**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, 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 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 August 8, 2019, Aimmune Therapeutics, Inc. ("Aimmune" or the "Company") issued a press release announcing its financial results for the quarter and six months ended June 30, 2019, and its financial position as of June 30, 2019. The Company will conduct a conference call to review its financial results on August 8, 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 August 8, 2019 |

**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, 2019

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

**Exhibit 99.1**

# Aimmune Therapeutics Announces Second Quarter 2019 Financial Results and Provides Operational Highlights

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

**BRISBANE, California** – **August 8, 2019** – 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, 2019. Operational highlights for the second quarter of 2019 include:

- *Company prepares for September 13, 2019, U.S. Food and Drug Administration (FDA) Allergenic Products Advisory Committee (APAC) Meeting for AR101 for peanut allergy*
- *Marketing Authorization Application (MAA) for AR101 for peanut allergy submitted to the European Medicines Agency (EMA), which has validated the filing and begun its review*
- *Presented results from the positive phase 3 ARTEMIS trial at European Academy of Allergy and Clinical Immunology (EAACI) Congress and presented new data at International Society for Pharmacoeconomics Outcomes Research (ISPOR) Annual Meeting*
- *Advanced pipeline with the initiation of a phase 2 trial of AR201 for egg allergy*
- *Strong balance sheet with $250.3 million in cash, cash equivalents and investments as of June 30, 2019, expected to fund commercialization of AR101 in the U.S. and Europe and development of pipeline*

"The second quarter of 2019 was marked by exceptional progress on all fronts. We continue to work with the FDA to facilitate an expeditious review of AR101. This means patients with food allergies may be only months away from finally having an FDA approved treatment option," said Jayson Dallas, M.D., President and CEO of Aimmune Therapeutics. "Our focus on commercial preparedness is ongoing and we plan to be launch ready in the fourth quarter of this year. Additionally, we submitted a MAA for AR101 to the EMA, and we are pleased to share that its review has begun."

Dr. Dallas added: "At EAACI, we presented positive results from our ARTEMIS European phase 3 trial, as well as important data that showed patients who received daily treatment with AR101 beyond one year experienced clinically meaningful improvements in disease-specific quality of life and continued immunomodulation. In addition, new and compelling patient quality of life data were presented at both EAACI and ISPOR, underscoring the urgent unmet need of people living with peanut allergy. Moreover, we began the enrollment process for our phase 2 clinical trial of AR201 in egg allergy and remain in a strong financial position to commercialize AR101 and advance our pipeline programs."

**Second Quarter 2019 Clinical and Operational Highlights**

- **FDA informed the Company that FDA's APAC is scheduled to advise on the review of data supporting the Company's Biologics License Application (BLA) for AR101 at a meeting on September 13, 2019.** The Company continues to prepare diligently for the meeting. In March 2019, the FDA accepted the BLA for AR101 for peanut allergy in children and adolescents ages 4 to 17, under a 12-month target review period, potentially taking until late January 2020. In addition, the FDA has completed all clinical and manufacturing site inspections scheduled to date. Following these inspections, the Company continues to anticipate approval by January 2020.

- **MAA for AR101 has been filed and validated for review by EMA.** In June 2019, the Company submitted a MAA to the EMA for AR101 to reduce the incidence and severity of allergic reactions following exposure to peanuts in children and adolescents ages 4 to 17. The Company expects a standard review time of 12- to 15-months.

- **New data presented at EAACI and ISPOR.** Aimmune presented results from the positive phase 3 ARTEMIS trial in an oral presentation at the EAACI Congress in June 2019 Safety and efficacy results were consistent with the results seen in the phase 3 PALISADE trial. The lead study author of ARTEMIS, Montserrat Fernandez- Rivas, M.D., Hospital Clinico San Carlos, Madrid, Spain, was named an EAACI Award Winner 2019.

  In addition, patients in the open-label extension of the phase 3 PALISADE trial who received daily treatment with AR101 beyond one year experienced clinically meaningful improvements in disease-specific quality of life. Continued immunomodulation also was observed, with almost half of patients tolerating as much as 2,000 mg of peanut protein with fewer adverse events. Further, results from APPEAL 2, the first European multi-country qualitative evaluation of the impact of living with peanut allergy, found that living in fear of a potentially fatal reaction to peanuts significantly impacts the quality of life of individuals with peanut allergy and their families.

  The Company also presented data, at the ISPOR 2019 Annual Meeting that showed that, over a 12-month period, more than half of participants required a visit to the emergency room or urgent care facility and one-third required hospitalization as a result of peanut exposure. This was true despite 100% of those surveyed reporting actively avoiding peanut products.

- **Launched enrollment of phase 2 trial of AR201 in egg allergy.** The phase 2 trial is a double-blind placebo-controlled trial in patients ages 4 to 26 diagnosed with an allergy to hen's egg. The trial is expected to enroll approximately 84 patients at 15 clinical trial sites in the U.S.

- **Commercial supply agreement with long-standing manufacturer of AR101 completed.** In May 2019, the Company entered into a commercial supply agreement with CoreRx, Inc., its long-standing manufacturer of AR101. The agreement will help secure sufficient supply of AR101, including at commercial launch, subject to regulatory approval. CoreRx began manufacturing commercial lots of AR101 in May 2019, following the consummation of the agreement, and the first commercial batch has now been released.

- **POSEIDON trial and AR101 with adjunctive dupilumab trial ongoing.** In December 2018, Aimmune initiated its phase 3 POSEIDON trial to explore the efficacy and safety of AR101 in young peanut-allergic children, ages 1 to <4 years. In October 2018, a phase 2 trial of AR101 with adjunctive dupilumab was initiated in peanut-allergic patients. Aimmune continues to supply AR101 clinical trial material to Regeneron, the latter trial's sponsor.

