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 3, 2017

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 8.01 Other Events.

On June 3, 2017, Agios Pharmaceuticals, Inc. (the "Company") issued a press release announcing updated clinical data from the dose-escalation and expansion cohorts of the Company's ongoing Phase 1 study evaluating single agent AG-120 (ivosidenib) in patients with isocitrate dehydrogenase-1 mutant positive cholangiocarcinoma. On June 6, 2017, the Company and Celgene Corporation issued a press release announcing new efficacy and safety data from the ongoing Phase 1 dose-escalation and expansion study evaluating investigational oral IDHIFA® (enasidenib) in patients with relapsed or refractory acute myeloid leukemia with an isocitrate dehydrogenase-2 mutation. The Company and Celgene presented these data at the American Society of Clinical Oncology (ASCO) Annual Meeting held June 2-6, 2017 in Chicago, Illinois.

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 June 3, 2017.
99.2	Press release issued by Agios Pharmaceuticals, Inc. and Celgene Corporation on June 6, 2017.

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 6, 2017

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release issued by Agios Pharmaceuticals, Inc. on June 3, 2017.
99.2	Press release issued by Agios Pharmaceuticals, Inc. and Celgene Corporation on June 6, 2017.

Exhibit 99.1

Agios Presents Phase 1 Data from Dose-Escalation and Expansion Cohorts of AG-120 (Ivosidenib) in Patients with Previously Treated IDH1 Mutant Positive Cholangiocarcinoma

- Durable Disease Control with Six Month PFS rate of 38.5% and 12 Month PFS Rate of 20.7%; Median PFS of 3.8 Months -

- Stable Disease Observed in 56% of Patients; 5% of Patients Achieved a Partial Response -

- AG-120 (Ivosidenib) Well-tolerated in Heavily Pre-Treated Cholangiocarcinoma Population -

CHICAGO, Ill., June 3, 2017 — Agios Pharmaceuticals, Inc. (Nasdaq:AGIO), a leader in the fields of cancer metabolism and rare genetic diseases, today presented updated data from the dose-escalation and expansion cohorts of the Phase 1 study evaluating single agent AG-120 (ivosidenib) in isocitrate dehydrogenase-1 (IDH1) mutant positive cholangiocarcinoma at the American Society of Clinical Oncology (ASCO) Annual Meeting being held June 2-6, 2017 in Chicago.

"The durable disease control signal seen with the Phase 1 data, combined with AG-120's favorable safety profile, are encouraging for patients with advanced IDH1 mutant cholangiocarcinoma who have received multiple prior therapies," said Maeve Lowery, M.D., Memorial Sloan Kettering Cancer Center who presented the study results. "With no approved treatments and few effective options beyond the first line setting in this challenging disease, we look forward to continuing to characterize AG-120's activity in the Phase 3 ClarIDHy study."

"Consistent with AG-120's unique mechanism of action and in the context of this heavily pre-treated patient population, we believe durable stable disease is a meaningful measure of clinical benefit," said Chris Bowden, M.D., chief medical officer at Agios. "These data support further development of AG-120 in our ongoing Phase 3 registration-enabling ClarIDHy study, where we aim to confirm the early efficacy signal and evaluate the potential to impact tumor biology."

The ongoing Phase 1 trial is assessing the safety and tolerability of AG-120 in advanced solid tumors, including glioma, cholangiocarcinoma and chondrosarcomas with an IDH1 mutation. Enrollment is now complete for the dose-escalation and expansion cohorts. As of March 10, 2017, 73 patients with IDH1 mutant positive cholangiocarcinoma have been treated with single agent AG-120 in the dose escalation (n=24) and expansion cohorts (n=49). Thirteen patients remain on treatment. AG-120 was administered at the following dose levels and schedules in the dose-escalation cohort: 100 mg twice daily, and 300, 400, 500, 800 and 1200 mg once a day over a 28 day cycle length. In the dose expansion cohort, patients received 500 mg once a day, which was the selected dose for the ongoing Phase 3 ClarIDHy trial. Among the Phase 1 cholangiocarcinoma population, the median age is 60 (ranging from 32-81). Sixty-five patients had intrahepatic cholangiocarcinoma and eight had extrahepatic disease. The median number of prior systemic therapies was two (ranging from one to five) and 97% of patients received a prior gemcitabine-based chemotherapy regimen.

Safety Data

A safety analysis conducted for all 73 treated patients as of the data cut-off demonstrated that AG-120 was well-tolerated with a favorable safety profile in IDH1 mutant positive cholangiocarcinoma patients.

