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): November 16, 2018

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 November 16, 2018, Agios Pharmaceuticals, Inc. (the "Company") issued a press release announcing updated clinical data from the Company's Phase 1 study evaluating single agent AG-881 in patients with isocitrate dehydrogenase mutant-positive advanced glioma and other solid tumors. The Company presented the data on November 16, 2018 at the Society for Neuro-Oncology Annual Meeting in New Orleans, Louisiana. The full text of the press release issued in connection with this announcement is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference..

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release issued by Agios Pharmaceuticals, Inc. on November 16, 2018.

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: November 16, 2018

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

Agios Presents Updated Data from Phase 1 Dose-Escalation Study of AG-881 in Patients with IDH Mutant Positive Advanced Glioma

– Median Treatment Duration of 15 Months Observed in Non-Enhancing Glioma with 13 Patients Remaining on Treatment Provides Evidence of Prolonged Disease Control –

– Favorable Safety Profile at 10 mg and 50 mg, Doses Under Evaluation in Ongoing Glioma Perioperative Study –

NEW ORLEANS, November 16, 2018 — Agios Pharmaceuticals, Inc. (NASDAQ:AGIO), a leader in the field of cellular metabolism to treat cancer and rare genetic diseases, today presented updated data from the ongoing Phase 1 study evaluating single agent AG-881 in advanced glioma. The data were featured in an oral presentation at the Society for Neuro-Oncology (SNO) Annual Meeting in New Orleans. AG-881 is an investigational, oral, selective, potent inhibitor of the mutant isocitrate dehydrogenase-1 (IDH1) and IDH2 enzymes and was designed for enhanced brain penetrance for development in IDH-mutant glioma.

“With additional follow-up, the AG-881 Phase 1 dose-escalation data continue to show a favorable safety profile at the doses selected for the perioperative study. Longer treatment duration and a reduction in tumor growth rates are encouraging signs of clinical activity in low-grade glioma,” said Ingo Mellinghoff, M.D., Memorial Sloan Kettering Cancer Center, an investigator for the study. “Ultimately, use of an IDH inhibitor in this difficult-to-treat disease has the potential to improve the current treatment paradigm by delaying the multiple rounds of surgery, radiation and chemotherapy that many patients endure.”

“With no curative or approved targeted therapies and a high frequency of IDH1 mutations in low-grade glioma, we are committed to advancing one of our IDH inhibitors to a registrational study in this disease,” said Chris Bowden, M.D., chief medical officer at Agios. “We are continuing to collect clinical data for both ivosidenib and AG-881, along with feedback from regulators and the neuro-oncology community, to make an internal decision on our glioma pivotal strategy by the end of this year.”

Study Status

AG-881 is being evaluated as a single agent in an ongoing Phase 1 dose-escalation trial in IDH1/2 mutant advanced solid tumors, including glioma. Enrollment was completed in June 2017. Dose escalation data as of March 29, 2018 were presented at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting. As of the updated July 20, 2018 data cut-off, study design, enrollment and baseline characteristics of the 52 glioma patients remain unchanged, as reported below.

- Forty-eight percent of patients (n=25) had World Health Organization (WHO) classified Grade 2 tumors, 42% (n=22) had Grade 3 tumors, 8% (n=4) had Grade 4 tumors and 2% (n=1) was unknown.

- The median age of these patients is 42.5 years (ranging from 16-73 years).
- Patients received a median of two prior systemic therapies (ranging from one to six).
    - Seventy-three percent of patients (n=38) had previously received temozolomide and 58% percent (n=30) had previously received radiotherapy.
- Patients received daily doses of AG-881 ranging from 10 mg to 300 mg.

Updated safety and efficacy data on the 52 patients with enhancing and non-enhancing glioma, including an exploratory tumor volume growth rate analysis, are reported below.

- Fourteen patients remain on treatment, including 13 patients with non-enhancing disease.
- Of the 38 patients who discontinued treatment, 76.3% (n=29) discontinued for disease progression and 5.2% (n=2) discontinued due to an AE.
- The median treatment duration was 6.3 months (ranging from 0.2-32 months) for all glioma patients, 15 months (ranging from 1-32 months) for non-enhancing glioma and 3.25 months (ranging from 0.2- 32 months) for patients with enhancing disease.
- Thirty-seven percent of patients (n=19, including 15 patients with non-enhancing disease) remained on treatment for ³1 year.

Safety Data

The safety analysis conducted for all 52 glioma patients as of the data cut-off demonstrated that AG-881 continues to have a favorable safety profile at dose levels below 100 mg.

- The majority of adverse events (AEs) reported by investigators were mild to moderate, with the most common (>30%) being increases in alanine aminotransferase (ALT) (n=23), increases in aspartate aminotransferase (AST) (n=21), headache (n=19) and fatigue (n=17).
- Grade 3 or higher AEs were observed in 19% of all patients (n=10). AEs occurring in more than one patient included seizure (n=4), ALT increases (n=3) and AST increases (n=2).
- As reported in June, dose limiting toxicities (DLTs) of Grade 2 or higher elevated transaminases occurred in five glioma patients at the higher dose levels (³100 mg) and resolved to Grade £1 with dose modification or discontinuation. There were no new DLTs reported as of the new data cut-off or any treatment-related on-treatment deaths.
- Doses of 10 mg and 50 mg are under evaluation in an ongoing perioperative study in non-enhancing glioma.

Efficacy Data

Efficacy data from the 52 glioma patients (22 with non-enhancing and 30 with enhancing disease) as of the data cut-off showed:

- One patient with non-enhancing disease and a 1p19q co-deletion had a confirmed / sustained partial response according to the investigator by Response Assessment in Neuro-Oncology for low grade glioma (RANO-LGG) and remains on treatment.
- One patient with non-enhancing disease and a 1p19q co-deletion had a confirmed / sustained minor response according to the investigator by RANO-LGG and remains on treatment.
- Sixty-nine percent of patients (n=36) had a best response of stable disease, including 82% (n=18) patients with non-enhancing disease.
- For non-enhancing patients with available data (n=18), the average volumetric six-month tumor growth was 6.8% following treatment with AG-881; pre-treatment volumetric growth rates were not available for these patients. For a similar population of IDHm low-grade glioma patients in the ongoing Natural History study, the average six-month volumetric growth prior to treatment was 24.5%.

Ongoing Glioma Perioperative Study Presented in Trials in Progress Poster

A perioperative ‘window’ trial with ivosidenib and AG-881 (10 mg and 50 mg) in up to 45 IDH1m non-enhancing low-grade glioma patients is ongoing and being presented today as part of a trials in progress poster. The goal of the trial is to confirm CNS penetrance and tumor 2-HG suppression of ivosidenib and AG-881 as part of the strategy to finalize internal pivotal development plans by year-end 2018.

About Glioma

Glioma presents in varying degrees of tumor aggressiveness, ranging from slower growing (low-grade glioma) to rapidly progressing (high-grade glioma-Glioblastoma Multiforme). Common symptoms include seizures, memory disturbance, sensory impairment and neurologic deficits. The long-term prognosis is poor with a five-year survival rate of 33 percent. Approximately 11,000 low-grade glioma patients are diagnosed annually in the U.S. and EU and approximately 80 percent have an IDH1 mutation.

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 two approved oncology precision medicines and multiple first-in-class investigational therapies 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-881; Agios’s plans for future clinical development of AG-881; and the potential benefit of Agios’s strategic plans and focus. The words “could,” “expect,” “intend,” “may,” “path,” “plan,” “potential,” “strategy,” “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 or its collaborator, Celgene, 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 agreements with Celgene and CStone Pharmaceuticals; 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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