

ELITE PHARMACEUTICALS INC /DE/
Form 8-K
June 07, 2011

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

June 1, 2011

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 June 1, 2011, Elite Pharmaceuticals Inc. (“Elite”) executed a Manufacturing and Supply Agreement (the “Agreement”) with Mikah Pharma, LLC (“Mikah”) to undertake and perform certain services relating to two generic products: Isradipine Capsules USP, 2.5 mg and 5 mg and Phendimetrazine Tartrate Tablets USP, 35 mg (the “Products”), including (a) developing and preparing the documentation required for the transfer of the manufacturing process to Elite’s facility and the appropriate regulatory filing for the ANDA, and (b) manufacturing finished dosage forms appropriate for commercial sale, marketing and distribution in the United States of America, its territories, possessions, and commonwealths in accordance with the requirements of this Agreement; Elite shall perform, at its sole cost and expense, all Technology Transfer, validation and qualification services (including: equipment, methods and facility qualification), validation and stability services required by Applicable Laws to commence manufacturing the Products for commercial sale by Mikah or its designees in accordance with the terms of this Agreement. During the term of this Agreement and subject to the provisions herein, Mikah shall purchase from Elite and Elite agrees to manufacture and supply solely and exclusively to Mikah, such Product as Mikah may order from time to time pursuant to this Agreement. Mikah will compensate Elite at an agreed upon transfer price for the manufacturing and packaging of the Products. For the Isradipine product, Elite will also receive a 10% royalty on net profits of the finished Product. The payment is to be calculated and paid quarterly. Elite will also receive a onetime milestone payment for each Product for the work associated with the Technology transfer. The milestone payment shall be made upon the successful manufacturing and testing of the exhibit batch.

The Manufacturing and Supply Agreement has a term of five (5) years and shall automatically renew for additional periods of one (1) year unless Mikah provides written notice of termination to Elite at least six (6) months prior to the expiration of the Term or any Renewal Term.

Item 9.01. Financial Statements and Exhibits.

(c) Exhibits

99.1 Press Release dated June 6, 2011.

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: June 6, 2011

ELITE PHARMACEUTICALS, INC.

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