

GERON CORP
Form 10-Q
November 05, 2014
[Table of Contents](#)

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2014

OR

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

For the transition period from to .

GERON CORPORATION

(Exact name of registrant as specified in its charter)

DELAWARE

(State or other jurisdiction of
incorporation or organization)

75-2287752

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

149 COMMONWEALTH DRIVE, SUITE 2070, MENLO PARK, CA

(Address of principal executive offices)

94025

(Zip Code)

(650) 473-7700

(Registrant's telephone number, including area code)

N/A

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

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

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

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

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

Accelerated filer
Smaller reporting company

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

Edgar Filing: GERON CORP - Form 10-Q

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

Class:
Common Stock, \$0.001 par value

Outstanding at October 31, 2014:
157,211,487 shares

Table of Contents

GERON CORPORATION

QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTER ENDED SEPTEMBER 30, 2014

TABLE OF CONTENTS

	Page
<u>PART I. FINANCIAL INFORMATION</u>	
<u>Item 1:</u>	
<u>Condensed Financial Statements (Unaudited)</u>	1
<u>Condensed Balance Sheets as of September 30, 2014 and December 31, 2013</u>	1
<u>Condensed Statements of Operations for the three and nine months ended September 30, 2014 and 2013</u>	2
<u>Condensed Statements of Comprehensive Loss for the three and nine months ended September 30, 2014 and 2013</u>	3
<u>Condensed Statements of Cash Flows for the nine months ended September 30, 2014 and 2013</u>	4
<u>Notes to Condensed Financial Statements</u>	5
<u>Item 2:</u>	
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	17
<u>Item 3:</u>	
<u>Quantitative and Qualitative Disclosures About Market Risk</u>	25
<u>Item 4:</u>	
<u>Controls and Procedures</u>	25
<u>PART II. OTHER INFORMATION</u>	
<u>Item 1:</u>	
<u>Legal Proceedings</u>	26
<u>Item 1A:</u>	
<u>Risk Factors</u>	27
<u>Item 2:</u>	
<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	53
<u>Item 3:</u>	
<u>Defaults Upon Senior Securities</u>	53
<u>Item 4:</u>	
<u>Mine Safety Disclosures</u>	53
<u>Item 5:</u>	
<u>Other Information</u>	53
<u>Item 6:</u>	
<u>Exhibits</u>	53
<u>SIGNATURE</u>	54

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

	SEPTEMBER 30, 2014 (UNAUDITED)	DECEMBER 31, 2013 (NOTE 1)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 7,600	\$ 12,990
Restricted cash	265	795
Current portion of marketable securities	118,801	52,234
Interest and other receivables	787	564
Prepaid assets	739	474
Total current assets	128,192	67,057
Noncurrent portion of marketable securities	15,801	
Property and equipment, net	63	92
Deposits and other assets	191	195
	\$ 144,247	\$ 67,344
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	\$ 2,365	\$ 1,397
Accrued compensation and benefits	2,685	3,946
Accrued restructuring charges		94
Accrued liabilities	2,018	1,783
Fair value of derivatives	1	367
Total current liabilities	7,069	7,587
Commitments and contingencies		
Stockholders' equity:		
Common stock	157	131
Additional paid-in capital	1,056,543	952,403
Accumulated deficit	(919,486)	(892,763)
Accumulated other comprehensive loss	(36)	(14)
Total stockholders' equity	137,178	59,757
	\$ 144,247	\$ 67,344

See accompanying notes.

Table of Contents

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

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2014	2013	2014	2013
Revenues:				
License fees and royalties	\$ 160	\$ 181	\$ 975	\$ 1,058
Operating expenses:				
Research and development	5,994	5,338	16,356	18,066
Restructuring charges		116		1,032
General and administrative	4,073	3,460	11,920	11,643
Total operating expenses	10,067	8,914	28,276	30,741
Loss from operations	(9,907)	(8,733)	(27,301)	(29,683)
Unrealized gain (loss) on derivatives	289	(208)	366	(207)
Interest and other income	91	699	273	836
Interest and other expense	(22)	(12)	(61)	(44)
Net loss	\$ (9,549)	\$ (8,254)	\$ (26,723)	\$ (29,098)
Basic and diluted net loss per share	\$ (0.06)	\$ (0.06)	\$ (0.18)	\$ (0.23)
Shares used in computing basic and diluted net loss per share	156,843,989	128,293,074	152,338,668	128,146,333

See accompanying notes.

Table of Contents

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

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2014	2013	2014	2013
Net loss	\$ (9,549)	\$ (8,254)	\$ (26,723)	\$ (29,098)
Net unrealized (loss) gain on marketable securities	(16)	1	(22)	(52)
Comprehensive loss	\$ (9,565)	\$ (8,253)	\$ (26,745)	\$ (29,150)

See accompanying notes.

Table of Contents

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

	NINE MONTHS ENDED SEPTEMBER 30,	
	2014	2013
Cash flows from operating activities:		
Net loss	\$ (26,723)	\$ (29,098)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	38	357
Accretion and amortization on investments, net	2,221	948
Loss (gain) on retirement/sales of property and equipment, net	3	(759)
Loss on write-downs of property and equipment		200
Stock-based compensation for services by non-employees	172	136
Stock-based compensation for employees and directors	5,752	3,456
Amortization related to 401(k) contributions	99	449
Unrealized (gain) loss on derivatives	(366)	207
Changes in assets and liabilities:		
Other current and noncurrent assets	(484)	904
Other current liabilities	161	(6,679)
Net cash used in operating activities	(19,127)	(29,879)
Cash flows from investing activities:		
Restricted cash transfer	530	(1)
Purchases of property and equipment	(12)	(56)
Proceeds from sales of property and equipment		1,116
Purchases of marketable securities	(159,172)	(57,446)
Proceeds from sales of marketable securities	4,513	
Proceeds from maturities of marketable securities	70,048	73,301
Net cash (used in) provided by investing activities	(84,093)	16,914
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of issuance costs	97,830	493
Net cash provided by financing activities	97,830	493
Net decrease in cash and cash equivalents	(5,390)	(12,472)
Cash and cash equivalents at the beginning of the period	12,990	22,063
Cash and cash equivalents at the end of the period	\$ 7,600	\$ 9,591

See accompanying notes.

Table of Contents

GERON CORPORATION

NOTES TO CONDENSED FINANCIAL STATEMENTS

SEPTEMBER 30, 2014

(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 financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. generally accepted accounting principles for complete financial statements. In the opinion of management of Geron, all adjustments (consisting only of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three and nine month periods ending September 30, 2014 are not necessarily indicative of the results that may be expected for the year ending December 31, 2014 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, 2013, included in the Company's Annual Report on Form 10-K. The accompanying condensed balance sheet as of December 31, 2013 has been derived from audited financial statements at that date.

Net Loss Per Share

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

Because we are in a net loss position, diluted loss per share excludes the effects of potential dilutive securities. Had we been in a net income position, diluted earnings per share would have included the shares used in the computation of basic net loss per share as well as an additional 1,926,886 and 138,344 shares for the three months ended September 30, 2014 and 2013, respectively, and 3,205,962 and 7,183 shares for the nine months ended September 30, 2014 and 2013, respectively, related to outstanding stock options, restricted stock awards and warrants (as determined using the treasury stock method at the estimated average market value).

Use of Estimates

Edgar Filing: GERON CORP - Form 10-Q

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.

Fair Value of Financial Instruments

Cash Equivalents and Marketable Securities

We consider all highly liquid investments with an original maturity of three months or less to be cash equivalents. We are subject to credit risk related to our cash equivalents and marketable securities. We place our cash and cash equivalents in money market funds and cash operating accounts. Our marketable securities include U.S. government-sponsored enterprise securities, commercial paper and corporate notes with original maturities ranging from five to 19 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 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 before recovery of the amortized cost basis. 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. We have not recorded any other-than-temporary impairment charges on our available-for-sale securities for the three and nine months ended September 30, 2014 and 2013. See Note 2 on Fair Value Measurements.

Table of Contents

GERON CORPORATION

NOTES TO CONDENSED FINANCIAL STATEMENTS

SEPTEMBER 30, 2014

(UNAUDITED)

Non-Marketable Equity Investments

Non-marketable equity investments in 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 non-marketable equity investments in companies 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 our 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. See Note 3 on Divestiture of Stem Cell Assets.

Fair Value of Derivatives

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

Nonmonetary Transactions

We account for nonmonetary transactions based on the fair values of the assets (or services) involved. The cost of a nonmonetary asset acquired in exchange for another nonmonetary asset is the fair value of the asset surrendered to obtain it with a gain or loss recognized on the exchange. We use the fair value of the asset received to measure the cost if it is more clearly evident than the fair value of the asset surrendered. If the fair value of neither the assets received nor the assets relinquished is determinable within reasonable limits, we use the recorded amount (or carrying value) of the nonmonetary assets relinquished to account for the exchange. Similarly, we use carrying value for an exchange of controlled assets that do not meet the definition of a business for a non-controlling non-marketable equity interest in a company with no gain or loss recognized

on the exchange. See Note 3 on Divestiture of Stem Cell Assets.

Table of Contents

GERON CORPORATION
NOTES TO CONDENSED FINANCIAL STATEMENTS
SEPTEMBER 30, 2014
(UNAUDITED)

Revenue Recognition

We have entered into several license agreements with various oncology, diagnostics, research tools and biologics production companies. With certain of these agreements, we receive non-refundable license payments in cash or equity securities, option payments in cash or equity securities, cost reimbursements, milestone payments, royalties on future sales of products, or any combination of these items. Upfront non-refundable signing, license or non-exclusive option fees are recognized as revenue when rights to use the intellectual property related to the license have been delivered and over the term of the agreement if we have continuing performance obligations. We recognize revenue under collaborative agreements as the related research and development costs for services are rendered. Milestone payments, which are subject to substantive contingencies, are recognized as revenue 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 unearned portion of research and license payments received. When payments are received in equity securities, we do not recognize any revenue unless such securities are determined to be realizable in cash.

Restricted Cash

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

(In thousands)	September 30, 2014	December 31, 2013
Certificate of deposit for unused equipment line of credit	\$	\$ 530
Certificate of deposit for credit card purchases	265	265
	\$ 265	\$ 795

In the third quarter of 2014, we closed the certificate of deposit for our unused equipment line of credit upon maturity and transferred the cash proceeds to our cash operating accounts. This action also canceled the availability of the equipment line of credit.

Research and Development Expenses

Edgar Filing: GERON CORP - Form 10-Q

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

Clinical Trial Costs

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

Table of Contents

GERON CORPORATION
NOTES TO CONDENSED FINANCIAL STATEMENTS
SEPTEMBER 30, 2014
(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 stock-based compensation expense on a straight-line basis over the requisite service period, which is generally the vesting period. The following table summarizes the stock-based compensation expense included in operating expenses on our condensed statements of operations related to stock options, restricted stock awards and employee stock purchases for the three and nine months ended September 30, 2014 and 2013 which was allocated as follows:

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Research and development	\$ 653	\$ 483	\$ 1,932	\$ 1,394
Restructuring charges				28
General and administrative	1,356	739	3,820	2,034
Stock-based compensation expense included in operating expenses	\$ 2,009	\$ 1,222	\$ 5,752	\$ 3,456

Modifications to the post-termination exercise period of outstanding options held by certain members of our executive management team resulted in additional stock-based compensation expense of \$205,000 for the three and nine months ended September 30, 2013. In addition, in connection with the April 2013 restructuring, the post-termination exercise period for certain stock options previously granted to terminated employees was extended through the end of December 2013 resulting in the recognition of \$28,000 of non-cash stock-based compensation expense for the nine months ended September 30, 2013. Stock-based compensation expense resulting from these modifications has been reflected in the table above. See Note 4 on Restructuring for a further discussion of the April 2013 restructuring.

As stock-based compensation expense recognized in our condensed statements of operations for the three and nine months ended September 30, 2014 and 2013 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures, but at a minimum, reflects the grant-date fair value of those awards that actually vested in the period. Forfeitures have been estimated at the time of grant based on historical data and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Stock Options

We grant options with service-based vesting under our equity plans to employees, non-employee directors and consultants. The vesting period for employee options is generally four years. The fair value of options granted during the nine months ended September 30, 2014 and 2013 has been estimated at the date of grant using the Black Scholes option-pricing model with the following assumptions:

	Nine Months Ended September 30,	
	2014	2013
Dividend yield	0%	0%
Expected volatility range	0.898 to 0.922	0.742 to 0.759
Risk-free interest rate range	1.64% to 1.92%	0.80% to 1.81%
Expected term	5.5 yrs	6 yrs

Table of Contents

GERON CORPORATION
NOTES TO CONDENSED FINANCIAL STATEMENTS
SEPTEMBER 30, 2014
(UNAUDITED)

Employee Stock Purchase Plan

The fair value of employees' purchase rights during the nine months ended September 30, 2014 and 2013 has been estimated using the Black Scholes option-pricing model with the following assumptions:

	Nine Months Ended September 30,	
	2014	2013
Dividend yield	0%	0%
Expected volatility range	0.835 to 1.666	0.506 to 1.391
Risk-free interest rate range	0.06% to 0.15%	0.09% to 0.21%
Expected term range	6 12 mos	6 12 mos

Dividend yield is based on historical cash dividend payments. The expected volatility is based on historical volatilities of our stock since traded options on Geron stock do not correspond to option terms and the trading volume of 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 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.

Restricted Stock Awards

We have granted restricted stock awards to employees and non-employee directors with service-based vesting schedules that generally vest annually over four years. The fair value for service-based restricted stock awards is determined using the fair value of our common stock on the date of grant. The fair value is amortized as stock-based compensation expense over the requisite service period of the award, which is generally the vesting period, on a straight-line basis and is reduced for estimated forfeitures, as applicable.

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 statements of operations.

Recent Accounting Pronouncements

In April 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standard Update No. 2014-08, Presentation of Financial Statements and Property, Plant, and Equipment: Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity, or ASU 2014-08. ASU 2014-08 raised the threshold for a disposal of assets to qualify as a discontinued operation and requires new disclosures for both discontinued operations and disposals of individually significant components of a business that do not qualify as discontinued operations. Under the new guidance, only disposals of assets representing a strategic shift in operations that has a major effect on the entity's operations and financial results should be presented as discontinued operations. If the disposal does qualify as a discontinued operation, the entity will be required to provide expanded disclosures, as well as disclosure of the pretax income attributable to the disposal of a significant part of an entity that does not qualify as a discontinued operation. ASU 2014-08 will be effective for us beginning January 1, 2015 and subsequent interim periods. We do not expect the adoption of ASU 2014-08 to have a material effect on our financial statements.

