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): January 29, 2024

LIXTE BIOTECHNOLOGY HOLDINGS, INC.

DELAWARE	001-39717	20-2903526
(State or other jurisdiction of incorporation)	(Commission File Number)	(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	LIXT	The Nasdaq Stock Market LLC
Warrant to Purchase Common Stock	LIXTW	The Nasdaq Stock Market LLC

Item 8.01 Other Events.

On January 29, 2024, Lixte Biotechnology Holdings, Inc. (the "Company") issued a press release announcing the dosing of the first patient in a clinical trial for the treatment of ovarian clear cell carcinoma.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The Company is filing as part of this Report 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.

Date: January 29, 2024

LIXTE BIOTECHNOLOGY HOLDINGS, INC.

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

INDEX TO EXHIBITS

Exhibit No.	Description
99.1	Press release announcing the dosing of the first patient in a clinical trial for the treatment of ovarian clear cell carcinoma
104	Cover Page Interactive Data File (embedded within the Inline XBRL Document)

First Patient Dosed with LIXTE's LB-100 and GSK's Immunotherapy Dostarlimab-gxly in Ovarian Clear Cell Carcinoma Trial

PASADENA, CA, January 29, 2024 — LIXTE Biotechnology Holdings, Inc. (Nasdaq: LIXT and LIXTW) ("LIXTE" or the "Company"), today announced the dosing of the first patient in a Phase 1b/2 clinical trial to assess whether adding LIXTE's LB-100 to GSK's programmed death receptor-1 (PD-1)-blocking monoclonal antibody, dostarlimab-gxly, may enhance the effectiveness of immunotherapy in the treatment of ovarian clear cell carcinoma (OCCC).

The clinical trial was initiated by and is being conducted at The University of Texas MD Anderson Cancer Center. LIXTE is providing LB-100; GSK is providing dostarlimab-gxly and financial support for the clinical trial.

The clinical trial (NCT06065462) is based on the observation by the lead clinical investigator of the trial, Amir Jazaeri MD, Professor of Gynecologic Oncology at MD Anderson, that a genetically acquired reduction in PP2A may enhance sensitivity to immunotherapy[i]. This raises the possibility that reducing PP2A pharmacologically with LB-100 may enhance the anti-tumor effect of the PD-1 blocking monoclonal antibody, dostarlimab-gxly, in patients with OCCC lacking the genetic reduction in PP2A.

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[ii]. Based on extensive published preclinical data (see www.lixte.com), LB-100 has the potential to significantly improve outcomes for patients undergoing various chemotherapies or immunotherapies. LIXTE's new approach has no known competitors and is covered by a comprehensive patent portfolio. Proof-of-concept clinical trials are in progress.

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.

[i] **Hinchcliff EM,** Patel A, Fellman B, Westin SN, Sood A, Soliman P, Shafer A, Meyer L, Fleming N, Bathala Y, Ganeshan D, Hwu P, Lu K, **Jazaeri A**. Loss-of-function mutations in PPP2R1A Correlate with Exceptional Survival in Ovarian Clear Cell Carcinomas Treated with Immune Checkpoint Inhibitors. National oral presentation at SGO Annual Meeting, March 2022

[ii] **Chung V** et. al. Safety, Tolerability, and Preliminary Activity of LB-100, an Inhibitor of Protein Phosphatase 2A, in Patients with Relapsed Solid Tumors: An Open-Label, Dose Escalation, First-in-Human, Phase I Trial. Clin Cancer Res. 2017;23(13):3277-84.

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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