
**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): March 31, 2025

LIXTE BIOTECHNOLOGY HOLDINGS, INC.

DELAWARE
(State or other jurisdiction
of incorporation)

001-39717
(Commission
File Number)

20-2903526
(IRS Employer
Identification No.)

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:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
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 March 31, 2025, Lixte Biotechnology Holdings, Inc. (the "Company") issued a news release announcing that it launched a new study to determine if certain pre-cancerous cells found in an aging population can be eliminated by LB-100. The pre-clinical study is being done in collaboration with the Netherlands Cancer Institute.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The Company is filing as part of this Current Report on Form 8-K the exhibits listed on the accompanying Index to Exhibits, which information is 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.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
(Registrant)

INDEX TO EXHIBITS

Exhibit No.	Description
99.1	News release announcing that the Company had launched a new study to determine if certain pre-cancerous cells found in an aging population can be eliminated by LB-100
104	Cover Page Interactive Data File (embedded within the Inline XBRL Document)



LIXTE Launches New Study to Determine if Certain Pre-Cancerous Cells Found in an Aging Population Can Be Eliminated by LB-100

Pre-Clinical Study in Collaboration with Netherlands Cancer Institute is in addition to LIXTE's Ongoing Clinical Trials for Ovarian and Colorectal Cancers

PASADENA, Calif., March 31, 2025—LIXTE Biotechnology Holdings, Inc. ("LIXTE" or the "Company") (Nasdaq: LIXT and LIXTW), a clinical stage pharmaceutical company, today announced it will conduct a new pre-clinical study in collaboration with Netherlands Cancer Institute (NKI) to test whether "initiated" cells that carry mutations found in cancer cells can be eliminated by treatment with LIXTE's proprietary compound LB-100.

"In addition to our ongoing clinical trials in ovarian and colorectal cancer, this study represents a new opportunity in cancer prevention," said Bas van der Baan, LIXTE's Chief Executive Officer. "Thus far in our Phase 1 clinical trials, LB-100 has shown patient tolerance, with little toxicity, making it a promising candidate as a broad and effective cancer prevention modality."

Increasing evidence indicates that as individuals age, certain mutations accumulate that are found in cancer cells. While these "initiated" cells behave essentially normally, they can propagate to form reservoirs of pre-malignant cells from which malignant cells may eventually emerge. Recent data from LIXTE's ongoing clinical collaboration with NKI shows that LB-100 activates oncogenic signaling and that this is detrimental to cancer cells.

The new study in animal models will investigate whether "initiated" cells, harboring a mutant RAS oncogene, can be eliminated with LB-100. If successful, LB-100 could have a significant role in the elimination of initiated cells in aged individuals and could reduce the risk of developing a wide range of cancers as a person ages.

The study will be led by René Bernards, Ph.D., a global leader in the field of molecular carcinogenesis and Senior Staff Scientist at NKI, one of the world's leading comprehensive cancer centers. Dr. Bernards also is a member of LIXTE's Board of Directors.

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.lixe.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 colon, small cell lung and sarcoma cancers. Additional information about LIXTE can be found at www.lixe.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.

For more information about LIXTE, contact: info@lixe.com
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or

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