

Press release

District Court of Delaware rules that Actavis does not infringes with their Suboxone® and Subutex® generics

Upsala, Sweden - March 29, 2019 – Orexo AB (publ.), the fully integrated specialty pharmaceutical company, **with strong long-term patent protection (no. 8,940,330) for its key product, Zubsolv® in the US**, until September 2032, announces that the US District Court for the District of Delaware has declared that Actavis does not infringes Zubsolv's short-term US patent no. 8,454,996 ("996"), expiring in September 2019, with their generic versions of Suboxone® and Subutex® in the patent infringement litigation against Actavis Elizabeth LLC, Actavis Pharma, Inc., and their parent company Teva (collectively "Actavis"). The court did not make a decision on the validity of the '996 patent and it remain valid until expiry in September 2019.

The decision has no implication on Zubsolv as Actavis previously has been found to infringe the Zubsolv patents (no. 8,940,330 and no. 8,454,996) with their generic versions of Zubsolv.

"Defending our technology, innovations and patents, is essential for the company and we cannot ignore when we find other companies are infringing our patents. I am very disappointed with the Court's decision and a ruling leading up to the jury trial by the judge that precluded Orexo from presenting evidence in the case related to a previous court case against Actavis. We will review this decision with our US lawyers and consider appealing the decision. **It is important to underline this decision has no impact on our profitable and growing Zubsolv business.** We will now continue to focus on delivering on our strategy of adding more products to our commercial platform and to invest in our pipeline to help more patients suffering from opioid addiction," said Nikolaj Sørensen, President and CEO at Orexo AB.

Orexo filed a patent infringement action in March 2017 alleging that Actavis's generic versions of Suboxone® and Subutex® tablets infringe Zubsolv's US patent no. '996. This followed an earlier decision by the US District Court for the District of Delaware in November 2017 which ruled patent '996 was valid and that Actavis was infringing this patent, with their generic versions of Zubsolv.

Actavis's generic versions of Suboxone® and Subutex® were approved by the FDA in February 2013 and in February 2015 respectively. Orexo was seeking compensation for damages caused by Actavis's infringement of the '996 patent since approval of these two generic products.

The legal costs related to the above litigation will decline from Q2, even if Orexo decide to appeal the decision. We expect the continued legal costs will be in line with the most recent guiding provided in the Full Year Report 2018 and any updates will be provided in the Q1 report to be published May 2nd.



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About Orexo

Orexo develops improved pharmaceuticals based on innovative drug delivery technologies. The focus is primarily on opioid addiction and pain but the aim is to address therapeutic areas where our competence and technologies can create value. The products are commercialized by Orexo in the US or via partners worldwide. The main market today is the American market for buprenorphine/naloxone products, where Orexo sells the product Zubsolv®. Total net sales for 2018 amounted to SEK 783.1 million and the number of employees was 129. Orexo is listed on the Nasdaq Stockholm Mid Cap (ORX) and is available as ADRs on OTCQX (ORXOY) in the US. The head office, where research and development is also performed, is situated in Uppsala, Sweden.

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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