

**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): November 30, 2022

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(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 7.01. Regulation FD Disclosure.

On November 30, 2022, the Company issued a press release to announce that it will be presenting at the Planet MicroCap Showcase: Virtual 2022 Investor Conference to be held on December 7, 2022 at 3:30 PM EST.

Attached as Exhibit 99.1 is the investor presentation which will be used at the conference. The presentation in whole or in part may also be used at subsequent meetings with investors, analysts, or others, and also will be subject to modification.

The information contained in this Current Report and Exhibit 99.1 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, unless specifically identified therein as being incorporated by reference.

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.

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: December 6, 2022

LIXTE BIOTECHNOLOGY HOLDINGS, INC.

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

INDEX TO EXHIBITS

Exhibit No.	Description
99.1	Investor Presentation
104	Cover Page Interactive Data File (embedded within the Inline XPRL Document)

A Breakthrough in Cancer Vulnerability



Dedicated to Creating
Better Treatments for Cancer

December 2022

LIXTE BIOTECHNOLOGY HOLDINGS, INC.

Nasdaq: LIXT



Forward Looking Statements

This information packet 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 www.sec.gov.

LIXTE - Dedicated to Creating Better Treatments for Cancer

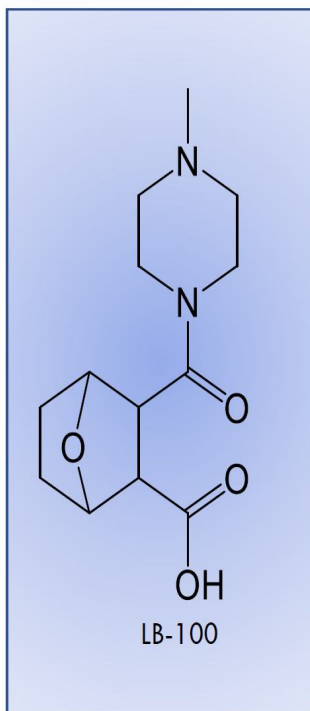
- Clinical-stage drug discovery company.
- Using biomarker technology to identify enzyme targets associated with cancer and other serious common diseases, and designing novel compounds to attack those targets.



Key Investment Considerations

- **Unique, active, and less toxic compound, LB-100 is a first-in-class anti-cancer agent with no known competitors.**
- **LB-100 increases the anti-tumor activity of chemotherapy, radiotherapy and immunotherapy without increasing the toxicity.**
- **Potential total market for LB-100 is great with potential to treat many cancers.**
- **Extensive international patent portfolio**, including LB-100 and its potential clinical applications.
- **Partnerships and collaborations with top medical institutions** and leading academic research centers to advance clinical development.
- **Distinguished and experienced management team** includes veterans of National Institutes of Health, Mayo Clinic and City of Hope.

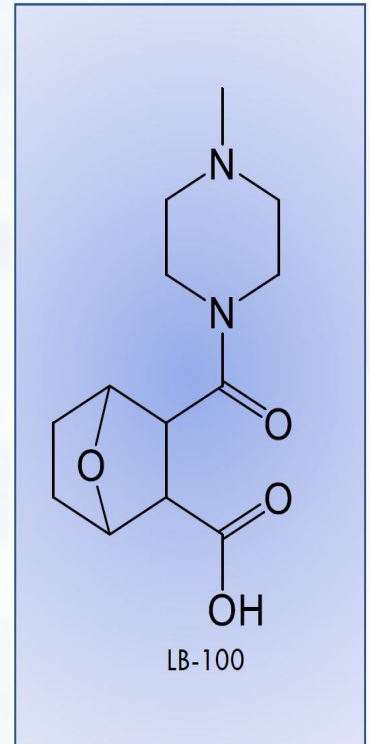
LB-100: Game-Changing Discovery



- **Rationale:** Natural products with potent anti-PP2A activity (certain shellfish toxins) have broad antitumor-activity in animal models but are very toxic.
- PP2A is a master regulator of numerous cell functions; it is known to be faulty and, thus, susceptible to inhibition in many human cancers.

LB-100: Game-Changing Discovery

- **Goal:** Identify a potent and safe inhibitor of PP2A.
- **Outcome:** Developed LB-100 as a novel compound that is a potent inhibitor of enzyme PP2A, **active against cancers in humans at non-toxic doses.**



LB-100: Unique, Active, Less Toxic Anti-Cancer Drug

- Multiple preclinical studies report that **LB-100** increases the anti-tumor activity of:
 - Chemotherapy
 - Radiotherapy
 - Immunotherapywithout increasing toxicity
- **No known competitor** to LB-100 in the market.



Why LB-100 Works



- **Basic cell activities require switches** to rapidly turn on and turn off biochemical pathways for proper cell function.
- The **major drivers of cancer are acquired defects in the switches.**

LB-100 Mechanism of Action

LB-100 **inhibits a master “off switch,”** PP2A, that regulates many aspects of cell growth, repair of DNA damage, and regulation of T-cell immune function.



