

Press release

Orexo wins patent litigation for ZUBSOLV® in the US

- The court found Orexo's patents valid and infringed by Sun
- The outcome once again confirms the strength of the company's intellectual property rights and the ability to develop innovative products
- The win will enable Orexo to maintain ZUBSOLV® net sales and profit contribution (SEK 573 million and SEK 299 million respectively the last twelve months)¹
- ZUBSOLV® has ten patents protecting the drug until September 2032

Uppsala, Sweden – July 1, 2023 – Orexo AB (publ.), **(STO:ORX) (OTCQX:ORXOY)**, today announces that the US District Court for the District of New Jersey ruled in favor of Orexo in its patent litigation against Sun Pharmaceutical Industries Limited, Sun Pharma Global FZE, Sun Pharma Global, Inc., and Sun Pharmaceutical Industries, Inc. (collectively "Sun") regarding ZUBSOLV® (buprenorphine and naloxone) sublingual tablets (CIII) in the US. The district court found that Orexo's patents are valid and infringed by Sun.

The district court's decision concludes the litigation that was initiated in September 2020 as a response to Sun's submission of an Abbreviated New Drug Application with the US Food and Drug Administration seeking approval of generic versions of ZUBSOLV®. As a result of the decision, Sun is prohibited from launching its generic ZUBSOLV® tablets until September 2032, and Orexo's patent protection remain unchanged. ZUBSOLV® is currently protected by ten patents listed in the Orange Book with expiration dates ranging from December 2027 to September 2032.

Nikolaj Sørensen, President and CEO of Orexo AB, said: "I am very pleased that me and my team in both the US and Sweden, yet another time have received confirmation about the strength of our patents protecting the innovation and technology behind ZUBSOLV®. Since its launch in the US in 2013, ZUBSOLV® has generated more than SEK 4.7 billion in net revenues and will continue to be an important cash generator. I want to thank all our shareholders and, most importantly, the employees for their continued support and commitment during the last three years. Now we look forward to focusing on continuing to grow our business and bringing innovative treatment solutions to patients."

¹ Q2 2022 – Q1 2023



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About Orexo

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 American market for buprenorphine/naloxone products is the largest, where Orexo commercializes its lead product ZUBSOLV® for treatment of opioid use disorder. Total net sales for 2022 amounted to SEK 624 million and the number of employees was 126. Orexo is listed on the Nasdaq Stockholm Main Market (ORX) and is available as ADRs on OTCQX (ORXOY) in the US. The company is headquartered in Uppsala, Sweden, where research and development activities are performed.

For more information about Orexo please visit www.orexo.com. You can also follow Orexo on Twitter, [@orexoabpubl](https://twitter.com/orexoabpubl), LinkedIn, and YouTube.

The information in the press release is information that Orexo is obliged to make public pursuant to the EU Market Abuse Regulation.
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