

**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 21, 2020**

Allakos Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38582
(Commission
File Number)

45-4798831
(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 October 21, 2020, Allakos Inc. issued a press release announcing the publication of results from the Phase 2 study of lirentelimab (AK002) in patients with eosinophilic gastritis and/or eosinophilic duodenitis (ENIGMA) in the New England Journal of Medicine (NEJM). 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 October 21, 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 21, 2020

By: _____
/s/ Robert Alexander
Robert Alexander
Chief Executive Officer

Allakos Announces Publication of Results from the Phase 2 Study of Lirentelimab (AK002) in Patients with Eosinophilic Gastritis and/or Eosinophilic Duodenitis (ENIGMA) in the New England Journal of Medicine

REDWOOD CITY, Calif., October 21, 2020 – Allakos Inc. (Nasdaq: ALLK), a biotechnology company developing lirentelimab (AK002) for the treatment of eosinophil and mast cell-related diseases, today announced the publication of results from the multicenter, randomized, double-blind, placebo-controlled Phase 2 study of lirentelimab (AK002) in patients with eosinophilic gastritis and/or eosinophilic duodenitis (ENIGMA) in the *New England Journal of Medicine* (NEJM). 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. Previously announced, top-line data from the study are available here. The peer-reviewed article, “Anti-Siglec-8 Antibody for Eosinophilic Gastritis and Duodenitis”, will also appear in the journal’s print issue.

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 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 which 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.

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' early stages of clinical drug development; Allakos' ability to timely complete clinical trials for, and if approved, commercialize lirentelimab, 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.

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