GERON CORP
Form 10-Q
May 05, 2016
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2016

OR

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

For the transition period from to .

Commission File Number: 0-20859

GERON CORPORATION

(Exact name of registrant as specified in its charter)

DELAWARE	**75-2287752**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
149 COMMONWEALTH DRIVE, SUITE 2070, MENLO PARK, CA	**94025**
(Address of principal executive offices)	(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 x No o

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 x No o

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

Large accelerated filer o	Accelerated filer x
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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

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

Class:	**Outstanding at April 29, 2016:**
Common Stock, $0.001 par value	158,960,258 shares

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GERON CORPORATION

QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTER ENDED MARCH 31, 2016

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PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED FINANCIAL STATEMENTS (UNAUDITED)

GERON CORPORATION

CONDENSED BALANCE SHEETS

(IN THOUSANDS)

	MARCH 31, 2016 (UNAUDITED)	DECEMBER 31, 2015 (NOTE 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 12,802	$ 21,248
Restricted cash	267	267
Marketable securities	96,846	92,524
Interest and other receivables	624	1,206
Prepaid assets	416	647
Total current assets	110,955	115,892
Noncurrent marketable securities	31,976	32,661
Property and equipment, net	212	207
	$ 143,143	$ 148,760
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 396	$ 160
Accrued compensation and benefits	1,619	2,974
Accrued collaboration charges	3,537	2,328
Accrued restructuring charges	35	52
Accrued liabilities	1,071	1,120
Total current liabilities	6,658	6,634
Commitments and contingencies		
Stockholders equity:		
Common stock	159	159
Additional paid-in capital	1,073,515	1,070,567
Accumulated deficit	(937,229)	(928,387)
Accumulated other comprehensive income (loss)	40	(213)
Total stockholders equity	136,485	142,126
	$ 143,143	$ 148,760

See accompanying notes.

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GERON CORPORATION

CONDENSED STATEMENTS OF OPERATIONS

(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)

(UNAUDITED)

	THREE MONTHS ENDED MARCH 31,	
	2016	**2015**
Revenues:		
License fees and royalties	$ 749	$ 537
Operating expenses:		
Research and development	5,033	4,987
Restructuring charges		406
General and administrative	4,793	4,600
Total operating expenses	9,826	9,993
Loss from operations	(9,077)	(9,456)
Unrealized gain on derivatives		16
Interest and other income	256	149
Interest and other expense	(21)	(24)
Net loss	$ (8,842)	$ (9,315)
Basic and diluted net loss per share	$ (0.06)	$ (0.06)
Shares used in computing basic and diluted net loss per share	158,896,038	157,547,568

See accompanying notes.

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GERON CORPORATION

CONDENSED STATEMENTS OF COMPREHENSIVE LOSS

(IN THOUSANDS)

(UNAUDITED)

	THREE MONTHS ENDED MARCH 31,	
	2016	**2015**
Net loss	$ (8,842)	$ (9,315)
Net unrealized gain on marketable securities	253	67
Comprehensive loss	$ (8,589)	$ (9,248)

See accompanying notes.

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GERON CORPORATION

CONDENSED STATEMENTS OF CASH FLOWS

CHANGE IN CASH AND CASH EQUIVALENTS

(IN THOUSANDS)

(UNAUDITED)

	THREE MONTHS ENDED MARCH 31,	
	2016	2015
Cash flows from operating activities:		
Net loss	$ (8,842)	$ (9,315)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	21	9
Accretion and amortization on investments, net	284	629
Stock-based compensation for services by non-employees	50	67
Stock-based compensation for employees and directors	2,019	2,013
Amortization related to 401(k) contributions	53	154
Unrealized gain on derivatives		(16)
Changes in assets and liabilities:		
Other current assets	813	(95)
Other current liabilities	24	(1,151)
Net cash used in operating activities	(5,578)	(7,705)
Cash flows from investing activities:		
Purchases of property and equipment	(26)	(7)
Purchases of marketable securities	(46,751)	(78,869)
Proceeds from maturities of marketable securities	43,083	52,490
Net cash used in investing activities	(3,694)	(26,386)
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of issuance costs	826	1,477
Net cash provided by financing activities	826	1,477
Net decrease in cash and cash equivalents	(8,446)	(32,614)
Cash and cash equivalents at the beginning of the period	21,248	42,796
Cash and cash equivalents at the end of the period	$ 12,802	$ 10,182
Supplemental Disclosure of Non-Cash Investing Activities:		
Net unrealized gain on marketable securities	$ 253	$ 67

See accompanying notes.

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GERON CORPORATION

NOTES TO CONDENSED FINANCIAL STATEMENTS

MARCH 31, 2016

(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 months ended March 31, 2016 are not necessarily indicative of the results that may be expected for the year ending December 31, 2016 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, 2015, included in the Company s Annual Report on Form 10-K. The accompanying condensed balance sheet as of December 31, 2015 has been derived from audited financial statements at that date.

Net Loss Per Share

Basic net income (loss) per share is calculated by dividing net income (loss) by the weighted-average number of shares of common stock outstanding during the periods presented, without consideration for common stock equivalents. Diluted net income per share is calculated by adjusting the weighted-average number of shares of common stock outstanding for the dilutive effect of common stock equivalents outstanding for the periods presented, as determined using the treasury-stock method. Potential dilutive securities primarily consist of outstanding stock options, restricted stock awards, and warrants to purchase our common stock. Diluted net loss per share excludes common stock equivalents outstanding for the periods presented, as determined using the treasury-stock method, as their effect would be anti-dilutive, resulting in the same number of shares being used for the calculation of basic and diluted net loss per share. For all periods presented in the accompanying condensed statements of operations, the net loss applicable to common stockholders is equal to the reported net loss.

Since we incurred a net loss for the three months ended March 31, 2016 and 2015, 3,593,074 and 4,122,123 common stock equivalents, respectively, related to outstanding stock options and restricted stock awards (as determined using the treasury-stock method at the estimated average market value) were excluded from the diluted net loss per share calculation as their effect would have been anti-dilutive. In addition, for the three months ended March 31, 2016 and 2015, 10,617,930 and 8,783,291 potentially dilutive securities, respectively, were excluded from the treasury-stock method and calculation of diluted net loss per share as their effect would have been anti-dilutive.

Use of Estimates

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

Fair Value of Financial Instruments

Cash Equivalents and Marketable Securities

We consider all highly liquid investments with an original maturity of three months or less to be cash equivalents. We are subject to credit risk related to our cash equivalents and marketable securities. We place our cash and cash equivalents in money market funds, commercial paper, corporate notes and cash operating accounts. Our marketable securities include U.S. government-sponsored enterprise securities, commercial paper and corporate notes with original maturities ranging from four to 24 months.

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MARCH 31, 2016

(UNAUDITED)

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 months ended March 31, 2016 and 2015. See Note 2 on Fair Value Measurements.

Revenue Recognition

We recognize revenue for each unit of accounting when all of the following criteria have been met: (a) persuasive evidence of an arrangement exists, (b) delivery has occurred or services have been rendered, (c) the seller s price to the buyer is fixed or determinable, and (d) collectability is reasonably assured. Amounts received prior to satisfying these revenue recognition criteria are recorded as deferred revenue. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current deferred revenue. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as noncurrent deferred revenue.

License and/or Collaboration Agreements

In addition to the exclusive collaboration and license agreement, or Collaboration Agreement, that we entered into with Janssen Biotech, Inc., or Janssen, in November 2014 (which is more fully described in Note 3 on Collaboration and License Agreement), we have entered into several license or collaboration agreements with various oncology, diagnostics, research tools and biologics production companies. Economic terms in these agreements may include non-refundable license payments in cash or equity securities, option payments in cash or equity securities, cost reimbursements, cost-sharing arrangements, milestone payments, royalties on future sales of products, or any combination of these items. In applying the appropriate revenue recognition guidance related to these agreements, we first assess whether the arrangement contains multiple elements. In this evaluation, we consider: (i) the deliverables included in the arrangement and (ii) whether the individual deliverables represent separate units of accounting or whether they must be accounted for as a combined unit of accounting. This evaluation involves subjective determinations and requires us to make judgments about the individual deliverables and whether such deliverables are separable from the other aspects of the contractual relationship. Deliverables are considered separate units of accounting provided that: (i) the delivered item(s) has value to the customer on a standalone basis, and (ii) if the arrangement includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in our control. In assessing whether an item has standalone value, we consider factors such as the research, manufacturing and commercialization capabilities of the collaboration partner or licensee and the

availability of the associated expertise in the general marketplace. In addition, we consider whether the collaboration partner or licensee can use the other deliverable(s) for their intended purpose without the receipt of the remaining element(s), whether the value of the deliverable is dependent on the undelivered item(s) and whether there are other vendors that can provide the undelivered element(s).

Arrangement consideration that is fixed or determinable is allocated among the separate units of accounting using the relative selling price method. We then apply the applicable revenue recognition criteria noted above to each of the separate units of accounting in determining the appropriate period and pattern of recognition. We determine how to allocate arrangement consideration to identified units of accounting based on the selling price hierarchy provided under relevant accounting guidance. The estimated fair value of deliverables under the arrangement may be derived using a best estimate of selling price if vendor-specific-objective evidence and third-party evidence are not available.

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(UNAUDITED)

Upfront non-refundable signing, license or non-exclusive option fees are recognized as revenue: (i) when rights to use the intellectual property have been delivered, if the license has standalone value from the other deliverables to be provided under the agreement, or (ii) over the term of the agreement if we have continuing performance obligations, as the arrangement would be accounted for as a single unit of accounting. When payments are received in equity securities, we do not recognize any revenue unless such securities are determined to be realizable in cash.

At the inception of an arrangement that includes milestone payments, we assess whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether: (i) the consideration is commensurate with either the performance to achieve the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the performance to achieve the milestone, (ii) the consideration relates solely to past performance and (iii) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. We consider various factors, such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the respective milestone and the level of effort and investment required to achieve the respective milestone, in making this assessment. There is considerable judgment involved in determining whether a milestone satisfies all of the criteria required to conclude that a milestone is substantive. Milestone payments for milestones that are considered substantive would be recognized as revenue in their entirety upon successful accomplishment of the milestone, assuming all other revenue recognition criteria are met. Milestone payments for milestones that are not considered substantive would be recognized as revenue over the remaining period of performance, assuming all other revenue recognition criteria are met.

Royalties are recognized as earned in accordance with contract terms when royalties from licensees can be reasonably estimated and collectability is reasonably assured. If royalties cannot be reasonably estimated or collectability of a royalty amount is not reasonably assured, royalties are recognized as revenue when the cash is received. Revenue from commercial milestone payments is accounted for as royalties and recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met.

Cost-sharing expenses are recorded as earned or owed based on the performance requirements by both parties under the respective contracts. For arrangements in which we and our collaboration partner in the agreement are exposed to significant risks and rewards depending on the commercial success of the activity, we recognize payments between the parties on a net basis and record such amounts as a reduction or addition to research and development expense. For arrangements in which we have agreed to perform certain research and development services for our collaboration partner and are not exposed to significant risks and rewards depending on the commercial success of the activity, we recognize the respective cost reimbursements as revenue under the collaborative agreement as the related research and development services are rendered.

Restricted Cash

Restricted cash consists of funds maintained in a separate certificate of deposit account for credit card purchases.

Research and Development Expenses

Research and development expenses consist of expenses incurred in identifying, developing and testing product candidates resulting from our independent efforts as well as efforts associated with collaborations. These expenses include, but are not limited to, in-process research and development acquired in an asset acquisition and 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, our proportionate share of research and development costs under cost-sharing arrangements with collaboration partners and research-related overhead. Research and development costs are expensed as incurred, including payments made under our collaboration and/or license agreements.

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(UNAUDITED)

For the clinical development activities being conducted by Janssen, we monitor patient enrollment levels and related activities to the extent possible through discussions with Janssen personnel and base our estimates on the best information available at the time. However, additional information may become available to us which would allow us to make a more accurate estimate in future periods. In this event, we may be required to record adjustments to research and development expenses in future periods when the actual level of activity becomes more certain.

