## orexo

### Press release, May 15, 2008

# Orexo has submitted the registration application (NDA) for Sublinox<sup>TM</sup> (OX22) to the FDA on May 14 2008

Sublinox<sup>TM</sup> (OX22), for treatment of short term insomnia, contains the well-documented substance zolpidem, and is based on Orexo's sublingual technology involving a tablet placed under the tongue.

This 505 (b) (2) NDA which is based on the clinical data completed October 2007. This data shows unique properties for Sublinox<sup>™</sup> (OX22) in insomnia patients, including an earlier onset of sleep as compared to Ambien<sup>®</sup>. In addition to the earlier onset of sleep, the data also shows maintenance of sleep throughout the night. Sublinox<sup>™</sup> (OX22) also offers a more convenient way of administration compared to oral tablets since it does not need to be swallowed with water. The first evaluation will take about two months and FDA will thereafter decide if the file is accepted for final evaluation.

Meda AB acquired the exclusive world-wide commercialization rights Sublinox<sup>™</sup> (OX22) on April 14, 2008.

"This is an important first step to get Sublinox<sup>™</sup> (OX22) out on the world market and we are proud of this accomplishment" said Torbjörn Bjerke, Orexo's President and CEO.

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### **About Orexo**

Orexo is a pharmaceutical company, focusing on development of new, patented drugs by combining welldocumented substances with innovative technologies, and the development of new treatments for respiratory and inflammatory diseases.

Orexo has a broad and competitive late-stage product portfolio, including two marketed products, five products in clinical phase and two undergoing registration.

To date, Orexo have out-licensed the market rights for Rapinyl for the US, the EU and Japan markets, the worldwide market rights for Sublinox (OX22) and OX-NLA, and a out-license and research collaboration with Boehringer Ingelheim regarding the development of a new class of drugs to treat pain and inflammation. Also, Orexo has established a Nordic sales force by entering into a joint venture with ProStrakan.

Orexo has head office in Uppsala and is listed on the OMX Nordic Exchange Stockholm, Small Cap (ticker: ORX). Find out more, visit <u>www.orexo.com</u>

#### About Meda

MEDA AB (publ) is an international specialty pharma company that concentrates on marketing and marketadapted product development. Acquisitions and long-term partnerships are fundamental factors that drive the company's strategy. Meda is represented by its own organisations in 26 countries and has more than 1 500 employees within marketing and sales. Meda's products are sold in approximately 120 countries world-wide. The Meda share is listed under Large Cap on the OMX Nordic Stock Exchange. Find out more, visit <u>www.meda.se</u>.