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 13, 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. ☐

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	**AIMT**	**NASDAQ**

Item 8.01 Other Events.

On September 13, 2019, Aimmune Therapeutics, Inc. issued a press release announcing the results of the previously announced meeting of the Allergenic Products Advisory Committee (APAC) convened by the U.S. Food and Drug Administration (FDA) held on September 13, 2019. The full text of the press release is filed as Exhibit 99.1 hereto and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press release dated September 13, 2019
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 13, 2019

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

Exhibit 99.1

FOR IMMEDIATE RELEASE

FDA ALLERGENIC PRODUCTS ADVISORY COMMITTEE VOTES TO SUPPORT THE USE OF AIMMUNE'S PALFORZIA™ (AR101) FOR PEANUT ALLERGY

BRISBANE, Calif. – September 13, 2019 – Aimmune Therapeutics, Inc. (Nasdaq: AIMT), a biopharmaceutical company developing treatments for potentially life-threatening food allergies, today announced that the Allergenic Products Advisory Committee (APAC) convened by the U.S. Food and Drug Administration (FDA) voted to support the use of AR101 (proposed trade name PALFORZIA™) in children and teens with peanut allergy. PALFORZIA is a complex, biologic oral immunotherapy (OIT) candidate designed to reduce the incidence and severity of allergic reactions, including anaphylaxis, after accidental exposure to peanut in patients aged 4 through 17 years with a confirmed diagnosis of peanut allergy.

The APAC voted 7 to 2 that the efficacy data and 8 to 1 that the safety data, in conjunction with additional safeguards, are adequate to support the use of PALFORZIA.

Peanut allergy is one of the most common food allergies, affecting more than 1.6 million children and teens in the U.S.[i] It can be a chronic and life-long condition, and reactions to peanut are severe and potentially life-threatening.[ii] For peanut-allergic individuals, the threat of a severe reaction interferes with their quality of life and has a daily effect on their families.

"We are very pleased that APAC voted in favor of PALFORZIA. This is an important day for the children, teens and their families who live with the profound daily impact of peanut allergy. We look forward to continuing to work with the FDA as we move towards a potential approval of PALFORZIA," said Jayson Dallas, M.D., President and Chief Executive Officer of Aimmune. "We are immensely grateful to the entire food allergy community for helping us bring PALFORZIA one step closer to becoming the first FDA-approved treatment for any food allergy."

As part of Aimmune's original Biologics License Application (BLA) submission, the Company proposed a number of risk management measures in line with today's Advisory Committee discussion which include: the requirement that the initial dose escalation and first dose of each dose-escalation level be administered in a facility equipped to treat systemic allergic reactions; documentation that patients have a prescription for injectable epinephrine prior to initiation of PALFORZIA; distribution of therapy through specialty pharmacies; and purposefully designed packaging so patients only receive their appropriate dose. Consistent with immunotherapies indicated to treat allergic conditions, Aimmune also proposed a Black Box warning within the product labeling in the original BLA submission.

"Patient safety has been central to us since the beginning of the PALFORZIA development program. We are gratified to be aligned with FDA in our focus on patient safety," added Dr. Dallas. "We look forward to working with the Agency to finalize our proposals, which we believe will support the safe and appropriate use of PALFORZIA."

Aimmune's BLA seeking approval for PALFORZIA for the treatment of children and adolescents with peanut allergy currently is under review by the FDA, with a review action due date of late January 2020. The FDA granted PALFORZIA Fast Track Designation in September 2014 and Breakthrough Therapy Designation in June 2015 for peanut-allergic children and adolescents aged 4 to 17. In addition, the European Medicines Agency (EMA) is reviewing Aimmune's Marketing Authorization Application (MAA) for PALFORZIA, which Aimmune submitted in June 2019. The FDA and EMA have conditionally accepted PALFORZIA as the trade name for AR101.

