Mirati Therapeutics, Inc.
Form 10-Q
August 13, 2013
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2013

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.)
9363 Towne Centre Drive, Suite 200 **San Diego, California**	**92121**
(Address of Principal Executive Offices)	(Zip Code)

(858) 332-3410

(Registrant s Telephone Number, Including Area Code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x 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	o	Accelerated filer	o
Non-accelerated filer	o (Do not check if a smaller reporting company)	Smaller reporting company	x

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

Total shares of common stock outstanding as of the close of business on August 9, 2013:

Class	**Number of Shares Outstanding**
Common Stock, $0.0001 par value	9,957,725

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MIRATI THERAPEUTICS, INC.

FORM 10-Q

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PART I. FINANCIAL INFORMATION

ITEM 1. ***Financial Statements***

MIRATI THERAPEUTICS, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands)

(Unaudited)

	June 30, 2013	December 31, 2012
ASSETS		
Current assets		
Cash and cash equivalents	**$ 9,740**	$ 18,403
Marketable securities	**10,516**	18,580
Restricted cash equivalents and marketable securities	**285**	302
Interest and other receivables	**108**	507
Other current assets	**1,787**	1,537
Total current assets	**22,436**	39,329
Security deposits	**101**	67
Restricted cash equivalents and marketable securities	**78**	72
Property and equipment, net	**425**	333
Total assets	**$ 23,040**	$ 39,801
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	**4,516**	5,272
Current portion of other liability	**68**	68
Warrant liability	**12,208**	
Total current liabilities	**16,792**	5,340
Other liability	**11**	45
Total liabilities	**16,803**	5,385
Stockholders equity		
Preferred stock, $0.001 par value, 10,000,000 shares authorized; none issued and outstanding at both June 30, 2013 and December 31, 2012		
Common stock, $0.001 par value; 100,000,000 authorized; 9,957,725 issued and outstanding at both June 30, 2013 and December 31, 2012	**10**	10
Warrants		11,153
Additional paid-in capital	**154,469**	154,224
Accumulated other comprehensive income	**9,520**	9,520
Accumulated deficit	**(157,762)**	(140,491)
Total stockholders equity	**6,237**	34,416

Total liabilities and stockholders equity	**$ 23,040**	**$** 39,801

See accompanying notes

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MIRATI THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands except for share and per share amounts)

(Unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2013	**2012**	**2013**	**2012**
Expenses				
Research and development, net	$ **4,510**	$ 3,652	$ **9,985**	$ 5,856
General and administrative	**2,382**	1,082	**4,906**	2,302
Total operating expenses	**6,892**	4,734	**14,891**	8,158
Loss from operations	**(6,892)**	(4,734)	**(14,891)**	(8,158)
Other (expense) income, net	**(1,079)**	70	**2,722**	138
Loss before income taxes	**(7,971)**	(4,664)	**(12,169)**	(8,020)
Income tax expense	**41**	13	**60**	13
Net loss and comprehensive loss	$ **(8,012)**	$ (4,677)	$ **(12,229)**	$ (8,033)
Basic and diluted net loss per share	$ **(0.81)**	$ (0.73)	$ **(1.23)**	$ (1.26)
Weighted average number of shares used in computing net loss per share, basic and diluted	**9,957,725**	6,358,266	**9,957,725**	6,358,266

See accompanying notes

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MIRATI THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Six months ended June 30,	
	2013	**2012**
Operating activities		
Net loss	$ **(12,229)**	$ (8,033)
Non-cash adjustments reconciling net loss to operating cash flows		
Depreciation of property and equipment	**64**	68
Stock-based compensation expense	**245**	652
Change in fair value of warrant liability	**(3,987)**	
Lease incentive	**(34)**	43
Changes in operating assets and liabilities		
Interest and other receivables	**399**	74
Other current assets	**(250)**	290
Accounts payable and accrued liabilities	**(756)**	(373)
Cash flows used for operating activities	**(16,548)**	(7,279)
Investing activities		
Purchases of property and equipment	**(156)**	(51)
Purchases of marketable securities	**(22,391)**	(13,419)
Security deposit	**(34)**	(15)
Restricted cash equivalents and marketable securities	**11**	
Disposal and maturities of marketable securities	**30,455**	18,905
Cash flows provided by investing activities	**7,885**	5,420
Financing activities		
Costs of reorganization		(16)
Cash flows used for financing activities		(16)
Decrease in cash and cash equivalents	**(8,663)**	(1,875)
Effect of exchange rate changes on cash and cash equivalents		44
Cash and cash equivalents, beginning of period	**18,403**	9,882
Cash and cash equivalents, end of period	**$ 9,740**	$ 8,051

See accompanying notes

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MIRATI THERAPEUTICS, INC.

Notes to Consolidated Financial Statements

June 30, 2013

(unaudited)

1. DESCRIPTION OF BUSINESS

Mirati Therapeutics, Inc. (Mirati or the Company) is a biopharmaceutical company and its primary business purpose is to develop and commercialize novel therapeutics for the treatment of patients with cancer.

The Company has a wholly owned subsidiary in Canada, Methylgene, Inc. (Methylgene). MethylGene s common stock was listed on the Toronto Stock Exchange from June 29, 2004 until July 26, 2013 under the ticker symbol MYG . The Company also has an indirect, wholly-owned subsidiary, Methylgene US Inc., which was incorporated in Princeton, New Jersey on December 20, 2011 and started business activity in 2012. The Company s common stock has been listed on the NASDAQ Capital Market since July 15, 2013 under the ticker symbol MRTX . The Company is a holding company with minimal assets other than the stock of its subsidiary in Canada, MethylGene Inc., and primarily conducts its operations through MethylGene and MethylGene US Inc. Refer to Note 2 under the heading Basis of Presentation and Going Concern Uncertainty for further discussion of the Company s corporate structure.

2. BASIS OF PRESENTATION AND GOING CONCERN UNCERTAINTY

The information contained herein has been prepared in accordance with instructions for Form 10-Q and Article 10 of Regulation S-X. The information as of June 30, 2013, and for the six months ended June 30, 2013 and 2012, is unaudited. 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 consolidated balance sheet at December 31, 2012 has been derived from the audited consolidated financial statements at that date, but does not include all information and footnotes required by U.S. generally accepted accounting principles for complete financial statements. For more complete financial information, these financial statements should be read in conjunction with the audited consolidated financial statements included in Mirati s Registration Statement on Form 10 (No. 001-35921), originally filed with the Securities and Exchange Commission (SEC) on May 10, 2013, as amended.

Mirati was incorporated under the laws of the State of Delaware on April 29, 2013. The Company was created to enter into an arrangement agreement with MethylGene described below.

On May 8, 2013, the Company s Board of Directors approved and the Company entered into an arrangement agreement with MethylGene. Subject to the terms and conditions of the arrangement agreement, which was consummated on June 28, 2013, the shareholders of MethylGene received one share of the Company s common stock in exchange for every 50 common shares of MethylGene, which had the effect of a 50 for 1

reverse split of MethylGene s common shares pursuant to a court-approved plan of arrangement under Section 192 of the Canada Business Corporations Act. Such transaction is referred to herein as the Arrangement . In addition, all outstanding options and warrants to purchase common shares of MethylGene became exercisable on a 50-for-1 basis for shares of the Company s common stock, and a proportionate adjustment was made to the exercise price. Upon completion of the Arrangement, MethylGene became the Company s wholly-owned subsidiary. The shares of the Company s common stock issued at the closing of the Arrangement were issued in reliance upon the exemption from registration under Section 3(A)(10) of the Securities Act of 1933, as amended.

These financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities in the normal course of business. The Company has incurred significant operating losses since inception and has relied on its ability to fund its operations through private and public equity financings and a debt financing. At June 30, 2013, the Company had $20.6 million in cash, cash equivalents, marketable securities and restricted cash.

As of June 30, 2013, substantial doubt exists over the ability of the Company to continue as a going concern. The Company believes that its current cash and cash equivalents, marketable securities and restricted cash equivalents and marketable securities are sufficient to carry out its currently planned clinical development and operating plans into the second quarter of 2014, without considering potential future financing. The Company s cash, cash equivalents and marketable securities decreased by $16.7 million in the six months ended June 30, 2013, reflecting an average rate of negative cash flow per month of approximately $2.8 million. Excluding non-recurring costs associated with the previously described Arrangement, listing on the NASDAQ Capital Market and recent management changes of $2.6 million, of which $1.4 million relates to the Arrangement and NASDAQ listing, our cash, cash equivalents and marketable securities decreased by $14.1 million in the six months ended June 30, 2013 reflecting an average rate of negative cash flow per month of approximately $2.4 million. While the rate of future negative cash flow per month will vary due to the timing of expenses incurred and the programs that are funded, at the current rate of negative cash flow per month the Company believes that its current cash, cash equivalents and marketable securities will enable it to complete Phase 1 development of MCGD265, which if successful would enable it to enter Phase 2 development. The Company s future cash requirements could increase if it decides to expand research and development efforts beyond the currently planned development of MCGD265.