- No dose limiting toxicities or treatment-related deaths have been observed.
- The majority of adverse events (AEs) reported were mild to moderate, with the most common regardless of causality being fatigue, nausea, diarrhea and decreased appetite.
- Four patients experienced drug-related AEs □ grade 3: two at the 500 mg dose level, fatigue (n=1) and blood alkaline phosphatase increases (n=1) and two at the 1200 mg dose level, fatigue (n=1) and blood phosphorous decreases (n=1).
- One patient had a dose reduction for a grade 2 AE of worsening leg cramps that was considered to be possibly drug-related.

Efficacy Data

Efficacy data from all 73 treated patients as of the data cut-off showed:

- Four patients (5%) experienced a confirmed partial response (one at 300 mg QD and three at 500 mg QD). A partial response is defined as at least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters according to the Response Evaluation Criteria in Solid Tumors (RECIST v1.1).
- Forty-one patients (56%) experienced stable disease.
- Landmark analyses of progression free survival at six (PFS6) and 12 months (PFS12) were 38.5% and 20.7% respectively. The median progression free survival (PFS) was 3.8 months (95% CI 3.6, 7.3).
- AG-120 treatment inhibited plasma 2-hydroxyglutarate (2-HG) to within levels found in healthy volunteers, and also reduced 2-HG in tumor biopsies, with 2-HG levels in plasma and tumor biopsies showing a positive correlation.
- Pathology review of on-study tumor biopsies were conducted in a patient achieving a partial response, which showed morphologic changes suggestive of cellular differentiation which is consistent with the proposed mechanism of action of AG-120.

ClarIDHy Phase 3 Trial

AG-120 (ivosidenib) is currently being evaluated in an ongoing, global, registration-enabling randomized Phase 3 trial known as ClarIDHy, enrolling 186 previously treated IDH1m positive cholangiocarcinoma patients who have documented disease progression following one or two systemic therapies in the advanced setting.

- Patients will be randomized 2:1 to receive either single-agent AG-120 500 mg once daily or placebo with crossover to AG-120 permitted at the time of progression.
- The primary endpoint of the trial is PFS with secondary endpoints including safety and tolerability, overall response rate, overall survival, duration of response, PK/PD and quality of life assessments.
- Assuming a median PFS of 3 months for the control group, the study was designed with 96% power to detect a hazard ratio of 0.5 for PFS (AG-120 vs placebo), with a one-sided alpha of 0.025.
- Thermo Fisher Scientific is providing next-generation sequencing to detect IDH1m for all tumor samples as inclusion criteria for enrollment in the study and will develop and commercialize the validated companion diagnostic.

About Cholangiocarcinoma

Cholangiocarcinoma (CC) is a rare cancer of the bile ducts within and outside of the liver. Cases that occur within the liver are known as intrahepatic cholangiocarcinoma (IHCC) and those that occur outside the liver are considered extrahepatic. Mutations in IDH1 occur in 13–15% of CC cases overall and in up to 25% of IHCC cases. Current treatment options for localized disease include surgery, radiation and/or other ablative treatments. There are no approved systemic therapies for cholangiocarcinoma and limited chemotherapy options are available in the advanced setting. Gemcitabine-based chemotherapy is often recommended for newly diagnosed metastatic disease. Progression-free survival (PFS) in patients with advanced biliary cancer receiving second-line chemotherapy is 2–3 months.

About Agios

Agios Pharmaceuticals is focused on discovering and developing novel drugs to treat cancer and rare genetic disorders of metabolism 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 cancer metabolism and rare genetic disorders of metabolism in clinical and/or preclinical development. All Agios programs focus on genetically identified patient populations, leveraging the company's knowledge of metabolism, biology and genomics. For more information, please visit Agios' 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 of IDH1 as a therapeutic targets; the potential benefits of Agios' product candidates targeting IDH1, including ivosidenib (AG-120); and the potential benefit of its strategic plans and focus. The words "believe," "aim" "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 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; 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.

