

GERON CORP  
Form 10-Q  
May 07, 2012

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 March 31, 2012

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_.

Commission File Number: 0-20859

**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.)

230 CONSTITUTION DRIVE, 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

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

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	<input type="radio"/>	Accelerated filer	<input checked="" type="radio"/>
Non-accelerated filer (Do not check if a smaller reporting company)	<input type="radio"/>	Smaller reporting company	<input type="radio"/>

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:	Outstanding at April 30, 2012:
Common Stock, \$0.001 par value	132,085,830 shares

---

**Table of Contents**

**GERON CORPORATION**  
**FORM 10-Q FOR THE QUARTER ENDED MARCH 31, 2012**  
**INDEX**

		<b>Page</b>
<b>PART I. FINANCIAL INFORMATION</b>		
<u>Item 1:</u>	<u>Condensed Consolidated Financial Statements</u>	<u>1</u>
	<u>Condensed Consolidated Balance Sheets as of March 31, 2012 and December 31, 2011</u>	<u>1</u>
	<u>Condensed Consolidated Statements of Operations for the three months ended March 31, 2012 and 2011</u>	<u>2</u>
	<u>Condensed Consolidated Statements of Comprehensive Loss for the three months ended March 31, 2012 and 2011</u>	<u>3</u>
	<u>Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2012 and 2011</u>	<u>4</u>
	<u>Notes to Condensed Consolidated Financial Statements</u>	<u>5</u>
<u>Item 2:</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>17</u>
<u>Item 3:</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>22</u>
<u>Item 4:</u>	<u>Controls and Procedures</u>	<u>22</u>
<b>PART II. OTHER INFORMATION</b>		
<u>Item 1:</u>	<u>Legal Proceedings</u>	<u>22</u>
<u>Item 1A:</u>	<u>Risk Factors</u>	<u>22</u>
<u>Item 2:</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>38</u>
<u>Item 3:</u>	<u>Defaults Upon Senior Securities</u>	<u>38</u>
<u>Item 4:</u>	<u>Mine Safety Disclosures</u>	<u>38</u>
<u>Item 5:</u>	<u>Other Information</u>	<u>38</u>
<u>Item 6:</u>	<u>Exhibits</u>	<u>39</u>
	<u>SIGNATURE</u>	<u>40</u>

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

	<b>MARCH 31, 2012 (UNAUDITED)</b>	<b>DECEMBER 31, 2011</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 19,031	\$ 16,105
Restricted cash	793	793
Current portion of marketable securities	100,394	105,208
Interest and other receivables	866	1,398
Current portion of prepaid assets	1,438	2,121
Total current assets	122,522	125,625
Noncurrent portion of marketable securities	16,712	32,133
Property and equipment, net	1,074	1,241
Deposits and other assets	879	1,048
	\$ 141,187	\$ 160,047
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 2,666	\$ 2,980
Accrued compensation and benefits	1,774	3,029
Accrued restructuring charges	1,417	3,730
Accrued liabilities	4,379	3,641
Fair value of derivatives	38	64
Total current liabilities	10,274	13,444
Commitments and contingencies		
Stockholders' equity:		
Common stock	132	131
Additional paid-in capital	935,069	932,066
Accumulated deficit	(804,242)	(785,503)
Accumulated other comprehensive loss	(46 )	(91 )
Total stockholders' equity	130,913	146,603
	\$ 141,187	\$ 160,047

See accompanying notes.

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

	<b>THREE MONTHS ENDED MARCH 31,</b>	
	<b>2012</b>	<b>2011</b>
Revenues from collaborative agreements	\$	\$ 150
License fees and royalties	1,254	1,355
<b>Total revenues</b>	<b>1,254</b>	<b>1,505</b>
<b>Operating expenses:</b>		
Research and development	15,107	16,755
General and administrative	5,065	9,106
<b>Total operating expenses</b>	<b>20,172</b>	<b>25,861</b>
<b>Loss from operations</b>	<b>(18,918)</b>	<b>(24,356)</b>
Unrealized gain on fair value of derivatives	26	39
Interest and other income	176	296
Losses recognized under equity method investment		(335)
Interest and other expense	(23)	(33)
<b>Net loss</b>	<b>\$ (18,739 )</b>	<b>\$ (24,389 )</b>
<b>Basic and diluted net loss per share</b>	<b>\$ (0.15 )</b>	<b>\$ (0.20 )</b>
<b>Shares used in computing basic and diluted net loss per share</b>	<b>126,372,846</b>	<b>123,098,728</b>

See accompanying notes.

**Table of Contents**

**GERON CORPORATION**

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

	<b>THREE MONTHS ENDED MARCH 31,</b>	
	<b>2012</b>	<b>2011</b>
Net loss	\$ (18,739)	\$ (24,389)
Other comprehensive income (loss):		
Net unrealized gain (loss) on available-for-sale securities	29	(55)
Foreign currency translation adjustments	16	12
Other comprehensive income (loss)	45	(43)
Comprehensive loss	\$ (18,694)	\$ (24,432)

See accompanying notes.

**Table of Contents****GERON CORPORATION**

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

	<b>THREE MONTHS ENDED</b>	
	<b>MARCH 31,</b>	
	<b>2012</b>	<b>2011</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (18,739)	\$ (24,389)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	251	418
Accretion and amortization on investments, net	669	1,226
Issuance of common stock for acquired in-process research and development		594
Issuance of common stock in exchange for services by non-employees	80	270
Stock-based compensation for employees and directors	1,391	6,319
Amortization related to 401(k) contributions	172	235
Loss on equity method investment		335
Unrealized gain on fair value of derivatives	(26)	(39)
Changes in assets and liabilities:		
Other current and noncurrent assets	1,384	2,157
Other current and noncurrent liabilities	(1,783)	154
Translation adjustment	16	12
Net cash used in operating activities	(16,585)	(12,708)
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(84)	(124)
Purchases of marketable securities	(17,895)	(51,395)
Proceeds from maturities of marketable securities	37,490	53,523
Net cash provided by investing activities	19,511	2,004
<b>Cash flows from financing activities:</b>		
Proceeds from issuances of common stock and warrants, net of issuance costs		144
Net cash provided by financing activities		144
Net increase (decrease) in cash and cash equivalents	2,926	(10,560)
Cash and cash equivalents at the beginning of the period	16,105	45,972
Cash and cash equivalents at the end of the period	\$ 19,031	\$ 35,412

See accompanying notes.

## **Table of Contents**

**GERON CORPORATION**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**MARCH 31, 2012**  
**(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 month period ended March 31, 2012 are not necessarily indicative of the results that may be expected for the year ending December 31, 2012 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, 2011, included in the Company's Annual Report on Form 10-K. The accompanying condensed consolidated balance sheet as of December 31, 2011 has been derived from audited financial statements at that date.

#### **Principles of Consolidation**

The consolidated financial statements include the accounts of Geron, our wholly-owned subsidiary, Geron Bio-Med Ltd. (Geron Bio-Med), a United Kingdom company, and our majority-owned subsidiary, TA Therapeutics, Ltd. (TAT), a Hong Kong company. We have eliminated intercompany accounts and transactions. We prepare the financial statements of Geron Bio-Med using the local currency as the functional currency. We translate the assets and liabilities of Geron Bio-Med at rates of exchange at the balance sheet date and translate income and expense items at average monthly rates of exchange. The resultant translation adjustments are included in accumulated other comprehensive income (loss), a separate component of stockholders' equity. The functional currency for TAT was U.S. dollars. In July 2010, the board of directors and shareholders of TAT approved actions to commence a voluntary winding up of the company. The full wind up of TAT was completed in March 2011.

We evaluate whether significant transactions require consideration of the variable interest consolidation model. For those entities in which we have a variable interest, we consider whether we are the primary beneficiary. Variable interest entities (VIEs) for which we are the primary beneficiary are required to be consolidated. We currently are not the primary beneficiary of any VIE. See Note 3 on Equity Method Investment.

#### **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 dilutive securities outstanding during the period. Potential dilutive securities primarily consist of outstanding employee 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 earnings (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 58,021 and 1,104,371 shares for the 2012 and 2011 periods, respectively, related to outstanding 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**  
**MARCH 31, 2012**  
**(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, commercial paper and cash operating accounts. Our investments include U.S. government-sponsored enterprise securities, commercial paper and corporate notes with original maturities ranging from five to 24 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 months ended March 31, 2012 and 2011. See Note 2 on Fair Value Measurements.

#### ***Non-Marketable Investments in Licensees***

Investments in non-marketable nonpublic companies, in which we own less than 20% of the outstanding voting stock and do not otherwise have the ability to exert significant influence over the investees, are carried at cost, as adjusted for other-than-temporary impairments.

We apply the equity method of accounting for investments in licensees in which we own more than 20% of the outstanding voting stock or otherwise have the ability to exert significant influence over the investees. Under this method, we increase (decrease) the carrying value of our investment by a proportionate share of the investee's earnings (losses). If losses exceed the carrying value of the investment, losses are then applied against any advances to the investee, including any commitment to provide financial support, until those amounts are reduced to zero. Commitments to provide financial support include formal guarantees, implicit arrangements, reputational expectations, intercompany relationships or a consistent past history of providing financial support. The equity method is then suspended until the investee has earnings. Any proportionate share of investee earnings is first applied to the share of accumulated losses not recognized during the period the equity method was suspended. We recognize previously suspended losses to the extent additional investment is determined to represent the funding of prior losses.

