

ELITE PHARMACEUTICALS INC /NV/
Form 8-K
June 09, 2015

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 4, 2015

Date of Report (Date of earliest event reported)

ELITE PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware 001-15697 22-3542636
(State or other jurisdiction (Commission (IRS Employer
of incorporation) 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 June 4, 2015, Elite Pharmaceuticals Inc. and its wholly-owned subsidiary Elite Laboratories, Inc. (collectively, “Elite”) executed an exclusive License Agreement (the “Agreement”) with Epic Pharma LLC. (“Epic”), to market and sell in the United States, ELI-200, an undisclosed opioid with sequestered naltrexone capsules, owned by Elite. Epic will have the exclusive right to market ELI-200 and its various dosage forms as listed in Schedule A of the Agreement (the “Products”). Epic is responsible for all regulatory and pharmacovigilance matters related to the products. Pursuant to the Agreement, Elite will receive a license fee and milestone payments. The license fee will be computed as a percentage of net sales of the Products as defined in the Agreement by Epic. Elite will manufacture the product for sale by Epic on a cost plus basis and both parties agree to execute a separate Manufacturing and Supply Agreement. The license fee is payable quarterly for the term of the Agreement. Epic shall pay to Elite certain milestone payments as defined by the Agreement. The first milestone payment was due and was received upon signing the agreement. Subsequent milestone payments are due upon the filing of a New Drug Application (“NDA”) with the U.S. Food and Drug Administration (“FDA”) for the Products and upon receipt of the approval letter for the NDA from the FDA. The term of the License Agreement is five years and may be extended for an additional five years upon mutual agreement of the parties. Elite can terminate the Agreement on 90 days’ written notice in the Event that Epic does not pay to Elite certain minimum annual license fees over the initial five year term of the Agreement. Either party may terminate this Agreement upon a material breach and failure to cure that breach by the other party within a specified period.

The Agreement will be filed as an exhibit to the Company’s annual report on Form 10-K for the fiscal year ended March 31, 2015.

Item 9.01. Financial Statements and Exhibits.

(c) Exhibits

99.1 Press Release dated June 9, 2015.

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 9, 2015

ELITE PHARMACEUTICALS, INC.

By: /s/ Nasrat Hakim

Name: Nasrat Hakim

Title: President & Chief Executive Officer