ALKERMES INC
Form 8-K
June 28, 2005

Table of Contents

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): June 23, 2005

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**	**02139**
(Address of principal executive offices)	(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))

TABLE OF CONTENTS

Table of Contents

Item 1.01 Entry into a Material Definitive Agreement

On June 23, 2005, Alkermes, Inc., a Pennsylvania corporation (Alkermes), and Cephalon, Inc., a Delaware corporation (Cephalon), entered into a License and Collaboration Agreement (the Agreement) to jointly develop, manufacture and commercialize sustained-release forms of naltrexone, including Vivitrex® (the Products), in the United States. Alkermes and Cephalon also concurrently entered into a Supply Agreement (the Supply Agreement) for the supply of Vivitrex to the collaboration by Alkermes. Vivitrex is a long-acting, injectable form of naltrexone that is under development by Alkermes as a once-monthly regimen for the treatment of alcohol dependence utilizing Alkermes proprietary Medisorb® drug delivery technology. Naltrexone is a non-addictive agent that binds to opioid receptors in the brain. On March 31, 2005, Alkermes submitted a New Drug Application (NDA) for Vivitrex for the treatment of alcohol dependence to the U.S. Food and Drug Administration (FDA), which was granted priority review status.

Pursuant to the terms of the Agreement, Alkermes granted Cephalon a co-exclusive license to Alkermes patents and know-how necessary to use, sell, offer for sale and import the Products for all current and future indications in the United States. For a defined period after June 23, 2005, Cephalon has the exclusive right to negotiate with Alkermes for the right to commercialize and market the Products outside of the United States.

Alkermes and Cephalon will form a joint development team and share responsibility for additional development of the Products. Alkermes will have primary responsibility for conducting such development and will be responsible for obtaining marketing approval for Vivitrex in the United States for the treatment of alcohol dependence (the Initial Indication). Alkermes and Cephalon will form a joint commercialization team and share responsibility for developing the commercial strategy for the Products, including Vivitrex. Cephalon will have primary responsibility for the commercialization, including distribution and marketing, of the Products in the United States, and Alkermes will support this effort with a team of treatment systems specialists. Alkermes has the option to field its own sales force at the time of the first sales force expansion should one occur.

Cephalon made an initial payment of $160 million to Alkermes in connection with the joint collaboration. Upon the occurrence of certain milestones, Cephalon will make payments to Alkermes as follows: (i) $110 million if the FDA approves the NDA for a Product, and (ii) up to an additional $220 million if calendar year net sales of the Products exceed certain agreed upon sales levels. Cephalon will record net sales from the Products in the United States . Alkermes and Cephalon will reconcile the costs of each party to develop, commercialize and manufacture the Products, excluding certain development and registration costs for Vivitrex for the Initial Indication to be paid solely by Alkermes, against revenues from the Products. Until the later of December 31, 2007 or 18 months after the first FDA approval of a Product, Alkermes will be responsible for any cumulative losses up to $120 million. Any losses exceeding this $120 million threshold during such period will be paid by Cephalon. After such period, any pre-tax loss will be shared equally by Alkermes and Cephalon. Any pre-tax profit will be shared equally by Alkermes and Cephalon.

Table of Contents

The Agreement and the Supply Agreement shall be in effect until the later of (i) the expiration of certain patent rights or (ii) fifteen (15) years from the date of the first commercial sale of the Products in the United States.

The foregoing is a summary of the material terms of the Agreement and the Supply Agreement and does not purport to be complete.

Table of Contents

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: June 28, 2005

By: /s/ Michael J. Landine
Michael J. Landine
Vice President, Corporate Development