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The Company has incurred operating losses in each year since its inception and expects to continue to incur operating losses into the foreseeable future as it advances the development of its product candidate MCGD265; evaluates opportunities for the potential initiation of further clinical development of mocetinostat; evaluates opportunities for the potential clinical development of MGCD516, and continues its research efforts. To fund future operations the Company will need to raise additional capital. The amount and timing of future funding requirements will depend on many factors including the timing and results of ongoing development efforts, the potential expansion of current development programs, potential new development programs and related general and administrative support. The Company anticipates that it will seek to fund its operations through public or private equity or debt financings or other sources, such as potential collaboration agreements. Additional financing may not be available to the Company on favorable terms, or at all. Although the Company has previously been successful in obtaining financing through its equity securities offerings, it may not be able to do so in the future. If the Company is not able to secure adequate additional financings it may be forced to make reductions in spending and/or liquidate assets where possible. Any of these actions could harm the Company s business and its results of operations.

These condensed interim consolidated financial statements do not reflect the adjustments that might be necessary to the carrying amount of reported assets, liabilities and expenses if the Company were unable to continue operations in accordance with the going concern assumption, and such adjustments could be material.

These condensed interim consolidated financial statements are presented in U.S. dollars, which effective January 1, 2013, is also the functional currency of the Company.

The Company has not early adopted any standard or amendment that has been issued but not yet effective.

3. SIGNIFICANT ACCOUNTING POLICIES

Foreign Currency Transactions

Foreign currency transactions are initially recorded by the Company using the exchange rates prevailing at the date of the transaction. At the balance sheet date, monetary assets and liabilities denominated in foreign currencies are translated at the period-end rates of exchange. Non-monetary assets and liabilities are translated at the historical exchange rates. Exchange gains and losses arising from the translation of foreign currency items are included in other (expense)/income in the consolidated statements of operations and comprehensive loss. The Company recognized net foreign exchange losses of $754,000 and net foreign exchange gains of $11,000 in other (expense)/income in the consolidated statement of operations and comprehensive loss for the three months ended June 30, 2013 and 2012, respectively. The Company recognized net foreign exchange losses of $1.4 million and net foreign exchange gains of $10,000 in other (expense)/income in the consolidated statement of operations and comprehensive loss for the six months ended June 30, 2013 and 2012, respectively.

Reclassification of Warrants

In 2011 and 2012, the Company issued common stock warrants in connection with the issuance of common stock through private placements with exercise prices denominated in Canadian dollars, referred to as the 2011 Warrants and 2012 Warrants, respectively. Upon the issuance of the 2011 and 2012 Warrants, the Company allocated the net proceeds to common stock and warrants based on their relative fair values, and calculated the fair value of the issued common stock warrants utilizing the Black-Scholes option-pricing model. The allocated fair value was then recorded as warrants within stockholders equity on the consolidated balance sheet. The fair value was not remeasured in periods subsequent to the date of issuance.

The change in its functional currency to the U.S. dollar effective January 1, 2013 changed how the Company accounts for its warrants which have exercise prices denominated in Canadian dollars. Upon the change in functional currency, the Company classified these warrants as a current liability and recorded a warrant liability of $16.2 million which represents the fair market value of the warrants at that date in accordance with Accounting Standards Codification, or ASC, 815, *Derivatives and Hedging* . The initial fair value recorded as warrants within stockholders equity of $11.2 million was reversed. The change in fair value related to periods prior to January 1, 2013 of $5.0 million was recorded as an adjustment to accumulated deficit. At each reporting period subsequent to January 1, 2013, the Company will adjust the fair value of the warrant liability and any corresponding increase or decrease to the warrant liability will be recorded as a component of other (expense)/income on the consolidated statement of operations and comprehensive loss. The estimated fair value is determined using the Black-Scholes option-pricing model based on the estimated value of the underlying common stock at the valuation measurement date, the remaining contractual term of the warrants, risk-free interest rates, expected dividends and expected volatility of the price of the underlying common stock. The fair value of the warrant liability was $12.2 million at June 30, 2013 and we recorded a loss of $385,000 for the three months ended June 30, 2013 and a gain of $4.0 million for the six months ended June 30, 2013 which is included in other (expense)/income in the consolidated statement of operations and comprehensive loss.

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4. COLLABORATION AGREEMENTS

Taiho Pharmaceutical Co., Ltd.

In October 2003, the Company entered into a license, research and development collaboration agreement with Taiho Pharmaceutical Co. Ltd. (Taiho) pursuant to which the Company licensed rights to mocetinostat and its small molecule HDAC inhibitor program for oncology in Japan, South Korea, Taiwan, and China. Under the terms of the agreement, the Company received an up-front license fee of $1.0 million, contract research funding of $3.9 million and equity investment of $2.7 million. In addition, the Company received $5.4 million for preclinical and clinical funding through January 2006 and $2.0 million for milestone payments in 2006 resulting in total proceeds of $12.3 million relating to licensing and research and development activities and $2.7 million relating to equity investment. In addition, the Company may receive milestone payments based on successful development, regulatory approval, and commercialization of an HDAC oncology product, and will receive royalties based on sales of HDAC oncology products in these territories as a percentage of annual net sales, which percentage is in the mid-single digit to mid-teen percent range, depending upon the total dollar amount of annual net sales, subject to reduction in the range of 20-30%, in the event a generic competitor is introduced in a particular market, other than in China. The term of the agreement will, on a country-by-country basis, continue until expiration of the last to expire issued patent, or ten years after the first commercial sale in Japan. Additionally, Taiho has a unilateral right to terminate the agreement for any reason with 30 days written notice, and we have a unilateral right to terminate the agreement if Taiho fails to make an undisputed payment. An arbitrator may terminate the agreement for a breach of obligations if such breach has remained uncured for 90 days. The duration of the agreement is subject to future events. Termination can occur due to breach which is not cured within 30 days; due to insolvency; or when the royalty term for all licensed products ends. If mocetinostat development is restarted, both Taiho s and the Company s obligations in connection with this program would need to be evaluated and such obligations may continue unless the agreement is modified by the parties. There was no revenue recognized from this agreement in either the three or six months ended June 30, 2013 or 2012, respectively.

Otsuka Pharmaceutical Co. Ltd.

On March 25, 2008, the Company entered into a worldwide research collaboration and license agreement with Otsuka Pharmaceutical Co. Ltd. (Otsuka) for the development of novel, small molecule, kinase inhibitors for local delivery and treatment of ocular diseases, excluding cancer. The Company was responsible for the design, characterization and initial screening of kinase inhibitors and determining which compounds to synthesize. Otsuka was responsible for funding efficacy and toxicity studies, as well as preclinical and clinical development of compounds. Otsuka is also responsible for the global commercialization of any resulting product. Under the terms of the agreement, the Company received an up-front license fee of $2.0 million. There was no revenue recognized from this agreement in either the three or six months ended June 30, 2013 or 2012, respectively. The Company may receive up to $50.5 million based on successful development, regulatory, commercialization and sales milestones and will receive royalties as a percentage of annual net sales, which percentage is in the mid-single digit to mid-teen percent range dependent upon the total dollar amount of annual net sales, subject to a reduction by a percentage in the range of 40-50% in the event a generic competitor is introduced in a particular market, or intellectual property protection in a particular market does not exist or expires.

The Company may receive aggregate milestone payments of up to $50.5 million under this agreement as follows: $7.5 million related to development activities, $22.0 million related to the completion of regulatory approvals and $21.0 million related to the achievement of certain sale goals.

Otsuka provided the Company with $1.9 million in research funding for the initial 18 months of the research collaboration which was then extended on three occasions: September 10, 2009, April 23, 2010 and June 30, 2010. The research component of the agreement ended on

June 30, 2011, subsequent to which the Company no longer has any significant ongoing obligations. In 2011, as the Company determined that its substantive performance obligations under the agreement ceased when the research component of the agreement ended on June 30, 2011, the Company accelerated the recognition of the remaining unamortized balance of $1.7 million associated with the up-front license fee in the year ended December 31, 2011. The Company received a total of $4.5 million in research funding from the research component of this agreement. In October 2009, Otsuka made, in relation to the terms of the agreement, a $1.5 million equity investment in the Company s shares of common stock at a share price of CND$21.30 (or $20.75, as converted) in which was a 20% premium over the five-day volume-weighted average closing price at the date of the transaction. Total proceeds received as of June 30, 2013 in connection with this agreement, included research funding of $6.5 million and equity investment of $1.5 million. On June 30, 2010, the collaboration agreement was amended to, among certain other changes; provide Otsuka the rights to synthesize a limited number of compounds predetermined by the Company. A lead molecule was selected in June 2011 for further development. Otsuka is currently advancing the lead compound through late preclinical development. The

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duration of the agreement is subject to future events. The term of the agreement will, on a country-by-country basis, continue until expiration of the last to expire issued patent, or if no patent has issued in such country, then 12 years after the first sale of a licensed product by Otsuka. Otsuka has a unilateral right to terminate the agreement for any reason with 90 days written notice and either party may terminate the agreement for a breach of obligations of the other party if such breach has remained uncured for 120 days (or 30 days for a breach of payment). Termination can occur by a material breach by either party which is not cured within up to 120 days; or in the event Otsuka has not exercised its right to designate at least one Selected Compound (as defined in the agreement) during the Selection Period (as defined in the agreement).

