



DIVISION OF
CORPORATION FINANCE

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

July 16, 2025

Robert Weingarten
Vice President and Chief Financial Officer
LIXTE BIOTECHNOLOGY HOLDINGS, INC.
680 East Colorado Boulevard
Suite 180
Pasadena, CA 91101

Re: LIXTE BIOTECHNOLOGY HOLDINGS, INC.
Form 10-K for the Fiscal Year Ended December 31, 2024
Filed March 24, 2025
File No. 001-39717

Dear Robert Weingarten:

We have reviewed your filing and have the following comments.

Please respond to this letter within ten business days by providing the requested information or advise us as soon as possible when you will respond. If you do not believe a comment applies to your facts and circumstances, please tell us why in your response.

After reviewing your response to this letter, we may have additional comments.

Annual Report on Form 10-K for the Fiscal Year Ended December 31, 2024

Item 1. Business, page 4

1. In future filings, please remove all statements indicating that your product candidates are safe and effective, as such determinations are solely within the authority of the FDA and comparable foreign regulatory authorities. For example only, without limitation, we note your statements throughout your annual report that LB-100 has been found to improve the effectiveness of anticancer drugs, as well as your disclosure on page 9 that LB-100 has "proven safe in patients at doses associated with anti-tumor activity."

Description of Business, page 4

2. We note your pipeline table on page 6. In future filings, please shorten the length of the arrows in your pipeline table as appropriate to accurately reflect the status of the product candidate. In this regard, we note the arrows in the second and third rows of the table extend through the end of the "Phase 1b" column, which may indicate the

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Phase 1b trials have been completed, but your disclosures on pages 7 and 8 indicate that the Phase 1b trial in patients with metastatic colon cancer is still enrolling patients and that the Phase 1b trial in patients with ASTS is still ongoing. Similarly, we note that the arrow in the first row of the table extends through most of the "Phase 2" column, which may indicate that a Phase 1b clinical trial has been completed and the Phase 2 clinical trial is nearly complete; however, your disclosures on pages 8 and F-32 indicate that this is a Phase 1b/2 clinical trial and that you expect the clinical trial will be completed by December 31, 2027.

Clinical Trial Agreements, page 7

3. We note your discussion on page 8 of your Phase 1b/2 collaborative clinical trial to assess whether adding LB-100, your lead product candidate, to dostarlimab-gsly may enhance the effectiveness of immunotherapy in the treatment of ovarian clear cell carcinoma. In future filings, please file the applicable clinical trial agreement as an exhibit, or tell us why you do not believe such exhibit is required. Refer to Item 601(b)(10) of Regulation S-K.

We remind you that the company and its management are responsible for the accuracy and adequacy of their disclosures, notwithstanding any review, comments, action or absence of action by the staff.

Please Jessica Dickerson at 202-551-8013 or Laura Crotty at 202-551-7614 if you have questions regarding the comments.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: David Ficksman