

Mirati Therapeutics, Inc.
Form 8-K
January 05, 2017

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): **January 5, 2017**

MIRATI THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State of incorporation)

001-35921
(Commission File No.)

46-2693615
(IRS Employer Identification No.)

9393 Towne Centre Drive, Suite 200

San Diego, California 92121

Edgar Filing: Mirati Therapeutics, Inc. - Form 8-K

(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):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
-

Item 2.02 Results of Operations and Financial Condition.

We estimate that we had between \$56 million and \$57 million in cash, cash equivalents and short-term investments as of December 31, 2016. This amount is preliminary and is subject to completion of financial closing procedures. As a result, this amount may differ from the amount that will be reflected in our consolidated financial statements as of and for the year ended December 31, 2016.

Item 8.01 Other Events.

On January 5, 2017 we announced data from two ongoing clinical programs, including the Phase 1b and Phase 2 trials of glesatinib, a spectrum selective kinase inhibitor for the treatment of non-small cell lung cancer (NSCLC) patients with genetic alterations of MET, and the Phase 1b trial of sitravatinib, a receptor tyrosine kinase inhibitor for the treatment of genetically-selected NSCLC and other solid tumors.

Glesatinib Program Update: The spray dried dispersion (SDD) formulation of glesatinib was introduced into the Phase 1b trial and Phase 2 AMETHYST trial in May of 2016. This formulation has thus far demonstrated improved tolerability versus the prior miglyol soft gel formulation.

Patients from both Phase 1b and Phase 2 trials were assessed as of December 2, 2016 to evaluate the impact of the new SDD formulation (n=41) as compared to the prior soft gel formulation (n=50). Adverse event-related (AE-related) dose reductions occurred in 17% (7/41) of patients treated with the new SDD formulation, versus 46% (23/50) of patients treated with the prior soft gel formulation. In patients who were transitioned to the SDD formulation during their therapy (n=12), AE-related dose reductions took place in 8% (1/12) of patients versus 33% (4/12) of patients treated with the soft gel formulation.

In an initial evaluation of 24 genetically-selected patients treated with the SDD formulation of glesatinib:

- 11 patients were in the Phase 2 MET Exon 14 deletion mutation cohort, of whom eight were evaluable.
- Eight patients were in the Phase 2 MET amplification cohort, all of whom were evaluable.
- Five patients were in the Phase 1b trial with MET Exon 14 deletion mutations, who had clinical characteristics and genetic driver alterations identical to the entry criteria in the ongoing Phase 2 trial, all of whom were evaluable.

In MET Exon 14 deletion patients treated with the SDD formulation across both the Phase 1b and Phase 2 trials, glesatinib demonstrated promising activity:

Edgar Filing: Mirati Therapeutics, Inc. - Form 8-K

- In the Phase 2 trial, one confirmed partial response (PR) and two unconfirmed PRs out of the eight evaluable patients were observed. One unconfirmed PR remains on study awaiting a confirmatory scan. Tumor reduction was observed in six of eight evaluable patients.
- In the Phase 1b trial, three confirmed PRs out of five evaluable patients were observed. Tumor reduction was observed in all five patients.
- Overall, data in these 13 patients reflect an objective response rate (ORR) of 46% across the Phase 1b and Phase 2 patient populations, including confirmed and unconfirmed responses. Tumor reduction was observed in 11 of 13 patients.
- The longest duration on study is more than 55 weeks and the patient remains on study.

In MET amplification patients treated with the SDD formulation, glesatinib also demonstrated clinical benefit:

- In the Phase 2 trial, two unconfirmed PRs out of eight evaluable patients were observed. Neither of the unconfirmed responses remains on study. Tumor reduction was observed in six of eight evaluable patients.
- The longest duration on study is more than 24 weeks and the patient remains on study.

We expect to provide an additional update on the glesatinib program in the second half of 2017.