EnVivo Pharmaceuticals

In March 2004, the Company entered into a proof of concept and option agreement with EnVivo Pharmaceuticals, Inc. (EnVivo) focusing on the treatment and prevention of neurodegenerative diseases, to exploit its HDAC inhibitors in diseases such as Huntington s, Parkinson s, and Alzheimer s. On February 7, 2005 the Company signed an exclusive research, collaboration and license agreement. During the year ended December 31, 2005, EnVivo paid the Company $0.6 million for research, plus a $0.5 million license fee for a total of $1.1 million. As part of this agreement, EnVivo received a warrant to purchase 1,050 shares of common stock of the Company at an exercise price of CND$214.30 (or $171.55, as converted). The warrant expired on March 4, 2007. On February 6, 2008, the Company exercised its right to opt-out of the program. As a result, the Company has granted EnVivo exclusive rights to its HDAC inhibitors for neurodegenerative diseases and the Company ceased research and development activities for this program. The Company is entitled to receive royalties equal to a single digit percentage of net sales of any approved compound and will share in any sublicense income from future partnerships that EnVivo may enter into. The duration of the agreement is subject to future events. Either party can terminate the agreement due to a material breach by the other party that is not cured within 30 days or the other party s insolvency. The agreement will also terminate upon mutual agreement by the parties or when no product is under development or being commercialized. The Company did not recognize any revenues in connection with this agreement in either the three or six months ended June 30, 2013 or 2012. The Company does not have any significant ongoing development obligations in connection with this agreement.

5. CASH AND CASH EQUIVALENTS

(in thousands)	June 30, 2013	December 31, 2012
Cash at bank and on hand	**$ 2,333**	$ 2,823
Bankers acceptances	**78**	1,369
Treasury bills	**949**	5,026
Promissory notes	**2,372**	6,020
Commercial papers	**2,184**	753
Term deposit notes	**1,902**	2,714
	9,818	18,705
Less: restricted cash equivalents	**(78)**	(302)
	$ 9,740	$ 18,403

6. MARKETABLE SECURITIES

(in thousands)	June 30, 2013	December 31, 2012
Bankers acceptance issued in Canadian currency, earning interest at a rate of 1.07%(1.20% in 2012) and maturing on August 23, 2013 (February 19, 2013 in 2012)	**$ 285**	$ 72

Commercial paper issued in Canadian currency, earning interest at a rate of 1.03% (1.01% to 1.12% in 2012) and maturing on August 15, 2013 (February 21, 2013 to May 14, 2013 in 2012)		**1,141**		5,026
Treasury bills issued in Canadian currency, earning interest at rates ranging from 0.98% to 1.06% and maturing on July 31, 2013 and September 4, 2013		**1,959**		
Guaranteed investment certificates issued in Canadian currency, earning interest at rates ranging from 1.15% to 1.30% (1.15% to 1.35% in 2012) and maturing on various dates from September 9, 2013 to February 7, 2014 (January 7, 2013 to September 16, 2013 in 2012)		**6,228**		6,518
Term deposits issued in Canadian currency, earning interest at a rate of 1.36% (1.30% to 1.33% in 2012) and maturing on September 13, 2013 (March 18, 2013 to April 15, 2013 in 2012)		**1,188**		7,036
		10,801		18,652
Less restricted marketable securities		**(285)**		(72)
	$	**10,516**	$	18,580

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7. INTEREST AND OTHER RECEIVABLES

(in thousands)	June 30, 2013	December 31, 2012
Other receivables	**$ 66**	$ 425
Interest receivable	**42**	82
	$ 108	$ 507

8. OTHER CURRENT ASSETS

(in thousands)	June 30, 2013	December 31, 2012
Refundable research and development tax credits	**$ 1,030**	$ 593
Commodity taxes	**328**	165
Prepaid expenses	**429**	779
	$ 1,787	$ 1,537

9. ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

(in thousands)	June 30, 2013	December 31, 2012
Accounts payable	**$ 1,405**	$ 1,752
Accrued compensation and benefits	**814**	834
Accrued expenses	**2,297**	2,686
	$ 4,516	$ 5,272

10. INVESTMENT TAX CREDITS

The Company recorded $253,000 and $482,000 related to refundable investment tax credits as a reduction of research and development expenses for the three-month period and six-month period ended June 30, 2013, respectively, and $91,000 and $1.4 million for the three-month period and six-month period ended June 30, 2012, respectively.

11. NET LOSS PER SHARE

Basic and diluted

Net loss per share is calculated by dividing the net loss of the Company by the weighted average number of shares of common stock outstanding during the year.

	Three months ended June 30,		Six months ended June 30,	
	2013	2012	2013	2012
Net loss and comprehensive loss for the period (in thousands)	$ (8,012)	$ (4,677)	$ (12,229)	$ (8,033)
Weighted average number of common shares	9,957,725	6,358,266	9,957,725	6,358,266
Basic and diluted net loss per share	$ (0.81)	$ (0.73)	$ (1.23)	$ (1.26)

Common stock equivalents from warrants and options were excluded from weighted average number of shares of common stock outstanding for the purpose of calculating diluted net loss per share, because the effect is anti-dilutive.

12. FAIR VALUE MEASUREMENT AND FINANCIAL INSTRUMENTS

The following tables present information about the Company s assets and liabilities that are measured at fair value on a recurring basis for the periods presented and indicates the fair value hierarchy of the valuation techniques we utilized to determine such fair value.

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In general, fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities.

Fair values determined by Level 2 inputs utilize data points that are observable such as quoted prices, interest rates and yield curves.

Fair values determined by Level 3 inputs are unobservable data points for the asset or liability, and include situations where there is little, if any, market activity for the asset or liability.

There were no transfers in or out of Level 1, Level 2 or Level 3 measurements for the periods presented (in thousands):

	June 30, 2013	**Level 1**	**Level 2**	**Level 3**
Assets				
Cash equivalents	**$ 7,407**		**$ 7,407**	**$**
Marketable securities	**10,516**		**10,516**	
Restricted cash equivalents and marketable securities	**363**		**363**	
	$ 18,286	**$**	**$ 18,286**	**$**
Liability				
Warrant liability	**12,208**			**12,208**
	$ 12,208	**$**	**$**	**$ 12,208**

	December 31, 2012	**Level 1**	**Level 2**	**Level 3**
Assets				
Cash equivalents	$ 15,580	$	$ 15,580	$
Marketable securities	18,580	$	18,580	
Restricted cash equivalents and marketable securities	374		374	
	$ 34,534	$	$ 34,534	$
Liability				
Warrant liability				
	$	$	$	$

The following table presents a reconciliation of the warrant liability measured at fair value using significant unobservable inputs (Level 3) from January 1, 2013 to June 30, 2013 (in thousands):

	Three months ended June 30,		**Six months ended June 30,**	
	2013	**2012**	**2013**	**2012**
Liabilities:				
Balance at beginning of period:	$ **11,823**	$	$ **16,195**	$
Change in fair value of warrant liability included in other (expense)/income	**385**		**(3,987)**	

Balance at end of period:	$	**12,208**	$	$	**12,208**	$

The fair value of the warrant liability was calculated utilizing the Black-Scholes option-pricing model, using the following assumptions:

	January 1, 2013		**June 30, 2013**	
	2011 Warrants	**2012 Warrants**	**2011 Warrants**	**2012 Warrants**
Risk-free interest rate	1.2%	1.4%	**1.2%**	**1.4%**
Volatility	107.5%	116.3%	**126.4%**	**116.6%**
Dividend yield	0%	0%	**0%**	**0%**
Expected life in years	3.3	4.9	**2.8**	**4.4**

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Other financial assets

The Company s other financial assets consist of interest receivable, other receivables and security deposits. The carrying amount of these financial assets is a reasonable approximation of their fair value due to the short-term nature of these financial assets.

Other financial liabilities

The Company s other financial liabilities include accounts payable and accrued liabilities. The carrying value of the accounts payable and accrued liabilities approximates their fair value due to the short-term nature of these financial liabilities.

13. CONCENTRATION OF CREDIT RISK

The maximum exposure to credit risk of the Company at June 30, 2013 is the carrying value of its cash and cash equivalents, marketable securities, restricted cash equivalents and marketable securities, interest receivable, other receivables and security deposits. The Company has an investment policy that monitors the safety and preservation of investments made, which requires them to be highly rated and which limits the amount invested in any one issuer. The investments are reviewed regularly by the Audit Committee.

