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 9, 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 8.01 Other Events.

On June 9, 2016, Agios Pharmaceuticals, Inc. ("the Company") issued a press release announcing the first data from its ongoing phase 1 integrated single ascending dose and multiple ascending dose trial evaluating AG-519 in healthy adult volunteers. AG-519 is the Company's potent, oral activator of wild-type and mutant pyruvate kinase-R ("PKR") enzymes. On June 11, 2016, the Company issued a press release announcing initial data from DRIVE PK, the Company's ongoing global phase 2, open-label safety and efficacy trial evaluating AG-348, the Company's novel, first-in-class, oral PKR activator, in adult transfusion-independent patients with pyruvate kinase deficiency.

The Company presented both data at the 21st Congress of the European Hematology Association in Copenhagen, Denmark on June 11, 2016. 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 are incorporated herein by reference.

In addition, on June 11, 2016, the Company updated one of its 2016 expected milestones for its AG-120 program. As a result of the Company recently obtaining global rights to AG-120 and the IDH1 program, the Company now expects to initiate a global, registration-enabling Phase 3 study of AG-120 in frontline acute myeloid leukemia patients with an IDH1 mutation in the first half of 2017, as opposed to prior guidance of a trial initiation in the second half of 2016.

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 the Company on June 9, 2016.
99.2	Press release issued by the Company on June 11, 2016.

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 13, 2016

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release issued by the Company on June 9, 2016.
99.2	Press release issued by the Company on June 11, 2016.

Exhibit 99.1

Agios Reports Initial Data from Phase 1 Study of AG-519 in Healthy Volunteers

- Data Demonstrate Favorable Safety Profile with up to 14 Days of Daily Dosing -

- Robust Dose-Dependent Changes in ATP and 2,3-DPG Blood Levels Observed Consistent with PKR Enzyme Activation -

- Company to Host Conference Call and Webcast Saturday, June 11 at 9:30am ET -

COPENHAGEN, June 9, 2016 — Agios Pharmaceuticals, Inc. (Nasdaq:AGIO) today announced the initial data from the Phase 1 integrated single ascending dose (SAD) and multiple ascending dose (MAD) clinical trial of AG-519 in healthy volunteers at the 21st Congress of the European Hematology Association (EHA) taking place June 9-12, 2016 in Copenhagen. These data provide early proof-of-mechanism for AG-519, a potent, oral, selective second pyruvate kinase-R (PKR) activator that is wholly owned by Agios. Agios is also developing AG-348, a first-in-class, oral PKR activator that is being evaluated in an ongoing Phase 2 study, DRIVE-PK.

In this Phase 1 study, dosing of AG-519 over 14-days in healthy volunteers resulted in a dose-dependent increase in PKR activity as evidenced by a substantial increase in ATP (adenosine triphosphate) and decrease in 2,3-DPG (2,3-diphosphoglycerate) levels, which are important biomarkers of PKR activation in healthy volunteers. These data support the hypothesis that AG-519 enhances PKR activity and has the potential to correct the underlying defect of pyruvate kinase (PK) deficiency, a rare, potentially debilitating, congenital anemia.

“Achieving proof-of-mechanism for AG-519, our second PKR activator, further advances Agios’ novel approach to the treatment of rare metabolic disorders,” said Chris Bowden, M.D., chief medical officer of Agios. “These Phase 1 data from AG-519 bring us closer to our goal of delivering the first disease-modifying treatment for patients with PK deficiency.”

Results from the Completed SAD Portion of the Phase 1 Study

- Four cohorts with doses of AG-519 ranging from 50 mg to 1250 mg were tested against placebo in 32 healthy volunteers.
- AG-519 demonstrated a favorable safety profile in all doses tested. There were no serious adverse events (SAEs) reported, with all adverse events (AEs) being mild to moderate, and the most common being headache. In addition, there were no early discontinuations due to AG-519 and the maximum tolerated dose was not reached.
- Mean decreases in blood 2,3-DPG levels up to 43 percent from baseline were observed in the SAD cohorts, reaching minimum levels after 24 hours. As expected, ATP levels did not change after a single dose of AG-519, consistent with SAD findings from AG-348. Healthy volunteers receiving placebo showed no changes in 2,3-DPG or ATP levels.