We monitor our investments in licensees for impairment on a quarterly basis and make appropriate reductions in carrying values when such impairments are determined to be other-than-temporary. Other-than-temporary charges are included in interest and other income. Factors used in determining whether an other-than-temporary charge should be recognized include, but are not limited to: the current business environment including competition and uncertainty of financial condition; going concern considerations such as the rate at which the investee company utilizes cash, and the investee company's ability to obtain additional private financing to fulfill its stated business plan; the need for changes to the investee company's existing business model due to changing business environments and its ability to successfully implement necessary changes; and the general progress toward product development, including clinical trial results. 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 of such classification 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 statement of operations as unrealized gain (loss) on derivatives. Fair value of

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

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.

**Table of Contents**

**GERON CORPORATION**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**MARCH 31, 2012**  
**(UNAUDITED)**

**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, royalties on future sales of products, milestone payments, or any combination of these items. Upfront nonrefundable 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. We recognize related party revenue under collaborative agreements as the related research and development services are rendered and when the source of funds has not been derived from our contributions to the related party.

**Restricted Cash**

The components of restricted cash are as follows:

	March 31, 2012	December 31, 2011
	(In thousands)	
Certificate of deposit for unused equipment line of credit	\$ 530	\$ 530
Certificate of deposit for credit card purchases	263	263
	\$ 793	\$ 793

**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, 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 will be enrolled in the study. 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 will 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.

**Table of Contents**

**GERON CORPORATION**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**MARCH 31, 2012**  
**(UNAUDITED)**

**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 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 months ended March 31, 2012 and 2011 which was allocated as follows:

	<b>Three Months Ended March 31,</b>	
	<b>2012</b>	<b>2011</b>
	<b>(In thousands)</b>	
Research and development	\$ 641	\$ 1,660
General and administrative	750	4,659
Stock-based compensation expense included in operating expenses	<u>\$ 1,391</u>	<u>\$ 6,319</u>

In February 2011, certain outstanding restricted stock awards and stock options held by Thomas B. Okarma, Ph.D., M.D., our former President and Chief Executive Officer, were modified in connection with his separation of employment from the Company, resulting in additional non-cash stock based compensation expense of \$3,472,000, which has been included in general and administrative expenses for the three months ended March 31, 2011.

As stock-based compensation expense recognized in the condensed consolidated statements of operations for the three months ended March 31, 2012 and 2011 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 experience and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

***Stock Options***

The fair value of options granted during the three months ended March 31, 2012 and 2011 has been estimated at the date of grant using the Black Scholes option-pricing model with the following assumptions:

	<b>Three Months Ended March 31,</b>	
	<b>2012</b>	<b>2011</b>
Dividend yield	None	None
Expected volatility	0.631	0.630
Risk-free interest rate range	1.08% to 1.25%	1.87% to 2.37%
Expected term	6 yrs	5 yrs

**Table of Contents**

**GERON CORPORATION**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**MARCH 31, 2012**  
**(UNAUDITED)**

***Employee Stock Purchase Plan***

The fair value of employees' purchase rights during the three months ended March 31, 2012 and 2011 has been estimated using the Black Scholes option-pricing model with the following assumptions:

	<b>Three Months Ended March 31,</b>	
	<b>2012</b>	<b>2011</b>
Dividend yield	None	None
Expected volatility range	0.458 to 0.774	0.529 to 0.584
Risk-free interest rate range	0.06% to 0.20%	0.19% to 0.32%
Expected term range	6 - 12 mos	6 - 12 mos

Dividend yield is based on historical cash dividend payments and Geron has paid no dividends to date. 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. We grant service-based options under our equity plans to employees, non-employee directors and consultants, for which the vesting period is generally four years.

***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 only upon achievement of discrete strategic corporate goals within a specified performance period, generally three years. Market-based awards vest only 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 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 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 ever. If performance-based restricted stock awards are modified such that no continuing service is required for the award to vest and achievement of the performance condition is not considered probable on the date of modification, then no stock-based compensation cost is recognized until it becomes probable that the performance condition will be met. 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 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 months ended March 31, 2012 and 2011 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

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

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 have not been achieved as of March 31, 2012.



**Table of Contents**

**GERON CORPORATION**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**MARCH 31, 2012**  
**(UNAUDITED)**

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

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.

**Accumulated Other Comprehensive Loss**

Comprehensive loss is comprised of net loss and other comprehensive income (loss). Other comprehensive income (loss) includes certain changes in stockholders' equity which are excluded from net loss.

The components of accumulated other comprehensive loss were as follows:

	March 31, 2012	December 31, 2011
	(In thousands)	
Unrealized gain on available-for-sale securities, net	\$ 107	\$ 78
Foreign currency translation adjustments	(153)	(169)
Accumulated other comprehensive loss	\$ (46)	\$ (91)

**2. FAIR VALUE MEASUREMENTS**

We categorize assets and liabilities 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 the 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 instruments measured at fair value on our condensed consolidated balance sheets, including the category for such instruments.

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

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

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.

**Table of Contents**

**GERON CORPORATION**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**MARCH 31, 2012**  
**(UNAUDITED)**

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

	Cost (In thousands)	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
<b>Included in cash and cash equivalents:</b>				
Money market funds	\$ 11,500	\$	\$	\$ 11,500
Commercial paper (due in less than 1 year)	3,899	1		3,900
	\$ 15,399	\$ 1	\$	\$ 15,400
<b>Restricted cash:</b>				
Certificates of deposit	\$ 793	\$	\$	\$ 793
<b>Marketable securities:</b>				
Government-sponsored enterprise securities (due in less than 1 year)	\$ 14,028	\$ 34	\$	\$ 14,062
Commercial paper (due in less than 1 year)	33,228	16		33,244
Corporate notes (due in less than 1 year)	53,043	58	(13)	53,088
Corporate notes (due in 1 to 2 years)	16,701	20	(9)	16,712
	\$ 117,000	\$ 128	\$ (22)	\$ 117,106

Cash equivalents, restricted cash and marketable securities by security type at December 31, 2011 were as follows:

	Cost (In thousands)	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
<b>Included in cash and cash equivalents:</b>				
Money market funds	\$ 12,885	\$	\$	\$ 12,885
<b>Restricted cash:</b>				
Certificates of deposit	\$ 793	\$	\$	\$ 793
<b>Marketable securities:</b>				
Certificate of deposit (due in less than 1 year)	\$ 329	\$	\$	\$ 329
Government-sponsored enterprise securities (due in less than 1 year)	15,061	25	(1)	15,085
Government-sponsored enterprise securities (due in 1 to 2 years)	6,998	18	(12)	7,004
Commercial paper (due in less than 1 year)	39,206	41		39,247
Corporate notes (due in less than 1 year)	50,556	19	(28)	50,547
Corporate notes (due in 1 to 2 years)	25,113	30	(14)	25,129
	\$ 137,263	\$ 133	\$ (55)	\$ 137,341

**Table of Contents**

**GERON CORPORATION**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**MARCH 31, 2012**  
**(UNAUDITED)**

Marketable securities with unrealized losses at March 31, 2012 and December 31, 2011 were as follows:

	Less Than 12 Months		12 Months or Greater		Total	
	Estimated	Gross Unrealized	Estimated	Gross Unrealized	Estimated	Gross Unrealized
	Fair Value (In thousands)	Losses	Fair Value	Losses	Fair Value	Losses
<b>As of March 31, 2012:</b>						
Corporate notes (due in less than 1 year)	\$ 20,372	\$ (13)	\$	\$	\$ 20,372	\$ (13)
Corporate notes (due in 1 to 2 years)	5,148	(9)			5,148	(9)
	\$ 25,520	\$ (22)	\$	\$	\$ 25,520	\$ (22)
<b>As of December 31, 2011:</b>						
Government-sponsored enterprise securities (due in less than 1 year)	\$ 5,021	\$ (1)	\$	\$	\$ 5,021	\$ (1)
Government-sponsored enterprise securities (due in 1 to 2 years)	3,988	(12)			3,988	(12)
Corporate notes (due in less than 1 year)	33,847	(28)			33,847	(28)
Corporate notes (due in 1 to 2 years)	13,096	(14)			13,096	(14)
	\$ 55,952	\$ (55)	\$	\$	\$ 55,952	\$ (55)

The gross unrealized losses related to government-sponsored enterprise securities and corporate notes as of March 31, 2012 and December 31, 2011 were due to changes in interest rates. We determined that the gross unrealized losses on our marketable securities as of March 31, 2012 and December 31, 2011 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.

**Non-Marketable Investments in Licensees**

As of March 31, 2012 and December 31, 2011, the carrying values of our investments in non-marketable nonpublic companies was zero. We recognized no charges related to other-than-temporary declines in fair values of investments in licensees for the three months ended March 31, 2012 and 2011. See Note 3 on Equity Method Investment for further discussion of investments in licensees.

