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): March 12, 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 March 12, 2018, Aimmune Therapeutics, Inc. ("Aimmune" or the "Company") issued a press release announcing its financial results for the quarter and full year ended December 31, 2017, and its financial position as of December 31, 2017. 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 March 12, 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: March 12, 2018

By: /s/ Douglas T. Sheehy
Douglas T. Sheehy
General Counsel & Corporate Secretary

Exhibit 99.1

Aimmune Therapeutics Announces Fourth Quarter and Full Year 2017 Financial Results

- *Company began 2018 with approximately $182 Million in cash and investments*
- *Pro-forma year-end 2017 cash and investments of approximately $372 Million, including net proceeds from the recently completed public offering*
- *Announced over-enrollment in the ARTEMIS Phase 3 trial*
- *Additional AR101 clinical data readouts expected throughout 2018*
- *Planned BLA Submission on Track for Year-End 2018*

BRISBANE, California, March 12, 2018 – Aimmune Therapeutics, Inc. (Nasdaq:AIMT), a biopharmaceutical company developing treatments for life-threatening food allergies, today announced financial results for the fourth quarter and full year 2017.

"The progress we made in 2017 has set up 2018 as a potentially transformational year for Aimmune," said Stephen Dilly, MBBS, Ph.D. "We kicked off this year with positive Phase 3 PALISADE results, which form the core clinical element for our regulatory submissions for approval of AR101 to treat peanut allergy in the U.S. and Europe. We are extremely pleased with the continued high level of enthusiasm from patients and investigators in our trials, which have exceeded enrollment targets. In parallel, we are advancing manufacturing and pre-commercial activities in anticipation of a potential commercial launch. With proceeds from our recently completed public offering, we are well financed to deliver on our goals for AR101 and to drive our pipeline of CODIT™ products forward for additional life-threatening food allergies."

Recent AR101 Program Highlights

Announced Positive Topline Results of Phase 3 PALISADE trial. In February 2018, Aimmune announced that the Phase 3 PALISADE trial met its primary endpoint, as 67% of AR101 patients ages 4–17 tolerated at least a 600-mg dose of peanut protein in the exit double-blind placebo-controlled food challenge (DBPCFC) compared to 4% of placebo patients ($p<0.00001$). The lower-bound of the 95% confidence interval of the difference between treatment arms at the primary endpoint was 53%, greatly exceeding the pre-specified threshold of 15% ($p<0.00001$). Serious adverse events related to study drug were reported in 1.1% of AR101 patients ages 4–17. Three suspected cases of eosinophilic esophagitis were observed with only one case confirmed following biopsy.

Over-Enrolled Phase 3 RAMSES Real-World Trial. In January 2018, Aimmune announced over-enrollment of RAMSES, which does not require a DBPCFC, and which will monitor treatment-emergent adverse events during a six-month up-dosing period. Patients will then be followed in an open-label manner for at least six months on the maintenance dose of 300 mg of AR101 per day. A total of 506 peanut-allergic patients ages 4-17 have been randomized to treatment with AR101 or placebo.

Over-Enrolled Phase 3 ARTEMIS Trial in Europe. In February 2018, Aimmune completed enrollment of ARTEMIS in Europe. ARTEMIS is designed to explore protection at an endpoint of tolerating a single dose of 1,000 mg of peanut protein in a DBPCFC after nine months of treatment. A total of 175 patients ages 4-17 have been randomized to treatment with AR101 or placebo.

Completed Enrollment in PALISADE Follow-On Trial ARC004. In January 2018, Aimmune completed enrollment in ARC004, which is designed to test the potential for reduced frequency of dosing during the maintenance phase of AR101 therapy. A total of 358 patients ages 4-17 years (92% of those who completed PALISADE) chose to participate in ARC004.

4Q 2017 and Recent Corporate Highlights

Formed Clinical Collaboration with Regeneron and Sanofi. In October 2017, Aimmune announced a partnership with Regeneron and Sanofi to explore desensitization with AR101 treatment with adjunctive dupilumab in peanut-allergic patients in a Phase 2 clinical trial, which is expected to begin in 2018.

Broadened and Extended Supply Agreement with Golden Peanut and Tree Nuts. In January 2018, Aimmune announced the expansion and extension of its exclusive supply agreement with Golden Peanut and Tree Nuts, the leading handler, processor, and exporter of peanuts and tree nuts, to support the anticipated potential commercialization of AR101.

Expanded the Aimmune Scientific Advisory Board. In February 2018, Aimmune announced that Prof. George du Toit and Dr. Wayne Shreffler, leading academic experts in allergy and immunology, joined the company's Scientific Advisory Board.