Preliminary Results from the Ongoing MAD Portion of the Phase 1 Study

- The first two cohorts reported data from 16 healthy volunteers dosed twice daily with 125 mg or 375 mg of AG-519 or placebo for 14 days.
- There were no SAEs reported, with all AEs being mild to moderate, and the most common being headache. One subject receiving AG-519 at the 375 mg dose experienced a low blood platelet count (Grade 2 thrombocytopenia) on Day 14. Platelet levels started to recover within five days of the last dose and returned to normal levels seven days after the last dose.
- Pharmacodynamic data from these cohorts showed a mean decrease of up to 47 percent in blood 2,3-DPG levels and a mean increase of up to 62 percent in blood ATP levels from baseline. In contrast, healthy volunteers receiving placebo showed no changes in 2,3-DPG or ATP levels.
- Subjects treated with AG-519 exhibited no significant changes in sex steroids levels, consistent with a lack of aromatase enzyme inhibition.
- Enrollment into additional MAD cohorts is ongoing.

Conference Call Information

Agios will host a conference call and webcast from EHA to review the data from the AG-348 DRIVE-PK study and the AG-519 Phase 1 Study in Healthy Volunteers on Saturday June 11, 2016 beginning at 9:30 a.m. ET (3:30 p.m. CEST). To participate in the conference call, please dial (877) 377-7098 (domestic) or (631) 291-4547 (international) and refer to conference ID 18475657. The webcast will be accessible live or in archived form under “Events & Presentations” in the Investors and Media section of the company’s website at www.agios.com.

About PK Deficiency

PK deficiency is a rare inherited disease that presents as hemolytic anemia, which is the accelerated destruction of red blood cells. The 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 levels and a build-up of upstream metabolites, including 2,3-DPG.

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. Currently, there is no approved therapy to treat the underlying cause of PK deficiency.

Boston Children’s Hospital in collaboration with Agios is also 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' PK-R Activators

AG-348 and AG-519 are orally available, potent, selective small molecule activators of PKR. Both molecules were discovered by the Agios research team and the company retains worldwide development and commercialization rights.

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 pyruvate kinase-R mutations, including AG-348 and AG-519; Agios' plans for the further clinical development of AG-519; and its 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'

Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, 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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Exhibit 99.2

AG-348 Achieves Proof-of-Concept in Ongoing Phase 2 DRIVE-PK Study and Demonstrates Rapid and Sustained Hemoglobin Increases in Adults with Pyruvate Kinase Deficiency

- 9 of 18 Total Patients and 9 of 13 Patients with at Least One Missense Mutation Showed Maximal Hemoglobin Increases Between 2.3 to 4.9 g/dL -

- AG-348 Well Tolerated with Up to Six Months of Daily Dosing -

- Results Validate Agios' Novel Approach to Treatment of Rare Metabolic Disorders -

- Company to Host Conference Call and Webcast Today at 9:30 a.m. ET -

COPENHAGEN, June 11, 2016 — Agios Pharmaceuticals, Inc. (Nasdaq:AGIO) today announced initial data demonstrating that AG-348 achieved proof-of-concept in an ongoing Phase 2 study (DRIVE-PK) of patients with pyruvate kinase (PK) deficiency, a rare, potentially debilitating, congenital anemia. AG-348 is a novel, first-in-class, oral activator of both wild-type (normal) and mutated pyruvate kinase-R (PKR) enzymes. AG-348 is wholly owned by Agios. Data will be presented today at the 21st Congress of the European Hematology Association (EHA) taking place June 9-12, 2016 in Copenhagen.

DRIVE-PK is the first study to evaluate the safety and efficacy of AG-348 in patients with PK deficiency. As of the March 27, 2016 data cut-off, 18 transfusion-independent patients (13 with at least one missense mutation and five with two non-missense mutations) were treated with twice-daily dosing of AG-348 for up to six months. Treatment resulted in rapid and sustained hemoglobin increases of >1.0 g/dL in nine out of 18 patients (nine of 13 patients with at least one missense mutation), ranging from 2.3–4.9 g/dL with a mean maximum hemoglobin increase of 3.4 g/dL. It is estimated that approximately 80 percent of all PK deficiency patients carry at least one missense mutation. These data support the hypothesis that AG-348 restores metabolic function and has the potential to correct the underlying defect in the red blood cells of patients with PK deficiency.

"People with PK deficiency suffer from chronic anemia and a range of other complications brought on by both their disease and existing supportive therapies, including blood transfusions and splenectomy," 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 data are exciting for the hematology community and patients, as they demonstrate the potential for AG-348 to provide the first disease-modifying treatment with impressive and prolonged increases in hemoglobin levels."

