Akouos Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Business Highlights

March 29, 2022

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

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

- Expanded leadership team with appointment of otology leader Aaron Tward, M.D., Ph.D., as chief scientific officer

- Ended 2021 with a strong cash position of $232.5 million

BOSTON, March 29, 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 fourth quarter and full year ended December 31, 2021 and provides business highlights.

"In 2021, we continued to execute on our core strategic objectives, ended the year with a strong cash position, and remained focused on our IND submission plans for AK-OTOF in the first half of 2022 and for AK-antiVEGF in 2022. In addition to AK-OTOF and AK-antiVEGF, we continue to leverage our genetic medicine platform to expand our pipeline and address a broader range of inner ear conditions, including some of the most common forms of hearing loss," said Manny Simons, Ph.D., M.B.A., co-founder, president, and chief executive officer of Akouos. "We recently presented nonclinical data at ARO that help support these future development plans, and we expanded our world-class team of experts with the appointment of renowned surgeon and scientist Aaron Tward, M.D., Ph.D., as our chief scientific officer. We believe the genetic medicines we are developing have the potential to create a new standard of care for, and to transform the lives of individuals and families with, disabling hearing loss."

Pipeline and Business Highlights

- **Continued progress toward IND submission readiness for lead programs AK-OTOF and AK-antiVEGF –** Akouos continued to advance its lead product candidate, AK-OTOF, a gene therapy intended for the treatment of 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 continues to plan for an IND submission in 2022 for AK-antiVEGF, a gene therapy candidate in preclinical development for the potential treatment of patients with vestibular schwannoma.

- **Applying genetic medicines platform to expand into broader range of inner ear conditions –** Akouos is leveraging its multimodal genetic medicine capabilities to address a broad range of inner ear conditions, including those that are monogenic and those of complex etiology. The company recently presented nonclinical data at the Association for Research in Otolaryngology (ARO) 45th Annual Mid-Winter Meeting that help support future development of gene therapies targeting inner ear conditions.

    - Two nonclinical studies in non-human primates evaluating protein expression and tolerability support future clinical development of AK-antiVEGF for the treatment of vestibular schwannoma.

    - AAVAnc80 with a supporting cell selective promoter drives widespread *GJB2* expression in supporting cells, while limiting expression in, and loss of, hair cells in mice. We continue to evaluate the most promising product candidate options in mice and non-human primates.

    - *In vitro* characterization of AAV-mediated RNA interference gene silencing and CRISPR/Cas9 gene editing methods demonstrates a reduction of protein expression for the gene of interest. We continue to consider targets for autosomal dominant nonsyndromic hearing loss.

    - We also continue to believe that AAVAnc gene therapy has the potential to restore hearing in individuals with a wide range of environmental hearing loss by regenerating hair cells from neighboring supporting cells. We have identified multiple factors that, when delivered in combination, result in new hair cell formation in neonate mice, and we plan to continue preclinical development work in 2022.

- **Expanded leadership team with appointment of Aaron Tward, M.D., Ph.D., as chief scientific officer –** In March 2022, Akouos announced the appointment of surgeon and scientist Aaron Tward, M.D., Ph.D., as chief scientific officer. Dr. Tward brings deep experience in genetics, genomics, gene delivery, high-throughput sequencing technologies, and the clinical care of patients with conditions of the ear and skull base to Akouos. Dr. Tward was previously a member of the Akouos scientific advisory board since 2018. In his new role as chief scientific officer, he will lead the research team and

provide strategic scientific expertise to advance the company's precision genetic medicine platform.

Fourth Quarter and Full Year 2021 Financial Results

- **Cash Position –** Cash, cash equivalents, and marketable securities were $232.5 million as of December 31, 2021, as compared to $308.0 million as of December 31, 2020.
- **Research and Development (R&D) Expenses –** R&D expenses were $18.8 million for the fourth quarter of 2021 and $64.6 million for the full year ended December 31, 2021, compared to $8.0 million for the fourth quarter of 2020 and $34.3 million for the full year ended December 31, 2020. The increase was primarily due to the increased efforts in IND-enabling studies and increased manufacturing costs for AK-OTOF and AK-antiVEGF 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 $6.2 million for the fourth quarter of 2021 and $22.2 million for the full year ended December 31, 2021, compared to $4.6 million for the fourth quarter of 2020 and $14.6 million for the full year ended December 31, 2020. The increase was due to the 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 and due to increased patent activities and increases in professional fees related to legal and accounting services.
- **Net Loss –** Net loss was $24.9 million, or $0.72 per share, for the fourth quarter of 2021 and $86.7 million, or $2.52 per share, for the full year ended December 31, 2021, compared to $12.5 million, or $0.37 per share, for the fourth quarter of 2020 and $48.6 million, or $2.77 per share, for the full year ended December 31, 2020.

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 Quarterly Report on Form 10-Q for the three months ended September 30, 2021 filed with the Securities and Exchange Commission on November 9, 2021, 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)

	December 31, 2021	December 31, 2020
Cash, cash equivalents and marketable securities	$ 232,452	$ 308,010
Total assets	278,755	333,350
Total liabilities	45,105	22,736
Total stockholders' equity	233,650	310,614

Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)

(in thousands, except share and per share data)

	Three Months Ended December 31,		Years Ended December 31,	
	2021	**2020**	**2021**	**2020**
Operating expenses:				
Research and development	$ 18,819	$ 7,977	$ 64,595	$ 34,297
General and administrative	6,158	4,646	22,226	14,583
Total operating expenses	24,977	12,623	86,821	48,880
Loss from operations	(24,977)	(12,623)	(86,821)	(48,880)
Other income (expense):				
Interest income	326	366	1,872	567
Other expense, net	(288)	(291)	(1,722)	(287)
Total other income, net	38	75	150	280
Net loss	$ (24,939)	$ (12,548)	$ (86,671)	$ (48,600)
Weighted-average common shares outstanding, basic and diluted	34,466,306	34,217,475	34,387,883	17,550,847
Net loss per share attributable to common stockholders, basic and diluted	$ (0.72)	$ (0.37)	$ (2.52)	$ (2.77)

Contacts

Media:
Katie Engleman, 1AB
katie@1abmedia.com

Investors:
Courtney Turiano, Stern Investor Relations
Courtney.Turiano@sternir.com