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): September 4, 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** **(Address of Principal Executive Offices)**	**40014** **(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 September 4, 2018, Apellis Pharmaceuticals, Inc. (the "Company") issued a press release announcing that all four patients enrolled in its ongoing Phase 1b PHAROAH clinical trial of APL-2 in patients with paroxysmal nocturnal hemoglobinuria have been transitioned from co-treatment with APL-2 and eculizumab to APL-2 monotherapy. The Company also announced additional data regarding these patients.

A copy of the press release announcing this event 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 September 4, 2018

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: September 4, 2018

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

Exhibit 99.1

Apellis Pharmaceuticals Announces that All Four Severely Anemic Soliris™ - Treated Patients with Paroxysmal Nocturnal Hemoglobinuria in Ongoing Phase 1b Trial Have Been Transitioned to APL-2 Monotherapy

PHAROAH Trial Results to-Date Show APL-2 Monotherapy Eliminated Transfusion Dependency and Improved Markers of Anemia in PNH Patients on Soliris™

CRESTWOOD, Ky. and WALTHAM, Mass., Sept. 04, 2018 (GLOBE NEWSWIRE) — Apellis Pharmaceuticals, Inc. (Nasdaq:APLS), a clinical-stage biopharmaceutical company focused on the development of novel therapeutic compounds to treat disease through the inhibition of the complement system, today announced an update on its US-based Phase 1b PHAROAH trial for patients with paroxysmal nocturnal hemoglobinuria (PNH). The ongoing PHAROAH trial is evaluating treatment with APL-f2, a novel inhibitor of complement factor C3, in patients on treatment with eculizumab (Soliris™) who are severely anemic and transfusion-dependent.

Patients enrolled in the PHAROAH trial were initially co-treated with APL-2 and eculizumab, with the potential for discontinuation of eculizumab at the discretion of the treating physician. Two of the six patients were removed from treatment with APL-2 due to pregnancy and BMI-associated comorbidities. Four of the six patients continued in the study for more than 32 weeks. In these four patients, co- treatment with APL-2 resulted in an improvement of hemoglobin levels and other markers for anemia and none of the four patients required a transfusion during the co-treatment period with eculizumab, which ranged from 17 to 20 months. Earlier this year Apellis announced that three of the four patients discontinued treatment with eculizumab and were continuing to receive APL-2. The fourth patient has now discontinued treatment with eculizumab and is continuing to receive APL-2. All four patients have improved hemoglobin and reticulocytes as compared to the baseline established with eculizumab monotherapy and have achieved lactate dehydrogenase (LDH) levels below the upper limit of normal (ULN).

	Eculizumab Monotherapy[i]	APL-2 + Eculizumab[ii]	APL-2 Monotherapy[iii]
Hemoglobin (g/dL)*	8.9	11.9	11.4
Annual Transfusions (avg.)	6.0	0	0
LDH (ULN)*	1.0x	0.8x	0.9x
Reticulocytes (ULN)*	2.7x	1.2x	0.8x
Patient Years (Total)	NA	5.9 Years	1.9 Years
Multiple of Eculizumab Label Dose (900mgx2wk.)	1.6x	1.0x	—

* Average last available reading for all four patients on each dosing regimen
(i) last reading during eculizumab monotherapy prior to co-treatment with APL-2
(ii) last reading during co-treatment and prior to APL-2 monotherapy
(iii) last reading while on APL-2 monotherapy

“By eliminating transfusion dependency and improving markers of anemia in patients in the study, APL-2 has given these patients a meaningful clinical benefit over eculizumab monotherapy,” said Dr. Cedric Francois, M.D., Ph.D., co-founder and CEO of Apellis. “This is precisely the benefit that we are aiming to confirm in our ongoing PEGASUS Phase 3 head-to-head trial against eculizumab.”

In addition to the PHAROAH trial and the ongoing Phase 3 head-to-head trial against eculizumab, APL-2 is also being evaluated in the PADDOCK Phase 1b trial in treatment naïve patients. Apellis previously reported that the patients in the PADDOCK trial experienced a mean 3.5 g/dL improvement in hemoglobin and an average reduction in LDH to within the normal range after daily subcutaneous administration of APL-2 for at least 28 days.

To date, subcutaneous APL-2 has been well-tolerated with cumulative systemic exposure of over 18 patient years of treatment on APL-2. No significant infections or thromboembolic events have been observed.

About Paroxysmal Nocturnal Hemoglobinuria

Paroxysmal nocturnal hemoglobinuria (PNH) is a rare, acquired, potentially life-threatening disease characterized by complement-mediated hemolysis with or without hemoglobinuria, an increased susceptibility to thrombotic episodes and/or some degree of bone marrow dysfunction. A significant subset of patients treated with the current standard of care still suffer from debilitating anemia and transfusion dependence.

About the PHAROAH Trial

PHAROAH is an ongoing open label safety and efficacy study of 270 mg of APL-2 administered daily by subcutaneous injection as a complementary therapy to patients with PNH who continue to be anemic (Hb <10 g/dL at screening or have a history of at least one transfusion in the previous year) despite treatment with eculizumab. The PHAROAH study was initiated in November 2014 and is being conducted at multiple clinical sites in the United States.

About the PEGASUS Phase 3 Trial

PEGASUS is a 70-patient, randomized, head-to-head study comparing APL-2 monotherapy to eculizumab monotherapy in patients currently on treatment with eculizumab who have a hemoglobin level <10.5 g/dL, regardless of eculizumab dose or transfusion history. Patients will be co-treated for 4 weeks with twice weekly subcutaneous infusions of 1080 mg of APL-2 alongside their existing eculizumab regimen and then randomized 1:1 to either APL-2 monotherapy or eculizumab monotherapy and monitored for 56 weeks. The primary endpoint will be change in hemoglobin from baseline to Week 16. Secondary endpoints include change from baseline to Week 16 in absolute reticulocyte count, LDH levels and FACIT-fatigue score. The number of packed red blood cell units transfused from Week 4 to 16 will also be compared.

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 PHAROAH trial, 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) and a Phase 1b clinical trial for systemic administration in treatment naïve PNH patients (the PADDOCK trial). Apellis is also testing APL-2 for systemic administration in a Phase 2 clinical trial in autoimmune hemolytic anemia (AIHA) and a Phase 2 clinical trial in complement dependent nephropathies, as well as a Phase 1b/2 clinical trial evaluating intravitreal APL-2 in wet age-related macular degeneration. Phase 3 studies are planned for APL-2 via intravitreal administration for geographic atrophy (GA). Future clinical studies of APL-2 are anticipated in PNH and other diseases in which complement is implicated.

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.

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 preliminary or interim results from a clinical trial such as the results reported in this release 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 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.

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