OREXO US AWARDED USD 8 MILLION BY BARDA FOR OX390 DEVELOPMENT PARTNERSHIP

Uppsala, Sweden – September 29, 2025 – Orexo AB (Publ.), **(STO:ORX) (OTCQX:ORXOY),** today announced its wholly owned US subsidiary, Orexo US, Inc., has been awarded USD 8 million in funding by the Biomedical Advanced Research and Development Authority (BARDA), part of the Administration for Strategic Preparedness and Response in the US Department of Health and Human Services. The funding will support the development of OX390, an intranasal rescue medication for adulterated opioid overdoses.

The award is structured in five stages and is valued at up to USD 50.9 million that could be awarded if specific milestones and deliverables are achieved. It will contribute to the funding for Orexo to perform non-clinical toxicology, human clinical studies, drug and device manufacturing, and regulatory filing for a formulation of OX390 suitable for community use.

OX390 is a New Chemical Entity (NCE) with a novel formulation and route of administration for human use. OX390 is intended to reverse respiratory depression associated with adulterated illicit opioid overdoses, which is a rapidly increasing problem in the US. OX390 uses Orexo's proprietary AmorphOX® dry-powder drug delivery technology which has been validated in multiple clinical studies with other molecules and has demonstrated rapid and extensive drug exposure. The first stage of the contract provides approximately USD 8 million to support the completion of the agreed activities. Upon completion of the project and FDA approval of the product, Orexo will retain all commercial rights to OX390.

"We are excited to initiate our partnership with BARDA in the development of OX390. We aim to develop a rapidly deployable intranasal rescue medication using our proprietary AmorphOX technology for the emergency treatment of respiratory depression associated with adulterated illicit opioids. There is a crucial need for new treatment options that can complement opioid antagonists for the increasing number of patients exposed to adulteration of illicitly manufactured opioids. We look forward to continuing our collective efforts to develop medical countermeasures as the American opioid epidemic continues to evolve and expose the public in the US to new lethal adulterations of opioids," **said Nikolaj Sørensen, President and CEO of Orexo AB**.

"This BARDA funding is an important step in addressing the rapidly evolving adulteration of illicitly manufactured opioids that is challenging US emergency responders and volunteers," added **Edward Kim, MD, MBA, Chief Medical Officer of Orexo US, Inc**. *"As the science struggles to catch up to the problem, we are seeking a solution driven by our ongoing dialogue with scientists, front line clinicians, and first responders."*

This project has been funded in whole or in part with federal funds from the US Department of Health and Human Services, Administration for Strategic Preparedness and Response, Biomedical Advanced Research and Development Authority, under contract number 75A50125C00010.

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About Orexo
Orexo is a Swedish pharmaceutical company with 30 years of experience developing improved pharma-ceuticals based on proprietary formulation technologies that meet large medical needs. On the US market, Orexo provides innovative treatment solutions for patients suffering from opioid use disorder. Products targeting other therapeutic areas are developed and commercialized worldwide with leading partners. Total net sales in 2024 amounted to SEK 590 million, and the number of employees to 110. Orexo is listed on Nasdaq Stockholm's main list and is available as ADRs on OTCQX market (ORXOY) in the US.

For more information about the company please visit www.orexo.com. You can also follow Orexo on
X, LinkedIn, and YouTube.

About OX390
OX390 is a new chemical entity (NCE) designed to reverse respiratory depression associated with adulterated illicit opioid overdoses. Emerging evidence indicates that opioid-induced respiratory suppression (OIRD) may be greatly magnified in the presence of increasingly common adulterants, and that opioid antagonists such as naloxone and nalmefene may not be sufficient to revive victims of these overdoses. OX390 will be developed as a rapidly acting intranasal powder using Orexo's proprietary powder-based drug delivery technology AmorphOX® for community-based use by first responders and laypersons. OX390 is an investigational compound and is not approved for human use by the FDA.

About AmorphOX
Orexo's proprietary drug delivery platform, AmorphOX, is a powder made up of particles that are built using a unique combination of a drug, carrier materials and, optionally, other ingredients. The particles are presented as an amorphous composite of the various ingredients providing for excellent chemical and physical stability, as well as rapid dissolution. The technology works for a broad scope of active ingredients and has been validated in several human clinical studies showing rapid and extensive drug exposure.

This information is information that Orexo AB 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 2025-09-29 20:30 CEST.

Attachments
Orexo US Awarded USD 8 Million by BARDA for OX390 Development Partnership