



FDA Extends PDUFA Date for VIVITREX(R) to December 30, 2005; Cephalon and Alkermes Continue to Anticipate VIVITREX Launch in First Half of 2006

September 20, 2005

FRAZER, Pa. & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Sept. 20, 2005--Cephalon, Inc. (Nasdaq: CEPH) and Alkermes, Inc. (Nasdaq: ALKS) announced today that they have received notification from the United States Food and Drug Administration (FDA) that the agency has extended the action date to December 30, 2005 for its priority review of the New Drug Application (NDA) for VIVITREX(R) (naltrexone long-acting injection) for the treatment of alcohol dependence. The original action date under the Prescription Drug User Fee Act (PDUFA) for the VIVITREX NDA was September 30, 2005. The companies continue to anticipate the launch of VIVITREX in the first half of 2006.

The extension is a result of the FDA classifying a recent response by Alkermes as a major amendment to the NDA, which permits the FDA to extend the action date by 90 days under PDUFA regulations.

"We will continue to work closely with the FDA to assist them in the completion of the review of the application in a timely manner," stated Richard Pops, CEO of Alkermes. "This extension does not affect our plans for the timing of the commercial launch of VIVITREX."

"We have made great progress in developing commercial launch plans for VIVITREX and remain on schedule for a product launch in the first half of 2006," said Frank Baldino, Jr., Ph.D., Chairman and CEO of Cephalon.

In June 2005, Cephalon and Alkermes entered into an agreement to develop and commercialize VIVITREX in the United States for the treatment of alcohol dependence.

About Cephalon, Inc.

Founded in 1987, Cephalon, Inc. is an international biopharmaceutical company dedicated to the discovery, development and marketing of innovative products to treat sleep and neurological disorders, cancer and pain. Cephalon currently employs approximately 2,300 people in the United States and Europe. U.S. sites include the company's headquarters in Frazer, Pennsylvania, and offices, laboratories or manufacturing facilities in West Chester, Pennsylvania, Salt Lake City, Utah, and suburban Minneapolis, Minnesota. Cephalon's European headquarters are located in Maisons-Alfort, France and other European offices are located in Guildford, England, and Martinsried, Germany.

The company currently markets four proprietary products in the United States: PROVIGIL(R) (modafinil) (C-IV), GABITRIL(R) (tiagabine hydrochloride), ACTIQ(R) (oral transmucosal fentanyl citrate) (C-II) and TRISENOX(R) (arsenic trioxide) injection, and more than 20 products internationally. Full prescribing information on its U.S. products is available at www.cephalon.com or by calling 1-800-896-5855.

About Alkermes, Inc.

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, RISPERDAL 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 subsidiary of Johnson & Johnson. The Company's lead proprietary product candidate, VIVITREX(R) (naltrexone long-acting injection) is being developed as a once-monthly 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, statements concerning regulatory approval for, and the launch and subsequent successful commercialization of VIVITREX. Although both Cephalon and Alkermes believe that such statements are based on reasonable assumptions within the bounds of their respective knowledge, the forward-looking statements are neither promises nor guarantees, and both the Alkermes and Cephalon businesses are subject to significant risk and uncertainties. As such, there can be no assurance that either or both of Cephalon's or Alkermes' actual results will not differ materially from their respective expectations. Such expectations are subject to risks, including, among others whether Alkermes can successfully scale up and manufacture VIVITREX at a commercial scale; whether VIVITREX will ultimately receive marketing approval from FDA, and, if approved, whether it will be launched and commercialized successfully by Alkermes and Cephalon; the outcome of clinical and preclinical work Alkermes and its partners are pursuing, including the results of clinical trials; decisions by the FDA regarding VIVITREX, which may be based on interpretations of data that differ from Alkermes' interpretations; and whether VIVITREX in commercial use, may have unintended side effects, adverse reactions or incidents of misuse that could cause the FDA or other health authorities to require post approval studies or require removal of the product from the market. For further information with respect to specific risks, uncertainties and factors that could cause actual results to differ from expectations, reference is made to the reports on Forms 8-K, 10-Q and 10-K that Cephalon and Alkermes each 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 both Cephalon and Alkermes disclaim any intention or responsibility for updating such statements, except as may be required by law.

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