**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.

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

	March 31, 2012	December 31, 2011
Dividend yield	None	None
Expected volatility	0.576	0.714

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

Risk-free interest rate	0.51%	0.36%
Expected term	3 yrs	3 yrs

Dividend yield is based on historical cash dividend payments and Geron has paid no dividends to date. 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 in effect on the reporting date. The expected term of derivatives is equal to the remaining contractual term of the instrument.

**Table of Contents**

**GERON CORPORATION**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**MARCH 31, 2012**  
**(UNAUDITED)**

As of March 31, 2012 and December 31, 2011, 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 March 31, 2012		At December 31, 2011	
				Number of Shares	Fair Value (In thousands)	Number of Shares	Fair Value (In thousands)
March 2005	\$ 6.39	January 2007	March 2015	284,600	\$ 38	284,600	\$ 64

Non-employee options 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 the three months ended March 31, 2012.

**Fair Value on a Recurring Basis**

The following table presents information about our financial assets and liabilities that are measured at fair value on a recurring basis as of March 31, 2012, and indicates the fair value category assigned.

(In thousands)	Fair Value Measurements at Reporting Date Using Quoted Prices in Active Markets for Identical Assets / Liabilities				Total
	Level 1	Level 2	Level 3		
<b>Assets</b>					
Money market funds <sup>(1)</sup>	\$ 11,500	\$	\$	\$	\$ 11,500
Government-sponsored enterprise securities <sup>(2)</sup>		14,062			14,062
Commercial paper <sup>(1)(2)</sup>		37,144			37,144
Corporate notes <sup>(2)(3)</sup>		69,800			69,800
Total	\$ 11,500	\$ 121,006	\$	\$	\$ 132,506
<b>Liabilities</b>					
Derivatives <sup>(4)</sup>	\$	\$	\$ 38	\$	\$ 38

(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 noncurrent marketable securities on our condensed consolidated balance sheets.

(4) Included in fair value of derivatives on our condensed consolidated balance sheets.  
**Changes in Level 3 Recurring Fair Value Measurements**

The table below includes a rollforward of the balance sheet amounts for the three months ended March 31, 2012 (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.

**Table of Contents**

**GERON CORPORATION**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**MARCH 31, 2012**  
**(UNAUDITED)**

**Fair Value Measurements Using Significant Unobservable Inputs (Level 3)**  
**Three Months Ended March 31, 2012**

	Fair Value at December 31, 2011	Total Unrealized Gains		Transfers In and/or Out of Level 3	Fair Value at March 31, 2012	Change in Unrealized Gains Related to Financial Instruments Held at March 31, 2012 <sup>(1)</sup>
		Earnings, net <sup>(1)</sup>	Purchases and Sales and Issuances and Settlements			
(In thousands)	2011	Earnings, net <sup>(1)</sup>	Purchases and Sales and Issuances and Settlements	3	2012	March 31, 2012 <sup>(1)</sup>
Derivative liabilities	\$ 64	\$ (26)	\$ \$	\$	\$ 38	\$ (26)

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

**3. EQUITY METHOD INVESTMENT**

In April 2005, Geron and Exeter Life Sciences, Inc. (Exeter) established Start Licensing, Inc. (Start), a joint venture to manage and license a broad portfolio of intellectual property rights related to animal reproductive technologies. We and Exeter owned 49.9% and 50.1% of Start, respectively. In connection with the establishment of Start, we granted a worldwide, exclusive, non-transferable license to our patent rights to nuclear transfer technology for use in animal cloning, with the right to sublicense such patent rights. Since there was no net book value associated with the patent rights at the execution of the joint venture, no initial value was recognized for our investment in Start.

In August 2008, Geron and Exeter entered into contribution agreements whereby we and Exeter exchanged our equity interests in Start for equity interests in ViaGen, Inc. (ViaGen). As a result of the exchange, Start became a wholly-owned subsidiary of ViaGen. In November 2010, we provided a loan of \$1,500,000 to ViaGen to fund its operations. Since the loan represented additional financial support to ViaGen, we applied the equity method of accounting by increasing (decreasing) the carrying value of the loan by our proportionate share of ViaGen's earnings (losses). Also in November 2010, we agreed to appoint one of our ViaGen board member representatives as executive chairman of the ViaGen board and purchased \$23,000 in ViaGen equity directly from another shareholder, Moral Compass Corporation (MCC, previously referred to as Exeter). As of March 31, 2012, ownership of ViaGen was as follows: MCC 58%; Geron 40%; and Smithfield Foods 2%.

Since ViaGen does not have sufficient equity to finance its own activities without additional subordinated financial support, it meets the definition of a VIE. By providing financial support to ViaGen, we are a variable interest holder. However, as of March 31, 2012, we lacked the power to direct activities that most significantly impact ViaGen's economic performance. Although one of our ViaGen board representatives serves as executive chairman of the ViaGen board, he has no additional rights or obligations to direct ViaGen's activities. Control over ViaGen's economic performance is driven by the ViaGen management team with authorization and approval from the entire ViaGen board, which as of March 31, 2012 was comprised of two Geron representatives and two MCC representatives. As the majority holder of the equity and debt of ViaGen, MCC maintains controlling financial interest over the company, including the right to appoint a third board member giving MCC majority control of the ViaGen board. Accordingly, we have not included ViaGen's financial information with our condensed consolidated results.

For the three months ended March 31, 2011, we recognized \$335,000 for our proportionate share of ViaGen's operating losses. Our share of losses is recorded in the condensed consolidated statements of operations under losses recognized under equity method investment. No amounts were recognized for the three months ended March 31, 2012 because we suspended the equity method of accounting in June 2011 since our proportionate share of net losses exceeded the value of our investment and we have no commitments to provide financial support or obligations to perform services or other activities for ViaGen.

Our maximum exposure to loss pertaining to ViaGen represents the balance sheet carrying amount of our investment in ViaGen which reflects the amount of cash invested less our proportionate share of losses over time. The adjusted basis of our investment in ViaGen at March



31, 2012 and December 31, 2011 was zero.

**Table of Contents**

**GERON CORPORATION**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**MARCH 31, 2012**  
**(UNAUDITED)**

**4. COLLABORATIVE AGREEMENT**

In June 2009, we entered into a worldwide exclusive license and alliance agreement with GE Healthcare UK, Limited (GEHC) to develop and commercialize cellular assay products derived from human embryonic stem cells (hESCs) for use in drug discovery, development and toxicity screening. Under the terms of the agreement, GEHC has been granted an exclusive license under Geron's intellectual property portfolio covering the growth and differentiation of hESCs, as well as a sublicense under Geron's rights to the hESC patents held by the Wisconsin Alumni Research Foundation. We established a multi-year alliance program with GEHC under which scientists from both companies worked to develop hESC-based products for drug discovery. The first product developed under the alliance, human cardiomyocytes derived from hESCs, was launched in October 2010 by GEHC.

In connection with the agreement, we received upfront non-refundable license payments under the exclusive license and sublicense and are eligible to receive milestone payments upon achievement of certain commercial development and product sales events and royalties on future product sales. Under the alliance program, GEHC was responsible for all costs incurred by GEHC and all costs incurred by us for activities undertaken at Geron, including the funding of our scientists who worked on the alliance program. An Alliance Steering Committee, with representatives from each company, coordinated and managed the alliance program.

License payments under the GEHC agreement were recorded as deferred revenue upon receipt and were recognized ratably as revenue over the alliance program period as a result of our continuing involvement with the collaboration. Funding received for our efforts under the alliance program was recognized as revenue as costs were incurred, which reflected our level of effort over the period of the alliance program. Since the milestone payments are subject to substantive contingencies, any such payments will be recognized upon completion of the specified milestones. Royalties received under the agreement generally have been recognized as revenue upon receipt of the related royalty payment. For the three months ended March 31, 2011, we recognized \$150,000 as revenue from collaborative agreements and \$175,000 as license fee revenue in our condensed consolidated statements of operations in connection with the GEHC agreement. No amounts were recognized from the GEHC agreement for the three months ended March 31, 2012, because the alliance program concluded in June 2011.

**5. RESTRUCTURING**

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 full-time positions were eliminated. Of those, as of March 31, 2012, 14 employees are continuing to provide services through various dates in the first half of 2012.

The outstanding restructuring liability is included in accrued restructuring charges on our condensed consolidated balance sheet as of March 31, 2012 and the components are summarized in the following table (in thousands):

	<b>Employee Severance And Other Benefits</b>
Beginning accrual balance as of December 31, 2011	\$ 3,730
Cash payments	(2,287)
Adjustments or non-cash credits	(26)
Ending accrual balance as of March 31, 2012	\$ 1,417

We may incur additional charges as a result of the restructuring as we exit one of the three buildings in which we lease space in Menlo Park, California. Such charges, if any, will be recorded as they are determined. We also plan to sell any excess equipment, the net proceeds of which may offset some of these future charges.



