

**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 09, 2023

Allakos Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware

(State or Other Jurisdiction
of Incorporation)

001-38582

(Commission File Number)

45-4798831

(IRS Employer
Identification No.)

825 Industrial Road, Suite 500

San Carlos, California

(Address of Principal Executive Offices)

94070

(Zip Code)

Registrant's Telephone Number, Including Area Code: 650 597-5002

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:

- 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, par value \$0.001	ALLK	The 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 9, 2023, Allakos Inc. (the “Company”) issued a press release reporting its financial results for the second quarter ended June 30, 2023. The full text of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 2.02 of this Form 8-K, including the attached Exhibit 99.1, is intended to be furnished and shall not be deemed “filed” for the 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 in any filing made 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 Number	Description
99.1	Press Release dated August 9, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

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

Allakos Inc.

Date: August 9, 2023

By: /s/ H. Baird Radford, III
H. Baird Radford, III
Chief Financial Officer

Allakos Provides Business Update and Reports Second Quarter 2023 Financial Results

SAN CARLOS, Calif., August 9, 2023 (GLOBE NEWSWIRE) – Allakos Inc. (the “Company”) (Nasdaq: ALLK), a biotechnology company developing antibodies for the treatment of allergic, inflammatory and proliferative diseases, today provided a business update and reported financial results for the second quarter ended June 30, 2023.

Recent Allakos Events

- Presented preclinical data at the European Academy of Allergy and Clinical Immunology (“EAACI”) Hybrid Congress 2023 highlighting lirentelimab and AK006 mechanisms of action and inhibitory activity on IgE and non-IgE activated mast cells. Key findings of the presentation included:
 - AK006 inhibits IgE mediated mast cell activation and shows similar IgE inhibitory activity as remibrutinib.
 - Siglec-6 interacts with mast cell proteins associated with metabolism and signaling that are not seen with Siglec-8.
 - AK006 also inhibits non-IgE mast cell activation pathways, including KIT-mediated activation.
- The AK006 Investigational New Drug (“IND”) application was accepted by the U.S. Food and Drug Administration. The Phase 1, first-in-human, study of AK006 consists of single and multiple ascending doses administered via infusion in healthy adult volunteers. In addition, the Phase 1 study will explore the activity of AK006 in a randomized, double-blind, placebo-controlled cohort of patients with chronic spontaneous urticaria (“CSU”).
- Appointed Rand Sutherland, M.D. and Dolca Thomas, M.D. to the Allakos Board of Directors.

Upcoming Allakos Anticipated Milestones

- Topline data expected from the Phase 2 study of subcutaneous lirentelimab in patients with atopic dermatitis in late Q4 2023 to Q1 2024.
- Topline data expected from the Phase 2b study of subcutaneous lirentelimab in patients with CSU in late Q4 2023 to Q1 2024.
- Following the single and multiple ascending dose portions of the Phase 1 AK006 study in healthy volunteers, initiation of the randomized, double-blind, placebo-controlled cohort in patients with CSU is expected in Q2 2024.

Second Quarter 2023 Financial Results

Research and development expenses were \$27.3 million in the second quarter of 2023 compared to \$34.4 million in the second quarter of 2022, a decrease of \$7.1 million. The decrease was primarily attributed to a \$4.6 million decrease in contract research and development costs and clinical costs related to lirentelimab and a \$2.9 million decrease in employee compensation, partially offset by increases in other research and development expenses.

General and administrative expenses were \$10.5 million for the three months ended June 30, 2023 compared to \$14.7 million for the three months ended June 30, 2022, a decrease of \$4.2 million. The decrease was primarily due to decreases in employee compensation and other administrative expenses.

Allakos reported a net loss of \$35.1 million in the second quarter of 2023 compared to \$49.1 million in the second quarter of 2022. The second quarter of 2023 included noncash expenses for stock-based compensation of \$9.8 million, compared to \$11.8 million in the same period in 2022, and depreciation of \$1.5 million, compared to \$1.9 million in the same period in 2022. Net loss per basic and diluted share was \$0.41 for the second quarter of 2023 compared to \$0.90 in the second quarter of 2022.

Allakos ended the second quarter of 2023 with \$221.1 million in cash, cash equivalents and investments resulting in a net decrease in cash, cash equivalents and investments of \$31.5 million during the second quarter of 2023.

