

Aimmune Therapeutics, Inc.  
Form 8-K  
September 20, 2016

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): September 20, 2016

AIMMUNE THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware                      001-37519      45-2748244  
(State or other jurisdiction) (Commission) (IRS Employer)

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of incorporation)

File Number) 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:

☐ 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))

Item 7.01 Regulation FD Disclosure.

On September 20, 2016, Aimmune Therapeutics, Inc. (“Aimmune” or the “Company”) issued a press release announcing completion of North American enrollment in its ongoing Phase 3 PALISADE trial of AR101 (the “Press Release”). The Company also announced that RAMSES (Real-World AR101 Market-Supporting Experience Study), a new clinical study designed to bolster real-world experience with AR101, will begin enrolling patients in the first quarter of 2017.

The Company will host an investor conference call at 2:00 PM PT (5:00 PM ET) on Tuesday, September 20, 2016 to discuss the announced AR101 clinical program updates. Conference call information is as follows:

Conference Call Numbers – 1-877-497-1438 (domestic) or 1-262-558-6296 (international); Conference ID# 85421977

The information in this Item 7.01 of this Current Report on Form 8-K 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 September 20, 2016, the Company issued the Press Release. The full text of the Press Release is filed as Exhibit 99.1 hereto and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

Reference is made to the Exhibit Index attached hereto.

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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: September 20, 2016 By: /s/ Warren L. DeSouza  
Warren L. DeSouza  
Chief Financial Officer

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EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release titled, “Aimmune Therapeutics Completes and Exceeds North American Enrollment Target Ahead of Schedule in Phase 3 PALISADE Trial of AR101 for the Treatment of Peanut Allergy; Company Accelerates Plans for Real-World Experience Study in the U.S.” dated September 20, 2016.