**Table of Contents**

**GERON CORPORATION**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**MARCH 31, 2012**  
**(UNAUDITED)**

**6. SEGMENT INFORMATION**

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

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

Supplemental schedule of non-cash operating and investing activities:

(In thousands)	Three Months Ended March 31,	
	2012	2011
<b>Supplemental Operating Activities:</b>		
Cash in transit from option exercises	\$	\$ 10
Issuance of common stock for performance bonus	2,807	2,807
Issuance of common stock for 401(k) matching contributions	1,361	1,294
Issuance of common stock for acquired in-process research and development	27,500	27,500
Issuance of common stock for services rendered to date or to be received in future periods		181
Reclassification of deposits to other current assets	81	81
<b>Supplemental Investing Activities:</b>		
Net unrealized gain (loss) on marketable securities	29	(55)

## **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. We use words such as anticipate, believe, plan, expect, future, intend, estimate, may, predict, project, potential, should, will, would and similar expressions to identify forward-looking statements. 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 the Company's Annual Report on Form 10-K for the year ended December 31, 2011, as filed with the Securities and Exchange Commission on March 7, 2012.

Geron is a biopharmaceutical company developing first-in-class therapies for cancer. Imetelstat, a telomerase inhibitor, is currently being evaluated in four Phase 2 clinical trials for the following indications: metastatic breast cancer, advanced non-small cell lung cancer, essential thrombocythemia and multiple myeloma. GRN1005, a lipoprotein receptor-related protein (LRP), directed peptide-drug conjugate, is being evaluated in two Phase 2 clinical trials: brain metastases arising from breast cancer and brain metastases arising from non-small cell lung cancer.

We are evaluating imetelstat, our telomerase inhibitor, in two randomized, controlled Phase 2 trials in solid tumors, one in metastatic breast cancer and the other in advanced non-small cell lung cancer (NSCLC). Both are diseases in which the prognosis for patients remains poor, and there is evidence that disease progression, relapse and metastasis are driven in part by cancer progenitor cells. We are also studying imetelstat in two single-arm Phase 2 trials in hematologic (blood-based) cancers, one in essential thrombocythemia and the other in multiple myeloma, where the effect of the drug on the malignant progenitor cells responsible for the disease can be more directly observed than is the case in solid tumors. We expect to have top-line data from our Phase 2 trials of imetelstat by the end of 2012.

GRN1005 is a peptide-drug conjugate designed to utilize a physiologic molecular transport mechanism known as lipoprotein receptor-related protein-1, or LRP-1, to deliver paclitaxel across the blood-brain barrier (BBB) and into tumors in the brain. The BBB prevents most drugs, including oncology drugs, from reaching the brain at levels that are clinically effective. GRN1005 is designed to overcome this challenge by linking paclitaxel to a proprietary peptide, Angiopep-2, that is actively transported across the BBB by LRP-1. Angiopep-2 also facilitates uptake of the conjugate into tumor cells inside and outside the brain. The bond linking Angiopep-2 peptide and paclitaxel is cleaved when it is taken up into cells, including tumor cells both inside and outside the brain, releasing active paclitaxel. GRN1005 was in-licensed from Angiochem in 2010 on an exclusive basis under a conventional milestone and royalty structure. We are conducting two single-arm Phase 2 trials of GRN1005, one in patients with brain metastases associated with breast cancer and the other in patients with brain metastases associated with non-small cell lung cancer. We selected these indications because in Phase 1 trials clinical activity was observed in patients with these tumor types. We expect to have top-line data from our Phase 2 trials of GRN1005 by the end of the second quarter of 2013.

In November 2011, we announced that we will focus on our oncology programs and consequently, we discontinued development of our stem cell programs. We continue to accrue data on the patients already enrolled in the Phase 1 trial of our human embryonic stem-cell derived oligodendrocyte progenitor cell therapy (GRNOPC1) for the treatment of spinal cord injury. We seek to divest our stem cell programs in 2012, including GRNOPC1 for spinal cord injury, cardiomyocytes for heart disease, pancreatic islet cells for diabetes, dendritic cells as an immunotherapy vehicle and chondrocytes for cartilage repair.

## **Table of Contents**

### **CRITICAL ACCOUNTING POLICIES AND ESTIMATES**

There have been no significant changes in our critical accounting policies and estimates during the three months ended March 31, 2012 as compared to the critical accounting policies and estimates disclosed in our Annual Report on Form 10-K for the year ended December 31, 2011 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 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.

### **RESULTS OF OPERATIONS**

Our results of operations, as well as the progress of our research and development efforts and variations in the level of expenses related to developmental efforts, have fluctuated from period to period and may continue to fluctuate in the future. 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 risks inherent in our research and development efforts, reliance upon our collaborative partners, enforcement of our patent and proprietary rights, need for future capital, potential competition and uncertainty of clinical trial results or regulatory approvals or clearances. 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 efficacy and safety of our product candidates, 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 therapeutic products for a number of years, if at all.

#### **Revenues**

We recognized revenues of \$150,000 from collaborative agreements for the three months ended March 31, 2011. Revenues in 2011 reflect revenue recognized under our collaboration with GE Healthcare UK, Ltd. (GE Healthcare). No amounts were recognized for the three months ended March 31, 2012 because the collaboration with GE Healthcare concluded in June 2011.

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 product sales, or any combination thereof. We recognized license fee revenues of \$393,000 for the three months ended March 31, 2012, compared to \$662,000 for the comparable 2011 period related to our various agreements. The decrease in license fee revenues in 2012 compared to 2011 primarily reflects the full recognition of the license fees under the GE Healthcare agreement upon the conclusion of the alliance program in June 2011. Current revenues may not be predictive of future revenues.

We received royalties of \$861,000 for the three months ended March 31, 2012, compared to \$693,000 for the comparable 2011 period on product sales of telomerase detection and telomere measurement kits to the research-use-only market, cell-based research products and nutritional products. Future license and royalty revenues are dependent upon additional agreements being signed.

**Table of Contents****Research and Development Expenses**

Research and development expenses were \$15.1 million for the three months ended March 31, 2012, compared to \$16.8 million for the comparable 2011 period. The decrease in 2012 compared to 2011 primarily reflects reduced personnel and related costs of \$2.7 million and lower expenses for scientific supplies of \$1.8 million resulting from the discontinued development of our stem cell programs, partially offset by increased clinical trial costs of \$1.6 million for the enrollment of four Phase 2 clinical trials of imetelstat and two Phase 2 clinical trials of GRN1005 and increased drug product purchases and manufacturing costs of \$1.5 million related to imetelstat and GRN1005. Overall, we expect research and development expenses to remain consistent with current levels as we incur expenses related to our clinical trials for imetelstat and GRN1005.

Research and development expenses incurred under our programs were as follows (in thousands):

(In thousands)	Three Months Ended March 31,	
	2012	2011
	(Unaudited)	
Oncology	\$ 13,345	\$ 9,204
hESC Therapies	1,762	7,551
Total	\$ 15,107	\$ 16,755

**General and Administrative Expenses**

General and administrative expenses were \$5.1 million for the three months ended March 31, 2012, compared to \$9.1 million for the comparable 2011 period. The decrease in 2012 compared to 2011 primarily reflects reduced non-cash stock-based compensation expense associated with the modification of outstanding equity awards held by Thomas B. Okarma Ph.D., M.D., our former President and Chief Executive Officer, in connection with his separation from the Company in February 2011.

**Unrealized Gain on Derivatives**

Unrealized gain on fair value of 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. The derivatives 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 them to be recorded as assets or liabilities, at which time these instruments are marked to fair value and reclassified from assets or liabilities to stockholders' equity. We incurred unrealized gains on derivatives of \$26,000 and \$39,000 for the three months ended March 31, 2012 and 2011, respectively. The unrealized gains on derivatives for 2012 and 2011 primarily reflected reduced fair values of derivative liabilities resulting from shortening of their contractual terms, decreases 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 \$176,000 for the three months ended March 31, 2012, compared to \$296,000 for the comparable 2011 period. The decrease in 2012 compared to 2011 reflects 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.

**Losses Recognized Under Equity Method Investment**

We own 40% of ViaGen, Inc. (ViaGen), a licensee with in-house breeding services and expertise in advanced reproductive technologies for animal cloning. In accordance with the equity method of accounting, we recognized losses of \$335,000 for the three months ended March 31, 2011 for our proportionate share of ViaGen's losses. No amounts were recognized for the three months ended March 31, 2012 because we suspended the equity method of accounting in June 2011 since our proportionate share of net losses exceeded the value of our investment and we

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

have no commitments to provide financial support or obligations to perform services or other activities for ViaGen. See Note 3 on Equity Method Investment in Notes to Condensed Consolidated Financial Statements of this Form 10-Q for further discussion of ViaGen.



## **Table of Contents**

### **Interest and Other Expense**

Interest and other expense was \$23,000 for the three months ended March 31, 2012, compared to \$33,000 for the comparable 2011 period. The decrease in 2012 compared to 2011 was primarily due to reduced bank charges as a result of lower cash and investment balances.

### **Net Loss**

Net loss was \$18.7 million for the three months ended March 31, 2012, compared to \$24.4 million for the comparable 2011 period. The decrease in net loss in 2012 compared to 2011 was primarily due to reduced research and development expenses as a result of discontinuing development of our stem cell programs and lower non-cash stock based compensation expense.

## **LIQUIDITY AND CAPITAL RESOURCES**

Cash, restricted cash, cash equivalents and marketable securities at March 31, 2012 were \$136.9 million, compared to \$154.2 million at December 31, 2011. 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 an 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 markets. The decrease in cash, restricted cash, cash equivalents and marketable securities in 2012 was the result of cash being used for operations.

