



## Decibel Therapeutics Reports Third Quarter 2021 Financial Results and Corporate Update

November 10, 2021

- Received Orphan Drug and Rare Pediatric Disease designations for DB-OTO for the treatment of otoferlin-related congenital hearing loss –
- On track for key 2022 milestones including submission of IND and/or CTA for DB-OTO and interim analysis of DB-020 Phase 1b trial for cisplatin-induced hearing loss –
- Announces AAV.104 gene therapy program for restoration of hearing in patients with congenital hearing impairment due to recessive mutations in the stereocilin gene –

BOSTON, Nov. 10, 2021 (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, 2021 and provided a corporate update.

"Decibel continues to work towards bringing transformative treatments to patients with hearing and balance disorders as we move to the end of a successful 2021 and look forward to 2022. We remain on track to initiate a Phase 1/2 clinical trial of DB-OTO in pediatric patients in 2022 and report the results of an interim analysis of our Phase 1b clinical trial of DB-020 in patients receiving cisplatin chemotherapy in the first half of 2022," said Laurence Reid, Ph.D., Chief Executive Officer of Decibel. "We are incredibly pleased to have received Orphan Drug and Rare Pediatric Disease designations for DB-OTO, reiterating the importance of our approach to gene therapies for congenital, monogenic hearing loss. Beyond DB-OTO, we have continued to leverage our precision gene therapy platform to advance our GJB2, stereocilin and regeneration gene therapy programs."

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

- **Received Orphan Drug and Rare Pediatric Disease Designations for DB-OTO:** In September 2021, Decibel announced that the U.S. Food and Drug Administration (FDA) granted both Orphan Drug Designation and Rare Pediatric Disease Designation for DB-OTO for the treatment of otoferlin-related congenital hearing loss.
- **On Track to Achieve DB-OTO Key Milestones in 2022:** Decibel expects to submit an investigational new drug application (IND) with the FDA and/or a Clinical Trial Application (CTA) in Europe for DB-OTO and initiate a Phase 1/2 clinical trial of DB-OTO for pediatric patients with congenital hearing loss due to an otoferlin deficiency in 2022.
- **Announces AAV.104 Gene Therapy Program for Restoration of Hearing in Patients with Congenital Hearing Impairment Due to Recessive Mutations in the Stereocilin (STRC) Gene:** AAV.104 aims to restore hearing to individuals with a STRC deficiency, the second most common cause of autosomal recessive, non-syndromic, congenital hearing loss. The Company estimates that the prevalence of individuals with this form of hearing loss in the United States and the major markets in Europe is approximately 70,000. STRC is a large, extracellular, structural protein expressed in outer hair cells of the cochlea. Functional outer hair cells amplify sound within the ear, a process required for normal hearing sensitivity and frequency selectivity. Despite the absence of the STRC protein and observed hearing loss in patients carrying STRC mutations, third-party research has shown that the outer hair cells remain intact and viable for gene therapy. AAV.104 is designed to express STRC selectively in outer hair cells, thus providing STRC specifically in its natural cellular location, a strategy that has the potential to restore expression of the protein and hearing. Decibel is working in collaboration with Regeneron to develop AAV.104 and plans to share preclinical data on this program at an upcoming scientific meeting.

### **Gene Therapies for Hair Cell Regeneration**

- **On Track to Announce AAV.201 Program Target:** Decibel continues to advance AAV.201, its gene therapy program for regeneration of hair cells in the vestibule for the treatment of bilateral vestibulopathy (BVP). Decibel plans to announce the program target(s) for AAV.201 in 2022.

### **Otoprotection Therapeutic**

- **On Track to Report Interim Results from Phase 1b Proof-of-Concept Trial of DB-020 for the Treatment of Cisplatin-Induced Hearing Loss:** Decibel expects to report interim results 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, in the first half of 2022. Cisplatin, a commonly used chemotherapy agent, is known to cause hearing loss, tinnitus and speech recognition difficulty. DB-020 comprises a proprietary formulation of sodium thiosulfate which has been optimized for delivery to the ear. By locally disabling cisplatin in the cochlea, DB-020 is designed to protect hearing without interfering

with cisplatin's anti-cancer activity.

- **Granted Key U.S. Patent Covering DB-020 Formulation:** In July 2021, the United States Patent and Trademark Office (USPTO) issued U.S. Patent No. 11,071,751, "Hypertonic pharmaceutical compositions containing an anti-platinum chemoprotectant agent," a foundational patent and component of Decibel's DB-020 intellectual property portfolio.

#### Research Highlights:

- **Announced Foundational Study of Noise-Related Inner Ear Damage:** In September 2021, Decibel announced the publication of new findings in *Cell Reports* from a study on noise-related inner ear damage conducted in collaboration with the University of Maryland School of Medicine and the Karolinska Institute. This study demonstrates how Decibel's platform is built to provide a molecular characterization of the cells of the inner ear to enable the identification of therapeutics that counter the underlying molecular pathology of noise-induced hearing loss in the future.

#### Third Quarter 2021 Financial Results:

- **Cash Position:** As of September 30, 2021, cash, cash equivalents and available-for-sale securities were \$172.4 million.
- **Research and Development Expenses:** Research and development expenses were \$9.0 million for the third quarter of 2021, compared to \$4.7 million for the third quarter of 2020. The increase in research and development expenses for the third quarter of 2021 was driven primarily by an increase in costs associated with IND/CTA enabling activities for DB-OTO.
- **General and Administrative Expenses:** General and administrative expenses were \$5.7 million for the third quarter of 2021, compared to \$2.4 million for the same period in 2020. The increase in general and administrative expenses for the third quarter of 2021 was primarily attributable to increases in professional fees, personnel costs and directors' and officers' insurance costs incurred as a result of becoming a public company.

#### 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](http://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 expected timeline for submitting investigational new drug applications and achieving other planned milestones 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 product 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, 2021 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.

(unaudited)

(in thousands)

	<u>September 30, 2021</u>	<u>December 31, 2020</u>
Cash, cash equivalents and available-for-sale securities	\$ 172,384	\$ 54,310
Total assets	185,287	67,285
Convertible preferred stock	—	93,091
Total stockholders' deficit	(201,609)	(162,689)

**Condensed Consolidated Statement of Operations**

(unaudited)

(in thousands)

	<u>For the three months ended</u>		<u>For the nine months ended</u>	
	<u>September 30, 2021</u>	<u>September 30, 2020</u>	<u>September 30, 2021</u>	<u>September 30, 2020</u>
Operating expenses:				
Research and development	\$ 9,020	\$ 4,691	\$ 21,867	\$ 17,426
General and administrative	5,680	2,397	15,462	9,130
Total Operating expenses	<u>14,700</u>	<u>7,088</u>	<u>37,329</u>	<u>26,556</u>
Loss from operations	(14,700)	(7,088)	(37,329)	(26,556)
Other income:				
Interest income	33	2	141	103
Other income	—	(25)	—	—
Total other income, net	<u>33</u>	<u>(23)</u>	<u>141</u>	<u>103</u>
Income before income tax provision	<u>(14,667)</u>	<u>(7,111)</u>	<u>(37,188)</u>	<u>(26,453)</u>
Provision for income taxes	(1,732)	—	(1,732)	—
Net loss	<u>\$ (16,399)</u>	<u>\$ (7,111)</u>	<u>\$ (38,920)</u>	<u>\$ (26,453)</u>

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