Akouos Reports Third Quarter 2022 Financial Results and Provides Business Highlights

November 14, 2022

-Received clearance from FDA for the AK-OTOF IND application to initiate a Phase 1/2, first in human, pediatric clinical trial

-Continued progress toward planned IND submission for AK-antiVEGF in 2023

-Announced on October 18 definitive agreement for Eli Lilly and Company to acquire Akouos

BOSTON, Nov. 14, 2022 (GLOBE NEWSWIRE) -- **Akouos**, Inc. (NASDAQ: AKUS), a precision genetic medicine company dedicated to developing potential gene therapies for individuals living with disabling hearing loss worldwide, today reports financial results for the third quarter ended September 30, 2022 and provides business highlights.

"This has been a transformative year for us, and we've achieved important milestones that help us advance toward our goal of developing first in class genetic medicines with the potential to address a broad range of inner ear conditions and to create a new standard of care for individuals and families with disabling hearing loss worldwide. We received clearance from FDA for our IND application to initiate a Phase 1/2, first in human, pediatric clinical trial of AK-OTOF for OTOF-mediated hearing loss, a condition where there are currently no approved pharmacologic treatment options," said Manny Simons, Ph.D., M.B.A., co-founder, president, and chief executive officer of Akouos. "Additionally, we announced a definitive agreement with Eli Lilly and Company to acquire Akouos. We believe joining Lilly will help us accelerate the development of our broad pipeline of inner ear genetic medicines and help us fulfill our mission to make healthy hearing available to all."

Pipeline and Business Highlights

- **Received Clearance from FDA for IND application for AK-OTOF to initiate a Phase 1/2, first in human, pediatric clinical trial** – AK-OTOF is a dual adeno-associated viral (AAV) vector-based gene therapy intended to treat patients with *OTOF*-mediated hearing loss. A one-time, unilateral intracochlear administration of AK-OTOF may lead to recovery of auditory function. The Company plans to initiate a pediatric Phase 1/2 clinical trial, designed to assess both safety and efficacy. The first two participants in the clinical trial will be as young as seven years of age, subsequent participants will be as young as two years of age. The second part of the trial will be a cohort expansion phase to assess both continued safety and efficacy in participants and is expected to include children younger than two years of age. The planned Phase 1/2 clinical trial is expected to be global and will initially be activated in the U.S. followed by activation in other countries.

- **Announced definitive agreement for Eli Lilly and Company to acquire Akouos –** The Company and Lilly announced on October 18 the entry into an agreement for Lilly to acquire Akouos to accelerate development of gene therapies that aim to restore, improve, and preserve hearing for patients living with disabling hearing loss worldwide. The transaction is valued at approximately $487 million plus a contingent value right for an aggregate amount up to approximately $610 million. The merger 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. Additional details can be found in the announcement press release as well as the Company's recent SEC filings.

- **Continued progress toward planned IND submission for AK-antiVEGF for vestibular schwannoma –** The Company continues to prepare for submission of a planned second IND for AK-antiVEGF, a gene therapy intended for the treatment of patients with vestibular schwannoma. The Company remains on track to submit an IND in 2023 for AK-antiVEGF.

Third Quarter Financial Results

- **Cash Position –** Cash, cash equivalents, and marketable securities were $169.3 million as of September 30, 2022, compared to $249.7 million as of September 30, 2021. Akouos expects its cash, cash equivalents, and marketable securities to fund operations beyond the next eighteen months.
- **Research and Development (R&D) Expenses –** R&D expenses were $13.9 million for the third quarter ended September 30, 2022, compared to $17.4 million for the same period in 2021. The decrease was due to timing of manufacturing activities conducted by existing third-party manufacturers, in addition to the substantial completion of activities with one of our third-party manufacturers related to our AK-OTOF program, partially offset by increased expenses due to the growth in the number of R&D employees and their related activities.
- **General and Administrative (G&A) Expenses –** G&A expenses were $6.3 million for the third quarter ended September 30, 2022, compared to $5.5 million for the same period in 2021. The increase was primarily due to the growth in the number of G&A employees and their related activities.
- **Net Loss –** Net loss was $19.8 million, or $0.54 per share, for the third quarter ended September 30, 2022, compared to $22.9 million, or $0.67 per share, for the same period in 2021.

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.

Forward-Looking Statements

Statements in this press release about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may constitute "forward-looking statements" within the meaning of The Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, initiation, plans, and timing of our future clinical trials and our research and development programs, including plans for our expected AK-OTOF Phase 1/2 clinical trial. timing of our IND submission for AK-anti-VEGF, the occurrence of any event, change, or other circumstance that could give rise to the termination of the Agreement and Plan of Merger with Eli Lilly and Company, prospective benefits of the proposed acquisition, the value of potential contingent consideration amounts, and timing of the closing for the transaction. The words "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "might," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: risks related to our proposed acquisition by Lilly, our limited operating history; uncertainties inherent in the development of product candidates, including the initiation and completion of nonclinical studies and clinical trials; whether results from nonclinical studies will be predictive of results or success of clinical trials; the timing of and our ability to submit applications for, and obtain and maintain regulatory approvals for, our product candidates; our expectations regarding our regulatory strategy; our ability to fund our operating expenses and capital expenditure requirements with our cash, cash equivalents, and marketable securities; the potential advantages of our product candidates; the rate and degree of market acceptance and clinical utility of our product candidates; our estimates regarding the potential addressable patient population for our product candidates; our commercialization, marketing, and manufacturing capabilities and strategy; our ability to obtain and maintain intellectual property protection for our product candidates; our ability to identify additional products, product candidates, or technologies with significant commercial potential that are consistent with our commercial objectives; the impact of government laws and regulations and any changes in such laws and regulations; risks related to competitive programs; the potential that our internal manufacturing capabilities and/or external manufacturing supply may experience delays; the impact of the COVID-19 pandemic on our business, results of operations, and financial condition; our ability to maintain and establish collaborations or obtain additional funding; and other factors discussed in the "Risk Factors" included in the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, filed with the Securities and Exchange Commission on August 15, 2022, and in other filings that the Company makes with the Securities and Exchange Commission in the future. Any forward-looking statements contained in this press release speak only as of the date hereof, and the Company expressly disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

Condensed Consolidated Balance Sheet Data
(Unaudited)

(in thousands)

	September 30, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	$ 169,328	$ 232,452
Total assets	225,509	278,755
Total liabilities	44,671	45,105
Total stockholders' equity	180,838	233,650

Condensed Consolidated Statements of Operations
(Unaudited)

(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 13,937	$ 17,399	$ 48,643	$ 45,776
General and administrative	6,267	5,513	19,595	16,068
Total operating expenses	20,204	22,912	68,238	61,844
Loss from operations	(20,204)	(22,912)	(68,238)	(61,844)
Other income (expense):				
Interest income	522	483	1,074	1,546
Other expense, net	(157)	(477)	(489)	(1,434)
Total other income, net	365	6	585	112

Net loss	$ (19,839)	$ (22,906)	$ (67,653)	$ (61,732)
Weighted-average common shares outstanding, basic and diluted	36,905,818	34,436,793	35,766,217	34,360,274
Net loss per share attributable to common stockholders, basic and diluted	$ (0.54)	$ (0.67)	$ (1.89)	$ (1.80)

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