Press release - Uppsala, Sweden – August 21, 2012

Orexo reports successful achievement of product stability data for OX219 – submission of the US file now advanced 5 months to September 2012

Swedish specialty pharmaceutical company Orexo today communicated that it projects a late Q3 regulatory submission to the US regulatory agency FDA of its treatment of opioid dependence, OX219. Opioid dependence is in the US increasingly being recognized as a major health problem, with over two million Americans affected and costing the society an estimated USD 25 billion in related health care cost.

As communicated in July, following the pre-NDA meeting with FDA, the final product development task outstanding before OX219 could be submitted in the US, was completion of certain product stability tests. The necessary data have now been successfully obtained and Orexo anticipates submitting a regulatory file for OX219 in September 2012.

"I am very proud that our R&D organization has executed the development of OX219 so well. The OX219 program, which is based on Orexo's proprietary formulation technologies, has progressed with high quality and faster than originally anticipated. It is the quality of our data and regulatory approach, which we gained comfort in at the pre-NDA meeting with FDA in July, that has enabled Orexo to project submission 5 months ahead of schedule. A US submission in this quarter, gives us a potential commercial launch of OX219 in Q3 2013," says Anders Lundström, CEO of Orexo.

"Finalization of the regulatory development process for OX219, supports the aspiration of Orexo to be the first company to offer an alternative to Suboxone®, which reached sales of USD 1.3 billion in 2011 and had exhibited a steady growth of more than 15 per cent annually over the past years. Orexo estimates potential peak sales of USD 300-500 million annually of its new product." continues Anders Lundström.

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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 has 100 employees and is listed on NASDAQ-OMX. The largest shareholders are Danish Novo A/S and Swedish HealthCap.

About OX219

OX219 is a sublingual formulation of buprenorphine /naloxone using Orexo's extensive knowledge in sublingual technologies. OX219 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 strong patient preference of OX219 in comparison with Suboxone tablet. OX219 has the potential to be the first new entrant into a US$1.3bn market, with more than 2.3 million patients suffering from opioid dependence and where a majority of patients are not adequately treated today. Market potential for OX219 is at peak estimated at year sales 300 – 500 MUSD.

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 August 21, 2012.