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): May 13, 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 May 13, 2021, Akouos, Inc. (the "Company") issued a press release announcing the Company's financial results for the quarter ended March 31, 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 May 13, 2021

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: May 13, 2021

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

Akouos Reports First Quarter 2021 Financial Results and Provides Business Updates

- Leadership team expanded with appointment of Kathy Reape, M.D. as chief development officer

- AK-OTOF granted both Orphan Drug Designation and Rare Pediatric Disease Designation by FDA and is on track for planned IND submission in first half of 2022

- Nonclinical data supporting future clinical development of AK-OTOF and AK-antiVEGF presented at the American Society of Gene and Cell Therapy (ASGCT) 24th Annual Meeting

- Construction for an internal cGMP manufacturing facility completed, and expansion of laboratory footprint underway, contributing to continued infrastructure build to support future development activities

BOSTON, May 13, 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 first quarter ended March 31, 2021 and provides business updates.

“We continue to demonstrate our leadership in the field of inner ear genetic medicines. Recently, FDA granted AK-OTOF, our lead product candidate, what we believe are the first Orphan Drug and Rare Pediatric Disease designations for a genetic form of hearing loss. At the ASGCT Annual Meeting, our team presented nonclinical data demonstrating the unique applicability of our genetic medicine platform to potentially restore, improve, and preserve physiologic hearing for a monogenic condition and a condition of complex etiology,” said Manny Simons, Ph.D., M.B.A., co-founder, president, and chief executive officer of Akouos. “These accomplishments have been made possible by our team of leaders in the fields of neurotology, genetics, inner ear drug delivery, and AAV gene therapy, including the recent addition of Dr. Kathy Reape as chief development officer. We continue to build our team’s capabilities, infrastructure, and facilities to support our planned IND submissions for AK-OTOF and AK-antiVEGF in 2022, and are progressing our earlier stage programs towards candidate selection or target announcement.”

Business Highlights

- **Appointment of Kathy Reape, M.D. as chief development officer –** Dr. Kathy Reape joined Akouos as chief development officer and brings over 20 years of experience in clinical drug development and medical affairs to Akouos, most notably from her recent role as chief medical officer of Spark Therapeutics.

- **Orphan Drug Designation (ODD) and Rare Pediatric Disease Designation (RPDD) granted by FDA for AK-OTOF –** AK-OTOF is a gene therapy intended for the treatment of otoferlin gene (*OTOF*)-mediated hearing loss, a condition that often results in Severe to Profound sensorineural hearing loss from birth and does not currently have any

pharmacologic treatment options available. The receipt of these designations could support acceleration of development of AK-OTOF.

- **Presented nonclinical data at the ASGCT 24th Annual Meeting reflecting broad applicability of genetic medicine platform to treat inner ear conditions –** In May 2021, Akouos presented nonclinical data that support the future clinical development for both AK-OTOF and AK-antiVEGF, a gene therapy intended for the treatment of vestibular schwannoma, at the ASGCT 24th Annual Meeting. The digital presentations are located at https://akouos.com/gene-therapy-resources/.

- **Continued advancement of both AK-OTOF and AK-antiVEGF towards expected IND submissions in 2022 –** Akouos continues to make progress towards an investigational new drug application (IND) submission for AK-OTOF planned in the first half of 2022. The Company expects to submit an IND for AK-antiVEGF in 2022. Both programs utilize key components of Akouos's genetic medicine platform, which incorporates a proprietary AAVAnc capsid library, including AAVAnc80, and a novel delivery approach that leverages minimally-invasive surgical techniques familiar to otologic surgeons

- **Building infrastructure to support future development –** Akouos expanded its facility at 645 Summer Street in Boston, MA to support additional research, development, and manufacturing activities. In 2021, the Company plans to complete build of infrastructure and capabilities to enable internal cGMP manufacturing expected to support clinical development of product candidates, at the anticipated commercial scale.

First Quarter 2021 Financial Results

- **Cash Position –** Cash, cash equivalents, and marketable securities were $286.6 million as of March 31, 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 $11.3 million for the first quarter ended March 31, 2021, compared to $8.0 million for the same period in 2020. The increase was primarily due to the increased efforts in IND-enabling studies 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 $4.9 million for the first quarter ended March 31, 2021, as compared to $2.5 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 $16.1 million, or $0.47 loss per share, for the first quarter ended March 31, 2021, compared to $10.4 million, or $14.74 loss 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, 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 Annual Report on Form 10-K for the year ended December 31, 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)

	March 31, 2021	December 31, 2020
Cash, cash equivalents and marketable securities	$ 286,619	$ 308,010
Total assets	321,859	333,350
Total liabilities	25,057	22,736
Total stockholders' equity	296,802	310,614

Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)

(in thousands, except share and per share data)

	Three months ended March 31,	
	2021	2020
Operating expenses:		
Research and development	$ 11,258	$ 8,034
General and administrative	4,890	2,504
Total operating expenses	16,148	10,538
Loss from operations	(16,148)	(10,538)
Other income (expense):		
Interest income	509	100
Other expense, net	(447)	(2)
Total other income, net	62	98
Net loss	$ (16,086)	$ (10,440)
Weighted-average common shares outstanding, basic and diluted	34,284,419	708,204
Net loss per share attributable to common stockholders, basic and diluted	$ (0.47)	$ (14.74)

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