

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

April 11, 2014

Via E-mail
Alfred Altomari
Chief Executive Officer
Agile Therapeutics, Inc.
101 Poor Farm Road
Princeton, New Jersey 08540

Re: Agile Therapeutics, Inc.

**Registration Statement on Form S-1** 

Filed March 17, 2014 File No. 333-194621

Dear Mr. Altomari:

We have reviewed your registration statement 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 yet to submit several of your exhibits. Please be advised that we may have further comments upon examination of these exhibits once they have been submitted by amendment.
- 2. 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 issued under separate cover.
- 3. Please provide us proofs of all graphic, visual or photographic information you will provide in the printed prospectus prior to its use, for example in a preliminary prospectus. Please note that we may have comments regarding this material.

4. 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.

#### <u>Prospectus Summary</u> Overview, page 1

# 5. Please explain in this disclosure that progestin, as used in this context, is a synthetic steroid hormone.

- 6. Please provide a basis for your assertion that many other contraceptive trials have enrolled a high proportion of subjects who were current users.
- 7. Here, and in your Business discussion, please include the ratio of noncompliance in new users to that in experienced users in your clinical trials.
- 8. You state that the FDA's complete response letter was based in part on the Pearl Index in your Phase 3 trials. Please also list the other bases for the complete response letter in your summary, as you have done on page 106 of your disclosure.
- 9. Please indicate the developmental stage of your product candidates other than Twirla. If they are in a preclinical stage, please state this or, if they have undergone clinical trials, state the latest phase completed or currently underway. To the extent that you have not done so already, please include similar information in your narrative disclosure on pages 109-110.
- 10. Where you make reference to the FDA's Orange Book on page 4, please include a brief explanation of what the Orange Book is and the significance of patents being listed in it.

#### Risks Associated with Our Business, page 4

11. In your sixth bullet point, please include your accumulated deficit to date and reference the going concern opinion issued by your independent auditor.

#### **Risk Factors**

<u>Risks Relating to the Commercialization of Our Product Candidates</u>
"Physicians, patients and payors may not adopt a new contraceptive patch . . .," page 30

12. Please define "pharmacokinetic study" in this risk factor.

### Risks Related to Our Business Operations and Industry "If product liability lawsuits are brought against us...," page 54

13. Please expand the discussion to quantify the current amount of liability coverage.

#### Use of Proceeds, page 67

- 14. Please indicate in this section the approximate amount of net proceeds you intend to allocate toward each of the following:
  - the next Phase 3 trial for Twirla;
  - the completion of Corium International's manufacturing capabilities;
  - the development of your product candidate pipeline; and
  - payments on your outstanding term loan.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Critical Accounting Policies and Significant Judgments and Estimates
Stock-Based Compensation, page 80

15. We may have additional comments on your accounting for stock compensation or any beneficial conversion features once you have disclosed an estimated offering price. Please supplementally provide us with a quantitative and qualitative analysis explaining the difference between the estimated offering price and the fair value of the most recent equity issuance.

#### Contractual Obligations and Commitments, page 88

16. Please revise your tabular disclosure of contractual obligations and commitments to include the interest payments and the final payment of \$675,000 if not otherwise included for your term loan.

#### **Business**

#### Our Product Candidates, page 97

- 17. Please define the term "pharmacokinetic profile" on page 98.
- 18. Please disclose the inactive ingredients in Twirla that are used to transport EE and LNG.
- 19. Please provide a basis for your statement that "it has been well-documented that contraceptive failure rates are highest in black and Hispanic subjects."

#### Strategic Agreements, page 116

20. Please disclose the total milestone payments you have paid to Corium International, Inc. to date and, if there are any additional milestone payments to be made, disclose their aggregate.

## Shares Eligible for Future Sale Lock-Up and Market Standoff Agreements, page 165

21. Please either file your form lock-up agreement as an exhibit or confirm that it will be filed as an exhibit to the form underwriting agreement.

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 Scott Wuenschell at (202) 551-3467 or Joel Parker at (202) 551-3651 if you have questions regarding comments on the financial statements and related matters. Please contact Scot Foley at (202) 551-3383, John Krug at (202) 551-3862 or me at (202) 551-3715 with any other questions.

Sincerely,

/s/ Jeffrey P. Riedler

Jeffrey P. Riedler Assistant Director

cc: Steven M. Cohen
Emilio Ragosa
Morgan, Lewis & Bockius LLP
502 Carnegie Center
Princeton, New Jersey 08540