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 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** **(Address of Principal Executive Offices)**	**94065** **(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.

On October 24, 2021, Allakos Inc. (the "Company") issued a press release announcing multiple presentations related to eosinophil and mast cell-driven diseases at the 2021 American College of Gastroenterology Annual Meeting ("ACG 2021").

On October 25, 2021, the Company issued a press release on its presentation of data at the ACG 2021 from a prospective study showing high prevalence rates of eosinophilic gastritis and/or eosinophilic duodenitis (EG/EoD) with systematic evaluation.

The full text of both press releases are attached as Exhibit 99.1 and Exhibit 99.2 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 24, 2021 announcing presentations at ACG 2021
99.2	Press release dated October 25, 2021 on presentation of data at ACG 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, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Allakos Inc.

Date: October 25, 2021

By: /s/ H. Baird Radford, III

H. Baird Radford, III
Chief Financial Officer

Exhibit 99.1

Allakos Announces Multiple Presentations Related to Eosinophil and Mast Cell-Driven Diseases at the American College of Gastroenterology 2021 Annual Scientific Meeting

REDWOOD CITY, Calif., October 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, today announced the acceptance of six poster presentations at the upcoming American College of Gastroenterology (ACG) Annual Scientific Meeting.

The presentations will take place during the ACG Annual Meeting being held in Las Vegas, Nev. and virtually Oct 22 to 27, 2021. Access to all accepted ePosters and ePresentations will be available on the ACG program website and in the October online supplement to the American Journal of Gastroenterology.

EG and/or EoD Prevalence Data Presentations:

Title (Presenter):	Endoscopy and Systematic Biopsy of Patients With Moderate-Severe Unexplained Gastrointestinal Symptoms Compared With Healthy Controls: High Discovery Rate of Eosinophilic Gastritis and/or Eosinophilic Duodenitis (Nicholas Talley, MD, PhD)
Session (#, Time):	Poster Session: Stomach (FP0999/S1405, Oct 24, 5:15-6:30pm PDT)
Title (Presenter):	Patients With Eosinophilic Esophagitis and Gastrointestinal Symptoms May Have Eosinophilic Gastritis and/or Duodenitis, Not Associated With Peak Esophageal Eosinophil Count (Kathryn Peterson, MD)
Session (#, Time):	Poster Session: Esophagus (P0306/S376, Oct 24, 5:15-6:30pm PDT)

Lirentelimab (AK002) Presentations:

Title (Presenter):	Safety and Efficacy of Long-Term Treatment With Lirentelimab, a Monoclonal Antibody Against Siglec-8, in Patients With Eosinophilic Gastritis and/or Duodenitis (Joseph Murray, MD)
Session (#, Time):	Poster Session: Stomach (P2033/S1421, Oct 25, 1:00-2:15pm PDT)
Title (Presenter):	Similar Efficacy of Lirentelimab in Patients With New vs Prior Diagnoses of Eosinophilic Gastritis and/or Duodenitis in a Randomized Trial (Kathryn Peterson, MD)
Session (#, Time):	Poster Session: Stomach (P2043/S1431, Oct 25, 1:00-2:15pm PDT)

Diagnosis of EG and/or EoD Presentations:

Title (Presenter):	Systematic Collection of Biopsies and Quantification of Eosinophils in Multiple High-Power Fields is Required for Diagnosis of Eosinophilic Gastritis and/or Duodenitis (Kevin Turner, MD)
Session (#, Time):	Poster Session: Stomach (P3085/S1453, Oct 26, 1:00-2:15pm PDT)
Title (Presenter):	General Pathologists Do Not Routinely Evaluate Gastric or Duodenal Eosinophilia (Robert Genta, MD)
Session (#, Time):	Poster Session: Functional Bowel Disease (P1445/S524, Oct 25, 1:00-2:15pm PDT)

Following the presentations, the posters and slides will be available on the Allakos website.

