Mirati Therapeutics, Inc.
Form 10-Q
April 29, 2019
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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 March 31, 2019

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)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Common Stock, par value $0.001 per share	MRTX	The Nasdaq Stock Market LLC

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 every Interactive Data File required to be submitted 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 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	x	Accelerated filer	o
Non-accelerated filer	¨	Smaller reporting company	o
		Emerging growth company	o

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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 financing accounting standards provided pursuant to Section 13(a) of the Exchange Act.¨

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 April 22, 2019:

Class	Number of Shares Outstanding
Common Stock, $0.001 par value	36,047,127

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

	March 31, 2019 (Unaudited)	December 31, 2018
ASSETS		
Current assets		
Cash and cash equivalents	$ 74,605	$ 32,694
Short-term investments	226,380	190,096
Other current assets	5,397	3,870
Total current assets	306,382	226,660
Property and equipment, net	429	473
Other long-term assets	2,550	1,321
Total assets	$ 309,361	$ 228,454
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	$ 24,465	$ 25,775
Deferred revenue and other current liabilities	638	371
Total current liabilities	25,103	26,146
Deferred revenue and other liabilities	704	732
Total liabilities	25,807	26,878
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.001 par value, 10,000,000 shares authorized; none issued and outstanding at both March 31, 2019 and December 31, 2018	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized; 36,029,093 and 32,538,857 issued and outstanding at March 31, 2019 and December 31, 2018, respectively	36	33
Additional paid-in capital	873,838	751,109
Accumulated other comprehensive income	9,637	9,479
Accumulated deficit	(599,957)	(559,045)
Total stockholders' equity	283,554	201,576
Total liabilities and stockholders' equity	$ 309,361	$ 228,454

See accompanying notes

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

	Three Months Ended March 31,	
	2019	2018
Revenue		
License and collaboration revenues	$1,244	$9,467
Total revenue	1,244	9,467
Operating expenses		
Research and development	$34,240	$19,659
General and administrative	9,762	5,154
Total operating expenses	44,002	24,813
Loss from operations	(42,758)	(15,346)
Other income, net	1,846	637
Net loss	$(40,912)	$(14,709)
Unrealized gain (loss) on available-for-sale investments	158	(288)
Comprehensive loss	$(40,754)	$(14,997)
Basic and diluted net loss per share	$(1.17)	$(0.51)
Weighted average number of shares used in computing net loss per share, basic and diluted	34,980,361	28,843,578

See accompanying notes

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Mirati Therapeutics, Inc.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(Unaudited, in thousands, except share data)

Three Months Ended March 31, 2019

	Common Stock		Additional paid-in capital	Accumulated other comprehensive income	Accumulated deficit	Total stockholders' equity
	Shares	Amount				
Balance at January 1, 2019	32,538,857	$ 33	$751,109	$ 9,479	$ (559,045)	$ 201,576
Net loss for the period	—	—	—	—	(40,912)	(40,912)
Issuance of common stock, net of issuance costs	1,854,838	2	107,881	—	—	107,883
Share-based compensation expense	—	—	11,131	—	—	11,131
Exercise of options for cash	235,398	—	2,668	—	—	2,668
Net exercise of warrants	1,400,000	1	(1)	—	—	—
Unrealized gain on investments	—	—	—	158	—	158
Proceeds from disgorgement of stockholders' short-swing profits	—	—	1,050	—	—	1,050
Balance at March 31, 2019	36,029,093	$ 36	$873,838	$ 9,637	$ (599,957)	$ 283,554

Three Months Ended March 31, 2018

	Common Stock		Additional paid-in capital	Accumulated other comprehensive income	Accumulated deficit	Total stockholders' equity
	Shares	Amount				
Balance at January 1, 2018	28,622,886	$ 29	$ 594,407	$ 9,479	$ (460,627)	$ 143,288
Net loss for the period	—	—	—	—	(14,709)	(14,709)
Share-based compensation expense	—	—	3,660	—	—	3,660
Exercise of options for cash	402,948	—	5,890	—	—	5,890
Unrealized loss on investments	—	—	—	(288)	—	(288)
Balance at March 31, 2018	29,025,834	$ 29	$ 603,957	$ 9,191	$ (475,336)	$ 137,841

See accompanying notes

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

	Three Months Ended March 31,	
	2019	2018
Operating activities:		
Net loss	$ (40,912)	$ (14,709)
Non-cash adjustments reconciling net loss to operating cash flows:		
Depreciation of property and equipment	44	41
Accretion of discount on investments	(917)	(162)
Share-based compensation expense	11,131	3,660
Changes in operating assets and liabilities:		
Other current assets	(1,528)	502
Other long-term assets	(1,229)	(25)
Accounts payable, accrued liabilities, deferred revenue and other liabilities	(1,071)	2,745
Cash flows used in operating activities	(34,482)	(7,948)
Investing activities:		
Purchases of short-term investments	(127,458)	(102,820)
Sales and maturities of short-term investments	92,250	17,742
Cash flows used in investing activities	(35,208)	(85,078)
Financing activities:		
Proceeds from issuance of common stock, net of issuance costs	107,883	—
Proceeds from exercise of common stock options	2,668	5,890
Proceeds from disgorgement of	1,050	—

stockholders' short-swing profits				
Cash flows provided by financing activities	111,601		5,890	
Increase (decrease) in cash and cash equivalents	41,911		(87,136	)
Cash and cash equivalents, beginning of period	32,694		107,703	
Cash and cash equivalents, end of period	$	74,605	$	20,567

See accompanying notes

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MIRATI THERAPEUTICS, INC.
Notes to Condensed Consolidated Financial Statements
March 31, 2019
(Unaudited)

1. Description of Business

Mirati Therapeutics, Inc. ("Mirati" or the "Company") is a clinical-stage oncology company developing product candidates to address the genetic and immunological promoters of cancer. The Company was incorporated under the laws of the State of Delaware on April 29, 2013 as Mirati Therapeutics, Inc. and is located in San Diego, California. The Company has a wholly owned subsidiary in Canada, MethylGene, Inc., and operates in one business segment, primarily in the United States. The Company's common stock has been listed on the NASDAQ Global Select Market since June 5, 2018, and was previously listed on the NASDAQ Capital Market since July 15, 2013 under the ticker symbol "MRTX."

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, 2018 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, 2018.

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 revenue and 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 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.

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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.

Revenue Recognition

The Company recognizes revenue in connection with a collaboration and license agreement in accordance with the guidance of Revenue From Contracts With Customers, Accounting Standards Codification ("ASC") Topic 606 ("Topic 606). Under Topic 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements the Company determines are within the scope of Topic 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. See Note 9 for a complete discussion of the revenue recognition for the Company’s collaboration and license agreement.

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 common share equivalents. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares and common share equivalents 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 common share equivalents, calculated using the treasury stock method, not included in the calculation of diluted net loss per share due to the anti-dilutive effect of the securities:

	Three Months Ended March 31,	
	2019	2018
Common stock options	2,316,993	1,458,774
Common stock warrants	11,005,602	11,395,851
Total	13,322,595	12,854,625

3. Recently Adopted and Recently Issued 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.

Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued Accounting Standards Update ("ASU") 2016-02, Leases (Topic 842) in order to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet for those leases classified as operating leases under previous GAAP. ASU 2016-02 requires a lessee to recognize a liability for lease payments (the lease liability) and a right-of-use asset (representing its right to use the underlying asset for the lease term) on the balance sheet. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018 (including interim periods within those periods) using a modified retrospective approach.

In July 2018, the FASB issued ASU 2018-11, Leases (Topic 842): Targeted Improvements, which provides entities an optional transition method to apply the new guidance as of the adoption date, rather than as of the earliest period presented. In

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transition, entities may also elect a package of practical expedients that must be applied in its entirety to all leases commencing before the effective date, unless the lease was modified, to not reassess (a) the existence of a lease, (b) lease classification or (c) determination of initial direct costs, which effectively allows entities to carryforward accounting conclusions under previous U.S. GAAP.

The Company adopted ASU 2016-02, using the optional transition method and electing the package of practical expedients described above on January 1, 2019. Due to the adoption, the Company recognized a new lease liability on the Company's consolidated balance sheet for its operating lease of office and lab space of $367,000 on January 1, 2019, with a corresponding right-of-use asset of the same amount based on the present value of the remaining minimum rental payments. See Note 11 for further discussion.

In July 2017, the FASB issued ASU 2017-11, Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Non-controlling Interests with a Scope Exception. This ASU allows companies to exclude a down round feature when determining whether a financial instrument (or embedded conversion feature) is considered indexed to the entity’s own stock. As a result, financial instruments (or embedded conversion features) with down round features may no longer be required to be classified as liabilities. A company will recognize the value of a down round feature only when it is triggered and the strike price has been adjusted downward. For equity-classified freestanding financial instruments, such as warrants, an entity will treat the value of the effect of the down round, when triggered, as a dividend and a reduction of income available to common shareholders in computing basic earnings per share. For convertible instruments with embedded conversion features containing down round provisions, entities will recognize the value of the down round as a beneficial conversion discount to be amortized to earnings. Effective January 1, 2019, the Company adopted the provisions of ASU 2017-11. The adoption did not have a material impact on the Company's consolidated financial statements or related financial statement disclosures.

On August 17, 2018, the SEC adopted amendments to certain disclosure requirements in Securities Act Release No. 33-10532, Disclosure Update and Simplification. Among the amendments is the requirement to present the changes in stockholders’ equity in the interim financial statements (either in a separate statement or footnote) in quarterly reports on Form 10-Q. The amendments are effective for all filings made on or after November 5, 2018. In light of the timing of effectiveness of the amendments and proximity of effectiveness to the filing date for most filers’ quarterly reports, the SEC indicated it would not object if the filer’s first presentation of the changes in stockholders’ equity is included in its Form 10-Q for the quarter that begins after the effective date of the amendments. The Company has included a condensed consolidated statement of changes in stockholders' equity for the three months ended March 31, 2019 and 2018 in the Company's consolidated financial statements included herein.

In November 2018, the FASB issued ASU 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606. The amendments provide guidance on whether certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC 606. It also specifically (i) addresses when the participant should be considered a customer in the content of a unit of account, (ii) adds unit-of-account guidance in ASC 808 to align with guidance with ASC 606, and (iii) precludes presenting revenue from a collaborative arrangement together with revenue recognized under ASC 606 if the collaborative arrangement participant is not a customer. The guidance in ASU 2018-18 is effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. Early adoption is permitted and should be applied retrospectively. The Company elected to early adopt this guidance effective January 1, 2019. The adoption had no impact on the Company's consolidated financial statements.

Recently Issued Accounting Pronouncements

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement. The new guidance modifies the disclosure requirements on fair value measurements in Topic 820. The amendments in ASU 2018-13 are effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. The Company does not anticipate that the adoption of ASU 2018-13 will have a material impact on the Company's consolidated financial statements or related financial statement disclosures.

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4. Short-term Investments

The following tables summarize the Company's short-term investments (dollars in thousands):

		As of March 31, 2019			
	Maturity	Amortized cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
Corporate debt securities	1 year or less	$91,173	$ 75	$ (4)	$91,244
Commercial paper	1 year or less	114,219	44	(1)	114,262
U.S. Treasury bills	1 year or less	18,881	5	—	18,886
Other sovereign securities	1 year or less	1,988	—	—	1,988
		$226,261	$ 124	$ (5)	$226,380

		As of December 31, 2018			
	Maturity	Amortized cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
Corporate debt securities	1 year or less	$111,933	$ 26	$ (43)	$111,916
Commercial paper	1 year or less	74,433	—	(24)	74,409
U.S. Treasury bills	1 year or less	3,771	—	—	3,771
		$190,137	$ 26	$ (67)	$190,096

The Company has classified all of its investment securities as available-for-sale as the sale of such securities may be required prior to maturity to implement management strategies, and accordingly, carries these investments at fair value. Unrealized gains and losses on available-for-sale securities are included as a component of comprehensive loss. At March 31, 2019, 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 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 measured at fair value on a recurring basis (in thousands):

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	March 31, 2019			
	Total	Level 1	Level 2	Level 3
Assets				
Cash and cash equivalents:				
Cash	$1,909	$1,909	$—	$ —
Money market funds	72,696	72,696	—	—
Total cash and cash equivalents	74,605	74,605	—	—
Short-term investments:				
U.S. Treasury bills	18,886	18,886	—	—
Corporate debt securities	91,244	—	91,244	—
Commercial paper	114,262	—	114,262	—
Other sovereign securities	1,988	—	1,988	—
Total short-term investments	226,380	18,886	207,494	—
Total	$300,985	$93,491	$207,494	$ —

	December 31, 2018			
	Total	Level 1	Level 2	Level 3
Assets				
Cash and cash equivalents:				
Cash	$3,731	$3,731	$—	$ —
Money market funds	28,963	28,963	—	—
Total cash and cash equivalents	32,694	32,694	—	—
Short-term investments:				
U.S. Treasury bills	3,771	3,771	—	—
Corporate debt securities	111,916	—	111,916	—
Commercial paper	74,409	—	74,409	—
Total short-term investments	190,096	3,771	186,325	—
Total	$222,790	$36,465	$186,325	$ —

The Company’s investments in Level 1 assets are valued based on publicly available quoted market prices for identical securities as of March 31, 2019 and December 31, 2018. The Company determines the fair value of Level 2 related securities with the aid of valuations provided by third parties using proprietary valuation models and analytical tools. These valuation models and analytical tools use market pricing or prices for similar instruments that are both objective and publicly available, including matrix pricing or reported trades, benchmark yields, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids and/or offers. There were no transfers between fair value measurement levels during the three months ended March 31, 2019 or the year ended December 31, 2018.

