Aimmune Therapeutics, Inc.
Form 8-K
November 13, 2018

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): November 11, 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 1.01 Entry into a Material Definitive Agreement.

On November 11, 2018, Aimmune Therapeutics, Inc., a Delaware corporation (Aimmune or the Company), announced a $98.0 million equity investment into the Company by Nestle Health Science S.A. and the extension of their existing strategic collaboration designed to enable the development and commercialization of innovative food allergy therapies.

In connection with the equity investment, Aimmune entered into a Securities Purchase Agreement (the Purchase Agreement), dated as of November 11, 2018 (the Effective Date), by and between the Company and Nestle Health Science US Holdings, Inc., a Delaware corporation (NHSc US). In connection with the extension of the strategic collaboration, Aimmune entered into an Amended and Restated Strategic Collaboration Agreement (the Strategic Collaboration Agreement), dated as of the Effective Date, with Nestec, Ltd., a limited company organized and existing under the laws of Switzerland (Nestec), which is a research and development subsidiary of Swiss food, nutrition and wellness company, Nestlé S.A.. Pursuant to the Purchase Agreement, the Company and NHSc US also entered into an Amended and Restated Standstill Agreement (the Standstill Agreement) and an Amended and Restated Registration Rights Agreement (the Registration Rights Agreement), each dated as of the Effective Date.

The following are summaries of the material terms and conditions of the Strategic Collaboration Agreement, the Purchase Agreement, the Standstill Agreement and the Registration Rights Agreement (collectively, the Agreements). The following summaries of the material terms and conditions of the Agreement are qualified in their entirety by the actual Agreements, which will be filed as exhibits to the Company s Annual Report on Form 10-K for the year ending December 31, 2018 and are incorporated by reference herein.

A copy of the Company s related press release announcing the transactions is attached hereto as Exhibit 99.1.

Strategic Collaboration Agreement

Pursuant to the Strategic Collaboration Agreement, the Company and Nestec (through itself and one or more affiliated entities) agreed to continue to collaborate with one another in connection with the development of the Company s products, including by (i) sharing information relating to the Company s activities directed towards the development of the Company s products for the treatment of allergies to one or more particular types of food (the Development Programs) and commercialization plans for AR101, the Company s investigational product for the treatment of peanut allergy, and (ii) providing the Company access to Nestec s scientific, clinical, regulatory and commercial expertise relevant to such Development Programs. In connection with the foregoing, the Company and Nestec will maintain their existing Pipeline Committee (reconstituted as the Strategic Collaboration Committee), which will continue to be comprised of up to five (5) representatives of each party. The input that the Company receives from Nestec in the Strategic Collaboration Committee is advisory only; the Company retains full decision-making control for all Development Programs and for the commercialization of AR101. In addition, for so long as Nestle holds not less than fourteen percent (14%) of the Company s outstanding common stock, Nestlé will continue to be entitled to designate one (1) nominee to serve as a director on Aimmune s Board of Directors, which shall initially continue to be Greg Behar, Chief Executive Officer of Nestlé HealthScience S.A.

The term of the Strategic Collaboration Agreement (the Term) commences on the Effective Date and will terminate two (2) years from the Effective Date, unless earlier terminated in accordance with the terms thereof. The Strategic Collaboration Agreement Term may be terminated by either party (i) upon 60 days written notice of an uncured material breach or (ii) upon a change of control of the other party. In addition, Aimmune may terminate the Strategic Collaboration Agreement upon 60 days written notice in the event Nestec (or an affiliated entity) acquires or combines with a company engaged in the research, development or commercialization of certain oral immunotherapies intended to desensitize a patient to a food allergen. Further, Nestec may terminate the Strategic Collaboration Agreement upon 60 days written notice in the event that Aimmune sells, conveys, transfers or licenses to a third party commercial rights to one or more of its products or Development Programs. The Strategic Collaboration Agreement also provides

that it shall automatically terminate if the Purchase Agreement is terminated prior to the Closing (as defined below).

