Akouos Reports Fourth Quarter and Full Year 2020 Financial Results and Provides Business Highlights

March 29, 2021

- In 2020, continued to advance genetic medicine pipeline with execution of IND-enabling studies for AK-OTOF and general alignment with FDA on the path to a 2022 IND submission for AK-antiVEGF

- Raised approximately $349 million in gross proceeds, which is expected to fund operations for at least two years

- Due to recent third-party manufacturing delays, IND submission for AK-OTOF program now expected in the first half of 2022; all other IND-enabling activities remain on track

- Establishing internal cGMP manufacturing infrastructure and capabilities in 2021

BOSTON, March 29, 2021 (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 reported financial results for the fourth quarter and full year ended December 31, 2020 and provided business highlights.

“2020 was a year of tremendous progress for Akouos, marked by continued advancement of our pipeline, expansion of our team, and strengthening of our capital position to further our leadership in the development of precision genetic medicines for inner ear conditions,” said Manny Simons, Ph.D., founder, president, and CEO of Akouos. “We continue to be excited by the nonclinical data reported to date, which demonstrate the durable recovery of function of AK-OTOF. Due to third-party manufacturing delays, including impacts from the ongoing COVID-19 pandemic, we now expect to submit the IND for AK-OTOF in the first half of 2022. All other IND-enabling activities remain on track. We continue to work with multiple third-party manufacturers to advance cGMP campaigns, for both the AK-OTOF and AK-antiVEGF IND submissions planned for 2022, and we continue to build our internal cGMP manufacturing infrastructure and capabilities.”

Business and Pipeline Highlights for 2020, Recent Developments, and Anticipated Milestones

- **Continued to build pipeline with potential for broad applicability for inner ear conditions –** In 2020, Akouos made progress towards Investigational New Drug (IND) submissions to the U.S. Food and Drug Administration (FDA) for AK-OTOF, a gene therapy intended for the treatment of otoferlin gene (*OTOF*)-mediated hearing loss, and AK-antiVEGF, a gene therapy intended for the treatment of vestibular schwannoma. Earlier this year, Akouos completed internal manufacturing of AK-antiVEGF for an IND-enabling good laboratory practices (GLP) toxicology study. Additionally, in 2020, the Company selected a product candidate for the AK-CLRN1 program. In 2021, the Company plans to announce a product candidate for its GJB2 program, and targets for its hair cell regeneration and autosomal dominant hearing loss programs.

- **Updated timeline for AK-OTOF IND submission** – The submission of an IND to FDA for AK-OTOF is now planned for the first half of 2022 due to third-party manufacturing delays, including delays related to the COVID-19 pandemic. The manufacturing process for Akouos’s product candidates, including AK-OTOF, has resulted in seven (of seven) successful at-scale batches of AAVAnc80 vectors. These third-party and internal manufacturing activities were performed using the same clinical-scale, and planned commercial-scale, manufacturing process intended for cGMP manufacturing of Akouos’s product candidates. Apart from the third-party cGMP manufacturing delays, all other IND-enabling activities remain on track.

- **Improving access to genetic testing for eligible individuals with auditory neuropathy –** In January 2021, Akouos announced the Resonate™ program with Blueprint Genetics. The program provides access to the Blueprint Genetics Comprehensive Hearing Loss and Deafness Panel that includes more than 230 genes associated with genetic forms of hearing loss, helping individuals and their healthcare providers better understand an individual’s condition and foster connections within the deaf and hard of hearing community.

- **Data presentation at ARO supporting Akouos’s novel delivery approach –** In February 2021, Akouos presented data at the Association for Research in Otolaryngology (ARO) that demonstrated that intracochlear administration of AAVAnc80 is well tolerated by non-human primates at doses that achieve efficient transduction of target cells. Akouos’s novel delivery approach utilizes a minimally invasive surgical approach, a delivery device that is designed for delivery of a product candidate in a fixed volume and at a controlled flow rate, and direct intracochlear administration that allows for distribution of product candidates along the full length of the cochlea.

- **Expanded Akouos team and board of directors with multiple appointments –** By the end of 2020, Akouos had

expanded to a total of 67 team members with expertise across a range of critical functions, including research, clinical development, regulatory, quality, technical operations, finance, and legal. The Company added Heather Preston, Saira Ramasastry, and Vicki Sato to the board of directors, and named Arthur Tzianabos as chairman.

- **Ended 2020 with a strong cash position of $308.0 million to continue to drive growth across the Company and within the pipeline –** In February 2020, Akouos executed a Series B financing raising $105.0 million in gross proceeds. In June 2020, Akouos completed an upsized initial public offering raising $244.4 million in gross proceeds.

Fourth Quarter and Full Year 2020 Financial Results

- **Cash Position –** Cash, cash equivalents, and marketable securities were $308.0 million as of December 31, 2020, as compared to $25.1 million as of December 31, 2019. Akouos expects its cash balance to fund operations for at least the next two years.
- **Research and Development (R&D) Expenses –** R&D expenses were $8.0 million for the fourth quarter of 2020 and $34.3 million for the full year ended December 31, 2020, compared to $8.5 million for the fourth quarter of 2019 and $20.5 million for the full year ended December 31, 2019. The increase was primarily due to the increased efforts in IND-enabling studies 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 $4.6 million for the fourth quarter of 2020 and $14.6 million for the full year ended December 31, 2020, compared to $1.1 million for the fourth quarter of 2019 and $3.4 million for the full year ended December 31, 2019. The increase was primarily 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.
- **Net Loss –** Net loss was $12.5 million, or $0.37 loss per share, for the fourth quarter of 2020 and $48.6 million, or $2.77 loss per share, for the full year ended December 31, 2020, compared to $9.5 million, or $14.31 per share, for the fourth quarter of 2019 and $25.7 million, or $42.49 loss per share, for the full year ended December 31, 2019.

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.

Cautionary Note Regarding 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, the timing of our IND submissions for AK-OTOF and AK-antiVEGF, our expectations regarding our manufacturing capabilities and timelines, and the period over which we believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our operating expenses. 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; 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, 2020 filed with the Securities and Exchange Commission, 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, 2020	December 31, 2019

Cash, cash equivalents and marketable securities	$ 308,010	$ 25,078
Total assets	333,350	45,162
Total liabilities	22,736	19,273
Convertible preferred stock	—	58,690
Total stockholders' equity (deficit)	310,614	(32,801)

Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)

(in thousands, except share and per share data)

	Three months ended December 31,		Year ended December 31,	
	2020	**2019**	**2020**	**2019**
Operating expenses:				
Research and development	$ 7,977	$ 8,475	$ 34,297	$ 20,473
General and administrative	4,646	1,134	14,583	3,410
Total operating expenses	12,623	9,609	48,880	23,883
Loss from operations	(12,623)	(9,609)	(48,880)	(23,883)
Other income (expense):				
Change in fair value of preferred stock tranche liability	—	—	—	(2,260)
Interest income	366	115	567	413
Other income (expense), net	(291)	(2)	(287)	(11)
Total other income (expense), net	75	113	280	(1,858)
Net loss	$ (12,548)	$ (9,496)	$ (48,600)	$ (25,741)
Weighted-average common shares outstanding, basic and diluted	34,217,475	663,659	17,550,847	605,824
Net loss per share attributable to common stockholders, basic and diluted	$ (0.37)	$ (14.31)	$ (2.77)	$ (42.49)

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