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6. Other current assets and other long-term assets

Other current assets consisted of the following (in thousands):

	March 31, 2019	December 31, 2018
Prepaid expenses	$1,333	$ 1,261
Deposits and other receivables	2,985	1,841
Interest receivables	792	768
Right-of-use asset	287	—
	$5,397	$ 3,870

The other long-term assets balance consisted of $2.6 million and $1.3 million in deposits paid in conjunction with the Company's research and development activities as of March 31, 2019 and December 31, 2018, respectively.

7. Property and equipment, net

Property and equipment consisted of the following (in thousands):

	March 31, 2019	December 31, 2018
Computer equipment	$201	$ 201
Office and other equipment	260	260
Laboratory equipment	729	729
Leasehold improvements	63	63
Gross property and equipment	1,253	1,253
Less: Accumulated depreciation	(824)	(780)
Property and equipment, net	$429	$ 473

The Company incurred immaterial depreciation expense for both the three months ended March 31, 2019 and 2018.

8. Accounts payable, accrued liabilities and long-term liabilities

Accounts payable and accrued liabilities consisted of the following (in thousands):

	March 31, 2019	December 31, 2018
Accounts payable	$10,067	$ 8,531
Accrued clinical expense	10,506	10,154
Accrued development and other expense	1,454	1,243
Accrued compensation and benefits	2,438	5,847
	$24,465	$ 25,775

The long-term liabilities balance of $0.7 million as of March 31, 2019 consisted primarily of other liabilities. As of December 31, 2018 the long-term liabilities balance of $0.7 million consisted of $0.1 million in deferred revenue and $0.6 million in other liabilities.

9. BeiGene Agreement

Terms of Agreement

On January 7, 2018, the Company and BeiGene Ltd, ("BeiGene") entered into a Collaboration and License Agreement (the “Agreement”), pursuant to which the Company and BeiGene agreed to collaboratively develop sitravatinib in Asia (excluding

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Japan and certain other countries), Australia and New Zealand (the "Licensed Territory"). Under the Agreement, the Company granted BeiGene an exclusive license to develop, manufacture and commercialize sitravatinib in the Licensed Territory, with Mirati retaining exclusive rights for the development, manufacture and commercialization of sitravatinib outside the Licensed Territory.

As consideration for the rights granted to BeiGene under the Agreement, BeiGene paid the Company a non-refundable, non-creditable up-front fee of $10.0 million. BeiGene is also required to make milestone payments to the Company of up to an aggregate of $123.0 million upon the first achievement of specified clinical, regulatory and sales milestones. The Agreement additionally provides that BeiGene is obligated to pay to the Company royalties at tiered percentage rates ranging from mid-single digits to twenty percent on annual net sales of licensed products in the Licensed Territory, subject to reduction under specified circumstances. The Agreement also provides that the Company will supply BeiGene with sitravatinib for use in BeiGene's development activities in the Licensed Territory.

The Agreement will terminate upon the expiration of the last royalty term for the licensed products, which is the latest of (i) the date of expiration of the last valid patent claim related to the licensed products under the Agreement, (ii) 10 years after the first commercial sale of a licensed product and (iii) the expiration of any regulatory exclusivity as to a licensed product. BeiGene may terminate the Agreement at any time by providing 60 days prior written notice to the Company. Either party may terminate the Agreement upon a material breach by the other party that remains uncured following 60 days after the date of written notice of such breach or upon certain bankruptcy events. In addition, the Company may terminate the Agreement upon written notice to BeiGene under specified circumstances if BeiGene challenges the licensed patent rights.

Revenue Recognition

The Company evaluated the Agreement under Topic 606. In determining the appropriate amount of revenue to be recognized as the Company fulfills its obligations under the Agreement, the Company performed the following steps: (i) identified the promised goods or services in the contract; (ii) determined whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measured the transaction price, including any constraints on variable consideration; (iv) allocated the transaction price to the performance obligations; and (v) recognized revenue when (or as) the Company satisfied each performance obligation.

The Company determined the transaction price is equal to the up-front fee of $10.0 million. The transaction price was allocated to the performance obligations on the basis of the relative stand-alone selling price estimated for each performance obligation. In estimating the stand-alone selling price for each performance obligation, the Company developed assumptions that require judgment and included forecasted revenues, expected development timelines, discount rates, probabilities of technical and regulatory success and costs for manufacturing clinical supplies. A description of the performance obligations identified under the Agreement, as well as the amount of revenue allocated to each performance obligation, follows:

Licenses of Intellectual Property. The license to the Company's intellectual property, bundled with the associated know-how, represents a distinct performance obligation. The transfer of the license and associated know-how to BeiGene was completed during the three months ended March 31, 2018. The Company recognized no revenue associated with the license and know-how during the three months ended March 31, 2019 and recognized $9.5 million during the three months ended March 31, 2018 as license and collaboration revenues in its condensed consolidated statements of operations and comprehensive loss.

Manufacturing Supply Services. The Company's initial obligation to supply sitravatinib for clinical development in the Licensed Territory represents a distinct performance obligation. As such, the Company deferred $0.5 million of

the transaction price related to the manufacturing supply services. The Company recognizes revenue when BeiGene obtains control of the goods, upon delivery, over the period of the obligation, which began in late 2018 and will continue into 2020. The Company recognized $1.2 million as license and collaboration revenues for this performance obligation for the three months ended March 31, 2019, of which $1.1 million relates to cost-sharing payments due from BeiGene and $0.1 million relates to recognition from the deferred revenue balance. No revenue related to the manufacturing supply services obligation was recognized during the three months ended March 31, 2018. At March 31, 2019, $1.1 million of cost-sharing receivable from BeiGene was recorded in other current assets on the condensed consolidated balance sheets.

Milestone Payments. The Company is entitled to development milestones under the agreement. The next clinical development milestone is for BeiGene initiating the first pivotal clinical trial in the Licensed Territory upon which the Company will be paid a $5.0 million milestone payment. The Company is also entitled to certain regulatory milestone payments which are paid upon receipt of regulatory approvals within the Licensed Territory. No milestone payments were earned during the three months ended March 31, 2019 or 2018. The Company

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evaluated whether the remaining milestones are considered probable of being reached and determined that the remaining potential milestone payments are probable of significant revenue reversal as their achievement is highly dependent on factors outside the Company's control. Therefore, these payments have been fully constrained and are not included in the transaction price. At the end of each subsequent reporting period, the Company will re-evaluate the probability of achievement of each milestone and any related constraint, and if necessary, adjust its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect the reported amount of license and collaboration revenues in the period of adjustment.

Royalties. As the license is deemed to be the predominant item to which sales-based royalties relate, the Company will recognize revenue when the related sales occur. No royalty revenue was recognized during the three months ended March 31, 2019 or 2018.

The following table presents a summary of the activity in the Company's contract liabilities during the three months ended March 31, 2019 (in thousands):

Opening balance, January 1, 2019	$(481)
Revenue from performance obligations satisfied during reporting period	108
Closing Balance, March 31, 2019	$(373)

The closing balance represents deferred revenue and is classified primarily within current liabilities at March 31, 2019.

10. Warrants

As of March 31, 2019, the following warrants for common stock were issued and outstanding:

Issue date	Expiration date	Exercise price	Number of warrants outstanding
January 11, 2017	None	$ 0.001	5,858,238
November 20, 2017	None	$ 0.001	4,137,999
June 11, 2018	None	$ 0.001	421,650
			10,417,887

During the three months ended March 31, 2019, 1,400,025 warrants for shares of the Company's common stock were exercised via cashless exercise, resulting in the issuance of 1,400,000 shares of common stock. During the three months ended March 31, 2018, no warrants were exercised.

11. Commitments and Contingencies

On June 24, 2014, the Company entered into a lease agreement for completed office and laboratory space located in San Diego, California. The office space under the lease is the Company's corporate headquarters. The lease commenced in two phases (in July 2014 and March 2015) at a combined total initial monthly rent of $24,100 per month. The leased property is subject to a 3% annual rent increase following availability. In addition to such base monthly rent, the Company is obligated to pay certain customary amounts for its share of operating expenses and facility amenities. The original lease provided for expiration on January 31, 2018. On March 23, 2017, the Company entered into a First Amendment to Lease Agreement to amend the original lease agreement and to extend the term of the original lease for one year through January 31, 2019. On April 5, 2018, the Company entered into a Second Amendment to Lease Agreement to extend the lease term through January 31, 2020. Subsequently, on August 2, 2018, the Company entered into a Third Amendment to Lease Agreement to expand the size of the existing space for an

additional base rent of $4,000 per month. All other terms and covenants from the original lease agreement remain unchanged.

The Company's building lease is considered to be an operating lease. The lease agreement indicates the interest rate applicable to the lease is 12%, therefore the Company used a discount rate of 12% to calculate the value of its lease obligations. As of March 31, 2019, the condensed consolidated balance sheet includes a $0.3 million operating lease right-of-use asset within other current assets, and a $0.3 million operating lease liability in deferred revenue and other current liabilities. For the three months ended March 31, 2019, the Company recorded $0.1 million in operating lease cost and the building lease has a remaining lease term of approximately one year from March 31, 2019. As of March 31, 2019, remaining lease payments on an undiscounted basis are $0.3 million for 2019 and an immaterial amount for 2020.

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12. Stockholders' Equity

Sale of Common Stock

In January 2019, the Company sold 1,854,838 shares of its common stock at a public offering price of $62.00 per share. After deducting underwriter discounts, commissions and offering expenses, the Company received net cash proceeds from the transaction of $107.9 million.

Share-based Compensation

Total share-based compensation expense by statement of operations classification is presented below (in thousands):

	Three Months Ended March 31,	
	2019	2018
Research and development expense	$5,157	$1,493
General and administrative expense	5,974	2,167
	$11,131	$3,660

During the three months ended March 31, 2019, 235,398 shares were issued pursuant to stock option exercises, generating net proceeds of $2.7 million. During the three months ended March 31, 2018, 402,948 shares were issued pursuant to stock option exercises, generating net proceeds of $5.9 million.

Disgorgement Proceeds

In January 2019, the Company received a payment of $1.1 million representing a disgorgement of short-swing profits from the sale of common stock by a beneficial owner pursuant to Section 16(b) of the Securities Exchange Act of 1934, as amended. The Company recognized these proceeds as a capital contribution from stockholders and reflected a corresponding increase to additional paid-in capital.

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ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited financial statements and related notes included in this Quarterly Report on Form 1O-Q and the audited financial statements and notes thereto as of and for the year ended December 31, 2018 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K filed by us with the Securities and Exchange Commission ("SEC").

This Quarterly Report on Form 10-Q may contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Such forward-looking statements, which represent our intent, belief, or current expectations, involve risks and uncertainties. We use words such as "may," "will," "expect," "anticipate," "estimate," "intend," "plan," "predict," "potential," "believe," "should" and similar expressions to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Such statements may include, but are not limited to, statements concerning projections about our accounting and finances, plans and objectives for the future, future operating and economic performance and other statements regarding future performance. Although we believe the expectations reflected in these forward-looking statements are reasonable, such statements are inherently subject to risk and we can give no assurances that our expectations will prove to be correct. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this Quarterly Report on Form 10-Q. As a result of many factors, including without limitation those set forth under "Risk Factors" under Item 1A of Part II below, and elsewhere in this Quarterly Report on Form 10-Q, our actual results may differ materially from those anticipated in these forward-looking statements. We undertake no obligation to update these forward-looking statements to reflect events or circumstances after the date of this report or to reflect actual outcomes.

References in the following discussion to "we," "our," "us," "Mirati" or "the Company" refer to Mirati Therapeutics, Inc. and its subsidiaries.

Overview

Company Overview

Mirati Therapeutics, Inc. is a clinical-stage oncology company developing product candidates to address the genetic and immunological promoters of cancer. Our precision oncology clinical programs utilize genomic testing to identify and select cancer patients who we believe would be most likely to benefit from targeted treatment. In immuno-oncology, we are advancing a clinical program where our product candidate has the potential to improve the immune environment of tumor cells and enhance and expand the efficacy of existing cancer immunotherapy medicines when given in combination. Our KRAS inhibitor program is focused on developing novel inhibitors of KRAS mutations and includes one clinical program and a preclinical program. We also have additional preclinical programs which include potentially first-in-class and best-in-class product candidates specifically designed to address mutations and tumors where few treatment options exist. We approach each of our discovery and development programs with a singular focus: to translate our deep understanding of the molecular drivers of cancer into better therapies and better outcomes for patients.

Our clinical programs consist of two product candidates: sitravatinib, a multi-kinase inhibitor, and MRTX849, a KRAS G12C inhibitor. We have several early discovery programs, including a preclinical program for a KRAS G12D inhibitor.

Sitravatinib

Sitravatinib is a spectrum-selective kinase inhibitor designed to potently inhibit receptor tyrosine kinases ("RTK"s), including TAM family receptors (TYRO3, Axl, Mer), split family receptors (VEGFR2, KIT) and RET. Sitravatinib is

an investigational agent that is being evaluated both in combination with an immune checkpoint inhibitor and as a single agent.

Sitravatinib in Combination with Immune Checkpoint Inhibitors

Background

Sitravatinib's potent inhibition of TAM and split family RTKs may overcome resistance to checkpoint inhibitor therapy through targeted reversal of an immunosuppressive tumor microenvironment, enhancing antigen-specific T cell response and expanding dendritic cell-dependent antigen presentation.

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As an immuno-oncology agent, sitravatinib is being evaluated in combination with nivolumab (OPDIVO®), Bristol-Myers Squibb Company's ("BMS") anti-PD-1 checkpoint inhibitor, in patients with non-small cell lung cancer ("NSCLC") who have experienced documented disease progression following treatment with a checkpoint inhibitor. Sitravatinib is also being developed in certain Asian territories in collaboration with BeiGene, Ltd. ("BeiGene") who are evaluating sitravatinib in combination with tislelizumab, BeiGene's investigational anti-PD-1 checkpoint inhibitor in a number of advanced solid tumors.

