

GERON CORP  
Form 10-Q  
August 08, 2013  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON D.C. 20549

---

**FORM 10-Q**

---

(Mark One)

**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

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

For the transition period from            to            .

---

## GERON CORPORATION

(Exact name of registrant as specified in its charter)

**DELAWARE**

(State or other jurisdiction of  
incorporation or organization)

**75-2287752**

(I.R.S. Employer  
Identification No.)

**149 COMMONWEALTH DRIVE, SUITE 2070, MENLO PARK, CA**

(Address of principal executive offices)

**94025**

(Zip Code)

**(650) 473-7700**

(Registrant's telephone number, including area code)

**N/A**

(Former name, former address and former fiscal year, if changed since last report)

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 for 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  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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 Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer   
(Do not check if a smaller reporting company)

Smaller reporting company

Edgar Filing: GERON CORP - Form 10-Q

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

**Class:**  
Common Stock, \$0.001 par value

**Outstanding at August 1, 2013:**  
128,649,378 shares

---

Table of Contents

**GERON CORPORATION**  
**QUARTERLY REPORT ON FORM 10-Q**  
**FOR THE QUARTER ENDED JUNE 30, 2013**

**TABLE OF CONTENTS**

	<b>Page</b>
<b><u>PART I. FINANCIAL INFORMATION</u></b>	
<u>Item 1:</u>	
<u>Condensed Consolidated Financial Statements</u>	1
<u>Condensed Consolidated Balance Sheets as of June 30, 2013 and December 31, 2012</u>	1
<u>Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2013 and 2012</u>	2
<u>Condensed Consolidated Statements of Comprehensive Loss for the three and six months ended June 30, 2013 and 2012</u>	3
<u>Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2013 and 2012</u>	4
<u>Notes to Condensed Consolidated Financial Statements</u>	5
<u>Item 2:</u>	
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	15
<u>Item 3:</u>	
<u>Quantitative and Qualitative Disclosures About Market Risk</u>	22
<u>Item 4:</u>	
<u>Controls and Procedures</u>	22
<b><u>PART II. OTHER INFORMATION</u></b>	
<u>Item 1:</u>	
<u>Legal Proceedings</u>	23
<u>Item 1A:</u>	
<u>Risk Factors</u>	23
<u>Item 2:</u>	
<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	45
<u>Item 3:</u>	
<u>Defaults Upon Senior Securities</u>	45
<u>Item 4:</u>	
<u>Mine Safety Disclosures</u>	45
<u>Item 5:</u>	
<u>Other Information</u>	45
<u>Item 6:</u>	
<u>Exhibits</u>	45
<u>SIGNATURE</u>	46

---

Table of Contents**PART I. FINANCIAL INFORMATION****ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****GERON CORPORATION****CONDENSED CONSOLIDATED BALANCE SHEETS****(IN THOUSANDS)**

	<b>JUNE 30, 2013 (UNAUDITED)</b>	<b>DECEMBER 31, 2012</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 8,834	\$ 22,063
Restricted cash	795	794
Marketable securities	61,966	73,472
Interest and other receivables	480	752
Prepaid assets	356	1,336
Total current assets	72,431	98,417
Property and equipment, net	566	974
Deposits and other assets	414	410
	\$ 73,411	\$ 99,801
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,176	\$ 3,429
Accrued compensation and benefits	2,046	5,216
Accrued restructuring charges	374	1,972
Accrued liabilities	1,358	3,480
Fair value of derivatives	50	51
Total current liabilities	5,004	14,148
Commitments and contingencies		
Stockholders' equity:		
Common stock	130	130
Additional paid-in capital	943,518	939,867
Accumulated deficit	(875,228)	(854,384)
Accumulated other comprehensive (loss) income	(13)	40
Total stockholders' equity	68,407	85,653
	\$ 73,411	\$ 99,801

See accompanying notes.



Table of Contents

**GERON CORPORATION**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)**  
**(UNAUDITED)**

	THREE MONTHS ENDED JUNE 30,		SIX MONTHS ENDED JUNE 30,	
	2013	2012	2013	2012
<b>Revenues:</b>				
License fees and royalties	\$ 112	\$ 130	\$ 877	\$ 1,384
<b>Operating expenses:</b>				
Research and development	4,807	12,777	12,728	27,884
Restructuring charges	838		916	
General and administrative	3,432	5,832	8,183	10,897
Total operating expenses	9,077	18,609	21,827	38,781
Loss from operations	(8,965)	(18,479)	(20,950)	(37,397)
Unrealized (loss) gain on derivatives	(24)	8	1	34
Interest and other income	56	165	137	341
Interest and other expense	(14)	(20)	(32)	(43)
Net loss	\$ (8,947)	\$ (18,326)	\$ (20,844)	\$ (37,065)
Basic and diluted net loss per share	\$ (0.07)	\$ (0.14)	\$ (0.16)	\$ (0.29)
Shares used in computing basic and diluted net loss per share	128,162,993	126,891,909	128,072,962	126,632,377

See accompanying notes.

Table of Contents

**GERON CORPORATION**  
**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**  
**(IN THOUSANDS)**  
**(UNAUDITED)**

	<b>THREE MONTHS ENDED</b>		<b>SIX MONTHS ENDED</b>	
	<b>JUNE 30,</b>		<b>JUNE 30,</b>	
	<b>2013</b>	<b>2012</b>	<b>2013</b>	<b>2012</b>
Net loss	\$ (8,947)	\$ (18,326)	\$ (20,844)	\$ (37,065)
Other comprehensive (loss) income:				
Net unrealized loss on available-for-sale securities	(31)	(35)	(53)	(6)
Foreign currency translation adjustments				16
Other comprehensive (loss) income	(31)	(35)	(53)	10
Comprehensive loss	\$ (8,978)	\$ (18,361)	\$ (20,897)	\$ (37,055)

See accompanying notes.



Table of Contents

**GERON CORPORATION**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**CHANGE IN CASH AND CASH EQUIVALENTS**  
**(IN THOUSANDS)**  
**(UNAUDITED)**

	SIX MONTHS ENDED	
	2013	2012
	JUNE 30,	
<b>Cash flows from operating activities:</b>		
Net loss	\$ (20,844)	\$ (37,065)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	264	465
Accretion and amortization on investments, net	647	1,264
Gain on sales of property and equipment	(116)	(14)
Loss on write-downs of property and equipment	200	
Stock-based compensation for services by non-employees	53	110
Stock-based compensation for employees and directors	2,234	2,753
Amortization related to 401(k) contributions	465	281
Unrealized gain on derivatives	(1)	(34)
Changes in assets and liabilities:		
Other current and noncurrent assets	1,248	1,864
Other current liabilities	(8,304)	12
Translation adjustment		16
Net cash used in operating activities	(24,154)	(30,348)
<b>Cash flows from investing activities:</b>		
Restricted cash transfer	(1)	(1)
Purchases of property and equipment	(56)	(470)
Proceeds from sales of property and equipment	116	20
Purchases of marketable securities	(40,110)	(35,386)
Proceeds from maturities of marketable securities	50,916	64,124
Net cash provided by investing activities	10,865	28,287
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of common stock, net of issuance costs	60	79
Net cash provided by financing activities	60	79
Net decrease in cash and cash equivalents	(13,229)	(1,982)
Cash and cash equivalents at the beginning of the period	22,063	16,105
Cash and cash equivalents at the end of the period	\$ 8,834	\$ 14,123

See accompanying notes.

Table of Contents

**GERON CORPORATION**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**JUNE 30, 2013**

**(UNAUDITED)**

**1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Basis of Presentation**

The terms Geron, the Company, we and us as used in this report refer to Geron Corporation. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. generally accepted accounting principles for complete financial statements. In the opinion of management of Geron, all adjustments (consisting only of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three and six month periods ended June 30, 2013 are not necessarily indicative of the results that may be expected for the year ending December 31, 2013 or any other period. These financial statements and notes should be read in conjunction with the financial statements for each of the three years ended December 31, 2012, included in the Company's Annual Report on Form 10-K. The accompanying condensed consolidated balance sheet as of December 31, 2012 has been derived from audited financial statements at that date.

**Principles of Consolidation**

The 2012 condensed consolidated financial statements include the accounts of Geron and our former wholly-owned subsidiary, Geron Bio-Med Ltd. (Geron Bio-Med), a United Kingdom company. In March 2012, the board of directors and shareholders of Geron Bio-Med approved actions to commence a voluntary winding up of the company. The full wind up of Geron Bio-Med was completed in August 2012. Prior to 2013, we eliminated intercompany accounts and transactions and prepared the financial statements of Geron Bio-Med using the local currency as the functional currency. We translated the assets and liabilities of Geron Bio-Med at rates of exchange at the balance sheet date and translated income and expense items at average monthly rates of exchange. The resultant translation adjustments were included in accumulated other comprehensive income (loss), a separate component of stockholders' equity.

**Net Loss Per Share**

Basic earnings (loss) per share is calculated based on the weighted average number of shares of common stock outstanding during the period. Diluted earnings (loss) per share is calculated based on the weighted average number of shares of common stock and potential dilutive securities outstanding during the period. Potential dilutive securities primarily consist of outstanding stock options, restricted stock and warrants to purchase common stock and are determined using the treasury stock method at an average market price during the period.

Because we are in a net loss position, diluted loss per share excludes the effects of potential dilutive securities. Had we been in a net income position, diluted earnings per share would have included the shares used in the computation of basic net loss per share as well as an additional 6,533 and 23,391 shares for the 2013 and 2012 periods, respectively, related to outstanding stock options, restricted stock and warrants (as determined using the treasury stock method at the estimated average market value).

**Use of Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires us to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On a regular basis, management evaluates these estimates and assumptions. Actual results could differ from those estimates.

Table of Contents

**GERON CORPORATION**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**JUNE 30, 2013**

**(UNAUDITED)**

**Fair Value of Financial Instruments**

*Cash Equivalents and Marketable Securities*

We consider all highly liquid investments with an original maturity of three months or less to be cash equivalents. We are subject to credit risk related to our cash equivalents and marketable securities. We place our cash and cash equivalents in money market funds and cash operating accounts. Our marketable securities include U.S. government-sponsored enterprise securities, commercial paper and corporate notes with original maturities ranging from three to 22 months.

We classify our marketable securities as available-for-sale. We record available-for-sale securities at fair value with unrealized gains and losses reported in accumulated other comprehensive income (loss) in stockholders' equity. Realized gains and losses are included in interest and other income and are derived using the specific identification method for determining the cost of securities sold and have been insignificant to date. Dividend and interest income are recognized when earned and included in interest and other income in our condensed consolidated statements of operations. We recognize a charge when the declines in the fair values below the amortized cost basis of our available-for-sale securities are judged to be other-than-temporary. We consider various factors in determining whether to recognize an other-than-temporary charge, including whether we intend to sell the security or whether it is more likely than not that we would be required to sell the security. Declines in market value associated with credit losses judged as other-than-temporary result in a charge to interest and other income. Other-than-temporary charges not related to credit losses are included in accumulated other comprehensive income (loss) in stockholders' equity. No other-than-temporary impairment charges were recorded for our available-for-sale securities for the three and six months ended June 30, 2013 and 2012. See Note 2 on Fair Value Measurements.

*Fair Value of Derivatives*

For non-employee options classified as assets or liabilities, the fair value of these instruments is recorded on the condensed consolidated balance sheet at inception and adjusted to fair value at each financial reporting date. The change in fair value of the non-employee options is recorded in the condensed consolidated statements of operations as unrealized gain (loss) on derivatives. Fair value of non-employee options is estimated using the Black Scholes option-pricing model. The non-employee options continue to be reported as an asset or liability until such time as the instruments are exercised or expire or are otherwise modified to remove the provisions which require this treatment, at which time these instruments are marked to fair value and reclassified from assets or liabilities to stockholders' equity. For non-employee options classified as permanent equity, the fair value of the non-employee options is recorded in stockholders' equity as of their respective vesting dates and no further adjustments are made. See Note 2 on Fair Value Measurements.

**Revenue Recognition**

We have entered into several license agreements with various oncology, diagnostics, research tools, agriculture and biologics production companies. With certain of these agreements, we receive nonrefundable license payments in cash or equity securities, option payments in cash or equity securities, cost reimbursements, milestone payments, royalties on future sales of products, or any combination of these items. Upfront non-refundable signing, license or non-exclusive option fees are recognized as revenue when rights to use the intellectual property related to the license have been delivered and over the term of the agreement if we have continuing performance obligations. Milestone payments, which are subject to substantive contingencies, are recognized upon completion of specified milestones, representing the culmination of the earnings process, according to contract terms. Royalties are generally recognized upon receipt of the related royalty payment. Deferred revenue represents the portion of research and license payments received which has not been earned. When payments are received in equity securities, we do not recognize any revenue unless such securities are determined to be realizable in cash. We recognize revenue under collaborative agreements as the related research and development services are rendered.

Table of Contents**GERON CORPORATION****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****JUNE 30, 2013****(UNAUDITED)****Restricted Cash**

Restricted cash consists of funds maintained in separate certificate of deposit accounts for specified purposes. The components of restricted cash were as follows:

<b>(In thousands)</b>	<b>June 30,</b>		<b>December 31,</b>	
	<b>2013</b>		<b>2012</b>	
Certificate of deposit for unused equipment line of credit	\$	530	\$	530
Certificate of deposit for credit card purchases		265		264
	\$	795	\$	794

**Research and Development Expenses**

Research and development expenses consist of expenses incurred in identifying, developing and testing product candidates resulting from our independent efforts as well as efforts associated with collaborations. These expenses include, but are not limited to, acquired in-process research and development deemed to have no alternative future use, payroll and personnel expense, lab supplies, preclinical studies, clinical trials, including support for investigator-sponsored clinical trials, raw materials to manufacture clinical trial drugs, manufacturing costs for research and clinical trial materials, sponsored research at other labs, consulting, costs to maintain technology licenses and research-related overhead. Research and development costs are expensed as incurred, including payments made under our license agreements.

***Clinical Trial Costs***

A significant component of our research and development expenses is clinical trial costs. Substantial portions of our preclinical studies and all of our clinical trials have been performed by third-party contract research organizations, or CROs, and other vendors. We accrue expenses for preclinical studies performed by our vendors based on certain estimates over the term of the service period and adjust our estimates as required. We accrue expenses for clinical trial activities performed by CROs based upon the estimated amount of work completed on each study. For clinical trial expenses, the significant factors used in estimating accruals include the number of patients enrolled, the number of active clinical sites and the duration for which the patients have been enrolled in the study. Pass through costs from CROs include, but are not limited to, regulatory expenses, investigator fees, lab fees, travel costs and other miscellaneous costs, including shipping and printing fees. We accrue pass through costs based on estimates of the amount of work completed for the clinical trial. We monitor patient enrollment levels and related activities to the extent possible through internal reviews, review of contractual terms and correspondence with CROs. We base our estimates on the best information available at the time. However, additional information may become available to us which would allow us to make a more

accurate estimate in future periods. In this event, we may be required to record adjustments to research and development expenses in future periods when the actual level of activity becomes more certain.

### **Depreciation and Amortization**

We record property and equipment at cost and calculate depreciation using the straight-line method over the estimated useful lives of the assets, generally four years. Leasehold improvements are amortized over the shorter of the estimated useful life or remaining term of the lease.

