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): August 8, 2024

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.)**

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)

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 August 8, 2024, Apellis Pharmaceuticals, Inc. ("Apellis") and Sobi® announced positive topline results from the Phase 3 VALIANT study investigating systemic pegcetacoplan in patients with C3 glomerulopathy (C3G) or primary immune complex membranoproliferative glomerulonephritis (IC-MPGN), which are rare kidney diseases with no approved treatments.

The study met the primary endpoint, demonstrating a statistically significant and clinically meaningful 68% ($p<0.0001$) proteinuria reduction (log-transformed ratio of urine protein-to-creatinine ratio) in C3G and IC-MPGN patients treated with pegcetacoplan compared to placebo, both in addition to background therapy, at Week 26. Results were consistent across all subgroups, including C3G and IC-MPGN, adolescent and adult patients, and native and post-transplant kidneys.

Pegcetacoplan also demonstrated statistical significance on the key secondary endpoints of composite renal endpoint, which combines proteinuria reduction and estimated glomerular filtration rate (eGFR) stabilization, and proteinuria reduction of at least 50 percent compared to baseline, as well as nominal significance on the histological endpoint of reduction in C3c staining on kidney biopsy and stabilization of kidney function as measured by eGFR compared to placebo.

In the VALIANT study, pegcetacoplan demonstrated favorable safety and tolerability results, consistent with its established profile. Rates of adverse events (AEs), serious AEs, and AEs leading to study drug discontinuation were similar between the pegcetacoplan and placebo groups. There were no cases of meningitis or serious infections attributed to encapsulated bacteria.

All patients who have already completed the VALIANT study have now enrolled into the VALE long-term extension study.

Apellis plans to submit a supplemental new drug application to the U.S. Food and Drug Administration in early 2025, and Sobi plans to submit a marketing application with the European Medicines Agency in 2025. Detailed data will be presented at an upcoming medical congress.

Forward-Looking Statements

Statements in this Current Report on 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 regarding plans to submit applications for regulatory approval for the treatment of patients with C3G and IC-MPGN. 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 systemic pegcetacoplan will receive approval for those indications from the FDA or equivalent foreign regulatory agencies when expected or at all; and any other factors discussed in the "Risk Factors" section of Apellis' Annual Report on Form 10-K with the Securities and Exchange Commission on February 27, 2024 and the risks described in other filings that Apellis 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 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: August 8, 2024

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