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 31, 2020

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))

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**

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 31, 2020, Aimmune Therapeutics, Inc. ("Aimmune" or the "Company") issued a press release announcing that the U.S. Food and Drug Administration had approved PALFORZIA™ (Peanut (*Arachis hypogaea*) Allergen Powder-dnfp). PALFORZIA is the first approved treatment for patients with peanut allergy. PALFORZIA is an oral immunotherapy indicated for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut. PALFORZIA is approved for use in patients with a confirmed diagnosis of peanut allergy. Initial dose escalation may be administered to patients aged 4 through 17 years. Up-dosing and maintenance may be continued in patients 4 years of age and older. PALFORZIA is to be used in conjunction with a peanut-avoidant diet. The full text of the press release is filed as Exhibit 99.1 hereto and incorporated herein by reference.

PALFORZIA is available only through a Risk Evaluation and Mitigation Strategy ("REMS"). Requirements of the REMS include: the prescribing physician and patient must be enrolled in the REMS prior to initiation of treatment; the initial dose escalation and the first dose of each up-dosing level must be administered in a certified healthcare setting; epinephrine must always be immediately available to patients; and pharmacies/distributors must be certified with the REMS and dispense PALFORZIA only to certified healthcare settings or to patients who are enrolled in the REMS. Consistent with approved immunotherapies indicated to treat allergic conditions, the Prescribing Information for PALFORZIA contains a boxed warning.

The wholesale acquisition cost for PALFORZIA in the United States will be $890 per month, and Aimmune plans to offer a patient co-pay program that could reduce the patient's out-of-pocket costs to as low as $20 per month. This price will be consistent regardless of whether the patient is in the up-dosing or maintenance phase of treatment. Aimmune believes that this flat pricing model will provide predictability for both patients and payers, and that this price reflects the value that PALFORZIA offers as the first FDA-approved biologic therapy for children and adolescents with peanut allergy. Aimmune also plans to offer a patient assistance program, which will provide drug at no cost for those eligible patients who do not have coverage by either a commercial plan or a government-sponsored plan, such as Medicaid.

Cautionary note on forward-looking statements

Statements contained in this report 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 potential commercial launch of PALFORZIA in the United States; Aimmune's expectations for the wholesale acquisition cost of PALFORZIA; and Aimmune's plans to offer a co-pay program and a patient assistance program for patients. 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; Aimmune's dependence on the success of PALFORZIA; Aimmune's ability to build a commercial field organization and distribution network; the degree of acceptance of PALFORZIA among physicians, patients, healthcare payors, patient advocacy groups and the general medical community; Aimmune's ability to obtain favorable coverage and reimbursement from third-party payors for PALFORZIA; Aimmune's reliance on third parties for the manufacture of PALFORZIA; and Aimmune's ability to implement and comply with the REMS for PALFORZIA. 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, 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated January 31, 2020
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: January 31, 2020

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

FDA Approves Aimmune's PALFORZIA™ as First Treatment for Peanut Allergy

- *More than 1.6 Million Children and Teens in the U.S. are Allergic to Peanuts*[i,ii]
- *Company to Host Conference Call Today at 5:30 p.m. ET*

BRISBANE, Calif. – January 31, 2020 – Aimmune Therapeutics, Inc. (Nasdaq: AIMT), a biopharmaceutical company developing and commercializing treatments for potentially life-threatening food allergies, today announced that the U.S. Food and Drug Administration (FDA) approved PALFORZIA™ (Peanut (*Arachis hypogaea*) Allergen Powder-dnfp). PALFORZIA is the first approved treatment for patients with peanut allergy. It is an oral immunotherapy indicated for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut. PALFORZIA is approved for use in patients with a confirmed diagnosis of peanut allergy. Initial dose escalation may be administered to patients aged 4 through 17 years. Up-dosing and maintenance may be continued in patients 4 years of age and older. PALFORZIA is to be used in conjunction with a peanut-avoidant diet. PALFORZIA is not indicated for the emergency treatment of allergic reactions, including anaphylaxis.

