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 27, 2020

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 1.01. Entry into a Material Definitive Agreement.

On October 27, 2020, Apellis Pharmaceuticals, Inc. and its subsidiaries Apellis Switzerland GmbH and APL DEL Holdings, LLC (collectively, the "Company") entered into a Collaboration and License Agreement with Swedish Orphan Biovitrum AB (Publ) ("Sobi") concerning the development and commercialization of pegcetacoplan and specified other compstatin analogues or derivatives for use systemically or for local non-ophthalmic administration ("Licensed Products"). The agreement does not cover pegcetacoplan or other compstatin analogues or derivatives used for non-systemic ophthalmic administration or the Company's APL-9 compound.

Under the agreement, the Company granted Sobi an exclusive (subject to certain retained rights of the Company), sublicensable license under certain patent rights and know-how to develop and commercialize Licensed Products in all countries outside of the United States.

The Company retains the right to commercialize Licensed Products in the United States, and, subject to specified limitations, to develop Licensed Products worldwide for commercialization in the United States.

Under the agreement, the Company and Sobi have agreed to collaborate to develop Licensed Products for the treatment of paroxysmal nocturnal hemoglobinuria, cold agglutinin disease, hematopoietic stem cell transplantation thrombotic microangiopathy, C3 glomerulopathy and immune complex membranoproliferative glomerulonephritis, and amyotrophic lateral sclerosis (the "Initial Indications"), and any other indications subsequently agreed upon by the parties, for commercialization by or on behalf of the Company in the United States and by or on behalf of Sobi outside of the United States. If the parties do not agree to jointly pursue any development activities for the Licensed Products (whether for an Initial Indication or otherwise), the party proposing to pursue such activities may conduct such activities at its sole expense (with the non-proposing party having the right to obtain rights to the data generated by such development activities by paying a specified percentage of that expense), subject to agreed-upon exceptions that limit each party's unilateral development rights.

The initial development plan sets forth the initial development activities to be conducted by each of the Company and Sobi, with the Company bearing all costs incurred in conducting the activities set forth in such initial development plan, as well as certain specified additional costs that are not included in the initial development plan that may be incurred by the parties in developing Licensed Products for paroxysmal nocturnal hemoglobinuria in the European Union and the United Kingdom.

Each party is obligated to use commercially reasonable efforts to complete the development obligations assigned to it in the development plan, with the Company obligated to use commercially reasonable efforts to obtain regulatory approval from the FDA for a Licensed Product in each of the Initial Indications, to obtain regulatory approval from the EMA for a Licensed Product in paroxysmal nocturnal hemoglobinuria and to assist Sobi to obtain other regulatory and reimbursement approvals for Licensed Products outside of the United States, and with Sobi obligated to use commercially reasonable efforts to develop and obtain regulatory approval for, and to commercialize, Licensed Products for each of the Initial Indications in specified major markets.

The Company has agreed to supply to Sobi, pursuant to a supply agreement to be negotiated by the parties, Licensed Products for development and for commercialization outside of the United States in accordance with the agreement. The agreement grants Sobi the right to perform or have performed drug product manufacturing of Licensed Products for development and for commercialization outside the United States and to manufacture or have manufactured drug substance under certain circumstances.

The Company and Sobi will form several governance committees to oversee the development and manufacture, and to review and discuss the commercialization, of Licensed Products.

The Company has agreed not to, directly or indirectly, alone or with or for any other person or entity, conduct any clinical development or commercialization of APL-9 for any Initial Indication or any other indications subsequently agreed upon by the parties.

