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): August 8, 2017

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 August 8, 2017, Aimmune Therapeutics, Inc. ("Aimmune" or the "Company") issued a press release announcing its financial results for the quarter and six months ended June 30, 2017 and its financial position as of June 30, 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.

Reference is made to the Exhibit Index attached hereto.

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: August 8, 2017

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release dated August 8, 2017.

Aimmune Therapeutics Announces Second Quarter 2017 Financial Results

BRISBANE, California, August 8, 2017 — Aimmune Therapeutics, Inc. (Nasdaq:AIMT), a biopharmaceutical company developing treatments for life-threatening food allergies, today announced financial results for the quarter and six months ended June 30, 2017. As of June 30, 2017, cash, cash equivalents, and investments totaled $237.3 million.

"During the second quarter, Aimmune continued to make significant progress in our Phase 3 clinical development program for AR101 as well as in our commercial manufacturing readiness," said Aimmune CEO Stephen Dilly, M.B.B.S., Ph.D. "We are looking forward to completing our core Phase 3 PALISADE trial around the end of this year, and we continue to anticipate sharing topline results in the first quarter of 2018."

"Also during the second quarter, we initiated the RAMSES and ARTEMIS trials, which are designed to support regulatory filings in the U.S. and Europe, respectively, which we expect to occur in late 2018," continued Dr. Dilly. "In parallel with our clinical activities, we achieved an important milestone on the commercial front as we celebrated the ribbon-cutting for our commercial manufacturing plant. Financially, we continue to be in a strong position to support our planned development activities through regulatory submissions for AR101."

Second Quarter Corporate Highlights

Initiated the ARTEMIS Phase 3 Trial. In June, Aimmune initiated ARTEMIS (**AR**101 **T**rial in **E**urope **M**easuring oral **I**mmunotherapy **S**uccess), a randomized, double-blind, placebo-controlled clinical trial of AR101, which will enroll approximately 160 peanut-allergic children and adolescents ages 4-17 at multiple sites in several European countries. The trial is designed to evaluate a primary endpoint of tolerating at least 1,000 mg of peanut protein after nine months of treatment.

Reported new AR101 clinical data at EAACI. In June, Aimmune reported findings from pre-randomization, preliminary clinical data collected from the European screening population of the PALISADE trial at the 2017 European Academy of Allergy and Clinical Immunology (EAACI) Congress. More than 100 patients, many with multiple food allergies, in eight EU countries were enrolled in PALISADE.

Reported on up-dosing in PALISADE. In June, Aimmune announced its estimate from the blended rate of discontinuations in PALISADE that the proportion of AR101-treated patients successfully completing up-dosing appears to be similar to what was observed in Aimmune's Phase 2 clinical trial. Aimmune believes this is positive in the context of a much larger trial (554 vs. 55 patients) and a much larger number of treatment centers in PALISADE compared to the Phase 2 clinical trial (74 vs. 8 centers).

Announced commercial manufacturing milestone. In June, Aimmune hosted a ribbon-cutting ceremony to celebrate the completion of its commercial manufacturing facility in Clearwater, Florida. The new manufacturing facility contains more than 20,000 square feet of space and will handle full-scale cGMP (current Good Manufacturing Practices) commercial production of AR101 in anticipation of potential regulatory approvals. It will also supply future clinical trials of AR101 as well as trials of future product candidates.

Initiated the RAMSES Phase 3 trial. In May, Aimmune initiated RAMSES (The **R**eal-World **A**R101 **M**arket-**S**upporting **E**xperience **S**tudy in Peanut-Allergic Children Age 4-17 Years, or RAMSES (ARC007), which is designed to gain experience with AR101 in a real-world setting, without the use of a double-blind, placebo-controlled food challenge to confirm peanut allergy. The trial will assess the safety and tolerability of AR101 versus placebo.

Appointed healthcare industry veteran Eric Bjerkholt as CFO. In April, Aimmune announced the appointment of Eric Bjerkholt as CFO. Mr. Bjerkholt was most recently CFO at Sunesis Pharmaceuticals, Inc., where he oversaw multiple aspects of governance, corporate relations, and other functions. Prior to Sunesis, he was CFO at IntraBiotics Pharmaceuticals, Inc., and LifeSpring Nutrition, Inc. Mr. Bjerkholt began his healthcare career at J.P. Morgan & Co. as an investment banker in New York and then launched the company's Western U.S. healthcare practice.

