Mirati Therapeutics, Inc.
Form 10-Q
November 03, 2016
Table of Contents

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

FORM 10-Q

ý QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2016

or

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission File Number: 001-35921

MIRATI THERAPEUTICS, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	46-2693615
(State of Incorporation)	(I.R.S. Employer Identification No.)
9393 Towne Centre Drive, Suite 200	
San Diego, California	92121
(Address of Principal Executive Offices)	(Zip Code)

(858) 332-3410
(Registrant’s Telephone Number, Including Area Code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes S No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes S No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer”, “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Securities Exchange Act of 1934.

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨(Do not check if a smaller reporting company)	Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

Total shares of common stock outstanding as of the close of business on October 31, 2016:

Class	Number of Shares Outstanding
Common Stock, $0.001 par value	19,924,005

1

Table of Contents

MIRATI THERAPEUTICS, INC.
FORM 10-Q

TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION		3
Item 1.	Condensed Consolidated Financial Statements (Unaudited)	3
	Condensed Consolidated Balance Sheets as of September 30, 2016 and December 31, 2015	3
	Condensed Consolidated Statements of Operations and Comprehensive Loss for the Three and Nine Months Ended September 30, 2016 and 2015	4
	Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2016 and 2015	5
	Notes to Condensed Consolidated Financial Statements	6
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	12
Item 3.	Quantitative and Qualitative Disclosure about Market Risk	17
Item 4.	Controls and Procedures	17
PART II. OTHER INFORMATION		19
Item 1.	Legal Proceedings	19
Item 1A.	Risk Factors	19
Item 2.	Unregistered Sale of Securities and Use of Proceeds	39
Item 3.	Defaults Upon Senior Securities	39
Item 4.	Mine Safety Disclosures	39
Item 5.	Other Information	39
Item 6.	Exhibits	41
SIGNATURES		42

Table of Contents

PART I. FINANCIAL INFORMATION
ITEM 1. Financial Statements
MIRATI THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except for share and per share amounts)

	September 30, 2016 (Unaudited)	December 31, 2015
ASSETS		
Current assets		
Cash and cash equivalents	$ 19,802	$49,493
Short-term investments	53,180	72,834
Other current assets	2,504	3,075
Total current assets	75,486	125,402
Property and equipment, net	537	614
Other long-term assets	3,135	2,001
Total assets	$ 79,158	$128,017
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	$ 13,661	$9,798
Total current liabilities	13,661	9,798
Other long-term liability	13	43
Total liabilities	13,674	9,841
Stockholders' equity		
Preferred stock, $0.001 par value, 10,000,000 shares authorized; none issued and outstanding at both September 30, 2016 and December 31, 2015	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized; 19,924,005 and 19,282,935 issued and outstanding at September 30, 2016 and December 31, 2015, respectively	20	19
Additional paid-in capital	425,909	415,232
Accumulated other comprehensive income	9,584	9,558
Accumulated deficit	(370,029)	(306,633)
Total stockholders' equity	65,484	118,176
Total liabilities and stockholders' equity	$ 79,158	$128,017

See accompanying notes

Table of Contents

MIRATI THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited, in thousands, except for share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Expenses				
Research and development	$16,106	$14,563	$52,535	$34,046
General and administrative	3,475	4,161	11,391	12,180
Total operating expenses	19,581	18,724	63,926	46,226
Loss from operations	(19,581)	(18,724)	(63,926)	(46,226)
Other income (expense), net	160	(17)	530	99
Net loss	$(19,421)	$(18,741)	$(63,396)	$(46,127)
Unrealized gain (loss) on available-for-sale investments	(34)	6	26	2
Comprehensive loss	$(19,455)	$(18,735)	$(63,370)	$(46,125)
Basic and diluted net loss per share	$(0.97)	$(1.11)	$(3.21)	$(2.86)
Weighted average number of shares used in computing net loss per share, basic and diluted	19,924,005	16,841,954	19,739,935	16,103,326

See accompanying notes

Table of Contents

MIRATI THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited, in thousands)

	Nine Months Ended September 30,	
	2016	2015
Operating activities:		
Net loss	$(63,396)	$(46,127)
Non-cash adjustments reconciling net loss to operating cash flows:		
Depreciation of property and equipment	139	153
Amortization of premium on investments	6	320
Share-based compensation expense	8,086	7,912
Changes in operating assets and liabilities:		
Other current assets	571	329
Other long-term assets	(1,134)	(1,675)
Accounts payable, accrued liabilities and other long-term liability	3,834	4,404
Cash flows used for operating activities	(51,894)	(34,684)
Investing activities:		
Purchases of short-term investments	(67,261)	(41,024)
Maturities of short-term investments	86,935	35,280
Purchases of property and equipment	(63)	(296)
Cash flows provided by (used in) investing activities	19,611	(6,040)
Financing activities:		
Proceeds from sale of common stock, net	—	143,289
Proceeds from exercise of warrants and common stock options	2,355	472
Proceeds from stock issuances under employee stock purchase plan	237	251
Cash flows provided by financing activities	2,592	144,012
(Decrease) increase in cash and cash equivalents	(29,691)	103,288
Cash and cash equivalents, beginning of period	49,493	6,593
Cash and cash equivalents, end of period	$19,802	$109,881

