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 1, 2019

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 August 1, 2019, Agios Pharmaceuticals, Inc. issued a press release announcing its results for the quarter ended June 30, 2019 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 August 1, 2019.

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 1, 2019

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

Exhibit 99.1

Agios Reports Business Highlights and Second Quarter 2019 Financial Results

– Strong Topline Performance for IDH Inhibitors: TIBSOVO® Net Revenue Increased 50% from Q1 2019 to $13.7M; IDHIFA® Royalty Increased to $2.7M –

– Achieved Important Expansion Opportunities for TIBSOVO® Including sNDA Approval in Frontline AML and Positive Phase 3 Trial in Previously Treated IDH1 Mutant Cholangiocarcinoma –

– AG-270 Phase 1 Dose Escalation Complete and Data Submitted to AACR-NOI-EORTC Conference; Program Advancing to Expansion Phase This Quarter –

CAMBRIDGE, Mass., August 1, 2019 — Agios Pharmaceuticals, Inc. (NASDAQ: AGIO), a leader in the field of cellular metabolism to treat cancer and rare genetic diseases, today reported business highlights and financial results for the second quarter ended June 30, 2019.

“In the second quarter we demonstrated our ability to execute across all areas of our business. Our commercial team continues to deliver on the AML launch for TIBSOVO® and prepare for our first potential solid tumor launch on the heels of the positive ClarIDHy study in cholangiocarcinoma,” said Jackie Fouse, Ph.D., chief executive officer at Agios. “On the clinical side, we continued to broaden our IDH program into earlier lines of AML therapy and expand our PKR programs into new disease areas while enrolling the PK deficiency pivotal studies. In addition, we completed dose escalation in our AG-270 Phase 1 trial and are on track to initiate the next phase of development. The great progress we made during the quarter keeps us on track to deliver on our remaining 2019 milestones and drive further value across our portfolio.”

SECOND QUARTER 2019 HIGHLIGHTS & RECENT PROGRESS

- Received approval from the U.S. Food and Drug Administration (FDA) on May 2, 2019 for single agent TIBSOVO® for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) with an IDH1 mutation who are ³ 75 years old or who have comorbidities that preclude use of intensive induction chemotherapy.
- Announced the Phase 3 ClarIDHy trial of TIBSOVO® in advanced previously treated cholangiocarcinoma patients with an IDH1 mutation met its primary endpoint, demonstrating improvement in progression-free survival by independent radiology review compared with patients who received placebo.
- Presented updated data from the Phase 1 studies of TIBSOVO® in frontline AML, both as a monotherapy and in combination with azacitidine, and the first data from the perioperative study of TIBSOVO® and vorasidenib in glioma at the 2019 American Society of Clinical Oncology Annual Meeting. The data presentations can be found here.
- Began dosing patients in the Phase 1 dose-escalation trial of AG-636, an inhibitor of the metabolic enzyme dihydroorotate dehydrogenase (DHODH), in advanced lymphoma.
- Completed the single agent dose-escalation portion of the ongoing Phase 1 study of AG-270 in methylthioadenosine phosphorylase (MTAP)-deleted tumors.

- Appointed Orlando Oliveira to the role of senior vice president and general manager, international. Mr. Oliveira will be responsible for building and leading the company's operations outside of the U.S. in support of the expected launch of TIBSOVO® in Europe and potentially other select markets.

KEY UPCOMING MILESTONES

The company plans to achieve the following key milestones in the remainder of 2019:

Oncology:

- Submit a supplemental new drug application to the FDA for TIBSOVO® for advanced previously treated IDH1 mutant cholangiocarcinoma by year-end.
- Initiate a registration-enabling Phase 3 study of vorasidenib in low-grade glioma with an IDH mutation by year-end.
- Initiate expansion phase for the Phase 1 study of AG-270 in MTAP-deleted tumors, including two combination arms with AG-270 and taxanes in non-small cell lung cancer and pancreatic ductal adenocarcinoma, in the third quarter.

Rare Genetic Diseases:

- Complete enrollment in two global pivotal trials for mitapivat in adults with pyruvate kinase (PK) deficiency by year-end 2019:
    - ACTIVATE-T: A single-arm trial of up to 40 regularly transfused patients
    - ACTIVATE: A 1:1 randomized, placebo-controlled trial of 80 patients who do not receive regular transfusions
- Achieve proof-of-concept for mitapivat in thalassemia in the second half of 2019.

ANTICIPATED 2019 DATA PRESENTATIONS

- Full data from the Phase 3 ClarIDHy study of TIBSOVO® in IDH1 mutant advanced previously treated cholangiocarcinoma have been submitted for presentation at the European Society for Medical Oncology Congress taking place in Barcelona, Spain from September 27-October 1, 2019.
- Data from the single agent dose-escalation portion of the ongoing Phase 1 study of AG-270 in patients with MTAP-deleted tumors have been submitted to the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics taking place in Boston from October 26-30, 2019.
- Data from IDH and PKR programs have been submitted for presentation at the American Society of Hematology Annual Meeting taking place in Orlando, Fla. from December 7-10, 2019, including new data from the extension phase of the Phase 2 DRIVE PK study of mitapivat in adults with PK deficiency and important translational data from the Phase 1 combination study of TIBSOVO® and azacitidine in frontline AML.

