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 3, 2021

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 November 3, 2021, Agios Pharmaceuticals, Inc. issued a press release announcing its results for the quarter ended September 30, 2021 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 November 3, 2021.
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: November 3, 2021

By: /s/ Jacqualyn A. Fouse
Jacqualyn A. Fouse, Ph.D.
Chief Executive Officer

Exhibit 99.1

Agios Reports Business Highlights and Third Quarter 2021 Financial Results

– Received FDA Priority Review for Mitapivat for the Treatment of Adults with Pyruvate Kinase (PK) Deficiency; PDUFA Date Set for Feb. 17, 2022 –

– Initiated ENERGIZE and ENERGIZE-T Phase 3 Studies in Thalassemia –

– Agios to Host Investor Day on Nov. 17 to Share Pipeline Updates and Commercial Launch Strategy for Mitapivat in PK Deficiency –

CAMBRIDGE, Mass., Nov. 3, 2021 – Agios Pharmaceuticals, Inc. (NASDAQ: AGIO), a leader in the field of cellular metabolism to treat genetically defined diseases, today reported business highlights and financial results for the third quarter ended Sept. 30, 2021.

"In the third quarter, we have continued our strong clinical and operational execution. Following our NDA and MAA filings for mitapivat for adults with PK deficiency, the team is laser-focused on launch preparations in this indication, as well as on initiating three pivotal trials across thalassemia and sickle cell disease by year-end," said Jackie Fouse, Ph.D., chief executive officer at Agios. "As we look ahead to the end of the year and to 2022, Agios is extremely well-positioned to enter our next phase of growth, with our first genetically defined disease commercial launch on the horizon, the expected initiation of three pivotal adult trials and two pediatric PK deficiency trials and a robust pipeline filled with optionality and possibility. We look forward to sharing more insights on our clinical and preclinical pipeline and our commercial launch efforts at our investor day in November."

THIRD QUARTER 2021 & RECENT HIGHLIGHTS

- Received Priority Review designation for the new drug application of mitapivat in PK deficiency by the U.S. Food and Drug Administration (FDA), accelerating review time from 10 months to six months from the day of filing acceptance; Prescription Drug User Fee Act (PDUFA) action date set for Feb. 17, 2022.
- Initiated first global trial sites for Phase 3 ENERGIZE and ENERGIZE-T studies of mitapivat in not regularly transfused and regularly transfused adults with α- or b- thalassemia.
- Continued start-up activities for the Phase 2/3 study of mitapivat in sickle cell disease. In collaboration with a global team of sickle cell disease patients and caregivers, developed study name – RISE UP – and unveiled it at the Sickle Cell Disease Association of America 49th Annual National Convention last month.
- In Q3, repurchased approximately 5.3 million shares of Agios common stock at an average price of $47.94 per share. To date, the company has completed more than $800 million of the up to $1.2 billion of share repurchases authorized by the Board of Directors following the company's sale of its oncology business to Servier, representing a reduction of just over 23% of our starting share count.

KEY UPCOMING MILESTONES

- Host investor day on Nov. 17 to share updates on the company's research and development pipeline, as well as provide additional insights into the commercial launch strategy and expectations for mitapivat in PK deficiency.
- Initiate Phase 2/3 RISE UP study of mitapivat in sickle cell disease by year-end.

Data Presentations

- Submitted the following select data for presentation at the 63rd American Society of Hematology (ASH) Annual Meeting & Exposition, hosted Dec. 11-14:
    - Long-term efficacy data of mitapivat in adults with PK deficiency who participated in the Phase 3 ACTIVATE and ACTIVATE-T trials
    - Long-term efficacy and safety data of mitapivat in adults with thalassemia who do not receive regular transfusions
    - Efficacy, safety and translational data of mitapivat in sickle cell disease from ongoing collaborator-led studies
    - Phase 1 healthy volunteer study data of AG-946, the company's novel PK activator

THIRD QUARTER 2021 FINANCIAL RESULTS

The financial results discussion compares Agios' continuing operations. All periods have been adjusted to exclude discontinued operations related to the divested oncology business.

Research and Development (R&D) Expenses: R&D expenses for continuing operations were $64.0 million for the third quarter of 2021 compared to $51.9 million for the third quarter of 2020. The year-over-year increase in R&D was driven primarily by start-up costs associated with the Phase 3 studies of mitapivat in thalassemia and sickle cell disease, as well as disease education and engagement efforts for mitapivat in PK deficiency, thalassemia and sickle cell disease.

Selling, General and Administrative (SG&A) Expenses: SG&A expenses for continuing operations were $27.2 million for the third quarter of 2021 compared to $28.3 million for the third quarter of 2020.

Non-Operating Income: Non-operating income included approximately $2.0 million from TIBSOVO® (ivosidenib) royalties for the third quarter of 2021.