"These data have established proof-of-concept for AG-348, validating our novel approach to the treatment of rare genetic metabolic disorders by correcting the underlying enzymatic defect with

a small molecule," said Chris Bowden, M.D., chief medical officer at Agios. "The rapid and sustained hemoglobin increases and well-tolerated safety profile shown in this trial to date support continued study and moving into late-stage development. In addition, these data demonstrate the important potential role that PK activation may have in transforming treatment of PK deficiency."

About the DRIVE-PK Study

DRIVE-PK is a global Phase 2, open-label safety and efficacy trial evaluating AG-348 in adult, transfusion-independent patients with PK deficiency. The study includes two arms of up to 25 patients each, receiving a dose of 50 milligrams (mg) or 300 mg twice daily for at least six months. Hemoglobin levels are assessed in weekly intervals for the first 3 weeks of study and then at weeks 6, 9, 12, 16, 20 and 24. As of the March 27, 2016 data cut-off, 18 patients had been treated with AG-348 for at least three weeks in the DRIVE-PK study. Three of the 18 patients had completed 24 weeks of treatment with either 50 mg or 300 mg twice daily. The mean patient age was 31. The mean baseline hemoglobin was 9.3 g/dL. Thirteen of the 18 patients underwent prior splenectomy.

Safety Data

A safety analysis was conducted based on all 18 treated patients as of the data cut-off.

- AG-348 was well tolerated, and no patients discontinued treatment early.
- The majority of adverse events (AEs) reported by investigators were mild to moderate (Grade 1-2) and transient.
- The most frequent AEs included nausea, headache, hot flush and insomnia.
- One patient received a dose reduction due to rapidly increasing hemoglobin. This patient was dose-reduced from 300 mg to 50 mg and remained on study.
- One Grade 2 AE of osteoporosis has been reported since the cut-off date. This patient had osteopenia at baseline assessment.
- Sex steroids were assessed at baseline, week 12 and week 24. Free testosterone and estradiol were available for four and five male patients, respectively. An upward trend in free testosterone and a downward trend in estradiol were observed. Additional data and longer follow up are needed to determine if hormonal changes are clinically significant.

Efficacy Data

Nine of 18 total patients and nine of 13 patients with at least one missense mutation achieved rapid, robust and sustained hemoglobin increases of >1.0 grams per deciliter (g/dL) as of the data cut-off.

- Both doses of AG-348 demonstrated clinical activity, with four patients in the 50 mg group and five patients in the 300 mg group experiencing increases of >1.0 g/dL.
- In patients who had hemoglobin increases of >1.0 g/dL, the mean maximum hemoglobin increase was 3.4 g/dL (range 2.3–4.9 g/dL).

- The median time to a hemoglobin increase of >1.0 g/dL was 1.9 weeks (range 1.1–9.1 weeks).
- Further data are needed to obtain a greater understanding of the relationship between genotype and response. Preliminary observations show:
    - Of the 13 patients with at least one missense mutation, nine have shown an increase in hemoglobin of >1.0 g/dL.
    - None of the five patients with two non-missense mutations showed increases in hemoglobin of >1.0 g/dL.
- Pharmacokinetics were favorable and consistent with those observed in healthy volunteers.
- Pharmacodynamics data did not demonstrate a correlation with hemoglobin increases and ATP (adenosine triphosphate) elevation. More data are needed to clarify if any correlation exists between 2,3-DPG (2,3-diphosphoglycerate) decreases and Hb increases of >1.0 g/dL.

About Pyruvate Kinase Deficiency and Genetic Background

Pyruvate Kinase Deficiency (PKD) 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 levels and a build-up of upstream metabolites, including 2,3-DPG.

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' PK-R Activators

Agios has discovered and is currently evaluating two orally available, potent, selective small molecule activators of PKR in clinical trials, AG-348 and AG-519. Agios scientists previously reported that AG-348 is a potent activator of the wild-type and mutated PKR enzymes. Agios retains worldwide development and commercialization rights to AG-348 and AG-519.

Conference Call Information

Agios will host a conference call and webcast to review data presented at EHA and corporate milestones on Saturday, June 11, 2016 beginning at 9:30 a.m. ET (3:30 p.m. CEST). To participate in the conference call, please dial (877) 377-7098 (domestic) or (631) 291-4547 (international) and refer to conference ID 18475657. The webcast will be accessible live or in archived form under "Events & Presentations" in the Investors and Media section of the company's website at www.agios.com.

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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' Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, 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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1 Bianchi P et al. poster, 2015 ASH Annual Meeting