Under the terms of the agreement, Sobi has agreed to pay the Company an upfront payment of $250 million, and up to an aggregate of $915 million upon the achievement of specified one-time regulatory and commercial milestone events, and to reimburse the Company for up to $80 million in development costs. The Company will also be

entitled to receive tiered, low double-digit royalties (ranging from high teens to high twenties) on sales of Licensed Products outside of the United States, subject to customary deductions and third-party payment obligations, until the latest to occur of: (i) expiration of the last-to-expire of specified licensed patent rights; (ii) expiration of regulatory exclusivity; and (iii) ten (10) years after the first commercial sale of the applicable Licensed Product, in each case on a Licensed Product-by-Licensed Product and country-by-country basis. Under the agreement, the Company remains responsible for its license fee obligations (including royalty obligations) to the University of Pennsylvania as a licensor of the Company and for its payment obligations to SFJ Pharmaceuticals.

Unless earlier terminated, the agreement will expire upon the expiration of the last royalty term for the last Licensed Product outside of the United States. The agreement may be terminated in its entirety by Sobi upon 90 days' prior written notice at any time after the earlier of (i) October 27, 2022 or (ii) receipt of the first regulatory approval for the first Licensed Product in any of France, Germany, Italy, Spain, or the United Kingdom. Either party may, subject to specified cure periods, terminate the agreement in its entirety in the event of the other party's uncured material breach. In addition, the Company may, subject to specified cure periods, terminate the agreement in any of China, Japan, Brazil, or Canada if Sobi materially breaches its obligation to use commercially reasonable efforts to develop, obtain regulatory approval for, and commercialize a Licensed Product for paroxysmal nocturnal hemoglobinuria and amyotrophic lateral sclerosis in such country. Either party may also terminate the agreement under specified circumstances relating to the other party's insolvency. The Company may terminate the agreement in the event Sobi or its specified affiliates or sublicensees challenges the validity, scope or enforceability of the licensed patent rights under specified circumstances.

The foregoing description of certain terms of the agreement does not purport to be complete and is qualified in its entirety by reference to the agreement that the Company intends to file as an exhibit to its annual report on Form 10-K for the year ended December 31, 2020. The press release announcing the agreement is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated October 27, 2020, of Apellis Pharmaceuticals, Inc.
104	Cover Page Interactive Date 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 27, 2020

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

Apellis and Sobi Enter Collaboration for Global Co-development and Ex-US Commercialization of Systemic Pegcetacoplan in Rare Diseases with Urgent Need for New Treatments

- *Sobi obtains global co-development and exclusive ex-U.S. commercialization rights for systemic pegcetacoplan, a targeted C3 therapy*
- *Apellis retains U.S. commercialization rights for systemic pegcetacoplan and worldwide commercialization rights for ophthalmological pegcetacoplan (geographic atrophy program in Phase 3)*
- *The companies will jointly advance systemic pegcetacoplan in five parallel registrational programs including two new hematological studies planned to start in 2021 (CAD and HSCT-TMA). These join ongoing registrational programs in hematology (PNH), nephrology (IC-MPGN/C3G) and neurology (ALS)*
- *Sobi will make an upfront payment of $250 million to Apellis and $80 million in committed development reimbursements over four years and up to $915 million in regulatory and commercial milestones plus tiered double-digit royalties*
- *Apellis to host conference call today at 8:30 a.m. ET*

WALTHAM, Mass. and STOCKHOLM, Sweden – October 27, 2020 - Apellis Pharmaceuticals, Inc. (Nasdaq: APLS) and Swedish Orphan Biovitrum AB (publ) (Sobi™) (STO:SOBI) today announced a strategic collaboration to accelerate the advancement of systemic pegcetacoplan, a targeted C3 therapy, for the treatment of multiple rare diseases with high unmet need that impact more than 275,000 patients globally.

Sobi will receive global co-development and exclusive ex-US commercialization rights for systemic pegcetacoplan. Apellis retains U.S. commercialization rights for systemic pegcetacoplan and worldwide commercial rights for ophthalmological pegcetacoplan, which is being evaluated by Apellis in two fully enrolled Phase 3 studies in geographic atrophy (GA). Pegcetacoplan targets excessive activation of C3 in the complement cascade, part of the body's immune system, which can lead to the onset and progression of many serious diseases.

