
**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): January 3, 2019

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 1.01 Entry Into a Material Definitive Agreement.

On January 3, 2019, Aimmune Therapeutics, Inc. (the “Company”) entered into a Credit Agreement (the “Agreement”) with KKR Peanut Aggregator L.P., an affiliate of KKR LLC (together with the several banks and other financial institutions from time to time party to the Agreement, collectively, the “Lenders”) and Cortland Capital Market Services LLC, as the administrative agent and the collateral agent (the “Agent”). The Agreement consists of a six-year term loan facility for an up to aggregate principal amount of \$170.0 million (the “Term Loans”). The Agreement provides for an initial Term Loan of \$40.0 million, which was funded on January 4, 2019 (the “Closing Date”). Subject to the fulfillment of certain customary conditions precedent, including the issuance of an approval letter by the FDA with respect to a Biologic License Application for AR101 on or prior to December 31, 2020 (“Regulatory Approval”), the Company must draw an additional \$85.0 million of the Term Loans. At the Company’s option and, subject to the fulfillment of customary conditions precedent, including the Company’s achievement of aggregate net sales (as defined in the Agreement) for AR101 by July 31, 2020 in an amount of at least \$30.0 million, the Company may draw the remaining \$45.0 million of the Term Loans. The Term Loans under the Agreement bear interest through maturity, at the Company’s election, with respect to (a) ABR Loans, 6.50% per annum and (b) LIBOR Loans, 7.50% per annum. The Company will begin paying accrued interest on outstanding Term Loans on March 31, 2019, and on the last Business Day of each March, June, September and December thereafter while any Term Loan is outstanding, as well as on the final maturity date of the Term Loans (each such date, an “Interest Payment Date”). For each Interest Payment Date until and including the fiscal quarter ending June 30, 2020, the Company has the option to elect whether the interest payments due on such Interest Payment Date shall be paid in cash or paid in kind and capitalized. The Company has selected to pay in kind and have the interest capitalized for the fiscal quarter ending March 31, 2019.

Principal payments on the Term Loans are paid according to the following schedule: (i) on December 31, 2023, 50.0% of the outstanding principal amount of the Term Loans as of such date, including any capitalized interest, (ii) on each Interest Payment Date thereafter, 12.5% of the outstanding principal amount of the Term Loans as of December 31, 2023 and (iii) on January 3, 2025 (the “Maturity Date”), any remaining outstanding balance of the Term Loans. The Company is also required to make mandatory prepayments of the Term Loans under the Agreement, subject to specified exceptions, with the proceeds of asset sales, debt issuances, royalty transactions, collaboration transactions, and specified other events. In addition, upon the occurrence of a change of control, the Company must prepay, the outstanding amount of the Term Loans.

If all or any of the Term Loans are prepaid or required to be prepaid under the Agreement, then the Company shall pay, in addition to such prepayment, a prepayment premium (the “Prepayment Premium”) equal to (i) with respect to any such prepayment paid on or prior to January 3, 2021, the amount, if any, by which (a) the present value as of such date of determination of (x) 105.00% of the principal amount of the Term Loans prepaid plus (y) all required interest payments that would have been due on the principal amount of the Term Loans prepaid through and including January 3, 2021, computed using a discount rate equal to the treasury rate most nearly equal to the period from such date of prepayment to January 3, 2021 plus 50 basis points exceeds (b) the principal amount of the Term Loans prepaid, (ii) with respect to any prepayment paid or required to be paid after January 3, 2021 but on or prior to January 3, 2022, 5.00% of the principal amount of the Term Loans prepaid, (iii) with respect to any prepayment paid or required to be paid after January 3, 2022 but on or prior to January 3, 2023, 2.00% of the principal amount of the Term Loans prepaid and (iv) with respect to any prepayment paid or required to be prepaid thereafter, 0.00% of the principal amount of the Term Loans prepaid. If the Company receives Regulatory Approval, the Company must pay on the earlier of (i) the date on which commitments have been terminated and no Term Loans are outstanding and (ii) the Interest Payment Date falling in the first full fiscal quarter after receipt of Regulatory Approval, a premium in an amount equal to \$3.4 million and the Prepayment Premium for such date on a principal amount equal to \$85.0 million. The premium with respect to the Regulatory Approval described in the immediately preceding sentence is not due if the Company draws the additional (after the first \$40.00 million on the Closing Date) \$85.0 million of the Term Loans.

