



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



Aktiespararna Aktiedagen GBG, Sep. 21 2020

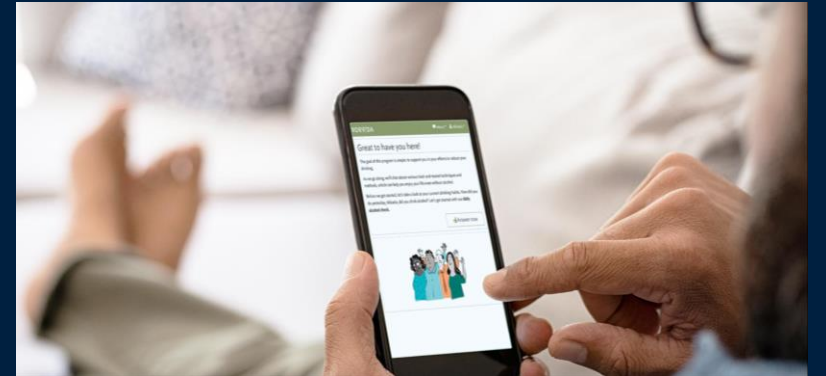
Nasdaq Stockholm: ORX US OTC Market: ORXOY (ADR)

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Overview

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Orexo in brief

- Developed **four commercial products** with worldwide approval
- 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**
- 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 Commercial Platform

Since 2013 direct presence in the US with a fully-owned sales force covering nearly all states

Net revenues
SEK, LTM² Q220

823 m

EBITDA
SEK, LTM Q220

239 m

Cash position
SEK, Q220

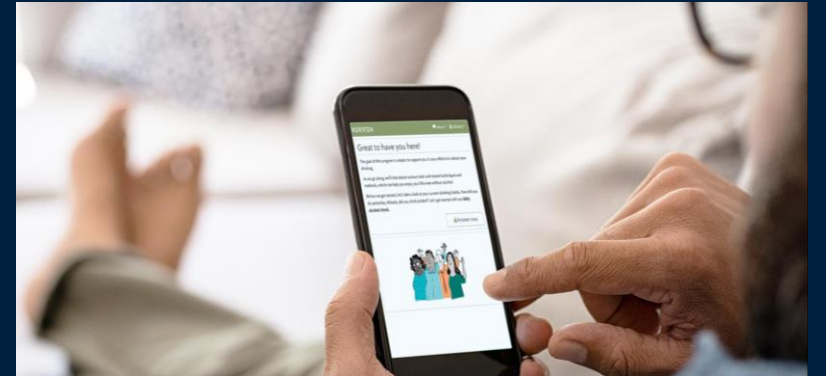
677 m

¹ As of August 31, 2020

² Last Twelve Months

Pharmaceuticals & Digital therapies

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Product & pipeline portfolio addressing large markets with unmet patient needs

		Exploratory	Preclinical	Phase			Registration	Approved/Launched		
				1	2	3		US	EU	RoW
Pharmaceuticals										
ZUBSOLV®	Opioid Use Disorder									▲
Abstral®	Breakthrough Cancer Pain, Kyowa Kirin									
Edluar®	Insomnia Mylan Worldwide									
OX124	Naloxone - Opioid Overdose									
OX125	Nalmefene - Opioid Overdose									
OX338	Ketorolac – Moderate to moderately severe pain									
OX382	Buprenorphine – Opioid Use Disorder									
OX-MPI	BI1029539 – Microvascular Disease Gesynta Pharma									
Digital Therapies										
		Preclinical		Phase 3		Registration	Approved/Launched			
							US	EU	RoW	
deprexis®	Depression GAIA AG									
vorvida®	Heavy alcohol use, incl. Alcohol Use Disorder GAIA AG									
OXD01	Opioid use Disorder GAIA AG									

▲ ZUBSOLV® has been approved in Australia

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

Deaths from opioid overdose increase



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.