In May 2014, the FASB issued Accounting Standard Update No. 2014-09, Revenue from Contracts with Customers, or ASU 2014-09. ASU 2014-09 provides a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. ASU 2014-09 will require an entity to recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. This update creates a five-step model that requires entities to exercise judgment when considering the terms of the contract(s). The five-step model includes (i) identifying the contract(s) with the customer, (ii) identifying the separate performance obligations in the contract, (iii) determining the transaction price, (iv) allocating the transaction price to the separate performance obligations, and

Table of Contents

GERON CORPORATION

NOTES TO CONDENSED FINANCIAL STATEMENTS

SEPTEMBER 30, 2014

(UNAUDITED)

(v) recognizing revenue when each performance obligation is satisfied. ASU 2014-09 also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. ASU 2014-09 will be effective for us beginning January 1, 2017 and subsequent interim periods. We have the option to apply the provisions of ASU 2014-09 either retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of applying this accounting standard recognized at the date of initial application. Early adoption is not permitted. We are currently evaluating the transition method and the impact that the adoption of ASU 2014-09 will have on our financial statements.

In August 2014, the FASB issued ASU No. 2014-15, Presentation of Financial Statements – Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern, or ASU 2014-15. ASU 2014-15 is intended to define management’s responsibility to evaluate whether there is substantial doubt about an organization’s ability to continue as a going concern and to provide related footnote disclosures. Substantial doubt about an entity’s ability to continue as a going concern exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year after the date that the financial statements are issued (or available to be issued). ASU 2014-15 provides guidance to an organization’s management, with principles and definitions that are intended to reduce diversity in the timing and content of disclosures that are commonly provided by organizations in financial statement footnotes. ASU 2014-15 is effective for us beginning December 31, 2016 and subsequent interim periods. Early adoption is permitted. We are currently in the process of evaluating the impact of adoption of ASU 2014-15 on our financial statements and related disclosures.

2. FAIR VALUE MEASUREMENTS

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

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

Edgar Filing: GERON CORP - Form 10-Q

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

Cash Equivalents and Marketable Securities

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 FINANCIAL STATEMENTS
SEPTEMBER 30, 2014
(UNAUDITED)

Cash equivalents, restricted cash and marketable securities by security type at September 30, 2014 were as follows:

	Amortized Cost		Gross Unrealized Gains		Gross Unrealized Losses		Estimated Fair Value
	(In thousands)						
Included in cash and cash equivalents:							
Money market funds	\$ 5,445	\$		\$		\$	5,445
Restricted cash:							
Certificate of deposit	\$ 265	\$		\$		\$	265
Marketable securities:							
Government-sponsored enterprise securities (due in less than 1 year)	\$ 1,909	\$	1	\$	(1)	\$	1,909
Government-sponsored enterprise securities (due in 1 to 2 years)	3,751				(3)		3,748
Commercial paper (due in less than 1 year)	12,981		18				12,999
Corporate notes (due in less than 1 year)	103,927		4		(38)		103,893
Corporate notes (due in 1 to 2 years)	12,070		1		(18)		12,053
	\$ 134,638	\$	24	\$	(60)	\$	134,602

Cash equivalents, restricted cash and marketable securities by security type at December 31, 2013 were as follows:

	Amortized Cost		Gross Unrealized Gains		Gross Unrealized Losses		Estimated Fair Value
	(In thousands)						
Included in cash and cash equivalents:							
Money market funds	\$ 8,079	\$		\$		\$	8,079
Corporate notes	2,206						2,206
	\$ 10,285	\$		\$		\$	10,285
Restricted cash:							
Certificates of deposit	\$ 795	\$		\$		\$	795
Marketable securities:							
Government-sponsored enterprise securities (due in less than 1 year)	\$ 7,369	\$	1	\$	(1)	\$	7,369
Commercial paper (due in less than 1 year)	5,496		3				5,499
Corporate notes (due in less than 1 year)	39,383		1		(18)		39,366
	\$ 52,248	\$	5	\$	(19)	\$	52,234

Edgar Filing: GERON CORP - Form 10-Q

Marketable securities with unrealized losses at September 30, 2014 and December 31, 2013 were as follows:

	Less Than 12 Months		12 Months or Greater		Total	
	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses
	(In thousands)					
As of September 30, 2014:						
Government-sponsored enterprise securities (due in less than 1 year)	\$ 401	\$ (1)	\$	\$	\$ 401	\$ (1)
Government-sponsored enterprise securities (due in 1 to 2 years)	3,748	(3)			3,748	(3)
Corporate notes (due in less than 1 year)	77,087	(38)			77,087	(38)
Corporate notes (due in 1 to 2 years)	11,222	(18)			11,222	(18)
	\$ 92,458	\$ (60)	\$	\$	\$ 92,458	\$ (60)

Table of Contents

GERON CORPORATION

NOTES TO CONDENSED FINANCIAL STATEMENTS

SEPTEMBER 30, 2014

(UNAUDITED)

	Less Than 12 Months		12 Months or Greater		Total	
	Estimated	Gross	Estimated	Gross	Estimated	Gross
	Fair Value	Unrealized	Fair Value	Unrealized	Fair Value	Unrealized
		Losses		Losses		Losses
As of December 31, 2013:						
Government-sponsored enterprise securities (due in less than 1 year)	\$ 3,947	\$ (1)	\$	\$	\$ 3,947	\$ (1)
Corporate notes (due in less than 1 year)	37,060	(18)			37,060	(18)
	\$ 41,007	\$ (19)	\$	\$	\$ 41,007	\$ (19)

The gross unrealized losses related to government-sponsored enterprise securities and corporate notes as of September 30, 2014 and December 31, 2013 were due to changes in interest rates. We determined that the gross unrealized losses on our marketable securities as of September 30, 2014 and December 31, 2013 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 amortized 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 before recovery of the amortized cost basis. We currently do not intend to sell these securities before recovery of their amortized cost basis.

Derivatives

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

Options held by non-employees whose performance obligations are complete are classified as derivative liabilities on our condensed balance sheets. Upon the exercise of these options, the instruments are marked to fair value and reclassified from derivative liabilities to stockholders equity. We have not reclassified any derivative liabilities to stockholders equity for any non-employee option exercises during the nine months ended September 30, 2014.

As of September 30, 2014 and December 31, 2013, the following non-employee options to purchase common stock were considered derivatives and classified as current liabilities:

Edgar Filing: GERON CORP - Form 10-Q

Issuance Date	Exercise Price	Exercisable Date	Expiration Date	September 30, 2014		December 31, 2013	
				Number of Shares	Fair Value (In thousands)	Number of Shares	Fair Value (In thousands)
March 2005	\$ 6.39	January 2007	March 2015	284,600	\$ 1	284,600	\$ 367

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

	September 30, 2014	December 31, 2013
Dividend yield	0%	0%
Expected volatility	0.635	0.844
Risk-free interest rate	0.03%	0.13%
Expected term	0.5 yr	1 yr

Dividend yield is based on historical cash dividend payments. The expected volatility is based on historical volatilities of our stock since trading volume of Geron options is limited. The risk-free interest rate is based on the U.S. Zero Coupon Treasury Strip Yields for the expected term of the derivatives in effect on the reporting date. The expected term of derivatives is equal to the remaining contractual term of the instruments.

Fair Value on a Recurring Basis

The following table presents information about our financial instruments that are measured at fair value on a recurring basis as of September 30, 2014 and indicates the fair value category assigned.

Table of Contents

GERON CORPORATION
NOTES TO CONDENSED FINANCIAL STATEMENTS
SEPTEMBER 30, 2014
(UNAUDITED)

(In thousands)	Fair Value Measurements at Reporting Date Using				Total
	Quoted Prices in Active Markets for Identical Assets / Liabilities Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3		
Assets					
Money market funds (1)	\$ 5,445	\$	\$	\$	5,445
Government-sponsored enterprise securities (2)(3)			5,657		5,657
Commercial paper (2)			12,999		12,999
Corporate notes (2)(3)			115,946		115,946
Total	\$ 5,445	\$	134,602	\$	\$ 140,047
Liabilities					
Derivatives (4)	\$	\$	\$	1	\$ 1

The following table presents information about our financial instruments that are measured at fair value on a recurring basis as of December 31, 2013 and indicates the fair value category assigned.

(In thousands)	Fair Value Measurements at Reporting Date Using				Total
	Quoted Prices in Active Markets for Identical Assets / Liabilities Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3		
Assets					
Money market funds (1)	\$ 8,079	\$	\$	\$	8,079
Government-sponsored enterprise securities (2)			7,369		7,369
Commercial paper (2)			5,499		5,499
Corporate notes (1)(2)			41,572		41,572
Total	\$ 8,079	\$	54,440	\$	\$ 62,519
Liabilities					
Derivatives (4)	\$	\$	\$	367	\$ 367

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

- (2) Included in current portion of marketable securities on our condensed balance sheets.
- (3) Included in noncurrent portion of marketable securities on our condensed balance sheets.
- (4) Included in fair value of derivatives on our condensed balance sheets.

Changes in Level 3 Recurring Fair Value Measurements

The table below includes a rollforward of the balance sheet amounts for the three and nine months ended September 30, 2014, 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 FINANCIAL STATEMENTS

SEPTEMBER 30, 2014

(UNAUDITED)

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)
Three Months Ended September 30, 2014

(In thousands)	Fair Value at June 30, 2014	Total Unrealized Gain Included in Earnings (1)	Purchases and Issuances	Sales and Settlements	Transfers In and/or Out of Level 3	Fair Value at September 30, 2014	Change in Unrealized Gain Related to Financial Instruments Held at September 30, 2014 (1)
Derivative liabilities	\$ 290	\$ (289)	\$	\$	\$	\$ 1	\$ (289)

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)
Nine Months Ended September 30, 2014

(In thousands)	Fair Value at December 31, 2013	Total Unrealized Gain Included in Earnings (1)	Purchases and Issuances	Sales and Settlements	Transfers In and/or Out of Level 3	Fair Value at September 30, 2014	Change in Unrealized Gain Related to Financial Instruments Held at September 30, 2014 (1)
Derivative liabilities	\$ 367	\$ (366)	\$	\$	\$	\$ 1	\$ (366)

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

3. DIVESTITURE OF STEM CELL ASSETS

On October 1, 2013, we closed the transaction to divest our human embryonic stem cell assets and our autologous cellular immunotherapy program pursuant to the terms of the previously disclosed asset contribution agreement, or the Contribution Agreement, that we entered into in January 2013 with BioTime, Inc., or BioTime, and BioTime's subsidiary, Asterias Biotherapeutics, Inc., or Asterias (formerly known as BioTime Acquisition Corporation).

In accordance with the terms of the Contribution Agreement, on October 1, 2013 we received 6,537,779 shares of Asterias Series A common stock representing 21.4% of Asterias' outstanding common stock as a class as of that date. In accordance with our contractual obligations under the Contribution Agreement, we distributed all of the shares of Asterias Series A common stock to our stockholders on a pro rata basis, other than with respect to fractional shares and shares that would otherwise have been distributed to Geron stockholders residing in certain excluded jurisdictions, which shares, as required by the Contribution Agreement, were sold with the net cash proceeds therefrom distributed ratably to the stockholders who would otherwise have been entitled to receive such shares. We refer to the distribution by us of the Asterias Series A common

Edgar Filing: GERON CORP - Form 10-Q

stock, or cash in lieu thereof, as the Series A Distribution. We completed the Series A Distribution to eligible stockholders on August 15, 2014. As of September 30, 2014, we have no remaining obligations for the Series A Distribution.

We applied the equity method of accounting to our investment in Asterias Series A common stock. Asterias incurred net losses from October 1, 2013 through August 15, 2014. Since our investment in Asterias had an initial carrying amount of zero upon the closing of the transactions contemplated by the Contribution Agreement on October 1, 2013 and we had no commitments to provide financial support or obligations to perform services or other activities for Asterias, we suspended the equity method of accounting on October 1, 2013. Accordingly, the completion of the Series A Distribution had no impact on our condensed financial statements.

4. RESTRUCTURING

On April 25, 2013, we announced the decision to discontinue our discovery research programs and companion diagnostics program based on telomere length and close our research laboratory facility located at 200 Constitution Drive, Menlo Park, California. With this decision, a total of 20 positions were eliminated. In connection with this restructuring, we incurred aggregate restructuring charges of \$1,370,000 for the year ended December 31, 2013, of which \$940,000 was recorded during the nine months ended September 30, 2013. As of September 30, 2013, the restructuring charges recognized under the April 2013 restructuring included \$624,000 related to one-time

Table of Contents**GERON CORPORATION****NOTES TO CONDENSED FINANCIAL STATEMENTS****SEPTEMBER 30, 2014****(UNAUDITED)**

termination benefits, including \$28,000 of non-cash stock-based compensation expense relating to the extension of the post-termination exercise period through the end of December 2013 for certain stock options previously granted to terminated employees, \$200,000 related to non-cash charges for write-downs of excess equipment and leasehold improvements and \$116,000 related to costs associated with the closure of our research laboratory facility. The remaining restructuring charges related to costs associated with the closure of our research laboratory facility and were recorded in the fourth quarter of 2013. All actions associated with this restructuring were completed in 2013, and we do not anticipate incurring any further charges in connection with this restructuring.

The components of the accrued restructuring charges relating to the April 2013 restructuring are summarized in the following table. As of September 30, 2014, we have no remaining obligations under the April 2013 restructuring.

(In thousands)	Employee Severance and Other Benefits	Facility Related Charges	Total
Beginning accrual balance as of December 31, 2013	\$ 21	\$ 73	\$ 94
Cash payments	(19)	(73)	(92)
Adjustments or non-cash credits	(2)		(2)
Ending accrual balance as of September 30, 2014	\$	\$	\$

5. COMMITMENTS AND CONTINGENCIES**Purported Securities and Derivative Lawsuits**

On March 14, 2014, a purported securities class action lawsuit was commenced in the United States District Court for the Northern District of California, or the California District Court, naming as defendants us and certain of our officers. The lawsuit alleges violations of the Securities Exchange Act of 1934 in connection with allegedly false and misleading statements made by us related to our Phase 2 trial of imetelstat in patients with essential thrombocythemia, or ET, or polycythemia vera, or PV. The plaintiff alleges, among other things, that we failed to disclose facts related to the occurrence of persistent low-grade liver function test, or LFT, abnormalities observed in our Phase 2 trial of imetelstat in ET or PV patients and the potential risk of chronic liver injury following long-term exposure to imetelstat. The plaintiff seeks damages and an award of reasonable costs and expenses, including attorneys' fees. On March 28, 2014, a second purported securities class action lawsuit was commenced in the California District Court, and on June 6, 2014, a third purported securities lawsuit, not styled as a class action, was commenced in the United States District Court for the Southern District of Mississippi, or the Mississippi District Court, naming as defendants us and certain of our officers. These lawsuits, which are based on the same factual background as the purported securities class action lawsuit that commenced on March 14, 2014, also allege violations of the Securities Exchange Act of 1934 and seek damages and an award of reasonable costs and expenses, including attorneys' fees. On June 30, 2014, the California District Court consolidated both of the purported class

Edgar Filing: GERON CORP - Form 10-Q

actions filed in the California District Court and appointed a lead plaintiff and lead counsel to represent the purported class. On July 21, 2014, the California District Court ordered the lead plaintiff to file its consolidated amended complaint, which was filed on September 19, 2014. Our response to the consolidated amended complaint is due by November 18, 2014. On August 11, 2014, we filed a motion to transfer the purported securities lawsuit filed in the Mississippi District Court to the California District Court so it can be consolidated with the purported class action lawsuits. On November 4, 2014, the Mississippi District Court granted our motion and transferred the case to the California District Court, and we intend to seek to consolidate the transferred case with the purported class action lawsuits filed in the California District Court.