The Company also manages credit risk by maintaining bank accounts with reputable banks and financial institutions and investing only in investments from banking, governmental or highly rated companies with securities that are traded on active markets and are capable of immediate liquidation, subject to some minor market price variations upon sale.

Cash and cash equivalents and restricted cash were comprised of bankers acceptances, treasury bills, promissory notes, commercial papers, and term deposits at June 30, 2013 and at December 31, 2012. Cash and cash equivalents and restricted cash as of June 30, 2013 and December 31, 2012 were held in two Canadian chartered banks and one United States bank as follows (in thousands):

	June 30, 2013	December 31, 2012
Cash and cash equivalents	$ **9,740**	$ 18,403
Restricted cash	**363**	374
	$ **10,103**	$ 18,777

Management has determined that other receivables are collectible and has not recorded a provision against these amounts.

The Company continues to have ongoing license and collaboration agreements with three partners. As per the term of these agreements there were no revenues or expenses with these partners for the period ended June 30, 2013 and 2012.

14. SUBSEQUENT EVENTS

For its financial statements as of June 30, 2013 and for the six-months then ended, the Company evaluated subsequent events through August 9, 2013, the date on which those financial statements were available to be issued.

On July 15, 2013, the Company s common stock was listed on the NASDAQ Capital Market and began trading under the ticker symbol MRTX . Effective July 26, 2013, the Company voluntarily delisted its shares of common stock from the Toronto Stock Exchange (TSX).

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

Except for the historical information herein, the following discussion and analysis in this quarterly report on Form 10-Q contains forward-looking statements that involve risks and uncertainties. These statements include projections about our accounting and finances, plans and objectives for the future, future operating and economic performance and other statements regarding future events or conditions. These statements are not guarantees of future performance or events. Our actual results may differ materially from those discussed here. Factors that could cause or contribute to differences in our actual results include those discussed under the caption Risk Factors, as well as those discussed elsewhere in this quarterly report on Form 10-Q or in our other public disclosures. You should consider carefully those cautionary factors, together with all of the other information included in this quarterly report on Form 10-Q. Each of the cautionary factors, either alone or taken together, could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our common stock. There may be additional risks that we are not presently aware of or that we currently believe are immaterial which could also impair our business and financial position. We disclaim any obligation to update any forward-looking statements except as required by law.

We were incorporated under the laws of the State of Delaware on April 29, 2013. Our common shares are listed on the NASDAQ Capital Market since July 15, 2013 under the ticker symbol MRTX . On May 8, 2013, our Board of Directors approved and we entered into an arrangement agreement with MethylGene Inc. (MethylGene). Pursuant to the terms and conditions of the arrangement agreement which was consummated on June 28, 2013, the shareholders of MethylGene received one share of our common stock for every 50 common shares of MethylGene , which had the effect of a 50-for-1 reverse split of the common shares pursuant to a court-approved plan of arrangement under Section 192 of the *Canada Business Corporations Act*. Such transaction is referred to herein as the Arrangement. In addition, all outstanding options and warrants to purchase common shares of MethylGene became exercisable on a 50-for-1 basis for shares of our common stock, and a proportionate adjustment was made to the exercise price. Upon consummation of the Arrangement on June 28, 2013, MethylGene became our wholly-owned subsidiary. As a result, the discussion contained in this Management s Discussion and Analysis of Financial Condition and Results of Operations reflect the consolidated operations of MethylGene .

We are a holding company whose only asset is the stock of MethylGene . We conduct virtually all of our business operations through MethylGene and its wholly owned subsidiary, MethylGene US Inc.

Our historical functional currency was Canadian dollars as of December 31, 2012. Effective January 1, 2013, our functional currency became U.S. dollars. Our reporting currency is U.S. dollars and prior to January 1, 2013, for presentation purposes, assets and liabilities have been translated to U.S. dollars at exchange rates at the reporting date. Income and expenses have been translated to U.S. dollars at the average exchange rate for the period in which the transactions occurred. Equity transactions have been translated at the spot exchange rates on the date the transactions occurred. Exchange rate differences are recognized in a separate component of stockholders equity titled accumulated other comprehensive income.

Overview

We are a biopharmaceutical company engaged in the development of novel therapeutics for the treatment of patients with cancer. Our common shares have been listed on the NASDAQ Capital Market since July 15, 2013 under the ticker symbol MRTX . Our compounds result from internal chemistry efforts targeting the active sites of enzymes that are key drivers of tumor growth. Our clinical development programs are focused on targeted cancer patient populations with unmet medical need. Our kinase programs are being developed by treating cancer patients with selected tumor types that express high levels or key driver mutations of these targeted pathways in order to provide the greatest clinical benefit while minimizing side effects.

Our program in clinical development is MGCD265, a multi-targeted small molecule kinase inhibitor for treatment of oncology patients with solid tumors and we are evaluating opportunities for the potential initiation of further clinical development of mocetinostat, a spectrum-selective HDAC inhibitor for the treatment of patients with myelodysplastic syndrome or lymphoma. In addition, MGCD516 is a unique kinase inhibitor with a distinct target profile which is in preclinical development for the treatment of patients with non-small cell lung cancer and other solid tumors.

MGCD265 is in Phase 1 clinical development and we are evaluating opportunities to begin new studies with mocetinostat which is in Phase 2 clinical development. In addition, we have the opportunity to advance the preclinical product candidate MGCD516, into clinical development. We own all rights to MGCD265 and MGCD516. We have certain royalty and licensing arrangements pursuant to a partnership with Taiho Pharmaceutical Co. Ltd. covering mocetinostat in certain Asian territories and we own all rights to mocetinostat outside of those territories. In addition, we have partnerships with Otsuka Pharmaceutical Co. Ltd. and EnVivo Pharmaceuticals, Inc. for other pipeline programs.

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We have not generated any revenues from product sales. To date, we have funded our operations primarily through the sale of our common stock and through up-front payments, research funding and milestone payments from our collaboration arrangements.

We have incurred losses in each year since our inception. Our net losses were $12.2 million for the six months ended June 30, 2013, and $20.3 million and $9.8 million for 2012 and 2011, respectively. As of June 30, 2013 we had an accumulated deficit of $157.8 million. Substantially all of our operating losses resulted from expenses incurred in connection with our drug candidate development programs, our research activities and general and administrative costs associated with our operations.

We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. In the near term, we anticipate that our expenses will increase as we:

- advance the ongoing clinical development of MDCD265 for the treatment of cancer patients with solid tumors;
- evaluate opportunities for the potential further clinical development of mocetinostat for the treatment of patients with myelodysplastic syndromes and lymphoma;
- evaluate opportunities for the potential clinical development of our preclinical programs, including MGCD516 a novel multi-targeted kinase inhibitor for the treatment of patients with solid tumors, including non small cell lung cancer;
- continue our translational science research efforts;
- maintain, expand and protect our intellectual property portfolio;;
- evaluate opportunities to expand our pipeline through partnerships or collaborations; and
- provide general and administrative support for our operations.

To fund future operations we will need to raise additional capital. The amount and timing of future funding requirements will depend on several 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 assure you that 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.

Critical Accounting Policies and Significant Judgments and Estimates

Our management s discussion and analysis of financial condition and results of operations are based upon our 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, revenues and expenses and related

disclosures. On an ongoing basis, our actual results may differ significantly from our estimates.

There were no significant changes in critical accounting policies from those at December 31, 2012. The financial information as of June 30, 2013 should be read in conjunction with the financial statements for the year ended December 31, 2012, contained in our Registration Statement on Form 10 (No. 001-35921), originally filed with the SEC on May 10, 2013, as amended.

For a further discussion of our critical accounting policies, see Item 2. Financial Information under the heading Management s Discussion and Analysis of Financial Condition and Results of Operations contained in our Registration Statement on Form 10 (No. 001-35921), originally filed with the SEC on May 10, 2013, as amended.

