



Alkermes Announces Submission of Complete Response to FDA for VIVITROL(TM) New Drug Application

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CAMBRIDGE, Mass., Feb 17, 2006 (BUSINESS WIRE) -- Alkermes, Inc. (Nasdaq: ALKS) today announced the submission of a complete response to the approvable letter issued in December 2005 by the U.S. Food and Drug Administration (FDA) regarding the New Drug Application (NDA) for VIVITROL(TM) (naltrexone for extended-release injectable suspension). Alkermes expects the FDA to classify the complete response as a Class 1 resubmission, under which the FDA will seek to complete its review of the resubmission within 60 days from the time of resubmission.

VIVITROL is under review for the treatment of alcohol dependence in combination with a treatment program that includes psychosocial support. In March 2005, Alkermes submitted an NDA for VIVITROL(TM). In June 2005, Alkermes and Cephalon, Inc. (Nasdaq: CEPH) entered into a collaboration agreement to develop and commercialize VIVITROL(TM) in the United States for the treatment of alcohol dependence.

About Alkermes

Alkermes, Inc. is a pharmaceutical company that develops products based on sophisticated drug delivery technologies to enhance therapeutic outcomes in major diseases. The Company's lead commercial product, RISPEDAL(R) CONSTA(R) ((risperidone) long-acting injection), is the first and only long-acting atypical antipsychotic medication approved for use in schizophrenia, and is marketed worldwide by Janssen-Cilag (Janssen), a wholly-owned division of Johnson & Johnson. The Company's lead proprietary product candidate, VIVITROL(TM) (naltrexone for extended-release injectable suspension), is a once-a-month injection for the treatment of alcohol dependence. The Company has a pipeline of extended-release injectable products and pulmonary drug products based on its proprietary technology and expertise. Alkermes' product development strategy is twofold: the Company partners its proprietary technology systems and drug delivery expertise with several of the world's finest pharmaceutical companies; and it also develops novel, proprietary drug candidates for its own account. The Company's headquarters are in Cambridge, Massachusetts, and it operates research and manufacturing facilities in Massachusetts and Ohio.

Certain statements set forth above may constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to whether the complete response will be characterized as a Class 1 resubmission and assigned a 60 day review period by the FDA. Although the Company believes that such statements are based on reasonable assumptions within the bounds of its knowledge of its business and operations, the forward-looking statements are neither promises nor guarantees and the Company's business is subject to significant risk and uncertainties and there can be no assurance that its actual results will not differ materially from its expectations. For further information with respect to factors that could cause the Company's actual results to differ materially from expectations, reference is made to the reports the Company filed with the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended. The forward-looking statements made in this release are made only as of the date hereof and the Company disclaims any intention or responsibility for updating predictions or financial expectations contained in this release.

SOURCE: Alkermes, Inc.

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