



Decibel Therapeutics Reports Third Quarter 2022 Financial Results and Corporate Update

November 9, 2022

- Received FDA Clearance of IND Application for DB-OTO, Gene Therapy Product Candidate Designed to Provide Hearing to Individuals with Otoferlin-Related Hearing Loss -
- Announced Submission of CTAs for DB-OTO in the United Kingdom and Spain -
- Expect to Initiate a Phase 1/2 Clinical Trial of DB-OTO in the First Half of 2023 -
- Plan to Identify AAV.103 Product Candidate in the Fourth Quarter of 2022-

BOSTON, Nov. 09, 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 third quarter ended September 30, 2022 and provided a corporate update.

"Decibel continued to maintain strong momentum throughout 2022 as we achieved the goals we set forth for the year. The FDA clearance of our IND application and the submission of our CTAs in the UK and Spain for our lead gene therapy product candidate, DB-OTO, mark significant milestones for us, and we look forward to initiating the Phase 1/2 clinical trial in the first half of 2023," said Laurence Reid, Ph.D., Chief Executive Officer of Decibel. "Looking ahead, we plan to continue to strengthen our position as a leader in the broader hearing loss space and we look forward to the opportunity to further our goal of developing transformative gene therapies for the inner ear."

Pipeline Highlights and Upcoming Milestones:

Gene Therapies for Congenital, Monogenic Hearing Loss

- **Received FDA Clearance of IND Application for DB-OTO:** In October 2022, Decibel announced that it had received clearance from the U.S. Food and Drug Administration (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. DB-OTO is being developed in collaboration with Regeneron Pharmaceuticals and is an adeno-associated virus (AAV)-based dual-vector gene therapy designed to provide durable hearing to individuals with profound congenital hearing loss caused by mutations of the otoferlin gene. DB-OTO uses a proprietary, cell-selective promoter to express the otoferlin transgene in hair cells, with the goal of enabling the ear to transmit sound to the brain and provide hearing to such individuals. DB-OTO received Orphan Drug and Rare Pediatric Disease designations from the FDA in 2021.
- **CTA Applications Filed for DB-OTO in Europe:** In November 2022, Decibel announced submission of Clinical Trial Applications (CTAs) to the Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom and the Spanish Agency of Medicines and Medical Devices (AEMPS) for a Phase 1/2 clinical trial of DB-OTO in pediatric patients.
- **Plan to Identify a Product Candidate for AAV.103 Program in Fourth Quarter of 2022:** Decibel plans to select a product candidate for further development in its AAV.103 program to restore hearing in individuals with mutations in the gap junction beta-2 (GJB2) gene, the most common cause of autosomal recessive, non-syndromic, congenital hearing loss. Decibel is developing the AAV.103 program in collaboration with Regeneron Pharmaceuticals and retains global commercial rights to the AAV.103 program.

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- **Intend to Provide Update on DB-020 in First Half of 2023:** Decibel plans to report additional data from the interim analysis of the Phase 1b clinical trial of DB-020 at an upcoming conference. The Company continues to evaluate strategic opportunities to continue development of DB-020, including seeking feedback from regulatory authorities.

Corporate Update:

- **Board of Directors Update:** In October 2022, Decibel announced the appointment of Kevin F. McLaughlin to its Board of Directors. Kevin brings more than 40 years of financial and operating management experience spanning the biotech, high-tech and education industries.

Third Quarter 2022 Financial Results:

- **Cash Position:** As of September 30, 2022, cash, cash equivalents and available-for-sale securities were \$111.9 million, compared to \$162.3 million as of December 31, 2021.
- **Research and Development Expenses:** Research and development expenses were \$10.0 million for the third quarter of 2022, compared to \$9.0 million for the same period in 2021. The increase in research and development expenses for the third quarter of 2022 was primarily due to additional costs to advance DB-OTO in support of the Company's IND filing, higher research costs related to 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 \$6.3 million for the third quarter of 2022, compared to \$5.7 million for the same period in 2021. The increase in general and administrative expenses for the third quarter of 2022 was primarily due to higher 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 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 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 September 30, 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)

	September 30, 2022	December 31, 2021
Cash, cash equivalents and available-for-sale securities	\$ 111,946	\$ 162,294
Total assets	\$ 142,273	\$ 184,477
Total stockholders' equity	\$ 96,814	\$ 141,689

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	\$ 10,030	\$ 9,020	\$ 28,737	\$ 21,867
General and administrative	6,319	5,680	18,734	15,462
Total Operating expenses	16,349	14,700	47,471	37,329
Loss from operations	(16,349)	(14,700)	(47,471)	(37,329)
Other income:				
Interest income	374	33	532	141
Total other income, net	374	33	532	141
Net loss before provision for income taxes	(15,975)	(14,667)	(46,939)	(37,188)
Provision for income taxes	(30)	(1,732)	(128)	(1,732)
Net loss	\$ (16,005)	\$ (16,399)	\$ (47,067)	\$ (38,920)

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