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): February 27, 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, par value $0.0001 per share	AIMT	Nasdaq Global Select Market

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 2.02 Results of Operations and Financial Conditions.

On February 27, 2020, Aimmune Therapeutics, Inc. ("Aimmune" or the "Company") issued a press release announcing its financial results for the quarter and year ended December 31, 2019, and its financial position as of December 31, 2019. The Company will conduct a conference call to review its financial results on February 27, 2020, at 4:30 p.m., Eastern Time. The full text of the press release is furnished as Exhibit 99.1 hereto.

The information in this Item 2.02 of this Form 8-K and the Exhibit 99.1 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section, or incorporated by reference into any filings of the Company made under the Securities Act of 1933, as amended, regardless of any general incorporation language in the filing unless specifically stated so therein.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press release dated February 27, 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: February 27, 2020

By: /s/ Eric H. Bjerkholt
Eric H. Bjerkholt
Chief Financial Officer

Exhibit 99.1

Aimmune Therapeutics Announces Fourth Quarter and Full Year 2019 Financial Results and Provides Recent Operational Highlights

- *Launch underway for FDA-approved PALFORZIA™, the first treatment for peanut allergy*
- *In-licensing of AIMab7195 monoclonal antibody as potential adjunctive treatment with select CODIT™ programs*
- *Pro-forma cash and investments of $443 million*
- *Webcast and conference call today at 4:30 p.m. ET*

BRISBANE, California, February 27, 2020 – Aimmune Therapeutics, Inc. (Nasdaq: AIMT), a biopharmaceutical company developing and commercializing treatments for potentially life-threatening food allergies, today announced financial results for the fourth quarter and full year 2019.

"The FDA approval of PALFORZIA was a defining moment for the peanut allergy community and Aimmune, and a culmination of years of commitment to bring an approved treatment to people with potentially life-threatening peanut allergy. We are thrilled to have achieved the first regulatory approval for a therapy for peanut allergy – in fact, for any food allergy," said Jayson Dallas, M.D., President and CEO of Aimmune Therapeutics. "We are now focused on PALFORZIA launch execution, which is well underway. Our field commercial team is engaging with allergists to help them learn how to safely incorporate PALFORZIA into their practices, and our market access team has begun its work to secure formulary access for PALFORZIA. We are encouraged by the amount of early interest we have received from allergists who want to offer PALFORZIA to their patients. We also are delighted with the funding we received from Nestle Health Science and KKR, which bolster both our commercial and development endeavors, including the addition of AIMab7195 to our pipeline."

PALFORZIA Highlights:

- **FDA approval received**. On January 31, 2020, the U.S. Food and Drug Administration (FDA) approved PALFORZIA [Peanut (*Arachis hypogaea*) Allergen Powder-dnfp], an oral immunotherapy indicated for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut, for use in patients ages 4 through 17 years in conjunction with a peanut-avoidant diet. The treatment is the first approved therapy for any food allergy. 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 four peanut-allergic patients visiting emergency rooms each year due to accidental exposures.[iv] The FDA approval, for the first time, offers children and teens with peanut allergy and their treating physicians a medicine that employs an established therapeutic approach.

- **U.S. launch underway.** Since FDA approval, Aimmune's commercial field force of 80 Practice Account Managers has been actively meeting with allergists and their staff; the market access team has been conducting meetings with payers to discuss formulary status; and the Risk Evaluation and Mitigation Strategy (REMS) website has gone live so allergists and their practices can enroll and become certified to prescribe PALFORZIA.

- **The European Medicines Agency (EMA) and Swissmedic reviews of PALFORZIA are ongoing.** In June 2019, the Company submitted a Marketing Authorization Application (MAA) to the EMA for PALFORZIA and expects a standard overall review period of 12- to 15-months with potential approval in the fourth quarter of 2020. In September 2019, the Company submitted an application to Swissmedic and assuming successful review, the Company anticipates approval to commercialize PALFORZIA in Switzerland in mid-2021.

Ongoing Clinical Trials to Expand Pipeline and Support CODIT™ Platform:

- In December 2018, Aimmune initiated its POSEIDON phase 3 clinical trial to explore the efficacy and safety of PALFORZIA in young peanut-allergic children ages 1 to <4 years. Completion of enrollment is expected in the second half of 2020.
- In October 2018, Regeneron initiated a phase 2 clinical trial of PALFORZIA with adjunctive dupilumab in peanut-allergic patients.
- In August 2019, Aimmune enrolled the first patient in a phase 2 clinical trial of AR201 in patients with egg allergy. Completion of the trial is expected in the first half of 2021.