Net Loss: Net loss was $88.8 million for the third quarter of 2021 compared to a net loss of $99.0 million for the third quarter of 2020.

Cash Position and Guidance: Cash, cash equivalents and marketable securities as of Sept. 30, 2021, were $1.4 billion compared to $722.4 million as of Sept. 30, 2020. The company expects that its cash, cash equivalents and marketable securities will enable the company to execute its operating plan through major catalysts and to cash-flow positivity without the need to raise additional equity.

CONFERENCE CALL INFORMATION

Agios will host a conference call and live webcast with slides today at 8:00 a.m. ET to discuss third quarter 2021 financial results and recent business activities. To participate in the conference call, please dial 1-877-377-7098 (domestic) or 1-631-291-4547 (international) and refer to conference ID 5748074. 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.

November 17 Investor Event Webcast Information

Agios will host an investor webcast on November 17, 2021 at 2:00 p.m. ET to discuss the company’s research and development pipeline, as well as provide additional insights into the commercial launch strategy and expectations for mitapivat in PK deficiency. The event will be webcast live and can be accessed under “Events & Presentations” in the Investors section of Agios’ website at www.agios.com. The archived webcast will be available on Agios’ website beginning approximately two hours after the event.

About Agios

Agios is focused on discovering and developing novel investigational medicines to treat genetically defined diseases through scientific leadership in the field of cellular metabolism. The company’s most advanced drug candidate is a first-in-class pyruvate kinase R (PKR) activator, mitapivat, that is currently being evaluated for the treatment of three distinct hemolytic anemias. In addition to its active late-stage clinical pipeline, Agios has multiple novel, investigational therapies in clinical and preclinical development. 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 Agios’ plans, strategies and expectations for the preclinical, clinical and commercial advancement of its drug development programs, including mitapivat and AG-946; the potential benefits of Agios’ products and product candidates; Agios’ key milestones and guidance for 2021; its financial guidance regarding the period in which it will have capital available to fund its operations; expectations regarding the return of capital to shareholders following the sale of Agios’ oncology business; Agios’ expectations for the FDA’s review of its NDA for mitapivat; 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. 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 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; the impact of the COVID-19 pandemic on 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 future approved products, and launching, marketing and selling 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, including with respect to the regulatory submissions for mitapivat, 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 and 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 establish and maintain collaborations; 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, or SEC, including the risks and uncertainties set forth under the heading Risk Factors in our filings with the SEC. While the list of factors presented here is considered representative, this list should not be considered to be a complete statement of all potential risks and uncertainties. Any forward-looking statements contained in this communication are made only as of the date hereof, and we undertake no obligation to update forward-looking statements to reflect developments or information obtained after the date hereof and disclaim any obligation to do so other than as may be required by law.

Consolidated Balance Sheet Data
(in thousands)
(Unaudited)

	September 30, 2021	December 31, 2020
Cash, cash equivalents, and marketable securities	$ 1,396,196	$ 670,537
Assets held for discontinued operations	—	50,460
Total assets	1,541,498	852,952
Liabilities held for discontinued operations	—	299,728
Stockholders' equity	1,394,762	399,500

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

(In thousands, except share and per share data)	Three Months Ended September 30, 2021	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Cost and expenses:				
Research and development	$ 64,000	$ 51,943	$ 183,674	$ 161,388
Selling, general and administrative	27,152	28,347	89,917	89,196
Total cost and expenses	91,152	80,290	273,591	250,584
Loss from operations	(91,152)	(80,290)	(273,591)	(250,584)
Gain on sale of oncology business	1,996	—	3,996	—
Interest income, net	256	1,115	504	5,820
Other income, net	4,641	—	11,165	—
Net loss from continuing operations	(84,259)	(79,175)	(257,926)	(244,764)
Net (loss) income from discontinued operations, net of tax	(4,507)	(19,804)	1,957,268	15,051
Net (loss) income	$ (88,766)	$ (98,979)	$ 1,699,342	$ (229,713)
Net loss from continuing operations per share—basic and diluted	$ (1.48)	$ (1.15)	$ (4.13)	$ (3.55)
Net (loss) income from discontinued operations per share—basic and diluted	$ (0.08)	$ (0.29)	$ 31.31	$ 0.22
Net (loss) income per share—basic and diluted	$ (1.56)	$ (1.43)	$ 27.19	$ (3.33)
Weighted-average number of common shares used in computing net loss per share from continuing operations, net (loss) income per share from discontinued operations and net (loss) income per share – basic and diluted	57,048,175	69,144,061	62,503,087	68,905,853

# # #

Contacts

Investors:
Holly Manning, 617-844-6630
Senior Director, Investor Relations
Holly.Manning@agios.com

Media:
Jessica Rennekamp, 857-209-3286
Director, Corporate Communications
Jessica.Rennekamp@agios.com