Upon the prepayment or repayment of all or any of the Term Loans, the Company shall pay an additional (in addition to the Prepayment Premium) exit fee in an amount equal to 4.00% of the principal amount of the Term Loans prepaid or repaid. In addition, the Company paid certain customary fees and expenses to the Agent and other service providers on the Closing Date.

The obligations under the Agreement are secured by a lien on substantially all of the Company’s tangible and intangible property. The Agreement contains certain affirmative covenants, negative covenants and events of default, including, covenants and restrictions that among other things, require the Company and its subsidiary guarantors to satisfy a minimum cash balance covenant and restricts the ability of the Company and its subsidiary’s ability to, incur liens, incur additional indebtedness, make loans and investments, engage in mergers and acquisitions, engage in asset sales or sale and leaseback transactions, and declare dividends or redeem or repurchase capital stock. A failure to comply with these covenants could permit the Lenders under the Agreement to declare the Term Loans, together with accrued interest and fees, to be immediately due and payable.

The foregoing description of the material terms of the Agreement does not purport to be complete and is subject to, and is qualified in its entirety by, reference to the Agreement, which will be filed as an exhibit to the Company's Annual Report on Form 10-K for the year ending December 31, 2018 and is incorporated by reference herein.

Item 2.03. Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant.

The information set forth in Item 1.01 of this Current Report on Form 8-K relating to the Credit Agreement is incorporated by reference into this Item 2.03.

Item 7.01. Regulation FD Disclosure.

On January 4, 2019, the Company issued a press release announcing the execution of the Credit Agreement. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

The Company expects that, following its entry into the Credit Agreement, the addition of the full Term Loans of \$170.0 million (assuming the satisfaction of closing conditions for each subsequent tranche of the Agreement) to its existing cash, cash equivalents and short-term investments, will enable the Company to fully fund the commercialization of AR101 for the treatment of peanut allergy. The Company has based this estimate on assumptions that may prove to be wrong, and it could use its capital resources sooner than it currently expects.

Item 9.01 Financial Statements and Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Press release titled "Aimmune Therapeutics and KKR Enter into \$170M Loan Agreement to Fund AR101 Commercialization and Pipeline Advancement."</u>

Forward-Looking Statements

Any statements contained in this Form 8-K 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: the Company's expectations regarding the timing and availability of the full amount of proceeds under the loan agreement; the Company's expectations regarding the sufficiency of its cash resources; the Company's expectations regarding the potential benefits of AR101; the Company's expectations regarding the potential commercialization of AR101, including the timing of a potential approval of AR101. Risks and uncertainties that contribute to the uncertain nature of the forward-looking statements include: the satisfaction of closing conditions for each subsequent tranche of the loan agreement; the expectation that the Company will need additional funds to finance its operations; the unpredictability of the regulatory process; the Company's reliance on third parties for the manufacture of its 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 the Company'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 Form 8-K speak only as of the date on which they were made. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this Form 8-K. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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: January 4, 2019

By: /s/ Douglas T. Sheehy

Douglas T. Sheehy

General Counsel and Secretary



**Aimmune Therapeutics and KKR Enter into \$170M Loan Agreement to Fund AR101
Commercialization and Pipeline Advancement**

BRISBANE, CA, January 4, 2019 — Aimmune Therapeutics, Inc. (Nasdaq: AIMT), a biopharmaceutical company developing treatments for potentially life-threatening food allergies, today announced that it has entered into a \$170 million loan agreement with an affiliate of KKR, a leading global investment firm.

“The addition of the KKR loan financing to Aimmune’s capital resources is expected to fully fund the commercialization of AR101, an investigational biologic oral immunotherapy for the treatment of peanut allergy,” said Eric Bjerkholt, Chief Financial Officer of Aimmune Therapeutics. “In addition, this financing secures resources to support the continued advancement of our pipeline of additional food allergy treatments, including the Phase 2 trial of AR201 for egg allergy, which is anticipated to commence this year.”