On April 21, 2014, a stockholder purporting to act on our behalf filed a derivative lawsuit in the Superior Court of California for the County of San Mateo against certain of our officers and directors. The lawsuit alleges breaches of fiduciary duties by the defendants and other violations of law. In general, the lawsuit alleges that the defendants caused or allowed the dissemination of allegedly false and misleading statements related to our Phase 2 trial of imetelstat in patients with ET or PV. The plaintiff is seeking unspecified monetary damages and other relief, including reforms and improvements to our corporate governance and internal procedures.

For a further discussion of these ongoing lawsuits, refer to the section entitled "Legal Proceedings" in Part II, Item 1 of this Form 10-Q. These lawsuits and any other related lawsuits are subject to inherent uncertainties, and the actual defense and disposition costs will depend upon many unknown factors. The outcome of these lawsuits is necessarily uncertain. We could be forced to expend significant resources in the defense against these and any other related lawsuits and we may not prevail. We currently are not able to estimate the possible cost to us from these lawsuits, as they are currently at an early stage, and we cannot be certain how long it may take to resolve these lawsuits or the possible amount of any damages that we may be required to pay. Such amounts could be material to our financial statements even if we prevail in the defense against these lawsuits. We have not established any reserves for any potential liability relating to these lawsuits. It is possible that we could, in the future, incur judgments or enter into settlements of claims for monetary damages.

Table of Contents

GERON CORPORATION
NOTES TO CONDENSED FINANCIAL STATEMENTS
SEPTEMBER 30, 2014
(UNAUDITED)

6. STOCKHOLDERS EQUITY

On February 4, 2014, we completed an underwritten public offering of 25,875,000 shares of our common stock at a public offering price of \$4.00 per share, resulting in net cash proceeds of approximately \$96,805,000 after deducting the underwriting discount and offering expenses payable by us.

7. SEGMENT INFORMATION

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

8. CONDENSED STATEMENTS OF CASH FLOWS DATA

Supplemental schedule of non-cash operating and investing activities:

(In thousands)	Nine Months Ended September 30,	
	2014	2013
Supplemental Operating Activities:		
Issuance of common stock for 401(k) matching contributions	\$ 313	\$ 839
Reclassification of deposits to other current assets, net		219
Supplemental Investing Activities:		
Net unrealized loss on marketable securities	(22)	(52)

9. SUBSEQUENT EVENT

Removal of Full Clinical Hold on Imetelstat IND

Effective October 31, 2014 the U.S. Food and Drug Administration removed the full clinical hold on our investigational new drug application for imetelstat which enables us to resume clinical development, including initiation of new clinical trials.

Table of Contents

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

FORWARD-LOOKING STATEMENTS

This Form 10-Q contains forward-looking statements that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause the results of the Company to differ materially from those expressed or implied by such forward-looking statements. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. In some cases, forward-looking statements can be identified by the use of terminology such as may, expect, plan, intend, will, should, project, predict, anticipate, estimate, potential or continue, or the negative thereof or other comparable terminology. These statements are within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements appear throughout the Form 10-Q and are statements regarding our intent, belief, or current expectations, primarily with respect to our business 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 financial statements and notes thereto included in Part I, Item 1 of this Form 10-Q and with Management's Discussion and Analysis of Financial Condition and Results of Operations contained in our Annual Report on Form 10-K for the year ended December 31, 2013, as filed with the Securities and Exchange Commission, or SEC, on March 17, 2014.

We are a clinical stage biopharmaceutical company developing a telomerase inhibitor, imetelstat, in hematologic myeloid malignancies. The discovery and early development of imetelstat, our sole product candidate, was based on our core expertise in telomerase and telomere biology. Telomerase is an enzyme that enables cancer cells, including malignant progenitor cells, to maintain telomere length, which provides them with the capacity for limitless, uncontrolled proliferation.

Imetelstat is a potent and specific inhibitor of telomerase. Using our proprietary nucleic acid chemistry, we designed imetelstat to be an oligonucleotide that targets and binds with high affinity to the active site of telomerase, thereby directly inhibiting telomerase activity and impeding malignant cell proliferation. We developed imetelstat from inception, and we own exclusive worldwide commercial rights for imetelstat with United States, or U.S., patent coverage extending through 2025.

We intend to develop imetelstat to treat one or more hematologic myeloid malignancies such as myelofibrosis, or MF, which includes patients with primary MF, or PMF, post essential thrombocythemia MF, or post ET MF, or post polycythemia vera MF, or post PV MF, all of which are referred to collectively in this document as MF; myelodysplastic syndromes, or MDS; or acute myelogenous leukemia, or AML.

Edgar Filing: GERON CORP - Form 10-Q

We have incurred operating losses every year since our operations began in 1990. Losses have resulted principally from costs incurred in connection with our research and development activities and from general and administrative costs associated with our operations. Substantially all of our revenues to date have been research support payments under collaborative agreements, and milestones, royalties and other revenues from our licensing arrangements. We currently have no source of product revenue. Since inception, we have primarily financed our operations through the sale of equity securities, interest income on our marketable securities and payments we received under our collaborative and licensing arrangements. As of September 30, 2014, we had an accumulated deficit of \$919.5 million. We expect to incur additional operating losses and, as clinical development activities continue, our operating losses may increase in size.

Table of Contents

Our future revenues will depend on the successful development of imetelstat and the clinical and commercial success of imetelstat. In this regard, imetelstat, which is our sole product candidate, will require significant additional clinical testing prior to possible regulatory approval in the U.S. and other countries, and we do not expect imetelstat to be commercially available for many years, if at all. 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. In any event, any revenues generated from collaborative agreements and revenues from our licensing arrangements may not be sufficient alone to sustain our operations.

As of September 30, 2014, we had cash, restricted cash, cash equivalents and marketable securities of \$142.5 million compared to \$66.0 million at December 31, 2013. We estimate that our existing capital resources and future interest income will be sufficient to fund our current level of operations through at least the next 12 months. However, our future capital requirements will be substantial, and we may use our available capital resources sooner than we anticipate.

Developing Imetelstat to Treat Hematologic Myeloid Malignancies

Removal of Full Clinical Hold on Geron's IND for Imetelstat

In March 2014, we received written notice from the FDA that our Investigational New Drug application, or IND, for imetelstat had been placed on full clinical hold following the U.S. Food and Drug Administration's, or FDA's, review of safety data in our then ongoing clinical studies. A full clinical hold is an order that the FDA issues to a trial sponsor to suspend all ongoing clinical trials and delay all proposed trials under a given IND. With this clinical hold, any patients in an ongoing Geron-sponsored clinical trial could not receive any further treatment with imetelstat. Therefore, we stopped imetelstat treatment in our Phase 2 Geron-sponsored clinical trials in ET and multiple myeloma, or MM. For our Phase 2 ET trial, eight patients were affected and for our Phase 2 MM trial, two patients were affected.

In their notice to us, the FDA cited the following safety issues as the basis for the clinical hold: lack of evidence of reversibility of hepatotoxicity, risk for chronic liver injury and lack of adequate follow up in patients who experienced hepatotoxicity. To address the clinical hold, we were required to provide clinical follow up information on patients who experienced liver function test, or LFT, abnormalities until LFT abnormalities resolved to normal or baseline and to provide information regarding the reversibility of the liver toxicity after chronic imetelstat administration in animals.

We submitted a complete response to the FDA to seek release of the full clinical hold. In the complete response, we provided clinical follow-up information from patients in the previously ongoing Geron-sponsored Phase 2 trials in ET and MM. Our analysis of these data concluded that in the ET trial, LFT abnormalities resolved to normal or baseline in 14 of 18 follow-up patients. For the remaining four ET patients, at the time of the data cut-off, three showed improvement in LFT abnormalities and one had unresolved LFT abnormalities. Two of the remaining four ET patients continue in follow-up. In the MM trial, LFT abnormalities resolved to normal or baseline in all nine follow-up patients. In addition, no emergent hepatic adverse events were reported during follow-up for either study. We also provided data from our previously conducted non-clinical toxicology studies, which included a six-month study in mice and a nine-month study in cynomolgus monkeys. In those studies, no clinical pathology changes indicative of hepatocellular injury were observed, and no clear signal of LFT abnormalities were identified.

Edgar Filing: GERON CORP - Form 10-Q

On October 31, 2014, the FDA removed the full clinical hold on our IND for imetelstat. In addition, the FDA stated that our proposed clinical development plan for imetelstat that is focused on high-risk myeloid malignancies, such as MF, is acceptable. The FDA acknowledged that we do not intend to conduct further studies in, or develop imetelstat for, the treatment of ET or polycythemia vera, which is consistent with our plans as originally disclosed in April 2013. With the removal of the full clinical hold, a multi-center Phase 2 clinical trial in MF is projected to begin in the first half of 2015.

Pilot Study in Myelofibrosis and Other Myeloid Malignancies (MF Pilot Study)

In November 2012, Dr. Ayalew Tefferi at Mayo Clinic, Rochester, Minnesota, initiated an investigator-sponsored trial, or the MF Pilot Study, to assess the effect of imetelstat in patients with MF. Preliminary efficacy and safety data from this trial were presented by the investigator at the American Society of Hematology, or ASH, Annual Meeting in December 2013. In the MF Pilot Study, the investigator is also evaluating imetelstat in patients with refractory anemia with ringed sideroblasts, or RARS, a subpopulation of MDS, and patients with MF that has transformed into AML, known as blast-phase MF. Data we receive from the MF Pilot Study regarding patients with RARS-MDS or blast-phase MF may inform, in part, our decision to initiate one or more potential studies of imetelstat in MDS or AML.

Table of Contents

In January 2014, Mayo Clinic closed the MF Pilot Study to new patient enrollment. Mayo Clinic's notification informing us of its decision to cease new patient enrollment did not indicate any concerns regarding efficacy or safety. In March 2014, we were informed by Mayo Clinic that the investigator's IND for the MF Pilot Study was placed on partial clinical hold by the FDA due to a safety signal of hepatotoxicity that was identified in our Phase 2 clinical trials of imetelstat and that it was unknown if this hepatotoxicity was reversible. In order to resolve the partial clinical hold, the investigator was required to provide follow-up information regarding reversibility of hepatotoxicity for all patients who received imetelstat in the MF Pilot Study. The investigator submitted a complete response to the FDA to seek release of the partial clinical hold, and the partial hold was lifted by the FDA on June 11, 2014.

On July 31, 2014, we and Mayo Clinic entered into an agreement under which Mayo Clinic and the investigator agreed to transfer to us certain data and information from the MF Pilot Study, and agreed that we will assume full responsibility for the investigator's IND, as well as responsibility for the conduct of the MF Pilot Study as the trial sponsor. In September 2014, the investigator's IND, under which the MF Pilot Study has been conducted, was transferred to us and we assumed responsibility for the MF Pilot Study as the trial sponsor. Dr. Tefferi continues as the principal investigator for the trial. As of October 15, 2014, 23 patients out of the 80 patients enrolled in the MF Pilot Study continue to receive imetelstat treatment, which includes 17 out of 62 patients with MF, five out of nine patients with RARS-MDS and one out of nine patients with blast-phase MF. We do not intend to enroll additional patients in the MF Pilot Study. The remaining patients in the MF Pilot Study will continue to receive imetelstat treatment and we will continue to collect data and information from the MF Pilot Study.

The investigator has informed us that he has submitted an abstract for the ASH annual meeting in December 2014 in which he has analyzed certain safety and efficacy data from MF patients in the MF Pilot Study and updated his analysis from the preliminary data he presented in December 2013. In accordance with ASH policies, abstracts submitted to the ASH annual meeting are embargoed from the time of submission. To be eligible for presentation at the ASH annual meeting, information contained in the abstract, as well as additional data and information to be presented at the annual meeting, may not be made public before the abstract has been published/presented in connection with the ASH annual meeting. We have not reviewed or independently analyzed the data selected by the investigator for inclusion in the abstract. Our analyses may result in conclusions that are materially different from the investigator's analyses and therefore additional or updated data should be considered carefully and with caution. Please refer to the risk factor entitled, *Risks Related to Our Business* Success in early clinical trials may not be indicative of results in subsequent clinical trials. Likewise, data reported by investigators from time-to-time is subject to review and verification procedures that could result in material differences to final data and may change as more patient data becomes available. In Part II, Item 1A entitled, *Risk Factors*, in this Form 10-Q.

Stem Cell Divestiture; Completion of Asterias Series A Distribution

On October 1, 2013, we closed the transaction to divest our human embryonic stem cell assets and our autologous cellular immunotherapy program pursuant to the terms of the previously disclosed asset contribution agreement, or the Contribution Agreement, that we entered into in January 2013 with BioTime, Inc., or BioTime, and BioTime's subsidiary, Asterias Biotherapeutics, Inc., or Asterias (formerly known as BioTime Acquisition Corporation) and received 6,537,779 shares of Asterias Series A common stock. In accordance with our contractual obligations under the Contribution Agreement, we distributed all of the shares of Asterias Series A common stock to our stockholders on a pro rata basis, or cash in lieu thereof. We completed the Series A Distribution to eligible stockholders on August 15, 2014 and have no remaining obligations for the Series A Distribution. See further discussion in Note 3 on Divestiture of Stem Cell Assets in Notes to Condensed Financial Statements of this quarterly report on Form 10-Q.

Table of Contents

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

There have been no significant changes in our critical accounting policies and estimates during the nine months ended September 30, 2014 as compared to the critical accounting policies and estimates disclosed in our Annual Report on Form 10-K for the year ended December 31, 2013 that materially impact our condensed financial statements.

Our condensed 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 Financial Statements of this Form 10-Q describes the significant accounting policies used in the preparation of the condensed 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 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 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 have fluctuated from period to period and may continue to fluctuate in the future, based upon the progress of our research and development efforts and variations in the level of expenses related to developmental efforts during any given period. Results of operations for any period may be unrelated to results of operations for any other period. In addition, historical results should not be viewed as indicative of future operating results. We are subject to risks common to companies in our industry and at our stage of development, including, but not limited to, risks inherent in research and development efforts, our dependence on the success of our sole product candidate, imetelstat, uncertainty of preclinical and clinical trial results or regulatory approvals or clearances, need for future capital, enforcement of our patent and proprietary rights, reliance upon our collaborators, investigators and other third parties, and potential competition. In order for imetelstat to be commercialized based on our research, we and our collaborators must conduct preclinical tests and clinical trials, demonstrate the safety and efficacy of imetelstat, obtain regulatory approvals or clearances and enter into manufacturing, distribution and marketing arrangements, as well as obtain market acceptance. We do not expect to receive revenues or royalties based on imetelstat for many years, if at all.