Results of Operations

Comparison of the Three Months Ended June 30, 2013 and 2012

The following table summarizes our results of operations for the three months ended June 30, 2013 and 2012 (in thousands):

	Three Months Ended June 30,		
	2013	**2012**	**Increase (Decrease)**
Research and development expenses, net	$ 4,510	$ 3,652	$ 858
General and administrative expenses	2,382	1,082	1,300
Other (loss)/income, net	(1,079)	70	(1,149)

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Research and Development Expenses

Our research and development efforts have been focused on MGCD265 for oncology and MGCD290 for antifungal indications. In future periods, we intend to focus our research and development efforts on oncology, including MGCD265, mocetinostat and MGCD516. The following table summarizes our research and development expenses for the three months ended June 30, 2013 and 2012 (in thousands):

	Three months ended June 30,	
	2013	**2012**
Third-party clinical development costs:		
MGCD265	**$ 2,046**	$ 1,308
MGCD290	**166**	639
Mocetinostat	**532**	18
MGCD516	**372**	
Total third-party clinical development costs:	**3,116**	1,965
Internal clinical development costs	**1,132**	1,107
Total clinical development	**4,248**	3,072
Non-clinical research and development	**515**	671
Research and development, gross	**4,763**	3,743
Less: Investment tax credits	**(253)**	(91)
Research and development, net	**4,510**	**$** 3,652

Net research and development expenses were $4.5 million for the three months ended June 30, 2013 compared to $3.7 million for the same period in 2012. The increase primarily reflects increased third-party clinical development costs due to ongoing formulation development for MGCD265 as we work to achieve the maximum tolerated dose as well as costs associated with the preparation for a potential study for mocetinostat in the fourth quarter of 2013, and costs associated with preparation for an Investigational New Drug application for MGCD516, being evaluated and planned for the first quarter of 2014. Partially offsetting these increases were reduced costs for MGCD290 which we are no longer actively pursuing internally and an increase in investment tax credits due to our higher level of investment in research and development activities.

General and Administrative Expenses

General and administrative expenses were $2.4 million for the three months ended June 30, 2013 compared to $1.1 million for the same period in 2012. The increase primarily reflects costs associated with the previously described arrangement agreement and subsequent listing on the NASDAQ Capital Market, which was effective on July 15, 2013.

Other (Expense)/ Income, Net

Other (expense)/income, net was a loss of $1.1 million for the three months ended June 30, 2013 compared to income of $70,000 for the same period in 2012. This increase primarily reflects a foreign exchange loss of $0.8 million as a result of transitioning to the U.S. dollar as the functional currency and a loss of $0.4 million due to the change in fair value of our warrant liability.

Comparison of the Six Months Ended June 30, 2013 and 2012

The following table summarizes the results of our operations for the six months ended June 30, 2013 and 2012 (in thousands):

	Six Months Ended June 30,		
	2013	**2012**	**Increase**
Research and development expenses, net	$ 9,985	$ 5,856	$ 4,129
General and administrative expenses	4,906	2,302	2,604
Other income, net	2,722	138	2,584

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Research and Development Expenses

Our research and development efforts have been focused on MGCD265 for oncology and MGCD290 for antifungal indications. In future periods, we intend to focus our research and development efforts on oncology, including MGCD265. The following table summarizes our research and development expenses for the six months ended June 30, 2013 and 2012 (in thousands):

	Six months ended June 30,	
	2013	**2012**
Third-party clinical development costs:		
MGCD265	**$ 3,917**	$ 2,477
MGCD290	**998**	1,174
Mocetinostat	**615**	32
MGCD516	**457**	
Total third-party clinical development costs:	**5,987**	3,683
Internal clinical development costs	**2,820**	2,194
Total clinical development	**8,807**	5,877
Non-clinical research and development	**1,660**	1,374
Research and development, gross	**10,467**	7,251
Less: Investment tax credits	**(482)**	(1,393)
Research and development, net	**$ 9,985**	$ 5,858

Net research and development expenses were $10.0 million for the six months ended June 30, 2013 compared to $5.9 million for the same period in 2012. The increase primarily reflects the same factors that influenced similar fluctuations in the three months ended June 30, 2013 discussed above as well as costs associated with management changes implemented in the first and second quarter of 2013 and a reduction in investment tax credits due to the fact the prior year included a favorable adjustment of prior year calculations subsequent to the completion of an audit by the provincial tax authority in Canada.

General and Administrative Expenses

General and administrative expenses were $4.9 million for the six months ended June 30, 2013 compared to $2.3 million for the same period in 2012. The increase primarily reflects the same factors that influenced similar fluctuations in the three months ended June 30, 2013 as well as costs associated with the plan of arrangement and management changes implemented in the first and second quarter of 2013.

Other Income, Net

Other income, net was $2.7 million for the six months ended June 30, 2013 compared to $0.1 million for the same period in 2012. The increase primarily reflects a gain of $4.0 million from the change in fair value of our warrant liability, partially offset by a foreign exchange loss of $1.4 million primarily due to the transition to the U.S. dollar as the functional currency.

Liquidity and Capital Resources

Since our inception, our operations have been primarily financed through public and private sales of our equity and payments received under our collaboration arrangements. Since inception, we have devoted our resources to funding research and development programs, including discovery research, preclinical and clinical development activities.

Going Concern

As of June 30, 2013, substantial doubt exists over our ability to continue as a going concern. We believe that our current cash and cash equivalents, marketable securities and restricted cash equivalents and marketable securities are sufficient to carry out our currently planned clinical development and operating plans into the second quarter of 2014, without considering potential future financing. Our cash and cash equivalents and marketable securities decreased by $16.7 million in the six months ended June 30, 2013, reflecting an average rate of negative cash flow per month of approximately $2.8 million. Excluding non-recurring costs associated with recent management changes and costs associated with the previously described Arrangement and listing on the NASDAQ Capital

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Market of $2.6 million, of which $1.4 million relate to the Arrangement and NASDAQ listing, our cash and cash equivalents, and marketable securities decreased by $14.1 million in the six months ended June 30, 2013 reflecting an average rate of negative cash flow per month of approximately $2.4 million. While our rate of future negative cash flow per month will vary due to the timing of expenses incurred and the programs that are funded, at the current rate of negative cash flow per month we believe that our current cash and cash equivalents and marketable securities will enable us to complete Phase 1 development of MCGD265, which if successful would enable us to enter Phase 2 development. Our future cash requirements could increase if we decide to expand our research and development efforts beyond the currently planned development of MCGD265.

We have incurred operating losses in each year since our inception and we expect to continue to incur operating losses into the foreseeable future as we advance the ongoing development of our lead product candidate MCGD265; evaluate opportunities for the potential initiation of further clinical development of mocetinostat; evaluate opportunities for the potential clinical development of our preclinical programs, including MGCD516, and continue our research efforts. To fund future operations we will 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. Additional financing may not be available to us on favorable terms, or at all. Although we have previously been successful in obtaining financing through our equity securities offerings, we may not be able to do so in the future. If we are not able to secure adequate additional financings we may be forced to make reductions in spending and/or liquidate assets where possible. Any of these actions could harm our business and our results of operations.

At June 30, 2013 we had $20.6 million of cash and cash equivalents, marketable securities, and restricted cash and marketable securities compared to $37.4 million at December 31, 2012.

Cash Flows for the Six Months Ended June 30, 2013 and 2012

Operating Activities

Cash used for operating activities for the six months ended June 30, 2013 was $16.5 million compared to $7.3 million for the same period in 2012. The increase relates primarily to the increased operating costs in the first six months of 2013, including non-recurring costs associated with the previously discussed plan of arrangement, the NASDAQ listing and recent management changes, compared to the same period in 2012 discussed above.

Investing Activities

Investing activities consist primarily of purchases, sales and maturities of marketable securities and purchases of property and equipment. Investing activities provided cash of $7.9 million and $5.4 million for the six months ended June 30, 2013 and 2012, respectively. We acquired $0.2 million of property and equipment in the six months ended June 30, 2013 compared to $0.1 million in the six months ended June 30, 2012. This increase reflects higher capital expenditures for information technology.

Financing Activities

Financing activities consist primarily of net proceeds from the sale of common stock and warrants and proceeds from the exercise of stock options and warrants. There were no financing activities for the six months ended June 30, 2013. We used $16,000 of cash for reorganization costs for the six months ended June 30, 2012.

As of June 30, 2013 and December 31, 2012 we had restricted cash equivalents and marketable securities of $0.4 million. We expect the restricted cash equivalents and marketable securities to reduce to $0.1 million by December 2013 related to letters of credit underlying the Company s corporate credit cards.

Off-Balance Sheet Arrangements

During the six months ended June 30, 2013, 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.

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ITEM 4. Controls and Procedures

As of June 30, 2013, an evaluation was performed under the supervision and with the participation of our management, including our President and Chief Executive Officer (referred to as our CEO) and our Executive Vice President, and Chief Operations Officer (referred to as our COO), of the effectiveness of the design and operation of our disclosure controls and procedures. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on that evaluation, our management, including our CEO and COO, concluded that our disclosure controls and procedures were effective at a reasonable level of assurance as of June 30, 2013.

Our management does not expect that our disclosure control and procedures or our internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, or misstatements due to error, if any, within the company have been detected. While we believe that our disclosure controls and procedures and internal control over financial reporting are and have been effective, in light of the foregoing we intend to continue to examine and refine our disclosure controls and procedures and internal control over financial reporting.

An evaluation was also performed under the supervision and with the participation of our management, including our CEO and COO, of any change in our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. That evaluation did not identify any change in our internal control over financial reporting that occurred during our latest fiscal quarter and that has materially affected, or is reasonably likely to affect, our internal control over financial reporting.

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PART II OTHER INFORMATION

ITEM 1A. Risk Factors.