Second Quarter Financial Results

For the quarter and six months ended June 30, 2017, net loss was $32.5 million and $58.4 million, respectively, compared to net loss of $18.1 million and $33.7 million for the comparable periods of 2016.

On a per share basis, net loss for the quarter and six months ended June 30, 2017 was $0.65 and $1.16, respectively, compared to net loss per share of $0.43 and $0.81 for the comparable periods of 2016. The weighted average shares outstanding for each of the quarter and six months ended June 30, 2017 was 50.2 million compared to 41.8 million and 41.7 million shares for the comparable periods in 2016.

Research and development expenses for the quarter and six months ended June 30, 2017 were $22.2 million and $39.6 million, respectively, compared to $11.8 million and $21.8 million for the comparable periods in 2016. The increase was primarily due to the progression of the PALISADE trial, enrollment of patients in the open-label follow-on study of PALISADE (ARC004) and other AR101 clinical trials and contract manufacturing related costs of AR101.

General and administrative expenses for the quarter and six months ended June 30, 2017 were $10.8 million and $19.7 million, respectively, compared to $6.5 million and $12.2 million for the comparable periods in 2016. The increase was primarily due to additional employee-related costs, including stock-based compensation expense, as Aimmune continues to build the infrastructure to support the development and potential commercialization of AR101.

Cash, cash equivalents, and investments totaled $237.3 million at June 30, 2017, compared to $282.5 million at December 31, 2016. The decrease primarily reflects cash used in operations.

About Aimmune Therapeutics

Aimmune Therapeutics, Inc., is a clinical-stage biopharmaceutical company developing treatments for life-threatening food allergies. The company's Characterized Oral Desensitization ImmunoTherapy (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 for its Phase 3 PALISADE trial of AR101, including that final study visits will be completed around year-end 2017, that topline data for the trial will be available in the first quarter of 2018 and that the proportion of AR101-treated patients successfully completing up-dosing in PALISADE appears to be similar to what was observed in Phase 2; Aimmune's plan to submit marketing approval regulatory filings for AR101 in the United States and the European Union in late 2018; Aimmune's expectations for its RAMSES and ARTEMIS trials; Aimmune's expectations for its commercial manufacturing facility for AR101, including expectations that the facility will be cGMP compliant and capable of producing commercial supplies of AR101 and clinical supplies for additional product candidates; Aimmune's expectations regarding the potential benefits of AR101; Aimmune's expectations regarding the sufficiency of its capital 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 ability to initiate and/or complete clinical trials; the unpredictability of the regulatory process; 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; and possible regulatory developments in the United States and foreign countries. 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 June 30, 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)

	June 30, 2017 (Unaudited)	December 31, 2016 (1)
Assets		
Cash and cash equivalents	$ 84,451	$ 124,010
Short-term investments	152,874	124,921
Prepaid expenses and other current assets	5,287	2,749
Total current assets	242,612	251,680
Long-term investments	—	33,602
Property and equipment, net	13,142	10,391
Prepaid expenses and other assets	600	3,116
Total assets	$ 256,354	$ 298,789
Liabilities and Stockholders' Equity		
Current liabilities	$ 18,040	$ 11,450
Other liabilities	1,523	1,367
Stockholders' equity	236,791	285,972
Total liabilities and stockholders' equity	$ 256,354	$ 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, 2016.

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

	Quarter Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Operating expenses				
Research and development (1)	$ 22,191	$ 11,820	$ 39,608	$ 21,796
General and administrative (1)	10,813	6,466	19,737	12,189
Total operating expenses	33,004	18,286	59,345	33,985
Loss from operations	(33,004)	(18,286)	(59,345)	(33,985)
Interest income, net	507	147	978	323
Net loss	$ (32,497)	$ (18,139)	$ (58,367)	$ (33,662)
Net loss per common share, basic and diluted	$ (0.65)	$ (0.43)	$ (1.16)	$ (0.81)
Weighted average shares used in computing net loss per common share, basic and diluted	50,230	41,800	50,150	41,678

(1)Includes stock-based compensation expenses of:

	Quarter Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Research and development	$ 1,191	$ 1,272	$ 2,177	$ 2,217
General and administrative	3,008	1,802	5,615	3,388
Total stock-based compensation expense	$ 4,199	$ 3,074	$ 7,792	$ 5,605