Program Update

In an ongoing Phase 2 clinical trial, we are evaluating sitravatinib in combination with nivolumab in patients with NSCLC who have experienced documented disease progression following prior treatment with a checkpoint inhibitor. On October 22, 2018, we reported data from this clinical trial at the 2018 European Society of Medical Oncology Congress ("ESMO"), based on a data cutoff date of August 27, 2018. A summary of these data, with response confirmations updated after the data cutoff date, is presented below:

- 56 patients were evaluable for response with at least one radiographic scan. Patients had a median of two lines of previous therapy;
- 45 of 56 evaluable patients demonstrated tumor reductions; 18 of whom demonstrated tumor reductions greater than 30%;
- 11 of 56 evaluable patients achieved a confirmed Partial Response ("PR") or Complete Response;
- 26 of 56 evaluable patients remained on treatment at the time of data cut-off including eight responding patients;
- A preliminary Kaplan-Meier estimate of median duration of response was greater than nine months, with six responding patients treated for more than six months and two responding patients treated for more than 12 months; and
- The combination has shown an acceptable toxicity profile, and most adverse events reported by investigators were Grade 1 or 2.

We held an end of Phase 2 meeting with the U.S. Food and Drug Administration ("FDA") in the third quarter of 2018 with respect to the development of sitravatinib in combination with a checkpoint inhibitor in NSCLC. Based on feedback received from the FDA, early in the second quarter of 2019 we expect to initiate a Phase 3 randomized clinical trial in second-line NSCLC patients. The Phase 3 clinical trial is comparing the combination of sitravatinib plus nivolumab to docetaxel in patients whose tumors have progressed on prior therapy with platinum-chemotherapy in combination with a checkpoint inhibitor. Ultimately, we expect the results of this clinical trial to enable a new drug application ("NDA") submission for the treatment of NSCLC patients whose tumors have progressed following treatment with a platinum-containing regimen in combination with a checkpoint inhibitor. This Phase 3 clinical trial will include an interim analysis of objective response rates (which we expect to complete by the end of 2020) as a surrogate endpoint to serve as the basis for a potential NDA submission seeking accelerated approval in the United States. The primary endpoint of the final analysis for the Phase 3 clinical trial (which we expect to complete by the end of 2021) will be overall survival.

On January 7, 2019, we announced a clinical collaboration with BMS in connection with the aforementioned Phase 3 clinical trial. Under the terms of the collaboration, Mirati will sponsor and fund the clinical trial and BMS will provide nivolumab at no cost. In certain specified cases, BMS will have an exclusive right to negotiate a commercial agreement with us for a limited period of time with respect to developing and commercializing sitravatinib worldwide

excluding certain territories in Asia, Australia and New Zealand. We maintain global development and commercial rights to sitravatinib outside of certain Asian territories, where we have partnered with BeiGene, and we are free to develop the program in combination with other agents.

During the third quarter of 2018, we initiated an open label Phase 2 clinical trial of sitravatinib in combination with nivolumab in patients with advanced or metastatic urothelial carcinoma who previously failed treatment with an immune checkpoint inhibitor. We expect to receive initial data from this clinical trial in the second half of 2019.

During the third quarter of 2018, we also initiated an open label Phase 2 window of opportunity clinical trial to assess the mechanism of action of sitravatinib combined with nivolumab in patients with advanced clear cell renal cell cancer ("RCC"). We expect to receive initial data from this clinical trial in the second half of 2019.

Sitravatinib as a Single Agent

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Background

Sitravatinib is also being evaluated as a single agent in a Phase 1b expansion clinical trial in patients with NSCLC and other tumor types who have genetic alterations in Casitas B-lineage Lymphoma ("CBL").

Program update

On October 21, 2018, we reported data from this Phase 1b clinical trial in a presentation at ESMO. The presentation provided an update from the pre-planned expansion cohort of the Phase 1b clinical trial of single agent sitravatinib in patients with CBL inactivating mutations. CBL mutations are present in approximately 1.5% of NSCLC tumors, 3.5% of melanoma tumors, and 2% of cancers of unknown origin. As of the data cut-off on September 4, 2018, eight patients were evaluable:

- In the subset of evaluable NSCLC patients (n=2), one confirmed PR was observed, and one patient experienced stable disease with significant tumor regression;
- In the subset of evaluable melanoma patients (n=2), one confirmed PR was observed, and one patient had stable disease; and
- In the subset of evaluable patients with other solid tumors (n=4), two had stable disease and two had progression of disease.

Enrollment continues in this Phase 1b expansion clinical trial with an emphasis on patients with CBL inactivating mutations in NSCLC and melanoma. We expect to provide a clinical update in the second half of 2019 and to define a potential registration pathway based on updated data at that time.

Sitravatinib Development in Collaboration with BeiGene, Ltd.

In January 2018, we entered into a Collaboration and License Agreement (the “BeiGene Agreement”) with BeiGene, pursuant to which we and BeiGene agreed to collaboratively develop sitravatinib in Asia (excluding Japan and certain other countries), Australia and New Zealand (the “Licensed Territory”). Under the BeiGene Agreement, we granted BeiGene an exclusive license to develop, manufacture and commercialize sitravatinib in the Licensed Territory, and we retained exclusive rights for the development, manufacturing and commercialization of sitravatinib outside the Licensed Territory.

In November 2018, we announced the dosing of the first patient under the BeiGene Agreement in a Phase 1b clinical trial to assess the safety and tolerability, pharmacokinetics and preliminary anti-tumor activity of sitravatinib in combination with BeiGene's investigational anti-PD-1 antibody, tislelizumab, in patients with advanced solid tumors. The clinical trial is currently enrolling patients in China and Australia. BeiGene's clinical trials will evaluate the combination of sitravatinib and tislelizumab in patients with NSCLC, RCC, hepatocellular cancer, gastric cancer and ovarian cancer. We expect to receive initial proof of concept data from these clinical trials in the second half of 2019 and the first half of 2020.

KRAS Inhibitor Program

Background

The RAS family of genes is the most commonly mutated oncogene and mutations in this gene family occur in up to approximately 25% of all human cancers. Among the RAS family members, mutations most frequently occur in

KRAS (approximately 85% of all RAS family mutations). Tumors characterized by KRAS mutations are commonly associated with poor prognosis and resistance to therapy. Nonclinical studies have demonstrated that cancer cells exhibiting KRAS mutations are highly dependent on KRAS function for cell growth and survival. Historically, KRAS has been extremely difficult to directly inhibit due to the absence of a tractable small molecule drug binding site. Our KRAS inhibitor program is focused on the discovery and development of small molecule compounds that target KRAS G12C and G12D. We intend to pursue development of our KRAS G12C inhibitor program in both single agent and rational combination approaches to maximize the potential market opportunity.

Program Update

Our lead KRAS G12C compound, MRTX849, is an investigational, specific, potent and orally available small molecule. MRTX849 is designed to directly inhibit KRAS G12C mutations which are present in approximately 14% of NSCLC adenocarcinoma patients, 4% of colorectal cancer (“CRC”) patients, 2% of pancreatic cancer patients, as well as smaller percentages of several other difficult-to-treat cancers. Single agent treatment with MRTX849 has shown complete regression in a subset of

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KRAS G12C-positive human tumor models implanted in mice. We received FDA authorization of our Investigational New Drug Application for MRTX849 in November 2018, and on January 15, 2019, we announced that we had dosed the first patient in the dose escalation phase of a phase 1/2 clinical trial in patients with advanced solid tumors that harbor G12C mutations. This trial is designed to enable rapid expansion of the single agent cohorts and could potentially serve as the basis of an NDA filing for accelerated approval by the FDA. This trial also enables exploratory combination cohorts. Following single agent dose escalation, we plan to expand into cohorts that include patients with NSCLC, CRC and those with other tumors that carry the G12C mutation. We expect to report early clinical results in the second half of 2019. We also have a preclinical program targeting KRAS G12D mutations and expect to identify a clinical candidate by the fourth quarter of 2019.

Critical Accounting Policies and Significant Judgments and Estimates

Our discussion and analysis of financial condition and results of operations are based upon our condensed consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make significant estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses and related disclosures. On an ongoing basis, our actual results may differ significantly from our estimates.

There have been no material changes to our critical accounting policies and estimates from the information provided in Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations, included in our Annual Report on Form 10-K for the year ended December 31, 2018.

Results of Operations

Comparison of the Three Months Ended March 31, 2019 and 2018

The following table summarizes the significant items within our results of operations for the three months ended March 31, 2019 and 2018 (in thousands):

	Three months ended March 31,		Increase
	2019	2018	(Decrease)
License and collaboration revenues	$1,244	$9,467	$(8,223)
Research and development expenses	$34,240	$19,659	$14,581
General and administrative expenses	9,762	5,154	4,608
Other income, net	1,846	637	1,209

Revenues

License and collaboration revenues relate to the BeiGene Agreement under which BeiGene was granted an exclusive license to develop, manufacture and commercialize sitravatinib in the Licensed Territory. License and collaboration revenues for the three months ended March 31, 2019 were $1.2 million and relate to revenues earned related to a manufacturing supply services agreement with BeiGene. License and collaboration revenues for the three months ended March 31, 2018 were $9.5 million and relate to the transfer of the license and associated know-how to BeiGene.

Research and development expenses

Research and development expenses consist primarily of:

- salaries and related expenses for personnel, including expenses related to stock options or other share-based compensation granted to personnel in research and development functions;
- fees paid to external service providers such as Clinical Research Organizations ("CROs") and contract manufacturing organizations related to clinical trials, including contractual obligations for clinical development, clinical sites, manufacturing and scale-up, and formulation of clinical drug supplies;
- fees paid to contract services related to drug discovery efforts including chemistry and biology services; and

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- costs for allocated facilities and depreciation of equipment.

We record research and development expenses as incurred. We account for nonrefundable advance payments for goods and services that will be used in future research and development activities as expense when the services have been performed or when the goods have been received. At this time, due to the risks inherent in the clinical development process and the early stage of our product development programs and preclinical programs, we are unable to estimate with any certainty the costs we will incur in the continued development of sitravatinib, MRTX849, and our preclinical programs. The process of conducting clinical trials necessary to obtain regulatory approval and manufacturing scale-up to support expanded development and potential future commercialization is costly and time consuming. Any failure by us or delay in completing clinical trials, manufacturing scale-up or in obtaining regulatory approvals could lead to increased research and development expense and, in turn, have a material adverse effect on our results of operations. We expect that our research and development expenses may increase if we are successful in advancing our sitravatinib, MRTX849 and our preclinical KRAS G12D program, or any of our other preclinical programs, into more advanced stages of clinical development.

Our research and development efforts during the three months ended March 31, 2019 and 2018 were focused on our clinical development programs and our preclinical programs. The following table summarizes our research and development expenses (in thousands):

	Three months ended March 31,		Increase (Decrease)
	2019	2018	
Third-party research and development expenses:			
Clinical development programs:			
Sitravatinib	13,729	7,148	6,581
MRTX849	4,622	—	4,622
Mocetinostat	689	1,373	(684)
Glesatinib	400	2,099	(1,699)
Pre-clinical development programs:			
KRAS inhibitors	4,438	3,689	749
Preclinical and early discovery	787	348	439
Total third-party research and development expenses	24,665	14,657	10,008
Salaries and other employee related expense	3,816	2,790	1,026
Share-based compensation expense	5,157	1,493	3,664
Other research & development costs	602	719	(117)
Research and development expense	$34,240	$19,659	$14,581

Research and development expenses for the three months ended March 31, 2019 were $34.2 million compared to $19.7 million for the three months ended March 31, 2018. The increase of $14.6 million primarily relates to increases in third-party development expense of $10.0 million, share-based compensation expense of $3.7 million and salaries and other employee related expense of $1.0 million. The increase in third-party research and development expense relates to an increase in expenses associated with development of sitravatinib of $6.6 million and MRTX849 of $4.6 million, offset by decreases in expenses associated with the development of glesatinib and mocetinostat of $1.7 million and $0.7 million, respectively. The increase in development expense for sitravatinib is due to increased manufacturing production expenses, investigator payment expenses, and CRO expenses to support the expansion of existing and new sitravatinib clinical trials. The increase in expenses associated with MRTX849 relates to the Phase 1 clinical trial for this compound which was initiated in the first quarter of 2019 and the costs are comprised largely of manufacturing production expenses and CRO and other clinical trial-related expenses. The decreases in expense associated with glesatinib and mocetinostat are due to the decision to discontinue development for each program. The increase in share-based compensation expense of $3.7 million is due to an increase in the fair value of stock options granted during the three months ended March 31, 2019 compared to the same period in 2018. The increase in salaries

and other employee related expense of $1.0 million is primarily due to an increase in the number of research and development employees employed during the three months ended March 31, 2019 compared to the same period in 2018.

General and administrative expenses

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General and administrative expenses consist primarily of salaries and related benefits, including share-based compensation, related to our executive, finance, business development, legal and support functions. Other general and administrative expenses include professional fees for auditing and tax services, rent and utilities and insurance.

General and administrative expenses for the three months ended March 31, 2019 and 2018 were $9.8 million and $5.2 million, respectively, resulting in an increase of $4.6 million. The increase is largely due to an increase in share-based compensation expense of $3.8 million due to an increase in the fair value of stock options granted during the three months ended March 31, 2019 compared to the same period in 2018.

Other Income, Net

Other income, net for the three months ended March 31, 2019 was $1.8 million compared to $0.6 million for the same period in 2018 and consists primarily of interest income. The increase primarily reflects higher average cash balances available for investment.

Liquidity and Capital Resources

At March 31, 2019, we had $301.0 million of cash, cash equivalents and short-term investments compared to $222.8 million at December 31, 2018. In January 2019, we completed a public offering of our common stock that generated net cash proceeds of $107.9 million. Based on our current and anticipated level of operations, we believe that our cash, cash equivalents and short-term investments will be sufficient to meet our anticipated obligations for at least one year from the date that this Quarterly Report on Form 10-Q is filed with the SEC.

