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 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 2.02 Results of Operations and Financial Conditions.

On November 8, 2018, Aimmune Therapeutics, Inc. ("Aimmune" or the "Company") issued a press release announcing its financial results for the quarter and nine months ended September 30, 2018, and its financial position as of September 30, 2018. 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 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: November 8, 2018

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

Exhibit 99.1

Aimmune Therapeutics Announces Third Quarter 2018 Financial Results and Recent Corporate Highlights

- Recently completed Phase 3 RAMSES study confirms safety profile of AR101 in peanut-allergic children and teens
- BLA submission for AR101 on track for December 2018
- Management to host analyst event on Wednesday, December 12th, in New York

BRISBANE, California, November 8, 2018 – Aimmune Therapeutics, Inc. (Nasdaq: AIMT), a biopharmaceutical company developing treatments for life-threatening food allergies, today announced financial results for the quarter and nine months ended September 30, 2018. As of September 30, 2018, cash, cash equivalents and investments totaled $255.2 million.

Aimmune also announced that the safety profile of AR101 demonstrated in its recently completed Phase 3 RAMSES trial was consistent with the safety profile observed in its previously reported pivotal Phase 3 PALISADE trial in peanut-allergic children and teens, ages 4-17. Approximately 80% of participants treated with AR101 completed each trial. There were no serious adverse events related to treatment with AR101 in the RAMSES study.

RAMSES was a double-blind, placebo-controlled safety study, which enrolled 506 peanut-allergic children and teens, ages 4-17 years, in the United States. The study monitored treatment-emergent adverse events during the initial six-month up-dosing period. As this was a safety study, there were no oral food challenges at entry or exit.

“We are very pleased that RAMSES further confirms the favorable safety profile of AR101,” said Jayson Dallas, M.D., President and CEO of Aimmune. “The BLA submission is our top priority now and remains on track for December. We will have a robust data package on approximately 1,200 patients treated with AR101. PALISADE is the core of our BLA, having shown the potential for AR101 to reduce the frequency and severity of allergic reactions due to accidental ingestion of peanut.

“Our goal is to provide families of peanut-allergic children and teens the certainty and convenience of a once-daily, oral medication for desensitization. We believe the clinical data on AR101 support that goal, and we look forward to sharing our plans in December for making AR101 available to the peanut-allergic community, assuming approval.”

Third Quarter and Recent Highlights

- Aimmune held a pre-Biologics License Application (BLA) meeting with the U.S. Food and Drug Administration to discuss requirements for submission of a BLA for AR101 for the treatment of peanut allergy in children and teens, ages 4-17 years. The encouraging outcome of the meeting supports a BLA submission in December 2018 as planned.
- A planned Phase 2 clinical trial of AR101 with adjunctive dupilumab was initiated in collaboration with Regeneron and Sanofi. The study is designed to assess the potential to improve desensitization to peanut with adjunctive use of dupilumab. Regeneron is the study sponsor and Aimmune is providing clinical supply of AR101.

Third Quarter Financial Results

For the quarter and nine months ended September 30, 2018, net loss was $51.7 million and $153.8 million, respectively, compared to net loss of $31.8 million and $90.2 million for the comparable periods in 2017.

On a per share basis, net loss for the quarter and nine months ended September 30, 2018, was $0.89 and $2.72, respectively, compared to net loss per share of $0.63 and $1.79 for the comparable periods in 2017. The weighted average shares outstanding for the quarter and nine months ended September 30, 2018, was 58.3 million and 56.6 million, respectively, compared to 50.5 million and 50.3 million shares for the comparable periods in 2017. In the first quarter of 2018, the Company completed an underwritten public offering with net proceeds of $190.4 million through the sale and issuance of an aggregate of 6,325,000 shares of common stock.

Research and development expenses for the quarter and nine months ended September 30, 2018, were $31.7 million and $100.4 million, respectively, compared to $21.1 million and $60.7 million for the comparable periods in 2017. The increase was primarily due to higher costs from the progression of certain AR101 clinical trials and higher contract manufacturing costs to support clinical development and regulatory activities.

General and administrative expenses for the quarter and nine months ended September 30, 2018, were $21.3 million and $56.5 million, respectively, compared to $11.2 million and $31.0 million for the comparable periods in 2017. The increase was primarily due to additional employee-related costs and external professional services as Aimmune continues to build its infrastructure to support the development and potential commercialization of AR101. Stock-based compensation expense also increased primarily due to the expansion and extension of our long-term commercial supply agreement with Golden Peanut Company and modification of certain executives' stock options resulting from their planned separation.

