

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

June 7, 2013

<u>Via E-mail</u>

Mark J. Gergen Executive Vice President and Chief Operations Officer Mirati Therapeutics, Inc. 4660 La Jolla Village Drive, Suite 500 San Diego, CA 92122

**Re:** Mirati Therapeutics, Inc.

**Registration Statement on Form 10-12(b)** 

Filed May 10, 2013 File No. 001-35921

Dear Mr. Gergen:

We have reviewed your filing and have the following comments. In our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter within 10 business days by providing the requested information or by advising us when you will provide the requested response. If you do not believe our comments apply to your facts and circumstances, please tell us why in your response.

After reviewing the information you provide in response to these comments, we may have additional comments.

#### General

- 1. Please note that in accordance with Section 12(d) of the Securities and Exchange Act, this Form 10 registration statement filed pursuant to Section 12(b) of the Act will become effective 30 days after the Commission receives certification from the NASDAQ that the company's listing application has been approved. The Division of Corporation Finance has the authority to accelerate the 30-day period at either the company's or the exchange's request.
- 2. Once the Final Order is received, as set forth in the Arrangement Agreement of May 8, 2013, please file a copy as an exhibit to this registration statement.

## Business, page 6

3. Please define the term "kinase" the first time it appears in your registration statement.

### Corporate History, page 6

- 4. Please expand your disclosure to discuss the reasons for the May 8, 2013 Arrangement between MethylGene and Mirati Therapeutics, Inc., pursuant to which MethylGene will change its jurisdiction of incorporation from Canada to Delaware. In this regard, we note the MethylGene press release, dated May 9, 2013, and the Management Information Circular, dated May 29, 2013, which discuss the rationale of MethylGene's board of directors and management for recommending the Arrangement to shareholders.
- 5. We note your discussion of an investigational new drug application (IND) submitted for MGCD290. Please also disclose in this section whether there is an effective IND for each of the following products:
  - MGCD 265 for any indication;
  - mocetinostat for any indication; and

If an IND has not been filed, please explain why. For each IND that has been filed, please disclose the identity of the filer and the date the application was filed.

# Pipeline Programs, page 9

6. Please define each of the terms "histone" and "deacetylate" the first time it appears in your registration statement.

#### Clinical Product Candidate MGCD265, page 11

7. Please clarify the role that receptor tyrosine kinases (RTKs) play in tumor cell growth and the mechanism by which MGCD265 inhibits RTKs.

# <u>Pipeline Product – Mocetinostat, page 16</u>

- 8. Please clarify the role that histone deacetylation and acetylation play in the regulation of gene expression and explain more clearly:
  - how histone deacetylation can lead to the proliferation of tumor cells and;
  - how mocetinostat inhibits the action of HDACs.

# Pipeline Product MGCD516, page 18

- 9. Please explain the mechanism by which MGCD516 inhibits RTKs.
- 10. Please define the term "HER2 inhibitors" and clarify the significance of your statement that Eph receptors are associated with resistance to HER2 inhibitors.

# <u>Strategic Alliances and Commercial Agreements</u> <u>Collaboration with Taiko Pharmaceutical Co. Ltd., page 20</u>

- 11. Please expand the discussion of the material terms of your agreement with Taiko to include the following:
  - the provisions of the agreement covering its duration;
  - the amount of royalties you may receive expressed as a percentage or range within 10% (i.e. single digits, teens, twenties, etc.).

#### Collaboration with Otsuka, page 20

- 12. Please expand the discussion of the material terms of your agreement with Otsuka to include the following:
  - the total amount of potential aggregate milestone payments you could collect under the agreement;
  - the provisions of the agreement covering its duration;
  - the amount of royalties you may receive expressed as a percentage or range within 10% (i.e. single digits, teens, twenties, etc.).

#### Collaboration with EnVivo, page 21

13. Please disclose the amount of royalties you may receive for the remainder of this agreement expressed as a percentage or range within 10% (i.e. single digits, teens, twenties, etc.

#### Intellectual Property, pages 21

14. We note your statement that at the top of page 22 that "[e]xclusivity for MGCD265 extends to at least 2026." Please clarify the nature of the patent coverage for MGCD265 that extends to 2026.

#### Licensing Agreements, page 22

15. Please identify the license agreement to which you refer and disclose the parties involved, the intellectual property covered and any other material provisions. If you have not already filed this agreement as an exhibit to the registration statement, please do so with your next amendment.

