

AGIOS PHARMACEUTICALS INC
Form 8-K
June 13, 2016

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
(State or Other Jurisdiction

of Incorporation)

001-36014
(Commission

File Number)

26-0662915
(IRS Employer

Identification No.)

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88 Sidney Street, Cambridge, MA
(Address of Principal Executive Offices)

02139
(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

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