Press release, August 6, 2009

Abstral™ file submitted to the FDA for approval in the USA

Uppsala, Sweden, August 6, 2009 - Orexo AB (STO: ORX) today announces that its partner, UK-based international specialty pharmaceutical company ProStrakan Group plc (LSE: PSK), has submitted the New Drug Application (NDA) for Abstral™ (for the treatment of breakthrough cancer pain in opioid-tolerant patients) to the US Food and Drug Administration (FDA).

The filing of Abstral™ will generate a milestone payment to Orexo as part of the agreement with ProStrakan for North America that in total can give USD 27 million in certain regulatory and sales milestone payments. In addition, Orexo will receive royalties on product sales.

Commenting on the filing, Torbjörn Bjerke, Orexo's President and CEO, said: "This submission is the first stage of bringing Abstral™ to the thousands of patients in the USA we believe will benefit from this novel, convenient and effective treatment. The US market is the world's largest market for breakthrough cancer pain with the number of breakthrough cancer pain attacks amounting to approximately 376 million per year(1). We are excited about the prospect of a US launch of Abstral™ by ProStrakan, Orexo's partner for Abstral™ in both North America and Europe."

The filing of Abstral™ has yet to be validated by the FDA before being accepted for review, and therefore no PDUFA date has yet been assigned.

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1) Source: Datamonitor 2006, Pipeline Insight: Breakthrough Pain

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About Abstral™

Abstral™ is a fast-dissolving tablet for sub-lingual administration of fentanyl, intended for the management of breakthrough cancer pain in patients who are already receiving opioid analgesics. It is based on Orexo's unique and patented sublingual tablet technology in which a rapidly dissolving tablet is placed under the tongue and the active substance is absorbed by the mucous membrane. Currently Abstral™ is sold in Sweden, UK, Germany and France. The product is also being prepared for registration in Japan.

License agreements for Abstral™ have been signed with ProStrakan for Europe and North America and with Kyowa Hakko Kirin for Japan. Distribution agreements regarding Abstral™ for Russia and the CIS, Bulgaria and Rumania have been signed with Gedeon Richter. A distribution agreement has been signed with Hospira for the Southeast Asian market. For the Chinese market, Orexo has signed a distribution agreement with NovaMed, and for the Israeli market Orexo has signed a distribution agreement with Neopharm.

About Orexo

Orexo is a pharmaceutical company focusing on developing treatments for pain and inflammation. The company has four commercialized products as well as a broad project portfolio in late stages of development. Sales and product development are mainly carried out through worldwide partnership agreements with larger pharmaceutical companies. Orexo has 128 employees, and has its head office located in Uppsala, Sweden. More information can be found at www.orexo.com.

Note:
This is information that Orexo AB (publ) is required to disclose pursuant to the Swedish Securities Markets Act. The information was provided for public release on August 6, 2009 at 08:30 CET.