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ELITE PHARMACEUTICALS INC /DE/
Form 8-K
October 11, 2002

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

Date of Report (Date of earliest event reported): October 1, 2002

ELITE PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

State or other jurisdiction of incorporation: Delaware

Commission File No.: 333-45241

I.R.S. Employer Identification No.: 22-3542636

Address of principal executive offices 165 Ludlow Avenue
Northvale, New Jersey

Registrant's telephone number, including area code: 201 750-2646

ITEM 5. OTHER EVENTS

On September 30, 2002, Elite Pharmaceuticals, Inc. ("Elite") consummated an agreement with Elan Corporation, plc ("Elan") to acquire all of Elan's interest in a joint venture company, Elite Research Limited, ("Elite Research"), which had been formed by Elite and Elan. The termination of the joint venture results from Elan's restructuring efforts and a desire on the part of Elite to expedite development of the joint venture's products. Elite now owns 100 percent of the joint venture company.

The joint venture has completed the initial Phase I study for its first product, a once-a-day Oxycodone formulation. The study compared the once a day formulation against the twice-daily reference product that is currently marketed. The data showed comparable bioavailability. Accordingly, Elite intends to proceed with the next stage of development. The US market for twice a day oxycodone products exceeds \$1 billion. Currently there is no once a day

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formulation for this compound.

The joint venture has also been developing a second product in the CNS therapeutic area to compete with a currently marketed product whose US sales exceed \$1 billion.

Under the termination agreement, Elite acquired all proprietary, development and commercial rights for the worldwide markets for the products developed by the joint venture. In exchange for this assignment, Elite Research has agreed to pay Elan a royalty on certain revenues that may be realized from the once-a-day Oxycodone product only that has been developed by the joint venture. . In the future, Elite will be solely responsible to fund product development, which it will do from internal resources or through loans or investment by third parties.

Under the joint venture, Elan had received 409,165 shares of common stock in Elite; warrants exercisable at \$18.00 per share for 100,000 shares of common stock of Elite; and Series A and Series B preferred stock of Elite Laboratories, Inc. (a wholly owned subsidiary of Elite), which are convertible into 749,292 shares and 52,089 shares, respectively, of Elite common stock. Under the termination agreement, Elan and its transferees retained the securities, and the shares of Series A and Series B preferred stock are being converted to Elite common stock under the preexisting terms for conversion.

Elite did not pay, nor did Elan receive any cash consideration under the termination agreement.

Elite Laboratories, Inc. specializes in oral drug delivery and applies its proprietary controlled release technology to the development of delayed release, sustained release, targeted release and pulse release products for NDA or ANDA submission. Elite Laboratories, Inc. has been issued several patents, and additional patent applications are pending.

This report contains forward-looking statements which involve known and unknown risks, delays, uncertainties and other factors not under Elite's control, which may cause actual results, performance or achievements of the Elite to be materially different from the results, performance or other expectations implied by these forward-looking statements. These factors include outcomes of current or pending research and development activities, actions by the FDA and other regulatory authorities, changes in competitive or market conditions, and those factors detailed in Elite's filings with the Securities and Exchange Commission such as 10K, 10Q, and 8K reports.

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 hereunto duly authorized.

Date: October 11, 2002

ELITE PHARMACEUTICALS, INC.

By:/s/ Atul M. Mehta

Atul M. Mehta
President