

ELITE PHARMACEUTICALS INC /DE/
Form 8-K
January 09, 2008

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

January 3, 2008

Date of Report (Date of earliest event reported)

ELITE PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware

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 1.01
Item 3.02
Item 5.02

Entry into a Material Definition Agreement
Unregistered Sales of Equity Securities
Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On January 3, 2008, the Registrant entered into an employment agreement with Dr. Stuart Apfel (the "Employment Agreement") providing for Dr. Apfel to serve as the Registrant's Chief Medical Officer through January 3, 2009 and automatically renewable for one year periods thereafter unless terminated by Dr. Apfel or the Registrant upon at least 60 days notice prior to the end of the then scheduled expiration date.

The Employment Agreement provides that Dr. Apfel shall be entitled to an initial base annual salary of \$220,000. Dr. Apfel shall be entitled to a discretionary bonus following the end of each calendar year, commencing with the calendar year beginning January 1, 2008, of up to 50% of Dr. Apfel's then annual base salary. The amount, if any, of the discretionary bonus will be determined by the Board of Directors (the "Board") or the Compensation Committee of the Board. The discretionary bonus which may be paid to Dr. Apfel shall be based on the achievement of goals discussed with the executive in good faith and within a reasonable time following the commencement of each calendar year and may be paid in cash or shares of the Registrant's common stock, par value \$0.01 per share (the "Common Stock") valued at the closing price of the Common Stock on the immediately preceding trading day, for the relevant calendar year (pro-rated for periods of less than a full calendar year).

Pursuant to the terms of the Employment Agreement, the Registrant has granted to Dr. Apfel under the 2004 Stock Option Plan (the "2004 Plan") fully vested options to purchase 120,000 shares of Common Stock at an exercise price of \$1.75 per share.

Pursuant to the terms of the Employment Agreement, the Registrant has granted to Dr. Apfel under the 2004 Plan options to purchase up to and additional 280,000 shares of Common Stock ("Milestone Options") at an exercise price of \$1.75 per share. Such Milestone Options vest and become exercisable as follows: (A) 80,000 shares upon the successful completion, as determined by the Board, of a Registrant sponsored Phase III clinical trial of the Registrant's developmental drug product referred to as ELI-216; (B) 80,000 shares upon the successful completion, as determined by the Board, of a Registrant sponsored Phase III clinical trial of the Registrant's developmental drug product referred to as ELI-154; (C) 80,000 shares upon the successful completion, as determined by the Board, by the Registrant during the term of the Employment Agreement of a Registrant sponsored long-term safety study for the Registrant's developmental drug product referred to as ELI-216; and (D) 40,000 shares upon the closing of an exclusive product license for the United States national market, or product sale transaction of all of the Registrant's ownership rights, for either ELI-216 or ELI-154. Upon the earlier to occur of (x) January 3, 2017 and (y) the termination of Dr. Apfel's employment hereunder, all unvested Milestone Options granted shall automatically terminate and all vested but unexercised Milestone Options shall terminate to the extent unexercised within ninety (90) days of such date and in accordance with the terms of the stock option agreement by and between Dr. Apfel and the Registrant with respect to the Milestone Options and the 2004 Plan. The shares of Common Stock issuable upon exercise of the Milestone Options are subject to an effective registration statement filed with the Securities and Exchange Commission

The Registrant, in its discretion, may grant to Dr. Apfel additional options under the 2004 Plan.

Pursuant to the terms of the Employment Agreement Dr. Apfel is entitled to a \$420 per month automobile allowance, 15 business days of paid vacation per calendar year, and reimbursement of expenses (including business, travel and entertainment) reasonably incurred in the performance of his duties, provided that reimbursement of expenses in excess of \$500 per month are subject to the approval of the Registrant's Chief Executive Officer. Dr. Apfel is entitled to participate in such employee benefit and

welfare plans and programs, which may be offered to senior executives of the Registrant including life insurance, health and accident, medical plans and programs and profit sharing and retirement plans. The Registrant will obtain and maintain during the term of the Employment Agreement a term life insurance policy in the amount of \$500,000 on the life of Dr. Apfel payable to the estate of Dr. Apfel in the event of Dr. Apfel's death during the term of the employment agreement.

