

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

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

Allakos Reports Fourth Quarter and Full Year 2020 Financial Results and Provides Business Update

REDWOOD CITY, Calif., March 1, 2021 – Allakos Inc. (the “Company”) (Nasdaq: ALLK), a biotechnology company developing lirentelimab (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, 2020 and provided a business update.

2020 Accomplishments

- Announced positive results from our prospective prevalence study showing that 45% (181/405) of symptomatic patients biopsied with chronic unexplained gastrointestinal (GI) symptoms or functional gastrointestinal disorders (FGIDs) such as irritable bowel syndrome (IBS) and functional dyspepsia (FD) met the histologic criteria for eosinophilic gastritis (EG) and/or eosinophilic duodenitis (EoD). The results suggest that EG and/or EoD are significantly underdiagnosed among these patients. Millions of patients in the U.S. are under the care of a gastroenterologist and suffer from chronic unexplained gastrointestinal symptoms or FGIDs. These results provide evidence that prevalence of EG and EoD is significantly higher than reported in the literature.
- Announced positive safety, pharmacokinetic and pharmacodynamic results from a randomized, double-blind, placebo-controlled Phase 1 study of subcutaneous (SC) lirentelimab in healthy volunteers. Bioavailability of SC lirentelimab was 63% and SC lirentelimab resulted in extended eosinophil suppression at all dose levels tested. At dose levels of 3.0 and 5.0 mg/kg and with the fixed dose of 300 mg, SC lirentelimab resulted in eosinophil suppression in all subjects through Day 85. The pharmacokinetic and pharmacodynamic results suggest that SC lirentelimab may be given monthly or potentially less frequently. SC lirentelimab was well tolerated, and there were no serious adverse events, no injection site reactions and no infusion-related reactions with SC lirentelimab.
- Published results from a Phase 2 study of lirentelimab in patients with EG and/or EoD (ENIGMA) in the *New England Journal of Medicine*.
- Announced positive interim results from an open-label long term extension study of ENIGMA. The results were accepted for oral presentation and presented virtually at the Digestive Disease Week (DDW) Annual Meeting.
- Closed an underwritten public offering, issuing 3,506,098 shares of common stock at an offering price of \$82.00 per share. Aggregate net proceeds received from the offering were approximately \$271.7 million, after deducting underwriting discounts and commissions.

Upcoming 2021 Milestones

- Topline data from a randomized, double-blind, placebo-controlled Phase 3 study of lirentelimab in patients with EG and/or EoD expected in the fourth quarter of 2021.
 - Topline data from a randomized, double-blind, placebo-controlled Phase 2/3 study of lirentelimab in patients with eosinophilic esophagitis (EoE) expected in the fourth quarter of 2021.
 - Initiation of a randomized, double-blind, placebo-controlled Phase 3 study of lirentelimab in patients with EoD expected in the second quarter of 2021.
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- Initiation of a randomized, double-blind, placebo-controlled Phase 2/3 study of SC lirentelimab in patients with EG and/or EoD expected in the second half of 2021.

Fourth Quarter and Full Year 2020 Financial Results

Research and development expenses were \$28.5 million in the fourth quarter of 2020 as compared to \$16.6 million in the same period in 2019, an increase of \$11.9 million. Research and development expenses were \$105.5 million for the full year 2020 as compared to \$61.9 million in the same period in 2019, an increase of \$43.6 million.

General and administrative expenses were \$15.8 million in the fourth quarter of 2020 as compared to \$10.3 million in the same period in 2019, an increase of \$5.5 million. General and administrative expenses were \$51.5 million for the full year 2020 as compared to \$29.6 million in the same period in 2019, an increase of \$21.9 million.

Allakos reported a net loss of \$44.3 million in the fourth quarter of 2020 as compared to \$24.6 million in the same period in 2019, an increase of \$19.7 million. Net loss per basic and diluted share was \$0.86 for the fourth quarter of 2020 compared to \$0.51 in the same period in 2019. Net loss was \$153.5 million for the full year 2020 as compared to \$85.4 million in the same period in 2019, an increase of \$68.1 million. Net loss per basic and diluted share was \$3.10 for the full year 2020 compared to \$1.89 in the same period in 2019.

Allakos ended the fiscal year 2020 with \$659.0 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, 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.

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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, 2020		December 31, 2020	
	2020	2019	2020	2019
Operating expenses				
Research and development	\$ 28,522	\$ 16,582	\$ 105,533	\$ 61,858
General and administrative	15,823	10,268	51,524	29,560
Total operating expenses	44,345	26,850	157,057	91,418
Loss from operations	(44,345)	(26,850)	(157,057)	(91,418)
Interest income	274	2,313	4,313	6,201
Other expense, net	(207)	(78)	(736)	(155)
Net loss	(44,278)	(24,615)	(153,480)	(85,372)
Unrealized gain (loss) on marketable securities	(159)	35	(129)	152
Comprehensive loss	\$ (44,437)	\$ (24,580)	\$ (153,609)	\$ (85,220)
Net loss per common share:				
Basic and diluted	\$ (0.86)	\$ (0.51)	\$ (3.10)	\$ (1.89)
Weighted-average number of common shares outstanding:				
Basic and diluted	51,475	48,665	49,492	45,191

ALLAKOS INC.
CONDENSED BALANCE SHEETS
(in thousands)

	<u>December 31,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 207,177	\$ 38,367
Investments in marketable securities	451,820	457,534
Prepaid expenses and other current assets	10,270	3,969
Total current assets	669,267	499,870
Property and equipment, net	8,345	8,410
Operating lease right-of-use assets	39,731	5,775
Other long-term assets	2,275	2,839
Total assets	<u>\$ 719,618</u>	<u>\$ 516,894</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 13,960	\$ 5,963
Accrued expenses and other current liabilities	8,490	7,098
Total current liabilities	22,450	13,061
Operating lease liabilities, net of current portion	42,773	8,112
Total liabilities	65,223	21,173
Stockholders' equity:		
Common stock	53	48
Additional paid-in capital	997,298	685,020
Accumulated other comprehensive gain	8	137
Accumulated deficit	(342,964)	(189,484)
Total stockholders' equity	654,395	495,721
Total liabilities and stockholders' equity	<u>\$ 719,618</u>	<u>\$ 516,894</u>