

**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)
February 25, 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 February 25, 2020, Allakos Inc. (the “Company”) issued a press release reporting its financial results for the fourth quarter and full year ended December 31, 2019. 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 February 25, 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: February 25, 2020

By: _____
Robert Alexander
Chief Executive Officer

Allakos Reports Fourth Quarter and Full Year 2019 Financial Results and Provides Business Update

REDWOOD CITY, Calif., February 25, 2020 – Allakos Inc. (the “Company”) (Nasdaq: ALLK), a biotechnology company developing antolimab (AK002) for the treatment of eosinophil and mast cell related diseases, today reported financial results for the fourth quarter and full year ended December 31, 2019 and provided an update of its ongoing and planned development activities.

2019 Accomplishments

- Reported positive results from ENIGMA, a randomized, double-blind, placebo-controlled Phase 2 study using antolimab (AK002) in patients with Eosinophilic Gastritis (EG) and/or Eosinophilic Gastroenteritis (EGE). The study met all prespecified primary and secondary endpoints.
- Podium presentations of the ENIGMA study results were made at the 2019 United European Gastroenterology Week (Barcelona, Spain; October 2019) by Dr. Joseph Murray, MD and at the 2019 American College of Gastroenterology Annual Scientific Meeting (San Antonio, Texas; October 2019) by Dr. Evan Dellon, MD, MPH.
- Reported positive topline results with antolimab (AK002) in three open-label studies in patients with Chronic Urticaria (CU), Severe Allergic Conjunctivitis (SAC) and Indolent Systemic Mastocytosis (ISM). In these studies, antolimab (AK002) depleted blood eosinophils and improved patient and physician reported symptoms.
- Closed an underwritten public offering in August 2019, issuing 5,227,272 shares of common stock at an offering price of \$77.00 per share. Aggregated net proceeds received from the offering were approximately \$377.5 million, net of underwriting discounts and commissions and offering expenses.
- Granted orphan drug designation in October 2019 from the United States Food and Drug Administration for the treatment of Eosinophilic Esophagitis (EoE) with antolimab (AK002).

Upcoming 2020 Milestones

- Initiation of a randomized, double-blind, placebo-controlled Phase 3 study using antolimab (AK002) in patients with EG and/or EGE in the first quarter 2020.
 - Initiation of a randomized, double-blind, placebo-controlled Phase 2/3 study using antolimab (AK002) in patients with EoE in the first quarter 2020.
 - Clinical safety and efficacy results from a six-month, open-label Phase 1 study using antolimab (AK002) in patients with Mast Cell Gastrointestinal Disease (MGID) in the first quarter of 2020.
 - Clinical safety and efficacy results from the open-label, long-term extension component of the ENIGMA study in patients with EG and/or EGE in the first half of 2020.
 - Completion of a Phase 1 study in healthy volunteers evaluating the safety, tolerability and pharmacokinetics of a subcutaneous formulation of antolimab (AK002) in the second half of 2020.
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Fourth Quarter and Full Year 2019 Financial Results

Research and development expenses were \$16.6 million in the fourth quarter of 2019 as compared to \$11.0 million in the same period in 2018, an increase of \$5.6 million. Research and development expenses were \$61.9 million for the full year 2019 as compared to \$33.3 million in the same period in 2018, an increase of \$28.6 million.

General and administrative expenses were \$10.3 million in the fourth quarter of 2019 as compared to \$4.5 million in the same period in 2018, an increase of \$5.8 million. General and administrative expenses were \$29.6 million for the full year 2019 as compared to \$12.4 million in the same period in 2018, an increase of \$17.2 million.

Allakos reported a net loss of \$24.6 million in the fourth quarter of 2019 as compared to \$14.5 million in the same period in 2018, an increase of \$10.1 million. Net loss per basic and diluted share was \$0.51 for the fourth quarter of 2019 compared to \$0.35 in the same period in 2018. For the full year 2019, net loss was \$85.4 million and net loss per basic and diluted share was \$1.89 compared to \$43.5 million and \$2.20, respectively, for the same period in 2018.

Allakos ended fiscal year 2019 with \$495.9 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, antolimab (AK002), targets Siglec-8, an inhibitory receptor selectively expressed on human mast cells and eosinophils. Antolimab (AK002) has been shown to inhibit mast cells and deplete 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. Antolimab (AK002) has been tested in five clinical studies. In these studies, antolimab (AK002) eliminated blood and tissue eosinophils, inhibited mast cells and improved disease symptoms in patients with eosinophilic gastritis and/or eosinophilic gastroenteritis, eosinophilic esophagitis, 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 antolimab (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 antolimab (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, 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)

	Three Months Ended		Twelve Months Ended	
	December 31,		December 31,	
	2019	2018	2019	2018
Operating expenses				
Research and development	\$ 16,582	\$ 11,031	\$ 61,858	\$ 33,287
General and administrative	10,268	4,482	29,560	12,434
Total operating expenses	26,850	15,513	91,418	45,721
Loss from operations	(26,850)	(15,513)	(91,418)	(45,721)
Interest income, net	2,313	1,023	6,201	2,375
Other expense, net	(78)	(38)	(155)	(192)
Net loss	(24,615)	(14,528)	(85,372)	(43,538)
Unrealized gain (loss) on marketable securities, net of tax	35	18	152	(15)
Comprehensive loss	\$ (24,580)	\$ (14,510)	\$ (85,220)	\$ (43,553)
Net loss per common share:				
Basic and diluted	\$ (0.51)	\$ (0.35)	\$ (1.89)	\$ (2.20)
Weighted-average number of common shares outstanding:				
Basic and diluted	48,665	42,068	45,191	19,833

ALLAKOS INC.
CONDENSED BALANCE SHEETS
(in thousands)

	December 31,	
	2019	2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 38,367	\$ 33,660
Investments in marketable securities	457,534	145,246
Prepaid expenses and other current assets	3,969	2,703
Total current assets	499,870	181,609
Property and equipment, net	8,410	8,848
Operating lease right-of-use assets	5,775	—
Other long-term assets	2,839	802
Total assets	<u>\$ 516,894</u>	<u>\$ 191,259</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 5,963	\$ 2,092
Accrued expenses and other current liabilities	7,098	3,164
Total current liabilities	13,061	5,256
Other long-term liabilities	8,112	2,009
Total liabilities	21,173	7,265
Stockholders' equity:		
Common stock	48	42
Additional paid-in capital	685,020	288,079
Accumulated other comprehensive income (loss)	137	(15)
Accumulated deficit	(189,484)	(104,112)
Total stockholders' equity	495,721	183,994
Total liabilities and stockholders' equity	<u>\$ 516,894</u>	<u>\$ 191,259</u>