Apellis and Sobi plan to jointly advance the clinical development of systemic pegcetacoplan in five parallel registrational programs across hematology, nephrology, and neurology. These include new registrational programs in cold agglutinin disease (CAD) and hematopoietic stem cell transplantation-associated thrombotic microangiopathy (HSCT-TMA), both of which are expected to start in 2021. By controlling complement activation centrally, pegcetacoplan offers the potential to become a transformative new therapy in several rare diseases where patients have few or no treatment options today.

"This collaboration enables us to further expand on the broad platform potential of targeting C3 for serious rare diseases that impact hundreds of thousands of patients around the world," said Cedric Francois, M.D., Ph.D., co-founder and chief executive officer of Apellis. "We evaluated numerous companies, medium and large, and chose Sobi because of their global leadership in hematology and rare diseases, track record of successful product launches, and deep commitment to patients. Together, we will quickly advance systemic pegcetacoplan in multiple registrational programs across hematology, nephrology, and neurology while also preparing for our first potential U.S. launch in PNH. Financially, this transaction also strengthens our position, with our cash runway expected to extend into the second half of 2022."

"We are excited to collaborate with Apellis, a leader in targeted C3 therapies. The collaboration will significantly strengthen and broaden our late-stage R&D portfolio and be a catalyst for further internationalization. The products have an excellent fit with our strategic focus on hematology and immunology," said Guido Oelkers, chief executive officer and president of Sobi. "Given the central role of C3 in the complement cascade, pegcetacoplan has the potential to become the foundation for a broader platform in rare diseases. With positive Phase 3 data in PNH, pegcetacoplan can elevate the standard of care for this debilitating blood disorder."

As part of the collaboration, Apellis and Sobi will co-develop systemic pegcetacoplan in the following rare diseases:

Hematology – Paroxysmal nocturnal hemoglobinuria (PNH), CAD, and HSCT-TMA

PNH represents the first potential indication to market for systemic pegcetacoplan. Marketing applications for pegcetacoplan for the treatment of PNH were submitted to the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) based on positive results from the Phase 3 PEGASUS study. Top-line results from the Phase 3 PRINCE study, which is evaluating pegcetacoplan in treatment-naïve patients with PNH, are expected in the first half of 2021.

Sobi will lead development activities for the Phase 3 study in CAD and a potentially registrational Phase 2 study in HSCT-TMA, both planned to start in 2021.

Nephrology – Immune complex membranoproliferative glomerulonephritis (IC-MPGN) and C3 glomerulopathy (C3G)

Apellis has initiated and will continue to lead a registrational program in IC-MPGN and C3G, which includes Phase 2 and Phase 3 studies.

Neurology – Amyotrophic lateral sclerosis (ALS)

Apellis has initiated and will continue to lead a potentially registrational Phase 2 study in ALS. Multiple other neurological conditions are under consideration for future clinical development.

About the Transaction

Sobi will make an upfront payment of $250 million to Apellis and up to $915 million in other regulatory and commercial milestone payments, and will contribute $80 million in reimbursement payments over a four-year period for research and development to support the initial development plan, which includes ongoing studies in PNH, IC-MPGN/C3G, and ALS and new studies in CAD and HSCT-TMA. Apellis will also be eligible for tiered double-digit royalties on sales ranging from high teens to high twenties. Sobi intends to finance these payments with available funds. Sobi will receive reimbursement payments for the costs incurred by Sobi in connection with the CAD and HSCT-TMA trials that Sobi will conduct. The parties have agreed to split costs 50/50 for any future global studies beyond the initial development plan.

Per the terms of the agreement, Apellis will be responsible for all regulatory and commercial activities in the United States and the ongoing Marketing Authorization Application (MAA) review for PNH in the European Union, which will be subsequently transferred to Sobi. Sobi will be responsible for regulatory and commercial activities for systemic pegcetacoplan in ex-US markets. The co-development of systemic pegcetacoplan will be overseen by a joint development committee, and the commercial strategy will be overseen by a joint commercial committee.

