



Regeneron to Acquire Decibel Therapeutics, Strengthening Gene Therapy and Hearing Loss Programs

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Proposed acquisition builds on existing collaboration between Decibel and Regeneron, will accelerate and further resource key gene therapy programs for hearing loss

Decibel's lead investigational gene therapy DB-OTO, designed to provide hearing to people with otoferlin-related hearing loss, is in its first clinical trial

TARRYTOWN, N.Y. and BOSTON, Aug. 09, 2023 (GLOBE NEWSWIRE) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) and Decibel Therapeutics, Inc. (NASDAQ: DBTX), a clinical-stage biotechnology company dedicated to discovering and developing transformative treatments to restore and improve hearing and balance, today announced a definitive agreement for the acquisition of Decibel by Regeneron at a price of \$4.00 per share of Decibel common stock payable in cash at closing, with an additional non-tradeable contingent value right (CVR) to receive up to \$3.50 per share in cash upon achievement of certain clinical development and regulatory milestones for Decibel's lead investigational candidate, DB-OTO, within specified time periods. 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 CVR milestones are achieved.

"We at Decibel are deeply committed to discovering and advancing innovative new therapies with the potential to be transformative for people with severe forms of hearing loss. We have built a pipeline of gene therapy product candidates for the ear that we believe have such potential. After full consideration, the Decibel Board has determined that this transaction is the best way to maximize shareholder value and ultimately benefit patients," said Laurence E. Reid, Ph.D., President and Chief Executive Officer of Decibel. "We have collaborated with our colleagues at Regeneron for the past six years and have huge respect for their research and development capabilities. We have full confidence that with Regeneron's expertise and resources the Decibel pipeline can be optimally developed, and our team is committed to enabling that long-term success."

Decibel and Regeneron established their [initial collaboration in 2017, with an extension announced in 2021](#), and are developing three gene therapy programs targeting different forms of congenital, monogenic hearing loss. DB-OTO, which is currently in the global Phase 1/2 [CHORD™ clinical trial](#), is an investigational cell-selective, adeno-associated virus (AAV) gene therapy designed to provide durable, physiological hearing to individuals with profound, congenital hearing loss caused by mutations of the otoferlin gene. Preclinical programs include AAV.103 for people with GJB2-related hearing loss and AAV.104 for people with stereocilin (STRC)-related hearing loss.

"We are delighted to announce the planned acquisition of Decibel, who have been long-standing collaborators, notable for their deep scientific knowledge and commitment to people with hearing loss," said George D. Yancopoulos, M.D., Ph.D., Board co-Chair, Chief Scientific Officer and President of Regeneron. "DB-OTO, our shared lead investigational gene therapy, will soon reach patients in its first clinical trial, offering new promise to children with this rare form of congenital hearing loss, as well as potential proof-of-concept for future gene therapies addressing more common forms of genetic hearing loss. We believe that Decibel's assets and specialized team will further strengthen our genetic medicines portfolio, enabling Regeneron to accelerate the development of innovative genetic therapies and a rich pipeline of hearing loss treatments."

Congenital hearing loss is a significant unmet medical need with no approved medical therapies that affects approximately 1.7 out of every 1,000 children born in the United States. While hearing loss caused by mutations of the otoferlin gene is rare, the majority of permanent, congenital hearing loss cases diagnosed in developed countries are sensorineural and result from a single gene defect, making them appealing targets for gene therapy. Hearing aids and cochlear implants may offer benefits, but they fall short of replicating normal hearing function.

The merger agreement provides for Regeneron, through its wholly owned subsidiary Symphony Acquisition Sub, Inc., to initiate a tender offer to acquire all outstanding shares of Decibel at a price of \$4.00 per share of Decibel common stock payable in cash at closing plus one CVR payable in cash subject to the terms and conditions contained in a contingent value rights agreement ("CVR Agreement"). CVR holders would become entitled to receive contingent payments as follows: (i) \$2.00 in cash, upon the fifth participant being administered with DB-OTO in a clinical trial on or prior to December 31, 2024 (the DB-OTO Milestone); and (ii) \$1.50 in cash, upon (a) the first participant being administered with DB-OTO in a registration enabling trial (as defined in the CVR Agreement) or (b) acceptance for review of a Biologics License Application by the U.S. Food and Drug Administration, a Marketing Authorization Application by the European Medicines Agency or the U.K. Medicines and Healthcare Products Regulatory Agency, or an equivalent application by the applicable national regulatory authority in any of Germany, France, Italy or Spain for DB-OTO, whichever occurs first, on or prior to December 31, 2028; provided the DB-OTO Milestone is achieved on or prior to December 31, 2024. There can be no assurance that any payments will be made with respect to the CVR. The closing of the tender offer will be

subject to certain conditions, including the tender of at least a majority of the outstanding shares of Decibel common stock and other customary closing conditions. Upon the successful completion of the tender offer, Regeneron will acquire all shares not acquired in the tender through a second-step merger for the same consideration per share paid in the tender offer. The transaction is expected to close in the third quarter of 2023.

