

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 8-K**

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**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 7, 2020**

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**Apellis Pharmaceuticals, Inc.**

(Exact Name of Registrant as Specified in its Charter)

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**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-38276**  
(Commission  
File Number)

**27-1537290**  
(IRS Employer  
Identification No.)

**100 Fifth Avenue**  
**Waltham, MA**  
(Address of Principal Executive Offices)

**02451**  
(Zip Code)

**Registrant's telephone number, including area code: (617) 977-5700**

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

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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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	APLS	Nasdaq Global Select Market

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

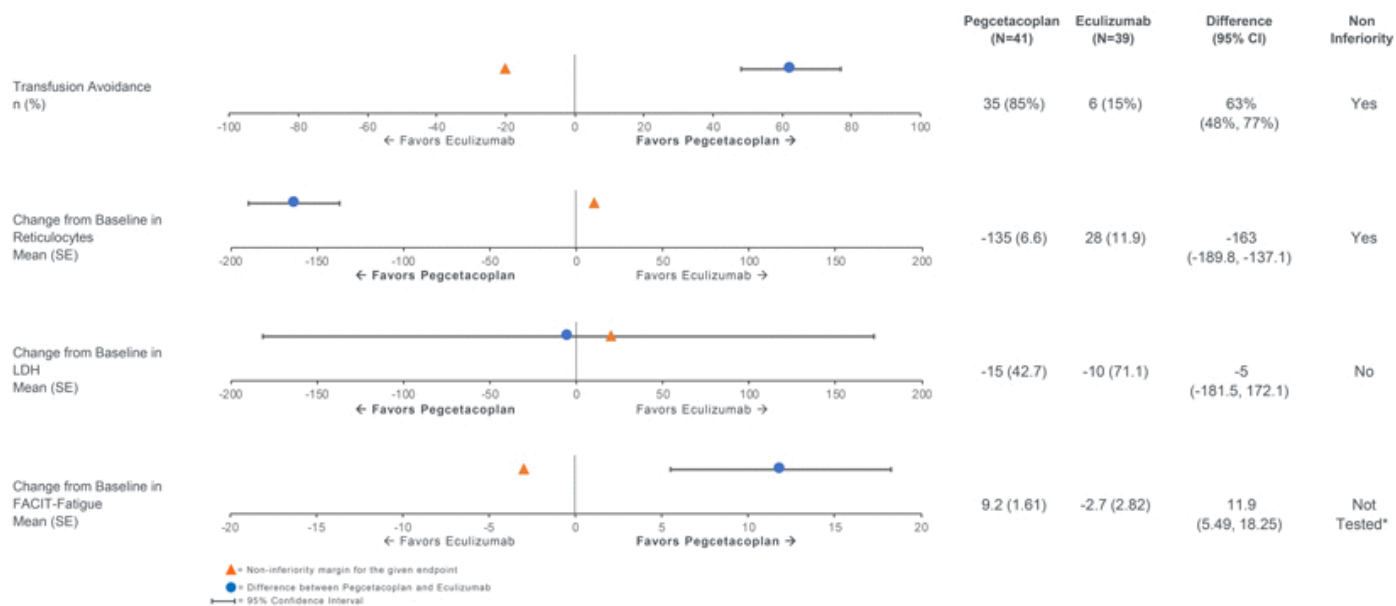
If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 8.01. Other Events.**

On January 7, 2020, Apellis Pharmaceuticals, Inc. (the “Company”) announced top-line data from its Phase 3 clinical trial of pegcetacoplan (APL-2) in patients with paroxysmal nocturnal hemoglobinuria, or PNH, which it refers to as the PEGASUS trial. The top-line data showed that pegcetacoplan met the trial’s primary efficacy endpoint, demonstrating superiority to eculizumab with a statistically significant improvement in adjusted means of 3.8 g/dL of hemoglobin at week 16 (p<0.0001). At week 16, pegcetacoplan-treated patients (n=41) had an adjusted mean hemoglobin increase of 2.4 g/dL from a baseline of 8.7 g/dL, compared to eculizumab-treated patients (n=39) who had a change of -1.5 g/dL from a baseline of 8.7 g/dL.