Conference Call and Webcast

Apellis will host a conference call and webcast to discuss its collaboration with Sobi today, October 27, 2020, at 8:30 a.m. ET. To access the conference call, please dial (866) 774-0323 (local) or (602) 563-8683 (international) at least 10 minutes prior to the start time and refer to conference ID 5774165. A live audio webcast of the event and accompanying slides may also be accessed through the “Events and Presentations” page of the “Investors and Media” section of the company’s website at http://investors.apellis.com/events-and-presentations. A replay of the webcast will be available for 30 days following the event.

About Pegcetacoplan (APL-2)

Pegcetacoplan is an investigational, targeted C3 therapy designed to regulate excessive complement activation, which can lead to the onset and progression of many serious diseases. Pegcetacoplan is a synthetic cyclic peptide conjugated to a polyethylene glycol polymer that binds specifically to C3 and C3b. Apellis is evaluating pegcetacoplan in several clinical studies across hematology, ophthalmology, nephrology, and neurology. Pegcetacoplan was granted Fast Track designation by the U.S. Food and Drug Administration (FDA) for the treatment of PNH and the treatment of geographic atrophy and received orphan drug designation for the treatment of C3G by the FDA and European Medicines Agency.

About Pegcetacoplan for Paroxysmal Nocturnal Hemoglobinuria (PNH)

In October, the European Medicines Agency validated the Marketing Authorization Application (MAA) for pegcetacoplan in PNH, and an opinion from the Committee for Medicinal Products for Human Use is expected in 2021. A decision by the U.S. Food and Drug Administration regarding the acceptance of the New Drug Application (NDA) and a Prescription Drug User Fee Act (PDUFA) target action date is expected in the fourth quarter of 2020. Top-line results from the Phase 3 PRINCE study, which is evaluating pegcetacoplan in treatment-naïve patients with PNH, are expected in the first half of 2021.

The NDA and MAA submissions for pegcetacoplan for the treatment of PNH are based on positive results from the Phase 3 PEGASUS study (APL2-302; NCT03500549), a multi-center, randomized, active-comparator controlled Phase 3 study in 80 adults with PNH. The primary objective of PEGASUS was to establish the efficacy and safety of pegcetacoplan compared to eculizumab. Pegcetacoplan is also being evaluated in the Phase 3 PRINCE study (APL2-308; NCT04085601), a randomized, multi-center, controlled study evaluating pegcetacoplan in 53 patients with PNH who had not received a complement inhibitor within three months before entering the study.

About PNH

PNH is a rare, chronic, life-threatening blood disorder characterized by the destruction of oxygen-carrying red blood cells through extravascular and intravascular hemolysis. Persistently low hemoglobin can result in frequent transfusions and debilitating symptoms such as severe fatigue, hemoglobinuria, and difficulty breathing (dyspnea). A retrospective analysis shows that, even on eculizumab, approximately 72% of people with PNH have anemia, a key indicator of ongoing hemolysis.[1] The analysis also finds that 36% of patients require one or more transfusions a year and 16% require three or more.[1]

About Cold Agglutinin Disease (CAD)

CAD is a severe, chronic, rare blood disorder[2] that currently has no approved therapies and impacts ~10,500 people across the United States and Europe.[3] People living with CAD may suffer from chronic anemia, transfusion requirements, and an increased risk of life-threatening thrombotic events such as stroke.[4] In people with CAD, immunoglobin M (IgM) autoantibodies cause red blood cells to agglutinate, or clump together, at temperatures below 30ºC or as a result of a compromised immune system or infection.[5] This activates the complement cascade to destroy healthy red blood cells through extravascular and intravascular hemolysis.[6,7]

About Hematopoietic Stem Cell Transplantation Thrombotic Microangiopathy (HSCT-TMA)

