



## The FDA has accepted for filing the registration application for Sublinox

The submitted registration application for Sublinox has been accepted by the FDA as complete for substantive review after initial evaluation. Sublinox contains the well-known active substance zolpidem and is based on Orexo's sublingual technology, involving a rapidly disintegrating tablet placed under the tongue.

Meda AB acquired the exclusive world-wide commercialization rights for Sublinox on April 14, 2008. *"This FDA's acceptance increases the chances for a registration approval during 2009"*, said Anders Larnholt, CEO of Meda.

The data supporting the product includes a clinical study in insomnia patients that was completed in October 2007. That study showed that Sublinox induced sleep 30 percent earlier compared to Ambien and that patients remained asleep throughout the night with comparable safety.

*"This is an important first step to get Sublinox out on the world markets"*, 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 well-documented 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. Orexo has head office in Uppsala and is listed on the OMX Nordic Exchange Stockholm, Small Cap (ticker: ORX) [www.orexo.com](http://www.orexo.com).