Mirati Therapeutics, Inc.
Form 8-K
June 06, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d)

of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **June 5, 2016**

MIRATI THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-35921**	**46-2693615**
(State of incorporation)	(Commission File No.)	(IRS Employer Identification No.)

9393 Towne Centre Drive, Suite 200

San Diego, California 92121

(Address of principal executive offices and zip code)

Registrant s telephone number, including area code: **(858) 332-3410**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events.

On June 5, 2016 Mirati Therapeutics, Inc. (the Company) provided an interim update on three ongoing clinical programs in patients with non-small cell lung cancer (NSCLC) and other solid tumors.

Glesatinib Program Update: As of May 20, 2016, 28 patients with MET and AXL alterations were enrolled in the Phase 1b trial across multiple tumor types, including 22 NSCLC patients. 11 of the NSCLC patients had genetic driver alterations comparable to the criteria in the Company s ongoing Phase 2 trial, including two NSCLC patients with MET amplification, eight NSCLC patients with MET exon14 deletion mutations, and one NSCLC patient with AXL amplification. The interim results consisted of the following confirmed responses to glesatinib in the selected NSCLC patients with genetic driver alterations: 3 of 11 NSCLC patients had partial responses (PR s) confirmed per RECIST, including patients with a MET amplification, MET exon14 deletion mutation and AXL amplification; patients with confirmed responses were on study for 39 weeks, 23 weeks and 56 weeks, with the 23 and 56 week patients continuing on study; and tumor regression was seen in 10 of the 11 patients, three of which had confirmed PRs.

The Phase 2 trial for glesatinib continues in NSCLC patients with MET genetic alterations of interest who were previously treated with platinum-based chemotherapy and those who may also have had prior treatment with a checkpoint inhibitor. Enrollment is ongoing and the new spray-dried dispersion formulation is being introduced this month. Patients who started on the original formulation will be transitioned to the new formulation. An interim update on response rates in patients from the Phase 2 study on the new formulation will be provided once a meaningful number of patients have been treated and are evaluable.

Sitravatinib Program Update: Initial data from the Phase 1b trial of sitravatinib show early signs of clinical activity, including a confirmed PR in a renal cell carcinoma patient, as well as durable tumor regressions in multiple other tumor types, including NSCLC patients with RET mutations. An additional update on this trial is expected by the end of the year, when a greater number of patients have been enrolled.

Mocetinostat Program Update: The Company has initiated a trial for the combination study of mocetinostat, a histone deacetylase inhibitor, with the AstraZeneca/MedImmune anti-PD-L1 checkpoint inhibitor, durvalumab, in patients with NSCLC. The Company plans to provide an update on this Phase 2 trial as progress continues, with the potential to see initial signals of activity by early 2017.

On June 5, 2016, the Company issued a press release providing an update on the three clinical programs. A copy of the press release is attached as Exhibit 99.1 hereto.

Forward-Looking Statements

Certain statements contained in this Item 8.01 and attached Exhibit 99.1, other than statements of fact that are independently verifiable at the date hereof, contain forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, that involve significant risks and uncertainties. For more detailed disclosures and discussions regarding such forward looking statements, please refer to the Company s filings with the U.S. Securities and Exchange Commission (SEC), including without limitation the Company s filings on Forms 10-K, 10-Q, and 8-K. Forward looking statements are based on the current expectations of management and upon what management believes to be reasonable assumptions based on information currently available to it. Such statements can usually be identified by the use of words such as may, would, believe, intend, plan, anticipate, estimate, expect, and other similar terminology, or by statements that certain actions, results may or would be taken, occur or be achieved. Such statements include, but are not limited to, statements regarding the Company s development plans and timelines, potential regulatory actions, expected use of cash resources, the timing and results of clinical trials, and the potential benefits of and markets for the Company s product candidates. Forward looking statements involve significant risks and uncertainties and are neither a prediction nor a guarantee that future events or circumstances will occur. Such risks include, but are not limited to, potential delays in development timelines or negative clinical trial results, reliance on third parties for development efforts, changes in the competitive landscape, changes in the standard of care, as well as other risks described in the Company s filings with the SEC. We are including this cautionary note to make applicable, and to take advantage

of, the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 for forward-looking statements. The information in this news release is given as of the date above and the Company expressly disclaims any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	**Description**
99.1	Press Release dated June 5, 2016.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: June 6, 2016

MIRATI THERAPEUTICS, INC.

By: /s/ Mark J. Gergen
Mark J. Gergen
Executive Vice President and Chief Operations Officer

INDEX TO EXHIBITS

Exhibit No.	Description
99.1	Press Release dated June 5, 2016.