April 17, 2014

**VIA EDGAR AND FEDEX**

Jeffrey P. Riedler
Assistant Director
United States Securities and Exchange Commission
Division of Corporate Finance
100 F Street, N.E.
Washington, D.C. 20549

**Re: Agile Therapeutics, Inc.**
**Registration Statement on Form S-1**
**Filed March 17, 2014**
**File No. 333-194621**

Dear Mr. Riedler:

On behalf of our client, Agile Therapeutics, Inc. ("we" or the "Company"), set forth below is the Company's response to the letter dated April 11, 2014 (the "April 11 Comment Letter") from the staff (the "Staff") of the Securities and Exchange Commission (the "Commission"), which relates to the Company's Registration Statement on Form S-1, File No. 333-194621 (the "Registration Statement") filed with the Commission on March 17, 2014 (the "Initial Filing"). The Company is filing Amendment No. 1 to the Registration Statement ("Amendment No. 1"), which includes revisions made to the Initial Filing in response to the April 11 Comment Letter, and to reflect certain additional information. An electronic version of Amendment No. 1 has been filed concurrently with the Commission through its EDGAR system. The enclosed copy of Amendment No. 1 has been marked to reflect changes made to the Registration Statement.

The numbered paragraphs and headings below correspond to the headings set forth in the April 11 Comment Letter. Each of the Staff's comments is set forth in bold, followed by the Company's response to each comment. The page numbers in the bold captions refer to pages in the Initial Filing, while the page numbers in the Company's responses refer to page numbers in Amendment No. 1. Capitalized terms used in this letter but not defined herein have the meaning given to such terms in Amendment No. 1.

**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.**

Response:

The Company acknowledges the Staff's comment and respectfully advises the Staff that one of the exhibits not filed with the Initial Filing is being filed with the attached

---

Amendment No. 1. The Company will provide the remaining exhibits as promptly as possible.

**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.**

Response:

The Company acknowledges the Staff's comment.

**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.**

Response:

The Company acknowledges the Staff's comment and respectfully advises the Staff that the images included in the Registration Statement are all of the graphic, visual or photographic information the Company currently intends to include in the Registration Statement. If the Company decides to use any additional images, it will provide the Staff with proofs of such materials as soon as practicable.

**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.**

Response:

The Company acknowledges the Staff's request. The Company has supplementally provided the Staff written communications presented to potential investors in reliance on Section 5(d) of the Securities Act. The Company advises the Staff that potential investors have not been permitted to retain copies of such written communications. The Company further advises the Staff that to its knowledge, as of the date hereof, no research reports have been distributed by any broker or dealer participating in the offering. The Company intends to supplementally provide the Staff copies of any such

materials as promptly as practicable in the event that any additional materials are presented to potential investors pursuant to Section 5(d) of the Securities Act or any materials are distributed by any broker or dealer participating in the offering.



**Prospectus Summary**
**Overview, page 1**

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

Response:

In response to the Staff's comment, the Company proposes to revise the following sentence on page 1 of Amendment No. 1 to now state:

"Twirla is a combined hormonal contraceptive, or CHC, patch that contains the active ingredients ethinyl estradiol, or EE, which is a synthetic estrogen, and levonorgestrel, or LNG, which is a type of progestin, a synthetic steroid hormone, both of which have an established history of efficacy and safety in currently marketed combination low-dose, oral contraceptives."

**6. Please provide a basis for your assertion that many other contraceptive trials have enrolled a high proportion of subjects who were current users.**

Response:

In response to the Staff's comment, the Company proposes to add the following sentence to page 2 of Amendment No. 1:

"For example, the subject population for the primary contraceptive efficacy clinical trial for the product Yaz® consisted of 60% current users and for the North American clinical trial for the product Natazia® consisted of 59% 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.**

Response:

In response to the Staff's comment, the Company proposes to add the following sentence to page 3 of Amendment No. 1:

"In our Phase 3 studies, noncompliance, as verified by nondetectable serum levels of LNG and EE in a subject, was approximately three times as high in new users as compared to experienced users in both the Twirla and oral contraceptive arms of the study."