**Upcoming Milestones**

| | |
|---|---|
| Sept. 13, 2019 | Scheduled FDA APAC meeting to review AR101 BLA |
| January 2020 | Potential FDA approval of AR101 for peanut allergy in children and adolescents ages 4 to 17 |
| Q1 2020 | Potential U.S. commercial launch of AR101 |
| Mid-2020 | Complete enrollment of AR201 phase 2 trial |
| H2 2020 | Potential EU approval of AR101 for peanut allergy in children and adolescents ages 4 to 17 |
| H2 2020 | Potential EU commercial launch of AR101 |

**Second Quarter 2019 Financial Results**

For the quarter and six months ended June 30, 2019, net loss was $62.9 million and $117.1 million, respectively, compared to net loss of $52.6 million and $102.1 million for the comparable period in 2018. On a per share basis, net loss for the quarter and six months ended June 30, 2019, was $1.01 and $1.88, respectively, compared to net loss per share of $0.91 and $1.83 for the comparable period in 2018. The weighted average shares outstanding for the quarter and six months ended June 30, 2019, were 62.3 million and 62.2 million shares, respectively, compared to 57.9 million and 55.8 million shares for the comparable period in 2018.

Research and development expenses for the quarter and six months ended June 30, 2019, were $32.0 million and $63.3 million, respectively, compared to $35.3 million and $68.7 million for the comparable period in 2018. The decrease was primarily due to lower costs related to the completion of certain AR101 clinical trials, partially offset by higher costs related to regulatory activities and increased contract manufacturing costs to support potential commercialization.

General and administrative expenses for the quarter and six months ended June 30, 2019, were $31.2 million and $54.9 million, respectively, compared to $18.6 million and $35.2 million for the comparable period 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 AR101.

Cash, cash equivalents, and investments totaled $250.3 million on June 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 1564807. 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 Aimmune Therapeutics**

Aimmune Therapeutics, Inc., is a biopharmaceutical company developing oral treatments for 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 biologic product, AR101, is being developed as a treatment to reduce the frequency and severity of adverse events following exposure to peanut. The BLA for AR101 is under review by the U.S. FDA, which in 2015 granted AR101 Breakthrough Therapy Designation for the desensitization of peanut-allergic patients 4 to 17 years of age. In June 2019, Aimmune submitted a Marketing Authorization Application to the European Medicines Agency (EMA) for AR101, which has begun its review. In July 2019 Aimmune began the enrollment process for a phase 2 clinical trial for its second product, AR201, for egg allergy. 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 regarding the potential commercial launch of AR101, including the review period of the BLA and MAA for AR101; Aimmune's expectations on the timing of receipt and announcement of data for its phase 2 clinical trial for AR201; Aimmune's expectations on the planned timing for the announcement of data from its POSEIDON trial of AR101 and Regeneron's clinical trial of AR101 in combination with dupilumab; Aimmune's expectations regarding the adequacy and sufficiency of its commercial supply of AR101; 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 AR101; 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 June 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 AR101 and AR201, product candidates that are under clinical investigation. Neither AR101 nor AR201 has been approved for marketing by the FDA or the EMA. AR101 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.

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

| | June 30, 2019 (Unaudited) | December 31, 2018 (1) |
|---|---|---|
| **Assets** | | |
| Cash and cash equivalents | $ 72,564 | $ 107,511 |
| Short-term investments | 171,108 | 196,421 |
| Prepaid expenses and other current assets | 6,859 | 8,687 |
| Total current assets | 250,531 | 312,619 |
| | | |
| Long-term investments | 6,584 | — |
| Property and equipment, net | 29,414 | 26,328 |
| Operating lease right-of-use assets | 11,736 | — |
| Prepaid expenses and other assets | 511 | 608 |
| Total assets | $ 298,776 | $ 339,555 |
| | | |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities | $ 43,211 | $ 38,012 |
| Long term debt, net of discount | 38,526 | — |
| Operating lease liabilities, non-current | 11,036 | — |
| Other liabilities | 1,029 | 2,596 |
| Stockholders' equity | 204,974 | 298,947 |
| Total liabilities and stockholders' equity | $ 298,776 | $ 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 June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2019 | 2018 | 2019 | 2018 |
| Operating Expenses | | | | |
| Research and development(1) | $ 31,988 | $ 35,254 | $ 63,304 | $ 68,700 |
| General and administrative(1) | 31,200 | 18,559 | 54,912 | 35,232 |
| Total operating expenses | 63,188 | 53,813 | 118,216 | 103,932 |
| Loss from operations | (63,188) | (53,813) | (118,216) | (103,932) |
| Interest income, net | 358 | 1,294 | 1,149 | 1,930 |
| Loss before provision for income taxes | (62,830) | (52,519) | (117,067) | (102,002) |
| Provision for income taxes | 48 | 33 | 77 | 50 |
| Net loss | $ (62,878) | $ (52,552) | $ (117,144) | $ (102,052) |
| | | | | |
| Net loss per common share, basic and diluted | $ (1.01) | $ (0.91) | $ (1.88) | $ (1.83) |
| Shares used in computing net loss per common share, basic and diluted | 62,332 | 57,903 | 62,178 | 55,752 |

(1) Includes stock-based compensation expenses of:

| | Quarter Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2019 | 2018 | 2019 | 2018 |
| Research and development | $ 2,957 | $ 2,923 | $ 5,700 | $ 4,970 |
| General and administrative | 5,783 | 5,751 | 10,805 | 11,311 |
| Total stock-based compensation expenses | $ 8,740 | $ 8,674 | $ 16,505 | $ 16,281 |