"This is a defining moment for the peanut allergy community and for Aimmune Therapeutics, and we are excited to bring the first FDA-approved treatment for peanut allergy to patients and their families," said Jayson Dallas, M.D., President and CEO of Aimmune Therapeutics. "Our commercial field team is ready to begin engaging with allergists to help them prepare to safely incorporate PALFORZIA into their practices and, with approval in hand, our payer team can also immediately begin work to secure formulary access to PALFORZIA. We view this approval as just the beginning for Aimmune, and it underscores our continued commitment to bringing innovative treatments to people with potentially life-threatening food allergies."

"Not only is PALFORZIA the first approved therapy for peanut allergy, but it is the first approved therapy for any food allergy," said Daniel Adelman, M.D., Chief Medical Officer of Aimmune Therapeutics. "We truly appreciate the efforts of the peanut allergy community who contributed to the development of PALFORZIA – including the more than 1,200 patients and their families who participated in our clinical trials, the study investigators and their staff, the advocacy community, and our dedicated employees – all of whom have helped us develop and deliver this first-of-its kind therapy."

Peanut allergy is one of the most common food allergies in the world, affecting more than 1.6 million children and teens in the United States alone.[i,ii] It can be a chronic and life-long condition, and reactions to peanut can range from mild to potentially life-threatening,[iii] with one in five peanut-allergic patients visiting emergency rooms each year due to accidental exposures.[iv]

“Peanut allergy is more common now than ever before and has become a serious public health concern. The food allergy community has been eagerly awaiting an FDA-approved treatment that can help mitigate allergic reactions to peanut and, as allergists, we want nothing more than to have a treatment option to offer our patients that has demonstrated both the safety and efficacy to truly impact the lives of patients who live with peanut allergy,” said Christina Ciaccio, M.D., Associate Professor of Pediatrics and Medicine and Chief of Allergy/Immunology and Pediatric Pulmonary Medicine at the University of Chicago Medical Center and Biological Sciences. “With today’s approval of PALFORZIA, we can — for the first time — offer children and teens with peanut allergy a proven medicine that employs an established therapeutic approach.”

PALFORZIA is a complex biologic drug used with a structured dosing approach that builds on a century of oral immunotherapy (OIT) research[v] With OIT, the specific allergenic proteins are ingested initially in very small quantities, followed by incrementally increasing amounts, resulting in the ability to mitigate allergic reactions to the allergen over time. PALFORZIA is a rigorously developed, pharmaceutical-grade OIT for peanut allergy with a well-defined allergen profile to assure that every dose, whether 0.5 mg (equivalent to 1/600th of a peanut) or 300 mg, has been prepared and analyzed for consistency.

The Biologics License Application (BLA) for PALFORZIA included efficacy and safety data from seven clinical studies, including the pivotal Phase 3 PALISADE and RAMSES clinical trials. In addition, data from the Phase 2 ARC001 study and the ARC002 open-label follow-on study were included, as well as data from ARC004, ARC008 and ARC011, which are ongoing studies.

PALFORZIA is available only through a Risk Evaluation and Mitigation Strategy (REMS). Requirements of the REMS include: the prescribing physician and patient must be enrolled in the REMS prior to initiation of treatment; the initial dose escalation and the first dose of each up-dosing level must be administered in a certified healthcare setting; epinephrine must always be immediately available to patients; and pharmacies/distributors must be certified with the REMS and dispense PALFORZIA only to certified healthcare settings or to patients who are enrolled in the REMS. Consistent with approved immunotherapies indicated to treat allergic conditions, the Prescribing Information for PALFORZIA contains a boxed warning.

Aimmune will provide resources to patients and families who, upon consultation with their physician, wish to seek treatment with PALFORZIA. These resources will include educational materials, a dedicated call center, a co-pay program for eligible patients, and a Patient Assistance Program to provide PALFORZIA at no cost to eligible patients.

“Peanut allergy carries an overwhelming psychosocial burden that impacts patients and their families daily – peanuts are everywhere, and the threat of a severe reaction related to an accidental peanut exposure dominates families’ daily lives,” said Lisa Gable, Chief

Executive Officer, Food Allergy Research and Education (FARE). “The risk of accidental exposure is real, and we, as a community, have long awaited an option beyond avoiding peanuts alone. As one of the organizations that originally highlighted the need for an FDA-approved oral treatment approach to food allergy back in 2011, we are thrilled with today’s FDA approval of PALFORZIA as it fills a long-standing need in the treatment of peanut allergy.”

