Akouos Reports First Quarter 2022 Financial Results and Provides Business Highlights

May 12, 2022

- Continued progress toward planned IND submissions for AK-OTOF in the first half of 2022 and AK-antiVEGF in 2022

- Presenting new nonclinical data at ASGCT supporting the planned clinical development of AK-OTOF and highlighting the potential use of microRNA target sites in AAV vectors for regulated gene expression in the inner ear

- Presented new nonclinical data at ARO demonstrating potential of precision genetic medicine platform to address a broad range of inner ear conditions

-Ended the first quarter with a strong cash position of $209.1 million

BOSTON, May 12, 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 first quarter ended March 31, 2022 and provides business highlights.

"The year is off to a strong start for us as we continue to progress toward planned IND submissions for AK-OTOF and for AK-antiVEGF in 2022. With the AK-OTOF drug product now vialed, and analytical testing and IND filing preparation underway, we look forward to providing updates later this year regarding the AK-OTOF-101 trial," said Manny Simons, Ph.D., M.B.A., co-founder, president, and chief executive officer of Akouos. "Building on this momentum, we are presenting new, nonclinical data at ASGCT that support the clinical development of AK-OTOF. These upcoming presentations also highlight the breadth of capabilities within our genetic medicine platform and how they may be applied to address a broad range of inner ear conditions, including those of complex etiology. Our world-class team continues to work diligently to realize the full potential of our platform for individuals who live with disabling hearing loss."

Pipeline and Business Highlights

- **Continued progress toward IND submissions for preclinical gene therapy programs AK-OTOF and AK-antiVEGF –** Akouos continued to advance AK-OTOF, a gene therapy intended for the treatment of patients with otoferlin gene (*OTOF*)-mediated hearing loss and is on track to submit an investigational new drug (IND) application in the first half of 2022. Additionally, Akouos is on track to submit an IND in 2022 for AK-antiVEGF, a gene therapy intended for the treatment of patients with vestibular schwannoma.

- **Advancing genetic medicine platform beyond lead programs to build a product candidate pipeline with the potential to address a broad landscape of inner ear conditions –** Akouos is working to leverage its multimodal genetic medicine capabilities to address a broad range of inner ear conditions, including those that are monogenic and those of complex etiology. At the Association for Research in Otolaryngology (ARO) 45th Annual Mid-Winter meeting, the Company presented data that demonstrated genetic medicine platform capabilities, such as AAV-mediated RNA interference gene silencing and CRISPR/Cas9 gene editing methods. The Company continues to progress early-stage pipeline programs, including programs for *GJB2*-mediated hearing loss and hair cell regeneration.

- **Nonclinical data will be presented at the American Society of Gene and Cell Therapy (ASGCT) 25th Annual Meeting –** In May 2022, Akouos plans to present new nonclinical data at the upcoming ASGCT 25th Annual Meeting. These data support the planned clinical development of AK-OTOF and highlight the potential use of microRNA target sites in AAV vectors for regulated gene expression in the inner ear. Coupled with the nonclinical data presented at ARO, these data build upon and support the potential use of the company's precision genetic medicine platform to address a broad range of inner ear conditions.

First Quarter Financial Results

- **Cash Position –** Cash, cash equivalents, and marketable securities were $209.1 million as of March 31, 2022, as compared to $232.5 million as of December 31, 2021.
- **Research and Development (R&D) Expenses –** R&D expenses were $20.4 million for the first quarter ended March 31, 2022, compared to $11.3 million for the same period in 2021. The increase was primarily due to increased efforts in IND-enabling studies and increased manufacturing costs for AK-OTOF and the growth in the number of R&D employees and their related activities, as well as the expense allocated to R&D related to Akouos's leased facilities.
- **General and Administrative (G&A) Expenses –** G&A expenses were $6.6 million for the first quarter ended March 31, 2022, compared to $4.9 million for the same period in 2021. The increase was due to growth in the number of G&A employees and other administrative expenses related to operating as a public company, as well as the expense allocated to G&A related to Akouos's leased facilities.

- **Net Loss –** Net loss was $27.0 million, or $0.78 per share, for the first quarter ended March 31, 2022, compared to $16.1 million, or $0.47 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, statements relating to the initiation, plans, and timing of our future clinical trials and our research and development programs, and the timing of our IND submissions for AK-OTOF and AK-antiVEGF. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "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: 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 Annual Report on Form 10-K for the year ended December 31, 2021 filed with the Securities and Exchange Commission on March 29, 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)

	March 31, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	$ 209,098	$ 232,452
Total assets	255,958	278,755
Total liabilities	46,974	45,105
Total stockholders' equity	208,984	233,650

Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)

(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2022	2021
Operating expenses:		
Research and development	$ 20,388	$ 11,258
General and administrative	6,646	4,890
Total operating expenses	27,034	16,148
Loss from operations	(27,034)	(16,148)
Other income (expense):		
Interest income	257	509
Other expense, net	(206)	(447)
Total other income, net	51	62

Net loss	$ (26,983)	$ (16,086)
Weighted-average common shares outstanding, basic and diluted	34,528,992	34,284,419
Net loss per share attributable to common stockholders, basic and diluted	$ (0.78)	$ (0.47)

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