URGENT
PRESS RELEASE



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## Wockhardt announces Entacapone patent settlement with Orion Corporation

## Mumbai, April 29, 2009

Pharmaceutical and biotechnology major Wockhardt Limited today announced that the Company and Wockhardt USA LLC, a subsidiary of the Company, have executed a settlement and license agreement with Orion Corporation regarding Wockhardt's submission of Abbreviated New Drug Applications (ANDAs) for the generic versions of Orion's Comtan® and Stalevo® products. Comtan is used in the treatment of Parkinson's disease as an adjunct to levodopa / carbidopa therapy. Stalevo is a combination of carbidopa, levodopa and entacapone for the treatment of Parkinson's disease. Both products contain entacapone, a COMT enzyme-inhibiting agent. As per IMS Dec 2008, the annual sales of Comtan and Stalevo products in the US were \$87 million and \$113 million respectively.

Commenting on the settlement, Wockhardt Chairman Habil Khorakiwala commented, "We are pleased with the agreement and are excited to have capitalised on these first-to-file opportunities, which are an indication of the strength of our R&D and Intellectual Property initiatives. With over sixty products in the US market and a growing ANDA pipeline of technologically challenging products, we will look to continue our success in the United States market."

Orion filed the first lawsuit in the US in 2007 and thereafter two additional lawsuits were filed in 2008. The settlement agreement relates to all three suits. Under the terms of the settlement agreement, Wockhardt will be able to launch generic versions of Comtan and Stalevo on September 30, 2012, or possibly even earlier, subject to certain conditions. Wockhardt, as the first generic challenger to the Comtan patents, is eligible for 180 days of marketing exclusivity upon launch. Wockhardt also is the first-to-file on four strengths of Stalevo and is hence eligible to have 180 days of marketing exclusivity on these strengths upon launch. Additional terms related to the settlement remain confidential, and the agreement is subject to review by the US Department of Justice and the Federal Trade Commission.

With 23 ANDA approvals by the US FDA in 2008, Wockhardt was amongst the Top 5 companies in the world, in terms of the highest number of generic approvals (source: Generics Bulletin 2009).

## About Wockhardt

Wockhardt is a technology-driven global pharmaceutical and biotechnology major with an innovative multi-disciplinary research and development programme. It has 5 research centres and 15 world-class manufacturing plants dotting various countries and continents that are compliant to international regulatory standards such as the US FDA, MHRA and other global regulatory bodies. It has end-to-end integrated capabilities for its products, starting with manufacture of the oral and sterile API's, the dosage forms and marketing through its wholly owned subsidiary in the US. Wockhardt has a global footprint including the US, UK, Ireland, France and Germany with a multi-ethnic workforce from 14 different nationalities.