ELITE PHARMACEUTICALS INC /DE/
Form 8-K
November 13, 2007

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

November 9, 2007
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Date of Report (Date of earliest event reported)

ELITE PHARMACEUTICALS, INC.
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(Exact name of registrant as specified in its charter)

| Delaware | 333-45241 | 22-3542636 |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

165 Ludlow Avenue, Northvale, New Jersey 07647
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(Address of principal executive offices)

(201) 750-2646
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(Registrant's telephone number, including area code)

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(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))

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**Item 8.01 Other Events**

On November 9, 2007, the Registrant issued a press release announcing that it has reached an agreement with the U.S. Food and Drug Administration (FDA) under a Special Protocol Assessment on a Phase 3 trial of ELI-216, the Registrants abuse deterrent oxycodone product. The Registrant is now cleared to commence the Phase 3 clinicals trials. The primary objective of the ELI-216 Phase 3 study is to evaluate the safety and efficacy of ELI-216 controlled-release capsules administered once daily compared with placebo in the treatment of a pain associated with osteoarthritis. This study will be targeted to enroll approximately 150 patients in each treatment group in the double blind randomized maintenance period of the study (approximately 300 patients in total). A copy of the press release is attached hereto as Exhibit 99.1.

**Item 9.01 Financial Statements and Exhibits**

a) Not applicable.

b) Not applicable.

c) Exhibits

99.1. Press Release, dated November 9, 2007

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: November 13, 2007

ELITE PHARMACEUTICALS, INC.

By: /s/ Bernard Berk
Name: Bernard Berk
Title: Chief Executive Officer