



Press release

Orexo announces FDA acceptance of IZIPRY™ NDA resubmission for review

- IZIPRY™ is a high-dose naloxone rescue medication designed to reverse overdoses involving highly potent synthetic opioids such as fentanyl, using Orexo's AmorphOX® drug delivery platform.
- If approved, it would be the first nasal naloxone powder available in the United States
- The FDA has accepted the resubmission for review and confirmed a six-month review timeline.
- The Prescription Drug User Fee Act (PDUFA) target action date is March 29, 2027.

Uppsala, Sweden – October 29, 2026 – Orexo AB (publ.) (**STO: ORX**) (**OTCQX: ORXOY**) today announces that the U.S. Food and Drug Administration (FDA) has accepted for review the resubmitted New Drug Application (NDA) for IZIPRY™ (naloxone nasal powder). The FDA has set a Prescription Drug User Fee Act (PDUFA) target action date of March 29, 2027.

IZIPRY™ is a high-dose naloxone rescue medication for opioid overdose, developed using Orexo's proprietary AmorphOX® powder-based drug delivery platform. It is designed to address the growing prevalence of overdoses requiring high doses of naloxone, including those involving highly potent synthetic opioids such as fentanyl¹. Its dry powder nasal formulation is highly stable, has low sensitivity to temperature fluctuations, and can be used in freezing temperatures, differentiating it from other liquid naloxone alternatives.

Real-world evidence shows increasing use of multiple naloxone doses by bystanders and emergency medical services providers^{2,3}. The U.S. Drug Enforcement Administration (DEA) has also advised that fentanyl combined with emerging synthetic opioids may require several naloxone doses to be effective⁴. By combining a high dose with rapid absorption, high bioavailability, and temperature resilience, IZIPRY™ has the potential to reduce repeat dosing and rapidly reverse life-threatening opioid overdoses in warmer and colder climates.

The FDA's acceptance confirms that the resubmission contains the additional information and documentation needed to review whether it addresses the observations in the agency's July 2024 Complete Response Letter (CRL).



Nikolaj Sørensen, President and CEO of Orexo AB, said:

“Confirmation of the March 29, 2027 PDUFA target action date marks another important milestone toward potential FDA approval of IZIPRY™. Acceptance for review confirms that the application contains the information needed for the FDA to assess whether the issues previously raised have been adequately addressed. We look forward to the review process and work with the agency to respond to any questions raised during the review while seeking a commercialization partner for the U.S. market.”

Commercialization and partnership opportunities

Orexo continues to prepare for the potential U.S. commercialization of IZIPRY™, focusing on commercial partnerships to secure market access and broad patient reach. If approved, IZIPRY™ is expected to be the first nasal naloxone powder available in the United States and will address growing demand for high-dose rescue medications in a market increasingly affected by synthetic opioids such as fentanyl.

About IZIPRY™

IZIPRY™ is a high-dose naloxone nasal powder rescue medication for opioid overdose. Based on Orexo’s proprietary AmorphOX® technology, it enables rapid absorption, high bioavailability, and improved stability compared with conventional liquid naloxone formulations. IZIPRY™ is designed to address the growing need for effective overdose rescue medications in the era of synthetic opioids and is under FDA review.

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About Orexo

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



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

References:

¹ Moss, R.B., Carlo, D.J. Higher doses of naloxone are needed in the synthetic opioid era. *Subst Abuse Treat Prev Policy* 14, 6 (2019). <https://doi.org/10.1186/s13011-019-0195-4>

² Abdelal, R., Raja Banerjee, A., Carlberg-Racich, S. et al. Real-world study of multiple naloxone administration for opioid overdose reversal among bystanders. *Harm Reduct J* 19, 49 (2022). <https://doi.org/10.1186/s12954-022-00627-3>

³ Abdelal R, Banerjee AR, Carlberg-Racich S, Darwaza N, Ito D, Epstein J. The need for multiple naloxone administrations for opioid overdose reversals: A review of the literature. *Subst Abus.* 2022;43(1):774-784. doi: 10.1080/08897077.2021.2010252. PMID: 35112993.

⁴ <https://www.dea.gov/press-releases/2026/05/12/public-safety-advisory>

The information was submitted for publication at 11.00 am CET on October 29, 2026.