Akouos Reports Third Quarter 2020 Financial Results and Provides Business Highlights

November 12, 2020

- Expanded leadership team with appointment of Sachiyo Minegishi as CFO and promotion of Jennifer Wellman to COO -

- Continued progress towards 2021 IND submission for AK-OTOF, a gene therapy intended for the treatment of hearing loss due to mutations in the OTOF gene -

- Execution on build of internal manufacturing capabilities and infrastructure to support future research and clinical trials is on track -

BOSTON, Nov. 12, 2020 (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 third quarter ended September 30, 2020 and provided updated business highlights.

"We continue to advance AK-OTOF, a gene therapy intended for the treatment of hearing loss due to mutations in the *OTOF* (otoferlin) gene, towards a 2021 IND filing. Today, individuals with *OTOF*-mediated hearing loss have no therapeutic options. Our novel gene therapy candidate has the potential to restore hearing for these individuals, who typically have no functional hearing at birth," said Manny Simons, Ph.D., founder, president and CEO of Akouos. "Also, despite the challenging environment around us, the team is executing on our plan to establish internal manufacturing capabilities and infrastructure to support IND-enabling studies and clinical trials. Our progress towards our long-term mission, making healthy hearing available to all, is a testament to our deeply committed, experienced team and our strategic partners."

Business and Pipeline Highlights

- **Appointed Sachiyo Minegishi as chief financial officer –** In October 2020, Sachiyo Minegishi joined Akouos as chief financial officer. Ms. Minegishi has 20 years of experience in the biotechnology and pharmaceutical industry, serving in various roles at global companies, as well as in investment banking, most recently leading the gene therapy program for sickle cell disease at bluebird bio.

- **Promoted Jennifer Wellman to chief operating officer –** In October 2020, Akouos announced the promotion of Jennifer Wellman to chief operating officer, from her prior role as senior vice president of regulatory and quality. Ms. Wellman brings to Akouos over 20 years of experience in adeno-associated viral (AAV) vector gene therapy research and development, and was previously co-founder and head of product development strategy at Spark Therapeutics, Inc.

- **Continued progress towards IND filing in 2021 to enable a Phase 1/2 clinical trial for AK-OTOF, a gene therapy intended for the treatment of hearing loss due to mutations in the *OTOF* gene –** Through a targeted delivery of a proprietary ancestral AAV, known as AAVAnc80, containing the *OTOF* gene, Akouos aims to restore otoferlin expression, potentially restoring physiologic hearing and providing long-lasting benefits to individuals with *OTOF*-mediated hearing loss. Akouos plans to submit an IND application to the FDA in 2021 to conduct a Phase 1/2 clinical trial. The planned Phase 1/2 clinical trial consists of two parts. The first part is a dose escalation phase designed to assess the safety, tolerability and bioactivity of AK-OTOF, administered to trial participants through a single unilateral intracochlear injection. The second part is a cohort expansion phase designed to assess safety and efficacy.

- **Execution on build of internal manufacturing capabilities to support future research and clinical activities is on track –** Akouos is leveraging its expertise in gene therapy to develop internal, scalable manufacturing capabilities to support research, including IND-enabling studies, and current Good Manufacturing Practice activities for clinical trials. The plans to internalize manufacturing will enable more influence on the manufacturing process, associated analytics, and supporting quality systems, as well as increase the ability to control timelines, costs, and intellectual property.

Third Quarter 2020 Financial Results

- **Cash Position –** Cash, cash equivalents and marketable securities were $320.1 million as of September 30, 2020, as compared to $25.1 million as of December 31, 2019. Akouos expects the cash balance to fund operations for at least the next two years.
- **Research and Development (R&D) Expenses –** R&D expenses were $8.6 million for the third quarter ended September 30, 2020, compared to $4.4 million for the same period in 2019. The increase was primarily due to the increased efforts in preclinical 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 $4.5 million for the third quarter ended September 30, 2020, compared to $0.9 million for the same period in 2019. The increase was primarily due to the growth in the

number of G&A employees and other administrative expenses, as well as the expense allocated to G&A related to Akouos's leased facilities.

- **Net Loss –** Net loss was $13.1 million, or $0.85 loss per share, for the third quarter ended September 30, 2020, compared to $8.2 million, or $13.21 loss per share, for the same period in 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, our expectations regarding our manufacturing capabilities, 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 plans to develop and, if approved, subsequently commercialize our product candidates; 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 expectations regarding 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 expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates; our intellectual property position; 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; our competitive position and expectations regarding developments and projections relating to our competitors and any competing therapies that are or become available; developments and expectations regarding developments and projections relating to our competitors and our industry; 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 June 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)

	September 30, 2020	December 31, 2019
Cash, cash equivalents and marketable securities	$ 320,074	$ 25,078
Total assets	342,247	45,162
Total liabilities	20,939	19,273
Convertible preferred stock	—	58,690
Total stockholders' equity (deficit)	321,308	(32,801)

Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)

(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 8,641	$ 4,377	$ 26,612	$ 11,886
General and administrative	4,478	887	9,646	2,267

Total operating expenses	13,119	5,264	36,258	14,153
Loss from operations	(13,119)	(5,264)	(36,258)	(14,153)
Other income (expense):				
Change in fair value of preferred stock tranche liability	—	(3,013)	—	(2,260)
Interest income	21	70	201	298
Other income (expense), net	9	(3)	5	(8)
Total other income (expense), net	30	(2,946)	206	(1,970)
Net loss	$ (13,089)	$ (8,210)	$ (36,052)	$ (16,123)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.85)	$ (13.21)	$ (3.01)	$ (27.48)
Weighted-average common shares outstanding, basic and diluted	15,334,241	621,581	11,991,870	586,728
Other comprehensive income:				
Unrealized gain on marketable securities	8	—	8	—
Total other comprehensive income	8	—	8	—
Total comprehensive loss	$ (13,081)	$ (8,210)	$ (36,044)	$ (16,123)

Contacts

Media:

Katie Engleman, 1AB
katie@1abmedia.com

Investors:

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