Revenues

We have entered into license and option agreements with companies involved with oncology, diagnostics, research tools and biologics production. In each of these agreements, we have granted certain rights to our technologies. In connection with the agreements, we are eligible to receive license fees, option fees, milestone payments and royalties on future sales of products, or any combination thereof. We recognized license fee revenues of \$100,000 and \$635,000 for the three and nine months ended September 30, 2014, respectively, compared to \$117,000 and \$782,000 for the comparable 2013 periods related to our various agreements. The decrease in license fee revenues for the nine months ended

Edgar Filing: GERON CORP - Form 10-Q

September 30, 2014 compared to the comparable 2013 period primarily reflects the full recognition of a non-refundable up-front license payment in 2013 for an exclusive commercial license using our telomerase promoter technology for oncology-related in vitro assays. We recognized royalty revenues of \$60,000 and \$340,000 for the three and nine months ended September 30, 2014, respectively, compared to \$64,000 and \$276,000 for the comparable 2013 periods on product sales of telomerase detection and telomere measurement kits to the research-use-only market and cell-based research products. The increase in royalty revenues for the nine months ended September 30, 2014 compared to the comparable 2013 periods primarily reflects the receipt of a milestone fee in the second quarter of 2014 in connection with the achievement of a net sales milestone by a licensee of our human telomerase reverse transcriptase technology. Current revenues may not be predictive of future revenues. Future license and royalty revenues are dependent upon additional agreements being signed and current agreements being maintained.

Table of Contents**Research and Development Expenses**

For our research and development programs, we incur direct external, personnel related and other research and development costs. Direct external expenses primarily consist of costs to outside parties to perform laboratory studies, develop manufacturing processes and manufacture raw materials and clinical trial drug materials, conduct and manage clinical trials, including investigator-sponsored clinical trials, and provide advice and consultation for scientific, clinical and regulatory strategies. Personnel related expenses primarily consist of salaries and wages, stock-based compensation, payroll taxes and benefits for those individuals involved with ongoing research and development efforts. Other research and development expenses primarily consist of laboratory supplies, research-related overhead associated with leasing, operating and maintaining our facilities and equipment depreciation and maintenance. All of these costs apply to our current and historical clinical programs and our historical preclinical programs and discovery research efforts. A product candidate is designated a clinical candidate once an IND has been filed with the FDA, or a similar filing with regulatory agencies outside the United States, for the purpose of commencing clinical trials in humans. Preclinical programs represented product candidates undergoing toxicology, pharmacology, metabolism and efficacy studies and manufacturing process development required before testing in humans could commence.

Research and development expenses were \$6.0 million and \$16.4 million for the three and nine months ended September 30, 2014, respectively, compared to \$5.3 million and \$18.1 million for the comparable 2013 periods. The increase in research and development expenses for the three months ended September 30, 2014 compared to the comparable 2013 period is primarily the net result of an increase in direct external costs for the manufacturing of imetelstat drug product, partially offset by lower imetelstat clinical trial costs as a result of the full clinical hold placed on our IND for imetelstat by the FDA in March 2014. The decrease in research and development expenses for the nine months ended September 30, 2014 compared to the comparable 2013 period is primarily the net result of lower direct external costs due to the wind-down of our GRN1005 trials in patients with brain metastases and imetelstat trials in solid tumors, reduced personnel related costs resulting from previous restructurings and lower costs for scientific supplies and services and other research-related overhead costs due to the discontinuation of our discovery research programs in April 2013, partially offset by an increase in direct external costs for the manufacturing of imetelstat drug product. Overall, we expect research and development expenses to increase as we advance the development of imetelstat in hematologic myeloid malignancies.

Research and development expenses for the three and nine months ended September 30, 2014 and 2013 were as follows:

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
			(Unaudited)	
Direct external research and development expenses:				
Clinical program: Imetelstat	\$ 3,341	\$ 2,450	\$ 7,531	\$ 5,343
Clinical program: GRN1005 (1)		36		1,087
Clinical program: GRNOPC1 (2)		44		199
Preclinical programs (3)		1		225
Personnel related expenses	2,172	2,059	7,227	8,556
All other research and development expenses	481	748	1,598	2,656
Total	\$ 5,994	\$ 5,338	\$ 16,356	\$ 18,066

(1) In December 2012, we discontinued the GRN1005 program and returned the asset to Angiochem, Inc. in May 2013.

Edgar Filing: GERON CORP - Form 10-Q

(2) On October 1, 2013, we closed the transaction to divest our human embryonic stem cell assets and our autologous cellular immunotherapy program to Asterias. Asterias assumed all post-closing liabilities with respect to all of the assets contributed by us, including any liabilities related to the GRNOPC1 and autologous cellular immunotherapy clinical trials.

(3) In April 2013, we announced the decision to discontinue our discovery research programs and companion diagnostics program based on telomere length and close our research laboratory facility located at 200 Constitution Drive, Menlo Park, California.

Table of Contents

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

Restructuring Charges

In April 2013, we announced the decision to discontinue our discovery research programs and companion diagnostics program based on telomere length and close our research laboratory facility located at 200 Constitution Drive, Menlo Park, California. With this decision, a total of 20 positions were eliminated. In connection with this restructuring, we incurred aggregate restructuring charges of approximately \$1.4 million for the year ended December 31, 2013, of which \$940,000 was recorded during the nine months ended September 30, 2013. As of September 30, 2013, the restructuring charges recognized under the April 2013 restructuring included \$624,000 related to one-time termination benefits, including \$28,000 of non-cash stock-based compensation expense relating to the extension of the post-termination exercise period through the end of December 2013 for certain stock options previously granted to terminated employees, \$200,000 related to non-cash charges for write-downs of excess equipment and leasehold improvements and \$116,000 related to costs associated with the closure of our research laboratory facility. The remaining restructuring charges related to costs associated with the closure of our research laboratory facility and were recorded in the fourth quarter of 2013. All actions associated with this restructuring were completed in 2013, and we have no remaining obligations under the April 2013 restructuring. See Note 4 on Restructuring in Notes to Condensed Financial Statements of this Form 10-Q for further discussion of the restructuring charges.

General and Administrative Expenses

General and administrative expenses were \$4.1 million and \$11.9 million for the three and nine months ended September 30, 2014, respectively, compared to \$3.5 million and \$11.6 million for the comparable 2013 periods. The increase in general and administrative expenses for the three and nine months ended September 30, 2014 compared to the comparable 2013 periods is primarily the net result of higher non-cash stock-based compensation expense and increased legal costs associated with the purported securities lawsuits and the derivative lawsuit filed against us and/or certain of our officers and directors, partially offset by reduced patent costs and transaction fees associated with the stem cell divestiture which closed in October 2013. We expect our legal expenses to increase during the remainder of 2014 as we intend to vigorously defend against the lawsuits filed against us.

Unrealized Gain (Loss) on Derivatives

Unrealized gain (loss) on derivatives reflects a non-cash adjustment for changes in fair value of options held by non-employees that are classified as current liabilities. Derivatives classified as assets or liabilities are marked to fair value at each financial reporting date with any resulting unrealized gain (loss) recorded in the condensed statements of operations. We incurred unrealized gains on derivatives of \$289,000 and \$366,000 for the three and nine months ended September 30, 2014, respectively, compared to unrealized losses on derivatives of \$208,000 and \$207,000 for the comparable 2013 periods. The unrealized gains and losses on derivatives for the three and nine months ended September 30, 2014 and 2013 primarily reflected the change in fair values of derivative liabilities as a result of fluctuations in the market value of our stock and changes in other inputs factored into the estimate of their fair value such as the volatility of our stock. See Note 2 on Fair Value Measurements in Notes to Condensed Financial Statements of this Form 10-Q for further discussion of the fair value of derivatives.

Table of Contents

Interest and Other Income

Interest income was \$91,000 and \$273,000 for the three and nine months ended September 30, 2014, respectively, compared to \$47,000 and \$184,000 for the comparable 2013 periods. The increase in interest income for the three and nine months ended September 30, 2014 compared to the comparable 2013 periods is primarily due to an increase in our marketable securities portfolio in connection with the receipt of the net cash proceeds from the underwritten public offering of shares of our common stock that we completed in February 2014. Interest earned in future periods will depend on the size of our marketable securities portfolio and prevailing interest rates.

Other income was \$652,000 for the three and nine months ended September 30, 2013 representing a net gain on the sale of excess laboratory equipment in connection with the closure of our research laboratory facility. No comparable amounts were recognized for the three and nine months ended September 30, 2014.

Interest and Other Expense

Interest and other expense was \$22,000 and \$61,000 for the three and nine months ended September 30, 2014, respectively, compared to \$12,000 and \$44,000 for the comparable 2013 periods. The increase in interest and other expense for the three and nine months ended September 30, 2014 compared to the comparable 2013 periods is primarily due to higher bank charges related to the increase in our cash and investment balances in connection with the receipt of the net cash proceeds from the underwritten public offering of shares of our common stock that we completed in February 2014.

Net Loss

Net loss was \$9.5 million and \$26.7 million for the three and nine months ended September 30, 2014, respectively, compared to \$8.3 million and \$29.1 million for the comparable 2013 periods. The increase in net loss for the three months ended September 30, 2014 compared to the comparable 2013 period is primarily due to higher operating expenses related to costs for the manufacturing of imetelstat drug product and increased non-cash stock-based compensation expense. The decrease in net loss for the nine months ended September 30, 2014 compared to the comparable 2013 period is primarily due to reduced operating expenses as a result of the wind-down of our GRN1005 trials in patients with brain metastases and imetelstat trials in solid tumors, decreased personnel related costs resulting from previous restructurings, reduced costs for scientific supplies and services and other research-related overhead costs with the discontinuation of our discovery research programs in April 2013 and lower patent costs and transaction fees associated with the stem cell divestiture which closed in October 2013.

LIQUIDITY AND CAPITAL RESOURCES

Cash, restricted cash, cash equivalents and marketable securities at September 30, 2014 were \$142.5 million, compared to \$66.0 million at December 31, 2013. We estimate that our existing capital resources and future interest income will be sufficient to fund our current level of

Edgar Filing: GERON CORP - Form 10-Q

operations through at least the next 12 months. We have an investment policy to invest these funds in liquid, investment grade securities, such as interest-bearing money market funds, certificates of deposit, municipal securities, U.S. government and agency securities, corporate notes and commercial paper. Our investment portfolio does not contain securities with exposure to sub-prime mortgages, collateralized debt obligations, asset-backed securities or auction rate securities and, to date, we have not recognized any other-than-temporary impairment charges on our marketable securities or any significant changes in aggregate fair value that would impact our cash resources or liquidity. To date, we have not experienced lack of access to our invested cash and cash equivalents; however, access to our invested cash and cash equivalents may be impacted by adverse conditions in the financial and credit markets. The increase in cash, restricted cash, cash equivalents and marketable securities in 2014 was the result of the receipt of net cash proceeds of approximately \$96.8 million, after deducting the underwriting discount and offering expenses payable by us, from an underwritten public offering of 25,875,000 shares of our common stock at a public offering price of \$4.00 per share that we completed in February 2014.

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

Table of Contents

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 2014 and beyond;

- changes or delays in our development plans for imetelstat, including changes which may result from any future clinical holds on our IND or any other INDs, including the IND for the MF Pilot Study that was transferred to us in September 2014, for imetelstat;

- our ability to meaningfully reduce manufacturing costs of imetelstat;

- the timing, magnitude and scope of our imetelstat research and development program, including the number of indications we may pursue, subject to permission from the FDA;

- the progress made, if any, in our imetelstat research and development program, including existing or potential future Geron-sponsored and investigator-sponsored clinical trials;

- our ability to establish, enforce and maintain strategic arrangements for research, development, clinical testing, manufacturing and marketing of imetelstat;

- the time and costs involved in obtaining regulatory clearances and approvals in the United States and in other countries;

- the sales price and availability of adequate third-party reimbursement for imetelstat;

- expenses associated with the pending and potential additional related purported securities lawsuits and derivative lawsuits, as well as any other litigation; and

- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims.

Edgar Filing: GERON CORP - Form 10-Q

In addition, changes in our business may occur that would consume available capital resources sooner than we expect. If our existing capital resources and future interest income are insufficient to meet future capital requirements, we will need to raise additional capital to fund our operations. We anticipate that we will need to seek additional funding through public or private equity financings, including pursuant to our sales agreement with MLV, or other financing sources that may be available, including debt financings or collaborative and licensing arrangements. However, we may be unable to raise sufficient additional capital when we need it, on favorable terms or at all. Our ability to raise additional funds will be severely impaired if future clinical holds are placed on our IND or any other INDs, including the IND for the MF Pilot Study that was transferred to us in September 2014, for imetelstat, or if imetelstat fails to show adequate safety or efficacy in existing or potential future clinical trials, including the MF Pilot Study. 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 collaborative agreements on unattractive terms or we may be required to relinquish rights to technology or imetelstat or to grant licenses on terms that are unfavorable to us, or we may otherwise be required to delay, reduce the scope of, suspend or eliminate some or all of the elements of our imetelstat program, any of which could have a material adverse effect on our business.

Cash Flows from Operating Activities. Net cash used in operations for the nine months ended September 30, 2014 and 2013 was \$19.1 million and \$29.9 million, respectively. The decrease in net cash used in operations in 2014 compared to 2013 primarily reflects the wind-down of our GRN1005 trials in patients with brain metastases and imetelstat trials in solid tumors, decreased personnel related costs resulting from previous restructurings, reduced costs for scientific supplies and services and other research-related overhead costs with the discontinuation of our discovery research programs in April 2013 and lower patent costs and transaction fees associated with the stem cell divestiture which closed in October 2013.

Table of Contents

Cash Flows from Investing Activities. Net cash used in investing activities for the nine months ended September 30, 2014 was \$84.1 million. Net cash provided by investing activities for the nine months ended September 30, 2013 was \$16.9 million. The decrease in net cash provided by investing activities in 2014 compared to 2013 primarily reflects higher purchases of marketable securities with the net cash proceeds received from an underwritten public offering of shares of our common stock that we completed in February 2014.

In the third quarter of 2014, we closed the certificate of deposit for our unused equipment line of credit upon maturity and transferred the cash proceeds to our cash operating accounts. This action also canceled the availability of the equipment line of credit.

Cash Flows from Financing Activities. Net cash provided by financing activities was \$97.8 million and \$493,000 for the nine months ended September 30, 2014 and 2013, respectively. Net cash provided by financing activities in 2014 primarily reflects the receipt of net cash proceeds of approximately \$96.8 million, after deducting the underwriting discount and offering expenses payable by us, from an underwritten public offering of 25,875,000 shares of our common stock at a public offering price of \$4.00 per share that we completed in February 2014.

Contractual Obligations

Our future minimum contractual obligations were reported in our Annual Report on Form 10-K for the year ended December 31, 2013, as filed with the SEC.

On February 27, 2014, we amended the lease agreement for our premises at 149 Commonwealth Drive to extend the lease term from July 2014 through January 2016. Operating lease obligations under the amended lease agreement for the extended lease term include aggregate future minimum payments of \$1.4 million.

Other than as described above, there have been no other material changes from the contractual obligations previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2013.

Off-Balance Sheet Arrangements

We have not engaged in any off-balance sheet arrangements, including the use of structured finance, special purpose entities or variable interest entities.