Corporate Highlights:

- **Balance sheet strengthened with $200 million investment from Nestlé in February 2020 bringing Nestlé's total investment in Aimmune to date to $473 million. Balance sheet is further strengthened through the pre-arranged borrowing of an additional $85 million from KKR bringing the total loan to $125 million plus accrued interest.** Pro-forma cash, cash equivalents and investments of $443 million as of December 31, 2019, including Nestlé Health Science's $200 million equity investment in Aimmune and the draw of the $85 million second loan tranche from KKR. The Company anticipates that based on its current business plan, these financial resources fully fund the Company.
- **AIMab7195 in-licensed from Xencor.** In February 2020, Aimmune completed the in-licensing of AIMab7195 (formerly XmAb7195) from Xencor, Inc. Initially, AIMab7195 will be developed as an adjunctive treatment with the Company's existing CODIT pipeline assets, including PALFORZIA, to explore treatment outcomes, including the potential path to remission, in patients with food allergies.

Upcoming Milestones

1Q 2020	Roll-out of U.S. launch of PALFORZIA following FDA approval in January 2020 (ongoing)
4Q 2020	Expected European Medicines Agency (EMA) action date for MAA of PALFORZIA for peanut allergy in children and adolescents ages 4 to 17 years
H2 2020	Expected completion of enrollment of POSEIDON phase 3 clinical trial
H1 2021	Expected completion of AR201 phase 2 clinical trial for egg allergy
Mid-2021	Expected completion of Swissmedic review of PALFORZIA for marketing authorization in Switzerland

Fourth Quarter and Full Year 2019 Financial Results

For the fourth quarter and year ended December 31, 2019, net loss was $66.9 million and $248.5 million, respectively, compared to net loss of $57.0 million and $210.8 million, respectively, for the comparable periods in 2018. On a per share basis, net loss for the quarter and year ended December 31, 2019, was $1.06 and $3.97, respectively, compared to net loss per share of $0.95 and $3.67, respectively, for the comparable periods in 2018. The weighted average shares outstanding for the quarter and year ended December 31, 2019, were 63.2 million and 62.6 million shares, respectively, compared to 59.8 million and 57.4 million shares, respectively, for the comparable periods in 2018.

Research and development expenses for the quarter and year ended December 31, 2019 were $30.1 million and $124.0 million, respectively, compared to $33.0 million and $133.4 million, respectively, for the comparable periods in 2018. The decrease was primarily due to lower external clinical-related expenses, partially offset by increases in regulatory, quality and manufacturing expenses.

General and administrative expenses for the quarter and year ended December 31, 2019 were $36.9 million and $125.8 million, respectively, compared to $25.4 million and $81.9 million, respectively, for the comparable periods in 2018. The increase was primarily due to increased external professional services costs, employee-related costs and facilities and other costs related to medical affairs and the preparations for commercial launch.

Cash, cash equivalents, and investments totaled $158.2 million on December 31, 2019, compared to $303.9 million on December 31, 2018. The decrease primarily reflects net cash used in operating activities, partially offset by cash provided by financing activities, including net borrowings from our debt issuance in January 2019 of $36.1 million. In February 2020, we borrowed an additional $85.0 million under our debt agreement with KKR, and Nestlé Health Sciences invested an additional $200.0 million in the company.

Conference Call Details

In connection with this announcement, Aimmune Therapeutics will host a conference call and webcast today at 4:30 p.m. ET. To access the live call by phone, dial (877) 497-1438 (domestic) or (262) 558-6296 (international) and enter the passcode 4527099. 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.

About AIMab7195

AIMab7195 is an anti-IgE monoclonal antibody with enhanced binding to the Fc gamma receptor IIb (FcγRIIb). IgE recognizes and interacts with allergens and, as a result, can activate immune cells, such as mast cells and basophils, that drive an allergic response in patients. AIMab7195 is designed to clear IgE rapidly from circulation, to prevent the production of IgE by preventing the activation of IgE-positive B cells, and to block IgE from interacting with its receptor on immune cells. AIMab7195 has been evaluated in two phase 1 studies that enrolled more than 100 healthy volunteers and patients with allergy and atopic disease.

In February 2020, Aimmune licensed exclusive worldwide rights to Xencor’s XmAb®7195 for the development of next-generation food allergy treatments.

