Press release - Uppsala, Sweden – September 6, 2012

Swedish specialty pharmaceutical company Orexo announced today the submission of a New Drug Application for Zubsolv™ (OX219) to the US FDA

Orexo is the first company to submit a New Drug Application (NDA) for a novel combination product of buprenorphine and naloxone for treatment of opioid dependence, a condition affecting over two million Americans.

The development of Zubsolv (OX219), a product comprising buprenorphine and naloxone based on Orexo's proprietary sublingual drug delivery technology, has progressed well and faster than originally anticipated. A total of four clinical studies were completed in support of the filing, along with a CMC product stability program covering two independent manufacturing sites.

"Today´s FDA submission, the third in our short history, constitutes a substantial milestone. Very few companies of our size and lifetime have ever managed to complete three development programs, Edluar™, Abstral® and now Zubsolv. Orexo will potentially be the first company to offer an alternative treatment option to Suboxone®, which reached sales of USD 1.3 billion in 2011 and continues to exhibit steady growth of more than 15 per cent annually.

The earlier submission is expected to be of major commercial importance, as it provides a potential launch of Zubsolv in the third quarter of 2013 – ahead of other branded competitors. In our clinical studies Zubsolv has demonstrated an accelerated dissolve time, has a smaller tablet size and an improved taste, resulting in a strong preference in comparison with the Suboxone tablet. Our market insights indicate that these properties, which are important product characteristics for particularly sublingual therapies, will be important drivers for the market uptake of the product and we estimate peak sales to reach USD 500 million annually", says Anders Lundström.

Opioid dependence is increasingly recognized as a major health problem in the US, with over two million Americans affected, costing the society an estimated USD 25 billion in related health care cost. The Zubsolv (OX219) treatment option will, once approved by the FDA, be directed towards the authorized specialized prescribers of Suboxone in US, of which 5000 physicians account for about 90% of all US prescriptions.

"With the NDA submission for Zubsolv (OX219) five months ahead of schedule, we will now finalize our US commercialization plans for the brand to ensure that the substantial value of Zubsolv (OX219) will be realized", continues Anders Lundström, CEO of Orexo.

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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 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 two 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.

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