

**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): June 14, 2024

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(e))

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

Item 8.01. Other Events.

Reference is made to the Current Report on Form 8-K of Lixte Biotechnology Holdings, Inc. (the "Company") filed on June 14, 2024 relating to a collaboration with Roche and the Netherlands Cancer Institute to conduct a new clinical trial in immune therapy unresponsive (MSI Low) metastatic colon cancer. On June 14, 2024, the Company issued an updated press release regarding such collaboration.

Item 9.01. Financial Statements and Exhibits.

(d) The Exhibits listed on the accompanying Index to 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: June 14, 2024

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
(Registrant)

By: /s/ BASTIAAN VAN DER BAAN
Bastiaan van der Baan
Chief Executive Officer

INDEX TO EXHIBITS

Exhibit No.	Description
99.1	Updated Press Release regarding the collaboration with Roche and the Netherlands Cancer Institute to conduct a new clinical trial in immune therapy unresponsive (MSI Low) metastatic colon cancer.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

LIXTE Biotechnology Holdings announces collaboration on a New Colon Cancer Clinical Trial**Clinical trial to test recent findings that show LIXTE's lead clinical compound, LB-100, increases recognition of colon cancer cells by the immune system**

PASADENA, CA, June 14, 2024 (GLOBE NEWSWIRE) -- LIXTE Biotechnology Holdings, Inc. ("LIXTE" or the "Company") (Nasdaq: LIXT and LIXTW), a clinical stage pharmaceutical company, today announced a collaboration with Roche and the Netherlands Cancer Institute (NKI) to conduct a new clinical trial in immune therapy unresponsive (MSI Low) metastatic colon cancer.

As part of the new clinical trial, listed as NCT06012734 at clinicaltrials.gov, LIXTE will provide its lead compound, LB-100, and Roche will provide atezolizumab (Tecentriq®, a PD-L1 inhibitor) through the imCORE Network, an academic-industry collaboration that aims to accelerate cancer immunotherapy research through institution-sponsored studies.

"This is an exciting new clinical trial," said Neeltje Steeghs, M.D., Ph.D., medical oncologist from NKI and Antoni van Leeuwenhoek Hospital, who is serving as principal investigator of the trial. "Only about 15% of colon cancers are responsive to immunotherapy, the so-called MSI High cancers. However, approximately 85% of colon cancers are MSI Low where immunotherapy has no activity at all. If we are able to sensitize these tumors to immunotherapy with LB-100, we could bring immunotherapy as an effective treatment option to a large group of colon cancer patients."

Bas van der Baan, LIXTE's Chief Executive Officer, said, "The ongoing interest in and support of this clinical trial underscores the strength of the scientific rationale and potential of our lead compound, LB-100. This is the second recent clinical trial combining LB-100 with immunotherapy that is supported by a major pharmaceutical company, following the start of a clinical trial earlier this year that is being funded by GSK for the treatment of clear cell ovarian cancer."

NKI is one of the world's leading comprehensive cancer centers. René Bernards, Ph.D., a leader in the field of molecular carcinogenesis and Senior Staff Scientist at the Netherlands Cancer Institute, is a member of LIXTE's Board of Directors.

A recent publication of new pre-clinical data in the journal *EMBO Reports* showed that LIXTE's lead compound, LB-100, can turn immunologically "cold" tumors "hot," thereby potentially enhancing the response to immunotherapy. This publication builds on a large body of scientific and emerging clinical evidence that LB-100 has strong synergy with checkpoint immunotherapy.

Tecentriq® (atezolizumab) is a registered trademark of Genentech, a member of the Roche Group.

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 colon, small cell lung and sarcoma cancers. 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.

For more information about LIXTE, Contact: info@lixte.com

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