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): April 29, 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 April 29, 2021, Agios Pharmaceuticals, Inc. issued a press release announcing its results for the quarter ended March 31, 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 April 29, 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: April 29, 2021

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

Exhibit 99.1

Agios Reports Business Highlights and First Quarter 2021 Financial Results

– Data from ACTIVATE and ACTIVATE-T Phase 3 Studies of Mitapivat in Pyruvate Kinase (PK) Deficiency and Phase 2 Study of Mitapivat in Thalassemia Accepted for Presentation at EHA 2021 Virtual Congress –

– Company Expects to File for Regulatory Approval for Mitapivat for the Treatment of Adults with PK Deficiency in the U.S. This Quarter and in the EU in Mid-2021 –

– Sale of Oncology Portfolio to Servier Closed on March 31; Agios Received $1.8 Billion Upfront Payment to Accelerate and Expand Genetically Defined Disease Portfolio –

CAMBRIDGE, Mass., April 29, 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 first quarter ended March 31, 2021.

“With the recent closing of the sale of our oncology business, we are excited to embrace a focused future in genetically defined diseases” said Jackie Fouse, Ph.D., chief executive officer at Agios. “In the weeks and months ahead, we look forward to a number of important catalysts, beginning with presentations at the EHA 2021 Virtual Congress, where we will share data from our ACTIVATE and ACTIVATE-T studies of mitapivat in adults with pyruvate kinase (PK) deficiency, as well as data from our Phase 2 study of mitapivat in thalassemia. The PK deficiency data will form the basis of our upcoming submissions for regulatory approval in the U.S. this quarter and in the EU mid-year. Additionally, we look forward to further exploring the impact of mitapivat in thalassemia and sickle cell disease as we launch two Phase 3 studies and a Phase 2/3 study, respectively, later this year. The courage and needs of the patients and families that we seek to serve continue to be our great motivation, and we are proud of our recent educational and patient-focused efforts that aim to make a meaningful impact on rare hemolytic anemia communities.”

FIRST QUARTER 2021 & RECENT HIGHLIGHTS

- Closed the sale of commercial, clinical and research-stage oncology portfolio to Servier Pharmaceuticals, LLC, on March 31, 2021.
- Initiated the repurchase of up to $1.2 billion of outstanding shares, as authorized by the board of directors, and entered into a definitive agreement with Bristol-Myers Squibb Company (BMS) to repurchase 7,121,658 shares of Agios common stock held by BMS and its affiliates for an aggregate purchase price of $344.5 million, or $48.38 per share. Agios expects to execute a meaningful portion of the planned repurchases by year-end through a combination of 10b5-1 plans and open market purchases.
- Supported several educational and patient-focused initiatives, including the sponsorship of a health literacy program for sickle cell disease and the launch of a collaboration with 23andMe that led to addition of the very first PK deficiency carrier status report.

KEY UPCOMING MILESTONES

- Finalize global regulatory filings for mitapivat in adults with PK deficiency; submit new drug application (NDA) in the U.S. in the second quarter of 2021 and marketing authorization application (MAA) in the EU in mid-2021.
- Initiate two Phase 3 studies of mitapivat, ENERGIZE and ENERGIZE-T, in not regularly transfused and regularly transfused adults with thalassemia in the second half of 2021.
- Initiate Phase 2/3 study of mitapivat in sickle cell disease by year-end.
- Prioritize new indications for pyruvate kinase R (PKR) and pyruvate kinase M2 (PKM2) activator clinical development by year-end.

Data Presentations

- Present data from the following clinical studies for presentation at the EHA Virtual Congress, hosted June 9-17, 2021:
  - Phase 3 ACTIVATE study of mitapivat in adults with PK deficiency who do not receive regular transfusions
  - Phase 3 ACTIVATE-T study of mitapivat in adults with PK deficiency who receive regular transfusions
  - Phase 2 study of mitapivat in adults with α- and ß-thalassemia who do not receive regular transfusions
- Submit data from ongoing clinical studies of mitapivat in sickle cell disease for presentation at medical meetings in 2021.
- Present data from the Phase 1 study of AG-946, the company's next-generation PKR activator, in healthy volunteers by year-end.

FIRST QUARTER 2021 FINANCIAL RESULTS

Research and Development (R&D) Expenses: R&D expenses for continuing operations were $57.7 million for the first quarter of 2021 compared to $55.4 million for the first 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.

Selling, General and Administrative (SG&A) Expenses: SG&A expenses for continuing operations were $33.6 million for the first quarter of 2021 compared to $31.7 million for the first quarter of 2020. The year-over-year increase in SG&A expenses was primarily attributable to one-time workforce expense.

Discontinued Operations: Due to the sale of the oncology business during the first quarter of 2021, we have reclassified the results of the oncology business as discontinued operations, including total revenue of $41.4 million, TIBSOVO® net sales of $37 million, and operating expenses of $50.2 million related to discontinued operations.

Net Income: Net income was $1.9 billion for the first quarter of 2021 compared to a net loss of $40.3 million for the first quarter of 2020.

Cash Position and Guidance: Cash, cash equivalents and marketable securities as of March 31, 2021 were $2.4 billion compared to $613.1 million as of March 31, 2020. The company expects that its cash, cash equivalents and marketable securities as of March 31, 2021, together with anticipated interest income, future product sales and TIBSOVO® royalties, will enable the company to fund its planned operating expenses and capital expenditure requirements 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 first 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 4497151. 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 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; 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; 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; the impact of the COVID-19 pandemic 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 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, 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.

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Contact
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Consolidated Balance Sheet Data
(in thousands)
(Unaudited)

	March 31, 2021	December 31, 2020
Cash, cash equivalents and marketable securities	$ 2,357,201	$ 670,537
Assets held for discontinued operations	—	50,460
Total assets	2,488,434	852,952
Liabilities held for discontinued operations	—	299,728
Stockholders' equity	2,296,630	399,500

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

	Three Months Ended March 31, 2021	2020
Cost and expenses:		
Research and development	$ 57,667	$ 55,358
Selling, general and administrative	33,550	31,672
Total cost and expenses	91,217	87,030
Loss from operations	(91,217)	(87,030)
Interest income, net	340	2,936
Net loss from continuing operations	(90,877)	(84,094)
Net income from discontinued operations, net of tax	1,965,202	43,838
Net Income (loss)	$ 1,874,325	$ (40,256)
Net loss from continuing operations per share - basic and diluted	$ (1.31)	$ (1.23)
Net income from discontinued operations per share - basic and diluted	$ 28.26	$ 0.64
Net income (loss) per share - basic and diluted	$ 26.95	$ (0.59)
Weighted-average number of common shares used in computing net income (loss) per share – basic and diluted	69,543,510	68,608,279