### **Stock-Based Compensation**

We recognize stock-based compensation expense on a straight-line basis over the requisite service period, which is generally the vesting period. The following table summarizes the stock-based compensation expense related to stock options, restricted stock awards and employee stock purchases for the three and six months ended June 30, 2013 and 2012 which was allocated as follows:

Table of Contents

## GERON CORPORATION

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

JUNE 30, 2013

(UNAUDITED)

(In thousands)	Three Months Ended June 30,			Six Months Ended June 30,		
	2013	2012	2013	2012	2013	2012
Research and development	\$ 231	\$ 626	\$ 911	\$ 1,267		
Restructuring charges	28		28			
General and administrative	627	736	1,295	1,486		
Stock-based compensation expense included in operating expenses	\$ 886	\$ 1,362	\$ 2,234	\$ 2,753		

As stock-based compensation expense recognized in the condensed consolidated statements of operations for the three and six months ended June 30, 2013 and 2012 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures, but at a minimum, reflects the grant-date fair value of those awards that actually vested in the period. Forfeitures have been estimated at the time of grant based on historical data and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. In connection with the April 2013 restructuring, the post-termination exercise period for certain stock options previously granted to terminated employees was extended through the end of December 2013 resulting in the recognition of \$28,000 of non-cash stock-based compensation expense for the stock option modification. See Note 3 on Restructurings for a further discussion of the April 2013 restructuring.

*Stock Options*

We grant options with service-based vesting under our equity plans to employees, non-employee directors and consultants. The vesting period for employee options is generally four years. The fair value of options granted during the six months ended June 30, 2013 and 2012 has been estimated at the date of grant using the Black Scholes option-pricing model with the following assumptions:

	Six Months Ended June 30,	
	2013	2012
Dividend yield	None	None
Expected volatility range	0.742 to 0.745	0.631 to 0.636
Risk-free interest rate range	0.80% to 1.26%	0.91% to 1.25%
Expected term	6 yrs	6 yrs

*Employee Stock Purchase Plan*



## Edgar Filing: GERON CORP - Form 10-Q

The fair value of employees' purchase rights during the six months ended June 30, 2013 and 2012 has been estimated using the Black Scholes option-pricing model with the following assumptions:

	Six Months Ended June 30,	
	2013	2012
Dividend yield	None	None
Expected volatility range	0.674 to 1.391	0.458 to 0.774
Risk-free interest rate range	0.12% to 0.21%	0.06% to 0.20%
Expected term range	6 - 12 mos	6 - 12 mos

Dividend yield is based on historical cash dividend payments. The expected volatility range is based on historical volatilities of our stock since traded options on Geron stock do not correspond to option terms and the trading volume of options is limited. The risk-free interest rate range is based on the U.S. Zero Coupon Treasury Strip Yields for the expected term in effect on the date of grant for an award. The expected term of options is derived from actual historical exercise and post-vesting cancellation data and represents the period of time that options granted are expected to be outstanding. The expected term of employees' purchase rights is equal to the purchase period.

Table of Contents

**GERON CORPORATION**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**JUNE 30, 2013**

**(UNAUDITED)**

***Restricted Stock Awards***

We grant restricted stock awards to employees and non-employee directors with three types of vesting schedules: (i) service-based, (ii) performance-based or (iii) market-based. Service-based awards generally vest annually over four years. Performance-based awards vest upon achievement of discrete strategic corporate goals within a specified performance period, generally three years. Market-based awards vest upon achievement of certain market price thresholds of our common stock within a specified performance period, generally three years.

The fair value for service-based restricted stock awards is determined using the fair value of our common stock on the date of grant. The fair value is amortized as stock-based compensation expense over the requisite service period of the award, which is generally the vesting period, on a straight-line basis and is reduced for estimated forfeitures, as applicable.

The fair value for performance-based restricted stock awards is determined using the fair value of our common stock on the date of grant. Stock-based compensation expense for awards with vesting based on performance conditions is recognized over the period from the date the performance condition is determined to be probable of occurring through the date the applicable condition is expected to be met and is reduced for estimated forfeitures, as applicable. If the performance condition is not considered probable of being achieved, no stock-based compensation expense is recognized until such time as the performance condition is considered probable of being met, if at all. If that assessment of the probability of the performance condition being met changes, the impact of the change in estimate would be recognized in the period of the change. If the requisite service period has been met prior to the change in estimate, the effect of the change in estimate would be immediately recognized. We have not recognized any stock-based compensation expense for performance-based restricted stock awards in our condensed consolidated statements of operations for the three and six months ended June 30, 2013 and 2012 as the achievement of the specified performance criteria was not considered probable during that time.

The fair value for market-based restricted stock awards is determined using a lattice valuation model with a Monte Carlo simulation. The model takes into consideration the historical volatility of our stock and the risk-free interest rate at the date of grant. In addition, the model is used to estimate the derived service period for the awards. The derived service period is the estimated period of time that would be required to satisfy the market condition, assuming the market condition will be satisfied. Stock-based compensation expense is recognized over the derived service period for the awards using the straight-line method and is reduced for estimated forfeitures, as applicable, but is accelerated if the market condition is achieved earlier than estimated. The market conditions for the market-based restricted stock awards had not been achieved as of June 30, 2013.

***Non-Employee Stock-Based Awards***

## Edgar Filing: GERON CORP - Form 10-Q

For our non-employee stock-based awards, the measurement date on which the fair value of the stock-based award is calculated is equal to the earlier of (i) the date at which a commitment for performance by the counterparty to earn the equity instrument is reached or (ii) the date at which the counterparty's performance is complete. We recognize stock-based compensation expense for the fair value of the vested portion of non-employee awards in our condensed consolidated statements of operations.

### **Reclassification**

Certain reclassifications of prior quarter amounts have been made to conform to current quarter presentation. Restructuring costs included in research and development expenses have been reclassified to restructuring charges in the condensed consolidated statements of operations.

Table of Contents

**GERON CORPORATION**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**JUNE 30, 2013**

**(UNAUDITED)**

**2. FAIR VALUE MEASUREMENTS**

We categorize financial instruments recorded at fair value on our condensed consolidated balance sheets based upon the level of judgment associated with inputs used to measure their fair value. The categories are as follows:

- |         |  |
|---------|--|
| Level 1 | Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date. An active market for an asset or liability is a market in which transactions for the asset or liability occur with sufficient frequency and volume to provide pricing information on an ongoing basis. |
| Level 2 | Inputs (other than quoted market prices included in Level 1) are either directly or indirectly observable for the asset or liability through correlation with market data at the measurement date and for the duration of the instrument's anticipated life.   |
| Level 3 | Inputs reflect management's best estimate of what market participants would use in pricing the asset or liability at the measurement date. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model.  |

A financial instrument's categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement. Below is a description of the valuation methodologies used for financial instruments measured at fair value on our condensed consolidated balance sheets, including the category for such financial instruments.

**Cash Equivalents and Marketable Securities Available-for-Sale**

Certificates of deposit and money market funds are categorized as Level 1 within the fair value hierarchy as their fair values are based on quoted prices available in active markets. U.S. Treasury securities, U.S. government-sponsored enterprise securities, municipal securities, corporate notes and commercial paper are categorized as Level 2 within the fair value hierarchy as their fair values are estimated by using pricing models, quoted prices of securities with similar characteristics or discounted cash flows.

Cash equivalents, restricted cash and marketable securities by security type at June 30, 2013 were as follows:

Edgar Filing: GERON CORP - Form 10-Q

	Amortized Cost		Gross Unrealized Gains		Gross Unrealized Losses		Estimated Fair Value
(In thousands)							
Included in cash and cash equivalents:							
Money market funds	\$ 5,542	\$		\$		\$	5,542
Restricted cash:							
Certificates of deposit	\$ 795	\$		\$		\$	795
Marketable securities:							
Government-sponsored enterprise securities (due in less than 1 year)	\$ 6,440	\$	1	\$		\$	6,441
Commercial paper (due in less than 1 year)	20,236		11				20,247
Corporate notes (due in less than 1 year)	35,303		5		(30)		35,278
	\$ 61,979	\$	17	\$	(30)	\$	61,966

Table of Contents

## GERON CORPORATION

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

JUNE 30, 2013

(UNAUDITED)

Cash equivalents, restricted cash and marketable securities by security type at December 31, 2012 were as follows:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
	(In thousands)			
Included in cash and cash equivalents:				
Money market funds	\$ 15,660	\$	\$	\$ 15,660
Corporate notes	3,136		(1)	3,135
	\$ 18,796	\$	\$ (1)	\$ 18,795
Restricted cash:				
Certificates of deposit	\$ 794	\$	\$	\$ 794
Marketable securities:				
Government-sponsored enterprise securities (due in less than 1 year)	\$ 8,618	\$ 5	\$	\$ 8,623
Commercial paper (due in less than 1 year)	20,623	21		20,644
Corporate notes (due in less than 1 year)	44,190	22	(7)	44,205
	\$ 73,431	\$ 48	\$ (7)	\$ 73,472

Marketable securities with unrealized losses at June 30, 2013 and December 31, 2012 were as follows:

	Less Than 12 Months		12 Months or Greater		Total	
	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses
	(In thousands)					
<b>As of June 30, 2013:</b>						
Corporate notes (due in less than 1 year)	\$ 31,257	\$ (30)	\$	\$	\$ 31,257	\$ (30)
<b>As of December 31, 2012:</b>						
Corporate notes (due in less than 1 year)	\$ 27,045	\$ (8)	\$	\$	\$ 27,045	\$ (8)

The gross unrealized losses related to corporate notes as of June 30, 2013 and December 31, 2012 were due to changes in interest rates. We determined that the gross unrealized losses on our marketable securities as of June 30, 2013 and December 31, 2012 were temporary in nature. We review our investments quarterly to identify and evaluate whether any investments have indications of possible impairment. Factors considered in determining whether a loss is temporary include the length of time and extent to which the fair value has been less than the cost basis and whether we intend to sell the security or whether it is more likely than not that we would be required to sell the security. We currently

do not intend to sell these securities before recovery of their amortized cost basis.

### **Derivatives**

Non-employee options are normally traded less actively, have trade activity that is one way, and/or traded in less-developed markets and are therefore valued based upon models with significant unobservable market parameters, resulting in Level 3 categorization.

Options held by non-employees whose performance obligations are complete are classified as derivative liabilities on our condensed consolidated balance sheets. Upon the exercise of these options, the instruments are marked to fair value and reclassified from derivative liabilities to stockholders' equity. There were no reclassifications from current liabilities to stockholders' equity for non-employee option exercises during 2013.

Table of Contents

**GERON CORPORATION**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**JUNE 30, 2013**

**(UNAUDITED)**

As of June 30, 2013 and December 31, 2012, the following non-employee options to purchase common stock were considered derivatives and classified as current liabilities:

Issuance Date	Exercise Price	Exercisable Date	Expiration Date	At June 30, 2013		At December 31, 2012	
				Number of Shares	Fair Value (In thousands)	Number of Shares	Fair Value (In thousands)
March 2005	\$ 6.39	January 2007	March 2015	284,600	\$ 50	284,600	\$ 51

The fair value of derivatives has been calculated at each reporting date using the Black Scholes option-pricing model with the following assumptions:

	June 30, 2013	December 31, 2012
Dividend yield	None	None
Expected volatility	0.897	0.828
Risk-free interest rate	0.36%	0.25%
Expected term	2 yrs	2 yrs

Dividend yield is based on historical cash dividend payments. The expected volatility is based on historical volatilities of our stock since traded options on Geron stock do not correspond to derivatives terms and trading volume of Geron options is limited. The risk-free interest rate is based on the U.S. Zero Coupon Treasury Strip Yields for the expected term of the derivatives in effect on the reporting date. The expected term of derivatives is equal to the remaining contractual term of the instruments.

**Fair Value on a Recurring Basis**

The following table presents information about our financial instruments that are measured at fair value on a recurring basis as of June 30, 2013 and indicates the fair value category assigned.

Quoted Prices in Active Markets	Fair Value Measurements at Reporting Date Using	
	Significant Other	Significant



Edgar Filing: GERON CORP - Form 10-Q

(In thousands)	for Identical Assets / Liabilities Level 1	Observable Inputs Level 2	Unobservable Inputs Level 3	Total
<b>Assets</b>				
Money market funds (1)	\$ 5,542	\$	\$	\$ 5,542
Government-sponsored enterprise securities (2)		6,441		6,441
Commercial paper (2)		20,247		20,247
Corporate notes (2)		35,278		35,278
<b>Total</b>	<b>\$ 5,542</b>	<b>\$ 61,966</b>	<b>\$</b>	<b>\$ 67,508</b>
<b>Liabilities</b>				
Derivatives (3)	\$	\$	\$ 50	\$ 50

---

(1) Included in cash and cash equivalents on our condensed consolidated balance sheets.

(2) Included in current marketable securities on our condensed consolidated balance sheets.

(3) Included in fair value of derivatives on our condensed consolidated balance sheets.

Table of Contents

## GERON CORPORATION

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

JUNE 30, 2013

(UNAUDITED)

**Changes in Level 3 Recurring Fair Value Measurements**

The table below includes a rollforward of the balance sheet amounts for the three and six months ended June 30, 2013, including the change in fair value, for financial instruments in the Level 3 category. When a determination is made to classify a financial instrument within Level 3, the determination is based upon the significance of the unobservable parameters to the overall fair value measurement. However, Level 3 financial instruments typically include, in addition to the unobservable components, observable components (that is, components that are actively quoted and can be validated to external sources). Accordingly, the gains and losses in the table below include changes in fair value due in part to observable factors that are part of the methodology.

**Fair Value Measurements Using Significant Unobservable Inputs (Level 3)  
Three Months Ended June 30, 2013**

(In thousands)	Fair Value at March 31, 2013	Total Unrealized Loss Included in Earnings (1)	Purchases and Issuances	Sales and Settlements	Transfers In and/or Out of Level 3	Fair Value at June 30, 2013	Change in Unrealized Loss Related to Financial Instruments Held at June 30, 2013 (1)
Derivative liabilities	\$ 26	\$ 24	\$	\$	\$	\$ 50	\$ 24

**Fair Value Measurements Using Significant Unobservable Inputs (Level 3)  
Six Months Ended June 30, 2013**

(In thousands)	Fair Value at December 31, 2012	Total Unrealized Gain Included in Earnings (1)	Purchases and Issuances	Sales and Settlements	Transfers In and/or Out of Level 3	Fair Value at June 30, 2013	Change in Unrealized Gain Related to Financial Instruments Held at June 30, 2013 (1)
Derivative liabilities	\$ 51	\$ (1)	\$	\$	\$	\$ 50	\$ (1)

(1) Reported as unrealized (loss) gain on derivatives in our condensed consolidated statements of operations.

**3. RESTRUCTURINGS**

On April 25, 2013, we announced the decision to discontinue our discovery research programs and companion diagnostics program based on telomere length and close our research laboratory facility located at 200 Constitution Drive, Menlo Park, California. With this decision, a total of 20 positions were eliminated. In connection with this restructuring, we expect to record aggregate restructuring charges of approximately \$1,500,000, of which \$824,000 was recorded in the second quarter of 2013. As of June 30, 2013, the restructuring charges recognized under the April 2013 restructuring included \$624,000 related to one-time termination benefits, including \$28,000 of non-cash stock-based compensation expense relating to the extension of the post-termination exercise period through the end of December 2013 for certain stock options previously granted to terminated employees, and \$200,000 related to non-cash charges for write-downs of excess equipment and leasehold improvements. The remaining projected restructuring charges relate to costs associated with the exit of our research laboratory facility and are expected to be recorded in the second half of 2013. We expect the restructuring will result in aggregate cash expenditures of approximately \$1,250,000, of which \$396,000 were paid as of June 30, 2013 and related to one-time termination benefits. The remaining cash expenditures are expected to be paid during the second half of 2013 and relate to one-time termination benefits and facility-related charges.