ITEM 3.

QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Edgar Filing: GERON CORP - Form 10-Q

During the nine months ended September 30, 2014, 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, 2013.

ITEM 4. CONTROLS AND PROCEDURES

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

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

Table of Contents

(b) *Changes in Internal Control Over Financial Reporting.* There was no change in our internal control over financial reporting for the three months ended September 30, 2014 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On March 14, 2014, a purported securities class action lawsuit was commenced in the United States District Court for the Northern District of California, or the California District Court, naming as defendants us and certain of our officers. The lawsuit alleges violations of the Securities Exchange Act of 1934 in connection with allegedly false and misleading statements made by us related to our Phase 2 trial of imetelstat in patients with ET or PV. The plaintiff alleges, among other things, that we failed to disclose facts related to the occurrence of persistent low-grade LFT abnormalities observed in our Phase 2 trial of imetelstat in ET or PV patients and the potential risk of chronic liver injury following long-term exposure to imetelstat. The plaintiff seeks damages and an award of reasonable costs and expenses, including attorneys' fees. On March 28, 2014, a second purported securities class action lawsuit was commenced in the California District Court, and on June 6, 2014, a third purported securities lawsuit, not styled as a class action, was commenced in the United States District Court for the Southern District of Mississippi, or the Mississippi District Court, naming as defendants us and certain of our officers. These lawsuits, which are based on the same factual background as the purported securities class action lawsuit that commenced on March 14, 2014, also allege violations of the Securities Exchange Act of 1934 and seek damages and an award of reasonable costs and expenses, including attorneys' fees. On June 30, 2014, the California District Court consolidated both of the purported class actions filed in the California District Court and appointed a lead plaintiff and lead counsel to represent the purported class. On July 21, 2014, the California District Court ordered the lead plaintiff to file its consolidated amended complaint, which was filed on September 19, 2014. Our response to the consolidated amended complaint is due by November 18, 2014. On August 11, 2014, we filed a motion to transfer the purported securities lawsuit filed in the Mississippi District Court to the California District Court so it can be consolidated with the purported class action lawsuits. On November 4, 2014, the Mississippi District Court granted our motion and transferred the case to the California District Court, and we intend to seek to consolidate the transferred case with the purported class action lawsuits filed in the California District Court. It is possible that additional suits will be filed, or allegations made by stockholders, with respect to these same or other matters and also naming us and/or our officers and directors as defendants. We believe that we have meritorious defenses and intend to defend against these lawsuits vigorously.

On April 21, 2014, a stockholder purporting to act on our behalf filed a derivative lawsuit in the Superior Court of California for the County of San Mateo against certain of our officers and directors. The lawsuit alleges breaches of fiduciary duties by the defendants and other violations of law. In general, the lawsuit alleges that the defendants caused or allowed the dissemination of allegedly false and misleading statements related to our Phase 2 trial of imetelstat in patients with ET or PV. The plaintiff is seeking unspecified monetary damages and other relief, including reforms and improvements to our corporate governance and internal procedures. It is possible that additional derivative lawsuits will be filed with respect to these same or other matters and also naming our officers and directors as defendants. We have not yet responded to the derivative lawsuit, but intend to vigorously defend against the claims alleged and to seek dismissal of the lawsuit.

These lawsuits and any other related lawsuits are subject to inherent uncertainties, and the actual defense and disposition costs will depend upon many unknown factors. The outcome of these lawsuits is necessarily uncertain. We could be forced to expend significant resources in the defense against these and any other related lawsuits and we may not prevail. We currently are not able to estimate the possible cost to us from these lawsuits, as they are currently at an early stage, and we cannot be certain how long it may take to resolve these lawsuits or the possible amount of any damages that we may be required to pay. Such amounts could be material to our financial statements even if we prevail in the defense against these lawsuits.

Table of Contents

ITEM 1A. RISK FACTORS

Our business is subject to various risks and uncertainties that may have a material adverse effect on our business, financial condition or results of operations. You should carefully consider the risks and uncertainties described below, 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, 2013, or the Form 10-K. Our business faces significant risks and uncertainties, and those described below may not be the only risks and uncertainties we face. Additional risks and uncertainties not presently known to us or that we currently believe are immaterial may also significantly impair our business, financial condition or results of operations. If any of these risks or uncertainties occur, our business, financial condition or results of operations could suffer, the market price of our common stock could decline and you could lose all or part of your investment in our common stock. We have marked with an asterisk () those risks described below that reflect substantive changes from, or additions to, the risks described under Part I, Item 1A, Risk Factors included in the Form 10-K. In addition, the risk factor entitled: The FDA has placed a full clinical hold on our IND for imetelstat, and if we are unable to submit the required information to the FDA to obtain the release of the full clinical hold, or if the FDA does not lift the full clinical hold in a timely manner, or at all, or does not permit us to study imetelstat for other indications, such as under a partial clinical hold, our business will be severely harmed, and we could potentially cease operations that appeared in the Form 10-K has been removed.*

RISKS RELATED TO OUR BUSINESS

*Our success is solely dependent on the success of our sole early stage product candidate, imetelstat, and we cannot be certain that we will be able to continue to pursue the development of imetelstat, advance imetelstat to subsequent clinical trials, or that we will be able to receive regulatory approval for imetelstat on a timely basis, or at all. **

Our business is at an early stage of development, and we are wholly dependent on the success of imetelstat, our sole product candidate. We do not have any products that are commercially available. Although the FDA has removed the full clinical hold on our IND for imetelstat, if patients in current or future clinical trials experience similar or more severe hepatotoxicity, including elevations of liver function tests or severe hepatic adverse events, our IND for imetelstat may again be placed on clinical hold, and we may be precluded from further developing imetelstat. In addition, our ability to develop imetelstat to and through regulatory approval and commercial launch is subject to significant risks and uncertainties and our ability to, among other things:

- maintain the IND that we received from the investigator for the MF Pilot Study without such IND being placed on full or partial clinical hold by the FDA, which could result in discontinuation of imetelstat treatment for the remaining patients in the MF Pilot Study, and would likely reduce the amount and quality of data and information available to us from the MF Pilot Study and delay or jeopardize our receipt of further data and information;
- receive FDA clearance to permit us to study imetelstat for other indications with higher unmet medical need than ET or MM and/or to file for and/or obtain marketing approvals for such indications;

Edgar Filing: GERON CORP - Form 10-Q

- receive positive safety and efficacy data from existing and potential future trials of imetelstat that provide the clinical rationale for the potential or continued development of imetelstat in hematologic myeloid malignancies;
- ascertain that the use of imetelstat does not result in significant systemic or organ toxicities, including hepatotoxicity, or other safety issues resulting in an unacceptable benefit-risk profile;
- develop clinical plans for, and successfully enroll and complete, potential future Geron-sponsored clinical trials of imetelstat in hematologic myeloid malignancies;

Edgar Filing: GERON CORP - Form 10-Q

Table of Contents

- collaborate successfully with clinical trial sites, academic institutions, clinical research organizations, physician investigators, including any physician investigators conducting investigator-sponsored trials of imetelstat, and other third parties;
- obtain positive clinical data from potential future Geron-sponsored clinical trials to enable subsequent clinical trials;
- obtain required regulatory clearances and approvals for imetelstat; for example, it is uncertain:
 - whether the FDA and regulatory authorities in other countries will require us to obtain and submit additional preclinical, manufacturing, or clinical data to proceed with any potential future Geron-sponsored clinical trials,
 - how the FDA and other regulatory authorities will interpret safety and efficacy data from any clinical trial, including the MF Pilot Study,
 - what the required scope and type of clinical development and other data will be before the FDA and other regulatory authorities might grant us clearance to initiate clinical trials or to grant a marketing approval, if any, and
 - what the length of time and cost for us will be to complete any such requirements;
- enter into arrangements with third parties to provide services needed to further research and develop imetelstat, or to manufacture imetelstat, in each case at commercially reasonable costs;
- enter into arrangements with third parties, or establish internal capabilities, to provide sales, marketing and distribution functions in compliance with applicable laws;
- obtain appropriate coverage and reimbursement levels for the cost of imetelstat from governmental authorities, private health insurers and other third-party payors;
- maintain and enforce adequate intellectual property protection for imetelstat;

- maintain adequate financial resources and personnel to advance imetelstat to and through subsequent clinical trials, regulatory approval and commercial launch; and
- obtain financing on commercially reasonable terms to fund our operations.

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

Although the full FDA clinical hold on our IND has been removed, we may be unable to develop, or initiate the development of, imetelstat in subsequent clinical trials in MF or any additional hematologic myeloid malignancies and file for marketing approvals for such indications, which would likely result in our decision to discontinue development of imetelstat and to potentially cease operations. This is because the development of imetelstat will require significant additional clinical testing prior to possible regulatory approval in the United States and other countries. As such, we do not expect imetelstat to be commercially available for many years, if at all. Our clinical development program for imetelstat may not lead to regulatory approval from the FDA and similar foreign regulatory agencies if we fail to demonstrate that imetelstat is safe and effective. We may therefore fail to commercialize imetelstat. Any failure to advance imetelstat to subsequent clinical trials, failure to obtain regulatory approval of imetelstat, or limitations on any regulatory approval that we might receive, would severely harm our business and prospects, and could potentially cause us to cease operations.

Table of Contents

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

If imetelstat were to have an unacceptable benefit-risk profile, our business and prospects could be severely harmed.*

Although the full FDA clinical hold on our IND has been removed, if there are any additional safety results that cause the benefit-risk profile of imetelstat to become unacceptable with respect to patients enrolled in the MF Pilot Study or potential future clinical trials of imetelstat conducted by us or any independent investigator, imetelstat may again be placed on clinical hold, and we would be delayed or prevented from advancing imetelstat into further clinical development and may decide or be required to discontinue our development of imetelstat. In addition, if regulatory submissions requesting approval to market imetelstat are made, after reviewing the data in such submissions, the FDA and regulatory agencies in other countries may conclude that the overall benefit-risk profile of imetelstat treatment, including hepatotoxicity or severe hepatic adverse events, may preclude approval of imetelstat for marketing or further development for any indications, including hematologic malignancies. Any of these events would severely harm our business and prospects, and would likely cause us to cease operations.

Imetelstat may prove to have undesirable or unintended side effects or other characteristics adversely affecting its safety, efficacy or cost effectiveness that could prevent or limit its approval for marketing and successful commercial use, or that could delay or prevent the commencement and/or completion of clinical trials for imetelstat. For example, in our Phase 1 clinical trials of imetelstat, we observed dose-limiting toxicities, including reduced platelet count, or thrombocytopenia, when the drug was used as a single agent, and reduced white blood cell count, or neutropenia, when the drug was used in combination with paclitaxel, as well as a low incidence of severe infusion reactions. In our Phase 2 clinical trials of imetelstat in ET, MM and solid tumors, we have observed hematologic toxicities as well as gastrointestinal events, infections, muscular and joint pain, fatigue and infusion reactions. In addition, in our Phase 2 clinical trials of imetelstat, we have observed LFT abnormalities, the clinical significance and long-term consequences of which are currently undetermined. In our Phase 2 trial in ET, one patient died of bleeding esophageal varices, a complication of chronic liver disease, which was assessed by the investigator as possibly related to imetelstat. In the MF Pilot Study, myelosuppression has been the primary dose-limiting toxicity reported to date, consistent with our observations in previous Geron-sponsored imetelstat studies. However, during the MF Pilot Study, more persistent and profound myelosuppression, particularly thrombocytopenia, was observed with imetelstat administered on a weekly basis. This included one case of febrile neutropenia after prolonged myelosuppression with intracranial hemorrhage resulting in patient death, which was assessed as possibly related to imetelstat by the investigator. In addition, the MF Pilot Study is an ongoing study and we are continuing to assess the benefit-risk profile of imetelstat in MF, including the risk of hepatotoxicity.

Clinical trials by their nature examine the effect of a potential therapy in a sample of the potential future patient population. As such, clinical trials conducted with imetelstat, to date and in the future, may not uncover all possible adverse events that patients treated with imetelstat may experience. We may in the future observe or report dose-limiting or hematologic toxicities or other safety issues in potential future Geron or investigator-sponsored trials of imetelstat. Likewise, because previously enrolled patients continue to receive imetelstat in the MF Pilot Study, we or the investigator may observe or report additional or more severe toxicities or safety issues in the MF Pilot Study, including additional serious adverse events and LFT abnormalities, as patient treatment continues and more data become available. If such toxicities or other safety issues in any Geron-sponsored or investigator-sponsored clinical trial of imetelstat result in an unacceptable benefit-risk profile, this would likely delay or prevent the commencement and/or completion of any clinical trials or investigator-sponsored trials, including the MF Pilot Study, might result in the MF Pilot Study or any potential future Geron-sponsored or investigator-sponsored clinical trial being placed on clinical hold or halted by regulators, such as the previous clinical holds placed by the FDA on our IND for imetelstat and the IND for the MF Pilot Study, and might require us to conduct additional, unforeseen trials or preclinical studies, or to abandon our development of imetelstat entirely which would materially adversely affect our business.

Table of Contents

*Success in early clinical trials may not be indicative of results in subsequent clinical trials. Likewise, data reported by investigators from time-to-time are subject to review or verification procedures that could result in material differences to final data and may change as more patient data become available.**

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

Data from our preclinical studies and Phase 1 and Phase 2 clinical trials of imetelstat, as well as preliminary, additional or updated data from investigator-sponsored trials, including the MF Pilot Study, should not be relied upon as evidence that subsequent or larger-scale clinical trials of imetelstat will succeed. The positive efficacy results we have obtained from the patients enrolled in the Phase 2 clinical trial of imetelstat in ET may not predict the future therapeutic benefit of imetelstat, if any, in other hematologic myeloid malignancies, including MF. For example, the known LFT abnormalities and dose-limiting toxicities associated with imetelstat, such as profound thrombocytopenia and febrile neutropenia and other safety issues, including death, that have been observed in both Geron-sponsored and investigator-sponsored trials, including the MF Pilot Study, could cause complexities in treating patients with MF and could result in the discontinuation of the MF Pilot Study and any future clinical trials of imetelstat. Also, the criteria used to assess efficacy in the MF Pilot Study have not been validated for clinical use and may not be considered by the FDA or other regulatory agencies to be accurate predictors of efficacy for different endpoints that may be required by the FDA or other regulatory agencies for Phase 3 clinical trials.

In addition, although we have assumed responsibility as the trial sponsor of the MF Pilot Study, the MF Pilot Study was initiated by the investigator and therefore we will continue to rely on the investigator's plan and design of the trial. The preliminary efficacy results of the MF Pilot Study presented by the investigator at the ASH annual meeting in December 2013 were based solely on data from the first two cohorts of the MF Pilot Study, consisting of 22 patients, and we are currently assessing the recent data and information we have received for the MF Pilot Study from Mayo Clinic. We will need to confirm the results of the MF Pilot Study in one or more larger Phase 2 and Phase 3 trials in MF at multiple treating centers. The results reported by us or by the investigator in the MF Pilot Study may not be confirmed in any subsequent imetelstat trials conducted by Geron or by any other investigator or group of investigators, or in any trial enrolling a larger number of patients or conducted at multiple treating centers, and thus should not be relied upon as indicative of future clinical results of imetelstat in MF or any other hematologic myeloid malignancy.

