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 11, 2025

LIXTE BIOTECHNOLOGY HOLDINGS, INC.

DELAWARE	001-39717	20-2903526
(State or other jurisdiction of incorporation)	(Commission File Number)	(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, 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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 1.01 Entry into a Material Definitive Agreement.

Reference is made to the Current Report on Form 8-K of Lixte Biotechnology Holdings, Inc. (the "Company") filed with the Securities and Exchange Commission on August 6, 2019 relating to the Collaboration Agreement For An Investigator-Initiated Clinical Trial (the "Clinical Trial Agreement") between the Company and Grupo Español de Investigación en Sarcomas ("GEIS") effective July 31, 2019.

The Clinical Trial Agreement set forth the terms under which GEIS would conduct a clinical research protocol to study the safety and/or efficacy of LB-100, the Company's lead compound (the "Study"). The Clinical Trial Agreement was intended to support a Phase 1b/randomized Phase 2 Study of doxorubicin, the global standard for initial treatment of advanced soft tissue sarcomas versus doxorubicin plus LB-100. The Company had agreed to provide funding for the Study. The Clinical Trial Agreement was filed as Exhibit 10.1 to the previously referenced Current Report on Form 8-K.

This Study commenced during the quarter ended June 30, 2023 and is expected to be completed and a report prepared by December 31, 2026. The recruitment for the Phase 1b portion of the Study was completed during the quarter ended September 30, 2024, and the Company expects to have initial data on toxicity and preliminary efficacy from this portion of the Study during the quarter ending December 31, 2025.

Effective March 11, 2025, the Company and GEIS entered into Amendment No. 1 to the Clinical Trial Agreement that relieved the Company of the financial obligation to support the randomized Phase 2 portion of this Study contemplated in the Clinical Trial Agreement of approximately $3,095,000. Amendment No. 1 to the Clinical Trial Agreement is filed as Exhibit 10.1 to this Current Report on Form 8-K (the "Report") and is incorporated herein by reference. The description of Amendment No. 1 to the Clinical Trial Agreement is qualified in its entirety by reference to Exhibit 10.1 to the Report..

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.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
(Registrant)

Date: March 14, 2025

By: */s/ BASTIAAN VAN DER BAAN*
Bastiaan van der Baan
President and Chief Executive Officer

INDEX TO EXHIBITS

Exhibit No.	Description
10.1	Amendment No. 1 to the Clinical Trial Agreement between the Company and GEIS dated March 11, 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL Document)

AMENDMENT NO. 1

to Collaboration Agreement for an investigator-initiated clinical trial

THIS AMENDMENT NO. 1 to Collaboration Agreement for an investigator-initiated clinical trial ("Amendment No. 1") is made as of March 11th 2025 ("Effective Date"), by and between Lixte Biotechnology Holdings, Inc., having its principal place of business at 680 E Colorado Blvd. Suite 180 Pasadena CA 91101, United States of America ("LIXTE") and Grupo Español de Investigación en Sarcomas (GEIS), having a place of business at C/ Diego de León 47, 28006 Madrid, Spain ("Sponsor").

WHEREAS, the parties have entered into a Collaboration Agreement for an investigator-initiated clinical trial effective as of 31 July 2019 (the "Collaboration Agreement") and relating to the protocol entitled, "*Randomized phase I/II trial of LB-100 plus doxorubicin vs. doxorubicin alone in first line of advanced soft tissue sarcoma*" (the "Trial").

WHEREAS, the parties have agreed to amend the Collaboration Agreement as set forth in this Amendment No. 1.

Unless the context requires otherwise, terms and expressions set out in the Collaboration Agreement shall have the same meanings when used in this Amendment No 1.

NOW, THEREFORE, the parties have agreed as follows:

Article 1

1.1 Sponsor acknowledges and agrees that LIXTE is no longer interested in obtaining information resulting from phase II of the Trial, because of the recent approval of a new standard of care in the largest STS subgroup and that LIXTE will limit its contributions in cash and in kind to Phase 1 of the Trial as set forth in this Amendment No. 1. Therefore, the parties hereby replace Appendix 1 (Budget & Payment Schedule) to the Collaboration Agreement its entirety by a new and amended Appendix 1 attached to this Amendment No. 1 as Schedule A.

Article 2

2.2 The parties hereby amend and restate Section 6.1 of the Collaboration Agreement in its entirety to read as follows:

"In consideration for the performance of the Trial, LIXTE undertakes to collaborate financially with the Sponsor in carrying out the Trial by means of a maximum contribution of nine hundred and three thousand one hundred and thirty-nine euro and fifty-seven eurocent (EUR 903,139.57). Sponsor acknowledges receipt of an amount of six hundred and fifty-three thousand nine hundred and ninety-seven euro and sixty-two eurocent (EUR 653,997.62) in accordance with Appendix 1 and hereby discharges LIXTE for its payment obligations under the Collaboration Agreement to this amount."

Article 3

3.1 This Amendment No. 1 shall become inseparable part of the Collaboration Agreement.

3.2 All other terms and provisions of the Collaboration Agreement shall remain in full force and effect.

3.3 Any amendment to this Amendment No. 1 must be made in writing and signed by the parties.

3.4 This Amendment No.1 constitutes the entire agreement between the parties regarding the subject matter thereof and supersedes all prior agreements or understandings, whether in writing or orally regarding the subject matter of this Amendment No. 1.

3.5 This Amendment No. 1 may be executed in any number of counterparts, including electronically (by PDF), each of which when executed shall be an original but all the counterparts together shall constitute one and the same instrument.

IN WITNESS WHEREOF, Sponsor and LIXTE have caused this Amendment No. 1 to be executed by their duly authorized representatives as of the Effective Date.

Lixte Biotechnology Holdings, Inc.

Signed by:
By: Bas van der Baan
AF79A878514A46F...

Name Printed: Bas van der Baan

Title: Chief Executive Officer

Date: 13-Mar-2025 | 2:55 PM CET

Grupo Español de Investigación en Sarcomas (GEIS)

DocuSigned by:
By: Claudia Valverde
846449051C18458...

Name Printed: Claudia Valverde

Title: GEIS Chair

Date: 13-mar.-2025 | 6:25 AM PDT

Schedule A

Amended Appendix 1: Budget & Payment Schedule

to the Collaboration Agreement for an investigator-initiated clinical trial

Payment No.	Total	Milestone	Estimated Date
1	77,856.86 €	Upon CTA signature	Q3 2019
2	77,856.86 €	Protocol reviewed by FDA and delivery of required documentation/permits for LB-100 import and use in the EU	Q3 2019
3	249,141.95 €	EC and RA approvals in Spain	Q4 2022
4	249,141.95 €	Phase 1: First patient in	Q2 2023
5	249,141.95 €	Phase 1: Final clinical report	Q2 2025