

UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

May 30, 2024

Cecilia Jones Chief Financial Officer AGIOS PHARMACEUTICALS, INC. 88 Sidney Street Cambridge, MA 02139

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

Dear Cecilia Jones:

We have reviewed your filing and have the following comment(s).

Please respond to this letter within ten business days by providing the requested information or advise us as soon as possible when you will respond. If you do not believe a comment applies to your facts and circumstances, please tell us why in your response.

After reviewing your response to this letter, we may have additional comments.

Form 10-K for Fiscal Year Ended December 31, 2023

<u>Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations Financial Operations Overview</u>

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.

Cecilia Jones AGIOS PHARMACEUTICALS, INC. May 30, 2024 Page 2

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 remind you that the company and its management are responsible for the accuracy and adequacy of their disclosures, notwithstanding any review, comments, action or absence of action by the staff.

Please contact Sasha Parikh at 202-551-3627 or Tracie Mariner at 202-551-3744 if you have questions regarding comments on the financial statements and related matters.

Sincerely,

Division of Corporation Finance Office of Life Sciences