

**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): March 06, 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 March 6, 2023, Allakos Inc. (the “Company”) issued a press release reporting its financial results for the fourth quarter and full year ended December 31, 2022. 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 March 6, 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: March 6, 2023

By: /s/ H. Baird Radford, III

H. Baird Radford, III
Chief Financial Officer

Allakos Provides Business Update and Reports Fourth Quarter and Full Year 2022 Financial Results

SAN CARLOS, Calif., March 6, 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 fourth quarter and full year ended December 31, 2022. The Company’s most advanced antibodies are lirentelimab (AK002) and AK006.

Recent Allakos Events

- Initiated a Phase 2b randomized, double-blind, placebo-controlled study of subcutaneous lirentelimab in patients with chronic spontaneous urticaria (CSU) in the third quarter of 2022.
- Continued enrollment of a Phase 2 randomized, double-blind, placebo-controlled study of subcutaneous lirentelimab in patients with moderate-to-severe atopic dermatitis during the fourth quarter of 2022.
- Completed IND-enabling toxicity studies for AK006 in the second half of 2022.

Upcoming Allakos Anticipated Milestones

- Initiate the first-in-human study with AK006 in the first half of 2023.
- Report topline data from the Phase 2 study of subcutaneous lirentelimab in patients with atopic dermatitis in the second half of 2023.
- Report topline data from the Phase 2b study of subcutaneous lirentelimab in patients with chronic spontaneous urticaria in the second half of 2023.

Fourth Quarter 2022 Financial Results

Research and development expenses were \$35.4 million in the fourth quarter of 2022 compared to \$72.9 million in the fourth quarter of 2021. Fourth quarter of 2022 research and development expenses decreased significantly compared to the prior year fourth quarter primarily as a result of cost cutting efforts implemented during the first quarter of 2022. These efforts reduced manufacturing costs by \$26.0 million and compensation expenses by \$4.7 million in the fourth quarter of 2022 compared to the same period in 2021. Additionally, clinical related costs decreased by \$7.0 million primarily due to the completion of the ENIGMA 2 and KRYPTOS studies in the fourth quarter of 2021 and EoDyssey study in the third quarter of 2022.

General and administrative expenses were \$10.8 million in the fourth quarter of 2022 compared to \$23.2 million in the fourth quarter of 2021. Fourth quarter of 2022 general and administrative expenses decreased by \$12.4 million compared to the same period in 2021 due to cost cutting efforts initiated in the first quarter of 2022, including a \$5.6 million decrease in compensation expenses with the remaining decrease attributed to decreases in professional, market access and other general and administrative expenses.

Allakos reported a net loss of \$43.0 million in the fourth quarter of 2022 compared to \$94.4 million in the fourth quarter of 2021. Additionally, the fourth quarter of 2022 included non-cash expenses for stock-based compensation of \$9.3 million, compared to \$14.6 million in the same period in 2021, and depreciation of \$1.5 million, compared to \$1.2 million in the same period in 2021. Net loss per basic and diluted share was \$0.50 for the fourth quarter of 2022 compared to \$1.73 in the fourth quarter of 2021. Weighted-average shares outstanding used to calculate basic and diluted loss per share was 85.3 million and 54.4 million for

the fourth quarter of 2022 and 2021, respectively. As part of the September 21, 2022 common stock offering, 29.9 million shares were sold during 2022.

Allakos ended the fourth quarter of 2022 with \$279.8 million in cash, cash equivalents and investments.

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. In proliferative diseases like cancer, blocking an inhibitory receptor can restore the immune system's ability to identify and kill proliferative 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. Allakos is developing lirentelimab for the treatment of atopic dermatitis, chronic spontaneous urticaria and potentially additional indications. Lirentelimab has received orphan drug designations for eosinophilic gastritis (EG), eosinophilic duodenitis (EoD), and eosinophilic esophagitis (EoE) from the U.S. Food and Drug Administration. AK006 targets Siglec-6, an inhibitory receptor expressed selectively on mast cells. In pre-clinical research, AK006 appears to provide deeper mast cell inhibition than lirentelimab and, in addition to its inhibitory activity, reduce mast cell numbers. Allakos plans to begin human clinical trials with AK006 in the first half of 2023. AK007 targets Siglec-10, a key inhibitory myeloid checkpoint receptor that is selectively expressed on tumor associated macrophages (TAMs) and dendritic cells (DCs). AK007 is designed to block known ligand interaction with Siglec-10, including the "don't eat me" signal CD24. More recently, "don't eat me" signals, such as CD47 and CD24, have been identified to be overexpressed in tumors and allow cancer cells to avoid destruction by macrophages and other myeloid cells of the innate immune system. In pre-clinical research, AK007 polarizes tumor-associated myeloid cells and promotes anti-tumor immunity. Allakos is currently conducting pre-clinical studies with AK007. 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 initiation of a first-in-human study with 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 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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ALLAKOS INC.
UNAUDITED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except per share data)

	Three Months Ended		Twelve Months Ended	
	December 31,		December 31,	
	2022	2021	2022	2021
Operating expenses				
Research and development	\$ 35,388	\$ 72,868	\$ 265,081	\$ 196,328
General and administrative	10,828	23,211	57,348	75,147
Total operating expenses	<u>46,216</u>	<u>96,079</u>	<u>322,429</u>	<u>271,475</u>
Loss from operations	(46,216)	(96,079)	(322,429)	(271,475)
Interest income	2,775	70	3,673	377
Other income (expense), net	452	1,645	(1,196)	1,238
Net loss	(42,989)	(94,364)	(319,952)	(269,860)
Unrealized gain (loss) on investments	(220)	(172)	(131)	(161)
Comprehensive loss	<u>\$ (43,209)</u>	<u>\$ (94,536)</u>	<u>\$ (320,083)</u>	<u>\$ (270,021)</u>
Net loss per common share:				
Basic and diluted	<u>\$ (0.50)</u>	<u>\$ (1.73)</u>	<u>\$ (5.06)</u>	<u>\$ (5.01)</u>
Weighted-average number of common shares outstanding:				
Basic and diluted	<u>85,262</u>	<u>54,391</u>	<u>63,284</u>	<u>53,832</u>

ALLAKOS INC.
UNAUDITED CONDENSED BALANCE SHEETS
(in thousands)

	December 31,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 87,217	\$ 152,822
Investments	192,569	271,416
Prepaid expenses and other current assets	29,057	27,343
Total current assets	<u>308,843</u>	<u>451,581</u>
Property and equipment, net	39,144	43,100
Operating lease right-of-use assets	30,225	31,707
Other long-term assets	8,208	8,436
Total assets	<u>\$ 386,420</u>	<u>\$ 534,824</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 4,832	\$ 13,692
Accrued expenses and other current liabilities	25,206	26,557
Total current liabilities	<u>30,038</u>	<u>40,249</u>
Operating lease liabilities, net of current portion	45,949	49,099
Total liabilities	<u>75,987</u>	<u>89,348</u>
Stockholders' equity:		
Common stock	85	54
Additional paid-in capital	1,243,408	1,058,399
Accumulated other comprehensive loss	(284)	(153)
Accumulated deficit	(932,776)	(612,824)
Total stockholders' equity	<u>310,433</u>	<u>445,476</u>
Total liabilities and stockholders' equity	<u>\$ 386,420</u>	<u>\$ 534,824</u>

