

## Press release March 7, 2008

# Rapinyl<sup>™</sup> has received Swedish Marketing Authorization

Uppsala, Sweden, 7<sup>th</sup> March 2008 - Orexo´s licensing partner for Rapinyl<sup>™</sup>in Europe, ProStrakan Group plc announces that Rapinyl<sup>™</sup> has received Swedish Marketing Authorization. It is anticipated that the product branded as "Abstral" will be launched in Sweden in Q3 2008 through Orexo´s joint venture with ProStrakan, which operates in the Nordic countries.

Rapinyl $^{\text{TM}}$  is a fast-dissolving tablet for sublingual administration of fentanyl intended for the treatment of breakthrough cancer pain, for which ProStrakan Group plc, the international specialty pharmaceutical company, has in-licensed exclusive rights in Europe from Orexo. ProStrakan today announces that it has received Marketing Authorization in Sweden for Rapinyl $^{\text{TM}}$ .

Sweden is the reference member state (RMS) for the wider EU regulatory filing of Rapinyl $^{\text{TM}}$ . The Swedish Medical Products Agency has taken the decision to issue a Marketing Authorization for Sweden alone based on its assessment report made as RMS for the EU regulatory procedure.

ProStrakan expects that the wider EU regulatory procedure will complete during 2008. Meanwhile, it is anticipated that the product, branded as "Abstral", will be launched in Sweden in Q3 2008. Abstral will be marketed in Sweden through Orexo´s joint venture with ProStrakan, which operates in the Nordic countries.

"This is an important milestone for Orexo and our late stage product portfolio. The Swedish regulatory authority's decision to issue a Marketing Authorization for Rapinyl™ (Abstral) while the EU regulatory procedure is still under way underlines their continued support for Europe-wide approval of this product", said Dr Torbjörn Bjerke, President & CEO of Orexo.

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#### TO THE EDITORS

## About Rapinyl<sup>™</sup>

Rapiny $1^{TM}$  is a product for the treatment of acute pain. The first indication is breakthrough pain in cancer. Rapinyl<sup>™</sup> is based on Orexo's unique proprietary technology for sublingual administration, where a tablet is placed under the tongue and rapidly disintegrates into ordered mucoadhesive units of the active substance. This novel pharmaceutical preparation combines the properties of fast dissolution, quicker onset of action and predictable effect.

#### **About Orexo**

Orexo is a specialty pharmaceutical company, focusing on development of new, patented drugs by combining welldocumented 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.

To date, Orexo have out-licensed the market rights for Rapinyl<sup>™</sup> for the US, the EU and Japan markets, and signed a research collaboration with Boehringer Ingelheim regarding the development of a new class of drugs to treat pain and inflammation. Also, Orexo has established a Nordic sales force by entering into a joint venture with ProStrakan.

Orexo has head office in Uppsala and is listed on the OMX Nordic Exchange Stockholm, Small Cap (ticker: ORX).

www.orexo.com

### **About ProStrakan**

ProStrakan Group plc is a rapidly growing international specialty pharmaceutical company engaged in the development and commercialisation of prescription medicines for the treatment of unmet therapeutic needs in major markets.

ProStrakan's head office and development facilities are situated in Galashiels in Scotland. EU-wide sales and marketing of ProStrakan's portfolio of products are handled by commercial subsidiaries in the UK, France, Germany, Spain and other EU countries. ProStrakan has recently announced plans to expand its operations into the US.

www.prostrakan.com

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