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

Exhibit 99.1

Agios and CStone Pharmaceuticals Announce Exclusive Collaboration and License Agreement to Develop and Commercialize Ivosidenib in Greater China

- Agios to Receive $12 Million Upfront Payment and is Eligible to Receive Development, Regulatory, and Sales-Based Milestones and Tiered Royalties -

- Collaboration Provides Opportunity for Patients with IDH1m Cancers in Greater China to Benefit from Ivosidenib -

CAMBRIDGE, Mass. and Suzhou, China, June 26, 2018 — Agios Pharmaceuticals, Inc. (NASDAQ:AGIO), a leader in the field of cellular metabolism to treat cancer and rare genetic diseases, and CStone Pharmaceuticals, a privately-held biopharmaceutical company devoted to developing a new generation of innovative drugs, today announced an exclusive collaboration and license agreement for the development and commercialization of ivosidenib (TIBSOVO®; AG-120) in Mainland China, Hong Kong, Macau and Taiwan ("Territory"), either as a monotherapy or in combination with other therapies. Discovered and developed by Agios, ivosidenib is an investigational, first-in-class, oral, targeted inhibitor of the mutant isocitrate dehydrogenase-1 (IDH1) enzyme. CStone Pharmaceuticals will be responsible for conducting the development and commercialization activities for ivosidenib in hematologic and solid tumor indications in the Territory, with an initial focus in acute myeloid leukemia (AML) and cholangiocarcinoma. Agios will retain all rights to ivosidenib in the rest of the world.

"CStone Pharmaceuticals brings together a highly experienced leadership team and drug development capabilities that will enable us to reach patients with IDH1 mutant cancers in Greater China who could benefit from ivosidenib," said David Schenkein, M.D., chief executive officer at Agios. "In addition to the clinical development activities that CStone will be leading, we also have the opportunity to leverage CStone's network to expand our ongoing and future global clinical trials of ivosidenib into Greater China."

Subject to the terms of the agreement, Agios will receive an upfront payment of $12 million and will be eligible to receive up to $412 million in milestone payments, of which $147 million are related to development and regulatory events and $265 million to the achievement of certain sales levels. Approximately half of the milestone payments are related to the development and commercialization of ivosidenib in AML, cholangiocarcinoma and other potential indications. The other half are payable only if development and commercialization of ivosidenib in brain cancer indications, including glioma, are pursued as part of the collaboration at a later date. In addition, CStone Pharmaceuticals will pay Agios tiered royalties ranging from the mid to high-teens as a percentage of annual net sales of ivosidenib in the Territory. CStone Pharmaceuticals will be responsible for all costs associated with development and commercialization activities for ivosidenib conducted in the Territory under the agreement.

"We're very pleased to partner with Agios to advance the global development of ivosidenib, which has clearly demonstrated significant benefit to patients with AML as well as potential

utility in other IDH1m cancers," said Frank Jiang, M.D., Ph.D., chief executive officer at CStone Pharmaceuticals. "Given ivosidenib is currently under U.S. FDA priority review for IDH1m relapsed or refractory AML patients, it is the most advanced program in our pipeline. The partnership will also allow us to explore ivosidenib in combination with other products in our portfolio."

About Ivosidenib (TIBSOVO® / AG-120)

Ivosidenib is an investigational first-in-class, orally available, selective, potent inhibitor of the mutated IDH1 protein and is a highly targeted investigational medicine for the treatment of patients with cancers that harbor an IDH1 mutation. IDH1 is a metabolic enzyme that is mutated in a wide range of cancers, including acute myeloid leukemia, cholangiocarcinoma and glioma. Ivosidenib is currently under U.S. FDA priority review for IDH1m R/R AML patients with a PDUFA action date of August 21, 2018. The following clinical trials of ivosidenib are ongoing:

- Phase 1 trial of ivosidenib or enasidenib in combination with 7+3 in patients with newly diagnosed IDHm AML who are eligible for standard-of-care chemotherapy
- Phase 3 AGILE trial of ivosidenib in combination with azacitidine in patients with newly diagnosed IDH1m AML who are not eligible for standard-of-care chemotherapy
- Phase 3 ClarIDHy trial of ivosidenib in advanced IDH1m cholangiocarcinoma
- Perioperative study comparing ivosidenib and AG-881 in IDH1m low-grade glioma

About CStone Pharmaceuticals

CStone Pharmaceuticals is a clinical stage biopharmaceutical company devoted to the development of innovative drugs. With a broad pipeline, the company engages in the development of cancer therapeutics with a special focus on immuno-oncology based combination therapies. All members of the management team are seasoned executives from top multinational pharmaceutical companies. CStone has successfully built up its core competency in clinical development and translational medicine. The company is backed by prestigious VC/PE funds via two financing rounds to date, raising $150 million in a Series A round in July 2016, followed by $260 million in a Series B round in May 2018. With an experienced team, a rich pipeline, a robust R&D model, and substantial funding, CStone is well positioned as the partner of choice for multinational pharmaceutical and biotech companies to develop drugs in China and the Asia-Pacific region. For more information about CStone Pharmaceuticals, please visit: www.cstonepharma.com.

About Agios

Agios is focused on discovering and developing novel investigational medicines to treat cancer and rare genetic diseases through scientific leadership in the field of cellular metabolism. In addition to an active research and discovery pipeline across both therapeutic areas, Agios has an approved oncology precision medicine and multiple first-in-class investigational therapies in clinical and/or preclinical development. All Agios programs focus on genetically identified patient populations, leveraging our knowledge of metabolism, biology and genomics. For more information, please visit the company's website at www.agios.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Such forward-looking statements include those regarding the potential benefits of, and plans relating to, the collaboration and license agreement between Agios and CStone Pharmaceuticals, including anticipated milestone and other payments under the collaboration; the potential of IDH1 as a therapeutic target; the potential benefits of ivosidenib, either as monotherapy or in combination with other therapies, in treating patients, including patients in the Territory; expectations regarding Agios' ability to expand its program for ivosidenib in the Territory; and the benefit of each company's strategic plans and focus. The words "could," "milestone," "opportunity," "potential," "will" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from current expectations and beliefs. For example, there can be no guarantee that any product candidate will be successfully developed or complete necessary preclinical and clinical phases, or that development of any product candidates will successfully continue. There can be no guarantee that any positive developments will result in stock price appreciation. Management's expectations and, therefore, any forward-looking statements in this press release could also be affected by risks and uncertainties relating to a number of other important factors, including: results of clinical trials and preclinical studies, including subsequent analysis of existing data and new data received from ongoing and future studies; the content and timing of decisions made by the U.S. FDA and other regulatory authorities, including those in the Territory, investigational review boards at clinical trial sites and publication review bodies; the ability to obtain and maintain requisite regulatory approvals and to enroll patients in its planned clinical trials; unplanned cash requirements and expenditures; competitive factors; the ability to obtain, maintain and enforce patent and other intellectual property protection for any product candidates; the ability to maintain key collaborations, including its collaborations with Celgene Corporation and CStone Pharmaceuticals; and general economic and market conditions. These and other risks are described in greater detail under the caption "Risk Factors" included in Agios' public filings with the Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of the date hereof, and Agios expressly disclaims any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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