You should carefully consider the following risk factors, as well as the other information in this report, before deciding whether to purchase, hold or sell shares of our common stock. The occurrence of any of the following risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this quarterly report on Form 10-Q and those we may make from time to time. You should consider all of the risk factors described when evaluating our business.

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 net research and development expenses were $10.0 million for the six months ended June 30, 2013, and $15.1 million and $8.9 million for 2012 and 2011, respectively. We believe that our current cash will sustain our operations into the second quarter of 2014. We will require substantial additional capital to pursue additional clinical development for our lead clinical programs, including conducting 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, or FDA or any foreign regulatory agency, such as the European Medicines Agency, or EMA, requires that we perform studies or trials in addition to those that we currently anticipate with respect to the development of MGCD265, or repeat studies or trials, our expenses would further increase beyond what we currently expect. Any delay resulting from such further or repeat studies or trials could also result in the need for additional financing. There is no assurance that we can adequately finance our development programs, which could lead to delays, limit our ability to move our programs forward in a timely and satisfactory manner or abandon the programs, any of which would harm our business, financial condition and results of operations.

We currently do not have sufficient cash to complete advanced clinical development of any of our product candidates or, if applicable, to prepare for commercializing any product candidate that is approved. Accordingly, we will require substantial additional capital to continue our clinical development activities and potentially engage in commercialization activities. 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, including on a timely basis, we may be required to (1) seek 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.

Substantial doubt exists over our ability to continue as a going concern

As of June 30, 2013, substantial doubt exists over our ability to continue as a going concern. We believe that our current cash and cash equivalents, marketable securities and restricted cash equivalents and marketable securities are sufficient to carry out our currently planned clinical development and operating plans into the second quarter of 2014, without considering potential future financing. Our cash and cash equivalents and marketable securities decreased by $16.7 million in the six months ended June 30, 2013, reflecting an average rate of negative cash flow per month of approximately $2.8 million. Excluding non-recurring costs associated with recent management changes and costs associated with the previously described arrangement agreement and listing on the NASDAQ Capital Market of $2.6 million, of which $1.4 million relates to the Arrangement and NASDAQ listing, our cash and cash equivalents, marketable securities decreased by $14.1 million in the six months ended June 30, 2013 reflecting an average rate of negative cash flow per month of approximately $2.4 million. While our rate of future negative cash flow per month will vary due to the timing of expenses incurred and the programs that are funded, at the current rate of negative cash flow per month we believe that our current cash and cash equivalents and marketable securities will enable us to complete Phase 1 development of MCGD265, which if successful would enable us to enter Phase 2 development. Our future cash requirements could increase if we decide to expand our research and development efforts beyond the currently planned development of MCGD265.

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We are a clinical stage company with no approved products and no historical product revenues. We cannot predict when we will generate significant revenues and may never achieve or maintain profitability.

We are an early-stage development 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;
- 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 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, or 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 improve our accounting systems and controls.

Accordingly, the likelihood of our success must be evaluated in light of many potential challenges and variables associates with an early-stage drug development 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. 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 revenues from the sale of any approved product, we may never become profitable. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to predict the timing or amount of expenses and when we will be able to achieve or maintain profitability, if ever.

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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 revenues from our research and licensing agreements which have not been sufficient to cover the substantial expenses we have incurred in our efforts to develop our products. Consequently, we have accumulated net losses since inception in 1995. Our net loss for the six months ended June 30, 2013 was $12.2 million and for 2012 and 2011 it was $20.3 million and $9.8 million, respectively. As of June 30, 2013, we had an accumulated deficit of $157.8 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 revenues 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. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our ability to generate future revenues from product sales depends heavily on our success in:

- completing development and clinical trial programs for our product candidate MGCD265;
- entering into collaboration and license agreements;
- 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, 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 collaboration and licensing arrangements, it may be necessary to relinquish potentially valuable rights to our products or proprietary technologies, or grant licenses on terms that are not favorable to us. Additional funding may not be available to us on acceptable terms, or at all.

We may incur losses associated with foreign currency fluctuation.

Our head office was previously located in Canada and many of our material contracts were entered into in Canada. A significant portion of our expenditures are in foreign currencies, most notably in Canadian dollars; therefore, we are subject to foreign currency fluctuations which may, from time to time, impact (positively or negatively) our financial position and results. Exchange rates can fluctuate significantly and cannot be easily predicted; thus, we may experience significant shifts in currency exchange variances in the future. We maintain bank accounts in both Canadian and United States dollars and do not hedge our positions. Our functional currency at December 31, 2012 was the Canadian dollar and based on extensive analysis of projected expenses we have changed the functional currency to the United States dollar effective January 1, 2013.

As a public company in the United States, we will be 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 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 Exchange Act to contain a report from management assessing the effectiveness of a company s internal control over financial reporting.

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As a smaller reporting company as defined in the Exchange Act we will be required to comply with Section 404 of the Sarbanes-Oxley Act although, as an emerging growth company and a smaller reporting company, we are not required to comply with Section 404(b) which requires attestation from our external auditors on our internal control over financial reporting. We will, however, be subject to Section 404(a) which requires management to provide a report regarding the effectiveness of internal controls. We were previously listed on the TSX since June 2004 until July 2013 and were subject to similar governance requirements under Multi-lateral Instrument 52-109. We are required to review all of our control processes to align them to the SOX 404 requirements. Failure to provide assurance that our financial controls are effective could lead to lack of confidence by investors which could lead to a lower share price. When and if we are a large accelerated filer or an accelerated filer and are no longer an emerging growth company, (each as defined in the Exchange Act or the Securities Act), our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing, and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we may need to upgrade our systems including information technology, implement additional financial and management controls, reporting systems, and procedures, and hire additional accounting and finance staff.

We will incur significant increased costs as a result of operating as a U.S. public company and continuing to be a Canadian reporting issuer.

Although we de-listed from the TSX effective as of July 26, 2013, we will continue to be subject to Canadian reporting obligations. Our Canadian reporting obligations will continue until we meet certain prescribed thresholds which would allow us to apply to cease being a Canadian reporting issuer . We may incur significant additional accounting, reporting and other expenses in order to maintain listing The NASDAQ Capital Market, and fulfill our obligations as a Canadian reporting issuer. For example, we may incur additional expenses if we are required to continue to present our financial information according to International Financial Reporting Standards in Canada, as well as according to U.S. GAAP in the United States. In addition, as a U.S. listed public company, we will incur significant additional legal, accounting and other expenses that we did not incur as a company listed on the TSX. 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. Incremental recurring external costs associated with being a publicly traded company in the United States are estimated to be approximately $0.5 million per year consisting primarily of increased legal, accounting and insurance costs.

Our operating results may fluctuate significantly, and any failure to meet financial expectations may disappoint securities analysts or investors and result in a decline in the price of our securities.

We have a history of operating losses. Our operating results have fluctuated in the past and are likely to do so in the future. These fluctuations could cause our share price to decline. Due to fluctuations in our operating results, we believe that period-to-period comparisons of our results are not indicative of our future performance. It is possible that in some future quarter or quarters, our operating results will be above or below the expectations of securities analysts or investors. In this case, the price of our securities could decline.

We are an emerging growth company and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company. Under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We plan to avail ourselves of this exemption from new or revised accounting standards and, therefore, we may not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

For as long as we continue to be an emerging growth company, we also intend to take advantage of certain other exemptions from various reporting requirements that are applicable to other public companies including, but not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding advisory stockholder vote on executive compensation and any golden parachute payments not previously approved, exemption from the requirement of auditor attestation in the assessment of our internal control over financial reporting and exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board. If we do, the information that we provide stockholders may be different than what is available with respect to other public companies. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

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We will remain an emerging growth company until the earliest of (1) the end of the fiscal year in which the market value of our common stock that is held by non-affiliates exceeds $700 million as of the end of the second fiscal quarter, (2) the end of the fiscal year in which we have total annual gross revenues of $1 billion or more during such fiscal year, (3) the date on which we issue more than $1 billion in non-convertible debt in a three-year period or (4) the end of the fiscal year following the fifth anniversary of the date of the first sale of our common stock pursuant to an effective registration statement filed under the Securities Act.

Decreased disclosures in our SEC filings due to our status as an emerging growth company may make it harder for investors to analyze our results of operations and financial prospects.

We are a smaller reporting company and we cannot be certain if the reduced disclosure requirements applicable to smaller reporting companies will make our common stock less attractive to investors.

We are currently a smaller reporting company , meaning that we are not an investment company, an asset-backed issuer, or a majority-owned subsidiary of a parent company that is not a smaller reporting company and have a public float of less than $75 million and annual revenues of less than $50 million during the most recently completed fiscal year. In the event that we are still considered a smaller reporting company , at such time are we cease being an emerging growth company , we will be required to provide additional disclosure in our SEC filings. However, similar to emerging growth companies , smaller reporting companies are able to provide simplified executive compensation disclosures in their filings; are exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring that independent registered public accounting firms provide an attestation report on the effectiveness of internal control over financial reporting; and have certain other decreased disclosure obligations in their SEC filings, including, among other things, only being required to provide two years of audited financial statements in annual reports.

