

**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 1, 2022

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.)

975 Island Drive, Suite 201
Redwood City, California 94065
(Address of principal executive offices, including zip code)

(650) 597-5002
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

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

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))

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 1, 2022, Allakos Inc. (the “Company”) issued a press release reporting its financial results for the fourth quarter and full year ended December 31, 2021. 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 1, 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.

Date: March 1, 2022

Allakos Inc.

By: _____
H. Baird Radford, III
Chief Financial Officer

Allakos Provides Business Update and Reports Fourth Quarter and Full Year 2021 Financial Results

REDWOOD CITY, Calif., March 1, 2022 (GLOBE NEWSWIRE) – Allakos Inc. (the “Company”) (Nasdaq: ALLK), a biotechnology company developing lirentelimab (AK002) and AK006 for the treatment of allergic and inflammatory diseases, today provided a business update and reported financial results for the fourth quarter and full year ended December 31, 2021.

Recent Events

- Initiated a Phase 2 randomized, double-blind, placebo-controlled study of subcutaneous lirentelimab in patients with moderate-to-severe atopic dermatitis in the fourth quarter of 2021.
- Reported topline data from ENIGMA 2, a Phase 3 randomized, double-blind, placebo-controlled study of lirentelimab in patients with eosinophilic gastritis/eosinophilic duodenitis (“EG”/“EoD”) in the fourth quarter of 2021.
- Reported topline data from KRYPTOS, a Phase 2/3 randomized, double-blind, placebo-controlled study of lirentelimab in patients with eosinophilic esophagitis (“EoE”) in the fourth quarter of 2021.

Upcoming Milestones

- Hold an End-of-Phase 2 meeting with the FDA during second quarter of 2022 to discuss the Phase 2/3 KRYPTOS data and the development path with subcutaneous lirentelimab in patients with EoE.
- Report topline data from the Phase 3 study of lirentelimab in patients with EoD (EoDyssey) in the third quarter of 2022.
- Initiate a Phase 2b randomized, double-blind, placebo-controlled study of subcutaneous lirentelimab in patients with chronic spontaneous urticaria in the middle of 2022.
- Complete IND-Enabling studies of AK006 during 2022 and initiate the first-in-human study in the first half of 2023.

Fourth Quarter and Full Year 2021 Financial Results

Research and development expenses were \$72.9 million in the fourth quarter of 2021 as compared to \$28.5 million in the same period in 2020, an increase of \$44.4 million. Research and development expenses were \$196.3 million for the full year 2021 as compared to \$105.5 million in the same period in 2020, an increase of \$90.8 million.

General and administrative expenses were \$23.2 million in the fourth quarter of 2021 as compared to \$15.8 million in the same period in 2020, an increase of \$7.4 million. General and administrative expenses were \$75.1 million for the full year 2021 as compared to \$51.5 million in the same period in 2020, an increase of \$23.6 million.

Allakos reported a net loss of \$94.4 million in the fourth quarter of 2021 as compared to \$44.3 million in the same period in 2020, an increase of \$50.1 million. Net loss per basic and diluted share was \$1.73 for the fourth quarter of 2021 compared to \$0.86 in the same period in 2020. Net loss was \$269.9 million for the full year 2021 as compared to \$153.5 million in the same period in 2020, an increase of \$116.4 million. Net

loss per basic and diluted share was \$5.01 for the full year 2021 compared to \$3.10 in the same period in 2020.

Allakos ended the fourth quarter of 2021 with \$424.2 million in cash, cash equivalents and marketable securities.

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 us to directly target 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. We are developing lirentelimab for the treatment of eosinophilic esophagitis, eosinophilic gastritis, eosinophilic duodenitis, atopic dermatitis, chronic spontaneous urticaria and potentially additional indications. Lirentelimab has received orphan disease status for EG, EoD, and EoE from the U.S. Food and Drug Administration (the "FDA"). AK006 targets Siglec-6, an inhibitory receptor expressed selectively on mast cells. AK006 appears to provide deeper mast cell inhibition than lirentelimab and, in addition to its inhibitory activity, reduce mast cell numbers. We plan to begin human studies with AK006 in the first half of 2023. 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 and business plans, the expected timing of anticipated study results and plans relating to its future clinical trials. 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 complete clinical trials for, and if approved, commercialize lirentelimab (AK002), its lead compound; Allakos' ability to obtain required regulatory approvals for its product candidates; 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 later-stage clinical trials, regardless of the outcomes of preclinical testing and early-stage trials; 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; and other important risk factors set forth in Allakos' most recent Annual Report on Form 10-K filed with the SEC on March 1, 2021, Quarterly Report on Form 10-Q filed with the SEC on November 8, 2021, and future reports to be filed 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 and COO
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		Twelve Months Ended	
	December 31,		December 31,	
	2021	2020	2021	2020
Operating expenses				
Research and development	\$ 72,868	\$ 28,522	\$ 196,328	\$ 105,533
General and administrative	23,211	15,823	75,147	51,524
Total operating expenses	96,079	44,345	271,475	157,057
Loss from operations	(96,079)	(44,345)	(271,475)	(157,057)
Interest income	70	274	377	4,313
Other income (expense), net	1,645	(207)	1,238	(736)
Net loss	(94,364)	(44,278)	(269,860)	(153,480)
Unrealized loss on marketable securities	(172)	(159)	(161)	(129)
Comprehensive loss	<u>\$ (94,536)</u>	<u>\$ (44,437)</u>	<u>\$ (270,021)</u>	<u>\$ (153,609)</u>
Net loss per common share:				
Basic and diluted	<u>\$ (1.73)</u>	<u>\$ (0.86)</u>	<u>\$ (5.01)</u>	<u>\$ (3.10)</u>
Weighted-average number of common shares outstanding:				
Basic and diluted	<u>54,391</u>	<u>51,475</u>	<u>53,832</u>	<u>49,492</u>

ALLAKOS INC.
UNAUDITED CONDENSED BALANCE SHEETS
(in thousands)

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 152,822	\$ 207,177
Investments in marketable securities	271,416	451,820
Prepaid expenses and other current assets	27,343	10,270
Total current assets	451,581	669,267
Property and equipment, net	43,100	8,345
Operating lease right-of-use assets	31,707	39,731
Other long-term assets	8,436	2,275
Total assets	<u>\$ 534,824</u>	<u>\$ 719,618</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 13,692	\$ 13,960
Accrued expenses and other current liabilities	26,557	8,490
Total current liabilities	40,249	22,450
Operating lease liabilities, net of current portion	49,099	42,773
Total liabilities	89,348	65,223
Stockholders' equity:		
Common stock	54	53
Additional paid-in capital	1,058,399	997,298
Accumulated other comprehensive gain (loss)	(153)	8
Accumulated deficit	(612,824)	(342,964)
Total stockholders' equity	445,476	654,395
Total liabilities and stockholders' equity	<u>\$ 534,824</u>	<u>\$ 719,618</u>