About AR201

AR201 is an investigational biological drug in phase 2 clinical development for use in oral immunotherapy for egg allergy. Academic studies of the oral immunotherapy approach for egg allergy treatment have shown efficacy, and Aimmune is studying this more broadly with AR201 in order to enable widespread availability of a potential treatment.

About PALFORZIA™

PALFORZIA [Peanut (*Arachis hypogaea*) Allergen Powder-dnfp] was approved by the U.S. Food and Drug Administration (FDA) in January 2020 as 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.

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 each Up-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 Therapeutics

Aimmune Therapeutics, Inc. is a biopharmaceutical company developing and commercializing treatments for potentially life-threatening 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, AR201 and AIMab7195; Aimmune's expectations regarding the commercial launch of PALFORZIA; Aimmune's expectations regarding the timing of a potential acceptance and applicable review period of the MAA for AR101 by the EMA and by Swissmedic; Aimmune's expectations on the timing of completing a phase 2 clinical trial for AR201; Aimmune's expectations on the planned timing for the announcement of the completion of the POSEIDON clinical trial for PALFORZIA; Aimmune's expectations on the mechanisms of action of AIMab7195; Aimmune's expectations regarding the timing

and availability of the full amount of proceeds under its loan agreement with KKR; Aimmune's expectations regarding the sufficiency of its cash resources; 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 satisfaction of closing conditions for each tranche of its loan agreement; Aimmune's or any of its collaborative partners' ability to initiate and/or complete clinical trials; 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 products and 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 Annual Report on Form 10-K for the year ended December 31, 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, which has been approved for marketing in the United States by the FDA; AR101, a product candidate that is under clinical investigation in Europe; AR201, a product candidate under clinical investigation in the United States; and AIMab7195, a product candidate that Aimmune expects will be under clinical investigation. AR201 and AIMab7195 have not been approved for marketing by the FDA, the EMA or Swissmedic. AR101, in Europe, AR201 and AIMab7195 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.

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

References

[i] United States Census Bureau Quick Facts (2015 estimates)

[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)

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AIMMUNE THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)

	December 31, 2019 (Unaudited)	December 31, 2018 (1)
Assets		
Cash and cash equivalents	$ 79,880	$ 107,511
Short-term investments	63,633	196,421
Prepaid expenses and other current assets	5,564	8,687
Total current assets	149,077	312,619
Long-term investments	14,661	—
Property and equipment, net	28,604	26,328
Operating lease right-of-use assets	11,512	—
Prepaid expenses and other assets	515	608
Total assets	$ 204,369	$ 339,555
Liabilities and Stockholders' Equity		
Current liabilities	$ 47,448	$ 38,012
Long-term debt, net of discount	41,028	—
Operating lease liabilities, non-current	10,524	—
Other liabilities	1,345	2,596
Stockholders' equity	104,024	298,947
Total liabilities and stockholders' equity	$ 204,369	$ 339,555

(1) Derived from the audited financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2018.

AIMMUNE THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)
(Unaudited)

	Quarter Ended December 31,		Year Ended December 31,	
	2019	**2018**	**2019**	**2018**
Operating Expenses				
Research and development[1]	$ 30,125	$ 33,029	$ 123,987	$ 133,420
General and administrative[1]	36,861	25,404	125,817	81,921
Total operating expenses	66,986	58,433	249,804	215,341
Loss from operations	(66,986)	(58,433)	(249,804)	(215,341)
Interest income	925	1,482	5,851	4,984
Interest expense	(1,250)	(28)	(4,916)	(113)
Other income (expense), net	1,156	(37)	1,088	(221)
Loss before provision (benefit) for income taxes	(66,155)	(57,016)	(247,781)	(210,691)
Provision (benefit) for income taxes	743	(18)	716	61
Net loss	$ (66,898)	$ (56,998)	$ (248,497)	$ (210,752)
Net loss per share, basic and diluted	$ (1.06)	$ (0.95)	$ (3.97)	$ (3.67)
Shares used in computing net loss per basic and diluted share	63,249	59,780	62,558	57,403

[1]Includes employee stock-based compensation expense of:

	Quarter Ended December 31,		Year Ended December 31,	
	2019	**2018**	**2019**	**2018**
Research and development	$ 2,793	$ 2,569	$ 11,245	$ 9,945
General and administrative	5,550	5,500	21,684	22,787
Total stock-based compensation expense	$ 8,343	$ 8,069	$ 32,929	$ 32,732