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): May 4, 2023

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 2.02 Results of Operations and Financial Condition.

On May 4, 2023, Agios Pharmaceuticals, Inc. issued a press release announcing its results for the quarter ended March 31, 2023 and other business highlights. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (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, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release issued May 4, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: May 4, 2023

By: /s/ Brian Goff

Brian Goff
Chief Executive Officer

Agios Reports Business Highlights and First Quarter 2023 Financial Results

- *On Track for PYRUKYND® (mitapivat) Data Readouts of the Phase 2 Portion of the RISE UP Study in Sickle Cell Disease in Mid-2023 and the Phase 3 ENERGIZE and ENERGIZE-T Studies in Thalassemia in 2024*

- *U.S. PYRUKYND® Net Revenue of $5.6 Million in Q1; $1.0 Billion of Cash, Cash Equivalents and Marketable Securities as of March 31, 2023*

CAMBRIDGE, Mass., May 04, 2023 (GLOBE NEWSWIRE) -- Agios Pharmaceuticals, Inc. (Nasdaq: AGIO), a leader in the field of cellular metabolism pioneering therapies for rare diseases, today reported business highlights and financial results for the first quarter ended March 31, 2023.

“In the first quarter of the year, Agios made significant progress executing across our industry-leading pipeline of PK activators, with clinical studies spanning thalassemia, sickle cell disease, lower-risk MDS and pediatric PK deficiency,” said Brian Goff, chief executive officer at Agios. “We closed screening of the Phase 3 studies of PYRUKYND® in thalassemia with enrollment expected to be complete later this month, and look forward to the data readout of the Phase 2 portion of the RISE UP study of PYRUKYND® in sickle cell disease in the middle of this year.”

First Quarter 2023 & Recent Highlights

- *PYRUKYND® U.S. Launch:* Generated $5.6 million in U.S. net revenue for the first quarter of 2023, the fourth full quarter following FDA approval. A total of 127 unique patients have completed prescription enrollment forms, representing an increase of 21 percent over the fourth quarter of 2022. A total of 89 patients are on PYRUKYND® therapy, representing a 14 percent increase over the fourth quarter of 2022.
- *Thalassemia:* Closed screening of the Phase 3 ENERGIZE and ENERGIZE-T studies of PYRUKYND® in not regularly transfused and regularly transfused adults with thalassemia, respectively.
- *Leadership:* Appointed Jeffrey Capello to the board of directors. Paul Clancy will step down from the board of directors at the end of his term, effective June 13, 2023.
- *Environmental, Social, and Governance (ESG):* Published 2023 ESG Report, which provides corporate sustainability disclosures for the period January 1, 2022 to December 31, 2022.
- *Other:* Servier’s Phase 3 trial of vorasidenib in patients with residual or recurrent IDH mutant low-grade glioma met both its primary endpoint and key secondary endpoints. As part of the divestiture of Agios’ oncology business to Servier, Agios retains rights to a potential $200 million milestone upon FDA approval of vorasidenib and 15% royalties on potential U.S. net sales.

Key Upcoming Milestones & Priorities

Agios expects to execute on the following additional key milestones and priorities by the end of 2023:

- **Thalassemia**: Complete enrollment of the Phase 3 ENERGIZE and ENERGIZE-T studies of PYRUKYND® in not regularly transfused and regularly transfused adults with thalassemia, respectively, by mid-year.
- **Sickle Cell Disease:** Announce data readout from the Phase 2 portion of the RISE UP study of PYRUKYND® and go/no-go to Phase 3 decision by mid-year.
- **Pediatric PK Deficiency:** Enroll more than half of patients in the Phase 3 ACTIVATE-kids and ACTIVATE-kidsT studies of PYRUKYND® by year-end.
- **Lower-risk Myelodysplastic Syndromes (LR-MDS):** Complete enrollment of the Phase 2a study of novel PK activator AG-946 by year-end.
- **Pipeline:** File investigational new drug (IND) application for phenylalanine hydroxylase (PAH) stabilizer for the treatment of phenylketonuria (PKU) by year-end.

First Quarter 2023 Financial Results

Revenue: Net U.S. product revenue from sales of PYRUKYND® for the first quarter of 2023 was $5.6 million. This revenue reflects the fourth full quarter of PYRUKYND® launch, following FDA approval on February 17, 2022.

Cost of Sales: Cost of sales for the first quarter of 2023 was $0.6 million.

Research and Development (R&D) Expenses: R&D expenses were $67.3 million for the first quarter of 2023 compared to $70.1 million for the first quarter of 2022. The year-over-year decrease was primarily driven by the $1.5 million of reimbursable transition-related expenses provided to Servier in the first quarter of 2022 related to the sale of the oncology business.

