
**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 5, 2018

LIXTE BIOTECHNOLOGY HOLDINGS, INC.

DELAWARE
(State or other jurisdiction
of incorporation)

000-51476
(Commission
File Number)

20-2903526
(IRS Employer
Identification No.)

248 Route 25A, No. 2
East Setauket, New York 11733
(Address of principal executive offices)

(631) 880-2907
(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))

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 8.01. Other Events.

On November 5, 2018, the Company issued a press release regarding the approval by the FDA of the Company's IND to conduct a Phase 1b/2 trial of the safety and therapeutic benefit of the Company's lead clinical compound, LB-100, in patients with low and intermediate-1 risk myelodysplastic syndrome (MDS) who have failed or are intolerant of standard treatment.

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: November 7, 2018

LIXTE BIOTECHNOLOGY HOLDINGS, INC.

By: /s/ JOHN S. KOVACH

John S. Kovach, Chief Executive Officer

INDEX TO EXHIBITS

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release regarding the approval of the Company's IND



FDA Approves Lixte Biotechnology's IND to Conduct a Phase 1b/2 Trial of LB-100 in Patients with Myelodysplastic Syndrome at Moffitt Cancer Center

EAST SETAUKET, NY — (November 5, 2018) - Lixte Biotechnology Holdings, Inc. (OTCQB: LIXT) announced that the FDA approved its IND to conduct a Phase 1b/2 trial of the safety and therapeutic benefit of Lixte's lead clinical compound, LB-100, in patients with low and intermediate-1 risk myelodysplastic syndrome (MDS) who have failed or are intolerant of standard treatment. The study will be conducted at Moffitt Cancer Center, Tampa, FL.

Dr. John S. Kovach, founder and CEO of Lixte, said, "We are very pleased to receive approval to proceed with a study of the potential benefit of our lead protein phosphatase 2A inhibitor, LB-100, in the treatment of refractory MDS to be conducted by the team at Moffitt, long-time leaders in this field. Low and intermediate-1 risk MDS are often characterized by failure to produce normal amounts of red blood cells, so that patients with this syndrome require frequent blood transfusions. Reduction in the number of transfusions needed by these patients is one major goal of therapy, and provides a readily assessable parameter of therapeutic benefit within a few months of initiating treatment. At present, there is only one drug, Revlimid (Celgene), approved for one subtype of MDS."

About Lixte Biotechnology Holdings, Inc.

Lixte is a biotech company that identifies enzyme targets associated with serious common diseases and then designs novel compounds to attack those targets. Lixte's product pipeline is primarily focused on inhibitors of protein phosphatases, used alone and in combination with cytotoxic agents and immune checkpoint blockers.

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 product demand, supply, manufacturing, costs, marketing and pricing factors 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 <http://www.sec.gov/edgar.shtml>.

Additional information on the Company is available at www.liخته.com.

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