Regeneron's legal advisor for the transaction is Wachtell, Lipton, Rosen & Katz. Centerview Partners LLC and Leerink Partners LLC are serving as Decibel's financial advisors and Wilmer Cutler Pickering Hale and Dorr LLP is serving as Decibel's legal advisor.

About Regeneron

Regeneron (NASDAQ: REGN) is a leading biotechnology company that invents life-transforming medicines for people with serious diseases. Founded and led for 35 years by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to nine FDA-approved treatments and numerous product candidates in development, almost all of which were homegrown in our laboratories. Our medicines and pipeline are designed to help patients with eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, hematologic conditions, infectious diseases and rare diseases.

Regeneron is accelerating and improving the traditional drug development process through our proprietary *VelociSuite*[®] technologies, such as *VelocImmune*[®], which uses unique genetically humanized mice to produce optimized fully human antibodies and bispecific antibodies, and through ambitious research initiatives such as the Regeneron Genetics Center, which is conducting one of the largest genetics sequencing efforts in the world.

For additional information about the company, please visit www.regeneron.com or follow Regeneron on LinkedIn.

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 creating a world of connection for people with hearing and balance disorders. 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 risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. ("Regeneron") and Decibel Therapeutics, Inc. ("Decibel"), including regarding Regeneron's proposed acquisition of Decibel, the prospective benefits of the proposed acquisition, the potential contingent consideration amounts and terms and the anticipated occurrence, manner and timing of the proposed tender offer and the closing of the proposed acquisition. Actual events or results may differ materially from these forward-looking statements. Words such as "anticipate," "expect," "intend," "plan," "propose," "provide," "believe," "seek," "estimate," variations of such words, and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. Risks that may cause these forward-looking statements to be inaccurate include, without limitation: uncertainties as to the timing of the tender offer and merger; uncertainties as to how many of Decibel's stockholders will tender their stock in the offer; the possibility that competing offers will be made; the possibility that various closing conditions for the transaction may not be satisfied or waived, including that a governmental entity may prohibit, delay, or refuse to grant approval for the consummation of the transaction (or only grant approval subject to adverse conditions or limitations); the difficulty of predicting the timing or outcome of regulatory approvals or actions, if any; the possibility that the transaction does not close; risks related to Regeneron's ability to realize the anticipated benefits of the proposed acquisition, including the possibility that the expected benefits from the proposed acquisition will not be realized or will not be realized within the expected time period and that Regeneron and Decibel will not be integrated successfully; the effects of the transaction on relationships with employees, other business partners or governmental entities; negative effects of this announcement or the consummation of the proposed acquisition on the market price of Regeneron's or Decibel's common stock and/or Regeneron's or Decibel's operating results; significant transaction costs; unknown liabilities; the risk of litigation and/or regulatory actions related to the proposed acquisition; Regeneron's and Decibel's ability to continue to conduct research and clinical programs; Regeneron's and Decibel's ability to manage their respective supply chains; Regeneron's ability to manage net product sales of products marketed or otherwise commercialized by Regeneron and/or its collaborators or licensees (collectively, "Regeneron's Products"); the nature, timing, and possible success and therapeutic applications of Regeneron's Products, product candidates being developed by Regeneron and/or its collaborators or licensees (including without limitation Regeneron's and Decibel's investigational gene therapy DB-OTO for the treatment of congenital hearing loss and the other gene therapy programs being developed as part of the companies' collaboration (collectively, "Regeneron's Product Candidates")), and development programs and product candidates being developed by Decibel independently (collectively, "Decibel's Product Candidates"); the extent to which the results from the research and development programs conducted by Regeneron, Decibel, and/or their respective collaborators or licensees may be replicated in other studies and/or lead to advancement of product candidates to clinical trials, therapeutic applications, or regulatory approval; uncertainty of the utilization, market acceptance, and commercial success of Regeneron's Products, Regeneron's Product Candidates, and Decibel's Product Candidates and the impact of studies (whether conducted by Regeneron, Decibel or others and whether mandated or voluntary) on any of the foregoing or any potential regulatory approval of Regeneron's

Products, Regeneron's Product Candidates, and Decibel's Product Candidates; uncertainty regarding each of the contingent value rights milestones referenced in this press release and the possibility that any or all of such milestones will never be achieved and that some or all milestone payments may not be made; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's Product Candidates and Decibel's Product Candidates and new indications for Regeneron's Products; the ability of Regeneron's and Decibel's collaborators, licensees, suppliers, or other third parties (as applicable) to perform manufacturing, filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron's Products, Regeneron's Product Candidates, and Decibel's Product Candidates; the ability of Regeneron and/or its collaborators to manufacture and manage supply chains for multiple products and product candidates; safety issues resulting from the administration of Regeneron's Products, Regeneron's Product Candidates, and Decibel's Product Candidates in patients, including serious complications or side effects in connection with the use of Regeneron's Products, Regeneron's Product Candidates, and Decibel's Product Candidates in clinical trials; determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize Regeneron's Products or Regeneron's Product Candidates, or Decibel's ability to continue to develop Decibel's Product Candidates; competing drugs and product candidates that may be superior to, or more cost effective than, Regeneron's Products, Regeneron's Product Candidates, or Decibel's Product Candidates; and the impact of public health outbreaks, epidemics, or pandemics (such as the COVID-19 pandemic) on Regeneron's or Decibel's respective businesses.