Additionally, pegcetacoplan showed promising results in key secondary endpoints. Pegcetacoplan met non-inferiority on transfusion avoidance and absolute reticulocyte count. Pegcetacoplan showed positive trends on mean lactate dehydrogenase, or LDH, and fatigue as measured by the Functional Assessment of Chronic Illness Therapy, or FACIT, -fatigue score.

The following table summarizes the reported results from the key secondary endpoints of the PEGASUS trial.



LDH = Lactate Dehydrogenase. FACIT = Functional Assessment of Chronic Illness Therapy. Mean (SE) = Adjusted means (SE) are based on the mixed model repeated measures (MMRM) analysis. CI = Confidence Interval. SE = Standard Error.

Key Secondary Endpoints analyses are based on pre-specified Non-Inferiority Margins. Non-inferiority is achieved if the LCL or UCL of the 95% CI of the treatment difference meets the pre-specified margin.

\* Not Tested: As LDH did not achieve non-inferiority, no other endpoints were tested.

The statistical analysis plan for the PEGASUS trial provided for use of the mixed model - repeated measures (MMRM) method. To avoid the effect of transfusions in hemoglobin levels during the 16-week randomization period of the trial, if a patient received a transfusion during the 16-week randomization period, any measurements after the first transfusion were censored from the data used in the MMRM analysis. The treatment effects using observed data from the trial, which included all post-transfusion measurements, were consistent with and supportive of the reported results from the MMRM analysis.

In the trial, the safety profile of pegcetacoplan was comparable to eculizumab. Seven of 41 patients (17.1%) in the pegcetacoplan group experienced a serious adverse event, or SAE, and 6 of 39 patients (15.4%) in the eculizumab group experienced SAEs. No cases of meningitis and no deaths were reported in either treatment group. The most common adverse events reported during the 16-week, randomized, controlled treatment period in the pegcetacoplan and eculizumab groups, respectively, were injection site reactions (36.6% vs. 2.6%), diarrhea (22.0% vs. 0%), headache (7.3% vs. 20.5%) and fatigue (4.9% vs. 15.4%). Another common adverse event was hemolysis, which was reported in four patients in the pegcetacoplan group (9.8%) and nine patients in the eculizumab group (23.1%). This led to the three discontinuations in pegcetacoplan group.

All patients who completed the randomization period in both groups (77/80) entered the 32-week open-label pegcetacoplan treatment period.

The Company intends to meet with regulatory agencies in the first half of 2020 to discuss what information is required to support regulatory submissions of a new drug application and a marketing authorization application for pegcetacoplan in PNH. The FDA has advised us that, for the approval of a new treatment for PNH, hemoglobin stabilization in conjunction with change in transfusion dependence constitute accepted clinical benefit, but that a rise in hemoglobin levels may not translate to clinical benefit in patients who entered the trial with high hemoglobin levels, such as permitted by the inclusion criteria of the PEGASUS trial, and who do not require transfusions. The Company believes that the data from the PEGASUS trial support a finding of clinical benefit. As clinical data is susceptible to varying interpretations and analyses, the Company will need to discuss the data with the FDA, European Medicines Agency and other regulatory agencies before the Company can determine its next steps.

**Forward-Looking Statements**

Statements in this Current Report on Form 8-K hereto 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 will be predictive of the final results of the trial; whether results obtained in preclinical studies and clinical trials such as the results reported in this Current Report on Form 8-K will be indicative of results that will be generated in future clinical trials; whether pegcetacoplan will successfully advance through the clinical trial process on a timely basis, or at all; whether the results of the PEGASUS or other clinical trials will be sufficient to form the basis of regulatory submissions, whether the Company's clinical trials will warrant regulatory submissions and whether pegcetacoplan will receive approval from the FDA or equivalent foreign regulatory agencies for geographic atrophy, PNH, C3 glomerulopathy or any other indication; whether, if the Company's products receive approval, they will be successfully distributed and marketed; and other factors discussed in the "Risk Factors" section of the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 5, 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 Current Report on 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.

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**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: January 7, 2020

By: /s/ Timothy Sullivan  
Timothy Sullivan  
Chief Financial Officer