**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.**

Response:

In response to the Staff's comment, the Company proposes to add the following sentences to page 3 of Amendment No. 1:

"The FDA recommended that we conduct an additional Phase 3 trial with a simplified clinical trial design and improved study conduct, including site monitoring and data collection procedures. The FDA also required additional information relating to the laser etching of label information on each patch and required that the patch used in the new trial utilize the same etching as will be used for the commercial product, in order to demonstrate that it does not adversely affect the performance of the patch. Furthermore, the FDA also requested in the CRL additional information on controls and release specifications related to the patch, and manufacturing and control information related to the Drug Master File of one of the raw materials in Twirla."

**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.**

Response:

In response to the Staff's comment, the Company proposes to add the following sentences to pages 4 and 113 of Amendment No. 1:

"AG200-ER utilizes the same drug product as Twirla, and therefore requires no further patch development. We believe that a regimen for AG200-ER could be presented to the FDA and a Phase 3 study started once a protocol is developed. AG200-SP requires additional patch development work prior to conducting Phase 1 studies. Initial Phase 1/2 work has been conducted on AG890, but this product candidate requires additional patch development work for dose selection prior to conducting further Phase 1 and 2 studies. We do not expect to be required to conduct preclinical studies for any of these product candidates. Based upon a number of factors, including, but not limited to, our available capital resources and feedback from the FDA, we intend to review the clinical path for each of these three product candidates in 2015."

**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.**

Response:

In response to the Staff's comment, the Company proposes to add the following sentence to page 4 of Amendment No. 1:

"The Orange Book lists drug products, including related patent and exclusivity information, approved by the FDA under the Federal Food, Drug, and Cosmetic Act. If a patent is listed in the Orange Book, potential competitors seeking approval of drug products under an Abbreviated New Drug Application, which provides for the marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use, among other things, of a previously approved product, or a 505(b)(2) application, for which the listed drug is a reference product, must provide a patent certification in their application stating either that (1) no patent information on the drug product has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted."

**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.**

Response:

In response to the Staff's comment, the Company proposes to revise the bullet point referenced above on page 5 of Amendment No. 1 to now state:

- We have incurred significant operating losses since our inception and had an accumulated deficit of approximately $118.3 million as of December 31, 2013.
- We anticipate that we will continue to incur losses for the foreseeable future and we may never be profitable. Our recurring losses from operations have raised substantial doubt regarding our ability to continue as a going concern, and as a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as of and for the year ended December 31, 2013 with respect to this uncertainty.



**Risk Factors**
**Risks Relating to the Commercialization of Our Product Candidates**
**"Physicians, patients and payors may not adopt a new contraceptive patch . . .," page 30**

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

Response:

In response to the Staff's comment, the Company proposes to add the following sentence to page 32 of Amendment No. 1:

"A pharmacokinetic study evaluates how the body handles a given drug over time; these studies are conducted by measuring the amount of time it takes for the drug to be absorbed, distributed and eliminated throughout the body."

**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.**

Response:

In response to the Staff's comment, the Company proposes to add the following sentence to page 57 of Amendment No. 1:

"We have obtained limited product liability insurance coverage for our products and our clinical trials with a $2.0 million annual aggregate coverage limit."

**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.**

Response:

In response to the Staff's comment, the Company proposes to revise the second and third paragraphs on page 69 of Amendment No. 1 to now state:



"We intend to use approximately $31 million of the proceeds from this offering to fund an additional Phase 3 clinical trial for Twirla, our lead product candidate.

