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): January 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 2.02 Results of Operations and Financial Condition

On January 8, 2024, Apellis Pharmaceuticals, Inc. (the "Company") issued a press release announcing preliminary unaudited total U.S. net product revenues and net product revenue for SYFOVRE and EMPAVELI for the fourth quarter and full year ended December 31, 2023. 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.

The Company's U.S. net product revenue figures are preliminary and unaudited, represent management's estimate as of the date of this report and are subject to completion of the Company's financial closing procedures. The Company's independent registered public accounting firm has not conducted an audit or review of, and does not express an opinion or any other form of assurance with respect to, the Company's net product revenue figures.

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 January 8, 2024
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: January 8, 2024

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

Apellis

Apellis Announces Preliminary Fourth Quarter and Full Year 2023 U.S. Net Product Revenues

- *Approximately $114 million in preliminary fourth quarter SYFOVRE® revenue as strong launch continues*
- *Approximately $24 million in preliminary fourth quarter EMPAVELI® revenue*

WALTHAM, Mass., January 8, 2024 (GLOBE NEWSWIRE) – Apellis Pharmaceuticals, Inc. (Nasdaq: APLS) today announced preliminary U.S. net product revenues of approximately $138 million for the fourth quarter and approximately $366 million for the full year 2023 for SYFOVRE® (pegcetacoplan injection) for geographic atrophy (GA) secondary to age-related macular degeneration and for EMPAVELI® (pegcetacoplan) for adults with paroxysmal nocturnal hemoglobinuria (PNH).

Strong SYFOVRE launch continues:

- Approximately $114 million and $275 million expected in preliminary U.S. net product revenues in the fourth quarter and full year 2023, respectively.[i]
- Approximately 62,000 doses (commercial and sample vials) distributed to physician practices in the fourth quarter; approximately 160,000 total doses have been distributed in 2023.
- Approximately 95% of treated GA patients are estimated to be using SYFOVRE.[ii]

Continued momentum with EMPAVELI:

- Approximately $24 million and $91 million expected in preliminary U.S. net product revenues in the fourth quarter and full year 2023, respectively.[i]
- High patient compliance rate of 97%.[iii]
- More than 50% of existing patients and more than 90% of new patients now use the EMPAVELI Injector, an on-body device designed to streamline self-administration, since the October Injector approval.[iii]

“SYFOVRE is the market-leading treatment for GA, with approximately 160,000 doses distributed since launch. More patients than ever are benefiting from SYFOVRE, including the increasing treatment effects over time and flexible dosing, and we look forward to building on the momentum this year,” said Cedric Francois, M.D., Ph.D., co-founder and chief executive officer, Apellis. “Additionally, the high compliance observed with EMPAVELI speaks to the important impact of this medicine on patients’ lives. In addition to advancing our pipeline, we believe the tremendous commercial progress made in the past year has positioned us for an even stronger 2024.”

J.P. Morgan Healthcare Conference Presentation and Webcast

Dr. Francois will discuss these updates in a corporate presentation at the 42nd Annual J.P. Morgan Healthcare Conference today, Monday, January 8, 2024, at 9:45 a.m. PT. The event will be available via a live webcast from the “Events and Presentations” page of the “Investors and Media” section of the company’s website. A replay of the webcast will be available for approximately 30 days following the event.

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.

About EMPAVELI®/Aspaveli® (pegcetacoplan)

EMPAVELI®/Aspaveli® (pegcetacoplan) is a targeted C3 therapy designed to regulate excessive activation of the complement cascade, part of the body’s immune system, which can lead to the onset and progression of many

serious diseases. It is approved for the treatment of paroxysmal nocturnal hemoglobinuria (PNH) in the United States, European Union, and other countries globally. The therapy is also under investigation for several other rare diseases across hematology and nephrology.

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.
- Retinal Vasculitis and/or Retinal Vascular Occlusion
    - Retinal vasculitis and/or retinal vascular occlusion, typically in the presence of intraocular inflammation, have been reported with the use of SYFOVRE. Cases may occur with the first dose of SYFOVRE and may result in severe vision loss. Discontinue treatment with SYFOVRE in patients who develop these events. Patients should be instructed to report any change in vision without delay.
- 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.

Please see accompanying full Prescribing Information for more information.

U.S. Important Safety Information for EMPAVELI® (pegcetacoplan)

BOXED WARNING: SERIOUS INFECTIONS CAUSED BY ENCAPSULATED BACTERIA

- **Meningococcal infections may occur in patients treated with EMPAVELI and may become rapidly life-threatening or fatal if not recognized and treated early. Use of EMPAVELI may predispose individuals to serious infections, especially those caused by encapsulated bacteria, such as *Streptococcus pneumoniae*, *Neisseria meningitidis* types A, C, W, Y, and B, and *Haemophilus influenzae* type B.**

