
**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): May 8, 2018

AIMMUNE THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-37519
(Commission File Number)

45-2748244
(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 May 8, 2018, Aimmune Therapeutics, Inc. ("Aimmune" or the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2018, and its financial position as of March 31, 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated May 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: May 8, 2018

By: /s/ Eric H. Bjerkholt

Eric H. Bjerkholt
Chief Financial Officer



Aimmune Therapeutics Announces First Quarter 2018 Financial Results

BRISBANE, California, May 8, 2018 – Aimmune Therapeutics, Inc. (Nasdaq: AIMT), a biopharmaceutical company developing treatments for life-threatening food allergies, today announced financial results for the first quarter 2018. As of March 31, 2018, cash, cash equivalents and investments totaled \$331.7 million.

“We have come out of the first quarter of 2018 in a strong position with positive Phase 3 results for AR101, which have been met with widespread enthusiasm across the food allergy community,” said Stephen Dilly, MBBS, Ph.D., CEO of Aimmune. “Throughout 2018, we expect to present additional data from the AR101 Phase 3 program and to complete clinical and manufacturing activities in support of BLA and MAA filings. In parallel, we are ramping up precommercial activities for a potential commercial launch of AR101 in the United States in 2019. We are in a strong financial position following our successful public offering completed in the first quarter and continue to own world-wide rights to AR101 and all our other CODIT product candidates. We look forward to an event-rich year ahead as we continue to lead the way in developing therapies for life-threatening food allergies.”

First Quarter Highlights

AR101: Pivotal-stage biologic for the treatment of peanut allergy

- Announced positive results from the pivotal Phase 3 PALISADE trial and presented findings at the annual meeting of the American Academy of Allergy, Asthma and Immunology.
- Completed enrollment in the PALISADE follow-on trial (ARC004), the real-world RAMSES trial, and the European ARTEMIS trial; data from RAMSES and ARC004 will support a Biologics License Application (BLA) in the United States, and data from ARTEMIS will support a Marketing Authorisation Application (MAA) in Europe.

Corporate

- Strengthened balance sheet with total net proceeds of \$190.5 million from public offering of common stock.
- Broadened and extended supply agreement for the starting material of AR101 with Golden Peanut and Tree Nuts, a subsidiary of Archer Daniels Midland Company.
- Expanded the Aimmune Scientific Advisory Board with appointments of Prof. George du Toit and Dr. Wayne Shreffler, leading academic experts in allergy and immunology.



Upcoming Anticipated Milestones

Timing	Anticipated Milestone
2Q 18	Presentation of Phase 3 PALISADE data at the EAACI 37 th Annual Congress
2H 18	RAMSES data available
2H 18	Initiate ARC005 trial of AR101 in infants and toddlers
2H 18	Data cut from ARC004
YE 18	Regeneron / Sanofi expected to initiate Phase 2 trial of AR101 with adjunctive dupilumab
YE 18	Submit BLA 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 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 of AR101 in the U.S.

First Quarter Financial Results

For the quarter ended March 31, 2018, net loss was \$49.5 million, compared to net loss of \$25.9 million for the comparable period of 2017.

On a per share basis, net loss for the quarter ended March 31, 2018, was \$0.92, compared to net loss per share of \$0.52 for the comparable period of 2017. In the first quarter of 2018, the Company completed an underwritten public offering for 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.

Research and development expenses for the quarter ended March 31, 2018, were \$33.4 million, compared to \$17.4 million for the comparable period in 2017. The increase was primarily due to the progression of the AR101 program, which includes the RAMSES, ARC008, ARTEMIS and ARC011 trials that commenced in 2017, and higher contract manufacturing costs to support clinical development.

General and administrative expenses for the quarter ended March 31, 2018, were \$16.7 million, compared to \$8.9 million for the comparable period 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 January 2018 issuance of restricted common stock in connection with the expansion and extension of our long-term commercial supply agreement with Golden Peanut Company and modification of certain executives' stock option arrangements.

Cash, cash equivalents, and investments totaled \$331.7 million at March 31, 2018, compared to \$182.4 million at December 31, 2017. The increase primarily reflects net cash proceeds of \$189.5 million received as of March 31, 2018 from an underwritten public offering, partially off-



set by net cash used in operating activities of \$39.8 million and purchase of property and equipment of \$2.4 million in the first quarter of 2018.

About Aimmune Therapeutics

Aimmune Therapeutics, Inc., is a clinical-stage biopharmaceutical company developing treatments for life-threatening food allergies. The company's Characterized **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; the presentation of data from the PALISADE clinical trial of AR101, including at the EAACI 37th Annual Congress; 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 year ended May 8, 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)**

	March 31, 2018 (Unaudited)	December 31, 2017 (1)
Assets		
Cash and cash equivalents	\$ 209,324	\$ 73,487
Short-term investments	112,560	108,943
Prepaid expenses and other current assets	8,413	6,681
Total current assets	330,297	189,111
Long-term investments	9,863	—
Property and equipment, net	21,021	17,205
Prepaid expenses and other assets	664	618
Total assets	<u>\$ 361,845</u>	<u>\$ 206,934</u>
Liabilities and Stockholders' Equity		
Current liabilities	\$ 30,412	\$ 26,599
Other liabilities	2,341	2,530
Stockholders' equity	329,092	177,805
Total liabilities and stockholders' equity	<u>\$ 361,845</u>	<u>\$ 206,934</u>

(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 March 31,	
	2018	2017
Operating Expenses		
Research and development ⁽¹⁾	\$ 33,446	\$ 17,417
General and administrative ⁽¹⁾	16,673	8,924
Total operating expenses	50,119	26,341
Loss from operations	(50,119)	(26,341)
Interest income, net	636	471
Loss before provision for income taxes	(49,483)	(25,870)
Provision for income taxes	17	0
Net loss	<u>\$ (49,500)</u>	<u>\$ (25,870)</u>
Net loss per common share, basic and diluted	<u>\$ (0.92)</u>	<u>\$ (0.52)</u>
Shares used in computing net loss per common share, basic and diluted	53,578	50,069

(1) Includes stock-based compensation expenses of:

	Quarter Ended March 31,	
	2018	2017
Research and development	\$ 2,047	\$ 986
General and administrative	5,560	2,607
Total stock-based compensation expenses	<u>\$ 7,607</u>	<u>\$ 3,593</u>