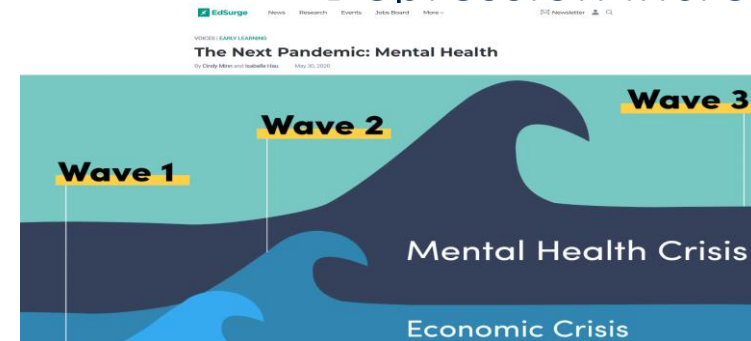
Opioid misuse increase

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

NATIONAL POST

Depression increase



ZUBSOLV® stable in “open” segments despite Covid-19 challenges

Competition in previous exclusive agreements explain decline year over year

A dynamic market impacted by Covid 19

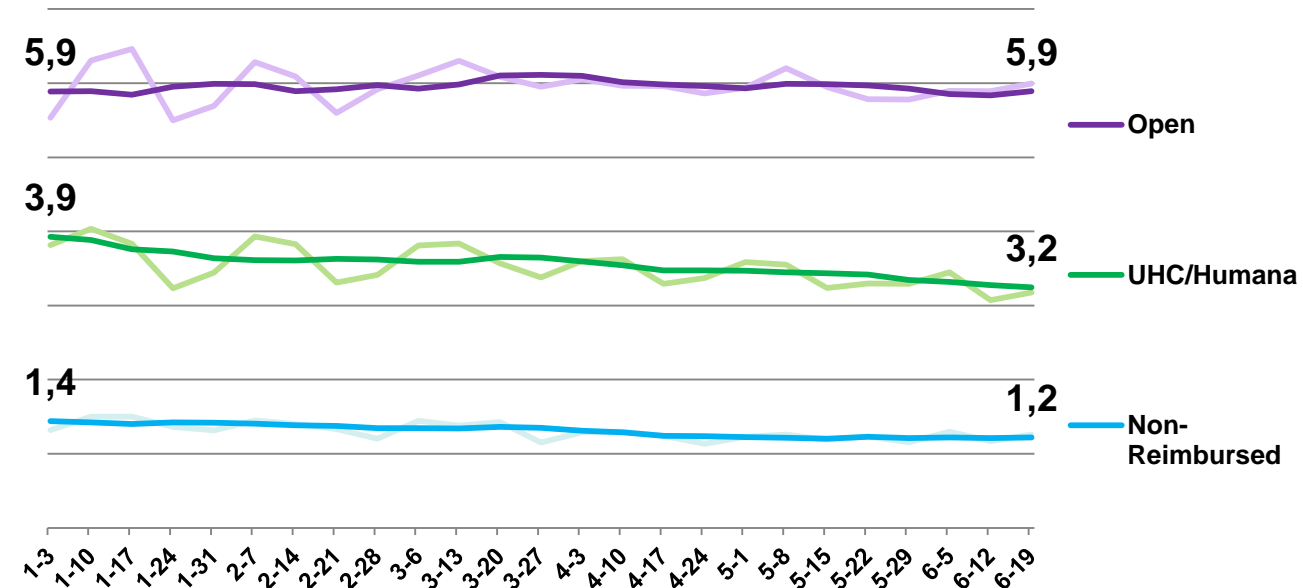
Increased opioid addiction lead to a record market growth of 15%

Primary growth driver is the “public segment” where Zubsolv has unfavorable reimbursement

Zubsolv has continued growth in the ~35% of public segment where the product has “open access”

Zubsolv’s main segment, commercial has been negatively impacted by Covid-19 due to increased unemployment in the US

ZUBSOLV® by Access Segments¹



Market grew 4 % QoQ and 15 % YoY. The main growth took place in the public segment where ZUBSOLV has access to 34 percent of the market. In the commercial segment the corresponding number is 98 percent.

