June 11, 2024

By EDGAR Submission

U.S. Securities and Exchange Commission
Division of Corporation Finance
100 F Street, NE
Washington, DC 20549
Attention: Sasha Parikh
Tracie Mariner

Re: AGIOS PHARMACEUTICALS, INC.
Form 10-K for Fiscal Year Ended December 31, 2023
Filed February 15, 2024
File No. 001-36014

Ladies and Gentlemen:

This letter is in response to the letter (the "Letter") dated May 30, 2024, from Sasha Parikh and Tracie Mariner, Office of Life Sciences, on behalf of the Staff (the "Staff") of the U.S. Securities and Exchange Commission (the "Commission"), to Cecilia Jones, the Chief Financial Officer of Agios Pharmaceuticals, Inc. ("we," "us," or "our"). The text of the Staff's comments in the Letter has been included below in bold type for your convenience, and responses are keyed to the numbering of the comments and the headings used in the Letter.

Form 10-K for Fiscal Year Ended December 31, 2023
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations
Financial Operations Overview
Cost of Sales, page 70

1. ***You disclose that it is your policy to expense costs associated with the manufacturing of your products prior to regulatory approval and, therefore, they are not included in costs of sales. With regards to PYRUKYND®, please tell us, and provide proposed disclosure to be included in future periodic reports, the following:***

    - ***The cost of the inventory build-up prior to regulatory approval that had been expensed in prior periods as research and development expenses (i.e. zero cost inventories)***
    - ***The estimated selling value of zero cost inventory on hand at December 31, 2023 and when you expect, based on your current sales trends, the zero cost inventories to be depleted***
    - ***The shelf life of your inventory and your consideration of whether or not your inventory will be determined to be obsolete in future periods.***

We respectfully acknowledge the Staff's comment and provide the following information in response. For your convenience, each bullet of the Staff's comment is reproduced in bold, italicized type below, followed by our responses thereto.

- ***The cost of the inventory build-up prior to regulatory approval that had been expensed in prior periods as research and development expenses (i.e. zero cost inventories)***

The cost of inventory build-up prior to regulatory approval that had been expensed in prior periods as research and development expenses (i.e., zero-cost inventories) up until the launch of PRYUKYND® in the first quarter of 2022 was $3.0 million, and at each of December 31, 2023 and March 31, 2024, this cost was $0.4 million. We do not consider the amounts for these periods to be significant to our financial condition or our results of operations.

- ***The estimated selling value of zero cost inventory on hand at December 31, 2023 and when you expect, based on your current sales trends, the zero cost inventories to be depleted***

Of the $0.4 million in zero-cost inventories at December 31, 2023 and March 31, 2024, approximately $0.3 million will expire during the period ending June 30, 2024, with the remaining $0.1 million expiring in 2025. With respect to this remaining amount of zero-cost inventory, and the corresponding estimated selling value of that inventory, we do not consider such amount to be significant to our financial condition or our results of operations.

- ***The shelf life of your inventory and your consideration of whether or not your inventory will be determined to be obsolete in future periods.***

PYRUKYND® (mitapivat) sold for the treatment of hemolytic anemia in adults with pyruvate kinase ("PK") deficiency in the United States is manufactured in three stages: 1) bulk active pharmaceutical ingredient ("API") manufacturing, 2) drug product manufacturing, which converts the API into tablets, and 3) labeling and packaging of the drug product into cartons, which yields a ready-to-sell finished good. After the first stage of the manufacturing process is completed, the API has an initial shelf life of 60 months from the date of manufacture. However, the end of the 60 months represents a retest date and not an expiration date. Upon completion of the second stage of the manufacturing process, the drug product has a shelf life of 36 months from the manufacture date. The labeling and packaging of the drug product in the third stage does not change the expiration date from the original 36 months from the manufacture date. We utilize third-party contract manufacturing organizations to perform each step in this manufacturing process.

On a quarterly basis, we perform an assessment to determine if there is any excess, obsolete or expired inventory and whether we need to reserve for such amounts. Based on this assessment, we have not reserved for any inventory at December 31, 2023 or March 31, 2024.

We will modify our disclosures in the Management's Discussion and Analysis of Financial Condition and Results of Operations sections of our Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q filed with the Commission commencing with our Quarterly Report on Form 10-Q for the period ending June 30, 2024. The changes set forth below are based on our Annual Report on Form 10-K for the period ended December 31, 2023 (the "2023 Form 10-K") as follows, with changes underlined:

Cost of Sales

Cost of sales consists primarily of manufacturing costs for sales of PYRUKYND®. Based on our policy to expense costs associated with the manufacturing of our products prior to regulatory approval, certain of the manufacturing costs associated with product shipments of PYRUKYND® recorded during the years ended December 31, 2023 and December 31, 2022 were expensed prior to February 17, 2022, and, therefore, are not included in costs of sales during the years ended December 31, 2023 and December 31, 2022. The amounts excluded from cost of sales were not significant during the years ended December 31, 2023 and December 31, 2022.

Inventories are reviewed periodically to identify excess or obsolete inventory based on projected sales activity as well as product shelf-life. Expired inventory is disposed of, and the related costs are recognized as cost of sales in our consolidated statement of operations, when, based on the expiry date, we do not believe we are able to sell the inventory. We have not reserved for excess or obsolete inventory during the years ended December 31, 2023 and December 31, 2022.

