



## Press release

### Orexo Settles Abstral® US Patent Litigation with Actavis

**Uppsala, Sweden – October 27, 2015** – Orexo AB (publ) today announced that it has entered into a settlement and license agreement with Actavis Laboratories FL, Inc. (“Actavis”) to settle the patent litigation regarding Abstral® in the U.S.

The agreement settles the patent infringement litigation commenced early this year by Orexo following Actavis’ filing of an Abbreviated New Drug Application (“ANDA”) seeking approval to market generic versions of Abstral® (fentanyl) sublingual tablets in the U.S. prior to the expiration of Orexo’s patents listed in FDA’s Orange Book for Abstral®.

The agreement allows Actavis to enter the market in June 2018, or earlier under certain conditions. Orexo’s patents listed in FDA’s Orange Book for Abstral® expire in September 2019.

#### **For further information, please contact:**

Nikolaj Sørensen, President and CEO, Orexo AB  
Tel: +46 703 50 78 88, E-mail: [ir@orexo.com](mailto:ir@orexo.com)

#### **About Abstral®**

Abstral is the leading fast-acting fentanyl product in EU intended for treatment of breakthrough pain in cancer patients. Abstral employs Orexo’s proprietary sublingual delivery technology (under the tongue). After the product development Abstral was out-licensed to Kyowa Hakko Kirin Co., Ltd and the European subsidiary ProStrakan Group plc, which still holds the rights in the EU and Japan, whereas Galena Biopharma Inc holds the rights for Abstral in the US.

For information about Abstral, please visit [www.abstral.com](http://www.abstral.com).

#### **About Orexo**

Orexo is a specialty pharmaceutical company commercializing its proprietary product Zubsolv® for treatment of opioid dependence in the US. Zubsolv is an advanced formulation of buprenorphine and naloxone using Orexo’s unique knowledge and expertise in sublingual drug delivery. R&D is focusing on reformulation of known substances to new improved products that meet great unmet medical needs by using its patented proprietary technologies. Orexo’s share is listed on Nasdaq Stockholm Exchange Mid Cap (STO: ORX) and is available as ADRs on OTCQX (ORXOY) in the US. Orexo’s global headquarters and R&D are based in Uppsala, Sweden.

For more information please visit [www.orexo.com](http://www.orexo.com) and [www.zubsolv.com](http://www.zubsolv.com).

# orexo

*Orexo AB (publ) discloses the information provided herein pursuant to the Financial Instruments Trading Act and/or the Securities Markets Act. The information was submitted for publication at 08:30 am CET on October 27, 2015.*