UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

Date of report (Date of earliest event reported): November 12, 2021

Akouos, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-39343**	**81-1716654**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

645 Summer Street **Suite 200** **Boston, MA**	**02210**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's telephone number, including area code: (857) 410-1818

Not applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading symbol(s)**	**Name of each exchange on which registered**
Common stock, $0.0001 par value per share	**AKUS**	**Nasdaq Global Select Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On November 12, 2021, Akouos, Inc. (the "Company") issued a press release announcing the Company's financial results for the quarter ended September 30, 2021. A copy of this press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 2.02 (including Exhibit 99.1 attached hereto) is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any filing by the Company, under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release Issued by Akouos, Inc. on November 12, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AKOUOS, INC.

Date: November 12, 2021

By: /s/ Emmanuel Simons
Name: Emmanuel Simons, Ph.D., M.B.A.
Title: President and Chief Executive Officer

Akouos Reports Third Quarter 2021 Financial Results and Provides Business Highlights

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

- Expanded leadership team with appointment of Stacy Price as chief technical officer

BOSTON, November 12, 2021 – 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 third quarter ended September 30, 2021, and provides business highlights.

"This quarter we advanced our lead programs, AK-OTOF and AK-antiVEGF, toward planned 2022 IND submissions, and we continue to apply our genetic medicines platform to the discovery and research of additional potential therapies for inner ear conditions," said Manny Simons, Ph.D., M.B.A., co-founder, president, and chief executive officer of Akouos. "We also strengthened our leadership team with the recent appointment of Stacy Price as our chief technical officer. Her extensive operations background, including the build of internal manufacturing capabilities, will be critical as we move our pipeline toward clinical development and ultimately commercialization."

Pipeline and Business Highlights

- **AK-OTOF and AK-antiVEGF advancing toward planned IND submissions –** The company continued to advance its lead product candidate, AK-OTOF, a gene therapy intended for the treatment of otoferlin gene (*OTOF*)-mediated hearing loss. An investigational new drug application (IND) submission for AK-OTOF is planned for the first half of 2022. Additionally, Akouos continues to plan for IND submission in 2022 for AK-antiVEGF, a gene therapy intended for the treatment of vestibular schwannoma.

- **Applying our genetic medicines platform to a broader range of inner ear conditions –** Akouos is leveraging its multimodal genetic medicine capabilities to address a range of inner ear conditions, including those that are monogenic and those of complex etiology. The company expects to provide updates on additional pipeline programs in early 2022.

- **Chief technical officer joins leadership team –** In November 2021, Akouos announced the appointment of Stacy Price as chief technical officer. Ms. Price brings more than 25 years of experience managing clinical and commercial biotechnology manufacturing and technical operations for a wide range of therapeutic modalities, including gene therapy, most recently as senior vice president of technical operations at Ziopharm Oncology. At Akouos, she will be responsible for the strategy and operations of vector manufacturing and device development and manufacturing.

- **European Commission designates AK-OTOF as an orphan drug –** In August 2021, Akouos announced that the European Medicines Agency Committee for Orphan Medicinal Products issued a positive opinion on the company's application for orphan drug designation for AK-OTOF for the treatment of OTOF-mediated hearing loss. Subsequently, the positive opinion was adopted by the European Commission. AK-OTOF was previously granted Orphan Drug Designation and Rare Pediatric Disease Designation by the U.S. Food and Drug Administration for this same indication.

Third Quarter 2021 Financial Results

- **Cash Position –** Cash, cash equivalents, and marketable securities were $249.7 million as of September 30, 2021, as compared to $308.0 million as of December 31, 2020. 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 $17.4 million for the third quarter ended September 30, 2021, compared to $8.6 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 $5.5 million for the third quarter ended September 30, 2021, compared to $4.5 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 $22.9 million, or $0.67 per share, for the third quarter ended September 30, 2021, compared to $13.1 million, or $0.85 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.

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, 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 June 30, 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)

	September 30, 2021	December 31, 2020
Cash, cash equivalents and marketable securities	$ 249,658	$ 308,010
Total assets	297,454	333,350
Total liabilities	41,230	22,736
Total stockholders' equity	256,224	310,614

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,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 17,399	$ 8,641	$ 45,776	$ 26,612
General and administrative	5,513	4,478	16,068	9,646
Total operating expenses	22,912	13,119	61,844	36,258
Loss from operations	(22,912)	(13,119)	(61,844)	(36,258)
Other income (expense):				
Interest income	483	21	1,546	201
Other income (expense), net	(477)	9	(1,434)	5
Total other income, net	6	30	112	206
Net loss	$ (22,906)	$ (13,089)	$ (61,732)	$ (36,052)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.67)	$ (0.85)	$ (1.80)	$ (3.01)
Weighted-average common shares outstanding, basic and diluted	34,436,793	15,334,241	34,360,274	11,991,870
Other comprehensive income (loss):				
Unrealized gain (loss) on marketable securities	(31)	8	(26)	8
Total other comprehensive income (loss)	(31)	8	(26)	8
Total comprehensive loss	$ (22,937)	$ (13,081)	$ (61,758)	$ (36,044)

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