
**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 7, 2015

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.)

38 Sidney Street, 2nd Floor, 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))
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Item 2.02 Results of Operations and Financial Condition.

On May 7, 2015, Agios Pharmaceuticals, Inc. (the “Company”) issued a press release announcing its results for the quarter ended March 31, 2015. 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) The following exhibits are included in this report:

<u>Exhibit</u> <u>No.</u>	<u>Description</u>
99.1	Press release issued by the Company on May 7, 2015.

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 7, 2015

By: /s/ David P. Schenkein
David P. Schenkein, M.D.
Chief Executive Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by the Company on May 7, 2015.



AgiOS Reports First Quarter 2015 Financial Results and Outlines Late-Stage Clinical Development for AG-221 and AG-120

- *AG-221: Ongoing Phase 1 study expanded by an additional 125 patients in selected AML (acute myeloid leukemia) populations*
- *AG-120: Ongoing Phase 1 hematologic malignancy study expanded by 175 patients in three cohorts, including 125 patients in a defined AML population*
- *EHA: Abstracts for three lead clinical programs accepted for presentation at the 20th Congress of the European Hematology Association (EHA)*

CAMBRIDGE, Mass, May 7, 2015 — Agios Pharmaceuticals, Inc. (NASDAQ: AGIO), a leader in the fields of cancer metabolism and rare genetic disorders of metabolism, today reported financial results and business highlights for the first quarter ended March 31, 2015 and announced late stage clinical development plans for AG-221 and AG-120.

“Leveraging the foundation we built in 2014 and our unique scientific approach, the expansion of the AG-221 and AG-120 trials in hematologic malignancies positions Agios as a late-stage clinical development company,” said David Schenkein, M.D., chief executive officer of Agios. “We are on track to achieve our remaining milestones for 2015, which include several important initiations: a global Phase 3 study for AG-221 in previously treated AML patients with an IDH2 mutation, clinical development for our third IDH mutant inhibitor, AG-881, and the first study evaluating AG-348 in patients with PK deficiency. We also plan to share the first data from AG-120 in solid tumor patients with an IDH1 mutation in the second half of the year. Our financial position remains strong to support all of these efforts.”

AG-221 AND AG-120 CLINICAL DEVELOPMENT UPDATES

AgiOS today provided the following updates on its clinical development programs in collaboration with Celgene:

AG-221: a first-in-class, oral, selective, potent inhibitor of the mutated IDH2 protein

Added Additional Cohort to AG-221’s Ongoing Phase 1 Expansion Study in Hematologic Malignancies

- AG-221 is currently being evaluated in an ongoing Phase 1 trial that includes a dose escalation phase and four expansion cohorts of 25 patients each evaluating patients with relapsed or refractory AML who are 60 years of age and older and transplant ineligible, relapsed or refractory AML patients under age 60, untreated AML patients who decline standard of care chemotherapy, and patients with other IDH2-mutant positive hematologic malignancies. Based on encouraging data from the dose escalation phase, Celgene and Agios have expanded the Phase 1 trial to add an additional more homogenous cohort of 125 patients with IDH2 mutant-positive AML who are in second or later relapse, refractory to second-line induction or reinduction treatment, or have relapsed after allogeneic transplantation. Consistent with the ongoing expansion cohorts, AG-221 will be administered at a dose of 100 mg once daily. This multicenter, single-arm, open-label, expanded clinical trial will be



conducted at the current treatment centers in the U.S. and France. The primary objectives of the study are to confirm the safety and clinical activity of AG-221 in a select, highly resistant AML population.

- Agios also continues to conduct a Phase 1/2 clinical trial evaluating AG-221 in IDH2-mutant positive advanced solid tumors, including gliomas, as well as angioimmunoblastic T-cell lymphoma (AITL).

AG-120: a first-in-class, oral, selective, potent inhibitor of the mutated IDH1 protein

Initiated Three Expansion Cohorts in Ongoing Phase 1 Study in Hematologic Malignancies

- AG-120 is currently being evaluated in an ongoing Phase 1 trial in patients with advanced hematologic malignancies. Three expansion cohorts have been added to this study and will evaluate AG-120 in 175 patients with IDH1 mutated advanced hematologic malignancies at approximately 15 clinical trial sites in the U.S. and France. The first cohort will evaluate a more homogenous population of 125 AML patients who relapsed after bone marrow transplantation, are in second or later relapse, refractory to second line induction or reinduction treatment. The second cohort will evaluate 25 untreated AML patients, and the third cohort will evaluate 25 patients with IDH1 mutated advanced hematologic malignancies not eligible for cohorts one or two. AG-120 will be administered at a 500 mg once daily oral dose, in 28-day cycles. The study's primary objectives are to confirm the safety and clinical activity of AG-120.
- Agios also continues to advance a Phase 1 clinical trial evaluating AG-120 in patients with IDH1-mutant positive advanced solid tumors, including glioma.

