ELITE PHARMACEUTICALS INC /NV/
Form 424B3
July 15, 2016

Filed Pursuant to Rule 424(b)(3)

Registration No. 333- 212266

PROSPECTUS SUPPLEMENT

Number 1

to

Prospectus dated July 13, 2016

of

ELITE PHARMACEUTICALS, INC.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR PASSED UPON THE ACCURACY OR ADEQUACY OF THIS PROSPECTUS SUPPLEMENT. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

This Prospectus Supplement No. 1 supplements the information provided in our Prospectus dated July 13, 2016. This Prospectus Supplement should be read in conjunction with that Prospectus, which is to be delivered with this Prospectus Supplement.

This Prospectus Supplement includes our Current Report on Form 8-K filed with the Securities and Exchange Commission on July 15, 2016.

The date of this Prospectus Supplement is 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

Exhibit 99.1

FDA Issues Complete Response Letter for SequestOx™ New Drug Application

NORTHVALE, N.J. – July 15, 2016 – Elite Pharmaceuticals, Inc. (“Elite” or the “Company”) (OTCBB: ELTP) today announced that the U.S. Food and Drug Administration (the “FDA”) has issued a Complete Response Letter (the “CRL”) regarding the New Drug Application (the “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.

The FDA issues CRLs to indicate that the Agency considers the review cycle for an application is complete and whether the application is ready for approval in its present form. CRLs often include guidance that describes deficiencies that the FDA has identified in the application. When possible, the FDA recommends actions that the applicant may take to place the application in condition for approval. The CRL determined that the NDA was not ready for approval in its present form.

“We are evaluating the CRL received and hope to meet as soon as possible with the FDA to discuss how to address their concerns. We will work closely with the FDA to determine the appropriate next steps and path forward for the NDA,” said Nasrat Hakim, President and CEO of Elite.

After the Company has met with the FDA and the Agency is able to provide greater clarity to the issues raised in the CRL, Elite will host a conference call to discuss the pathway forward for SequestOx™.

About Elite Pharmaceuticals, Inc.

Elite Pharmaceuticals, Inc. is a specialty pharmaceutical company which is developing a pipeline of proprietary pharmacological abuse-deterrent opioid products as well as niche generic products. Elite specializes in oral sustained and controlled release drug products which have high barriers to entry. Elite owns generic and OTC products which have been licensed to TAGI Pharma, Epic Pharma and Valeant Pharmaceuticals International. Elite currently has eight commercial products being sold, additional approved products pending manufacturing site transfer and the NDA for

SequestOx™, for which it just received the CRL from the FDA. Elite's lead pipeline products include abuse-deterrent opioids which utilize the Company's patented proprietary technology and a once-daily opioid. These products include sustained release oral formulations of opioids for the treatment of chronic pain. These formulations are intended to address two major limitations of existing oral opioids: the provision of consistent relief of baseline pain levels and deterrence of potential opioid abuse. Elite also provides contract manufacturing for Ascend Laboratories (a subsidiary of Alkem Laboratories Ltd.). Elite operates a GMP and DEA registered facility for research, development, and manufacturing located in Northvale, NJ. Learn more at www.elitepharma.com.

This press release 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 press release, 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.

Contact:

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