HSCT-TMA is rare blood disease that can be a fatal complication of a bone marrow transplant or HSCT.[8] In HSCT-TMA, microscopic blood clots form in small blood vessels, leading to organ damage. The kidneys are commonly affected, although any organ may be involved.[8] HSCT-TMA occurs in up to 40% of HSCT recipients;[9] every year, there are ~9,000 allogeneic transplants in the United States and ~18,000 in the EU+.[10,11] Excessive complement activation is a high-risk feature in patients with HSCT-TMA,[12] and C3 is believed to play a critical role in TMA based on proinflammatory and procoagulant properties of C3a and C3b.[13]

About Immune Complex Membranoproliferative Glomerulonephritis (IC-MPGN) and C3 Glomerulopathy (C3G)

IC-MPGN and C3G are rare, debilitating kidney diseases that affect ~18,000 people in the United States and Europe.[14] There are no approved therapies for the diseases, and symptoms include blood in the urine, dark foamy urine due to the presence of protein, swelling, and high blood pressure.[15] Approximately 50% of people living with IC-MPGN and C3G ultimately suffer kidney failure within five to 10 years of diagnosis.[16] Although IC-MPGN is considered a distinct disease from C3G, the underlying cause and progression of the two diseases are remarkably similar and include overactivation of the complement cascade, with excessive accumulation of C3 breakdown products in the kidney causing inflammation and damage to the organ. [17,18]

About Amyotrophic Lateral Sclerosis (ALS)

ALS is a devastating neurodegenerative disease that results in progressive muscle weakness and paralysis due to the death of nerve cells, called motor neurons, in the brain and spinal cord.[19, 20] The death of motor neurons leads to the progressive loss of voluntary muscle movement required for speaking, walking, swallowing and breathing.[19,20] In individuals with ALS, high levels of C3 are present at the neuromuscular junction[21] where motor neurons communicate directly to muscle cells. Numerous studies suggest that elevated levels of C3 present throughout the motor system of ALS patients are likely to contribute to chronic neuroinflammation and the death of motor neurons.[21,22,23] There are no treatments that stop or reverse the progression of ALS, which impacts ~225,000 patients worldwide.[24]

About Apellis

Apellis Pharmaceuticals, Inc. is a global biopharmaceutical company that is committed to leveraging courageous science, creativity, and compassion to deliver life-changing therapies. Leaders in targeted C3 therapies, we aim to develop transformative therapies for a broad range of debilitating diseases that are driven by excessive activation of the complement cascade, including those within hematology, ophthalmology, nephrology, and neurology. For more information, please visit http://apellis.com.

About Sobi

Sobi is a specialized international biopharmaceutical company transforming the lives of people with rare diseases. Sobi is providing sustainable access to innovative therapies in the areas of hematology, immunology and specialty indications. Today, Sobi employs approximately 1,500 people across Europe, North America, the Middle East, Russia and North Africa. In 2019, Sobi's revenue amounted to SEK 14.2 billion. Sobi's share (STO:SOBI) is listed on Nasdaq Stockholm. You can find more information about Sobi at www.sobi.com.

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 relating to the implications of preliminary clinical data. 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 company's clinical trials will be fully enrolled and completed when anticipated; whether preliminary or interim results from a clinical trial will be predictive of the final results of the trial; whether results obtained in preclinical studies and clinical trials will be indicative of results that will be generated in future clinical trials; whether pegcetacoplan will successfully advance through the clinical trial process on a timely basis, or at all; whether the results of the company's clinical trials will warrant regulatory submissions and whether pegcetacoplan will receive approval from the FDA or equivalent foreign regulatory agencies for GA, PNH, CAD, C3G, IC-MPGN,

ALS or any other indication when expected or at all; whether, if Apellis' products receive approval, they will be successfully distributed and marketed; and other factors discussed in the "Risk Factors" section of Apellis' Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on July 30, 2020 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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