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): February 12, 2026

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 February 12, 2026, Agios Pharmaceuticals, Inc. issued a press release announcing its results for the quarter and year ended December 31, 2025 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 February 12, 2026
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: February 12, 2026

By: /s/ Brian Goff

Brian Goff
Chief Executive Officer

Exhibit 99.1

Agios Reports Fourth Quarter and Full Year 2025 Financial Results and Provides Business Update

- PYRUKYND® (mitapivat) worldwide net revenues of $20.0 million in fourth quarter and $54.0 million for full year
- AQVESME™ (mitapivat) for thalassemia now available in U.S. following FDA approval
- Company will have pre-sNDA meeting with FDA for mitapivat in sickle cell disease in first quarter of 2026
- Phase 2 tebapivat trial in sickle cell disease fully enrolled; topline results expected in second half of 2026
- $1.2 billion dollars in cash, cash equivalents, and marketable securities as of December 31, 2025

CAMBRIDGE, Mass., Feb. 12, 2026 – Agios Pharmaceuticals, Inc. (Nasdaq: AGIO), a commercial-stage biopharmaceutical company focused on delivering innovative medicines for patients with rare diseases, today announced financial results and updates for the fourth quarter and year ended December 31, 2025.

“2025 was another year of continued execution across our portfolio, highlighted by the historic U.S. approval of AQVESME – the only medicine approved to treat anemia in adults with non-transfusion-dependent and transfusion-dependent alpha- or beta-thalassemia. The U.S. launch is off to a strong start, with AQVESME now available and earning an enthusiastic response from the thalassemia community,” said Brian Goff, Chief Executive Officer, Agios. “In 2026, we are focused on driving a high-impact U.S. launch of AQVESME, expanding our PK activation franchise into additional high-value indications such as sickle cell disease and lower-risk myelodysplastic syndromes, and advancing our promising early-stage pipeline to further diversify across hematologic and other rare diseases. With disciplined capital allocation and strong operational execution, we are very well positioned at this critical inflection point to deliver a transformative medicine for the thalassemia community and advance our clinical programs as we work toward our goal of becoming a sustainable rare disease company.”

Fourth Quarter 2025 and Recent Corporate Highlights

Mitapivat Commercial Performance and Update

- **PYRUKYND® (mitapivat 5 mg, 20 mg, 50 mg)**
  - **$16.0 million in U.S. net revenue** in the fourth quarter of 2025, driven by continued commercial focus in pyruvate kinase (PK) deficiency ahead of the U.S. commercial launch of AQVESME™ (mitapivat) in thalassemia, an additional ordering week in the fourth quarter, and favorable gross-to-net adjustments. This represents an increase of 49 percent from $10.7 million in the fourth quarter of 2024 and a 24 percent increase from $12.9 million in the third quarter of 2025.

- **$4.0 million in ex-U.S. net revenue** in the fourth quarter of 2025, driven by inventory stocking ahead of demand pull-through in Europe for PK deficiency, as patients transition onto commercial supply.

- **AQVESME™ (mitapivat 100 mg)**
  - In December 2025, the U.S. Food and Drug Administration (FDA) approved AQVESME as the only medicine for the treatment of anemia in adults with alpha- or beta-thalassemia, regardless of transfusion burden.
  - AQVESME is now available in the U.S. following the implementation of its Risk Evaluation and Mitigation Strategy (REMS) program in late January 2026.

R&D Highlights

- **Mitapivat**
  - **Sickle Cell Disease –**
    - Topline results from the RISE UP Phase 3 trial of mitapivat in sickle cell disease were reported in November 2025.
    - Agios will have a pre-supplemental New Drug Application (sNDA) meeting with the FDA in the first quarter of 2026 and intends to submit a U.S. marketing application for mitapivat in sickle cell disease following that engagement. The company will provide an update on its regulatory filing strategy following receipt of the meeting minutes.

- **Tebapivat**
  - **Sickle Cell Disease –**
    - Agios has completed enrollment for the Phase 2 trial of tebapivat in sickle cell disease, and expects to report topline results in the second half of 2026. This double-blind, randomized, placebo-controlled trial is evaluating three tebapivat doses (2.5 mg, 5 mg, and 7.5 mg) versus matched placebo over a 12-week period. The primary endpoint is hemoglobin response, defined as a ≥1.0 g/dL increase in average hemoglobin concentration from Week 10 through Week 12 compared with baseline.

Fourth Quarter 2025 Financial Results

For the quarter ended December 31, 2025, net loss was $108.0 million dollars, compared to net loss of $96.5 million dollars for the quarter ended December 31, 2024.

