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): October 5, 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 2.02 Results of Operations and Financial Condition.

On October 5, 2023, Apellis Pharmaceuticals, Inc. (the "Company") issued a press release announcing preliminary U.S. net product revenues for SYFOVRE® (pegcetacoplan injection) for the three months ended September 30, 2023 and since commercial launch of SYFOVRE in March 2023, and providing other business updates. The full text of the press release issued by the Company in connection with the announcement is being furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 2.02, including Exhibit 99.1 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (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 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated October 5. 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: October 5, 2023

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

Apellis Announces Preliminary U.S. Net Revenues of Approximately $74 Million for SYFOVRE® (pegcetacoplan injection) in the Third Quarter of 2023

- *Continued strong demand, with more than 100,000 vials (commercial and sample) distributed to date; growth in week-over-week demand returned starting in August*
- *Permanent J-code effective as of October 1, and more than 95% of all Medicare payers now covering SYFOVRE*
- *Up to 45% reduction of nonsubfoveal GA lesion growth observed between Months 24-30 compared to projected sham in the GALE extension study*
- *Estimated rate of retinal vasculitis continues to be rare at 0.01% per injection*

WALTHAM, Mass., October 5, 2023 (GLOBE NEWSWIRE) – Apellis Pharmaceuticals, Inc. (Nasdaq: APLS) today provided an update on the launch of SYFOVRE® (pegcetacoplan injection) for geographic atrophy (GA) secondary to age-related macular degeneration (AMD).

“In only seven months, more than 100,000 vials have been shipped to physician practices, which we believe is a testament to the unmet need and the strength of SYFOVRE’s product profile. SYFOVRE offers increasing treatment effects over time with as few as six doses per year,” said Adam Townsend, chief commercial officer, Apellis. “It is very encouraging to see the return to weekly growth in demand as physicians and patients have learned more about the long-term efficacy from the GALE study and real-world safety of SYFOVRE. With our permanent J-code now in place, we look forward to building on these trends and continuing to bring SYFOVRE to people living with this chronic disease.”

Highlights from the launch to date include:

Strong growth in demand

- Apellis expects approximately $74 million in preliminary U.S. net product revenue for SYFOVRE in the third quarter and approximately $160 million in preliminary total U.S. net product revenue for SYFOVRE since launch in March 2023 through September 30, 2023.[i]
- Approximately 37,000 commercial vials and 10,000 samples were distributed to physician practices in the third quarter; more than 100,000 total vials have been delivered to date.
    - Continued strong demand; week-over-week growth returned starting in August, with weekly orders from both new and existing sites of care.

Positive reimbursement of SYFOVRE

- Permanent J-code effective as of October 1, which will help ensure accurate and efficient reimbursement of SYFOVRE.
- 93% of Medicare Advantage payers and 100% of Original Medicare (fee-for-service) payers are now covering SYFOVRE.
    - Apellis estimates that 94% of the U.S. GA population is covered by Medicare.

[i] The estimated revenue figures are preliminary and based on management’s estimate as of the date of this press release and are subject to completion of the Company’s financial closing and review procedures.

Long-term efficacy and visual function benefit

- In the GALE long-term extension study, which was reported in July 2023, SYFOVRE continued to slow GA progression between Months 24 and 30 compared to projected sham (all p-values nominal):
    - SYFOVRE reduced GA lesion growth with both monthly (39%; p<0.0001) and every-other-month (EOM) (32%; p<0.0001) treatment.
    - SYFOVRE reduced nonsubfoveal GA lesion growth with monthly (45%; p<0.0001) and EOM (33%; p=0.0023) treatment.
- New functional data from post-hoc microperimetry analysis demonstrating that SYFOVRE prolonged foveal sensitivity in the Phase 3 OAKS study will be presented as a late-breaking presentation at the EURETINA Congress on Friday, October 6 at 12:24 CEST.

Long-term and real-world safety

- In the GALE study at 30 Months, the safety profile of SYFOVRE continued to be consistent with previously reported Phase 3 data.
- The estimated real-world rate of retinal vasculitis remains rare, at 0.01% per injection.
    - In total, there have been 10 confirmed events of retinal vasculitis (seven occlusive, three non-occlusive) and two suspected events.
    - Since the last update on August 22, there was one new confirmed event that occurred in early August and two new suspected events, one that occurred in mid-August and one in September. Of the two events that were previously classified as suspected, one event has been confirmed and the other was adjudicated to not be retinal vasculitis.
    - Of the confirmed retinal vasculitis events, six patients have recovered vision either fully or partially, three patients have severe vision impairment that is unlikely to be resolved, and one patient's outcome is pending. Visual outcomes in both suspected events are pending.
    - All suspected retinal vasculitis events reported to Apellis are independently evaluated and adjudicated by two external sources: a panel of four retina/uveitis experts and an independent reading center as well as Apellis' internal safety and medical teams.
- Apellis submits all reported adverse events to the U.S. FDA consistent with reporting guidelines for drug manufacturers. Apellis and the American Society of Retina Specialists (ASRS) are in close communication regarding reported cases of retinal vasculitis.

