

**Press release, October 23, 2006**

## **Orexo receives SEK 38 M from Endo Pharmaceuticals Inc.**

*Orexo AB is receiving license revenue amounting to USD 5.2 M (slightly more than SEK 38 M) from Endo Pharmaceuticals Inc. pertaining to Rapinyl™. Endo Pharmaceuticals has exclusive rights to the further development and marketing of Rapinyl™ on the North American market and is currently conducting a Phase III program to support registration in the US for treatment of breakthrough pain in opioid-tolerant cancer patients. To date, Orexo has received license revenues from Endo Pharmaceuticals Inc. totaling about SEK 161 M.*

Rapinyl™ is intended for the management of cancer-related breakthrough pain. It is based on Orexo's unique and patented sublingual dosage method whereby a fast-dissolving tablet is placed under the tongue and the active substance is absorbed through the mucous membrane in the mouth. This new drug form is designed for rapid onset of action and predictable pain relief and also results in a simplified treatment of patients suffering from breakthrough pain.

Orexo and Endo Pharmaceuticals signed a license agreement in August 2004 that grants Endo Pharmaceuticals exclusive rights to the further development and marketing of Rapinyl™ on the North American market. Orexo received a signing fee of USD 10 M for this agreement. After completion of clinical tests, Orexo has also received a milestone-payment of SEK 51.6 M. In addition to the payments already received totaling about SEK 161 M, Orexo could also receive up to an additional USD 44.4 M (about SEK 328 M), comprising USD 10.4 M in license revenues and USD 34.0 M as a lump-sum payment on achievement of sales goals. The agreement also includes a double-digit royalty payment from future American sales.

In addition to the agreement with Endo Pharmaceuticals regarding the North America Market, market rights for Rapinyl™ are licensed to Kyowa Hakko Kogyo Co. Ltd pertaining to the Japanese market and to ProStrakan Group plc for the European market. Up to now Rapinyl™ has generated net revenues since the first license agreement 2003 of approximately SEK 218 M.

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

Orexo is a pharmaceutical company that focuses on developing new pharmaceutical drugs within areas currently subject to considerable unmet medical 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, three under regulatory and/or clinical development, one of which has been out-licensed in the US, Europe and Japan, and two projects in pharmaceutical formulation phase. Orexo has adopted an active intellectual property rights strategy and has, since its inception, built up an extensive patent portfolio to protect its products and technologies.

[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 breakthrough pain**

Breakthrough pain is defined as one or several daily, often intermittent flares ("breakthroughs") of pain that can occur even though a person is taking medications for regular pain control. Many patients with chronic cancer-related pain also experience episodes of breakthrough cancer pain.

**About 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.