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): January 8, 2018

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 8.01 Other Events.

On January 8, 2018, Aimmune Therapeutics, Inc., a Delaware corporation, issued a press release announcing its 2018 outlook, including the expected timing of the release of data from its pivotal Phase 3 PALISADE trial of AR101 for peanut allergy. 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.

Exhibit No.	Description
99.1	Press Release dated as of January 8, 2018

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: January 8, 2018

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

Aimmune Therapeutics Announces 2018 Outlook, Including Upcoming Data from Pivotal Phase 3 PALISADE Trial of AR101 for Peanut Allergy

— PALISADE Completed in 2017; Topline Results Anticipated in February —

— Late-Breaking Abstract Presentation at the 2018 American Academy of Allergy, Asthma & Immunology–World Allergy Organization Joint Congress in March —

— PALISADE Follow-On Study, ARC004, Fully Enrolled —

— RAMSES Real-World Safety Study in North America Fully Enrolled —

— AR101 BLA Submission Expected at the End of 2018—

BRISBANE, California, January 8, 2018 — Aimmune Therapeutics, Inc. (Nasdaq:AIMT), a biopharmaceutical company developing treatments for potentially life-threatening food allergies, today announced its outlook for the coming year, including its plans to report topline results in February from its pivotal Phase 3 PALISADE trial of AR101 for peanut allergy, following the completion of the 554-subject trial in late 2017. AR101 is Aimmune's investigational biologic oral immunotherapy (OIT) for desensitization of patients with peanut allergy.

"The last PALISADE food challenge and final rollover into ARC004 in December capped a year of fantastic progress for Aimmune," said Aimmune CEO Stephen Dilly, M.B.B.S., Ph.D. "Thanks to the dedication of our employees, investigators, and patients, we accomplished what we laid out at the beginning of 2017 — the completion of PALISADE, the opening and qualification of our commercial manufacturing facility, and the initiation of our additional AR101 Phase 3 studies amidst high patient demand that exceeded our projections. We also saw further confirmation of our position as a partner of choice, as we formed a clinical collaboration with Regeneron and Sanofi to study AR101 treatment with adjunctive dupilumab, and we continued to benefit from our important relationships with Nestlé Health Science and Golden Peanut and Tree Nuts.

"We're looking forward to even more progress in 2018, especially sharing the topline results from our pivotal Phase 3 PALISADE trial of AR101 in February," said Dr. Dilly. "We're hopeful that we'll see data that strongly support the final steps toward a viable treatment for peanut allergy, and we're eager to apply our expertise to programs for additional allergens."

AAAAI-WAO Joint Congress Late-Breaking Oral Abstract Presentation
Following expected topline results in February, Aimmune will report more detailed data from the PALISADE trial in a late-breaking oral abstract presentation on Sunday, March 4, 2018, at the American Academy of Allergy, Asthma & Immunology–World Allergy Organization Joint Congress in Orlando.

Progress in RAMSES, ARTEMIS and ARC004 Phase 3 AR101 Studies
Aimmune anticipates milestones in its additional Phase 3 studies of AR101 throughout 2018. The RAMSES (ARC007) trial, taking place in the United States and Canada and designed to illuminate real-world patient and allergist experiences with AR101, exceeded enrollment projections. Aimmune expects data from RAMSES in the second half of 2018. The ARTEMIS (ARC010) trial, a dedicated European study of AR101, is on track to complete enrollment in the first quarter of 2018, and Aimmune expects data from ARTEMIS in early 2019. To support regulatory filings, Aimmune also plans a data readout from the PALISADE follow-on trial, ARC004, in the third quarter of 2018.

Plans for AR101 Regulatory Filings
Aimmune continues to expect to file a Biologics License Application (BLA) for AR101 with the U.S. Food and Drug Administration (FDA) at the end of 2018. Soon afterward, the company plans to begin a similar process in Europe, with the intention of filing a Marketing Authorisation Application (MAA) with the European Medicines Agency (EMA) in the first half of 2019.