- **Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against encapsulated bacteria.**
- **Vaccinate patients at least 2 weeks prior to administering the first dose of EMPAVELI unless the risks of delaying therapy with EMPAVELI outweigh the risk of developing a serious infection.**
- **Vaccination reduces, but does not eliminate, the risk of serious infections. Monitor patients for early signs of serious infections and evaluate immediately if infection is suspected.**
- **EMPAVELI is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS). Under the EMPAVELI REMS, prescribers must enroll in the program.**

CONTRAINDICATIONS

- Hypersensitivity to pegcetacoplan or to any of the excipients
- Not currently vaccinated against certain encapsulated bacteria, unless the risks of delaying EMPAVELI treatment outweigh the risks of developing a bacterial infection with an encapsulated organism
- Unresolved serious infection caused by encapsulated bacteria including *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae*

WARNINGS AND PRECAUTIONS

Serious Infections Caused by Encapsulated Bacteria

The use of EMPAVELI may predispose individuals to serious, life-threatening, or fatal infections caused by encapsulated bacteria, including *Streptococcus pneumoniae*, *Neisseria meningitidis* types A, C, W, Y, and B, and *Haemophilus influenzae* type B (Hib). To reduce the risk of infection, all patients must be vaccinated against these bacteria according to the most current ACIP recommendations for patients with altered immunocompetence associated with complement deficiencies. Revaccinate patients in accordance with ACIP recommendations considering the duration of therapy with EMPAVELI.

For patients without known history of vaccination, administer required vaccines at least 2 weeks prior to receiving the first dose of EMPAVELI. If immediate therapy with EMPAVELI is indicated, administer required vaccine as soon as possible and provide patients with 2 weeks of antibacterial drug prophylaxis.

Closely monitor patients for early signs and symptoms of serious infection and evaluate patients immediately if an infection is suspected. Promptly treat known infections. Serious infection may become rapidly life-threatening or fatal if not recognized and treated early. Consider discontinuation of EMPAVELI in patients who are undergoing treatment for serious infections.

EMPAVELI REMS

Because of the risk of serious infections, EMPAVELI is available only through a restricted program under a REMS. Under the EMPAVELI REMS, prescribers must enroll in the program and must counsel patients about the risk of serious infection, provide the patients with the REMS educational materials, and ensure patients are vaccinated against encapsulated bacteria. Enrollment and additional information are available by telephone: 1-888-343-7073 or at www.empavelirems.com.

Infusion-Related Reactions

Systemic hypersensitivity reactions (e.g., facial swelling, rash, urticaria) have occurred in patients treated with EMPAVELI. One patient (less than 1% in clinical studies) experienced a serious allergic reaction which resolved after treatment with antihistamines. If a severe hypersensitivity reaction (including anaphylaxis) occurs, discontinue EMPAVELI infusion immediately, institute appropriate treatment, per standard of care, and monitor until signs and symptoms are resolved.

Monitoring PNH Manifestations after Discontinuation of EMPAVELI

After discontinuing treatment with EMPAVELI, closely monitor for signs and symptoms of hemolysis, identified by elevated LDH levels along with sudden decrease in PNH clone size or hemoglobin, or reappearance of symptoms such as fatigue, hemoglobinuria, abdominal pain, dyspnea, major adverse vascular events (including thrombosis),

dysphagia, or erectile dysfunction. Monitor any patient who discontinues EMPAVELI for at least 8 weeks to detect hemolysis and other reactions. If hemolysis, including elevated LDH, occurs after discontinuation of EMPAVELI, consider restarting treatment with EMPAVELI.

Interference with Laboratory Tests

There may be interference between silica reagents in coagulation panels and EMPAVELI that results in artificially prolonged activated partial thromboplastin time (aPTT); therefore, avoid the use of silica reagents in coagulation panels.

ADVERSE REACTIONS

Most common adverse reactions in patients with PNH (incidence ≥10%) were injection-site reactions, infections, diarrhea, abdominal pain, respiratory tract infection, pain in extremity, hypokalemia, fatigue, viral infection, cough, arthralgia, dizziness, headache, and rash.

USE IN SPECIFIC POPULATIONS

Females of Reproductive Potential

EMPAVELI may cause embryo-fetal harm when administered to pregnant women. Pregnancy testing is recommended for females of reproductive potential prior to treatment with EMPAVELI. Advise female patients of reproductive potential to use effective contraception during treatment with EMPAVELI and for 40 days after the last dose.

Please see full Prescribing Information, including Boxed WARNING regarding serious infections caused by encapsulated bacteria, and Medication Guide.

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. We believe we have only begun to unlock the potential of targeting C3 across serious retinal, rare, and neurological 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 preliminary financial information for the fourth quarter and full year ended December 31, 2023. 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 adjustments to Apellis’ preliminary revenue figures resulting from, among other things, the completion of financial closing and review procedures for the quarter and year ended December 31, 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 Quarterly Report on Form 10-Q filed on November 1, 2023 and the risks described 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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[i] The revenue figures presented in this press release 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.

[ii] This is an estimation based on ECP injection demand data on file as of December 31, 2023. This dataset may not represent the entire patient population.

[iii] As of December 31, 2023.