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): October 17, 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**	**02215**
(Address of Principal Executive Offices)	**(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 October 17, 2022, Decibel Therapeutics, Inc. (the "Company") announced that it has received clearance from the U.S. Food and Drug Administration (the "FDA") for its investigational new drug ("IND") application to initiate a Phase 1/2 clinical trial in pediatric patients of DB-OTO, its lead gene therapy product candidate.

The Phase 1/2 dose escalation clinical trial is designed to evaluate the safety, tolerability and efficacy of DB-OTO in pediatric patients with congenital hearing loss due to an otoferlin deficiency. In addition to safety and tolerability endpoints, established, clinically relevant, objective and behavioral measurements of hearing will be used as efficacy endpoints in the clinical trial. The auditory brainstem response, which was used to characterize dose-response of DB-OTO after intra-cochlear delivery in translational studies, will serve as an early, objective, clinically accepted readout of hearing thresholds in the clinical trial.

Based on discussions with the FDA during the IND review period, the Company expects the first two participants in the U.S. portion of the Phase 1/2 clinical trial will be as young as seven years of age and that subsequent participants will include children as young as two years of age and infants younger than two years of age. The Company intends to provide an update on the design of the clinical trial in the future. The DB-OTO IND is part of an international regulatory strategy for development of DB-OTO, which also includes plans to submit one or more clinical trial applications in Europe.

Forward-Looking Statements

This Form 8-K contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this 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, the potential benefits of cell-selective expression, plans to submit one or more clinical trial applications in Europe and the expected timeline for initiating a Phase 1/2 clinical trial of DB-OTO 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 timing of and the Company's ability to obtain approval to initiate clinical development of its program candidates, whether results from preclinical studies will be predictive of the results of later preclinical studies and 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 June 30, 2022 and in other filings the Company may make with the SEC. In addition, the forward-looking statements included in this Form 8-K represent the Company's views as of the date of this 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 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: October 17, 2022

By: /s/ Laurence Reid
Name: Laurence Reid, Ph.D.
Title: President and Chief Executive Officer