Aimmune Therapeutics was founded directly in response to a united call to action by leading stakeholders in food allergy. At an advocacy-sponsored research retreat in 2011 aimed at reaching consensus on the direction of food allergy treatment research, a group of parents of children with severe food allergies, patient advocacy organizations, leading clinical and academic physicians, representatives from government, and members of the pharmaceutical industry recognized the need for a structured approach to OIT and approved treatments. This meeting eventually led to the formation of Aimmune Therapeutics to specifically address that need.

Conference Call Details

In connection with this announcement, Aimmune Therapeutics will host a conference call and webcast today at 5:30 p.m. ET. To access the live call by phone, dial (877) 497-1438 (domestic) or (262) 558-6296 (international) and enter the passcode 2388617. To access a live or recorded webcast of the call, please visit the Investor Relations section of the Aimmune Therapeutics website at www.aimmune.com. The recorded webcast will be available for approximately 30 days following the call.

INDICATION

PALFORZIA is an oral immunotherapy indicated for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut. PALFORZIA is approved for use in patients with a confirmed diagnosis of peanut allergy. Initial Dose Escalation may be administered to patients aged 4 through 17 years. Up-Dosing and Maintenance may be continued in patients 4 years of age and older.

PALFORZIA is to be used in conjunction with a peanut-avoidant diet.

Limitations of Use: Not indicated for the emergency treatment of allergic reactions, including anaphylaxis.

IMPORTANT SAFETY INFORMATION

Boxed WARNING:

PALFORZIA can cause anaphylaxis, which may be life threatening and can occur at any time during PALFORZIA therapy.

Prescribe injectable epinephrine, instruct and train patients on its appropriate use, and instruct patients to seek immediate medical care upon its use.

Do not administer PALFORZIA to patients with uncontrolled asthma.

Dose modifications may be necessary following an anaphylactic reaction.

Observe patients during and after administration of the Initial Dose Escalation and the first dose of eachUp-Dosing level, for at least 60 minutes.

PALFORZIA is available only through a restricted program called the PALFORZIA REMS.

CONTRAINDICATIONS

PALFORZIA is contraindicated in patients with uncontrolled asthma, or with a history of eosinophilic esophagitis and other eosinophilic gastrointestinal disease.

WARNINGS AND PRECAUTIONS

Anaphylaxis

PALFORZIA can cause anaphylaxis, which may be life threatening. PALFORZIA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the PALFORZIA REMS because of the risk of anaphylaxis. Only prescribers, healthcare settings, pharmacies, and patients certified and enrolled in the REMS Program can prescribe, receive, dispense or administer PALFORZIA.

Anaphylaxis has been reported during all phases of PALFORZIA dosing, including Maintenance and in subjects who have undergone recommended Up-Dosing and dose modification procedures.

Do not initiate PALFORZIA treatment in a patient who has had severe or life-threatening anaphylaxis within the previous 60 days. PALFORZIA may not be suitable for patients with certain medical conditions that may reduce the ability to survive anaphylaxis, including but not limited to markedly compromised lung function, severe mast cell disorder, or cardiovascular disease. In addition, PALFORZIA may not be suitable for patients taking medications that can inhibit or potentiate the effects of epinephrine.

All Initial Dose Escalation doses and the first dose of each Up-Dosing level must be administered in a certified health care setting.

Patients may be more likely to experience allergic reactions following PALFORZIA administration in the presence of cofactors such as exercise, hot water exposure, intercurrent illness (e.g., viral infection), or fasting. Other potential cofactors may include menstruation, sleep deprivation, nonsteroidal anti-inflammatory drug use, or uncontrolled asthma. Patients should be proactively counseled about the potential for the increased risk of anaphylaxis in the presence of these cofactors. If possible, adjust the time of dosing to avoid these cofactors. If it is not possible to avoid these cofactors, consider withholding PALFORZIA temporarily.

