



## Press release

# Orexo announces decision to explore strategic alternatives for commercialization in the US

**Uppsala, Sweden – October 4, 2012** – Orexo, a Swedish specialty pharmaceutical company with a focus on innovative sublingual drug delivery technologies, today announced that it has retained Guggenheim Securities, LLC as its financial advisor to assist in the Company's review and evaluation of a full range of strategic alternatives. The Board of Directors initiated this review in conjunction with the Company's ongoing evaluation of its US commercial plan, with the aim of enhancing both commercial prospects for the Company's products and shareholder value.

Based on the recent submission of a New Drug Application (NDA) for Zubsolv™ (OX219) to the United States Food and Drug Administration (FDA) and the transfer of Abstral® US commercial rights to Orexo from January 1, 2013, Orexo projects to have two commercially available products in the United States in 2013.

Zubsolv is expected to be the first branded competitor to Reckitt Benckiser's Suboxone®, which achieved sales of USD 1.3 billion in 2011 and during 2012 has continued growing with 15 %. No generic competitors have been approved since this brand lost market exclusivity in September 2009. In clinical studies Zubsolv demonstrated an accelerated dissolve time, smaller tablet size and improved taste, resulting in a preference for Zubsolv in comparison with the Suboxone tablet. Following approval by the FDA, the Company projects to launch Zubsolv in the third quarter of 2013 after having submitted an NDA on September 6, 2012. Opioid dependence is increasingly recognized as a major health problem in the United States, with over two million Americans affected, of which only 40% receive any treatment for their addiction, costing an estimated USD 25 billion in related health care cost.

Abstral is a fast-acting sublingual fentanyl tablet intended for treatment of breakthrough cancer pain that is approved in the US, EU, and Canadian markets. In Europe, Abstral has, following its launch in 2009, become market leader amongst the novel fentanyl brands in France, Spain, Italy and UK. Based on a June 2012 agreement with partner ProStrakan Ltd plc, Orexo has reacquired the US commercial rights to Abstral from January 1, 2013, and sold a part of its future royalties from sales of Abstral in Europe. As part of the agreement, Orexo received GBP 22.5 million in upfront and will receive fixed payments of GBP 20.0 million in 2013 and GBP 12.5 million in 2014, in addition to royalties on ex-US sales of Abstral.

Orexo has not made a decision to pursue any specific transaction or other strategic alternative, so there can be no assurance that the evaluation of strategic alternatives will result in a transaction. The Company intends to provide further comments only as appropriate.

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### **About Orexo**

Orexo AB is an emerging specialty pharmaceutical company 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 EU and US approved products currently marketed under licence and a pipeline of several reformulations of approved compounds for areas of unmet medical need. Orexo also has collaboration projects with several international pharma companies. Orexo AB, with its headquarters in Sweden, is listed on NASDAQ-OMX. The largest shareholders are Novo A/S and HealthCap.

### **About Zubsolv™ (OX219)**

Zubsolv is a novel sublingual formulation of buprenorphine and naloxone using Orexo's extensive knowledge in sublingual technologies. Zubsolv is intended for maintenance treatment of people suffering from opioid dependence. Through application of its proprietary technologies Orexo has increased the bioavailability of the active ingredient, accelerated dissolve time, reduced tablet size and improved taste resulting in a preference of Zubsolv in comparison with Suboxone tablet. Zubsolv has the potential to be the first new entrant into a USD 1.3 billion market, with more than 2 million patients suffering from opioid dependence and where a majority of patients are not adequately treated today. Market potential for Zubsolv is at peak estimated at USD 500 million in sales annually. Zubsolv application for approval was submitted to FDA in September 2012, commercial launch is expected Q3, 2013, subject to FDA approval of the application.

### **About Abstral®**

Abstral is the novel, rapidly-disintegrating, sublingual (under the tongue) formulation of fentanyl, a well-established opioid used for the management of episodes of breakthrough pain experienced by cancer patients who are already receiving opioid analgesics for chronic pain. Abstral is approved in the EU, US and Canadian markets.

For more information about Orexo please visit [www.orexo.com](http://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 October 4, 2012.*