



Press release, August 20, 2010

Orexo launches next step in strategy, new development programs and announces change of CEO

Uppsala, August 20, 2010 - Orexo AB's (STO: ORX) Board of Directors today have launched the next step in its strategy to focus its business model on deploying Orexo's well established and proven reformulation technologies to develop new proprietary products targeted at the Specialty Pharmaceutical market. As part of this strategy, Orexo has initiated the first three development programs. The company intends to commercialise these products through an Orexo-owned marketing and sales organization, starting in one of the major markets EU or USA.

To optimise execution of this strategy, the company is seeking to add leadership with broad international commercial experience. The company has therefore initiated a search for a new Chief Executive Officer. Torbjörn Bjerke will continue his leadership position as President and Chief Executive of Orexo AB until a successor has been found. To leverage Torbjörn Bjerke's successful history with the company and his business development expertise, Orexo's two largest shareholders, Healthcap and Novo A/S, will recommend the nomination committee of Orexo to nominate him to become a non-executive director.

Chairman of the Board Håkan Åström commented: "Orexo has built detailed knowledge of drug-formulation, clinical development and regulatory approval processes, and has established itself as a high-quality organisation with a track record of developing competitive products. Until today, we have focused on out-licensing our products to international partners.

Our successful partnership agreements with ProStrakan Group plc and others related to Abstral™, the recent alliance with Ortho-McNeil-Janssen Pharmaceuticals and Janssen Pharmaceutica within the areas of asthma and inflammatory diseases, the collaboration with Boehringer Ingelheim within pain and inflammation, the agreement with Meda regarding Edluar™ and OX-NLA, and the agreement with Novartis within gastrointestinal disorders are important out-licensing agreements, which represent significant potential financial value for Orexo. The potential development milestones of these assets amount to more than SEK 6 billion, not including sales milestones or royalties. Torbjörn Bjerke's



leadership has played an important role in completing these agreements, and we are very pleased with his achievements during his time as CEO of the company.

The Board of Directors today decided that future programs should be aimed at developing proprietary products which Orexo intends to commercialise itself, starting in one of the major markets; the EU or the USA. This will involve the building or acquisition of an international sales organisation in order to retain more of the economic value from sales of products developed by Orexo.

From an R&D perspective, the new strategy is fully aligned with the core competences in Orexo, which have previously resulted in successful development, regulatory approval and commercialization of several products in EU and the US, of which Abstral™ is the most promising today.

Current funds will support all the programs below through clinical Phase I, and at least one of these programs through to approval, even in the absence of additional milestones from partnered discovery and development programs. Further development activities on currently un-partnered programs will be discontinued.”

Three new development programs within specialty areas initiated

Orexo today announces that the first patients have been dosed in a Phase I clinical study with a proprietary reformulation product candidate, OX219, directed towards treatment of opioid addiction. OX219 is an improved version of the product candidate originally acquired with the PharmaKodex transaction using Orexo proprietary technologies. This product will compete in the opioid addiction market which is today worth an estimated US\$ 1.4 billion globally and is currently dominated by Suboxone®. Results from the initial study will be communicated during the fourth quarter along with further details of the development program.

Later this year a Phase I clinical trial of a second reformulation program, OX51, will be initiated aiming at treatment and prevention of acute intense pain episodes in opioid-tolerant and opioid-naïve patients treated in the hospital setting. This program addresses a market opportunity of approximately 100 million acute intense pain episodes in Europe and the USA. Results from the initial clinical trial of this program will be communicated during the first quarter of 2011 along with further details of the development program.

Finally, Orexo also announces today progress of a third new reformulation program, OX27, directed towards the treatment of breakthrough pain in cancer patients, which will reach clinical Phase I early in Q1-2011. The program, built on Orexo’s experience and expertise in developing Abstral™, will aim to provide



further clinical benefits, and thereby advance the treatment of breakthrough pain for cancer patients further. This market amounts to approximately US\$ 1.5 billion in the EU and the USA. Abstral™ constitutes a leading brand on the EU markets where it is available today. Results from this program will be communicated during the second quarter of 2011 along with further details of the development program.

Orexo owns all commercial rights to OX219, OX51 and OX27 globally.

All three new development programs are based on the proprietary Orexo sublingual tablet formulation technologies and know-how originally developed for Abstral™ and Edluar™. Further technology improvements, which for example enable taste improvements, faster and more controlled absorption and lower inter- and intra-patient variability, are also being deployed.

Orexo's President and CEO Torbjörn Bjerke comments: "Since my appointment as CEO, Orexo has undergone a major transformation, from having both discovery of new chemical entities and programs with product re-formulation towards becoming a commercially-focused specialty pharma company which is directing its internal development activities on reformulation of products with known chemical entities. During my time at Orexo, we have accomplished a number of important milestones; we have proven that we are capable of developing products up until the marketing phase, we have reached successful license agreements with strong partners around the world and we have implemented radical cost savings during the last year which have significantly improved our cost efficiency. These measures have collectively created a foundation for Orexo's future and with the launch of the next step in our strategy, we now have a stronger company."

Audiocast telephone conference held today at 10:00 CET:

Orexo's Chairman Håkan Åström and CEO Torbjörn Bjerke will present the updated strategy in a telephone conference at 10.00 CET.

To participate in the telephone conference, please use the following details to dial-in:

SE: +46 (0)8 505 598 53

UK: +44 (0) 203 043 24 36

To listen to the telephone conference via internet, please use the following link

<http://webcast.zoomvision.se/clients/orexo/100820/> or visit **www.orexo.com**.



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More information about Orexo can be found at www.orexo.com.

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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 August 20, 2010 at 08:00 a.m. CET.