

**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 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)

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.

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

Item 8.01 Other Events

On May 7, 2019, Allakos Inc. (the “Company”) issued a press release announcing positive results with AK002 in patients with severe allergic conjunctivitis. 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

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	<u>Press Release dated May 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: May 7, 2019

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

Allakos Announces Positive Results with AK002 in Patients with Severe Allergic Conjunctivitis

-- Substantial reduction of patient reported symptoms and physician assessed signs and symptoms --

-- Improvements also observed in atopic dermatitis, asthma and allergic rhinitis --

-- Conference call and webcast today at 5:00 pm ET --

REDWOOD CITY, Calif., May 7, 2019 – Allakos Inc. (Nasdaq: ALLK), a biotechnology company developing AK002 for the treatment of eosinophil and mast cell related diseases, today announced positive Phase 1 results in patients with severe allergic conjunctivitis. Patients administered AK002 reported a 78% median improvement in ocular symptoms by Allergic Conjunctivitis Symptom (ACS) Score and a 71% median improvement in physician assessed signs and symptoms using the Ocular Symptom Score (OSS). In addition, patients suffering from comorbid atopic dermatitis, asthma and allergic rhinitis, despite treatment with currently available therapies, reported improvements in their symptoms while receiving AK002.

“Patients receiving AK002 had a dramatic reduction in allergic conjunctivitis signs and symptoms, including resolution of eyelid papillae. The results are exciting because severe allergic conjunctivitis is a sight-threatening disease with no safe chronic treatment options,” said principal investigator of the study, Dr. C. Stephen Foster, M.D., Professor of Ophthalmology at Harvard Medical School. “Many patients with allergic conjunctivitis also suffer from other atopic conditions like asthma, atopic dermatitis and rhinitis, and AK002 not only improved allergic conjunctivitis but also had a dramatic impact on these comorbid atopic conditions.”

Phase 1 Study Design

This open-label, multi-dose, 6-month, Phase 1 trial of AK002 enrolled 29 patients with severe allergic conjunctivitis requiring steroid treatment, consisting of 13 patients with atopic keratoconjunctivitis, 16 patients with perennial allergic conjunctivitis, and one patient with vernal keratoconjunctivitis. Patients received a 0.3 mg/kg dose of AK002 for the first month, followed by a 1 mg/kg dose the next month, then monthly doses of 1 or 3 mg/kg for four additional months. Disease symptoms were reported by patients using a daily ACS questionnaire and disease signs and symptoms were assessed by investigators monthly using the OSS. Patients with comorbid asthma, atopic dermatitis and rhinitis also reported severity of these diseases using a zero to 10 point daily global severity questionnaire.

Data are presented below; more detailed results from the study will be presented during the conference call being held today and at an upcoming medical conference.

ACS Symptom (N=29)	Patient Assessed Median Change from Baseline to Weeks 21 to 22
Itching	-75%
Light Sensitivity	-57%
Eye Pain	-75%
Foreign Body Sensation	-80%
Watering Eyes	-76%

OSS Symptom (N=29)	Investigator Assessed Median Change from Baseline to Day 140
Itching	-67%
Redness	-67%
Tearing	-50%
Chemosis	-100%

Comorbid Condition	Patient Assessed Change in Median Global Severity from Baseline to Weeks 21 to 22
Asthma (N = 9)	-72%
Atopic Dermatitis (N = 11)	-65%
Rhinitis (N = 11)	-69%

Similar improvements in allergic conjunctivitis symptoms were observed across all three disease subtypes of atopic keratoconjunctivitis (AKC), perennial allergic conjunctivitis (PAC), and vernal keratoconjunctivitis (VKC). AK002 was generally well tolerated. The most common adverse event was mild to moderate infusion-related reactions (flushing, feeling of warmth, headache, nausea, dizziness) which occurred mostly during the first infusion.

AK002 has been tested in four clinical studies. In these studies, AK002 eliminated blood eosinophils and improved disease symptoms in patients with chronic urticaria, severe allergic conjunctivitis, and indolent systemic mastocytosis.

Conference Call

The Company will host a conference call and webcast today at 5:00 p.m. Eastern Time / 2:00 p.m. Pacific Time. To participate by telephone, please dial 1-888-882-4478 (domestic) or 323-794-2590 (international). The conference ID number is 1381640. A live and archived audio webcast can be accessed through the Investors section of the Company's website at <https://www.allakos.com/>. The archived audio webcast will remain available on the Company's website for 30 days following the conference call.

About Severe Allergic Conjunctivitis

Severe allergic conjunctivitis, including atopic keratoconjunctivitis, perennial allergic conjunctivitis, and vernal keratoconjunctivitis, is a group of a severe ocular disorders resulting from allergic inflammation of the conjunctiva (tissue lining the eye and eyelids). Patients with severe allergic conjunctivitis suffer from persistent severe ocular pain, itching, photophobia (sensitivity to light), foreign body sensation, watering eyes, redness, swelling and the formation of papillae and can experience loss of vision. First-line therapy consists of topical steroid treatment, however steroid use is limited by serious side effects such as glaucoma and cataract formation when used chronically. Patients with severe allergic conjunctivitis also often suffer from other atopic conditions such as asthma, atopic dermatitis and rhinitis. Approximately 50,000 to 150,000 patients in the United States have severe AKC, VKC or PAC requiring steroid treatment and could be candidates for treatment 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. AK002 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. AK002 has been tested in four clinical studies. In these studies, AK002 eliminated blood eosinophils and improved disease symptoms in patients with chronic urticaria, severe allergic conjunctivitis, and indolent systemic mastocytosis. AK002 is currently being tested in a double-blind, placebo-controlled Phase 2 trial for the treatment of eosinophilic gastritis and eosinophilic gastroenteritis. 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' Form 10-K filed with the SEC on March 14, 2019 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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