We estimate that our existing capital resources, interest income and amounts available to us under our equipment financing facility 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 2012 and beyond;
- changes in our clinical development plans for our product candidates, imetelstat and GRN1005;
- our ability to meaningfully reduce manufacturing costs of current product candidates;
- the magnitude and scope of our research and development programs, including the number and type of product candidates we intend to pursue;
- the progress we make in our research and development programs, preclinical development and clinical trials;
- our ability to establish, enforce and maintain strategic arrangements for research, development, clinical testing, manufacturing and marketing;
- the timing of a potential divestiture of our stem cell program assets and the consideration, if any, we may receive as a result of such divestiture;
- the time and costs involved in obtaining regulatory approvals and clearances; and
- the costs involved in preparing, filing, prosecuting, defending and enforcing patent claims.

## Table of Contents

If our capital resources 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 strategic collaborations, public or private equity financings, equipment loans or other financing sources that may be available. 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 any of our product candidates 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 product candidates or to grant licenses on terms that are unfavorable to us.

*Cash Flows from Operating Activities.* Net cash used in operations for the three months ended March 31, 2012 and 2011 was \$16.6 million and \$12.7 million, respectively. The increase in net cash used in operations in 2012 compared to 2011 was primarily the result of cash payments incurred in connection with our November 2011 restructuring and reduced usage of our common stock in exchange for services.

*Cash Flows from Investing Activities.* Net cash provided by investing activities for the three months ended March 31, 2012 and 2011 was \$19.5 million and \$2.0 million, respectively. The increase in net cash provided by investing activities in 2012 compared to 2011 reflected higher proceeds from maturities of marketable securities relative to purchases of marketable securities during the respective periods.

As of March 31, 2012 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 cash resources for capital expenditures.

*Cash Flows from Financing Activities.* Net cash provided by financing activities was zero and \$144,000 for the three months ended March 31, 2012 and 2011, respectively.

## Significant Cash and Contractual Obligations

As of March 31, 2012, our contractual obligations for the next five years and thereafter were as follows:

Contractual Obligations <sup>(1)</sup>	Principal Payments Due by Period				
	Total	Remainder in 2012	2013- 2014	2015- 2016	After 2016
Equipment leases	\$ 20	\$ 14	\$ 6	\$	\$
Operating leases <sup>(2)</sup>	1,932	433	1,499		
Research funding <sup>(3)</sup>	1,731	467	389	350	525
Total contractual cash obligations	\$ 3,683	\$ 914	\$ 1,894	\$ 350	\$ 525

(1) This table does not include any milestone payments under research collaborations or license agreements as the timing and likelihood of such payments are not known. In addition, this table does not include payments under our severance plan if there were a change in control of the company or severance payments to key employees in the event of an involuntary termination.

(2) In March 2008, we issued 742,158 shares of our common stock to the lessor of our premises at 200 and 230 Constitution Drive in payment of our monthly rental obligation from August 1, 2008 through July 31, 2012. In January 2010 and April 2010, we issued an aggregate of 187,999 shares of our common stock to the lessor of our premises at 149 Commonwealth Drive in payment of our monthly rental obligation from May 1, 2010 through July 31, 2012. The fair value of the common stock issuances has been recorded as a prepaid asset and is being amortized to rent expense on a straight-line basis over the lease periods. As a result, we have no cash rental obligation for our existing facilities through July 31, 2012.

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

In February 2012, we entered into a new lease agreement at 149 Commonwealth Drive which expands the current space from approximately 14,500 square feet to approximately 30,000 square feet of office space. Our new lease at 149 Commonwealth Drive includes an option to extend the lease for one additional period of two years. The new lease at 149 Commonwealth Drive commences in July 2012 and expires in July 2014.

- (3) Research funding is comprised of sponsored research commitments at various laboratories around the world.

## **Table of Contents**

### **Off-Balance Sheet Arrangements**

None.

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

During the three months ended March 31, 2012, 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, 2011.

### **ITEM 4. CONTROLS AND PROCEDURES**

(a) *Evaluation of Disclosure Controls and Procedures.* The Company has 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 a reasonable assurance level.

(b) *Changes in Internal Controls Over Financial Reporting.* There was no change in our internal control over financial reporting for the three months ended March 31, 2012 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.

## **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, 2011. 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 the risks described under Part I, Item 1A Risk Factors included in our Annual Report on Form 10-K for the year ended December 31, 2011.

## **Table of Contents**

### **RISKS RELATED TO OUR BUSINESS**

*Our business is at an early stage of development, and we must overcome numerous risks and uncertainties to become successful. \**

Our business is at an early stage of development, and we do not yet have product candidates in late-stage clinical trials or any products commercially available. Our ability to develop product candidates to and through commercial launch is subject to our ability to, among other things:

- achieve success in Phase 2 and Phase 3 clinical trials;
- collaborate successfully with clinical trial sites, academic institutions, physician investigators, clinical research organizations and other third parties;
- manufacture product candidates at commercially reasonable costs;
- obtain required regulatory clearances and approvals;
- maintain and enforce adequate intellectual property protection for our product candidates; and
- obtain financing on commercially reasonable terms to fund our operations.

There are many reasons why we may need to delay or abandon efforts to research, develop or obtain regulatory approvals to market our product candidates, including as a result of a product candidate failing at any stage of the development process or if we otherwise determine for business or financial reasons to delay or discontinue development of that product candidate. For example, in November 2011 we announced that we were discontinuing further development of our human embryonic stem cell programs in order to focus on our oncology programs. Our current product candidates require significant additional clinical testing prior to regulatory approval in the United States and other countries, and we do not expect that any of our current product candidates will be commercially available for a number of years, if ever. It may also be difficult to assess the success or failure of any of our clinical trials for many reasons, including but not limited to the subjectivity and changing landscape that accompanies the benefit-to-risk assessment in any given patient population, and because subpopulation data might not be available at the time we report top-line data or other results. Our product candidates also may prove to have undesirable and unintended side effects or other characteristics adversely affecting their safety, efficacy or cost-effectiveness that could prevent or limit their approval for marketing and successful commercial use. In addition, our product candidates may not prove to be more effective for treating disease than current therapies. Competitors may also have proprietary rights that prevent us from developing and marketing our product candidates, or those competitors may sell similar, superior or lower-cost products that make our product candidates unsuitable for marketing. Our product candidates also may not be able to be manufactured in commercial quantities at an acceptable cost. Any of the foregoing factors could delay or prevent us from developing, commercializing and marketing our product candidates, which would materially adversely affect our business.

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

The science and technology of telomere biology and telomerase, as well as receptor-targeting peptides that cross the blood-brain barrier (BBB), are relatively new. There is no precedent for the successful commercialization of therapeutic product candidates based on these technologies. In addition, we, our licensees, and our collaborators must undertake significant research and development activities to develop product candidates based on these technologies, which will require additional funding and may take years to accomplish, if ever.

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 may be delayed or abandoned, even after we have expended significant resources on it. Such a delay or abandonment of our programs in telomerase technology or receptor-targeting peptide technology to cross the BBB would have a material adverse effect on our business.

In our Phase 1 clinical trials of imetelstat, we observed dose-limiting toxicities, including thrombocytopenia when the drug was used as a single agent, and neutropenia when the drug was used in combination with paclitaxel, as well as a low incidence of severe infusion reactions. We also did not observe single-agent efficacy with imetelstat in our Phase 1 program. Further, the information we have related to the ability of GRN1005 to penetrate brain tissue and its anti-tumor activity is preliminary and based on Phase 1 clinical trials conducted by Angiochem. In the Phase 1 trials of GRN1005, Grade 4 neutropenia was the primary dose-limiting toxicity observed. In our Phase 2 clinical trials of imetelstat or

GRN1005, we may observe similar dose-limiting toxicities or other safety issues which may require us to conduct additional, unforeseen trials or abandon these programs entirely.

## **Table of Contents**

***If we are not able to divest our stem cell assets for substantial financial value, or at all, the proceeds of the divestiture will be limited and our stock price may decline.***

In November 2011, we announced that we will focus on our oncology programs and consequently, we discontinued development of and are seeking to divest our stem cell programs. Our stem cell programs are at an early stage of development, and we can give no assurance regarding the consideration we will receive, if any, for their disposition. In addition, 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, and that we will receive such value through the divestiture of our stem cell programs. However, we may not be able to receive the financial value that these stockholders may attribute to our stem cell assets, or any financial value at all, and, as a result, our stock price may decline.

## **RISKS RELATED TO CLINICAL AND COMMERCIALIZATION ACTIVITIES**

***Our ability to complete ongoing clinical trials on a timely basis is subject to risks and uncertainties related to factors such as patient enrollment, drug supply and regulatory approval. \****

Completion of ongoing clinical trials of our product candidates may be delayed, or not occur, due to insufficient patient enrollment, which is a function of many factors, including the size and nature of the patient populations, the nature of the protocols, the proximity of patients to clinical sites, the availability of effective treatments for the relevant disease, and the eligibility criteria for the clinical trials. Other delays could be caused by matters such as:

- disruptions in drug supply;
- not receiving timely regulatory clearances or approvals, including, for example, acceptance of new manufacturing specifications 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;
- unavailability of any study-related treatment (including comparator therapy); or
- unanticipated issues with key vendors of clinical services, such as contract research organizations.

