

**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): January 3, 2025

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.)

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))

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.

On January 3, 2025, the U.S. Food and Drug Administration approved an update to the U.S. Prescribing Information (“USPI”) for PYRUKYND® (mitapivat) for the treatment of hemolytic anemia in adults with pyruvate kinase (“PK”) deficiency. The “Warnings and Precautions” and “Adverse Reactions” sections of the USPI will now include information regarding liver injury observed in patients with another condition. The “Warnings and Precautions” section of the USPI now states that:

- in patients with another condition treated with PYRUKYND at a higher dose than that recommended for patients with PK deficiency, liver injury has been observed;
- these events were characterized by a time to onset within the first 6 months of treatment with peak elevations of alanine aminotransferase of >5 times the upper limit of normal (“ULN”) with or without jaundice; and
- all patients discontinued treatment with PYRUKYND, and these events improved upon treatment discontinuation.

The “Warnings and Precautions” section further instructs prescribers to obtain liver tests prior to the initiation of PYRUKYND and monthly thereafter for the first 6 months and as clinically indicated, to interrupt PYRUKYND if clinically significant increases in liver tests are observed or alanine aminotransferase is >5 times the ULN, and to discontinue PYRUKYND if hepatic injury due to PYRUKYND is suspected.

The “Adverse Reactions” section of the USPI now refers to hepatocellular injury in another condition and refers readers to the updated “Warnings and Precautions” section described above.

The information in this Item 7.01 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

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: January 6, 2025

By: /s/ Brian Goff
Brian Goff
Chief Executive Officer