# 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): September 4, 2024

# 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 | LIXT | The Nasdaq Stock Market LLC |
| Warrant to Purchase Common Stock | LIXTW | The Nasdaq Stock Market LLC |

**Item 8.01 Other Events.**

On September 4, 2024, Lixte Biotechnology Holdings, Inc. (the "Company") issued a press release announcing that it has received a Notice of Allowance from the United States Patent and Trademark Office (USPTO) for U.S. Patent application number 16/467,721, titled, "Oxabicycloheptanes for Modulation of Immune Response," for combining the Company's LB-100 compound with various innovative cancer immunotherapies.

**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.

Date: September 5, 2024

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
(Registrant)

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

**INDEX TO EXHIBITS**

| Exhibit No. | Description |
|---|---|
| 99.1 | Press release announcing receipt of U.S. Patent Issue Notification for immune oncology covering combining LIXTE's LB-100 with various innovative cancer immunotherapies |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL Document) |

**Exhibit 99.1**

**LIXTE Receives U.S. Patent Issue Notification for Immune Oncology**

**Patent Covers Combining LIXTE's LB-100**
**with Various Innovative Cancer Immunotherapies**

**PASADENA, Calif., September 4, 2024** — LIXTE Biotechnology Holdings, Inc. (Nasdaq: LIXT and LIXTW) ("LIXTE" or the "Company") today announced it has received a Notice of Allowance from the United States Patent and Trademark Office (USPTO) for U.S. Patent application number 16/467,721, titled, "Oxabicycloheptanes for Modulation of Immune Response," for combining the Company's LB-100 compound with various innovative cancer immunotherapies.

"The patent award further bolsters LIXTE's existing intellectual property portfolio and underscores the Company's commitment to pioneering research and delivering innovative solutions to patients battling cancer," said Bas van der Baan, LIXTE's Chief Executive Officer.

LIXTE is developing its first-in-class lead clinical PP2A inhibitor, LB-100, as a potentiator of cancer immunotherapy. The Company is testing LB-100 in combination with immunotherapies in clinical trials at the Netherlands Cancer Institute (NKI) in Amsterdam and at The University of Texas MD Anderson Cancer Center in Houston.

At NKI, LIXTE is providing LB-100, and F. Hoffmann-La Roche Ltd. ("Roche") is providing atezolizumab (Tecentriq®, a PD-L1 inhibitor) through the imCORE Network as part of a new clinical trial in immune therapy for unresponsive (MSI Low) metastatic colon cancer. The imCORE Network is an academic-industry collaboration that aims to accelerate cancer immunotherapy research through institution-sponsored studies

A second trial underway at MD Anderson is testing the combination of LB-100 and GSK's dostarlimab-gxly for the treatment of ovarian clear cell carcinoma (OCCC).

The new patent award follows the signing of an exclusive patent license agreement earlier this year between LIXTE and the National Institute of Neurological Disorders and Stroke (NINDS) and National Cancer Institute (NCI), each a component of the National Institute of Health (NIH). The agreement provides LIXTE with an opportunity to explore and develop novel combination therapies that can potentially transform the landscape of cancer treatment.

**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 demonstrated 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), LB-100 has the potential to significantly enhance chemotherapies and immunotherapies and improve outcomes for patients with cancer.

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LIXTE's lead compound, LB-100, is part of a pioneering effort in an entirely new field of cancer biology – activation lethality – that is advancing a new treatment paradigm. LIXTE's new approach is covered by a comprehensive patent portfolio. Proof-of-concept clinical trials are currently in progress for colon, ovarian, and sarcoma cancers. Additional information about LIXTE can be found at www.lixte.com.

**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
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or

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