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)
February 19, 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 February 19, 2019, Allakos Inc. (the "Company") issued a press release announcing positive multiple dose Phase 1 results in patients with indolent systemic mastocytosis. 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 February 19, 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: February 19, 2019

By: /s/ Robert Alexander

Robert Alexander
President and Chief Executive Officer

Exhibit 99.1

Allakos Announces Positive Phase 1 Results with AK002 in Indolent Systemic Mastocytosis

-- AK002 has now shown clinical activity in multiple mast cell diseases --

REDWOOD CITY, Calif., February 19, 2019 – Allakos Inc. (NASDAQ: ALLK), a biotechnology company developing AK002 for the treatment of eosinophil and mast cell related diseases, today announced positive multiple dose Phase 1 results in patients with indolent systemic mastocytosis (ISM), a debilitating disorder caused by the release of inflammatory mediators from mast cells.

The multiple dose portion of the Phase 1 study enrolled 11 patients with ISM who had an unsatisfactory response to antihistamine and steroid treatment. Patients were enrolled in two cohorts and received open label AK002 doses of 1 mg/kg monthly for 6 months (cohort 9) or 1 mg/kg for the first month, followed by monthly doses of 3 to 10 mg/kg for 5 additional doses (cohort 10). Symptoms were collected daily using three ISM questionnaires: Mastocytosis Questionnaire (MSQ), Mastocytosis activity and symptom severity questionnaire (MAS2), and Mastocytosis Quality of Life questionnaire (MC-QoL). Baseline scores were collected over 14 to 28 days and compared to scores at Weeks 21 to 22, two weeks after the final AK002 dose.

“AK002 produced clinically meaningful improvements in symptoms and improved quality of life measures in patients with ISM. These results are quite exciting because there are no approved treatments for patients with this difficult to treat disease,” said principal investigator of the study, Dr. Marcus Maurer, M.D., Professor of Dermatology and Allergy at Charité University in Berlin.

Data for the combined cohorts are presented below; more detailed results from the study will be presented at an upcoming medical conference.

MSQ Symptom (N=8) *	**Median Change from Baseline at Weeks 21 to 22**
Hives	-56%
Flushing (#)	-38%
Abdominal Pain	-46%
Diarrhea	-60%
Itching	-49%
Headache	-50%
Fatigue	-47%
Difficulty Concentrating	-59%
Muscle Pain	-27%
Joint Pain	-26%

*The MSQ was not available for use in 3 patients

MAS2 Symptom (N=11)	Median Change from Baseline at Weeks 21 to 22
Itching	-53%
Hives	-59%
Flushing	-57%
Abdominal Pain	-84%
Diarrhea	-72%
Headache	-57%
Fatigue	-22%
Difficulty Concentrating	-30%
Bone-Joint-Muscle Pain	-22%

MC-QoL Domain (N=11)	Median Change from Baseline at Weeks 21 to 22
Symptoms	-39%
Social Life / Functioning	-42%
Emotions	-57%
Skin	-44%

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.

These results are consistent with the symptom improvements reported in the single ascending dose Phase 1 ISM study. In the single dose study, 13 patients received single escalating doses of 0.0003 to 1.0 mg/kg, including three patients receiving 0.3 mg/kg and three patients receiving 1.0 mg/kg of AK002. Five out of six patients receiving 0.3 or 1.0 mg/kg reported to the study investigators that they had improvements in symptoms, including diarrhea, abdominal pain, fatigue, pruritus, difficulty concentrating and headaches.

About Indolent Systemic Mastocytosis
Indolent systemic mastocytosis (ISM) is a disorder caused by increased numbers and activation of mast cells throughout the body. The most common areas affected are the skin, gastrointestinal tract, musculoskeletal system and central nervous system. The symptoms of ISM are caused by the increased release of mast cell mediators in tissue and include pruritus, flushing, headache, cognitive impairment, fatigue, diarrhea, gastrointestinal cramps, hypotension and skin lesions, as well as an increased risk for osteoporosis and anaphylaxis, which in some cases can be life threatening. ISM affects approximately 30,000 people in the United States. There are no approved therapies for the treatment of ISM. Treatment options include antihistamines and/or corticosteroids, although most patients typically continue to experience significant symptoms and disease burden even while on these medications. AK002 has received orphan drug designation from the European Medicines Agency for the treatment of ISM.

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 phase 1 studies in healthy volunteers, indolent systemic mastocytosis, and a

Phase 2 trial in patients with chronic urticaria. AK002 demonstrated pharmacodynamic activity in trials and, in the trials involving patients with chronic urticaria and 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 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.

Investor Contact:
Adam Tomasi, COO, CFO
ir@allakos.com

Media Contact:
Denise Powell
denise@redhousecomms.com