SECOND QUARTER 2019 FINANCIAL RESULTS

Revenue: Total revenue for the second quarter of 2019 was $26.2 million, which includes $13.7 million of net product revenue from U.S. sales of TIBSOVO®, $9.0 million in collaboration revenue and $2.7 million in royalty revenue from net global sales of IDHIFA® under our collaboration agreement with Celgene. This compares to revenue of $40.4 million for the second quarter of 2018, which included recognition of a $15 million milestone from Celgene related to Celgene's filing of an MAA to the EMA for IDHIFA® and $12.4 million from the signing of the CStone collaboration.

Cost of Sales: We began U.S. sales of TIBSOVO® in the third quarter of 2018. Cost of sales were $0.3 million for the second quarter of 2019.

Research and Development (R&D) Expenses: R&D expenses were $107.4 million for the second quarter of 2019 compared to $86.7 million for the second quarter of 2018. The increase in R&D expense was primarily attributable to vorasidenib Phase 3 low grade glioma trial start-up costs, the mitapivat pivotal program in PK deficiency and Phase 2 study in thalassemia, and clinical trial activity related to the ongoing Phase 1 trials for AG-270 and AG-636.

Selling, General and Administrative (SG&A) Expenses: SG&A expenses were $32.4 million for the second quarter of 2019 compared to $26.6 million for the second quarter of 2018. The increase in SG&A expense was primarily attributable to costs to support commercialization of TIBSOVO® and personnel costs related to increased headcount.

Net Loss: Net loss was $109.9 million for the second quarter of 2019 compared to $68.7 million for the second quarter of 2018.

Cash Position and Guidance: Cash, cash equivalents and marketable securities as of June 30, 2019 were $624.0 million compared to $805.4 million as of December 31, 2018. The net decrease of $181.4 million in cash position was primarily driven by net expenditures to fund operations, including a onetime cash expense of $19.2 million for bonus payouts during the first quarter. The company expects that its cash, cash equivalents and marketable securities as of June 30, 2019, together with anticipated product and royalty revenue, anticipated interest income, and anticipated expense reimbursements under our collaboration and license agreements, but excluding any additional program-specific milestone payments, will enable the company to fund its anticipated operating expenses and capital expenditure requirements through at least the end of 2020.

CONFERENCE CALL INFORMATION

Agios will host a conference call and live webcast with slides today at 8:00 a.m. ET to discuss second quarter 2019 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 9319039. 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 cancer and rare genetic diseases through scientific leadership in the field of cellular metabolism and adjacent areas of biology. In addition to an active research and discovery pipeline across both therapeutic areas, Agios has two approved oncology precision medicines and multiple first-in-class investigational therapies in clinical and/or preclinical development. All Agios programs focus on genetically identified patient populations, leveraging our knowledge of metabolism, biology and genomics. For more information, please visit the company's website at www.agios.com.

About Agios/Celgene Collaboration

IDHIFA® (enasidenib) and AG-270 are part of our collaboration with Celgene Corporation. Under the terms of our 2010 collaboration agreement focused on cancer metabolism, Celgene has worldwide development and commercialization rights for IDHIFA®. Agios continues to conduct certain clinical development activities within the IDHIFA® development program and is eligible to receive reimbursement for those development activities and up to $80 million in remaining milestone payments, and royalties on any net sales. Celgene and Agios are currently co-commercializing IDHIFA® in the U.S. Celgene will reimburse Agios for costs incurred for its co-commercialization efforts. AG-270 is part of a 2016 global research collaboration agreement with Celgene focused on metabolic immuno-oncology. Celgene has the option to participate in a worldwide 50/50 cost and profit share with Agios, under which Agios is eligible for up to $169 million in clinical and regulatory milestone payments for the program.

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 its and its collaborator's preclinical, clinical and commercial advancement of its drug development programs including TIBSOVO®, IDHIFA®, vorasidenib, mitapivat, AG-270 and AG-636; the potential benefits of Agios' product candidates; its key milestones for 2019; its plans regarding future data presentations; its financial guidance regarding the period in which it will have capital available to fund its operations; and the potential benefit of its strategic plans and focus. The words "anticipate," "expect," "hope," "milestone," "plan," "potential," "possible," "strategy," "will," 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 or its collaborators 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: 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 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; 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.

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

	June 30, 2019	December 31, 2018
Cash, cash equivalents and marketable securities	$ 624,039	$ 805,421
Accounts receivable, net	7,147	5,076
Collaboration receivable – related party	2,524	2,462
Royalty receivable – related party	2,700	2,234
Inventory	4,659	869
Total assets	783,870	858,457
Deferred revenue – related party	70,070	92,519
Stockholders' equity	532,677	687,537

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenues:				
Product revenue, net	$ 13,727	$ —	$ 22,865	$ —
Collaboration revenue – related party	8,979	26,401	26,898	33,746
Collaboration revenue – other	812	12,440	1,782	12,440
Royalty revenue – related party	2,703	1,573	4,903	2,990
Total Revenue	26,221	40,414	56,448	49,176
Cost and expenses:				
Cost of sales	303	—	637	—
Research and development, net	107,389	86,730	202,974	164,954
Selling, general and administrative	32,390	26,633	64,181	51,183
Total cost and expenses	140,082	113,363	267,792	216,137
Loss from operations	(113,861)	(72,949)	(211,344)	(166,961)
Interest income	3,990	4,204	8,395	7,391
Net loss	$ (109,871)	$ (68,745)	$ (202,949)	$ (159,570)
Net loss per share – basic and diluted	$ (1.87)	$ (1.19)	$ (3.46)	$ (2.81)
Weighted-average number of common shares used in computing net loss per share – basic and diluted	58,722,244	57,721,786	58,589,167	56,713,795

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