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): **December 20, 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 8.01. Other Events.

On December 20, 2018, Apellis Pharmaceuticals, Inc. issued a press release providing an update on the status of its Phase 3 clinical program for APL-2 in patients with geographic atrophy. A copy of the press release has been filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated December 20, 2018, of Apellis Pharmaceuticals, Inc.

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: December 20, 2018

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

EXHIBIT 99.1

Apellis Provides Update on Its Phase 3 Program for Patients with Geographic Atrophy

Phase 3 geographic atrophy program enrollment timeline currently unchanged; program enrollment is expected to restart in Q2 2019 and enrollment completion is expected in Q1 2020

CRESTWOOD, Ky., and WALTHAM Mass., December 20, 2018 (GLOBE NEWSWIRE) – Apellis Pharmaceuticals Inc. (Nasdaq:APLS) today provided an update on the status of its Phase 3 program for APL-2 in patients with Geographic Atrophy (GA). Apellis expects to be able to restart enrollment of its two Phase 3 GA trials (DERBY & OAKS) in Q2 2019 and to have fully enrolled both studies by the end of Q1 2020, within the originally planned timeline for completion.

As previously disclosed, the Company voluntarily implemented a temporary 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 drug product. The Company believes the source of inflammation in the Phase 3 trials resides in an impurity or contaminant in the active pharmaceutical ingredient (API). Inflammation in all affected patients has resolved. In the Phase 2 FILLY trial, where more than 1,500 intravitreal injections of APL-2 were given, APL-2 was well tolerated with only a single case of non-infectious inflammation reported. The source of inflammation has had no known impact on the studies utilizing systemic administration of APL-2.

Based on Apellis' investigation, which included a full manufacturing process review, six non-clinical studies in two species and an ongoing Phase 1b clinical study in patients with GA with low vision, the Company does not believe that the following were the root causes for the observed inflammation in the Phase 3 GA program: (i) The pharmacology or chemical composition of APL-2, (ii) A formulation change that was implemented between the Phase 2 FILLY trial and the Phase 3 trials, and (iii) The fill and finish process for the APL-2 intravitreal drug product.

In order to resume the Phase 3 GA program in a safe and expeditious manner, the company has introduced improvements to the manufacturing process in order to eliminate impurities and potential contaminants like those that are believed to have caused inflammation in the Phase 3 trials. A new lot of API incorporating these improvements has been manufactured and is ready for release in a quantity sufficient to complete both the DERBY and OAKS Phase 3 clinical trials. The Company believes that the improved manufacturing process can be used to supply API at a scale required for global commercialization. In non-clinical testing, treatment with API manufactured through the improved manufacturing process did not cause inflammation. Finally, prior to introduction in the Phase 3 clinical trials, new lots of API may first be introduced in a small Phase 1b study of patients with GA with low vision.

“We believe that APL-2 has the potential to offer significant benefit to patients with geographic atrophy, a disease that results in blindness, and for which there are no FDA approved treatments,” said Cedric Francois, CEO and co-founder of Apellis. “We are pleased to have clarity around our path forward so that we can continue development of this important potential treatment, and on schedule.”

About the DERBY and OAKS trials

The Derby and OAKS trials are 600-patient prospective, international, multicenter, randomized, double-masked, sham-injection controlled Phase 3 studies assessing the efficacy and safety of multiple intravitreal (IVT) injections of APL-2 in patients with Geographic Atrophy (GA) secondary to age-related macular degeneration (AMD). For more information, please visit https://gastudy.com/.

About the FILLY trial

The FILLY trial was a 246-patient Phase 2 multicenter, randomized, single-masked, sham-controlled clinical trial of APL-2 in patients with GA conducted at over 40 clinical sites, located in the United States, Australia and New Zealand. APL-2 was administered as an intravitreal injection in the study eye monthly or every other month for 12 months, followed by six months of monitoring without active treatment until Month 18. Eyes were evaluated for GA by fundus autofluorescence photographs (FAF). The rate of GA area growth was measured from baseline to Month 18. The primary efficacy endpoint was the change in GA lesion size from baseline to Month 12, compared to sham.

About Geographic Atrophy (GA)

GA is an advanced form of age-related macular degeneration (AMD), a disorder of the central portion of the retina, known as the macula, which is responsible for central vision and color perception. GA is a chronic, progressive condition that leads to central blind spots and permanent loss of vision. Based on published studies, the company estimates that approximately one million people have GA in the United States alone. There are currently no FDA-approved treatments for GA.

About APL-2

APL-2 is designed to inhibit the complement cascade centrally at C3 and may have the potential to treat a wide range of complement-mediated diseases more effectively than is possible with partial inhibitors of complement. APL-2 is a synthetic cyclic peptide conjugated to a polyethylene glycol (PEG) polymer that binds specifically to C3 and C3b, effectively blocking all three pathways of complement activation (classical, lectin, and alternative). In addition to the DERBY and OAKS trials, Apellis is currently evaluating APL-2 in a head-to-head Phase 3 clinical trial for systemic administration comparing APL-2 to Soliris in PNH patients with hemoglobin levels less than 10.5g/dL (the PEGASUS trial), a Phase 1b clinical trial for systemic administration in treatment naïve PNH patients (the PADDOCK trial), and a Phase 1b clinical trial for systemic administration in eculizumab-treated PNH patients (the PHAROAH trial).

About Apellis

Apellis Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company focused on the development of novel therapeutic compounds for the treatment of a broad range of life-threatening or debilitating autoimmune diseases based upon complement immunotherapy through the inhibition of the complement system at the level of C3. Apellis is the first company to advance chronic therapy with a C3 inhibitor into clinical trials. For additional information about Apellis and APL-2, please visit http://www.apellis.com. For additional information regarding our clinical trials, visit www.apellis.com/clinical-trials.html.

Forward-Looking Statements

Statements in this press release 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 we are able to resume dosing of patients in the Phase 3 GA trials on the timelines anticipated or at all; whether we will be able to enroll patients in the Phase 3 GA trials rapidly enough to meet the projected timelines; 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; whether APL-2 will successfully advance through the clinical trial process on a timely basis, or at all; 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 November 13, 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.

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