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): December 5, 2015

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 8.01 Other Events.

On December 5, 2015, Agios Pharmaceuticals, Inc. ("the Company") issued a press release announcing new data from its ongoing phase 1 trial evaluating single agent AG-120, the Company's first-in-class inhibitor of IDH1 mutations, in patients with advanced hematologic malignancies. On December 6, 2015, the Company issued a press release announcing new data from the dose escalation phase and expansion cohorts from its ongoing phase 1/2 trial evaluating single agent AG-221, the Company's first-in-class inhibitor of IDH2 mutations, in patients with advanced hematologic malignancies. The Company presented both data at the 2015 American Society of Hematology Annual Meeting and Exposition held on December 5 – 8, 2015. The full text of the press releases issued in connection with these announcements are attached as Exhibit 99.1 and Exhibit 99.2 to this Current Report on Form 8-K and 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 by Agios Pharmaceuticals, Inc. on December 5, 2015.
99.2	Press release issued by Agios Pharmaceuticals, Inc. on December 6, 2015.

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: December 7, 2015

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release issued by Agios Pharmaceuticals, Inc. on December 5, 2015.
99.2	Press release issued by Agios Pharmaceuticals, Inc. on December 6, 2015.

Exhibit 99.1

Agios Announces Data from Ongoing Phase 1 Trial of AG-120 Showing Durable Responses in Patients with Advanced Hematologic Malignancies

- Patients on Study for up to 14.1 Months with a Median Response Duration of 5.6 Months -

- Four Phase 1 Expansion Cohorts Enrolling; Planned Global Registration-enabling Phase 3 Study On Track -

- Company to Host Investor Event and Webcast Monday, December 7, 2015 -

CAMBRIDGE, Mass., December 5, 2015 — Agios Pharmaceuticals, Inc. (Nasdaq:AGIO), a leader in the fields of cancer metabolism and rare genetic metabolic disorders, today announced new data from the ongoing Phase 1 study evaluating single agent AG-120, a first-in-class, oral, selective, potent inhibitor of mutant isocitrate dehydrogenase-1 (IDH1), in advanced hematologic malignancies. The data are being presented at the 2015 American Society of Hematology Annual Meeting and Exposition (ASH) taking place December 5-8, 2015 in Orlando. AG-120 is being developed in collaboration with Celgene.

Data as of October 1, 2015 from 87 patients with advanced IDH1 mutant positive hematologic malignancies confirmed a favorable safety profile consistent with previously reported data and showed durable clinical activity in 78 dose-escalation patients. Twenty-nine patients remain on study as of the analysis. Efficacy data is provided from the dose-escalation phase of the study only, where an overall response rate of 35 percent (27 of 78 response-evaluable patients) and a complete remission rate of 15 percent (12 of 78 response-evaluable patients) were observed. Patients were on study treatment for up to 14.1 months with a median duration of treatment of 2.9 months (ranging from 0.1 to 14.1 months). Data continue to show durable clinical activity for AG-120, with responses maintained for up to 12.5 months and a median duration of response of 5.6 months (previously unreported).

“With the addition of 30 new patients to the study, AG-120 has maintained durable responses and continues to demonstrate an impressive single-agent overall response rate of 35 percent,” said Courtney DiNardo, M.D., lead investigator and assistant professor, department of leukemia at the University of Texas MD Anderson Cancer Center. “These data further validate AG-120’s potential to provide clinical benefit for IDH1 mutant relapsed/refractory AML patients with few, if any effective therapeutic options.”

“These data increase our confidence in the favorable safety and efficacy profile of AG-120,” said Chris Bowden, M.D., chief medical officer of Agios. “Our focus remains on bringing AG-120 to patients with IDH1 mutant cancers as quickly as possible, and we look forward to continuing to enroll our 125-patient expansion arm in relapsed/refractory AML and initiating two frontline studies to reach additional IDH1 mutant AML patients in need of better options.”

About the Ongoing Phase 1 Trial for AG-120 in Advanced Hematologic Malignancies

AG-120 is being evaluated in an ongoing Phase 1 trial that includes a dose escalation phase and four expansion cohorts, including:

- Arm 1: 125 IDH1 mutant positive AML patients who relapsed after bone marrow transplantation, are in second or later relapse, refractory to second line induction or reinduction treatment
- Arm 2: 25 untreated IDH1 mutant positive AML patients who are not candidates for standard-of-care chemotherapy
- Arm 3: 25 patients with other non-AML IDH1 mutant, relapsed or refractory advanced hematologic malignancies
- Arm 4: 25 patients with relapsed IDH1 mutant positive AML not eligible for arm 1 or standard of care

Data reported are from patients treated with AG-120 administered from 200 mg to 1,200 mg total daily doses as of October 1, 2015. The median age of these patients is 68 (ranging from 36-89). Patients received a median of two prior lines of therapy (ranging from zero to five). A safety analysis was conducted for all 87 treated patients and an efficacy analysis was conducted in the evaluable population of 78 dose-escalation patients, which includes all patients with a pre-AG-120 screening assessment and day 28 or later response assessment or an earlier discontinuation for any reason.

