orexo

Develops improved pharmaceuticals and digital therapies addressing unmet needs within the growing space of substance use disorders and mental health



Life Science Investor Forum, Sep. 17 2020

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

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Overview & strategic agenda









Addresses unmet needs within the growing space of substance use disorders (SUD) and mental health

- Direct presence in the **US**, with a **fully-owned commercial** platform
- Developed **four commercial products** with worldwide approval
- 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 shareholders¹: **Novo Holdings** (27.8%) 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 EBITDA USD, LTM² Q220 USD, LTM Q220

Cash position USD, Q220

85 m

² Last Twelve Months, conversion rate USD/SEK 9.7



¹ As of August 31, 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

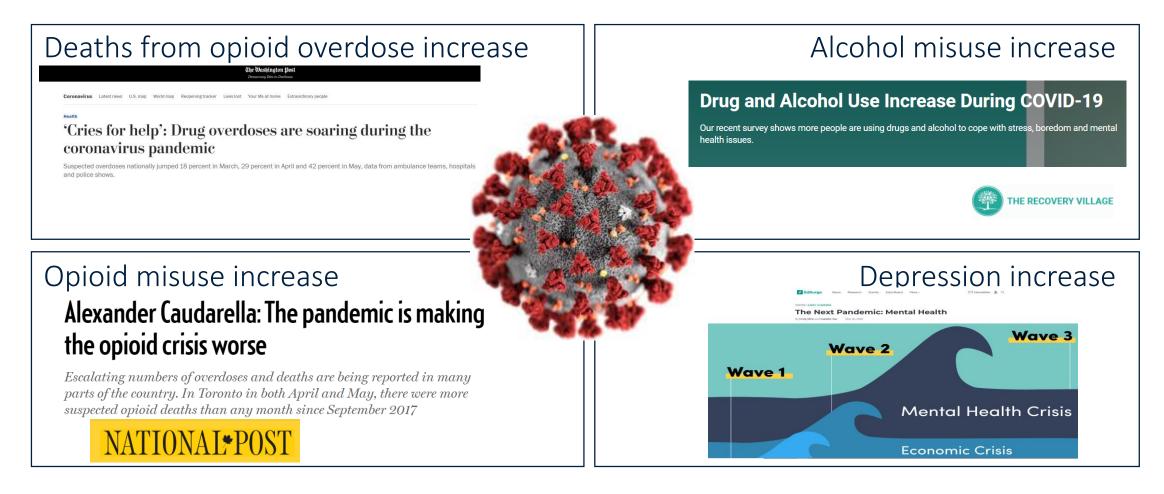
..a new revenue generating business area within Digital Therapeutics (DTx) and launch first new product in 2020

Launch

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



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





Pharmaceuticals

- Pipeline
- ZUBSOLV®
- OX124









Pharmaceuticals

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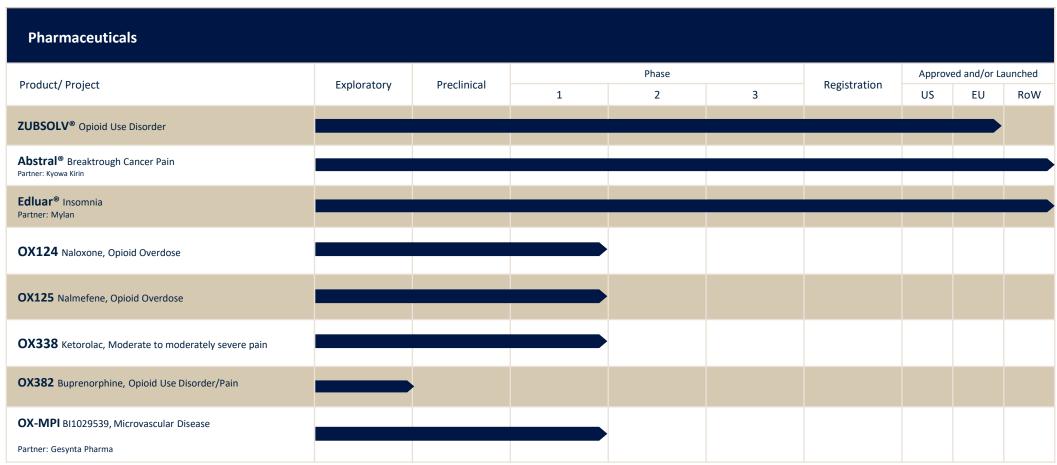








Pharmaceutical products and pipeline addressing large markets with significant patient needs





