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)
August 5, 2019

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)

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. ☒

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

Item 8.01 Other Events

On August 5, 2019, Allakos Inc. (the "Company") issued a press release announcing results from its Phase 2 trial in patients with Eosinophilic Gastritis and/or Eosinophilic Gastroenteritis. 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 August 5, 2019.

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: August 5, 2019

By: /s/ Robert Alexander

Robert Alexander
Chief Executive Officer

Exhibit 99.1

Allakos Announces AK002 Met All Prespecified Primary and Secondary Endpoints in Phase 2 Randomized, Double-Blind, Placebo-Controlled Study in Patients with Eosinophilic Gastritis (EG) and/or Eosinophilic Gastroenteritis (EGE)

- *Primary efficacy endpoint met with 95% reduction in gastrointestinal tissue eosinophils vs. 10% increase on placebo ($p < 0.0001$)*
- *Treatment response secondary endpoint met with 69% of AK002 treated patients meeting the response criteria vs. 5% on placebo ($p = 0.0008$)*
- *Total symptom score secondary endpoint met with 53% reduction in patient reported total symptom score vs. 24% on placebo ($p = 0.0012$)*
- *In the 14 patients with eosinophilic esophagitis ("EoE"), 13 (93%) patients had esophageal eosinophils reduced to <5 Eos/HPF and dysphagia was reduced 53% on AK002 vs. 17% on placebo*
- *Allakos plans to initiate studies in EG/EGE and EoE in Q1 2020*

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

REDWOOD CITY, Calif., August 5, 2019 – Allakos Inc. (the "Company") (Nasdaq: ALLK) today announced positive results from its Phase 2 randomized, double-blind, placebo-controlled trial of AK002 in patients with eosinophilic gastritis and/or eosinophilic gastroenteritis. All AK002 dose arms showed clinically meaningful and statistically significant benefits compared to placebo on all prespecified primary and secondary endpoints, including gastrointestinal tissue eosinophil counts and patient reported disease symptoms. Statistically significant differences in patient symptoms between the active and placebo groups occurred one day following AK002 administration. In addition, patients with comorbid eosinophilic esophagitis treated with AK002 experienced statistically significant decreases in esophageal eosinophil counts and substantial reductions in patient reported dysphagia symptoms.

"Eosinophilic gastritis, eosinophilic gastroenteritis, and eosinophilic esophagitis are severe debilitating diseases with no approved therapies. AK002 is unique in that it targets both eosinophils and mast cells, two major effector cell types that cause disease-related tissue damage. In this study, AK002 reduced eosinophil and mast cell counts and showed a statistically significant improvement in disease symptoms one day after administration," said Dr. Evan Dellon, M.D., a principal investigator of the study and Professor of Gastroenterology at the University of North Carolina, Chapel Hill. "These are clinically meaningful changes, and these data suggest that AK002 could provide rapid and sustained benefit in patients with eosinophil gastrointestinal diseases. I look forward to the continued development of AK002 in these severe orphan conditions."

Phase 2 ENIGMA Study Design
This randomized, double-blind, placebo-controlled Phase 2 trial of AK002 enrolled patients with active, biopsy-confirmed EG and/or EGE. Patients were required to be moderately to severely symptomatic based on a patient reported symptom questionnaire and have biopsy confirmed eosinophilia of the stomach (≥30 eosinophils/HPF in 5 HPFs) and/or duodenum (≥30 eosinophils/HPF in 3 HPFs). Qualifying patients were randomized 1:1:1 to receive: (a) 0.3 mg/kg of AK002 for the first month followed by three doses of 1.0 mg/kg given monthly, (b) 0.3 mg/kg of AK002 for the first month followed by 1.0 mg/kg, 3.0 mg/kg and

3.0 mg/kg given monthly, or (c) a monthly placebo. Disease symptoms were measured daily using a patient reported symptom questionnaire that scored 8 symptoms on a scale from 0 to 10 (abdominal pain, nausea, vomiting, early satiety, loss of appetite, abdominal cramping, bloating, and diarrhea).

Endpoints were assessed per protocol in a prespecified hierarchical order using biopsies collected at the end of study and symptoms collected over the last two weeks of study prior to biopsy. The primary endpoint was the percent change from baseline in the number of tissue eosinophils obtained from gastric or duodenal biopsies. The secondary endpoints were (1) proportion of patients with a greater than 75% reduction in tissue eosinophil counts from biopsies and a greater than 30% reduction in Total Symptom Score (TSS) from the patient reported questionnaire and (2) the percent change from baseline in the TSS.