Safety Data

Of the 87 treated patients, 78 were from the dose-escalation phase and nine from the expansion.

- The majority of adverse events reported by investigators were mild to moderate, with the most common being fatigue, diarrhea, pyrexia and nausea.
- 51 patients experienced at least one serious adverse event (SAE), the majority being disease related.
- A maximum tolerated dose (MTD) has not been reached.
- 19 patients discontinued from the study due to death, and all were considered unrelated to AG-120.
- All cause mortality at 30 and 60 days was 10.3 percent and 18.4 percent, respectively.

Efficacy Data

Twenty-seven out of 78 response-evaluable patients from the dose-escalation achieved investigator-assessed objective responses for an overall response rate of 35 percent.

- Of the 27 patients who achieved an objective response, there were 12 complete remissions (CR), seven CRs with incomplete platelet recovery (CRp), six marrow CRs (mCR), one CR with incomplete hematologic recovery (CRi) and one partial remission (PR).
- Patients were on study treatment for up to 14.1 months with a median duration of treatment of 2.9 months (ranging from 0.1 to 14.1 months).
- Data continue to show durable clinical activity for AG-120, with responses maintained for up to 12.5 months and a median duration of response of 5.6 months.

2015 Milestones for AG-120 in Hematologic Malignancies

Remaining milestones for AG-120 in 2015 include:

- Continue to enroll patients in the expansion cohort of 125 patients with IDH1 mutant positive AML who relapsed after bone marrow transplantation, are in second or later relapse, refractory to second line induction or reinduction treatment.
- Initiate a Phase 1b combination study of either AG-221 or AG-120 with standard induction (7+3, Ara-C and idarubicin/daunorubicin) and consolidation (Ara-C, or mitoxantrone with etoposide) chemotherapy in newly diagnosed AML patients eligible for intensive chemotherapy by the end of 2015.

Investor Event and Webcast Information

Agios will host an investor event on Monday, December 7, 2015 beginning at 12:00 p.m. ET in Orlando to review data presented at ASH, including new data from the ongoing studies of AG-221 and AG-120. The event will be webcast live and can be accessed under "Events & Presentations" in the Investors and Media section of the company's website at www.agios.com.

About IDH Mutations and Cancer

IDH1 and IDH2 are two metabolic enzymes that are mutated in a wide range of hematologic and solid tumor malignancies. Normally, IDH enzymes help to break down nutrients and generate energy for cells. When mutated, IDH increases production of an oncometabolite 2-hydroxyglutarate (2HG) that alters the cells' epigenetic programming, thereby promoting cancer. 2HG has been found to be elevated in several tumor types. Agios believes that inhibition of the mutated IDH proteins may lead to clinical benefit for the subset of cancer patients whose tumors carry them.

About Acute Myelogenous Leukemia (AML)

AML, a cancer of blood and bone marrow characterized by rapid disease progression, is the most common acute leukemia affecting adults. Undifferentiated blast cells proliferate in the bone marrow rather than mature into normal blood cells. AML incidence significantly increases with age, and according to the American Cancer Society, the median age of onset is 66. Less than 10 percent of U.S. AML patients are eligible for bone marrow transplant and the vast majority of patients do not respond to chemotherapy and progress to relapsed/refractory AML. The five-year survival rate for AML is approximately 20 to 25 percent. IDH1 and IDH2 mutations are present in about 15 to 23 percent of AML cases.

About Agios/Celgene Collaboration

AG-221, AG-120 and AG-881 are part of Agios' global strategic collaboration with Celgene Corporation. Under the terms of the collaboration, Celgene has worldwide development and commercialization rights for AG-221 (CC-90007). Agios continues to conduct clinical development activities within the AG-221 development program and is eligible to receive up to $120 million in payments on achievement of certain milestones and royalties on net sales. For AG-120, Agios retains U.S. development and commercialization rights. Celgene has an exclusive license outside the United States. Celgene is eligible to receive royalties on net sales in the U.S. Agios is eligible to receive royalties on net sales outside the U.S. and up to $120 million in payments on achievement of certain milestones. For AG-881, the companies have a joint worldwide development and 50/50 profit share collaboration, and Agios is eligible to receive regulatory milestone payments of up to $70 million.

