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)
June 3, 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 June 3, 2020, Allakos Inc. issued a press release announcing it has initiated patient recruitment for two previously announced registrational clinical studies of AK002, its lead product candidate. 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release dated June 3, 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: June 3, 2020

By: /s/ Robert Alexander

Robert Alexander
Chief Executive Officer

Exhibit 99.1

Allakos Initiates Patient Recruitment for AK002 Registrational Studies

-- Phase 3 study in eosinophilic gastritis and/or eosinophilic duodenitis and Phase 2/3 study in eosinophilic esophagitis --

-- Top-line safety and efficacy results from both studies expected in the second half of 2021 --

REDWOOD CITY, Calif., June 3, 2020 – Allakos Inc. (Nasdaq: ALLK), a biotechnology company developing antolimab (AK002) for the treatment of eosinophil and mast cell related diseases, today announced that it is recruiting patients for two previously announced registrational clinical studies of AK002; a Phase 3 study in eosinophilic gastritis (EG) and/or eosinophilic duodenitis (EoD) and a Phase 2/3 study in eosinophilic esophagitis (EoE). Top-line safety and efficacy results from both studies are expected in the second half of 2021. 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 study 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 5 hpfs in the stomach and/or ≤15 eosinophils in 3 hpfs 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 comprises 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 study 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).

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. 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 antolimab in eosinophilic gastritis, eosinophilic gastroenteritis, and eosinophilic esophagitis.

About Allakos
Allakos is a late-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), 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). Antolimab 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. Antolimab has been tested in multiple clinical studies, in which 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. 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 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, Quarterly Report on Form 10-Q filed with the SEC on May 11, 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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