

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

April 30, 2025
Date of Report (Date of earliest event reported)

ELITE PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Nevada
(State or other jurisdiction
of incorporation)

001-15697
(Commission
File Number)

22-3542636
(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.

On April 30, 2025, Elite Pharmaceuticals, Inc. ("Elite" or the "Company") issued a press release to announce the launch of Elite's generic version of Percocet® (oxycodone hydrochloride and acetaminophen tablets, USP CII) 5mg/325mg, 7.5mg/325mg and 10mg/325mg tablets. This product is marketed and sold under the Elite Laboratories, Inc. label.

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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated April 30, 2025
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: April 30, 2025

ELITE PHARMACEUTICALS, INC.

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



Elite Pharmaceuticals Announces Commercial Launch of Oxycodone and Acetaminophen Tablets

NORTHVALE, N.J. – April 30, 2025 – Elite Pharmaceuticals, Inc. (“Elite” or the “Company”) (OTCQB: ELTP), a specialty pharmaceutical company developing niche generic products, today announced that the company has launched Elite’s generic version of Percocet[®] (oxycodone hydrochloride and acetaminophen tablets, USP CII) 5mg/325mg, 7.5mg/325mg and 10mg/325mg tablets. Oxycodone HCl and acetaminophen is indicated for the relief of moderate to moderately severe pain.

IQVIA reported 2024 annual sales of approximately \$317 million for this product.

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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