On December 3, 2012, we announced the decision to discontinue development of GRN1005. With this decision, a total of 43 positions were eliminated. As of June 30, 2013, we have recognized aggregate restructuring charges of \$2,794,000 for the December 2012 restructuring, of which \$2,702,000 was recorded in the fourth quarter of 2012 and \$92,000 was recorded in the first half of 2013. All actions associated with the December 2012 restructuring were completed in the first half of 2013, and we do not anticipate incurring any further charges in connection with the December 2012 restructuring.

Table of Contents**GERON CORPORATION****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****JUNE 30, 2013****(UNAUDITED)**

On November 14, 2011, we announced the decision to focus on the development of our oncology programs and consequently, we discontinued further development of our stem cell programs. With this decision, a total of 66 positions were eliminated. All actions associated with the November 2011 restructuring were completed in 2012, and we do not anticipate incurring any further charges in connection with the November 2011 restructuring. All payments due under the November 2011 restructuring have been made as of June 30, 2013.

The components relating to the April 2013, December 2012 and November 2011 restructurings, including the outstanding restructuring liability which is included in accrued restructuring charges on our condensed consolidated balance sheet as of June 30, 2013, are summarized in the following table:

<b>(In thousands)</b>	<b>Employee Severance and Other Benefits</b>	<b>Asset Write Downs</b>	<b>Total</b>
Beginning accrual balance as of December 31, 2012	\$ 1,972	\$ 200	\$ 1,972
Restructuring charges	716	200	916
Cash payments	(2,140)		(2,140)
Adjustments or non-cash credits, including stock-based compensation expense	(174)	(200)	(374)
Ending accrual balance as of June 30, 2013	\$ 374	\$ 200	\$ 574

We may incur other charges associated with the April 2013 restructuring. Such charges, if any, will be recorded as they are determined. We plan to sell any excess equipment, the net proceeds of which, if any, may offset some of these future charges.

**4. SEGMENT INFORMATION**

Our executive management team represents our chief decision maker. We view our operations as one segment, the discovery and development of therapeutic products for oncology. As a result, the financial information disclosed herein materially represents all of the financial information related to our principal operating segment.

**5. CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS DATA**

Edgar Filing: GERON CORP - Form 10-Q

Supplemental schedule of non-cash operating and investing activities:

(In thousands)	Six Months Ended	
	2013	June 30, 2012
<b>Supplemental Operating Activities:</b>		
Issuance of common stock for 401(k) matching contributions	\$ 839	\$ 1,361
Issuance of common stock for services rendered to date or to be received in future periods		69
Reclassification of deposits to other current assets		135
<b>Supplemental Investing Activities:</b>		
Net unrealized loss on available-for-sale securities	(53)	(6)

Table of Contents

**ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

**FORWARD-LOOKING STATEMENTS**

This Form 10-Q contains forward-looking statements that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause the results of Geron Corporation, or Geron or the Company, to differ materially from those expressed or implied by such forward-looking statements. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. In some cases, forward-looking statements can be identified by the use of terminology such as may, expect, plan, intend, will, should, project, believe, predict, anticipate, estimate, potential or continue, or the negative thereof or other comparable terminology. These statements are within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements appear throughout the Form 10-Q and are statements regarding our intent, belief, or current expectations, primarily with respect to our operations and related industry developments. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this Form 10-Q. Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including the risks faced by us and described in Part II, Item 1A, entitled Risk Factors, and in Management's Discussion and Analysis of Financial Condition and Results of Operations in Part I, Item 2 of this Form 10-Q.

**OVERVIEW**

The following discussion should be read in conjunction with the unaudited condensed consolidated financial statements and notes thereto included in Part I, Item 1 of this Form 10-Q and with Management's Discussion and Analysis of Financial Condition and Results of Operations contained in our Annual Report on Form 10-K for the year ended December 31, 2012, as filed with the Securities and Exchange Commission on March 15, 2013.

We are a clinical stage biopharmaceutical company developing a first-in-class telomerase inhibitor, imetelstat, in hematologic myeloid malignancies. The discovery and early development of imetelstat was based on our core expertise in telomerase and telomere biology. Telomerase is an enzyme that enables cancer cells to maintain telomere length, which provides them with the capacity for limitless cellular replication. Imetelstat is a potent and specific inhibitor of telomerase. Based on clinical data we obtained in late 2012, we may develop imetelstat to treat one or more hematologic myeloid malignancies such as myelofibrosis, or MF, myelodysplastic syndromes, or MDS, or acute myelogenous leukemia, or AML.

We have incurred operating losses every year since our operations began in 1990. Losses have resulted principally from costs incurred in connection with our research and development activities and from general and administrative costs associated with our operations. As of June 30, 2013, we had an accumulated deficit of \$875.2 million. Since inception, we have primarily financed our operations through the sale of equity securities, interest income on our marketable securities and payments under our collaborative and licensing arrangements.

Substantially all of our revenues to date have been research support payments under collaboration agreements and milestones, royalties and other revenues from our licensing arrangements. Any revenues generated from collaboration agreements, and revenues from our licensing arrangements, will not be sufficient alone to continue or expand our research or development activities and otherwise sustain our operations. We

## Edgar Filing: GERON CORP - Form 10-Q

also currently have no source of product revenue. Imetelstat, which is our only product candidate, will require significant additional clinical testing prior to possible regulatory approval in the United States and other countries, and we do not expect imetelstat to be commercially available for many years, if at all.

As of June 30, 2013, we had cash, restricted cash, cash equivalents and marketable securities of \$71.6 million compared to \$96.3 million at December 31, 2012. We estimate that our existing capital resources, amounts available to us under our equipment financing facility and future interest income will be sufficient to fund our current level of operations through at least the next 12 months. However, our future capital requirements will be substantial, and we may use our available capital resources sooner than we anticipate.

Table of Contents

***Development of Imetelstat in Hematologic Myeloid Malignancies***

Top-line data from the essential thrombocythemia, or ET, Phase 2 trial that we presented at the American Society of Hematology, or ASH, annual meeting in December 2012 and at the Congress of the European Hematology Association in June 2013 showed durable hematologic and molecular responses in patients enrolled in the ET Phase 2 trial, suggesting that imetelstat inhibited the progenitor cells of the malignant clone believed to be responsible for the underlying disease in a relatively selective manner. The Phase 2 trial of imetelstat in ET is no longer enrolling patients, and we are continuing to treat and follow patients previously enrolled in the trial. Our rationale for studying imetelstat in ET was to provide proof-of-concept for further development of imetelstat in a broader range of hematologic myeloid malignancies. Although high hematologic and molecular response rates led us to explore the feasibility of further development of imetelstat in ET, medical experts have advised us that ET patients are adequately served by existing therapies and recommended that we pursue other hematologic malignancies, such as MF, where there is a clear unmet medical need for a product that could be disease-modifying.

Based on data from the Phase 2 trial of imetelstat in patients with ET, in November 2012, Dr. Ayalew Tefferi at Mayo Clinic initiated an investigator-sponsored trial to evaluate the safety and efficacy of imetelstat in patients with MF, and to determine an appropriate dose and schedule for further evaluation. This investigator-sponsored trial, or the Myelofibrosis IST, is an open-label trial in patients with primary MF, post-essential thrombocythemia MF or post-polycythemia vera MF who have two to three risk factors (intermediate-2) or four or more risk factors (high risk) as defined by the Dynamic International Prognostic Scoring System Plus, or DIPSS Plus, described by Gangat, et al, in the Journal of Clinical Oncology (2011). The primary endpoint is overall response rate, which is defined by the proportion of patients who are classified as responders having achieved either a clinical improvement, partial remission, or complete remission according to the International Working Group for Myelofibrosis Research and Treatment, or IWG-MRT, criteria. Secondary endpoints include reduction of spleen size, transfusion independence, safety and tolerability.

The investigator has provided the following communications to us regarding the status of the Myelofibrosis IST:

- Enrollment of the first cohort of 11 patients in which the dose of imetelstat was given once every three weeks was completed at the end of March 2013;
- Pre-specified criteria in the clinical protocol of at least two responders in the first cohort were met to enable expanded enrollment;
- Enrollment of the second cohort of 11 patients in which the dose intensity of imetelstat was increased to levels similar to those used in the ET trial was completed at the end of May 2013;
- Pre-specified criteria in the clinical protocol of at least two responders in the second cohort were met to enable further expanded enrollment;



## Edgar Filing: GERON CORP - Form 10-Q

- Additional cohorts to enable continued testing of the effect of different dosing intensities of imetelstat are being considered by the investigator; and
  
- A protocol amendment to add a new cohort of 11 patients with MF that has transformed into AML, or blast-phase MF, was recently approved by the Mayo Clinic Institutional Review Board.

Table of Contents

Dr. Tefferi also indicated to us that he expects to submit data from the Myelofibrosis IST for presentation at the ASH annual meeting in December 2013. Data from this trial, if positive, will inform any future Geron-sponsored clinical trial in patients with MF and will be necessary for future clinical development of imetelstat in MF. In addition, we may expand our directed program of investigator-sponsored trials to other hematologic myeloid malignancies, including MDS and AML.

***Discontinuation of Discovery Research and Companion Diagnostics Programs and Closure of Research Laboratory Facility***

On April 25, 2013, we announced the decision to discontinue our discovery research programs and companion diagnostics program based on telomere length and close our research laboratory facility located at 200 Constitution Drive, Menlo Park, California. Going forward, our resources will be concentrated on the clinical development of imetelstat in hematologic myeloid malignancies, including myelofibrosis. In connection with this strategic focus, we are no longer pursuing further development of imetelstat in solid tumors with short telomeres.

With the foregoing changes to our business, we also announced a restructuring to reduce our workforce from 64 positions to 44 full-time positions, representing a reduction of approximately 31% of our workforce. We anticipate we will incur aggregate restructuring charges of approximately \$1.5 million, of which approximately \$1.25 million is expected to be paid in cash during 2013. The aggregate projected restructuring charges consist of approximately \$624,000 related to one-time termination benefits, comprised principally of severance payments, benefit continuation costs, outplacement services and non-cash stock-based compensation expense associated with the elimination of 20 positions and approximately \$650,000 for facility-related charges as well as approximately \$200,000 for non-cash charges related to write-downs of equipment and leasehold improvements. The majority of these charges were recognized in the second quarter of 2013. We may incur other charges and will record these expenses in the appropriate period as they are determined. We plan to sell any excess equipment, the net proceeds of which, if any, may offset some of these future charges. See Note 3 on Restructurings in Notes to Condensed Consolidated Financial Statements of this Form 10-Q for further discussion of the restructuring charges.

**CRITICAL ACCOUNTING POLICIES AND ESTIMATES**

There have been no significant changes in our critical accounting policies and estimates during the six months ended June 30, 2013 as compared to the critical accounting policies and estimates disclosed in our Annual Report on Form 10-K for the year ended December 31, 2012 that materially impact our condensed consolidated financial statements.

Our condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported assets, liabilities, revenues and expenses. Note 1 of Notes to Condensed Consolidated Financial Statements describes the significant accounting policies used in the preparation of the condensed consolidated financial statements.

Estimates and assumptions about future events and their effects cannot be determined with certainty. We base our estimates on historical experience and on various other assumptions believed to be applicable and reasonable under the circumstances. These estimates may change as new events occur, as additional information is obtained and as our operating environment changes. These changes historically have been minor and have been included in the condensed consolidated financial statements as soon as they became known. Based on a critical assessment of our accounting policies and the underlying judgments and uncertainties affecting the application of those policies, management believes that our

Edgar Filing: GERON CORP - Form 10-Q

condensed consolidated financial statements are fairly stated in accordance with accounting principles generally accepted in the United States, and present a meaningful presentation of our financial condition and results of operations.

Table of Contents

**RESULTS OF OPERATIONS**

Our results of operations have fluctuated from period to period and may continue to fluctuate in the future, based upon the progress of our research and development efforts and variations in the level of expenses related to developmental efforts during any given period. Results of operations for any period may be unrelated to results of operations for any other period. In addition, historical results should not be viewed as indicative of future operating results. We are subject to risks common to companies in our industry and at our stage of development, including, but not limited to, risks inherent in our research and development efforts, uncertainty of preclinical and clinical trial results or regulatory approvals or clearances, need for future capital, enforcement of our patent and proprietary rights, reliance upon our collaborators and potential competition. In order for a product candidate to be commercialized based on our research, we and our collaborators must conduct preclinical tests and clinical trials, demonstrate the safety and efficacy of our product candidate, imetelstat, obtain regulatory approvals or clearances and enter into manufacturing, distribution and marketing arrangements, as well as obtain market acceptance. We do not expect to receive revenues or royalties based on imetelstat for many years, if at all.

**Revenues**

We have entered into license and option agreements with companies involved with oncology, diagnostics, research tools, agriculture and biologics production. In each of these agreements, we have granted certain rights to our technologies. In connection with the agreements, we are eligible to receive license fees, option fees, milestone payments and royalties on future sales of products, or any combination thereof. We recognized license fee revenues of \$20,000 and \$665,000 for the three and six months ended June 30, 2013, respectively, compared to \$80,000 and \$473,000 for the comparable 2012 periods related to our various agreements. The decrease in license fee revenues for the three months ended June 30, 2013 compared to the comparable 2012 period primarily reflected the termination of certain research license agreements. The increase in license fee revenues for the six months ended June 30, 2013 compared to the comparable 2012 period primarily reflected the full recognition of a non-refundable up-front license payment for an exclusive commercial license using our telomerase promoter technology for oncology-related in vitro assays. Current revenues may not be predictive of future revenues.

We recognized royalty revenues of \$92,000 and \$212,000 for the three and six months ended June 30, 2013, respectively, compared to \$50,000 and \$911,000 for the comparable 2012 periods on product sales of telomerase detection and telomere measurement kits to the research-use-only market, cell-based research products and nutritional products. The increase in royalty revenues for the three months ended June 30, 2013 compared to the comparable 2012 period reflected an increase in annual minimum royalty payments. The decrease in royalty revenues for the six months ended June 30, 2013 compared to comparable 2012 period primarily reflected the assignment of our telomerase activation technology to Telomerase Activation Sciences, Inc. in December 2012 and termination of our license agreement with Asia Biotech Corporation. Future royalty obligations by Asia Biotech Corporation were terminated as of December 2012.

Future license and royalty revenues are dependent upon additional agreements being signed and current agreements being maintained. Upon the closing of the divestiture of the stem cell assets, which is expected to occur no later than September 30, 2013, our license with GE Healthcare, including any future revenue payments thereunder, will be transferred to Asterias Biotherapeutics, Inc. (formerly known as BioTime Acquisition Corporation).

**Research and Development Expenses**

## Edgar Filing: GERON CORP - Form 10-Q

For each of our research and development programs, we incur direct external, personnel related and other research and development costs. Direct external expenses primarily consist of costs to outside parties to perform laboratory studies, develop manufacturing processes and manufacture raw materials and clinical trial drug materials, conduct and manage clinical trials, including investigator-sponsored clinical trials, and provide advice and consultation for scientific and clinical strategies. Personnel related expenses primarily consist of salaries and wages, stock-based compensation, payroll taxes and benefits for those individuals involved with ongoing research and development efforts. Other research and development expenses

Table of Contents

primarily consist of laboratory supplies, research-related overhead associated with leasing, operating and maintaining our facilities and equipment depreciation and maintenance. These costs apply to our clinical programs, preclinical programs as well as our discovery research efforts. A product candidate is designated a clinical candidate once an investigational new drug application has been filed with the U.S. Food and Drug Administration, or a similar filing with regulatory agencies outside the United States, for the purpose of commencing clinical trials in humans. Preclinical programs include product candidates undergoing toxicology, pharmacology, metabolism and efficacy studies and manufacturing process development required before testing in humans can commence.