To date, we have funded our operations primarily through the sale of our common stock, pre-funded warrants to purchase our common stock, and to a lesser extent through up-front payments, research funding and milestone payments under collaborative arrangements. Since inception, we have primarily devoted our resources to funding research and development programs, including discovery research, preclinical and clinical development activities. To fund future operations, we will likely need to raise additional capital. The amount and timing of future funding requirements will depend on many factors, including the timing and results of our ongoing development efforts, the potential expansion of our current development programs, potential new development programs and related general and administrative support. We anticipate that we will seek to fund our operations through public or private equity or debt financings or other sources, such as potential collaboration agreements. We cannot make assurances that anticipated additional financing will be available to us on favorable terms, or at all. Although we have previously been successful in obtaining financing through our equity securities offerings, there can be no assurance that we will be able to do so in the future.

Cash Flows for the Three Months Ended March 31, 2019 and 2018

The following table provides a summary of the net cash flow activity for each of the periods set forth below (in thousands):

	Three months ended March 31,	
	2019	2018
Net cash used in operating activities	$(34,482)	$(7,948)
Net cash used in investing activities	(35,208)	(85,078)
Net cash provided by financing activities	111,601	5,890
Increase (decrease) in cash	41,911	(87,136)

Net cash used in operating activities

Net cash used in operating activities for the three months ended March 31, 2019 was $34.5 million, compared to $7.9 million for the three months ended March 31, 2018, an increase of $26.5 million. Cash used in operating activities during 2019 primarily related to our net loss of $40.9 million, adjusted for non-cash items such as share-based compensation of $11.1 million and net cash inflows from a change in our operating assets and liabilities of $3.8 million. Cash used in operating activities during 2018 primarily related to our net loss of $14.7 million, adjusted for non-cash items such as share-based compensation expense of $3.7 million and net cash outflows from a change in our operating assets and liabilities of $3.2 million.

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Net cash used in investing activities

For the three months ended March 31, 2019 and March 31, 2018, investing activities used cash of $35.2 million and $85.1 million, respectively due to purchases of short-term investments, offset by maturities of short-term investments.

Net cash provided by financing activities

Net cash provided by financing activities for the three months ended March 31, 2019 was $111.6 million and consisted of proceeds received from the issuance of common stock, exercise of common stock options, and disgorgement of stockholders' short-swing profits. Net cash provided by financing activities for the three months ended March 31, 2018 was $5.9 million and consisted entirely of proceeds from the exercise of common stock options.

Off-Balance Sheet Arrangements

During the three months ended March 31, 2019, we did not have any off-balance sheet arrangements (as defined by applicable SEC regulations) that are reasonably likely to have a current or future material effect on our financial condition, results of operations, liquidity, capital expenditures or capital resources.

Contractual Obligations and Commitments

There were no material changes outside of the ordinary course of business to our specific contractual obligations during the three months ended March 31, 2019.

Recent Accounting Pronouncements

Occasionally, new accounting standards are issued or proposed by the Financial Accounting Standards Board, or other standard-setting bodies that we adopt by the effective date specified within the standard. Unless otherwise discussed, standards that do not require adoption until a future date are not expected to have a material impact on our financial statements upon adoption.

ITEM 3. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

Some of our short-term investments have market risk in that a change in prevailing interest rates may cause the fair value of the principal amount of the investment to fluctuate. Financial instruments that potentially subject us to significant concentrations of credit risk consist primarily of cash, cash equivalents and short-term investments. We invest our excess cash primarily in commercial paper and debt instruments of financial institutions, corporations, U.S. government-sponsored agencies and the U.S. Treasury. We mitigate credit risk by maintaining a well-diversified portfolio and limiting the amount of investment exposure as to institution, maturity and investment type. We invest our excess cash in accordance with our investment policy.

Because of the short-term maturities of our cash equivalents and short-term investments, we do not believe that an increase in market rates would have any significant impact on the realized value of our investments. If a 1% change in interest rates were to have occurred on March 31, 2019, this change would not have had a material effect on the fair value of our investment portfolio as of that date.

Effects of Inflation

We do not believe that inflation and changing prices had a significant impact on our results of operations for any periods presented herein.

ITEM 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(b) and Rule 15d-15(b) of the Exchange Act, our management, including our principal executive officer and our principal financial officer, conducted an evaluation as of the end of the period covered by this Quarterly Report

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on Form 10-Q of the effectiveness of the design and operation of our disclosure controls and procedures. Based on that evaluation, management has concluded that as of March 31, 2019, the Company's disclosure controls and procedures were effective at the reasonable assurance level and we believe the condensed consolidated financial statements included in this Form 10-Q for the three months ended March 31, 2019 present, in all material respects, our financial position, results of operations, comprehensive loss and cash flows for the periods presented in conformity with U.S. generally accepted accounting principles.

Changes in Internal Control over Financial Reporting

As required by Rule 13a-15(d) and Rule 15d-15(d) of the Exchange Act, our management, including our principal executive officer and our principal financial officer, conducted an evaluation of the internal control over financial reporting to determine whether any changes occurred during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Based on that evaluation, our principal executive officer and principal financial officer concluded that there were no changes in our internal controls over financial reporting during the period covered by this Quarterly Report on Form 10-Q that materially affected, or were reasonably likely to materially affect, our internal control over financial reporting.

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PART II-OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

ITEM 1A. Risk Factors.

You should consider carefully the following information about the risks described below, together with the other information contained in this Quarterly Report and in our other public filings in evaluating our business. The risk factors set forth below with an asterisk (*) next to the title contain changes to the description of the risk factors associated with our business previously disclosed in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2018. Additional risks and uncertainties that we are unaware of may also become important factors that affect us. If any of the following risks actually occurs, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline.

Risks Relating to Our Financial Position and Capital Requirements

* We will require additional financing and may be unable to raise sufficient capital, which could lead us to delay, reduce or abandon development programs or commercialization.

Our operations have consumed substantial amounts of cash since inception. Our research and development expenses were $34.2 million and $19.7 million for the three months ended March 31, 2019 and 2018, respectively. We will require substantial additional capital to pursue additional clinical development for our lead clinical programs, including conducting late-stage clinical trials, manufacturing clinical supplies and potentially developing other assets in our pipeline, and, if we are successful, to commercialize any of our current product candidates. If the U.S. Food and Drug Administration ("FDA") or any foreign regulatory agency, such as the European Medicines Agency ("EMA") requires that we perform studies or trials in addition to those that we currently anticipate with respect to the development of our product candidates, or repeat studies or trials, our expenses would further increase beyond what we currently expect. We may not be able to adequately finance our development programs, which could limit our ability to move our programs forward in a timely and satisfactory manner or require us to abandon the programs, any of which would harm our business, financial condition and results of operations. Because successful development of our product candidates is uncertain, we are unable to estimate the actual funds we will require to complete research and development and commercialize our product candidates.

If we are unable to obtain funding from equity offerings or debt financings on a timely basis, we may be required to (1) seek additional collaborators for one or more of our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; (2) relinquish or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves; or (3) significantly curtail one or more of our research or development programs or cease operations altogether.
We are a clinical-stage company with no approved products and no historical product revenue. Consequently, we expect that our financial and operating results will vary significantly from period to period.

We are a clinical-stage company that has incurred losses since its inception and expect to continue to incur substantial losses in the foreseeable future. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of uncertainty.

Our actual financial condition and operating results have varied significantly in the past and are expected to continue to fluctuate significantly from quarter-to-quarter or year-to-year due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include:

- the success of our clinical trials through all phases of clinical development;

- delays in the commencement, enrollment and timing of clinical trials;

- our ability to secure and maintain collaborations, licensing or other arrangements for the future development and/or commercialization of our product candidates, as well as the terms of those arrangements;

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- our ability to obtain, as well as the timeliness of obtaining, additional funding to develop our product candidates;
- the results of clinical trials or marketing applications for product candidates that may compete with our product candidates;
- competition from existing products or new products that may receive marketing approval;
- potential side effects of our product candidates that could delay or prevent approval or cause an approved drug to be taken off the market;
- any delays in regulatory review and approval of our clinical development plans or product candidates;
- our ability to identify and develop additional product candidates;
- the ability of patients or healthcare providers to obtain coverage or sufficient reimbursement for our products;
- our ability, and the ability of third parties such as Clinical Research Organizations ("CROs") to adhere to clinical study and other regulatory requirements;
- the ability of third-party manufacturers to manufacture our product candidates and key ingredients needed to conduct clinical trials and, if approved, successfully commercialize our products;
- the costs to us, and our ability as well as the ability of any third-party collaborators, to obtain, maintain and protect our intellectual property rights;
- costs related to and outcomes of potential intellectual property litigation;
- our ability to adequately support future growth;
- our ability to attract and retain key personnel to manage our business effectively; and
- our ability to build our finance infrastructure and, to the extent required, improve our accounting systems and controls.

Accordingly, the likelihood of our success must be evaluated in light of many potential challenges and variables associated with a clinical-stage company, many of which are outside of our control, and past operating or financial results should not be relied on as an indication of future results. Fluctuations in our operating and financial results could cause our share price to decline. It is possible that in some future periods, our operating results will be above or below the expectations of securities analysts or investors, which could also cause our share price to decline.

* We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future. We have never generated any revenue from product sales and may never be profitable.

We have derived limited revenue from our research, collaboration and licensing agreements which has not been sufficient to cover the substantial expenses we have incurred in our efforts to develop our product candidates. Consequently, we have accumulated net losses since inception in 1995. Our net loss for the three months ended March 31, 2019 and 2018 was $40.9 million and $14.7 million, respectively. As of March 31, 2019, we had an accumulated deficit of $600.0 million. Our prior losses, combined with expected future losses, have had and will

continue to have an adverse effect on our stockholders' equity and working capital. Such losses are expected to increase in the future as we continue the development of our product candidates and seek regulatory approval and commercialization for our product candidates. We are unable to predict the extent of any future losses or when we will become profitable, if ever. Even if we do achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis.

We do not anticipate generating revenue from sales of products for the foreseeable future, if ever. If any of our product candidates fail in clinical trials or do not gain regulatory approval, or if any of our product candidates, if approved, fail to achieve market acceptance, we may never become profitable. If one or more of our product candidates is approved for commercial sale and we retain commercial rights, we anticipate incurring significant costs associated with commercializing any such approved product candidate. Therefore, even if we are able to generate revenue from the sale of any approved product, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our ability to generate future revenue from product sales depends heavily on our success in:

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- completing development and clinical trial programs for our product candidates;
- maintaining existing collaboration and licensing agreements and entering into additional ones;
- seeking and obtaining marketing approvals for any product candidates that successfully complete clinical trials;
- establishing and maintaining supply and manufacturing relationships with third parties;
- successfully commercializing any product candidates for which marketing approval is obtained; and
- successfully establishing a sales force and marketing and distribution infrastructure.

Raising additional funds through debt or equity financing will be dilutive and raising funds through licensing agreements may be dilutive, restrict operations or relinquish proprietary rights.

To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of those securities could result in substantial dilution for our current stockholders and the terms may include liquidation or other preferences that adversely affect the rights of our current stockholders. Existing stockholders may not agree with our financing plans or the terms of such financings. Moreover, the incurrence of debt financing could result in a substantial portion of our operating cash flow being dedicated to the payment of principal and interest on such indebtedness and could impose restrictions on our operations. In addition, if we raise additional funds through future collaboration and licensing arrangements, it may be necessary to relinquish potentially valuable rights to our products or proprietary technologies, or to grant licenses on terms that are not favorable to us. Additional funding may not be available to us on acceptable terms, or at all.

As a public company in the United States, we incur significant legal and financial compliance costs and we are subject to the Sarbanes-Oxley Act. We can provide no assurance that we will, at all times, in the future be able to report that our internal controls over financial reporting are effective.

Companies that file reports with the Securities and Exchange Commission ("SEC"), including us, are subject to the requirements of Section 404 of the Sarbanes-Oxley Act of 2002. Section 404 requires management to establish and maintain a system of internal control over financial reporting, and annual reports on Form 10-K filed under the Securities Exchange Act of 1934, as amended ("the Exchange Act"), must contain a report from management assessing the effectiveness of a company’s internal control over financial reporting. Ensuring that we have adequate internal financial and accounting controls and procedures in place to produce accurate financial statements on a timely basis remains a costly and time-consuming effort that needs to be re-evaluated frequently. Failure on our part to have effective internal financial and accounting controls would cause our financial reporting to be unreliable, could have a material adverse effect on our business, operating results, and financial condition, and could cause our stock price to decline as a result.

If we cannot conclude that we have effective internal control over our financial reporting, or if our independent registered public accounting firm is unable to provide an unqualified opinion regarding the effectiveness of our internal control over financial reporting, investors could lose confidence in the reliability of our financial statements. Failure to comply with reporting requirements could also subject us to sanctions and/or investigations by the SEC, The NASDAQ Global Select Market or other regulatory authorities.

Furthermore, shareholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently

anticipate. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, any new regulations or disclosure obligations may increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

The timing of the milestone and royalty payments we are entitled to receive from BeiGene, Ltd. is uncertain and could adversely affect our cash flows and results of operations.

In January 2018 we entered into a collaboration and license agreement with BeiGene, Ltd. (“BeiGene”) (the “BeiGene Agreement”), pursuant to which we agreed to collaboratively develop sitravatinib in Asia (excluding Japan and certain other countries), Australia and New Zealand (the “BeiGene Territory”) and we granted BeiGene an exclusive license to develop, manufacture and commercialize sitravatinib in the BeiGene Territory. In addition to an up-front payment, we may be entitled to receive additional payments upon the achievement of certain milestones under the BeiGene Agreement. However, the receipt of

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these payments is inherently uncertain. The receipt of milestone payments under the BeiGene Agreement can have a significant impact on our cash flows and results of operations for the periods of time in which such payments are made. While receipt of milestone and royalty payments would result in significant income, the absence of collaboration revenues in subsequent quarters could result in significant reductions in net income and could cause our stock price to drop.

