

ELITE PHARMACEUTICALS INC /NV/

Form 8-K

December 22, 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

December 22, 2016 (December 21, 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 8.01 Other Events.**

Elite Pharmaceuticals, Inc. ("Elite" or the "Company") met with the U.S. Food and Drug Administration (the "FDA") on December 21, 2016 for an end-of-review meeting to discuss steps that Elite can take to obtain approval of SequestOx™. Based on the FDA response, the Company believes there is a clear path forward to address the issues cited in the July 14<sup>th</sup> Complete Response Letter. The FDA will provide minutes of the meeting by the end of January and the Company will issue a further update at that time.

For more information on the SequestOx end-of-review meeting, please see the December 22, 2016 press release, a copy of which is furnished herewith as Exhibit 99.1.

### **Caution Concerning Forward Looking Statements**

This Current Report contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Including those related to the effects, if any, on future results, performance or other expectations that may have some correlation to the subject matter of this Current Report, readers are cautioned that such forward-looking statements involve risks and uncertainties including, without limitation, Elite's ability to obtain FDA approval of the transfers of the ANDAs or the timing of such approval process, delays, uncertainties, inability to obtain necessary ingredients and other factors not under the control of Elite, which may cause actual results, performance or achievements of Elite to be materially different from the results, performance or other expectations that may be implied by these forward-looking statements. These forward-looking statements may include statements regarding the expected timing of approval, if at all, of SequestOx™ by the FDA, the steps Elite may take as a result of the CRL, the results of an End of Review Meeting and what actions the FDA may require of Elite in order to obtain approval of the NDA. These forward-looking statements are not guarantees of future action or performance. These risks and other factors, including, without limitation, Elite's ability to obtain sufficient funding under the LPC Agreement or from other sources, the timing or results of pending and future clinical trials, regulatory reviews and approvals by the Food and Drug Administration and other regulatory authorities, intellectual property protections and defenses, and the Elite's ability to operate as a going concern, are discussed in Elite's filings with the Securities and Exchange Commission, including its reports on forms 10-K, 10-Q and 8-K. Elite is under no obligation to update or alter its forward-looking statements, whether as a result of new information, future events or otherwise.

### **Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

Exhibit No. Description

99.1 Press Release dated December 22, 2016

**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 22, 2016 ELITE PHARMACEUTICALS, INC.

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