For example, enrollment in our Phase 2 trials of imetelstat in multiple myeloma and essential thrombocythemia has been slower than expected, and enrollment goals for our clinical trials of GRN1005 are aggressive. Delays in timely completion of clinical testing of our product candidates could increase research and development costs and could prevent or would delay us from obtaining regulatory approval for our product candidates, both of which would likely have a material adverse effect on our business. Additionally, our enrollment goals may not be met as we have projected, or at all.

***Delays in the initiation of later-stage clinical trials of our current product candidates could result in increased costs to us and would delay our ability to generate revenues.***

The commencement of later-stage clinical trials can be delayed for a variety of reasons, including delays in:

- demonstrating sufficient safety and efficacy in Phase 2 clinical trials to obtain regulatory clearance to commence a Phase 3 clinical trial;
- obtaining sufficient funding;
- manufacturing sufficient quantities of drug;
- producing drugs that meet the quality standards of the United States Food and Drug Administration (FDA) and other regulatory agencies;
- ensuring our ability to manufacture drugs at acceptable costs for later-stage clinical trials and commercialization;

Edgar Filing: GERON CORP - Form 10-Q

- obtaining clearance or approval of a proposed trial design or manufacturing specifications from the FDA and other regulatory authorities;



## **Table of Contents**

- reaching agreement on acceptable terms with our collaborators on all aspects of the clinical trial, including the contract research organizations and the trial sites; and
- obtaining institutional review board or ethics committee approval to conduct a clinical trial at a prospective site.

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

Our product candidates are 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 and GRN1005 will need to be significantly lower than our current costs in order for these product candidates to become commercially successful products. 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 Phase 2 clinical trials. Similarly, our GRN1005 manufacturing processes are currently conducted at a relatively small scale, and there is also limited history of manufacturing of GRN1005. Accordingly, we may not be able to achieve sufficient scale increases or cost reductions necessary for successful commercial production of imetelstat or GRN1005. Additionally, given the complexities of our manufacturing process, the resulting costs that we incur to conduct our clinical trials may be higher than would be anticipated for other comparable treatments, requiring us to expend relatively larger amounts of cash to complete our clinical trials.

***Manufacturing our product candidates is subject to process and technical challenges and regulatory risks.***

We face numerous risks and uncertainties with regard to manufacturing imetelstat and GRN1005. Regulatory requirements for product quality of 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. Similarly, our GRN1005 manufacturing process, including the consistency and quality of batches made, while appropriate for Phase 2 clinical trials, will need to improve to meet regulatory requirements for Phase 3 clinical trials and commercial approval. Also, changes in our manufacturing processes for imetelstat or GRN1005 made during later stages of clinical development, including during Phase 3 trials, may result in regulatory delays, the need for further clinical trials, or rejection of a marketing application 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, late-stage clinical trials, or in those areas required for the successful commercialization of our product candidates. \****

We have no experience as a company in conducting large-scale, late-stage clinical trials. We cannot be certain that any large-scale, late-stage planned clinical trials will begin or be completed on time, if at all. Large-scale, late-stage clinical trials will require additional financial and management resources and reliance on third-party clinical investigators, clinical research organizations 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 our product candidates, and we will need to establish sales, marketing and distribution capabilities or establish and maintain agreements with third parties to market and sell our product candidates. Developing internal sales, marketing and distribution capabilities would be an expensive and time-consuming process. We may not be able to enter into third-party 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 any of our product candidates.

***Obtaining regulatory approvals to market our product candidates 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 our product candidates.***

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 creating commercially viable products from our discoveries, and from successfully conducting our development efforts and commercializing our product candidates. The regulatory process, particularly for biopharmaceutical product candidates like ours, is uncertain, can take many years and requires the expenditure of substantial resources.



## **Table of Contents**

Our product candidates will require extensive preclinical and clinical testing prior to submission of any regulatory application seeking approval to commence commercial sales. 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, safety and efficacy data from any of our Phase 2 clinical trials, even if favorable, may not provide sufficient rationale for us to proceed to a Phase 3 clinical trial. In addition, delays or rejections 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.

Any product candidate that we, or our collaborators, develop 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 certain of our product candidates involve the application of new technologies or are based upon a new therapeutic approach, they may be subject to substantial additional review by various government regulatory authorities, and, as a result, the process of obtaining regulatory approvals for them may proceed more slowly than for product candidates based upon more conventional technologies.

Delays in obtaining regulatory agency approvals could:

- significantly harm the marketing of any products that we or our collaborators develop;
- impose costly procedures upon our activities or the activities of our collaborators;
- diminish any competitive advantages that we or our collaborators 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 any product candidates developed by us or in collaboration with us. If we obtain regulatory agency approval for a new product, 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 the product.

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

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 or our collaborators 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.

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;

Edgar Filing: GERON CORP - Form 10-Q

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

## **Table of Contents**

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 RELATIONSHIPS WITH THIRD PARTIES**

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

Our strategy for the development, clinical testing and commercialization of our product candidates requires that we enter into collaborations with clinical research organizations, vendors, corporate partners, licensors, licensees or 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 imetelstat and GRN1005 Phase 2 clinical trials including clinical trial site monitoring activities. In addition, we have contracted with single vendors for each of our clinical programs to develop and maintain the clinical databases for each respective program, and a single vendor maintains our safety database for both programs. 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, our collaborators could terminate their agreements with us, and we may not receive any development or milestone payments. If we do not achieve milestones set forth in agreements with collaborators, or if our collaborators breach or terminate their collaborative agreements with us, our business may be materially harmed.

*Our ability to manufacture our product candidates and products is risky and uncertain because we must rely on third parties for manufacturing. There may be shortages of key materials, and we may have only one source of manufacture or supply.*

We rely on other companies for certain process development, supply of starting materials, manufacturing or other technical and scientific work with respect to our imetelstat and GRN1005 product candidates, but we do not have direct control over their personnel or operations. If these companies do not perform the work which they were assigned or do not complete the work within the expected timelines, or if they choose to exit the business, our ability to develop or manufacture our product candidates 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. In addition, we have not established long-term agreements for the supply of imetelstat or GRN1005.

In addition, our manufacturers may need to make substantial investments to enable sufficient capacity increases, 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.

There are other risks and uncertainties that we face with respect to manufacturing. For example, we do not have a secondary source for the supply of GRN1005 bulk drug substance (unformulated peptide-paclitaxel conjugate). In addition, we currently have an agreement with only a single contractor for distribution of imetelstat and GRN1005 final drug product to clinical sites in North America. As another example, certain commonly used reagents and solvents can experience market shortages and, if these shortages occur, they may adversely impact our ability to manufacture our product candidates.

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

We rely extensively upon and have relationships with scientific consultants and contractors at academic and other institutions. Some of our scientific consultants and contractors conduct research at our request, and others assist us in formulating our research and development and clinical strategy or other matters. These consultants 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 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.

## **Table of Contents**

In addition, we have formed research collaborations with many academic and other research institutions throughout the world. These research facilities may have commitments to other commercial and noncommercial entities. We have limited control over the operations of these laboratories and can expect only limited amounts of their time to be dedicated to our research goals.

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 our product candidates could be significantly harmed.

### **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 March 31, 2012, our accumulated deficit was approximately \$804.2 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 development efforts and clinical testing 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 revenues from our licensing arrangements. We may be unsuccessful in entering into any new corporate collaboration or license agreements that result in revenues. We do not expect that the revenues generated from these arrangements will be sufficient alone to continue or expand our research or development activities and otherwise sustain our operations.

While we receive royalty revenue from licenses, we do not expect to receive sufficient royalty revenues from these licenses to independently sustain our operations. Our ability to continue or expand our research and development activities and otherwise sustain our operations is dependent on our ability, alone or with others, to, among other things, discover, develop, manufacture and market therapeutic products.

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 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 cannot assure you that we would 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 our product candidates, and our ability to obtain the necessary funding is uncertain. \**

We will require substantial capital resources in order to conduct our operations and develop our product candidates, and we cannot assure you that our existing capital resources, interest income and equipment financing arrangement will be sufficient to fund future planned operations. The timing and degree of any future capital requirements will depend on many factors, including:

- the accuracy of the assumptions underlying our estimates for our capital needs for the remainder of 2012 and beyond;
- changes in our clinical development plans for our product candidates, imetelstat and GRN1005;
- our ability to meaningfully reduce manufacturing costs of current product candidates;
- the magnitude and scope of our research and development programs, including the number and type of product candidates we intend to pursue;
- the progress we make in our research and development programs, preclinical development and clinical trials;

## **Table of Contents**

- our ability to establish, enforce and maintain strategic arrangements for research, development, clinical testing, manufacturing and marketing;
- the timing of a potential divestiture of our stem cell program assets and the consideration, if any, we may receive as a result of such divestiture;
- 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. 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 any of our product candidates fails to show adequate safety or efficacy in clinical testing. At our 2012 annual meeting of stockholders, we are seeking stockholder approval of an increase in the number of authorized shares of common stock from 200,000,000 to 300,000,000 shares, and if the proposal is not approved, it is possible that financing alternatives for our company may become limited by the lack of sufficient unissued and unreserved authorized shares of common stock.

