



## Decibel Therapeutics Reports Fourth Quarter and Full Year 2022 Financial Results and Corporate Update

March 14, 2023

- Received clearance from US FDA for IND and from UK MHRA for CTA to initiate CHORD™, a global Phase 1/2 dose escalation clinical trial of DB-OTO in pediatric patients -
- Plan to initiate the CHORD™ trial in the First Half of 2023 -
- Presented key non-clinical data at the 46<sup>th</sup> Annual ARO MidWinter Meeting supporting compelling safety profile of DB-OTO and preclinical data supporting selection of AAV.103 product candidate -

BOSTON, March 14, 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 fourth quarter and full year ended December 31, 2022 and provided a corporate update.

"I am incredibly pleased with the progress Decibel made throughout 2022. We believe the clearance of our IND and CTA for DB-OTO supports our belief that AAV gene therapy is an ideal modality for the inner ear. We remain on track to initiate CHORD™, the global Phase 1/2 clinical trial of DB-OTO in the first half of the year, evaluating DB-OTO in pediatric patients of diverse ages, including infants two years of age and younger. Beyond our clinical stage product candidates, we are making encouraging progress on our other programs and platform and were pleased to present data supporting the selection of a product candidate for our GJB2 program. GJB2-related hearing loss is the leading cause of autosomal recessive, non-syndromic, congenital hearing loss worldwide. We believe cell-selective expression of GJB2 will be critical for future success of any gene therapy targeting GJB2-related hearing loss, and the identification of gene regulatory elements to confer this precise expression showcases the strength of our platform," said Laurence Reid, Ph.D., Chief Executive Officer of Decibel. "In June 2022, we reported positive data from an interim analysis of our Phase 1b clinical trial of DB-020, supporting both its potential benefit and the integrated capabilities Decibel has implemented to develop innovative therapeutics for conditions of the inner ear. As we look ahead, we remain deeply committed to our mission of restoring and improving hearing and balance for those in need."

### Pipeline Highlights and Upcoming Milestones:

#### *Gene Therapies for Congenital, Monogenic Hearing Loss*

- **Received Investigational New Drug (IND) Application and Clinical Trial Application (CTA) Clearance and On Track for Phase 1/2 Trial Initiation:**
  - DB-OTO is an AAV-based dual-vector gene therapy product candidate designed to be delivered one 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 retains global commercial rights to the product candidate.
  - In October 2022, Decibel received clearance from the FDA for its IND application to initiate CHORD™, a Phase 1/2 clinical trial in pediatric patients of DB-OTO. Additionally, in January 2023, Decibel announced authorization of its CTA by the United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA) for its CTA for the trial. Decibel plans to initiate the CHORD™ clinical trial of DB-OTO in pediatric patients in the first half of 2023.
  - Decibel expects that the first two patients in the U.S. will be as young as seven years of age and that participants in the U.K. will be infants two years of age and younger.
- **CTA Application Filed for DB-OTO in Spain:** In November 2022, Decibel announced the submission of its CTA to the Spanish Agency of Medicines and Medical Devices (AEMPS) to open sites in Spain for CHORD™.
- **Presented New Non-Clinical Data of DB-OTO at the 46<sup>th</sup> Annual Association for Research in Otolaryngology (ARO) MidWinter Meeting:** In February 2023, Decibel presented new non-clinical data supporting the strong safety profile of DB-OTO, Decibel's lead gene therapy product candidate. In Good Laboratory Practices ("GLP") 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.
- **Identified Product Candidate for AAV.103 GJB2-Related Hearing Loss Program:** In February 2023, Decibel presented

preclinical data at ARO on its AAV.103 gene therapy program 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. In the data presented, selective targeting of GJB2-expressing cells 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 retains global commercial rights to the program.

#### **Otoprotection Therapeutic**

- **Provided Interim Analysis Update on DB-020 Phase 1b Clinical Trial:** In February 2023, Decibel presented additional data from the interim analysis of the Phase 1b clinical trial of DB-020 in patients receiving cisplatin chemotherapy. The Company continues to explore strategic opportunities to advance development of DB-020 and expects to consult with regulatory authorities in 2023 regarding its clinical development plan.

#### **Corporate Update:**

- **Board of Directors Update:** In October 2022, Decibel announced the appointment of Kevin F. McLaughlin to its Board of Directors.

#### **Fourth Quarter and Full Year 2022 Financial Results:**

- **Cash Position:** As of December 31, 2022, cash, cash equivalents and available-for-sale securities were \$104.6 million, compared to \$162.3 million as of December 31, 2021.
- **Research and Development Expenses:** Research and development expenses were \$11.6 million for the fourth quarter of 2022, compared to \$8.0 million for the same period in 2021. Research and development expenses were \$40.3 million for the full year 2022, compared to \$29.8 million for the full year 2021. The increase in research and development expenses for the fourth quarter and full year 2022 were primarily due to additional costs to advance DB-OTO in support of the Company's IND and CTA filings, higher clinical development costs to support its upcoming 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, wages and stock-based compensation.
- **General and Administrative Expenses:** General and administrative expenses were \$4.9 million for the fourth quarter of 2022, compared to \$4.9 million for the same period in 2021. General and administrative expenses were \$23.6 million for the full year 2022, compared to \$20.4 million for the full year 2021. The increase in general and administrative expenses for the full year 2022 was primarily due to higher professional fees including external consulting, advisory, legal 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 cash, cash equivalents and available-for-sale securities as of December 31, 2022 will fund its 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](http://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 Annual Report on Form 10-K for the fiscal year ended December 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 Sheets**  
(in thousands)

	December 31,	
	2022	2021
Cash, cash equivalents and available-for-sale securities	\$ 104,561	\$ 162,294
Total assets	\$ 123,373	\$ 184,477
Total stockholders' equity	\$ 81,793	\$ 141,689

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

	Year ended December 31,	
	2022	2021
Operating expenses:		
Research and development	\$ 40,330	\$ 29,847
General and administrative	23,627	20,384
Total Operating expenses	63,957	50,231
Loss from operations	(63,957)	(50,231)
Other income:		
Interest income	1,192	193
Other income, net	-	12
Total other income, net	1,192	205
Net loss before provision for income taxes	(62,765)	(50,026)
Provision for income taxes	(240)	(1,797)
Net loss	\$ (63,005)	\$ (51,823)

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