Press release

Orexo launches deprexis® and vorvida® in the US and provides updated financial guidance

- *FDA´s "Enforcement Policy" and Orexo´s strong financial position enable investments in an accelerated commercialization of its scientifically proven digital therapies*
- *Preliminary estimated sales potential of USD 420-650 million for the DTx portfolio five years post launch*
- *To enable accelerated launch of all three products investments will increase and OPEX for FY 2020 is expected to be in the range of SEK 750-800 million, from SEK 550-600 million*

Uppsala, Sweden – July 2, 2020 - Orexo AB (publ.), **(STO:ORX) (OTCQX:ORXOY)** announces today the US launch of the scientifically proven digital therapies deprexis® and vorvida®, for treatment of symptoms of depression and management of problematic alcohol misuse respectively. deprexis® is available to patients from July 1st and vorvida® from July 15th. The decision to accelerate the launch is based on the patient need for access to low-risk clinically-validated digital health devices during the ongoing COVID-19 pandemic and the recent US Food and Drug Administration (FDA) "Enforcement Policy" providing a fast pathway to market for digital therapies for treatment of psychiatric disorders. As a result of the "Enforcement Policy" the development of OXD01, a digital therapy for the treatment of opioid use disorders, will be accelerated and tested in collaboration with selected customers in Q4 2020, in preparation of a broad launch in Q2, 2021, a year ahead of original plan.

The COVID-19 pandemic, with society lockdowns and social distancing is expected to lead to a significant increase in mental health issues and substance use disorders. A report published by ODMAP (Overdose Detection Mapping Application Program) indicates a double-digit percentage increase in the number of overdoses in the US related to COVID-19.[1] In addition, a recently published report by World Health Organization (WHO) suggests COVID-19 is expected to have a large negative impact on mental health, highlighting the need for countries to take necessary measures to alleviate the impact on individuals, their families and society more broadly.[2] Recognizing the need for additional treatment solutions for rising mental health conditions, the FDA has introduced an "Enforcement Policy" with the aim of increasing access to digital therapies within the area of psychiatric disorders during the COVID-19 pandemic.

With 16.6 million heavy alcohol users, 21.2 million people diagnosed with depression and 10.3 million opioid misusers,[3] before the COVID-19 pandemic, this new venture is a cornerstone of

[1] **https://files.constantcontact.com/a923b952701/dbf0b5a5-f730-4a6f-a786-47097f1eea78.pdf**
[2] **https://www.un.org/sites/un2.un.org/files/un_policy_brief-covid_and_mental_health_final.pdf**
[3] **SAMHSA, Substance Abuse and Mental Health Service Administration**

the company´s strategy for future growth. The COVID-19 pandemic has created a unique need for new solutions and in response to the untold suffering, Orexo brings forward the launch of the digital therapies to help the millions of patients suffering from depression, alcohol misuse and opioid addiction. While digital therapies are still in the early stages of adoption by healthcare providers and payers, the sales potential is significant and Orexo´s preliminary estimates suggest that its three digital therapies could have a combined annual sales potential of USD 420-650 million five years post launch.

To capture the patient need arising from the COVID-19 pandemic and accelerate the commercialization, Orexo will leverage the company's strong financial position to invest in the early launch of the digital therapies during 2020. The new OPEX guidance for 2020 is increased to SEK 750-800 million from SEK 550-600 million reflecting investments related to the accelerated commercialization and establishment of the DTx business. Except for depreciation, the OPEX guidance does not include capitalized investments such as the previously communicated investments related to the acquisition of the rights to deprexis® in the US and other one-time investments related to the digital therapeutics of approximately SEK 115 million. Initial revenues from digital therapeutics are expected in Q3 2020 and total net revenues in 2020 from digital therapies are dependent on the pace Orexo can secure product reimbursement.

The launch of Orexo's digital therapies will initially focus on securing access and reimbursement with a selected group of payers, leveraging Orexo's long relationship with many payers in the US. As access and reimbursement is established, Orexo will increase the sales force and direct marketing efforts to promote the products directly to relevant healthcare professionals. On July 1 Orexo initiated the launch of the product information website for deprexis®, meetdeprexis.com, to enable promotion to eligible patients, providers, and payers.

Nikolaj Sørensen, President and CEO at Orexo AB said: "*Due to the COVID-19 pandemic, the need for clinically validated digital therapies is unprecedented. This pressing need, combined with the FDA's measures to expand availability of digital therapies for psychiatric disorders, have accelerated launch plans for Orexo's digital offering. This aligns with our strategy to increase our product offering and to further leverage our commercial US infrastructure. Orexo has a profitable and well-funded pharmaceutical business enabling the investment required to capitalize on the current digital therapies opportunity, drive longer term growth and address patient need.*"

Forecasted numbers in SEK above are based on a USD/SEK exchange rate as of December 31 2019.

At 1.30 pm CET, Orexo invites analysts, investors and media to attend a teleconference where Nikolaj Sørensen, President and CEO and Dennis Urbaniak, EVP Digital Therapeutics, will provide a short presentation on the commercialization plans for the digital therapies and answer questions. Questions can also be sent in advance to ir@orexo.com, no later than 11.00 am CET. Please view the instructions below on how to participate.

Dial in number: SE: +46 8 566 42 707, UK: +44 33 330 09 271, US: +1 83 382 305 86 (no code needed)
Internet link: https://tv.streamfabriken.com/2020-07-02-orexo-pressconference

The presentation can be downloaded from the company´s website approximately one hours ahead of the presentation at, **https://orexo.com/investors/reports-presentations-and-audiocasts/**

For more information please contact:
Orexo AB (publ.)
Nikolaj Sørensen, President and CEO
Tel: +46 18 780 88 00
E-mail: ir@orexo.com

Dennis Urbaniak, EVP Digital Therapeutics
Tel: +1 855 982 76 58
E-mail: ir@orexo.com

Lena Wange, IR & Communications Director
Tel: +46 18 780 88 00
E-mail: ir@orexo.com

About Orexo
Develops improved pharmaceuticals and digital therapies addressing unmet needs within the growing space of substance use disorders and mental health. 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 commercialize its lead product Zubsolv® for treatment of opioid use disorder. Total net sales for 2019 amounted to SEK 844,8 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 head office, where research and development is also performed, is situated in Uppsala, Sweden.

For more information about Orexo please visit, www.orexo.com. You can also follow Orexo on Twitter, @orexoabpubl, LinkedIn and YouTube.

About Digital Therapeutics
Digital therapeutics (DTx) deliver evidence-based therapeutic interventions to patients that are driven by high quality software programs to prevent, manage, or treat a medical disorder or disease. Digital therapeutics are used independently or in concert with medications, devices, or other therapies to optimize patient care and health outcomes. (As defined by Digital Therapeutics Alliance).

About Orexo DTx
Orexo DTx is the digital health arm of Orexo AB, a pharmaceutical company that develops and commercializes improved pharmaceuticals and digital therapies. The company addresses unmet needs mainly within the growing space of substance use disorders and mental health. Orexo DTx was created in Q4 of 2019 and currently has three products in the pipeline, vorvida® for alcohol

misuse, deprexis® for depression, and OXD01 for opioid use disorder, all in partnership with the GAIA group.

Orexo DTx's mission is to redefine treatment of addiction by offering clinically validated digital therapeutics to ensure more successful treatment for patients and cost-effective solutions for payers. The digital products will be commercialized by Orexo DTx worldwide, with the US as the principal market, where Orexo also commercializes its lead product Zubsolv® (buprenorphine and naloxone) sublingual tablets (CIII) for treatment of opioid use disorder.