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): August 15, 2024

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 ClassTrading Symbol(s)Name of each exchange on which registeredCommon StockLIXTThe Nasdaq Stock Market LLCWarrant to Purchase Common StockLIXTWThe Nasdaq Stock Market LLC

Item 8.01 Other Events.

On August 15, 2024, Lixte Biotechnology Holdings, Inc. (the "Company") issued a press release announcing that it will be presenting at two investor conferences.

On August 19, 2024, the Company issued a press release providing an update on the Company's recent activities.

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: August 19, 2024

LIXTE BIOTECHNOLOGY HOLDINGS, INC. (Registrant)

By: /s/ BASTIAAN VAN DER BAAN

Bastiaan van der Baan Chief Executive Officer

Exhibit No. Description 99.1 Press release announcing that the Company will be presenting at two investor conferences 99.2 Press release providing an update on the Company's recent activities 104 Cover Page Interactive Data File (embedded within the Inline XBRL Document)



LIXTE Biotechnology Holdings to Present at Two Investor Conferences

-Company to Present August 20 at Investor Summit Summer 2024 Virtual Conference; and September 9-11 at H.C. Wainwright 26th Annual Global Investment Conference-

PASADENA, CALIF., August 15, 2024 - LIXTE Biotechnology Holdings, Inc. ("LIXTE" or the "Company") (Nasdaq: LIXT) and LIXTW), a clinical stage pharmaceutical company, today announced it will be presenting at two investor conferences:

- The Investor Summit Summer 2024 Virtual Conference Tuesday, August 20, 2024, at 2 p.m. EDT/11 a.m. PDT. To access the presentation, visit LIXTE's investor relations website at https://ir.lixte.com/news-events/ir-calendar.
- The H.C. Wainwright 26th Annual Global Investor Conference, on demand starting at 7 a.m. EDT/4 a.m. PDT, September 9-11, 2024. To access the virtual presentation, register for the conference at <u>www.hcwevents.com/annualconference</u>.

Bas van der Baan, CEO of LIXTE, will present an overview of the Company's clinical trials with LB-100, its proprietary compoundfocused on enhancing chemotherapy and immunotherapy treatments as cancer therapies. Proof-of-concept clinical trials are currently in progress for colorectal, ovarian and sarcoma cancers, including trials funded by GSK and Roche.

About LIXTE Biotechnology Holdings

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 <u>www.lixte.com</u>), 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 colorectal, ovarian and sarcoma cancers. Additional information about LIXTE can be found at <u>www.lixte.com</u>.

For more information about LIXTE, Contact:

info@lixte.com General Phone: (631) 830-7092 Investor Phone: (888) 289-5533

or

<u>PondelWilkinson Inc</u>. Investor Relations <u>pwinvestor@pondel.com</u> Roger Pondel: (310) 279-5965 Laurie Berman: (310) 279-5962

###



LIXTE Biotechnology Provides Update On Recent Activities and Developments

-Collaboration with NKI and Funding Support for New Colorectal Cancer Clinical Trial by Major Pharma Company-

-Distinguished Oncologist Jan Schellens Joins LIXTE as Chief Medical Officer-

-Preclinical Data Published in Journal <u>EMBO Reports</u> Shows LB-100 as Potentially Enhancing the Benefit of Immunotherapy-

-LIXTE to Present at Two Upcoming Investor Conferences-

PASADENA, CA, August 19, 2024 — <u>LIXTE Biotechnology Holdings, Inc.</u> ("LIXTE" or the "Company") (Nasdaq: LIXT and LIXTW), a clinical-stage pharmaceutical company developing a new class of cancer therapy to enhance chemotherapy and immunotherapy, today provided an update on the Company's recent activities.

"We are encouraged by the growing interest shown by major pharmaceutical companies in our proprietary compound, LB-100, as demonstrated by their support in clinical trial collaborations," said Bas van der Baan, LIXTE's President and Chief Executive Officer.

