Mirati Therapeutics, Inc.
Form 8-K
November 13, 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): November 13, 2017

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

Emerging growth company ý

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ý

Item 8.01 Other Events.

On November 13, 2017 Mirati Therapeutics, Inc. (the "Company") provided updates on its sitravatinib and KRAS inhibitor programs, including selection of a clinical lead and backup compounds for its KRAS program that have shown to potently target KRAS G12C mutations in preclinical studies. The clinical lead and backup compounds are orally-available small molecule inhibitors of KRAS G12C, that have shown potencies as low as 1 nM (cellular IC50) and selectivity of greater than 1,000-fold for target inhibition in tumor cells harboring KRAS G12C mutations compared with cells exhibiting wild-type KRAS in preclinical studies. In addition, the lead and backup compounds demonstrated complete tumor regression of KRAS G12C-positive tumors implanted in mice. Investigational new drug, or IND, enabling preclinical studies are underway for the clinical lead and backup compounds, and an IND submission is expected by the fourth quarter of 2018, with initial proof-of-concept clinical data potentially available in 2019. KRAS-driven cancers remain an area of high unmet need with KRAS G12C driver mutations occurring in approximately 14% of non-small cell lung cancer adenocarcinoma patients and 5% of colorectal cancer patients.

Mirati's clinical lead and backup compounds in its KRAS program were discovered and have been developed in collaboration with Array BioPharma Inc. ("Array"), and Mirati has an exclusive license to further develop and commercialize products based on the program. Pursuant to the related collaboration agreement, Array is entitled to certain future development and commercialization milestone payments as well as royalties upon future net sales.

As previously reported at the IASLC 18th World Conference on Lung Cancer in October 2017, initial data from the ongoing Phase 2 study of sitravatinib in combination with nivolumab included three confirmed Partial Responses (PRs) in the first 11 evaluable patients. Eight of these patients exhibited tumor reduction and duration of treatment greater than four months. As of August 10, 2017, seven patients (including all three patients with PRs) remained on study, with treatment duration ranging from four months to 10.5 months. The Company believes these initial encouraging results may be applicable to other tumor types, including renal cell, bladder and liver cancer, where checkpoint inhibitors have demonstrated efficacy that may potentially be enhanced by combining with sitravatinib. The Company plans to provide an update on the first two stages of this trial in up to 34 patients in mid-2018. Sitravatinib is also being evaluated as a single agent in an ongoing Phase 1b study, where an objective response with tumor reduction of 77% was observed in the first evaluable NSCLC patient with a CBL mutation. Mirati continues to enroll patients in this trial to confirm this early promising activity and expects to provide a further update across all cohorts in mid-2018.

The Company also announced the de-prioritization of glesatinib to focus its resources on its most promising programs where it believes there is significantly greater market potential. The Company will stop further enrollment in all glesatinib clinical trials and will pursue opportunities to partner or license the program. In addition, the Company announced that it has elected to suspend further development of its preclinical LSD1 inhibitor program and will seek a partner to continue development of the program. The planned re-allocation of resources is expected to allow acceleration of the sitravatinib and KRAS programs and provide funding for operations into late 2019.

On November 13, 2017, the Company issued a press release providing these program updates. A copy of the press release is attached as Exhibit 99.1 hereto.

Forward-Looking Statements

This current report contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Any statements in this current report regarding the business of the Company that are not historical facts may be considered "forward-looking statements," including, but not limited to, statements regarding Mirati's development plans and timelines, potential regulatory actions, expected use and duration of cash resources, the timing and results of clinical trials, and the potential benefits of and markets for Mirati's 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, delays in or inability to obtain regulatory approvals, reliance on third parties for development and manufacturing efforts, changes in the competitive landscape, changes in the standard of care, unanticipated expenses or uses of cash resources, as well as other risks detailed in Mirati's recent filings on Forms 10-K and 10-Q with the United States Securities and Exchange Commission. Mirati undertakes no obligation to update any forward-looking statements to reflect new information, events or circumstances, or to reflect the occurrence of unanticipated events.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated November 13, 2017

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: November 13, 2017 Mirati Therapeutics, Inc.

By: /s/ Charles M. Baum

Charles M. Baum

President and Chief Executive Officer

INDEX TO EXHIBITS

Exhibit No.	Description
99.1	Press Release dated November 13, 2017