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 24, 2021

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 24, 2021, Allakos Inc. (the "Company") issued a press release announcing results from a prospective study examining the rates of elevated eosinophil and mast cell levels in patients with chronic unexplained gastrointestinal symptoms or functional gastrointestinal disorders. The Company presented the results at the 2021 Digestive Disease Week (DDW) meeting. 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 May 24, 2021.
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 24, 2021

By: /s/ Robert Alexander

Robert Alexander, Ph.D.
Chief Executive Officer

Exhibit 99.1

New Allakos Data Presented at DDW 2021 Suggest that Eosinophilic Gastritis and/or Eosinophilic Duodenitis (EG/EoD) is Highly Underdiagnosed and may be a Common Cause of Moderate-to-Severe Gastrointestinal Symptoms

-- 45% (181/405) of patients with chronic functional gastrointestinal symptoms who underwent upper endoscopy with biopsy met the diagnostic criteria for eosinophilic gastritis and/or eosinophilic duodenitis (EG/EoD) --

REDWOOD CITY, Calif., May 24, 2021 (GLOBE NEWSWIRE) – Allakos Inc. (the "Company") (Nasdaq: ALLK), a biotechnology company developing lirentelimab (AK002) for the treatment of eosinophil and mast cell-related diseases, reported data at Digestive Disease Week (DDW) 2021. Results from a prospective study examined the rates of elevated tissue eosinophils in patients with chronic unexplained gastrointestinal (GI) symptoms or functional gastrointestinal disorders (FGIDs) such as irritable bowel syndrome (IBS) and functional dyspepsia (FD). The results suggest that eosinophilic gastritis (EG) and/or eosinophilic duodenitis (EoD) may be an underrecognized cause of chronic unexplained GI symptoms in these patients, and that EG/EoD is highly underdiagnosed.

"Chronic functional GI symptoms such as early satiety, bloating, nausea/vomiting, loss of appetite, diarrhea and abdominal pain/cramping, affect millions of adults in the United States. Indeed, IBS and functional dyspepsia are among the most common diagnoses made by gastroenterologists," said Dr. Anthony Lembo, Associate Professor of Medicine at Harvard Medical School. "These data suggest that EG/EoD may be associated with these unexplained chronic GI symptoms in these patients and that targeted EG/EoD therapies could provide a benefit."

"The results of this study indicate that EG/EoD is highly underdiagnosed, likely due to the lack of a standardized approach to evaluating patients with chronic non-specific symptoms," said Dr. Nicholas Talley, Pro Vice-Chancellor, Global Research at the University of Newcastle, Australia and Adjunct Professor of Medicine, Division of Gastroenterology and Hepatology Department of Medicine, University of North Carolina at Chapel Hill. "In practice, gastroenterologists may not always take enough biopsies during upper endoscopy (EGD), especially in the absence of obvious mucosal abnormalities. This study shows that systematic collection of at least 12 biopsies from the stomach and duodenum during EGD is important to detect EG/EoD. In addition, close collaboration between gastroenterologists and pathologists is essential to ensure tissue eosinophils are counted and reported, so that patients who meet the diagnostic threshold for EG/EoD are not missed. We anticipate these findings will be critical in shaping future diagnostic guidelines for how patients with chronic, unexplained moderate-to-severe GI symptoms are evaluated."

Prevalence Study Design

This prospective, multi-center study assessed eosinophil and mast cell levels in biopsies obtained from patients with active, chronic unexplained gastrointestinal symptoms or FGIDs. Inclusion in the study required patients to have ≥6-month history of abdominal pain, abdominal cramping, nausea, vomiting, diarrhea, bloating and/or early satiety without an identifiable cause and be unresponsive to pharmacologic or dietary intervention, or have a diagnosis of IBS or FD. Gastric and duodenal biopsies were collected in patients who had an average weekly single symptom severity score ≥3 (0-10 scale) for abdominal pain, abdominal cramping, nausea, vomiting, diarrhea, bloating or early satiety and a total symptom severity

score ≥10 as assessed by the patient reported outcome (PRO) questionnaire used in the Company's Phase 2 (ENIGMA) and Phase 3 EG/EoD (ENIGMA 2) studies. A key primary endpoint of the Prevalence Study was:

- The proportion of symptomatic patients that underwent biopsy and met the histologic criteria for EG/EoD (≥30 eosinophils/ high-power field [HPF] in five HPFs of the stomach or ≥30 eosinophils/HPF in three HPFs of the duodenum, respectively).

Prevalence Study Results
73% (405 of 556) of patients screened met the symptom severity criteria and underwent upper endoscopy with biopsy. Of the patients biopsied, 45% (181 of 405) met the histologic criteria for EG/EoD, representing 33% (181 of 556) of all the patients who entered screening.

The presentation at DDW 2021 included details related to the EG/EoD prevalence results and the eosinophil endpoints assessed in this study. Full results from the prevalence study will be presented at future meetings and in publications.

About Eosinophilic Gastritis and/or Eosinophilic Duodenitis
Eosinophilic gastritis and/or eosinophilic duodenitis (EG/EoD) is a chronic, often severe, inflammatory disease characterized by persistent gastrointestinal symptoms and elevated and activated eosinophils in the stomach and/or, duodenum, respectively. Emerging data suggests that activated mast cells also contribute to disease pathogenesis. Common symptoms include abdominal pain, nausea, diarrhea, bloating, cramping, early satiety, loss of appetite, vomiting and weight loss. Published literature reports the prevalence of eosinophilic gastritis and/or eosinophilic duodenitis in the United States to be approximately 50,000 people. The Company believes that EG/EoD may be significantly underdiagnosed or misdiagnosed as other gastrointestinal diseases. The results from this study suggest that EG/EoD may be more common than documented in the literature. There are no treatments approved specifically for EG/EoD. Treatment with systemic steroids can provide symptomatic improvement. However, long-term treatment with steroids is generally not possible due to the numerous side effects.

About Lirentelimab Development in EG/EoD
Lirentelimab (AK002), targets Siglec-8, an inhibitory receptor selectively expressed on human mast cells and eosinophils. Lirentelimab has been studied in a prospective, multi-center, randomized, double-blind, placebo controlled, Phase 2 Study in patients with EG/EoD (ENIGMA). In ENIGMA, all lirentelimab dose arms showed clinically meaningful and statistically significant benefits when compared to placebo across all prespecified primary and secondary endpoints, including reductions in gastrointestinal tissue eosinophil counts and patient-reported disease symptoms. Detailed results were published in the New England Journal of Medicine on October 22, 2020. Lirentelimab has received orphan disease designation for eosinophilic gastritis, eosinophilic duodenitis/eosinophilic gastroenteritis and eosinophilic esophagitis. A Phase 3 Study of lirentelimab in patients with EG/EoD (NCT04322604) and a Phase 2/3 Study in patients with eosinophilic esophagitis (NCT04322708) are currently underway. Data from these studies are expected in the fourth quarter of 2021.

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), targets Siglec-8, an inhibitory receptor selectively expressed on human mast cells and eosinophils. Lirentelimab 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. Lirentelimab has been tested in multiple clinical studies. In these studies, lirentelimab 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, the expected timing of anticipated study results 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' stages of clinical drug development; Allakos' ability to timely complete clinical trials for, and if approved, commercialize lirentelimab (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 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 March 1, 2021, Quarterly Report on Form 10-Q filed with the SEC on May 10, 2021 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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