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): August 4, 2025

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, Par Value $0.001 per share	AGIO	Nasdaq Global Select Market

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 7.01 Regulation FD Disclosure

Matters Relating to PYRUKYND® in the United States

Agios Pharmaceuticals, Inc. ("Agios" or the "Company") is aware of the securities analyst report published on August 4, 2025 (the "Analyst Report"), detailing recent PYRUKYND® data from the U.S. Food and Drug Administration's ("FDA") Adverse Event Reporting System (FAERS), received in connection with a Freedom of Information Act (FOIA) request.

Patient safety is of the utmost importance to Agios, and the Company maintains robust pharmacovigilance practices to collect, assess and, where appropriate, submit safety information to regulatory authorities in accordance with applicable regulations.

To date, the information available to the Company, including the cases referenced in the Analyst Report, has not altered the established benefit-risk profile of PYRUKYND, which is described in the U.S. Prescribing Information (USPI).

The Analyst Report references four patient cases. Three of the cases were reported to Agios, and subsequently reported to FDA, as part of the Company's standard pharmacovigilance processes. Two of these cases relate to patients on commercially-available PYRUKYND, which is approved in the U.S. for the treatment of hemolytic anemia in adults with pyruvate kinase (PK) deficiency. The third case relates to a patient with sickle cell disease who received treatment with PYRUKYND through individual patient expanded access, also referred to as compassionate use, at the request of the patient's treating physician. Under FDA regulations and guidance, FDA permits such expanded access upon a determination that, among other things, the patient to be treated has a serious or immediately life-threatening disease or condition and there is no comparable or satisfactory alternative therapy to diagnose, monitor or treat the disease or condition ("Expanded Access").

The fourth patient case was reported directly to the FDA. Agios is evaluating this case in connection with its pharmacovigilance processes.

Based on information available at this time we understand the following regarding the cases referenced in the Analyst Report:

The first case involves a 61-year-old male receiving PYRUKYND for pyruvate kinase (PK) deficiency. No other medical history or concomitant medications were reported. Following a reported fall, an MRI revealed a shoulder mass. The patient's relative reported he had advanced liver cancer; a healthcare professional confirmed the cause of death was metastatic cancer.

The second case involves a 93-year-old female with pyruvate kinase (PK) deficiency. No other medical history or concomitant medications were reported. A caregiver reported that the patient entered hospice due to kidney failure and cardiac issues, with minimal nutritional intake. The patient passed away while in hospice care.

The Expanded Access case involves a 26-year-old female with sickle cell disease and a pertinent medical history of heart arrhythmia, silent infarct and aneurysm. The report states that patient was receiving Procrit and Bactrim for a urinary tract infection and died from a pulmonary embolism. Transaminitis was incidentally noted in the medical record during hospitalization and was not attributed to PYRUKYND by the reporting healthcare professional.

The fourth case, which was reported directly to the FDA, involves a 28-year-old female with no medical history provided, several adverse event terms provided and Bactrim listed as another suspect drug. The adverse event terms, which include hypertransaminasaemia, lack sufficient medical context at this time. Agios is following FDA's established process for receiving FAERS data and will evaluate any new information against the known safety profile of PYRUKYND.

To date, the information available to the Company, including the cases referenced in the Analyst Report, has not altered the established benefit-risk profile of PYRUKYND, which is represented in the USPI.

Agios is committed to delivering safe, effective treatments for patients with rare diseases, and will continue to follow our established, rigorous pharmacovigilance processes.

Regulatory Update in Saudi Arabia

Separately, on August 4, 2025, the Saudi Food and Drug Authority announced that it has approved PYRUKYND for the treatment of adult patients with non-transfusion-dependent and transfusion-dependent alpha- or beta-thalassemia.

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: August 4, 2025

By: /s/ Brian Goff

Brian Goff
Chief Executive Officer