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): November 6, 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))

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 November 6, 2019, Aimmune Therapeutics, Inc. ("Aimmune" or the "Company") issued a press release announcing its financial results for the quarter and nine months ended September 30, 2019, and its financial position as of September 30, 2019. The Company will conduct a conference call to review its financial results on November 6, 2019, 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 November 6, 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: November 6, 2019

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

Exhibit 99.1

Aimmune Therapeutics Announces Third Quarter 2019 Financial Results and Provides Operational Highlights

--Webcast and conference call today at 4:30 p.m. ET --

BRISBANE, California – **November 6, 2019** – Aimmune Therapeutics, Inc. (Nasdaq: AIMT), a biopharmaceutical company developing treatments for potentially life-threatening food allergies, today announced financial results for the quarter and nine months ended September 30, 2019 and provided operational highlights.

"This is a transformative time for the company as we prepare to launch PALFORZIA™, our first drug candidate and potentially the first FDA-approved treatment for any food allergy. We were encouraged by the positive vote from the FDA APAC to support the use of PALFORZIA as a treatment for peanut allergy in children and teens, and we look forward to the FDA's completed review of our BLA in January," said Jayson Dallas, M.D., President and CEO of Aimmune Therapeutics. "We have continued to make important progress in preparation for PALFORZIA's commercial launch, if approved, in the first quarter of 2020 - we have completed hiring for our commercial field leadership team, have had further conversations with payors, and have conducted additional physician and patient research to improve our understanding of the market. Finally, we have been working with the FDA to finalize the REMS program which will support the safe and appropriate use of PALFORZIA."

Third Quarter 2019 Clinical and Operational Highlights

- **The U.S. Food and Drug Administration (FDA) Allergenic Products Advisory Committee (APAC) voted to support the use of PALFORZIA in children and teens with peanut allergy on September 13, 2019.** 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. As part of Aimmune's original Biologics License Application (BLA) submission, the Company proposed risk management measures in line with the Advisory Committee's discussion and recommendation for a Risk Evaluation and Mitigation Strategy (REMS).

- **PALFORZIA U.S. launch preparations in final stages.** Commercial field leadership positions have been filled and offers have been accepted for almost all of the 80 Practice Account Manager positions. The market access team has already met with payers representing nearly 90% of covered lives. Finally, in ongoing consultation with the FDA, the Company continues to finalize the REMS program that will help support the safe and appropriate use of PALFORZIA, if approved.

- **The European Medicines Agency (EMA) continues its review of the Marketing Authorization Application (MAA) for PALFORZIA.** In June 2019, the Company submitted a MAA to the EMA for PALFORZIA. The Company expects to receive the Day 120 questions in November 2019 at which time there will be a pause while the Company prepares to answer the questions. A standard overall review period of 12- to 15-months is expected.

- **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.
  - 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.

- **Strong balance sheet.** $200.5 million in cash, cash equivalents and investments as of September 30, 2019, and access to up to an additional $130 million from our loan agreement with KKR upon satisfaction of borrowing conditions.

Upcoming Milestones

January 2020	Expected FDA review action date for PALFORZIA BLA
Q1 2020	Potential U.S. commercial launch of PALFORZIA, if approved
H2 2020	Expected completion of enrollment of AR201 phase 2 trial
H2 2020	Expected EMA action date for MAA of PALFORZIA for peanut allergy in children and adolescents ages 4 to 17 years
H2 2020	Potential EU commercial launch of PALFORZIA, if approved

Third Quarter 2019 Financial Results

For the quarter and nine months ended September 30, 2019, net loss was $64.5 million and $181.6 million, respectively, compared to net loss of $51.7 million and $153.8 million, respectively, for the comparable periods in 2018. On a per share basis, net loss for the quarter and nine months ended September 30, 2019, was $1.03 and $2.91, respectively, compared to net loss per share of $0.89 and $2.72, respectively, for the comparable periods in 2018. The weighted average shares outstanding for the quarter and nine months ended September 30, 2019, were 62.6 million and 62.3 million shares, respectively, compared to 58.3 million and 56.6 million shares, respectively, for the comparable periods in 2018.

