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): June 28, 2022

Decibel Therapeutics, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-40030**	**46-4198709**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

1325 Boylston Street, Suite 500 **Boston, Massachusetts** **(Address of Principal Executive Offices)**	**02215** **(Zip Code)**

Registrant's telephone number, including area code: (617) 370-8701

Not applicable
(Former Name or Former Address, if Changed Since Last Report)

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 (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(c) 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, $0.001 par value per share	**DBTX**	**Nasdaq Global Select Market**

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 June 28, 2022, Decibel Therapeutics, Inc. (the "Company") announced top-line results from an interim analysis of its ongoing Phase 1b clinical trial of DB-020, the Company's product candidate to protect against hearing loss in cancer patients receiving cisplatin chemotherapy.

Patients enrolled in the Phase 1b clinical trial were randomized to receive one of two doses of DB-020 in one ear while the contralateral ear received placebo, enabling each patient to serve as their own control. Patients were administered DB-020 and placebo up to three hours prior to each cisplatin infusion. Consistent with the results of a Phase 1 clinical trial of DB-020 previously completed by the Company in healthy volunteers, data from the interim analysis demonstrated that DB-020 was well tolerated, with adverse events generally mild to moderate. In the data from the interim analysis, 88% of patients experienced ototoxicity in their placebo-treated ear, and of these patients, 87% were partially or completely protected from ototoxicity in their DB-020-treated ears.

The interim analysis includes data collected as of February 4, 2022 from 19 cisplatin-naïve cancer patients being treated with high doses of cisplatin every 21 or 28 days. Of the 19 patients in the interim analysis, 17 patients had evaluable audiograms at baseline and after being dosed with DB-020 in one ear and placebo in the contralateral ear in conjunction with their prescribed infusion of cisplatin chemotherapy. Ototoxicity was defined according to the American Speech-Language-Hearing-Association ("ASHA") criteria for significant ototoxic change.

Key findings from the interim analysis include the following:

- DB-020 was generally well tolerated, with mostly mild to moderate adverse events and no significant safety issues observed.
    - 14 of 19 patients reported ear pain in the ear treated with DB-020, and 2 of 18 patients reported ear pain in the ear treated with placebo. One patient received DB-020 in one ear and discontinued participation in the trial before receiving placebo in the contralateral ear.
    - 2 of 19 patients reported tinnitus, which is a ringing in the ear, in the ear treated with DB-020 and 8 of 18 patients reported tinnitus in the placebo-treated ear. Patients reporting tinnitus for the DB-020 and placebo treated ears included one patient who reported bilateral tinnitus in both ears and one patient who reported worsening of pre-existing tinnitus without specified laterality in both ears.
- DB-020, administered prior to cisplatin, had no apparent effect on systemic cisplatin levels.
- 13 of 17 (76.5%) patients experienced cisplatin-induced ototoxicity in the placebo ear after the first cycle of cisplatin; 15 of 17 (88.2%) patients experienced cisplatin-induced ototoxicity in the placebo ear by the last evaluable test.
    - Placebo-treated ears lost approximately 30 decibels ("dB") on average from baseline in high frequencies, shifting patients from normal or slight hearing loss to moderate hearing loss (two hearing loss categories) on average.
- In the 15 patients who experienced ototoxicity in the placebo ear by the last evaluable test, DB-020 protected 13 (87%) from ototoxicity in their DB-020-treated ear.
    - 8 of 15 (53.3%) were completely protected, and 5 of 15 (33.3%) were partially protected. (Complete protection was defined as no change in hearing from baseline in the ear that received DB-020 according to the ASHA ototoxicity criteria in the clinically assessed range.)
    - Ears treated with DB-020 lost approximately 8dB on average from baseline.
- DB-020 reduced cisplatin-induced loss of speech audibility by 80% as measured by the Speech Intelligibility Index, suggesting treatment with DB-020 may reduce the risk of needing assistive hearing devices after receiving cisplatin.

The Company plans to report additional data from the interim analysis of the Phase 1b clinical trial at an upcoming medical conference.

About the Phase1b Clinical Trial

The Phase 1b clinical trial of DB-020 is an ongoing, randomized, double-blind, placebo-controlled, multicenter trial designed to determine safety and tolerability of transtympanic injections of DB-020 in cancer patients receiving high doses of cisplatin. Audiometric measurements are made at the baseline before the first cisplatin infusion, before each subsequent cycle of cisplatin, and at the end of treatment in order to assess cisplatin-induced

ototoxicity. ASHA criteria for significant ototoxic change are defined as either a ≥20 dB decrease at any one test frequency, ≥10 dB decrease at any two adjacent frequencies, or loss of response at three consecutive frequencies where responses were previously obtained. Ototoxicity is evaluated from baseline to post-cisplatin administration timepoints in each ear and comparative ototoxicity measurements are made between the ears dosed with DB-020 and placebo in each patient. Partial protection is defined using ASHA ototoxicity criteria being applied to between ear changes.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Current Report on Form 8-K, including statements regarding the Company's strategy, future operations, prospects, plans, objectives of management, the therapeutic potential for the Company's product candidates and preclinical programs constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "objective," "ongoing," "plan," "predict," "project," "potential," "should," or "would," or the negative of these terms, or other comparable terminology are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. The Company may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements as a result of various important factors, including: uncertainties inherent in the identification and development of product candidates, including the conduct of research activities and the initiation and completion of preclinical studies and clinical trials, the timing of and the Company's ability to submit and obtain approval to initiate clinical development of its program candidates, whether interim data from a clinical trial will be predictive of the results of the trial and future clinical trials, whether the Company's cash resources are sufficient to fund its foreseeable and unforeseeable operating expenses and capital expenditure requirements, uncertainties related to the impact of the COVID-19 pandemic on the Company's business and operations, as well as the risks and uncertainties identified in the Company's filings with the Securities and Exchange Commission ("SEC"), including those risks detailed under the caption "Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2022 and in other filings the Company may make with the SEC. In addition, the forward-looking statements included in this Current Report on Form 8-K represent the Company's views as of the date of this Current Report on Form 8-K. The Company anticipates that subsequent events and developments will cause its views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this Current Report on Form 8-K.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

DECIBEL THERAPEUTICS, INC.

Date: June 28, 2022

By: /s/ Elisabeth Leiderman
Name: Elisabeth Leiderman, M.D.
Title: Chief Financial Officer and Head of Corporate Development