

**Press release, June 2, 2010**

## **Orexo confirms Abstral PDUFA date update**

**Uppsala, Sweden, June 2, 2010** –Orexo AB (STO: ORX) today confirms that its partner, ProStrakan Group plc (LSE: PSK) has today announced that the US Food and Drug Administration (“FDA”) has extended the review period under the Prescription Drug User Fee Act (“PDUFA”) for Abstral™ by three months.

The FDA has issued the extension following its earlier request for additional information on the Abstral Risk Evaluation and Mitigation Strategy (“REMS”). ProStrakan has submitted this information.

Abstral is a rapidly-disintegrating tablet for sub-lingual (under the tongue) administration of fentanyl intended for the management of breakthrough pain in cancer patients who are already receiving opioid analgesics for their underlying persistent cancer pain.

**Dr Wilson Totten, ProStrakan’s Chief Executive Officer, said:**

“We have provided the clarifications on the Abstral REMS that the FDA requested and we view the extension as a positive sign of the review progress.

“Based on the FDA review progress for other REMS programmes, we had already factored in contingency timing for additional REMS review and we remain on schedule for the launch of Abstral in the US in the second half of 2010.”

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**About Abstral™**

Abstral™, developed by Orexo AB is a new, rapidly disintegrating, sublingual formulation of fentanyl, a long-established opioid used for the management of episodes of breakthrough pain experienced by cancer patients who are already receiving opioid analgesics for their chronic pain. It is based on Orexo’s unique and patented sublingual tablet technology in which a rapidly disintegrating tablet is placed under the tongue and the active substance is absorbed by the mucous

membrane. Currently Abstral™ is sold in Sweden, UK, Germany, Spain, Greece, Ireland, Slovenia, Norway, France and other. An NDA for Abstral™ has been filed in the US and Canada by the partner ProStrakan and in Japan by the partner Kyowa Hakko Kirin.

### **About Orexo**

Orexo is a pharmaceutical company focusing on developing treatments for pain and inflammation. The company has four products on the market 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's most important product is for the management of breakthrough cancer pain. It is based on Orexo's unique and patented sublingual tablet technology in which a rapidly disintegrating tablet is placed under the tongue and the active substance fentanyl is absorbed by the mucous membrane. Currently Abstral™ is launched in most of Europe. Orexo has its head office located in Uppsala, Sweden. More information can be found at [www.orexo.com](http://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 June 2, 2010 at 13:30 CET.*