

**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 24, 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(e) under the Exchange Act (17 CFR 240.13e-4(e))

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 24, 2023, the Company issued a press release regarding the activation of the first Spanish site to begin accrual of patients for a Phase 1b/2 clinical trial of LB-100, the Company's lead anti-cancer compound, added to Doxorubicin as first-line treatment of Advanced Soft Tissue Sarcoma.

**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.

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: April 25, 2023

LIXTE BIOTECHNOLOGY HOLDINGS, INC.

By: /s/ JOHN S. KOVACH

John S. Kovach, Chief Executive Officer

3

INDEX TO EXHIBITS

**Exhibit No. Description**

---

99.1 [Press Release regarding the activation of the first Spanish site to begin accrual of patients for a Phase 1b/2 clinical trial of LB-100, the Company's lead anti-cancer compound, added to Doxorubicin as first-line treatment of Advanced Soft Tissue Sarcoma.](#)

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



**LIXTE Biotechnology Reports First Spanish Site Activated to Begin Accrual of Patients for a Phase 1b/2 Clinical Trial of LIXTE's Lead Anti-Cancer Compound, LB-100, Added to Doxorubicin as First-Line Treatment of Advanced Soft Tissue Sarcoma**

*First clinical trial seeking to determine if the potentiation of cytotoxic chemotherapy by LB-100 occurs in cancer patients as has been shown in multiple animal studies across a spectrum of cancers*

PASADENA, CA, April 24, 2023 - LIXTE Biotechnology Holdings, Inc. (Nasdaq: LIXT) ("LIXTE") a clinical-stage drug discovery company developing pharmacologically active drugs for use in cancer treatment, announced that the Spanish Sarcoma Research Group (Grupo Español de Investigación en Sarcomas, or GEIS) completed its first site initiation visit in preparation for the advanced soft tissue sarcoma (ASTS) clinical trial at Fundación Jiménez Díaz University Hospital (Madrid).

Fundación Jiménez Díaz University Hospital is the home base of Dr. Javier Martín-Broto, Coordinating Investigator of the clinical trial, GEIS Co-Founder, and an internationally recognized expert in sarcoma research and therapy. Three additional GEIS-associated cancer research centers, located in Valencia, Barcelona, and Madrid, Spain, are expected to be activated in the near-term, with Phase 1b patient accrual planned to begin by mid-May 2023.

The Phase 1b portion of the clinical trial to determine the recommended phase 2 dose (RP2D) is expected to be completed within approximately nine months from commencement. Subsequently, up to ten more clinical sites are expected to join the international Phase 2 portion of the study to enter up to 150 patients, randomized to standard cytotoxic chemotherapy with doxorubicin alone, versus doxorubicin plus LB-100. Given the lack of effective first-line treatments for ASTS, this trial has been designed to provide data expected to be sufficient to justify proceeding to a Phase 3 comparative study.

John S. Kovach, MD, Founder and CEO of LIXTE, said, "We are very pleased to finally have an opportunity to test whether LB-100 improves the treatment of ASTS. GEIS has been very patient, having had to wait several months for various regulatory approvals to introduce LB-100 into a European clinical trial program. The fact that this trial design is still relevant attests to the slow pace of finding better treatments for this disease."

1

For a more complete description of the science underlying the study developed by Dr. Martín-Broto and his colleagues, please see:

*LIXTE Biotechnology Announces Approval of a Phase 1b/2 Randomized Trial of Doxorubicin +/-Lb-100 in Advanced Soft Tissue Sarcomas to be Conducted by the Spanish Sarcoma Group*

*The Spanish Sarcoma Group Will Lead a European Consortium to Evaluate the Ability of Lixte Biotechnology Holdings' LB-100 to Improve First Line Therapy for Advanced Soft Tissue Sarcomas*

**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 demonstrating 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 [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 GEIS (Grupo Español de Investigación en Sarcomas)**

GEIS is a non-profit organization in Spain engaged in the research, development and management of studies and clinical trials for sarcomas. GEIS has a mission to ensure the best healthcare to sarcoma patients by helping bring new treatments to them through clinical research. GEIS has successfully partnered with various institutions and companies to help bring new treatments to patients with sarcomas. Through the group's many research projects it has created or participated in over the years, it has made a significant impact in the global research effort to better treat patients with sarcomas. For more information: <http://www.grupogeis.org>.

**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, 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:**

PondelWilkinson Inc. Investor Relations

[pwinvestor@pondel.com](mailto:pwinvestor@pondel.com)

Roger Pondel: (310) 279-5965

Laurie Berman: (310) 279-5962

[info@lixte.com](mailto:info@lixte.com)

General Phone: (631) 830-7092

Investor Phone: (888) 289-5533