The BLA includes extensive clinical data from the largest and only phase 3 clinical trials to meet their primary endpoints in children and teens with peanut allergy, with over 1,000 patients enrolled. The results demonstrated that PALFORZIA treatment resulted in a significant increase in the amount of peanut protein tolerated compared to placebo, and that PALFORZIA-treated patients could expect fewer and less severe reactions to accidental peanut exposures, compared to placebo-treated patients, and significantly reduces the incidence and severity of allergic reactions, including anaphylaxis, after accidental exposure to peanut.

About PALFORZIA™

PALFORZIA™ is an investigational, peanut-derived, biologic drug candidate for use in oral immunotherapy in patients with peanut allergy. The drug candidate, which is manufactured in accordance with current Good Manufacturing Practices (cGMP), delivers a daily dose of peanut protein with a consistent protein profile, analyzed to ensure reliable major allergen content. The amount of active ingredient in each PALFORZIA capsule is controlled to ensure minimal variability of allergen content across doses of a given strength. PALFORZIA is administered as an oral powder in graduated doses in pull-apart capsules or foil-laminate sachets. The contents are mixed thoroughly with a few spoonfuls of age-appropriate, unheated food of the patient's choice.

About Aimmune

Aimmune Therapeutics, Inc., is a biopharmaceutical company developing oral treatments for potentially life-threatening food allergies. The Company's **C**haracterized **O**ral **D**esensitization **I**mmuno**T**herapy (CODIT™) approach is intended to provide meaningful levels of protection against allergic reactions resulting from exposure to food allergens by desensitizing patients with defined, precise amounts of key allergens. Aimmune's first, investigational, complex biologic product candidate, PALFORZIA™ (AR101), is being developed as a treatment to reduce the frequency and severity of adverse events following exposure to peanut. The BLA for PALFORZIA is under review by the FDA, which granted PALFORZIA Breakthrough Therapy Designation in 2015 for the desensitization of peanut-allergic patients 4 to 17 years of age. The European Medicines Agency (EMA) is reviewing Aimmune's Marketing Authorization Application (MAA) for PALFORZIA, which Aimmune submitted in June 2019. Aimmune initiated a randomized phase 2 clinical trial of its second investigational, complex biologic product, AR201, for the treatment of egg allergy in August 2019. For more information, please see www.aimmune.com.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding: Aimmune's expectations regarding the potential benefits of PALFORZIA; Aimmune's expectations regarding the timing of potential approval of the BLA for PALFORZIA; Aimmune's expectations regarding the potential risk management measures for PALFORZIA; and Aimmune's expectations regarding potential applications of the CODIT™ approach to treating potentially life-threatening food allergies. Risks and uncertainties that contribute to the uncertain nature of the forward-looking statements include: the expectation that Aimmune will need additional funds to finance its operations; the unpredictability of the regulatory process; the possibility that Aimmune's or any of its collaborative partners' clinical trials will not be successful; Aimmune's dependence on the success of PALFORZIA; Aimmune's reliance on third parties for the manufacture of Aimmune's product candidates; possible regulatory developments in the United States and foreign countries; and Aimmune's ability to attract and retain senior management personnel. These and other risks and uncertainties are described more fully in Aimmune's most recent filings with the Securities and Exchange Commission, including its Quarterly Report on Form 10-Q for the quarter ended June 30, 2019. All forward-looking statements contained in this press release speak only as of the date on which they were made. Aimmune undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

This press release concerns AR101 and AR201, product candidates that are under clinical investigation. Neither AR101 nor AR201 has been approved for marketing by the FDA or the EMA. AR101 and AR201 are currently limited to investigational use, and no representation is made as to their safety or effectiveness for the purposes for which they are being investigated.

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i Aimmune market research.

ii American College of Allergy, Asthma & Immunology. Available here: https://acaai.org/allergies/types/food-allergies/types-food-allergy/peanut-allergy. Accessed May 15, 2019.