In December 2018, Aimmune submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for AR101 for the treatment of peanut allergy in children and adolescents ages 4–17 years based on data from the landmark Phase 3 PALISADE trial, which met its primary and key secondary endpoints, and from additional ongoing and completed AR101 clinical trials. The FDA has granted Breakthrough Therapy Designation to AR101 for the desensitization of peanut-allergic patients 4–17 years of age.

The loan agreement provides Aimmune with an up to \$170 million term loan in three tranches. Forty million dollars was funded at close, with \$85 million to follow upon FDA approval of AR101 and satisfaction of other customary borrowing conditions, and \$45 million at the company’s option in 2020 upon the satisfaction of certain borrowing conditions. The loan can be prepaid at Aimmune’s discretion, at any time, subject to prepayment fees. Further information with respect to the term loan is set forth in a Form 8-K filed by Aimmune with the Securities and Exchange Commission on January 4, 2019.

Aimmune reported September 30, 2018, cash, cash equivalents and short-term investments of \$255 million. With the \$98 million equity investment from Nestlé Health Science announced in November 2018 and the \$170 million KKR loan, assuming full borrowings under all tranches, Aimmune’s capital resources as of September 30, 2018, would have exceeded \$500 million.

For KKR, the investment is part of the firm’s Health Care Royalty and Income strategy, which is focused on providing non-dilutive capital to companies for which KKR can help reach scale and achieve strategic objectives.

“Aimmune is leading the way in meeting the critical, growing need to offer treatment to the millions of people affected by food allergies,” said Emily Janvey, M.D., Head of Health Care Royalty and Income strategy at KKR. “We’re proud to help support Aimmune’s important work, especially as the company prepares to launch what could be the world’s first approved medical treatment for peanut allergy.”



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 accidental exposure to food allergens by desensitizing patients with defined, precise amounts of key allergens. Aimmune's first investigational biologic product using CODIT™ is AR101. Aimmune intends to submit a regulatory filing for marketing approval of AR101 in Europe during the first half of 2019 based on data from Aimmune's pivotal Phase 3 PALISADE clinical trial of AR101, which in 4–17-year-old subjects met its primary and key secondary endpoints, and additional ongoing and completed AR101 clinical trials. Aimmune has filed an IND application for its second product, AR201, for the treatment of egg allergy and intends to start a randomized Phase 2 clinical trial in the first half of 2019. For more information, please see www.aimmune.com.

About KKR

KKR is a leading global investment firm that manages multiple alternative asset classes, including private equity, energy, infrastructure, real estate and credit, with strategic partners that manage hedge funds. KKR aims to generate attractive investment returns for its fund investors by following a patient and disciplined investment approach, employing world-class people, and driving growth and value creation with KKR portfolio companies. KKR invests its own capital alongside the capital it manages for fund investors and provides financing solutions and investment opportunities through its capital markets business. References to KKR's investments may include the activities of its sponsored funds. For additional information about KKR & Co. Inc. (NYSE: KKR), please visit KKR's website at www.kkr.com and on Twitter @KKR_Co.

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 timing and availability of the full amount of proceeds under the loan agreement; Aimmune's expectations regarding the sufficiency of its cash resources; Aimmune's expectations regarding the potential benefits of AR101; Aimmune's expectations regarding the potential commercialization of AR101, including the timing of a potential approval of AR101; Aimmune's expectations on the timing of initiating a Phase 2 clinical trial for AR201; Aimmune's expectations on regulatory submissions for marketing approval of AR101 for peanut allergy in Europe; 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 satisfaction of closing conditions for each subsequent tranche of the loan agreement; 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; 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 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 AR101, a product that is under clinical investigation, and AR201, a product that Aimmune expects will be under clinical investigation in 2019. Neither AR101 nor AR201 has been approved for marketing by the U.S. Food and Drug Administration (FDA) or the European Medicines Agency (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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