Additional equity financings, if we obtain them, could result in significant dilution to our stockholders. Further, in the event that additional funds are obtained through arrangements with collaborative partners, these arrangements may require us to relinquish rights to some of our technologies, product candidates or proposed products that we would otherwise seek to develop and commercialize ourselves.

If sufficient capital is not available, we may be required to delay, reduce the scope of, suspend or eliminate one or more of our programs, any of which could have a material adverse effect on our business. For example, in November 2011 we announced that we were discontinuing further development of our human embryonic stem cell programs in order to focus on our oncology programs.

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

*Our success will depend on our ability to protect our technologies and our product candidates through patents and other intellectual property rights and to operate without infringing the rights of others. If we or our licensors are unsuccessful in either of these regards, the value of our technologies and product candidates will be adversely affected and we may be unable to continue our development work.*

Protection of our proprietary technology is critically important to our business. Our success will depend in part on our ability to obtain and enforce our patents and maintain trade secrets, both in the United States and in other countries. By way of example, we do not yet have issued patents for GRN1005 in Europe or Japan, or 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 our product candidates and our business would be negatively impacted. By way of example, we depend in part on the ability of Angiochem to obtain, maintain and enforce patent rights for the proprietary peptide-drug conjugate technology that we have licensed.

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 technology, or enforce issued patents, is uncertain.

## **Table of Contents**

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 our product candidates.

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

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 U.S. Patent and Trademark Office, or 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. Notably, under the America Invents Act (AIA) signed into law in September 2011, interference proceedings will be eliminated for patent applications filed on or after March 2013, to be replaced with other types of proceedings, including post-grant review procedures. 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.

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 products internationally, 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 (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. The rights to GV1001 passed from GemVax, a Norwegian company, to Pharmexa, a Danish company, as a result of a 2005 acquisition. In late 2008, Pharmexa reported that it sold its telomerase vaccine program to a Korean company, KAEL Co. Ltd., and the continuing company now operates under the name KAEL-GemVax. Various clinical trials of GV1001 are underway, including a Phase 3 combination study in pancreatic cancer. Pharmexa originally obtained a European patent with broad claims to the use of telomerase vaccines for the treatment of cancer, and we opposed that patent in 2004. In 2005, the Opposition Division (OD) of the EPO revoked the claims originally granted to Pharmexa, but permitted Pharmexa to add new, narrower claims limited to five specific small peptide fragments of telomerase. The decision was appealed to the Technical Board of Appeals (TBA). In August 2007, the TBA ruled, consistent with the decision of the OD, that Pharmexa was not entitled to the originally granted broad claims but was only entitled to the narrow claims limited to the five small peptides. KAEL-GemVax was recently granted a further related European patent covering its telomerase peptide vaccine against which we have filed an opposition. That opposition is ongoing and we cannot predict the outcome.

In parallel, Pharmexa opposed a European patent held by us, the claims of which cover many facets of human telomerase, including the use of telomerase peptides in cancer vaccines. In June 2006, the OD of the EPO revoked three of the granted claims in our patent, specifically the three claims covering telomerase peptide cancer vaccines. The remaining 47 claims were upheld, and that decision was recently affirmed by the TBA. We have now been awarded a second European patent with claims to telomerase peptides, and this patent has also been opposed by KAEL-GemVax. We believe that GV1001 is covered by our telomerase patents and our goal in these proceedings is to maintain strong patent protection that will enable us to enter into a licensing arrangement with KAEL-GemVax that could result in commercial benefit for Geron if GV1001 is successfully commercialized; however, we may not be able to maintain that protection or enter into such a licensing arrangement on commercially reasonable terms, if at all. We cannot predict the outcome of this opposition or any subsequent appeal of the decision in the opposition.

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.

Under the AIA, effective in March 2013, U.S. patents will be subject to post-grant review procedures similar to European oppositions. Patents owned or licensed by us may therefore be subject to post-grant review procedures, as well as other forms of review and reexamination. A decision in such proceedings adverse to our interests could result in the loss of valuable patent rights and negatively impact our business.



## **Table of Contents**

As more groups become engaged in scientific research and product development in the areas of telomerase biology and peptide-drug conjugates for delivery of therapeutics across the BBB, the risk of our patents being challenged through patent interferences, oppositions, reexaminations, 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);
- subjecting us to litigation, or otherwise preventing us from commercializing product candidates 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.

By way of example, an anonymous party has recently filed papers at the EPO challenging the proposed issuance of a patent to Angiochem that is relevant to GRN1005. If such challenges to our patent rights covering our product candidates are not resolved promptly in our favor, our existing business relationships may be jeopardized and we could be delayed or prevented from entering into new collaborations or from commercializing product candidates, which could materially harm our business.

***If we fail to meet our obligations under license agreements, we may lose our rights to key technologies on which our business depends.***

Our business depends on several critical technologies that are based in part on patents licensed from third parties, including the exclusive worldwide license rights we obtained from Angiochem in December 2010. 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 our obligations under a license agreement, 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. During the period of any such litigation our ability to carry out the development and commercialization of product candidates could be significantly and negatively affected. If our license rights were restricted or ultimately lost, particularly those rights licensed from Angiochem, our ability to continue our business based on the affected technology would be severely adversely affected.

***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 product candidates.***

Our commercial success depends significantly on our ability to operate without infringing patents and the proprietary rights of others. Our technologies may infringe the patents or proprietary rights of others. In addition, we may become aware of discoveries and technology controlled by third parties that are advantageous to our programs. In the event our technologies infringe the rights of others or we require the use of discoveries and technology controlled by third parties, we may be prevented from pursuing research, development or commercialization of product candidates or may be required to obtain licenses to those patents or other proprietary rights or develop or obtain alternative technologies. We have obtained licenses from several universities and companies for technologies that we anticipate incorporating into our product candidates, and we initiate negotiation for licenses to other technologies as the need or opportunity arises. We may not be able to obtain a license to patented technology on commercially favorable terms, or at all. If we do not obtain a necessary license, we may need to redesign our technologies or obtain rights to alternate technologies, the research and adoption of which could cause delays in our product development. In cases where we are unable to license necessary technologies, we could be prevented from developing certain product candidates. Our failure to obtain alternative technologies or a license to any technology that we may require to research, develop or commercialize our product candidates 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 our product candidates continue to progress in development, we will see more efforts by others to obtain patents that are positioned to cover our product candidates.

## **Table of Contents**

*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 divest our stem cell programs, and the value that we receive from any such arrangements depends at least in part on the strength of our hESC-related intellectual property. \**

We developed an extensive portfolio of Geron-owned patent filings covering our prior development of human embryonic stem cell, or hESC, 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 are seeking to divest. Our ability to divest our hESC programs, and the value that we receive, if any, will depend in part on the strength, scope and term of the patents in our hESC portfolio, as well as our ability to maintain our license rights to the patents that we licensed from third parties. Legal developments and proceedings that may impact the value of our hESC patent portfolio include:

- *European court ruling:* In 2011, the European Court of Justice (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 hESC technologies in member states of the European Union (EU). This decision may reduce the value of our hESC patent portfolio in a divestiture transaction.
- *Patent interferences:* Two of our patent applications covering the production of endoderm from hESCs (part of the process for making pancreatic islet cells) are involved in interferences with patents held by ViaCyte, Inc. A number of outcomes are possible: (i) the claims may be awarded to ViaCyte; (ii) the claims may be awarded to us, or (iii) neither party may be found to be entitled to the claims. The decision from the Patent Office may also be subject to appeal. Since the interferences are still ongoing, we cannot predict what the outcome will be.
- *Reexaminations:* 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 (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 hESCs, as well as non-exclusive rights for other product opportunities. After initially rejecting the patent claims, 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 and not subject to further appeal. Consumer Watchdog appealed the decision on the 7,029,913 patent and, in April 2010, the Board of Patent Appeals and Interferences (BPAI) reversed the earlier decision of the Patent Office on the 7,029,913 patent 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 and the case is currently under further review by the BPAI. The case could be subject to further appeal.

## **RISKS RELATED TO COMPETITIVE FACTORS**

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

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. 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.

## **Table of Contents**

*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 programs in oncology therapies, including the study of telomeres, telomerase and receptor-targeting peptides crossing the BBB. In addition, other products and therapies that could directly compete with the product candidates that we are seeking to develop and market 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., GlaxoSmithKline, Bristol-Myers Squibb Company and Novartis AG) 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 programs.

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 we do. Most significantly, competitive products may render any product candidates that we develop obsolete, which would negatively impact our business and ability to sustain operations.

## **Table of Contents**

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

Our product candidates and those developed by our collaborators, if approved for marketing, may not achieve market acceptance since hospitals, physicians, patients or the medical community in general may decide not to accept and utilize these products. The product candidates that we are attempting to develop will compete with a number of conventional drugs and therapies manufactured and marketed by major pharmaceutical companies. The degree of market acceptance of any of our product candidates will depend on a number of factors, including:

- our establishment and demonstration to the medical community of the clinical efficacy and safety of our product candidates;
- our ability to create products that are superior to alternatives currently on the market;
- our ability to establish in the medical community the potential advantage of our treatments over alternative treatment methods; and
- reimbursement policies of government and third-party payers.

