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): October 17, 2018

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: (520) 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 7.01. Regulation FD.

Apellis Pharmaceuticals, Inc. (the "Company" or "Apellis") announced today that it has voluntarily implemented a temporary pause in dosing in its Phase III geographic atrophy program due to observed cases of non-infectious inflammation in patients treated from a single manufacturing lot of APL-2 intravitreal drug product. A total of eight patients, four in the Phase III GA program and four in the Company's ongoing Phase II wet AMD study, were treated with this manufacturing lot and all developed non-infectious inflammation. Inflammation in seven of the eight patients has completely resolved and the other is expected to resolve. Dosing in the Phase II wet AMD is continuing with a different APL-2 intravitreal manufacturing lot.

The Company has reviewed these events with the data safety monitoring board for the Phase III GA program and believes that the cause of inflammation is isolated to this single lot of APL-2 intravitreal drug product based upon the results of an initial preliminary toxicity analysis and the extensive prior safety history from the Phase II FILLY study (more than 1,500 intravitreal injections with APL-2). After consultation with the data safety monitoring board, the Company has commenced a series of confirmatory non-human studies and anticipates completion of these non-human studies by late November. If these studies support the conclusion that the single lot is the cause of the inflammation, the Company expects that it will resume dosing in the Phase III GA program by the end of 2018 and that there will be no delay to its projected enrollment timeline of 18 months for the Phase III GA program.

The information in this Item 7.01 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.

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 implications of preliminary clinical data. 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 preliminary toxicity analysis referenced in this Form 8-K will be confirmed by the confirmatory studies being conducted by Apellis; whether results obtained in preclinical studies and clinical trials will be indicative of results that will be generated in future preclinical and clinical trials; whether APL-2 will successfully advance through the clinical trial process on a timely basis, or at all, including whether dosing in the Phase III GA program will resume when anticipated; whether the results of such clinical trials will warrant regulatory submissions and whether APL-2 will receive approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies for GA, PNH or any other indication; whether, if Apellis' products receive approval, they will be successfully distributed and marketed; and other factors discussed in the "Risk Factors" section of Apellis' Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on July 31, 2018 and the risks described in other filings that Apellis may make with the Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of the date hereof, and Apellis 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: October 17, 2018

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