Lilly to Acquire Akouos to Discover and Develop Treatments for Hearing Loss

October 18, 2022

Proposed acquisition will accelerate gene therapies that aim to restore, improve, and preserve hearing for patients living with disabling hearing loss worldwide

Transaction valued at approximately $487 million plus a contingent value right for an aggregate amount up to approximately $610 million

INDIANAPOLIS and BOSTON, Oct. 18, 2022 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) and Akouos, Inc. (NASDAQ: AKUS) today announced a definitive agreement for Lilly to acquire Akouos, a precision genetic medicine company that is developing a portfolio of first-in-class adeno-associated viral gene therapies for the treatment of inner ear conditions, including sensorineural hearing loss.

"We are honored to work with the talented team at Akouos who are breaking new ground in the science of treating hearing loss," said Andrew C. Adams, Ph.D., senior vice president of genetic medicine and co-director of the Institute for Genetic Medicine, Lilly. "We believe that with Lilly's resources, global reach, and growing capabilities in gene therapy, we can help Akouos fulfill their mission of making healthy hearing available to all."

Akouos has integrated expertise across otology, inner ear drug delivery, and gene therapy with the goal of addressing the needs of people living with disabling hearing loss worldwide. Akouos's lead product candidate, AK-OTOF, is a gene therapy for the treatment of hearing loss due to mutations in the otoferlin gene (*OTOF*). Additional pipeline programs span across multiple inner ear conditions, and include AK-CLRN1 for Usher Type 3A, an autosomal recessive disorder characterized by progressive loss of both hearing and vision; *GJB2* (which encodes connexin 26) for a common form of monogenic deafness and hearing loss; and AK-antiVEGF for the treatment of vestibular schwannoma.

"I am proud of the commitment and passion of our team, which has established Akouos as a pioneer in inner ear genetic medicine, as demonstrated by our work to advance the first investigational therapy for a genetic form of hearing loss into clinical development," said Emmanuel Simons, Ph.D., M.B.A., co-founder, president, and chief executive officer of Akouos. "Joining Lilly – a company that shares our purpose to make life better for people around the world – will help us accelerate the development of a broad pipeline of inner ear genetic medicines."

Under the terms of the transaction, Lilly will acquire all of the outstanding shares of Akouos for $12.50 per share in cash, plus one contingent value right (CVR) of up to $3.00 per share. The deal has been approved by the boards of directors of both companies.

"Gene therapy offers tremendous opportunity to provide durable treatments for patients with genetically defined disease; this is our second acquisition in gene therapy, following the 2021 acquisition of Prevail Therapeutics," added Daniel Skovronsky, M.D., Ph.D., Lilly's chief scientific and medical officer, and president of Lilly Research Laboratories. "With Akouos, we are optimistic that we can make a difference for people with hearing loss and other inner ear conditions."

Terms of the Agreement

Lilly will commence a tender offer to acquire all outstanding shares of Akouos for a purchase price of $12.50 per share in cash (an aggregate of approximately $487 million) payable at closing plus one non-tradeable contingent value right per share ("CVR") that entitles the holder to receive up to an additional $3.00 in cash, for a total consideration of up to $15.50 per share in cash without interest (an aggregate of up to approximately $610 million).

CVR holders would become entitled to receive contingent payments as follows: (i) $1.00 in cash, upon the fifth (5th) participant being administered with AK-OTOF in a Phase 1 or Phase 1/2 trial on or prior to Dec. 31, 2024; (ii) $1.00 in cash, upon the fifth (5th) participant being administered with an Akouos gene therapy product for a second monogenic form of sensorineural hearing loss (excluding AK-OTOF and AK-antiVEGF) on or prior to Dec. 31, 2026; and (iii) $1.00 in cash, upon (a) the first (1st) participant being administered with an Akouos gene therapy product (excluding AK-antiVEGF) for a monogenic form of sensorineural hearing loss in a Phase 3 trial, or (b) receipt of FDA approval in the U.S. for such Akouos product, whichever occurs first, on or prior to Dec. 31, 2026, or its value will be reduced by approximately 4.2 cents per month until Dec. 1, 2028 (at which point the CVR will expire).

