

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

DIVISION OF CORPORATION FINANCE

June 19, 2013

<u>Via E-mail</u> David P. Schenkein, M.D. Chief Executive Officer Agios Pharmaceuticals, Inc. 38 Sidney Street, 2<sup>nd</sup> Floor Cambridge, MA 02139

> Re: Agios Pharmaceuticals, Inc. Draft Registration Statement on Form S-1 Submitted May 23, 2013 CIK No. 0001439222

Dear Dr. Schenkein:

We have reviewed your draft registration statement and subsequently filed Form S-1 dated June 10, 2013 and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by amending your registration statement and providing the requested information. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing any amendment to your registration statement and the information you provide in response to these comments, we may have additional comments.

### General

- 1. We note that you have submitted an application for confidential treatment relating to one of your exhibits. Please be advised that comments to this application, if any, will be sent under separate cover and that any such comments must be resolved prior to your requesting effectiveness of your registration statement.
- 2. Please confirm that the graphics included in your registration statement are the only graphics you will use in your prospectus. If those are not the only graphics, please provide any additional graphics prior to their use for our review.
- 3. Please supplementally provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications. Similarly, please

supplementally provide us with any research reports about you that are published or distributed in reliance upon Section 2(a)(3) of the Securities Act of 1933 added by Section 105(a) of the Jumpstart Our Business Startups Act by any broker or dealer that is participating or will participate in your offering.

4. In the summary and elsewhere you describe yourself as a "first-mover" and also suggest that your products are based upon a cellular metabolism approach that is unique. However, on page 17 you state "Some of these competitive products are based on scientific approaches that are the same or similar to our approach." This appears to be an inconsistency that you should reconcile in your disclosure. Further, to the extent that other drug discovery companies employ approaches that use their knowledge of the human metabolic network and related bibliomic or genomic information you should eliminate the suggestion that your approach is unique and your characterization of yourself as a "first-mover" throughout the filing. Please advise or revise as may be appropriate.

### Prospectus summary Overview, page 1

- 5. It is not apparent from your disclosure that you have yet to file an Investigational New Drug Application (IND) and commence clinical studies for any of your three lead product candidates. Please amend your disclosure in the first paragraph of this section, in the corresponding disclosure in your Business section and wherever else applicable to so state.
- 6. Please define the following terms you have included in this discussion in such a way as to make them more easily understandable by the lay reader:
  - biomarker;
  - pharmacodynamics marker;
  - genetically validated;
  - metabolites;
  - metabolite level and
  - chelation therapy.
- 7. In the first full paragraph on page 2 you state that your use of biomarkers to define patient populations will result in the potential for early proof of concept, a higher probability of technical success and accelerated clinical development and product approval. Please modify this disclosure and similar disclosure elsewhere to state that you hope that the use of biomarkers will increase the potential and probability of these outcomes but that you have no assurance that such will actually occur as there may be circumstances or outcomes that you cannot anticipate.
- 8. Here, and where applicable in your Business discussion, please explain how you obtained the technology relating to your pending patent applications. To the extent that you

acquired this technology through in-licensing agreements, please describe such agreements and file them as exhibits to your registration statement.

## Risks associated with our business, page 3

9. In your first bullet point, please include the amount of your accumulated deficit to date.

#### **Risk Factors**

"We will need substantial additional funding. If we are unable to raise capital when needed . . .," page 10

10. Please remove the fifth and sixth bullet points from this risk factor and the corresponding sixth and seventh bullet points on page 64 as they are not material to your future capital requirements at this time.

"If we are unable to successfully develop companion diagnostic for our therapeutic product candidates . . .," page 15

11. In this risk factor, and in the related disclosure on pages 95-96, please provide a definition of "companion diagnostics."

"Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights . . .," page 25

12. Please disclose in this risk factor any litigation that has been filed against you or any of your founders, scientific advisors, directors and/or executive officers.

"We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers," page 26

13. Please disclose in this risk factor any such claims made against your employees.

"We are an 'emerging growth company,' and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors," page 33

14. Please explain in this risk factor all of the circumstances under which you may lose your status as an emerging growth company.

"We will incur increased costs as a result of operating as a public company ...," page 34

15. Please include in this risk factor, to the extent practicable, an estimate of the annual costs associated with being a public company.

### Use of Proceeds, page 37

16. Please amend this disclosure to provide your best estimate of the amount of funds you intend to allocate to the clinical development of each of your three lead product candidates. Specify the amounts to be devoted to each of these three products and how far in the clinical process you expect the employment of those funds to take you.

#### Dilution, page 41

17. It appears that your calculation of historical net tangible book value includes convertible preferred stock amounts. The amounts attributable to preferred shareholders would only be available to common shareholders upon the conversion of preferred stock to common stock. Please revise your calculations of historical net tangible book value to exclude convertible preferred stock or explain to us the basis for your calculation.

