ALKERMES INC
Form 8-K
March 07, 2006

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SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K
CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934
Date of report (Date of earliest event reported): March 7, 2006
ALKERMES, INC.
(Exact Name of Registrant as Specified in its Charter)

PENNSYLVANIA	**1-14131**	**23-2472830**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

88 Sidney Street **Cambridge, Massachusetts** (Address of principal executive offices)	**02139** (Zip Code)

Registrant s telephone number, including area code: **(617) 494-0171**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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Item 7.01. Regulation FD Disclosure.

On March 1, 2006, Alkermes, Inc., received notification from the U.S. Food and Drug Administration (FDA) regarding the Company s response to the approvable letter for the VIVITROL (naltrexone for extended-release injectable suspension) New Drug Application (NDA) issued by the FDA in December 2005. The FDA considers the response, received on February 16, 2006, to be a complete, Class I response. Under the Prescription Drug User Fee Act (PDUFA), the FDA has set a targeted response date of April 16, 2006.

In March 2005, Alkermes submitted an NDA for VIVITROL. In June 2005, Alkermes and Cephalon, Inc. entered into a collaboration agreement to develop and commercialize VIVITROL in the United States for the treatment of alcohol dependence.

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® [(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™ (naltrexone for extended-release injectable suspension), 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.

About Cephalon, Inc.

Founded in 1987, Cephalon, Inc. is an international biopharmaceutical company dedicated to the discovery, development and marketing of innovative products in four core therapeutic areas: central nervous system, pain, oncology and addiction. Cephalon currently employs approximately 3,000 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. The company currently markets four proprietary products in the United States: PROVIGIL® (modafinil) [C-IV], GABITRIL® (tiagabine hydrochloride), ACTIQ® (oral transmucosal fentanyl citrate) [C-II] and TRISENOX® (arsenic trioxide) injection, and numerous products internationally.

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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 related to attaining final regulatory approval of VIVITROL. Although both Alkermes and Cephalon 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 Alkermes or Cephalon s actual results will not differ materially from their respective expectations. Such expectations are subject to risks, including, among others; whether VIVITROL will ultimately receive marketing approval from the FDA in a timely fashion or at all, and, if approved, whether it will be launched and commercialized successfully by Cephalon and Alkermes; whether Alkermes can successfully scale up and manufacture VIVITROL at a commercial scale; decisions by the FDA regarding VIVITROL, which may be based on interpretations of data that differ from Alkermes interpretations; and whether VIVITROL 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 Alkermes and Cephalon 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 Alkermes and Cephalon disclaim any intention or responsibility for updating such statements, except as may be required by law.

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SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ALKERMES, INC.

Date: March 7, 2006

By: /s/ James M. Frates
James M. Frates
Vice President, Chief Financial Officer
and Treasurer