About Agios

Agios is focused on discovering and developing novel investigational medicines to treat cancer and rare genetic metabolic disorders through scientific leadership in the field of cellular metabolism. In addition to an active research and discovery pipeline across both therapeutic areas, Agios has multiple first-in-class investigational medicines 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 Agios' product candidates targeting IDH mutations, including AG-120; its plans for the clinical development of AG-120; its plans regarding future data presentations; and the benefit of its strategic plans and focus. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "potential," "hope," "could," "would" 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 Agios' current expectations and beliefs. For example, there can be no guarantee that any product candidate Agios is developing will successfully commence or complete necessary preclinical and clinical development phases, or that development of any of Agios' product candidates will successfully continue. There can be no guarantee that any positive developments in Agios' business 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: Agios' 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, investigational review boards at clinical trial

sites and publication review bodies; Agios' ability to obtain and maintain requisite regulatory approvals and to enroll patients in its planned clinical trials; unplanned cash requirements and expenditures; competitive factors; Agios' ability to obtain, maintain and enforce patent and other intellectual property protection for any product candidates it is developing; Agios' ability to maintain key collaborations, such as its agreement with Celgene; and general economic and market conditions. These and other risks are described in greater detail under the caption "Risk Factors" included in Agios' Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, and other filings that Agios may make with the Securities and Exchange Commission in the future. 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.

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Contact:

Renee Leck, Senior Manager, Investor Relations and Public Relations
Renee.Leck@agios.com
617-649-8299

Exhibit 99.2

Agios Announces Data from Ongoing Phase 1/2 Trial of AG-221 Showing Durable Responses in Patients with Advanced Hematologic Malignancies

- Patients on Study for up to 18 Months with a Median Response Duration of 6.9 Months in Relapsed/Refractory Acute Myeloid Leukemia (AML) -

- Enrollment Complete for Four 25-Patient Expansion Cohorts; 125-Patient Expansion Cohort and Phase 3 IDHENTIFY Study Open for Enrollment -

- Company to Host Investor Event and Webcast Monday, December 7, 2015 -

CAMBRIDGE, Mass., December 6, 2015 — Agios Pharmaceuticals, Inc. (Nasdaq:AGIO), a leader in the fields of cancer metabolism and rare genetic metabolic disorders, today announced new data from the dose-escalation phase and expansion cohorts from the ongoing Phase 1/2 study evaluating single agent AG-221, a first-in-class, oral, selective, potent inhibitor of mutant isocitrate dehydrogenase-2 (IDH2), in advanced hematologic malignancies. The data are being presented at the 2015 American Society of Hematology Annual Meeting and Exposition (ASH) taking place December 5-8, 2015 in Orlando. AG-221 is being developed in collaboration with Celgene.

Data as of September 1, 2015 from 209 patients with IDH2 mutant positive advanced hematologic malignancies treated with single agent AG-221 showed durable clinical activity and a favorable safety profile. More than 50 patients were added as of the last analysis, and 66 patients remain on treatment. In patients with relapsed or refractory AML, the study had an overall response rate of 37 percent (59 of 159 response-evaluable patients) and a complete remission rate of 18 percent (29 of 159 response-evaluable patients). Responding relapsed or refractory AML patients were on study treatment for up to 18 months with a 6.9-month median response duration (not reported at previous data presentations). The overall safety profile observed was consistent with previously reported data.

“With data from more than 200 patients, it is clear that single agent AG-221 has a favorable safety profile and durable response rate in IDH2 mutant hematologic malignancies,” said Eytan Stein, M.D., lead investigator and attending physician in the leukemia service at Memorial Sloan Kettering Cancer Center. “In addition, a subset of patients with stable disease had improvements in neutrophil and platelet counts, which may have important clinical implications for reductions in infections and bleeding. We look forward to developing these data further to describe the overall clinical profile for AG-221 in patients with advanced cancers.”

“The consistency of the overall response rate and complete remission rate in this study over time is encouraging,” said Chris Bowden, M.D., chief medical officer of Agios. “We continue to believe that AG-221 can make a meaningful difference for patients with IDH2 mutant positive cancers and are focused on executing our strategy of speed and breadth with our partner Celgene. We are making rapid progress in the relapsed/refractory and frontline AML settings, with the Phase 3 IDHENTIFY study open for enrollment and plans to initiate the first of two frontline combination studies by the end of the year.”

About the Ongoing Phase 1/2 Trial for AG-221 in Advanced Hematologic Malignancies

AG-221 is currently being evaluated in an ongoing Phase 1/2 trial that includes a dose-escalation phase and five expansion cohorts. The first four expansion cohorts have completed enrollment.