Research and development expenses were \$4.8 million and \$12.7 million for the three and six months ended June 30, 2013, respectively, compared to \$12.8 million and \$27.9 million for the comparable 2012 periods. As shown in the table below, the decrease in research and development expenses for the three and six months ended June 30, 2013 compared to the comparable 2012 periods primarily reflected lower direct external research and development costs for the manufacturing of imetelstat and GRN1005 drug products and reduced clinical trial expenses resulting from the wind-down of our imetelstat trials in metastatic breast cancer and advanced non-small cell lung cancer and our GRN1005 trials in patients with brain metastases. The decrease in research and development expenses also reflected lower personnel related costs resulting from the recent restructurings as well as reduced costs for scientific supplies and services with the discontinuation of our discovery research programs. Overall, we expect research and development expenses for 2013 to be lower as compared to 2012 as a result of our decision to focus our resources on the clinical development of imetelstat in hematologic myeloid malignancies.

Research and development expenses for the three and six months ended June 30, 2013 and 2012 were as follows:

(In thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
	(Unaudited)			
Direct external research and development expenses:				
Clinical program: Imetelstat	\$ 1,215	\$ 2,938	\$ 2,732	\$ 8,146
Clinical program: GRN1005	59	3,377	1,051	5,396
Clinical program: GRNOPC1	97	91	155	244
Preclinical programs	23	153	224	535
Personnel related expenses	2,401	4,606	6,497	9,984
All other research and development expenses	1,012	1,612	2,069	3,579
Total	\$ 4,807	\$ 12,777	\$ 12,728	\$ 27,884

At this time, we cannot provide reliable estimates of how much time or investment will be necessary to commercialize imetelstat. For a more complete discussion of the risks and uncertainties associated with the development of imetelstat, see the sub-sections entitled, *Risks Related to Our Business* and *Risks Related to Clinical and Commercialization Activities*, in Part II, Item 1A entitled, *Risk Factors*, in this Form 10-Q.

**Restructuring Charges**

In April 2013, we announced the decision to discontinue our discovery research programs and companion diagnostics program based on telomere length and close our research laboratory facility located at 200 Constitution Drive, Menlo Park, California. With this decision, a total of 20 positions were eliminated. In connection with this restructuring, we expect to record aggregate restructuring charges of approximately \$1.5 million, of which \$824,000 was recorded in the second quarter of 2013. As of June 30, 2013, the restructuring charges recognized for the

## Edgar Filing: GERON CORP - Form 10-Q

April 2013 restructuring included \$624,000 related to one-time termination benefits, including \$28,000 of non-cash stock-based compensation expense relating to the extension of the post-termination exercise period through the end of December 2013 for certain stock options previously granted to terminated employees, and \$200,000 related to non-cash charges for write-downs of excess equipment and leasehold improvements. The remaining projected restructuring charges for the April 2013 restructuring relate to costs associated with the exit of our research laboratory facility and are expected to be recorded in the second half of 2013.

Table of Contents

In December 2012, we announced the decision to discontinue development of GRN1005. With this decision, a total of 43 positions were eliminated. As of June 30, 2013, we have recognized aggregate restructuring charges of approximately \$2.8 million for the December 2012 restructuring, of which \$2.7 million was recorded in the fourth quarter of 2012 and \$92,000 was recorded in the first half of 2013. All actions associated with the December 2012 restructuring were completed in the first half of 2013, and we do not anticipate incurring any further charges in connection with the December 2012 restructuring. See Note 3 on Restructurings in Notes to Condensed Consolidated Financial Statements of this Form 10-Q for further discussion of the restructuring charges.

**General and Administrative Expenses**

General and administrative expenses were \$3.4 million and \$8.2 million for the three and six months ended June 30, 2013, respectively, compared to \$5.8 million and \$10.9 million for the comparable 2012 periods. The decrease in general and administrative expenses for the three and six months ended June 30, 2013 compared to the comparable 2012 periods primarily reflected lower personnel related expenses resulting from the recent restructurings and reduced legal costs associated with our patent portfolio.

**Unrealized Gain (Loss) on Derivatives**

Unrealized gain (loss) on derivatives reflects a non-cash adjustment for changes in fair value of options held by non-employees that are classified as current liabilities. Derivatives classified as assets or liabilities are marked to fair value at each financial reporting date with any resulting unrealized gain (loss) recorded in the condensed consolidated statements of operations. We incurred an unrealized loss on derivatives of \$24,000 for the three months ended June 30, 2013 compared to an unrealized gain on derivatives of \$8,000 for the comparable 2012 period. We incurred unrealized gains on derivatives of \$1,000 and \$34,000 for the six months ended June 30, 2013 and 2012, respectively. The unrealized gains and losses on derivatives for the three and six months ended June 30, 2013 and 2012 primarily reflected the change in fair values of derivative liabilities as a result of fluctuations in the market value of our stock and changes in other inputs factored into the estimate of their fair value such as the volatility of our stock. See Note 2 on Fair Value Measurements in Notes to Condensed Consolidated Financial Statements of this Form 10-Q for further discussion of the fair value of derivatives.

**Interest and Other Income**

Interest income was \$56,000 and \$137,000 for the three and six months ended June 30, 2013, respectively, compared to \$165,000 and \$341,000 for the comparable 2012 periods. The decrease in interest income for the three and six months ended June 30, 2013 compared to the comparable 2012 periods reflected lower cash and investment balances resulting from the use of cash for operations. Interest earned in future periods will depend on the size of our securities portfolio and prevailing interest rates.

**Interest and Other Expense**



## Edgar Filing: GERON CORP - Form 10-Q

Interest and other expense was \$14,000 and \$32,000 for the three and six months ended June 30, 2013, respectively, compared to \$20,000 and \$43,000 for the comparable 2012 periods. The decrease in interest and other expense for the three and six months ended June 30, 2013 compared to the comparable 2012 periods was primarily due to reduced bank charges as a result of lower cash and investment balances.

### **Net Loss**

Net loss was \$8.9 million and \$20.8 million for the three and six months ended June 30, 2013, respectively, compared to \$18.3 million and \$37.1 million for the comparable 2012 periods. The decrease in net loss for the three and six months ended June 30, 2013 compared to the comparable 2012 periods was primarily due to reduced research and development expenses as a result of the wind-down of our imetelstat trials in metastatic breast cancer and advanced non-small cell lung cancer and our GRN1005 trials in patients with brain metastases. The decrease in net loss also reflected lower personnel related costs resulting from the recent restructurings as well as reduced costs for scientific supplies and services with the discontinuation of our discovery research programs.

Table of Contents

**LIQUIDITY AND CAPITAL RESOURCES**

Cash, restricted cash, cash equivalents and marketable securities at June 30, 2013 were \$71.6 million, compared to \$96.3 million at December 31, 2012. We have an investment policy to invest these funds in liquid, investment grade securities, such as interest-bearing money market funds, certificates of deposit, municipal securities, U.S. government and agency securities, corporate notes and commercial paper. Our investment portfolio does not contain securities with exposure to sub-prime mortgages, collateralized debt obligations, asset-backed securities or auction rate securities and, to date, we have not recognized any other-than-temporary impairment on our marketable securities or any significant changes in aggregate fair value that would impact our cash resources or liquidity. To date, we have not experienced lack of access to our invested cash and cash equivalents; however, access to our invested cash and cash equivalents may be impacted by adverse conditions in the financial and credit markets. The decrease in cash, restricted cash, cash equivalents and marketable securities in 2013 was the result of cash being used for operations.

In October 2012, we entered into an At-The-Market Issuance Sales Agreement, or sales agreement, with MLV & Co. LLC, or MLV, which provides that, upon the terms and subject to the conditions and limitations set forth in the sales agreement, we may elect to issue and sell shares of our common stock having an aggregate offering price of up to \$50.0 million from time to time through MLV as our sales agent. We are not obligated to make any sales of common stock under the sales agreement. To date, we have not sold any common stock pursuant to the sales agreement.

We estimate that our existing capital resources, amounts available to us under our equipment financing facility and future interest income will be sufficient to fund our current level of operations through at least the next 12 months. However, our future capital requirements will be substantial. Changes in our research and development plans or other changes affecting our operating expenses or cash balances may result in the unexpected expenditure of available resources. Factors that may require us to use our available capital resources sooner than we anticipate include:

- the accuracy of the assumptions underlying our estimates for our capital needs for the remainder of 2013 and beyond;
- changes in our clinical development plans for imetelstat;
- our ability to meaningfully reduce manufacturing costs of imetelstat;
- the magnitude and scope of our imetelstat research and development program, including the number of indications we intend to pursue;
- the progress made, if any, in our imetelstat research and development program, including our potential future clinical trials and existing or future investigator-sponsored trials;

## Edgar Filing: GERON CORP - Form 10-Q

- our ability to establish, enforce and maintain strategic arrangements for research, development, clinical testing, manufacturing and marketing;
- our ability to fully complete the divestiture of our stem cell assets to Asterias Biotherapeutics, Inc.;
- the time and costs involved in obtaining regulatory clearances and approvals; and
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims.

Table of Contents

If our existing capital resources, equipment financing arrangement and future interest income are insufficient to meet future capital requirements, we will need to raise additional capital to fund our operations. We anticipate that we would need to seek additional funding through public or private equity financings, including pursuant to our sales agreement with MLV, equipment loans or other financing sources that may be available, including debt financings or collaborative and licensing arrangements. However, we may be unable to raise sufficient additional capital when we need it, on favorable terms or at all. Our ability to raise additional funds may be severely impaired if imetelstat fails to show adequate safety or efficacy in clinical testing. If we are unable to obtain adequate funds on reasonable terms, we may be required to curtail operations significantly or obtain funds by entering into financing, supply or collaboration agreements on unattractive terms or we may be required to relinquish rights to technology or imetelstat or to grant licenses on terms that are unfavorable to us.

*Cash Flows from Operating Activities.* Net cash used in operations for the six months ended June 30, 2013 and 2012 was \$24.2 million and \$30.3 million, respectively. The decrease in net cash used in operations in 2013 compared to 2012 primarily reflected reduced operating expenses due to the wind-down of our imetelstat trials in metastatic breast cancer and advanced non-small cell lung cancer and our GRN1005 trials in patients with brain metastases and recent restructurings.

*Cash Flows from Investing Activities.* Net cash provided by investing activities for the six months ended June 30, 2013 and 2012 was \$10.9 million and \$28.3 million, respectively. The decrease in net cash provided by investing activities in 2013 compared to 2012 primarily reflected higher purchases of marketable securities and lower proceeds from maturities of marketable securities.

As of June 30, 2013 we had approximately \$500,000 available for borrowing under our equipment financing facility. We renewed the commitment for this equipment financing facility in 2009 to further fund equipment purchases. If we are unable to renew the commitment in the future, we will use our existing cash resources to fund capital expenditures.

*Cash Flows from Financing Activities.* Net cash provided by financing activities was \$60,000 and \$79,000 for the six months ended June 30, 2013 and 2012, respectively. Net cash provided by financing activities in the first half of 2013 and the comparable 2012 period reflected receipt of cash from the issuance of common stock under our employee equity plans.

**Off-Balance Sheet Arrangements**

None.

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

During the six months ended June 30, 2013, there were no material changes to our market risk disclosures as set forth in Part II, Item 7A, Quantitative and Qualitative Disclosures About Market Risk in our Annual Report on Form 10-K for the year ended December 31, 2012.

**ITEM 4.**

**CONTROLS AND PROCEDURES**

(a) *Evaluation of Disclosure Controls and Procedures.* We have established disclosure controls and procedures, as defined in Rule 13a-15(e) of the Securities Exchange Act of 1934, as amended. Our Chief Executive Officer and our Chief Financial Officer have concluded, based on the evaluation of the effectiveness of our disclosure controls and procedures by our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, as of the end of the period covered by this report, that our disclosure controls and procedures were effective at the reasonable assurance level.

Table of Contents

(b) *Changes in Internal Controls Over Financial Reporting.* There was no change in our internal control over financial reporting for the three months ended June 30, 2013 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

It should be noted that any system of controls, however well designed and operated, can provide only reasonable assurance, and not absolute assurance, that the objectives of the system are met. In addition, the design of any control system is based in part upon certain assumptions about the likelihood of future events. Because of these and other inherent limitations of control systems, there can be no assurance that any design will succeed in achieving its stated goals in all future circumstances. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met and, as set forth above, our Chief Executive Officer and Chief Financial Officer have concluded, based on their evaluation as of the end of the period covered by this report, that our disclosure controls and procedures were effective to provide reasonable assurance that the objectives of our disclosure control system were met.

**PART II. OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

None.

**ITEM 1A. RISK FACTORS**

Our business is subject to various risks, including those described below. You should carefully consider these risk factors, together with all of the other information included in this Form 10-Q and our most recent Annual Report on Form 10-K for the year ended December 31, 2012, or the Form 10-K. Any of these risks could materially adversely affect our business, operating results and financial condition. We have marked with an asterisk (\*) those risks described below that reflect substantive changes from, or additions to, the risks described under Part I, Item 1A,

Risk Factors included in the Form 10-K. In addition, the risk factor entitled *Any further development of imetelstat in solid tumors with short telomeres is dependent upon confirmation of the magnitude of the treatment effect of imetelstat in NSCLC patients whose tumors have short telomeres, and our ability to refine or validate a telomere length assay and to obtain any rights to third-party intellectual property that may be necessary for commercial use* that appeared in the Form 10-K has been removed.

**RISKS RELATED TO OUR BUSINESS**

*Our success is solely dependent on the success of one early-stage product candidate, imetelstat, and we cannot be certain that imetelstat will advance to subsequent clinical trials or receive regulatory approval on a timely basis, or at all. \**

## Edgar Filing: GERON CORP - Form 10-Q

Our business is at an early stage of development, and we are solely dependent on the success of imetelstat, our sole product candidate. We do not have any products that are commercially available. Our ability to develop imetelstat to and through regulatory approval and commercial launch is subject to significant risk and uncertainty and our ability to, among other things:

- receive positive data from investigator-sponsored trials of imetelstat, such as the Myelofibrosis IST, that provide the clinical rationale for the potential development of imetelstat in hematologic myeloid malignancies;
- ascertain that the use of imetelstat does not result in significant systemic or organ toxicities;
- develop clinical plans for, and successfully enroll and complete, potential subsequent clinical trials of imetelstat in hematologic myeloid malignancies;

Table of Contents

- collaborate successfully with clinical trial sites, academic institutions, clinical research organizations, physician investigators, including any physician investigators conducting investigator-sponsored trials of imetelstat, and other third parties;
  
- obtain positive clinical data to enable subsequent clinical trials;
  
- obtain required regulatory clearances and approvals for imetelstat;
  
- enter into arrangements with third parties to provide services needed to further research and develop imetelstat, or to manufacture imetelstat, in each case at commercially reasonable costs;
  
- enter into arrangements with third parties, or establish internal capabilities, to provide sales, marketing and distribution functions in compliance with applicable laws;
  
- obtain appropriate coverage and reimbursement levels for the cost of imetelstat from governmental authorities, private health insurers and other third party payers;
  
- maintain and enforce adequate intellectual property protection for imetelstat;
  
- maintain adequate financial resources and personnel to advance imetelstat to and through subsequent clinical trials; and
  
- obtain financing on commercially reasonable terms to fund our operations.

If we are not able to successfully achieve the above-stated goals and overcome other challenges that we may encounter in the research, development, manufacturing and commercialization of imetelstat, we may be forced to abandon our development of imetelstat, which would severely harm our business and could potentially cause us to cease operations.