Significant Breakthrough

- **Landmark Phase 1** clinical trial conducted and completed at Mayo Clinic, City of Hope, and US Oncology Network.
- Study showed **LB-100 is well tolerated by cancer patients at doses associated with anti-cancer activity.**

Can LB-100 Improve Immune Therapy in General?

- Studies in animals show that **low doses of LB-100 enhance the effectiveness of immunotherapy of diverse cancer types** by several mechanisms.^{1,2}
- Patients with PP2A inactivating mutations in their cancers respond exceptionally well to immunotherapy. PP2A inactivating mutations lower PP2A activity **but are present in relatively few cancers.**
- Patients with genetic changes in ovarian clear cell cancers (OCCC) expected to reduce PP2A activity (inactivating mutations) have **exceptionally long survival when treated with immune checkpoint therapy.**³

1. Ho et al., Nature Comm 2018

2. Yen et al., Nature Comm 2021

3. Hinchcliff et al. Presentation/Abstract, Annual Meeting SGO, Phoenix, AZ, March 21, 2022

New Opportunity: Demonstrate that LB-100 Enhances Immune Checkpoint Therapy

- LB-100 lowers PP2A activity, and **it may do so in many, if not all cancers, rendering these cancers more susceptible to immunotherapy.**
- **New trials are planned in the near future** to determine if the addition of LB-100 is a general way to enhance immune checkpoint therapy.

Strategy and Opportunities

- Demonstrate that **LB-100 markedly enhances chemotherapy and immunotherapy.**
- Focus on aggressive tumors in which clinical benefit can be detected early after initiating treatment.
- Evaluate LB-100 in a number of cancers because extensive preclinical data indicate that LB-100 **may be effective in the treatment of many, if not most human cancers.**

Promising Clinical Trials Testing LB-100's Ability to Enhance Chemotherapy and Immunotherapy

LB-100 markedly improves standard anti-cancer therapy in animal models of two aggressive diseases. This has led to clinical trials in humans:

- Small Cell Lung Cancer (SCLC) – Open and accruing patients
- Advanced Soft Tissue Sarcoma (ASTS) – Opening very soon

Potential Impact of Current and Planned Clinical Trials

- If LB-100 proves to enhance significantly the standard treatment with chemotherapy and immunotherapy for small cell lung cancer, it will be **a long-awaited achievement in improving the outcome of patients with this very aggressive cancer.**
- **Similarly, if the addition of LB-100 to standard chemotherapy for Advanced Soft Tissue Sarcomas improves the outcome for these patients, this will be a major achievement.**
- If LB-100 proves to enhance significantly the effectiveness of immune checkpoint therapy, it will be **a landmark advance in cancer treatment for many cancers.**

The Distinguished LIXTE Team

John S. Kovach, MD: Founder and CEO. Medical Oncologist and Clinical Pharmacologist; former director of NCI Comprehensive Cancer Centers at Mayo Clinic and City of Hope.

James Miser, MD: Chief Medical Officer. Pediatric hematologist/oncologist, internationally recognized as an expert in the study and treatment of childhood cancers and in the design and monitoring of clinical cancer trials.

Eric J. Forman, Esq: Chief Operating Officer. Intellectual property attorney and business development lead with 10 years of tech/biotech experience.

Robert N Weingarten: Chief Financial Officer. CPA responsible for working with management on all financial regulatory matters.

Robert Volkman, PhD: Pre-Clinical Drug Development. Chief Scientific Officer for BioPharmaWorks; 34 years at Pfizer in Neuroscience, Immunology, Infectious Diseases, Diabetes, Process Chemistry.

Daniel Von Hoff, MD: Cancer Clinical Trials. Physician in Chief, Distinguished Professor and Director of Clinical Translational Research Division at TGen (Translational Genomics Research Institute) in Phoenix, Arizona; Chief Scientific Officer for US Oncology and for Scottsdale Healthcare's Clinical Research Institute.

Board of Directors

John S. Kovach, MD: Internationally recognized oncologist and former director of the cancer center at Mayo Clinic and City of Hope National Medical Center

Prof. René Bernards: Leader in the field of molecular carcinogenesis at the Netherlands Cancer Institute in Amsterdam with extensive experience in the development of effective anti-cancer drugs

Bas van der Baan: Internationally recognized business development executive with over 20 years of experience in the biotechnology industry with a key focus on oncology and diagnostics

Stephen J. Forman, MD: Internationally recognized expert in hematological cancers at the City of Hope National Medical Center

Yun Yen MD, PhD, FACP: Distinguished cancer investigator for many years at City of Hope and former President of Taipei Medical University

Regina Brown, CPA: Accountant with decades of expertise in compliance, taxation and internal control implementation

A Promising Future: Key Investment Highlights

- **LB-100 is a unique, active, well tolerated compound that has the potential to enhance cancer treatment without increasing toxicity.**
- **LB-100 may be effective in the treatment of particularly aggressive cancers where new treatments are urgently needed.**
- **Extensive international patent portfolio.**
- **Partnerships and collaborations with top global medical institutions and leading academic research centers to advance clinical development.**
- **Distinguished, experienced management team, including veterans of National Institutes of Health, Mayo Clinic, and City of Hope.**

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THANK YOU



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