- Arm 1: 25 patients with IDH2 mutant positive relapsed or refractory AML age ≥60 years, or any patient with AML regardless of age who has relapsed following a bone marrow transplant (BMT)
- Arm 2: 25 patients with IDH2 mutant positive relapsed or refractory AML age <60 years, excluding patients with AML who have relapsed following a BMT
- Arm 3: 25 patients with IDH2 mutant positive untreated AML age ≥60 years who decline standard of care chemotherapy
- Arm 4: 25 patients with IDH2 mutant positive advanced hematologic malignancies not eligible for arms 1 to 3
- Arm 5: The Phase 2 portion of the trial includes 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

Data reported here are from patients receiving AG-221 administered from 50 mg to 650 mg total daily doses in the dose escalation arm and 100 mg once daily in the first four expansion arms, as of September 1, 2015. The median age of these patients is 69 (ranging from 19-100). Patients with relapsed or refractory AML received a median of two prior lines of therapy (ranging from one to six). These new data reflect responses in the evaluable population, which include all patients with a day 28 or later response assessment or discontinued before assessment.

Safety Data

A safety analysis was conducted for all 231 treated patients.

- The majority of adverse events reported by investigators were mild to moderate, with the most common being nausea, diarrhea, fatigue and febrile neutropenia.
- The serious adverse events (SAE) were mainly disease related. Twenty-three percent of patients had treatment-related SAEs, notably differentiation syndrome (4 percent), leukocytosis (4 percent) and nausea (2 percent). Drug-related Grade 5 SAEs include atrial flutter (one patient), cardiac tamponade (one patient), pericardial effusion (one patient) and respiratory failure (one patient).
- A maximum tolerated dose (MTD) has not been reached.

Efficacy Data

Seventy-nine out of 209 total response-evaluable patients achieved investigator-assessed objective responses for an overall response rate of 38 percent.

- Of the 79 patients who achieved an objective response, there were 37 (18 percent) complete remissions (CR), three CRs with incomplete platelet recovery (CRp), 14 marrow CRs (mCR), three CRs with incomplete hematologic recovery (CRi) and 22 partial remissions (PR).
- Of the 159 patients with relapsed or refractory AML, 59 (37 percent) achieved an objective response, including 29 (18 percent) CRs, one CRp, nine mCRs, three CRis and 17 PRs.
- Of the 24 patients with AML who declined standard of care chemotherapy, 10 achieved an objective response, including four CRs, one CRp, one mCR and four PRs.
- Of the 14 patients with myelodysplastic syndrome (MDS), seven achieved an objective response, including three CRs, one CRp and three mCRs.
- Responding relapsed or refractory AML patients were on study treatment for up to 18 months with a median duration of treatment of 6.8 months (ranging from 1.8 to 18 months).
- Responses were durable, with a median response duration of 6.9 months in patients with relapsed or refractory AML.
- Neutrophil and platelet improvements were observed in some patients with stable disease.

2015 Milestones for AG-221 in Hematologic Malignancies

Remaining milestones for AG-221 in 2015 include:

- Enroll patients in the Phase 3 IDHENTIFY study of AG-221, an international, multi-center, open-label, randomized clinical trial designed to compare the efficacy and safety of AG-221 versus conventional care regimens in patients age $\geq$60 with IDH2 mutant-positive AML that is refractory to or relapsed after second- or third-line therapy. This study is being conducted by Celgene.
- Continue to enroll patients into the Phase 2 portion of 125 patients with IDH2 mutant-positive AML who are in second or later relapse, refractory to second-line induction or re-induction treatment, or have relapsed after allogeneic transplantation.
- Initiate a Phase 1b combination study of either AG-221 or AG-120 with standard induction (7+3, Ara-C and idarubicin/daunorubicin) and consolidation (Ara-C, or mitoxantrone with etoposide) chemotherapy in newly diagnosed AML patients eligible for intensive chemotherapy by the end of 2015.

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About Myelodysplastic Syndrome (MDS)

MDS comprises a diverse group of bone marrow disorders in which immature blood cells in the bone marrow do not mature or become healthy blood cells. The National Cancer Institute estimates that more than 10,000 people are diagnosed with MDS in the U.S. each year. Failure of the bone marrow to produce mature healthy cells is a gradual process, and reduced blood cell and/or reduced platelet counts may be accompanied by the loss of the body's ability to fight infections and control bleeding. For roughly 30 percent of the patients diagnosed with MDS, this bone marrow failure will progress to AML. Chemotherapy and supportive blood products are used to treat MDS.

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