# **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 24, 2024

# Agios Pharmaceuticals, Inc. (Exact Name of Registrant as Specified in Charter)

001-36014

(Commission File Number)

Delaware

(State or Other Jurisdiction

of Incorporation)

26-0662915

(IRS Employer Identification No.)

|   | 88 Sidney Street, Cambridge, MA (Address of Principal Executive Offices)                               |  | 02139<br>(Zip Code)  |
|---|--|--|--|
|   | Registrant's telepho   | one number, including area code: (6      | 517) 649-8600  |
|   | (Former Name   | or Former Address, if Changed Since Last | Report)  |
|   | appropriate box below if the Form 8-K filing is interprovisions (see General Instruction A.2. below):  | ended to simultaneously satisfy the fi   | ling obligation of the registrant under any of the               |
|   | Written communications pursuant to Rule 425 u  | 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                                      |
|   | check mark whether the registrant is an emerging<br>Rule 12b-2 of the Securities Exchange Act of 193   |  | 405 of the Securities Act of 1933 (§230.405 of this              |
| Emerging                                  | growth company $\square$   |  |  |
|   | ging growth company, indicate by check mark if the ised financial accounting standards provided pursu  |  | extended transition period for complying with any Act. $\square$ |

## Item 1.01 Entry into a Material Definitive Agreement.

On May 24, 2024, Agios Pharmaceuticals, Inc. (the "Company") entered into a Purchase and Sale Agreement (the "Purchase Agreement") with Royalty Pharma Investments 2019 ICAV, an Irish collective management vehicle (the "Purchaser"). Pursuant to the Purchase Agreement, the Company agreed to sell to the Purchaser, and the Purchaser agreed to purchase for \$905,000,000, the Company's rights to an earn-out equal to 15% of U.S. net sales of vorasidenib (the "Earn-Out") owing from Servier Pharmaceuticals, LLC, a Delaware limited liability company ("Servier"), under that certain Purchase and Sale Agreement, dated as of December 20, 2020, by and among the Company, Servier, and, solely for purposes of guaranteeing certain obligations of Servier, Servier S.A.S., a French societe par actions simplifiee (the "Counterparty Agreement"). The consummation of the sale and payment of the purchase price are subject to approval of vorasidenib by the U.S. Food and Drug Administration (the "FDA") on or before October 31, 2024, and other customary closing conditions.

Upon the consummation of the sale, the Purchaser will acquire 100% of Earn-Out payments made by Servier on account of up to \$1 billion in net sales for each calendar year. Any such Earn-Out payments made by Servier on account of U.S. net sales in each calendar year in excess of \$1 billion will be split, with the Purchaser having the rights to a 12% earn-out on those excess payments and with the Company retaining a 3% earn-out on those excess payments. The Company will also retain its rights to a potential milestone payment of \$200 million from Servier upon approval of vorasidenib by the FDA. Under the Purchase Agreement, and in connection with its sale of the Earn-Out, the Company has agreed to certain covenants with respect to the exercise of its rights under the Counterparty Agreement, including with respect to the Company's right to amend, assign and terminate the Counterparty Agreement. The Purchase Agreement contains other customary terms and conditions, including representations and warranties, covenants and indemnification obligations in favor of each party.

The foregoing description of the Purchase Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Purchase Agreement, a copy of which will be filed with the Company's Quarterly Report on Form 10-Q for the quarter ending June 30, 2024.

## Item 8.01 Other Events.

The full text of the press release announcing the Company's entry into the Purchase Agreement is attached as Exhibit 99.1 hereto and is incorporated herein by reference.

## Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

| Exhibit<br>No. | Description  |
|----------------|--|
| 99.1           | Press release issued May 28, 2024.   |
| 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.