In addition, from time-to-time, we may report or announce preliminary data from investigator-sponsored trials and potential future Geron-sponsored trials. For example, we announced our analysis of preliminary efficacy data from the first two cohorts of the MF Pilot Study in December 2013. Since those data were preliminary, the final data from the trial may be materially different than the data we previously reported in December 2013, or may be materially different from the data and information we recently received from Mayo Clinic and are currently assessing. Since patients previously enrolled in the MF Pilot Study continue to receive imetelstat, safety and efficacy data continue to be generated, and such additional and updated data may materially change the overall conclusions from the preliminary data presented by the investigator at the ASH annual meeting in December 2013. Therefore, such preliminary data should be considered carefully and with caution. Additional and updated data from the MF Pilot Study are also subject to any review or verification procedures we may conduct as the trial sponsor for the MF Pilot Study, and since this could result in material differences from the data reported by the investigator, additional or updated data that may be reported by the investigator from the MF Pilot Study should be considered carefully and with caution.

Material adverse changes in final data could significantly harm our business prospects. Even if final safety and efficacy data from the MF Pilot Study are positive, significant additional clinical testing will be necessary for the future development of imetelstat in MF. Any such final safety and efficacy data from the MF Pilot Study may not be reproducible in future clinical trials.

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

Table of Contents

Our research and development of imetelstat is subject to numerous risks and uncertainties.

The science and technology of telomere biology, telomerase and our proprietary oligonucleotide chemistry are relatively new. There is no precedent for the successful commercialization of a therapeutic product candidate based on these technologies. We must undertake significant research and development activities to develop imetelstat based on these technologies, which will require significant additional funding beyond the net proceeds received from our public offering of common stock that closed in February 2014, and may take years to accomplish, if at all.

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

Our stockholders who received Asterias Series A common stock, or cash in lieu thereof, in the Series A Distribution may realize little or no value from the Series A Distribution and the divestiture of our stem cell assets, and as a result we could be subject to litigation, our stock price may decline, and our business may be adversely affected.*

The distribution of the Asterias Series A common stock by us, as well as the distribution by Asterias of the warrants to purchase BioTime, Inc. common stock, or the BioTime Warrants, as contemplated by the Contribution Agreement, and related transactions, as well as the asset contribution transaction itself, could result in litigation against us, including litigation arising from or related to the value, if any, from the Asterias Series A common stock and/or the BioTime Warrants or our role as a named underwriter with respect to the Series A Distribution, or litigation based on other matters related to the Contribution Agreement or the transactions contemplated thereby, including the delays we experienced with respect to the completion of the Series A Distribution. For example, 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 have attributed substantial financial value to our stem cell assets. In addition, the absence of an active public market for Asterias Series A common stock or BioTime Warrants may make it difficult for holders of Asterias Series A common stock to sell their shares of Asterias Series A common stock or BioTime Warrants and may adversely affect the value of the Asterias Series A common stock and the BioTime Warrants. If Geron stockholders who received shares of Asterias Series A common stock in the Series A Distribution believe that the financial value received by them from the divestiture of our former stem cell assets is inadequate, litigation may occur and our stock price may decline. Likewise, litigation against us could also result because Geron stockholders residing in certain excluded jurisdictions did not receive shares of Asterias Series A common stock, and instead only received cash, which may be viewed as inadequate, and resulted in those Geron stockholders having no continuing interest in our divested human embryonic stem cell programs as stockholders or otherwise. In addition, such stockholders were not automatically eligible to receive BioTime Warrants distributed by Asterias. As a result of these and other factors, we may be exposed to a number of risks related to the transactions contemplated by the Contribution Agreement, including declines or fluctuations in our stock price, additional advisor and legal fees, and distractions to our management caused by activities undertaken in connection with resolving any disputes related to the transaction. The occurrence of any one or more of the above could have an adverse impact on our business and financial condition.

Table of Contents

We may not be able to successfully manage our growth and expand our operations.

We plan to advance imetelstat through clinical trials in the United States and abroad. To do so, we will need to expand our clinical development, regulatory, manufacturing, and corporate capabilities, and contract with additional third parties to support our development efforts. As our operations potentially expand, we expect that we will need to manage new and additional relationships with various development partners, service providers, vendors, suppliers and other third parties. Such potential growth and expansion will require members of our management to assume significant added responsibilities. Our performance in managing any such future growth, if ineffective, could negatively impact our business prospects. We may not successfully manage our ongoing development efforts and potential future clinical trials effectively. If we fail to achieve key development goals, our abilities to grow as a company could be prevented or hindered and we could potentially cease operations.

RISKS RELATED TO CLINICAL AND COMMERCIALIZATION ACTIVITIES

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

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

- our inability to obtain regulatory clearance to commence subsequent clinical trials of imetelstat in a timely manner, or at all, in the United States or in other countries;
- our inability to maintain our IND or the IND that we received from the investigator for the MF Pilot Study without such IND being placed on full or partial clinical hold by the FDA;
- our inability to properly design, conduct and/or complete current and potential future Geron-sponsored clinical trials of imetelstat, including the MF Pilot Study;
- data showing lack of effectiveness of imetelstat during clinical trials, or results that do not demonstrate statistically significant efficacy;
- safety issues, side effects or dose-limiting toxicities, including any additional or more severe safety issues related to imetelstat in addition to those which have been observed to date in Geron-sponsored or investigator-sponsored trials, whether or not in the same indications or therapeutic areas;

- disruptions due to drug supply or quality issues;
- failure by independent physicians conducting existing or future investigator-sponsored trials of imetelstat to timely commence, enroll, complete or report data from such investigator-sponsored trials;
- not receiving timely regulatory clearances or approvals in any jurisdiction, whether within or outside of the United States, including, if we or future investigators do not obtain regulatory clearance to commence studies of imetelstat in MF or any additional hematologic myeloid malignancies in a timely manner or at all, or if we do not receive acceptance of new manufacturing specifications or procedures or clinical trial protocol amendments by regulatory authorities;
- not receiving timely institutional review board or ethics committee approval of clinical trial protocols or protocol amendments;
- delays in patient enrollment due to size or nature of patient population, nature of protocols, proximity of patients to clinical sites, availability of effective treatments for the relevant disease and eligibility criteria for the trial;
- inability to retain patients to complete clinical trials or to return for post-treatment follow-up;
- difficulty in obtaining or accessing necessary clinical data, including additional and future data from the MF Pilot Study, which may result in incomplete data sets;
- unavailability of any study-related treatment (including comparator therapy);

Table of Contents

- lack of adequate funding to continue any clinical trial, including funding requirements resulting from unforeseen costs due to enrollment delays or discontinued participation by patients;
- issues with key vendors of clinical services, such as contract research organizations, clinical trial sites and laboratory service providers; or
- governmental or regulatory delays in any jurisdiction, whether within or outside of the United States, information requests, clinical holds, such as the previous clinical holds placed by the FDA on our IND for imetelstat and the IND for the MF Pilot Study, and changes in regulatory requirements, policies and guidelines.

Clinical development of imetelstat in the United States is dependent on us obtaining positive results from existing and potential future Geron-sponsored and investigator-sponsored clinical trials of imetelstat in hematologic myeloid malignancies, including additional and future data from the MF Pilot Study. Our ability to obtain additional and future data from the MF Pilot Study in a timely manner is important for our further development of imetelstat. Accordingly, a delay in the timely completion of the MF Pilot Study, including any delay caused by any future clinical hold placed on the IND for the MF Pilot Study by the FDA, could have a material adverse effect on our ability to further develop imetelstat or to advance imetelstat to subsequent clinical trials. Also, adverse safety results from Geron-sponsored or investigator-sponsored trials of imetelstat, including those results that have been reported and those that may in the future be reported from the MF Pilot Study, could delay or prevent the initiation or continuation of Geron-sponsored clinical development of imetelstat.

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

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

To date, we have not initiated any clinical trials evaluating imetelstat in any hematologic myeloid malignancies (other than ET), including MF. We are currently focused on the development of imetelstat in hematologic myeloid malignancies, other than ET, and clinical development of imetelstat is dependent on us obtaining positive results from existing and potential future clinical trials of imetelstat in hematologic myeloid malignancies. Because investigator-sponsored trials, including the MF Pilot Study, which was not a Geron-sponsored trial until we assumed responsibility as the trial sponsor for the MF Pilot Study in September 2014, are not Geron-sponsored trials, the clinical testing of imetelstat in investigator-sponsored trials requires us to rely on the applicable investigator's design and conduct of the trial, which we do not control, and it is possible that the FDA or other regulatory agencies will not view these investigator-sponsored trials, including the MF Pilot Study, as providing adequate support for future clinical trials, whether controlled by us or third parties, for any one or more reasons, including elements of the design

Edgar Filing: GERON CORP - Form 10-Q

or execution of these investigator-sponsored trials or safety concerns or other trial results. Accordingly, failure by independent physician investigators to properly design or conduct existing or potential future investigator-sponsored trials of imetelstat could produce results that might delay or prevent us from advancing imetelstat into further clinical development. In addition, we do not have control over the timing and reporting of the data from investigator-sponsored trials, nor do we own the data from investigator-sponsored trials. Our arrangements with independent physician investigators may provide us certain information rights with respect to the investigator-sponsored trials, including access to and the ability to use and reference the data, including for our own regulatory filings, resulting from the investigator-sponsored trials. If these obligations are breached by the independent physician investigators, or if the data prove to be inadequate compared to the first-hand knowledge we might have gained had the investigator-sponsored trials been Geron-sponsored clinical trials, or if the data cannot be reviewed or verified by us, including the data from the MF Pilot Study that was transferred to us by Mayo Clinic, then our ability to design and conduct any potential subsequent Geron-sponsored clinical trials may be adversely affected.

Table of Contents

Additionally, the FDA or other regulatory agencies may disagree with our interpretation of clinical data generated by any investigator-sponsored trials, including the data from the MF Pilot Study that was transferred to us by Mayo Clinic. If so, the FDA or other regulatory agencies may require us to obtain and submit additional preclinical, manufacturing, or clinical data before we may initiate potential future Geron-sponsored clinical trials of imetelstat and/or the FDA may not accept such additional data as adequate to initiate any such Geron-sponsored clinical trials. Further, if we are unable to verify or confirm the results from the MF Pilot Study or if negative results are obtained, we would likely be further delayed or prevented from advancing imetelstat into further clinical development and might decide to discontinue our development of imetelstat, which would severely harm our business and prospects, and could potentially cause us to cease operations.

In addition to the matters discussed above, the commencement of subsequent clinical trials for imetelstat could be delayed or abandoned for a variety of reasons, including as a result of failures or delays in:

- obtaining regulatory clearance to commence subsequent clinical trials of imetelstat in a timely manner, or at all, in the U.S. or other countries;
- the ability to properly design, conduct and/or complete current and potential future Geron-sponsored clinical trials of imetelstat, including the MF Pilot Study that we received from Mayo Clinic in September 2014;
- commencing, enrolling or completing clinical trials conducted by physician investigators conducting investigator-sponsored trials, or independent physician investigators promptly or adequately reporting data from such trials;
- demonstrating sufficient safety and efficacy in Phase 2 clinical trials that may in the future be conducted by us or independent physician investigators to obtain regulatory clearance to commence subsequent clinical trials;
- obtaining sufficient funding;
- manufacturing sufficient quantities of imetelstat;
- producing imetelstat in a manner that meets the quality standards of the FDA and other regulatory agencies;
- ensuring our ability to manufacture imetelstat at acceptable costs for Phase 3 clinical trials and commercialization;

Edgar Filing: GERON CORP - Form 10-Q

- obtaining clearance or approval of proposed trial designs or manufacturing specifications from the FDA and other regulatory authorities;
- reaching agreement on acceptable terms and on a timely basis, if at all, with collaborators and vendors located in the United States or foreign jurisdictions, including contract research organizations, laboratory service providers and trial sites, on all aspects of clinical trials;
- obtaining institutional review board or ethics committee approval to conduct clinical trials at prospective clinical trial sites; and
- securing and successfully screening appropriate subjects for participation in clinical trials.

Failures or delays with respect to any of these events could adversely affect our ability to initiate, maintain or successfully complete any subsequent clinical trials of imetelstat, which could increase our development costs or could impair our ability to generate revenues, either of which could adversely impact our financial results and have a material adverse effect on our business.

Table of Contents

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

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

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

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

We have never conducted large-scale, Phase 3 clinical trials, nor do we have experience as a company in those areas required for the successful commercialization of imetelstat.

We have never conducted large-scale, Phase 3 clinical trials. We cannot be certain that any large-scale, Phase 3 clinical trials of imetelstat that we may design or conduct will begin or be completed in a timely manner, if at all. In order to initiate large-scale, randomized, Phase 3 clinical trials, we will need to obtain regulatory clearances to initiate and then to complete one or more Geron-sponsored Phase 2 clinical trials with positive data generated from those trials. Phase 3 clinical trials also will require additional financial and management resources and reliance on third-party clinical investigators, clinical research organizations, lab service providers, trial sites and consultants. Relying on third-party clinical investigators or clinical research organizations may cause delays that are outside of our control. Any such delays could have a material adverse effect on our business.

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

*Obtaining regulatory clearances and approvals to develop and market imetelstat in the United States and other countries is a costly and lengthy process, and we cannot predict whether or when regulatory authorities will permit additional development or approve imetelstat for commercial sale.**

Federal, state and local governments in the United States and governments in other countries have significant regulations in place that govern drug research and development and may prevent us from successfully conducting our development efforts or from commercializing imetelstat. Imetelstat must receive all relevant regulatory approvals before it may be marketed in the United States or other countries. Obtaining regulatory approval is a

Table of Contents

lengthy, expensive and uncertain process. Because imetelstat involves the application of new technologies and a new therapeutic approach, it may be subject to substantial additional review by various government regulatory authorities, and, as a result, the process of obtaining regulatory approvals for imetelstat may proceed more slowly than for product candidates based upon more conventional technologies, and any approval that we may receive could limit the use of imetelstat.

Prior to submission of any regulatory application seeking approval to commence commercial sales of imetelstat, we will be required to conduct extensive preclinical and clinical testing. If our interpretation of safety and efficacy data obtained from preclinical and clinical studies varies from interpretations by the FDA or regulatory authorities in other countries, this would likely delay, limit or prevent further development and approval of imetelstat and have a material adverse effect on our business. For example, the FDA and regulatory authorities in other countries may require more or different data than what has been generated from our preclinical studies and our previously ongoing Geron-sponsored Phase 2 clinical trials, or that has been generated from the MF Pilot Study or may be generated by potential future Geron-sponsored clinical trials. In addition, delays or rejections of regulatory approvals, or limitations in marketing authorizations, may be encountered as a result of changes in regulatory environment or regulatory agency policy during the period of product development and/or the period of review of any application for regulatory agency approval for imetelstat. We do not expect imetelstat to be approved for commercial sale for many years, if at all.

