ELITE PHARMACEUTICALS INC /NV/
Form 424B3
July 21, 2016

Filed Pursuant to Rule 424(b)(3)

Registration No. 333-212266

PROSPECTUS SUPPLEMENT

Number 2

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. 2 supplements the information provided in our Prospectus dated July 13, 2016 and Prospectus Supplement No. 1 dated July 15, 2016. This Prospectus Supplement should be read in conjunction with that Prospectus and Prospectus Supplement No. 1, which are 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 21, 2016.

The date of this Prospectus Supplement is July 21, 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 21, 2016 (July 18, 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.

As reported in a Current Report on Form 8-K filed with the SEC on July 15, 2016, 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. 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.

On July 18, 2016, Elite held a conference call to provide more detail about the CRL.

A copy of the transcript of that call 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 transcript 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.

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 8.01 Other Events.

See Item 7.01 above.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Transcript of Conference Call held on July 18, 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 21, 2016 ELITE PHARMACEUTICALS, INC.

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

Exhibit 99.1

Elite Pharmaceuticals

07/18/16

8:30 AM EST

OPERATOR: Good morning ladies and gentlemen and welcome to the Elite Pharmaceuticals conference call. At this time all lines have been placed on a listen only mode.

Before management begins speaking the company has the following statement: this conference call contains forward looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and including those related to the affects, if any, on future results performance or other expectations that may have some correlation to the subject matter of this conference call. Listeners that caution that such forward looking statements involve risks and uncertainties including without limitation Elite's ability to obtain FDA approval of the transfers of the ANDA's 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 expectation timing of approval, if at all, of SequestOx by the FDA, the steps Elite may take as a result of the CLR and 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 actionable performance. These results 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 or future clinical trials, regulatory reviews and approvals by the Food and Drug administration and other regulatory authorities, intellectual property protections and defenses and Elite's ability to operate as a going concern or discuss the lead filings with the Securities and Exchange Commission including certain reports on forms 10-K, 10-Q and 8-K. Elite is under no obligation to update or alter these forward looking statements whether as a result of new information or future events or otherwise.

With that covered it is now my pleasure to turn the floor over to your host, Mr. Nasrat Hakim President and Chief Executive Officer at Elite Pharmaceuticals. Sir, the floor is yours.

MR. HAKIM: Thank you Dave. Good morning ladies and gentlemen and thank you for joining us this morning. Friday we issued a press release informing you that we have received a complete response letter from the FDA stating and I quote, “We can’t approve the application in its present form.” Today I’ll walk you through the details so you understand why the FDA made that decision and how we’re going to overcome it and get SequestOx approved.

In 2014 we ran a BE study, a bio-equivalence study, of all our SequestOx against the brand Roxicodone. This was a standard instant release BE study in that the product is compared to the brand under fasted conditions. Then you compare the product to itself under fed conditions. That’s done to determine the labeling of the product, should you advise the patient to take it any time you want, take it with food or take it an hour before a meal and two hours after a meal. The result of the BE study for SequestOx as comparing SequestOx to the brand were bioequivalent for the area under the curve, Cmax and Tmax. Comparing the profile of SequestOx under fasted versus fed conditions indicated that a fatty meal slows down the Tmax, not the Cmax or AUC but the Tmax. Historically this has been a labeling issue whereby the product is labeled and the doctor and the pharmacist will instruct the patients to take the product an hour before a meal or two hours after a meal.

In our meeting with the FDA in November of 2014, Dr. Hertz requested three extra studies: an efficacy study (a Bunionectomy), an anti-abuse study and a BE study - sorry, it was a withdrawal study and a BE study. We indicated that we know that there is a food effect on our product so why are we doing another BE study for fed? FDA clearly stated that this is not a pass or fail, it's a BE for labeling issue. We complied and we ran the study. We ran a three armed study: SequestOx fed intact, the capsule with a fatty meal; SequestOx sprinkled on applesauce with a light meal - bagel cream cheese, yogurt and applesauce - over 400 - 500 calories - and the brand. The fatty meal, as expected, showed that we are bio-equivalent for the AUC and Cmax but not the Tmax. For the light meal we were bio-equivalent for all three; AUC, Cmax and Tmax.

Let me very quickly summarize, when you're on SequestOx against the brand on fasted conditions we are bioequivalent for AUC, Cmax, and Tmax. When you compare SequestOx in the fed condition using a light meal - a bagel, cream cheese, yogurt and applesauce - that's sprinkled we are also bio-equivalent under AUC, Cmax and Tmax. When you compare SequestOx under fed conditions - a fatty meal, the brand and SequestOx are bio-equivalent for AUC and Cmax but not Tmax. What that means is that there's a delay in getting the effect. We also ran 163 patients in a Bunionectomy that met all its primary points. The Bunionectomy was critical in that these patients ate wherever they fed them at the hospital or the clinic and they went home and ate whatever they wanted for the remainder of the week. The results were successful and we met all of our primary end points.