U.S. federal income tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, U.S. federal income tax legislation was signed into law (H.R. 1, "An Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018", informally titled the Tax Cuts and Jobs Act, or the Tax Act) that significantly revises the Internal Revenue Code of 1986, as amended. The Tax Act, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, repeal of the alternative minimum tax for corporations, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the Tax Act. The impact of the Tax Act on holders of our common stock is also uncertain and could be adverse.

Our ability to use our U.S. net operating loss carryforwards and certain other tax attributes may be limited.

Our U.S. net operating loss, or NOL, carryforwards generated in tax years ending on or prior to December 31, 2017, are only permitted to be carried forward for 20 years under applicable U.S. tax law. Under the Tax Act, our federal NOLs generated in tax years ending after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal NOLs generated in tax years beginning after December 31, 2017, is limited. It is uncertain if and to what extent various states will conform to the Tax Act. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change U.S. tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. We believe we have experienced at least one ownership change based on past financing transactions and may experience ownership changes in the future as a result of subsequent shifts in our stock ownership.

As a result, our pre-2018 NOL carryforwards may expire prior to being used, and our NOL carryforwards generated in 2018 and thereafter will be subject to a percentage limitation. In addition, it is possible that we have in the past undergone, and in the future may undergo, additional ownership changes that could limit our ability to use all of our pre-change NOLs and other pre-change tax attributes (such as research tax credits) to offset our post-change income or taxes. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, we may be unable to use all or a material portion of our NOLs and other tax attributes, which could adversely affect our future cash flows.

Risks Relating to Our Business and Industry

* Our research and development programs and product candidates are at an early stage of development. As a result, we are unable to predict if or when we will successfully develop or commercialize our product candidates.

Our clinical-stage product candidates as well as our other pipeline assets are at an early stage of development and will require significant further investment and regulatory approvals prior to commercialization. Sitravatinib is in a Phase 1b single agent clinical trial and a Phase 2 combination clinical trial, and a Phase 3 combination clinical trial is expected to be initiated in the second quarter of 2019. MRTX849 is in a Phase 1/2 clinical trial and we have a KRAS G12D inhibitor preclinical program. Each of our product candidates will require the selection of suitable patients for our clinical trials and additional clinical development, management of clinical, preclinical and manufacturing activities, obtaining regulatory approval, obtaining manufacturing supply, building of a commercial organization, substantial investment and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. The treatment of cancer is a rapidly evolving field and will continue to evolve. By such time, if ever, as we may receive necessary regulatory approvals for our product candidates, the standard of care for the

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treatment of cancers may have evolved such that it would be necessary to modify our plans for full approval and commercial acceptance of our products may be limited by a change in the standard of care. In addition, some of our product development programs contemplate the development of companion diagnostics. Companion diagnostics are subject to regulation as medical devices and we or our future collaborators may be required to obtain marketing approval for accompanying companion diagnostics before we may commercialize our product candidates.

Even if we obtain the required financing or establish a collaboration to enable us to conduct late-stage clinical development of our product candidates and pipeline assets, we cannot be certain that such clinical development would be successful, or that we will obtain regulatory approval or be able to successfully commercialize any of our product candidates and generate revenue. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and the clinical trial process may fail to demonstrate that our product candidates are safe and effective for their proposed uses. Any such failure could cause us to abandon further development of any one or more of our product candidates and may delay development of other product candidates. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Any delay in, or termination of, our clinical trials will delay and possibly preclude the submission of any new drug applications ("NDAs") with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenue.

We have not previously submitted an NDA to the FDA, or similar drug approval filings to comparable foreign authorities, for any product candidate, and we cannot be certain that any of our product candidates will receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more of our product candidates, our revenues will be dependent, in part, upon our or our collaborators' and future collaborators’ ability to obtain regulatory approval for the companion diagnostics to be used with our product candidates, if required, and upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

All of our product candidates are subject to extensive regulation, which can be costly and time consuming, cause delays or prevent approval of such product candidates for commercialization.

The clinical development of product candidates is subject to extensive regulation by the FDA in the United States and by comparable regulatory authorities in foreign markets. Product development is a very lengthy and expensive process, and its outcome is inherently uncertain. The product development timeline can vary significantly based upon the product candidate’s novelty and complexity. Regulations are subject to change and regulatory agencies have significant discretion in the approval process.

Numerous statutes and regulations govern human testing and the manufacture and sale of human therapeutic products in the United States, Europe and other countries and regions where we intend to market our products. Such legislation and regulation bears upon, among other things, the approval of trial protocols and human testing, the approval of manufacturing facilities, safety of the product candidates, testing procedures and controlled research, review and approval of manufacturing, preclinical and clinical data prior to marketing approval including adherence to good manufacturing practices ("GMP") during production and storage as well as regulation of marketing activities including advertising and labeling.

In order to obtain regulatory approval for the commercial sale of any of our product candidates, we must demonstrate through preclinical studies and clinical trials that the potential product is safe and effective for use in humans for each target indication. The failure to adequately demonstrate the safety and efficacy of a product under development could

delay or prevent regulatory approval of our product candidates.

No assurance can be given that current regulations relating to regulatory approval will not change or become more stringent in the United States or foreign markets. Regulatory agencies may also require that additional trials be run in order to provide additional information regarding the safety or efficacy of any drug candidates for which we seek regulatory approval. Moreover, any regulatory approval of a drug which is eventually obtained may entail limitations on the indicated uses for which that drug may be marketed. Furthermore, product approvals may be withdrawn or limited in some way if problems occur following initial marketing or if compliance with regulatory standards is not maintained. Regulatory agencies could become more risk averse to any side effects or set higher standards of safety and efficacy prior to reviewing or approving a product. This could result in a product not being approved. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

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The failure to maintain the BeiGene Agreement or the failure of BeiGene to perform its obligations under the BeiGene Agreement, could negatively impact our business.

Pursuant to the terms of the BeiGene Agreement, we granted to BeiGene an exclusive license to develop, manufacture and commercialize sitravatinib in the BeiGene Territory. Consequently, our ability to generate any revenues from sitravatinib in the BeiGene Territory depends on our ability to maintain our collaboration with BeiGene. We have limited control over the amount and timing of resources that BeiGene will dedicate to these efforts.

We are subject to a number of other risks associated with our dependence on the BeiGene Agreement with respect to sitravatinib in the BeiGene Territory, including:

- BeiGene may not comply with applicable regulatory guidelines with respect to developing, manufacturing or commercializing sitravatinib, which could adversely impact sales or future development of sitravatinib in the BeiGene Territory or elsewhere;

- We and BeiGene could disagree as to future development plans and BeiGene may delay, fail to commence or stop future clinical trials or other development;

- There may be disputes between us and BeiGene, including disagreements regarding the BeiGene Agreement, that may result in (1) the delay of or failure to achieve developmental, regulatory and commercial objectives that would result in milestone or royalty payments, (2) the delay or termination of any future development or commercialization of sitravatinib in the BeiGene Territory, and/or (3) costly litigation or arbitration that diverts our management's attention and resources;

- BeiGene may not provide us with timely and accurate information regarding development, sales and marketing activities or supply forecasts, which could adversely impact our ability to comply with our obligations to BeiGene and manage our own inventory of sitravatinib, as well as our ability to generate accurate financial forecasts;

- Business combinations or significant changes in BeiGene' business strategy may adversely affect BeiGene' ability or willingness to perform its obligations under the BeiGene Agreement; and

- BeiGene may not properly defend our intellectual property rights, or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential litigation.

The BeiGene Agreement is also subject to early termination, including through BeiGene's right to terminate without cause upon advance notice to us. If the agreement is terminated early, we may not be able to find another collaborator for the further development and commercialization of sitravatinib in the BeiGene Territory on acceptable terms, or at all, and we may be unable to pursue continued development and commercialization of sitravatinib in the BeiGene Territory on our own.

We may not be successful in establishing development and commercialization collaborations which could adversely affect, and potentially prohibit, our ability to develop our product candidates.

Developing pharmaceutical products, conducting clinical trials, obtaining regulatory approval, establishing manufacturing capabilities and marketing approved products is expensive, and therefore we may seek to enter into additional collaborations with companies that have more resources and experience in order to continue to develop and commercialize our product candidates. We also may be required due to financial or scientific constraints to enter into additional collaboration agreements to research and/or to develop and commercialize our product candidates. The

establishment and realization of such collaborations may not be possible or may be problematic. There can be no assurance that we will be able to establish such additional collaborations on favorable terms, if at all, or that our current or future collaborative arrangements will be successful or maintained for any specific product candidate or indication. If we are unable to reach successful agreements with suitable collaboration partners for the ongoing development and commercialization of our product candidates, we may face increased costs, we may be forced to limit the scope and number of our product candidates we can commercially develop or the territories in which we commercialize such product candidates, and we may be unable to commercialize products or programs for which a suitable collaboration partner cannot be found. If we fail to achieve successful collaborations, our operating results and financial condition will be materially and adversely affected.

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In addition, the terms of any collaboration agreements may place restrictions on our activities with respect to other products, including by limiting our ability to grant licenses or develop products with other third parties, or in different indications, diseases or geographical locations, or may place additional obligations on us with respect to development or commercialization of our product candidates. If we fail to comply with or breach any provision of a collaboration agreement, a collaborator may have the right to terminate, in whole or in part, such agreement or to seek damages.

Some of our collaboration agreements, including the BeiGene Agreement, are complex and involve sharing or division of ownership of certain data, know-how and intellectual property rights among the various parties. Accordingly, our collaborators could interpret certain provisions differently than we or our other collaborators which could lead to unexpected or inadvertent disputes with collaborators. In addition, these agreements might make additional collaborations, partnering or mergers and acquisitions difficult.

There is no assurance that a collaborator who is acquired by a third party would not attempt to change certain contract provisions that could negatively affect our collaboration. The acquiring company may also not accept the terms or assignment of our contracts and may seek to terminate the agreements. Any one of our collaborators could breach covenants, restrictions and/or sub-license agreement provisions leading us into disputes and potential breaches of our agreements with other partners.

If we or third parties are unable to successfully develop companion diagnostics for our product candidates, or experience significant delays in doing so, we may not achieve marketing approval or realize the full commercial potential of such product candidates.

A key part of our development strategy for our product candidates is to identify subsets of patients with specific types of tumors that express specific genetic markers. Identification of these patients will require the use and development of companion diagnostics. The FDA generally will either require approval or clearance of the diagnostic at the same time the FDA approves the therapeutic product, or as a post-marketing commitment at the time of the therapeutic product's approval. We do not have experience or capabilities in developing or commercializing diagnostics and plan to rely in large part on third parties to perform these functions. We do not currently have any long-term arrangements in place with any third party to develop or commercialize companion diagnostics for our product candidates.

Companion diagnostics are subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and will likely require separate regulatory approval prior to commercialization. If we or third parties are unable to successfully develop companion diagnostics for our product candidates, or experience delays in doing so:

- the development of these product candidates may be delayed because it may be difficult to identify patients for enrollment in our clinical trials in a timely manner;
- these product candidates may not receive marketing approval if their safe and effective use depends on a companion diagnostic; and
- we may not realize the full commercial potential of these product candidates that receive marketing approval if, among other reasons, we are unable to appropriately identify patients or types of tumors with the specific genetic alterations targeted by these product candidates.

Even if our product candidates and any associated companion diagnostics are approved for marketing, the need for companion diagnostics may slow or limit adoption of our product candidates. Although we believe genetic testing is becoming more prevalent in the diagnosis and treatment of cancer, our product candidates may be perceived negatively compared to alternative treatments that do not require the use of companion diagnostics, either due to the additional cost of the companion diagnostic or the need to complete additional procedures to identify genetic markers

prior to administering our product candidates.

If any of these events were to occur, our business and growth prospects would be harmed, possibly materially.

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We rely upon third-party contractors and service providers for the execution of some aspects of our development programs. Failure of these collaborators to provide services of a suitable quality and within acceptable timeframes may cause the delay or failure of our development programs.

We outsource certain functions, tests and services to CROs, medical institutions and collaborators and outsource manufacturing to collaborators and/or contract manufacturers, and we rely on third parties for quality assurance, clinical monitoring, clinical data management and regulatory expertise. In particular, we rely on CROs to run our clinical trials on our behalf and contract manufacturers to manufacture our product candidates. There is no assurance that such individuals or organizations will be able to provide the functions, tests, drug supply or services as agreed upon or to acceptable quality standards, and we could suffer significant delays in the development of our products or processes.

In some cases, there may be only one or few providers of such services, including manufacturing services. In addition, the cost of such services could increase significantly over time. We rely on third parties as mentioned above to enroll qualified patients and conduct, supervise and monitor our clinical trials. Our reliance on these third parties and collaborators for clinical development activities reduces our control over these activities, but does not relieve us of our regulatory responsibilities, including ensuring that our clinical trials are conducted in accordance with good clinical practices ("GCP") regulations and the investigational plan and protocols contained in the regulatory agency applications. In addition, these third parties may not complete activities on schedule or may not manufacture compounds under GMP conditions. Preclinical studies may not be performed or completed in accordance with good laboratory practices, or GLP, regulatory requirements or our trial design. If we or our CROs fail to comply with GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, the EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving any marketing applications. If these third parties or collaborators do not successfully carry out their contractual duties or meet expected deadlines, obtaining regulatory approval for manufacturing and commercialization of our product candidates may be delayed or prevented. We rely substantially on third-party data managers for our clinical trial data. There is no assurance that these third parties will not make errors in the design, management or retention of our data or data systems. There is no assurance that these third parties will pass FDA or regulatory audits, which could delay or prohibit regulatory approval.

Our CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could harm our competitive position. If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. Further, switching or adding additional CROs involves additional cost and requires management time and attention. In addition, there is a natural transition period when a new CRO commences work. As a result, delays may occur, which could materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

The timelines of our clinical trials may be impacted by numerous factors and any delays may adversely affect our ability to execute our current business strategy.

