Press release, September 7, 2010

Update on the FDA review for Abstral™

Uppsala, September 7, 2010 - Orexo AB (STO: ORX) announces that the US Food and Drug Administration ("FDA") has informed Orexo's partner, ProStrakan Group plc (LSE: PSK), the international specialty pharmaceutical company, that it will not yet be making a decision under the Prescription Drug User Fee Act ("PDUFA") for Abstral™.

Discussions between ProStrakan and the FDA on the review of Abstral™ are ongoing and constructive and are focused on the Risk Evaluation and Mitigation Strategy ("REMS") programme. However due to the ongoing nature of these discussions, the FDA has indicated to ProStrakan that it will not meet its previously expected PDUFA date for Abstral™ in early September. ProStrakan remains confident of approval in the near term and awaits further information from the FDA.

Abstral™ is a rapidly-disintegrating tablet for sublingual (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 pain.

Torbjörn Bjerke, Orexo's Chief Executive Officer, said:
"We are confident in the positive benefit-risk profile of Abstral™ as demonstrated from its solid clinical development and its extensive in market use in Europe, and will do everything we can to assist our partner ProStrakan in its ongoing discussions with the FDA."

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About Orexo:
Orexo is a pharmaceutical company focusing on developing treatments for pain and inflammation. Orexo is developing proprietary products based on its proven reformulation technologies, targeted at the Specialty Pharmaceutical market. Orexo intends to commercialise some of these products itself in one or more major markets. Its development activity builds on Orexo's core competences in R&D, which have previously resulted in several successful products, currently out-licensed through worldwide partnership agreements to larger pharmaceutical companies. Today, Orexo has four products on the market of which Abstral™ is a leading brand for the treatment of breakthrough pain in cancer patients in most of Europe. Orexo also has three significant partnerships with major pharmaceutical companies for research and development programs: discovery stage collaborations with Ortho-McNeil Janssen and Janssen Pharmaceutica in respiratory inflammation and with Boehringer Ingelheim for pain, both within the arachidonic acid cascade and a clinical stage development agreement with Novartis in gastrointestinal disorders. Orexo's head office is 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 September 7, 2010 at 08:15 a.m. CET.