Pharmaceuticals

Pipeline



OX124



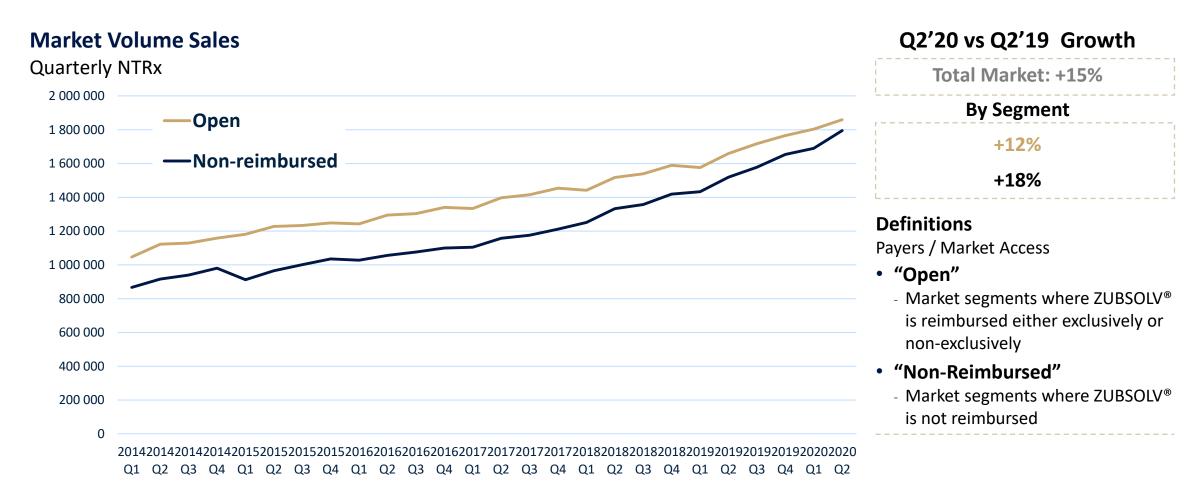






ZUBSOLV®- 2020 market volume has strongest growth rate since launch

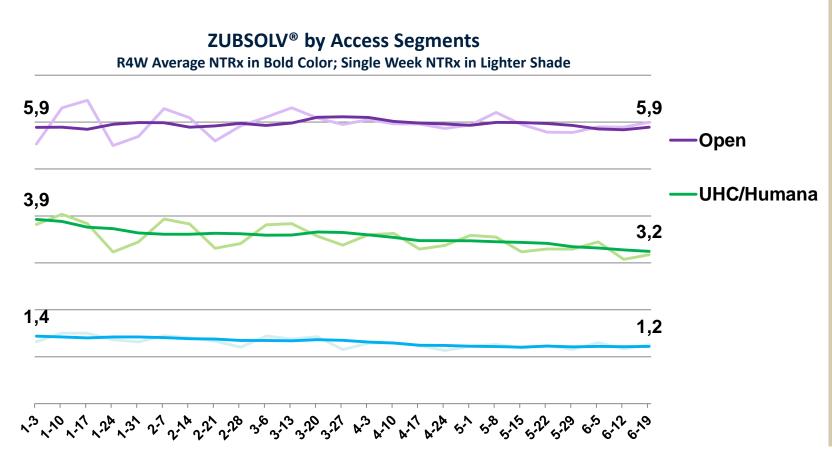
Market growth solely driven by the "Public Segment"





ZUBSOLV®- Mild negative impact from Covid-19 lockdown

Open segment stable, UHC/Humana segment declining due to increased competition from Gx



ZUBSOLV® net sales up in Q2 vs Q1 despite a mild volume decline due to Covid-19 challenges during lockdown

- ... ZUBSOLV® grew net sales 5% though volume declined 4% QoQ
- ...Commercial segment showed a volume decline during Q2 due primarily to Covid related unemployment spike
- ...Main driver of market growth was Medicaid where ZUBSOLV® has limited access though ZUBSOLV® grew volume where it has "open" access in Medicaid



Source: IMS XPC

NTRx =Total prescriptions adjusted to 30 tablet/film scripts

Open: Market segments where ZUBSOLV® is reimbursed either exclusively or non-exclusively

Non-Reimbursed: Market segments where ZUBSOLV® is not reimbursed

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



Continued improvement in ZUBSOLV® market access

- ...Louisiana Medicaid added ZUBSOLV® to preferred formulary increasing "public access" from 35% to 37% (effective July 1)
- ...Orexo continues to pursue expanding market access in Medicare and Medicaid while maintaining 98% commercial market access leadership position
- ...Generic Film availability pressuring access status of largest branded competitor

Orexo Sales Force now back to office-based selling after 3 months

- ...Orexo stopped all office selling March 16th and the selling model was converted entirely to virtual setting (audio, video and e-mail) as necessitated by prescriber
- ...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



Pharmaceuticals

- Pipeline
- ZUBSOLV®
- OX124









OX124 a new stronger rescue medication

Expected launch in H1 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)