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. For more information, please visit the Company's website at www.allakos.com.

Source: Allakos Inc.

Investor Contact:
Adam Tomasi, President & COO
Alex Schwartz, VP Strategic Finance and Investor Relations
ir@allakos.com

Media Contact:
Denise Powell
denise@redhousecomms.com

Exhibit 99.2

Allakos Presents Data at ACG 2021 from Prospective Study Showing High Prevalence Rates of Eosinophilic Gastritis and/or Eosinophilic Duodenitis with Systematic Evaluation

– Study shows 45% (181/405) of patients with moderate-to-severe unexplained gastrointestinal symptoms who underwent upper endoscopy with biopsy met the histologic criteria for eosinophilic gastritis and/or eosinophilic duodenitis (EG/EoD) –
– Presentation selected for "ACG Presidential Poster Award" –

REDWOOD CITY, Calif., October 25, 2021 (GLOBE NEWSWIRE) -- Allakos Inc. (the "Company") (Nasdaq: ALLK), a biotechnology company developing investigational medicine lirentelimab (AK002) for the treatment of eosinophil and mast cell-related diseases, today announced that its poster, "High Discovery Rate of Eosinophilic Gastritis and/or Duodenitis Among Patients with Chronic Unexplained Gastrointestinal Symptoms", received a Presidential Poster Award at the American College of Gastroenterology (ACG) 2021 Annual Scientific Meeting.

The poster reports the results from a prospective study which examined the rates of elevated tissue eosinophils in over 400 patients with moderate-severe unexplained gastrointestinal (GI) symptoms, most of whom had a diagnosis of gastroesophageal reflux (GER) or a functional gastrointestinal disorder (FGID) such as irritable bowel syndrome (IBS) or functional dyspepsia (FD). Millions of people in the U.S. suffer with chronic, unexplained GI symptoms, which can dramatically impact quality of life. The results suggest that EG/EoD may be an underrecognized cause of chronic unexplained GI symptoms, and that systematic evaluation for EG/EoD, including a standardized biopsy and histopathology method, is warranted in these patients.

"In recent clinical studies, we've seen that many patients previously diagnosed with a functional GI disorder or those with moderate-to-severe unexplained symptoms met the strict histologic criteria for EG/EoD. It is increasingly evident that we should be systematically evaluating patients with chronic moderate-severe unexplained GI symptoms for EG/EoD, as there may be many patients who are undiagnosed or misdiagnosed with another GI condition," said Dr. Nicholas Talley, Laureate Professor 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. "We anticipate the findings from this study will be critical in shaping future diagnostic guidelines for how patients with chronic, unexplained moderate-to-severe GI symptoms are evaluated."

"Diagnosis of eosinophilic gastritis and/or eosinophilic duodenitis is achieved through a clinicopathologic evaluation, highlighting the need for education among both gastroenterologists and pathologists," said Dr. Evan Dellon, Professor of Medicine and Epidemiology, Division of Gastroenterology and Hepatology, University of North Carolina School of Medicine, Chapel Hill, North Carolina. "These findings further demonstrate that deliberate counting of eosinophils under high-power magnification may improve detection of this disease and help more patients achieve a precise diagnosis. This is not always part of the current pathologic exam, and taking this step likely improves the chances of diagnosis after endoscopy."

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), is an investigational medicine that 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 statistical significance when compared to placebo across all prespecified primary and secondary endpoints, including reductions in gastrointestinal tissue eosinophil counts and patient-reported disease symptoms. In this study, lirentelimab was generally well tolerated and the only treatment emergent adverse event occurring more frequently on lirentelimab than on placebo was mild to moderate infusion-related reactions. Treatment emergent SAEs occurred in 9% of patients on lirentelimab versus 14% on placebo. Detailed results were published in the *New England Journal of Medicine* on October 22, 2020. 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 ongoing. Topline 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), 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. 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 August 9, 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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