Depreciation and Amortization

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

Stock-Based Compensation

We recognize stock-based compensation expense on a straight-line basis over the requisite service period, which is generally the vesting period. The following table summarizes the stock-based compensation expense included in operating expenses on our condensed statements of operations related to stock options, restricted stock awards and employee stock purchases for the three months ended March 31, 2016 and 2015 which was allocated as follows:

	Three Months Ended March 31,	
(In thousands)	**2016**	**2015**
Research and development	$ 332	$ 622
Restructuring charges		90
General and administrative	1,687	1,301
Stock-based compensation expense included in operating expenses	$ 2,019	$ 2,013

In connection with a restructuring we announced in March 2015, the post-termination exercise period for certain stock options previously granted to employees affected by the restructuring was extended from 90 days to one year from their respective termination dates, subject to each employee s continuous service until his/her specified termination date. The incremental value associated with these stock option modifications was recognized as non-cash stock-based compensation expense over each employee s remaining service period with the Company and recorded as restructuring charges on our condensed statements of operations as reflected in the table above. See Note 4 on Restructuring for a further discussion of the March 2015 restructuring.

As stock-based compensation expense recognized in our condensed statements of operations for the three months ended March 31, 2016 and 2015 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.

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(UNAUDITED)

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 three months ended March 31, 2016 and 2015 has been estimated at the date of grant using the Black Scholes option-pricing model with the following assumptions:

	Three Months Ended March 31,	
	2016	**2015**
Dividend yield	0%	0%
Expected volatility	0.890	0.884
Risk-free interest rate	1.21%	1.70%
Expected term	5.5 yrs	5.5 yrs

Employee Stock Purchase Plan

The fair value of employees purchase rights during the three months ended March 31, 2016 and 2015 has been estimated using the Black Scholes option-pricing model with the following assumptions:

	Three Months Ended March 31,	
	2016	**2015**
Dividend yield	0%	0%
Expected volatility range	0.684	0.721 to 1.392
Risk-free interest rate range	0.28%	0.11% to 0.25%
Expected term range	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.

Segment Information

Our executive management team represents our chief decision maker. We view our operations as a single segment, the 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.

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NOTES TO CONDENSED FINANCIAL STATEMENTS

MARCH 31, 2016

(UNAUDITED)

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update No. 2014-09, or ASU 2014-09, which creates Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers*, or Topic 606, and supersedes the revenue recognition requirements in Accounting Standards Codification Topic 605, *Revenue Recognition*, including most industry-specific revenue recognition guidance throughout the Industry Topics of the Codification. In summary, the core principle of Topic 606 is to recognize revenue when promised goods or services are transferred to customers in an amount that reflects the consideration that is expected to be received for those goods or services. Companies are allowed to select between two transition methods: (1) a full retrospective transition method with the application of the new guidance to each prior reporting period presented, or (2) a retrospective transition method that recognizes the cumulative effect on prior periods at the date of adoption together with additional footnote disclosures. The amendments in ASU 2014-09 are effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period, and early application is not permitted. We are currently evaluating the impact that the adoption of ASU 2014-09 will have on our financial statements and related disclosures and have not made any decision on the method of adoption.

In November 2015, the FASB issued Accounting Standards Update No. 2015-17, *Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes*, or ASU 2015-17. Current generally accepted accounting principles requires an entity to separate deferred income tax liabilities and assets into current and noncurrent amounts in a classified statement of financial position. To simplify the presentation of deferred income taxes, ASU 2015-17 requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The current requirement that deferred tax liabilities and assets of a tax paying component of an entity be offset and presented as a single amount is not affected by the amendments in this update. The amendments in this update are effective for financial statements issued for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Earlier application is permitted for all entities as of the beginning of an interim or annual reporting period. We are currently evaluating the impact that the adoption of ASU 2015-17 will have on our financial statements and related disclosures and have not made any decision regarding the timing of adoption.

In February 2016, the FASB issued Accounting Standards Update No. 2016-02, *Leases (Topic 842)*, or ASU 2016-02. ASU 2016-02 requires an entity to recognize a right-of-use asset and lease liability for all leases with terms of more than 12 months. Recognition, measurement and presentation of expenses will depend on classification as a finance or operating lease. Certain quantitative and qualitative disclosures about leasing arrangements also are required. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. The updated guidance requires a modified retrospective adoption. We are currently evaluating the impact that the adoption of ASU 2016-02 will have on our financial statements and related disclosures and have not made any decision regarding the timing of adoption.

In March 2016, the FASB issued Accounting Standards Update No. 2016-09, *Improvements to Employee Share-Based Payment Accounting*, or ASU 2016-09, which amends Accounting Standards Codification Topic 718, *Compensation Stock Compensation*. ASU 2016-09 simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either

equity or liabilities and classification on the statement of cash flows. ASU 2016-09 is effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods and early adoption is permitted. We are currently evaluating the impact of the adoption of ASU 2016-09 on our financial statements and related disclosures and have not made any decision regarding the timing of adoption.

With the exception of the standards discussed above, there have been no new accounting pronouncements not yet effective that have significance, or potential significance, to our financial statements.

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NOTES TO CONDENSED FINANCIAL STATEMENTS

MARCH 31, 2016

(UNAUDITED)

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.

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. government-sponsored enterprise securities, commercial paper and corporate notes are categorized as Level 2 within the fair value hierarchy as their fair values are estimated by using pricing models, quoted prices of securities with similar characteristics or discounted cash flows.

Cash equivalents, restricted cash and marketable securities by security type at March 31, 2016 were as follows:

(In thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Included in cash and cash equivalents:				
Money market funds	$ 3,798	$	$	$ 3,798
Commercial paper	3,497	1		3,498
Corporate notes	3,251			3,251
	$ 10,546	$ 1	$	$ 10,547
Restricted cash:				
Certificate of deposit	$ 267	$	$	$ 267
Marketable securities:				
Government-sponsored enterprise securities (due in 1 to 2 years)	$ 17,021	$ 1	$ (2)	$ 17,020
Commercial paper (due in less than 1 year)	34,605	58	(1)	34,662
Corporate notes (due in less than 1 year)	62,186	15	(17)	62,184
Corporate notes (due in 1 to 2 years)	14,971	12	(27)	14,956
	$ 128,783	$ 86	$ (47)	$ 128,822

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GERON CORPORATION

NOTES TO CONDENSED FINANCIAL STATEMENTS

MARCH 31, 2016

(UNAUDITED)

Cash equivalents, restricted cash and marketable securities by security type at December 31, 2015 were as follows:

(In thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Included in cash and cash equivalents:				
Money market funds	$ 4,577	$	$	$ 4,577
Government-sponsored enterprise securities	1,999			1,999
Commercial paper	7,599			7,599
Corporate notes	5,002		(1)	5,001
	$ 19,177	$	$ (1)	$ 19,176
Restricted cash:				
Certificate of deposit	$ 267	$	$	$ 267
Marketable securities:				
Government-sponsored enterprise securities (due in 1 to 2 years)	$ 10,007	$	$ (57)	$ 9,950
Commercial paper (due in less than 1 year)	27,661	49	(2)	27,708
Corporate notes (due in less than 1 year)	64,892	1	(77)	64,816
Corporate notes (due in 1 to 2 years)	22,837		(126)	22,711
	$ 125,397	$ 50	$ (262)	$ 125,185

Cash equivalents and marketable securities with unrealized losses at March 31, 2016 and December 31, 2015 were as follows:

	Less Than 12 Months		12 Months or Greater		Total	
(In thousands)	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses
As of March 31, 2016:						
Government-sponsored enterprise securities (due in 1 to 2 years)	$ 5,002	$ (2)	$	$	$ 5,002	$ (2)
Commercial paper (due in less than 1 year)	4,967	(1)			4,967	(1)
Corporate notes (due in less than 1 year)	25,533	(16)	3,398	(1)	28,931	(17)
Corporate notes (due in 1 to 2 years)	8,587	(27)			8,587	(27)
	$ 44,089	$ (46)	$ 3,398	$ (1)	$ 47,487	$ (47)
As of December 31, 2015:						
Government-sponsored enterprise securities (due in 1 to 2 years)	$ 9,950	$ (57)	$	$	$ 9,950	$ (57)
Commercial paper (due in less than 1 year)	7,834	(2)			7,834	(2)
Corporate notes (due in less than 1 year)	61,006	(71)	6,301	(7)	67,307	(78)
Corporate notes (due in 1 to 2 years)	22,711	(126)			22,711	(126)

$ 101,501	$ (256)	$ 6,301	$ (7)	$ 107,802	$ (263)

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The gross unrealized losses related to government-sponsored enterprise securities, commercial paper and corporate notes as of March 31, 2016 and December 31, 2015 were due to changes in interest rates. We determined that the gross unrealized losses on our cash equivalents and marketable securities as of March 31, 2016 and December 31, 2015 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.

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 March 31, 2016 and indicates the fair value category assigned.

	Fair Value Measurements at Reporting Date Using			
(In thousands)	**Quoted Prices in Active Markets for Identical Assets Level 1**	**Significant Other Observable Inputs Level 2**	**Significant Unobservable Inputs Level 3**	**Total**
Money market funds(1)	$ 3,798	$	$	$ 3,798
Government-sponsored enterprise securities(3)		17,020		17,020
Commercial paper(1)(2)		38,160		38,160
Corporate notes(1)(2)(3)		80,391		80,391
Total	$ 3,798	$ 135,571	$	$ 139,369

The following table presents information about our financial instruments that are measured at fair value on a recurring basis as of December 31, 2015 and indicates the fair value category assigned.

	Fair Value Measurements at Reporting Date Using			
(In thousands)	**Quoted Prices in Active Markets for Identical Assets Level 1**	**Significant Other Observable Inputs Level 2**	**Significant Unobservable Inputs Level 3**	**Total**
Money market funds(1)	$ 4,577	$	$	$ 4,577
Government-sponsored enterprise securities(1)(3)		11,949		11,949

Commercial paper(1)(2)			35,307		35,307
Corporate notes(1)(2)(3)			92,528		92,528
Total	$ 4,577	$	139,784	$	$ 144,361

(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.

3. COLLABORATION AND LICENSE AGREEMENT

In November 2014, we and Janssen entered into the Collaboration Agreement, under which we granted to Janssen exclusive worldwide rights to develop and commercialize imetelstat for all human therapeutic uses, including hematologic myeloid malignancies. Upon the effectiveness of the Collaboration Agreement, we received $35,000,000 from Janssen as an upfront payment, which we classified as deferred revenue upon receipt.

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Under the Collaboration Agreement, Janssen is wholly responsible for the development, manufacturing and commercialization of, and seeking regulatory approval for imetelstat worldwide. To that end, Janssen is currently proceeding with the development of imetelstat with two clinical trials: a Phase 2 trial in myelofibrosis, referred to as IMbark , and a Phase 2/3 trial in myelodysplastic syndromes, referred to as IMerge . Development costs for IMbark and IMerge are being shared between us and Janssen on a 50/50 basis. Additionally, under the terms of the Collaboration Agreement, we remain responsible for prosecuting, at Janssen s direction, the patents licensed to Janssen at the time we entered into the Collaboration Agreement, with costs shared between us and Janssen on a 50/50 basis. The cost sharing arrangement with Janssen began in January 2015. As of March 31, 2016, accrued collaboration charges of $3,537,000 on our condensed balance sheet represent the net amount owed to Janssen for our proportionate share of research and development costs incurred by them under the Collaboration Agreement for the three months ended March 31, 2016.

Following completion of the protocol specified primary analysis of IMbark or after a certain time period after the initiation of the first Phase 3 myelofibrosis study, if any, Janssen must notify us whether it elects to maintain its license rights and continue to advance the development of imetelstat in any indication. In the event that IMbark has been terminated early or suspended, Janssen must instead notify us of its decision by the date that is the later of 24 months from the initiation of IMerge or 24 months from the termination of IMbark or commencement of the suspension period, as applicable.