Asthma

Uncontrolled asthma is a risk factor for a serious outcome, including death, in anaphylaxis. Ensure patients with asthma have their asthma under control prior to initiation of PALFORZIA.

PALFORZIA should be temporarily withheld if the patient is experiencing an acute asthma exacerbation. Following resolution of the exacerbation, resumption of PALFORZIA should be undertaken cautiously. Re-evaluate patients who have recurrent asthma exacerbations and consider discontinuation of PALFORZIA.

Eosinophilic Gastrointestinal Disease

Discontinue PALFORZIA and consider a diagnosis of eosinophilic esophagitis in patients who experience severe or persistent gastrointestinal symptoms, including dysphagia, vomiting, nausea, gastroesophageal reflux, chest pain, or abdominal pain.

Gastrointestinal Adverse Reactions

Gastrointestinal adverse reactions were commonly reported in PALFORZIA-treated subjects, and dose modification should be considered for patients who report these reactions. For severe or persistent gastrointestinal symptoms consider a diagnosis of eosinophilic esophagitis.

ADVERSE REACTIONS

The most common adverse events reported in subjects treated with PALFORZIA (incidence≥ 5% and ≥ 5% than placebo) are abdominal pain, vomiting, nausea, oral pruritus, oral paresthesia, throat irritation, cough, rhinorrhea, sneezing, throat tightness, wheezing, dyspnea, pruritus, urticaria, anaphylactic reaction, and ear pruritus.

Please see full Prescribing Information, including Boxed WARNING, and Medication Guide at www.PALFORZIA.com.

For more information about PALFORZIA, please call 1-844-PALFORZ (1-844-725-3679) or visit www.PALFORZIA.com.

About Aimmune

Aimmune Therapeutics, Inc. is a biopharmaceutical company that aspires to become the global leader in developing curative therapies and solutions for patients with food allergies. With a mission to improve the lives of people with food allergies, Aimmune is developing and commercializing oral treatments for potentially life-threatening food allergies. The Company's Characterized Oral Desensitization ImmunoTherapy (CODIT™) approach is intended to provide meaningful levels of protection against allergic reactions resulting from accidental exposure to food allergens by desensitizing patients with defined, precise amounts of key allergens. Aimmune has one FDA-approved medicine for peanut allergy and other investigational therapies in development to treat other food allergies. For more information, please visit 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 and elements of the potential commercial launch of PALFORZIA; 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; Aimmune's dependence on the success of PALFORZIA; Aimmune's ability to build a commercial field organization and distribution network; the degree of acceptance of PALFORZIA among physicians, patients, healthcare payors, patient advocacy groups and the general medical community; Aimmune's ability to obtain favorable coverage and reimbursement from third-party payors for PALFORZIA; Aimmune's reliance on third parties for the manufacture of PALFORZIA; Aimmune's ability to implement and comply with the REMS for PALFORZIA; 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 September 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 PALFORZIA (AR101), which has been approved for marketing by the FDA in the United States and has not been approved for marketing by the EMA or Swissmedic. AR101 in Europe 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.

PALFORZIA™, AIMMUNE™, AIMMUNE THERAPEUTICS™ and CODIT™ are trademarks of Aimmune Therapeutics, Inc.

Contacts:

Investors:
DeDe Sheel
(917) 834-1494
dsheel@aimmune.com

Media:
Julie Normart
(559) 947-3245
jnormart@w2ogroup.com

Lauren Barbiero
(646) 564-2156
lbarbiero@w2ogroup.com

References

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ii Gupta R, Warren C, Blumenstock J, et al. OR078 The Prevalence of Childhood Food Allergy in the United States: An Update. Ann Allergy Asthma Immunol. 2017;119(5 Suppl): S11.
iii American College of Allergy, Asthma & Immunology. Available here: https://acaai.org/allergies/types/food-allergies/types-food-allergy/peanut-allergy. Accessed December 20, 2019.
iv Gupta RS, Warren CM, Smith BM, et al. The public health impact of parent-reported childhood food allergies in the United States. Pediatrics. 2018;142(6):e20181235.
v As reviewed in Burks, Sampson, Plaut et al. Treatment for Food Allergy.*Journal Allergy Clin Immunol*(2018)