Form 10-K for Fiscal Year Ended December 31, 2023
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations
Research and Development Expenses
PYRUKYND (mitapivat): First-in-Class PK Activator, page 71

2. ***You note that in connection with your regulatory approvals in the EU and Great Britain, you are currently providing access to PYRUKYND® free of charge for eligible patients in those jurisdictions through a global managed access program and that you may provide access to PYRUKYND® for adult patients with PK deficiency in other jurisdictions upon request through the global managed access program. Please tell us, and provide proposed disclosure to be included in future periodic reports, the following:***

    - ***A robust description of the global managed access program and how your product is process through this program***
    - ***Your accounting policy for the free products provided through the global managed access program***
    - ***The expense incurred in each jurisdiction for the product provided free of charge through the global managed access program or a statement, if true, that the aggregated expense is not considered by management to be material***
    - ***A discussion regarding your future plans and/or obstacles you have encountered to commercialize PYRUKYND® in the EU and Great Britain.***

We respectfully acknowledge the Staff's comment and provide the following information in response. For your convenience, each bullet of the Staff's comment is reproduced in bold, italicized type below, followed by our responses thereto.

- ***A robust description of the global managed access program and how your product is process through this program***

Our global managed access program ("GMAP") is intended to provide a pathway for adult PK deficiency patients receiving care in selected countries to have access to PYRUKYND®. Healthcare providers must submit an inquiry on behalf of their patients to us for consideration when certain criteria are met. Criteria may include, but are not limited to, the following:

- The person has a current diagnosis of PK deficiency
- The person is 18 years of age or older
- The person does not have rare hereditary problems of galactose intolerance, total lactase deficiency, or glucose-galactose malabsorption
- Sufficient supply of PYRUKYND® is readily available and supply is allowed under the local rules and regulations
- Other criteria may be considered and reviewed with the treating provider based on the assessment of the person's condition and medical history

We utilize a third-party vendor to manage our GMAP, with inventory shipped via consignment from the third-party logistics company we utilize to manage distribution of PYRUKYND®.

- ***Your accounting policy for the free products provided through the global managed access program***
- ***The expense incurred in each jurisdiction for the product provided free of charge through the global managed access program or a statement, if true, that the aggregated expense is not considered by management to be material***

The aggregated expense associated with PYRUKYND® provided free of charge through our GMAP is not considered by management to be significant to our financial condition or results of operations, with amounts totaling $0.1 million for the period ended March 31, 2024, $0.2 million for the year ended December 31, 2023, and less than $0.1 million for the year ended December 31, 2022.

- ***A discussion regarding your future plans and/or obstacles you have encountered to commercialize PYRUKYND® in the EU and Great Britain.***

Our disclosure included in our 2023 Form 10-K and our Quarterly Report on Form 10-Q for the period ended March 31, 2024 concluded with the following sentence 'Beyond the global managed access program, we continue to evaluate options for the commercialization of PYRUKYND® outside of the United States, including through exploring potential partnership opportunities.' While we believe our GMAP provides patients with an effective channel to access PYRUKYND®, we continue to assess that and other channels for patients to access PYRUKYND® in the EU and Great Britain.

We will modify our disclosures in the Management's Discussion and Analysis of Financial Condition and Results of Operations sections of our Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q filed with the Commission commencing with our Quarterly Report on Form 10-Q for the period ending June 30, 2024. The changes set forth below are based on our 2023 Form 10-K as follows, with changes underlined:

PYRUKYND® (mitapivat): First-in-Class PK Activator

We are developing PYRUKYND® for the treatment of PK deficiency and other hemolytic anemias such as thalassemia and SCD. PYRUKYND® is an orally available small molecule and a potent activator of the wild-type and mutated PK enzymes.

In February 2022, the FDA approved PYRUKYND® for the treatment of hemolytic anemia in adults with PK deficiency in the United States. In November 2022, we received marketing authorization from the European Commission for PYRUKYND® for the treatment of PK deficiency in adult patients in the EU. In December 2022, we received marketing authorization in Great Britain for PYRUKYND® for the treatment of PK deficiency in adult patients under the European Commission Decision Reliance Procedure. In addition, we are currently evaluating PYRUKYND® in clinical trials for the treatment of thalassemia, SCD, and in pediatric patients with PK deficiency. We have worldwide development and commercial rights to PYRUKYND® and expect to fund the future development and commercialization costs related to this program. PYRUKYND® has been granted orphan drug designation for the treatment of PK deficiency by the FDA and the EMA. Additionally, PYRUKYND® has received orphan drug designation from the FDA for the treatment of thalassemia and SCD.

We have built our commercial infrastructure to support the commercial launch of PYRUKYND® in adult PK deficiency in the United States. In connection with our regulatory approvals in the EU and Great Britain, we are currently providing access to PYRUKYND® free of charge for eligible patients in those jurisdictions through a global managed access program. We may provide access to PYRUKYND® for adult patients with PK deficiency in other jurisdictions upon request through the global managed access program, on either a free of charge or for charge basis. Our global managed access program has not had a significant impact on our business, financial condition or results of operations. Beyond the global managed access program, we continue to evaluate options for the commercialization of PYRUKYND® outside of the United States, including through exploring potential partnership opportunities.

If you have any further questions or comments, or if you require any additional information, please contact the undersigned by telephone at (617) 649-8600. Thank you for your assistance.

Very truly yours,

/s/ Cecilia Jones

Cecilia Jones
Chief Financial Officer

cc: Brian Goff, Chief Executive Officer, Agios Pharmaceuticals, Inc.
James Burns, Chief Legal Officer, Agios Pharmaceuticals, Inc.
Cynthia T. Mazareas, Wilmer Cutler Pickering Hale and Dorr LLP
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