Contacts

Investors:
Kendra Adams, 617-844-6407
Senior Director, Investor & Public Relations
Kendra.Adams@agios.com

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

Media:
Holly Manning, 617-844-6630
Associate Director, Corporate Communications
Holly.Manning@agios.com

Exhibit 99.2

Updated Data from Phase 1 Trial of Oral IDHIFA® (enasidenib) Demonstrate Complete Responses and Duration of Response in Patients with Relapsed or Refractory AML and an IDH2 Mutation

40.3% Overall Response Rate (ORR) with Median Duration of Response of 5.8 Months and 19.3% Complete Response (CR) Rate with Median Duration of Response of 8.8 Months in Patients With a CR

Overall Safety Profile was Consistent with Previously Reported Data

Simultaneous Online Publications of Clinical and Translational Data Presented in Journal Blood

CHICAGO, June 6, 2017 – Celgene Corporation (NASDAQ:CELG) and Agios Pharmaceuticals, Inc. (NASDAQ:AGIO) today announced new efficacy and safety data from the ongoing Phase 1 dose-escalation and expansion study evaluating investigational oral IDHIFA® (enasidenib) in patients with relapsed or refractory acute myeloid leukemia (R/R AML) and an isocitrate dehydrogenase-2 (IDH2) mutation. IDHIFA is an investigational first-in-class, oral, targeted inhibitor of the mutant IDH2 enzyme, which demonstrated an overall response rate of 40.3 percent, including a complete response rate of 19.3 percent in the study. The data were presented in an oral session at the American Society of Clinical Oncology (ASCO) Annual Meeting and simultaneously published online in the journal *Blood*.*

"The updated results, including duration of response, from the Phase 1 study reinforce the potential for enasidenib as a first-in-class therapy for patients with relapsed or refractory AML and an IDH2 mutation," said Michael Pehl, President, Hematology/Oncology at Celgene. "Patients have very few treatment options for relapsed or refractory AML, so we are eager to advance this potential targeted therapy as quickly as possible."

As of April 15, 2016, a total of 239 patients with advanced hematologic malignances and an IDH2 mutation were enrolled into the Phase 1 study, of which 176 patients had R/R AML. Data reported include patients receiving enasidenib at total daily doses ranging from 50 mg to 650 mg in the dose-escalation arm and 100 mg once daily in the Phase 1 expansion arms. A maximum tolerated dose was not reached. The median age of the patients enrolled in the study is 70 (ranging from 19-100). Patients with R/R AML received a median of two prior lines of therapy (ranging from one to 14).

The overall safety profile observed for enasidenib was consistent with previously reported data. Twenty-four percent of patients had treatment-related serious adverse events (SAEs), notably IDH differentiation syndrome (8%), leukocytosis (4%), tumor lysis syndrome (3%) and hyperbilirubinemia (2%). The most common treatment-emergent AEs were nausea (46%) hyperbilirubinemia (45%), diarrhea (40%) and fatigue (40%).

Data from 176 R/R AML patients with an IDH2 mutation demonstrated a 40.3 percent (71 of 176 patients) overall response rate, which was the primary endpoint of the study. Further, the complete response rate was 19.3 percent (34 of 176 patients). Median duration of response was 5.8 months [95% CI 3.9, 7.4] for all patients who responded and 8.8 months [95% CI 6.4, NR] for patients who achieved a CR. Median time to first response was 1.9 months (0.5-9.4) and median time to CR was 3.8 months (0.5-11.2). Median overall survival (OS) for R/R AML patients as observed in the study was 9.3 months [95% CI 8.2, 10.9]. Additional results including qualitative improvement in response over time, improvement in hematological parameters over time, OS for patients achieving a CR and transfusion independence were also reported.

“In addition to the complete response in this study, we also observed changes in responses and hematologic parameters over time,” said Eytan Stein, M.D., lead investigator and attending physician in the leukemia service at Memorial Sloan Kettering Cancer Center. “This suggests that differentiation of myeloblasts – made possible by inhibition of mutated IDH2 – may drive the clinical efficacy of enasidenib.”

“Targeting IDH mutations is thought to allow for the differentiation of malignant cells and introduces a new paradigm in the treatment of AML,” said Chris Bowden, M.D., chief medical officer of Agios. “These data show that IDH inhibition plays an important role in segments of AML and will continue to inform our research into this novel class of potential therapies.”

Additional Data Available – IDH Differentiation Syndrome & Translational Analyses

A separate analysis of IDH-inhibitor-associated differentiation syndrome (IDH-DS) associated with enasidenib was also presented as a poster discussion during the ASCO meeting and detailed the findings of an independent Differentiation Syndrome Review Committee (DSRC). The committee reviewed investigator reported IDH-DS cases and determined that 13 of the 27 potential cases were consistent with IDH-DS (11.9% of 109 patients). These data demonstrate that the signs and symptoms of IDH-DS are recognizable. IDH-DS represents a novel clinical finding in patients with mutated IDH2 AML treated with enasidenib, and is likely due to its purported mechanism of action, differentiation of leukemic cells.