There are many additional reasons why we may need to delay or abandon efforts to research, develop or seek regulatory approvals to market imetelstat, at any stage of the development process or for any or all of the indications we may determine to pursue, or we may otherwise determine for business or financial reasons to delay or discontinue its development for any or all potential indications. Imetelstat may prove to have undesirable or unintended side effects or other characteristics adversely affecting its safety, efficacy or cost effectiveness that could prevent



or limit its approval for marketing and successful commercial use, or that could delay or prevent the commencement and/or completion of clinical trials for imetelstat. For example, in our Phase 1 clinical trials of imetelstat, we observed dose-limiting toxicities, including reduced platelet count, or thrombocytopenia, when the drug was used as a single agent, and reduced white blood cell count, or neutropenia, when the drug was used in combination with paclitaxel, as well as a low incidence of severe infusion reactions. In our Phase 2 clinical trials of imetelstat in ET, multiple myeloma and solid tumors, we have observed hematologic toxicities, abnormal laboratory liver function tests, and non-laboratory test findings such as gastrointestinal events, infections, muscular and joint pain and fatigue. We may in the future observe or report dose-limiting toxicities or other safety issues in our ongoing Phase 2 clinical trials of imetelstat in ET and multiple myeloma or in investigator-sponsored trials of imetelstat, including the Myelofibrosis IST. Such dose-limiting toxicities or other safety issues could delay or prevent the commencement and/or completion of our ongoing or potential subsequent clinical trials or investigator-sponsored trials, or may require us to conduct additional, unforeseen trials or to abandon our development of imetelstat entirely. In addition, if we obtain safety results that alter the benefit-to-risk ratio with respect to patients enrolled in our ongoing Phase 2 clinical trials of imetelstat in ET and multiple myeloma, or if negative or inconclusive efficacy results are obtained from the Myelofibrosis IST, we would likely be further delayed or prevented from advancing imetelstat into further clinical development and might decide to discontinue our development of imetelstat, which would severely harm our business and prospects, and would likely cause us to cease operations.

Table of Contents

We are currently focused on the development of imetelstat in hematologic myeloid malignancies, other than ET, and future Geron-sponsored clinical development of imetelstat is highly dependent on the results of existing and potential future investigator-sponsored trials of imetelstat in hematologic myeloid malignancies, including the Myelofibrosis IST. We may be unable to develop, or initiate the development of, imetelstat in any additional hematologic myeloid malignancy indications, which would likely result in our decision to discontinue development of imetelstat and to potentially cease operations. In any event, imetelstat will require significant additional clinical testing prior to possible regulatory approval in the United States and other countries, and we do not expect imetelstat to be commercially available for many years, if at all. Our clinical development program for imetelstat may not lead to regulatory approval from the U.S. Food and Drug Administration, or FDA, and similar foreign regulatory agencies if we fail to demonstrate that imetelstat is safe and effective. We may therefore fail to commercialize imetelstat. Any failure to advance imetelstat to subsequent clinical trials, failure to obtain regulatory approval of imetelstat, or limitations on any regulatory approval that we might receive, would severely harm our business and prospects, and could potentially cause us to cease operations.

Our ability to generate product revenue is dependent on the successful regulatory approval and commercialization of imetelstat. Imetelstat may not prove to be more effective for treating hematologic cancers than current therapies. Competitors or other third parties may also have proprietary rights that prevent us from developing and marketing imetelstat, or our competitors may discover or commercialize similar, superior or lower-cost products that make imetelstat unsuitable for marketing. Imetelstat also may not be able to be manufactured in commercial quantities at an acceptable cost. Any of the factors discussed above could delay or prevent us from developing, commercializing or marketing imetelstat, which would materially adversely affect our business and could potentially cause us to cease operations.

*Success in early clinical trials may not be indicative of results in subsequent clinical trials. \**

A number of new drugs and biologics have shown promising results in initial clinical trials, but subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval.

Data from our preclinical studies and Phase 1 and Phase 2 clinical trials of imetelstat should not be relied upon as evidence that subsequent or larger-scale clinical trials will succeed. The positive results we have obtained from the 18 patients enrolled in the Phase 2 trial of imetelstat in ET may not predict the future therapeutic benefit of imetelstat, if any, in other hematologic myeloid malignancies, including MF. The known dose-limiting toxicities associated with imetelstat, such as thrombocytopenia and neutropenia, could cause complexities in treating patients with MF. The Myelofibrosis IST has tested imetelstat in only a small number of patients and results obtained from any additional patients enrolled in the Myelofibrosis IST may differ from results communicated by the investigator to date. Data from the Myelofibrosis IST, if positive, will inform any future Geron-sponsored clinical trial in patients with MF and will be necessary for future clinical development of imetelstat in MF. Any results from the Myelofibrosis IST may not be reproducible in future clinical trials.

We will be required to demonstrate through larger-scale Phase 3 clinical trials that imetelstat is safe and effective for use in a diverse population before we can seek regulatory approval for its commercial sale. There is typically an extremely high rate of attrition from the failure of drug candidates proceeding through clinical trials. If we are unable to develop imetelstat into Phase 3 clinical trials, our business may fail.

*Our research and development programs are subject to numerous risks and uncertainties. \**

## Edgar Filing: GERON CORP - Form 10-Q

The science and technology of telomere biology, telomerase and our proprietary oligonucleotide chemistry are relatively new. There is no precedent for the successful commercialization of a therapeutic product candidate based on these technologies. We must undertake significant research and development activities to develop imetelstat based on these technologies, which will require significant additional funding and may take years to accomplish, if at all.

Table of Contents

Because of the significant scientific, regulatory and commercial milestones that must be reached for any of our research and development programs to be successful, any program, or any aspect of a program, may be delayed or abandoned, even after we have expended significant resources on it. Our decisions to discontinue our Phase 2 clinical trial of imetelstat in metastatic breast cancer in September 2012, development of GRN1005 in December 2012 and development of imetelstat in solid tumors with short telomeres in April 2013, are examples of this. Any further delay or abandonment of our development of imetelstat in hematologic myeloid malignancies would have a material adverse effect on, and likely result in the failure of, our business.

*If we are not able to fully complete the divestiture of our stem cell assets, our stock price may decline and our business may be adversely affected. \**

In January 2013, we entered into an Asset Contribution Agreement, or the Agreement, with BioTime, Inc., or BioTime, and BioTime's recently formed subsidiary, Asterias Biotherapeutics, Inc., or Asterias (formerly BioTime Acquisition Corporation), providing for the divestiture of our stem cell assets and autologous cellular immunotherapy program to Asterias upon the closing of the transaction. As consideration for the contribution of our stem cell assets to Asterias, upon the closing, Asterias will issue to Geron approximately 6.5 million shares of its Series A common stock, which we will distribute to our stockholders on a pro rata basis. Aside from the distribution of shares to our stockholders and potential royalties that we may receive on the sale of products that are commercialized, if any, in reliance upon our patents acquired by Asterias, we will not receive any consideration for these assets. The transaction, which is expected to close no later than September 30, 2013, is subject to negotiated closing conditions that may not be satisfied in a timely manner or at all, including the effectiveness of certain registration statements filed by BioTime and Asterias with the United States Securities and Exchange Commission, or SEC, with respect to the securities to be distributed as contemplated by the Agreement, which we do not control, and other customary closing conditions. Prior to the closing, we are subject to certain obligations, including the obligation to exercise reasonable best efforts to preserve intact and maintain the assets to be contributed by us to Asterias upon the closing of the transaction. If we are unable to preserve intact and maintain the assets to be contributed by us to Asterias, or if BioTime or Asterias are unable to satisfy their obligations with respect to the transaction contemplated by the Agreement, including the obligation to obtain the effectiveness of certain registration statements filed by them with the SEC, we may be unable to fully complete the transaction with BioTime and Asterias, which could have a material adverse effect on our business.

In addition, our ability to preserve intact and maintain the assets to be contributed by us to Asterias depends on our ability to maintain license agreements with third parties covering critical technologies related to our stem cell portfolio. These license agreements impose certain obligations on us, including obligations to diligently pursue development of stem cell products under the licensed patents. As a result of our discontinuation of further development of our stem cell programs in November 2011, our licensors could seek to limit or terminate our license rights, which could lead to costly and time-consuming litigation and, potentially, a loss of the licensed rights, which could impair our ability to complete the divestiture of our stem cell assets to Asterias.

Our agreement to contribute our stem cell assets and autologous cellular immunotherapy program to Asterias provides for indemnification by us of BioTime against all losses and expenses relating to breaches of our representations, warranties and covenants. Furthermore, any failure or inability by us to contribute our stem cell assets to Asterias, as contemplated under the Agreement, could expose us to a number of risks and costs, including declines or fluctuations in our stock price, potential limitations on our ability to execute strategic alternatives concerning our stem cell assets and/or on our ability to clarify or resolve intellectual property matters relating to our stem cell assets, additional advisor and legal fees, and distractions to our management caused by activities undertaken in connection with closing this transaction or any inability to close the transaction. The occurrence of any one or more of the above could have an adverse impact on our business and financial condition, as well as on our ability to fully complete the divestiture of our stem cell assets to Asterias, or at all.

Table of Contents

Some of our investors purchased shares of our common stock because they were interested in the opportunities presented by our human embryonic stem cell programs. Thus, certain stockholders may attribute substantial financial value to our stem cell assets. If our stockholders believe that the Agreement with BioTime and Asterias for the divestiture of our stem cell assets does not provide the financial value that our stockholders may attribute to our stem cell assets or the divestiture does not occur in a timely manner or at all, our stock price may decline and litigation may occur.

**RISKS RELATED TO CLINICAL AND COMMERCIALIZATION ACTIVITIES**

*The ability to conduct and complete potential future Geron-sponsored or any investigator-sponsored trials of imetelstat on a timely basis is subject to risks and uncertainties related to factors such as performance by investigator-sponsors, availability of drug supply, patient enrollment, and regulatory authorization. \**

Delays or terminations of our potential future clinical trials and of investigator-sponsored trials could be caused by matters such as:

- poor effectiveness of imetelstat during clinical trials or results that do not demonstrate statistically significant efficacy;
- safety issues, side effects or dose-limiting toxicities;
- disruptions due to drug supply or quality issues;
- failure by independent physicians conducting existing or future investigator-sponsored trials of imetelstat to timely commence, enroll, complete or report data from such investigator-sponsored trials;
- not receiving timely regulatory clearances or approvals, including, for example, acceptance of new manufacturing specifications or procedures or clinical trial protocol amendments by regulatory authorities;
- not receiving timely institutional review board or ethics committee approval of clinical trial protocols or protocol amendments;
- delays in patient enrollment due to size and nature of patient population, nature of protocols, proximity of patients to clinical sites, availability of effective treatments for the relevant disease and eligibility criteria for the trial;

## Edgar Filing: GERON CORP - Form 10-Q

- difficulty in obtaining or accessing necessary clinical data, which may result in incomplete data sets;
- unavailability of any study-related treatment (including comparator therapy);
- lack of adequate funding to continue any clinical trial, including funding requirements resulting from unforeseen costs due to enrollment delays or discontinued participation by patients;
- issues with key vendors of clinical services, such as contract research organizations and laboratory service providers; or
- governmental or regulatory delays, information requests, clinical holds, and changes in regulatory requirements, policies and guidelines.

Table of Contents

Our enrollment goals for future clinical trials of imetelstat, and the enrollment goals of independent physicians conducting existing or future investigator-sponsored trials of imetelstat, may not be met. In addition, our inability to retain, or the inability of independent physicians conducting investigator-sponsored trials of imetelstat to retain, patients who have enrolled in a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy or personal issues, or who are lost to further follow-up, could result in clinical trial delays, the inability to complete clinical trials, or incomplete data sets. Further, any of our future clinical trials may be overseen by an internal safety monitoring committee, or ISMC, and an ISMC may determine to delay or suspend one or more of these trials due to safety or futility findings based on events occurring during a clinical trial. Data that we receive from independent physician investigators may be flawed if the investigators fail to follow appropriate clinical or quality practices. Delays in timely completion of clinical testing of imetelstat, in clinical trials conducted by us or by independent physician investigators, could increase research and development costs and could prevent or would delay us from obtaining regulatory approval for imetelstat, both of which would likely have a material adverse effect on our business. In addition, future Geron-sponsored clinical development of imetelstat is dependent on the results of existing and potential future investigator-sponsored trials of imetelstat in hematologic myeloid malignancies, including the Myelofibrosis IST. Accordingly, a delay in the timely completion of or reporting of data from the Myelofibrosis IST could have a material adverse effect on our ability to further develop imetelstat or to advance imetelstat to subsequent clinical trials.

*Delays in the initiation of, or our inability to initiate, subsequent clinical trials of imetelstat could result in increased costs to us and would delay our ability to generate or prevent us from generating revenues. \**

The commencement of subsequent clinical trials for imetelstat could be delayed or abandoned for a variety of reasons, including as a result of failures or delays in:

- commencement, enrollment or completion of clinical trials conducted by physician investigators conducting investigator-sponsored trials, or independent physician investigators promptly or adequately reporting data from such trials;
- demonstrating sufficient safety and efficacy in Phase 2 clinical trials conducted by us or by independent physician investigators to obtain regulatory clearance to commence subsequent clinical trials;
- obtaining sufficient funding;
- manufacturing sufficient quantities of drug;
- producing drugs that meet the quality standards of the FDA and other regulatory agencies;
- ensuring our ability to manufacture drugs at acceptable costs for Phase 3 clinical trials and commercialization;

- obtaining clearance or approval of proposed trial designs or manufacturing specifications from the FDA and other regulatory authorities;
- reaching agreement on acceptable terms with our collaborators on all aspects of the clinical trial, including contract research organizations, laboratory service providers, and the trial sites;
- obtaining institutional review board or ethics committee approval to conduct a clinical trial at a prospective site; and
- securing and successfully screening appropriate subjects for treatment.

The occurrence of any of these events could adversely affect our ability to initiate subsequent clinical trials, which could increase our development costs or our ability to generate revenues could be impaired, either of which could adversely impact our financial results and have a material adverse effect on our business.



Table of Contents

***We may not be able to manufacture imetelstat at costs or scales necessary to conduct our clinical programs or potential future commercialization activities.\****

Imetelstat is likely to be more expensive to manufacture than most other treatments currently available today or that may be available in the future. The commercial cost of manufacturing imetelstat will need to be significantly lower than our current costs in order for imetelstat to become a commercially successful product. Oligonucleotides are relatively large molecules produced using complex chemistry, and the cost of manufacturing an oligonucleotide like imetelstat is greater than the cost of making typical small-molecule drugs. Our present imetelstat manufacturing processes are conducted at a relatively modest scale appropriate for our ongoing Phase 2 clinical trials and investigator-sponsored trials for which we provide clinical drug supply. We may not be able to achieve sufficient scale increases or cost reductions necessary for successful commercial production of imetelstat. Additionally, given the complexities of our manufacturing processes, the resulting costs that we incur to conduct our clinical trials may be higher than for other comparable treatments, requiring us to expend relatively larger amounts of cash to complete our clinical trials, which would negatively impact our financial condition and could increase our need for additional capital.

***Manufacturing imetelstat is subject to process and technical challenges and regulatory risks.***

We face numerous risks and uncertainties with regard to manufacturing imetelstat. Regulatory requirements for oligonucleotide products are less well-defined than for small-molecule drugs, and there is no guarantee that we will achieve sufficient product quality standards required for Phase 3 clinical trials or for commercial approval and manufacturing of imetelstat. Changes in our manufacturing processes or formulations for imetelstat that may be made during later stages of clinical development, including during Phase 3 trials, may result in regulatory delays, the need for further clinical trials, rejection of a marketing application, or limitation on marketing authorization by regulatory authorities, which would result in a material adverse effect on our business.

