

**Press release August 19, 2004**

## **Orexo AB announces a major pharmaceutical deal for Rapinyl<sup>TM</sup> in North America**

*Orexo AB and Endo Pharmaceuticals Inc. today announced that they have entered into a licensing agreement under which Endo Pharmaceuticals receives exclusive rights to develop and market Rapinyl<sup>TM</sup> – Orexo's patented product for management of breakthrough cancer pain – for the North American market.*

In return for these rights, Orexo will receive an up-front license fee payment of \$10 million, in addition to other license fees and payments based on development and regulatory milestones, which may total up to \$22.1 million through FDA approval of Rapinyl's New Drug Application. The agreement also provides for double-digit royalties upon commercial sales and may include sales milestones if defined sales thresholds are achieved.

Rapinyl<sup>TM</sup> is an oral, fast-dissolving tablet of fentanyl for the treatment of breakthrough cancer pain. It is based on Orexo's unique proprietary technology for sublingual administration. This novel pharmaceutical preparation provides rapid absorption of the active substance and a fast onset of action. Currently in Phase II clinical development, this product has demonstrated enhanced absorption characteristics and is intended for the management of breakthrough pain in opioid tolerant cancer patients. Endo anticipates that it will commence Phase III clinical trials in 2005.

"We are very pleased to be partnering Rapinyl with Endo Pharmaceuticals for the North American market", said Zsolt Lavotha, president and CEO of Orexo AB. "Endo Pharmaceuticals is a market leader in pain management products, with a strong reputation for research and development as well as marketing and sales. We believe Endo Pharmaceuticals is the ideal partner to fully exploit the potential of Rapinyl in North America. The agreement demonstrates the strength of our business model to target unmet therapeutic needs by innovative drug formulations based on well-known compounds."

"We are delighted to add this novel proprietary product to our portfolio," said Carol A. Ammon, chairman and chief executive officer of Endo. "We believe that this product is an excellent strategic fit for us and reinforces our continued leadership position in pain management. The benefits of Rapinyl are believed to include both a fast onset of action and added convenience, which we believe will improve compliance in cancer patients that experience breakthrough pain."

The Japanese marketing rights for Rapinyl were licensed to Kyowa Hakko Kogyo Co. Ltd in January 2003.

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**Orexo AB (publ)**

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### About Orexo

**Orexo AB** is a product focused drug delivery company. Orexo develops documents and registers innovative pharmaceutical products with clinical benefits, based on patented, proprietary technology platforms. The products are developed on the basis of defined therapeutic needs with the objective of reaching a global market. The company is based in Uppsala, Sweden.

[www.orexo.com](http://www.orexo.com)

### About Endo

A wholly owned subsidiary of Endo Pharmaceuticals Holdings Inc., **Endo Pharmaceuticals Inc.** is a fully integrated specialty pharmaceutical company with market leadership in pain management products. The company researches, develops, produces and markets a broad product offering of branded and generic pharmaceuticals, meeting the needs of healthcare professionals and consumers alike. Endo Pharmaceuticals is headquartered in Chadds Ford, Pennsylvania, USA.

[www.endo.com](http://www.endo.com)

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