In the event that Janssen elects to continue to maintain its license rights and advance the development of imetelstat in any indication within the applicable timeframe set forth in the Collaboration Agreement (such decision, the Continuation Decision), we then would have an option, or the U.S. Opt-In Rights, to share further U.S. development and promotion costs in exchange for higher tiered royalty rates and higher future development and regulatory milestone payments if imetelstat is successfully developed and approved. If we exercise the U.S. Opt-In Rights, then we and Janssen would share U.S. development and promotion costs beyond IMbark or IMerge on a 20/80 basis (Geron 20%, Janssen 80%), we would receive a $65,000,000 milestone payment, or the Continuation Fee, at the time of an affirmative Continuation Decision, and would be eligible to receive additional potential payments of up to $470,000,000 in development and regulatory milestones, up to $350,000,000 in sales milestones, and tiered royalties ranging from a mid-teens up to low twenties percentage rate on worldwide net sales of imetelstat in any countries where regulatory exclusivity exists or there are valid claims under the patent rights exclusively licensed to Janssen. In addition, if we exercise the U.S. Opt-In Rights, we then would also have a separate option, or the U.S. Co-Promotion Option, to provide 20% of the U.S. selling effort with sales force personnel, in lieu of funding 20% of U.S. promotion costs, upon regulatory approval and commercial launch of imetelstat in the United States. Such co-promotion would be conducted under a Janssen prepared promotion plan, and in accordance with a co-promotion agreement to be agreed by the parties at the time of our exercise of the U.S. Co-Promotion Option. We would be responsible for all costs associated with establishing and maintaining a sales force in any conduct of such co-promotion. All product sales would be booked by Janssen. If we do not exercise the U.S. Opt-In Rights, then all further development and promotion costs beyond IMbark or IMerge would be borne by Janssen, we would receive the $65,000,000 Continuation Fee at the time of an affirmative Continuation Decision plus a $70,000,000 payment, or the Full U.S. Rights Fee, for Janssen s retention of full U.S. rights to imetelstat, and would be eligible to receive additional potential payments of up to $415,000,000 in development and regulatory milestones, up to $350,000,000 in sales milestones, and tiered royalties ranging from a double-digit up to mid-teens percentage rate on worldwide net sales of imetelstat in any countries where regulatory exclusivity exists or there are valid claims under the patent rights exclusively licensed to Janssen.

After an affirmative Continuation Decision by Janssen, the Collaboration Agreement would remain in effect until the expiration of the last-to-expire patent or the royalty obligations on sales of imetelstat cease, unless terminated earlier. If Janssen does not effect an affirmative Continuation Decision, then the Collaboration Agreement would terminate and all rights to the imetelstat program would revert to us. Janssen may terminate the Collaboration Agreement at any time for convenience or due to a safety-related concern. If a notice of termination from Janssen occurs, we would be entitled to certain continued operational support and cost sharing under various circumstances and all rights to the imetelstat program would revert to us.

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We concluded the license for exclusive worldwide rights to develop and commercialize imetelstat has standalone value to Janssen and that delivery of the license rights granted by us to Janssen, together with our performance of certain technology transfer-related activities under the Collaboration Agreement, represented the sole non-contingent deliverable under the Collaboration Agreement associated with the upfront payment. Therefore, we accounted for our delivery of the imetelstat license rights and our performance of the technology transfer-related activities as a single unit of accounting. During the third quarter of 2015, we completed performance of the technology transfer-related activities to Janssen as outlined under the Collaboration Agreement. Combining this performance with the delivery of the imetelstat license rights, we fully recognized the $35,000,000 upfront payment from Janssen as collaboration revenue on our condensed statements of operations in the third quarter of 2015.

We have determined that each of the additional potential milestone payments to us under the Collaboration Agreement, including: (i) the Continuation Fee at the time of an affirmative Continuation Decision, (ii) the Full U.S. Rights Fee, if we do not exercise the U.S. Opt-In Rights and (iii) payments based on the achievement of certain development, regulatory or sales milestones, represent substantive milestones. Consequently, we will recognize revenue for these payments in their entirety upon successful accomplishment of the respective milestone. Royalties on future product sales of imetelstat, if successfully commercialized under the Collaboration Agreement, will be recognized as revenue when earned.

4. RESTRUCTURING

With projected reduced operational demands as a result of the Collaboration Agreement with Janssen, on March 3, 2015, we announced an organizational resizing to reduce our workforce from 39 to 21 positions. For the three months ended March 31, 2015, we recognized $406,000 in restructuring charges for the pro-rata portion of the one-time termination benefits, which included $90,000 of non-cash stock-based compensation expense relating to the extension of the post-termination exercise period for certain stock options previously granted to employees affected by the restructuring from 90 days to one year from their respective termination dates. For the year ended December 31, 2015, we recorded aggregate restructuring charges of approximately $1,306,000 related to one-time termination benefits which were recognized on a pro-rata basis commencing from the date of announcement of the resizing over the specified remaining service periods for the employees affected by the restructuring. All actions associated with this restructuring were completed in 2015, and we do not anticipate incurring any further charges in connection with this restructuring. We expect this restructuring to result in aggregate cash expenditures of approximately $999,000, of which $964,000 has been paid as of March 31, 2016.

The components relating to the restructuring, including the outstanding restructuring liability which is included in accrued restructuring charges on our condensed balance sheet as of March 31, 2016, are summarized in the following table:

(In thousands)		Employee Severance and Other Benefits
Beginning accrual balance as of December 31, 2015	$	52
Cash payments		(17)
Ending accrual balance as of March 31, 2016	$	35

5. COMMITMENTS AND CONTINGENCIES

Securities and Derivative Lawsuits

On March 14, 2014, a purported class action securities 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 class action securities lawsuit was commenced in the California District Court, and on June 6, 2014, a third 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 class action securities 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,

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including attorneys fees. On June 30, 2014, the California District Court consolidated both of the purported class action securities lawsuits filed in the California District Court, or the Class Action Lawsuits, 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 in the Class Action Lawsuits, which was filed on September 19, 2014. On August 11, 2014, we filed a motion to transfer the securities lawsuit filed in the Mississippi District Court to the California District Court. On November 4, 2014, the Mississippi District Court granted our motion and transferred the case to the California District Court, which was thereafter consolidated with the Class Action Lawsuits. We filed our motion to dismiss the consolidated amended complaint on November 18, 2014. On April 10, 2015, the California District Court granted our motion to dismiss with respect to some of the allegedly false and misleading statements made by us and denied our motion to dismiss with respect to other allegedly false and misleading statements made by us. On May 22, 2015, we filed our answer to the consolidated amended complaint in the Class Action Lawsuits. 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 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, or the San Mateo County Court, 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. On June 26, 2015 and June 29, 2015, respectively, two additional derivative lawsuits naming certain of our officers and directors as defendants were filed in the California District Court by stockholders purporting to act on our behalf. The two derivative cases filed in the California District Court were consolidated on August 17, 2015. On August 25, 2015, an additional derivative lawsuit naming certain of our officers and directors as defendants was filed in the San Mateo County Court. The two derivative cases filed in the San Mateo County Court were consolidated on September 25, 2015. These lawsuits, each of which is based on the same factual background as the derivative lawsuit filed on April 21, 2014 in the San Mateo County Court, also allege breaches of fiduciary duties by the defendants and other violations of law. The plaintiffs in each of the foregoing derivative lawsuits are 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. Proceedings in the derivative lawsuits have been stayed. We intend to vigorously defend against the claims alleged and to seek dismissal of these lawsuits.

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.

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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 our results 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, believ 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, 2015, as filed with the Securities and Exchange Commission, or SEC, on March 10, 2016.

We are a biopharmaceutical company that currently supports the clinical stage development of a telomerase inhibitor, imetelstat, in hematologic myeloid malignancies, by Janssen Biotech, Inc., or Janssen. 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. 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. Early clinical data, including molecular responses in essential thrombocythemia, or ET, and remission responses, including reversal of bone marrow fibrosis, in myelofibrosis, or MF, suggest imetelstat may have disease-modifying activity by inhibiting the progenitor cells of the malignant clones for the underlying diseases.

In November 2014, we entered into a collaboration and license agreement, or the Collaboration Agreement, with Janssen pursuant to which we granted Janssen the exclusive rights to develop and commercialize imetelstat worldwide for all indications in oncology, including hematologic myeloid malignancies, and all other human therapeutic uses. The Collaboration Agreement became effective in December 2014 and we received $35 million from Janssen as an

upfront payment, which we fully recognized as collaboration revenue during the third quarter of 2015. Additional consideration that we may receive under the Collaboration Agreement includes payments up to a potential total of $900 million for the achievement of development, regulatory and commercial milestones, as well as royalties on worldwide net sales of imetelstat.

Under the Collaboration Agreement, Janssen is wholly responsible for the worldwide development, manufacturing and commercialization of, and seeking regulatory approval for, imetelstat. To that end, Janssen is currently proceeding with the development of imetelstat with two clinical trials: a Phase 2 trial in MF, referred to as IMbark , and a Phase 2/3 trial in myelodysplastic syndromes, or MDS, referred to as IMerge . In July 2015, IMbark opened to patient enrollment, and the first patient was dosed in September 2015. In December 2015, IMerge opened to patient enrollment, and the first patient was dosed in January 2016. We are contributing 50% of the development costs for IMbark and IMerge , which Janssen is solely conducting. Janssen may consider initiating additional clinical trials, such as possible registration studies in MF and MDS, and possible exploratory Phase 1 and Phase 2 and potential follow on Phase 3 studies in acute myelogenous leukemia, or AML. The costs for such studies will be borne 100% by Janssen, unless and until Janssen elects to maintain its license rights and continue to advance the development of imetelstat in any indication and we subsequently elect certain opt-in rights to share further U.S. development and promotion costs in exchange for higher tiered royalty rates and higher future development and regulatory milestone payments if imetelstat is successfully developed and approved, as further described in Note 3 on Collaboration and License Agreement in Notes to Condensed Financial Statements of this Form 10-Q.

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We expect Janssen to perform a data cut for IMbark in the second half of 2017, and for Janssen to thereafter initiate the protocol-specified primary analysis; however, the timing of these activities by Janssen may vary based on numerous factors, including the pace of patient enrollment in the clinical trial. Following completion of the protocol-specified primary analysis of IMbark by Janssen or a certain time period after the initiation of the first Phase 3 MF study, if any, Janssen must notify us of their decision, or a Continuation Decision, as to whether they elect to maintain the license rights granted to them under the Collaboration Agreement and continue to advance the development of imetelstat in any indication. In the event that IMbark has been terminated early or suspended, Janssen must instead notify us of their Continuation Decision by the date that is the later of 24 months after the initiation of IMerge or 24 months after the termination of IMbark or commencement of the suspension period, as applicable. For a further discussion regarding the Collaboration Agreement, see Note 3 on Collaboration and License Agreement in Notes to Condensed Financial Statements of this Form 10-Q.

While we reported a small profit for the year ended December 31, 2015 due to our recognition of revenue in connection with an upfront payment from Janssen under the Collaboration Agreement, until 2015 we had never been profitable. We have incurred significant net losses since our inception in 1990, resulting principally from costs incurred in connection with our research and development activities and from general and administrative costs associated with our operations. As of March 31, 2016, we had an accumulated deficit of $937.2 million. Since our 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.

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. The significance of future losses, future revenues and any potential future profitability will depend on whether Janssen continues to develop and advance imetelstat and the clinical and commercial success of imetelstat, which would result in potential future revenues to us in the form of milestone payments and royalties under the Collaboration Agreement as described above, and whether we in-license or acquire other oncology products, product candidates, programs or companies to diversify our business. There can be no assurance that we will receive any milestone payments or royalties from Janssen in the future, or at all. Imetelstat will require significant additional clinical testing prior to possible regulatory approval in the United States and other countries, and we do not expect imetelstat to be commercially available for many years, if at all.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

There have been no significant changes in our critical accounting policies and estimates during the three months ended March 31, 2016 as compared to the critical accounting policies and estimates disclosed in our Annual Report on Form 10-K for the year ended December 31, 2015 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.

