

ELITE PHARMACEUTICALS INC /NV/
Form 8-K
August 23, 2013

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**

August 19, 2013

Date of Report (Date of earliest event reported)

ELITE PHARMACEUTICALS INC.

(Exact name of registrant as specified in its charter)

001-15697 22-3542636

Nevada

(State or other jurisdiction (Commission (IRS Employer
of incorporation) File Number) Identification No.)

165 Ludlow Avenue, Northvale NJ 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 (*see* General Instruction A.2. below):

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. Entry into a Material Definitive Agreement.

On August 19, 2013, Elite Pharmaceuticals, Inc. ("Elite" or the "Company") executed a Master Services Agreement ("Agreement") with Camargo Pharmaceutical Services, LLC ("Camargo"). Under the Agreement, Camargo will provide various services to assist Elite with the U. S. Food and Drug Administration 505(b)(2) regulatory pathway for the products utilizing the Company's abuse resistant technology. Elite is scheduled to begin clinical studies with the initial product later this year.

A 505(b)(2) is a new drug application that contains full safety and effectiveness reports, but allows at least some of the information required for approval to come from studies not conducted by or for the applicant. This method is a holistic approach for developing products that offer differentiated benefits and gains approval for new drugs in a fraction of the time and cost required by traditional paths. Conducting clinical trials does not assure a successful outcome or FDA approval.

Camargo is a full-service drug development partner specializing in the 505(b)(2) process — an approach for developing products that offer differentiated benefits. Camargo is capable of managing every facet of the plan throughout the development continuum, from feasibility assessments, formulation and testing the drug product, to conducting preclinical and clinical studies, to final submission.

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: August 23, 2013 **ELITE PHARMACEUTICALS, INC.**

By: /s/ Nasrat Hakim
Nasrat Hakim
President and Chief Executive Officer

