

ELITE PHARMACEUTICALS INC /NV/

Form 8-K

July 15, 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

July 15, 2016 (July 14, 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 7.01 Regulation FD Disclosure.**

On July 15, 2016, Elite Pharmaceuticals, Inc., or Elite, announced that the U.S. Food and Drug Administration, or the FDA, issued a Complete Response Letter, or CRL, regarding the New Drug Application, or NDA, for SequestOx™ (oxycodone hydrochloride and naltrexone hydrochloride), Elite's investigational abuse-deterrent opioid candidate for the management of moderate to severe acute pain where the use of an opioid analgesic is appropriate.

A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K. The information set forth in this Item 7.01 and contained in the press release furnished as Exhibit 99.1 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and is not incorporated by reference into any of Elite's filings under the Securities Act of 1933, as amended, or the Securities Act, or the Exchange Act, whether made before or after the date hereof, except as shall be expressly set forth by specific reference in any such filing.

**Item 8.01 Other Events.**

As described above, the FDA issued a CRL regarding the NDA for SequestOx. The CRL indicated that the review cycle for the SequestOx NDA is complete and the application is not ready for approval in its present form. Elite currently is evaluating the points raised in the CRL and intends to request an End of Review meeting with the FDA to determine the pathway forward for SequestOx.

**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 July 15, 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: July 15, 2016 ELITE PHARMACEUTICALS, INC.

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