

## Stock Exchange Release

13 August 2007 at 6.00 pm

## Orion comments on ANDA filing of generic entacapone (Orion's proprietary drug Comtan®) in the United States

Company states the realisation of generic competition is neither certain nor imminent

Orion Corporation has been informed that an Abbreviated New Drug Application (ANDA) has been filed with the U.S. Food and Drug Administration (FDA) by a generic drug company seeking authorisation to produce and market a generic version of entacapone (200 mg tablets) in the United States. Entacapone is the active ingredient in Comtan<sup>®</sup>, a product originated by Orion Corporation and marketed in the United States by its exclusive licensee, Novartis, for the treatment of Parkinson's disease. At this point, the ANDA review process is just beginning and the realisation of generic competition is neither certain nor imminent.

The applicant has filed so-called Paragraph IV certifications challenging three of five Orion U.S. patents covering Comtan and listed in the Orange Book, the FDA's official listing of approved drug products. The patents receiving Paragraph IV certifications are U.S. Patent No. 5,135,950, U.S. Patent No. 5,446,194, and U.S. Patent No. 6,599,530. Regarding the remaining two U.S. patents not receiving Paragraph IV certifications (U.S. Patent Nos. 4,963,590 and 5,112,861), the applicant has certified with the FDA that it would not seek approval to market generic entacapone before the expiry of those two patents, the latest of which expires May 12, 2009.

Paragraph IV certifications are not uncommon in the USA.

Orion is currently evaluating its legal options to protect its rights. Under the U.S. system, if a patent owner brings a lawsuit against an ANDA applicant within a certain time limit, there will be a 30-month stay of final FDA approval. During that time, the FDA can give only a tentative approval to the ANDA applicant unless the applicant obtains a favorable decision on all challenged patents in the lawsuit.

## **ABOUT ORION**

Orion is dedicated to treating and preventing disease by discovery and developing innovative medicinal treatments. In 2006, Orion generated sales of EUR 641.1 million, invested EUR 84.1 million in research and development and employed approximately 3,060 people Orion corporate headquarters are in Espoo, Finland. For more information, please visit: <a href="http://www.orion.fi/english/">http://www.orion.fi/english/</a>.

**Orion Corporation** 

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Statements in this news release other than historical information are forward-looking statement subject to risks and uncertainties. Actual results could differ materially depending on factors such as the availability of resources, the timing and effects of regulatory actions, the strength of competition, the outcome of litigation and the effectiveness of patent protection. Additional information regarding risks and uncertainties is set forth in Annual Report for 2006.

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