

Press release

Orexo resolves Zubsolv US patent litigation with Sun Pharmaceutical Industries

Uppsala, Sweden – December 15, 2024 – Orexo AB (publ.), (STO:ORX) (OTCQX:ORXOY), today announces that it has entered into a settlement agreement with Sun to resolve the patent litigation regarding Zubsolv® (buprenorphine and naloxone) sublingual tablet (CIII), for the treatment of opioid use disorder in the US.

The agreement resolves the patent litigation commenced in 2020 by Orexo following Sun's filing of an Abbreviated New Drug Application ("ANDA") seeking approval to market generic versions of Zubsolv in the US prior to the expiration of Orexo's patents listed in FDA's Orange Book for Zubsolv.

The agreement allows Sun to enter the US market with its generic versions of Zubsolv in September 2030. Zubsolv is protected by ten patents in the US with expiration dates ranging from 2027 to 2032. This settlement agreement does not implicate its patent protection.

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About Orexo

Orexo is a Swedish pharmaceutical company with 30 years of experience developing improved pharmaceuticals 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 and adjacent diseases. Products targeting other therapeutic areas are developed and commercialized worldwide with leading partners. Total net sales in 2023 amounted to SEK 639 million, and Orexo's total number of employees is 116. Orexo is listed on Nasdaq Stockholm's main list and is available as an ADR on OTCQX (ORXOY) in the US.

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



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 9 pm CET on December 15, 2024.