
**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 13, 2020

Akouos, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or Other Jurisdiction of Incorporation)	001-39343 (Commission File Number)	81- 1716654 (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))
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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 13, 2020, Akouos, Inc. (the “Company”) issued a press release announcing the Company’s financial results for the quarter ended June 30, 2020. 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 13, 2020

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 13, 2020

By: /s/ Emmanuel Simons

Name: Emmanuel Simons, Ph.D., M.B.A.

Title: President and Chief Executive Officer



Akouos Reports Second Quarter 2020 Financial Results and Provides Business Highlights

- Upsized IPO in June 2020 raised \$244.4 million in gross proceeds -

- Company plans to advance lead product candidate, AK-OTOF, for the treatment of hearing loss due to mutations in the *OTOF* gene, to IND submission in 2021 and advance development programs spanning multiple inner ear disorders -

BOSTON, Massachusetts, August 13, 2020 – 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 second quarter ended June 30, 2020 and provided an update on recent business highlights.

“Our upsized initial public offering, which we completed in June, leaves us in a strong position to continue to advance our lead product candidate, AK-OTOF, for the treatment of hearing loss due to mutations in the *OTOF* (otoferlin) gene, into the clinic and further develop our pipeline of programs that leverage various AAV-mediated modalities to treat multiple inner ear disorders,” said Manny Simons, Ph.D., founder, president and CEO of Akouos. “We have built a team with deep experience and expertise, which will be a tremendous asset as we continue to execute on our mission to make healthy hearing available to all.”

Recent Business Highlights

- **Appointed Alan Smith, Ph.D., as chief technology officer** – In June 2020, Alan Smith, Ph.D., joined Akouos as chief technology officer. Dr. Smith brings over 30 years of experience in cellular therapeutics and previously served as executive vice president, technical operations at Bellicum Pharmaceuticals.
 - **Strengthened board of directors with appointment of Saira Ramasastry** – In June 2020, Saira Ramasastry joined the board of directors of Akouos. Ms. Ramasastry currently serves as managing partner of Life Sciences Advisory, a firm that she founded to provide strategic advice and business development solutions for life science companies.
 - **Expanded the role of Arthur Tzianabos, Ph.D. to chairman of board of directors** – In August 2020, Akouos announced the appointment of its board member Arthur Tzianabos to chairman of the board of directors.
 - **Completed upsized Initial Public Offering** – In June 2020, Akouos completed its initial public offering of 14,375,000 shares of common stock at a public offering price of \$17.00 per share, including the full exercise of the underwriter’s option to purchase additional shares. Gross proceeds from the IPO were \$244.4 million and net proceeds from the offering, after deducting underwriting discounts, commissions and offering expenses, were approximately \$223.8 million.
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- **Presented two posters at the American Society of Gene & Cell Therapy 23rd Annual Meeting** – In May 2020, Akouos presented two posters highlighting Akouos’s use of AAVAnc80 vector technology and its potential to address many forms of hearing loss.

Second Quarter 2020 Financial Results

- **Cash Position** – Cash and cash equivalents were \$333.0 million as of June 30, 2020, as compared to \$120.2 million as of March 31, 2020. Total cash, cash equivalents and marketable securities at June 30, 2020 includes total net proceeds of approximately \$223.8 million from the company’s IPO in June 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 \$9.9 million for the second quarter ended June 30, 2020, compared to \$4.4 million for the same period in 2019. The increase was primarily due to contract manufacturing costs, the initiation of 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 \$2.7 million for the second quarter ended June 30, 2020, compared to \$0.7 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 \$12.5 million, or \$11.14 loss per share, for the second quarter ended June 30, 2020, compared to \$2.0 million, or \$3.42 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, and timing, of our future clinical trials and our research and development programs, and the period over which we believe that our existing cash and cash equivalents 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 and cash equivalents; 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 final prospectus related to its initial public offering 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)

	<u>June 30, 2020</u>		<u>December 31, 2019</u>	
Cash and cash equivalents	\$	333,004	\$	25,078
Total assets		354,154		45,162
Total liabilities		21,898		19,273
Convertible preferred stock		—		58,690
Total stockholders' equity (deficit)		332,256		(32,801)

**Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)**

(in thousands, except share and per share data)

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Operating expenses:				
Research and development	\$ 9,937	\$ 4,366	\$ 17,971	\$ 7,509
General and administrative	2,664	749	5,168	1,380
Total operating expenses	<u>12,601</u>	<u>5,115</u>	<u>23,139</u>	<u>8,889</u>
Loss from operations	<u>(12,601)</u>	<u>(5,115)</u>	<u>(23,139)</u>	<u>(8,889)</u>
Other income (expense):				
Change in fair value of preferred stock tranche liability	—	3,013	—	753
Interest income	80	100	180	228
Other income (expense), net	(2)	(2)	(4)	(5)
Total other income (expense), net	<u>78</u>	<u>3,111</u>	<u>176</u>	<u>976</u>
Net loss and comprehensive loss	<u>\$ (12,523)</u>	<u>\$ (2,004)</u>	<u>\$ (22,963)</u>	<u>\$ (7,913)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (11.14)</u>	<u>\$ (3.42)</u>	<u>\$ (25.05)</u>	<u>\$ (13.91)</u>
Weighted-average common shares outstanding, basic and diluted	<u>1,124,251</u>	<u>586,616</u>	<u>916,521</u>	<u>568,811</u>

Contacts

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