#### Manufacturing, page 24

16. Please identify the material terms of your manufacturing and supply agreements. Please file these agreements as exhibits to the registration statement as well. Alternatively, if you do not believe any of these agreements is material, please advise us as to the basis of your conclusions.

#### Risk Factors, page 29

"Our research and development programs and processes are at an early stage...," page 34

17. Please expand your discussion under this risk factor to include the fact that you currently have no pipeline candidates beyond Phase 2 clinical trials.

#### "We are subject to competition for our skilled personnel...,", page

18. You reference the fact that key members of your team may terminate their employment with you at any time. Please expand the discussion to disclose instances in which you have actually experienced this risk and the circumstances involved. For example, it appears that both a Chief Executive Officer and a Chief Scientific Officer have resigned in the past 2 years. As such, it appears that your statement that you "have not experienced problems attracting and retaining highly qualified personnel in the recent past" may be inconsistent with actual events.

# Management's Discussion and Analysis, page 48

- 19. Please clarify here and elsewhere in the filing, as applicable, if true, the following:
  - Mirati Therapeutics is a holding company and has no operations and assets or minimal assets;
  - The operations of the company are conducted through your wholly-owned subsidiaries, MethylGene US Inc. and MethylGene Canada;
  - The financial statements and related disclosures assume that the Arrangement has been approved by the court and shareholders; and
  - The effect of shareholders and the court not approving the Arrangement.

# Research and Development Expense, page 50

- 20. Regarding your research and development activities, please revise your disclosure to include the following for each of your research and development projects:
  - The costs incurred during each period presented and to date;
  - The nature of efforts and steps necessary to complete the project;
  - The risks and uncertainties associated with completing development;
  - The extent and nature of additional resources that need to be obtained if current liquidity is not expected to be sufficient to complete the project; and
  - Where a future milestone such as completion of a development phase, date of filing with a regulatory agency, or approval from a regulatory agency can be reliably determined, disclosure should be made.

If you do not maintain any research and development costs by project, disclose that fact and explain why management does not maintain and evaluate research and development costs by project. Provide other quantitative or qualitative disclosure that indicates the amount of the company's resources being used on the project.

#### General and Administrative Expenses, page 50

21. To the extent practicable, please quantify the estimated costs mentioned in this section that you will incur as a result of being a public company. Please also include this disclosure under the risk factor regarding your status as a U.S. public company on page 33.

#### Liquidity and Capital Resources, page 56

22. Please expand your disclosure in this section to include your rate of negative cash flow per month and how far into clinical trials you can develop MGCD265 with current cash and cash equivalents.

#### Item 15. Financial Statements and Exhibits, page 100

23. Please file as an exhibit the Arrangement Agreement, dated May 8, 2013, between Methylgene Inc. and Mirati Therapeutics, Inc.

# Note 4. Collaboration Agreements Otsuka Pharmaceutical Co. Ltd., page F-11

- 24. You disclose that you may receive additional payments based on successful development, regulatory, and commercialization and sales based milestones and will further receive royalties on net sales. Please revise your disclosure to quantify each of the amounts that can be potentially received and the nature of the underlying events which trigger the milestone payment. Separately disclose each individually material milestone payment. Refer to ASC 605-28-50-2.
- 25. You disclose that in 2011 you recognized \$1.7 million of the \$2 million up-front license fee received under the 2008 agreement with Otsuka. Please disclose how you accounted for the license fee that supports recognizing a majority of the fee in 2011.

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 all information the Securities Exchange Act of 1934 and all applicable Exchange 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.

In responding to our comments, please provide a written statement from the company acknowledging that:

• the company is responsible for the adequacy and accuracy of the disclosure in the filing;

- staff comments or changes to disclosure in response to staff comments do not foreclose the Commission from taking any action with respect to the filing; and
- the company may not assert staff comments as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

You may contact Sasha Parikh at (202) 551-3627 or Lisa Vanjoske at (202) 551-3614 if you have questions regarding comments on the financial statements and related matters. Please contact Austin Stephenson at (202) 551-3192, Dan Greenspan at (202) 551-3623, or me at (202) 551-3715 with any other questions.

Sincerely,

/s/ Daniel Greenspan for

Jeffrey P. Riedler Assistant Director

cc: <u>Via E-mail</u>
Kristin VanderPas, Esq.
Cooley LLP