ELITE PHARMACEUTICALS INC /NV/
Form 8-K
December 19, 2017

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

December 19, 2017 (December 15, 2017)

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ¨

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ¨

Item 8.01 Other Events

On December 15, 2017, Elite Pharmaceuticals, Inc., ("Elite" or the “Company") received a close-out letter from the Food and Drug Administration, Office of Compliance with respect to the August 25, 2016 FDA Warning Letter regarding Post Marketing Adverse Drug Experience (PADE) reporting. The FDA has concluded its evaluation and the corrective actions undertaken by the Company are now complete. There are no longer any potential restrictions from the Warning Letter. Elite remains responsible to continue to maintain compliance with FDA regulations.

On December 4, 2017, the FDA completed a pre-approval inspection for a filed generic product. The inspection was classified as “No Action Indicated” (NAI) because the FDA did not issue any observations.

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: December 19, 2017 ELITE PHARMACEUTICALS, INC.

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