***We do not have experience as a company in conducting large-scale, Phase 3 clinical trials, or in those areas required for the successful commercialization of imetelstat.***

We have no experience as a company in conducting large-scale, Phase 3 clinical trials. We cannot be certain that any large-scale, Phase 3 clinical trials will begin or be completed on time, if at all. Large-scale, Phase 3 clinical trials will require additional Phase 2 clinical trials and supportive Phase 2 data, additional financial and management resources and reliance on third-party clinical investigators, clinical research organizations, lab service providers and consultants. Relying on third-party clinical investigators or clinical research organizations may cause delays that are outside of our control. Any such delays could have a material adverse effect on our business.

We also do not have commercialization capabilities for imetelstat, and we will need to establish sales, marketing and distribution capabilities or establish and maintain agreements with third parties to market and sell imetelstat. Developing internal sales, marketing and distribution capabilities is an expensive and time-consuming process. We may not be able to enter into third-party sales, marketing and distribution agreements on terms that are economically attractive, or at all. Even if we do enter into such agreements, these third parties may not successfully market or distribute imetelstat, which may materially harm our business.

***Obtaining regulatory approvals to market imetelstat in the United States and other countries is a costly and lengthy process, and we cannot predict whether or when we will be permitted to commercialize imetelstat.\****

Federal, state and local governments in the United States and governments in other countries have significant regulations in place that govern many of our activities and may prevent us from successfully conducting our development efforts or from commercializing imetelstat. The regulatory process, particularly for a biopharmaceutical product candidate like imetelstat, is uncertain, can take many years and requires the expenditure of substantial resources.

Table of Contents

Prior to submission of any regulatory application seeking approval to commence commercial sales of imetelstat, we will be required to conduct extensive preclinical and clinical testing. In particular, human pharmaceutical therapeutic product candidates are subject to rigorous requirements of the FDA in the United States and similar health and regulatory authorities in other countries in order to demonstrate safety and efficacy. Data obtained from preclinical and clinical activities are susceptible to varying interpretations that could delay, limit or prevent regulatory agency approvals. For example, data from the Myelofibrosis IST, if positive, may not provide sufficient rationale for us to proceed to, or otherwise enable us to obtain regulatory clearance for, a subsequent clinical trial of imetelstat in patients with MF or any other hematologic myeloid malignancy. In addition, delays or rejections of regulatory approvals, or limitations in marketing authorizations, may be encountered as a result of changes in regulatory environment or regulatory agency policy during the period of product development and/or the period of review of any application for regulatory agency approval for a product candidate. We do not expect to receive regulatory approvals for imetelstat for many years, if at all.

Imetelstat must receive all relevant regulatory agency approvals before it may be marketed in the United States or other countries. Obtaining regulatory approval is a lengthy, expensive and uncertain process. Because imetelstat involves the application of new technologies and a new therapeutic approach, it may be subject to substantial additional review by various government regulatory authorities, and, as a result, the process of obtaining regulatory approvals for imetelstat may proceed more slowly than for product candidates based upon more conventional technologies, and any approval that we may receive could limit the use of imetelstat.

Delays in obtaining regulatory agency approvals or limitations in the scope of such approvals could:

- significantly harm the commercial potential of imetelstat;
- impose costly procedures upon our activities;
- diminish any competitive advantages that we may attain; or
- adversely affect our ability to receive royalties and generate revenues and profits.

Even if we commit the necessary time and resources, the required regulatory agency approvals may not be obtained for imetelstat. If we obtain regulatory agency approval for imetelstat, this approval may entail limitations on the indicated uses or other aspects of the product label for which it can be marketed that could limit the potential commercial use of imetelstat. The occurrence of any of these events could materially adversely affect our business.

***Failure to achieve continued compliance with government regulation over our products, if any, could delay or halt commercialization of our products.***

## Edgar Filing: GERON CORP - Form 10-Q

Approved products and their manufacturers are subject to continual review, and discovery of previously unknown problems with a product or its manufacturer may result in restrictions on the product or manufacturer, including withdrawal of the product from the market. The future sale by us of any commercially viable product will be subject to government regulation related to numerous matters, including the processes of:

- manufacturing;
- advertising and promoting;
- selling and marketing;
- labeling; and
- distribution.

Table of Contents

If, and to the extent that, we are unable to comply with these regulations, our ability to earn revenues from product sales will be materially and negatively impacted.

Failure to comply with regulatory requirements can result in severe civil and criminal penalties, including but not limited to:

- recall or seizure of products;
- injunction against the manufacture, distribution and sales and marketing of products; and
- criminal prosecution.

The imposition of any of these penalties or other commercial limitations could significantly impair our business, financial condition and results of operations.

**RISKS RELATED TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL FINANCING**

*We have a history of losses and anticipate continued future losses, and our continued losses could impair our ability to sustain operations. \**

We have incurred operating losses every year since our operations began in 1990. As of June 30, 2013, our accumulated deficit was approximately \$875.2 million. Losses have resulted principally from costs incurred in connection with our research and development activities and from general and administrative costs associated with our operations. We expect to incur additional operating losses and, as our clinical development activities continue, our operating losses may increase in size.

Substantially all of our revenues to date have been research support payments under collaboration agreements and milestones, royalties and other revenues from our licensing arrangements. We may be unsuccessful in entering into any new corporate collaboration or license agreements that result in revenues, or existing collaboration agreements or license arrangements may be terminated or expire. Any revenues generated from ongoing collaboration agreements and revenues from our licensing arrangements will not be sufficient alone to continue or expand our research or development activities and otherwise sustain our operations.

We also expect to experience negative cash flow for the foreseeable future as we fund our operating losses and capital expenditures. This will result in decreases in our working capital, total assets and stockholders' equity, which may not be offset by future financings. We will need to

## Edgar Filing: GERON CORP - Form 10-Q

generate significant revenues to achieve profitability. We may not be able to generate these revenues, and we may never achieve profitability. Our failure to achieve profitability could negatively impact the market price of our common stock and our ability to sustain operations. Even if we do become profitable, we may not be able to sustain or increase profitability on a quarterly or annual basis.

***We will need substantial additional capital to conduct our operations and develop imetelstat, and our ability to obtain the necessary funding is uncertain. \****

We will require substantial capital resources in order to conduct our operations and develop imetelstat, and we cannot assure you that our existing capital resources, equipment financing arrangement, future interest income and potential sales of our common stock, including pursuant to our At-The-Market Issuance Sales Agreement with MLV & Co. LLC, will be sufficient to fund future planned operations. The timing and degree of any future capital requirements will depend on many factors, including:

Table of Contents

- the accuracy of the assumptions underlying our estimates for our capital needs for the remainder of 2013 and beyond;
- changes in our clinical development plans for imetelstat;
- our ability to meaningfully reduce manufacturing costs of imetelstat;
- the magnitude and scope of our imetelstat research and development program, including the number of indications we intend to pursue;
- the progress made, if any, in our imetelstat research and development program, including our potential future clinical trials and existing or future investigator-sponsored trials;
- our ability to establish, enforce and maintain strategic arrangements for research, development, clinical testing, manufacturing and marketing;
- our ability to fully complete the divestiture of our stem cell assets to Asterias;
- the time and costs involved in obtaining regulatory clearances and approvals; and
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims.

In addition, changes in our business may occur that would consume available capital resources sooner than we expect. Additional financing through strategic collaborations, public or private equity financings, capital lease transactions or other financing sources may not be available on acceptable terms, or at all. In addition, we may raise equity capital at a stock price or on other terms that could result in substantial dilution of ownership for our stockholders. The receptivity of the public and private equity markets to proposed financings is substantially affected by the general economic, market and political climate and by other factors which are unpredictable and over which we have no control. In addition, our ability to raise additional funds may be severely impaired if our product candidate, imetelstat, fails to show adequate safety or efficacy in ongoing or potential subsequent clinical trials, including in investigator-sponsored trials.

Further, in the event that we obtain additional funds through arrangements with collaborative partners, these arrangements may require us to relinquish certain of our rights to imetelstat.

If sufficient capital is not available, we may be required to delay, reduce the scope of, suspend or eliminate some or all of the elements of our imetelstat program, any of which could have a material adverse effect on our business.

#### **RISKS RELATED TO PROTECTING OUR INTELLECTUAL PROPERTY**

*Our success will depend on our ability to protect our technologies and our product candidate, imetelstat, through patents and other intellectual property rights and to operate without infringing the rights of others.\**

Protection of our proprietary technology is critically important to our business. Our success will depend in part on our ability to obtain, enforce and extend our patents and maintain trade secrets, both in the United States and in other countries. If we are unsuccessful in either of these regards, the value of our technologies and imetelstat will be adversely affected, and we may be unable to continue our development of imetelstat. By way of example, we do not yet have issued compound patents for imetelstat in Europe after 2020. Further, our patents may be challenged, invalidated or circumvented, and our patent rights may not provide proprietary protection or competitive advantages to us. In the event that we or our licensors are unsuccessful in obtaining and enforcing patents, we may not be able to further develop or commercialize imetelstat and our business would be negatively impacted, and we might be unable to continue our operations.



Table of Contents

Publication of discoveries in scientific or patent literature tends to lag behind actual discoveries by at least several months and sometimes several years. Therefore, the persons or entities that we or our licensors name as inventors in our patents and patent applications may not have been the first to invent the inventions disclosed in the patent applications or patents, or the first to file patent applications for these inventions. As a result, we may not be able to obtain patents for discoveries that we otherwise would consider patentable and that we consider to be extremely significant to our future success.

The patent positions of pharmaceutical and biopharmaceutical companies, including ours, are highly uncertain and involve complex legal and technical questions. In particular, legal principles for biotechnology and pharmaceutical patents in the United States and in other countries are evolving, and the extent to which we will be able to obtain patent coverage to protect our technologies and imetelstat, or enforce issued patents, is uncertain. If we infringe the patents of others, we may be blocked from continuing development work or be required to obtain licenses on terms that may impact the value of imetelstat or cause it to be commercially impracticable.

In addition, on September 16, 2011, the Leahy-Smith America Invents Act, or the AIA, was signed into law. The AIA includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be prosecuted and may affect patent litigation. The United States Patent and Trademark Office, or the Patent Office, has developed new and untested regulations and procedures to govern the full implementation of the AIA. Many of the substantive changes to patent law associated with the AIA, and in particular, the first to file provisions, became effective on March 16, 2013. For example, under the AIA, patent rights are awarded to the first inventor to file a patent application with respect to a particular invention. Thus, after March 16, 2013, our ability to protect our patentable intellectual property depends, in part, on our ability to be the first to file patent applications with respect to our inventions. Delay in the filing of a patent application for any purpose, including further development or refinement of an invention, may result in the risk of loss of patent rights. The AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

The U.S. Supreme Court, or the Court, has also issued decisions for which the full impact is not yet understood. On June 13, 2013, in *Association for Molecular Pathology v. Myriad Genetics, Inc.* the Court held that claims to isolated genomic DNA were not patentable, but claims to complementary DNA (cDNA) molecules were valid. The effect of the decision on patents for other isolated natural products is uncertain. On March 20, 2012, in *Mayo Collaborative Services, DBA Mayo Medical Laboratories, et al. v. Prometheus Laboratories, Inc.*, the Court held that several claims drawn to measuring drug metabolite levels from patient samples and correlating them to drug doses were not patentable subject matter. The decision has created uncertainty around the ability to patent certain biomarker-related method patents. These decisions have increased the uncertainty with regard to our ability to obtain patents in the future as well as the value of current and future patents, once obtained. Depending on decisions by the U.S. federal courts and the Patent Office, the interpretation of laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents, all of which could have a material adverse effect on our business.

***Challenges to our patent rights can result in costly and time-consuming legal proceedings that may prevent or limit development of imetelstat. \****

Our patents may be challenged through administrative or judicial proceedings. Such proceedings are typically lengthy and complex, and an adverse decision can result in the loss of important patent rights. For example, where more than one party seeks U.S. patent protection for the same technology, the Patent Office may declare an interference proceeding in order to ascertain the party to which the patent should be issued. Patent interferences are typically complex, highly contested legal proceedings, subject to appeal. They are usually expensive and prolonged, and can cause significant delay in the issuance of patents. Our pending patent applications, or our issued patents, may be drawn into interference proceedings or be challenged through post-grant review procedures, which may delay or prevent the issuance of patents, or result in the loss of issued patent rights.



Table of Contents

Under the AIA, interference proceedings have been eliminated for patent applications filed on or after March 16, 2013, and have been replaced with other types of proceedings, including derivation proceedings. The AIA also includes post-grant review procedures subjecting U.S. patents to post-grant review procedures similar to European oppositions. U.S. patents owned or licensed by us may therefore be subject to post-grant review procedures, as well as other forms of review and re-examination. A decision in such proceedings adverse to our interests could result in the loss of valuable patent rights and negatively impact our business.

Certain jurisdictions, such as Europe, New Zealand and Australia, permit oppositions to be filed against granted patents or patents proposed to be granted. Because our intent is to commercialize imetelstat internationally if approved for commercial sale, securing both proprietary protection and freedom to operate outside of the United States is important to our business. We are involved in both opposing the grant of patents to others through such opposition proceedings and in defending our patent applications against oppositions filed by others.

For example, we have been involved in several patent oppositions before the European Patent Office, or EPO, with a series of companies (GemVax, Pharmexa and KAEL-GemVax) developing GV1001, a cancer vaccine that employs a short telomerase peptide to induce an immune response against telomerase. Pharmexa originally obtained a European patent with broad claims to the use of telomerase vaccines for the treatment of cancer. We opposed that patent and during the opposition proceedings and subsequent appeal the original claims were revoked and, new, narrower claims of the Pharmexa patent were allowed. In February 2010 and in March 2012, GemVax, AS, a company related to KAEL-GemVax, was granted two further related European patents covering its telomerase peptide vaccine, which we also opposed. In March 2013, GemVax, AS agreed to amend certain patent claims in these two patents to narrow their scope, and we withdrew our oppositions to GemVax's patents. On appeal, the Opposition Division (OD) has approved the amended claims for one patent.

In parallel, Pharmexa opposed a European patent held by us and the Regents of the University of Colorado which covers many aspects of human telomerase, including the use of telomerase peptides in cancer vaccines. The OD of the EPO and Technical Board of Appeals revoked three of the granted claims in our patent, but upheld the remaining 47 claims. In July 2009, Geron and the Regents of the University of Colorado were awarded a second European patent with claims to telomerase peptides, and this patent was also opposed by KAEL-GemVax. As part of our agreement, KAEL-GemVax withdrew its opposition against this second patent. These proceedings exemplify the time and costs required to protect our intellectual property rights. If we are unable to commit these types of resources for our imetelstat patent rights, we could be prevented or limited in the development of imetelstat, which would have a material adverse effect on our business.

European opposition and appeal proceedings can take several years to reach final decision. The oppositions discussed above reflect the complexity of the patent landscape in which we operate, and illustrate the risks and uncertainties. We are also currently involved in other patent opposition proceedings in Europe and Australia related to the stem cell assets to be divested to Asterias, and we cannot predict their outcomes or any potential subsequent appeal of the decision in these opposition proceedings.

As more groups become engaged in scientific research and product development in the areas of telomerase biology, the risk of our patents or patents that we have in-licensed being challenged through patent interferences, derivation proceedings, oppositions, re-examinations, litigation or other means will likely increase. Challenges to our patents through these procedures can be extremely expensive and time-consuming, even if the outcome is favorable to us. An adverse outcome in a patent dispute could severely harm our business by:

- causing us to lose patent rights in the relevant jurisdiction(s);

## Edgar Filing: GERON CORP - Form 10-Q

- subjecting us to litigation, or otherwise preventing us from commercializing imetelstat in the relevant jurisdiction(s);
- requiring us to obtain licenses to the disputed patents;
- forcing us to cease using the disputed technology; or
- requiring us to develop or obtain alternative technologies.