Date: May 28, 2024

## AGIOS PHARMACEUTICALS, INC.

By: <u>/s/ Brian</u> Goff

Brian Goff

Chief Executive Officer



### Agios Announces \$905 Million Purchase Agreement for Vorasidenib Royalty

Royalty Pharma to Acquire Rights to Agios' 15% Royalty on Potential Vorasidenib U.S. Net
 Sales for \$905 Million Upfront upon FDA Approval of Vorasidenib; Agios to Share in Economics
 Above Certain Revenue Thresholds –

 Agios Retains Rights to \$200 Million Milestone Payment from Servier upon FDA Approval of Vorasidenib –

 In Total, Agios to Receive \$1.1 Billion in Payments upon FDA Approval of Vorasidenib; PDUFA Action Date of August 20, 2024 –

CAMBRIDGE, Mass., May 28, 2024 – Agios Pharmaceuticals, Inc. (Nasdaq: AGIO), a leader in cellular metabolism and PK activation pioneering therapies for rare diseases, announced that the company has agreed to sell its rights to its 15% royalty on potential U.S. net sales of Servier's vorasidenib to Royalty Pharma. Under the terms of the agreement, Agios will receive an upfront payment of \$905 million upon approval of vorasidenib by the U.S. Food and Drug Administration (FDA) and Royalty Pharma will receive the entirety of the 15% royalty on annual U.S. net sales of vorasidenib up to \$1 billion, and a 12% royalty on annual U.S. net sales greater than \$1 billion. Agios will retain a 3% royalty on annual U.S. net sales greater than \$1 billion.

Vorasidenib is an oral, selective, highly brain-penetrant dual inhibitor of mutant isocitrate dehydrogenase 1 and 2 (IDH1/2) enzymes for the treatment of IDH-mutant diffuse glioma. In 2021, Agios completed the sale of its oncology portfolio – including vorasidenib – to Servier. As part of that divestiture, Agios is owed a milestone payment of \$200 million upon vorasidenib's approval by the FDA, as well as a 15% royalty on U.S. net sales of vorasidenib. Agios continues to retain the right to the approval milestone from Servier. Servier announced that the FDA has designated a Prescription Drug User Fee Act (PDUFA) action date of August 20, 2024.

"It's an exciting time at Agios with multiple near-term catalysts that we believe have the potential to make a meaningful difference in patients' lives and create significant shareholder value. With this transaction, we have added significant financial flexibility while retaining long-term value and have identified a partner in Royalty Pharma that shares our excitement about the potential of vorasidenib," said Brian Goff, chief executive officer at Agios. "This transaction will provide us with the financial independence to prepare for potential PYRUKYND® (mitapivat) launches in thalassemia and sickle cell disease as we build a PK activation franchise with multi-billion-dollar potential, and to opportunistically expand our pipeline through both internally and externally discovered assets."

Goldman Sachs & Co. LLC acted as exclusive financial advisor to Agios; WilmerHale served as legal advisor to Agios.



### **About Agios**

Agios is the pioneering leader in PK activation and is dedicated to developing and delivering transformative therapies for patients living with 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 deep scientific expertise in classical hematology and leadership in the field of cellular metabolism and rare hematologic diseases, Agios is advancing a robust clinical pipeline of investigational medicines with programs in alpha-and beta-thalassemia, sickle cell disease, pediatric PK deficiency, MDS-associated anemia and phenylketonuria (PKU). In addition to its clinical pipeline, Agios is advancing a preclinical TMPRSS6 siRNA as a potential treatment for polycythemia vera. 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 FDA approval of vorasidenib; Agios' use of proceeds from the transaction with Royalty Pharma; potential U.S. net sales of vorasidenib and potential future royalty payments; Agios' plans, strategies and expectations for the preclinical, clinical and commercial advancement and potential of its drug development programs, including PYRUKYND® (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. 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 pandemics 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 establish and maintain key collaborations; uncertainty regarding any milestone or royalty payments related to the sale of its oncology business or its in-licensing of TMPRSS6 siRNA, and the uncertainty of the timing of any such payments; uncertainty of the results and effectiveness of the use of Agios' cash and cash equivalents; 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.

## **Contacts for Agios:**

### **Investor Contact**

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