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 14, 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))

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 8.01. Other Events.

Aimmune Therapeutics, Inc. (the "Company") announced that it has been notified by the U.S. Food and Drug Administration (the "FDA") that as a result of the U.S. government shutdown and lapse in appropriations, the FDA will not commence review of the Company's Biologics License Application ("BLA") for AR101, the Company's investigational biologic oral immunotherapy for the treatment of peanut allergy in children and adolescents ages 4–17. The FDA indicated that it will initiate review of the BLA when the U.S. government shutdown and lapse in appropriations has ended.

As previously announced, the Company submitted its BLA for AR101 on December 21, 2018, prior to the U.S. government shutdown.

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 14, 2019

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