

**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)
November 8, 2021**

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 November 8, 2021, Allakos Inc. (the “Company”) issued a press release reporting its financial results for the third quarter ended September 30, 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 November 8, 2021.
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.

Allakos Inc.

Date: November 8, 2021

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

Allakos Provides Business Update and Reports Third Quarter 2021 Financial Results

REDWOOD CITY, Calif., November 8, 2021 (GLOBE NEWSWIRE) – Allakos Inc. (the “Company”) (Nasdaq: ALLK), a biotechnology company developing lirentelimab (AK002) for the treatment of eosinophil and mast cell-related diseases, today provided a business update and reported financial results for the third quarter ended September 30, 2021.

Recent Accomplishments

- Presented data at American College of Gastroenterology (ACG) 2021 Annual Scientific Meeting from prospective study showing high prevalence rates of eosinophilic gastritis and/or eosinophilic duodenitis (EG/EoD) with systemic evaluation. Forty-five percent (45%, 181/405) of patients with moderate-to-severe unexplained gastrointestinal symptoms who underwent upper endoscopy with biopsy met the diagnostic criteria for EG/EoD. This data suggests that these conditions are significantly underdiagnosed and may be a common cause of moderate-to-severe gastrointestinal symptoms.

Upcoming 2021 Milestones

- Topline data from a Phase 3 randomized, double-blind, placebo-controlled study of lirentelimab in patients with EG/EoD expected in the fourth quarter of 2021 or early in the first quarter of 2022.
- Topline data from a Phase 2/3 randomized, double-blind, placebo-controlled study of lirentelimab in patients with EoE expected in the fourth quarter of 2021 or early in the first quarter of 2022.
- Initiation of a Phase 2/3 randomized, double-blind, placebo-controlled study of subcutaneous lirentelimab in patients with EG and/or EoD expected in the fourth quarter of 2021.
- Initiation of a Phase 2 randomized, double-blind, placebo-controlled study in a non-eosinophilic gastrointestinal disease in the fourth quarter of 2021.

Third Quarter 2021 Financial Results

Research and development expenses were \$43.6 million in the third quarter of 2021 as compared to \$30.4 million in the same period in 2020, an increase of \$13.2 million.

General and administrative expenses were \$19.1 million in the third quarter of 2021 as compared to \$12.1 million in the same period in 2020, an increase of \$7.0 million.

Allakos reported a net loss of \$62.7 million in the third quarter of 2021 as compared to \$42.1 million in the same period in 2020, an increase of \$20.6 million. Net loss per basic and diluted share was \$1.16 for the third quarter of 2021 compared to \$0.86 in the same period in 2020.

Allakos ended the third quarter of 2021 with \$505.6 million in cash, cash equivalents and marketable securities.

About Allakos

Allakos is a clinical stage biotechnology company developing antibodies that target immunomodulatory receptors present on immune effector cells involved in allergic, inflammatory, and proliferative diseases. The Company's lead antibody, lirentelimab (AK002), is being evaluated in a Phase 3 study in eosinophilic gastritis (EG) and/or eosinophilic duodenitis (EoD) and a Phase 2/3 study in eosinophilic esophagitis (EoE). Lirentelimab targets Siglec-8, an inhibitory receptor selectively expressed on human mast cells and eosinophils. Inappropriately activated eosinophils and mast cells have been identified as key drivers in a number of severe diseases affecting the gastrointestinal tract, eyes, skin, lungs and other organs. Lirentelimab has been tested in multiple clinical studies. In these studies, lirentelimab eliminated blood and tissue eosinophils, inhibited mast cells and improved disease symptoms in patients with EG and/or EoD, EoE, mast cell gastrointestinal disease, severe allergic conjunctivitis, chronic urticaria and indolent systemic mastocytosis. 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.

###

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2021	2020	2021	2020
Operating expenses				
Research and development	\$ 43,560	\$ 30,380	\$ 123,460	\$ 77,011
General and administrative	19,056	12,055	51,936	35,701
Total operating expenses	62,616	42,435	175,396	112,712
Loss from operations	(62,616)	(42,435)	(175,396)	(112,712)
Interest income	74	766	307	4,039
Other expense, net	(187)	(417)	(407)	(529)
Net loss	(62,729)	(42,086)	(175,496)	(109,202)
Unrealized gain (loss) on marketable securities	(13)	(620)	11	30
Comprehensive loss	\$ (62,742)	\$ (42,706)	\$ (175,485)	\$ (109,172)
Net loss per common share:				
Basic and diluted	\$ (1.16)	\$ (0.86)	\$ (3.27)	\$ (2.24)
Weighted-average number of common shares outstanding:				
Basic and diluted	54,069	48,950	53,644	48,819

ALLAKOS INC.
CONDENSED BALANCE SHEETS
(in thousands)

	September 30, 2021 <u>(Unaudited)</u>	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 274,420	\$ 207,177
Investments in marketable securities	231,187	451,820
Prepaid expenses and other current assets	25,843	10,270
Total current assets	531,450	669,267
Property and equipment, net	40,329	8,345
Operating lease right-of-use assets	37,174	39,731
Other long-term assets	12,125	2,275
Total assets	<u>\$ 621,078</u>	<u>\$ 719,618</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 8,808	\$ 13,960
Accrued expenses and other current liabilities	31,815	8,490
Total current liabilities	40,623	22,450
Operating lease liabilities, net of current portion	55,902	42,773
Total liabilities	96,525	65,223
Stockholders' equity:		
Common stock	54	53
Additional paid-in capital	1,042,940	997,298
Accumulated other comprehensive gain	19	8
Accumulated deficit	(518,460)	(342,964)
Total stockholders' equity	524,553	654,395
Total liabilities and stockholders' equity	<u>\$ 621,078</u>	<u>\$ 719,618</u>