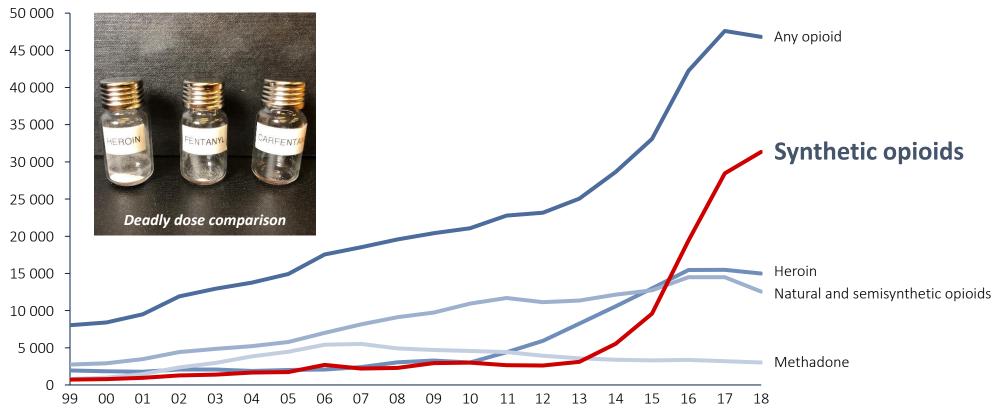




OX124 - While overall deaths from opioid overdoses showed a slight decline in 2018, deaths from synthetic opioids continue to rise

Deaths from opioid overdose

By type of opioid, United States

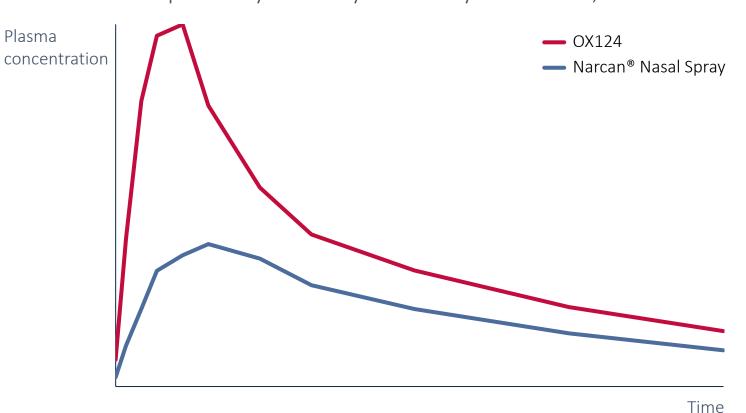


Source: Hedegaard H, et al. NCHS DATA Brief 356 - Drug Overdose Deaths in the United States, 1999-2018. NCHS, National Vital Statistics System, Mortality. Jan 2020.



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

Faster, stronger and longer-acting vs Narcan[®] 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)



Digital therapies

VORV!DA®

deprexís®









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									
							Approved and/or Launched		
	Technical Development					Registration	US	EU	RoW
deprexis® Depression									
Partner: GAIA AG									
vorvida® Alcohol misuse, incl. alcohol use disorder									
Partner: GAIA AG									
OXD01 Opioid Use Disorder									
Partner: GAIA AG									



OXD01 at a glance

The unmet need

Access to consistent high-quality counselling is a growing bottleneck in treatment of OUD. Medical assisted treatment should be complemented with psychosocial support

Our aim

Develop the first digital therapy showing significant sustainable positive outcome on patients' treatment of OUD and make it available globally

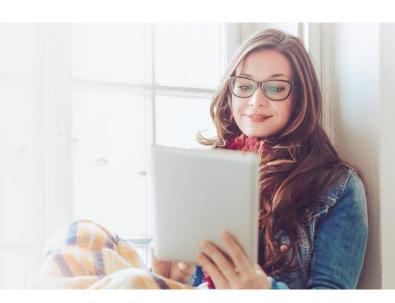
Launch

Will be accelerated and tested in collaboration with selected customers in Q4 2020, in preparation for a broad launch in Q2, 2021, a year ahead of the original plan.



