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 22, 2023

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**	**02451**
(Address of Principal Executive Offices)	**(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 22, 2023, Apellis Pharmaceuticals, Inc. ("Apellis" or the "Company") provided an update on injection kits supplied by Apellis and an update on the rare events of retinal vasculitis reported in real-world treatment with SYFOVRE® (pegcetacoplan injection) for geographic atrophy (GA) secondary to age-related macular degeneration.

Recommended use of filter needles included in certain injection kits

As part of the comprehensive investigation into the real-world safety events, internal structural variations were identified in the specific 19-gauge x 1½ inch filter needle included in certain injection kits. Filter needles are used to withdraw treatment from the vial when preparing for an injection procedure. A causal relationship has not been established between the structural variations in this 19-gauge filter needle and the rare events of retinal vasculitis in the real world.

The Company recommends that practitioners immediately discontinue use of any injection kits that contain 19-gauge filter needles, and use injection kits with the 18-gauge filter needle, which are already in distribution. While injection kits previously contained one of two types of filter needles (either 18- or 19-gauge), Apellis is now exclusively distributing injection kits with the 18-gauge filter needle.

Update on rare events of retinal vasculitis reported to date

- Over 100,000 SYFOVRE vials have been distributed for commercial use and for administration in clinical trials. This includes:
    - Over 78,000 vials distributed since launch, including commercial vials shipped and sample vials distributed to physician practices. Over 26,000 vials distributed in the third quarter to date.
    - Approximately 24,000 SYFOVRE injections administered in clinical trials to date.
- In total, eight events of retinal vasculitis (five occlusive, three non-occlusive) have been confirmed. The last confirmed event of retinal vasculitis occurred on June 20, based on a review of adverse events reported to the Company. Since then, more than 32,000 SYFOVRE vials have been distributed.
    - This includes one additional event of occlusive retinal vasculitis, which occurred in May, and was reported after the Company's last communication on July 29.
    - Two of the patients had their SYFOVRE injection in April, three in May, and three in June.
    - All events of retinal vasculitis were observed after the first injection of SYFOVRE.
    - One patient remained stable at baseline vision, two patients have recovered vision nearly back to baseline, two patients have severe vision impairment which is unlikely to be resolved, and three patients' outcomes are still pending.
- There are two events of suspected retinal vasculitis. As previously disclosed, there was one event that occurred in May and the patient's vision has returned to baseline. The other event occurred in August and the patient's outcome is pending. Neither event has been confirmed.

All post-marketing adverse events reported to the company, including events of retinal vasculitis, are reviewed by Apellis' Medical and Safety Committee. Any suspected events of vasculitis are also evaluated by external retina/uveitis specialists for adjudication.

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 the safety profile of SYFOVRE. 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 benefit/risk profile of SYFOVRE following these reported events will impact Apellis’ commercialization efforts; whether SYFOVRE will receive approval from foreign regulatory agencies for GA when expected or at all, including the impact on the likelihood and timing of such approvals of the reported events of retinal vasculitis; and other factors discussed in the “Risk Factors” section of Apellis’ Annual Report on Form 10-K with the Securities and Exchange Commission on February 21, 2023 and the Risk Factors section of Apellis’ Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on July 31, 2023 and 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 22, 2023

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