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

OX124 a new stronger overdose 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

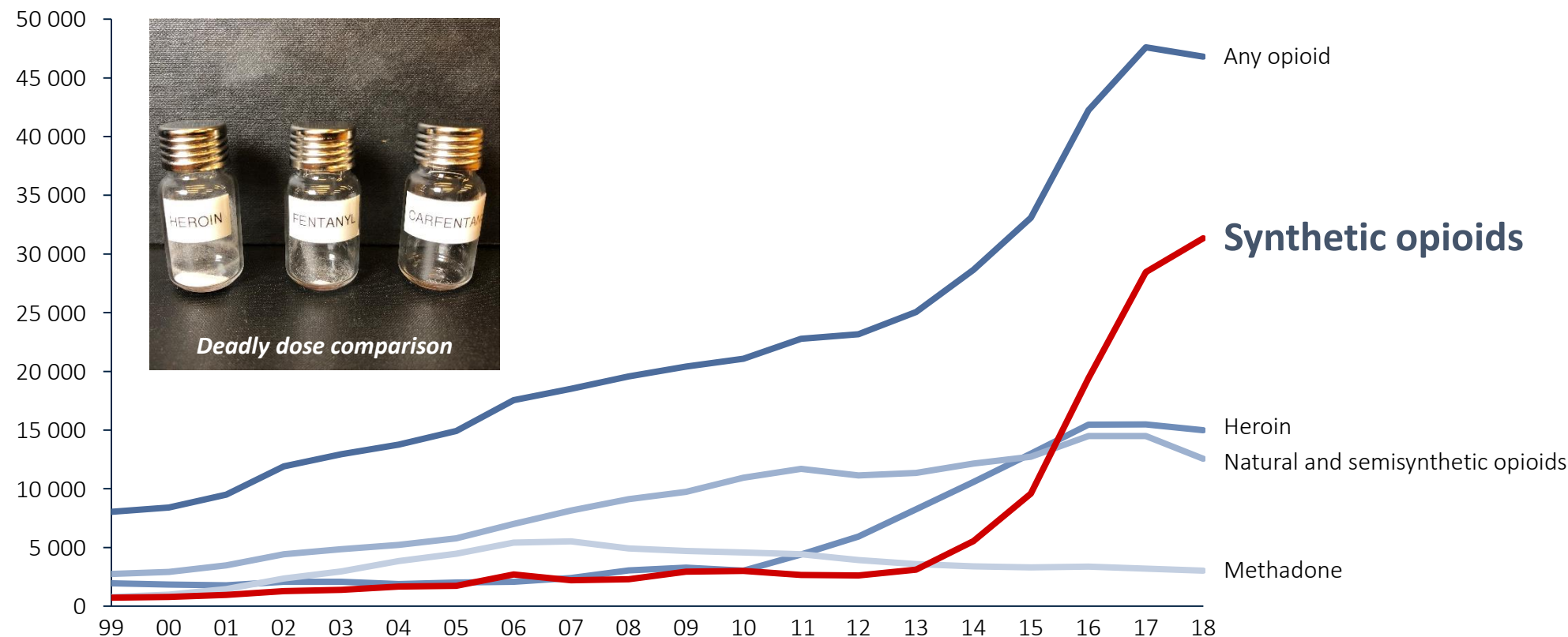
70-110

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