A more complete description of these and other material risks can be found in Regeneron's and Decibel's filings with the U.S. Securities and Exchange Commission (the "SEC"), including their Quarterly Reports on Form 10-Q for the quarterly period ended June 30, 2023 and March 31, 2023 for Regeneron and Decibel respectively, and their Annual Reports on Forms 10-K for the fiscal year ended December 31, 2022 as well as the Schedule TO and related tender offer documents to be filed by Regeneron and its acquisition subsidiary, Symphony Acquisition Sub, Inc., the Schedule 14D-9 to be filed by Decibel, and, if applicable, the proxy statement referenced below. Any forward-looking statements are made based on the current beliefs and judgments of Regeneron's and Decibel's management, and the reader is cautioned not to rely on any forward-looking statements made by Regeneron or Decibel. Except as required by law, Regeneron and Decibel do not undertake any obligation to update (publicly or otherwise) any forward-looking statement, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise.

Additional Information and Where to Find It

The tender offer referenced in this communication has not yet commenced. This communication is for informational purposes only and is neither an offer to purchase nor a solicitation of an offer to sell any securities, nor is it a substitute for the tender offer materials that Decibel, Regeneron or its acquisition subsidiary, Symphony Acquisition Sub, Inc., will file with the SEC. The solicitation and offer to buy Decibel stock will only be made pursuant to an Offer to Purchase and related tender offer materials that Regeneron intends to file with the SEC. At the time the tender offer is commenced, Regeneron and its acquisition subsidiary will file a Tender Offer Statement on Schedule TO and thereafter Decibel will file a Solicitation/Recommendation Statement on Schedule 14D-9 with the SEC with respect to the tender offer. Under certain circumstances described in the definitive transaction documents, Regeneron may determine to instead terminate or withdraw the offer and effect the transaction through a merger only, in which case the relevant documents to be filed with the SEC will include a proxy statement for the solicitation of votes of Decibel stockholders to approve the merger. DECIBEL'S STOCKHOLDERS AND OTHER INVESTORS ARE URGED TO READ CAREFULLY THE TENDER OFFER MATERIALS (INCLUDING AN OFFER TO PURCHASE, A RELATED LETTER OF TRANSMITTAL AND CERTAIN OTHER TENDER OFFER DOCUMENTS), THE SOLICITATION/RECOMMENDATION STATEMENT ON SCHEDULE 14D-9, AND, IF APPLICABLE, THE PROXY STATEMENT BECAUSE THEY WILL EACH CONTAIN IMPORTANT INFORMATION THAT HOLDERS OF DECIBEL SECURITIES AND OTHER INVESTORS SHOULD CONSIDER BEFORE MAKING ANY DECISION WITH RESPECT TO THE TENDER OFFER, OR, IF APPLICABLE, VOTING ON THE TRANSACTION. The Offer to Purchase, the related Letter of Transmittal, certain other tender offer documents, as well as the Solicitation/Recommendation Statement on Schedule 14D-9, and if applicable, the proxy statement will be made available to all stockholders of Decibel at no expense to them and will also be made available for free at the SEC's website at www.sec.gov. Additional copies may be obtained for free by contacting either Regeneron or Decibel. Copies of the documents filed with the SEC by Decibel will be available free of charge on Decibel's website at <https://ir.decibeltx.com> or by contacting Decibel Investor Relations at (617) 370-8701. Copies of the documents filed with the SEC by Regeneron will be available free of charge on Regeneron's website at <https://investor.regeneron.com> or by contacting Regeneron's Investor Relations Department at invest@regeneron.com or (914) 847-7741.

In addition to the Offer to Purchase, the related Letter of Transmittal and certain other tender offer documents, as well as the Solicitation/Recommendation Statement on Schedule 14D-9, and if applicable, the proxy statement, Regeneron and Decibel each file annual, quarterly and current reports, proxy statements and other information with the SEC, which are available to the public over the Internet at the SEC's website at <http://www.sec.gov>.

If the tender offer is terminated and the transaction is to be effected by merger only, in which case, the approval of Decibel stockholders must be obtained, Regeneron, Decibel and their respective directors and executive officers may be deemed to be participants in any such solicitation of proxies from Decibel's stockholders in connection with the proposed transaction. Information regarding Regeneron's directors and executive officers is available in its proxy statement that was filed with the SEC; information regarding Decibel's directors and executive officers is available in its proxy statement that was filed with the SEC. Other information regarding potential participants in any such proxy solicitation will be contained in any proxy statement filed in connection with the transaction.

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REGENERON

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Source: Decibel Therapeutics, Inc.