Press release – Uppsala, Sweden – December 19th, 2012

Orexo provides US commercialization progress update and direction for 2013 financial outlook

Orexo AB (Orexo) today informs about the progress towards becoming a full-fledged specialty pharmaceutical company with a US commercial presence. Orexo also announced the company project it will turn profitable in late 2013, with the current assumptions on regulatory timing and launch of Zubsolv™ in September 2013.

Zubsolv™ and Abstral® to be commercialized in partnership

Orexo have in the ongoing review of its strategic options for how to establish a US commercial infrastructure to drive sales of Zubsolv and Abstral reached important conclusions; both the Zubsolv and Abstral product lines in the US will provide healthy risk adjusted returns to Orexo and its shareholders. However, from an industrial point of view the products should ideally be commercialized by different sales forces, and should be commercialized in a partnership structure and not by Orexo alone.

During the coming months, Orexo will explore optimal deal and partnership models, which will secure Orexo a commercial presence in the US, without exposing the company to the full financial risk of commercializing both products on a stand-alone basis.

To secure sufficient time to identify the optimal partnership for Abstral, the agreement with the current license holder for Abstral in the US, ProStrakan Inc, has been extended until July 1st 2013. This matches the expected approval timelines for Zubsolv in US, which is in the beginning of July 2013. Orexo expects agreements to be finalized for both Zubsolv and Abstral in advance of this date.

Trade name for Zubsolv, acceptable to the FDA

On December 11th Orexo received notice from the FDA that the proposed trade name Zubsolv™ was acceptable to the agency. The final approval of trade name is pending the final approval of the Zubsolv label, which is standard practice from the FDA. The acceptance of the trade name is an important milestone for the tactical launch planning of this product.

Share buy-back program

Orexo launched a share buy-back program in July 2012, which initially was stopped as the company entered into a black-out period in advance of announcing the Q3-results. With the current partnering discussions showing good interests for our commercial assets, and a new black-out period emerging, the Board of Orexo do not consider it prudent to run this program now, and it will therefore not be resumed in the near term.

Orexo project profitability late 2013 - with current assumptions of a regulatory timing for Zubsolv outlined by FDA

Orexo has so far not provided guidance on its future financial performance, despite this has been a strong wish from the investor community. The Board of Orexo is for 2013 still not able to do so. The key reasons are the inherent timing risks associated with US regulatory drug approvals and timing of the commercial launch of Zubsolv. However, Orexo has a good financial position and the continuing ex-US royalties on Abstral provides a solid future

revenue base for Orexo. Directionally, and based on the assumption of a regulatory approval timing for Zubsolv as outlined by FDA with subsequent launch of Zubsolv in September, it is projected that Orexo will turn profitable in late 2013 and will have a positive cash flow in 2014.

A letter to shareholders has today December 19th, 2012, been sent to shareholders of Orexo AB and is an update of Orexo transformation and progress to a full-fledged specialty pharmaceutical company by the Chairman of Orexo, Martin Nicklasson. The letter is also available on Orexo's home page at www.orexo.com

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About Zubsolv™
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 growing USD 1.5 billion market, with more than five 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 above USD 500 million in sales annually.

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.

About Orexo
Orexo AB is an emerging specialty pharma 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 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 pharma companies. Orexo AB, 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 10:00 am CET on December 19, 2012.