ELITE PHARMACEUTICALS INC /NV/
Form 8-K
September 01, 2016

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 1, 2016 (August 26, 2016)

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 File Number)	(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 August 26, 2016, Elite Pharmaceuticals Inc. (the “Company”) amended and renewed its Manufacturing and Supply Agreement (the “TPN Agreement”) with The PharmaNetwork, LLC and its wholly owned subsidiary, Ascend Laboratories, LLC (together "TPN"). The Agreement was set to expire on December 31, 2016. TPN and the Company have agreed to extend it through December 31, 2017.

Item 8.01 Other Events

On August 26, 2016, Elite received a Warning Letter from the U. S. Food and Drug Administration (FDA) regarding Postmarketing Adverse Drug Experience (PADE) reporting. The Warning Letter relates to certain observations that the FDA believes were inadequately addressed by the Company’s response to a Form 483 issued by the FDA from a recent inspection at its facility. The Warning Letter cites that Elite’s Standard Operating Procedures (SOPs) do not adequately address how to monitor and receive adverse drug experiences (ADEs). While Elite has a contract with an external service provider for follow-up to ADEs, Elite remains responsible for ensuring the ADEs are appropriately investigated and that follow-up information is submitted in a timely manner to the FDA. The FDA believes that Elite does not have adequate SOPS for ADEs, and failed to investigate, evaluate, and timely report ADEs.

Elite takes the matters identified in the Warning Letter seriously and is currently addressing the deficiencies cited in the letter. The Company intends to work closely with the FDA to resolve any outstanding issues. The Warning Letter does not restrict the production or shipment of any of the Elite’s products, or the sale or marketing of the Company’s products, however unless and until the Company is able to correct outstanding issues to the FDA’s satisfaction, the FDA may withhold approval of pending drug applications or take other actions that would have a material adverse impact on the Company.

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 1, 2016 ELITE PHARMACEUTICALS, INC.

By: /s/ Nasrat Hakim
Nasrat Hakim, President and CEO