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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 research and development efforts in collaboration with Janssen and whether we are able to acquire and/or in license other oncology products, product candidates, programs or companies in order to grow and diversify our business. Results of operations for any period may be unrelated to results of operations for any other period. Thus, historical results should not be viewed as indicative of future operating results. For example, in 2015 we reported net income for the first time due to recognition of revenue in the third quarter of 2015 in connection with an upfront payment from Janssen under the Collaboration Agreement. We expect to incur operating losses in the future as clinical development activities for imetelstat continue under our Collaboration Agreement with Janssen, and our operating losses may increase in size. 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 Janssen for the development, regulatory approval, manufacture and commercialization of 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, we are wholly dependent on Janssen to conduct preclinical tests and clinical trials to 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 royalties based on sales of imetelstat for many years, if at all.

Revenues

In addition to the Collaboration Agreement with Janssen for imetelstat, we have entered into several license or collaboration agreements with companies involved with oncology, diagnostics, research tools and biologics production, whereby we have granted certain rights to our non-imetelstat related technologies. In connection with these 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 $463,000 for the three months ended March 31, 2016, compared to $375,000 for the same period in 2015 related to our various agreements. The increase in license fee revenue for the three months ended March 31, 2016 compared to the same period in 2015 primarily reflects the recognition of higher license fees in the first quarter of 2016 for research licenses related to our human telomerase reverse transcriptase, or hTERT, technology. We recognized royalty revenues of $286,000 for the three months ended March 31, 2016, compared to $162,000 for the same period in 2015. The increase in royalty revenues for the three months ended March 31, 2016 compared to the same period in 2015 reflects higher product sales by our licensees. Future license fee and royalty revenues are also dependent on additional agreements being signed and current agreements being maintained. Current revenues may not be predictive of future revenues.

Research and Development Expenses

During the three months ended March 31, 2016 and 2015, imetelstat was the sole research and development program we supported. For the imetelstat research and development program, we incur direct external, personnel related and other research and development costs. Direct external expenses primarily consist of our proportionate share of research and development costs incurred by Janssen under the Collaboration Agreement and costs paid in the past to outside parties to perform laboratory studies, develop manufacturing processes and manufacture raw materials and clinical trial drug materials, conduct and manage clinical trials, and provide advice and consultation for scientific and clinical strategies. Personnel related expenses primarily consist of salaries and wages, stock-based compensation, payroll taxes and benefits for Geron

employees involved with ongoing research and development efforts. Other research and development expenses primarily consist of research related overhead associated with allocated expenses for rent and maintenance of facilities and other supplies.

Research and development expenses were $5.0 million for each of the three months ended March 31, 2016 and 2015. Research and development expenses for 2016 primarily reflect the net result of higher direct external costs for our proportionate share of clinical development expenses under the Collaboration Agreement with Janssen, partially offset by lower personnel related expenses and research related overhead as a result of the March 2015 restructuring. During the remainder of 2016, we expect direct external research and development expenses to increase as the development of imetelstat progresses in collaboration with Janssen. This projected increase is expected to be partially offset by decreased personnel related research and development expenses as a result of the March 2015 restructuring which was complete as of December 31, 2015.

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Research and development expenses for the three months ended March 31, 2016 and 2015 were as follows:

(In thousands)	Three Months Ended March 31, 2016	2015
	(Unaudited)	
Direct external expenses	$ 3,969	$ 1,801
Personnel related expenses	856	2,602
All other expenses	208	584
Total research and development expenses	$ 5,033	$ 4,987

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 and elsewhere in this Form 10-Q.

Restructuring Charges

In connection with the organizational resizing announced on March 3, 2015, we recorded restructuring charges of approximately $1.3 million in 2015 related to one-time termination benefits which were recognized on a pro-rata basis commencing from the date of announcement of the resizing over the specified remaining service periods for the employees affected by the restructuring. For the three months ended March 31, 2015, we recognized $406,000 in restructuring charges for the pro-rata portion of the one-time termination benefits, which included $90,000 of non-cash stock-based compensation expense relating to the extension of the post-termination exercise period for certain stock options previously granted to employees affected by the restructuring from 90 days to one year from their respective termination dates. No comparable amount was recognized for the three months ended March 31, 2016 as all actions associated with this restructuring were completed in 2015, and we do not anticipate incurring any further charges in connection with this restructuring. See Note 4 on Restructuring in Notes to Condensed Financial Statements of this Form 10-Q for further discussion of the restructuring.

General and Administrative Expenses

General and administrative expenses were $4.8 million for the three months ended March 31, 2016, compared to $4.6 million for the same period in 2015. The increase in general and administrative expenses for the three months ended March 31, 2016 compared to the same period in 2015 primarily reflects the net result of higher non-cash stock-based compensation expense, partially offset by lower personnel related expenses as a result of the restructuring announced in March 2015. We expect general and administrative expenses to remain consistent during the remainder of 2016.

Unrealized Gain on Derivatives

Unrealized gain on derivatives reflects a non-cash adjustment for changes in the fair value of options held by non-employees that were classified as current liabilities. Derivatives classified as 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 an unrealized gain on derivatives of $16,000 for the three months ended March 31, 2015, which primarily reflected a decline in the fair values of options held by non-employees. No comparable amount was incurred for the three months ended March 31, 2016 as all non-employee options classified as derivative liabilities expired unexercised during the first quarter of 2015.

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Interest and Other Income

Interest income was $256,000 for the three months ended March 31, 2016, compared to $149,000 for the same period in 2015. The increase in interest income for the three months ended March 31, 2016 compared to the same period in 2015 primarily reflects higher yields on our marketable securities portfolio. Interest earned in future periods will depend on the size of our marketable securities portfolio and prevailing interest rates.

Interest and Other Expense

Interest and other expense was $21,000 for the three months ended March 31, 2016, compared to $24,000 for the same period in 2015. Interest and other expense primarily reflects bank charges related to our cash operating accounts and marketable securities portfolio.

LIQUIDITY AND CAPITAL RESOURCES

As of March 31, 2016, we had cash, restricted cash, cash equivalents and marketable securities of $141.9 million, compared to $146.7 million at December 31, 2015. The decrease in cash, restricted cash, cash equivalents and marketable securities in 2016 was the result of cash being used for operations. We expect to experience negative cash flow and to incur significant and increasing operating expenses for the foreseeable future as the development of imetelstat progresses in collaboration with Janssen. 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, we may use our available capital resources sooner than we anticipate. In addition, in order to grow and diversify our business, we plan to continue our business development efforts to identify and seek to acquire and/or in-license other oncology products, product candidates, programs or companies. Acquisition or in-licensing opportunities that we may pursue could materially affect our liquidity and capital resources and may require us to incur indebtedness, seek equity capital or both. In addition, there can be no assurance that sufficient additional capital would be available to us in order to pursue any of these opportunities.

We have an investment policy to invest our cash 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.

In August 2015, we entered into an At Market Issuance Sales Agreement, or 2015 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 2015 Sales Agreement, we may elect to issue and sell shares of our common stock having an aggregate offering price of up to $50 million from time to time through MLV as our sales agent. We are not obligated to make any sales of common stock under the 2015 Sales Agreement. To date, we have not sold any common stock pursuant to the 2015 Sales Agreement. The 2015 Sales Agreement will expire in August 2018 unless extended by the parties.

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We may need additional capital resources in order to support development and commercialization of imetelstat, especially if we elect to exercise certain options under the Collaboration Agreement and potentially independently pursue imetelstat development under our own independent development plan under the Collaboration Agreement, and to otherwise support the future growth of our business through the potential acquisition and/or in-licensing of other oncology products, product candidates, programs or companies. We cannot assure you that our existing capital resources, future interest income, potential milestone payments and royalties under the Collaboration Agreement with Janssen and potential future sales of our common stock, including pursuant to our 2015 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;

- in the event that Janssen provides an affirmative Continuation Decision to us, whether we then elect our U.S. Opt-In Rights to share further U.S. development and promotion costs for imetelstat beyond IMbark™ or IMerge™ under the Collaboration Agreement;

- to the extent permitted under the Collaboration Agreement, whether we independently pursue imetelstat development under our own independent development plan, or IDP;

- our potential reimbursement obligations to Janssen if any data from a Janssen IDP support approval by a regulatory agency in the United States or other countries;

- the achievement of development, regulatory and commercial milestones resulting in the payment to us from Janssen under the Collaboration Agreement and the timing of receipt of such payments, if any;

- changes or delays in Janssen s development plans for imetelstat, including changes which may result from any future clinical holds on any investigational new drug applications, or INDs, for imetelstat;

- Janssen s ability to meaningfully reduce manufacturing costs of imetelstat;

- the progress, timing, magnitude, scope and costs of clinical development, manufacturing and commercialization of imetelstat, including the number of indications being pursued, subject to permission from the U.S. Food and Drug Administration, or the FDA, and other regulatory authorities;

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

- Janssen s ability to successfully market and sell imetelstat, upon regulatory approval or clearance, in the United States and other countries;

- if we exercise our U.S. Opt-In Rights, our decision to also exercise our U.S. Co-Promotion Option, including the costs and timing of building a U.S. sales force;

- the timing, receipt and amount of royalties under the Collaboration Agreement on worldwide net sales of imetelstat, upon regulatory approval or clearance, if any;

- the cost of acquiring and/or in-licensing other oncology products, product candidates, programs or companies, if any;

- the timing, receipt and amount of royalties on sales of any stem cell products by Asterias Biotherapeutics Inc., or Asterias, upon development, regulatory approval or clearance, if any;

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

- expenses associated with the pending and potential additional related purported class action 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.

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In addition, changes in our business may occur that would consume available capital resources sooner than we expect. If our existing capital resources, future interest income, and potential milestone payments and royalties under the Collaboration Agreement with Janssen are insufficient to meet future capital requirements, we will need to raise additional capital to fund our operations. Further, if the Collaboration Agreement is terminated, including as a result of Janssen s failure to provide an affirmative Continuation Decision to us, we would not receive any milestone payments or royalties under the Collaboration Agreement, and we would be required to fund all clinical development, manufacturing and commercial activities for imetelstat ourselves, which would require us to raise additional capital or establish alternative collaborations with third-party collaboration partners, which may not be possible. If the Collaboration Agreement was terminated, and we were unable to raise additional capital or establish alternative collaborations with third-party collaboration partners, the development of imetelstat would be discontinued. Additional financing through public or private equity financings, including pursuant to our 2015 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 any IND for imetelstat;
- a failure to show adequate safety or efficacy of imetelstat in current or potential future clinical trials; or
- a termination of the Collaboration Agreement or if our collaboration with Janssen is otherwise unsuccessful.

If sufficient capital is not available, we may be unable to fulfill our funding obligations under the Collaboration Agreement with Janssen, resulting in our breach of the Collaboration Agreement, which could lead to Janssen paying lower milestone payments and lower royalties to us under a reduced royalty tier. This would have a material adverse effect on our results of operations and financial condition.

Moreover, in order to grow and diversify our business, we plan to continue our business development efforts to identify and seek to acquire and/or in-license other oncology products, product candidates, programs or companies. Acquisition or in-licensing opportunities that we may pursue could materially affect our liquidity and capital resources and may require us to incur indebtedness, seek equity capital or both. In addition, there can be no assurance that sufficient additional capital would be available to us in order to pursue any of these opportunities.

Cash Flows from Operating Activities. Net cash used in operations for the three months ended March 31, 2016 and 2015 was $5.6 million and $7.7 million, respectively. The decrease in net cash used in operations in 2016 compared to 2015 primarily reflects the net result of reduced costs for the manufacturing of imetelstat drug product and lower personnel related expenses as a result of the restructuring announced in March 2015, partially offset by payments to Janssen under the cost-sharing arrangement for imetelstat clinical development as outlined under the Collaboration Agreement.

