



Decibel Therapeutics Reports First Quarter 2022 Financial Results and Corporate Update

May 12, 2022

- Multiple milestones anticipated for 2022 including submission of IND and/or CTA for DB-OTO, top-line results from interim analysis of Phase 1b trial of DB-020 for cisplatin-induced hearing loss and product candidate selection for AAV.103 program –
- New preclinical data presented at the 45th Annual Association for Research in Otolaryngology Conference (ARO) supporting DB-OTO and emphasizing platform focus on cell-selective transgene expression –
- Preclinical data to be presented at the American Society of Gene and Cell Therapy (ASGCT) 25th Annual Meeting supporting DB-OTO, AAV.103 and AAV.104 –

BOSTON, May 12, 2022 (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 first quarter ended March 31, 2022 and provided a corporate update.

"2022 is slated to be a year of important growth and execution for Decibel as we have multiple catalysts expected throughout the remainder of the year. We have built a strong foundation both operationally and scientifically and are looking forward to these significant milestones, which potentially can further validate Decibel's inner ear expertise and commitment to further exploiting our proprietary gene therapy platform," said Laurence Reid, Ph.D., Chief Executive Officer of Decibel. "Notably, we plan to share data from an interim analysis of our Phase 1b trial of DB-020 for cisplatin-induced hearing loss in the second quarter of 2022, and we intend to initiate a Phase 1/2 clinical trial of DB-OTO later this year, subject to regulatory clearance."

Pipeline Highlights and Upcoming Milestones:

Gene Therapies for Congenital, Monogenic Hearing Loss

- **DB-OTO Program Remains On Track For 2022 Milestones:** Decibel remains on track to submit an investigational new drug application (IND) to the U.S. Food and Drug Administration and/or a Clinical Trial Application (CTA) in Europe for DB-OTO in 2022. Decibel also anticipates the initiation of a Phase 1/2 clinical trial of DB-OTO for pediatric patients with congenital hearing loss due to an otoferlin deficiency in 2022, subject to regulatory clearance.
- **Presented New Preclinical Data from Four Gene Therapy Programs at the 45th Annual Association for Research in Otolaryngology Conference (ARO):** In February 2022, Decibel presented preclinical data highlighting the identification of proprietary, cell-selective promoters for three of its gene therapy pipeline programs deployed from its platform, in addition to new DB-OTO data, which further characterized expression of otoferlin over time following DB-OTO administration in mice and non-human primates. These findings are consistent with the expression previously reported in mice that achieved stable functional recovery. Additionally, functional recovery and tolerability data associated with DB-OTO dosing over a 10-fold dose range in mice was observed. Decibel is developing DB-OTO in collaboration with Regeneron Pharmaceuticals and retains global commercial rights to DB-OTO.
- **On Track to Identify a Product Candidate for AAV.103 Program in 2022:** Product candidate selection for the AAV.103 program to restore hearing to individuals with a gap junction beta-2 (GJB2) deficiency, the most common cause of autosomal recessive, non-syndromic, congenital hearing loss, is expected in 2022. Decibel is developing AAV.103 in collaboration with Regeneron Pharmaceuticals and retains global commercial rights to the AAV.103 program.

Otoprotection Therapeutic

- **Phase 1b Proof-of-Concept Trial of DB-020 for the Treatment of Cisplatin-Induced Hearing Loss Interim Results Anticipated in the Second Quarter of 2022:** Results of the interim analysis from the ongoing Phase 1b clinical trial of DB-020 in patients with cisplatin-induced hearing loss, a serious and debilitating condition for which there are no approved therapies, are expected in the second quarter of 2022. Cisplatin, a commonly used chemotherapy agent, is known to cause hearing loss, tinnitus and speech recognition difficulty. DB-020 is comprised of a proprietary formulation of sodium thiosulfate that has been optimized for delivery to the ear. DB-020 is designed to protect hearing without interfering with cisplatin's anti-cancer activity by locally disabling cisplatin in the cochlea.

First Quarter 2022 Financial Results:

- **Cash Position:** As of March 31, 2022, cash, cash equivalents and available-for-sale securities were \$139.4 million,

compared to \$162.3 million as of December 31, 2021.

- **Research and Development Expenses:** Research and development expenses were \$7.5 million for the first quarter of 2022, compared to \$6.0 million for the same period in 2021. The increase in research and development expenses for the first quarter of 2022 was primarily due to higher development costs incurred to advance the DB-OTO and DB-020 programs, as well as higher personnel-related costs due to increased headcount, wages and stock-based compensation.
- **General and Administrative Expenses:** General and administrative expenses were \$6.6 million for the first quarter of 2022, compared to \$4.9 million for the same period in 2021. The increase in general and administrative expenses for the first quarter of 2022 was primarily due to higher professional fees including external consulting, advisory and audit services, as well as higher personnel-related costs due to increased headcount, wages and stock-based compensation.

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 creating a world of connection for people with hearing and balance disorders. For more information about Decibel Therapeutics, please visit www.decibeltx.com or follow us on [Twitter](https://twitter.com/DecibelTX).

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 clinical trial applications, initiating clinical trials, reporting clinical trial results and achieving other anticipated 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 Decibel's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2022 and in other filings Decibel may make with the SEC. 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.

Condensed Consolidated Balance Sheet Data (Unaudited) (in thousands)

	March 31, 2022	December 31, 2021
Cash, cash equivalents and available-for-sale securities	\$ 139,441	\$ 162,294
Total assets	\$ 173,785	\$ 184,477
Total stockholders' equity	\$ 128,120	\$ 141,689

Condensed Consolidated Statement of Operations (Unaudited) (in thousands)

	For the three months ended	
	March 31, 2022	March 31, 2021
Operating expenses:		
Research and development	\$ 7,466	\$ 6,020
General and administrative	6,553	4,883
Total Operating expenses	<u>14,019</u>	<u>10,903</u>
Loss from operations	(14,019)	(10,903)
Other income:		
Other income, net	63	33
Total other income, net	<u>63</u>	<u>33</u>
Income before income tax provision	(13,956)	(10,870)
Provision for income taxes	(60)	—
Net loss	<u>\$ (14,016)</u>	<u>\$ (10,870)</u>

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