Table of Contents

***We may be subject to infringement claims that are costly to defend, and which may limit our ability to use disputed technologies and prevent us from pursuing research and development or commercialization of imetelstat. \****

Our technologies may infringe the patents or proprietary rights of others. In addition, we may become aware of discoveries and technologies controlled by third parties that are advantageous to developing imetelstat. In the event our technologies infringe the rights of others or we require the use of discoveries and technologies controlled by third parties, we may be prevented from pursuing research, development or commercialization of imetelstat, or may be required to obtain licenses to those patents or other proprietary rights or develop or obtain alternative technologies. We initiate negotiations for licenses to other technologies as the need or opportunity arises. We may not be able to obtain a license to a technology required for the research, development or commercialization of imetelstat on commercially favorable terms, or at all, or our licenses may be terminated on certain grounds, including as a result of our failure to comply with our obligations under such licenses. If we do not obtain a necessary license or if such a license is terminated, we may need to redesign our technologies or obtain rights to alternate technologies, the research and adoption of which could cause delays in our development efforts for imetelstat. In cases where we are unable to license necessary technologies, we could be subject to litigation and prevented from developing imetelstat. Our failure to obtain alternative technologies or a license to any technology that we may require to research, develop or commercialize imetelstat would significantly and negatively affect our business. By way of example, we are aware of at least one entity that is seeking to obtain patent claims that may, if granted, be argued to read on imetelstat. While such claims have not been issued, and may not be valid if they do issue, we expect that as imetelstat continues to progress in development, we will see more efforts by others to obtain patents that are positioned to cover imetelstat. Our success depends significantly on our ability to operate without infringing patents and the proprietary rights of others.

***Much of the information and know-how that is critical to our business is not patentable, and we may not be able to prevent others from obtaining this information and establishing competitive enterprises.***

We sometimes rely on trade secrets to protect our proprietary technology, especially in circumstances in which we believe patent protection is not appropriate or available. We attempt to protect our proprietary technology in part by confidentiality agreements with our employees, consultants, collaborators and contractors. We cannot provide assurance that these agreements will not be breached, that we would have adequate remedies for any breach, or that our trade secrets will not otherwise become known or be independently discovered by competitors, any of which would harm our business significantly.

***Our ability to successfully complete the divestiture of our stem cell assets depends at least in part on our ability to maintain our stem cell-related intellectual property. \****

We developed an extensive portfolio of Geron-owned patent filings covering our prior development of human embryonic stem cell technologies, as well as patents that we licensed from other parties. This intellectual property is a substantial component of the stem cell assets that we have agreed to divest to Asterias. Our ability to successfully complete the divestiture of our stem cell assets will depend in part on our ability to maintain the scope and term of the patents in our stem cell patent portfolio. Legal developments and proceedings that may impact our stem cell patent portfolio and ability to successfully complete the divestiture of our stem cell program include:

Table of Contents

- *European court ruling:* In 2011, the European Court of Justice, or ECJ, rendered a decision in a case known as Brüstle v. Greenpeace that is widely viewed to have effectively abolished the ability to enforce patents on human embryonic stem cell technologies in member states of the European Union, or EU.
- *Patent interferences:* Two of our patent applications covering the production of endoderm from human embryonic stem cells (part of the process for making pancreatic islet cells) are involved in interferences with a patent held by ViaCyte, Inc., or ViaCyte. A decision was handed down by the U.S. Patent and Trademark Office Board of Patent Appeals and Interferences, or BPAI, in the first interference in July 2012, awarding all claims to ViaCyte. In August 2012, the BPAI ruled that its decision in the first interference was binding in the second interference because the involved claims of the patent application in the second interference were patentably indistinct from the claims of the patent in the first interference, and awarded all involved claims to ViaCyte. In September 2012, we appealed the decision of the BPAI in both interferences in a litigation proceeding brought before the United States District Court for the Northern District of California, or the District Court, and in September 2012, ViaCyte filed a counterclaim in the District Court, seeking affirmation of the rulings in the two interference proceedings and seeking costs and attorneys' fees in the District Court litigation and the two interference proceedings. The District Court has ordered a stay of the District Court litigation until October 31, 2013. At this time, we cannot predict the outcome of the appeal or the timing for resolution of the appeal to the District Court. The outcome of the District Court litigation could include judgments against us upholding or expanding the interference ruling. Upon the closing of the divestiture of the stem cell assets, Asterias will be substituted for us as a party in these appeal proceedings.
- *Re-examinations:* In July 2006, requests were filed on behalf of the Foundation for Taxpayer and Consumer Rights (now renamed as Consumer Watchdog) for reexamination of three issued U.S. patents owned by the Wisconsin Alumni Research Foundation, or WARF. These three patents (U.S. Patent Nos. 5,843,780, 6,200,806 and 7,029,913) are licensed to us pursuant to a January 2002 license agreement which conveys exclusive rights to us under the WARF patents for the development and commercialization of therapeutics based on neural cells, cardiomyocytes and pancreatic islet cells, derived from human embryonic stem cells, as well as non-exclusive rights for other product opportunities. The Patent Office issued decisions in all three cases upholding the patentability of the claims as amended. The decisions to uphold the 5,843,780 and 6,200,806 patents are final. Consumer Watchdog appealed the decision on the 7,029,913 patent and, in April 2010, the BPAI reversed the earlier decision of the Patent Office and remanded the case back to the Patent Office for further prosecution. In November 2011, the Patent Office again upheld the patentability of the claims. On January 22, 2013, the BPAI upheld the patentability of claims 1-3 of the 7,029,913 patent. On March 21, 2013, Consumer Watchdog filed an appeal to the United States Court of Appeals for the Federal Circuit from the BPAI's decision. We are not a party to the appeal, but the outcome of the appeal could affect the patentability of the claims in the 7,029,913 patent licensed to us by WARF.

**RISKS RELATED TO OUR RELATIONSHIPS WITH THIRD PARTIES**

*We depend on other parties to help us develop and test imetelstat, and our ability to develop and commercialize imetelstat may be impaired or delayed if collaborations are unsuccessful. \**

Our strategy for the development, clinical testing and commercialization of imetelstat requires that we enter into collaborations with clinical research organizations, vendors, corporate partners, licensors, licensees and others. We are dependent upon the ability of these parties to perform their responsibilities reliably. By way of example, we have contracted with two clinical research organizations that are primarily responsible for the execution of clinical site related activities for our ongoing imetelstat Phase 2 clinical trials, including clinical trial site monitoring activities. In addition, for our imetelstat program, we have contracted with a single vendor to develop and maintain the clinical database and a single vendor to maintain our safety database.



Table of Contents

Accordingly, if the performance of these services is not of the highest quality, or does not achieve necessary regulatory compliance standards, or if such organization or vendor stops or delays its performance for any reason, it would impair and delay our ability to report data from our clinical trials and make the necessary representations to regulatory authorities, if at all. In addition, licensors or licensees could terminate their agreements with us, and we may not receive any development or milestone payments. If we do not achieve milestones or perform diligence obligations set forth in agreements that we have entered with others, or if our licensors or licensees breach or terminate their agreements with us, our business may be materially harmed.

Our imetelstat development strategy is also dependent on the results of existing and potential future investigator-sponsored trials of imetelstat in hematologic myeloid malignancies, including the Myelofibrosis IST. For example, data from the Myelofibrosis IST, if positive, will inform any future Geron-sponsored clinical trial and will be necessary for future clinical development of imetelstat in MF. Because this is not a Geron-sponsored trial, the clinical testing of imetelstat in the Myelofibrosis IST requires us to rely on the investigator's design and conduct of the trial. In addition, we do not have control over the timing and reporting of the data from this trial, nor do we own the data from the trial. If we are unable to confirm or replicate the results from the Myelofibrosis IST or if negative results are obtained, we would likely be further delayed or prevented from advancing imetelstat into further clinical development and might decide to discontinue our development of imetelstat, which would severely harm our business and prospects, and could potentially cause us to cease operations.

*Our ability to manufacture imetelstat is uncertain because we must rely on third parties for manufacturing. \**

We rely on other companies for certain process development, supply of starting materials, manufacturing or other technical and scientific work with respect to imetelstat, but we do not have direct control over their personnel or operations. We rely on these manufacturers to produce and deliver sufficient quantities of imetelstat to support our clinical trials, including investigator-sponsored clinical trials, on a timely basis and to comply with applicable regulatory requirements. If these companies do not perform the work which they were assigned or do not complete the work within the expected timelines, if they fail to produce materials which are suitable for use in clinical trials, or if they choose to exit the business, our ability to develop or manufacture imetelstat could be significantly harmed. For example, we may need to change one or more of our suppliers due to these or other reasons and the change could lead to delays in drug supply. Manufacturing delays could adversely impact the initiation or completion of ongoing or future clinical trials, including investigator-sponsored trials.

In addition, our manufacturers may need to make substantial investments to enable sufficient capacity increases and cost reductions, and to implement those regulatory and compliance standards necessary for successful Phase 3 trials and commercial production. Our manufacturers may not be able to achieve such capacity increases, cost reductions, or regulatory and compliance standards, and even if they do, such achievements may not be at a commercially reasonable cost to us. We have not established long-term manufacturing commitments, and changing manufacturers may be prolonged and difficult due to inherent technical complexities, and because the number of potential manufacturers is limited. It may be difficult or impossible for us to find a replacement manufacturer on acceptable terms, or at all.

There are other risks and uncertainties that we face with respect to manufacturing. For example, we currently have an agreement with only a single contractor for distribution of imetelstat final drug product to clinical sites in North America. As another example, certain commonly used reagents and solvents may experience market shortages and, if these shortages occur, they may adversely impact our ability to manufacture imetelstat.



Table of Contents

*Our failure to meet our obligations under license agreements could result in us losing rights to key technologies required to complete the divestiture of our stem cell assets.*

Our ability to complete the divestiture of our stem cell assets depends on several critical technologies that are based in part on patents licensed from third parties. Those third-party license agreements impose obligations on us, such as payment obligations and obligations to diligently pursue development of commercial products under the licensed patents. If a licensor believes that we have failed to meet these or other obligations under a license agreement, including as a result of our discontinuation of further development of our stem cell programs, the licensor could seek to limit or terminate our license rights, which could lead to costly and time-consuming litigation and, potentially, a loss of the licensed rights, any of which could impair our ability to complete the divestiture of our stem cell assets.

*Our reliance on consultants, research institutions, and scientific contractors whose activities are not wholly within our control may lead to delays in development of imetelstat.\**

We rely extensively upon and have relationships with scientific consultants, collaborators, and contractors at academic, commercial and other institutions. Some of our scientific consultants, collaborators and contractors conduct research and development activities at our request or initiate investigator-sponsored clinical trials to test imetelstat, and others assist us in formulating and/or executing our research and development and clinical strategy or other matters related to imetelstat. These consultants, collaborators and contractors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. We have limited control over the activities of these consultants, collaborators and contractors and, except as otherwise required by our collaboration and consulting agreements, can expect only limited amounts of their time to be dedicated to our activities. If any of these third parties are unable or refuse to contribute to projects on which we need their help, our ability to generate advances in our technologies and develop imetelstat could be significantly harmed.

## **RISKS RELATED TO OUR COMMON STOCK AND FINANCIAL REPORTING**

*Historically, our stock price has been extremely volatile. \**

Historically, our stock price has been extremely volatile. Between July 1, 2003 and June 30, 2013, our stock has traded as high as \$16.80 per share and as low as \$0.91 per share. Between July 1, 2010 and June 30, 2013, the price has ranged between a high of \$6.40 per share and a low of \$0.91 per share. The significant market price fluctuations of our common stock have been due to and may in the future be influenced by a variety of factors, including:

- announcements regarding our clinical trial results or delays in any future clinical trials of imetelstat, or announcements regarding the results of or delays in investigator-sponsored trials of imetelstat, and investor perceptions thereof;
- announcements regarding the safety of imetelstat;

- announcements regarding our plans to discontinue certain programs or clinical trials;
- announcements regarding our research and development of imetelstat;
- our ability to successfully complete the divestiture of our stem cell assets to Asterias in a timely manner or at all, or perception by our stockholders about the adequacy of the consideration to be received for such divestiture, if any;
- the demand in the market for our common stock;
- the experimental nature of imetelstat;

Table of Contents

- fluctuations in our operating results;
- our declining cash balance as a result of operating losses;
- market conditions relating to the biopharmaceutical and pharmaceutical industries;
- announcements of technological innovations, new commercial products, or clinical progress or lack thereof by us, our collaborative partners or our competitors;
- announcements concerning regulatory developments, developments with respect to proprietary rights and our collaborations;
- comments by securities analysts;
- large stockholders exiting their position in our common stock;
- general market conditions;
- the issuance of common stock to partners, vendors or to investors to raise additional capital; and
- the occurrence of any other risks and uncertainties discussed in this Item 1A, Risk Factors .

Stock prices and trading volumes for many biopharmaceutical companies fluctuate widely for a number of reasons, including factors which may be unrelated to their businesses or results of operations, such as media coverage, legislative and regulatory measures and the activities of various interest groups or organizations. In addition to other risk factors described in this section, overall market volatility, as well as general domestic or international economic, market and political conditions, could materially and adversely affect the market price of our common stock and the return on your investment.

*If we fail to meet continued listing standards of NASDAQ, our common stock may be delisted, which could have a material adverse effect on the liquidity of our common stock.*

Our common stock is currently traded on the Nasdaq Global Select Market. The NASDAQ Stock Market LLC has requirements that a company must meet in order to remain listed on NASDAQ. In particular, NASDAQ rules require us to maintain a minimum bid price of \$1.00 per share of our common stock. If the closing bid price of our common stock were to fall below \$1.00 per share for 30 consecutive trading days or we do not meet other listing requirements, we would fail to be in compliance with NASDAQ's listing standards. There can be no assurance that we will continue to meet the minimum bid price requirement, or any other requirement in the future. If we fail to meet the minimum bid price requirement, The NASDAQ Stock Market LLC may initiate the delisting process with a notification letter. If we were to receive such a notification, we would be afforded a grace period of 180 calendar days to regain compliance with the minimum bid price requirement. In order to regain compliance, shares of our common stock would need to maintain a minimum closing bid price of at least \$1.00 per share for a minimum of 10 consecutive trading days. If our common stock were to be delisted, the liquidity of our common stock would be adversely affected and the market price of our common stock could decrease.

*We may be subject to litigation that will be costly to defend or pursue and uncertain in its outcome. \**

Securities-related class action litigation has often been brought against companies, including many biotechnology companies, which experience volatility in the market price of their securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies often experience significant stock price volatility in connection with their product development programs. If the results of our business activities are not successful, including without limitation, if:

Table of Contents

- the results from the Myelofibrosis IST, or any subsequent clinical trial of imetelstat, are not deemed to be successful;
- we ascertain that the use of imetelstat results in significant systemic or organ toxicities;
- we are unable to fully complete the divestiture of our stem cell assets to Asterias; or
- our stockholders believe the consideration to be received for such divestiture to be inadequate,

our stock price would likely decline, and may result in litigation. A decision adverse to our interests in any such lawsuit could result in the payment of substantial damages by us, and could have a material adverse effect on our cash flow, results of operations and financial position.