Cash Flows from Investing Activities. Net cash used in investing activities for the three months ended March 31, 2016 and 2015 was $3.7 million and $26.4 million, respectively. The decrease in net cash used in investing activities in 2016 compared to 2015 primarily reflects higher purchases of marketable securities in 2015 with the proceeds from the $35 million upfront payment we received from Janssen in December 2014.

Cash Flows from Financing Activities. Net cash provided by financing activities for the three months ended March 31, 2016 and 2015 was $826,000 and $1.5 million, respectively. The decrease in net cash provided by financing activities in 2016 compared to 2015 primarily reflects the receipt of cash proceeds of approximately $881,000 in March 2015 from the exercise of warrants to purchase 235,000 shares of our common stock at an exercise price of $3.75 per share.

Contractual Obligations

Our future minimum contractual obligations were reported in our Annual Report on Form 10-K for the year ended December 31, 2015, as filed with the SEC. 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, 2015.

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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

During the three months ended March 31, 2016, 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, 2015.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, prior to the filing of this quarterly report. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of the end of the period covered by this quarterly report, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

Effective January 2016, we migrated our existing financial processing and reporting system to Microsoft Dynamics GP (Microsoft GP). This system implementation was undertaken to modernize our financial recordkeeping and reporting capabilities, and was not in response to any actual or perceived deficiencies in our internal control over financial reporting. The implementation of Microsoft GP resulted in material changes to our internal control over financial reporting as that term is defined in Rule 13(a)-15(f) or 15(d)-15(f) under the Exchange Act, including modifications to the design and documentation of internal control processes and procedures relating to the new system to replace and supplement existing internal control over financial reporting. Evaluation of the operating effectiveness of these modified internal control processes and procedures will be conducted by December 31, 2016.

Except as described above, there were no other changes in our internal control over financial reporting during the quarter to which this report relates that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Effectiveness of Controls and Procedures

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

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On March 14, 2014, a purported class action securities 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 class action securities lawsuit was commenced in the California District Court, and on June 6, 2014, a third 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 class action securities 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 action securities lawsuits filed in the California District Court, or the Class Action Lawsuits, 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 in the Class Action Lawsuits, which was filed on September 19, 2014. On August 11, 2014, we filed a motion to transfer the securities lawsuit filed in the Mississippi District Court to the California District Court. On November 4, 2014, the Mississippi District Court granted our motion and transferred the case to the California District Court, which was thereafter consolidated with the Class Action Lawsuits. We filed our motion to dismiss the consolidated amended complaint on November 18, 2014. On April 10, 2015, the California District Court granted our motion to dismiss with respect to some of the allegedly false and misleading statements made by us and denied our motion to dismiss with respect to other allegedly false and misleading statements made by us. On May 22, 2015, we filed our answer to the consolidated amended complaint in the Class Action Lawsuits. 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, or the San Mateo County Court, 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. On June 26, 2015 and June 29, 2015, respectively, two additional derivative lawsuits naming certain of our officers and directors as defendants were filed in the California District Court by stockholders purporting to act on our behalf. The two derivative cases filed in the California District Court were consolidated on August 17, 2015. On August 25, 2015, an additional derivative lawsuit naming certain of our officers and directors as defendants was filed in the San Mateo County Court. The two derivative cases filed in the San Mateo County Court were consolidated on September 25, 2015. These lawsuits, each of which is based on the same factual background as the derivative lawsuit filed on April 21, 2014 in the San Mateo County Court, also allege breaches of fiduciary duties by the defendants and other violations of law. The plaintiffs in each of the foregoing derivative lawsuits are 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. Proceedings in the derivative lawsuits have been stayed. We intend to vigorously defend against the claims alleged and to seek dismissal of these lawsuits.

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.

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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 Quarterly Report on Form 10-Q and our most recent Annual Report on Form 10-K for the year ended December 31, 2015, 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.

RISKS RELATED TO OUR BUSINESS

We have exclusively outlicensed imetelstat, which was our sole product candidate, to Janssen. We are wholly dependent upon our collaborative relationship with Janssen to further develop, manufacture and commercialize imetelstat. If Janssen fails to perform as required by the Collaboration Agreement or abandons the imetelstat program, the potential for us to generate future revenues from milestone payments and royalties from imetelstat would be significantly reduced, the development and/or commercialization of imetelstat could be terminated or substantially delayed, and our business would be severely harmed.

Under the terms of the Collaboration Agreement, we and Janssen have created a joint governance structure, including joint committees and working groups, to oversee and manage worldwide regulatory, development, manufacturing and commercialization activities for imetelstat; however, Janssen is solely responsible for the operational execution of those activities. Accordingly, the timely and successful completion by Janssen of those activities will significantly affect the timing and amount of any revenues from milestone payments and royalties we may receive under the Collaboration Agreement, and these activities will be influenced by, among other things, the efforts and allocation of resources by Janssen, none of which we control. If Janssen does not perform in the manner we expect or fulfill its responsibilities in a timely manner, or at all, the clinical development, manufacturing, regulatory approval and/or commercialization of imetelstat could be delayed or terminated, and it could become necessary for us to assume the responsibilities for the clinical development, manufacturing, regulatory approval and/or commercialization of imetelstat at our own expense. Accordingly, there can be no assurance that any of the development, regulatory or sales milestones under the Collaboration Agreement will be achieved or that we will receive any future milestone or royalty payments under the Collaboration Agreement.

In addition, because Janssen is solely responsible for the operational execution of worldwide regulatory, development, manufacturing and commercialization activities related to imetelstat, we are solely dependent on Janssen to provide us with timely and accurate information concerning these activities as well as the costs incurred under the Collaboration Agreement. If we do not receive accurate information from Janssen in a timely manner, or at all, regarding these activities, including, for example, plans for, and enrollment of, and efficacy and safety results from, clinical trials of imetelstat, then the timeliness and accuracy of our public disclosures, as well as our governance-related decision-making regarding these activities, may be adversely affected.

Our collaboration with Janssen may be unsuccessful due to other factors, including the following:

- Janssen may choose to terminate the Collaboration Agreement for convenience;

- Janssen may provide a negative Continuation Decision and halt its development of imetelstat, in which case we would receive no further payments from Janssen under the Collaboration Agreement;

- the results of IMbark and/or IMerge may be negative or inconclusive, or Janssen may observe safety issues in either of these studies, which may result in a negative Continuation Decision by Janssen;

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- Janssen may choose not to develop and commercialize imetelstat in certain, or any, markets or for one or more indications, if at all;

- Janssen may take considerably more time advancing imetelstat through the clinical and regulatory process than we currently anticipate, which could materially delay the achievement of milestones and, consequently the receipt of milestone payments from Janssen, and ultimately, any royalties we might receive on worldwide net sales of imetelstat;

- in the event of a dispute between us and Janssen regarding Janssen s performance under the Collaboration Agreement, it may be difficult for us to prove that Janssen breached its obligations under the Collaboration Agreement, including the obligation to use commercially reasonable efforts with regard to the development, regulatory approval, manufacture and commercialization of imetelstat under the Collaboration Agreement;

- Janssen may not dedicate the resources necessary to carry imetelstat through clinical development or may not obtain the necessary regulatory approvals for imetelstat, and this would delay the achievement of development, regulatory or sales milestones;

- Janssen s ability to develop and manufacture imetelstat may be delayed or substantially impacted if we are unable to provide to Janssen in a timely manner, or at all, further information related to imetelstat that may be requested by Janssen;

- subject to our election of the U.S. Co-Promotion Option, Janssen will be responsible for all aspects of the commercialization of imetelstat worldwide, including pricing decisions which would affect the royalties on worldwide net sales we could receive;

- Janssen may change the focus of its commercialization efforts or prioritize other programs more highly and, accordingly, reduce the efforts and resources allocated to imetelstat, which might delay or halt the commercialization of imetelstat, and would have the direct effect of reducing our royalties or share of potential co-promotion activities since the extent of our U.S. Co-Promotion Option is limited to a percentage of overall promotion activities under the Collaboration Agreement;

- Janssen may fail to manufacture or supply sufficient quantities of imetelstat or other clinical trial materials for use in planned clinical trials, which could delay, suspend or stop any imetelstat clinical activities;

- Janssen may fail to develop a commercially viable formulation or manufacturing process for imetelstat, and may fail to manufacture or supply sufficient quantities of imetelstat for commercial use, if approved, which would result in lost sales revenue and reduced royalties for us;

- Janssen may not comply with all applicable regulatory requirements or may fail to report safety data from clinical trials of imetelstat in accordance with all applicable regulatory requirements, which could delay, suspend or stop clinical activities of imetelstat being performed by Janssen or by us; and

- if Janssen is acquired by a third party during the term of our collaboration with Janssen, the acquirer may have different strategic priorities that could cause it to terminate the Collaboration Agreement or reduce its commitment to our collaboration.

If our collaboration with Janssen is unsuccessful as a result of any of the above factors, or any other factors, then Janssen may terminate the Collaboration Agreement, and we would not be eligible for any further payments from Janssen under the Collaboration Agreement, which would severely and adversely affect our business and business prospects.

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Clinical development involves a lengthy and expensive process with uncertain outcomes. Current clinical trials of imetelstat being conducted by Janssen, including IMbark , IMerge and the study in MF at Mayo Clinic, or the MF Pilot Study, and potential future clinical trials of imetelstat, may fail to adequately demonstrate the safety and efficacy of imetelstat, which would prevent or delay regulatory approval and commercialization and negatively affect our ability to earn revenues from milestone payments or royalties under the Collaboration Agreement with Janssen.

Before regulatory approvals for the commercial sale of imetelstat can be obtained, clinical testing must be conducted to show that imetelstat is both safe and effective for use in each target indication. Such clinical testing is expensive, can take many years to complete, and is inherently uncertain. Failure can occur at any time during clinical testing. Most product candidates that commence clinical trials are never approved as commercial products.

The clinical development of imetelstat will be influenced by results from current clinical trials, including IMbark , IMerge and the MF Pilot Study, including the cohort of nine patients with a form of MDS known as refractory anemia with ring sideroblasts, or RARS, or the MDS-RARS Cohort, being conducted by Janssen, and potential future clinical trials of imetelstat. The advancement of current clinical trials of imetelstat and commencement of potential future clinical trials of imetelstat could be delayed or abandoned for a variety of reasons, including as a result of failures or delays by Janssen in:

- obtaining or maintaining regulatory clearance to commence, conduct or continue current or potential future clinical trials of imetelstat, including IMbark , IMerge and the MF Pilot Study, including the MDS-RARS Cohort, in a timely manner, or at all, in the United States or other countries;

- maintaining the INDs for imetelstat that we have transferred to Janssen, without such INDs being placed on full or partial clinical hold by the FDA;

- properly designing, enrolling, conducting or completing IMbark , IMerge and potential future clinical trials of imetelstat, and promptly or adequately reporting data from such trials;

- demonstrating sufficient safety and efficacy of imetelstat in IMbark , IMerge and potential future clinical trials without safety issues, side effects or dose-limiting toxicities, including any additional or more severe safety issues in addition to those that have been observed to date in previous or ongoing clinical trials related to imetelstat, whether or not in the same indications or therapeutic areas;

- properly conducting and/or completing the MF Pilot Study, including the MDS-RARS Cohort, and promptly or adequately reporting data from such trial;

- obtaining or accessing necessary clinical data in accordance with appropriate clinical or quality practices to ensure complete data sets;

- responding to safety or futility findings by the data review committees of clinical trials, including IMbark , IMerge and potential future clinical trials of imetelstat, based on emerging data occurring during such clinical trials;

- manufacturing sufficient quantities of imetelstat or other clinical trial materials in a manner that meets the quality standards of the FDA and other regulatory authorities, and responding to any disruptions to drug supply, clinical trial materials or quality issues that may arise;

- ensuring the ability to manufacture imetelstat at acceptable costs for potential Phase 3 clinical trials and commercialization;

- obtaining sufficient quantities of any study-related treatments, materials (including comparator or combination therapies) or ancillary supplies;

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- obtaining acceptance by regulatory authorities of manufacturing changes or clinical trial protocol amendments, as well as subsequently implementing such manufacturing changes and/or clinical trial protocol amendments successfully;

- complying with current and future regulatory requirements, policies or guidelines, including domestic and international laws and regulations pertaining to fraud and abuse, transparency, and the privacy and security of health information;

- 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 clinical trial sites, on all aspects of clinical development; and

- obtaining institutional review board or ethics committee approval of clinical trial protocols or protocol amendments to conduct clinical trials at prospective clinical trial sites.

