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): July 15, 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** **(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 7.01 Regulation FD Disclosure.

Apellis Pharmaceuticals, Inc. ("the Company") has received reports of six events of retinal vasculitis following SYFOVRE® (pegcetacoplan injection) treatment. The Company has reviewed these events with the American Society of Retina Specialists ("ASRS") Research and Safety in Therapeutics ("ReST") Committee. On July 15, 2023, the ReST Committee, in collaboration with the Company, sent a notification to its members. All events were observed after the first injection of SYFOVRE, between 7-13 days after drug administration, and with no specific lots implicated. Upon review with external experts, two of the events were confirmed as occlusive, one was confirmed as non-occlusive, and the remaining three were undetermined based on limited information and lack of imaging. The etiology of these events is unclear, and outcomes in these patients are still evolving.

The reported vasculitis events have occurred at an estimated rate of approximately 1 in 10,000 injections, or 0.01% per injection. To date, approximately 60,000 vials of SYFOVRE have been distributed since the U.S. Food and Drug Administration ("FDA") approval on February 17, 2023, including commercial vials shipped to physician practices as well as sample vials delivered. In addition, there were zero events of retinal vasculitis reported in the clinical trials, reflecting more than 23,000 injections to date.

The Company is continuing to conduct a thorough investigation of each of the events, working closely with the ReST Committee and several external specialists. Apellis takes adverse event reporting very seriously and immediately followed up with the FDA upon receiving the reports of vasculitis. In this regard, each event was reviewed with the FDA and no action is planned at this time. The Company has updated ReST on these interactions and will continue to do so should new information become available.

The information in this Item 7.01 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

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: July 17, 2023

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