See accompanying notes

Table of Contents

MIRATI THERAPEUTICS, INC.
Notes to Condensed Consolidated Financial Statements
September 30, 2016
(Unaudited)

1. Description of Business

Mirati Therapeutics, Inc. ("Mirati" or the "Company") is a clinical-stage biopharmaceutical company focused on developing a pipeline of targeted oncology products. The Company focuses its development programs on drugs intended to treat specific genetic and epigenetic drivers of cancer in selected subsets of cancer patients with unmet needs.

The Company's common stock has been listed on the NASDAQ Capital Market since July 15, 2013 under the ticker symbol "MRTX." The Company has a wholly owned subsidiary in Canada, MethylGene, Inc.

2. Summary of Significant Accounting Policies

Basis of Presentation

The unaudited condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission ("SEC") and, therefore, certain information and disclosures normally included in annual financial statements prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") have been omitted.

In the opinion of management, the information reflects all adjustments necessary to make the results of operations for the interim periods a fair statement of such operations. All such adjustments are of a normal recurring nature. Interim results are not necessarily indicative of results for the full year. The condensed consolidated balance sheet at December 31, 2015 has been derived from the audited consolidated financial statements at that date, but does not include all information and footnotes required by U.S. GAAP for complete financial statements. These unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2015.

Use of Estimates

The preparation of the Company's unaudited condensed consolidated financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period.

Reported amounts and note disclosures reflect the overall economic conditions that are most likely to occur and anticipated measures management intends to take. Actual results could differ materially from those estimates. Estimates and assumptions are reviewed quarterly. Any revisions to accounting estimates are recognized in the period in which the estimates are revised and in any future periods affected.

Cash, Cash Equivalents and Short-term Investments

Cash and cash equivalents consist of cash and highly liquid securities with original maturities at the date of acquisition of ninety days or less. Investments with an original maturity of more than ninety days are considered short-term investments and have been classified by management as available-for-sale. These investments are classified as current assets, even though the stated maturity date may be one year or more beyond the current balance sheet date, which reflects management's intention to use the proceeds from sales of these securities to fund its operations, as necessary. Such investments are carried at fair value, and the unrealized gains and losses are reported as a component of accumulated other comprehensive income (loss) in stockholders' equity until realized. Realized gains and losses from the sale of available-for-sale securities, if any, are determined on a specific identification basis.

Table of Contents

Concentration of Credit Risk

The Company invests its excess cash in accordance with its investment policy. The Company's investments are comprised primarily of commercial paper and debt instruments of financial institutions, corporations, U.S. government-sponsored agencies and the U.S. Treasury. The Company mitigates credit risk by maintaining a diversified portfolio and limiting the amount of investment exposure as to institution, maturity and investment type. Financial instruments that potentially subject the Company to significant credit risk consist principally of cash equivalents and short-term investments.

Foreign Currency Transactions

Foreign currency transactions are initially recorded by the Company using the exchange rates prevailing at the date of the transaction. At the balance sheet date, monetary assets and liabilities denominated in foreign currencies are translated at the period-end rates of exchange. Non-monetary assets and liabilities are translated at the historical exchange rates. Exchange gains and losses arising from the translation of foreign currency items are included in other income (expense), net in the condensed consolidated statements of operations and comprehensive loss.

Segment Reporting

Operating segments are components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker for purposes of making decisions regarding resource allocation and assessing performance. To date, the Company has viewed its operations and managed its business as one segment operating primarily in the United States.

Net loss per share

Basic net loss per common share is calculated by dividing the net loss by the weighted-average number of common shares outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares and potentially dilutive securities outstanding for the period. Common share equivalents outstanding, determined using the treasury stock method, are comprised of shares that may be issued under the Company’s stock option and warrant agreements.

The following table presents the weighted average number of potentially dilutive securities not included in the calculation of diluted net loss per share due to the anti-dilutive effect of the securities:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Common stock options	—	634,321	224,665	517,004
Common stock warrants	—	1,460,017	426,974	1,666,229
Total	—	2,094,338	651,639	2,183,233

3. Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies that are adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its consolidated financial position or results of operations upon adoption.

In March 2016, the FASB issued ASU 2016-09, Compensation-Stock Compensation (Topic 718). The new guidance changes the accounting and simplifies various aspects of the accounting for share-based payments to employees. The guidance allows for a policy election to account for forfeitures as they occur or based on an estimated number of awards that are expected to vest. ASU 2016-09 is effective for annual periods beginning after December 15, 2016, with early adoption permitted. The Company is currently evaluating the impact the standard will have on its consolidated financial statements, but does not believe the adoption of this standard will have a material impact on its financial position, results of operations or related financial statement disclosures.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). Under the new guidance, lessees are required to recognize most lease assets and lease liabilities on their balance sheets and record expenses on their income statements in a manner similar to current accounting. The new guidance is effective for fiscal years beginning after December 15, 2018, with early adoption permitted. The Company is currently evaluating the impact that this guidance will have on its consolidated financial statements and related financial statement disclosures.

