

ALKERMES INC
Form 8-K
October 12, 2005

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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): October 6, 2005

ALKERMES, INC.

(Exact Name of Registrant as Specified in its Charter)

PENNSYLVANIA

(State or Other Jurisdiction of
Incorporation)

1-14131

(Commission
File Number)

23-2472830

(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):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - ☐ 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

SIGNATURE

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Item 7.01 Regulation FD Disclosure

A federal magistrate judge of the United States District Court for the District of Massachusetts has issued a report and recommendation for dismissal, in its entirety, of purported securities class action litigation pending before the Court against Alkermes and certain of its current and former officers and directors.

Last year, Alkermes and the individual defendants filed a motion seeking dismissal of the litigation on numerous legal grounds, and the Court referred that motion to a magistrate judge for issuance of a report and recommendation as to disposition of the motion to dismiss. The magistrate judge's report and recommendation is subject to review and approval by the Court. If they choose to do so, the plaintiffs have the right to file with the Court an objection to the report and recommendation and to argue why the judge's recommendation should not be approved. The suit alleged purported misstatements by Alkermes regarding a new drug application filed with the U.S. Food and Drug Administration (FDA) for approval of RISPERDAL CONSTA®, which the FDA approved in 2003.

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 subsidiary of Johnson & Johnson. The Company's lead proprietary product candidate, VIVITREX® (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 constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding review and approval by the Court of the report and recommendation, the development of Vivitrex, the Company's pipeline of products, and the Company's product development strategy. Although the Company believes that such statements are based on reasonable assumptions within the bounds of its knowledge of its business and operations, these forward-looking statements are neither promises nor guarantees and are subject to significant risks and uncertainties that could cause actual results to differ materially from its expectations. Those risks and uncertainties include, but are not limited to, the risk that the Court does not accept the recommendation of the judge magistrate. For further information with respect to factors that could cause the Company's actual results to differ from expectations, reference is made to the reports the Company filed with the Securities and Exchange Commission, including the Company's annual report on SEC Form 10-K for the fiscal year ended March 31, 2005 and its quarterly report on SEC Form 10-Q for the fiscal quarter ending June 30, 2005. The forward-looking statements made herein are made and are current only as of the date hereof and the Company disclaims any intention or responsibility for updating predictions contained in this release in the event of changed circumstances or otherwise.

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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: October 12, 2005

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