# 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)**
**May 4, 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 May 4, 2020, Allakos Inc. issued a press release announcing interim results from a long-term open-label extension study of antolimab (AK002) for the treatment of patients with eosinophilic gastritis and/or eosinophilic duodenitis. 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 May 4, 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: May 4, 2020

By: /s/ Robert Alexander

**Robert Alexander**
**Chief Executive Officer**

**Exhibit 99.1**

**Allakos Announces Positive Interim Results from an Open-Label Extension Study of Antolimab (AK002) in Patients with Eosinophilic Gastritis and/or Eosinophilic Duodenitis**

*-- Antolimab treatment provided durable symptom improvement and blood and tissue eosinophil depletion --*

*-- Symptomatic benefit increased with duration of antolimab treatment --*

REDWOOD CITY, Calif., May 4, 2020 (GLOBE NEWSWIRE) -- Allakos Inc. (the "Company") (Nasdaq: ALLK), a biotechnology company developing antolimab (AK002) for the treatment of eosinophil and mast cell-related diseases, today reported results from a long-term open-label extension (OLE) study of antolimab for the treatment of patients with eosinophilic gastritis (EG) and/or eosinophilic duodenitis (EoD). The results were accepted for oral presentation and presented virtually at the Digestive Disease Week (DDW) Annual Meeting. The Company previously announced the initiation of a Phase 3 study in EG and/or EoD and initiation of a Phase 2/3 study in eosinophilic esophagitis.

**Phase 2 ENIGMA and Open-Label Extension Study Design**
ENIGMA was a multi-center, randomized, double-blind, placebo-controlled Phase 2 study that enrolled symptomatic patients with biopsy-confirmed eosinophilia of the stomach (≥30 eosinophils/HPF in 5 HPFs) and/or duodenum (≥30 eosinophils/HPF in 3 HPFs). Total symptom score (TSS) was measured daily using a patient reported questionnaire that scored symptoms on a scale from 0 to 10 (abdominal pain, nausea, vomiting, early satiety, loss of appetite, abdominal cramping, bloating, and diarrhea). Patients treated with antolimab showed statistically significant reductions in tissue eosinophil counts and improvements in patient reported symptoms. Patients who completed the Phase 2 ENIGMA study were eligible to enroll in the OLE study and received monthly doses of antolimab. In the OLE study, symptoms were assessed daily and tissue eosinophil levels were assessed on days 323 and 659. The goal of the OLE study was to examine the long-term use of 3.0 mg/kg antolimab for treatment of EG and/or EoD.

**Open-Label Extension (OLE) Interim Results**
Fifty-eight of 59 eligible ENIGMA patients elected to enter the long-term extension study. As of April 28, 2020, 35 patients completed at least 52 weeks of antolimab treatment, 12 patients discontinued prior to reaching 52 weeks of treatment, and 11 patients are active and have less than 52 weeks of treatment. Patients treated with antolimab experienced sustained eosinophil depletion in blood and tissue. Blood eosinophil levels rapidly decreased and remained suppressed (Figure 1). Histologic remission was achieved in 94% of patients (45/48). Disease symptoms improved over time with patients reaching 68% mean decrease in TSS at weeks 51-52 (Figure 2).

**Figure 1. Blood Eosinophils Levels Over Time from ENIGMA Baseline**

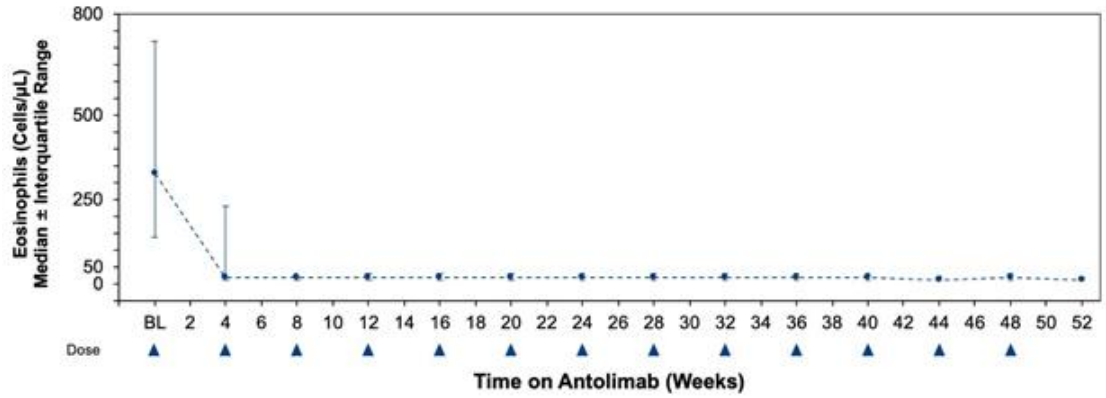
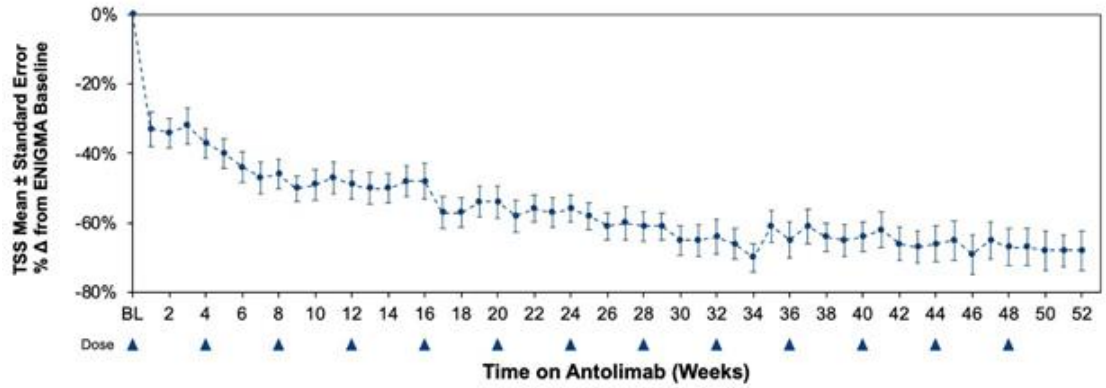



**Figure 2. Change in TSS Over Time**




**OLE Treatment Responses**

| Endpoint | Response |
|---|---|
| % of Patients with Histologic Remission[1] | 94% (45/48) |
| % Change in TSS at Weeks 51-52[2] | -68% |
| % of Patients with ≥50% Improvement in TSS Weeks 51-52 | 70% |
| % of Patients with ≥70% Improvement in TSS Weeks 51-52 | 57% |
| % of Patients with ≥90% Improvement in TSS Weeks 51-52 | 30% |

*1 Biopsies were collected on day 323 from entering ENIGMA. Histologic remission was defined as eosinophil counts of ≤4 eosinophil/hpf in the stomach and/or ≤15 eosinophils/hpf in the duodenum*

*2 TSS was measured daily and 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)*

Antolimab was generally well tolerated in the OLE study. The most common adverse event was infusion-related reactions (including flushing, feeling of warmth, headache, nausea, and/or dizziness) which occurred mostly on

the first infusion. No infusion-related reactions occurred in patients who received a single dose of oral prednisone the day prior to first infusion. There were no drug-related serious adverse events in the OLE.

Access to accepted abstracts, ePosters and ePapers is available from the DDW website. In addition, abstracts will publish in the May 2020 online supplement to the American Gastroenterological Society's journal - Gastroenterology. The posters and slides from multiple presentations made by the Company and its collaborators will also be made available on the Allakos website following each presentation.

**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 multiple 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 (AK002), 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 (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, 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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