Study Results
AK002 showed a statistically significant benefit when compared to placebo on all primary and secondary endpoints for each of the high dose, the low dose, and the combined high/low dose AK002 groups. The data demonstrate that AK002 produced histological resolution of gastrointestinal tissue eosinophilia and improved disease symptoms, and that these benefits occurred in the same individuals.

Data are presented below; more detailed results from the study will be presented during the conference call being held today.

Primary and Secondary Endpoints	**Placebo (N=20)**	**High Dose AK002 (n=20)**	**Low Dose AK002 (n=19)**	**Combined AK002 (n=39)**
1° Endpoint: % change in gastric or duodenal eosinophil counts	+10%	-97%	-92%	-95%
***p*–value**	-	**<0.0001**	**<0.0001**	**<0.0001**
2° Endpoint: treatment responders[1]	5%	70%	68%	69%
***p*–value**	-	**0.0009**	**0.0019**	**0.0008**
2° Endpoint: % change in total symptom score (TSS)[2]	-24%	-58%	-49%	-53%
***p*–value**	-	**0.0012**	**0.0150**	**0.0012**

[1] Treatment responders defined as greater than a 75% reduction in biopsy eosinophil counts and a greater than 30% reduction in TSS
[2] TSS is comprised of all 8 patient reported symptoms each measured on a scale from 0 to 10 (abdominal pain, nausea, vomiting, early satiety, loss of appetite, abdominal cramping, bloating, and diarrhea)

Safety
AK002 was generally well tolerated. The only treatment emergent adverse event occurring more frequently on AK002 than on placebo was mild to moderate infusion-related reactions (including flushing, feeling of warmth, headache, nausea, and/or dizziness) which occurred in 60% of AK002 treated patients and 23% of placebo treated patients. There was 1 drug-related serious adverse event (SAE) in the study, consisting of an infusion-related reaction which recovered within 24 hours. Treatment emergent SAEs occurred in 9% of patients on AK002 versus 14% on placebo.

Results in Eosinophilic Esophagitis Patients
Esophageal eosinophil counts and dysphagia improved in patients with comorbid eosinophilic esophagitis.

Exploratory Endpoints	Placebo	Combined AK002
EoE: proportion of patients with esophageal eosinophil counts <5/HPF	1/9 (11%)	13/14 (93%)
EoE: % change in patient reported dysphagia questionnaire	-17%	-53%

Steroid Use
Steroid use was balanced between drug and placebo groups. Statistically significant results were also observed on all primary and secondary endpoints in the subgroup of patients who did not receive steroids.

Extension Study
Ninety-two percent of patients in the Phase 2 study elected to enter a long-term AK002 extension study. Efficacy and safety results from the long-term extension study are expected in 2020.

Based on the results from the Phase 2 study, Allakos will request an end of Phase 2 meeting to discuss the design of the planned Phase 3 study in EG and/or EGE and Phase 2/3 study in EoE.

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 13693475. 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 Gastroenteritis, and Eosinophilic Esophagitis
Eosinophilic gastritis, eosinophilic gastroenteritis, and Eosinophilic Esophagitis are severe orphan inflammatory diseases characterized by the presence of high levels of eosinophils in the stomach, duodenum, or esophagitis, 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 estimated prevalence of eosinophilic gastritis and eosinophilic gastroenteritis in the United States is approximately 50,000 patients. The estimated prevalence of eosinophilic esophagitis in the United States is approximately 150,000 patients. There are no treatments approved specifically for these diseases. Treatment with systemic steroids can provide symptomatic improvements, but long-term treatment with steroids is generally not possible due to the numerous side effects caused by steroids. Allakos has received orphan drug designation for AK002 in eosinophilic gastritis and eosinophilic gastroenteritis.

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, AK002, targets Siglec-8, an inhibitory receptor selectively expressed on human mast cells and eosinophils. 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. AK002 has been tested in five clinical studies. In these studies, AK002 eliminated blood eosinophils 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. Such forward-looking statements include, but are not limited to, the ability of AK002 to continue to demonstrate rapid and sustained benefit in patients with eosinophil gastrointestinal diseases, the timing of the Company's long-term extension study and the efficacy and safety results from such study, the timing and outcome of its end of the phase 2 meeting and Allakos' ability to conduct a phase 3 study in EG and/or EGE and a phase 2/3 study in EoE. 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 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 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 March 14, 2019, Quarterly Report on Form 10-Q filed with the SEC on August 5, 2019 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.

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