



Press release

## **Orexo sells Abstral® in the United States to Galena Biopharma, Inc.**

**Telephone conference March 18 at 1:00pm CET**

**Uppsala, Sweden – March 18, 2013** – Orexo AB today announced that it sold Abstral® (fentanyl) Sublingual Tablets in the United States to Galena Biopharma, Inc. (NASDAQ: GALE). Under the terms of the agreement, Galena Biopharma will pay Orexo US\$10 million upfront and an additional US\$5 million within the first twelve months after signing, plus low double digit royalties and milestone payments based on pre-specified sales levels.

Galena Biopharma is a biopharmaceutical company developing innovative, targeted oncology treatments that address major unmet medical needs to advance cancer care. Abstral is a novel, rapidly-disintegrating, sublingual (under the tongue) rapid acting formulation of fentanyl, a well-established opioid, and is indicated for the management of breakthrough pain.

Abstral is the leading rapid acting fentanyl product in Europe, where it achieved full year sales of US\$54 million in 2012, and continues to exhibit a steady growth of 42% for Q4-2012 over Q4-2011. By the second half of 2012, the average volume market share of Abstral in the major European markets reached 29%. Abstral is marketed in Canada by Paladin Labs, and has been filed for regulatory approval in Japan by Kyowa Hakko Kirin Co Ltd.

Abstral was approved by the US Food and Drug Administration in 2011. Orexo announced in June 2012 the acquisition of all US rights to Abstral from ProStrakan Group plc as a part of a reconfiguration of the worldwide rights to Abstral. With completion of the current transaction Orexo has secured net cash payments of over SEK 700 million (US\$ 110 million) and in addition milestones and royalty payments, as a result of the worldwide reconfiguration of Abstral.

During the last five months, Orexo has evaluated the optimal path forward for Abstral in the United States. The US market for rapid acting fentanyl products reached US\$400 million in 2012. Given the continued success that Abstral achieves in Europe, Orexo wanted to secure a commercial team that could drive Abstral to a similar success in the United States. To attain this, Abstral needed to be commercialized by a dedicated partner with insight into the US pharmaceutical market for treatment of cancer and pain. Market research has documented a substantial unmet patient need for improved treatment of breakthrough cancer pain across oncology centers in the United States.



“With Galena Biopharma, Orexo has found a very committed partner for Abstral in the United States, who is well positioned to realize the significant potential that exists for Abstral. I have been impressed by the competence, experience and dedication to Abstral from the Galena Biopharma management team” stated Nikolaj Sørensen, President and CEO of Orexo. “With an agreement in place for Abstral, we have further strengthened our financial capacity to ensure the optimal launch of Zubsolv in the United States, which will be the primary focus for Orexo in 2013”.

“Orexo is a proven leader in developing and commercializing novel formulation technologies, particularly sublingual formulations to enhance drug delivery and performance,” said Mark J. Ahn, Ph.D., President and Chief Executive Officer of Galena Biopharma. “The acquisition of Abstral in the United States diversifies and strengthens our pipeline, providing Galena with an FDA approved product that will become the cornerstone of our commercial strategy. Galena’s launch of Abstral will build relationships with future prescribers of NeuVax™, which is currently in global Phase 3 clinical trials in node positive HER2 IHC 1+/2+ breast cancer patients. Medical oncologists, who manage tumor and treatment related pain, predominantly prescribe transmucosal immediate release fentanyl for advanced breast cancer and other solid tumor patients who represent the majority of overall prescriptions.”

Guggenheim Securities acted as exclusive financial advisor and Dechert LLP as legal advisor to Orexo in connection with the transaction.

### **Telephone conference**

CEO Nikolaj Sørensen will present the background to the agreement with Galena Biopharma at a teleconference today at 1:00pm CET. The audiocast will be accessible live via the link below and on the website.

Internet: <http://livecast.wehay.com/playontv/130318/orexo/>

Telephone: +44 (0) 20 3003 2666 - Standard International Access; 020-089 6377 - Stockholm Toll Free; 0808-109 0700 - UK Toll Free; +1 866 966 5335 - USA Toll Free

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### **About Abstral**

Abstral is the novel, rapidly-disintegrating, sublingual (under the tongue) formulation of fentanyl, a well-established opioid used for the management of episodes of breakthrough pain experienced by cancer patients who are already receiving opioid analgesics for chronic pain. Abstral is approved in the EU, US and Canadian markets.



### **About Orexo**

Orexo AB is an emerging specialty pharma company developing improved treatments using proprietary drug delivery technology. Orexo's expertise is within the area of reformulation technologies and especially sublingual formulations. The company has a portfolio of revenue generating EU and US approved products currently marketed under licence and a pipeline of several reformulations of approved compounds for areas of unmet medical need. Orexo also has collaboration projects with several international pharma companies. Orexo AB is headquartered in Sweden has 90 employees and is listed on NASDAQ-OMX. The largest shareholders are Novo A/S and HealthCap. For information about Orexo AB please visit **[www.orexo.com](http://www.orexo.com)**.

### **About Galena Biopharma**

Galena Biopharma, Inc. (NASDAQ: GALE) is a Portland, Oregon-based biopharmaceutical company that develops innovative, targeted oncology treatments that address major unmet medical needs to advance cancer care. For more information about Galena Biopharma Inc please visit **[www.galenabiopharma.com](http://www.galenabiopharma.com)**.

*Orexo is required under the Financial Instruments Trading Act to make the information in this press release public. The information was submitted for publication at 08:00am CET on March 18, 2013.*