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ALKERMES INC
Form 8-K
April 30, 2003

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 - APRIL 29, 2003
(Date of earliest event reported)

ALKERMES, INC.

(Exact name of Registrant as specified in its charter)

PENNSYLVANIA
(State of incorporation)

1-14131
(Commission file number)

23-2472830
(IRS employer
identification
number)

88 SIDNEY STREET, CAMBRIDGE, MASSACHUSETTS 02139
(Address of principal executive offices, zip code)

AREA CODE (617) 494-0171
(Telephone number)

ITEM 5. OTHER INFORMATION.

Alkermes, Inc. announced that its partner, Johnson & Johnson Pharmaceutical Research & Development (J&JPRD), has submitted additional data and analyses to the U.S. Food and Drug Administration (FDA) to fulfill a complete response to the "non-approvable" letter issued by the FDA regarding the New Drug Application (NDA) for Risperdal Consta(TM) long-acting injection. The specific data and analyses provided were generated following discussions with the FDA, particularly related to the agency's questions pertaining to aspects of the preclinical data presented in the NDA for the long-acting injection form of the atypical antipsychotic, risperidone. It is anticipated, based on criteria set forth in the Prescription Drug User Fee Act (PDUFA), that the FDA will issue a formal response to the submission in the fourth quarter of calendar year 2003. A copy of the press release issued by Alkermes on April 29, 2003, is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

ITEM 7. FINANCIAL STATEMENTS AND EXHIBITS.

(c) Exhibits

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99.1 Press Release issued by Alkermes, Inc., dated April 29, 2003.

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SIGNATURES

Pursuant to requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: April 29, 2003

Alkermes, Inc.

By: /s/ James M. Frates

James M. Frates
Vice President, Chief Financial
Officer, and Treasurer

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ALKERMES, INC.

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EXHIBIT INDEX

| Exhibit No. ----- | Exhibit ----- |
|----------------------|---|
| 99.1 | Press Release issued by Alkermes, Inc., dated April 29, 2003. |

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