Failures or delays with respect to any of these events could adversely affect Janssen s ability to maintain or successfully complete any current clinical trials of imetelstat or to initiate potential future clinical trials of imetelstat, which could increase development costs, impair our ability to earn revenues from milestone payments or royalties under the Collaboration Agreement or cause Janssen to terminate the Collaboration Agreement, any of which could adversely impact our financial results, would have severe adverse effects on our business and business prospects, and might cause us to cease operations.

If Janssen encounters difficulties enrolling or retaining patients in current and potential future clinical trials of imetelstat, clinical development and commercialization activities could be delayed or otherwise adversely affected, which could cause Janssen to terminate the Collaboration Agreement, and our business would be severely harmed.

The timely completion of a clinical trial in accordance with its protocol depends, among other things, on the ability to enroll a sufficient number of patients who remain in the study until its conclusion. Janssen may experience difficulties in patient enrollment or retention in IMbark and IMerge , or potential future clinical trials of imetelstat for a variety of reasons. The enrollment and retention of patients depends on many factors, including:

- the patient eligibility criteria in the protocol;

- the size of the patient population required for analysis of the trial s primary endpoint;

- the proximity of patients to study sites;

- the design of the trial;

- Janssen s ability to recruit clinical trial investigators with the appropriate competencies and experience;

- clinicians and patients perceptions as to the potential advantages of imetelstat in relation to other available therapies, including any new drugs that may be approved for the indications being investigated;

- the ability to obtain and maintain patient consents; and

- the risk that patients enrolled in the clinical trial will drop out of the trial before completion due to lack of efficacy, side effects or personal issues.

In addition, IMbark and IMerge , or potential future clinical trials of imetelstat, will compete with other clinical trials for product candidates that are in the same therapeutic areas with imetelstat, and this competition will reduce the number and type of patients available to enroll in the imetelstat clinical trials. Since the number of qualified clinical investigators is limited, we expect IMbark and IMerge , or potential future clinical trials of imetelstat, to be conducted at the same clinical trial sites that competitors use, which will reduce the number of patients who are available for the imetelstat clinical trials at such clinical trial site. Moreover, because imetelstat represents a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, rather than enroll patients in the imetelstat clinical trials.

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Delays in patient enrollment or the inability to retain or treat patients could result in increased costs, lead to incomplete data sets or adversely affect the timing or outcome of IMbark and IMerge , or potential future clinical trials of imetelstat, which could prevent completion of these trials and adversely affect the clinical development and commercialization of imetelstat, either of which would delay the timing of the Continuation Decision from Janssen or could cause Janssen to terminate the Collaboration Agreement. Such occurrences would severely and adversely affect the future of imetelstat and our business prospects and might cause us to cease operations.

Imetelstat may cause, or have attributed to it, undesirable or unintended side effects or other characteristics that delay or prevent the commencement and/or completion of clinical trials for imetelstat, delay or prevent its regulatory approval, or limit its commercial potential, which in each case could cause Janssen to terminate the Collaboration Agreement and which in turn would severely and adversely affect our business prospects and might cause us to cease operations.

Imetelstat may cause, or have attributed to it, undesirable or unintended side effects or other characteristics adversely affecting its safety or efficacy that could delay or prevent the commencement and/or completion of clinical trials for imetelstat. In our Phase 1 clinical trials of imetelstat, we observed dose-limiting toxicities, including thrombocytopenia when imetelstat was used as a single agent, and neutropenia when imetelstat was used in combination with paclitaxel, as well as a low incidence of severe infusion reactions. In our Phase 2 clinical trials of imetelstat in ET, multiple myeloma, or MM, and solid tumors, we 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 observed LFT abnormalities, the clinical significance and long-term consequences of which are currently undetermined. If patients in current or potential future clinical trials of imetelstat experience similar or more severe hepatotoxicity, including LFT abnormalities, severe hepatic or other severe adverse events, the IND for imetelstat may again be placed on clinical hold, and Janssen may be delayed or precluded from further developing imetelstat. In the Phase 2 clinical trial of imetelstat in ET, or the ET Trial, one patient died of bleeding esophageal varices, a complication of chronic liver disease, for which imetelstat initially could not be excluded as a causative agent but which was later determined by the investigator to be unrelated to imetelstat. In the MF Pilot Study, cytopenias have 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 cytopenias, particularly thrombocytopenia, were 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.

Serious adverse events observed in clinical trials could delay or prevent any regulatory approvals of imetelstat or could hinder or prevent market acceptance of imetelstat, which could cause Janssen to terminate the Collaboration Agreement or cause Janssen to limit its commercialization of imetelstat to certain indications. Such occurrences would adversely impact our financial results, have severe adverse effects on our business and business prospects, and might cause us to cease operations.

If Janssen does not elect to continue the development of imetelstat in a timely manner, or at all, our business and business prospects would be severely harmed.

Under the terms of the Collaboration Agreement, Janssen is not obligated to make any additional payments to us until it makes an affirmative Continuation Decision following the results of IMbark , or, if IMbark is terminated early or suspended for an extended period of time, within a certain time period thereafter as set forth in the Collaboration Agreement. The timing of Janssen s Continuation Decision also affects the timing and our opportunity to make our decision regarding our U.S. Opt-In Rights, as well as our election, if we exercise our U.S. Opt-In Rights, of our U.S. Co-Promotion Option. If IMbark is terminated early, suspended for an extended period of time, or is otherwise unsuccessful, Janssen may provide a negative Continuation Decision, in which case, the Collaboration Agreement would terminate, we would not be eligible for any further payments from Janssen under the Collaboration Agreement and our business and business prospects would be severely and adversely affected, which might cause us to cease operations.

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In addition, Janssen may terminate the Collaboration Agreement at any time for convenience. If Janssen terminates the Collaboration Agreement, then, depending on the timing of such event:

- we would no longer have the right to receive any milestone payments or royalties under the Collaboration Agreement;

- the development of imetelstat would likely be terminated or significantly delayed;

- we would bear all of the risks and costs related to the further clinical development, manufacturing, regulatory approval and commercialization of imetelstat;

- we would need to raise additional capital if we were to choose to pursue imetelstat development on our own, or we would need to establish alternative collaborations with third parties, which might not be possible in a timely manner, or at all, or might not be possible on terms acceptable to us, in which case it would likely be necessary for us to limit the size or scope of the imetelstat development program or to seek additional funding by other means to accommodate the increased expenditures; and

- we would need to hire additional employees to support the development and commercialization of imetelstat, which would increase our need for additional funding.

Any termination of the Collaboration Agreement by Janssen at any time would have a material adverse effect on our results of operations, financial condition, business prospects and the future of imetelstat, any of which would have severe adverse effects on our business and business prospects, and might cause us to cease operations.

If Janssen fails to manufacture or provide clinical and commercial quantities of imetelstat on a timely basis, or at all, this could result in a delay of clinical trials or regulatory approvals, or lost sales, and our business and business prospects could be severely harmed.

In accordance with the Collaboration Agreement, Janssen is now responsible for the manufacture and management of the supply of imetelstat on a global basis for all clinical trials and commercial activities. Consequently, we are, and expect to remain, dependent on Janssen to appropriately supply imetelstat and other clinical trial materials. The process of manufacturing imetelstat is complex and subject to several risks, including:

- scaling-up and attaining sufficient production yields with appropriate quality control and quality assurance;

- reliance on third-party manufacturers and suppliers;

- supply chain issues, including the timely availability and shelf life requirements of raw materials and other supplies;

- shortage of qualified personnel; and

- compliance with regulatory requirements, which are less well-defined for oligonucleotide products than for small molecule drugs, that vary in each country where imetelstat might be sold.

As a result of these risks, Janssen may not perform as agreed or may default in its obligations to supply imetelstat or other clinical trial materials for clinical trials and/or commercial activities. Janssen also may fail to deliver the required quantities of imetelstat or other clinical trial materials on a timely basis, or at required or applicable quality standards. Any such failure by Janssen could delay current and/or potential future clinical trials and any applications for regulatory approval and therefore delay the payment of potential milestone payments to us, or, if approved for commercial sale, could impair Janssen s ability to meet the market demand for imetelstat and therefore result in decreased sales and reduced royalties for us.

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Our decision to exercise our U.S. Opt-In Rights under the Collaboration Agreement must be made within a limited time after Janssen makes an affirmative Continuation Decision and, as a result, we may be required to invest substantial capital based on limited clinical data.

We must elect to exercise our U.S. Opt-In Rights within a short timeframe following Janssen s affirmative Continuation Decision. Although we expect to receive information from Janssen regarding data from IMbark and IMerge , proposed future clinical development plans and costs, estimates in timing for commercializing imetelstat and related promotional activities, and calculation of our share of development costs incurred to date by Janssen that we will be required to reimburse if we exercise our U.S. Opt-In Rights, we will be required to rapidly decide whether to make a substantial capital investment in imetelstat prior to the conclusion of any Phase 3 registration-enabling clinical trial. Accordingly, if imetelstat were to become unsuccessful in any Phase 3 registration-enabling clinical trial or were to fail to receive regulatory approval, we would not receive any financial return on this substantial capital investment. Such an occurrence would negatively impact our financial condition and results of operations, and might cause us to cease operations.

We may not be able to successfully identify and acquire and/or in-license other oncology products, product candidates, programs or companies to grow and diversify our business, and, even if we are able to do so, we may not be able to successfully manage the risks associated with integrating any such products, product candidates, programs or companies into our business or we may otherwise fail to realize the anticipated benefits of these acquisitions.

We have exclusively outlicensed imetelstat, which was our sole product candidate, to Janssen. Accordingly, we are relying exclusively upon our collaborative relationship with Janssen to further develop, manufacture and commercialize imetelstat. To grow and diversify our business, we plan to continue our business development efforts to identify and seek to acquire and/or in-license other oncology products, product candidates, programs or companies. Such efforts have not yet resulted in any transaction, and may never result in a transaction. Future growth through acquisition or in-licensing will depend upon the availability of suitable products, product candidates, programs or companies for acquisition or in-licensing on acceptable prices, terms and conditions. Even if appropriate opportunities are available, we may not be able to obtain them; and may not have the ability to develop, obtain regulatory approval for and commercialize such opportunities or the financial resources necessary to pursue them. The competition to acquire or in-license rights to promising products, product candidates, programs and companies is fierce, and many of our competitors are large, multinational pharmaceutical and biotechnology companies with considerably more financial, development and commercialization resources and experience than we have. In order to compete successfully in the current business climate, we may have to pay higher prices for assets than may have been paid historically, which may make it more difficult for us to realize an adequate return on any acquisition. Thus, even if we succeed in identifying promising products, product candidates or programs, we may not be able to acquire rights to them on acceptable terms, or at all.

Even if we are able to successfully identify and acquire or in-license new products, product candidates, programs or companies, we may not be able to successfully manage the risks associated with integrating any products, product candidates, programs or companies into our business or the risks arising from anticipated and unanticipated problems in connection with an acquisition or in-licensing. In any event, we may not be able to realize the anticipated benefits of any acquisition or in-licensing for a variety of reasons, including the possibility that a product candidate fails to advance to clinical development, proves not to be safe or effective in clinical trials, a product fails to reach its forecasted commercial potential or the integration of a product, product candidate, program or company gives rise to unforeseen difficulties and expenditures. Any failure in identifying and managing these risks and uncertainties effectively would have a material adverse effect on our business.

