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): August 15, 2022

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** **(Address of Principal Executive Offices)**	**02210** **(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 August 15, 2022, Akouos, Inc. (the "Company") issued a press release announcing the Company's financial results for the quarter ended June 30, 2022. 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 August 15, 2022
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: August 15, 2022

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

Akouos Reports Second Quarter 2022 Financial Results and Provides Business Highlights

- Submitted IND for AK-OTOF to FDA

- Continued progress toward planned IND submission for AK-antiVEGF

- Presented new nonclinical data at ASGCT supporting the proposed clinical development of AK-OTOF and highlighting strategies for regulated gene expression in the inner ear

- Received a notice of allowance from USPTO for claims covering compositions, including AK-OTOF, and methods of treatment useful for OTOF*-mediated hearing loss*

- Ended Q2 2022 with a strong cash position of $192.9 million

BOSTON, August 15, 2022 -- 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, 2022 and provides business highlights.

"We continue to progress toward our goal of developing genetic medicines with the potential to create a new standard of care for disabling hearing loss as we advance AK-OTOF and AK-antiVEGF toward clinical development. We recently submitted an IND for AK-OTOF; we believe this is the first IND to be submitted to FDA for a genetic form of hearing loss and the first for an AAV vector with the potential to treat an inner ear condition. We also continue to move toward our planned IND submission for AK-antiVEGF, with drug product for the planned clinical trial now vialed. We look forward to providing updates later this year on both product candidates," said Manny Simons, Ph.D., M.B.A., co-founder, president, and chief executive officer of Akouos. "We are also very happy to have received a notice of allowance from the USPTO expanding our patent portfolio and bolstering our leadership position for AK-OTOF and more generally for *OTOF*-mediated hearing loss. Additionally, we continue to see the potential for broad utility of our genetic medicine platform. The data we presented at the ASGCT 25th Annual Meeting highlight our team's unique capabilities and the potential to address a broad range of inner ear conditions."

Pipeline and Business Highlights

- **IND application recently submitted for AK-OTOF for the treatment of otoferlin gene (*OTOF*)-mediated hearing loss –** Akouos submitted an investigational new drug (IND) application to the U.S. Food and Drug Administration (FDA) for AK-OTOF, a gene therapy intended for the treatment of patients with *OTOF*-mediated hearing loss. The IND was submitted in August due to longer than expected timelines to receive analytical testing data.

- **Received notice of allowance from the U.S. Patent and Trademark Office (USPTO) for claims covering compositions and methods of treatment that are useful for *OTOF*-**

mediated hearing loss – Akouos's allowed patent application, once granted, will cover compositions and methods for the use of AK-OTOF as well as other dual vector otoferlin constructs and is expected to expire in 2037 but may also be eligible for additional patent term extension.

- **Continued progress toward planned IND submission for AK-antiVEGF for vestibular schwannoma –** Akouos continues to prepare for submission of a second IND for a genetic medicine to address unmet need for an inner ear condition with AK-antiVEGF, a gene therapy intended for the treatment of patients with vestibular schwannoma. Recently, the current good manufacturing practice drug product (AAVAnc80-antiVEGF) for the planned clinical trial was vialed; in 2021, the in-life phase of the AK-antiVEGF good laboratory practices toxicology study was completed. Based on expected analytical testing timelines, the Company is targeting an IND submission for AK-antiVEGF in 2023.

- **Presented new nonclinical data at the American Society of Gene and Cell Therapy (ASGCT) 25th Annual Meeting –** In May 2022, Akouos gave two presentations of nonclinical data at the meeting: one demonstrating that a single intracochlear administration of AAVAnc80-hOTOF (AK-OTOF) vector led to durable restoration of auditory function and was well tolerated, supporting proposed clinical development of AK-OTOF for the treatment of *OTOF*-mediated hearing loss; and another that supports the potential use of microRNA target site (miR-TS) in adeno-associated viral (AAV) vectors for regulated gene expression in the inner ear.

Second Quarter Financial Results

- **Cash Position –** Cash, cash equivalents, and marketable securities were $192.9 million as of June 30, 2022, compared to $271.8 million as of June 30, 2021. Akouos expects the cash balance to fund operations beyond the next eighteen months.
- **Research and Development (R&D) Expenses –** R&D expenses were $14.3 million for the second quarter ended June 30, 2022, compared to $17.1 million for the same period in 2021. The decrease was due to timing of manufacturing activities for existing third-party manufacturers, in addition to the substantial completion of activities with one of our third-party manufacturers related to our AK-OTOF program, partially offset by increased manufacturing costs related to the Company's AK-antiVEGF program and increased expenses due to the growth in the number of R&D employees and their related activities.
- **General and Administrative (G&A) Expenses –** G&A expenses were $6.7 million for the second quarter ended June 30, 2022, compared to $5.7 million for the same period in 2021. The increase was primarily due to the growth in the number of G&A employees and their related activities, partially offset by a decrease in professional fees.
- **Net Loss –** Net loss was $20.8 million, or $0.58 per share, for the second quarter ended June 30, 2022, compared to $22.7 million, or $0.66 per share, for the same period in 2021.

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 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, including timing of our IND submission for AK-antiVEGF, statements relating to our intellectual property protection for AK-OTOF and methods useful for the treatment of otoferlin gene-mediated hearing loss, 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," "contemplate," "continue," "could," "estimate," "expect," "intend," "might," "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 quarter ended March 31, 2022, filed with the Securities and Exchange Commission on May 12, 2022, 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, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	$ 192,895	$ 232,452
Total assets	244,537	278,755
Total liabilities	46,587	45,105
Total stockholders' equity	197,950	233,650

Condensed Consolidated Statements of Operations
(Unaudited)

(in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 14,318	$ 17,119	$ 34,706	$ 28,377
General and administrative	6,682	5,665	13,328	10,555
Total operating expenses	21,000	22,784	48,034	38,932
Loss from operations	(21,000)	(22,784)	(48,034)	(38,932)
Other income (expense):				
Interest income	295	554	552	1,063
Other expense, net	(126)	(510)	(332)	(957)
Total other income, net	169	44	220	106
Net loss	$ (20,831)	$ (22,740)	$ (47,814)	$ (38,826)
Weighted-average common shares outstanding, basic and diluted	35,837,724	34,372,262	35,186,973	34,324,477
Net loss per share attributable to common stockholders, basic and diluted	$ (0.58)	$ (0.66)	$ (1.36)	$ (1.13)

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