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)
October 26, 2020

Allakos Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-38582**	**45-4798831**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(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 8.01. Other Events

Prevalence Study

On October 26, 2020, Allakos Inc. (the "Company") issued a press release announcing results from a prospective study examining the rates of elevated eosinophil and mast cell levels in patients with chronic unexplained gastrointestinal symptoms or functional gastrointestinal disorders. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Phase 1 Study of Subcutaneously Administered Lirentelimab (AK002)

On October 26, 2020, the Company issued a press release announcing results from its Phase 1 study of subcutaneously administered lirentelimab (AK002). A copy of the press release is attached as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release regarding Prevalence Study dated October 26, 2020.
99.2	Press Release regarding Phase 1 Study dated October 26, 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: October 26, 2020

By: /s/ Robert Alexander

Robert Alexander, Ph.D.
Chief Executive Officer

Exhibit 99.1

Results from Prospective Prevalence Study Indicate that Eosinophilic Gastritis and Eosinophilic Duodenitis May be Significantly Underdiagnosed

-- 45% (181/405) of symptomatic patients biopsied with chronic functional gastrointestinal symptoms met the histologic criteria for eosinophilic gastritis and/or eosinophilic duodenitis --

-- Management to host conference call and webcast today at 8:00 am ET --

REDWOOD CITY, Calif., October 26, 2020 – Allakos Inc. (the "Company") (Nasdaq: ALLK), a biotechnology company developing lirentelimab (AK002) for the treatment of eosinophil and mast cell-related diseases, today reported results from a prospective study examining the rates of elevated eosinophil and mast cell levels in patients with chronic unexplained gastrointestinal (GI) symptoms or functional gastrointestinal disorders (FGIDs) such as irritable bowel syndrome (IBS) and functional dyspepsia (FD). The results suggest that eosinophilic gastritis (EG) and/or eosinophilic duodenitis (EoD) are significantly underdiagnosed.

"Millions of patients in the United States suffer from unexplained chronic gastrointestinal symptoms or FGIDs. FGIDs are diagnoses of exclusion that are characterized by persistent GI symptoms occurring without an identified cause," said Dr. William Chey, Professor of Gastroenterology at the University of Michigan. "I believe this is the first prospective study to examine the presence of tissue eosinophilia in patients with FGIDs and/or chronic gastrointestinal symptoms using a standardized biopsy protocol, standardized histologic criteria and daily self-reported symptoms. Today's results show that many of these patients have elevated and activated eosinophils suggesting that EG and/or EoD may be much more common than previously documented in the literature."

Prevalence Study Design
This prospective, multi-center study assessed eosinophil and mast cell levels in biopsies obtained from patients with active, chronic unexplained gastrointestinal symptoms or FGIDs. Inclusion in the study required patients to have ≥6-month history of abdominal pain, abdominal cramping, nausea, vomiting, diarrhea, bloating and/or early satiety without identifiable cause and unresponsive to pharmacologic or dietary intervention, or a diagnosis of IBS or FD. Gastric and duodenal biopsies were performed in patients who had an average weekly single symptom severity score ≥3 for abdominal pain, abdominal cramping, nausea, vomiting, diarrhea, bloating or early satiety and a total symptom severity score ≥10 as assessed by the patient reported outcome (PRO) questionnaire used in the Company's Phase 2 (ENIGMA) and Phase 3 EG and/or EoD studies. The primary endpoints were:

- The proportion of symptomatic patients that underwent biopsy and met the histologic criteria for EG and/or EoD (≥30 eosinophils/HPF in five HPFs of the stomach or ≥30 eosinophils/HPF in three HPFs of the duodenum, respectively).
- The proportion of symptomatic patients that underwent biopsy with ≥30 mast cells/HPF in five gastric HPFs and/or ≥30 mast cells/HPF in three duodenal HPFs and <30 eosinophils/HPF, referred to as MGID.

