# 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): June 25, 2024**

# 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** | | **94070** |
| **(Address of Principal Executive Offices)** | | **(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 June 25, 2024, Allakos Inc. (the "Company") issued a press release announcing positive results from the single and multiple ascending Phase 1 study of intravenous (IV) AK006 in healthy subjects. 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 by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit Number | Description |
|---|---|
| 99.1 | Press release dated June 25, 2024. |
| 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 hereunto duly authorized.

Allakos Inc.

Date: June 25, 2024

By: /s/ H. Baird Radford, III

**H. Baird Radford, III**
**Chief Financial Officer**

**Exhibit 99.1**

**Allakos Announces Positive Results from its Ongoing Phase 1 Trial of AK006 in Healthy Volunteers, with AK006 Demonstrating High Receptor Occupancy on Mast Cells and a Favorable Safety Profile**

– AK006 achieved serum concentrations consistent with levels demonstrating inhibitory activity in preclinical experiments –
– Skin biopsies from subjects treated with AK006 show high receptor occupancy –
– AK006 was well-tolerated with a favorable safety profile –

SAN CARLOS, Calif., June 25, 2024 (GLOBE NEWSWIRE) -- Allakos Inc. (Nasdaq: ALLK), a biotechnology company developing AK006 for the treatment of mast cell-driven diseases, today announced positive results from the single and multiple ascending Phase 1 study of intravenous (IV) AK006 in healthy volunteers. AK006 is a Siglec-6 monoclonal antibody that selectively inhibits mast cells. Inappropriate activation of mast cells has been identified as a pathogenic driver of multiple diseases, including chronic spontaneous urticaria, food allergy and asthma.

**Phase 1 Study Results**

- Single and multiple IV doses of AK006 up to 720 mg were well tolerated with a favorable safety profile
  - There were no serious adverse events (SAEs)
  - There were no treatment emergent adverse events leading to discontinuation of AK006
  - There were no dose limiting toxicities
  - The most common adverse events occurring in subjects on AK006 were headache and dysmenorrhea, all of which were mild-to-moderate in severity
- AK006 showed dose linear exposure and with an estimated half-life of 21 days for the 720 mg IV dose
- AK006 achieved serum concentrations consistent with those showing mast cell inhibition in preclinical experiments
- Skin biopsies taken from AK006 treated healthy volunteers showed high levels of receptor occupancy confirming AK006 reaches skin tissue mast cells
  - Single ascending dose cohorts of AK006 ≥20mg showed a mean Siglec-6 receptor occupancy of >90% on mast cells at day 29

**Phase 1 AK006 Study in Healthy Volunteers and Patients with Chronic Spontaneous Urticaria**

AK006 is being studied in an ongoing Phase 1 single IV and subcutaneous (SC) ascending dose (SAD) and multiple IV ascending dose (MAD) trial that includes a randomized, double-blind, placebo-controlled CSU arm (NCT06072157). The data announced today are from Parts A and B of the randomized, double-blind, placebo-controlled SAD and MAD IV cohorts of the study. In these cohorts, healthy volunteers were randomized 6:2 to receive doses of intravenous AK006 or placebo. AK006 was tested across five single ascending doses (5, 20, 80, 240 and 720 mg) and three MAD (80, 240 and 720 mg monthly) dose cohorts. The primary objective was to evaluate the safety and tolerability of single ascending doses and

multiple ascending IV doses of AK006 in healthy volunteers and to explore Siglec-6 receptor occupancy on mast cells in skin biopsy samples.

AK006 is also being studied in an ongoing randomized, double-blind, placebo-controlled cohorts of healthy volunteers receiving SC AK006 and also in a cohort of patients with CSU receiving IV AK006. In the CSU cohort, approximately 60 adult patients with antihistamine refractory CSU (including patients with prior biologics treatment), will be randomized 2:1 to receive 720 mg of IV AK006 or placebo once every four weeks (Q4W). The primary efficacy analysis will be the change in the urticaria activity score (UAS7) at week 14. Data from approximately 30 patients is expected at year end 2024.

**About AK006**

AK006 is a humanized IgG1 monoclonal antibody which activates the inhibitory receptor Siglec-6. Siglec-6 is found on the surface of mature mast cells and offers a way to selectively target mast cells. In preclinical experiments, AK006 inhibits IgE-dependent and IgE-independent mast cell activation including activation through IgE, MRGPRX2 and KIT receptors. In these experiments, AK006 drives deep mast cell inhibition and, in addition to its inhibitory activity, can reduce mast cell numbers via antibody-dependent cellular phagocytosis in the presence of activated macrophages.

**About Allakos**

Allakos is a clinical stage biotechnology company developing therapeutics that 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 antibody in ongoing clinical development is AK006. AK006 targets Siglec-6, an inhibitory receptor expressed on mast cells. Mast cells are widely distributed in the body and play a central role in the inflammatory response. Inappropriately activated mast cells have been identified as key drivers in a number of severe diseases affecting the gastrointestinal tract, eyes, skin, lungs and other organs. In preclinical studies, AK006 appears to provide deep mast cell inhibition and, in addition to its inhibitory activity, reduce mast cell numbers. 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, areas of focus and preclinical research; enrollment in Allakos's clinical study; timing and availability of data; the potential of AK006; and Allakos' anticipated milestones. 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 and complete 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 clinical trials, regardless of the outcomes of preclinical testing or early-stage trials; Allakos' ability to advance additional product candidates beyond AK006; uncertainties

related to Allakos' ability to realize the contemplated benefits of its restructuring and related reduction in force; Allakos' ability to accurately forecast financial results; Allakos' ability to obtain additional capital to finance its operations, research and drug development; general economic and market conditions, both domestic and international; domestic and international regulatory obligations; and other risks. Information regarding the foregoing and additional risks may be found in the section entitled "Risk Factors" in documents that Allakos files from time to time to 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.

Source: Allakos Inc.

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