In addition, acquisitions create other uncertainties and risks, particularly when the acquisition takes the form of a merger or other business consolidation. We may encounter unexpected difficulties, or incur unexpected costs, in connection with transition activities and integration efforts, which include:

- high acquisition costs;

- the need to incur substantial debt or engage in dilutive issuances of equity securities to pay for acquisitions;

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- the potential disruption of our historical business and our activities under the Collaboration Agreement;

- the strain on, and need to continue to expand, our existing operational, technical, financial and administrative infrastructure;

- our lack of experience in late-stage product development and commercialization;

- the difficulties in assimilating employees and corporate cultures;

- the difficulties in hiring qualified personnel and establishing necessary development and/or commercialization capabilities;

- the failure to retain key management and other personnel;

- the challenges in controlling additional costs and expenses in connection with and as a result of the acquisition;

- the need to write down assets or recognize impairment charges;

- the diversion of our management s attention to integration of operations and corporate and administrative infrastructures; and

- any unanticipated liabilities for activities of or related to the acquired business or its operations, products or product candidates.

If we fail to integrate or otherwise manage an acquired business successfully and in a timely manner, resulting operating inefficiencies could increase costs and expenses more than we planned, could negatively impact the market price of our common stock and could otherwise distract us from execution of our strategy. Failure to maintain effective financial controls and reporting systems and procedures could also impact our ability to produce timely and accurate financial statements.

In addition, the Collaboration Agreement with Janssen prohibits us from commercializing, under the intellectual property we have licensed exclusively to Janssen, any substance whose identified or known mechanism of action is telomerase inhibition. Further, if we exercise our U.S. Co-Promotion Option under the Collaboration Agreement, we will be required to certify to Janssen at the time of exercising our U.S. Co-Promotion Option that we are not marketing or promoting, and have no right to market or promote, any such products for any oncology indication. Our right to co-promote in the United States may be terminated by Janssen if we develop or commercialize a product for treating an oncology indication that acts through the same mechanism of action as imetelstat or that is substitutable for imetelstat. Accordingly, our Collaboration Agreement with Janssen could adversely affect our ability to acquire or in-license, or to research, develop or market, promising products, product candidates or programs.

We may be unable to successfully retain key personnel to support our collaboration with Janssen or to manage any future growth.

Under the terms of the Collaboration Agreement, we and Janssen have created a joint governance structure, including joint committees and working groups, to manage worldwide regulatory, development, manufacturing and commercialization activities for imetelstat, and we will have ongoing responsibilities to oversee and participate in the collaboration with Janssen. In addition, we remain responsible for prosecuting, at Janssen s direction, the patents we exclusively licensed to Janssen, and have sole responsibility for those patents that were non-exclusively licensed to Janssen. If we are unable to successfully retain, motivate and incentivize our personnel, our ability to support the Collaboration Agreement with Janssen could be impaired, and our business and the price of our common stock would be adversely impacted.

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In addition, our future growth and success depend to a significant extent on the skills, experience and efforts of our executive officers and key members of our 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, as well as the fact that we exclusively outlicensed imetelstat, which was our sole product candidate, to Janssen, and the uncertainties regarding our ability to diversify our business 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 development personnel in the future on acceptable terms. The loss of any or all of these individuals could harm our business and could impair our ability to support our collaboration with Janssen or to support future growth.

We and certain of our officers have been named as defendants in three securities lawsuits, two of which are purportedly class action lawsuits, and certain of our officers and/or directors have been named as defendants in four derivative lawsuits. 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 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 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 class action securities 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 class action securities 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 class action securities 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. We filed our motion to dismiss the consolidated amended complaint on November 18, 2014. On April 10, 2015, the California District Court granted our motion to dismiss with respect to some of the allegedly false and misleading statements made by us and denied our motion to dismiss with respect to other allegedly false and misleading statements made by us. On May 22, 2015, we filed our answer to the consolidated amended complaint in the Class Action Lawsuits.

On June 6, 2014, a 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 securities lawsuit filed in the Mississippi District Court to the California District Court so it could be consolidated with the Class Action Lawsuits. On November 4, 2014, the Mississippi District Court granted our motion and transferred the case to the California District Court, and the transferred case has been consolidated by the California District Court with the Class Action Lawsuits filed in the California District Court.

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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, or the San Mateo County Court, 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. On June 26, 2015 and June 29, 2015, respectively, two additional derivative lawsuits naming certain of our officers and directors as defendants were filed in the California District Court by stockholders purporting to act on our behalf. The two derivative cases filed in the California District Court were consolidated on August 17, 2015. On August 25, 2015, an additional derivative lawsuit naming certain of our officers and directors as defendants was filed in the San Mateo County Court. The two derivative cases filed in the San Mateo County Court were consolidated on September 25, 2015. These lawsuits, each of which is based on the same factual background as the derivative lawsuit filed on April 21, 2014 in the San Mateo County Court, also allege breaches of fiduciary duties by the defendants and other violations of law. The plaintiffs in each of the foregoing derivative lawsuits are seeking unspecified monetary damages and other relief, including reforms and improvements to our corporate governance and internal procedures. Proceedings in the derivative lawsuits have been stayed.

It is possible that additional suits will be filed, or allegations received from stockholders, with respect to these same or other matters, including, for example, the duration and nature of follow-up conducted by Janssen or us of patients enrolled in current and potential future clinical trials of imetelstat, and also naming us and/or our officers and directors as defendants. These lawsuits and any other 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.

We may also be subject to litigation arising from completed strategic transactions or if the results of our business and collaboration activities are not successful.

On November 13, 2014, we announced that we had entered into the Collaboration Agreement with Janssen to develop and commercialize imetelstat worldwide. We may face litigation arising from or related to the Collaboration Agreement or the transactions contemplated thereby, including if we are unable to generate substantial value under the Collaboration Agreement with Janssen or such collaboration is otherwise unsuccessful.

The Collaboration Agreement and other strategic transactions, such as the divestiture of our human embryonic stem cell assets and our autologous cellular immunotherapy program under the asset contribution agreement, or the Contribution Agreement, that we entered into in January 2013 with BioTime, Inc., or BioTime, and Asterias Biotherapeutics, Inc., or Asterias, could result in litigation arising out of any claims that our stockholders suffered financial losses due to the transactions, the approval of our stockholders was required under applicable law or otherwise should have been obtained prior to the completion of these transactions, or that our officers and directors breached their fiduciary duties in connection with the approval and completion of these transactions. Although we believe that stockholder approval was not required under applicable law in order to complete our transactions with Janssen and with BioTime and Asterias, and therefore we neither sought nor intend to seek such stockholder approval, it is possible that persons who were stockholders at the time of the applicable transaction may claim that their approval was required, in which case litigation could follow, which could result in substantial damages to us and/or could negatively affect our rights and obligations under either of these agreements or, in the case of the Collaboration Agreement, could result in the termination of that agreement.

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Likewise, our stockholders may believe that the financial and other terms of the Collaboration Agreement are not favorable to either us or our stockholders, including any belief that the potential payments we may receive under the Collaboration Agreement are inadequate. Litigation brought by our stockholders challenging the validity of, or financial losses resulting from, these transactions could also result in claims against us by Asterias and/or Janssen, and each of the Contribution Agreement and the Collaboration Agreement provide for indemnification by us of BioTime and Janssen, respectively, against all losses and expenses relating to breaches of our representations, warranties and covenants in the applicable agreement, which could expose us to further financial obligations and damages. The occurrence of any one or more of the above could have a significant adverse impact on our business and financial condition.

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

- Janssen is unable to continue development of imetelstat due to actions by regulatory authorities, such as the previous full clinical hold that was placed by the FDA in March 2014 on the IND for imetelstat;

- Janssen 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 conduct of current clinical trials, such as IMbark , IMerge and the MF Pilot Study, including the MDS-RARS Cohort, being conducted by Janssen, and potential future clinical trials, results in patient injury or death, or any failure to meet regulatory and/or compliance requirements;

- the final or any preliminary results from IMbark , IMerge or the MF Pilot Study, including the MDS-RARS Cohort, or any potential future clinical trial of imetelstat, are deemed not to be successful;

- Janssen is unable to obtain regulatory clearance to commercialize imetelstat for sale in the United States and other countries, in a timely manner, or at all, or such regulatory clearance is revoked or put on hold by governmental or regulatory authorities in any jurisdiction;

- Janssen discontinues the further development of imetelstat and terminates the Collaboration Agreement for any reason; or

- Asterias is unable to develop our stem cell assets, and we are not able to receive any royalties from the sale of any potential stem cell products by Asterias,

then our stock price would likely decline, and future litigation may result. A decision adverse to our interests in any such 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 or could otherwise severely harm our business.

Our business may also 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. For example, we are subject to the risk of possible disagreements with Janssen, including those regarding the development and/or commercialization of imetelstat, interpretation of the Collaboration Agreement and ownership of proprietary rights. In addition, in certain circumstances we may believe that a particular milestone under the Collaboration Agreement has been achieved, and Janssen may disagree with our belief. In that case, receipt of that milestone payment may be delayed or may never be received, which would adversely affect our financial condition and may require us to adjust our operating plans. While the Collaboration Agreement provides for a joint governance structure to oversee and manage worldwide regulatory, development, manufacturing and commercialization activities for imetelstat, Janssen generally will, subject to limited exceptions, have the deciding vote in the event of any disagreement. In any event, the joint governance structure contemplated by the Collaboration Agreement will be dissolved in the event that we do not exercise our U.S. Opt-In Rights, which would preclude our ability to participate in any further decision-making for imetelstat. Reliance on a joint governance structure also subjects us to the risk that changes in key management personnel that are members of the various joint committees may materially and adversely affect the functioning of these committees, which could significantly delay or preclude imetelstat development and/or commercialization. As a result of possible disagreements with Janssen, we also may become involved in litigation or arbitration, which would be time-consuming and expensive.

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Monitoring, initiating and defending against legal actions, including our currently-pending securities-related lawsuits and derivative litigations, are time-consuming for our management, 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 negatively affect our legal or contractual rights, which could have a significant adverse effect on our business. In addition, the inherent uncertainty of such litigation, including our currently-pending securities-related lawsuits and derivative litigations, could lead to increased volatility in our stock price and a decrease in the value of our stockholders investment in our common stock.

RISKS RELATED TO CLINICAL AND COMMERCIALIZATION ACTIVITIES

The 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. Significant research and development activities will be necessary to further develop imetelstat, which was our sole product candidate that we have exclusively outlicensed to Janssen, which may take years to accomplish, if at all.

Because of the significant scientific, regulatory and commercial challenges that must be overcome to successfully research, develop and commercialize imetelstat, the development of imetelstat in hematologic myeloid malignancies, including MF and MDS, or any other indications, may be delayed or abandoned, even after significant resources have been expended 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 delay or abandonment of the development of imetelstat in hematologic myeloid malignancies would have a material adverse effect on our collaboration with Janssen, which could result in the termination of the Collaboration Agreement. Any of these events would have severe adverse effects on our business and business prospects and likely result in the failure of our business.

Success in early clinical trials may not be indicative of results in potential future clinical trials. Likewise, preliminary data from clinical trials should be considered with caution since the final data may be materially different from the preliminary data, particularly as more patient data becomes available.

A number of new drugs and biologics have shown promising results in preclinical studies and initial clinical trials, but subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. Product candidates in later stages of clinical trials may fail to show the desired benefit-risk profile despite having progressed through preclinical studies and initial clinical trials. Most product candidates that commence clinical trials are never approved as products.

Data from our preclinical studies and Phase 1 and Phase 2 clinical trials of imetelstat, as well as preliminary, additional or updated data from the MF Pilot Study, including from the MDS-RARS Cohort, should not be relied upon as evidence that subsequent or larger-scale clinical trials of imetelstat will succeed. The results we obtained from the ET Trial may not predict the future therapeutic benefit of imetelstat, if any, in other

hematologic myeloid malignancies, including MF. In addition, the known LFT abnormalities and dose-limiting toxicities associated with imetelstat, such as profound thrombocytopenia and neutropenia and other safety issues, including death, that have been observed in both previous and ongoing clinical trials, including the MF Pilot Study and MDS-RARS Cohort, could cause complexities in treating patients with MF or MDS and could result in the discontinuation of the MF Pilot Study, including the MDS-RARS Cohort, or IMbark or IMerge . 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 authorities to be accurate predictors of efficacy for different endpoints that may be required by the FDA or other regulatory authorities for Phase 3 clinical trials.

