

**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): November 13, 2023

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 Blvd. 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 November 13, 2023, the Company issued a press release with respect to an update on positioning the Company's lead compound, LB-100, to enhance chemotherapy and immunology.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

We are filing as part of this Report the exhibits listed on the accompanying Index to Exhibits, which information is incorporated herein by reference.

-2-

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: November 13, 2023

LIXTE BIOTECHNOLOGY HOLDINGS, INC.

By: /s/ BASTIAAN VAN DER BAAN

Bastiaan van der Baan,
President and Chief Executive Officer

-3-

INDEX TO EXHIBITS

Exhibit No. **Description**

99.1 [Press Release with respect to an update on positioning the Company's lead compound, LB-100, to enhance chemotherapy and immunotherapy](#)
104 Cover Page Interactive Data File (embedded within the Inline XBRL Document)



LIXTE Biotechnology Provides Update on Clinical Progress and Expanding Collaborations

PASADENA, Calif., November 13, 2023 – LIXTE Biotechnology Holdings, Inc. (“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 benefit, today provided an update on its progress.

Clinical Trial and Other Advancements

Year-to-date, LIXTE has made advances in the development of LB-100 through important collaborations, including the following:

- Collaboration with GSK and The University of Texas - MD Anderson Cancer Center in an investigator-initiated Phase 1b/2 clinical trial assessing whether adding LB-100 to GSK’s programmed death receptor-1 (PD-1)-blocking monoclonal antibody may enhance the effectiveness of immunotherapy in the treatment of ovarian clear cell carcinoma. GSK will provide dostarlimab and financial support for the clinical trial. In addition to MD Anderson, the trial also will be open at Northwestern University’s Robert H. Lurie Comprehensive Cancer Center.
- The first patient was enrolled in the Spanish Sarcoma Group (Grupo Español de Investigación en Sarcomas – GEIS) trial to determine whether LB-100 given with a standard dose of doxorubicin for the treatment of advanced soft tissue sarcomas (ASTS) will improve progression-free survival and overall survival. This trial will enroll up to 170 patients and will begin in partnership with GEIS clinical sites.
- Sarah Cannon Research Institute (SCRI) joined the City of Hope’s ongoing Phase 1b clinical trial evaluating the addition of LB-100 to chemotherapy and immunotherapy for previously untreated, extensive-stage small cell lung cancer. Adding SCRI is expected to reduce the time required to demonstrate the feasibility, tolerability and efficacy of adding LB-100 to the current standard of care.
- Expanded collaboration with the Netherlands Cancer Institute (NKI) and Oncode Institute to study pre-clinical drug synergies of LB-100 with chemotherapy and immunotherapy in various cancers. The expansion follows a successful two-year collaboration in colon cancer and seeks to discover additional treatment combinations with LB-100 for other cancer types. A recently posted article in *BioRxiv* detailed that the collaboration demonstrated that inhibition of PP2A in colon cancer cells by LB-100 may lead to an improvement in immunotherapy response.

Bas van der Baan, LIXTE’s recently-appointed President and Chief Executive Officer, said, “Since the beginning of this year, LIXTE has been expanding its collaborations with several prestigious, world-renowned cancer research institutions and pharmaceutical companies that are testing our LB-100 compound to improve chemotherapy and immunotherapy treatment outcomes. We believe that LB-100 may offer broad applicability to many types and stages of cancer, with the potential to benefit a wide range of patients.”

Other Corporate News

- Bas van der Baan, 51, was named President and Chief Executive Officer of LIXTE in September 2023. He was subsequently named Chairman of the Board of Directors as a result of the passing of LIXTE’s founder, Dr. John S. Kovach, on October 5, 2023. He had previously joined LIXTE’s Board of Directors in June 2022. With more than two decades of experience in the biotechnology industry, focused on oncology and diagnostics, Mr. van der Baan will lead the Company as it works toward its mission of improving medical outcomes for patients undergoing various chemotherapies and immunotherapies for cancer, while establishing and commercializing LB-100.



- The Company closed a registered direct offering with an institutional investor for 583,334 shares of common stock (including pre-funded warrants) and a concurrent private placement of common warrants to purchase up to 583,334 shares of common stock at a purchase price of \$6.00 per common share in July 2023. The gross proceeds from the offering were approximately \$3,500,000, with net proceeds of approximately \$3,137,000.

Filing of September 30, 2023 Quarterly Report on Form 10-Q

Additional information with respect to LIXTE’s business, clinical trials and financial condition is contained in the Company’s Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2023, which has been filed with the U.S. Securities and Exchange Commission at www.sec.gov.

About LIXTE Biotechnology Holdings, Inc.

LIXTE Biotechnology Holdings, Inc. is a clinical-stage pharmaceutical company developing a new class of cancer therapy, PP2A inhibitors. The Company’s novel approach enhances the efficacy of both chemotherapy and immunotherapy, potentially providing new treatment options for patients. At the core of the Company’s therapy is LB-100, LIXTE’s proprietary molecule that acts as an inhibitor of the PP2A phosphatase with a favorable toxicity profile. LB-100 promotes the production of neoantigens and cytokines, boosts T-cell proliferation, and disrupts the DNA repair mechanisms of cancer cells, potentially improving treatment outcomes. The Company is conducting multiple clinical trials for solid tumors with unmet medical needs. LIXTE’s unique approach has no known competitors and is covered by a comprehensive patent portfolio.

Additional information about LIXTE can be found at www.lixte.com, on LinkedIn at <https://www.linkedin.com/company/lixte-biotechnology-holdings-inc/>, on Twitter at <https://twitter.com/LixteBiotech>, and by reviewing the Company’s filings with the United States Securities and Exchange Commission at <https://www.sec.gov>.

Forward-Looking Statements

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 clinical trials and collaborators in such clinical trials, 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, and the patent and legal costs to protect and maintain the Company's intellectual property worldwide, 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, research results, competition from other similar businesses, and market and general economic factors. This discussion should be read in conjunction with the Company's filings with the United States Securities and Exchange Commission at www.sec.gov.

For more information about LIXTE, Contact:

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or

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