



Press release

Orexo's patent win for ZUBSOLV® appealed

Uppsala, Sweden – July 24, 2023 – Orexo AB (publ.), (**STO:ORX**) (**OTCQX:ORXOY**), today announces that Sun Pharmaceutical Industries Limited, Sun Pharma Global FZE, Sun Pharma Global, Inc., and Sun Pharmaceutical Industries, Inc. (collectively "Sun") have appealed the patent litigation decision issued by the US District Court for the District of New Jersey relating to Orexo's patents protecting ZUBSOLV® (buprenorphine and naloxone) sublingual tablets (CIII) in the US.

The litigation was initiated in September 2020 because of Sun's submission of an Abbreviated New Drug Application with the US Food and Drug Administration seeking approval of generic versions of ZUBSOLV®. On June 30, 2023, the district court ruled in favour of Orexo and found that its patents are valid and infringed by Sun, thereby prohibiting Sun from launching its generic ZUBSOLV® tablets until September 2032. Sun has now appealed the district court's decision to the US Court of Appeals for the Federal Circuit.

Nikolaj Sørensen, President and CEO of Orexo AB, said: "The decision from the District Court was very well motivated and clearly outlined the significant shortfalls in SUN's non-infringement and invalidity claims against the ZUBSOLV® patents. We remain very confident in the strength of the patent portfolio and that the Court of Appeals will come to the same conclusion."

ZUBSOLV® is currently protected by ten patents listed in the Orange Book with expiration dates ranging from December 2027 to September 2032. An appeal process is expected to take approximately 18 months and will be related to legal costs in the range of SEK 5-15 million.

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About Orexo

Orexo is a Swedish pharmaceutical company with over 25 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 2022 amounted to SEK 624 million, and the number of employees to 126. 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 Twitter, @orexoabpubl, LinkedIn, and YouTube.

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