"Our novel IDH inhibitors are advancing at an important time for cancer patients, as many do not respond to current standard of care chemotherapy," said Chris Bowden, M.D., chief medical officer of Agios. "By demonstrating the safety and efficacy of AG-120 and AG-221 in later-stage studies in more highly defined patient populations, we hope to change the treatment paradigm and establish the utility of these IDH inhibitors as potential important new therapies for a significant portion of people diagnosed with AML worldwide."

ADDITIONAL CLINICAL DEVELOPMENT AND BUSINESS HIGHLIGHTS

Cancer Metabolism: IDH Mutant Inhibitors in Collaboration with Celgene

AG-120: a first-in-class, oral, selective, potent inhibitor of the mutated IDH1 protein

- Celgene exercised its option to obtain an exclusive license outside the United States for AG-120 in the first quarter.

AG-881: a brain-penetrant, pan-IDH mutant inhibitor

- In April, Agios announced that it selected its third IDH mutant inhibitor, AG-881, for clinic development and entered into a new joint worldwide development and profit share collaboration with Celgene for this investigational medicine.



Rare Genetic Disorders of Metabolism: Wholly Owned PKR Activator

AG-348: a novel, first-in-class, oral activator of pyruvate kinase-R (PKR) for the treatment of pyruvate kinase (PK) deficiency

- In March, AG-348 was granted orphan drug designation for the treatment of PK deficiency by the U.S. Food and Drug Administration (FDA).
- A natural history study of PK deficiency is also ongoing. Natural history studies are important to confirm and further understand clinical characteristics, symptoms and disease complications and potentially support the design of future clinical trials.

UPCOMING MILESTONES

AG-221 Clinical development milestones in collaboration with Celgene

- Present first data from Phase 1 hematological malignancy expansion cohorts at EHA in Vienna, June 11-14, 2015.
- Initiate combination trials to evaluate AG-221 as a potential frontline treatment for patients with AML and a broad range of hematologic malignancies in the second half of 2015.
- Initiate a global Phase 3 registration-enabling study in relapsed/refractory AML patients that harbor an IDH2 mutation in the second half of 2015.
- Continue dose escalation in the Phase 1/2 trial in patients with advanced solid tumors or AITL that carry an IDH2 mutation in 2015.

AG-120 Clinical development milestones in collaboration with Celgene

- Present new data from the ongoing Phase 1 study evaluating patients with IDH1 mutant positive advanced hematologic malignancies at EHA.
- Present first data from the Phase 1 trial in advanced solid tumors at a medical conference in the second half of 2015.
- Begin combination trials to evaluate AG-120 as a potential frontline treatment of AML and a broad range of hematologic malignancies in the second half of 2015.
- Intend to initiate a global registration-enabling Phase 3 study in AML patients that harbor an IDH1 mutation in the first half of 2016.

AG-881: Clinical development milestones in collaboration with Celgene

- Initiate Phase 1 clinical development of AG-881 in the second quarter of 2015.

AG-348: Clinical development milestones for wholly owned PKR activator

- Present final data for the Phase 1 multiple ascending dose (MAD) clinical trial of AG-348 in healthy volunteers and the first data from a natural history study of PK deficiency, a rare hemolytic anemia at EHA.
- Two abstracts submitted by Boston Children's Hospital on the natural history study have also been accepted for presentation at EHA.
- Expect to initiate a Phase 2 trial for AG-348 in the first half of 2015 in patients with PK deficiency.



FIRST QUARTER 2015 FINANCIAL RESULTS

Cash, cash equivalents and marketable securities as of March 31, 2015 were \$440.0 million, compared to \$467.4 million as of December 31, 2014. The decrease was driven by cash used to fund operating activities of approximately \$32.2 million, which was offset by cost reimbursements of approximately \$6.6 million made by Celgene during the first quarter of 2015 from the AG-221 program.

Total revenue was \$34.2 million for the first quarter of 2015, compared to \$8.4 million for the comparable period in 2014. The increase reflects revenues recognized under the company's collaboration agreement with Celgene.

Research and development (R&D) expense was \$32.4 million, including \$2.6 million of stock-based compensation expense in the first quarter of 2015, compared to \$17.4 million, including \$1.1 million in stock-based compensation expense for the comparable period in 2014. The increase in R&D expense was primarily due to increased costs to support advancement of the company's lead investigational medicines toward later-stage development.

General and administrative (G&A) expense was \$7.0 million, including \$2.4 million of stock-based compensation expense, in the first quarter of 2015, compared to \$3.3 million, including \$0.4 million of stock-based compensation expense, for the comparable period in 2014. The increase in G&A expense was largely due to increased headcount and other professional expenses to support growing operations.

Net loss for the first quarter of 2015 was \$5.0 million, compared to net loss of \$12.2 million for the comparable period in 2014.