Clinical testing is expensive, difficult to design and implement, can take many years to complete, and is uncertain as to outcome. We may experience delays in clinical trials at any stage of development and testing of our product candidates. Our planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of subjects, or be completed on schedule, if at all.

Events which may result in a delay or unsuccessful completion of clinical trials include:

- inability to raise funding necessary to initiate or continue a trial;
- delays in obtaining regulatory approval to commence a trial;
- delays in reaching agreement with the FDA on final trial design;
- imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites;
- delays in obtaining required institutional review board approval at each site;

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- delays in having subjects complete participation in a trial or return for post-treatment follow-up;
- delays caused by subjects dropping out of a trial due to side effects or otherwise;
- clinical sites dropping out of a trial to the detriment of enrollment;
- time required to add new clinical sites; and
- delays by our contract manufacturers to produce and deliver a sufficient supply of clinical trial materials.

Furthermore, enrollment may depend on the availability of suitable companion diagnostics to identify genetic markers we are targeting and the capability and willingness of clinical sites to conduct genetic screening of potential patients.

If initiation or completion of any of our clinical trials for our product candidates are delayed for any of the above reasons or for other reasons, our development costs may increase, our approval process could be delayed, any periods after commercial launch and before expiration of patent protection may be reduced and our competitors may have more time to bring products to market before we do. Any of these events could impair the commercial potential of our product candidates and could have a material adverse effect on our business.

If we experience delays or difficulties in the enrollment of patients in clinical trials, those clinical trials could take longer than expected to complete and our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or complete clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials. In particular, because we are focused on patients with specific genetic alterations in some of our trials, our pool of suitable patients may be smaller and more selective and our ability to enroll a sufficient number of suitable patients may be limited or take longer than anticipated. In addition, some of our competitors have ongoing clinical trials for product candidates that treat the same indications, including NSCLC, where we are studying sitravatinib in combination with checkpoint inhibitors, or target the same genetic alterations as our product candidates. Therefore, patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates.

Patient enrollment for any of our clinical trials may also be affected by other factors, including without limitation:

- the severity of the disease under investigation
- the frequency of the genetic alteration we are seeking to target in the applicable trial, and the ability to effectively identify such alteration;
- the willingness of clinical sites and principal investigators to subject candidate patients to genetic screening;
- the eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- the availability, effectiveness and safety of other treatment options;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
-

the proximity and availability of a sufficient number of clinical trial sites that are willing to comply with the requirements of our clinical protocols.

For example, due to the targeted indications and patient populations we intend to focus on for development of our product candidates, the number of study sites and patient populations available to us may be limited, and therefore enrollment of suitable patients to participate in clinical trials for these product candidates may take longer than would be the case if we were pursuing broader indications or patient populations.

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Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved product label, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial, or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the product label;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of any product candidate, if approved, and could significantly harm our business, results of operations and prospects.

We are and continue to be subject to stringent government regulations concerning the clinical testing of our products. We will also continue to be subject to government regulation of any product that receives regulatory approval.

Numerous statutes and regulations govern human testing and the manufacture and sale of human therapeutic products in the United States and other countries where we intend to market our products. Such legislation and regulation bears upon, among other things, the approval of trial protocols and human testing, the approval of manufacturing facilities, testing procedures and controlled research, the review and approval of manufacturing, preclinical and clinical data prior to marketing approval, including adherence to GMP during production and storage, and marketing activities including advertising and labeling.

Clinical trials may be delayed or suspended at any time by us or by the FDA or other similar regulatory authorities if it is determined at any time that patients may be or are being exposed to unacceptable health risks, including the risk of death, or if compounds are not manufactured under acceptable GMP conditions or with acceptable quality. Current regulations relating to regulatory approval may change or become more stringent. The agencies may also require additional trials be run in order to provide additional information regarding the safety, efficacy or equivalency of any product candidate for which we seek regulatory approval.

Moreover, any regulatory approval of a drug which is eventually obtained may entail limitations on the indicated uses for which that drug may be marketed or on the conditions of approval, or contain requirements for potentially costly

post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with GMPs and GCPs for any clinical trials that we conduct post-approval. In addition, if the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. For example, the FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Furthermore, product approvals may be withdrawn or limited in some way if problems occur following initial marketing or if compliance with regulatory standards is not maintained. Similar restrictions are imposed in foreign markets. Regulatory agencies could become more risk averse to any side effects or set higher standards of safety and efficacy prior to reviewing or approving a product. This could result in a product not being approved.

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If we, or any future marketing collaborators or contract manufacturers, fail to comply with applicable regulatory requirements, we may be subject to sanctions including fines, product recalls or seizures and related publicity requirements, injunctions, total or partial suspension of production, civil penalties, suspension or withdrawals of previously granted regulatory approvals, warning or untitled letters, refusal to approve pending applications for marketing approval of new products or of supplements to approved applications, import or export bans or restrictions, and criminal prosecution and penalties. Any of these penalties could delay or prevent the promotion, marketing or sale of our products and product candidates.

The FDA's policies, and policies of comparable foreign regulatory authorities, may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or to adopt new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

We have no experience in clinical or commercial manufacturing and depend on others for the production of our product candidates at suitable levels of quality and quantity. Any problems or delays in the manufacture of our products would have a negative impact on our ability to successfully execute our development and commercialization strategies.

We do not currently have nor do we plan to acquire the infrastructure or capability internally to manufacture our clinical drug supplies for use in the conduct of our clinical trials, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. We rely on collaborators and/or third parties for development, scale-up, formulation, optimization, management of clinical trial and commercial scale manufacturing and commercialization. There are no assurances we can scale-up, formulate or manufacture any product candidate in sufficient quantities with acceptable specifications for the conduct of our clinical trials or for the regulatory agencies to grant approval of such product candidate. We have not yet commercialized any products and have no commercial manufacturing experience. To be successful, our products must be properly formulated, scalable, stable and safely manufactured in clinical trial and commercial quantities in compliance with GMP and other regulatory requirements and at acceptable costs. Should any of our suppliers or our collaborators be unable to supply or be delayed in supplying us with sufficient supplies, no assurance can be given that we will be able to find alternative means of supply in a short period of time. Should such parties' operations suffer a material adverse effect, the manufacturing of our products would also be adversely affected. Furthermore, key raw materials could become scarce or unavailable. There may be a limited number of third parties who can manufacture our products. We may not be able to meet specifications previously established for product candidates during scale-up and manufacturing.

Our reliance on third parties to manufacture our product candidates will expose us and our partners to risks including the following, any of which could delay or prevent the commercialization of our products, result in higher costs, or deprive us of potential product revenue:

- Contract manufacturers can encounter difficulties in achieving the scale-up, optimization, formulation, or volume production of a compound as well as maintaining quality control with appropriate quality assurance. They may also experience shortages of qualified personnel. Contract manufacturers are required to undergo a satisfactory GMP inspection prior to regulatory approval and are obliged to operate in accordance with FDA, International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use ("ICH"), European and other nationally mandated GMP regulations and/or guidelines governing manufacturing processes, stability testing, record keeping and quality standards. A failure of these contract manufacturers to follow GMP and to document their adherence to such practices or failure of an inspection by a regulatory agency may lead to significant delays in the availability of our product candidate materials for clinical study, leading to delays in our trials.

- For each of our current product candidates we will initially rely on a limited number of contract manufacturers. Changing these or identifying future manufacturers may be difficult. Changing manufacturers requires re-validation of the manufacturing processes and procedures in accordance with FDA, ICH, European and other mandated GMP regulations and/or guidelines. Such re-validation may be costly and time-consuming. It may be difficult or impossible for us to quickly find replacement manufacturers on acceptable terms.

- Our contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to produce, store and distribute our products successfully.

The successful commercialization of our product candidates, if approved, will depend on achieving market acceptance and we may not be able to gain sufficient acceptance to generate significant revenue.

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Even if our product candidates are successfully developed and receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors such as private insurers or governments and other funding parties and the medical community. The degree of market acceptance for any of our products will depend on a number of factors, including:

- demonstration of the clinical efficacy and safety of our products;
- the prevalence and severity of any adverse side effects;
- limitations or warnings contained in the product's approved labeling;
- cost-effectiveness and availability of acceptable pricing;
- competitive product profile versus alternative treatment methods and the superiority of alternative treatment or therapeutics;
- the effectiveness of marketing and distribution methods and support for the products; and
- coverage and reimbursement policies of government and third-party payors to the extent that our products could receive regulatory approval but not be approved for coverage by or receive adequate reimbursement from government and quasi-government agencies or other third-party payors.

Disease indications may be small subsets of a disease that could be parsed into smaller and smaller indications as different subsets of diseases are defined. This increasingly fine characterization of diseases could have negative consequences; including creating an approved indication that is so small as not to have a viable market for us. If future technology allows characterization of a disease in a way that is different from the characterization used for large pivotal studies, it may make those studies invalid or reduce their usefulness, and may require repeating all or a portion of the studies. Future technology may supply better prognostic ability which could reduce the portion of patients projected to need a new therapy. Even after being cleared by regulatory authorities, a product may later be shown to be unsafe or not to have its purported effect, thereby preventing its widespread use or requiring withdrawal from the market.

If we fail to obtain coverage and adequate reimbursement for our products, our revenue-generating ability will be diminished and there is no assurance that the anticipated market for our products will be sustained.

We believe that there will be many different applications for products successfully derived from our technologies and that the anticipated market for products under development will continue to expand. However, due to competition from existing or new products and the yet-to-be established commercial viability of our products, no assurance can be given that these beliefs will prove to be correct. Physicians, patients, formularies, payors or the medical community in general may not accept or utilize any products that we or our collaborative partners may develop. Other drugs may be approved during our clinical testing which could change the accepted treatments for the disease targeted and make our product candidates obsolete.

Our and our collaborators' ability to commercialize our products successfully will depend, in part, on the extent to which coverage and adequate reimbursement for such products and related treatments will be available from governmental health payor programs at the federal and state levels, including Medicare and Medicaid, private health insurers, managed care plans and other organizations. No assurance can be given that third-party payor coverage and adequate reimbursement will be available that will allow us to maintain price levels sufficient for the realization of an appropriate return on our investment in product development.

Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and private health insurers, managed care plans and other organizations is critical to new product acceptance. There is no uniform coverage and reimbursement policy among third-party payors in the United States; however, private third-party payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Additionally, coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Even if we obtain coverage for our product candidates, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates.

Additionally, we or our collaborators may develop companion diagnostic tests for use with our product candidates. We or our collaborators will be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we seek for our product candidates, once approved. While we have not yet developed any companion diagnostic

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test for use with our product candidates, if we do, there is significant uncertainty regarding our ability to obtain coverage and adequate reimbursement for the same reasons applicable to our product candidates.

In the United States and in many other countries, pricing and/or profitability of some or all prescription pharmaceuticals and biopharmaceuticals are subject to varying degrees of government control. In the United States, there has recently been increased government enforcement and government and payor scrutiny relating to drug pricing and price increases. For example, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, at the federal level, on May 11, 2018, President Trump laid out his administration's "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. On January 31, 2019, the Department of Health and Human Services Office of Inspector General proposed modifications to federal Anti-Kickback Statute safe harbors which, among other things, if finalized, will affect discounts paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations. Although some of these and other proposals may require additional authorization to become effective, Congress and the Trump Administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. These changes may adversely impact the prices we or our future collaborators may charge for our products candidates, if commercialized.

Outside of the United States, the successful commercialization of our products will depend largely on obtaining and maintaining government coverage, because in many countries patients are unlikely to use prescription drugs that are not covered by their government healthcare programs. Negotiating coverage and reimbursement with governmental authorities can delay commercialization by 12 months or more. Coverage and reimbursement policies may adversely affect our ability to sell our products on a profitable basis. In many international markets, governments control the prices of prescription pharmaceuticals, including through the implementation of reference pricing, price cuts, rebates, revenue-related taxes and profit control, and we expect prices of prescription pharmaceuticals to decline over the life of the product or as volumes increase.

Healthcare reform and controls on healthcare spending may limit the price we charge for any products and the amounts thereof that we can sell. In particular, in the United States, the federal government and private insurers have changed and have considered ways to change, the manner in which healthcare services are provided. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, "ACA") became law in the United States. With respect to pharmaceutical products, the ACA, among other things, expanded and increased industry rebates for drugs covered by Medicaid and made changes to the coverage requirements under Medicare Part D, Medicare's prescription drug benefits program. Some of the provisions of the ACA have yet to be fully implemented, and there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump Administration to repeal or replace certain aspects of the ACA. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. While the Texas U.S. District Court Judge, as well as the Trump administration and the Centers for Medicare & Medicaid Services ("CMS"), have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the PPACA and our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013 and, as amended by subsequent legislation including the Bipartisan Budget Act of 2018, will stay in effect through 2027 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Moreover, the Drug Supply Chain Security Act, enacted in 2013, imposes obligations on manufacturers of pharmaceutical products related to product tracking and tracing. These laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

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We anticipate that the ACA, as well as alternative or replacement healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and additional downward pressure on the reimbursement we may receive for any approved product. Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives.

In addition, levels of reimbursement may be impacted by other current and future legislation, regulation or reimbursement policies of third-party payors in a manner that may harm the demand and reimbursement available for our products, including for companion diagnostics for our products, which in turn, could harm our future product pricing and sales. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

Competition in our targeted market area is intense and this field is characterized by rapid technological change. Therefore developments by competitors may substantially alter the predicted market or render our product candidates uncompetitive.

There are hundreds of drugs in clinical development today in the area of oncology therapeutics. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. In the oncology market, our major competitors include, but are not limited to: Amgen, Inc., Corvus Pharmaceuticals, Inc., Eisai Co. Ltd., Exelixis, Inc., F. Hoffman-La Roche Ltd., Johnson & Johnson, Merck & Co. Inc., Nektar Therapeutics, and Novartis AG among others.

