Aimmune Therapeutics, Inc.
Form 8-K
March 25, 2019

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): March 25, 2019

AIMMUNE THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-37519**	**45-2748244**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification Number)**

8000 Marina Blvd, Suite 300

Brisbane, CA 94005

(Address of principal executive offices, including Zip Code)

Registrant s telephone number, including area code: (650) 614-5220

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 Instructions 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 7.01 Regulation FD Disclosure.

On March 25, 2019, Aimmune Therapeutics, Inc. (Aimmune or the Company) issued a press release announcing the topline results of its Phase 3 European clinical trial of AR101 for the treatment of peanut allergy, known as ARTEMIS (**AR**101 **T**rial in **E**urope **M**easuring oral **I**mmunotherapy **S**uccess) (the Press Release). A copy of the Press Release is furnished as Exhibit 99.1 to this Current Report and is incorporated herein by reference.

The Company is also hosting an investor conference call at 8:30 AM PT (8:00 AM ET) on Monday, March 25, 2019 to discuss the topline results from the Company s ARTEMIS study of AR101. Conference call information is as follows:

Conference Call Numbers 1-877-497-1438 (domestic) or 1-262-558-6296 (international); Conference ID# 5157603

The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibits 99.1 and 99.2, shall not be deemed filed for purposes of Section 18 of the Securities Act of 1934, as amended (the Exchange Act), or otherwise subject to the liabilities of that Section, or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

On March 25, 2019, Aimmune announced that its Phase 3 European clinical trial of AR101 for the treatment of peanut allergy, known as ARTEMIS, met its primary efficacy endpoint. Topline data show that the proportion of AR101-treated patients who tolerated a 1,000-mg dose of peanut protein (2,043 mg cumulative) in a blinded exit challenge after approximately nine months of AR101 treatment was significantly higher ($p<0.00001$) than in the placebo group. Specifically, the median tolerated dose of peanut protein for AR101-treated patients improved 100-fold, from 10 mg at baseline to 1,000 mg at exit. The trial also greatly exceeded a 15% lower-bound of the 95% confidence interval (CI) of the difference between treatment arms for all endpoints.

In addition, the safety profile and completion rate observed in ARTEMIS are consistent with the results seen in previous AR101 clinical trials. Notably, no cases of anaphylaxis or of eosinophilic esophagitis (EoE) were observed. Aimmune plans to present full results in an oral presentation at the European Academy of Allergy and Clinical Immunology (EAACI) Congress in early June.

The randomized, double-blind, placebo-controlled Phase 3 ARTEMIS clinical trial enrolled 175 children and adolescents ages 4 to 17 from 18 sites in France, Germany, Ireland, Italy, Spain, Sweden and the United Kingdom. Patients underwent approximately six months of dose escalation and then three months at a daily therapeutic dose of AR101 at 300 mg or placebo, followed by an exit double-blind, placebo-controlled food challenge. The primary efficacy endpoint was patients ability to tolerate a 1,000-mg single dose of peanut protein, the equivalent of approximately three to four peanut kernels (2,043 mg cumulative, equivalent to seven or eight peanut kernels).

Based on the results from ARTEMIS, Aimmune intends to submit a marketing authorization application (MAA) for AR101 to the European Medicines Agency (EMA) in mid-2019.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	**Description**
99.1	Press release dated March 25, 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.

AIMMUNE THERAPEUTICS, INC.

Date: March 25, 2019

By: /s/ Douglas T. Sheehy
Douglas T. Sheehy
General Counsel and Secretary