Press release

Orexo wins appeal against Actavis on Zubsolv patent in the US

Uppsala, Sweden – September 10, 2018 – Orexo AB (publ.) today announces that the US Court of Appeals for the Federal Circuit found Orexo's long term Zubsolv patent US 8,940,330 to be valid, and reversed the invalidity decision previously rendered by the District Court of Delaware in November 2016. The '330 patent expires in 2032.

The decision was rendered in the patent litigation alleging that Actavis's generic Zubsolv 1.4/0.36 mg and 5.7/1.4 mg buprenorphine/naloxone products infringe Orexo's US Patent Nos. 8,454,996 (expiring in September 2019) and 8,940,330 (expiring in September 2032). In the November 15, 2016 judgment, the district court held that Orexo's '996 patent is valid and infringed by Actavis, and that Orexo's '330 patent is invalid. Orexo appealed the decision regarding the '330 patent to the Court of Appeals for the Federal Circuit on December 8, 2016, and the district court's decision has now been reversed by the Court of Appeals confirming the validity of the '330 patent until 2032. The decision on the '996 patent was not appealed and not affected by the decision of the Court of Appeals. Orexo will now request the District Court of Delaware to issue a judgment that Actavis's generic Zubsolv products infringe the '330 patent, and will not be FDA approved until 2032.

"We have continuously been confident in our IP protecting Zubsolv, not only in the US, but on a global basis. The decision today confirms the strength of our IP for Zubsolv until 2032. The patent litigation process with Actavis has been a lengthy and resource consuming process for Orexo and we are pleased we can now fully focus on growing our Zubsolv business and expanding our product pipeline, without the uncertainty created by the patent litigation process," says Nikolaj Sørensen, President and CEO of Orexo AB.

The decision does not change Orexo´s 2018 financial guidance provided previously.

Teleconference
Tomorrow, September 11, at 3 pm CET, Orexo invites analysts, investors and media to attend a teleconference, hosted by Nikolaj Sørensen, President and CEO. The event will include a Q&A session. Questions can also be sent in advance to ir@orexo.com, no later than 2.00 pm CET. Please view instructions below on how to participate.
Internet: https://tv.streamfabriken.com/pressconference-orexo**.** Telephone: (SE) +46 8 5059 6306, (UK) +44 20 313 948 30 or (US) +1 866 928 7517. Pin code: 90656232#

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About Orexo

Orexo develops improved pharmaceuticals based on innovative drug delivery technologies. The focus is primarily on opioid dependence 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 selected partners worldwide. The main market today is the American market for buprenorphine/naloxone products, where Orexo sells the product Zubsolv®. Total net sales for 2017 amounted to SEK 643.7 million and the number of employees at year-end was 90. 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.

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 8.45 pm CET on September 10, 2018.