FINANCIAL GUIDANCE FOR THE FULL YEAR 2015

AgiOS is reiterating that it expects to end 2015 with more than \$320.0 million of cash, cash equivalents and marketable securities. The anticipated year end 2015 cash position includes two one-time payments from Celgene: a \$20.0 million research extension fee, received in May 2015, and a \$10.0 million initial payment for the AG-881 collaboration, expected to be received in the second quarter of 2015, and does not include any additional program-specific milestone payments. The company expects that its cash, cash equivalents and marketable securities would be sufficient to fund its operating expenses and capital expenditure requirements until late 2017.

CONFERENCE CALL INFORMATION

AgiOS will host a conference call and live webcast with slides today at 8:30 a.m. EDT to discuss the first quarter 2015 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 29316015. The live webcast can be accessed under "Events & Presentations" in the Investors & Media 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/Celgene Collaboration

AG-221, AG-120 and AG-881 are part of Agios' global strategic collaboration with Celgene Corporation. Under the terms of the collaboration, Celgene has worldwide development and commercialization rights for AG-221. Agios continues to conduct clinical development activities within the AG-221 development program and is eligible to receive up to \$120 million in payments on achievement of certain milestones and royalties on any net sales. For AG-120, Agios retains U.S. development and commercialization rights. Celgene has an exclusive license outside the United States. Agios leads clinical development and commercialization in the U.S. and Celgene leads these efforts outside the United States. Celgene is eligible to receive royalties on any net sales in the U.S. Agios is eligible to receive royalties on any net sales outside the U.S. and up to \$120 million in payments on achievement of certain milestones. For AG-881, the companies have a joint worldwide development and 50/50 profit share collaboration. Agios is eligible to receive regulatory milestone payments of up to \$70 million.

About Agios Pharmaceuticals, Inc.

AgiOS Pharmaceuticals is focused on discovering and developing novel investigational medicines to treat cancer and rare genetic disorders of metabolism through scientific leadership in the field of cellular metabolism. In addition to an active research and discovery pipeline across both therapeutic areas, Agios has multiple first-in-class investigational medicines 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 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 Agios' product candidates targeting IDH1/IDH2 or pyruvate kinase-R mutations, including AG-221, AG-120, AG-881 and AG-348; its plans and timelines for the clinical development of AG-221, AG-120 and AG-348; its plans regarding future data presentations; its financial guidance regarding the amount of cash, cash equivalents and marketable securities that the company will have as of December 31, 2015; and the benefit of its strategic plans and focus. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "potential," "project," "hope," "could," "would" 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: 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 and 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, such as its agreement with Celgene; and general economic and market conditions. These and other risks are described in greater detail under the caption "Risk Factors" included in Agios' Annual Report on Form 10-K for the year ended December 31, 2014, and other filings that Agios may make with the Securities and Exchange Commission in the future. 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.



Consolidated Balance Sheet Data
(in thousands)
(Unaudited)

	<u>March 31,</u> <u>2015</u>	<u>December 31,</u> <u>2014</u>
Cash, cash equivalents and marketable securities	\$439,964	\$ 467,447
Collaboration receivable – related party	7,017	6,492
Total assets	474,336	491,904
Deferred revenue – related party	7,019	38,411
Stockholders' equity	426,817	424,366

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

	<u>Three Months Ended March 31,</u> <u>2015</u>	<u>2014</u>
Collaboration revenue – related party (1)	\$ 34,202	\$ 8,411
Operating expenses:		
Research and development (2)	32,443	17,407
General and administrative	6,954	3,288
Total operating expenses	39,397	20,695
Loss from operations	(5,195)	(12,284)
Interest income	238	36
Net loss	\$ (4,957)	\$ (12,248)
Net loss per share – basic and diluted	\$ (0.13)	\$ (0.39)
Weighted-average number of common shares used in net loss per share – basic and diluted	<u>37,214,747</u>	<u>31,394,563</u>

Note 1 (Collaboration revenue): The majority of the collaboration revenue increase was due to the application of new accounting guidance to the Company's 2010 collaboration agreement with Celgene which was amended in July 2014. Previously, all arrangement consideration was recognized ratably over the estimated period of performance. Under the new accounting guidance, revenue is recognized as services or goods are delivered, which during the first quarter of 2015 included \$15.8 million related to the delivery of an ex. U.S. license for AG-120. In addition, revenue for the first quarter of 2015 included recognition of a portion of certain reimbursement for costs incurred related to development services for on-going Phase 1 studies.



Note 2 (R&D expense): During the first quarter of 2015, the Company began offsetting R&D expense for amounts received from Celgene for reimbursement of costs incurred on Celgene's behalf. The R&D expense reported for the first quarter of 2015 is presented net of \$4.4 million of reimbursement compared to no offset for cost reimbursement for the comparable period in 2014. Celgene is responsible for all development costs for AG-221, and reimburses Agios for development costs it incurs for this investigational medicine.

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