

ELITE PHARMACEUTICALS INC /NV/
Form 8-K
October 08, 2013

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

October 2, 2013

Date of Report (Date of earliest event reported)

ELITE PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

| | | |
|---|---|----------------------|
| Nevada | 001-15697 | 22-3542636 |
| ----- | ----- | ----- |
| (State or other jurisdiction of incorporation) | (Commission (IRS Employer File Number) | (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 October 2, 2013, Elite Pharmaceuticals Inc. (“Elite”) executed a Manufacturing and License Agreement (“Agreement”) with Epic Pharma LLC. (“Epic”), to manufacture, market and sell in the United States and Puerto Rico 12 generic products owned by Elite. Of the 12 products, Epic will have the exclusive right to market six products as listed in Schedule A of the Agreement, and a non-exclusive right to market six products as listed in Schedule D of the Agreement. . Epic is responsible for all regulatory and pharmacovigilance matters related to the products and for all costs related to the site transfer for all products. Pursuant to the 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 Agreement, earned by Epic as a result of sales of the products. The manufacturing cost used for the calculation of the license fee is a predetermined amount per unit plus the cost of the drug substance (API) and the sales cost for the calculation is predetermined based on net sales. If Elite manufactures any product for sale by Epic, then Epic shall pay that same predetermined manufacturing cost per unit plus the cost of the API. The license fee is payable monthly for the term of the Agreement. Epic shall pay to Elite certain milestone payments as defined by the Agreement. The first milestone payment is due on or before November 15, 2013. Subsequent milestone payments are due upon the filing of each product’s supplement with the U.S. Food and Drug Administration (“FDA”) and the FDA approval of site transfer for each product as specifically itemized in the agreement. The term of the License Agreement is five years and may be extended for an additional five years upon mutual agreement of the parties. Twelve months following the launch of a product covered by the License Agreement, Elite may terminate the marketing rights for any product if the license fee paid by Epic falls below a designated amount for a six month period of that product. Elite may also terminate the exclusive marketing rights if Epic is unable to meet the annual unit volume forecast for a designated Product group for any year, subject to the ability of Epic, during the succeeding six 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 Epic, 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 Epic becoming a party to a bankruptcy, reorganization or other insolvency proceeding that continues for a period of 30 days or more.

Item 9.01. Financial Statements and Exhibits.

(c) Exhibits

99.1 Press Release dated October 8, 2013.

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: October 8, 2013

ELITE PHARMACEUTICALS, INC.

By: /s/ Nasrat Hakim

Name: Nasrat Hakim

Title: President & Chief Executive Officer