- **Net product revenue from U.S. sales** of PYRUKYND for the fourth quarter of 2025 was $16.0 million, compared to $10.7 million for the fourth quarter of 2024.

- **Net product revenue from ex-U.S. sales** of PYRUKYND for the fourth quarter of 2025 was $4.0 million.

- **Cost of sales** for the fourth quarter of 2025 was $1.9 million.

- **Research and Development (R&D) Expenses** were $88.1 million for the fourth quarter of 2025, compared to $82.8 million for the fourth quarter of 2024, associated with the advancement of the company's early-stage clinical programs.

- **Selling, General and Administrative (SG&A) Expenses** were $51.6 million for the fourth quarter of 2025, which were flat compared to $51.7 million for the fourth quarter of 2024.

- **Cash, cash equivalents and marketable securities** were $1.2 billion as of December 31, 2025, compared to $1.5 billion as of December 31, 2024. Agios expects that its cash, cash equivalents and marketable securities, together with anticipated product revenue and interest income, will provide the financial independence to execute the U.S. commercial launch of AQVESME in thalassemia, prepare for the potential U.S. commercial launch of mitapivat in sickle cell disease, advance the company's existing clinical programs, and opportunistically expand its pipeline through both internally and externally discovered assets.

Conference Call Information

Agios will host a conference call and live webcast today at 8:00 a.m. ET to discuss the company's fourth quarter and full year 2025 financial results and recent business highlights. The live webcast will be accessible on the Investors section of the company's website (www.agios.com) under the "Events & Presentations" tab. A replay of the webcast will be available on the company's website approximately two hours after the event.

About Agios: Fueled by Connections to Transform Rare Diseases™

At Agios, our vision is to redefine the future of rare disease treatment. Fueled by connections, we build trusted partnerships with communities – collaborating to develop and deliver innovative medicines that have the potential to transform lives. With a foundation in hematology, we combine biological expertise with real-world insights to advance a growing pipeline of rare disease medicines that reflect the priorities of the people we serve. Agios is a commercial-stage biopharmaceutical company headquartered in Cambridge, Massachusetts. To learn more, visit www.agios.com and follow us on LinkedIn and X.

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 PYRUKYND® (mitapivat), AQVESME™ (mitapivat), tebapivat, AG-236 and AG-181; Agios' plans, strategies and expectations for its preclinical, clinical and commercial advancement of its drug development, including mitapivat, tebapivat, AG-236 and AG-181; Agios' expectations for the review of marketing applications for mitapivat by regulatory agencies, including the FDA and European Commission; Agios' strategic vision and goals; 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 royalty payments related to the sale of its oncology business or any milestone or royalty payments related to its in-licensing of AG-236, 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.

Consolidated Balance Sheet Data
(in thousands)
(Unaudited)

	December 31, 2025	December 31, 2024
Cash, cash equivalents, and marketable securities	$ 1,164,438	$ 1,532,031
Accounts receivable, net	10,577	4,109
Inventory	32,920	27,616
Total assets	1,297,225	1,663,199
Stockholders' equity	1,193,114	1,540,956

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

	Years Ended Dec 31,		
	2025	2024	2023
Revenues:			
Product revenue, net	$ 54,028	$ 36,498	$ 26,823
Total revenue	54,028	36,498	26,823
Operating expenses:			
Cost of sales	$ 6,345	$ 4,165	$ 2,881
Research and development	339,535	301,286	295,526
Selling, general and administrative	180,280	156,784	119,903
Total operating expenses	526,160	462,235	418,310
Loss from operations	(472,132)	(425,737)	(391,487)
Gain on sale of contingent payments	—	889,136	—
Milestone payment from gain on sale of oncology business	—	200,000	—
Interest income, net	56,379	48,083	33,344
Other income, net	1,956	6,487	6,055
Net (loss) income before taxes	(413,797)	717,969	(352,088)
Income tax (benefit) expense	(1,016)	44,244	—
Net (loss) income	$ (412,781)	$ 673,725	$ (352,088)
Net (loss) income per share - basic	$ (7.12)	$ 11.86	$ (6.33)
Net (loss) income per share - diluted	$ (7.12)	$ 11.64	$ (6.33)
Weighted-average number of common shares used in computing net (loss) income per share – basic	57,972,004	56,807,415	55,651,487
Weighted-average number of common shares used in computing net (loss) income per share – diluted	57,972,004	57,889,255	55,651,487

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