Cash, cash equivalents, and investments totaled $255.2 million at September 30, 2018, compared to $182.4 million at December 31, 2017. The increase primarily reflects net cash proceeds of $190.4 million received as of September 30, 2018, from the sale of common stock, partially off-set by cash used in operating activities of $117.6 million and cash used for purchase of plant and equipment of $8.3 million.

Anticipated Upcoming Milestones

Timing	Anticipated Milestone
Q4 18	Initiate a study of AR101 in infants and toddlers 1 – 4 years old (ARC005)
Q4 18	Data cut from the pivotal Phase 3 (PALISADE) rollover study (ARC004)
Q4 18	Submit BLA for AR101 to the U.S. Food and Drug Administration
Q4 18	Publication of PALISADE data in peer-reviewed medical journal
Q4 18	Submit Investigational New Drug Application for AR201 in egg allergy
1H 19	European clinical study data available (ARTEMIS)
1H 19	Submit MAA for AR101 to the European Medicines Agency
1H 19	Initiate Phase 2 clinical trial of AR201 in egg allergy
2H 19	Submit Investigational New Drug Application for AR301 in walnut allergy
2H 19	Initiate Phase 2 clinical trial of AR301 in walnut allergy
2H 19	Potential approval and commercial launch of AR101 in the U.S.

About Aimmune Therapeutics

Aimmune Therapeutics, Inc., is a biopharmaceutical company developing treatments for 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 accidental exposure to food allergens 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. Aimmune plans to submit regulatory filings for marketing approval of AR101 in the United States and Europe based on data from the pivotal Phase 3 PALISADE clinical trial of AR101, which in 4-17 year-old subjects met all its primary and secondary endpoints, and additional ongoing and completed AR101 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 potential benefits of AR101; Aimmune's expectations for the ARTEMIS and ARC004 trials, including the expected timing of data readouts and data cuts for these trials; Aimmune's expectations on regulatory submissions for marketing approval of AR101 in the United States and Europe, including the timing of these submissions; Aimmune's expectations regarding the potential commercial launch of AR101, including the timing of a potential approval of AR101 in

the United States; Aimmune's expectations regarding the timing of initiating additional clinical trials for AR101, including ARC005; Aimmune's expectations on the timing of submitting an IND and initiating Phase 2 clinical trials for AR201 in egg allergy and AR301 in walnut allergy; 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 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; Aimmune's reliance on third parties for the manufacture of its 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, 2018. 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 U.S. Food and Drug Administration (FDA) or the European Medicines Agency (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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AIMMUNE THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)

	September 30, 2018 (Unaudited)	December 31, 2017 (1)
Assets		
Cash and cash equivalents	$ 78,420	$ 73,487
Short-term investments	176,829	108,943
Prepaid expenses and other current assets	6,543	6,681
Total current assets	261,792	189,111
Property and equipment, net	25,045	17,205
Prepaid expenses and other assets	626	618
Total assets	$ 287,463	$ 206,934
Liabilities and Stockholders' Equity		
Current liabilities	$ 37,451	$ 26,599
Other liabilities	2,848	2,530
Stockholders' equity	247,164	177,805
Total liabilities and stockholders' equity	$ 287,463	$ 206,934

(1) Derived from the audited financial statements, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2017.

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

	Quarter Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Operating Expenses				
Research and development(1)	$ 31,691	$ 21,063	$ 100,391	$ 60,671
General and administrative(1)	21,285	11,226	56,517	30,963
Total operating expenses	52,976	32,289	156,908	91,634
Loss from operations	(52,976)	(32,289)	(156,908)	(91,634)
Interest income, net	1,303	497	3,233	1,475
Loss before provision for income taxes	(51,673)	(31,792)	(153,675)	(90,159)
Provision for income taxes	29	—	79	—
Net loss	$ (51,702)	$ (31,792)	$ (153,754)	$ (90,159)
Net loss per common share, basic and diluted	$ (0.89)	$ (0.63)	$ (2.72)	$ (1.79)
Shares used in computing net loss per common share, basic and diluted	58,274	50,458	56,602	50,254

(1) Includes stock-based compensation expenses of:

	Quarter Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Research and development	$ 2,406	$ 1,305	$ 7,376	$ 3,482
General and administrative	5,976	2,774	17,287	8,389
Total stock-based compensation expenses	$ 8,382	$ 4,079	$ 24,663	$ 11,871