**Press release**

# FDA Approves Zubsolv™ for the Maintenance Treatment of Opioid Dependence

**Uppsala, Sweden – July 4, 2013 –** Orexo today announced that it has received approval from the U.S. Food and Drug Administration (FDA) for Zubsolv™ (buprenorphine/naloxone) sublingual tablet CIII. Zubsolv is indicated for use as maintenance treatment for people suffering from opioid dependence and should be used as part of a complete treatment plan to include counselling and psychosocial support. Zubsolv is a once-daily, sublingual tablet with an advanced formulation of buprenorphine and naloxone that fully dissolves within minutes. Compared with other buprenorphine/naloxone treatments, Zubsolv has higher bioavailability, faster dissolve time, and smaller tablet size with a new menthol taste. Zubsolv will be launched in September by our subsidiary in the United States, Orexo US, Inc and our partner Publicis Touchpoint Solutions.

Opioid dependence affects nearly 5 million people across the United States. Although it is a treatable condition only 20 percent of Americans suffering from opioid dependence receive treatment today. Orexo provides with Zubsolv an additional treatment choice with new unique product features that may be important for attracting and retaining more patients in treatment for opioid dependence.

“Orexo has developed Zubsolv as a novel sublingual therapy meeting the needs of millions of patients that suffers from opioid dependence to offer them a new choice of treatment. Zubsolv has in previous studies showed a high acceptability compared to the leading treatment modalities in the market. We expect Zubsolv will be well received by patients and prescribers and we anticipate a peak market potential of at least $500M,” said Nikolaj Sørensen, President and CEO of Orexo AB.

He continued adding “The approval of Zubsolv, which is based on our advanced formulation capabilities and developed using our proprietary technology, is a great tribute to the world class pharmaceutical formulation team at Orexo. Today is a proud day for Orexo with the third product approved in the US coming out of our R&D department in Uppsala.”

Opioid dependence greatly impacts the U.S. economy, with about $56 billion spent on the disease per year. In addition, the average healthcare cost per patient with opioid dependence is eight times higher compared to nondependent patients. There is also a great impact on human life, with almost 17,000 deaths from opioid pain relievers in the U.S. every year.

“In addiction medicine, the recovery process can be challenging. Products designed to meet patient preferences have the potential to more successfully support their recovery," said Louis E. Baxter, Sr., MD, FASAM, past president of the American Society of Addiction Medicine. "The approval of Zubsolv provides a new treatment option that offers unique advantages specifically designed to meet the unmet needs expressed by patients and has the

potential to improve patient adherence, thereby reducing relapse rates and improving successful patient outcomes."

Orexo's proprietary technology relating to Zubsolv is protected by patents and patent applications in the US and other markets worldwide. Projected expiry dates for this IP range from 2019 to 2032.

**For further information, please contact:**
Nikolaj Sørensen, President and CEO, Orexo AB
Tel: +46 70-350 78 88, E-mail: nikolaj.sorensen@orexo.com

**About Orexo AB**
Orexo is an emerging specialty pharma company with commercial operations in the United States and R&D in Sweden developing improved treatments using proprietary drug delivery technology. Orexo's expertise is within the area of reformulation technologies and especially sublingual formulations. The company has a portfolio of revenue-generating US and EU approved products currently marketed under license and a pipeline of several reformulations of approved compounds for areas of unmet medical need. Orexo also has collaboration projects with several international pharmaceutical companies. Orexo, with its headquarters in Sweden, is listed on NASDAQ-OMX. The largest shareholders are Novo A/S and HealthCap.

*For more information about Orexo please visit www.orexo.com.*

*Orexo is required under the Financial Instruments Trading Act to make the information in this press release public. The information was submitted for publication at 08:00 am CET on July 4, 2013.*