

**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 10, 2020**

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 August 10, 2020, Allakos Inc. (the “Company”) issued a press release reporting its financial results for the second quarter ended June 30, 2020. 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 10, 2020.
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: August 10, 2020

By: _____
/s/ Robert Alexander
Robert Alexander
Chief Executive Officer

Allakos Reports Second Quarter 2020 Financial Results and Provides Business Update

REDWOOD CITY, Calif., August 10, 2020 – Allakos Inc. (the “Company”) (Nasdaq: ALLK), a biotechnology company developing AK002 for the treatment of eosinophil and mast cell-related diseases, today reported financial results for the second quarter ended June 30, 2020 and provided an update of its ongoing development activities.

Business Updates

- Patient enrollment was initiated in a randomized, double-blind, placebo-controlled Phase 3 study of AK002 in patients with eosinophilic gastritis (EG) and/or eosinophilic duodenitis (EoD). Topline data are expected in the second half of 2021.
- Patient enrollment was initiated in a randomized, double-blind, placebo-controlled Phase 2/3 study of AK002 in patients with eosinophilic esophagitis (EoE). Topline data are expected in the second half of 2021.
- The Phase 1 safety, tolerability and pharmacokinetics study of the subcutaneous formulation of AK002 is fully enrolled. Results are expected in the second half of 2020.
- The non-interventional study examining the prevalence of EG, EoD, and mast cell gastrointestinal disease (MGID) in patients with chronic functional gastrointestinal disease is fully enrolled. Results are expected in the second half of 2020.
- Announced positive clinical safety and efficacy results from a six-month, open-label Phase 1 study of AK002 in patients with MGID in March 2020.
- Announced positive interim safety and efficacy results from the open-label, long-term extension component of the ENIGMA study with AK002 in patients with EG and/or EoD. The results were accepted for oral presentation and presented virtually at the Digestive Disease Week (DDW) Annual Meeting in May 2020.
- The nonproprietary (generic) name of AK002 was changed from antolimab to lirentelimab as a result of trademark issues identified outside of the United States. Lirentelimab has been adopted by the United States Adopted Names (USAN) Council and World Health Organization (WHO) International Nonproprietary Names (INN) Program.

Second Quarter 2020 Financial Results

Research and development expenses were \$28.3 million in the second quarter of 2020 as compared to \$14.1 million in the same period in 2019, an increase of \$14.2 million.

General and administrative expenses were \$12.1 million in the second quarter of 2020 as compared to \$5.9 million in the same period in 2019, an increase of \$6.2 million.

Allakos reported a net loss of \$39.3 million in the second quarter of 2020 as compared to \$19.1 million in the same period in 2019, an increase of \$20.2 million. Net loss per basic and diluted share was \$0.80 for the second quarter of 2020 compared to \$0.44 in the same period in 2019.

Allakos ended the second quarter of 2020 with \$454.9 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 which lirentelimab eliminated blood and tissue eosinophils, inhibited mast cells and improved disease symptoms in patients with eosinophilic gastritis and/or eosinophilic duodenitis, eosinophilic esophagitis, 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. 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' early 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 (AK002); 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 February 25, 2020, Quarterly Report on Form 10-Q filed with the SEC on August 10, 2020 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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ALLAKOS INC.
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except per share data)
(unaudited)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2020	2019	2020	2019
Operating expenses				
Research and development	\$ 28,346	\$ 14,111	\$ 46,631	\$ 29,209
General and administrative	12,058	5,946	23,646	11,775
Total operating expenses	40,404	20,057	70,277	40,984
Loss from operations	(40,404)	(20,057)	(70,277)	(40,984)
Interest income, net	1,284	971	3,273	2,001
Other income (expense), net	(172)	14	(112)	(42)
Net loss	(39,292)	(19,072)	(67,116)	(39,025)
Unrealized gain (loss) on marketable securities, net of tax	(1,219)	84	650	129
Comprehensive loss	\$ (40,511)	\$ (18,988)	\$ (66,466)	\$ (38,896)
Net loss per common share:				
Basic and diluted	\$ (0.80)	\$ (0.44)	\$ (1.38)	\$ (0.91)
Weighted-average number of common shares outstanding:				
Basic and diluted	48,816	43,115	48,753	42,868

ALLAKOS INC.
CONDENSED BALANCE SHEETS
(in thousands)

	June 30, 2020 <u>(unaudited)</u>	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 153,898	\$ 38,367
Investments in marketable securities	301,048	457,534
Prepaid expenses and other current assets	3,336	3,969
Total current assets	458,282	499,870
Property and equipment, net	7,703	8,410
Operating lease right-of-use assets	5,633	5,775
Other long-term assets	2,839	2,839
Total assets	<u>\$ 474,457</u>	<u>\$ 516,894</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 9,617	\$ 5,963
Accrued expenses and other current liabilities	9,962	7,098
Total current liabilities	19,579	13,061
Other long-term liabilities	7,875	8,112
Total liabilities	27,454	21,173
Stockholders' equity:		
Common stock	49	48
Additional paid-in capital	702,767	685,020
Accumulated other comprehensive gain	787	137
Accumulated deficit	(256,600)	(189,484)
Total stockholders' equity	447,003	495,721
Total liabilities and stockholders' equity	<u>\$ 474,457</u>	<u>\$ 516,894</u>