Sitravatinib Program Update: Sitravatinib is being evaluated in a Phase 1b expansion trial designed to evaluate its safety and efficacy in multiple pre-specified cohorts of cancer patients with genetic mutations involving sitravatinib targets, including a cohort of NSCLC patients with RET fusion mutations.

As of a data cut-off of December 9, 2016, a total of six NSCLC patients with RET fusion mutations had been enrolled, four of whom were evaluable:

- Of the four evaluable patients, one patient with a KIF5-B RET fusion demonstrated a confirmed PR and one patient with a DSP RET fusion has achieved an unconfirmed PR on initial scan, representing a 50% ORR, including confirmed and unconfirmed responses. Both patients remain on study. A third patient with RET fusion demonstrated tumor reduction of 29%, representing stable disease. Tumor reduction was observed in all four patients.
- The longest duration on study is more than 46 weeks and the patient remains on study.

The Phase 1b trial is also enrolling NSCLC patients with CBL mutations, CHR4q12 amplification, and AXL alterations. As of the data cut-off date, no patients with these genetic mutations were evaluable.

Sitravatinib is also being evaluated in combination with nivolumab, a checkpoint inhibitor approved for the treatment of patients with a variety of solid tumors including NSCLC and metastatic renal cell carcinoma. Pre-clinical data indicate sitravatinib is an exceptionally potent inhibitor of the TAM (Tyro, Axl, Mer) and split (KDR, KIT) family tyrosine kinases which regulate multiple stages in the cancer immunity cycle and are thought to enhance anti-tumor immunity by improving the efficacy of checkpoint inhibitors (anti PD-1/PDL-1). The multicenter Phase 2 NSCLC trial enrolled its first patient in November 2016.

We expect to provide an additional update on the sitravatinib program in the third quarter of 2017.

Mocetinostat Program Update: A Phase 1b/2 trial combining mocetinostat, an orally administered spectrum-selective Class 1 HDAC inhibitor, and durvalumab, MedImmune's monoclonal antibody inhibiting PD-L1, continues to enroll patients with advanced solid tumors and NSCLC. The Company expects to provide an additional update on the mocetinostat program mid-year 2017.

Pre-Clinical Program Update: Two internally developed candidates are in pre-clinical development. The first is a highly-potent and potentially best-in-class LSD1 inhibitor with potential for rapid clinical proof-of-concept in small cell lung cancer or acute myeloid leukemia. An investigational new drug (IND) submission is planned for this

compound in late 2017. Additionally, a mutant-selective KRAS inhibitor program is advancing to the candidate selection phase and prototype inhibitors have demonstrated marked tumor regression in KRAS mutant tumor models. An IND candidate selection is anticipated by the end of 2017.

Forward-Looking Statements

This report contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Any statements in this report regarding our business that are not historical facts may be considered forward-looking statements, including, but not limited to, statements regarding our development plans and timelines, the timing and potential future results of clinical trials, and the potential benefits of and markets for our product candidates. Forward-looking statements are typically, but not always, identified by the use of words such as may, would, believe, intend, plan, anticipate, estimate, expect, and other similar terminology. Forward-looking statements are based on current expectations of management and upon what management believes to be reasonable assumptions based on information currently available to it, and are subject to risks and uncertainties. Such risks and uncertainties may cause actual results to differ materially from the expectations set forth in the forward-looking statements. Such risks and uncertainties include, but are not limited to, potential delays in development timelines or negative clinical trial results, the fact that prior clinical or pre-clinical results may not be predictive of future results, reliance on third parties for development efforts, changes in the competitive landscape, changes in the standard of care, as well as other risks detailed in our recent filings on Forms 10-K and 10-Q with the United States Securities and Exchange Commission. We undertake no obligation to update any forward-looking statements to reflect new information, events or circumstances, or to reflect the occurrence of unanticipated events.

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: January 5, 2017

MIRATI THERAPEUTICS, INC.

By: */s/ Charles M. Baum, M.D., Ph.D.*
Charles M. Baum, M.D., Ph.D.
President and Chief Executive Officer