Decreased disclosures in our SEC filings due to our status as a smaller reporting company may make it harder for investors to analyze our results of operations and financial prospects.

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 commercialize our products.

Our clinical 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. We currently have no product candidates beyond Phase II clinical trials. Mocetinostat is our only oncology product candidate currently ready for Phase II clinical trials, with MGCD265 in Phase I and Phase I/II clinical trials and MGCD516 is still in advanced pre-clinical development. Even if we obtained the required financing we cannot assure successful product development or that we will obtain regulatory approval or successfully commercialize any of our product candidates and generate revenues. Success in pre-clinical 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 a product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay and possibly preclude the filing of any new drug applications with the FDA and, ultimately, our ability to commercialize our product

candidates and generate product revenues.

All of our clinical candidates will be subject to extensive regulation which can be costly and time consuming, cause delays or prevent approval of the products for commercialization.

The clinical development of product candidates is subject to extensive regulations by the FDA in the United States and by comparable regulatory authorities in Canada and other foreign markets. Product development is a very lengthy and expensive process and 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, Canada and other countries where we intend to market our products. Such legislation and regulation bears upon, among other things, the approval of 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, or GMP, during production and storage as well as regulation of marketing activities including advertising and labeling.

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In order to obtain regulatory clearance 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, efficacious for use in humans for each target indication and, in many cases, that it has significant advantages compared to existing approved treatments. The failure to adequately demonstrate the safety, efficacy, or superiority of a product under development could delay or prevent regulatory clearance of the 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, Canada or other foreign markets. The agencies may also require additional trials be run in order to provide additional information regarding the safety, efficacy or equivalency of any compound 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 adverse 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.

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 as well as outsourcing manufacturing to collaborators and/or contract manufacturers and we rely on third parties for quality assurance, clinical monitoring, clinical data management and regulatory expertise. We may also engage a CRO to run all aspects of a clinical trial on our behalf. 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 in a quality fashion 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 clinical data management or manufacturing services. In addition, the cost of such services could be significantly increased over time. We rely on third parties and collaborators 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. Our reliance on these parties, however, does not relieve us of our regulatory responsibilities, including ensuring that our clinical trials are conducted in accordance with 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. Pre-clinical studies may not be performed or completed in accordance with GLP regulatory requirements or our trial design. 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 these third parties will pass FDA or regulatory audits, which could delay or prohibit regulatory approval.

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.

Our expectations regarding the success of our product candidates, including our clinical candidates and lead compounds, and our business are based on projections which may not be realized for many scientific or business reasons. We therefore cannot assure investors that we will be able to adhere to our current schedule. We set goals and make public statements that forecast the accomplishment of objectives material to our

success: selecting clinical candidates, product candidates, timing of events, failures in research, the inability to identify or advance lead compounds, identifying target patient groups or clinical candidates, the commencement and completion of clinical trials, including reaching the MTD within a certain timeframe, and anticipated regulatory approval. The actual timing of these events can vary dramatically due to factors such as slow enrollment of patients in studies, difficulty in finding an MTD particularly for an oncology product candidate, uncertainties in scale-up, manufacturing and formulation of our compounds, failures in research, the inability to identify clinical candidates, failures in our clinical trials, and uncertainties inherent in the regulatory approval process and regulatory submissions. Decisions by our partners or collaborators may also affect our timelines and delays in achieving manufacturing capacity and marketing infrastructure sufficient to commercialize our biopharmaceutical products. The length of time necessary to complete clinical trials and to submit an application for marketing approval by applicable regulatory authorities may also vary significantly based on the type, complexity and novelty of the product candidate involved, as well as other factors. The duration of a Phase I clinical trial program can be significantly extended as the attainment of an appropriate dose may be delayed, resulting in additional costs and overall program delays. If a trial or phase of a trial has commenced, it could be placed on clinical hold if the regulatory authorities determine a trial or its design may be unsafe or require clarifications regarding protocol design.

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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 Canada, 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 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 TPD, the FDA or by 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 compound 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. Similar restrictions are imposed in foreign markets other than the United States and Canada. Regulatory agencies could become more risk adverse 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.

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.

We have no experience in 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.

There are no assurances we can scale-up, formulate or manufacture any compound in sufficient quantities with acceptable specifications for the regulatory agencies to grant approval. 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 compounds during scale-up and manufacturing.

We rely on collaborators and/or third parties for development, scale-up, formulation, optimization, management of clinical trial and commercial scale manufacturing and commercialization. This 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 revenues:

- Contract manufacturers can encounter difficulties in achieving the scale-up, optimization, formulation, 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 TPD, FDA, 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 material for clinical study, leading to delays in our trials.

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- 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 nationally 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, if at all.

- 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 will depend on achieving market acceptance and we may not be able to gain sufficient acceptance to generate significant revenues.

Even if our product candidates are successfully developed and receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payers 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 payers to the extent that our products could receive regulatory approval but not be approved for coverage or adequate reimbursement by government or quasi government agencies.

Disease indications for which regulatory approval is sought may be small or large. These 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 adequate healthcare 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, payers 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 compound obsolete.

Our ability to commercialize our products with success may depend, in part, on the extent to which coverage and adequate reimbursement to patients for the cost of such products and related treatment will be available from governmental health administration authorities, private health coverage insurers and other organizations, as well as the ability of private payers to pay for or afford our drugs. No assurance can be given that adequate third party coverage will be available to patients that will allow us to maintain price levels sufficient for the realization of an appropriate return on our investment in product development.

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Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payers is critical to new product acceptance. 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.

In the United States, in Canada 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. 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, or PPACA, became law in the United States. PPACA substantially changes the way healthcare is financed by both governmental and private insurers and significantly affects the healthcare industry. The provisions of PPACA of importance to our potential product candidates include the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, beginning in 2011;

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23% and 13% of the average manufacturer price for most branded and generic drugs, respectively;

- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;

- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer s outpatient drugs to be covered under Medicare Part D;

- extension of manufacturers Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;

- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals beginning in 2014 and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing manufacturers Medicaid rebate liability;

- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;

- new requirements to report annually certain financial arrangements with physicians, certain other healthcare professionals, and teaching hospitals, as defined in PPACA and its implementing regulations, including reporting any payments or transfers of value made or distributed to physicians, certain other healthcare providers, and teaching hospitals, and reporting any ownership and investment interests held by physicians and certain other healthcare providers and their immediate family members and applicable group purchasing organizations during the preceding calendar year, with data collection to be required beginning August 1, 2013 and reporting to the Centers for Medicare and Medicaid Services to be required by March 31, 2014 and by the 90th day of each subsequent calendar year;

- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and

- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted since PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011, created, among other things, 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,

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was unable to reach required goals, thereby triggering the legislation s automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new 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.

We anticipate that PPACA will result in additional downward pressure on the reimbursement we may receive for any approved and covered product, and could seriously harm our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payers. In the future, the U.S. government may institute further controls and different reimbursement schemes and limits on Medicare and Medicaid spending or reimbursement that may affect the payments we could collect from sales of any products in the United States. 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.

If we fail to comply with federal and state healthcare laws, including fraud and abuse and health information privacy and security laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected.

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 payers, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which constrains our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities, by prohibiting, among other things, soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, either the referral of an individual or the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and

- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, 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 and regulatory exceptions, 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 and criminal penalties, damages, fines, imprisonment, exclusion of products from reimbursement under U.S. federal or state healthcare programs, and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could materially adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management s attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

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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 several hundred 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.; ArQule Inc. and its partners Kyowa Hakko Kirin Pharma Inc. and Daiichi Sankyo Company Limited; Aveo Pharmaceuticals Inc.; Bristol-Myers Squibb Company; Exelixis Inc.; F. Hoffman-LaRoche Ltd.; GlaxoSmithKline PLC.; Novartis AG; and Pfizer Inc., among others.

Many companies have filed, and continue to file, patent applications in oncology which may or could affect our program. Some of these patent applications may have already been allowed or granted. These companies include, but are not limited to: Bristol-Myers Squibb Company; Compugen Limited; Exelixis Inc.; GlaxoSmithKline PLC.; Novartis; and Pfizer Inc. Since this area is competitive and of strong interest to pharmaceutical and biotechnology companies, there will most likely be additional patent applications published and filed in the future, and additional research and development programs expected in the future.

In addition to companies that have HDAC inhibitors or kinase inhibitors addressing oncology indications, 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. 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.

Most 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 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.

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. The marketing collaborators we work with may not be adequate, 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 revenues, or our marketing and sales efforts may be unsuccessful. If we are unable to develop an internal marketing and sales capability 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.

