

**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): April 4, 2023

**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(c) 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, 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.**

On April 4, 2023, Lixte Biotechnology Holdings, Inc. ("Lixte") issued a press release regarding Sarah Cannon Research Institute joining City of Hope's ongoing Phase 1b clinical trial in evaluating Lixte's lead compound, LB-100, in small cell lung cancer.

**Item 9.01. Financial Statements and Exhibits.**

(d) There is filed as part of this report the exhibit listed on the accompanying Index to Exhibits, which exhibit is incorporated herein by reference.

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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: April 5, 2023

LIXTE BIOTECHNOLOGY HOLDINGS, INC.

By: /s/ JOHN S. KOVACH  
John S. Kovach, Chief Executive Officer

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INDEX TO EXHIBITS

Exhibit No.	Description
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99.1 [Press Release regarding Sarah Cannon Research Institute joining City of Hope's ongoing Phase 1b clinical trial in evaluating Lixte's lead compound, LB-100, in small cell lung cancer.](#)

104 Cover Page Interactive Data File (embedded within the Inline XBRL document)



## **LIXTE Biotechnology Announces Sarah Cannon Research Institute Joins City of Hope's Ongoing Phase 1b Clinical Trial in Evaluating Lixte's Lead Anti-Cancer Compound, LB-100, in Small Cell Lung Cancer**

### **Clinical Trial Focuses on Assessing Whether LB-100 Enhances the Effectiveness of a Standard Regimen Combining Immunotherapy and Chemotherapy for Untreated Small Cell Lung Cancer as it Does in Animal Models**

PASADENA, CA, April 4, 2023 — LIXTE Biotechnology Holdings, Inc. (Nasdaq: LIXT) ("LIXTE" or the "Company"), a clinical-stage drug discovery company developing pharmacologically active drugs for use in cancer treatment, announced that Sarah Cannon Research Institute (SCRI) at Tennessee Oncology in Nashville, Tennessee, is joining an ongoing Phase 1b clinical trial initiated at City of Hope, one of the largest cancer research and treatment organizations in the United States, to assess the combination of LIXTE's first-in-class protein phosphatase 2A (PP2A) inhibitor LB-100 with a standard regimen for previously untreated, extensive stage disease small cell lung cancer (ED-SCLC) (NCT04560972).

City of Hope continues as the coordinating center for the trial with Ravi Salgia, M.D., PhD, as the principal investigator. The SCRI component of the trial will be led by Melissa Johnson, M.D. Drs. Salgia and Johnson are nationally recognized leaders in lung cancer research and care.

John S. Kovach, M.D., LIXTE's founder and Chief Executive Officer, commented, "We are excited to have SCRI at Tennessee Oncology joining this important clinical trial. The involvement of SCRI, one of the world's leading oncology research organizations, is expected to increase the accrual of patients to this clinical trial, thus reducing the time required to demonstrate the feasibility, tolerability, and efficacy of adding LB-100 to this regimen. If a significant improvement in outcome is seen with the addition of LB-100 to this regimen, this would be an important advance in the treatment of this very aggressive disease."

Ravi Salgia, M.D., Ph.D., City of Hope's Arthur & Rosalie Kaplan Chair in Medical Oncology, commented, "City of Hope is pleased that this trial is continuing and will be accessible to more small cell lung cancer patients who are in need of more therapeutics options."

Melissa Johnson, M.D., Director, Lung Cancer Research, SCRI, commented, "Small cell lung cancer is a very aggressive cancer with few therapeutic advances in recent years. We remain committed to identifying and advancing novel therapies for these patients. Dr. Salgia's protocol adds Lixte's lead compound, LB-100, to both chemotherapy and immunotherapy in a promising new approach to this disease."

#### **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 achieved a breakthrough with its novel, first-in-class lead clinical compound and PP2A inhibitor, LB-100, demonstrating that 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](http://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. Initial proof-of-concept clinical trials are in progress.

#### **About City of Hope**

City of Hope's mission is to deliver the cures of tomorrow to the people who need them today. Founded in 1913, City of Hope has grown into one of the largest cancer research and treatment organizations in the U.S. and one of the leading research centers for diabetes and other life-threatening illnesses. City of Hope research has been the basis for numerous breakthrough cancer medicines, as well as human synthetic insulin and monoclonal antibodies. With an independent, National Cancer Institute-designated comprehensive cancer center at its core, City of Hope brings a uniquely integrated model to patients spanning cancer care, research and development, academics and training, and innovation initiatives. City of Hope's growing national system includes its Los Angeles campus, a network of clinical care locations across Southern California, a new cancer center in Orange County, California, and treatment facilities in Atlanta, Chicago and Phoenix. City of Hope's affiliated group of organizations includes Translational Genomics Research Institute and AccessHope. For more information about City of Hope, follow us on Facebook, Twitter, YouTube, Instagram and LinkedIn.

#### **About Sarah Cannon Research Institute**

Sarah Cannon Research Institute (SCRI) is one of the world's leading oncology research organizations conducting community-based clinical trials. In 2022, SCRI formed a joint venture with US Oncology Research to enhance clinical trial access and availability across the country. Focused on advancing therapies for patients over the last three decades, SCRI is a leader in drug development. It has conducted more than 600 first-in-human clinical trials since its inception and contributed to pivotal research that has led to the majority of new cancer therapies approved by the FDA today. SCRI's research network brings together physicians who are actively accruing patients to clinical trials at more than 250 locations in 26 states across the United States.

#### **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 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, 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 <https://www.sec.gov>.

#### **For more information about LIXTE, Contact:**

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