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): September 7, 2016

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))

Item 7.01 Regulation FD Disclosure.

Agios Pharmaceuticals, Inc. (the "Company") today announced that its collaboration partner Celgene Corporation ("Celgene") expects to submit a new drug application ("NDA") to the U.S. Food and Drug Administration ("FDA") for enasidenib (AG-221), a first-in-class, oral, selective, potent inhibitor of mutant isocitrate dehydrogenase-2 ("IDH2"), in relapsed and/or refractory acute myeloid leukemia ("AML"). The NDA will be based on data from the ongoing phase 1/2 study of AG-221 in patients with advanced hematologic malignancies with an IDH2 mutation. The NDA submission is expected to occur by year-end 2016. Celgene will be discussing the planned enasidenib NDA submission at the Citi 11th Annual Biotech Conference in Boston in a webcast event on Wednesday, September 7, 2016 at 12:00 pm ET.

Patients with isocitrate dehydrogenase 1 ("IDH1") mutant-positive AML whose disease has progressed after standard therapies also have limited treatment options, and the Company plans to explore a similar regulatory path for AG-120, its wholly-owned, first-in-class, oral, potent inhibitor of mutant IDH1, which could lead to a NDA submission in 2017 in the U.S. The Company plans to provide a regulatory update on AG-120 by the end of 2016.

The ongoing AG-221 phase 1/2 trial includes a dose-escalation phase and the following five expansion cohorts, all of which have completed accrual: (i) a cohort of 25 patients aged 60 years or older with IDH2 mutant-positive relapsed or refractory AML, or any IDH2-mutant positive AML patient, regardless of age, who has relapsed following a bone marrow transplant ("BMT"); (ii) a cohort of 25 patients aged less than 60 years with IDH2 mutant-positive relapsed or refractory AML, not including patients with AML who have relapsed following a BMT; (iii) a cohort of 25 patients aged 60 years or older with untreated IDH2 mutant-positive AML who decline standard of care chemotherapy; (iv) a cohort of 25 patients with IDH2 mutant-positive advanced hematologic malignancies not eligible for cohorts (i) to (iii); and (v) a cohort of approximately 125 patients with IDH2 mutant-positive AML who are in second or later relapse, refractory to second-line induction or reinduction treatment, or have relapsed after allogeneic transplantation.

The information responsive to Item 7.01 of this Form 8-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (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, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Cautionary Note Regarding Forward-Looking Statements

This Current Report on Form 8-K contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements concerning the Company's expectations related to Celgene's planned NDA submission for enasidenib (AG-221) and the Company's potential NDA submission for AG-120. Submission of a NDA does not guarantee its acceptance, does not represent final evaluation of the adequacy of the data submitted in the NDA, and is not a guarantee of approval. There also can be no assurance as to the timing of the FDA's review, once a NDA is submitted. Any forward-looking statements in this Current Report on Form 8-K are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: risks associated with the regulatory review process generally; the risk that the FDA may determine that the data included in a NDA, when submitted, are insufficient for approval and that the Celgene and/or the Company must conduct additional clinical trials, or nonclinical or other studies, before enasidenib (AG-221) and/or AG-120 can be approved; the risk that the results of previously conducted studies involving enasidenib (AG-221), AG-120 or other product candidates will not be repeated or observed in ongoing or future studies or following commercial launch, if such product candidates are approved; and risks associated with the Company's dependence on third parties, including Celgene with respect to regulatory matters for enasidenib (AG-221). For a discussion of other risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" included in the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, and other filings that the Company may make with the Securities and Exchange Commission in the future. Any forward-looking statements contained in this Current Report on Form 8-K speak only as of the date hereof, and the Company 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.

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: September 7, 2016

By: /s/ David P. Schenkein
David P. Schenkein, M.D.
Chief Executive Officer