Historically, again, with this tremendous success and a small effect from the food it would have been a labeling issue where you instruct the patients to take the drug an hour before a meal or two hours after a meal. As a matter of fact that was the FDA's stand when we met with them in 2014. FDA today believes that this is a safety issue and this is exactly what they told us and I'm quoting from the FDA's complete response letter:
"The extent of the delay in the absorption and peak concentration of oxycodone from SequestOx under the fed conditions is unacceptable as it places patients at risk of unintentionally overdosing" the FDA goes on to say because the proposed indication is for acute pain and the product is to be taken as needed product labeling with a specific food recommendation cannot fully mitigate this risk".

Okay so let me paraphrase what the FDA is saying: a patient eats a fatty meal because this is for an acute indication and it's 'as needed'. It's not an extended release where you take one in the morning, so you can plan it before breakfast, and one at night. This is you go out and eat a super fatty meal, then you feel back pain and you go ahead and take a pain pill and you don't feel that it kicked in because of the later Tmax. You take another one, another one and you end up overdosing. That's the concern, okay.

We understand this concern and we would have dealt with it and conducted a BE study that addresses this concern but for the fact the FDA told us it's a labeling issue, okay. Elite demonstrated in a PK study that if SequestOx is sprinkled on food and we use the light meal; then the Tmax effect will go away. We could have ran, if we knew that the FDA now changed their mind that it's no longer a labeling issue that it's a safety issue, we could have ran another arm where we had another fatty meal whereby we sprinkled the contents of the beads of the capsule on applesauce; that they took it with a heavy meal and show that there would be no effect.

We will ask the FDA if proving that the Tmax delay effect goes away with a sprinkled SequestOx on a fatty meal, if that will subside their concern. If so, and it should, will proceed with the BE. I do not want to run another BE and go back to the FDA and have them tell me well we want something else. We're going to communicate with them, we're going to have a meeting with them, we're going to reach a meeting of the minds, get exactly what they want and then execute. We believe instructions to sprinkle when taken with food would avoid any safety concerns.

Next step we will meet with FDA, understanding their concerns we will make our proposal and listen to their proposals and come up with protocol and execute. As I said, the alternative may be as simple as a PK study with a sprinkled bead concept. We will do the right thing and we will work with the agency to make sure that we comply with what they're asking us for. The FDA is responsible for public safety and we take any recommendation they make seriously. The fact that this happened to work against us in this case is disappointing but that does not mean that we will not comply 100% with their requirements.

What I'm going to do is go through the highlights of everything that we've received in the complete response letter to make a point. There were several points, to be exact 7, that the FDA or 7 highlights that the FDA spoke of in the complete response letter. There was only one that really was critical for the product and it is what I already read to you. That is it's delayed for the fed conditions. The second was facilities - satisfactory resolution of the deficiencies is required. We responded to the 483 observations. That's already done. Prescribing information: we reserve comments until this is done, if you would revise your labeling use the SRPI checklist. Also nothing. Proprietary name: SequestOx, was acceptable pending approval of the application in the current review cycle. Resubmit the proposed proprietary name when you respond to the CRL. Not an issue. Safety update: when you respond update your safety as per 21CFR 314.50(d). Eight points under that: all of them are straight forward from the regulations. It's a checklist.

Additional comments, we have the following comments/recommendations that are not approvability issues; send us raw data and validation; send us chromatograms. And finally – seven, which is 'Other': you have one year to respond to this letter. You may request a meeting or teleconference with us to discuss what steps to take before the application may be approved, please contact blah blah and they give us a name to contact.

The reason I walked through all the headers with you for the complete response letter is because the silver lining in this whole disappointing issue is that this is a complete response letter and the FDA made no comment about Elite's

technology because it works and it’s solid. They made no comment on the human abuse liability studies because again they were solid and they work; or with the withdrawal study or the efficacy study – the Bunionectomy. This is great news for Elite’s ADT platform. There is no effect on Elite’s ER formulations because as I said their concern is that this is instant release and it’s used as needed so if you take it when you need it and you just ate a lot of fat then it affects you but for the ER they understand that a patient can plan to take it in the morning and then – before breakfast and before dinner.

I do believe the Tmax effect, we believe is not an issue and with other formulations. The ER's will not get a similar response most likely. In running any business you run through some obstacles, we don't roll over and play dead we solve them and move on. This is absolutely no different, we will work with the agency and hopefully this will not take that long because this will get expedited to review by the agency and executing along any BE or PK study they request or they approve we're going to propose it, should not take that long.

Elite today is in the best financial shape ever in her history. Elite has the best talent and best pipeline, ever. We continue to grow the genetic business and the ADT business and we will file an application every quarter starting with this quarter Q3, 2016 through 2017 and beyond my goal is to file at a minimum 6 applications by the end of next year. We will keep you updated as the FDA responds and we will talk to you in August. Thank you for joining us and have a wonderful day. Thank you Dave.

OPERATOR: Thank you very much ladies and gentlemen; this concludes today's conference call. You may disconnect your phone lines at this time and have a wonderful day. Thank you for your participation.

END