"Highlighting the Company's recent progress is our new agreement with The Netherlands Cancer Institute, supported by F. Hoffmann- La Roche Ltd. ("Roche"), which is funding the clinical trial in metastatic colorectal cancer and providing atezolizumab (Tecentriq[®], a PD-L1 inhibitor) through the imCORE network, an academic industry collaboration that aims at accelerating cancer immunotherapy research through institution sponsored studies. Already underway is a proof-of-concept trial, funded by GSK, of LB-100 plus GSK's dostarlimab-gxly in ovarian clear cell cancer.

"We are seeing encouraging results in the first phase of our clinical trial to determine appropriate dosing and toxicity for treating advanced soft tissue sarcomas with a combination of LB-100 and standard-of-care chemotherapy and expect to see the data from this first phase early in 2025. We are exploring alternative sites, including international locations, for our small cell lung cancer trial, following termination of that clinical trial at City of Hope due to limited patient accrual," Mr. van der Baan added.

Recent Company Highlights:

- Collaboration with the Netherlands Cancer Institute, supported by Roche, to conduct a new clinical trial (<u>NCT06012734 in clinicaltrials.gov</u>) in immune therapy for unresponsive (MSI Low) metastatic colorectal cancer. LIXTE is providing its lead compound, LB-100, and Roche will provide atezolizumab (Tecentriq[®], a PD-L1 inhibitor). The clinical trial will test recent findings that indicate that LB-100 increases recognition of colorectal cancer cells by the immune system.
- Jan Schellens, M.D., Ph.D., joined LIXTE as Chief Medical Officer effective August 1, 2024. Dr. Schellens brings to the Company more than 25 years of clinical experience as a medical oncologist, pharmacologist and clinical pharmacologist, including more than two decades developing and bringing new drugs to market. Co-author of more 900 publications in peer-reviewed scientific journals, Dr. Schellens has held leadership positions at the Netherlands Cancer Institute in Amsterdam and the Dr. Daniel den Hoed Clinic-Erasmus University in Rotterdam. He was professor of clinical pharmacology at Utrecht University in the Netherlands, where he earned his M.D. degree, and he served as a board member and Chief Medical Officer of Byondis B.V. in Nijmegen, Netherlands. Dr. Schellens also earned a Ph.D. degree in Pharmaceutical Sciences from Leiden University in Leiden, Netherlands.
- New pre-clinical data in the journal EMBO Reports shows that LIXTE's lead compound, LB-100, can turn immunologically "cold" tumors "hot," potentially enhancing the benefit of immunotherapy. In a paper titled, "<u>The Phosphatase Inhibitor LB-100 Creates Neoantigens in Colon Cancer Cells through Perturbation of mRNA Splicing</u>," the article reported that LIXTE's collaborators from the Netherlands Cancer Institute have demonstrated that treatment of cancer cells with LB-100 disrupts the normal processing of the mRNA that encodes proteins, thereby generating neo-antigens that are presented to the host immune system. This new mechanism adds to several previous discoveries showing that LB-100 sensitizes cancer cells to immune checkpoint blockade.
- LIXTE will present at two upcoming investor conferences: the 2004 Summit Summer 2024 Virtual Conference, August 20, 2024, and the H.C. Wainwright 26th Annual Global Investor Conference, September 9-11, 2024. Both conferences will be virtual presentations.

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 <u>www.lixte.com</u>), 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 colorectal, ovarian and sarcoma cancers. Additional information about LIXTE can be found at <u>www.lixte.com</u>.

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 a<u>https://www.sec.gov</u>. 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: <u>info@lixte.com</u> General Phone: (631) 830-7092; Investor Phone: (888) 289-5533

or

PondelWilkinson Inc. Investor Relations <u>pwinvestor@pondel.com</u> Roger Pondel: (310) 279-5965; Laurie Berman: (310) 279-5962