



Press release

Orexo acquires exclusive US rights to commercialize deprexis[®], a world-leading digital therapy to help patients manage the symptoms of depression

- Scientifically proven digital therapy further strengthens commitment to digital therapeutics*
- Significant commercial potential*
- COVID-19 expected to create a significant rise in clinical depression*
- Leveraging existing US infrastructure*

Uppsala, Sweden – May 11, 2020. Orexo AB (publ.) today announces it has acquired the exclusive US rights to GAIA AG's (GAIA) deprexis[®], a digital therapy to help patients manage their symptoms of depression and one of the most researched digital therapies in the world. Today's announcement follows two earlier agreements with GAIA where Orexo acquired the exclusive US commercial rights to vorvida[®] which has been scientifically proven to reduce risky drinking patterns in adults with alcohol use disorder (AUD), and also the exclusive global commercial rights to OXD01, a new digital therapy being developed for the treatment of opioid use disorder (OUD).

The need for digital therapies due to the COVID-19 crisis is unprecedented. The COVID-19 crisis and the actions taken to control the pandemic is expected to result in a significant rise in mental illness such as depression¹ and substance abuse². With three digital therapies, Orexo is well positioned to take a leading role in addressing these mental diseases, offering digital therapies with scientifically proven efficacy enabling patients to receive help while maintaining social distancing requirements. The recent emergency use authorization policy for digital health devices for treating Psychiatric disorders published by the US Food and Drug Administration (FDA)³ will allow Orexo to accelerate the launch of its three digital therapies, in 2020, in order to help society to address some of the negative consequences of the COVID-19 pandemic.

Under the terms of the agreement, GAIA is entitled to an upfront payment and royalties will be paid based on net sales from January 1, 2022 onwards. deprexis[®] has already been classified by the FDA and Orexo expects to launch deprexis[®] in the US during the summer of 2020. The annual net

¹ <https://theconversation.com/covid-19-could-lead-to-an-epidemic-of-clinical-depression-and-the-health-care-system-isnt-ready-for-that-either-134528>

² <https://news.usc.edu/168549/covid-19-alcohol-sales-abuse-stress-relapse-usc-experts/>

³ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-digital-health-devices-treating-psychiatric-disorders-during-coronavirus-disease>



sales potential of deprexis® are estimated to exceed the market potential of vorvida® (USD 120 m – USD 200 m) and OXD01 (USD 150 m – USD 225 m). deprexis® has successfully been launched in multiple countries across the world.

deprexis® is a fully automated digital therapy developed by GAIA based on its proprietary artificial intelligence (AI)-expert system, broca®. deprexis® provides the user with tailored therapeutic support by simulating effective, up-to-date and personalized cognitive behavioral therapy interventions. Its effectiveness in managing the symptoms of depression has been evaluated and published 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). In this study, patients were studied for eight weeks, with 79 percent and 89 percent remaining in treatment from each group, respectively.⁴

Nikolaj Sørensen, President and CEO at Orexo AB said: *“The COVID-19 pandemic and resulting isolation and economic distress is likely to trigger a wave of mental health issues such as depression and substance abuse. With deprexis®, vorvida® and OXD01 Orexo can offer a range of products which could provide patients with access to quality medical devices whilst maintaining social distancing requirements. The agreement today marks our third deal with GAIA and reflects our belief in the important role of digital therapeutics, which continue to generate compelling clinical data to support their use across a range of medical conditions, including depression. During this unprecedented time with COVID-19 we have seen accelerated adoption of digital therapeutics and are focused on advancing deprexis® towards a launch during the summer.”*

Dr. Mario Weiss, CEO and Founder of GAIA, commented: *“Even before COVID-19, we believed that deprexis® is almost tailor-made for the US: A proven effective, fully-automated digital depression treatment, accessible on any connected device 24/7 and available in 10 languages, including Spanish, French and Chinese. With Orexo we now have the right partner in the US to offer a digital depression treatment, with significant clinical data to support its use. Providers, payors and employers will soon be able to support the ones in need with this top-of-class solution. We are very pleased that Orexo was willing to extend our existing partnership and join us in our constant fight against the massive global burden of diseases such as depression.”*

Depression is a leading cause of disability around the world and contributes greatly to the global burden of mental health illness. The effects of depression can be long-lasting or recurrent and can dramatically affect a person’s ability to function and live a rewarding life.⁵ In the US, an estimated number of 17.3 million adults had at least one major depressive episode corresponding to 7.1

⁴ Beevers et al. 2017. Effectiveness of an Internet Intervention (deprexis) for Depression in a United States Adult Sample: A Parallel-Group Pragmatic Randomized Controlled Trial. J Cons and Clin Psych

⁵ World Health Organization (WHO)



percent of all US adults.⁶ About 20 percent of Americans with an anxiety or mood disorder, such as depression, also have a substance abuse disorder, and about 20 percent of those with a substance abuse problem also have an anxiety or mood disorder.⁷ With respect to opioid use disorder, Orexo's own retrospective data from the RESOLV study, showed over 30 percent of patients were diagnosed with co-existing depressive disorder.⁸

The investments related to the deal and the opportunity to accelerate the launch of all Orexo's digital therapies will impact Orexo's cash flow with approximately SEK 115 million in the second quarter and result in an increased OPEX for 2020. The company will provide further detail on additional investment required to support the expected launch of the three digital therapies, in its Q2 Interim Report, that will be published on July 16, 2020.

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About Orexo

Orexo develops improved pharmaceuticals and digital therapies addressing unmet needs mainly within the growing space of addiction. The products are commercialized by Orexo in the US or via partners worldwide. The main market today is the American market for buprenorphine/naloxone products, where Orexo commercializes its lead product Zubsolv® for treatment of opioid use disorder. Total net sales for 2019 amounted to SEK 845 million and the number of employees was 127. Orexo is listed on the Nasdaq Stockholm Mid Cap (ORX) and is available as ADRs on OTCQX (ORXOY) in the US. The company is headquartered in Uppsala, Sweden, where research and development activities are performed.

For more information about Orexo please visit, www.orexo.com. You can also follow Orexo on Twitter, [@orexoabpubl](https://twitter.com/orexoabpubl), LinkedIn and YouTube.

⁶ National Institute of Mental Health (NIH)

⁷ Anxiety and Depression Association of America (ADAA)

⁸ <https://orexo.com/products/zubsolv/>



About GAIA

GAIA is a global leader in digital therapeutics (DTx), launching its first product successfully in 2001. With its stringent focus on research and development of evidence based, fully-automated online interventions the company continuously shifts benchmarks when it comes to effect sizes and safety profiles for digital therapeutics in neuroscience, immunology, oncology, or behavioral health. With more than 150 experts in the field of Medicine, Psychology, Behavioral Medicine, Software Engineering as well as Regulatory and Market Access, GAIA is one of the most experienced and largest global players in the development of next generation digital solutions to support and treat patients with a broad variety of medical conditions.

For more information about GAIA please visit www.gaia-group.com. You can also follow GAIA on Twitter, @GAIA_COM, and LinkedIn

This information is information that Orexo AB (publ.) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 8.00 am CET on May 11, 2020.