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 24, 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 24, 2017, Agios Pharmaceuticals, Inc. (the "Company") issued a press release announcing updated clinical data from the Company's ongoing phase 2 DRIVE PK study evaluating AG-348 in patients with pyruvate kinase deficiency. Also on June 24, 2017, the Company issued a press release announcing new efficacy and safety data from the ongoing Phase 1/2 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. These data were presented at the 22nd Congress of the European Hematology Association (EHA) taking place June 22-25, 2017 in Madrid, Spain.

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 24, 2017.
99.2	Press release issued by Agios Pharmaceuticals, Inc. on June 24, 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 26, 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 24, 2017.
99.2	Press release issued by Agios Pharmaceuticals, Inc. on June 24, 2017.

Exhibit 99.1

Agios Announces Updated Data from Fully Enrolled DRIVE PK Study Demonstrating AG-348's Potential as the First Disease-modifying Treatment for Patients with Pyruvate Kinase Deficiency

– AG-348 Is Well-Tolerated and Demonstrates Clinically Relevant, Rapid and Sustained Hemoglobin Increases in 25 of 52 Patients Overall –

– New Data Show Improvements in Hemolysis Associated Parameters Indicate Positive Impact on Disease Biology –

– Program on Track to Enter Global Pivotal Development in First Half of 2018 –

MADRID, June 24, 2017 — Agios Pharmaceuticals, Inc. (Nasdaq:AGIO) presented updated data from its wholly owned pyruvate kinase-R (PKR) activator demonstrating the potential for the first disease-modifying treatment for patients with pyruvate kinase (PK) deficiency at the 22nd Congress of the European Hematology Association (EHA). PK deficiency is a rare, potentially debilitating, congenital anemia.

DRIVE PK is an ongoing global open-label, Phase 2, safety and efficacy trial evaluating AG-348 in adult, transfusion-independent patients with PK deficiency. As of the March 27, 2017 data cut-off, 48% of all 52 treated patients (n=25/52) and 57% of patients with at least 1 missense mutation (n=24/42) treated with AG-348 experienced a maximum Hb increase from baseline of >1.0 g/dL. Hb increases were rapid with a median time to a Hb increase of >1.0 g/dL of 10 days.

Enrollment in DRIVE PK was completed in November 2016 with 52 patients. Patients were randomized to a starting dose of 50 mg or 300 mg twice daily, treated for six months in a core treatment period and then offered up to two years of treatment in an extension period. As of the data cut-off, 15 patients remain in the core period, 29 patients completed the core treatment period and 21 remain in the extension period. The median baseline hemoglobin (Hb) for all patients was 8.9 gram per deciliter (g/dL) (ranging from 6.5 to 12.3 g/dL). Forty-three of the 52 patients (83%) had been splenectomized prior to study entry and 25 (48%) have received prior iron chelation therapy.

"With data now available from all 52 patients, AG-348 continues to demonstrate clinically relevant and sustained increases in hemoglobin in adults with PK deficiency," said Rachael Grace, M.D., of the Dana-Farber Boston Children's Cancer and Blood Disorder Center and a principal investigator for the study. "These findings offer patients and physicians a well-tolerated, oral therapy as the first potential disease-altering treatment for people suffering from this chronic anemia and its associated complications."

"The rapid and sustained hemoglobin increases shown in DRIVE PK, combined with improvements in hemolysis related parameters, indicate that AG-348 is having a meaningful impact on the biology of PK deficiency," said Chris Bowden, M.D., chief medical officer at Agios. "We look forward to advancing this novel investigational therapy into a planned global pivotal program in the first half of 2018."

Safety Data

A safety analysis conducted for all 52 treated patients as of the data cut-off shows that AG-348 continues to be well tolerated.