In addition to the clinical data publication, additional analyses describing the mechanism of action of enasidenib were also published online in *Blood*. An analysis of patient samples confirmed that the preclinical efficacy and mechanism of action of mutated IDH2 inhibition by enasidenib is through differentiation of AML cells. The authors conclude that the data provide insights into enasidenib resistance to inform future mechanism-based combination treatment studies.

Clinical Development

Enasidenib continues to be studied in the following ongoing clinical trials:

- Phase III IDHENTIFY study evaluating the efficacy and safety of enasidenib versus conventional care regimens in older patients with R/R AML with an IDH2 mutation (NCT02577406)

- Phase 1b study of either enasidenib or ivosidenib in combination with standard induction and consolidation chemotherapy in newly diagnosed AML (NCT02632708)
- Phase 1/2 study of either enasidenib or ivosidenib in combination with azacitidine in newly diagnosed AML (NCT02677922)

The New Drug Application (NDA) for IDHIFA is currently under Priority Review with the U.S. Food and Drug Administration for the treatment of patients with relapsed or refractory AML with an IDH2 mutation. The NDA has been given a Prescription Drug User Fee Act (PDUFA) action date of Aug. 30, 2017.

Ivosidenib (AG-120, wholly owned by Agios) is an investigational, oral, targeted inhibitor of the mutant IDH1 enzyme.

About AG221-C-001

Study AG221-C-001 includes three parts: a Phase 1 dose escalation, a part 1 (Phase 1) expansion and a Phase 2 expansion.

The Phase 1 dose escalation study was designed to determine the maximum tolerated dose and recommended Phase 2 dose, and to evaluate efficacy and safety of enasidenib (AG-221/CC-90007) in subjects with advanced hematologic malignancies with an IDH2 mutation. The Part 1 expansion further evaluated the safety, tolerability, and efficacy of enasidenib in subjects with R/R AML, untreated AML, myelodysplastic syndrome or other advanced hematologic malignancies with an IDH2 mutation. Based on the clinical activity observed in R/R AML subjects, the Phase 2 expansion was designed to assess efficacy of enasidenib at recommended 100 mg daily dose and to further evaluate safety in subjects with R/R AML and with IDH2 mutation. The study was not designed or statistically powered to reach a conclusion on OS. A phase 3 randomized controlled trial with OS as a primary endpoint has been initiated.

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. 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. IDH2 mutations are present in about 8 to 19 percent of AML cases.

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 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.

About Celgene

Celgene Corporation, headquartered in Summit, New Jersey, is an integrated global biopharmaceutical company engaged primarily in the discovery, development and commercialization of innovative therapies for the treatment of cancer and inflammatory diseases through next-generation solutions in protein homeostasis, immuno-oncology, epigenetics, immunology and neuro-inflammation. For more information, please visit www.celgene.com. Follow Celgene on Social Media: @Celgene, Pinterest, LinkedIn, Facebook and YouTube.

About Agios/Celgene Collaboration

IDHIFA® (enasidenib) and AG-881 are part of Agios' global strategic collaboration with Celgene Corporation focused on cancer metabolism. Under the terms of the 2010 collaboration agreement, Celgene has worldwide development and commercialization rights for IDHIFA. Agios continues to conduct clinical development activities within the IDHIFA development program and is eligible to receive reimbursement for those development activities and up to $95 million in remaining payments assuming achievement of certain milestones and royalties on net sales. Celgene and Agios intend to co-commercialize IDHIFA in the U.S. Celgene will reimburse Agios for costs incurred for its co-commercialization efforts.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements, which are generally statements that are not historical facts. Forward-looking statements can be identified by the words "expects," "anticipates," "believes," "intends," "estimates," "plans," "will," "outlook" and similar expressions. Forward-looking statements are based on management's current plans, estimates, assumptions and projections, and speak only as of the date they are made. Neither Celgene nor Agios undertake any obligation to update any forward-looking statement in light of new information or future events, except as otherwise required by law. Forward-looking statements involve inherent risks and uncertainties, most of which are difficult to predict and are generally beyond each company's control. Actual results or outcomes may differ materially from those implied by the forward-looking statements as a result of the impact of a number of factors, many of which are discussed in more detail in the Annual Report on Form 10-K and other reports of each company filed with the Securities and Exchange Commission.

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Celgene Contacts
Investors:
+1-908-673-9628
ir@celgene.com

Media:
+1-908-673-2275
media@celgene.com

Agios Contacts

Investors:
Kendra Adams, 617-844-6407
Senior Director, Investor & Public Relations
Kendra.Adams@agios.com

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

Media:
Holly Manning, 617-844-6630
Associate Director, Corporate Communications
Holly.Manning@agios.com