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): September 09, 2022

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.)**

825 Industrial Road, Suite 500 **San Carlos, California** **(Address of Principal Executive Offices)**	**94070** **(Zip Code)**

Registrant's Telephone Number, Including Area Code: 650 597-5002

(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:

☐ 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))

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

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.

Release of Study Results

On September 9, 2022, Allakos Inc. (the "Company") issued a press release announcing its topline Phase 3 data from the EoDyssey study of lirentelimab in patients with eosinophilic duodenitis met the histologic co-primary endpoint, but did not achieve statistical significance on the patient reported symptomatic co-primary endpoint. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press release dated September 9, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Allakos Inc.

Date: September 9, 2022

By: /s/ H. Baird Radford, III

H. Baird Radford, III
Chief Financial Officer

Allakos Announces Topline Phase 3 Data from the EoDyssey Study in Patients with Eosinophilic Duodenitis

– Lirentelimab met histologic co-primary endpoint but missed symptomatic co-primary endpoint –

SAN CARLOS, Calif., **SAN CARLOS, Calif., September 9, 2022 (GLOBE NEWSWIRE)** -- Allakos Inc. (the "Company") (Nasdaq: ALLK), a biotechnology company developing lirentelimab (AK002) and AK006 for the treatment of allergic and inflammatory diseases, today reported data from EoDyssey, a 24-week, Phase 3, randomized, double-blind, placebo-controlled study of lirentelimab in patients with biopsy confirmed eosinophilic duodenitis (EoD). The trial met its histologic co-primary endpoint, but it did not achieve statistical significance on the patient reported symptomatic co-primary endpoint, in both the intent to treat (ITT) population and in a prespecified subpopulation.

The prespecified subpopulation was based on a post hoc analysis of the Company's phase 3 ENIGMA2 study and excluded certain patients with conditions that could confound the patient reported symptomatic endpoint (e.g., non-eosinophilic/non-mast cell driven esophageal disorders or active irritable bowel syndrome). Although positive numerical trends in the symptomatic endpoint were observed in this prespecified subpopulation, the results were not statistically significant.

The safety results of the trial were generally consistent with previously reported intravenous lirentelimab studies. Mild to moderate infusion-related reactions (including flushing, feeling of warmth, headache, nausea, and/or dizziness) occurred in 19.6% of lirentelimab-treated patients and 14.9% of placebo-treated patients.

Currently Allakos is not planning to conduct additional studies in eosinophilic gastrointestinal diseases, but may do so in the future. Allakos is focusing development efforts for lirentelimab in atopic dermatitis and chronic spontaneous urticaria and on AK006.

Allakos Development Programs
Allakos is conducting a Phase 2 randomized, double-blind, placebo-controlled study of subcutaneous lirentelimab in patients with moderate-to-severe atopic dermatitis and a Phase 2b randomized, double- blind, placebo-controlled study of subcutaneous lirentelimab in patients with chronic spontaneous urticaria. The Company anticipates reporting topline data from these studies in the second half of 2023. Additionally, Allakos is advancing AK006, an anti-Siglec-6 antibody that selectively inhibits mast cells, including KIT- mediated signaling, into IND enabling studies and plans to initiate a Phase 1 study in healthy volunteers in the first half of 2023.

EoDyssey Phase 3 Design
The randomized, double-blind, placebo-controlled Phase 3 trial of intravenous lirentelimab enrolled 93 patients with moderate to severe symptoms (based on a patient reported symptom questionnaire) and biopsy-confirmed eosinophilia of the duodenum (≥30 eosinophils/hpf in 3 hpfs) without eosinophilia of the stomach (defined as having less than 30 eosinophils/hpf in 5 hpfs). Patients were randomized 1:1 to receive:
3.0 mg/kg of lirentelimab given monthly or a monthly placebo. Disease symptoms were measured daily using a patient reported symptom questionnaire that scored 6 symptoms (abdominal pain, nausea, bloating, early satiety, abdominal cramping, and loss of appetite) each on a scale from 0 to 10 (TSS). The co-primary endpoints for the Phase 3 study were (1) the proportion of patients achieving histologic response (defined as $\leq$15 eosinophils (eos) / high powered field (hpf) in 3 hpfs in the duodenum) and (2) symptomatic improvement as measured by mean absolute change in the six-symptom total symptom score (TSS).

About Allakos

Allakos is a clinical stage biotechnology company developing therapeutics which target immunomodulatory receptors present on immune effector cells involved in allergy, inflammatory and proliferative diseases.

Activating these immunomodulatory receptors allows for the direct targeting of cells involved in disease pathogenesis and, in the setting of allergy and inflammation, has the potential to result in broad inhibition of inflammatory cells. The Company's most advanced antibodies are lirentelimab (AK002) and AK006.

Lirentelimab selectively targets both mast cells and eosinophils, two types of white blood cells that are widely distributed in the body and play a central role in the inflammatory response. Inappropriately activated mast cells and eosinophils have been identified as key drivers in a number of severe diseases affecting the gastrointestinal tract, eyes, skin, lungs and other organs. Allakos is developing lirentelimab for the treatment of atopic dermatitis, chronic spontaneous urticaria and potentially additional indications. Lirentelimab has received orphan drug designations for eosinophilic gastritis (EG), EoD, and eosinophilic esophagitis (EoE) from the U.S. Food and Drug Administration. AK006 targets Siglec-6, an inhibitory receptor expressed selectively on mast cells. In pre-clinical research, AK006 appears to provide deeper mast cell inhibition than lirentelimab and, in addition to its inhibitory activity, reduce mast cell numbers. Allakos plans to begin human studies with AK006 in the first half of 2023. 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, business plans and areas of focus, the expected timing of reporting topline data from its Phase 2 and 2b studies of lirentelimab, the advancement of IND studies for AK006 and initiation of a Phase 1 study with AK006. 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 initiate clinical trials for AK006; Allakos' ability to obtain required regulatory approvals for its clinical trials; 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; Allakos' ability to obtain regulatory approvals to market its product candidates; 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; general economic and market conditions; and other risks. Information regarding the foregoing and additional risks may be found in the section entitled "Risk Factors" set forth in Allakos' most recent Annual Report on Form 10-K filed with the SEC on March 1, 2022, Allakos' Quarterly Report on Form 10-Q filed with the SEC on August 4, 2022, 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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