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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, Mark J. Gergen, our Executive Vice President and Chief Operations Officer, Rachel Humphrey, M.D., our Executive Vice President and Chief Medical Officer, and Jamie A. Donadio, our Vice President of Finance, whose services are critical to the successful implementation of our product candidate acquisition, development and regulatory strategies. 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.

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 or 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 acts. 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;

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- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenues from product sales; and
- the inability to commercialize any our product candidates, if approved.

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 CND$10 million in product liability insurance in Canada, 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, provincial and local 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 both Canada and the United States make it relatively easy for stockholders to sue. This could lead to frivolous law suits 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, 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, 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 programs. 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 as a result, our drug discovery 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. In addition our employees could become ill through pandemic diseases or other events that could materially interfere with, or stop, our operations.

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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.

Because developing pharmaceutical products, conducting clinical trials, obtaining regulatory approval, establishing manufacturing capabilities and marketing approved products are expensive, we may seek to enter into collaborations with companies that have more resources and experience and we may become dependent upon the establishment and successful implementation of collaboration agreements. We also may be required due to financial or scientific constraints to enter into additional corporate collaboration agreements to research and/or to develop and commercialize our compounds and/or our product candidates. The establishment and realization of such collaborative agreements may be not be possible or may be problematic. There can be no assurance, however, 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 project or indication. If we are unable to reach successful agreements with suitable partners for our product candidates, we would 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 them and we might fail to commercialize products or programs for which a suitable partner cannot be found. If we fail to achieve successful partnerships, our operating results and financial condition will be materially and adversely affected.

In addition collaboration agreements may place restrictions or additional obligations on our ability to license additional compounds in different indications, diseases or geographical locations. If we fail to comply with or breach any provision of a collaborative or license 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 are complex and involve sharing of certain data, know-how and intellectual property rights amongst the various parties. Accordingly our collaborators could interpret certain provisions differently than we or our other partners which could lead to unexpected or inadvertent disputes with partners. In addition, these agreements might make additional 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 partners could breach covenants, restrictions and/or sub-license agreement provisions leading us into disputes and potential breaches of our agreements with other partners.

Risks Relating to Our Intellectual Property

We may not obtain adequate protection for our products 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, Canada, Japan, Europe and other major markets via the Patent Cooperation Treaty or directly in countries of interest. The patent positions of healthcare companies, biopharmaceutical companies, including ours, and universities 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. Our patents may be challenged by third parties 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 based on incomplete facts. We cannot be certain that we are the first to invent 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 term of certain patents or all of the 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 a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. No assurance can be given that our patents would be declared by a court to be valid or enforceable or that a competitor s technology or product would be found by a court to infringe our patents. We may analyze our competitors patents or patent applications and believe we are free to operate but there could be claims granted to our competitors, potentially in unrelated patents, which block our efforts or cause us to infringe such claims. The possibility exists that others will develop products which have the same effect as our products on an independent basis or will design around products that we patented. The steps we have taken to protect our intellectual property may not prevent the appropriation of our proprietary information and technologies, particularly in foreign countries where laws or law enforcement practices may not protect proprietary rights as fully as in Canada, the United States or Europe. Unauthorized disclosure

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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 claims restricted or we may not be able to supply sufficient data to satisfy a patent office to support our claims and, as a result, may not obtain the original claims desired or we may receive restricted claims. Alternatively, it is possible that we may not receive any patent protection from an application. We could inadvertently abandon a patent or patent application (or trademark or trademark application), resulting in the loss of protection of certain intellectual property rights in a certain country. 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 in Canada, the United States and other countries that belong to us are subject to the same 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. 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 seriously affect how we draft, file, prosecute and/or maintain patents and patent applications. We cannot be certain that increasing costs for drafting, filing, prosecuting and maintaining patent applications and patents will not restrict our ability to file for patent protection. 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 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 have filed applications for trademark registrations in connection with our product candidates in various jurisdictions, including the United States. We intend to file further applications for other possible trademarks for our product candidates. 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 regulatory authority will approve of any of our trademarks or will not request reconsideration of one of our trademarks 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 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, non-disclosure and non-compete 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, may cause serious 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.

We may be required to reduce the scope of our intellectual property due to third-party intellectual property infringement claims. Patent litigation, including defense against third-party intellectual property claims may incur substantial costs.

Patent applications which may relate to or affect our business may have been filed by others. Such patent applications or patents resulting therefrom may conflict with our technologies, patents or patent applications and reducing the scope of our patent protection. Such events could cause us to stop or change the course of our research and development. 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. There can be no guarantees that an interference proceeding would be successful or that such an outcome could be reversed on appeal.

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.

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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. 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 and require us or any third-party licensors to obtain a license to continue to use the affected technologies. We cannot predict whether we would prevail in any of these types of actions or that any required license would be available on commercially acceptable terms or at all. 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.

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. We may attempt to invalidate a competitor s patent. There is no assurance such action will ultimately be successful and even if initially successful; it could be overturned upon appeal. 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 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 for 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 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.

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, Canada or abroad, 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 stock fluctuations 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 the shares. We may have little or no ability to impact or alter such decisions.

A small number of stockholders control the majority of our shares, and their actions may significantly influence the share price.

As of June 30, 2013, eleven stockholders beneficially owned approximately 89% of our outstanding common stock, or approximately 90.1% assuming exercise of outstanding warrants to purchase shares of common stock and stock options (vested and unvested). Baker Bros. Advisors LLC and Tavistock Life Sciences Co. and their affiliates collectively own approximately 40% of our

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outstanding common stock. In addition, in conjunction with certain financing transactions, we granted to Baker Brothers and Tavistock each the right to nominate a member of our Board of Directors and the right to appoint an observer on our Board of Directors. As a result, each of Baker Brothers and Tavistock has 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, Tavistock, or any of other of our major stockholders determine to exit from the industry or from their holdings in us, for whatever reason, the impact on the 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 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, or the 2013 plan, our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. Any increase in the number of shares outstanding as a result of the exercise of outstanding options will cause our stockholders to experience additional dilution, which could cause our stock price to fall. Currently, we plan to register the increased number of shares available for issuance under the 2013 plan each year.

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

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an ownership change, 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 net operating loss carryforwards, or NOLs, and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. 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.

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 are a holding company with no material assets other than the stock of our wholly-owned subsidiary. Accordingly, all our operations are conducted by MethylGene, our wholly-owned subsidiary (and its wholly-owned subsidiary, MethylGene US Inc.). MethylGene has never declared or paid any cash dividends on its common shares, and we currently expect that the earnings and cash flow of MethylGene will primarily be retained and used by it in its operations, including servicing any debt obligations it may have now or in the future. Accordingly, although we do not anticipate paying any dividends in the foreseeable future, our subsidiary may not be able to generate sufficient cash flow to distribute

funds to us 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

In June 2013, in connection with the consummation of the Arrangement, each of the securityholders of MethylGene received one share of our common stock in exchange for every 50 shares of MethylGene. In addition, all outstanding options and warrants to purchase common shares of MethylGene became exercisable on a 50-for-1 basis for shares of our common stock.

The issuances of the securities described above were deemed to be exempt from registration under the Securities Act of 1933, as amended, in reliance on Section 3(A)(10) of the Securities Act of 1933, as amended, after final approval of the Arrangement by the Ontario Superior Court of Justice. There were no underwriters employed in connection with any of the transactions set forth above.

Purchase of Equity Securities

We did not purchase any of our registered securities during the period covered by this Quarterly Report on Form 10-Q.

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ITEM 6. Exhibits

EXHIBIT INDEX

Exhibit	Description
2.1(1)	Arrangement Agreement, dated May 8, 2013, by and between MethylGene Inc. and the Registrant.
3.1(1)	Amended and Restated Certificate of Incorporation.
3.2(1)	Bylaws.
4.1(1)	Form of Common Stock Certificate.
10.1*(1)	Form of 2013 Equity Incentive Plan and Form of Stock Option Grant Notice and Form of Stock Option Agreement thereunder.
10. 2*(1)	Form of 2013 Employee Stock Purchase Plan.
10.3	Sublease Agreement, dated May 28, 2013, by and between Amylin Pharmaceuticals, LLC and MethylGene US Inc.
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Exchange Act.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Exchange Act.
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.
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.

* Indicates management contract or compensatory plan.

** Pursuant to applicable securities laws and regulations, we are deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and are not subject to liability under any anti-fraud provisions of the federal securities laws as long as we have made a good faith attempt to comply with the submission requirements and promptly amend the interactive data files after becoming aware that the interactive data files fail to comply with the submission requirements. Users of this data are advised that, pursuant to Rule 460T, these interactive data files are deemed not filed and otherwise are not subject to liability.

(1) Incorporated by reference to Mirati Therapeutics, Inc. s Registration Statement on Form 10 (No. 001-35921), as amended.

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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: August 13, 2013	By	/s/ Mark J. Gergen	
		Name:	Mark J. Gergen
		Title:	Executive Vice President and Chief Operations Officer