In January 2016, the FASB issued ASU No. 2016-01, Financial Instruments - Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities. The new guidance enhances the reporting model for financial instruments and includes amendments to address aspects of recognition, measurement, presentation and disclosure. The update to the standard is effective for public companies for interim and annual periods beginning after December 15, 2017. The Company does not believe the adoption of this standard will have a material impact on its financial position, results of operations or related financial statement disclosures.

In November 2015, the FASB issued ASU No. 2015-17, Balance Sheet Classification of Deferred Taxes, to simplify the presentation of deferred taxes. This amendment requires that all deferred tax assets and liabilities, along with any related valuation allowances, be classified as noncurrent on the balance sheet. ASU 2015-17 is effective for annual and interim reporting periods ending after December 15, 2016. Early adoption is permitted, and the new guidance is and may be applied either prospectively or retrospectively. We have adopted this guidance prospectively as of December 31, 2015. Therefore, prior periods have not been adjusted to reflect this adoption.

In August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern. Under the new guidance, management will be required to assess an entity’s ability to continue as a going concern, and to provide related footnote disclosures in certain circumstances. The provisions of this ASU are effective for annual periods beginning after December 15, 2016, and for annual and interim periods thereafter; early adoption is permitted. The Company has not elected to early adopt and is currently evaluating the potential changes from this ASU to its future financial reporting and disclosures.

In May 2014, the FASB issued Accounting Standard Update ("ASU") 2014-09, Revenue from Contracts with Customers (Topic 606), which will replace numerous requirements in U.S. GAAP, including industry-specific requirements, and provide companies with a single revenue recognition model for recognizing revenue from contracts with customers. The core principle of the new standard is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In August 2015, the FASB approved a proposal to defer the effective date of the guidance until annual and interim reporting periods beginning after December 15, 2017. The Company is currently evaluating the impact that this standard will have on its consolidated financial statements.

4. Investments

The following tables summarize our short-term investments (dollars in thousands):

	Maturity	As of September 30, 2016 Amortized cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
Corporate debt securities	1 year or less	$22,079	$ —	$ —	$22,079
Commercial paper	1 year or less	31,037	64	—	31,101
		$53,116	$ 64	$ —	$53,180

As of December 31, 2015

Maturity

		Amortized cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
Corporate debt securities	1 year or less	$27,644	$ —	$ (22)	$ 27,622
Commercial paper	1 year or less	45,158	54	—	45,212
		$72,802	$ 54	$ (22)	$ 72,834

Unrealized gains and losses on available-for-sale securities are included as a component of comprehensive loss. At September 30, 2016, the Company did not have any securities in material unrealized loss positions. The Company reviews its investments to identify and evaluate investments that have an indication of possible other-than-temporary impairment. Factors considered in determining whether a loss is other-than-temporary include the length of time and extent to which fair value has been less than the cost basis, the financial condition and near-term prospects of the investee, and the Company’s intent and ability

Table of Contents

to hold the investment for a period of time sufficient to allow for any anticipated recovery in market value. The Company does not intend to sell any investments prior to recovery of their amortized cost basis for any investments in an unrealized loss position.

5. Fair value measurements

The Company has certain financial assets and liabilities recorded at fair value which have been classified as Level 1 or 2 within the fair value hierarchy as described in the accounting standards for fair value measurements.

The authoritative guidance for fair value measurements defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or the most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Market participants are buyers and sellers in the principal market that are (i) independent, (ii) knowledgeable, (iii) able to transact, and (iv) willing to transact. The guidance prioritizes the inputs used in measuring fair value into the following hierarchy:

- Level 1- Quoted prices (unadjusted) in active markets for identical assets or liabilities;

- Level 2- Inputs other than quoted prices included within Level 1 that are either directly or indirectly observable; and

- Level 3- Unobservable inputs in which little or no market activity exists, therefore requiring an entity to develop its own assumptions about the assumptions that market participants would use in pricing.

The following tables summarize the assets and liabilities measured at fair value on a recurring basis (in thousands):

	September 30, 2016			
	Total	Level 1	Level 2	Level 3
Assets				
Cash and cash equivalents:				
Cash	$989	$989	$—	$ —
Money market funds	18,813	18,813	—	—
Total cash and cash equivalents	19,802	19,802	—	—
Short-term investments:				
Corporate debt securities	22,079	—	22,079	—
Commercial paper	31,101	—	31,101	—
Total short-term investments	53,180	—	53,180	—
Total	$72,982	$19,802	$53,180	$ —

	December 31, 2015			
	Total	Level 1	Level 2	Level 3
Assets				
Cash and cash equivalents:				
Cash	$875	$875	$	