## 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 21, 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 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 March 21, 2024, Lixte Biotechnology Holdings, Inc. (the "Company") issued a press release providing an update on the progress of its proprietary compound, LB-100.

#### 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.

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: March 22, 2024

LIXTE BIOTECHNOLOGY HOLDINGS, INC. (Registrant)

By: <u>/s/ BASTIAAN VAN DER BA</u>AN

Bastiaan van der Baan President and Chief Executive Officer

#### INDEX TO EXHIBITS

### Exhibit No. Description

- 99.1 Press release providing an update on the Company's proprietary compound, LB-100
- 104 Cover Page Interactive Data File (embedded within the Inline XBRL Document)

# **OLIXTE**

#### LIXTE Provides Update on Progress with LB-100 as a PP2A Inhibitor to Enhance Chemotherapy and Immunotherapy Cancer Treatments

#### -- Three Clinical Trials Currently Underway for Treating Ovarian, Lung and Sarcoma Cancers --

PASADENA, Calif., March 21, 2024 – 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, today provided an update on the Company's progress with its proprietary compound, LB-100.

"Clinical trials are underway at leading cancer centers in the United States and Spain using LB-100 in combination with chemotherapy and immunotherapy that we are hopeful will provide new and effective treatment options for patients with lung, ovarian and sarcoma cancers," said Bas van der Baan, LIXTE's President and Chief Executive Officer.

Clinical trials are taking place at the University of Texas MD Anderson Cancer (ovarian clear cell carcinoma); City of Hope Cancer Center and the Sarah Cannon Research Institute (small cell lung cancer); and the Spanish Sarcoma Group (advanced soft tissue sarcoma).

#### Click here for a brief video overview by LIXTE's Chief Executive Officer.

#### LIXTE recently announced the following significant developments:

- The dosing of the first patient in a Phase 1b/2 clinical trial to assess whether adding LB-100 to GSK's dostarlimab-gxly will 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, and GSK is providing dostarlimab-gxly and financial support.
- The signing of an <u>exclusive patent license agreement</u> with the National Institute of Neurological Disorders and Stroke and the National Cancer Institute, each an
  Institute of the National Institutes of Health (NIH). LIXTE has licensed NIH's intellectual property rights under a Cooperative Research and Development Agreement
  that, focused on LB-100 promoting anti-cancer activity alone and in combination with immune checkpoint inhibitors.
- On February 28, 2024, René Bernards, PhD, a leader in the field of molecular carcinogenesis and Senior Staff Scientist at the Netherlands Cancer Institute presented new pre-clinical data at the Joint Conference of European and American Associations for Cancer Research in Dublin, Ireland on how stress imposed onto colon cancer cells by LB-100 drives cancer cells to evolve to less cancerous behavior, underscoring a unique mechanism of action of LB-100. Dr. Bernards is a member of the Board of Directors of LIXTE.

#### Filing of Annual Report on Form 10-K for the fiscal year ended December 31, 2023

Additional information with respect to LIXTE's business, clinical trials and financial condition is contained in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, which has been filed with the U.S. Securities and Exchange Commission at <u>www.sec.gov</u>.

#### 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,potentiallyproviding newtreatment options for patients. At the core of the Company's therapy is LB-100, LIXTE's proprietary molecule that acts as aninhibitor of the PP2A phosphatasewith 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<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 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 General Phone: (631) 830-7092 Investor Phone: (888) 289-5533 or <u>PondelWilkinson Inc.</u> Investor Relations <u>pwinvestor@pondel.com</u> Roger Pondel or Laurie Berman: (310) 279-5980