Mirati Therapeutics, Inc.
Form 8-K
June 01, 2015

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): **May 30, 2015**

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 May 30, 2015 Mirati Therapeutics, Inc. (the Company) presented data that demonstrated preliminary evidence of clinical activity from its investigational targeted tyrosine kinase inhibitor candidate, MGCD265, as part of the developmental therapeutics category at the 2015 American Society of Clinical Oncology Annual Meeting being held in Chicago from May 29-June 2, 2015 (the Conference).

Tumor xenograft data demonstrated that treatment of tumors with MET exon 14 deletion mutations or MET gene amplification with MGCD265 resulted in tumor regression, and the genetic alterations were predictive of clinical data observed to date in the ongoing MGCD265 expansion study. The open label, single agent Phase 1/1b study is designed to evaluate the safety, tolerability, pharmacokinetics/pharmacodynamics and clinical activity of twice-daily (BID) MGCD265 in patients who have failed at least one prior therapy.

Patients receive 1050 mg of MGCD265 BID for 21-day cycles and are assessed for response after every second treatment cycle. At the time of this initial analysis, the first three non-small cell lung cancer patients with MET gene alterations showed a clinical benefit, including clear tumor regression and improvement in clinical symptoms such as pain and shortness of breath.

In the dose escalation phase of the study, the maximum tolerated dose of MGCD265 was 1050 mg BID. This dose was shown to result in >90% inhibition of MET and Axl based on preclinical predictions and biomarkers sMET and sAxl. The dose limiting toxicities were grade 3 fatigue in one patient and grade 3 diarrhea in one patient. In the dose escalation cohort, MGCD265 was well tolerated at the 1050 mg BID dose and diarrhea in subsequent patients is managed with standard doses of the anti-diarrhea agent loperamide.

On May 30, 2015, the Company issued a press release announcing the data presented at the Conference. A copy of the press release is attached as Exhibit 99.1 hereto.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	**Description**
99.1	Press Release dated May 30, 2015

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 1, 2015

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 May 30, 2015.