## U.S. SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## **FORM 10-Q**

| X   | QUARTERLY REPORT PURSUANT TO SECTION EXCHANGE ACT OF 1934  | V 13 OR 15(d) OF THE SECURITIES      |  |
|---|--|--------------------------------------|--|
|   | For the quarterly period ended September 30, 2002          |                                      |  |
|   | TRANSITION REPORT PURSUANT TO SECTION EXCHANGE ACT OF 1934 | 1 13 OR 15(d) OF THE SECURITIES      |  |
|   | For the transition period from                             | to                                   |  |
| Commissio   | n file number 0-26758                                      |                                      |  |
| _   | ALKERMES CLINICAI  | PARTNERS, L.P.                       |  |
| (Exact name of registrant as specified in its charter)  |  |                                      |  |
|   |  |                                      |  |
|   | DELAWARE   | 043-145043                           |  |
| (State or other jurisdiction of incorporation or organization)  |  | (I.R.S. Employer Identification No.) |  |
|   | 88 Sidney Street, Cambridge, MA 02139-4136                 |                                      |  |
| (Address of principal executive offices) (Zip Code)   |  | (Zip Code)                           |  |
| Registrant'   | s telephone number including area code: (617) 494-0171     |                                      |  |
|   | Former name, former address, and former fiscal             | year, if changed since last report   |  |
| 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 [X] No [ ] |  |                                      |  |
| Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).  Yes [ ] No [X]   |  |                                      |  |

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**CERTIFICATION PURSUANT TO SECT 906 SARBANES OXLEY** 

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## **Item 1. Financial Statements:**

## ALKERMES CLINICAL PARTNERS, L.P. (A Limited Partnership)

## **BALANCE SHEETS**

(Unaudited)

|   | September 30<br>2002 | December 31,<br>2001 |
|---|----------------------|----------------------|
| ASSETS                                  |                      |                      |
| ASSETS                                  |                      |                      |
| Total Assets                            | \$ —                 | \$ —                 |
|   |                      |                      |
| LIABILITIES AND PARTNERS' CAPITAL       |                      |                      |
| Total Liabilities and Partners' Capital | \$                   | \$ —                 |

See notes to financial statements.

## STATEMENTS OF OPERATIONS

(Unaudited)

|   | Three Months<br>Ended<br>September 30,<br>2002 | Three Months<br>Ended<br>September 30,<br>2001 | Nine Months<br>Ended<br>September 30,<br>2002 | Nine Months<br>Ended<br>September 30,<br>2001 |
|---|--|--|---|---|
| Revenue                                 | \$ —   | \$ —   | <u> </u>                                      | \$ —  |
| Expenses:                               |  |  |   |   |
| General and administrative              | 4,130  | 4,887  | 11,870  | 8,846   |
|   | 4,130  | 4,887  | 11,870  | 8,846   |
| Net Loss                                | (\$4,130)                                      | (\$4,887)                                      | (\$11,870)                                    | (\$8,846)                                     |
| Net Loss Per Class A and B Unit         | \$   | \$   | \$  | \$  |
| Average Class A and B Units Outstanding | 921  | 921  | 921   | 921   |
|   |  |  |   |   |

See notes to financial statements.

## STATEMENTS OF CASH FLOWS

(Unaudited)

|   | Nine Months<br>Ended<br>September 30,<br>2002 | Nine Months<br>Ended<br>September 30,<br>2001 |
|---|---|---|
| Cash flows from operating activities:     |   |   |
| Net loss                                  | (\$11,870)                                    | (\$8,846)                                     |
| Net cash used by operating activities     | (11,870)                                      | (8,846)                                       |
| Cash flows from financing activities:     |   |   |
| General Partner's capital contributions   | 11,870  | 8,846   |
| Net cash provided by financing activities | 11,870  | 8,846   |
| Net decrease in cash                      | _   | _   |
| Cash, beginning of period                 |   |   |
| Cash, end of period                       | \$ <u> </u>                                   | \$  |

See notes to financial statements.

