

ELITE PHARMACEUTICALS INC /DE/  
Form 8-K  
September 16, 2010

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

September 10, 2010

Date of Report (Date of earliest event reported)

ELITE PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction  
of incorporation)

001-15697  
(Commission  
File Number)

22-3542636  
(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 1.01 Entry Into A Material Definitive Agreement.

On September 10, 2010, Elite Pharmaceuticals Inc. (“Elite”) executed a License Agreement with Precision Dose, Inc. (“Precision Dose”), which is entitled to exercise the rights and benefits of the License Agreement through its wholly-owned subsidiary, TAGI Pharma, Inc., to market and sell four Elite generic products in the United States, Puerto Rico and Canada. Precision Dose will have the exclusive right to market the products in the United States and Puerto Rico and a non-exclusive right to market the products in Canada. Pursuant to the License Agreement, Elite will receive a license fee and milestone payments. The license fee will be computed as a percentage of the gross profit, as defined in the License Agreement, earned by Precision Dose as a result of sales of the products. The license fee is payable monthly for the term of the License Agreement. The milestone payments will be paid in 6 installments. The first installment was paid upon execution of the License Agreement. The remaining installments are to be paid upon FDA approval and initial shipment of the products to Precision Dose. The term of the License Agreement is 15 years and may be extended for 3 successive terms, each of 5 years. Twelve months following the launch of a product covered by the License Agreement, Elite may terminate the exclusive marketing rights if the license fee paid by Precision Dose falls below a designated amount. Elite may also terminate the exclusive marketing rights if Precision Dose is unable to meet the annual unit volume forecast for a designated Product group for any year, subject to the ability of Precision Dose, during the succeeding 6 month period, to achieve at least one-half of the prior year’s minimum annual unit volume forecast. The License Agreement may be terminated by mutual agreement of Elite and Precision Dose, as a result of a breach by either party that is not cured within 60 days notice of the breach or by Elite as a result of Precision Dose becoming a party to a bankruptcy, reorganization or other insolvency proceeding that continues for a period of 30 days or more.

Elite will manufacture the products on an exclusive basis for Precision Dose or TAGI Pharma, Inc. pursuant to a Manufacturing and Supply Agreement (the “Manufacturing Agreement”), also dated September 10, 2010. The term of the Manufacturing Agreement is co-extensive with the term of the License Agreement. Prices for the manufacture of the various products may be increased following the later of the first anniversary of the first shipment of a product or the first anniversary of the previous price increase related to the product. Prices for the manufacture of the products may also be decreased in the event of reductions in material or component costs. In the event that Elite cannot supply one or more of the products at a price that is low enough to allow Precision Dose or TAGI Pharma, Inc. to sell the product profitably, then Elite may provide the product through a third party supplier. Pursuant to the Manufacturing Agreement, each party has indemnified the other against damages resulting from, among other things, a failure of the party’s obligations under the Manufacturing Agreement or a breach of the party’s representations or warranties.

Item 2.01 Completion of Acquisition or Disposition of Assets.

On September 10, 2010, Elite, together with its subsidiary, Elite Laboratories, Inc., executed a Purchase Agreement with Epic Pharma LLC (the “Seller”) for the purpose of acquiring from the Seller Abbreviated New Drug Application (“ANDA”) number 20-272 for a generic product. The ANDA has been filed with the FDA and seeks authorization and approval to manufacture, package, ship and sell the product. The acquisition of the ANDA will close on the later of 60 days from the date of the Purchase Agreement or upon receipt of FDA approval of the ANDA. Upon the closing, Elite will pay a portion of the purchase price. The remainder of the purchase price will be paid in quarterly installments over a period of three years, beginning at the end of the first full quarter following the closing. Elite has agreed to pay expenses relating to the acquisition, including sales taxes, use taxes, transfer taxes and similar taxes (but not including taxes on income or gains earned by the Seller), fees and expenses incurred as a result of the transfer. Until all of the purchase price is paid, Elite may not convey, sell, assign, transfer, license or otherwise dispose of the assets acquired without the consent of the Seller, which may not be withheld unreasonably. The Purchase Agreement also includes mutual indemnification provisions pursuant to which the Seller indemnifies Elite for liabilities relating to the assets acquired which arise as a result of actions taken prior to the closing and Elite indemnifies the Seller for liabilities relating to the assets acquired which arise as a result of actions taken after the

closing. The right to market this product was licensed to Precision Dose on September 10, 2010. (See Item 1.01.)

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Item 9.01. Financial Statements and Exhibits.

(c) Exhibits

99.1 Press Release dated September 16, 2010.

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.

Dated: September 16, 2010

ELITE PHARMACEUTICALS, INC.

By: /s/ Chris Dick  
Name: Chris Dick  
Title: President & Chief Operating Officer

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