Press release

BARDA Supports Contract Modification extending the initial Development stage for the OX390 project to end of 2027

Uppsala, Sweden and Parsippany, NJ – September 10th 2026 – Orexo AB (publ) (STO: ORX) (OTCQX: ORXOY) today announced that its US subsidiary, Orexo US, Inc., received a contract modification from the Biomedical Advanced Research and Development Authority (BARDA). BARDA agrees to provide an additional USD 2.99 million to extend initial development phase to the end of 2027 and support additional FDA-required development activities for OX390.

OX390 is Orexo's innovative intranasal rescue medication being developed to treat respiratory depression associated with adulterated opioid overdoses, a problem that continues to rise despite the recent decrease in overall opioid overdose deaths.

In a recent publication the overall number of opioid overdose deaths declined in 2024, but the proportion of those deaths associated with the alpha-2 agonist xylazine increased over 50 percent from 8.3% to 12.6%[1]. In addition a newer and stronger alpha-2 agonist, medetomidine is surpassing xylazine in some areas of the US. In 2024, it replaced xylazine as the most common adulterant of the illegal opioid supply in the Philadelphia area. Medetomidine is estimated to be over 100 times as potent and than xylazine[2], underlining the urgent and increasing need for a rescue treatment.

Since the initial BARDA contract award, Orexo has continued advancing the OX390 development program through ongoing scientific, technical, and regulatory activities. Through interactions with the US Food and Drug Administration (FDA), we have agreed to additional scientific and technical work to align the development program with evolving FDA expectations and regulatory requirements. This will help to ensure a robust path toward future regulatory submission and potential approval.

The original BARDA contract was awarded in September 2025 and structured in multiple stages with a potential value of up to USD 50.9 million based on achievement of agreed milestones and deliverables. The supplemental funding will extend the first stage from March 2027 to the end of 2027 and will increase the overall value from up to USD 50.9 million to up to USD 53.8 million.

The supplemental funding will support activities for nonclinical safety and product testing to make OX390 available for patients, first responders, and communities impacted by the evolving opioid overdose crisis in the United States.

"*I am pleased with the continued progress in the project and the support from the U.S. government in the development of OX390. With the AmorphOX technology Orexo has a unique opportunity to develop new medications with rapid uptake, high bio-availability, thermostable and highly reliable, all features that are essential to develop OX390 to treat respiratory depression associated with adulterated opioid overdoses involving xylazine and other alpha-2 agonists*" **Nikolaj Sørensen, President and CEO of Orexo AB**.

Edward Kim, MD, MBA, Chief Medical Officer of Orexo US, Inc. continued, "*We are grateful to our partners at BARDA for their technical and financial support as we advance OX390 toward the clinic. Our pre-IND nonclinical program, bringing us closer to a first-in-class solution for this emerging public health threat that is only becoming more pervasive in the United States*."

OX390 utilizes Orexo's proprietary AmorphOX® powder technology platform and was developed to provide rapid delivery through a dry-powder intranasal formulation suitable for community use.

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 (BARDA), under Contract No. 75A50125C00010.

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About OX390
OX390 is 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, containing atipamezole, and is not approved for human use by the FDA.

About BARDA

BARDA, part of the Administration for Strategic Preparedness and Response within the US Department of Health and Human Services, supports the advanced development and procurement of medical countermeasures needed to prepare for and respond to public health emergencies.

About Orexo

Orexo is a Swedish pharmaceutical company dedicated to advance treatments for severe diseases and life-saving rescue medications to meet future healthcare needs. At the core of our innovation is AmorphOX®, a proprietary drug delivery technology that improves bioavailability and stability for both large and small molecules, enabling new approaches to administration, manufacturing, and distribution. With over 30 years of experience and multiple drugs approved globally, Orexo is advancing a diversified pipeline of programs in clinical and preclinical development. The company collaborates with partners in research, development, and commercialization. Headquartered in Uppsala, Sweden, Orexo is listed on Nasdaq Stockholm's main market and trades as ADRs on the OTCQX market in the United States.

References

[1] Friedman JR, Palamar JJ, Ciccarone D, Gaines TL, Borquez A, Shover CL, Strathdee SA. Charting the decline of the fourth wave: US overdose deaths by race, ethnicity and substance involvement. Addiction. 2026 Jun 2

[2] Huo S, Perrone J. The Shifting Landscape of a Fentanyl Adulterant: Moving From Xylazine to Medetomidine. J Addict Med. 2026 May-Jun 01.

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