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

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

Even if we commit the necessary time and resources, the required regulatory agency clearances and approvals may not be obtained for imetelstat. Even if we obtain regulatory agency clearances and approvals to commence commercial sales of imetelstat, they may entail limitations on the indicated uses or other aspects of the product label for which it can be marketed that could limit the potential commercial use of imetelstat or the approval may be contingent on the performance of costly additional clinical trials which may be required after approval. The occurrence of any of these events could materially adversely affect our business.

Failure to achieve continued compliance with government regulation could delay or halt commercialization of imetelstat, our sole product candidate.

Edgar Filing: GERON CORP - Form 10-Q

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

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

Table of Contents

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

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

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

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

Significant disruptions of information technology systems or breaches of data security could adversely affect our business.

Our business is increasingly dependent on critical, complex and interdependent information technology systems, including Internet-based systems, to support business processes as well as internal and external communications. The size and complexity of our computer systems make them potentially vulnerable to breakdown, malicious intrusion and computer viruses that may result in the impairment of key business processes.

In addition, our systems are potentially vulnerable to data security breaches whether by employees or others that may expose sensitive data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personal information (including sensitive personal information) of our employees, clinical trial patients, customers and others.

Such disruptions and breaches of security could have a material adverse effect on our business, financial condition and results of operations.

RISKS RELATED TO PROTECTING OUR INTELLECTUAL PROPERTY

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

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

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 the future success of imetelstat.

Table of Contents

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

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

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

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

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

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

Certain jurisdictions, such as Europe, New Zealand and Australia, permit oppositions to be filed against granted patents or patents proposed to be granted. Because our intent is to commercialize imetelstat internationally if approved for commercial sale, securing both proprietary protection and freedom to operate outside of the United States is important to our business.

Table of Contents

We have been 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. These opposition proceedings required significant time and costs to protect our intellectual property rights. If we are unable to commit these types of resources for our imetelstat patent rights, we could be prevented or limited in the development of imetelstat, which would have a material adverse effect on our business.

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

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

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

Our commercial success depends upon our ability to develop, manufacture, market and sell imetelstat without infringing or otherwise violating the intellectual property and other proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries, and many pharmaceutical companies, including potential competitors, have substantial patent portfolios. For example, we are aware that certain third parties have or may be prosecuting patents and patent estates, and while we believe these patents will expire before imetelstat is commercialized and/or that these patents are invalid and/or would not be infringed by the manufacture, use or sale of imetelstat, it is possible that the owner(s) of these patents will assert claims against us in the future. In addition, we may not be aware of all intellectual property rights potentially relating to imetelstat and its uses. Thus, we do not know with certainty that imetelstat, or our intended commercialization thereof, does not and will not infringe or otherwise violate any third party's intellectual property. Any infringement claims against us would likely be expensive to resolve, and if we are unable to resolve these successfully, could subject us to an injunction which would prevent us from commercializing imetelstat, and could also require us to pay substantial damages. In addition to infringement claims, in the future we may also be subject to other claims relating to intellectual property, such as claims that we have misappropriated the trade secrets of third parties.

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

Table of Contents

We may become involved in disputes with prior or future collaborators over intellectual property ownership, and publications by our investigators, scientific consultants and research collaborators could impair our ability to obtain patent protection or protect our proprietary information, which, in either case, could have a significant impact on our business.*

Inventions discovered under research, material transfer or other such collaborative agreements may become jointly owned by us and the other party to such agreements in some cases and the exclusive property of either party in other cases. Under some circumstances, it may be difficult to determine who owns a particular invention, or whether it is jointly owned, and disputes could arise regarding ownership of those inventions. These disputes could be costly and time consuming and an unfavorable outcome could have a significant adverse effect on our business if we were not able to protect or license rights to these inventions. In addition, our investigators, scientific consultants and research collaborators generally have contractual rights to publish our data and other proprietary information, subject to our prior review. Publications by our investigators, scientific consultants and research collaborators containing such information, either with our permission or in contravention of the terms of their agreements with us, may impair our ability to obtain patent protection or protect our proprietary information, which could significantly harm our business.

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.

RISKS RELATED TO OUR RELATIONSHIPS WITH THIRD PARTIES

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

Our strategy for the research, development, clinical testing and commercialization of imetelstat may require us to enter into collaborations with clinical research organizations, investigators, academic institutions, vendors, clinical trial sites, corporate partners, licensors, licensees and others. We are dependent upon the ability of these parties to perform their responsibilities reliably. By way of example, we contracted two clinical research organizations that have been primarily responsible for the execution of clinical site related activities for our imetelstat Phase 2 clinical trials, including clinical trial site monitoring activities. In addition, for our imetelstat program, we have contracted with a single vendor to develop and maintain the clinical database and a single vendor to maintain our safety database. For any future clinical trials of imetelstat that may be conducted by us, we may rely on new or different vendors, or other third parties, with which we may have little or no prior experience.

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 or provide the necessary information to regulatory authorities, if at all. In addition,

Edgar Filing: GERON CORP - Form 10-Q

collaborators, licensors or licensees could terminate their agreements with us, and we may not receive any development or milestone payments. If we do not achieve milestones or perform diligence obligations set forth in agreements that we have entered into with others, or if our collaborators, licensors or licensees breach or terminate their agreements with us, our business may be materially harmed.

Table of Contents

Our imetelstat development strategy is also dependent on the results of existing and potential future Geron-sponsored and investigator-sponsored clinical trials of imetelstat in hematologic myeloid malignancies, including the MF Pilot Study. Because investigator-sponsored trials, including the MF Pilot Study, which was not a Geron-sponsored trial until we assumed responsibility as the trial sponsor for the MF Pilot Study in September 2014, are not Geron-sponsored trials, the clinical testing of imetelstat in investigator-sponsored trials requires us to rely on the applicable investigator's design and conduct of the trial, which we do not control, and it is possible that the FDA or other regulatory agencies will not view these investigator-sponsored trials, including the MF Pilot Study, as providing adequate support for future clinical trials, whether controlled by us or third parties, for any one or more reasons, including elements of the design or execution of these investigator-sponsored trials or safety concerns or other trial results. Accordingly, failure by independent physician investigators to properly design or conduct existing or potential future investigator-sponsored trials of imetelstat could produce results that might delay or prevent us from advancing imetelstat into further clinical development. In addition, we do not have control over the timing and reporting of the data from investigator-sponsored trials, nor do we own the data from investigator-sponsored trials. Our arrangements with independent physician investigators may provide us certain information rights with respect to the investigator-sponsored trials, including access to and the ability to use and reference the data, including for our own regulatory filings, resulting from the investigator-sponsored trials. If these obligations are breached by the independent physician investigators, or if the data prove to be inadequate compared to the first-hand knowledge we might have gained had the investigator-sponsored trials been Geron-sponsored clinical trials, or if the data cannot be reviewed or verified by us, including the data from the MF Pilot Study that was transferred to us by Mayo Clinic, then our ability to design and conduct any Geron-sponsored clinical trials may be adversely affected.

Additionally, the FDA or other regulatory agencies may disagree with our interpretation of clinical data generated by any investigator-sponsored trials, including the data from the MF Pilot Study that was transferred to us by Mayo Clinic. If so, the FDA or other regulatory agencies may require us to obtain and submit additional preclinical, manufacturing, or clinical data before we may initiate potential future Geron-sponsored clinical trials of imetelstat and/or the FDA may not accept such additional data as adequate to initiate any such Geron-sponsored clinical trials. Further, if we are unable to verify, confirm or replicate the results from the MF Pilot Study or if negative results are obtained, we would likely be further delayed or prevented from advancing imetelstat into further clinical development and might decide to discontinue our development of imetelstat, which would severely harm our business and prospects, and could potentially cause us to cease operations.

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

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

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

Edgar Filing: GERON CORP - Form 10-Q

There are other risks and uncertainties that we face with respect to manufacturing that could materially adversely affect our operations. For example, one of our suppliers of active pharmaceutical ingredient for imetelstat is currently restricted by the FDA from importing materials into the United States. As another example, certain commonly used reagents and solvents may experience market shortages and, if these shortages occur, such shortages may adversely impact our ability to manufacture imetelstat.

Table of Contents

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

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

RISKS RELATED TO OUR 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 September 30, 2014, our accumulated deficit was approximately \$919.5 million. Losses have resulted principally from costs incurred in connection with our research and development activities and from general and administrative costs associated with our operations. We expect to incur additional operating losses and, as our clinical development activities continue, our operating losses may increase in size.

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

We also expect to experience negative cash flow for the foreseeable future as we fund our operating losses and capital expenditures. This will result in decreases in our working capital, total assets and stockholders' equity, which may not be offset by future financings. We will need to generate significant revenues to achieve profitability. We may not be able to generate these revenues, and we may never achieve profitability. Our failure to achieve profitability could negatively impact the market price of our common stock and our ability to sustain operations. Even if we do become profitable, we may not be able to sustain or increase profitability on a quarterly or annual basis.

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

Edgar Filing: GERON CORP - Form 10-Q

We will need to obtain substantial capital resources in order to conduct our operations and develop imetelstat, and we cannot assure you that our existing capital resources, future interest income and potential future sales of our common stock, including pursuant to our sales agreement with MLV, will be sufficient to fund future planned activities. 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 2014 and beyond;

Table of Contents

- changes or delays in our development plans for imetelstat, including changes which may result from any future clinical holds on our IND or any other INDs, including the IND that we received from the investigator for the MF Pilot Study, for imetelstat;
- our ability to meaningfully reduce manufacturing costs of imetelstat;
- the timing, magnitude, scope and costs of our imetelstat research and development program, including the number of indications we may pursue, subject to permission from the FDA;
- the progress made, if any, in our imetelstat research and development program, including existing or potential future Geron-sponsored and investigator-sponsored clinical trials;
- our ability to establish, enforce and maintain strategic arrangements for research, development, clinical testing, manufacturing and marketing of imetelstat;
- the time and costs involved in obtaining regulatory clearances and approvals in the United States and in other countries;
- the sales price and availability of adequate third-party reimbursement for imetelstat;
- expenses associated with the pending and potential additional related purported securities lawsuits and derivative lawsuits, as well as any other litigation; 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, including pursuant to our sales agreement with MLV, capital lease transactions or other financing sources may not be available on acceptable terms, or at all. We may raise equity capital at a stock price or on other terms that could result in substantial dilution of ownership for our stockholders. The receptivity of the public and private equity markets to proposed financings is substantially affected by the general economic, market and political climate and by other factors which are unpredictable and over which we have no control. Our ability to raise additional funds will be severely impaired in the event of any future clinical holds on our IND or any other INDs, including the IND that we received from the investigator for the MF Pilot Study, for imetelstat, or if imetelstat fails to show adequate safety or efficacy in existing or potential future Geron-sponsored and investigator-sponsored clinical trials, including the MF Pilot Study.

Further, in the event that we obtain additional funds through arrangements with collaborators or partners, these arrangements may require us to relinquish some or all of our rights to imetelstat, which could adversely affect our future business or operations. If sufficient capital is not available, we may be required to delay, reduce the scope of, suspend or eliminate some or all of the elements of our imetelstat program, any of which could have a material adverse effect on our business.

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

Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an ownership change, generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change taxable income or taxes may be limited. Changes in our stock ownership, some of which are outside of our control, may have resulted or could in the future result in an ownership change. If a limitation were to apply, utilization of a portion of our domestic net operating loss and tax credit carryforwards could be limited in future periods. In addition, a portion of the carryforwards may expire before being available to reduce future income tax liabilities.

Table of Contents

RISKS RELATED TO OUR COMMON STOCK AND FINANCIAL REPORTING

Historically, our stock price has been extremely volatile.

Historically, our stock price has been extremely volatile. Between October 1, 2004 and September 30, 2014, our stock has traded as high as \$12.18 per share and as low as \$0.91 per share. Between October 1, 2011 and September 30, 2014, the price has ranged between a high of \$7.79 per share and a low of \$0.91 per share. The significant market price fluctuations of our common stock have been due to and may in the future be influenced by a variety of factors, including:

- our obtaining regulatory clearance to commence subsequent clinical trials of imetelstat in a timely manner, or at all, in the U.S. or in other countries;
- announcements regarding our research and development of imetelstat, including clinical trial results or delays in any future clinical trials of imetelstat, or announcements regarding the results of or delays in clinical trials of imetelstat, and investor perceptions thereof;
- announcements regarding the safety of imetelstat, including announcements similar to our March 2014 announcements that the FDA had placed a full clinical hold on our IND for imetelstat and a partial clinical hold on the investigator's IND for the MF Pilot Study due to safety concerns;
- announcements regarding our plans to discontinue certain programs or clinical trials, such as our prior announcements regarding the discontinuation of our stem cell programs and certain clinical trials;
- perception by our stockholders about the adequacy of the consideration received for the divestiture of our stem cell assets to Asterias;
- the demand in the market for our common stock;
- the experimental nature of imetelstat;
- fluctuations in our operating results;

- our declining cash balance as a result of operating losses;
- general market conditions or 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 collaborators, licensees, partners or our competitors;
- announcements concerning regulatory developments and proprietary rights;
- comments by securities analysts;
- large stockholders exiting their position in our common stock;
- announcements of or developments concerning pending and/or potential future litigation;
- the issuance of common stock to partners, vendors or to investors to raise additional capital; and
- the occurrence of any other risks and uncertainties discussed under the heading Risk Factors.

Table of Contents

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

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

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

We and certain of our officers have been named as defendants in three purported securities lawsuits, two of which are securities class action lawsuits, and certain of our officers and directors have been named as defendants in a derivative lawsuit. These, and potential similar or related lawsuits, could result in substantial damages, divert management's time and attention from our business, and have a material adverse effect on our results of operations. These lawsuits and any other lawsuits to which we are subject will be costly to defend or pursue and are uncertain in their outcome. *

Securities-related class action lawsuits and derivative 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.

On March 14, 2014, a purported securities class action lawsuit was commenced in the United States District Court for the Northern District of California, or the California District Court, naming as defendants us and certain of our officers. The lawsuit alleges violations of the Securities Exchange Act of 1934 in connection with allegedly false and misleading statements made by us related to our Phase 2 trial of imetelstat in patients with ET or PV. The plaintiff alleges, among other things, that we failed to disclose facts related to the occurrence of persistent low-grade LFT abnormalities observed in our Phase 2 trial of imetelstat in ET or PV patients and the potential risk of chronic liver injury following long-term exposure to imetelstat. The plaintiff seeks damages and an award of reasonable costs and expenses, including attorneys' fees.

On March 28, 2014, a second purported securities class action lawsuit was commenced in the California District Court, naming as defendants us and certain of our officers. This lawsuit, which is based on the same factual background as the purported securities class action lawsuit that commenced on March 14, 2014, also alleges violations of the Securities Exchange Act of 1934 and seeks damages and an award of reasonable costs and expenses, including attorneys' fees.

