# 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)**
**January 29, 2019**

# 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)**

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 January 29, 2019, Allakos Inc. (the "Company") issued a press release announcing positive top-line results for the cholinergic urticaria and symptomatic dermographism cohorts from its Phase 2 chronic urticaria study. The full text of the press release is filed 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 January 29, 2019. |

**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: January 29, 2019

By: /s/ Robert Alexander

**Robert Alexander**
**President and Chief Executive Officer**

**Exhibit 99.1**

**Allakos Announces Positive Phase 2 Results in Patients with Cholinergic Urticaria and Symptomatic Dermographism**

*-- 82% (9 of 11) response rate in patients with cholinergic urticaria --*
*-- 70% (7 of 10) response rate in patients with symptomatic dermographism --*

**REDWOOD CITY, Calif., January 29, 2019** – Allakos Inc. (NASDAQ: ALLK), a biotechnology company developing AK002 for the treatment of eosinophil and mast cell related diseases, today announced positive Phase 2 results from two additional chronic urticaria cohorts: patients with cholinergic urticaria and symptomatic dermographism (also referred to as dermatographic urticaria). Earlier this month, Allakos reported that 12 of 13 patients (92%) in the Xolair-naïve chronic spontaneous urticaria (CSU) cohort achieved a complete response with AK002. Top-line results for the remaining urticaria cohort, patients with chronic spontaneous urticaria who failed to respond to Xolair, are expected later in the first quarter of 2019.

"We are excited by these data especially since there are no approved treatments for patients with cholinergic urticaria and symptomatic dermographism. Furthermore, the activity observed in patients with CSU and these patient cohorts suggests that AK002 may be used across multiple types of urticaria," said principal investigator of the study, Dr. Marcus Maurer, M.D., Professor of Dermatology and Allergy at Charité University in Berlin.

The study is being conducted at four sites in the U.S. and Germany. The cholinergic urticaria and symptomatic dermographism cohorts enrolled 11 and 10 patients, respectively, with uncontrolled urticaria despite treatment with H1 antihistamines at doses of up to four times the labeled antihistamine dosage. Antihistamine medication was maintained throughout the screening period and during the study. Baseline symptom scores, as measured by Urticaria Control Test (UCT)* were collected over a 4-week screening period. Patients with baseline UCT scores of less than 12, indicative of poorly-controlled urticaria, were enrolled in the study and treated with up to six doses of AK002 given once monthly. Patients received an initial dose of 0.3 mg/kg at baseline, followed by a dose of 1.0 mg/kg on day 28, and then received monthly doses of either 1.0 or 3.0 mg/kg, depending on response, for a total of six doses. The primary efficacy endpoint was change from baseline in UCT assessed at week 22, two weeks after the last dose of AK002.

Top-line data are presented below; more detailed results from the study will be presented at an upcoming medical conference.

| **Cholinergic Urticaria Cohort** | Baseline | Week 22 |
|---|---|---|
| Average UCT Score | 5.4 | 11.8 |
| UCT Complete Response | - | 9/11 (82%) |
| UCT Partial Response | - | 0/11 (0%) |
| UCT No Response | - | 2/11 (18%) |
| **Symptomatic Dermographism Cohort** | | |
| Average UCT Score | 5.7 | 9.1 |
| UCT Complete Response | - | 4/10 (40%) |
| UCT Partial Response | - | 3/10 (30%) |
| UCT No Response | - | 3/10 (30%) |

*UCT is an established patient-reported outcome scale for assessing urticaria control and measuring key symptoms.
UCT is a scale between 0 and 16, with higher scores indicating greater urticaria control.
UCT Complete Response was defined as a greater than 3-point improvement from baseline and a score of 12 or greater. UCT Partial Response was defined as a greater than 3-point improvement from baseline but less than 12.

AK002 was generally well tolerated. The most common adverse event was mild to moderate infusion-related reactions (flushing, feeling of warmth, headache, nausea, and dizziness) which occurred mostly during the first infusion.

**Phase 2 Chronic Urticaria Study**
The open-label Phase 2 study is being conducted at four sites in the U.S. and Germany. The study enrolled 45 patients with uncontrolled chronic urticaria with a UCT score less than 12 despite treatment with H1 antihistamines at doses up to four times the labeled dosage. Patients were enrolled in four cohorts depending on the form of urticaria and prior treatment: chronic spontaneous urticaria Xolair naïve (N=13), chronic spontaneous urticaria Xolair failures (N=11), cholinergic urticaria (N=11) and symptomatic dermographism (N=10). Antihistamine medication was maintained throughout the screening period and study. Baseline symptom scores, including UCT, were collected over a 4-week screening period. Patients with baseline UCT scores of less than 12 were enrolled in the study and treated with up to six doses of AK002 given monthly. Patients received an initial dose of 0.3 mg/kg, 1.0 mg/kg on day 28, and then received monthly doses of either 1.0 or 3.0 mg/kg for a total of six doses. Efficacy was assessed at week 22 using the urticaria control test (UCT) and UAS7 (for patients with chronic spontaneous urticaria only).

**About Chronic Urticarias**
Chronic urticarias are a group of inflammatory skin diseases that are believed to be caused by the inappropriate activation of the mast cells in the skin. Symptoms of urticaria include severe itching, hives, and edema with symptoms lasting for many years. Whereas there is no identified trigger for chronic spontaneous urticaria, other chronic urticarias are caused by triggers such as physical contact with the skin (symptomatic dermographism), or passive or active increases in body temperature (cholinergic urticaria). It has been estimated that 0.5 to 1.0 percent of the U.S. population suffers from a form of chronic urticaria. First-line treatment consists of antihistamine medication, however a significant number of patients do not receive adequate benefit even at four times the labeled dose. Xolair is the only agent approved for antihistamine refractory chronic spontaneous urticaria but is not indicated for other forms of chronic urticaria. Allakos estimates that approximately 200,000 to 500,000 patients with severe, uncontrolled chronic urticaria could be candidates for therapy with AK002.

**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, AK002, 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. AK002 has completed two Phase 1 trials, one in healthy volunteers and a single ascending dose trial in patients with indolent systemic mastocytosis. AK002 demonstrated pharmacodynamic activity in both trials and in the trial involving patients with indolent systemic mastocytosis, patients reported improvements in their symptoms. AK002 is being tested in a double-blind, placebo-controlled Phase 2 trial for the treatment of eosinophilic gastritis and eosinophilic gastroenteritis. In addition, Allakos is conducting multiple-dose trials with AK002 in chronic urticaria, indolent systemic mastocytosis, and severe allergic conjunctivitis. 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. Such forward-looking statements include, but are not limited to, the timing of top-line results from Allakos’ ongoing 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’ early stages of clinical drug development; Allakos’ ability to timely complete clinical trials for, and if approved, commercialize 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 AK002; Allakos' ability to obtain additional capital to finance its operations; and other important risk factors set forth in Allakos' Registration Statement on Form S-1 that is on file with the Securities and Exchange Commission ("SEC") and the prospectus dated July 18, 2018 relating to its initial public offering of common stock, Allakos' Form 10-Q filed with the SEC on November 8, 2018, and Allakos' future reports to be filed with the SEC. 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.

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Source: Allakos Inc.

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