There can be no assurance that any payments will be made with respect to the CVR. The transaction is not subject to any financing condition and is expected to close in the fourth quarter of 2022, subject to customary closing conditions, including receipt of required antitrust clearance and the tender of a majority of the outstanding shares of Akouos's common stock. Following the successful closing of the tender offer, Lilly will acquire any shares of Akouos that are not tendered in the tender offer through a second-step merger at the same consideration as paid in the tender offer.

The purchase price payable at closing represents a premium of approximately 121% to the 30-day volume-weighted average trading price of Akouos's common stock ended on Oct. 17, 2022, the last trading day before the announcement of the transaction. Akouos's Board of Directors unanimously recommends that Akouos's stockholders tender their shares in the tender offer. Additionally, certain Akouos stockholders, beneficially owning approximately 26% of Akouos's outstanding common stock, have (subject to certain terms and conditions) agreed to tender their shares in the tender offer.

Lilly will determine the accounting treatment of this transaction as a business combination or an asset acquisition, including any related acquired in-process research and development charges, according to Generally Accepted Accounting Principles (GAAP) upon closing, which is expected to occur in the fourth quarter of 2022. This transaction will thereafter be reflected in Lilly's financial results and financial guidance.

For Lilly, Kirkland & Ellis LLP is acting as legal counsel. For Akouos, Wilmer Cutler Pickering Hale and Dorr LLP is acting as legal counsel and Centerview Partners LLC as sole financial advisor.

About Akouos

Akouos is a precision genetic medicine company dedicated to developing gene therapies with the potential to restore, improve and preserve high-acuity physiologic hearing for individuals living with disabling hearing loss worldwide. Leveraging its precision genetic medicine platform that incorporates a proprietary adeno-associated viral (AAV) vector library and a novel delivery approach, Akouos is focused on developing precision therapies for forms of sensorineural hearing loss. Headquartered in Boston, Akouos was founded in 2016 by leaders in the fields of neurotology, genetics, inner ear drug delivery, and AAV gene therapy.

About Lilly

Lilly unites caring with discovery to create medicines that make life better for people around the world. We've been pioneering life-changing discoveries for nearly 150 years, and today our medicines help more than 47 million people across the globe. Harnessing the power of biotechnology, chemistry and genetic medicine, our scientists are urgently advancing new discoveries to solve some of the world's most significant health challenges, redefining diabetes care, treating obesity and curtailing its most devastating long-term effects, advancing the fight against Alzheimer's disease, providing solutions to some of the most debilitating immune system disorders, and transforming the most difficult-to-treat cancers into manageable diseases. With each step toward a healthier world, we're motivated by one thing: making life better for millions more people. That includes delivering innovative clinical trials that reflect the diversity of our world and working to ensure our medicines are accessible and affordable. To learn more, visit Lilly.com and Lilly.com/newsroom or follow us on Facebook, Instagram, Twitter and LinkedIn. C-LLY

