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 24, 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

On March 24, 2020, Allakos Inc. (the "Company") issued two press releases announcing the initiation of antolimab (AK002) clinical studies and positive Phase 1 results with antolimab (AK002) in mast cell gastrointestinal disease. The full text of the press releases issued in connection with these announcements are attached as Exhibit 99.1 and Exhibit 99.2 to this Current Report on Form 8-K and are incorporated herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release dated March 24, 2020.
99.2	Press Release dated March 24, 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: March 24, 2020

By: /s/ Robert Alexander

Robert Alexander
Chief Executive Officer

Exhibit 99.1

Allakos Announces the Initiation of Antolimab (AK002) Clinical Studies

- *Phase 3 study of antolimab for the treatment of eosinophilic gastritis and/or eosinophilic duodenitis (previously referred to as eosinophilic gastroenteritis)*
- *Phase 2/3 study of antolimab for the treatment of eosinophilic esophagitis*
- *Phase 1 study of subcutaneously administered antolimab in healthy volunteers*

-- Management to host conference call and webcast today at 5:00 pm ET --

REDWOOD CITY, Calif., March 24, 2020 – Allakos Inc. (Nasdaq: ALLK), a biotechnology company developing antolimab (AK002) for the treatment of eosinophil and mast cell related diseases, today reported the initiation of three clinical studies of antolimab: a Phase 3 study in eosinophilic gastritis (EG) and/or eosinophilic duodenitis (EoD), a Phase 2/3 study in eosinophilic esophagitis (EoE), and a Phase 1 study of subcutaneously administered antolimab in healthy volunteers. The Phase 3 EG and/or EoD study and the Phase 2/3 EoE study follow positive results from ENIGMA, the Company's multicenter, randomized, double-blind, placebo-controlled Phase 2 study in patients with EG and/or EoD.

Phase 3 Eosinophilic Gastritis (EG) and/or Eosinophilic Duodenitis (EoD) Study Design
The multicenter, randomized, double-blind, placebo-controlled Phase 3 trial will enroll approximately 160 patients with active, biopsy-confirmed EG (eosinophil count of ≥30 eosinophils in 5 high powered fields [hpfs] in the stomach) and/or EoD (eosinophil count of ≥30 eosinophils in 3 hpfs in duodenum). Patients will be randomized 1:1 to receive: (a) 1.0 mg/kg of antolimab for the first month followed by five doses of 3.0 mg/kg given monthly, or (b) monthly placebo. The co-primary endpoints of the study are: 1) the proportion of patients achieving ≤ 4 eosinophils in 5hpfs in the stomach and/or ≤15 eosinophils in 3hpfs in the duodenum and 2) absolute change in Total Symptom Score (TSS-6: abdominal pain, nausea, bloating, early satiety, abdominal cramping, loss of appetite) measured using the daily patient reported symptom questionnaire used in ENIGMA. The TSS-6 consists of the six most frequent and severe symptoms reported in ENIGMA.

Phase 2/3 Eosinophilic Esophagitis (EoE) Study Design
The multicenter, randomized, double-blind, placebo-controlled Phase 2/3 trial will enroll approximately 300 patients with active, biopsy-confirmed EoE (eosinophil count of ≥15 eosinophils in a single hpf). Patients will be randomized 1:1:1 to receive: (a) six antolimab doses of 1.0 mg/kg given monthly, (b) 1.0 mg/kg of antolimab for the first month followed by five doses of 3.0 mg/kg given monthly, or (c) monthly placebo. The co-primary endpoints of the study are: (1) the proportion of patients achieving ≤6 eosinophils in a single hpf and (2) absolute change in dysphagia symptoms measured using a daily patient reported symptom questionnaire known as the Dysphagia Symptom Questionnaire (DSQ).

Phase 1 Study of Subcutaneously Administered Antolimab in Healthy Volunteers
The randomized, double-blind, placebo-controlled Phase 1 trial will evaluate the safety, pharmacokinetics, and pharmacodynamics of subcutaneously administered antolimab in healthy volunteers.