The Registrant has the right to terminate Dr. Apfel's employment due to disability as defined in a long-term disability insurance policy reasonably satisfactory to him or, in the absence of such policy, due to his inability for 120 days in any 12 month period to substantially perform his duties as a result of a physical or mental illness.

In the event the Registrant terminates Dr. Apfel's employment for "Cause" (as defined in the Employment Agreement) or due to Dr. Apfel's death or disability, or Dr. Apfel terminates his employment for any reason other than "Good Reason" (as defined in the Employment Agreement), Dr. Apfel or his estate is to receive salary through date of termination, reimbursement for expenses incurred prior to termination, all unvested options will terminate as of the date of termination and vested options are to be exercisable for 90 days from the date of termination.

In the event of Dr. Apfel's termination by the Registrant without Cause or by Dr. Apfel for Good Reason, the Registrant is to pay Dr. Apfel, subject to his compliance with certain covenants, including non-competition, non-solicitation, confidentiality and assignment of intellectual property, his base salary for the balance of the calendar year and any accrued but unused vacation, maintain his benefits during the balance of the calendar year, and all unvested options will terminate as of the date of termination and his vested options are to be exercisable for 90 days from date of termination.

Pursuant to the Employment Agreement, Dr. Apfel has agreed to covenants not to disclose confidential information and assignment of intellectual property and a two year from termination non-competition covenant and non-solicitation covenant.

Dr. Apfel holds an ownership interest in Parallax Clinical Research, a New York-based consulting firm that provides strategic and practical assistance with clinical trial protocol design, planning, initiating and management to biotechnology and small pharmaceutical companies with making the transition from the bench to a clinical development program and during the term of the Employment Agreement, Dr. Apfel shall continue to devote a portion of his time to Parallax and provides services, on behalf of Parallax, to its clients, provided that such time and services do not interfere with the effective performance of his duties under the Employment Agreement and such services shall not violate any provision of the Employment Agreement or any of the Registrant's policies.

Dr. Stuart Apfel is currently founder and president of Parallax and in this capacity he has served as a consultant to the Registrant over the past year. From 2003 to 2006, Dr. Apfel was a senior director of clinical research at DOV Pharmaceuticals, Inc. (OTC:DOVP). From 2000 to 2003, Dr. Apfel was a director of clinical research at Purdue Pharma L.P. Dr. Apfel is a board certified neurologist, and is currently on faculty as Associate Professor of Neurology at the Albert Einstein College of Medicine and at Downstate Medical School, where he continues to teach. Previously he was a full time faculty member in the departments of Neurology and Neuroscience at Albert Einstein from 1990 to 2000, where his research focused on the application of neurotrophic factors to neurologic disease.

Item 2.01 Completion of Acquisition or Disposition of Assets.
Item 8.01 Other Events

Under the terms of the Strategic Alliance Agreement (the "*Alliance Agreement*"), dated as of December 6, 2006, between the Registrant, Dr. Veerappan S. Subramanian and VGS Pharma, LLC, a Delaware limited liability company ("*VGS*"), the Registrant and VGS jointly formed Novel Laboratories, Inc., a Delaware corporation ("*Novel*"), a specialty pharmaceutical company for the research,

development, manufacturing, licensing and acquisition of specialty generic pharmaceuticals. Under the Alliance Agreement, the Registrant acquired 49% and VGS acquired 51% of Novel's Class A Voting Common Stock, for \$9,800 and \$10,200 respectively. In order to maintain its full 49% interest in Novel, the Registrant agreed to provide additional cash contributions to Novel upon achievement by Novel of certain performance milestones. While the contributions were not mandatory obligations of the Registrant, under the Stockholders Agreement, dated as of December 6, 2006, between the Registrant and VGS (the *Stockholders Agreement*), if the Registrant does not fund an agreed upon contribution after the occurrence of the related performance milestone, VGS would have the right to purchase from the Registrant a pre-defined portion of the Registrant's shares of Class A Voting Common Stock, resulting in a decrease in the Registrant's ownership interest in Novel. Under the Stockholders Agreement, the Registrant was granted subscription rights entitling the Registrant to purchase, in subsequent Novel equity offerings, a portion of such subsequent offering necessary to maintain the Registrant's then current percentage ownership of Novel (the *Subscription Right*)

