
**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 7, 2019

Allakos Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38582
(Commission
File Number)

45-4798831
(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)

75 Shoreway Road, Suite A
San Carlos, California 94070
(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 7, 2019, Allakos Inc. (the "Company") issued a press release announcing positive top-line results for the Xolair-naïve chronic spontaneous urticaria cohort from its Phase 2 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

| <u>Exhibit Number</u> | <u>Description</u> |
|---------------------------|---|
| 99.1 | <u>Press Release dated January 7, 2019.</u> |

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 7, 2019

By: _____ /s/ Robert Alexander
Robert Alexander
President and Chief Executive Officer

Allakos Announces Positive Phase 2 Results in a Cohort of Xolair-Naïve Chronic Spontaneous Urticaria Patients

-- 12 of 13 (92%) patients achieved a complete response --

-- Results from 3 additional cohorts expected in the first quarter of 2019 --

REDWOOD CITY, Calif., January 7, 2019 – Allakos Inc. (NASDAQ:ALLK), a biotechnology company developing AK002 for the treatment of eosinophil and mast cell related diseases, today announced positive top-line results for the Xolair-naïve chronic spontaneous urticaria (CSU) cohort from its Phase 2 study. The study is being conducted at 4 sites in the U.S. and Germany. The principle investigator is Dr. Marcus Maurer, MD, Professor of Dermatology and Allergy at Charité University in Berlin.

The Xolair-naïve chronic spontaneous urticaria cohort enrolled 13 patients with uncontrolled urticaria despite treatment with H¹ antihistamines at doses of up to 4 times the labeled dosage. Antihistamine medication was maintained throughout the screening period and during the study. Baseline symptom scores, as measured by Urticaria Control Test (UCT) and Urticaria Activity Score (UAS7)* 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 6 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 for a total of 6 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; additional results from the study will be presented at an upcoming medical conference.

| | Baseline | Week 22 |
|--------------------------|----------|----------|
| Average UCT Score | 3.2 | 14.2 |
| UCT Complete Response | - | 12 (92%) |
| UCT Partial Response | - | 0 (0%) |
| UCT No Response | - | 1 (8%) |
| Average UAS7 Score | 18.5 | 4.6 |
| Proportion with UAS7 ≤ 6 | 0% | 8 (62%) |

*UCT and UAS7 are established patient-reported outcome scales for assessing urticaria control and measuring key symptoms. UCT is a scale between 0 and 16, with higher scores indicating greater urticaria control. UAS7 is a scale between 0 and 42, with lower scores indicating improvement of symptoms. 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.

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.

Data from the three remaining urticaria cohorts (dermatographic urticaria, cholinergic urticaria, and patients with chronic spontaneous urticaria who failed to respond to treatment with Xolair) are expected in the first quarter of 2019.

“We are very excited about the data from the Xolair Naïve cohort. AK002 appears to be quite active in these patients as evidenced by the high complete response rate. These data also provide strong evidence that AK002

is active against mast cells in addition to its proven activity against eosinophils,” said Dr. Marcus Maurer, MD, Professor of Dermatology and Allergy at Charité University in Berlin.

Phase 2 Chronic Urticaria Study

The open label Phase 2 study is being conducted at 4 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 4 times the labeled dosage. Patients were enrolled in 4 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 dermatographic urticaria (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 6 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 6 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 (dermatographic urticaria), or increases in body temperature (cholinergic urticaria). It has been estimated that 0.5 to 1.0% of the U.S. population suffers from a form of chronic urticaria. First-line treatment consists of antihistamines, however a significant number of patients do not receive adequate benefit even at 4 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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