
**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): March 29, 2021

Decibel Therapeutics, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-40030
(Commission
File Number)

46-4198709
(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 2.02 Results of Operations and Financial Condition.

On March 29, 2021, Decibel Therapeutics, Inc. issued a press release announcing its financial results for the quarter and fiscal year ended December 31, 2020. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information set forth in this Item 2.02, including Exhibit 99.1, shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liability of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

| Exhibit No. | Description |
|------------------------|--|
| 99.1 | Press Release dated March 29, 2021 |

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: March 29, 2021

By: /s/ Laurence Reid

Name: Laurence Reid, Ph.D.

Title: President and Chief Executive Officer



Decibel Therapeutics Reports Fourth Quarter and Full Year 2020 and Financial Results and Corporate Update

-Successfully completed an oversubscribed Series D financing and upsized Initial Public Offering raising approximately \$220.1M in gross proceeds-

-Established development and manufacturing agreement for otoferlin dual-vector gene therapy with Catalent-

-Launched Amplify™ genetic testing program with Invitae for congenital hearing loss-

-U.S. FDA Fast Track designation granted for DB-020-

-Presented 8 podium and poster presentations at ARO-

Boston, MA., March 29, 2021 – (GLOBE NEWSWIRE)—Decibel Therapeutics (Nasdaq: DBTX), a clinical-stage biotechnology company dedicated to discovering and developing transformative treatments to restore and improve hearing and balance, today reported financial results for the fourth quarter and full year ended December 31, 2020 and provided a corporate update.

“The past nine months have been a strong period of execution for Decibel as we accomplished several key milestones. The closing of two upsized financings - our Series D and IPO - as well as an important partnership with Catalent focused on development and manufacturing of our lead gene therapy program for hearing loss, DB-OTO, place Decibel in a strong position operationally and financially to execute on our goals for 2021,” said Laurence Reid, Ph.D., Chief Executive Officer of Decibel. “Across our pipeline, we expect to announce important advances throughout this year. We look forward to further leveraging our proprietary platform of integrated single-cell genomics and bioinformatics analyses applied to the inner ear, as we advance our precision gene therapy pipeline for hearing and balance disorders.”

Company Highlights:

- Advanced DB-OTO for otoferlin (OTOF)-related hearing loss; on track for IND submission and Phase 1/2 clinical trial initiation in 2022.
- **Signed New Development and Manufacturing Agreement for Dual-Vector Gene Therapy with Catalent:** In February 2021, Decibel announced a new agreement with Catalent to provide Decibel with process and analytical development, as well as cGMP manufacturing services for its lead gene therapy product candidate, DB-OTO, being developed for individuals with hearing loss due to mutation of the OTOF gene.
- **Announced Exclusive Licensing Agreements for Hearing Gene Therapy Technology with the University of Florida and the University of California, San Francisco:** In November 2020, Decibel announced two exclusive license agreements for an adeno-associated virus (AAV) gene therapy technology designed to restore hearing to individuals with profound, congenital hearing loss caused by mutations in the otoferlin gene.

- **Launched Amplify™ Genetic Testing Program with Invitae:** In December 2020, Decibel launched Amplify™, a no-charge genetic testing program to screen for the genetic cause of congenital hearing loss in children diagnosed with auditory neuropathy with the genetic testing company, Invitae.
- **Presented New Preclinical Data at the 44th Annual Association for Research in Otolaryngology Conference (ARO):** In February 2021, Decibel presented preclinical findings supporting the Company's lead gene therapy product candidate, DB-OTO. The presentations included data from studies in non-human primates of the surgical approach for DB-OTO in which dual vector AAV and Decibel's cell-selective promoter drove highly selective expression of GFP in hair cells of non-human primates which demonstrated successful distribution and expression across the cochlear length in non-human primates. Additionally, the Company presented findings from preclinical studies of DB-OTO in mice and non-human primates in which hair cell-selective expression of OTOF enabled efficacy and durability and minimized potential toxicity.
- **Received U.S. Food and Drug Administration (FDA) Fast Track Designation for DB-020:** In December 2020, Decibel announced that its clinical product candidate for the prevention of cisplatin-induced hearing loss, DB-020, was granted Fast Track designation by the U.S. FDA.