About Allakos

Allakos is a clinical stage biotechnology company developing therapeutics which target immunomodulatory receptors present on immune effector cells involved in allergy, inflammatory and proliferative diseases. Activating these immunomodulatory receptors allows for the direct targeting of cells involved in disease pathogenesis and, in the setting of allergy and inflammation, has the potential to result in broad inhibition of inflammatory cells. The Company's most advanced antibodies are lirentelimab (AK002) and AK006. Lirentelimab selectively targets both mast cells and eosinophils, two types of white blood cells that are widely distributed in the body and play a central role in the inflammatory response. Inappropriately activated mast cells and eosinophils have been identified as key drivers in a number of severe diseases affecting the gastrointestinal tract, eyes, skin, lungs and other organs. AK006 targets Siglec-6, an inhibitory receptor expressed selectively on mast cells. In pre-clinical studies, AK006 appears to provide deeper mast cell inhibition than lirentelimab and, in addition to its inhibitory activity, reduce mast cell numbers. For more information, please visit the Company's website at www.allakos.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 as contained in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Such forward-looking statements include, but are not limited to, Allakos' progress, business plans and areas of focus, the expected timing of reporting topline data from its Phase 2 and 2b clinical trials of lirentelimab, the clinical potential of Allakos' antibodies and the initiation of a Phase 1 study of AK006. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from current expectations and beliefs, including but not limited to: Allakos' stages of clinical drug development; Allakos' ability to timely initiate and complete clinical trials for lirentelimab and AK006; Allakos' ability to obtain required regulatory approvals for its clinical trials; uncertainties related to the enrollment of patients in its clinical trials; Allakos' ability to demonstrate sufficient safety and efficacy of its product candidates in its clinical trials; uncertainties related to the success of clinical trials, regardless of the outcomes of preclinical testing or early-stage trials; Allakos' ability to obtain regulatory approvals to market its product candidates; market acceptance of Allakos' product candidates; uncertainties related to the projections of the size of patient populations suffering from the diseases Allakos is targeting; Allakos' ability to advance additional product candidates beyond lirentelimab; Allakos' ability to obtain additional capital to finance its operations, research and drug development; general economic and market conditions, both domestic and international; domestic and international regulatory obligations; and other risks. Information regarding the foregoing and additional risks may be found in the section entitled "Risk Factors" in documents that Allakos files from time

to time to with the SEC. These documents contain and identify important factors that could cause the actual results for Allakos to differ materially from those contained in Allakos' forward-looking statements. Any forward-looking statements contained in this press release speak only as of the date hereof, and Allakos specifically disclaims any obligation to update any forward-looking statement, except as required by law. These forward-looking statements should not be relied upon as representing Allakos' views as of any date subsequent to the date of this press release.

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Source: Allakos Inc.

Investor Contact:

Adam Tomasi, President

Alex Schwartz, VP Strategic Finance and Investor Relations

ir@allakos.com

Media Contact:

Denise Powell

denise@redhousecomms.com

ALLAKOS INC.
UNAUDITED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except per share data)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2023	2022	2023	2022
Operating expenses				
Research and development	\$ 27,280	\$ 34,448	\$ 60,358	\$ 211,255
General and administrative	10,537	14,669	22,505	33,513
Total operating expenses	<u>37,817</u>	<u>49,117</u>	<u>82,863</u>	<u>244,768</u>
Loss from operations	(37,817)	(49,117)	(82,863)	(244,768)
Interest income	2,697	104	5,375	187
Other expense, net	—	(90)	(36)	(1,545)
Net loss	<u>(35,120)</u>	<u>(49,103)</u>	<u>(77,524)</u>	<u>(246,126)</u>
Unrealized gain (loss) on investments	(171)	209	125	(107)
Comprehensive loss	<u>\$ (35,291)</u>	<u>\$ (48,894)</u>	<u>\$ (77,399)</u>	<u>\$ (246,233)</u>
Net loss per common share:				
Basic and diluted	<u>\$ (0.41)</u>	<u>\$ (0.90)</u>	<u>\$ (0.90)</u>	<u>\$ (4.50)</u>
Weighted-average number of common shares outstanding:				
Basic and diluted	<u>86,646</u>	<u>54,798</u>	<u>86,246</u>	<u>54,742</u>

ALLAKOS INC.
UNAUDITED CONDENSED BALANCE SHEETS
(in thousands)

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 67,381	\$ 87,217
Investments	153,721	192,569
Prepaid expenses and other current assets	30,460	29,057
Total current assets	251,562	308,843
Property and equipment, net	36,446	39,144
Operating lease right-of-use assets	24,489	30,225
Other long-term assets	6,699	8,208
Total assets	<u>\$ 319,196</u>	<u>\$ 386,420</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 4,307	\$ 4,832
Accrued expenses and other current liabilities	20,177	25,206
Total current liabilities	24,484	30,038
Operating lease liabilities, net of current portion	39,734	45,949
Total liabilities	64,218	75,987
Stockholders' equity:		
Common stock	87	85
Additional paid-in capital	1,265,350	1,243,408
Accumulated other comprehensive loss	(159)	(284)
Accumulated deficit	(1,010,300)	(932,776)
Total stockholders' equity	<u>254,978</u>	<u>310,433</u>
Total liabilities and stockholders' equity	<u>\$ 319,196</u>	<u>\$ 386,420</u>

