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): March 4, 2019

Apellis Pharmaceuticals, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-38276**	**27-1537290**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

6400 Westwind Way, Suite A **Crestwood, KY**	**40014**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's telephone number, including area code: (502) 241-4114

Not applicable
(Former Name or Former Address, if Changed Since Last Report)

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 Instruction 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.

On March 4, 2019, Apellis Pharmaceuticals, Inc. (the "Company") announced that with the agreement of the independent safety monitoring committee for the Company's Phase 3 clinical program for APL-2 in patients with geographic atrophy ("GA"), the Company has resumed enrollment its two Phase 3 clinical trials in patients with GA (DERBY and OAKS) with intravitreal APL-2. The Company continues to expect that both trials will be fully enrolled by the end of the first quarter of 2020.

In October 2018, the Company announced that it had voluntarily implemented a pause in dosing in the DERBY and OAKS Phase 3 trials due to observed cases of non-infectious inflammation in patients treated from a single manufacturing lot of APL-2 intravitreal investigational material. Inflammation in all affected patients resolved.

Based on its investigation, the Company believes that the likely source of inflammation resided in an impurity in the active pharmaceutical ingredient that was introduced during the scale-up of the manufacturing process to produce commercial lot sizes. The Company has modified its manufacturing process in order to eliminate the impurity and has manufactured sufficient supply of APL-2 utilizing the modified manufacturing process to conduct the entire Phase 3 GA program.

APL-2 intravitreal drug product produced from the modified manufacturing process was introduced into the Company's ongoing Phase 1b trial in low vision patients with GA. Ten patients in the Phase 1b trial have received at least one intravitreal injection of APL-2 manufactured through the modified process, and there has been no inflammation observed in any patient injected with APL-2 from this new manufacturing lot. Patients in the Phase 1b trial will continue to receive monthly APL-2 injections for two years.

The independent safety monitoring committee reviewed all non-clinical data and clinical data from the Phase 1b trial and agreed that the Company could resume dosing in the Phase 3 program using APL-2 manufactured with the modified process.

Forward-Looking Statements

Statements in this Form 8-K about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may constitute "forward-looking statements" within the meaning of The Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements relating to the Company's expectations regarding its Phase 3 clinical program for APL in patients with GA, including that the two Phase 3 GA trials will be fully enrolled by the end of the first quarter of 2020. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including; whether the Company's clinical trials will be fully enrolled and completed when anticipated; whether preliminary or interim results from a clinical trial will be predictive of the final results of the trial; whether results obtained in preclinical studies and clinical trials will be indicative of results that will be generated in future clinical trials; and other factors discussed in the "Risk Factors" section of the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 26, 2019 and the risks described in other filings that the Company may make with the Securities and Exchange Commission. Any forward-looking statements contained in this Form 8-K speak only as of the date hereof, and the Company specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Apellis Pharmaceuticals, Inc.

Date: March 4, 2019

By: /s/ Cedric Francois
Cedric Francois, M.D., Ph.D.
President and Chief Executive Officer