- The majority of treatment-related adverse events (AEs) were Grade 1-2; the most frequent were headache, insomnia and nausea.
- Three patients experienced treatment related AEs leading to discontinuation: chest discomfort/pleural effusion (n=1), pharyngitis/nausea (n=1) and anemia (n=1).
- Five patients experienced drug-related serious adverse events: withdrawal hemolysis followed by anemia (n=1), anemia (n=1), osteoporosis (n=1), hypertriglyceridemia (n=1) and pharyngitis (n=1).
    - Grade 4 hypertriglyceridemia at week 24 resolved upon AG-348 discontinuation (patient had Grade 1 hypertriglyceridemia at baseline).
- Preliminary measurements of testosterone in men suggest aromatase inhibition by AG-348 with the majority of testosterone changes remaining within the normal range. Longer follow-up is required to assess clinical significance.

Efficacy Data

In the efficacy analysis of all 52 treated patients, 25 patients overall and 24 of 42 patients with at least one missense mutation achieved rapid, robust and sustained Hb increases from baseline of >1.0 g/dL as of the data cut-off.

- In patients who had Hb increases of >1.0 g/dL, the mean maximum Hb increase was 3.5 g/dL (range 1.1-5.8 g/dL).
- The median time to a Hb increase of >1.0 g/dL was 10 days (range 7–141 days).
- Median baseline Hb in patients who experienced a maximum Hb increase of >1.0 g/dL was 9.7 g/dL (range 7.5–12.3 g/dL) vs. 8.0 g/dL (range 6.5–10.1 g/dL) in patients who did not experience the increase.
- In patients with a Hb increase of >1.0 g/dL improvements in hemolysis associated parameters were observed:
    - An increase in haptoglobin and decrease in lactate dehydrogenase (LDH) were observed in the first weeks of dosing.
    - Rapid decreases in reticulocytes were observed.

About Pyruvate Kinase Deficiency and Genetic Background

PK deficiency is a rare inherited disease that presents as hemolytic anemia, which is the accelerated destruction of red blood cells. The inherited mutations in PKR enzymes cause a deficit in cellular energy within the red blood cell, as evidenced by lower pyruvate kinase enzyme activity and a decline in ATP (adenosine triphosphate) levels and a build-up of upstream metabolites, including 2,3-DPG (2,3-diphosphoglycerate).

The current standard of care for PK deficiency is supportive, including blood transfusions, splenectomy, chelation therapy to address iron overload and/or interventions for other treatment- and disease-related morbidities. There is no approved therapy to treat the underlying cause of PK deficiency.

PK deficiency is an autosomal recessive disease whereby all patients inherit two mutations, one from each parent. More than 250 different mutations have been identified to date. The mutations observed in PK deficiency patients are classified in two main categories. A missense mutation causes a single amino acid change in the protein, generally resulting in some functional protein. A non-missense mutation is any mutation other than a missense mutation, generally resulting in little functional protein. It is estimated that 53 percent of patients with PK deficiency have two missense mutations, 25 percent have one missense and one non-missense mutation, and 22 percent have two non-missense mutations[1].

Boston Children's Hospital, in collaboration with Agios, is conducting a Natural History Study to better understand the symptoms and complications of PK deficiency, identify patients and treatment centers, and capture other clinical data, including quality of life measures and genetic information.

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.

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 AG-348; Agios' plans for the further clinical development of AG-348; and Agios' strategic plans and prospects. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "would," "could," "potential," "possible," "hope" 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; that positive safety and efficacy findings observed in early stage clinical trials will be replicated in later stage trials; 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 agreements 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' 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.