Additional Peanut Allergy Trials and Food Allergy Programs
Aimmune's 2018 plans also include the initiation of the ARC005 clinical trial of AR101 for peanut allergy in young children ages 6–48 months, and the initiation, with Regeneron and Sanofi, of a Phase 2 clinical trial of AR101 and adjunctive dupilumab. Aimmune also expects to file an investigational new drug application (IND) for its egg allergy program in 2018 and continue work toward filing an IND for walnut allergy in 2019.

Financial Outlook
Aimmune ended 2017 in a strong financial position with approximately $182 million in cash, cash equivalents and investments as of December 31, 2017.

About Aimmune's AR101 Phase 3 Development Program
AR101 is an investigational biologic currently in Phase 3 clinical trials for the treatment of peanut allergy. AR101 has received U.S. Food and Drug Administration (FDA) Fast Track Designation, as well as FDA Breakthrough Therapy Designation for peanut allergy patients ages 4–17. Aimmune has completed its pivotal Phase 3 clinical trial of AR101, PALISADE (**P**eanut **AL**lergy Oral **I**mmunotherapy **S**tudy of **A**R101 for

Desensitization in Children and Adults), which enrolled 554 subjects ages 4–49 in the United States, Canada, and eight countries in Europe. Aimmune's open-label follow-on study to PALISADE, ARC004, which allowed eligible PALISADE AR101 subjects to roll over to additional maintenance therapy and PALISADE placebo subjects to cross over to AR101 treatment, has completed enrollment and is ongoing. Aimmune's real-world experience safety trial of AR101, RAMSES (**R**eal-World **A**R101 **M**arket-**S**upporting **E**xperience **S**tudy in Peanut Allergic Children Ages 4–17 Years), taking place in the United States and Canada, has competed enrollment. Aimmune's European Phase 3 efficacy trial of AR101, ARTEMIS (**AR**101 **T**rial in **E**urope **M**easuring Oral **I**mmunotherapy **S**uccess), designed with a higher efficacy bar and a shorter maintenance period than in PALISADE, remains open to enrollment. Aimmune expects to file a BLA with the FDA based on data from the PALISADE, ARC004, and RAMSES trials and an MAA with the EMA based on data from the PALISADE, ARC004, RAMSES and ARTEMIS trials.

About Aimmune Therapeutics

Aimmune Therapeutics, Inc., is a clinical-stage biopharmaceutical company developing treatments for potentially life-threatening food allergies. The company's Characterized Oral Desensitization ImmunoTherapy (CODIT™) approach is intended to achieve meaningful levels of protection by desensitizing patients with defined, precise amounts of key allergens. Aimmune's first investigational biologic product using CODIT™, AR101 for the treatment of peanut allergy, has received the FDA's Breakthrough Therapy Designation for the desensitization of peanut-allergic patients 4–17 years of age and is currently being evaluated in Phase 3 clinical trials. 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 availability of topline data from the PALISADE trial of AR101 in February 2018 and additional data in March 2018 at AAAAI-WAO; Aimmune's expectations regarding its RAMSES, ARTEMIS and ARC004 trials of AR101, including the timing of the completion of such trials and the availability of data from such trials; Aimmune's ability to develop and advance additional product candidates into and successfully complete clinical trials; Aimmune's expectations regarding the timing of potential regulatory filings; Aimmune's expectations regarding the potential benefits of AR101; and Aimmune's expectations regarding potential applications of the CODIT™ approach to treating 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 company's ability to initiate and/or complete clinical trials; the unpredictability of the regulatory process; the possibility that the results of early clinical trials may not be predictive of future results; the possibility that Aimmune's clinical trials will not be successful; Aimmune's dependence on the success of AR101; possible regulatory developments in the United States and foreign countries; and the company'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 September 30, 2017. 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 a product that is under clinical investigation and that has not yet been approved for marketing by the FDA or the EMA. It is currently limited to investigational use, and no representation is made as to its safety or effectiveness for the purposes for which it is being investigated.

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