UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended March 31, 2002

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____to _____
Commission file number 0-19267

ALKERMES, INC.

(Exact name of registrant as specified in its charter)

Pennsylvania	**23-2472830**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
64 Sidney Street, Cambridge, MA	**02139-4234**
(Address of principal executive offices)	(Zip Code)

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

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, par value $.01 per share ("Common Stock")
3 ¾% Convertible Subordinated Notes due 2007
(Title of Class)

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

As of June 14, 2002, 64,287,054 shares of the Registrant's Common Stock were issued and outstanding, and 382,632 shares of the Registrant's Non-Voting Common Stock were issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Definitive Proxy Statement to be filed within 120 days after March 31, 2002 for the Registrant's Annual Shareholders' Meeting are incorporated into Part III of this Report on Form 10-K.

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PART I

Item 1. Business

The following Business section contains forward-looking statements which involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors. See "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations — Forward-Looking Statements."

General

Alkermes, Inc. (together with its subsidiaries, referred to as "we", "us", "our" or the "Registrant"), a Pennsylvania corporation organized in 1987, is an emerging pharmaceutical company developing products based on applying its sophisticated drug delivery technologies to enhance therapeutic outcomes. Our areas of focus include: controlled, extended-release of injectable drugs using our ProLease® and Medisorb® delivery systems, and the development of inhaled pharmaceuticals based on our proprietary Advanced Inhalation Research, Inc. ("AIR™") pulmonary delivery system. Our business strategy is twofold. We partner our proprietary technology systems and drug delivery expertise with many of the world's finest pharmaceutical companies and we also develop novel, proprietary drug candidates for our own account. We have a pipeline of products in various stages of development. In addition to our Cambridge, Massachusetts headquarters, research and manufacturing facilities, we operate research and manufacturing facilities in Ohio and a medical affairs office in Cambridge, England.

Recent Developments

In August 2001, Janssen Pharmaceutica, L.P. filed a new drug application ("NDA") for Risperdal Consta™ with the U.S. Food and Drug Administration ("FDA") and similar regulatory filings have been submitted to other drug regulatory agencies worldwide. On June 28, 2002, Johnson & Johnson Pharmaceutical Research and Development, LLC ("J&J PRD") an affiliate of our collaborative partner Janssen Pharmaceutica, Inc. ("Janssen"), received a non-approvable letter for Risperdal Consta from the FDA. Risperdal Consta is a Medisorb long-acting formulation of Janssen's anti-psychotic drug Risperdal®. There can be no assurance that the issues raised in the letter will be resolved on a timely basis, if at all. The impact of the FDA's non-approvable letter on the other regulatory filings made worldwide is not known at this time. There can be no assurance that Risperdal Consta will be approved by the FDA or other regulatory agencies, on a timely basis, if at all. See "Risk Factors—J&J PRD received a non-approvable letter for Risperdal Consta from the FDA and the future of Risperdal Consta is uncertain."

In December 2001, we entered into a strategic alliance with Reliant Pharmaceuticals, LLC ("Reliant"), a privately held pharmaceutical company marketing branded, prescription pharmaceutical products to primary care physicians in the U.S. This relationship provides us with a strategic partner for the acquisition, development, marketing and sales of proprietary pharmaceutical products. At that time, we made a $100 million equity investment in Reliant in exchange for approximately a 19% ownership interest in the company. On March 20, 2002, we announced the signing of a merger agreement pursuant to which Reliant would become a wholly owned subsidiary in a tax-free transaction and we would be obligated to issue a maximum 31.25 million shares of our common stock. The closing of the transaction is subject to various conditions, including the approval by our shareholders and members of Reliant and the receipt of customary regulatory approvals. In addition, both we and Reliant have rights to terminate the merger agreement before the closing of the merger in certain circumstances, including if the closing has not occurred prior to August 31, 2002, if certain representations, warranties and covenants have been breached or if the average closing price of Alkermes common stock is below $17.70 per share for the ten trading days before the closing of the transaction. There can be no assurance that the transaction will be consummated and, if consummated, there can be no assurance that: (1) the businesses will be integrated successfully or that expected advantages of the combined companies will be achieved; (2) the market and sale of the combined businesses' products will develop as expected; and (3) we will not have to raise substantial funds to operate the combined businesses.

Business Strategy

We are building a pharmaceutical company in strategic steps, using our unique drug delivery capabilities and technologies as the means to develop our first commercial products—first with partners, then on our own. The key elements to our strategy are:

Develop and acquire broadly applicable drug delivery systems and apply them to multiple pharmaceutical products. We develop or acquire drug delivery systems that have the potential to be applied to multiple proteins, peptides and small molecule pharmaceutical compounds to create new product opportunities.

Collaborate with pharmaceutical and biotechnology companies to develop and finance product candidates. We have entered into multiple collaborations with pharmaceutical and biotechnology companies to develop product candidates incorporating our technologies, to provide us with funding for product development independent of capital markets and to share development risk.

Apply drug delivery systems to both approved drugs and drugs in development. We are applying our drug delivery technologies to novel applications and formulations of pharmaceutical products that have already been approved by the FDA or other regulatory authorities. In such cases, we and our partners can develop a novel dosage form or application with the knowledge of a drug's safety and efficacy profile and a body of clinical experience from which to draw information for the design of clinical trials and for regulatory submissions. We also are applying our technologies to pharmaceuticals in development that could benefit from one of our delivery systems.

Establish independent product development capabilities and infrastructure. Based upon the knowledge we have learned and the best practices we have adopted from our pharmaceutical company partners, our experienced scientists have built our in-house product development organization that enables us to develop product candidates for our collaborators and for ourselves. Our product development experience and infrastructure give us flexibility in structuring development programs and the ability to conduct both feasibility studies and clinical development programs for our collaborators and for ourselves.

Expand our pipeline with additional product candidates for our own account. We are now developing product candidates for our own account by applying our drug delivery technologies to certain off-patent pharmaceuticals. For example, we are developing Vivitrex™, a Medisorb formulation of naltrexone, for the treatment of alcoholism and opiate dependence. In addition, we may in-license or acquire certain compounds to develop on our own.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

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Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

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Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

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API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

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Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.