Prevalence Study Results
73% (405 of 556) of patients screened met the symptom severity criteria and underwent endoscopy with biopsy. Of the patients biopsied, 45% (181 of 405) met the histologic criteria for EG and/or EoD, representing

33% (181 of 556). In addition, 50% (204 of 405) of patients biopsied had ≥30 mast cells/HPF and <30 eosinophils/HPF (MGID). Results are presented below:

Entered Screening, N	556
Met Symptom Criteria for Biopsy, n	405
Met Histologic Criteria for EG/EoD[1], n (%)	181/405 (45%)
Met Histologic Criteria for MGID[2], n (%)	204/405 (50%)
Neither, n (%)	20/405 (5%)

[1] Patients with ≥30 eosinophils/high powered field (HPF) in five gastric HPFs and/or ≥30 eosinophils/HPF in three duodenal HPFs
[2] Patients ≥30 mast cells/HPF in five gastric HPFs and/or ≥30 mast cells/HPF in three duodenal HPFs; <30 eosinophils/HPF

Conference Call and Live Webcast
The Company will host a conference call and webcast with slides today at 8:00 a.m. Eastern Time / 5:00 a.m. Pacific Time. To participate by telephone, please dial 877-407-9039 (domestic) or 201-689-8470 (international). The conference ID number is 13712474. A live and archived audio webcast can be accessed through the Investors section of the Company's website at www.allakos.com. The archived audio webcast will remain available on the Company's website for 30 days following the conference call.

About Eosinophilic Gastritis and Eosinophilic Duodenitis
Eosinophilic gastritis and eosinophilic duodenitis (previously referred to as eosinophilic gastroenteritis) are chronic, often severe, inflammatory diseases characterized by persistent gastrointestinal symptoms and elevated and activated eosinophils in the stomach and/or, duodenum, respectively. Emerging data suggests that activated mast cells also contribute to disease pathogenesis. Common symptoms include abdominal pain, nausea, diarrhea, bloating, cramping, early satiety, loss of appetite, vomiting and weight loss. Published literature reports the prevalence of eosinophilic gastritis and eosinophilic duodenitis in the United States to be approximately 50,000 people. The Company believes that these diseases may be significantly underdiagnosed or misdiagnosed as other gastrointestinal diseases. The results from this study suggest that EG and/or EoD may be more common than documented in the literature. There are no treatments approved specifically for these diseases. Treatment with systemic steroids can provide symptomatic improvement, however, long-term treatment with steroids is generally not possible due to the numerous side effects.

About Lirentelimab Development in EG and/or EoD
Lirentelimab (AK002), targets Siglec-8, an inhibitory receptor selectively expressed on human mast cells and eosinophils. Lirentelimab has been studied in a prospective, multi-center, randomized, double-blind, placebo controlled, Phase 2 Study in patients with EG and/or EoD (ENIGMA). In ENIGMA, all lirentelimab dose arms showed clinically meaningful and statistically significant benefits when compared to placebo across all prespecified primary and secondary endpoints, including reductions in gastrointestinal tissue eosinophil counts and patient-reported disease symptoms. Detailed results were published in the *New England Journal of Medicine* on October 22, 2020. Lirentelimab has received orphan disease designation for eosinophilic gastritis, eosinophilic duodenitis/eosinophilic gastroenteritis and eosinophilic esophagitis. A Phase 3 Study of lirentelimab in patients with EG and/or EoD (NCT04322604) and a Phase 2/3 Study in patients with eosinophilic esophagitis (NCT04322708) are currently underway. Data from these studies is expected in the second half of 2021.

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), targets Siglec-8, an inhibitory receptor selectively expressed on human mast cells and eosinophils. Lirentelimab 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. 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 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, 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 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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Source: Allakos Inc.