Many companies have filed, and continue to file, patent applications in oncology which may or could affect our programs. Some of these patent applications may have already been allowed or issued, and others may issue in the future. These companies include, but are not limited to: Amgen, Inc., Astellas Pharma Inc., AstraZeneca plc, Bristol-Myers Squibb Company, Exelixis, Inc., Novartis AG, Pfizer Inc. and Johnson & Johnson. Since this area is competitive and of strong interest to pharmaceutical and biotechnology companies, there will likely be additional patent applications filed, and additional patents granted, in the future, as well as additional research and development programs expected in the future.

In addition to companies that have kinase inhibitors addressing our oncology indications of interest, our competition also includes hundreds of private and publicly traded companies that operate in the area of oncology but have therapeutics with different mechanisms of action. The oncology market in general is highly competitive with over 1,000 molecules currently in clinical development.

Developments by others may render our products or technologies non-competitive or obsolete or we may not be able to keep pace with technological developments. Our competitors may have developed or may be developing technologies which may be the basis for competitive products. Some of these products may prove to be more effective and less costly than the products developed or being developed by us. Our competitors may obtain regulatory approval for their products more rapidly than we do which may change the standard of care in the indications we are targeting, rendering our technology or products non-competitive or obsolete. For example, with the recent approval of immunotherapy agents for the treatment of NSCLC and other cancers, the standard of care for the treatment of cancer is evolving and will continue to evolve which could require us to change the design and timelines for our registration trails and may limit the commercial acceptance of our products in the future. Others may develop treatments or cures superior to any therapy we are developing or will develop. Moreover, alternate, less toxic forms of medical treatment may be developed which may be competitive with our products.

Many of the organizations which could be considered to be our competitors have substantially more financial and technical resources, more extensive discovery research, preclinical research and development capabilities and greater manufacturing, marketing, distribution, production and human resources than we do. Many of our current or potential competitors have more experience than us in research, preclinical testing and clinical trials, drug commercialization, manufacturing and marketing, and in obtaining domestic and foreign regulatory approvals. In addition, failure, unacceptable toxicity, lack of sales or disappointing sales or other issues regarding competitors' products or processes could have a material adverse effect on our product candidates, including our clinical candidates or our lead compounds. Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidates less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and brand recognition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA, EMA or other regulatory approval or discovering, developing and commercializing medicines before we do, which would have a material adverse impact on our business.

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We will not be able to successfully commercialize our product candidates without establishing sales and marketing capabilities internally or through collaborators.

We currently have no sales and marketing staff. We may not be able to find suitable sales and marketing staff and collaborators for all of our product candidates. We have no prior experience in the marketing, sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any collaborators may not be adequate or successful or could terminate or materially reduce the effort they direct to our products. The development of a marketing and sales capability will require significant expenditures, management resources and time. The cost of establishing such a sales force may exceed any potential product revenue, or our marketing and sales efforts may be unsuccessful. If we are unable to develop an internal marketing and sales capability in a timely fashion, or at all, or if we are unable to enter into a marketing and sales arrangement with a third party on acceptable terms, we may be unable to successfully develop and seek regulatory approval for our product candidates and/or effectively market and sell approved products, if any.

We are subject to competition for our skilled personnel and may experience challenges in identifying and retaining key personnel that could impair our ability to conduct our operations effectively.

Our future success depends on our ability to retain our executive officers and to attract, retain and motivate qualified personnel. If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy. Although we have not experienced problems attracting and retaining highly qualified personnel in the recent past, our industry has experienced a high rate of turnover of management personnel in recent years. Our ability to compete in the highly competitive biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel, especially Charles M. Baum, M.D., Ph.D., our President and Chief Executive Officer, Isan Chen, M.D., our Executive Vice President and Chief Medical and Development Officer, James Christensen, Ph.D. our Executive Vice President and Chief Scientific Officer, Jamie A. Donadio, our Senior Vice President and Chief Financial Officer, and Chris LeMasters, our Executive Vice President and Chief Business Officer whose services are critical to the successful implementation of our product candidate acquisition, development and regulatory strategies, as well as the management of our financial operations. We are not aware of any present intention of any of these individuals to leave our Company. In order to induce valuable employees to continue their employment with us, we have provided stock options that vest over time. The value to employees of stock options that vest over time is significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies.

Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us at any time, with or without notice. The loss of the services of any of our executive officers or other key employees and our inability to find suitable replacements could harm our business, financial condition and prospects. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

We may also experience growth in the number of our employees and the scope of our operations, especially in clinical development. This growth will place a significant strain on our management, operations and financial resources and we may have difficulty managing this future potential growth. No assurance can be provided that we will be able to attract new employees to assist in our growth. Many of the other pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. We also may employ consultants or part-time and contract employees. There can be no assurance

that these individuals are retainable. While we have been able to attract and retain skilled and experienced personnel and consultants in the past, no assurance can be given that we will be able to do so in the future.

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Our current and future relationships with customers and third-party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

As a pharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. Our current and future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, which may constrain the business or financial arrangements and relationships through which we sell, market and distribute any drugs for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation by U.S. federal and state governments and by governments in foreign jurisdictions in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order, lease, furnishing, prescribing or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs, such as Medicare and Medicaid. The term "remuneration" has been broadly interpreted to include anything of value. The ACA, among other things, amended the intent requirement of the federal Anti Kickback Statute such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate, in order to commit a violation;

- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act which can be enforced by private individuals on behalf of the government through civil whistleblower or qui tam actions, prohibits individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Entities can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers, promoting a product off label, or for providing medically unnecessary services or items. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which imposes criminal and civil liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of or payment for healthcare benefits, items or services;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and their respective implementing regulations, which impose obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as individuals and entities that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, known as business associates, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended

HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- the federal Open Payments program, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to CMS information related to "payments or other transfers of value" made to physicians, which is defined to include doctors, dentists, optometrists, podiatrists and chiropractors, and teaching hospitals and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members, and contains requirements for manufacturers to submit reports to CMS by the 90th day of each calendar year, and disclosure of such information to be made by CMS on a publicly available website; and

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analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures, or drug pricing; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of available statutory exceptions and regulatory safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. To the extent that any of our product candidates is ultimately sold in countries other than the United States, we may be subject to similar laws and regulations in those countries. If we or our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil, criminal and administrative penalties, damages, fines, imprisonment, disgorgement, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, exclusion from participation in government healthcare programs, and the curtailment or restructuring of our operations, any of which could have a material adverse effect on our business. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including any of our collaborators, is found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusion from participation in government healthcare programs, which could also materially affect our business.

We may become subject to the risk of product liability claims.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. Human therapeutic products involve the risk of product liability claims and associated adverse publicity. Currently, the principal risks we face relate to patients in our clinical trials, who may suffer unintended consequences. Claims might be made by patients, healthcare providers, pharmaceutical companies or others. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection laws. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates, if approved. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;

- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue from product sales; and
- the inability to commercialize any of our product candidates, if approved.

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We may not have or be able to obtain or maintain sufficient and affordable insurance coverage, and without sufficient coverage any claim brought against us could have a materially adverse effect on our business, financial condition or results of operations. We run clinical trials through investigators that could be negligent through no fault of our own and which could affect patients, cause potential liability claims against us and result in delayed or stopped clinical trials. We are required in many cases by contractual obligations to indemnify collaborators, partners, third-party contractors, clinical investigators and institutions. These indemnifications could result in a material impact due to product liability claims against us and/or these groups. We currently carry $10 million in product liability insurance, which we believe is appropriate for our clinical trials. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Our business involves the controlled use of hazardous materials and as such we are subject to environmental and occupational safety laws. Continued compliance with these laws may incur substantial costs and failure to maintain compliance could result in liability for damages that may exceed our resources.

Our preclinical research, manufacturing and development processes involve the controlled use of hazardous and radioactive materials. We are subject to federal, local and foreign laws and regulations governing the use, manufacture, storage, handling and disposal of such materials and certain waste products. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. The risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result, and any such liability could exceed our resources. We may not be adequately insured against this type of liability. We may be required to incur significant costs to comply with environmental laws and regulations in the future, and our operations, business or assets may be materially adversely affected by current or future environmental laws or regulations.

We may have to dedicate resources to the settlement of litigation.

Securities legislation in the United States, Canada and other countries makes it relatively easy for stockholders to sue. This could lead to frivolous lawsuits which could take substantial time, money, resources and attention or force us to settle such claims rather than seek adequate judicial remedy or dismissal of such claims.

If we are required to defend patent infringement actions brought by third parties, or if we sue to protect our own patent rights or otherwise to protect our proprietary information and to prevent its disclosure, or if we are involved in other litigation, whether as a plaintiff or defendant, we may be required to pay substantial litigation costs and managerial attention may be diverted from business operations even if the outcome is in our favor. If we are required to defend our patents or trademarks against infringement by third parties, we may be required to pay substantial litigation costs and managerial attention and financial resources may be diverted from our research and development operations even if the outcome is in our favor.

We may be vulnerable to disruption, damage and financial obligation as a result of system failures.

Despite the implementation of security measures, any of the internal computer systems belonging to us, our collaborators or our third-party service providers are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failure. Any system failure, accident or security breach that causes interruptions in our own, in collaborators' or in third-party service vendors' operations could result in a material disruption of our drug discovery and development programs. In addition, we rely upon third-party

contractors and service providers for the hosting, support and/or maintenance of some aspects of our computer hardware, computer software and telecommunications systems. Failure of those contractors and service providers to provide systems and services of a suitable quality and within acceptable timeframes may cause the delay or failure of our development programs, or loss of confidential or proprietary information. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability, our drug discovery and development programs may be adversely affected and the further development of our product candidates may be delayed. Furthermore, we may incur additional costs to remedy the damages caused by these disruptions or security breaches.

Changes in funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.

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The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including most recently beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Risks Relating to Our Intellectual Property

* We may not obtain adequate protection for our product candidates through patents and other intellectual property rights and as such our competitive advantage in the marketplace may be compromised.

Our success depends, in part, on our ability to secure and protect our patents, trade secrets, trademarks and other intellectual property rights and to operate without infringing on the proprietary rights of others or having third parties circumvent the rights that we own or license. We have filed and are actively pursuing patent applications in the United States, Japan, Europe and other major markets via the Patent Cooperation Treaty or directly in countries of interest. The patent positions of healthcare companies, universities and biopharmaceutical companies, including ours, are uncertain and involve complex questions of law and fact for which important legal issues may remain unresolved. Therefore, there is no assurance that our pending patent applications will result in the issuance of patents or that we will develop additional proprietary products which are patentable. Moreover, patents issued or to be issued to us may not provide us with any competitive advantage. Further, if the patent applications we hold or in-license with respect to our programs, product candidates and companion diagnostic fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our product candidates, it could dissuade companies from collaborating with us to develop product candidates, and threaten our ability to commercialize future products.

Our patents may be challenged by third parties at the United States Patent and Trademark Office ("USPTO"), comparable foreign patent offices, or in patent litigation. In addition, it is possible that third parties with products that are very similar to ours will circumvent our patents by means of alternate designs or processes or file applications or be granted patents that would block or hurt our efforts.

There are no assurances that our patent counsel, lawyers or advisors have given us correct advice or counsel. Opinions from such patent counsel or lawyers may not be correct or may be based on incomplete facts. We cannot be certain that we are the first to invent or first to file for patent protection for the inventions covered by pending patent applications and, if we are not, we may be subject to priority disputes. We may be required to disclaim part or all of the subject matter and/or term of certain patents or all of the subject matter and/or term of certain patent applications. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of one or more claims, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. No assurance can be given that if challenged, our patents would be declared by the USPTO, comparable foreign patent offices or a court to be valid or enforceable or that even if found valid and enforceable, a competitor’s technology or

product would be found by a court to infringe our patents. The possibility exists that others will develop products which have the same effect as our products on an independent basis which do not infringe our patents or other intellectual property rights, or will design around the claims of patents that we have had issued that cover our products. The steps we have taken to protect our intellectual property may not prevent the misappropriation of our proprietary information and technologies, particularly in foreign countries where laws or law enforcement practices may not protect proprietary rights to the same extent as in the United States, Europe or Japan. Unauthorized disclosure of our proprietary information could also harm our competitive position. We could also inadvertently use our collaborators' data inappropriately which could lead to liability. We may file patent applications but have the scope of the claims narrowed or significantly narrowed during prosecution or we may not be able to supply sufficient data to satisfy a patent office to support the full breadth of our claims and, as a result, may not obtain the original claims desired or we may receive amended claims with significantly reduced scope. Alternatively, it is possible that we may not receive any patent protection from an application.

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Maintaining our patents and applications requires timely payment of fees and other associated costs in the countries of filing, and we could inadvertently abandon a patent or patent application (or trademark or trademark application) due to non-payment of fees, or as a result of a failure to comply with filing deadlines or other requirements of the prosecution process, resulting in the loss of protection of certain intellectual property rights in a certain country. Alternatively, we, our collaborators or our patent counsel may take action resulting in a patent or patent application becoming abandoned which may not be able to be reinstated, or if reinstated, may suffer patent term adjustments. Any of these outcomes could hurt our ability to gain full patent protection for our products. Registered trademarks and/or applications for trademark registrations in the United States that belong to us are subject to similar risks as described above for patents and patent applications.

Many of our collaboration agreements are complex and may call for licensing or cross-licensing of potentially blocking patents, know-how or intellectual property. Due to the potential overlap of data, know-how and intellectual property rights there can be no assurance that one of our collaborators will not dispute our right to send data or know-how or other intellectual property rights to third parties and this may potentially lead to liability or termination of a program or litigation. There are no assurances that the actions of our collaborators would not lead to disputes or cause us to default with other collaborators. We cannot be certain that a collaborator will not challenge the validity of licensed patents.

