Press release

Orexo announces positive results supporting OX219 for treatment of opioid dependence

Uppsala, Sweden, September 21, 2011 – Orexo AB (STO: ORX) today announced that it has obtained positive results in a clinical study with OX219, which is being developed for the treatment of opioid dependence. The study was designed to decide the commercial formulation and dose for OX219.

Orexo has consulted with the FDA to define the optimal development path for OX219, and will plan to pursue a final drug development and registration path according to the 505 (b) (2) procedure. This enables regulatory clearance based on documentation from an already approved drug, in this case Suboxone®. It allows for Orexo to obtain an approval without costly clinical efficacy and safety studies, and thus leads to a much faster route to market.

"Since the program started about a year ago, the development of OX219 has been carried out at fast pace. With the clear study results now obtained, we have reached another significant milestone of having selected final commercial formulation and dose for the product," said Anders Lundström, President and CEO of Orexo. "This shows the strength in our strategy to develop new proprietary drugs based on successful therapies already in clinical use."

The formulation chosen is based exclusively on Orexo's proprietary developed sublingual technology. As a consequence of this a portion of previously acquired technology, carried at a value of approximately MSEK 38 on the balance sheet, will be written off in Q3. The decision will have no impact on liquid assets.

The goal of OX219 is to create a new, proprietary drug for the treatment of opioid dependence. Orexo is conducting the clinical development program in the U.S., which is the main market for the current market-leading product for treatment of opioid dependence, Suboxone. The global market for products for the treatment of opiate dependence is currently 1.4 billion USD and is estimated to amount to 2.2 billion USD in 2019 (Datamonitor, 2010).

OX219 is one of the three development programs that Orexo intends to take all the way to market launch on its own. All of these programs are based on already known substances that Orexo has reformulated, using the sublingual route of

administration. By working with already known substances, Orexo expects to reduce development risk, shorten development time and thereby lower cost.

For further information, please contact:
Anders Lundström, President and CEO, Orexo AB
Tel: +46 706 67 22 66
Email: **anders.lundstrom@orexo.com**

About Orexo
Orexo is a pharmaceutical company focusing on developing treatments for pain and inflammation. The company has four commercialized products, several projects developed in partnership as well as three proprietary development programs. Orexo's registered products are Abstral® for the treatment of break through cancer pain, sold by Kyowa Hakko Kirin/ProStrakan Group plc. in Europe and in the USA, the sleeping pill Edluar™, sold by Meda in the USA, as well as two products for the diagnosis of Helicobacter pylori which are being marketed by the subsidiary Kibion. More information can be found at **www.orexo.com**.

Note
Orexo AB (publ) discloses the information provided in this press release pursuant to the Securities Markets Act. The information was provided for public release on September 21, 2011 at 08:00a.m. CET. This press release has been prepared in both Swedish and English. In the event of any discrepancy in the content of the two versions, the Swedish version shall take precedence.