Corporate Highlights:

- **Closed Upsized Initial Public Offering:** In February 2021, Decibel completed its Initial Public Offering of 7,662,000 shares of common stock at a public offering price of \$18.00 per share. Net proceeds from the offering, after deducting underwriting discounts and offering expenses, were approximately \$124.8 million.
- **Closed \$82.2M Series D Financing:** In November 2020, Decibel announced the closing of its oversubscribed Series D financing, which raised proceeds of \$82.2 million. The financing was led by OrbiMed with new investments from BlackRock Health Sciences, Casdin Capital, Janus Henderson, Samsara BioCapital and Surveyor Capital, along with existing investor participation from Foresite Capital, GV, S-Cubed, Sobrato Capital, SR One and Third Rock Ventures.
- **Strengthened Board of Directors with Appointment of Peter A. Thompson, M.D., F.A.C.P.:** In November 2020, Decibel announced the appointment of Peter A. Thompson, M.D., F.A.C.P., to its board of directors. Dr. Thompson is currently a partner at OrbiMed.
- **Added to Russell 2000 Index:** Effective March 22, 2021, Decibel was added to the Russell 2000® Index as part of its quarterly IPO additions. The Russell 2000® Index is a subset of the Russell 3000® Index, which measures the performance of the small-cap segment of the U.S. equity market.

Fourth Quarter and Full Year 2020 Financial Results:

- **Cash Position:** As of December 31, 2020, cash, cash equivalents and available-for-sale securities were \$54.3 million, compared to \$32.3 million as of December 31, 2019. The increase in cash, cash equivalents and available-for-sale securities was primarily due to closing the initial tranche of the Series D financing in November 2020.

- **Research and Development Expenses:** Research and development expenses were \$7.9 million for the fourth quarter of 2020, compared to \$3.2 million for the same period in 2019. Research and development expenses were \$25.3 million for the full year 2020, compared to \$29.4 million for the full year 2019. The decrease in research and development expenses for the full year 2020 was primarily due to a decrease in expenses incurred to advance the Company's DB-020 program related to slower enrollment due to COVID-19 and a decrease in other indirect research and development expenses.
- **General and Administrative Expenses:** General and administrative expenses were \$5.1 million for the fourth quarter of 2020, compared to \$3.3 million for the same period in 2019. General and administrative expenses were \$14.2 million for the full year 2020, compared to \$14.7 million for the full year 2019. The decrease in general and administrative expenses for the full year 2020 was primarily attributable to a decrease in facilities and personnel-related expenses due to reduced headcount partially offset by an increase in professional fees.

Financial Guidance:

Based on its current operating and development plans, Decibel believes that its existing cash, cash equivalents and available-for-sale securities will fund its pipeline programs and operating expenses into 2024.

About Decibel Therapeutics

Decibel Therapeutics is a clinical-stage biotechnology company dedicated to discovering and developing transformative treatments to restore and improve hearing and balance, one of the largest areas of unmet need in medicine. Decibel has built a proprietary platform that integrates single-cell genomics and bioinformatic analyses, precision gene therapy technologies and expertise in inner ear biology. Decibel is leveraging its platform to advance gene therapies designed to selectively replace genes for the treatment of congenital, monogenic hearing loss and to regenerate inner ear hair cells for the treatment of acquired hearing and balance disorders. Decibel's pipeline, including its lead gene therapy program, DB-OTO, to treat congenital, monogenic hearing loss, is designed to deliver on our vision of a world in which the privileges of hearing and balance are available to all.



Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this press release, including statements regarding Decibel's strategy, future operations, prospects, plans, objectives of management, the therapeutic potential for Decibel's product candidates and preclinical programs, the potential benefits of cell-selective expression, the expected timeline for submitting investigational new drug applications and achieving other planned milestones, expectations regarding the translation of preclinical findings to human disease and the sufficiency of Decibel's existing cash resources for the period anticipated, 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. Decibel 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 Decibel's ability to submit and 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 Decibel'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 Decibel's business and operations, as well as the risks and uncertainties identified in Decibel's filings with the Securities and Exchange Commission (SEC), including those risks detailed under the caption "Risk Factors" in the final prospectus for Decibel's initial public offering filed with the SEC on February 12, 2021. In addition, the forward-looking statements included in this press release represent Decibel's views as of the date of this press release. Decibel anticipates that subsequent events and developments will cause its views to change. However, while Decibel 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 Decibel's views as of any date subsequent to the date of this press release.

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Consolidated Balance Sheet
(in thousands)

| | December 31, | |
|--|--------------|-----------|
| | 2020 | 2019 |
| Cash, cash equivalents and available-for-sale securities | \$ 54,310 | \$ 32,314 |
| Total assets | 67,285 | 42,835 |
| Convertible preferred stock | 93,091 | 137,644 |
| Total stockholders' deficit | (162,689) | (123,352) |

Consolidated Statement of Operations
(in thousands)

| | Year ended December 31, | |
|----------------------------|-------------------------|-------------|
| | 2020 | 2019 |
| Operating expenses: | | |
| Research and development | \$ 25,322 | \$ 29,405 |
| General and administrative | 14,241 | 14,676 |
| Total Operating expenses | 39,563 | 44,081 |
| Loss from operations | (39,563) | (44,081) |
| Other income: | | |
| Other income, net | 171 | — |
| Interest income | 55 | 1,409 |
| Total other income, net | 226 | 1,409 |
| Net loss | \$ (39,337) | \$ (42,672) |