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ELITE PHARMACEUTICALS INC /DE/
Form 8-K
March 30, 2006

UNITED STATES
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

March 29, 2006

Date of Report (Date of earliest event reported)

ELITE PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

| | | |
|---|-----------------------------|--------------------------------------|
| Delaware | 333-45241 | 22-3542636 |
| ----- | ----- | ----- |
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

165 Ludlow Avenue, Northvale, New Jersey 07647

(Address of principal executive offices)

(201) 750-2646

(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report.)

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:

- 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))

ITEM 7.01 REGULATION FD DISCLOSURE.

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On March 29, 2006, the Registrant held a conference call for analysts and investors to review the Registrant's accomplishments and outline future goals. Management reported the following:

- (i) The Registrant anticipates starting a second pilot Phase I clinical trial for its OxyQD(TM) drug product as early as May 2006. Management reported that the Registrant intends to complete the pilot Phase I study and begin Phase II studies during calendar year 2006 and then meet with the FDA for the OxyQD(TM) drug product following completion of the Phase II study.
- (ii) The Registrant intends to begin dose ranging studies for the OxyNal(TM) drug product during the calendar year 2006 and to hold a pre-Phase II meeting with the FDA. After meeting with the FDA, the Registrant intends to commence the Phase II study.
- (iii) The Registrant expects to complete all pilot studies on the OxyNal(TM) project by the first quarter of 2007, commence Phase III studies in 2007 and file an NDA in 2008, with the hope, but no assurance, that assuming 12 months for approval of the NDA, the OxyNal(TM) drug product may go to the market in 2009.
- (iv) The Registrant may enter into partnership agreements with respect to the OxyNal(TM) and OxyQD(TM) drug products prior to entering into Phase III clinical studies, and discussions with interested parties are ongoing.
- (v) Management, in response to a question, indicated they anticipate the market to be significantly larger than \$100 million. While management did not provide an estimated market size for the OxyNal(TM) product during the conference call, the Registrant commissioned a market consulting group to prepare a report which indicated that the market size for OxyNal(TM) can be \$800 million or greater.
- (vi) With respect to the OxyQD(TM) product, such market consulting group's report indicated that the market size for OxyQD(TM) can be \$400 million or greater.
- (vii) With respect to the Registrant's ANDA projects, it intends to file two ANDA's in 2006.
- (viii) The Registrant intends to enter into one or more agreements with marketing partners in the next 12 months for those ANDA projects for which marketing rights have not yet been assigned.
- (ix) The Registrant intends to launch a second allergy drug product by the end of 2006.

There is no assurance that the Registrant will be able to achieve the results, performance or other expectations, including market revenue.

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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.

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Dated: March 29, 2006

ELITE PHARMACEUTICALS, INC.

By: /s/ Bernard Berk

Name: Bernard Berk
Title: Chief Executive Officer