Our business may bring us into conflict with our licensees, licensors, or others with whom we have contractual or other business relationships, or with our competitors or others whose interests differ from ours. If we are unable to resolve those conflicts on terms that are satisfactory to all parties, we may become involved in litigation brought by or against us. In addition, the conduct of clinical trials, including our ongoing and any subsequent clinical trials of imetelstat and any investigator-sponsored trials, and our discontinued trials of GRN1005, are inherently risky and may expose us to liability for matters such as patient injury or death, or for any failure to meet regulatory and compliance requirements. Monitoring, initiating and defending against legal actions are time-consuming for our management, are likely to be expensive and may detract from our ability to fully focus our internal resources on our business activities. The outcome of litigation is always uncertain, and in some cases could include judgments against us that require us to pay damages, enjoin us from certain activities, or otherwise affect our legal or contractual rights, which could have a significant adverse effect on our business. In addition, the inherent uncertainty of such litigation could lead to increased volatility in our stock price and a decrease in the value of your investment in our common stock.

***The sale of a substantial number of shares may adversely affect the market price of our common stock. \****

The sale of a substantial number of shares of our common stock in the public market, or the perception that such sales could occur, could significantly and negatively affect the market price of our common stock. As of June 30, 2013, we had 300,000,000 shares of common stock authorized for issuance and 129,895,878 shares of common stock outstanding. In addition, as of June 30, 2013, we had reserved approximately 34,448,216 shares of common stock for future issuance pursuant to our option and equity incentive plans and outstanding warrants. Issuing additional shares could negatively affect the market price of our common stock and the return on your investment.

Future sales of our common stock, including pursuant to our At-The-Market Issuance Sales Agreement with MLV & Co. LLC, or the issuance of common stock to satisfy our current or future cash payment obligations or to acquire technology, property, or other businesses, could cause immediate dilution and adversely affect the market price of our common stock. In addition, under the universal shelf registration statement filed by us in July 2012 and declared effective by the SEC in October 2012, we may sell any combination of common stock, preferred stock, debt securities and warrants in one or more offerings, up to a cumulative value of \$200 million. The sale or issuance of our securities, as well as the existence of outstanding options and shares of common stock reserved for issuance under our option and equity incentive plans and outstanding

warrants also may adversely affect the terms upon which we are able to obtain additional capital through the sale of equity securities.

***Our undesignated preferred stock may inhibit potential acquisition bids; this may adversely affect the market price of our common stock and the voting rights of holders of our common stock.***

Our certificate of incorporation provides our Board of Directors with the authority to issue up to 3,000,000 shares of undesignated preferred stock and to determine or alter the rights, preferences, privileges and restrictions granted to or imported upon these shares without further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change in control transaction without further action by our stockholders. As a result, the market price of our common stock may be adversely affected.

Table of Contents

In addition, if we issue preferred stock in the future that has preference over our common stock with respect to the payment of dividends or upon our liquidation, dissolution or winding up, or if we issue preferred stock with voting rights that dilute the voting power of our common stock, the rights of holders of our common stock or the market price of our common stock could be adversely affected.

***Provisions in our charter, bylaws and Delaware law may inhibit potential acquisition bids for us, which may prevent holders of our common stock from benefiting from what they believe may be the positive aspects of acquisitions and takeovers.***

Provisions of our charter documents and bylaws may make it substantially more difficult for a third party to acquire control of us and may prevent changes in our management, including provisions that:

- prevent stockholders from taking actions by written consent;
- divide the Board of Directors into separate classes with terms of office that are structured to prevent all of the directors from being elected in any one year; and
- set forth procedures for nominating directors and submitting proposals for consideration at stockholders' meetings.

Provisions of Delaware law may also inhibit potential acquisition bids for us or prevent us from engaging in business combinations. In addition, we have severance agreements with several employees and a severance plan which could require an acquiror to pay a higher price. Either collectively or individually, these provisions may prevent holders of our common stock from benefiting from what they may believe are the positive aspects of acquisitions and takeovers, including the potential realization of a higher rate of return on their investment from these types of transactions.

***We do not intend to pay cash dividends on our common stock in the foreseeable future.***

We do not anticipate paying cash dividends on our common stock in the foreseeable future. Any payment of cash dividends will depend upon our financial condition, results of operations, capital requirements and other factors and will be at the discretion of our Board of Directors.

***Failure to achieve and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act of 2002 could have a material adverse effect on our business and stock price.***

## Edgar Filing: GERON CORP - Form 10-Q

Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, requires that we establish and maintain an adequate internal control structure and procedures for financial reporting. Our annual reports on Form 10-K must contain an assessment by management of the effectiveness of our internal control over financial reporting and must include disclosure of any material weaknesses in internal control over financial reporting that we have identified. In addition, our independent registered public accounting firm must annually provide an opinion on the effectiveness of our internal control over financial reporting.

The requirements of Section 404 are ongoing and also apply to future years. We expect that our internal control over financial reporting will continue to evolve as our business develops. Although we are committed to continue to improve our internal control processes and we will continue to diligently and vigorously review our internal control over financial reporting in order to ensure compliance with Section 404 requirements, any control system, regardless of how well designed, operated and evaluated, can provide only reasonable, not absolute, assurance that its objectives will be met. Therefore, we cannot be certain that in the future material weaknesses or significant deficiencies will not exist or otherwise be discovered. If material weaknesses or other significant deficiencies occur, these weaknesses or deficiencies could result in misstatements of our results of operations, restatements of our consolidated financial statements, a decline in our stock price, or other material adverse effects on our business, reputation, results of operations, financial condition or liquidity.



Table of Contents

**RISKS RELATED TO COMPETITIVE FACTORS**

*The loss of key personnel could slow our ability to conduct research and develop imetelstat. \**

Our future success depends to a significant extent on the skills, experience and efforts of our executive officers and key members of our clinical and scientific staff. We face intense competition for qualified individuals from numerous pharmaceutical, biopharmaceutical and biotechnology companies, as well as academic and other research institutions. The recent restructurings we implemented could have an adverse impact on our ability to retain and recruit qualified personnel or we may incur unanticipated inefficiencies caused by our reduced personnel resources. We may be unable to retain our current personnel or attract or assimilate other highly qualified management and scientific personnel in the future on acceptable terms. The loss of any or all of these individuals could harm our business and might significantly delay or prevent the achievement of research, development or business objectives.

*Some of our competitors may develop technologies that are superior to or more cost-effective than ours, which may significantly impact the commercial viability of our technologies and damage our ability to sustain operations.*

The pharmaceutical and biotechnology industries are intensely competitive. Other pharmaceutical and biotechnology companies and research organizations currently engage in or have in the past engaged in efforts related to the biological mechanisms that are the focus of our imetelstat program, including the study of telomeres, telomerase and our proprietary oligonucleotide chemistry. In addition, other products and therapies that could directly compete with imetelstat currently exist or are being developed by pharmaceutical and biopharmaceutical companies and by academic and other research organizations.

Many companies are developing alternative therapies to treat cancer and, in this regard, are competitors of ours. There are more than 200 approved anti-cancer products on the market in the United States, and several thousand in clinical development. Many of the pharmaceutical companies developing and marketing these competing products (e.g. Sanofi, Bristol-Myers Squibb Company, Novartis AG, Incyte Corporation and Gilead Sciences, Inc.) have significantly greater financial resources and expertise than we do in:

- research and development;
  
- manufacturing;
  
- preclinical and clinical testing;
  
- obtaining regulatory approvals; and

- marketing, sales and distribution.

Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Academic institutions, government agencies and other public and private research organizations may also conduct research, seek patent protection and establish collaborative arrangements for research, clinical development and marketing of products similar to ours. These companies and institutions compete with us in recruiting and retaining qualified scientific and management personnel as well as in acquiring technologies complementary to our imetelstat program.

Table of Contents

In addition to the above factors, we expect to face competition in the following areas:

- product efficacy and safety;
- the timing and scope of regulatory consents;
- availability of resources;
- reimbursement coverage;
- price; and
- patent position, including potentially dominant patent positions of others.

As a result of the foregoing, our competitors may develop more effective or more affordable products, or achieve earlier patent protection or product commercialization than us. Most significantly, competitive products may render imetelstat obsolete, which would negatively impact our business and ability to sustain operations.

***To be successful, imetelstat must be accepted by the health care community, which can be very slow to adopt or unreceptive to new technologies and products.\****

If approved for marketing, imetelstat may not achieve market acceptance since hospitals, physicians, patients or the medical community in general may decide not to accept and utilize these products. If approved for commercial sale, imetelstat will compete with a number of conventional drugs and therapies manufactured and marketed by major pharmaceutical companies. The degree of market acceptance of imetelstat will depend on a number of factors, including:

- our establishment and demonstration to the medical community of the clinical efficacy and safety of imetelstat;

## Edgar Filing: GERON CORP - Form 10-Q

- our ability to demonstrate that imetelstat is superior to alternatives currently on the market;
- our ability to establish in the medical community the potential advantage of imetelstat over alternative treatment methods;
- the label and promotional claims allowed by the FDA for imetelstat, if any;
- sales, marketing and distribution support for imetelstat; and
- reimbursement policies of government and third-party payers.

If the health care community does not accept imetelstat for any of the foregoing reasons, or for any other reason, our business would be materially harmed.

***If we fail to obtain acceptable prices or adequate reimbursement for imetelstat, the use of imetelstat could be severely limited.***

Our ability to successfully commercialize imetelstat will depend significantly on our ability to obtain acceptable prices and the availability of reimbursement to the patient from third-party payers. In March 2010, the Patient Protection and Affordability Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the PPACA) became law. In June 2012, the United States Supreme Court upheld the constitutionality of key provisions of the PPACA. The PPACA contains numerous initiatives that impact the pharmaceutical industry. These include, among other things:

- increasing existing price rebates in federally funded health care programs;
- expanding rebates, or other pharmaceutical company discounts, into new programs;

Table of Contents

- imposing a new non-deductible excise tax on sales of certain prescription pharmaceutical products by prescription drug manufacturers and importers;
- reducing incentives for employer-sponsored health care;
- creating an independent commission to propose changes to Medicare with a particular focus on the cost of biopharmaceuticals in Medicare Part D;
- providing a government-run public option with biopharmaceutical price-setting capabilities;
- allowing the Secretary of Health and Human Services to negotiate drug prices within Medicare Part D directly with pharmaceutical manufacturers;
- reducing the number of years of data exclusivity for innovative biological products potentially leading to earlier biosimilar competition; and
- increasing oversight by the FDA of pharmaceutical research and development processes and commercialization tactics.

While the PPACA may increase the number of patients who have insurance coverage for imetelstat, its cost containment measures could also adversely affect reimbursement for imetelstat. Cost control initiatives could decrease the price that we receive for imetelstat in the future. If imetelstat is not considered cost-effective or if we fail to generate adequate third-party reimbursement for the users of imetelstat, then we may be unable to maintain price levels sufficient to realize an appropriate return on our investment for imetelstat, which could have an adverse impact on our business.

**RISKS RELATED TO ENVIRONMENTAL AND PRODUCT LIABILITY**

*Our activities involve hazardous materials, and improper handling of these materials by our employees, contractors, or agents could expose us to significant legal and financial penalties.\**

## Edgar Filing: GERON CORP - Form 10-Q

Our research and development activities involve the controlled use of hazardous materials, chemicals and various radioactive compounds. As a consequence, we, our contractors and agents are subject to numerous environmental and safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of biohazardous materials. Our inability to comply with federal, state and county environmental laws and regulations could subject us to considerable additional cost or liability that would have a material adverse effect on our financial condition. We, our contractors or agents may be required to incur significant costs to comply with current or future environmental laws and regulations and may be adversely affected by the cost of compliance with these laws and regulations.

Although we believe that our safety procedures for using, handling, storing and disposing of hazardous materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. In the event of such an accident, state or federal authorities could curtail our use of these materials and we, our contractors or agents could be liable for any civil damages that result, the cost of which could be substantial. In addition, we may incur significant unanticipated costs associated with the closure and exit of our research laboratory facility. Further, any failure by us to control the use, disposal, removal or storage, or to adequately restrict the discharge, or assist in the clean up, of hazardous chemicals or hazardous, infectious or toxic substances, including in connection with the closure of our research facility, could subject us to significant liabilities, including joint and several liability under certain statutes. Any such liability or costs could exceed our resources and could have a material adverse effect on our business, financial condition and results of operations. Additionally, an accident could damage the manufacturing facilities and operations of any third party contracted by us to perform services with respect to our imetelstat program. Additional federal, state and local laws and regulations affecting us may be adopted in the future. We, our contractors and agents may incur substantial costs to comply with these laws and regulations and substantial fines or penalties if we violate any of these laws or regulations, which would adversely affect our business.

Table of Contents

*We may not be able to obtain or maintain sufficient insurance on commercially reasonable terms or with adequate coverage against potential liabilities in order to protect ourselves against product liability claims.*

Our business exposes us to potential product liability risks that are inherent in the testing, manufacturing and marketing of human therapeutic and diagnostic products. We may become subject to product liability claims if the use of imetelstat, or GRN1005 in our discontinued trials, is alleged to have injured patients. We currently have limited clinical trial liability insurance and we may not be able to maintain this type of insurance for any of our clinical trials. In addition, product liability insurance is becoming increasingly expensive. Being unable to obtain or maintain product liability insurance in the future on acceptable terms or with adequate coverage against potential liabilities could have a material adverse effect on our business.

*Our headquarters are located near known earthquake fault zones, and the occurrence of an earthquake or other catastrophic disaster could cause damage to our offices and equipment, which could cause delays or even require us to cease or curtail operations. \**

Our headquarters are located in the San Francisco Bay Area near known earthquake fault zones and are vulnerable to significant damage from earthquakes. We do not carry earthquake insurance. We are also vulnerable to damage from other types of disasters, including fires, floods, power loss, communications failures, terrorism and similar events. If any disaster were to occur, our ability to operate our business at our office would be seriously, or potentially completely, impaired. The insurance we maintain may not be adequate to cover our losses from such disasters or other business interruptions.

**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

None.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**ITEM 5. OTHER INFORMATION**

None.

**ITEM 6. EXHIBITS**

See Exhibit Index.



Table of Contents

**SIGNATURE**

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, thereunto duly authorized.

GERON CORPORATION

Date: August 8, 2013

By:

/s/ OLIVIA K. BLOOM  
OLIVIA K. BLOOM  
*Senior Vice President, Finance, Chief Financial  
Officer and Treasurer*

Table of Contents**EXHIBIT INDEX**

Exhibit Number	Description	Exhibit Number	Incorporation by Reference		File No.
			Filing	Filing Date	
10.1	Termination Agreement between the Registrant and Stephen M. Kelsey, effective as of April 25, 2013 *				
10.2	Amended and Restated Severance Plan, effective as of May 23, 2013 *	10.1	8-K	May 24, 2013	000-20859
31.1	Certification of Chief Executive Officer pursuant to Form of Rule 13a-14(a), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated August 8, 2013				
31.2	Certification of Chief Financial Officer pursuant to Form of Rule 13a-14(a), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated August 8, 2013				
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated August 8, 2013 **				
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated August 8, 2013 **				
101	The following materials from the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, formatted in Extensible Business Reporting Language (XBRL) include: (i) Condensed Consolidated Balance Sheets as of June 30, 2013 and December 31, 2012, (ii) Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2013 and 2012, (iii) Condensed Consolidated Statements of Comprehensive Loss for the three and six months ended June 30, 2013 and 2012, (iv) Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2013 and 2012, and (v) Notes to Condensed Consolidated Financial Statements ***				

\* Management contract or compensation plan or arrangement.

\*\* The certifications attached as Exhibits 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q, are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of this Form 10-Q), irrespective of any general incorporation language contained in such filing.

\*\*\* Pursuant to applicable securities laws and regulations, the Registrant is deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and is not subject to liability under any anti-fraud provisions of the federal securities laws as long as the Registrant has made a good faith attempt to comply with the submission requirements and promptly amends the interactive data files after becoming aware that the interactive data files fail to comply with the submission requirements. These interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under these sections.