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[1] Bianchi P et al. poster, 2015 ASH Annual Meeting

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Exhibit 99.2

New Data from Phase 1/2 Trial of Oral IDHIFA® (enasidenib) Demonstrate Durable Complete Responses in Patients with IDH2 Mutant Relapsed or Refractory AML

Inclusion of Phase 2 Expansion Data Demonstrates Overall Efficacy and Safety Profile Consistent with Previously Reported Data

In 214 R/R AML Patients Treated with Enasidenib at 100 mg Daily Dose in Phase 1/2 Trial, 20.1% Complete Response (CR) Rate with Median Duration of Response of 8.8 Months in Patients with a CR

MADRID, June 24, 2017 – Agios Pharmaceuticals, Inc. (NASDAQ:AGIO) today announced new efficacy and safety data from the ongoing Phase 1/2 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®, being developed in collaboration with Celgene Corporation, is an investigational first-in-class, oral, targeted inhibitor of the mutant IDH2 enzyme. Data in an oral session at the 22nd Congress of the European Hematology Association (EHA) demonstrated an overall response rate (ORR) of 37 percent, including a complete response (CR) rate of 20.1 percent in 214 patients with R/R AML who received enasidenib at 100 mg daily, which was the recommended starting dose in the expansion phases of the trial.

"With data from an additional 105 patients and the first look at data from the Phase 2 expansion in R/R AML patients treated at the recommended Phase 2 starting dose of 100 mg once daily, these updated results underscore the consistency and durability of response for enasidenib as a potential first-in-class therapy for patients with relapsed or refractory AML and an IDH2 mutation," said Chris Bowden, M.D., chief medical officer of Agios. "We are working with our partner Celgene to quickly bring this oral, targeted therapy to patients with limited treatment options."

As of October 14, 2016, a total of 345 patients with advanced hematologic malignances and an IDH2 mutation were enrolled into the Phase 1/2 study, which includes three parts: a Phase 1 dose escalation, a part 1 (Phase 1) expansion and a Phase 2 expansion. In the study, 281 patients had R/R AML and 214 of the R/R AML patients were treated at 100 mg daily. This is the first presentation of data from the Phase 2 expansion. 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 daily in the Phase 1 and Phase 2 expansion arms. A maximum tolerated dose was not reached. The median age of the R/R AML patients enrolled in the study is 68 (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. The most common treatment-emergent AEs were nausea (48%), diarrhea (41%), fatigue (41%), decreased appetite (34%) and blood bilirubin increased (33%). For all patients in the study, 26.1 percent had treatment-related serious adverse events (SAEs), notably IDH differentiation syndrome (7%), leukocytosis (4%), tumor lysis syndrome (3%) and hyperbilirubinemia (2%).

Data from 214 of the R/R AML patients with an IDH2 mutation who were treated at the recommended Phase 2 starting dose of 100 mg daily demonstrated a 37 percent (79 of 214 patients) overall response rate, which was the primary endpoint of the study. Further, the complete response rate was 20.1 percent (43 of 214 patients). Median duration of response was 5.6 months [95% CI 4.6, 7.4] for all patients who responded and 8.8 months [95% CI 5.6, NR] for patients who achieved a CR. Median time to first response was 1.9 months (0.5-11.1) and median time to CR was 3.7 months (0.7-11.2). At the time of the data cut-off, median overall survival (OS) as observed in the study was 8.3 months [95% CI 7.5,9.4]. 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.

“Enasidenib’s unique profile as a targeted differentiation agent distinguishes it in a field that has seen few new medicines in decades,” said Eytan Stein, M.D., lead investigator and attending physician in the leukemia service at Memorial Sloan Kettering Cancer Center. “Even in the absence of CR, some patients became transfusion independent with enasidenib treatment, suggesting a proportion of patients on study are deriving clinical benefit from an oral, single agent therapy in the relapsed/refractory setting.”

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 August 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 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 within the meaning of The Private Securities Litigation Reform Act of 1995. Such forward-looking statements include those regarding the potential of the IDH2 mutation as a therapeutic target; the potential benefits of IDHIFA® (enasidenib); and the potential benefit of Agios' strategic plans and focus. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "would," "could," "potential," "possible," "hope" 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: 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; the ability to obtain and maintain requisite regulatory approvals and to enroll patients in 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 it is developing; Agios' ability to maintain key collaborations, such as its agreements 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' 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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