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements regarding Lilly's proposed acquisition of Akouos, regarding prospective benefits of the proposed acquisition, regarding potential contingent consideration amounts and terms, regarding the anticipated occurrence, manner and timing of the proposed tender offer and the closing of the proposed acquisition, regarding Akouos's product candidates and ongoing clinical and preclinical development, regarding Lilly's development of a gene therapy program for inner ear conditions and existing genetic medicine programs, and regarding the accounting treatment of the potential acquisition under GAAP and its potential impact on Lilly's financial results and financial guidance. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Forward-looking statements reflect current beliefs and expectations; however, these statements involve inherent risks and uncertainties, including with respect to consummating the proposed acquisition and any competing offers or acquisition proposals for Akouos, drug research, development and commercialization, Lilly's evaluation of the accounting treatment of the potential acquisition and its potential impact on its financial results and financial guidance, uncertainties as to how many of Akouos's stockholders will tender their stock in the tender offer, the effects of the proposed acquisition (or the announcement thereof) on Akouos's stock price, relationships with key third parties or governmental entities, transaction costs, risks that the proposed acquisition disrupts current plans and operations or adversely affects employee retention, potentially diverting management's attention from Akouos's ongoing business operations, changes in Akouos's business during the period between announcement and closing of the proposed acquisition, and any legal proceedings that may be instituted related to the proposed acquisition. Actual results could differ materially due to various factors, risks and uncertainties. Among other things, there can be no guarantee that the proposed acquisition will be completed in the anticipated timeframe or at all, that the conditions required to complete the proposed acquisition will be met, that any event, change or other circumstance that could give rise to the termination of the definitive agreement for the proposed acquisition will not occur, that Lilly will realize the expected benefits of the proposed acquisition, that product candidates will be approved on anticipated timelines or at all, that Lilly will be successful in building a gene therapy program for inner ear conditions, that any products, if approved, will be commercially successful, that all or any of the contingent consideration will become payable on the terms described herein or at all, that Lilly's financial results will be consistent with its expected 2022 guidance or that Lilly can reliably predict the impact of the proposed acquisition on its financial results or financial guidance. For further discussion of these and other risks and uncertainties, see Lilly's and Akouos's most recent Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission (the "SEC"). Except as required by law, neither Lilly nor Akouos undertakes any duty to update forward-looking statements to reflect events after the date of this press release.

Additional Information about the Acquisition and Where to Find It

The tender offer for the outstanding shares of Akouos described 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 Lilly and its acquisition subsidiary will file with the SEC upon commencement of the tender offer. A solicitation and offer to buy outstanding shares of Akouos will only be made pursuant to the tender offer materials that Lilly and its acquisition subsidiary intend to file with the SEC. At the time the tender offer is commenced, Lilly and its acquisition subsidiary will file tender offer materials on Schedule TO, and Akouos will file a Solicitation/Recommendation Statement on Schedule 14D-9 with the SEC with respect to the tender offer. THE TENDER OFFER MATERIALS (INCLUDING AN OFFER TO PURCHASE, A RELATED LETTER OF TRANSMITTAL AND CERTAIN OTHER TENDER OFFER DOCUMENTS) AND THE SOLICITATION/RECOMMENDATION STATEMENT WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTION AND THE PARTIES THERETO. INVESTORS AND STOCKHOLDERS OF AKOUOS ARE URGED TO READ THESE DOCUMENTS CAREFULLY WHEN THEY BECOME AVAILABLE (AND EACH AS IT MAY BE AMENDED OR SUPPLEMENTED FROM TIME TO TIME) BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION THAT INVESTORS AND STOCKHOLDERS OF AKOUOS SHOULD CONSIDER BEFORE MAKING ANY DECISION REGARDING TENDERING THEIR SHARES OF COMMON STOCK IN THE TENDER OFFER. The tender offer materials (including the Offer to Purchase and the related Letter of Transmittal), as well as the Solicitation/Recommendation Statement, will be made available to all stockholders of Akouos at no expense to them at Lilly's website at investor.lilly.com and (once they become available) will be mailed to the stockholders of Akouos free of charge. The information contained in, or that can be accessed through, Lilly's website is not a part of, or incorporated by reference herein. The tender offer materials (including the Offer to Purchase and the related Letter of Transmittal), as well as the Solicitation/Recommendation Statement, will also be made available for free on the SEC's website at www.sec.gov. 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, Lilly and Akouos file annual, quarterly, and current reports, proxy statements and other information with the SEC. You may read any reports, statements or other information filed by Lilly and Akouos with the SEC for free on the SEC's website at www.sec.gov.

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