We intend to use the remainder of the proceeds as follows:

- approximately $4 to $6 million for the completion of the equipment qualification and validation related to the expansion of Corium's manufacturing capabilities;
- approximately $2 to $4 million for the development of our product candidate pipeline, including Twirla line extensions; and
- the remainder of the net proceeds for making scheduled principal and interest payments beginning in February 2015 on our outstanding term loan with Oxford Finance, LLC and for working capital and general corporate purposes. For additional information related to this outstanding loan, including the interest rate and maturity, see "*Management Discussion and Analysis — December 2012 Loan Agreement*"."

**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.**

Response:

The Company acknowledges the Staff's comment and respectfully advises the Staff that the Company will provide quantitative and qualitative disclosures in a later amendment of the Registration Statement at such time as an estimated offering price has been determined.



**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.**

Response:

In response to the Staff's comment, the Company proposes to revise the tabular disclosure on page 90 of Amendment No. 1 to now state:

| | Total | Less than 1 year | 1 - 3 years | 3 - 5 years | More than 5 years |
|---|---|---|---|---|---|
| | | | (In thousands) | | |
| Term loan | $ 17,638 | $ 6,293 | $ 11,345 | — | — |
| Operating lease | 308 | 159 | 149 | — | — |
| Total | $ 17,946 | $ 6,452 | $ 11,494 | — | — |

**Business**
**Our Product Candidates, page 97**

**17. Please define the term "pharmacokinetic profile" on page 98.**

Response:

In response to the Staff's comment, the Company proposes to add the following sentence to page 101 of Amendment No. 1:

"A drug's pharmacokinetic profile refers to the specific way in which a given drug is handled by the body over time, reflecting the particular patterns of absorption, distribution and elimination of the drug in the body."

**18. Please disclose the inactive ingredients in Twirla that are used to transport EE and LNG.**

Response:

In response to the Staff's comment, the Company proposes to revise the following sentence on page 102 of Amendment No. 1 to now state:

"Twirla is a matrix patch consisting of several layers of material that contain the active ingredients EE and LNG, as well as the inactive ingredients Dimethylsulfoxide, Ethyl Lactate, Capric Acid and Lauryl Lactate, which are ingredients to assist in the transport of EE and LNG across the skin, and adhesives that enable adherence to the skin."

**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."**

Response:

In response to the Staff's comment, the Company proposes to revise the following sentence on page 107 of Amendment No. 1 to now state:

"Although the underlying reasons are not well-understood, several articles in medical journals, such as *Contraception* and the *American Journal of Obstetrics & Gynecology,* and in at least one report by the U.S. Department of Health and Human Services, state 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.**

Response:

In response to the Staff's comment, the Company has deleted the word "milestone" from page 120 of the Registration Statement because the payments made to Corium International, Inc. ("Corium") were not "milestone payments" as described in accounting literature (ASC 605-28). The payments made by the Company were not "at risk" at inception of the arrangement and were not based on performance or upon the occurrence of specific outcomes. In addition to contract and research development payments, as we have already disclosed on page [116] of the Registration Statement, the Company paid Corium a total of $3.5 million representing the Company's portion of the facility expansion incurred by Corium in order to provide adequate manufacturing space for the Company's product candidates.

In addition, in response to the Staff's comment, the Company proposes to add the following sentence to page 120 of Amendment No. 1:

"To date, we have not made any milestone payments to Corium. Corium is not eligible for any milestone payments in the future."



**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.**

Response:

The Company respectfully advises the Staff that the form of lock-up agreement will be filed as an exhibit to the Underwriting Agreement to be filed as Exhibit 1.1 with a subsequent amendment to the Registration Statement.

* * * * * * *

The Company believes that the above responses will be acceptable to the Staff. Please contact the undersigned at (609) 919-6633 if you have any questions regarding the foregoing.

Sincerely,

/s/ Emilio Ragosa

cc: Alfred Altomari, Agile Therapeutics, Inc.
Steven M. Cohen, Morgan, Lewis & Bockius LLP
Peter N. Handrinos, Latham & Watkins LLP