



Decibel Therapeutics Reports Second Quarter 2023 Financial Results and Corporate Update

August 11, 2023

- Activated CHORD™ clinical trial sites in U.S., U.K. and Spain and commenced patient screening activities; anticipate dosing first patient in the Phase 1/2 clinical trial in the second half of 2023 -

- Received FDA Breakthrough Therapy Designation for DB-020 for protection against hearing loss associated with cisplatin chemotherapy -

- Announced on August 9 definitive agreement for Regeneron Pharmaceuticals to acquire Decibel -

BOSTON, Aug. 11, 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 second quarter ended June 30, 2023 and provided a corporate update.

"This week we announced a definitive agreement with Regeneron Pharmaceuticals to acquire Decibel, which we believe reflects the tremendous promise of gene therapy for hearing loss," said Laurence Reid, Ph.D., Chief Executive Officer of Decibel. "We remain highly focused on executing on the CHORD clinical trial and excited by the potential benefit that DB-OTO may provide to people with otoferlin-related hearing loss. With six active clinical trial sites at prestigious institutions across three countries, we continue to work towards our goal of addressing this unmet medical need."

Pipeline Highlights and Upcoming Milestones:

Gene Therapies for Congenital, Monogenic Hearing Loss

- **Phase 1/2 CHORD™ Dose Escalation Clinical Trial of DB-OTO in Pediatric Patients:**

- 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 has been developing DB-OTO in collaboration with Regeneron Pharmaceuticals.
- In May 2023, Decibel announced the initiation of CHORD, a global Phase 1/2 dose escalation clinical trial of DB-OTO in pediatric patients. Decibel has opened clinical trial sites in the U.S., the U.K. and Spain and has commenced patient screening activities. DB-OTO received Orphan Drug Designation from the European Medicines Agency (EMA) Committee on Orphan Medicinal Products (COMP) in May 2023, adding to its Orphan Drug and Rare Pediatric Disease Designations from the U.S. Food and Drug Administration (FDA).

- **Continued Progress with IND-Enabling Activities to Support the Advancement of AAV.103 for GJB2-Related Hearing Loss Program:**

- In March 2023, Decibel achieved a pre-investigational new drug (IND) milestone under its collaboration agreement with Regeneron Pharmaceuticals related to the initiation of manufacturing of AAV.103, Decibel's 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.

Otoprotection Therapeutic

- **Received FDA Breakthrough Therapy Designation for DB-020:**

- In July 2023, Decibel received FDA Breakthrough Therapy Designation for DB-020, a novel, proprietary formulation of sodium thiosulfate (STS), designed to protect against hearing loss in cancer patients receiving cisplatin chemotherapy. This was supported by Decibel's Phase 1b clinical trial in which 87% of treated patients experiencing ototoxicity in their placebo-treated ear were partially or completely protected from ototoxicity. Breakthrough Therapy Designation is intended to expedite the development and review of medicines intended to treat serious or life-threatening conditions that have preliminary clinical evidence indicating that the drug may demonstrate substantial improvement over available treatments. A Breakthrough Therapy Designation conveys all the fast-track program features, more intensive FDA guidance on the drug development program, an organizational commitment involving senior FDA managers and eligibility for rolling review and priority review.

Corporate Update:

- **Announced definitive agreement for Regeneron Pharmaceuticals to acquire Decibel:**
 - On August 9, 2023, Decibel and Regeneron announced the entry into an agreement for Regeneron to acquire Decibel to build on the existing collaboration, and accelerate and further resource key gene therapy programs for hearing loss. The proposed acquisition values Decibel at a total equity value of approximately \$109 million based on the amount payable at closing, and a total equity value of up to approximately \$213 million if the contingent value right (CVR) milestones are achieved.

Second Quarter 2023 Financial Results:

- **Cash Position:** As of June 30, 2023, cash, cash equivalents and available-for-sale securities were \$78.3 million, compared to \$104.6 million as of December 31, 2022.
- **Research and Development Expenses:** Research and development expenses were \$12.8 million for the second quarter of 2023, compared to \$11.2 million for the same period in 2022. The increase in research and development expenses for the second quarter 2023 was primarily due to higher clinical development and related costs for the Company's Phase 1/2 clinical trial of DB-OTO, additional regulatory and clinical costs for DB-020, and higher personnel-related costs due to increased headcount, wages and stock-based compensation.
- **General and Administrative Expenses:** General and administrative expenses were \$6.2 million for the second quarter of 2023, compared to \$5.9 million for the same period in 2022. The increase in general and administrative expenses for the second quarter 2023 was primarily due to increased facility-related costs due to decreased sublease income and higher personnel-related costs due to increased headcount, wages and stock-based compensation, partially offset by decreased professional fees year over year.

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](#).

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 and gene therapy for the inner ear, 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, the sufficiency of Decibel's existing cash resources for the period anticipated, the occurrence of any event, change, or other circumstance that could give rise to the termination of the Agreement and Plan of Merger with Regeneron Pharmaceuticals, Inc., the prospective benefits of the proposed acquisition, the value of potential contingent consideration amounts and timing of the closing for the transaction, 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: risks related to our proposed acquisition by Regeneron, 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, 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 June 30, 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.

	<u>June 30, 2023</u>	<u>December 31, 2022</u>
Cash, cash equivalents and available-for-sale securities	\$ 78,300	\$ 104,561
Total assets	\$ 94,387	\$ 123,373
Total stockholders' equity	\$ 53,312	\$ 81,793

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

	<u>For the three months ended</u>		<u>For the six months ended</u>	
	<u>June 30, 2023</u>	<u>June 30, 2022</u>	<u>June 30, 2023</u>	<u>June 30, 2022</u>
Operating expenses:				
Research and development	\$ 12,828	\$ 11,241	\$ 20,762	\$ 18,707
General and administrative	6,213	5,862	12,400	12,415
Total Operating expenses	<u>19,041</u>	<u>17,103</u>	<u>33,162</u>	<u>31,122</u>
Loss from operations	(19,041)	(17,103)	(33,162)	(31,122)
Other income:				
Other income, net	976	95	1,854	158
Total other income, net	<u>976</u>	<u>95</u>	<u>1,854</u>	<u>158</u>
Income before income tax provision	(18,065)	(17,008)	(31,308)	(30,964)
Provision for income taxes	(80)	(38)	(141)	(98)
Net loss	<u>\$ (18,145)</u>	<u>\$ (17,046)</u>	<u>\$ (31,449)</u>	<u>\$ (31,062)</u>

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