Research and development expenses for the quarter and nine months ended September 30, 2019 were $30.6 million and $93.9 million, respectively, compared to $31.7 million and $100.4 million, respectively, for the comparable periods in 2018. The decrease was primarily due to lower costs related to the completion of certain PALFORZIA clinical trials, partially offset by higher costs related to regulatory activities and increased contract manufacturing costs to support potential commercialization of PALFORZIA as well as costs related to the phase 2 clinical trial of AR201 for egg allergy.

General and administrative expenses for the quarter and nine months ended September 30, 2019 were $34.0 million and $89.0 million, respectively, compared to $21.3 million and $56.5 million, respectively, for the comparable periods in 2018. The increase was primarily due to additional employee-related costs and external professional services as Aimmune continued to build its infrastructure to support the development and potential commercialization of PALFORZIA.

Cash, cash equivalents, and investments totaled $ 200.5 million on September 30, 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.

Conference Call

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 7842939. 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 PALFORZIA™

PALFORZIA™ is an investigational, peanut-derived, biologic product 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 AR201

AR201 is an investigational biologic product candidate in clinical development for use in oral immunotherapy in patients with 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. Aimmune has an exclusive supply agreement for egg protein with Michael Foods, Inc., the largest U.S. processor of value-added eggs. The agreement includes all of the company's egg products, worldwide, and gives Aimmune exclusive access to the clinical and commercial use of Michael Foods egg products for any egg allergy treatment, prevention or cure for a period of up to 15 years beyond the potential approval of AR201.

About Aimmune Therapeutics

Aimmune Therapeutics, Inc., is a biopharmaceutical company developing 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 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 potential commercial launch of PALFORZIA, including the review period of the BLA and MAA for PALFORZIA and launch timelines in the United States and Europe; Aimmune's expectations on the timing of the completion of enrollment for its phase 2 clinical trial for AR201: Aimmune's expectations regarding the adequacy and sufficiency of its commercial supply of PALFORZIA; 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; 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 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 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 and AR201, product candidates that are under clinical investigation. Neither PALFORZIA nor AR201 has been approved for marketing by the FDA or the EMA. PALFORZIA 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.

PALFORZIA™ is a trademark of Aimmune Therapeutics, Inc.

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

	September 30, 2019 (Unaudited)	December 31, 2018 (1)
Assets		
Cash and cash equivalents	$ 76,844	$ 107,511
Short-term investments	118,626	196,421
Prepaid expenses and other current assets	6,766	8,687
Total current assets	202,236	312,619
Long-term investments	5,038	—
Property and equipment, net	28,713	26,328
Operating lease right-of-use assets	11,904	—
Prepaid expenses and other assets	507	608
Total assets	$ 248,398	$ 339,555
Liabilities and Stockholders' Equity		
Current liabilities	$ 43,605	$ 38,012
Long term debt, net of discount	39,782	—
Operating lease liabilities, non-current	11,153	—
Other liabilities	1,166	2,596
Stockholders' equity	152,692	298,947
Total liabilities and stockholders' equity	$ 248,398	$ 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)

	Quarter Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Operating Expenses				
Research and development(1)	$ 30,558	$ 31,691	$ 93,862	$ 100,391
General and administrative(1)	34,044	21,285	88,956	56,517
Total operating expenses	64,602	52,976	182,818	156,908
Loss from operations	(64,602)	(52,976)	(182,818)	(156,908)
Interest income, net	43	1,303	1,192	3,233
Loss before provision for income taxes	(64,559)	(51,673)	(181,626)	(153,675)
(Benefit) Provision for income taxes	(104)	29	(27)	79
Net loss	$ (64,455)	$ (51,702)	$ (181,599)	$ (153,754)
Net loss per common share, basic and diluted	$ (1.03)	$ (0.89)	$ (2.91)	$ (2.72)
Shares used in computing net loss per common share, basic and diluted	62,615	58,274	62,325	56,602

(1) Includes stock-based compensation expenses of:

	Quarter Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Research and development	$ 2,752	$ 2,406	$ 8,452	$ 7,376
General and administrative	5,329	5,976	16,134	17,287
Total stock-based compensation expenses	$ 8,081	$ 8,382	$ 24,586	$ 24,663