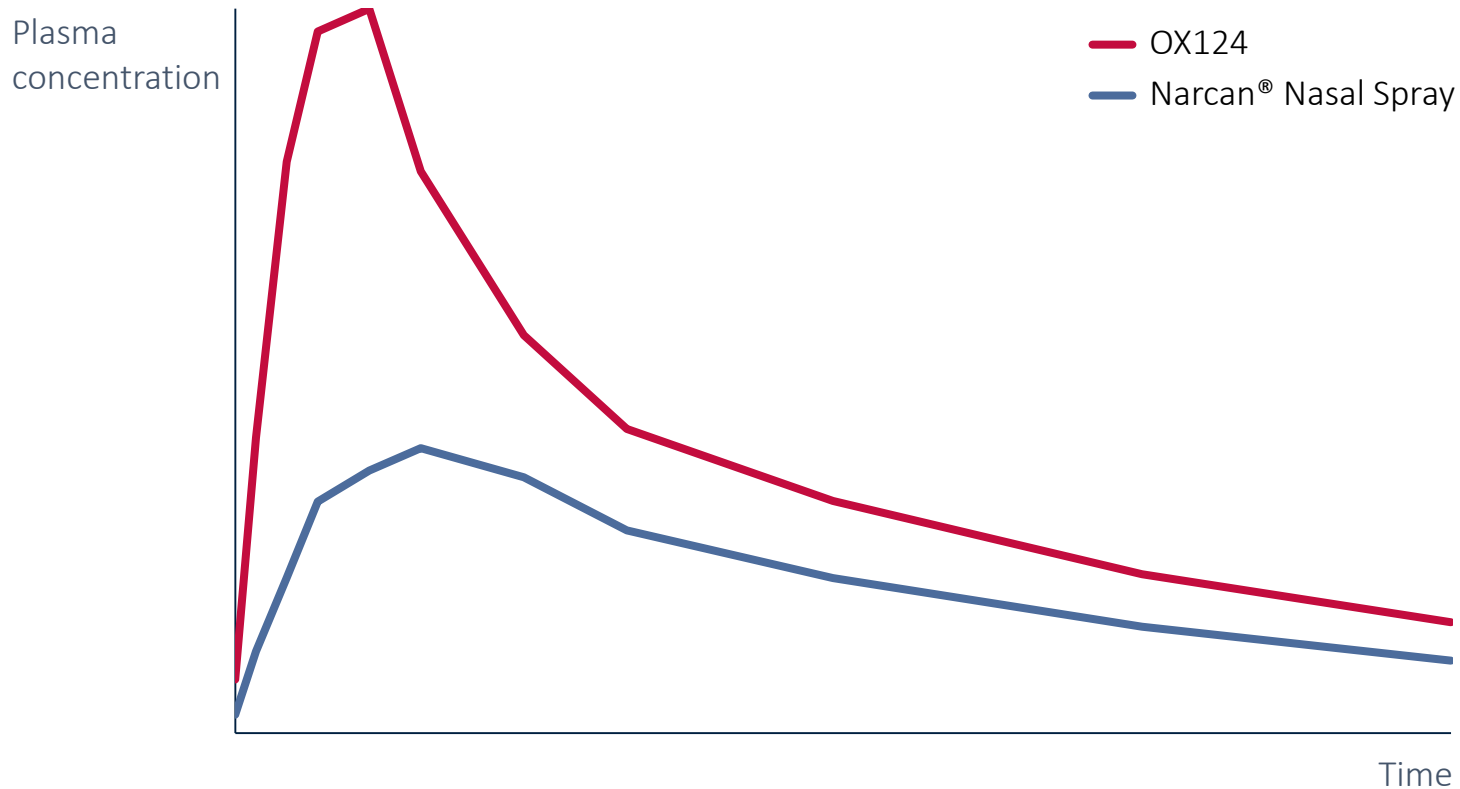


Source: Hedegaard H, et al. NCHS DATA Brief 356 - Drug Overdose Deaths in the United States, 1999-2018. NCHS, National Vital Statistics System, Mortality. Jan 2020.