150-225

MUSD net sales potential in the US





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

deprexis®

deprexis® 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



VORV!DA®

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





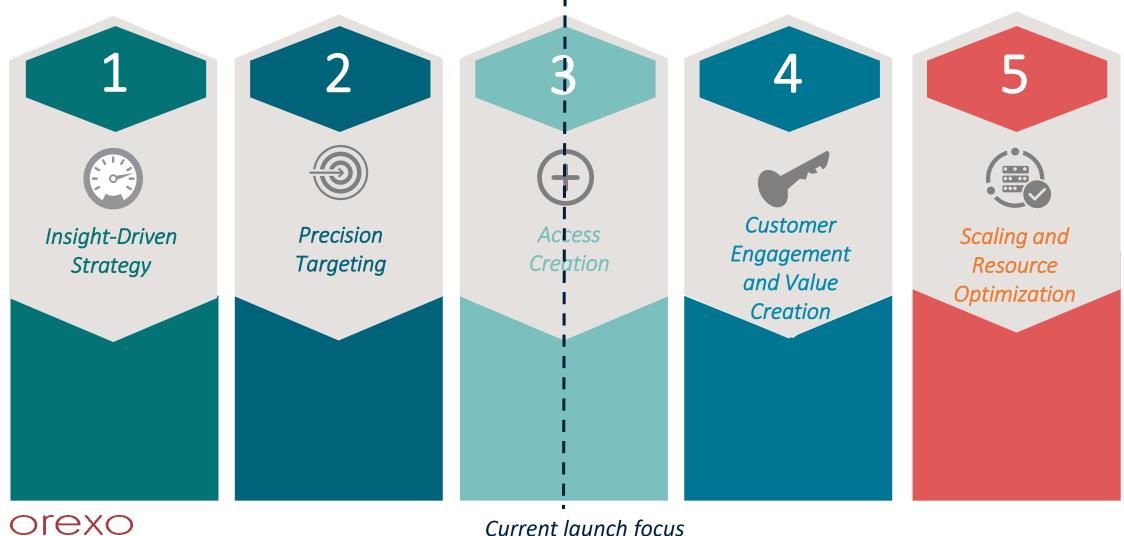
NEWS: First DTx distribution agreement just signed with GoGoMed

- Partnership to make the scientifically-proven digital therapies deprexis® and vorvida® available for the treatment of depression and management of problematic alcohol misuse respectively
- OXD01 for opioid use disorders, will also be available by GoGoMed in Q4 2020
- 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 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

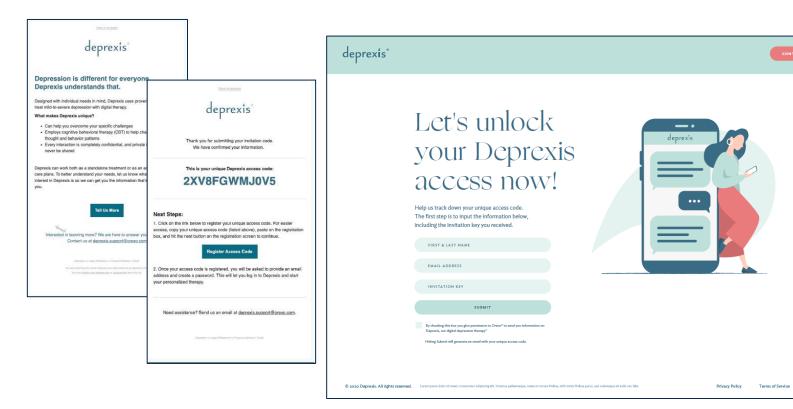




Our investment and go to market strategy is highly targeted and will scale as access is created in high need markets



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







Patients services available from September include user friendly patient services spanning specialty hub services for insurance reimbursement, customer service, e-commerce storefronts, and on-going customer relationship management tools



Financials and legal update









Strong financial position to drive future growth Growth in net revenue impacted by less royalty from Abstral® due to patent expiration in the EU and US

Group net revenues LTM ¹	Growth				
USD 85 m	0%				
Of which 86% from ZUBSOLV® US	ZUBSOLV® US 3%				
Group EBITDA LTM ¹	Growth				
USD 25 m	54%				
US Pharma EBIT (ZUBSOLV® US) LTM ¹	Growth				
USD 36 m	24%				
Cash position Q2 2020	Positive net cash position				
USD 70 m	USD 47 m				

¹ Last Twelve Months, conversion rate USD/SEK 9.7 June 2020 and 9.5 June 2019



Two new legal processes emerging 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 14th 2020.

Patent infringement litigation against Sun Pharma

- In collaboration with our US lawyers Orexo has decided to commence a patent infringement litigation against Sun. This follows their FDA filing of an ANDA¹ 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 from Dec. 2027 to Sep. 2032
- Ongoing lawsuit statutorily preclude FDA from approving Sun's ANDA for 30 months
- Orexo has previously successfully defended the ZUBSOLV® patents and is well prepared for a new process with Sun

¹ Abbreviated New Drug Application



Outlook









Strong value drivers for long-term growth

Future value drivers

Product portfolio addressing large and growing markets Strong cash conversion to support growth

- Leveraging our US commercial excellence
- Expanding pipeline targeting unmet medical needs
- Entering digital therapeutics, a new evidence-based frontier in patient care



Thank You