If the health care community does not accept our product candidates 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 our product candidates, the use of our product candidates could be severely limited. \**

Our ability to successfully commercialize our product candidates 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. 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;
- 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.

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

The United States Supreme Court recently heard oral arguments regarding the constitutionality of the PPACA, and a ruling on the matter is expected as early as June 2012. If the United States Supreme Court rules that the PPACA is unconstitutional, we may need to adjust to the new competitive environment, and new legislation could later become law that could adversely affect the pharmaceutical industry.

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

## **Table of Contents**

### **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.*

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. As an example, one of the components of GRN1005, paclitaxel, is considered a cytotoxic agent, which makes the manufacturing of GRN1005 subject to additional regulations, and limits the number of manufacturing facilities in which GRN1005 can be made. 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. 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 could subject us to significant liabilities, including joint and several liability under certain statutes. Any such liability 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 our research and manufacturing facilities and operations.

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.

*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 our product candidates is alleged to have injured subjects or patients. This risk exists for our product candidates currently being tested in human clinical trials as well as product candidates that are sold commercially in the future. 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.

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

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

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. Since the latter half of 2008, broad distress in the financial markets and the economy has resulted in greatly increased market uncertainty and instability in both U.S. and international capital and credit markets. These conditions, combined with foreign credit concerns, declining business and consumer confidence and high unemployment have recently contributed to substantial market volatility. This 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.

## **Table of Contents**

Historically, our stock price has been extremely volatile. Between January 1, 2002 and March 31, 2012, our stock has traded as high as \$16.80 per share and as low as \$1.35 per share. Between January 1, 2009 and March 31, 2012, the price has ranged between a high of \$9.24 per share and a low of \$1.35 per share. The significant market price fluctuations of our common stock are due to a variety of factors, including:

- announcements regarding our clinical trial results;
- the demand in the market for our common stock;
- the experimental nature of our product candidates;
- 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;
- general market conditions;
- the issuance of common stock to partners, vendors or to investors to raise additional capital; and
- the occurrence of any of those risks and uncertainties discussed in this Item 1A Risk Factors .

*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. For example, after we announced the discontinuation of our stem cell business, our stock price declined 20%. Further, if the results of our Phase 2 trials are not successful, or if we are unable to receive what stockholders believe to be adequate compensation for our stem cell assets, our stock price would likely decline, and may result in litigation. Securities-related litigation may be filed in the future and 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. Monitoring and defending against legal actions is time-consuming for our management, is 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.

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

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

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 March 31, 2012, we had 200,000,000 shares of common stock authorized for issuance and 132,104,026 shares of common stock outstanding. In addition, as of March 31, 2012, we had reserved approximately 36,870,641 shares of common stock for future issuance pursuant to our option and equity incentive plans, potential milestone payments and outstanding warrants. At our 2012 annual meeting of stockholders, we are seeking stockholder approval of an increase in the number of authorized shares of common stock from 200,000,000 to 300,000,000 shares, and if the proposal is approved, the additional shares could be used, without further stockholder approval, for various purposes including, without limitation, raising additional capital, which could negatively affect the market price of our common stock.



## **Table of Contents**

In addition, we have issued common stock to certain third parties, such as vendors and service providers, as payment for products and services. Under these arrangements, we have typically agreed to register the shares for resale soon after their issuance. We may continue to pay for certain goods and services in this manner, which would dilute your interest in us. Also, sales of the shares issued in this manner could negatively affect the market price of our common stock.

Future sales of the shares of the common stock, or the registration for sale of such common stock, 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. By way of example, in July 2009 we filed a universal shelf registration statement to sell any combination of debt securities, common stock, preferred stock and warrants in one or more offerings. The cumulative value allowed to be sold of all securities under this universal shelf registration statement is limited to \$250 million and as of March 31, 2012, we have approximately \$113 million remaining available. The sale or issuance of such stock, as well as the existence of outstanding options and shares of common stock reserved for issuance under our option and equity incentive plans, potential milestone payments 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.

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 change of control 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.

## **Table of Contents**

*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.*

Section 404 of the Sarbanes-Oxley Act of 2002 (the Sarbanes-Oxley Act) 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 of the Sarbanes-Oxley Act 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.

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

None.

#### **Purchases of Equity Securities by the Issuer and Affiliated Purchasers**

None.

### **ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

### **ITEM 4. MINE SAFETY DISCLOSURES**

None.

### **ITEM 5. OTHER INFORMATION**

None.

**Table of Contents****ITEM 6. EXHIBITS**

<b>Exhibit Number</b>	<b>Description</b>	<b>Incorporation by Reference</b>			<b>Filing Date</b>	<b>Filed Herewith</b>
		<b>Filing</b>	<b>File No.</b>	<b>Exhibit Number</b>		
10.1	Form of Indemnification Agreement	10-K	000-20859	10.1	March 7, 2012	
10.2	Employment agreement between the Registrant and Graham Cooper, dated January 1, 2012	10-K	000-20859	10.27	March 7, 2012	
10.3	Transition and Separation Agreement between the Registrant and David L. Greenwood, dated February 7, 2012	10-K	000-20859	10.29	March 7, 2012	
10.4	Separation Agreement between the Registrant and Jane S. Lebkowski, dated December 7, 2011.	10-K	000-20859	10.30	March 7, 2012	
10.5	Consulting Agreement between the Registrant and Jane S. Lebkowski, dated January 14, 2012	10-K	000-20859	10.31	March 7, 2012	
10.6	Employment agreement between the Registrant and Stephen N. Rosenfield, dated February 16, 2012	10-K	000-20859	10.32	March 7, 2012	
10.7	Office Lease Agreement by and between the Registrant and Exponent Realty, LLC, dated February 29, 2012	10-K/A	000-20859	10.36	March 27, 2012	
10.8	Transition and Separation Agreement between the Registrant and David J. Earp, dated April 2, 2012					X
10.9	Amended and Restated 2006 Directors Stock Option Plan					X
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 May 7, 2012.					X
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 May 7, 2012.					X
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 May 7, 2012.					X
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 May 7, 2012.					X
101	The following materials from the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2012, formatted in Extensible Business Reporting Language (XBRL) include: (i) Condensed Consolidated Balance Sheets as of March 31, 2012 and December 31, 2011, (ii) Condensed Consolidated Statements of Operations for the three months ended March 31, 2012 and 2011, (iii) Condensed Consolidated Statements of Comprehensive Loss for the three months ended March 31, 2012 and 2011, (iv) Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2012 and 2011, and (v) Notes to Condensed Consolidated Financial Statements.*					X

**Table of Contents**

---

Confidential treatment has been granted for certain portions of this exhibit. Omitted information has been filed separately with the Securities and Exchange Commission.

- \* 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.

**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: May 7, 2012

By: /s/ GRAHAM K. COOPER  
Graham K. Cooper  
Executive Vice President, Finance and Business  
Development, and Chief Financial Officer  
(Duly Authorized Signatory)

**Table of Contents****EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description</b>	<b>Incorporation by Reference</b>			<b>Filing Date</b>	<b>Filed Herewith</b>
		<b>Filing</b>	<b>File No.</b>	<b>Exhibit Number</b>		
10.1	Form of Indemnification Agreement	10-K	000-20859	10.1	March 7, 2012	
10.2	Employment agreement between the Registrant and Graham Cooper, dated January 1, 2012	10-K	000-20859	10.27	March 7, 2012	
10.3	Transition and Separation Agreement between the Registrant and David L. Greenwood, dated February 7, 2012	10-K	000-20859	10.29	March 7, 2012	
10.4	Separation Agreement between the Registrant and Jane S. Lebkowski, dated December 7, 2011.	10-K	000-20859	10.30	March 7, 2012	
10.5	Consulting Agreement between the Registrant and Jane S. Lebkowski, dated January 14, 2012	10-K	000-20859	10.31	March 7, 2012	
10.6	Employment agreement between the Registrant and Stephen N. Rosenfield, dated February 16, 2012	10-K	000-20859	10.32	March 7, 2012	
10.7	Office Lease Agreement by and between the Registrant and Exponent Realty, LLC, dated February 29, 2012	10-K/A	000-20859	10.36	March 27, 2012	
10.8	Transition and Separation Agreement between the Registrant and David J. Earp, dated April 2, 2012					X
10.9	Amended and Restated 2006 Directors' Stock Option Plan					X
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 May 7, 2012.					X
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 May 7, 2012.					X
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 May 7, 2012.					X
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 May 7, 2012.					X
101	The following materials from the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2012, formatted in Extensible Business Reporting Language (XBRL) include: (i) Condensed Consolidated Balance Sheets as of March 31, 2012 and December 31, 2011, (ii) Condensed Consolidated Statements of Operations for the three months ended March 31, 2012 and 2011, (iii) Condensed Consolidated Statements of Comprehensive Loss for the three months ended March 31, 2012 and 2011, (iv) Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2012 and 2011, and (v) Notes to Condensed Consolidated Financial Statements.*					X

**Table of Contents**

---

Confidential treatment has been granted for certain portions of this exhibit. Omitted information has been filed separately with the Securities and Exchange Commission.

- \* 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.
-