

**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

Date of Report (Date of earliest event reported): July 11, 2025 (July 9, 2025)

LIXTE BIOTECHNOLOGY HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE
(State or other jurisdiction
of incorporation)

001-39717
(Commission
File Number)

20-2903526
(I.R.S. Employer
Identification Number)

680 East Colorado Boulevard, Suite 180
Pasadena, California 91101
(Address of principal executive offices)

(631) 830-7092
(Registrant's telephone number, including area code)

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 of 1933 (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(e) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of Each Class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$0.0001 per share	LIXT	The NASDAQ Stock Market, LLC
Warrants to Purchase Common Stock, par value \$0.0001 per share	LIXTW	The NASDAQ Stock Market, LLC

Indicate by check mark whether the registrant is an emerging growth company 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. ☐

Item 8.01. Other Events.

On July 9, 2025, Lixte Biotechnology Holdings, Inc. (the "Company") issued a press release announcing that the Medical Journal *Nature* published findings by a team of physician scientists that validate the scientific premise underlying the Company's ongoing clinical trials for Ovarian and Colorectal cancers. A copy of the press release is filed as Exhibit 99.1 hereto and is incorporated by reference.

Item 9.01. Financial Statements and Exhibits.

(d) There is filed as part of this report the exhibits listed on the accompanying Index to Exhibits, which exhibits are incorporated herein by reference.

SIGNATURES

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.

Date: July 11, 2025

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
(Registrant)

By: /s/ Geordan Pursglove
Geordan Pursglove
Chief Executive Officer

INDEX TO EXHIBITS

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated July 9, 2025 regarding an article in the publication <i>Nature</i>
104	Cover Page Interactive Data File (embedded within the Inline XBRL Document)

**New Clinical Findings Published in Scientific Journal *Nature*
Validate LIXTE's Ongoing Ovarian and Colorectal Cancer Trials**

***Article Indicates that Inhibition of PP2A Enhances Immunotherapy Response
with LIXTE's Proprietary Compound LB100***

PASADENA, Calif., July 9, 2025—**LIXTE Biotechnology Holdings, Inc.** ("LIXTE" or the "Company") (Nasdaq: **LIXT** and **LIXTW**), a clinical stage pharmaceutical company, today announced that the medical journal *Nature* has published findings by a team of physician-scientists that validate LIXTE's ongoing clinical trials with its proprietary compound LB100 for Ovarian and Colorectal cancers (<https://www.nature.com/articles/s41586-025-09203-8>).

A team led by principal investigator Amir Jazaeri, MD, professor of Gynecologic Oncology and Reproductive Medicine at The University of Texas MD Anderson Cancer Center, studied survival outcomes of Ovarian Clear Cell Carcinoma (OCCC) patients treated with immune checkpoint blockade therapy (clinicaltrials.gov identifier: NCT03026062). The study showed that patients having tumors with inactivating mutations in PPP2R1A - the major scaffold subunit of protein phosphatase 2A (PP2A) - had significantly better overall survival, compared with patients who did not have this mutation in their tumors.

Inactivating mutations in PPP2R1A are known to reduce the enzymatic activity of PP2A, which is the target of LIXTE's lead compound LB-100. Tumors with mutations in PPP2R1A were found to have increased the interferon gamma response pathway, which is known to be associated with improved immune checkpoint responses.

LIXTE is currently investigating the activity of LB-100 in combination with checkpoint immunotherapy in two clinical trials. The first is enrolling patients with OCCC, led by Dr. Jazaeri at MD Anderson Cancer Center, and also is open at Northwestern University. In this trial, LIXTE is collaborating with GSK to test LB-100 in combination with dostarlimab (anti PD1). In the second trial, at the Netherlands Cancer Institute, LIXTE is collaborating with Roche to test LB-100 in combination with atezolizumab (anti PDL1) in colon cancer patients.

"Not only did we identify a new biomarker for improved survival with immunotherapy in ovarian cancer, but we also confirmed the correlation of this biomarker with survival benefit in other cancer types," said Dr. Jazaeri, who was co-senior author of the *Nature* article. "Since PPP2R1A mutations are relatively uncommon, we believe the same benefits may be possible by targeting the PPP2A pathway using drugs, which we currently are evaluating in a clinical trial at MD Anderson."

Bas van der Baan, LIXTE's Chief Scientific Officer, added, "This work extends a body of pre-clinical evidence indicating that LB-100 is strongly synergistic with checkpoint immunotherapy in a range of cancer types. We look forward to the first results of our clinical studies in the second half of this year."

About LIXTE Biotechnology Holdings, Inc.

LIXTE Biotechnology Holdings, Inc. is a clinical-stage pharmaceutical company focused on new targets for cancer drug development and developing and commercializing cancer therapies. LIXTE has demonstrated that its first-in-class lead clinical PP2A inhibitor, LB-100, is well-tolerated in cancer patients at doses associated with anti-cancer activity. Based on extensive published preclinical data (see www.lixte.com), LB-100 has the potential to significantly enhance chemotherapies and immunotherapies and improve outcomes for patients with cancer.

LIXTE's lead compound, LB-100, is part of a pioneering effort in an entirely new field of cancer biology – activation lethality – that is advancing a new treatment paradigm. LIXTE's new approach is covered by a comprehensive patent portfolio. Proof-of-concept clinical trials are currently in progress for Ovarian Clear Cell Carcinoma, Metastatic Colon Cancer and Advanced Soft Tissue Sarcoma. Additional information about LIXTE can be found at www.lixte.com.

Forward-Looking Statement Disclaimer

This announcement contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, and Section 21E of the Securities Exchange Act of 1934. For example, statements regarding the Company's financial position, business strategy and other plans and objectives for future operations, and assumptions and predictions about future activities, including the continuing development of proprietary compounds, the planning, funding, coordination and potential results of clinical trials, the patent and legal costs to protect and maintain the Company's intellectual property worldwide, and the Company's ability to obtain and maintain compliance with Nasdaq's continued listing requirements, are all forward-looking statements. These statements are generally accompanied by words such as "intend," "anticipate," "believe," "estimate," "potential(ly)," "continue," "forecast," "predict," "plan," "may," "will," "could," "would," "should," "expect" or the negative of such terms or other comparable terminology.

The Company believes that the assumptions and expectations reflected in such forward-looking statements are reasonable, based on information available to it on the date hereof, but the Company cannot provide assurances that these assumptions and expectations will prove to have been correct or that the Company will take any action that the Company may presently be planning. However, these forward-looking statements are inherently subject to known and unknown risks and uncertainties. Actual results or experience may differ materially from those expected or anticipated in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, regulatory policies, available cash resources, research results, competition from other similar businesses, and market and general economic factors.

Readers are urged to read the risk factors set forth in the Company's filings with the United States Securities and Exchange Commission at <https://www.sec.gov>. The Company disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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