Management's discussion and analysis of financial condition and results of operations Critical accounting policies and estimates Accrued research and development expenses, page 51

18. You disclose that you do not expect your estimates to be materially different from the amounts actually incurred. Please revise to disclose how accurate these estimates have been in the past and how much the estimate has changed in the past. Please refer to Section 501.14 of the Financial Reporting Codification added by FR-72.

Common stock valuation, page 53

19. Please expand your disclosure to include a discussion of each significant factor contributing to the difference between the fair value as of the date of each grant and the estimated IPO price.

### Liquidity and capital resources Contractual obligations, page 65

20. You disclose that contracts with CROs and other vendors are not included in the table of contractual obligations because they are cancellable contracts. The contracts with CROs and other vendors appear to be needed in your research and development and appear to meet the definition of purchase obligations. Please revise your disclosure to include any contracts with CROs or other vendors that meet the definition of purchase obligations. As noted in Item 303(a)(5) of Regulation S-K the tabular presentation may be accompanied by footnotes to describe provisions that create, increase or accelerate obligations, or other pertinent data to the extent necessary for an understanding of the timing and amount of the registrant's specified contractual obligations.

21. You have omitted future milestone payments because the achievement and timing of these milestones is not fixed and determinable and you typically have the ability to terminate these agreements upon 60- 90 days' notice. Please disclose the amount and timing of milestone commitments that are reasonably likely to be paid. Please refer to Section 501.13 of the Financial Reporting Codification added by FR-72.

### Business General, page 67

- 22. Please define the following terms you have included in this discussion in such a way as to make them more easily understandable by the lay reader:
  - hematopoietic cells and
  - glioblastoma multiforme.

## Our development programs, page 73

23. Please revise the disclosure in the last column of the table on page 74, "Commercial rights," to more clearly convey the rights possessed by either you or your collaborator.

### Intellectual property, page 85

24. Please explain what a Patent Cooperation Treaty application is and clarify whether you still have to file separate applications. If so, specify in which jurisdictions.

# Government regulation

United States drug approval process, page 89

25. From your disclosure, it appears that the information you provide in this discussion concerning Abbreviated New Drug Applications and Section 505(b)(2) new drug applications is not relevant to the clinical development process that you intend to pursue. If you agree with this assessment, you should remove this disclosure. If you disagree, please explain why in a response.

### Shares eligible for future sale Lock-up agreements, page 135

26. Please file a copy of the form lock-agreement as an exhibit to your registration statement. If it is to be filed as an exhibit to your underwriting agreement, please confirm this for us.

Consolidated Financial Statements Notes to Consolidated Financial Statements 10. Income Taxes, page F-28

27. Since the income tax rate reconciliation starts with an income tax benefit computed at federal statutory tax rate it appears that the tax rates in the table should be consistent with introductory sentence before the rate reconciliation. For example, it appears that an income tax benefit should be in parentheses and the income tax should not. Please revise to correct any inconsistency.

We urge all persons who are responsible for the accuracy and adequacy of the disclosure in the filing to be certain that the filing includes the information the Securities Act of 1933 and all applicable Securities Act rules require. Since the company and its management are in possession of all facts relating to a company's disclosure, they are responsible for the accuracy and adequacy of the disclosures they have made.

Notwithstanding our comments, in the event you request acceleration of the effective date of the pending registration statement please provide a written statement from the company acknowledging that:

- should the Commission or the staff, acting pursuant to delegated authority, declare the filing effective, it does not foreclose the Commission from taking any action with respect to the filing;
- the action of the Commission or the staff, acting pursuant to delegated authority, in declaring the filing effective, does not relieve the company from its full responsibility for the adequacy and accuracy of the disclosure in the filing; and
- the company may not assert staff comments and the declaration of effectiveness as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

Please refer to Rules 460 and 461 regarding requests for acceleration. We will consider a written request for acceleration of the effective date of the registration statement as confirmation of the fact that those requesting acceleration are aware of their respective responsibilities under the Securities Act of 1933 and the Securities Exchange Act of 1934 as they relate to the proposed public offering of the securities specified in the above registration statement. Please allow adequate time for us to review any amendment prior to the requested effective date of the registration statement.

You may contact Donald Abbott at (202) 551-3608 or Lisa Vanjoske at (202) 551-3614 if you have questions regarding comments on the financial statements and related matters. Please contact Scot Foley at (202) 551-3383 or me at (202) 551-3715 with any other questions.

Sincerely,

/s/ Jeffrey P. Riedler

Jeffrey P. Riedler Assistant Director

cc: Steven D. Singer, Esq. Cynthia T. Mazareas, Esq. Wilmer Cutler Pickering Hale and Dorr LLP 60 State Street Boston, MA 02109