We cannot be certain that any country’s patent and/or trademark office will not implement new rules which could affect how we draft, file, prosecute and/or maintain patents and patent applications, or that certain patent rights and/or trademark rights will be granted by governmental authorities in particular foreign countries. We cannot be certain that increasing costs for drafting, filing, prosecuting and maintaining patent applications and patents will not limit our ability to file for patent protection, or to prosecute applications through to grant. We may be forced to abandon or return the rights to specific patents due to a lack of financial resources. There is no assurance that we could enter into licensing arrangements at a reasonable cost, or develop or obtain alternative technology in respect of patents issued to third parties that incidentally cover our products. Any inability to secure such licenses or alternative technology could result in delays in the introduction of some of our products or even lead to prohibition of the development, manufacture or sale of certain products by us.

We may file applications for trademark registrations in connection with our product candidates in various jurisdictions, including the United States. No assurance can be given that any of our trademark applications will be registered in the United States or elsewhere, or that the use of any registered or unregistered trademarks will confer a competitive advantage in the marketplace. Furthermore, even if we are successful in our trademark registrations, the FDA and regulatory authorities in other countries have their own process for drug nomenclature and their own views concerning appropriate proprietary names. No assurance can be given that the FDA or any other comparable regulatory authority will accept any of our trademarks or will not request reconsideration of one of our trademarks, for use in connection with our drug product candidates, whether currently or at some time in the future. The loss, abandonment, or cancellation of any of our trademarks or trademark applications could negatively affect the success of the product candidates to which they relate.

Moreover, some of our know-how and technology which is not patented or not patentable may constitute trade secrets. Therefore, we require our consultants, advisors and collaborators to enter into confidentiality agreements and our employees to enter into invention and non-disclosure agreements. However, no assurance can be given that such agreements will provide for a meaningful protection of our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure of information. Furthermore, we cannot provide assurance that any of our employees, consultants, contract personnel or collaborators, either accidentally or through willful misconduct, will not cause serious negative impact to our programs and/or our strategy. All of our employees have signed confidentiality agreements, but there can be no assurance that they will not inadvertently or through their misconduct give trade secrets away.

Third-party patents or intellectual property infringement claims may result in a reduction in the scope of our patent protection and competitive exclusivity with respect to our product candidates. Patent litigation, including defense against third-party intellectual property claims, may result in us incurring substantial costs.

Patent applications which may relate to or affect our business may have been filed by others. Such patent applications or patents resulting there from may conflict with our technologies, patents or patent applications, potentially reducing the scope or strength of our patent protection, and may ultimately be determined to limit or prohibit our freedom to operate with respect to our product candidates. Such events could cause us to stop or change the course of our research and development or modify our intellectual property strategies. We could also become involved in interference proceedings in connection with one or more of our patents or patent applications to determine priority of invention, or in post-grant opposition proceedings at the USPTO or comparable foreign patent offices. There can be no guarantees that an interference proceeding or defense of a post-grant opposition would be successful or that such an outcome would be upheld on appeal. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does

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not offer us a license on commercially reasonable terms. Our defense of such interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees.

No assurance can be given that our patents, once issued, would be declared by a court to be valid or enforceable, or that we would not be found to infringe a competitor's patent.

Third parties may assert that we are using their proprietary information without authorization. Third parties may also have or obtain patents and may claim that technologies licensed to or used by us infringe their patents. Because patent applications can take many years to issue, third parties may have currently pending patent applications which may later result in issued patents that our product candidates or companion diagnostic may infringe, or which such third parties claim are infringed by the use of our technologies. If any third-party patents are held by a court of competent jurisdiction to cover any aspect of our product candidates, including the formulation or method of use of such product candidate, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtain a license under the applicable patents, or until such patents expire. In any such case, such a license may not be available on commercially reasonable terms or at all. We may attempt to invalidate a competitor's patent or trademark. There is no assurance such action will ultimately be successful and, even if initially successful, it could be overturned upon appeal. In addition, any legal action that seeks damages or an injunction to stop us from carrying on our commercial activities relating to the affected technologies could subject us to monetary liability. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources.

Parties making claims against us for alleged infringement of their intellectual property rights may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we could be required to redesign our infringing products or obtain a license from such third party to continue developing and commercializing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms, or at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. It may be impossible to redesign our products and technology, or it may require substantial time and expense, which could force us to cease commercialization of one or more of our product candidates, or some of our business operations, which could materially harm our business. In addition, in any such proceeding, we may be required to pay substantial damages, including treble damages and attorneys' fees in the event we are found liable for willful infringement.

Our intellectual property may be infringed upon by a third party.

Third parties may infringe one or more of our issued patents or trademarks. We cannot predict if, when or where a third party may infringe one or more of our issued patents or trademarks. There is no assurance that we would be successful in a court of law to prove that a third party is infringing one or more of our issued patents. Even if we are successful in proving in a court of law that a third party is infringing one or more of our issued patents there can be no assurance that we would be successful in halting their infringing activities, for example, through a permanent injunction, or that we would be fully or even partially financially compensated for any harm to our business. We may be forced to enter into a license or other agreement with the infringing third party at terms less profitable or otherwise less commercially acceptable to us than if the license or agreement were negotiated under conditions between those of a willing licensee and a willing licensor. We may not become aware of a third party infringer within legal timeframes that would enable us to seek adequate compensation, or at all, thereby possibly losing the ability to be compensated for any harm to our business. Such a third-party may be operating in a foreign country where the infringer is difficult to locate, where we do not have issued patents and/or the patent laws may be more difficult to enforce. Some third-party infringers may be able to sustain the costs of complex patent infringement litigation more effectively than

we can because they have substantially greater resources. Any inability to stop third-party infringement could result in loss in market share of some of our products or even lead to a delay, reduction and/or inhibition of the development, manufacture or sale of certain products by us. There is no assurance that a product produced and sold by a third-party infringer would meet our or other regulatory standards or would be safe for use. Such third-party infringer products could irreparably harm the reputation of our products thereby resulting in substantial loss in market share and profits.

Third parties may seek to obtain approval of a generic version of approved products. Defense against entry of a generic product may result in us incurring substantial costs and ultimate failure to prevail against approval of a generic product could result in a substantial loss of market share and profits.

Even if we are successful in obtaining regulatory approval to sell any of our product candidates in one or more countries, we cannot be certain that our patents and other intellectual property rights will ultimately prevent approval during the patent term

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of generic products developed and commercialized by third parties. A generic manufacturer may seek approval of a generic version of any of our products in the United States by filing an Abbreviated New Drug Application ("ANDA"), with the FDA asserting that our patents are invalid and/or unenforceable to maintain market exclusivity for any of our products, if approved. We cannot predict if, or when, one or more generic manufacturers may attempt to seek regulatory approval for a generic version of any of our products, if approved. There is no assurance that we will ultimately be successful in a court of law to prevent entry of a generic version of any of our products during the applicable patent term and we may incur substantial costs defending our patents and intellectual property rights. An inability to stop a generic manufacturer from selling a generic version of our products could result in a substantial loss of market share and profits or even preclude the ability to continue to commercialize any of our products, if approved.

Risks Related to Our Shares of Common Stock

Our share price is volatile and may be influenced by numerous factors that are beyond our control.

A low share price and low market valuation may make it difficult to raise sufficient additional cash due to the significant dilution to current stockholders. Market prices for shares of biotechnology and biopharmaceutical companies such as ours are often volatile. Factors such as clinical and regulatory developments regarding our products or processes, developments regarding potential or future third-party collaborators, announcements of technological innovations, new commercial products, patents, the development of proprietary rights by us or by others or any litigation relating to these rights, regulatory actions, general conditions in the biotechnology and pharmaceutical industries, failure to meet analysts’ expectations, publications, financial results or public concern over the safety of biopharmaceutical and biotechnological products, economic conditions in the United States and other countries, terrorism and other factors could have a significant effect on the share price for our shares of common stock. Any setback or delay in the clinical development of our programs could result in a significant decrease in our share price. In recent years the stock of other biotechnology and biopharmaceutical companies has experienced extreme price fluctuations that have been unrelated to the operating performance of the affected companies. There can be no assurance that the market price of our shares of common stock will not experience significant fluctuations in the future, including fluctuations that are unrelated to our performance. These fluctuations may result due to macroeconomic and world events, national or local events, general perception of the biotechnology industry or to a lack of liquidity. In addition, other biotechnology companies' or our competitors’ programs could have positive or negative results that impact their stock prices and their results or experience stock price fluctuations that could have a positive or negative impact on our stock price, regardless whether such impact is direct or not.

Stockholders may not agree with our business, scientific, clinical and financial strategy, including additional dilutive financings, and may decide to sell their shares or vote against such proposals. Such actions could materially impact our stock price. In addition, portfolio managers of funds or large investors can change or change their view on us and decide to sell our shares. These actions could have a material impact on our stock price. In order to complete a financing, or for other business reasons, we may elect to consolidate our shares of common stock. Investors may not agree with these actions and may sell our shares. We may have little or no ability to impact or alter such decisions.

* Our principal stockholders control the majority of our shares, and their actions may significantly influence matters submitted to our stockholders for approval and our share price.

Based on the information available to us as of March 31, 2019, our stockholders and their affiliates who owned more than 5% of our outstanding common stock collectively owned 52% of our outstanding common stock. Baker Bros. Advisors, LLC ("Baker Brothers") and Boxer Capital, LLC ("Boxer Capital") and their affiliates collectively own 23% of our outstanding common stock. In addition, in conjunction with certain financing transactions, we granted to Baker Brothers and Boxer Capital each the right to nominate a member of our Board of Directors and the right to appoint an observer on our Board of Directors. Collectively Baker Brothers and Boxer Capital may have significant influence

over matters submitted to our stockholders for approval, including the election and removal of directors and the approval of any merger, consolidation, or sale of all or substantially all of our assets. Furthermore, as a thinly traded stock, if Baker Brothers, Boxer Capital or any other of our major stockholders determine to exit from the industry or from their holdings in us, for whatever reason, the impact on our share price could be detrimental over a prolonged period of time.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from

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time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Pursuant to our 2013 Equity Incentive Plan ("the 2013 Plan"), and our 2013 Employee Stock Purchase Plan ("the ESPP"), our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants, and to sell our common stock to our employees, respectively. Any increase in the number of shares outstanding as a result of the exercise of outstanding options, the vesting or settlement of outstanding stock awards, or the purchase of shares pursuant to the ESPP will cause our stockholders to experience additional dilution, which could cause our stock price to fall.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, would be our stockholders' only source of gain.

We have never declared or paid any cash dividends on our common shares, and we currently expect that earnings, if any, and cash flow will primarily be retained and used in our operations, including servicing any debt obligations we may have now or in the future. Accordingly, although we do not anticipate paying any dividends in the foreseeable future, we may not be able to generate sufficient cash flow in order to allow us to pay future dividends on, or make any distributions with respect to our common stock. As a result, capital appreciation, if any, of our common stock would be our stockholders' sole source of gain on their investment in our common stock for the foreseeable future.

ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

ITEM 3. Defaults Upon Senior Securities

None.

ITEM 4. Mine Safety Disclosures

Not applicable.

ITEM 5. Other Information

None.

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ITEM 6. Exhibits

Exhibit number	Description of document
2.1	Arrangement Agreement, dated May 8, 2013, by and between MethylGene Inc. and the Company.(2)
3.1	Amended and Restated Certificate of Incorporation.(1)
3.2	Bylaws.(1)
3.3	Amendment to Bylaws.(3)
4.1	Form of Common Stock Certificate.(2)
4.2	Form of Warrant to Purchase Common Stock(4)
4.3	Form of Warrant to Purchase Common Stock(5)
4.4	Form of Warrant to Purchase Common Stock(6)
5.1	Opinion of Cooley LLP.
10.1*	Clinical Trial Collaboration and Supply Agreement, dated January 3, 2019, by and between Mirati Therapeutics, Inc. and Bristol-Myers Squibb Company, and related Supply/Quality Addendum dated March 29, 2019.
10.2*	Drug Discovery Collaboration Option Agreement, dated October 1, 2014, by and between Mirati Therapeutics, Inc. and Array BioPharma Inc., and related amendments dated August 13, 2015, November 9, 2015, February 13, 2016, and August 24, 2018.
23.1	Consent of Cooley LLP (included in Exhibit 5.1)
31.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
31.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
32.1	Certifications Pursuant to U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Public Company Accounting Reform and Investor Protection Act of 2002.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Schema Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

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* Certain portions of this exhibit (indicated by "[***]") have been omitted as Mirati Therapeutics, Inc. has determined (i) the omitted information is not material and (ii) the omitted information would likely cause harm to Mirati Therapeutics, Inc. if publicly disclosed.

(1) Incorporated by reference to Mirati Therapeutics, Inc.'s Registration Statement on Form 10-12B (No. 001-35921), filed with the Securities and Exchange Commission on May 10, 2013.

(2) Incorporated by reference to Mirati Therapeutics, Inc.’s Amended Registration Statement on Form 10-12B/A (No. 001-35921), filed with the Securities and Exchange Commission on June 14, 2013.

(3) Incorporated by reference to Mirati Therapeutics, Inc.'s Current Report on Form 8-K, filed with the Securities and Exchange Commission on June 16, 2016.

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(4) Incorporated by reference to Mirati Therapeutics, Inc.'s Current Report on Form 8-K, filed with the Securities and Exchange Commission on January 6, 2017.

(5) Incorporated by reference to Mirati Therapeutics, Inc.'s Current Report on Form 8-K, filed with the Securities and Exchange Commission on November 16, 2017.

(6) Incorporated by reference to Mirati Therapeutics, Inc.'s Current Report on Form 8-K, filed with the Securities and Exchange Commission on June 7, 2018.

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.

MIRATI THERAPEUTICS, INC.

Date: April 29, 2019 by: /s/ Charles M. Baum
Chief Executive Officer
(Principal Executive Officer)

Date: April 29, 2019 by: /s/ Jamie A. Donadio
Senior Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)