

**Press release, December 20, 2006**

## **Orexo submits registration application (IND) to FDA to complete the Phase III clinical study for the insomnia product Sublinox™ (OX 22)**

*Orexo AB has submitted a registration application to FDA to complete Orexo's clinical Phase III program for the insomnia product Sublinox™ (OX 22) - Orexo's patented product for treatment of temporary sleeping disturbances. The studies are expected to be completed in the second half of 2007. A registration application for the US and EU markets are estimated to be submitted at the end of 2007.*

The global market for insomnia is valued at USD 3.7 billion. Orexo has in previous studies successfully proved that Sublinox™ (OX 22) shortens sleep induction in comparison with existing drugs and offers good and maintained sleep without "day-after" residual effects.

"We now complete our clinical Phase III-program to further document Sublinox™ (OX 22) and its unique clinical profile in preparation for registration and out-licensing. This means that two of our products in short time have taken important steps towards registration and market entry", says Zsolt Lavotha, President and CEO of Orexo AB.

Sublinox™ (OX 22) is a drug for the treatment of temporary sleeping disturbances. The product helps the patient to fall asleep quickly and remain asleep throughout the night. Sublinox™ (OX 22) is based on Orexo's sublingual technology, involving a tablet placed under the tongue for fast onset of action and effective uptake of the active substance over the oral sublingual mucosa. The tablet contains the well documented substance zolpidem, one of the world's most widely used substances for treating insomnia.

The technology is protected by patents in countries including the US, Japan and Australia. A patent application has also been submitted to the European Patent Office. Discussions with potential partners for out-licensing of marketing rights for Sublinox™ (OX 22) are ongoing and are expected to be concluded during the first half of 2007.

### **For more information, please contact:**

Zsolt Lavotha, President & CEO, Orexo AB

+46 (0)18 780 88 12, e-mail: [zsolt.lavotha@orexo.se](mailto:zsolt.lavotha@orexo.se)

Claes Wenthzel, Executive Vice President and CFO, Orexo AB

+46 (0)18 780 88 44, +46 (0)708-62 01 22, e-mail: [claes.wenthzel@orexo.se](mailto:claes.wenthzel@orexo.se)

**TO THE EDITORS****About Orexo**

Orexo is a pharmaceutical company that focuses on developing new pharmaceutical drugs within areas currently subject to considerable clinical needs. Orexo's products are based on existing pharmaceuticals and the company's patented drug-delivery technologies. Orexo applies its broad expertise in medicine and pharmacy to the further development of existing pharmaceutical substances. By combining well-documented compounds with its own patented drug-delivery methods and its unique expertise in "dry formulations" (for example, tablets), Orexo is able to develop new patented pharmaceuticals.

At present, the company has two products on the market, one product submitted for registration on the European market, three in late stage clinical development - one of which has been out-licensed in the US, Europe and Japan - and two projects in pharmaceutical formulation phase. Orexo has an active intellectual property rights strategy and an extensive patent portfolio to protect its products and technologies.

Orexo is listed on the OMX Nordic List Mid Cap (ticker: ORX).

[www.orexo.com](http://www.orexo.com)

**About drug delivery**

The science of drug delivery can be summarized as the process of ensuring that the active substance in a pharmaceutical product is optimally delivered to the site of action. The demand for drug-delivery products is increasing rapidly due to the fact that these new pharmaceuticals can for example offer shorter time to onset of effect or improved safety profiles.

Many pharmaceutical products on the market today have shortcomings - for example, they are slow-acting, have side effects, must be administered frequently or perhaps can only be injected. This is why demand for technologies that can make already existing products more efficient is increasing rapidly. In 2004, industry sources estimated that sales of pharmaceutical products that utilize drug-delivery methods exceeded USD 79 billion, a figure that is expected to grow to USD 117 billion by 2009 (Datamonitor 2004).

**About insomnia**

Sleep is vital. It's during sleep the body recovers and the brain works with and stores information. Most part of all learning takes place during sleep. Besides, the stress hormone cortisol is reduced during sleep.

Lack of sleep leads to stress, which in turn leads to poorer sleep and can lead to anxiety, less pain resistance and as an extension, to depression. At loss of sleep the ability to among others, perform activities of daily life demanding attention, thinking or make decisions, are influenced. Other effects of lack of sleep are, for example, shifts of temper, difficulties with coordination and ache.

**About Orexo's oral sublingual tablet formulation**

Orexo's sublingual tablet technology combines fast disintegration and dissolution in the oral cavity with rapid, site-specific absorption of the active substance across the sublingual mucosa.

When administered, the tablet is placed under the tongue where it rapidly disintegrates into ordered mucoadhesive units of the active substance. Orexo believes that the rapid and reproducible absorption of the active substance makes the dosage form ideal for treatment of conditions requiring immediate onset of effect such as acute pain. The technology can also be applied to substances such as peptides, which cannot be absorbed from the gastrointestinal tract.