Selling, General and Administrative (SG&A) Expenses: SG&A expenses were $28.4 million for the first quarter of 2023 compared to $31.5 million for the first quarter of 2022. The year-over-year decrease was primarily attributable to a reduction in workforce-related expenses.

Net Loss: Net loss was $81.0 million for the first quarter of 2023 compared to $94.8 million for the first quarter of 2022.

Cash Position and Guidance: Cash, cash equivalents and marketable securities as of March 31, 2023, were $1.0 billion compared to $1.1 billion as of December 31, 2022. Agios expects that its cash, cash equivalents and marketable securities together with anticipated product revenue and interest income will enable the company to execute its operating plan, including funding the currently planned development programs for mitapivat, AG-946 and PAH stabilization and commercializing mitapivat outside of the U.S. through one or more partnerships.

Conference Call Information

Agios will host a conference call and live webcast with slides today at 8:00 a.m. ET to discuss first quarter 2023 financial results and recent business activities. The live webcast can be accessed under “Events & Presentations” in the Investors section of the company’s website at www.agios.com. The archived webcast will be available on the company's website beginning approximately two hours after the event.

About Agios

Agios is a biopharmaceutical company that is fueled by connections. The Agios team cultivates strong bonds with patient communities, healthcare professionals, partners and colleagues to discover, develop and deliver therapies for rare diseases. In the U.S., Agios markets a first-in-class pyruvate kinase (PK) activator for adults with PK deficiency, the first disease-modifying therapy for this rare, lifelong, debilitating hemolytic anemia. Building on the company's leadership in the field of cellular metabolism, Agios is advancing a robust clinical pipeline of investigational medicines with programs in alpha- and beta-thalassemia, sickle cell disease, pediatric PK deficiency and MDS-associated anemia. In addition to its clinical pipeline, Agios has a PAH stabilizer in preclinical development as a potential treatment for phenylketonuria (PKU) and deep scientific expertise in classical hematology. 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 PYRUKYND® (mitapivat), AG-946 and its PAH stabilizer; Agios’ plans, strategies and expectations for its preclinical, clinical and commercial advancement of its drug development, including PYRUKYND®, AG-946 and its PAH stabilizer; Agios’ strategic vision and goals, including its key milestones for 2023; and the potential benefits of Agios’ strategic plans and focus. The words “anticipate,” “expect,” “goal,” “hope,” “milestone,” “plan,” “potential,” “possible,” “strategy,” “will,” “vision,” 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, 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, without limitation: risks and uncertainties related to the impact of the COVID-19 pandemic or other public health emergencies to Agios’ business, operations, strategy, goals and anticipated milestones, including its ongoing and planned research activities, ability to conduct ongoing and planned clinical trials, clinical supply

of current or future drug candidates, commercial supply of current or future approved products, and launching, marketing and selling current or future approved products; 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, the EMA or 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; the failure of Agios to receive milestone or royalty payments related to the sale of its oncology business, the uncertainty of the timing of any receipt of any such payments, and the uncertainty of the results and effectiveness of the use of proceeds from the transaction with Servier; 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.

Consolidated Balance Sheet Data
(in thousands)
(Unaudited)

	March 31, 2023	December 31, 2022
Cash, cash equivalents, and marketable securities	$ 1,010,928	$ 1,096,993
Accounts receivable, net	1,778	2,206
Inventory	11,374	8,492
Total assets	1,151,298	1,238,718
Stockholders' equity	1,036,526	1,100,814

Consolidated Statements of Operations Data
(in thousands, except share and per share data)
(Unaudited)

	Three Months Ended March 31,	
	2023	2022
Revenues:		
Product revenue, net	$ 5,609	$ 832
Total revenue	5,609	832
Operating expenses:		
Cost of sales	$ 554	$ 339
Research and development	67,301	70,123
Selling, general and administrative	28,367	31,515
Total operating expenses	96,222	101,977
Loss from operations	(90,613)	(101,145)
Royalty income from gain on sale of oncology business	—	2,704
Interest income, net	8,091	694
Other income, net	1,504	2,973
Net loss	$ (81,018)	$ (94,774)
Net loss per share - basic and diluted	$ (1.47)	$ (1.74)
Weighted-average number of common shares used in computing net loss per share – basic and diluted	55,265,390	54,555,467

Contacts:

Investor Contact

Cecilia Jones, Chief Financial Officer
Agios Pharmaceuticals
IR@agios.com

Media Contact

Dan Budwick
1AB Media
dan@1abmedia.com