#### NOTES TO FINANCIAL STATEMENTS

#### 1. BASIS OF PRESENTATION

The financial statements for Alkermes Clinical Partners, L.P. (the "Partnership") for the three and nine month periods ended September 30, 2002 and 2001, are unaudited and include all adjustments which, in the opinion of management, are necessary to present fairly the results of operations for the periods then ended. All such adjustments are of a normal recurring nature. These financial statements should be read in conjunction with the Partnership's Annual Report on Form 10-K for the year ended December 31, 2001, which includes financial statements and notes thereto for the years ended December 31, 2001, 2000 and 1999.

The results of the Partnership's operations for any interim period are not necessarily indicative of the results of the Partnership's operations for any other interim period or for a full year.

#### 2. NET LOSS PER CLASS A AND B LIMITED PARTNERSHIP INTEREST

Net loss per Class A and B limited partnership interest is calculated with the net loss attributable only to the limited partners of the Partnership (each, a "Limited Partner" and collectively, the "Limited Partners") and excludes the loss attributable to Alkermes Development Corporation II (the "General Partner"). There were no losses attributable to the Limited Partners for the three and nine months ended September 30, 2002 and 2001.

#### 3. COMPLETION OF SCHEDULED FUNDING

For the three and nine months ended September 30, 2002 and 2001, the Partnership incurred no research and development expenses related to the RMP<sup>TM</sup> program, notwithstanding the continuing development of the product candidate. The Partnership had previously provided funding to Alkermes, Inc. ("Alkermes") for research and development expenses for Cereport® from capital contributions received from Partners. Funding to Alkermes ended during the quarter ended June 30, 1996 when such capital contributions were substantially depleted. None of the Partners of the Partnership is obligated to make any further capital contributions. Since the funding was not sufficient for Alkermes to complete clinical trials and seek regulatory approval of Cereport, Alkermes has used its own resources, and intends to continue to use its own resources, to develop Cereport. Alkermes has obtained and intends to continue to obtain such resources through equity offerings, bank borrowings and its collaborative arrangements. Alkermes is required to fund the development of Cereport to maintain its Purchase Option with the Limited Partners.

Alkermes is also obligated, through the General Partner, to perform administrative services for the Partnership, such as preparing financial statements, tax returns and reports to Partners. Alkermes intends to continue to cause the General Partner to perform such services at its expense since the Partnership's current assets are depleted, unless it exercises its Purchase Option and thereby acquires all the interests in the Partnership. The services performed by Alkermes and the General Partner constitute all of the activities undertaken by or on behalf of the Partnership.

After September 30, 2002, the Partnership is expected to continue to have no future liquidity or capital resources requirements other than those funded by Alkermes.

#### Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

#### INTRODUCTION

Alkermes Clinical Partners, L.P. (the "Partnership") was formed on February 7, 1992, and is managed by its general partner, Alkermes Development Corporation II (the "General Partner"), a wholly owned subsidiary of Alkermes, Inc. ("Alkermes" or the "Company"). The Partnership was organized to fund the further development and clinical testing of a family of molecules, designated by Alkermes as Receptor-Mediated Permeabilizers<sup>TM</sup> ("RMPs<sup>TM</sup>"), for human pharmaceutical use in the United States and Canada.

#### IMPORTANT FACTORS REGARDING FORWARD-LOOKING STATEMENTS

Any statements set forth below or otherwise made in writing or orally by the Partnership or the General Partner with regard to its expectations as to financial results and other aspects of its business may constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements can be identified by forward-looking words such as "may," "will," "expects," "anticipates," "believes," "estimates," "continues" or similar words. Although the General Partner believes that its expectations are based on reasonable assumptions within the bounds of its knowledge of its business and operations, there can be no assurance that actual results of the Partnership's or the Company's development activities and the Partnership's results of operations will not differ materially from its expectations. Factors which could cause actual results to differ from expectations include, among others:

- (i) clinical trials for Cereport® may not proceed as planned, the trials may require more time to enroll patients than anticipated, and even if they are completed Cereport could prove to be ineffective or unsafe;
- (ii) the Company could reduce or discontinue funding of Cereport;
- (iii) the Partnership and the Company could not be permitted by regulatory authorities to undertake additional clinical trials for Cereport or clinical trials could be delayed or regulatory authorities could require additional clinical trials before approving Cereport;
- (iv) the Company could incur difficulties or set-backs in obtaining the substantial additional funding required to continue research and development programs and clinical trials;
- (v) even if Cereport appears promising at an early stage of development, it could fail to receive necessary regulatory approvals, be difficult to manufacture on a large scale, be uneconomical, fail to achieve market acceptance, be precluded from commercialization by proprietary rights of third parties or experience substantial competition in the marketplace; and
- (vi) technological change in the biotechnology or pharmaceutical industries and the approval of other drugs or therapies to treat brain tumors could render Cereport obsolete or noncompetitive.

#### RESULTS OF OPERATIONS

#### Revenue

The Partnership had no revenue for the three and nine months ended September 30, 2002 and 2001. The Partnership anticipates that it will have no revenue in the foreseeable future.

#### Expenses

The Partnership had no research and development expenses for the three and nine months ended September 30, 2002 and 2001. There were no research and development expenses because of the completion of the development funding to Alkermes pursuant to the product development agreement between Alkermes and the Partnership (the "Product Development Agreement").

General and administrative expenses for the three and nine months ended September 30, 2002 were \$4,130 and \$11,870 as compared to \$4,887 and \$8,846 for the three and nine months ended September 30, 2001. The decrease for three months ended September 30, 2002 compared to September 30, 2001 was mainly a result of decreased professional service fees. The increase for the nine months ended September 30, 2002 compared to September 30, 2001 was mainly a result of increased professional service fees. Alkermes is obligated through the General Partner to perform general and administrative services for the Partnership at its expense, unless Alkermes exercises its Purchase Option and thereby acquires all limited partnership interests in the Partnership (see Liquidity and Capital Resources).

#### LIQUIDITY AND CAPITAL RESOURCES

At September 30, 2002, the Partnership had no remaining assets or liabilities.

The Partnership's primary source of funding and capital resources had been the annual capital contributions by the Limited Partners and the General Partner. The Limited Partners' capital contributions were remitted to the Partnership in four annual installments, the fourth and final payment of which was due on April 15, 1995. There have been and will be no additional capital contributions received by the Partnership from the Limited Partners after the quarter ended June 30, 1996.

The Partnership was funding research and development expenses for Cereport from capital contributions received from Partners. Such development was and continues to be conducted for the Partnership by Alkermes pursuant to the Product Development Agreement. The research and development funding to Alkermes ended during the quarter ended June 30, 1996 when such capital contributions were substantially depleted. None of the Partners is obligated to make any further capital contributions. Because the funding was not sufficient for Alkermes to complete clinical trials and seek regulatory approval of Cereport, Alkermes has used its own resources, and intends to continue to obtain such resources through equity offerings, bank borrowings and its collaborative arrangements. Effective September 30, 1997, Alkermes entered into an agreement with ALZA Corporation related to the development and commercialization of Cereport. Alkermes is required to fund the development of Cereport to maintain its Purchase Option with the Limited Partners.

The Partnership used its remaining cash and cash equivalents during the quarter ended September 30, 1997 to pay for administrative services for the Partnership. Alkermes is obligated, through the General Partner, to perform administrative services for the Partnership, such as preparing

financial statements, tax returns and reports to the Limited Partners. Since the Partnership's current assets are depleted, Alkermes intends to continue to cause the General Partner to perform such services at its expense in order to maintain its Purchase Option with the Limited Partners, unless it exercises its Purchase Option and thereby acquires all limited partnership interests in the Partnership. The activities performed by Alkermes and the General Partner constitute all of the activities undertaken by or on behalf of the Partnership.