During the Term, the Company may conduct licensing or partnering discussions with other potential partners, with respect to the Development Programs. During the Term, if Nestec decides to pursue development of a drug or biologic product that can be combined with an oral immunotherapy product and that is intended to improve the efficacy or safety of such oral immunotherapy product for the treatment of one or more food allergies, then NHSc shall provide Aimmune with the opportunity to enter into an exclusive negotiating period with respect to such opportunity for a period of three (3) months and the parties will negotiate in good faith during such period. If the parties have not entered into a definitive agreement governing the opportunity as of the end of any such negotiating period, NHSc would be free to partner or pursue a transaction with third parties with respect to such opportunity.

The Strategic Collaboration Agreement contains a non-competition covenant pursuant to which Nestec has agreed not to engage in certain activities relating to oral immunotherapies for the treatment of food allergies, including, with respect to the treatment of peanut allergy, the research, development or commercialization of any drug or biologic for use as an oral immunotherapy, other than any product for the prevention of food allergies for egg or milk that are currently part of a development program of Nestec. The Strategic Collaboration Agreement also contains mutual non-solicitation and confidentiality provisions.

Purchase Agreement

Pursuant to the Purchase Agreement, the Company agreed to issue and sell to NHSc US 3,237,529 shares (the Shares) of its common stock, par value $0.0001 (Common Stock), for an aggregate cash purchase price of $98.0 million, representing approximately 5.5% of Aimmune s outstanding Common Stock. The Shares are to be issued and sold to NHSc US at a price per share of $30.27. The closing of the sale and issuance of the Shares (the Closing) is subject to certain closing conditions, including the delivery of the aggregate purchase price and expiration or termination of any applicable waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended. Following the Closing, NHSc US will hold shares representing 18.9% of Aimmune s outstanding Common Stock.

The sale and issuance of the Shares is intended to be exempt from registration pursuant to the exemption for transactions by an issuer not involving any public offering under Section 4(a)(2) the Securities Act of 1933, as amended (the Securities Act), and Regulation D under the Securities Act.

The Purchase Agreement also contains customary representations, warranties and covenants by, among and for the benefit of the parties, as well as mutual indemnification obligations.

The Company expects that the net proceeds from the sale of the Shares to NHSc US, together with the Company s cash position of $255.2 as of September 30, 2018, would fund the Company through approximately the first year of the anticipated launch of AR101 in the United States.

Standstill Agreement

Pursuant to the Standstill Agreement, the Company and NHSc US agreed to the Standstill Restrictions (as defined below) and, subject to certain limited exceptions, that neither NHSc US nor its affiliates shall sell or transfer any Common Stock or securities convertible into, exchangeable for, exercisable for, or repayable with Common Stock for the period commencing on the Effective Date and lasting through the two (2) years from the Effective Date (the Termination Date).

Pursuant to the Standstill Agreement, NHSc US agreed that until the Termination Date, neither NHSc US nor any of its affiliates shall (without the prior written consent of a majority of the members of Aimmune s Board of Directors who are not affiliated with NHSc US):

a. effect or seek, offer or propose (whether publicly or otherwise) to effect, or announce any intention to effect or cause or in any way advise, assist, knowingly facilitate or encourage any other person to effect or seek, offer or propose (whether publicly or otherwise) to effect, or announce any intention to effect or cause:

    i. any acquisition, or obtaining any economic interest in, any right to direct the voting or disposition of, or any other right with respect to, any securities of the Company or any of its subsidiaries (or any rights, options or other securities convertible into or exercisable or exchangeable for such securities or any obligations measured by the price or value of any securities of the Company or any of its subsidiaries, including without limitation any swaps or other derivative arrangements), in each case, whether or not any of the foregoing may be acquired or obtained immediately or only after the passage of time or upon the satisfaction of one or more conditions pursuant to any agreement, arrangement or understanding, without the prior consent of the Company s Board of Directors;

ii. any tender or exchange offer, merger, consolidation, business combination or acquisition or disposition of assets of the Company or any of its subsidiaries;

iii. any recapitalization, restructuring, liquidation, dissolution or other extraordinary transaction with respect to the Company or any of its subsidiaries; or