Subsequent to the entry into the Alliance Agreement, the Registrant and VGS agreed that the performance milestones relating to the funding of the Registrant's remaining \$20,000,000 of cash contributions would be as follows: (i) \$10,000,000 upon the submission to the FDA of three abbreviated new drug applications (ANDAs) related to three different prospective products developed by Novel and (ii) \$10,000,000 upon the submission to the FDA of three ANDAs related to at least three additional different prospective products developed by Novel. In October 2007, the Registrant was notified by Novel of the submission to the FDA of its third ANDA and, pursuant to the terms of the Alliance Agreement, the Registrant requested and received, in November 2007, written evidence verifying that such ANDA filings related to prospective products developed by Novel.

The Registrant elected not to fund its remaining contributions to Novel upon the terms set forth in the Alliance Agreement because (i) the Registrant recently reached agreement with the FDA under a Special Protocol Assessment on the Phase III clinical trial of ELI-216, Elite's Abuse Deterrent Oxycodone product and determined that its funds would be better used to support the clinical trials for ELI-216 and (ii) the Registrant determined it would utilize its rights to participate in future equity investment in Novel rather than invest at the valuation set forth under the Alliance Agreement in order to maintain its 49% interest in the Class A Voting Common Stock of Novel. The Registrant is scheduled to commence Phase III trials for ELI-216 in the first quarter 2008.

The Registrant and VGS negotiated alternative structures that would permit investments by the Registrant at valuations which differed from those set forth in the Alliance Agreement, however the parties were unable to agree upon an alternative acceptable to both parties. Accordingly, upon the Registrant's determination not to fund its remaining contributions to Novel at the valuation set forth in the Alliance Agreement, VGS exercised its rights under the Stockholders Agreement to purchase from the Registrant shares of Class A Voting Common Stock of Novel proportionate to the amount of remaining contributions which were not funded by the Registrant. As a result, the Registrant's remaining ownership interest in Class A Voting Common Stock of Novel is approximately 10% of the outstanding shares of Class A Voting Common Stock of Novel.

The Registrant intends to rely upon its Subscription Rights in order to maintain its ownership in Novel and to determine, on an offering by offering basis, whether the valuation ascribed to Novel is appropriate for additional investments by Registrant.

The Registrant and VGS continue their discussions as to the possible restructuring of the capital structure of Novel.

On January 8, 2008, the Registrant issued a press release announcing the appointment of Stuart Apfel as the Registrant's Chief Medical Officer. A copy of the press release is attached hereto as exhibit 99.1.

The Registrant's policy regarding director fees has been revised as follows: (i) directors who are employees or consultants of the Registrant (and/or any of its subsidiaries) receive no additional remuneration for serving as directors or members of committees of the Board; (ii) all directors are entitled to reimbursement for out-of-pocket expenses incurred by them in connection with their attendance at the Board or committee meetings; (iii) directors who are not employees or consultants of the Registrant (and/or any of its subsidiaries) receive \$15,000 annual retainer fee for their service on the Board and all committees; (iv) directors who are not employees or consultants of the Registrant (and/or any of its subsidiaries) receive a per board meeting fee of \$1,000 for each board meeting and a per committee meeting fee of \$1,000 for each committee meeting attended by such director; provided that the chairperson of the committee conducting such meeting shall (in place of the \$1,000 meeting fee) receive a per committee meeting fee of \$1,500 for each committee meeting attended; and (v) for purposes of the compensation schedule set forth above, (x) a meeting shall only constitute a meeting of the Board or a committee entitling a participant to a meeting fee if such meeting extends to at least sixty (60) minutes (including the time of any reconvened portion of a meeting after an adjournment), (y) a meeting shall include all meetings attended in-person (whether at the Registrant's offices or at any other location) or via telephone conference, and (z) only one fee may be payable to per director and/or committee member per calendar day.

Item 9.01 Financial Statements and Exhibits

- a) Not applicable.
- b) Not applicable.
- c) Exhibits

Exhibit No. Exhibit

- 10.1 Employment Agreement, dated as of January 3, 2008, by and between the Registrant and Stuart Apfel.
- 99.1 Press Release, dated January 8, 2008.

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: January 9, 2008

ELITE PHARMACEUTICALS, INC.

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