After September 30, 2002, the Partnership is expected to continue to have no future liquidity or capital resources requirements other than those funded by Alkermes.

#### Item 3. Quantitative and Qualitative Disclosures about Market Risk:

Not applicable.

#### **Item 4. Controls and Procedures**

As of November 4, 2002, the chief executive officer and chief financial officer evaluated the General Partner's controls and procedures related to the Partnership's reporting and disclosure obligations. These officers have concluded that these disclosure controls and procedures are sufficient to provide that (a) material information relating to the Partnership, including its consolidated subsidiaries, is made known to these officers by other employees of Alkermes, the parent entity of the General Partner, and its consolidated subsidiaries, particularly material information related to the period for which this periodic report is being prepared; and (b) this information is recorded, processed, summarized, evaluated and reported, as applicable, within the time periods specified in the rules and forms promulgated by the Securities and Exchange Commission.

There have been no significant changes in the General Partner's internal controls or in other factors that could significantly affect these internal controls subsequent to the date of the evaluation.

## Item 6. Exhibits, Financial Statement Schedules and Reports on Form 8-K

## (a) Exhibits:

| Number | Exhibit   |
|--------|---|
| 3.1    | Alkermes Clinical Partners, L.P. Agreement of Limited Partnership, dated as of February 7, 1992.*                           |
| 3.1(a) | Amendment No. 1 to Alkermes Clinical Partners, L.P. Agreement of Limited Partnership, dated as of September 29, 1992.*      |
| 3.1(b) | Amendment No. 2 to Alkermes Clinical Partners, L.P. Agreement of Limited Partnership, dated as of March 30, 1993.*          |
| 4.1    | Alkermes Clinical Partners, L.P. Agreement of Limited Partnership, dated as of February 7, 1992.*                           |
| 4.1(a) | Amendment No. 1 to Alkermes Clinical Partners, L.P. Agreement of Limited Partnership, dated as of September 29, 1992.*      |
| 4.1(b) | Amendment No. 2 to Alkermes Clinical Partners, L.P. Agreement of Limited Partnership, dated as of March 30, 1993.*          |
| 99.1   | Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350 by Chief Executive Officer. |
| 99.2   | Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350 by Chief Financial Officer. |

<sup>\*</sup> Incorporated by reference to Exhibits to the Registrant's Registration Statement on Form 10 filed September 13, 1995.

<sup>(</sup>b) Since the beginning of the quarter ended September 30, 2002, the Registrant has not filed any reports on Form 8-K.

#### **SIGNATURES**

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 thereunto duly authorized.

ALKERMES CLINICAL PARTNERS, L.P. (Registrant)

By its General Partner

#### ALKERMES DEVELOPMENT CORPORATION II

Date: November 14, 2002 By: /s/ Richard F. Pops

Richard F. Pops

Director, President and Chief Executive Officer (Principal Executive Officer)

Date: November 14, 2002 By: /s/ James M. Frates

James M. Frates
Director, Vice President, Chief
Financial Officer, Treasurer and
Assistant Secretary (Principal
Financial and Accounting Officer)

#### **CERTIFICATIONS**

- I, Richard F. Pops, certify that:
- 1. I have reviewed this quarterly report on Form 10-Q of Alkermes Clinical Partners, L.P.;
- 2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - a. designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
  - b. evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
  - c. presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date:
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a. all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
- 6. The registrant's other certifying officer and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 14, 2002 /s/ Richard F. Pops

Richard F. Pops Chief Executive Officer of Alkermes Development Corporation II, the Registrant's General Partner

#### **CERTIFICATIONS**

#### I, James M. Frates, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of Alkermes Clinical Partners, L.P.;
- 2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - a. designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
  - b. evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
  - c. presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date:
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a. all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
- 6. The registrant's other certifying officer and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 14, 2002 /s/ James M. Frates

James M. Frates Chief Financial Officer of Alkermes Development Corporation II, the Registrant's General Partner

## **Exhibit Index**

| Exhibit<br>Number | Description   |
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