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)

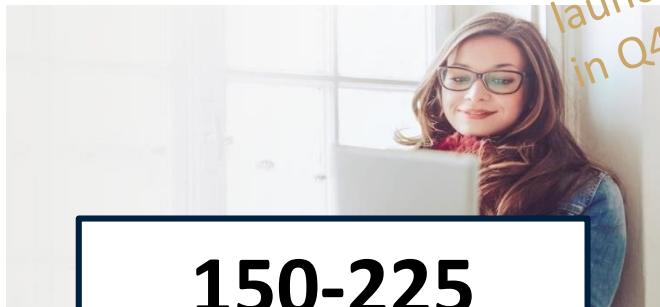
Digital therapeutics to become an integral part of the healthcare landscape

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

OXD01

“Digitizing” counselling at scale to offer with ZUBSOLV®, a full medication assisted therapy (MAT) solution for so many opioid use disorder (OUD) patients in need

To be
launched
in Q4



150-225

MUSD net sales potential in the US

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

Launched



> 150-225

MUSD net sales potential in the US

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)

Launched



120-200

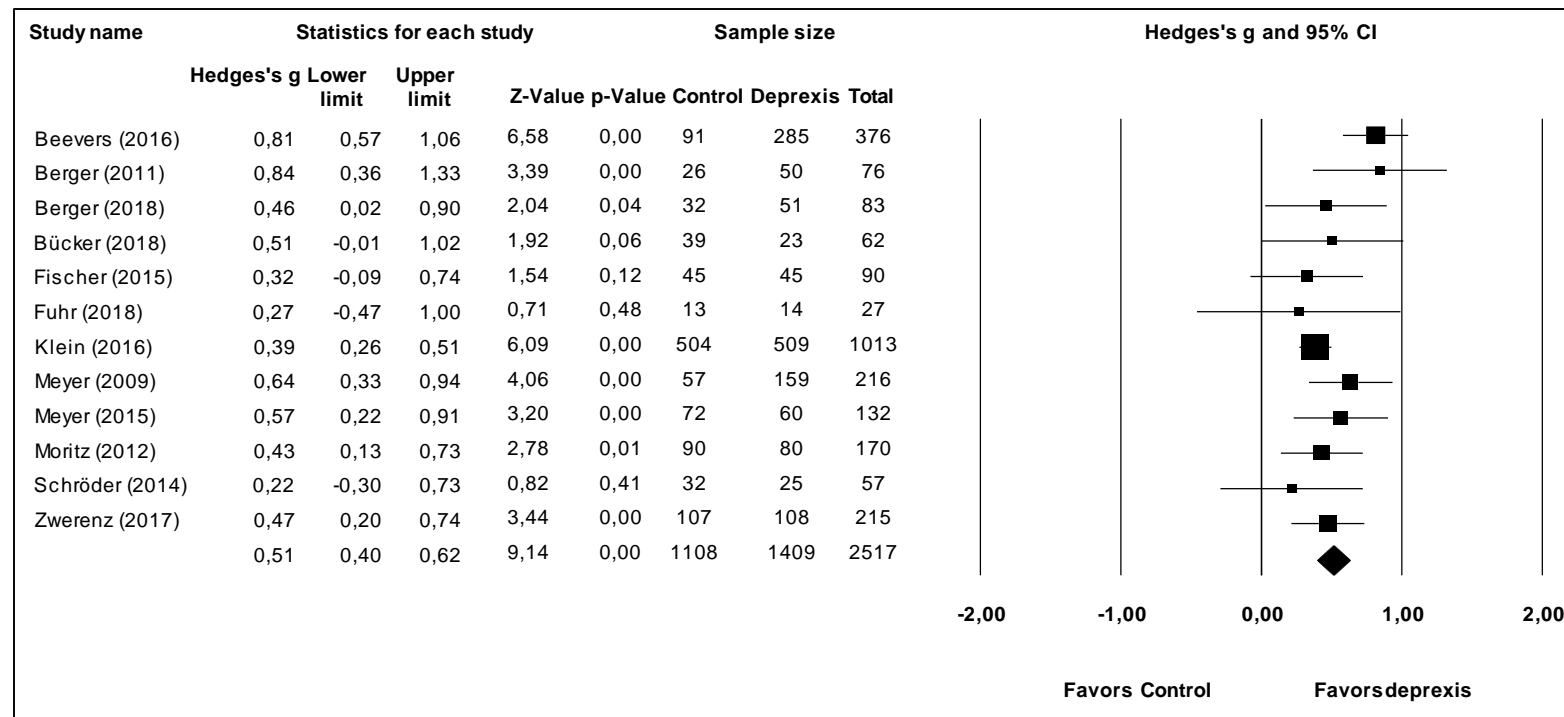
MUSD net sales potential in the US

Orexo offers scientifically proven digital therapies

E.g. deprexis® is one of the world's most clinically proven therapies demonstrating strong effectiveness

