



Press release

Orexo presents new focus and plans for commercial expansion – accelerated development of OX219

Uppsala, May 3, 2012 – At today's Capital Markets Day, Orexo announces that – following a successful restructuring – Orexo is now sharpening focus further on development and commercializing own products based on its proprietary drug-delivery technologies applied to well-known substances. The switch from relying solely on partners to commercialize the Company's innovations entails substantially higher control of the value created, and the chosen product development focus is associated with reduced risks, shorter lead-times and thus lower development costs compared to conventional drug-discovery efforts.

Orexo's management explains that the company will focus its resources on two very attractive assets, **OX219** and **OX51**, and reports on the status of the development programs and future market potential. Of these two projects, OX219 has advanced the most and is considered by Orexo to be the company's most valuable asset.

OX219 is intended for the treatment of opioid dependence. Orexo has assigned this project the highest priority and currently believes that OX219 could be ready for submission of a registration application to the FDA as early as in the first quarter of 2013, assuming that the results of the clinical studies are favorable.

The total US market for the treatment of opioid dependence is estimated to about USD 1.2 billion (SEK 8 billion) and is growing above 20 percent annually. Assuming that OX219 is one of the first new products to be launched in the US market, it will represent a significant commercial value for Orexo. Given that the product would be able to obtain a 10-20 percent market share, this would correspond to an annual sales of SEK 1-2 billion.

OX51 is being developed for the treatment of acute intensive pain in conjunction with care-related diagnostic or therapeutic procedures. Today, Orexo is proud to reveal that OX51 is based on the active substance alfentanil. To date, no one has yet made alfentanil available in an oral tablet formulation. Consequently, OX51 is estimated to have a highly attractive profile in relation to pain relief for such indication. The annual sales potential is estimated at SEK 0.7-1 billion.

Orexo is currently analyzing various strategic options to establish a commercial presence in the US market, and this process will be completed by Q4-2012. Furthermore, the company expects that strategic partnerships on the lead projects will be implemented in other markets, once product development has been completed.

The new integrated sales model for diagnostic breath tests for *Helicobacter Pylori*, which is sold via Orexo's wholly owned subsidiary Kibion, is also presented. Kibion has now established a direct market presence in Germany through the acquisition of Wagner Analysen Technik GmbH. Kibion projects an increase in sales of more than 35 percent in



2012 and plan to further grow sales to 100 MSEK by year 2015. Kibion plans to expand into other geographical markets in the years ahead.

“Orexo’s new management is currently fully focused on taking our exciting OX219 and OX51 programs to registration and successful launch. Our assessment is that both programs have very high sales potential. Revenues from Orexo’s already launched drugs, such as Abstral, and revenues from Kibion are expected to continue to grow favorably, providing financial strength to deliver our prioritized development programs. These activities in combination with establishment of a commercial presence in the US, will create significant value for Orexo’s shareholders and others,” says Anders Lundström, President and CEO.

The presentation used at the Capital Markets Day will be published at Orexo’s homepage www.orexo.com.

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About Orexo

Orexo develops and markets pharmaceuticals based on proprietary drug delivery technologies applied to well-known substances. The company's largest product is Abstral, a treatment of breakthrough cancer pain. Orexo’s shares are listed on the Stockholm Stock Exchange and Danish Novo A/S and Swedish HealthCap are the largest shareholders. More information can be found at www.orexo.com.

Note:

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