About Geographic Atrophy (GA)

Geographic atrophy (GA) is an advanced form of age-related macular degeneration and a leading cause of blindness worldwide, impacting more than one million Americans and five million people worldwide.[1,2] It is a progressive and irreversible disease caused by the growth of lesions, which destroy the retinal cells responsible for vision. The vision loss caused by GA severely impairs independence and quality of life by making it difficult to participate in daily activities. On average, it takes only 2.5 years for GA lesions to start impacting the fovea, which is responsible for central vision.[3]

About SYFOVRE® (pegcetacoplan injection)

SYFOVRE® (pegcetacoplan injection) is the first and only approved therapy for geographic atrophy (GA). By targeting C3, SYFOVRE is designed to provide comprehensive control of the complement cascade, part of the body's immune system. SYFOVRE is approved in the United States for the treatment of GA secondary to age-related macular degeneration.

Marketing applications are currently under review with five regulatory agencies worldwide. A decision in the EU is expected in early 2024, and decisions in Canada, Australia, Switzerland, and the United Kingdom are expected in the first half of 2024.

1 Rudnicka AR, Jarrar Z, Wormald R, et al. Age and gender variations in age-related macular degeneration prevalence in populations of European ancestry: a meta analysis. Ophthalmology 2012;119:571–580.

2 Wong WL, Su X, Li X, et al. Global prevalence of age-related macular degeneration and disease burden projection for 2020 and 2040: a systematic review and meta-analysis. Lancet Glob Health 2014;2:e106–116.

3 Lindblad AS, et al, and AREDS Research Group. Arch Ophthalmol. 2009;127(9):1168-1174.

U.S. Important Safety Information for SYFOVRE® (pegcetacoplan injection)

CONTRAINDICATIONS

- SYFOVRE is contraindicated in patients with ocular or periocular infections, and in patients with active intraocular inflammation

WARNINGS AND PRECAUTIONS

- Endophthalmitis and Retinal Detachments
    - Intravitreal injections, including those with SYFOVRE, may be associated with endophthalmitis and retinal detachments. Proper aseptic injection technique must always be used when administering SYFOVRE to minimize the risk of endophthalmitis. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately.
- Neovascular AMD
    - In clinical trials, use of SYFOVRE was associated with increased rates of neovascular (wet) AMD or choroidal neovascularization (12% when administered monthly, 7% when administered every other month and 3% in the control group) by Month 24. Patients receiving SYFOVRE should be monitored for signs of neovascular AMD. In case anti-Vascular Endothelial Growth Factor (anti-VEGF) is required, it should be given separately from SYFOVRE administration.
- Intraocular Inflammation
    - In clinical trials, use of SYFOVRE was associated with episodes of intraocular inflammation including: vitritis, vitreal cells, iridocyclitis, uveitis, anterior chamber cells, iritis, and anterior chamber flare. After inflammation resolves, patients may resume treatment with SYFOVRE.
- Increased Intraocular Pressure
    - Acute increase in IOP may occur within minutes of any intravitreal injection, including with SYFOVRE. Perfusion of the optic nerve head should be monitored following the injection and managed as needed.

ADVERSE REACTIONS

- Most common adverse reactions (incidence ≥5%) are ocular discomfort, neovascular age-related macular degeneration, vitreous floaters, conjunctival hemorrhage.
- To report suspected adverse reactions, contact Apellis Pharmaceuticals, Inc. at 1-833-866-3346 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see accompanying full Prescribing Information for more information.

About Apellis

Apellis Pharmaceuticals, Inc. is a global biopharmaceutical company that combines courageous science and compassion to develop life-changing therapies for some of the most challenging diseases patients face. We ushered in the first new class of complement medicine in 15 years and now have two approved medicines targeting C3. These include the first-ever therapy for geographic atrophy, a leading cause of blindness around the world. With nearly a dozen clinical and pre-clinical programs underway, we believe we have only begun to unlock the potential of targeting C3 across many serious diseases. For more information, please visit http://apellis.com or follow us on Twitter and LinkedIn.

Apellis Forward-Looking Statement

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 regarding Apellis’s preliminary financial information and 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 the events of retinal vasculitis will impact its commercialization efforts; whether SYFOVRE will receive approval from foreign regulatory agencies

for GA when expected or at all, including the impact of the reported events of retinal vasculitis on the likelihood and timing of such approvals; adjustments to Apellis' preliminary revenue figures resulting from, among other things, the completion of financial closing and review procedures for the quarter ended September 30, 2023; 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 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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