Results from 12 studies demonstrated the effectiveness of deprexis for depressive symptoms, with a medium effect size ($g = 0.51$, 95% CI: 0.40- 0.62) and low heterogeneity ($I^2 = 26\%$)

- Varied symptom severity
- Multiple clinical situations
- No publication bias
- No developer bias



Twomey C, O'Reilly G, Bültmann O, Meyer B (2020) Effectiveness of a tailored, integrative Internet intervention (deprexis) for depression: Updated meta-analysis. PLoS ONE 15(1): e0228100. <https://doi.org/10.1371/journal.pone.0228100>

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

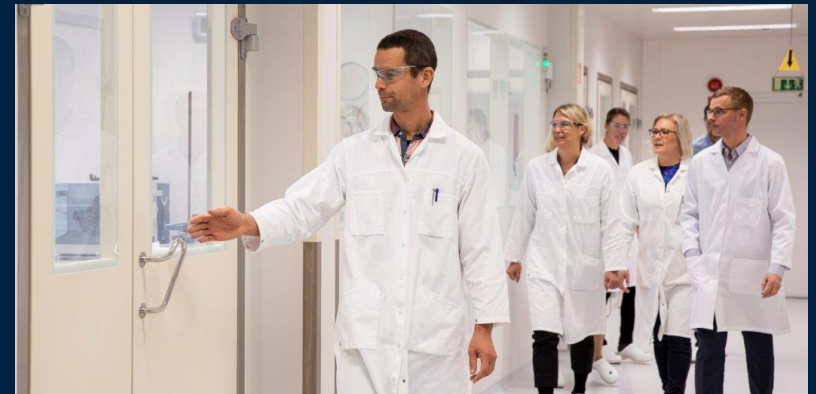
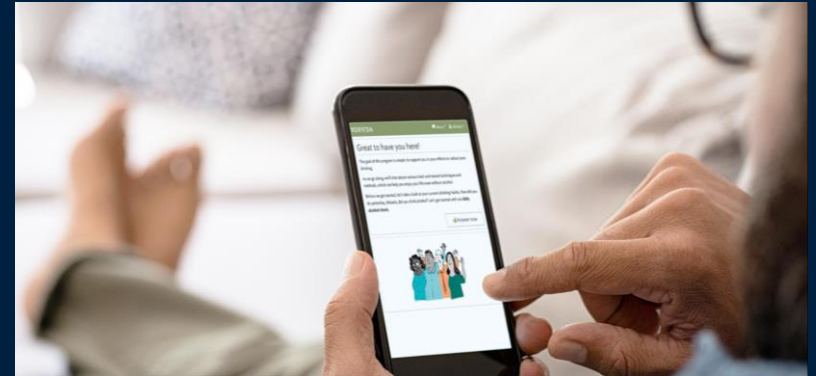


vorvida[®] video

View <https://youtu.be/Sm7yMNQI6oE>

Legal update, Financials & Strategic agenda

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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

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 SEK 823 m <i>Of which 86% from ZUBSOLV® US</i>	Growth 1% <i>ZUBSOLV® US 5%</i>
Group EBITDA LTM ¹ SEK 239 m	Growth 54%
US Pharma EBIT (ZUBSOLV® US) LTM ¹ SEK 349 m	Growth 26%
Cash position Q2 2020 SEK 677 m	Positive net cash position SEK 453 m

¹ Last Twelve Months

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



Thank You

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