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

June 15, 2026
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))

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	ELTP	OTCQB

Item 7.01 Regulation FD Disclosure.

In a press release on June 15, 2026, Elite Pharmaceuticals, Inc., or Elite, reported positive results from a pivotal bioequivalence study for an undisclosed generic drug product in a class of medications called anticonvulsants. The results indicate that the generic product is bioequivalent to the branded product.

The studies conducted were open-label, randomized, balanced, single oral dose, two-treatment, two-period, two-sequence, crossover bioequivalence studies in normal, healthy, adult, human subjects under fasting conditions. The results indicated that the generic product is bioequivalent to the branded product. Elite is compiling the data for this product to file an Abbreviated New Drug Application with the US Food and Drug Administration.

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.

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 ANDA 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 are not guarantees of future action or performance, 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, 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 June 15, 2026
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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: June 15, 2026

ELITE PHARMACEUTICALS, INC.

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

Exhibit 99.1

Elite Pharmaceuticals Reports Positive Results from a Pivotal Bioequivalence Study

NORTHVALE, N.J. – June 15, 2026 – Elite Pharmaceuticals, Inc. ("Elite" or the "Company") (OTCBB: ELTP), a specialty pharmaceutical company engaged in the development, manufacture, and distribution of niche generic products, today reported positive results from a pivotal bioequivalence study for an undisclosed anticonvulsant generic drug product.

IQVIA reported branded and generic product sales for the twelve months ending April 2026 of $840 million.

The studies conducted were open-label, randomized, balanced, single oral dose, two-treatment, two-period, two-sequence, crossover bioequivalence studies in normal, healthy, adult, human subjects under fasting conditions. The results indicated that the generic product is bioequivalent to the branded product. Elite is compiling the data for this product to file an Abbreviated New Drug Application with the US Food and Drug Administration.

About Elite Pharmaceuticals, Inc.

Elite Pharmaceuticals, Inc. is a specialty pharmaceutical company that develops, manufactures, and distributes niche generic products. Elite's product lines consist of immediate-release and controlled-release, solid oral dose products, which are marketed under the Elite Laboratories label, as well as pursuant to licenses granted to third-party pharmaceutical marketing and distribution organizations. Elite operates a cGMP and DEA registered facility for research, development, and manufacturing located in Northvale, NJ. For more information, visit www.elitepharma.com.

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, without limitation, 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, without limitation, risks, uncertainties, 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 products by the FDA and the actions the FDA may require of Elite in order to obtain such approvals. These forward-looking statements are not guarantees of future action or performance. These risks and other factors are discussed, without limitation, 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.

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