iv. any solicitation of proxies (as such terms are used in Regulation 14A of the Securities Exchange Act of 1934, as amended (the Exchange Act)) or consents to vote any voting securities of the Company, or become a participant in any election contest (as such terms are defined in Rule 14a-11 of the Exchange Act) or propose, or solicit stockholders of the Company for the approval of, any stockholder proposals with respect to the Company or seek to advise or influence any person with respect to the voting of any voting securities of the Company;

b. form, join or in any way participate in a group (as defined under the securities laws) with respect to any securities of the Company or any securities convertible into Common Stock or any other voting securities of the Company or otherwise act in concert with any person in respect of any such securities;

c. otherwise act, alone or in concert with others, to seek to control or influence the management, Board of Directors or policies of the Company;

d. take any action which would reasonably be expected to result in the Company or its representatives being obligated to make a public announcement regarding any of the types of matters set forth in the Standstill Agreement;

e. enter into any discussions or arrangements with any third party with respect to any of the foregoing; or

f. publicly disclose any intention, plan or arrangement regarding any of the matters referred to above. (collectively (a) through (f), the Standstill Restrictions).

The Standstill Restrictions shall not apply after (A) a public announcement by the Company of the initiation of any merger, consolidation, acquisition, scheme, business combination or other extraordinary transaction in which the Company or any of its subsidiaries is a constituent corporation or party and following consummation of such transaction, either (i) substantially all of the persons or entities who, immediately prior to such transaction, had beneficial ownership of 50% or more of the voting power of the Company would not continue to beneficially own at least 50% of the voting power of the combined entity and would not have the ability to elect a majority of the directors of the combined entity or (ii) all or a substantial part of the assets of the Company and its subsidiaries would be transferred to a third party or (B) the submission of any bona fide offer by any third party to acquire all or a substantial portion of the securities or assets of the Company or its subsidiaries (which for the avoidance of doubt shall exclude any offer with respect to which the Company elects not to engage in substantive negotiations), prompt notice of which shall be provided to NHSc US.

The Standstill Agreement also provides that, in connection with any transaction constituting a change of control of the Company approved by the Board during the period beginning on the Effective Date and ending on the Termination Date, NHSc US shall not seek an appraisal remedy under Section 262 of the Delaware General Corporation Law with respect to any shares of common stock of the Company held by NHSc US as of the date of the consummation of such change of control transaction.

The Standstill Agreement further provides that it shall automatically terminate in the event that the Purchase Agreement is terminated prior to the Closing.

Registration Rights Agreement

Pursuant to the Registration Rights Agreement, the Company has agreed to register the resale of the Shares on a registration statement to be filed with the Securities and Exchange Commission upon the request of NHSc US, which request cannot be made prior to the 45th day preceding the Termination Date. The Registration Rights Agreement contains customary indemnification provisions and terminates if NHSc US fails to request that the Shares be registered within the four (4) year anniversary of the Effective Date or, if earlier, such date that NHSc US and its affiliates own in the aggregate less than 30% of the number of shares of Common Stock that NHSc US and its Affiliates owned in the aggregate as of the date of the Registration Rights Agreement. In the event that the Purchase Agreement is terminated prior to the Closing, the Registration Rights Agreement shall automatically terminate and the registration rights agreement entered into with NHSc US in November 2016 shall be reinstated in full.

Item 3.02 Unregistered Sales of Equity Securities.

Reference is made to the disclosures set forth in Item 1.01, which disclosures are incorporated by reference into this Item 3.02.

The sale and issuance of the Shares is being made in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act, and Rule 506 promulgated thereunder, and NHSc US represented to the Company that it is an accredited investor within the meaning of Rule 501 under the Securities Act. Accordingly, the Shares have not been registered under the Securities Act, and until so registered, these securities may not be offered or sold in the United States absent registration or availability of an applicable exemption from registration. No underwriting discounts or commissions or similar fees are payable in connection with the issuance.

Item 9.01 Financial Statements and Exhibits.

Exhibit

No.	**Description**
99.1	Press release titled Aimmune Therapeutics Announces Additional Equity Investment by Nestlé Health Science dated November 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: November 12, 2018

By: /s/ Douglas T. Sheehy
Douglas T. Sheehy
General Counsel and Secretary