	Positive net cash position	
SEK 861 m	SEK 612 m	



## Limited impact from the COVID-19 disease currently<sup>1</sup>

### Development

### Supply

### Sales

### Finance

OX125 — First clinical phase 1 study initated according to plan in May

**OX124** - Orexo works with several partners in different geographies, so far no impact, but delays cannot be excluded

#### **Digital Therapies –**

Accelerated launch of the digital therapies due to FDA's emergency policy for digital health targeting psychiatric disorders

**Zubsolv®** - Manufacturing of Zubsolv® is solely done in the US by companies whose businesses are classified as "Life sustainable business".

Significant inventory exist to secure uninterrupted supply.

Zubsolv®, vorvida®, deprexis® - Sales calls have been redirected to digital channels

Zubsolv® is well established and experience from unstaffed sales territories shows no impact short term on existing sales from no sales calls

Continued travel restrictions may impact access to physicians and market growth

Orexo has SEK 861 m in cash and a profitable operations from Zubsolv®

Short term we expect limited to no impact on financial results

No financing risk exist in the company



### 2020 a year with a steady news flow expected

Q2 Q3 Q4 > Launch of deprexis® > FDA clearance of vorvida® Initiation of OX124 pivotal trial > Launch of vorvida® > Patent for nasal spray technology > Potential launch of OXD01 > FDA decision on fast track designation of OX124 > OX125 exploratory study OXMPI phase I results > OXD01 technical development finished



## THANK YOU!