Akouos Reports Second Quarter 2021 Financial Results and Provides Business Highlights

August 12, 2021

- Announced European Commission designation of AK-OTOF as an orphan drug for the treatment of otoferlin gene-mediated hearing loss

- Advanced both AK-OTOF and AK-antiVEGF towards planned IND submissions in the first half of 2022 and in 2022, respectively

- Continued to broaden application of genetic medicines platform to treat additional inner ear conditions

BOSTON, Aug. 12, 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 reports financial results for the second quarter ended June 30, 2021 and provides business highlights.

“During the past quarter, we have continued to advance the development of our two lead programs,” said Manny Simons, Ph.D., M.B.A., co-founder, president, and chief executive officer of Akouos. “All IND-enabling activities for both AK-OTOF and AK-antiVEGF remain on track to support our planned submissions in 2022, including the completion of dosing in the GLP toxicology study for AK-antiVEGF. We also continue to strengthen our precision genetic medicine platform and progress our earlier stage programs towards the announcement of a product candidate for the treatment of *GJB2*-mediated hearing loss and targets for hair cell regeneration and autosomal dominant hearing loss, planned for later this year. Our team’s exceptional expertise in neurotology, genetics, inner ear drug delivery, and AAV gene therapy has helped establish our leadership in the field of inner ear genetic medicine, and enables us to drive forward the development of gene therapies with the potential to restore, improve, and preserve high-acuity physiologic hearing for individuals living with disabling hearing loss worldwide.”

Business Highlights

- **AK-OTOF is on track for planned IND submission in the first half of 2022 –** All IND-enabling activities for AK-OTOF, a gene therapy intended for the treatment of otoferlin gene (*OTOF*)-mediated hearing loss, continue to advance as planned.
    - Along with the Orphan Drug Designation and Rare Pediatric Disease Designation previously granted by FDA, the orphan drug designation for AK-OTOF in the European Union could accelerate our development and provide other potential benefits
    - Following the Hearing Loss Association of America-sponsored Patient-Focused Drug Development meeting for people and families living with sensorineural hearing loss, the Company convened a community advisory board of families affected by *OTOF*-mediated hearing loss to learn about their experiences living with the condition and gain their input on the clinical development plan for AK-OTOF
- **Advanced AK-antiVEGF toward planned IND submission in 2022 –** IND-enabling activities for AK-antiVEGF, a gene therapy intended for the treatment of vestibular schwannoma, continue to make progress, including completion of dosing for the good laboratory practice (GLP) toxicology study.
- **Applying genetic medicines platform beyond lead programs to address broader range of inner ear conditions –** 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.

Second Quarter 2021 Financial Results

- **Cash Position –** Cash, cash equivalents, and marketable securities were $271.8 million as of June 30, 2021, as compared to $308.0 million as of December 31, 2020. 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 $17.1 million for the second quarter ended June 30, 2021, compared to $9.9 million for the same period in 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 $5.7 million for the second quarter ended June 30, 2021, compared to $2.7 million for the same period in 2020. 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 $22.7 million, or $0.66 per share, for the second quarter ended June 30, 2021, compared to $12.5 million, or $11.14 per share, for the same period in 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.

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, the potential receipt of exclusivity and other benefits from Orphan Drug Designation in the European Union and Orphan Drug Designation and Rare Pediatric Disease Designation in the United States, 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 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 March 31, 2021 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)

	June 30, 2021	December 31, 2020
Cash, cash equivalents and marketable securities	$ 271,751	$ 308,010
Total assets	316,583	333,350
Total liabilities	40,055	22,736
Total stockholders' equity	276,528	310,614

Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)

(in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 17,119	$ 9,937	$ 28,377	$ 17,971
General and administrative	5,665	2,664	10,555	5,168
Total operating expenses	22,784	12,601	38,932	23,139
Loss from operations	(22,784)	(12,601)	(38,932)	(23,139)
Other income (expense):				
Interest income	554	80	1,063	180
Other expense, net	(510)	(2)	(957)	(4)
Total other income, net	44	78	106	176

Net loss	$ (22,740)	$ (12,523)	$ (38,826)	$ (22,963)
Net loss per share attributable to common stockholders basic and diluted	$ (0.66)	$ (11.14)	$ (1.13)	$ (25.05)
Weighted-average common shares outstanding, basic and diluted	34,372,262	1,124,251	34,324,477	916,521
Other comprehensive income (loss):				
Unrealized gain (loss) on marketable securities	(23)	—	5	—
Total other comprehensive income (loss)	(23)	—	5	—
Total comprehensive loss	$ (22,763)	$ (12,523)	$ (38,821)	$ (22,963)

Contacts

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

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