# 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): August 26, 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

(Reg	gistrant's telephone number, including area co	ode)
Check the appropriate box below if the Form 8-K filing is intend General Instruction A.2. below):	led to simultaneously satisfy the filing obligation	ation of the registrant under any of the following provisions (See
☐ Written communications pursuant to Rule 425 under the Secu	urities 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 Warrant to Purchase Common Stock	LIXT LIXTW	The Nasdaq Stock Market LLC The Nasdaq Stock Market LLC
Item 8.01 Other Events.		
On August 26, 2024, Lixte Biotechnology Holdings, Inctrial for the treatment of unresponsive (MSI Low) metastatic color		nouncing the dosing of the first patient with LB-100 in a clinical
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	s, which information is incorporated herein by reference.
	SIGNATURES	
Pursuant to the requirements of the Securities Exchange duly authorized.	Act of 1934, the registrant has duly caused to	this report to be signed on its behalf by the undersigned hereunto
Date: August 26, 2024	L	IXTE BIOTECHNOLOGY HOLDINGS, INC. (Registrant)
	By: /s/BASTIAAN V	VAN DER BAAN

Bastiaan van der Baan Chief Executive Officer

Exhibit No.	Description
99.1 104	Press release announcing the dosing of the first patient with LB-100 in a clinical trial for the treatment of unresponsive (MSI Low) metastatic colorectal cancer. Cover Page Interactive Data File (embedded within the Inline XBRL Document)



#### First Patient Dosed with LIXTE's LB-100 in New Clinical Trial to Treat Colorectal Cancer, Collaborating with NKI, Supported by Major Pharma Company

PASADENA, Calif. August 26, 2024 — <u>LIXTE Biotechnology Holdings, Inc.</u> (Nasdaq: LIXT and LIXTW) ("LIXTE" or the "Company"), today announced the dosing of the first patient in a new clinical trial in collaboration with the Netherlands Cancer Institute (NKI) and supported by F. Hoffmann-La Roche Ltd. ("Roche") for treatment of unresponsive (MSI Low) metastatic colorectal cancer.

As part of the clinical trial (NCT06012734, clinicaltrials.gov), LIXTE is providing its lead compound, LB-100, and Roche is providing atezolizumab (Tecentriq ®, a PDL1 inhibitor) through the imCORE Network, a global academic-industry partnership that aims to accelerate cancer immunotherapy research through institution-sponsored studies.

"Our objective with this trial is to bring immunotherapy as an effective treatment option to approximately 85 percent of all colorectal cancer patients, who thus far have not been responsive to traditional protocols," said Neeltje Steeghs, M.D., Ph.D., medical oncologist at NKI.

Bas van der Baan, LIXTE's Chief Executive Officer, said, "We are pleased to begin this important trial, which is being funded by Roche. This is the second recent clinical trial combining LB-100 with immunotherapy that is funded by a major pharmaceutical company, following the start of a clinical trial earlier this year with GSK for treatment of clear cell ovarian cancer."

#### About LIXTE Biotechnology Holdings, Inc.

<u>LIXTE Biotechnology Holdings, Inc.</u> 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 <a href="https://www.lixte.com">www.lixte.com</a>), LB-100 has the potential to significantly enhance chemotherapies and immunotherapies and improve outcomes for patients with cancer.

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 colorectal, ovarian and sarcoma cancers. Additional information about LIXTE can be found at <a href="https://www.lixte.com">www.lixte.com</a>.

#### 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 a<a href="https://www.sec.gov">https://www.sec.gov</a>. 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: <u>info@lixte.com</u> General Phone: (631) 830-7092; Investor Phone: (888) 289-5533

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PondelWilkinson Inc. Investor Relations <u>pwinvestor@pondel.com</u> Roger Pondel: (310) 279-5965; Laurie Berman: (310) 279-5962