On June 30, 2014, both of the foregoing lawsuits, or the Class Action Lawsuits, were consolidated for all purposes, and a lead plaintiff and lead counsel were appointed by the California District Court. On July 21, 2014, the California District Court ordered the lead plaintiff to file its consolidated amended complaint in the Class Action Lawsuits, which was filed on September 19, 2014. Our response to the consolidated amended complaint is due by November 18, 2014.

Table of Contents

On June 6, 2014, a purported securities lawsuit, not styled as a class action, was commenced in the United States District Court for the Southern District of Mississippi, or the Mississippi District Court, naming as defendants us and certain of our officers. This lawsuit, which is based on the same factual background as the Class Action Lawsuits, also alleges violations of the Securities Exchange Act of 1934 and seeks damages and an award of reasonable costs and expenses, including attorneys' fees. On August 11, 2014, we filed a motion to transfer the purported securities lawsuit filed in the Mississippi District Court to the California District Court so it can be consolidated with the purported Class Action Lawsuits. On November 4, 2014, the Mississippi District Court granted our motion and transferred the case to the California District Court, and we intend to seek to consolidate the transferred case with the purported Class Action Lawsuits filed in the California District Court.

On April 21, 2014, a stockholder purporting to act on our behalf filed a derivative lawsuit in the Superior Court of California for the County of San Mateo against certain of our officers and directors. The lawsuit alleges breaches of fiduciary duties by the defendants and other violations of law. In general, the lawsuit alleges that the defendants caused or allowed the dissemination of allegedly false and misleading statements related to our Phase 2 trial of imetelstat in patients with ET or PV. The plaintiff is seeking unspecified monetary damages and other relief, including reforms and improvements to our corporate governance and internal procedures.

It is possible that additional suits will be filed, or allegations received from stockholders, with respect to these same or other matters and also naming us and/or our officers and directors as defendants. These lawsuits and any other related lawsuits are subject to inherent uncertainties, and the actual defense and disposition costs will depend upon many unknown factors. The outcome of these lawsuits is necessarily uncertain. We could be forced to expend significant resources in the defense against these lawsuits and we may not prevail. In addition, we may incur substantial legal fees and costs in connection with these lawsuits. We currently are not able to estimate the possible cost to us from these matters, as these lawsuits are currently at an early stage, and we cannot be certain how long it may take to resolve these matters or the possible amount of any damages that we may be required to pay. We have not established any reserve for any potential liability relating to these lawsuits. It is possible that we could, in the future, incur judgments or enter into settlements of claims for monetary damages. A decision adverse to our interests on these actions could result in the payment of substantial damages, or possibly fines, and could have a material adverse effect on our cash flow, results of operations and financial position.

In addition, if the results of our business activities are not successful, including without limitation, if:

- we are unable to successfully conduct and complete the MF Pilot Study for which we assumed responsibility as the trial sponsor in September 2014 or we are otherwise unable to continue development of imetelstat due to regulatory actions, such as the previous full clinical hold that was placed by the FDA on our IND for imetelstat in March 2014;
- we or any investigators ascertain that the use of imetelstat results in significant systemic or organ toxicities, including hepatotoxicity, or other safety issues resulting in an unacceptable benefit-risk profile;
- the final or any preliminary results from the MF Pilot Study, or any subsequent clinical trial of imetelstat, are not deemed to be successful;
- we or any investigators discontinue the further development of imetelstat; or

- our stockholders believe the consideration received from the divestiture of our stem cell assets to be inadequate;

our stock price would likely decline further, and additional future litigation may result. A decision adverse to our interests in the current or potential future lawsuits could result in the payment of substantial damages by us, and could have a material adverse effect on our cash flow, results of operations and financial position.

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

Table of Contents

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

The sale of a substantial number of shares of our common stock in the public market, or the perception that such sales could occur, could significantly and negatively affect the market price of our common stock. As of September 30, 2014, we had 300,000,000 shares of common stock authorized for issuance and 156,934,133 shares of common stock outstanding. In addition, we had reserved 33,354,582 shares of our common stock for future issuance pursuant to our option and equity incentive plans and outstanding warrants as of September 30, 2014. Issuing additional shares could negatively affect the market price of our common stock and the return on your investment.

Future sales of our common stock, including pursuant to our sales agreement with MLV, or the issuance of common stock to satisfy our current or future cash payment obligations or to acquire technology, property, or other businesses, could cause immediate dilution and adversely affect the market price of our common stock. In addition, under the universal shelf registration statement filed by us in July 2012 and declared effective by the SEC in October 2012, we may sell any combination of common stock, preferred stock, debt securities and warrants in one or more offerings, up to a cumulative value of \$96.5 million. The sale or issuance of our securities, as well as the existence of outstanding options and shares of common stock reserved for issuance under our option and equity incentive plans and outstanding warrants also may adversely affect the terms upon which we are able to obtain additional capital through the sale of equity securities which could negatively affect the market price of our common stock and the return on your investment.

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;

Edgar Filing: GERON CORP - Form 10-Q

- 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.

Table of Contents

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

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

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

*Our stockholders may incur U.S. federal income taxes as a result of the Series A Distribution, and non-U.S. stockholders may be subject to withholding taxes with respect to the Series A Distribution. **

The Series A Distribution does not qualify as a tax-free spin-off under Section 355 of the Code. Accordingly, the fair market value of the Asterias Series A common stock at the time of the Series A Distribution and the amount of cash that was distributed could be treated as dividend income for U.S. federal income tax purposes for Geron stockholders who received shares of Asterias Series A common stock, or cash in lieu thereof, in the Series A Distribution to the extent made out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles), if any. Because the amount of our 2014 current earnings and profits, if any, cannot be known before the end of 2014 and because we have not performed a formal study of our accumulated earnings and profits as of the end of 2013, we can provide no assurance that the Series A Distribution will not result in any dividend income to Geron stockholders who received shares of Asterias Series A common stock, or cash in lieu thereof, in the Series A Distribution. Similarly, we can provide no assurance that the distribution of BioTime Warrants by Asterias will not result in dividend income. Any gain recognized by a Geron stockholder from the Series A Distribution or the distribution of the BioTime Warrants will be short-term capital gain if the Geron stockholder has held our stock or, as applicable, the Asterias Series A common stock for one year or less at the time of the relevant distribution.

If any dividend income or gain were recognized by Geron stockholders with respect to the Series A Distribution, then Geron stockholders could incur U.S. federal income taxes with respect to the receipt of such distribution. Similarly, if any dividend income or gain were recognized by Geron stockholders with respect to the distribution by Asterias of the BioTime Warrants, Geron stockholders could incur U.S. federal income taxes with respect to the receipt of such distribution. In addition, non-U.S. Geron stockholders may be subject to U.S. federal withholding. The lack of an active public market for the Asterias Series A common stock could limit or preclude the sale of a sufficient quantity of Asterias Series A common stock to satisfy such potential tax liabilities. As a result, Geron stockholders who received shares of Asterias Series A common stock may incur tax liabilities as a result of the Series A Distribution, but be unable to realize sufficient value from shares of any Asterias Series A common stock distributed by Geron and/or the BioTime Warrants distributed by Asterias.

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

Edgar Filing: GERON CORP - Form 10-Q

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

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

Table of Contents

RISKS RELATED TO COMPETITIVE FACTORS

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

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

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

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

Many companies are developing alternative therapies to treat hematologic myeloid malignancies and, in this regard, are competitors of ours. For example, if approved for commercial sale for the treatment of MF, imetelstat would compete against Incyte Corporation's ruxolitinib, or Jakafi®, which is orally administered. In clinical trials, Jakafi® reduced spleen size, abdominal discomfort, early satiety, bone pain, night sweats and itching in MF patients. Recently, there have also been reports of overall survival benefit as well as improvement in bone marrow fibrosis from Jakafi® treatment. Other treatment modalities for MF include hydroxyurea for the management of splenomegaly, leukocytosis, thrombocytosis and constitutional symptoms; splenectomy and splenic irradiation for the management of splenomegaly and co-existing cytopenias, or low blood cells; chemotherapy and pegylated interferon. Drugs for the treatment of MF-associated anemia include erythropoiesis-stimulating agents, androgens, danazol, corticosteroids, thalidomide and lenalidomide. There are other investigational treatments further along in development than imetelstat, such as momelotinib by Gilead Sciences, Inc. and pacritinib by Cell Therapeutics, Inc., which are currently in Phase 3 clinical trials, and other inhibitors of the JAK-STAT pathway, as well as several investigational treatments in early phase testing such as histone deacetylase inhibitors, inhibitors of heat shock protein 90, hypomethylating agents, PI3 Kinase and mTOR inhibitors, hedgehog inhibitors, anti-LOX2 inhibitors, recombinant pentraxin 2 protein, KIP-1 activators, TGF-beta inhibitors, FLT inhibitors, and other tyrosine kinase inhibitors.

There are more than 200 approved anti-cancer products on the market in the United States, and several thousand in clinical development. Pharmaceutical companies developing and marketing these competing products (e.g. Sanofi S.A., Bristol-Myers Squibb Company, Novartis AG, Incyte Corporation and Gilead Sciences, Inc.) have significantly greater financial, technical and human resources than we do, and greater expertise than we do in:

Edgar Filing: GERON CORP - Form 10-Q

- research and development;
- manufacturing;
- preclinical and clinical testing;
- obtaining regulatory clearances and approvals; and
- marketing, sales and distribution.

Table of Contents

Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. We anticipate increased competition in the future as new companies explore treatments for hematologic myeloid malignancies, which may significantly impact the commercial viability of imetelstat. Academic institutions, government agencies and other public and private research organizations may also conduct research, seek patent protection and establish collaborative arrangements for research, clinical development and marketing of products similar to ours. These companies and institutions compete with us in recruiting and retaining qualified scientific and management personnel as well as in acquiring technologies complementary to our imetelstat program.

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

- product efficacy and safety;

- the timing and scope of regulatory consents;

- availability of resources;

- reimbursement coverage;

- price; and

- patent position, including potentially dominant patent positions of others.

As a result of the foregoing, our competitors may develop more effective or more affordable products, or achieve earlier patent protection or product commercialization than us. Our competitors have developed, or are in the process of developing, technologies that are, or in the future may be, competitive to imetelstat. Some of these products may have an entirely different approach or means of accomplishing therapeutic effects similar to those demonstrated by imetelstat. Our competitors may develop products that are safer, more effective or less costly than imetelstat, or more convenient to administer to patients and, therefore, present a serious competitive threat to imetelstat. In addition, our competitors may price their products below what we may determine to be an acceptable price for imetelstat, may receive better third-party payor coverage and/or reimbursement, or may be more cost effective than imetelstat. Such competitive products or activities by our competitors may render imetelstat obsolete, which would negatively impact our business and ability to sustain operations.

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

Edgar Filing: GERON CORP - Form 10-Q

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

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

Table of Contents

The established use of conventional products competitive with imetelstat may limit or preclude the potential for imetelstat to receive market acceptance upon any commercialization. We may be unable to demonstrate any pharmacoeconomic advantage for imetelstat compared to established or standard-of-care therapies, or newly developed therapies, for hematologic myeloid malignancies. Third-party payors may decide that any potential improvement that imetelstat may provide to clinical outcomes in hematologic myeloid malignancies is not adequate to justify the costs of treatment with imetelstat. If third-party payors do not view imetelstat as offering a better balance between clinical benefit and treatment cost compared to standard-of-care therapies or other treatment modalities currently in development, imetelstat may not be commercially viable. If the health care community does not accept imetelstat for any of the foregoing reasons, or for any other reason, our business would be materially harmed.

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

Our ability to successfully commercialize imetelstat will depend significantly on our ability to obtain acceptable prices and the availability of reimbursement to the patient from third-party payors. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively known as the Affordable Care Act, became law and substantially changed the way healthcare will be financed by both governmental and private insurers, and significantly impacted the pharmaceutical industry. The Affordable Care Act contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse, which will impact existing government healthcare programs and will result in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program. Additionally, the Affordable Care Act:

- mandates a further shift in the burden of Medicaid payments to the states;
- increases the minimum level of Medicaid rebates payable by manufacturers of brand-name drugs from 15.1% to 23.1%;
- requires collection of rebates for drugs paid by Medicaid managed care organizations;
- requires manufacturers to participate in a coverage gap discount program, under which they must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D, beginning January 2011; and
- imposes a non-deductible annual fee on pharmaceutical manufacturers or importers who sell branded prescription drugs to specified federal government programs.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. The American Taxpayer Relief Act of 2012, signed into law in January 2013, among other things, also reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover

Edgar Filing: GERON CORP - Form 10-Q

overpayments to providers from three to five years. On March 1, 2013, the President signed an executive order implementing sequestration, and on April 1, 2013, Medicare payment reductions of 2% went into effect.

Table of Contents

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

RISKS RELATED TO ENVIRONMENTAL AND PRODUCT LIABILITY

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

If we are unable to comply with federal, state and county environmental and safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of biohazardous materials, chemicals and various radioactive compounds previously used by us in our discontinued research facility, we could be subject to considerable additional cost or liability that would have a material adverse effect on our financial condition. We, our contractors or agents may be required to incur significant costs to comply with current or future environmental laws and regulations and may be adversely affected by the cost of compliance with these laws and regulations.

Although we believe that the safety procedures previously used by us for using, handling, storing and disposing of hazardous materials in our discontinued research facility complied with the standards prescribed by state and federal regulations, we may incur significant unanticipated costs associated with the closure and exit of our research facility. Further, any failure by us to control the use, disposal, removal or storage, or to adequately restrict the discharge, or assist in the clean up, of hazardous chemicals or hazardous, infectious or toxic substances in connection with the closure of our research facility could subject us to significant liabilities, including joint and several liability under certain statutes. Any such liability or costs could exceed our resources and could have a material adverse effect on our business, financial condition and results of operations. Additionally, an accident could damage the manufacturing facilities and operations of any third party contracted by us to perform services with respect to our imetelstat program. Additional federal, state and local laws and regulations affecting us may be adopted in the future. We, our contractors and agents may incur substantial costs to comply with these laws and regulations and substantial fines or penalties if we violate any of these laws or regulations, which would adversely affect our business.

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

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

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

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

Table of Contents

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

See Exhibit Index.

Table of Contents

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

GERON CORPORATION

Date: November 5, 2014

By:

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

Table of Contents**EXHIBIT INDEX**

Exhibit Number	Description
10.1	Transfer Agreement by and between the Registrant and Mayo Clinic, effective as of July 31, 2014
31.1	Certification of Chief Executive Officer pursuant to Form of Rule 13a-14(a), as Adopted Pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002, dated November 5, 2014
31.2	Certification of Chief Financial Officer pursuant to Form of Rule 13a-14(a), as Adopted Pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002, dated November 5, 2014
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 November 5, 2014 *
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 November 5, 2014 *
101	The following materials from the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, formatted in Extensible Business Reporting Language (XBRL) include: (i) Condensed Balance Sheets as of September 30, 2014 and December 31, 2013, (ii) Condensed Statements of Operations and Comprehensive Loss for the three and nine months ended September 30, 2014 and 2013, (iii) Condensed Statements of Cash Flows for the nine months ended September 30, 2014 and 2013 and (iv) Notes to Condensed Financial Statements