



Decibel Therapeutics Reports First Quarter 2023 Financial Results and Corporate Update

May 15, 2023

- Initiated CHORD™, a global Phase 1/2 dose escalation clinical trial of lead gene therapy product candidate, DB-OTO -
- Announced approval from the U.K. MHRA and Spanish AEMPS for CTAs for CHORD to expand the Phase 1/2 clinical trial to the U.K. and Spain in patients two years of age and younger -
- Initiated manufacturing activities to support IND-enabling studies for our AAV.103 product candidate designed to restore hearing in individuals with mutations in the GJB2 gene -

BOSTON, May 15, 2023 (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, 2023 and provided a corporate update.

"2023 is a very important year for Decibel as we work to advance the CHORD global Phase 1/2 trial for DB-OTO, our gene therapy pipeline and DB-020. The initiation of our first gene therapy clinical study is the first of several important inflection points that we expect to occur in 2023, including dosing the initial patients and early clinical readouts from the CHORD clinical trial. We believe DB-OTO has the potential to be a best-in-class gene therapy for individuals with otoferlin-related hearing loss," said Laurence Reid, Ph.D., Chief Executive Officer of Decibel. "The multiple challenges of severe hearing loss continue to drive our vision. Congenital hearing loss is recognized as a potential neurodevelopmental emergency and with our product candidates we are aiming to provide durable, physiological hearing to address this."

Pipeline Highlights and Upcoming Milestones:

Gene Therapies for Congenital, Monogenic Hearing Loss

- **Initiated CHORD Phase 1/2 Clinical Trial of DB-OTO; Received European Orphan Drug Designation for DB-OTO:**
 - DB-OTO is an AAV-based, dual-vector, gene therapy product candidate designed to be administered a single time to selectively express functional otoferlin (OTOF) in the inner hair cells of individuals with OTOF deficiency with the goal of enabling the ear to transmit sound to the brain and enable durable, physiological hearing. Decibel is developing DB-OTO in collaboration with Regeneron Pharmaceuticals, and Decibel retains global commercial rights to the product candidate.
 - In May 2023, Decibel announced approval from the Spanish Agency of Medicines and Medical Devices (AEMPS) and in January 2023, Decibel announced approval from the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA) for its Clinical Trial Applications (CTAs) for its CHORD clinical trial of DB-OTO. The Company has previously announced clearance from the U.S. Food and Drug Administration (FDA) for its Investigational New Drug (IND) application for CHORD. Decibel expects that the first two patients in CHORD in the U.S. will be as young as seven years of age and that participants in the U.K. and Spain will be infants two years of age and younger.
 - In March 2023, the European Medicines Agency (EMA) Committee on Orphan Medicinal Products (COMP) and European Commission (EC) issued orphan drug designation for DB-OTO. Orphan drug designation is granted by the EC for medicines in development to treat rare conditions affecting no more than five in 10,000 people in the European Union, provided there is no other satisfactory treatment option or the medicine can be of significant benefit to those affected by a specific condition. Medicines that are granted orphan drug designation by the EC qualify for financial and regulatory incentives including protocol assistance, possible exemptions or reductions in certain regulatory fees, and, if approved for marketing, ten years of market exclusivity in the European Union.
- **Announced Presentations Related to DB-OTO and AAV.103 at the American Society of Gene and Cell Therapy (ASGCT) 26th Annual Meeting; Presented New Non-Clinical Safety Data from DB-OTO at the 46th Annual Association for Research in Otolaryngology (ARO) MidWinter Meeting:**
 - In May 2023, Decibel announced it will deliver podium presentations related to DB-OTO and AAV.103 at ASGCT. Decibel will also present posters related to its preclinical pipeline and its platform.
 - In February 2023, Decibel presented new non-clinical data supporting the clinical development of DB-OTO. In Good Laboratory Practices studies, Decibel did not observe any adverse DB-OTO-related findings in otic or non-otic tissues across any evaluation of OTOF-deficient mice or non-human primates.

- **Selected a Product Candidate for AAV.103 GJB2-Related Hearing Loss Program and Initiated Manufacturing Activities to Support IND-Enabling Studies:** In February 2023, Decibel presented preclinical data at ARO on its AAV.103 gene therapy product candidate designed to restore hearing in individuals with mutations in the gap junction beta-2 (GJB2) gene, the leading cause of autosomal recessive, non-syndromic, congenital hearing loss worldwide. Results demonstrated that selective expression of GJB2 in non-sensory cells that normally express GJB2 resulted in robust and durable hearing restoration in a mouse model of GJB2 deficiency. Decibel is developing the AAV.103 program in collaboration with Regeneron Pharmaceuticals and has achieved a pre-IND milestone in April 2023 related to initiation of manufacturing under the collaboration agreement. Decibel retains global commercial rights to the product candidate.

Otoprotection Therapeutic

- **DB-020 Phase 1b Clinical Trial Data to Be Presented at the American Society of Clinical Oncology (ASCO) 2023 Annual Meeting:** Decibel will present data from the Phase 1b clinical trial of DB-020, its product candidate for prevention of cisplatin-induced hearing loss in patients receiving cisplatin chemotherapy. In the interim results from the trial, DB-020 demonstrated reduced ototoxicity, a favorable safety and tolerability profile and no observed effect on systemic cisplatin pharmacokinetics (PK) in such patients. The Company is seeking advice from regulatory agencies concerning the future development of DB-020.

Corporate Update:

- **Board of Directors Update:** In March 2023, Decibel announced the appointment of Matthew Kapusta, MBA, to its Board of Directors. Mr. Kapusta serves as the CEO of uniQure, a gene therapy company.

First Quarter 2023 Financial Results:

- **Cash Position:** As of March 31, 2023, cash, cash equivalents and available-for-sale securities were \$87.9 million, compared to \$104.6 million as of December 31, 2022.
- **Research and Development Expenses:** Research and development expenses were \$7.9 million for the first quarter of 2023, compared to \$7.5 million for the same period in 2022. The increase in research and development expenses for the first quarter of 2023 was primarily due to costs to prepare for the Company's Phase 1/2 clinical trial of DB-OTO, higher research costs related to its other preclinical gene therapy programs and higher personnel-related costs due to increased headcount and wages.
- **General and Administrative Expenses:** General and administrative expenses were \$6.2 million for the first quarter of 2023, compared to \$6.6 million for the same period in 2022. The decrease in general and administrative expenses for the first quarter of 2023 was primarily due to lower professional fees including external consulting, advisory, legal and audit services.

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 planned operating expenses into the first half of 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 product candidate, 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. 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 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, 2023 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, 2023	December 31, 2022
Cash, cash equivalents and available-for-sale securities	\$ 87,941	\$ 104,561
Total assets	\$ 110,454	\$ 123,373
Total stockholders' equity	\$ 69,844	\$ 81,793

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

	Three Months Ended March 31,	
	2023	2022
Operating expenses:		
Research and development	\$ 7,934	\$ 7,466
General and administrative	6,187	6,553
Total Operating expenses	14,121	14,019
Loss from operations	(14,121)	(14,019)
Other income:		
Interest income	878	63
Total other income, net	878	63
Net loss before provision for income taxes	(13,243)	(13,956)
Provision for income taxes	(61)	(60)
Net loss	\$ (13,304)	\$ (14,016)

Investor Contact:

Julie Seidel
Stern IR, Inc.
julie.seidel@sternir.com
212-362-1200

Media Contact:

Chris Railey
Ten Bridge Communications
chris@tenbridgecommunications.com
617-834-0936