AGIOS PHARMACEUTICALS INC
Form 8-K
June 29, 2018

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): June 25, 2018

Agios Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	**001-36014**	**26-0662915**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
88 Sidney Street, Cambridge, MA		**02139**

(Address of Principal Executive Offices) **(Zip Code)**

Registrant s telephone number, including area code: (617) 649-8600

(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))

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 June 25, 2018, Agios Pharmaceuticals, Inc. (the Company) entered into an exclusive license agreement (the License Agreement) with CStone Pharmaceuticals (CStone) for the development and commercialization of certain products containing ivosidenib in the forms clinically developed by the Company (Licensed Products) in mainland China, Hong Kong, Macau and Taiwan (the Territory), either as a monotherapy or in combination with other therapies, in all therapeutic uses in humans, excluding brain cancer, unless later added by the Company in its sole discretion (the Field). The Company retains development and commercialization rights with respect to Licensed Products in the rest of the world.

Pursuant to the License Agreement, CStone will initially be responsible for the development and commercialization of Licensed Products in acute myeloid leukemia (AML) and cholangiocarcinoma in the Territory, as well as other indications that the parties mutually agree to in the future. CStone will also be responsible, at the Company s discretion, for the development and commercialization of Licensed Products in brain cancer indications in the Territory. The Company has granted CStone specified intellectual property licenses to enable CStone to perform its obligations and exercise its rights under the License Agreement, including license grants to enable CStone to conduct development and commercialization activities pursuant to the terms of the License Agreement.

Pursuant to the License Agreement, the Company is entitled to receive an upfront payment of $12 million and is entitled to receive up to an additional $412 million in milestone payments upon the achievement of certain development, regulatory and sales milestone events. Approximately half of the milestone payments are related to the development and commercialization of Licensed Products in AML, cholangiocarcinoma and other potential indications in the Territory. The other half of the milestone payments are related to the development and commercialization in the Territory of Licensed Products in brain cancer indications, including glioma, to the extent they are included in the Field. The Company will also be entitled to receive tired royalties, ranging from 15 to 19 percent, on annual net sales, if any, of Licensed Products in the Territory.

CStone is responsible for all costs it incurs in developing, obtaining regulatory approval of, and commercializing Licensed Products in the Field in the Territory, as well as certain costs incurred by the Company in conducting certain clinical trials that include clinical sites in the Territory.

During the term of the License Agreement, each party and its affiliates are prohibited from developing or commercializing in the Field any other compound or product that inhibits IDH-1 mutations at specified levels of binding (Competing Products), in the case of CStone, anywhere in the world, and in the case of the Company, in the Territory. Subject to specified exceptions, CStone and its affiliates are also prohibited from developing or commercializing certain other compounds or products that directly or indirectly treat AML, cholangiocarcinoma or, if added to the Field by the Company, glioma in patients that have an IDH-1 mutation (Restricted Products).

Unless earlier terminated, the License Agreement will expire upon the expiration of the last royalty term for the last Licensed Product in the Field in the Territory. In the event that Agios does not obtain regulatory approval from the United States Food and Drug Administration for any Licensed Product in relapsed/refractory (R/R) AML by December 31, 2018, CStone may terminate the License Agreement in its entirety upon 90 days prior written notice. At any time after CStone has obtained regulatory approval for a Licensed Product in mainland China in R/R AML and the last patient has been enrolled in a specified clinical trial (or, if earlier, at any time that CStone acquires or is acquired by an entity with a Competing or Restricted Product), CStone may terminate the License Agreement in its entirety upon 12 months prior written notice. Either party may, subject to specified cure periods, terminate the License Agreement in the event of the other party s uncured material breach, and either party may terminate the License Agreement under specified circumstances relating to the other party s insolvency. The Company has the right to terminate the License Agreement immediately if CStone or its affiliates or sublicensees or subcontractors challenges the validity, patentability, or enforceability of certain patent rights that relate to ivosidenib and are owned by or licensed to the Company or its affiliates.

The License Agreement contemplates that the Company will enter into ancillary arrangements with CStone, including clinical and commercial supply agreements and a pharmacovigilance agreement.

The foregoing description of certain terms of the License Agreement does not purport to be complete and is qualified in its entirety by reference to the License Agreement that the Company intends to file as an exhibit to its Quarterly Report on Form 10-Q for the quarterly period ending June 30, 2018.

Item 8.01 Other Events.

The full text of the press release announcing the Company s entry into the License Agreement is attached as Exhibit 99.1 hereto and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) The following exhibits are included in this report:

Exhibit No.	Description
99.1	Press release issued June 26, 2018.

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.

AGIOS PHARMACEUTICALS, INC.

Date: June 29, 2018

By: /s/ David P. Schenkein
David P. Schenkein, M.D.

President and Chief Executive Officer