Investor Contact:
Adam Tomasi, President and COO
ir@allakos.com

Media Contact:
Denise Powell
denise@redhousecomms.com

Exhibit 99.2

Allakos Announces Results from a Phase 1 Study of Subcutaneously Administered Lirentelimab (AK002)

-- Subcutaneous formulation of lirentelimab was safe and well tolerated and demonstrated sustained eosinophil suppression supporting once monthly dosing --

-- Management to host conference call and webcast today at 8:00 am ET --

REDWOOD CITY, Calif., October 26, 2020 – Allakos Inc. (the "Company") (Nasdaq: ALLK), a biotechnology company developing lirentelimab (AK002) for the treatment of eosinophil and mast cell-related diseases, today announced results from a Phase 1 Study of subcutaneously administered lirentelimab in healthy volunteers. Based on these results, Allakos intends to investigate monthly dosing of the subcutaneous (SC) formulation of lirentelimab in patients with eosinophilic gastritis, eosinophilic duodenitis, eosinophilic esophagitis and other diseases.

Study Design: Phase 1 Subcutaneous Lirentelimab in Adult Healthy Volunteers
The randomized, double-blind, placebo-controlled, single dose, dose ranging Phase 1 Study was designed to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of subcutaneous lirentelimab in healthy volunteers over 85 days. Subjects enrolled in subcutaneously administered cohorts received a single SC dose of one of the following: 0.3, 1.0, 3.0, 5.0 mg/kg of lirentelimab, a 2 mL SC dose containing 300 mg of lirentelimab, or placebo. Bioavailability of SC lirentelimab was determined by comparing SC cohorts to cohorts that received intravenously (IV) administered lirentelimab.

Results: Phase 1 Subcutaneous Lirentelimab in Adult Healthy Volunteers
Bioavailability of SC lirentelimab was 63 percent. Subcutaneously administered 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.

Blood Eosinophil Levels Over Time

Route	Dose Cohort	n	Median Blood Eosinophils 10^3/mL						
			BL	1 hr	3 hr	Day 15	Day 35	Day 56	Day 85
SC	Placebo	10	100	100	200	200	100	200	100
	0.3 mg/kg	6	110	200	20	0	0	50	100
	1.0 mg/kg	6	150	0	0	0	0	0	50
	3.0 mg/kg	6	150	0	0	0	0	0	0
	5.0 mg/kg	6	100	0	0	0	0	0	0
	300 mg	6	100	0	0	0	0	0	0
IV	1.0 mg/kg	6	100	0	0	0	0	0	0
	3.0 mg/kg	12	100	0	0	0	0	0	0

Subcutaneously administered lirentelimab was well tolerated. Across all SC and IV lirentelimab cohorts there were no serious adverse events, no injection site reactions, no injection reactions and no infusion-related reactions. One subject receiving placebo reported an injection reaction (mild flushing two hours post-injection).

Conference Call and Live Webcast
The Company will host a conference call and webcast with slides today at 8:00 a.m. Eastern Time / 5:00 a.m. Pacific Time. To participate by telephone, please dial 877-407-9039 (domestic) or 201-689-8470 (international). The conference ID number is 13712474. A live and archived audio webcast can be accessed through the Investors section of the Company's website at www.allakos.com. The archived audio webcast will remain available on the Company's website for 30 days following the conference call.

About Eosinophilic Gastritis, Eosinophilic Duodenitis, and Eosinophilic Esophagitis
Eosinophilic gastritis, eosinophilic duodenitis (previously referred to as eosinophilic gastroenteritis), and eosinophilic esophagitis are chronic, often severe, inflammatory diseases characterized by the presence of high levels of eosinophils in the stomach, duodenum, or esophagus, respectively. Common symptoms of the diseases include abdominal pain, nausea, diarrhea, bloating, cramping, early satiety, loss of appetite, vomiting, dysphagia, and weight loss. The current estimated prevalence of eosinophilic gastritis and eosinophilic duodenitis in the United States is approximately 50,000 people. The estimated prevalence of eosinophilic esophagitis in the United States is approximately 150,000 people. The Company believes that these diseases may be significantly under-diagnosed, or misdiagnosed, as other gastrointestinal diseases. There are no treatments approved specifically for these diseases. Treatment with systemic steroids can provide symptomatic improvement, but long-term treatment with steroids is generally not possible due to the numerous side effects. Allakos has received orphan drug designation for lirentelimab in eosinophilic gastritis, eosinophilic gastroenteritis, and eosinophilic esophagitis.

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.

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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 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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