Upcoming Milestones

Timing	Milestone
2Q 18	Presentation of Phase 3 PALISADE data at the EAACI 37th Annual Congress
2H 18	RAMSES data available
2H 18	Initiate ARC005 trial of AR101 in infants and toddlers
3Q 18	Data cut from ARC004
YE 18	Initiate Phase 2 trial of AR101 with adjunctive dupilumab
YE 18	Submit Biologics License Application for AR101 to the U.S. Food and Drug Administration
YE 18	Submit Investigational New Drug Application for AR201 in egg allergy
1H 19	ARTEMIS data available
1H 19	Submit Marketing Authorisation Application 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 of AR101 in the U.S.

Fourth Quarter and Full Year Financial Results

For the quarter and year ended December 31, 2017, net loss was $41.2 million and $131.3 million, respectively, compared to net loss of $25.1 million and $80.8 million for the comparable periods of 2016.

On a per share basis, net loss for the quarter and year ended December 31, 2017, was $0.81 and $2.61, respectively, compared to net loss per share of $0.55 and $1.89 for the comparable periods of 2016. The weighted average shares outstanding for each of the quarter and year ended December 31, 2017, were 50.8 million and 50.4 million shares, respectively, compared to 45.5 million and 42.8 million shares for the comparable periods in 2016.

Research and development expenses for the quarter and year ended December 31, 2017, were $28.7 million and $89.3 million, respectively, compared to $17.0 million and $54.6 million for the comparable periods in 2016. The increase was primarily due to the progression of the AR101 program, which include the RAMSES, ARC008, ARTEMIS and ARC011 that commenced in 2017, and higher contract manufacturing costs to support clinical development.

General and administrative expenses for the quarter and year ended December 31, 2017, were $13.0 million and $43.9 million, respectively, compared to $8.3 million and $26.9 million for the comparable periods in 2016. The increase was primarily due to additional employee-related costs, including stock-based compensation expense, and external professional services as Aimmune continues to build the infrastructure to support the development and potential commercialization of AR101.

Cash, cash equivalents, and investments totaled $182.4 million at December 31, 2017, compared to $282.5 million at December 31, 2016. The decrease primarily reflects cash used in operations. In the first quarter of 2018, the Company completed the sale and issuance of an aggregate of 6,325,000 shares of Common Stock, which includes the exercise in full of the underwriters' option to purchase an additional 825,000 shares of common stock, the Company received net proceeds from the Offering of approximately $190.0 million.

About Aimmune Therapeutics

Aimmune Therapeutics, Inc., is a clinical-stage 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 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 potential benefits of AR101; Aimmune's expectations for the RAMSES, 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 or AR101; Aimmune's expectations regarding the timing of initiating additional clinical trials for AR101, including ARC005 and a trial exploring AR101 with adjunctive dupilumab; 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; 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; the company's reliance on third parties for the manufacture of the company's product candidates; 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 Annual Report on Form 10-K for the year ended December 31, 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 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)

	December 31, 2017(1)	December 31, 2016(1)
Assets		
Cash and cash equivalents	$ 73,487	$ 124,010
Short-term investments	108,943	124,921
Prepaid expenses and other current assets	6,681	2,749
Total current assets	189,111	251,680
Long-term investments	—	33,602
Property and equipment, net	17,205	10,391
Prepaid expenses and other assets	618	3,116
Total assets	$ 206,934	$ 298,789
Liabilities and Stockholders' Equity		
Current liabilities	$ 26,599	$ 11,450
Other liabilities	2,530	1,367
Stockholders' equity	177,805	285,972
Total liabilities and stockholders' equity	$ 206,934	$ 298,789

(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)
(Unaudited)

	Quarter Ended December 31,		Year Ended December 31,	
	2017	2016	2017	2016
Operating Expenses				
Research and development(1)	$ 28,654	$ 16,958	$ 89,325	$ 54,642
General and administrative(1)	12,986	8,343	43,949	26,885
Total operating expenses	41,640	25,301	133,274	81,527
Loss from operations	(41,640)	(25,301)	(133,274)	(81,527)
Interest income, net	530	225	2,005	703
Loss before provision for income taxes	(41,110)	(25,076)	(131,269)	(80,824)
Provision for income taxes	56	—	56	—
Net loss	$ (41,166)	$ (25,076)	$ (131,325)	$ (80,824)
Net loss per common share, basic and diluted	$ (0.81)	$ (0.55)	$ (2.61)	$ (1.89)
Shares used in computing net loss per basic and diluted share	50,839	45,491	50,401	42,751

(1)Includes employee stock-based compensation expense of:

	Quarter Ended December 31,		Year Ended December 31,	
	2017	2016	2017	2016
Research and development	$ 1,595	$ 1,128	$ 5,077	$ 4,838
General and administrative	3,253	2,420	11,642	7,803
Total stock-based compensation expense	$ 4,848	$ 3,548	$ 16,719	$ 12,641