Conference Call and Live Webcast
The Company will host a conference call and webcast with slides today at 5:00 p.m. Eastern Time / 2:00 p.m. Pacific Time. To participate by telephone, please dial 877-407-9039 (domestic) or 201-689-8470 (international). The conference ID number is 13700828. 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 severe inflammatory orphan diseases characterized by the presence of high levels of eosinophils in the stomach, duodenum, or esophagus, respectively. Common symptoms of the diseases include severe 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. 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 antolimab 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, antolimab (AK002), targets Siglec-8, an inhibitory receptor selectively expressed on human mast cells and eosinophils. Antolimab 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 has been tested in six clinical studies. In these studies, antolimab 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 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’ early stages of clinical drug development; Allakos’ ability to timely complete clinical trials for, and if approved, commercialize antolimab, its lead compound; Allakos’ ability to obtain required regulatory approvals and appropriate labelling 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; 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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Exhibit 99.2

Allakos Announces Positive Phase 1 Results with Antolimab (AK002) in Mast Cell Gastrointestinal Disease

-- Antolimab (AK002) reduced gastrointestinal symptoms by 64 percent in patients with mast cell gastrointestinal disease --

-- Management to host conference call and webcast today at 5:00 pm ET --

REDWOOD CITY, Calif., March 24, 2020 – Allakos Inc. (Nasdaq: ALLK), a biotechnology company developing antolimab (AK002) for the treatment of eosinophil and mast cell related diseases, today reported results from a Phase 1 study evaluating the safety and efficacy of antolimab for the treatment of patients with mast cell gastrointestinal disease.

Mast Cell Gastrointestinal Disease
During enrollment of the Company's Phase 2 ENIGMA study in patients with eosinophilic gastritis (EG) and/or eosinophilic duodenitis (EoD), patients were identified with chronic moderate to severe gastrointestinal symptoms and elevated stomach and/or duodenal mast cell counts who did not have elevated eosinophils counts. These patients appeared to have a mast cell driven condition, currently referred to as mast cell gastrointestinal disease (MGID), and were offered the opportunity to participate in an open-label study of antolimab.

Phase 1 MGID Study Design
This open-label, multi-dose, 6-month, Phase 1 trial of antolimab consisted of seven patients with moderate to severe gastrointestinal symptoms and elevated mast cells (≥30 mast cells per hpf in at least 5hpfs in the stomach and/or ≥30 mast cells per hpf in at least 3hpfs in the duodenum) who did not have elevated eosinophils. Patients received 0.3 mg/kg of antolimab for the first dose, followed by 1.0 mg/kg the following month, then monthly doses of 3.0 mg/kg for four additional months. Disease symptoms were assessed using a daily patient reported questionnaire measuring eight symptoms (Total Symptom Score [TSS-8: abdominal pain, nausea, vomiting, early satiety, loss of appetite, abdominal cramping, bloating, and diarrhea]).

Study Results
Six-month treatment with antolimab resulted in a 64 percent mean reduction in TSS-8 compared to baseline. Five of seven (71 percent) patients had >50 percent reduction in TSS-8. The treatment effect of antolimab in this open label study was similar to that observed with antolimab in patients with EG and/or EoD in the Phase 2 ENIGMA Study.

Tissue and Symptom Results	**MGID (N=7)**	
	Baseline	**% Change**
Change in median GI eosinophil counts	17 eos/hpf	-100%
Change in median GI mast cell counts	55 mc/hpf	-18%
Mean change in Total Symptom Score (TSS-8)	27.1	-64%

Safety
Antolimab was generally well tolerated and no drug-related serious adverse events occurred during the study. The most common treatment emergent adverse event was infusion related reactions, all of which were mild.

Given the encouraging treatment response observed in this study, MGID may represent a novel market opportunity. Allakos is conducting additional clinical studies to better characterize MGID and assess the disease prevalence in patients with chronic functional gastrointestinal symptoms including those with irritable bowel syndrome, functional dyspepsia, and chronic gastritis.

Conference Call and Live Webcast

The Company will host a conference call and webcast with slides today at 5:00 p.m. Eastern Time / 2:00 p.m. Pacific Time. To participate by telephone, please dial 877-407-9039 (domestic) or 201-689-8470 (international). The conference ID number is 13700828. 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.

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