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The preliminary results of the MF Pilot Study presented by the investigator at the American Society of Hematology, or ASH, annual meeting in December 2013, and updated by the investigator at ASH in December 2014, will need to be confirmed in one or more larger Phase 2 and Phase 3 trials in MF at multiple treating centers. The results reported by us, Janssen or by the investigator in the MF Pilot Study, including in the MDS-RARS Cohort, may not be reproduced in IMbark , IMerge or in any potential imetelstat trials conducted in the future, 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, MDS or in any other hematologic myeloid malignancy.

In addition, from time-to-time, preliminary data from current or potential future clinical trials, such as the ongoing MF Pilot Study, IMbark and IMerge may be reported or announced by Janssen, its investigators, or us. For example, the investigator for the MF Pilot Study reported preliminary data from the trial in December 2013, which the investigator updated in December 2014, and reported preliminary data from the MDS-RARS Cohort in December 2015. Since those data were preliminary, the final data from the MF Pilot Study, including the MDS-RARS Cohort, may be materially different than the preliminary data reported by the investigator. Since remaining patients previously enrolled in the MF Pilot Study, including the MDS-RARS Cohort, continue to receive imetelstat, principally safety data continue to be generated, and additional and updated data may materially change the overall conclusions from the preliminary data reported for the MF Pilot Study, including the MDS-RARS Cohort. Therefore, such preliminary data should be considered carefully and with caution. Material adverse changes in the final data from the MF Pilot Study, including the MDS-RARS Cohort, could jeopardize our Collaboration Agreement with Janssen and if Janssen were to terminate the Collaboration Agreement, our business prospects would be severely and adversely affected, and we might cease operations. Even if final safety data from the MF Pilot Study, including the MDS-RARS Cohort, are positive, significant additional clinical testing will be necessary for the future development of imetelstat in MF or MDS.

Clinical trials of imetelstat may not uncover all possible adverse effects that patients may experience from imetelstat treatment.

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. Because previously enrolled patients who remain on study continue to receive imetelstat in the MF Pilot Study, including the MDS-RARS Cohort, additional or more severe toxicities or safety issues, including additional serious adverse events and clinically significant LFT abnormalities, may be observed in the MF Pilot Study, including the MDS-RARS Cohort, as patient treatment continues and more data become available. Likewise, additional or more severe toxicities or safety issues, including additional serious adverse events and clinically significant LFT abnormalities, may be observed in IMbark and IMerge , particularly given the larger target patient enrollment in those studies. Since IMbark , IMerge and the MF Pilot Study, including the MDS-RARS Cohort, are ongoing studies in which additional data is being generated, the benefit-risk profile of imetelstat will continue to be assessed, including the risk of hepatotoxicity, severe cytopenias and any other severe adverse effects that may be associated with life-threatening clinical outcomes. If such toxicities or other safety issues in any clinical trial of imetelstat result in an unacceptable benefit-risk profile, then:

- the commencement and/or completion of any current or potential future clinical trials, including IMbark , IMerge and the MF Pilot Study, including the MDS-RARS Cohort, would likely be delayed, for example by being placed on a clinical hold, halted or prohibited; or

- additional, unexpected clinical trials or preclinical studies may be required to be conducted.

The occurrence of any of these events could cause Janssen to abandon the development of imetelstat entirely and terminate the Collaboration Agreement. Any termination of the Collaboration Agreement by Janssen would have a severe adverse effect on our results of operations, financial condition, business prospects and the future of imetelstat, any of which might cause us to cease operations.

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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 imetelstat 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, in collaboration with Janssen, from successfully conducting 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 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 may be received could limit the use of imetelstat.

Prior to initiating potential future clinical trials of imetelstat, clinical trial protocols must be submitted to the FDA or regulatory authorities in other countries. Questions or comments from these agencies that must be addressed would likely delay further clinical development of imetelstat and potentially the timing of any Continuation Decision by Janssen or could cause Janssen to terminate the Collaboration Agreement, which would severely and adversely affect the future of imetelstat and our business prospects.

Before Janssen can seek to obtain regulatory approval for the commercial sale of imetelstat, multiple clinical trials, including larger-scale Phase 3 clinical trials, will need to be conducted to demonstrate that imetelstat is safe and effective for use in a diverse population. If imetelstat cannot be developed in potential future clinical trials, including Phase 3 clinical trials, our Collaboration Agreement with Janssen will be negatively impacted and likely be terminated altogether, which would have severe adverse effects on our business and business prospects, and might result in the failure of our business.

If the interpretation by us or Janssen 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 which may cause Janssen to terminate the Collaboration Agreement. 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 previous or ongoing clinical trials, such as IMbark , IMerge or the MF Pilot Study, including the MDS-RARS Cohort. In addition, delays or rejections of regulatory approvals, or limitations in marketing authorizations, may be encountered as a result of changes in the 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.

The benefit-risk profile of imetelstat will also affect the assessment by the FDA and regulatory authorities in other countries of the drug s cost-effectiveness and/or marketability, which assessment could prevent or limit its approval for marketing and successful commercial use. If regulatory submissions requesting approval to market imetelstat are submitted, the FDA and regulatory authorities in other countries may conclude that the overall benefit-risk profile of imetelstat treatment does not merit approval of imetelstat for marketing or further development for any indication. Any of these events could cause Janssen to terminate the Collaboration Agreement, which would severely harm our business and business prospects, and might cause us to cease operations.

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 future development activities;

- diminish any competitive advantages that may have been available; or

- adversely limit the amount of, or affect our ability to receive, any milestone payments or royalties under the Collaboration Agreement with Janssen.

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Even if the necessary time and resources are committed by Janssen, the required regulatory agency clearances and approvals may not be obtained for imetelstat. Further, if regulatory agency clearances and approvals are obtained to commence commercial sales of imetelstat, they may impose significant limitations on the indicated uses or other aspects of the product label for which imetelstat can be marketed. Further, an approval might be contingent on the performance of costly additional post-marketing clinical trials that would be required after approval. The occurrence of any of these events could limit the potential commercial use of imetelstat, and therefore delay the payment of potential milestone payments to us, or, if approved for commercial sale, could reduce the market demand for imetelstat and therefore result in decreased sales and reduced royalties for us under the Collaboration Agreement. Occurrence of any of these events could negatively impact our collaboration with Janssen or cause Janssen to terminate the Collaboration Agreement, which would severely and adversely affect our business and business prospects.

Although orphan drug designation has been granted to imetelstat for the treatment of MF and MDS, these designations may not be maintained, which would eliminate the benefits associated with orphan drug designation, including the potential for market exclusivity, which would likely result in potential sales revenue for imetelstat, if any, to be reduced, and would likely harm our business and business prospects.

Although the FDA granted orphan drug designation to imetelstat in June 2015 for the treatment of MF and for the treatment of MDS in December 2015, and the European Medicines Agency, or EMA, granted it in November 2015 for the treatment of MF, Janssen may not be the first to obtain marketing approval of a product candidate for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States or the European Union, if granted, may be limited if Janssen seeks approval for an indication broader than the orphan-designated indication or such marketing exclusivity may be lost if the FDA or the EMA later determines that the request for orphan drug designation was materially defective, or if Janssen is unable to ensure and provide sufficient quantities of imetelstat to meet the needs of patients with the rare disease or condition. Further, even if Janssen obtains orphan drug exclusivity for imetelstat, that exclusivity may not effectively protect imetelstat from competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan drug product is approved, the FDA or EMA can subsequently approve a different drug with the same active moiety for the same condition if the FDA or EMA concludes that the later drug is safer, more effective, or makes a major contribution to patient care. Occurrence of any of these events could result in decreased sales and reduced royalties for us, and may harm our business and business prospects. In addition, orphan drug designation will neither shorten the development time nor regulatory review time for imetelstat, and does not give imetelstat any advantage in the regulatory review or approval process.

Failure to achieve continued compliance with government regulation could delay or halt commercialization of imetelstat, which we have exclusively out-licensed to Janssen.

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. If approved for commercial sale, future sales of imetelstat will be subject to government regulation related to numerous matters, including the processes of:

- manufacturing;
- advertising and promoting;

- selling and marketing;
- labeling; and
- distribution.

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If, and to the extent that, we are or Janssen is unable to comply with these regulations, our ability to earn potential milestone payments and royalties from worldwide net sales of imetelstat would be materially and adversely 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 negatively impact our collaboration with Janssen or cause Janssen to terminate the Collaboration Agreement, either of which would severely and adversely affect our business and business prospects and might cause us to cease operations.

Any development activities conducted by Janssen under a Janssen Independent Development Plan, or IDP, may create significant reimbursement obligations for us, which could result in reduced cash inflow from future milestone payments and royalties until we have fully paid our reimbursement obligations under the Collaboration Agreement.

Under the Collaboration Agreement, Janssen may conduct certain development activities for imetelstat under a Janssen IDP if we and Janssen agree that such activities should be performed outside of the mutually agreed global clinical development plan. Although Janssen would bear all of the costs for such Janssen IDP, if we exercised our U.S. Opt-In Rights and if any data from a Janssen IDP supports approval by a regulatory agency in the United States or other countries, then we would be required to reimburse Janssen for our share of the costs of that Janssen IDP plus a premium pursuant to the terms of the Collaboration Agreement. This cost reimbursement is payable as a lump sum up to a certain threshold upon receipt of regulatory approval for the Janssen IDP. Any remaining amounts in excess of the threshold are payable in installments by offsetting milestone payments or royalties received by us over a certain period of time, at which time any remaining reimbursement amount would be payable in a lump sum. This payment mechanism could result in reduced cash inflow from future milestone payments and royalties, which would adversely affect our results of operations and financial condition.

Under the Collaboration Agreement, if we develop imetelstat independently under our own IDP, the success of that IDP may depend on our ability to provide adequate financial and technical resources, and failure to successfully conduct or fund our own IDP activities may adversely affect our business.

Under the Collaboration Agreement, we may conduct certain development activities for imetelstat under a Geron IDP if we and Janssen agree that such activities should be performed outside of the mutually agreed global clinical development plan. In the event we conduct any clinical activities under a Geron IDP, we will be responsible for paying all of the development costs for the Geron IDP. Because the outcome of any clinical activities and/or regulatory approval process is highly uncertain, we cannot reasonably estimate whether any Geron IDP activities we may undertake will succeed. Since we are only eligible for reimbursement from Janssen for their share of the Geron IDP costs plus a premium if any data from a Geron IDP supports approval by a regulatory agency in the United States or other countries, we may not recoup our investment in any Geron IDP, which could adversely affect our financial condition. In addition, we may need additional capital to support any Geron IDP activities and we cannot assure you that our existing capital resources, future interest income, potential milestone payments and royalties under the Collaboration Agreement and potential future sales of our common stock will be sufficient to fund these future activities. If sufficient capital is not available, we may be unable to pursue activities under a Geron IDP, which could adversely affect our business.

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To execute activities under a Geron IDP, we likely would be required to collaborate with contract research organizations, investigators, academic institutions, vendors, clinical trial sites, scientific consultants and others. We would be dependent upon the ability of these parties to perform their responsibilities reliably. In addition, we would have limited control over the activities of these organizations, investigators, scientific consultants and vendors. Except as otherwise required by our agreements with them, we could expect only limited amounts of their time to be dedicated to our activities. If any of these third parties were unable or refused to contribute to projects on which we needed their help, our ability to conduct activities under a Geron IDP could be significantly harmed. Also, if the performance of these services is not of the highest quality, 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 clinical activities under a Geron IDP which would, in turn, hinder our ability to make the necessary representations or provide the necessary information to regulatory authorities, if at all. As a result, we may not obtain regulatory approval and receive any reimbursement from Janssen for their share of the costs for the Geron IDP, which could adversely affect our business and financial condition.

If third parties that manufacture imetelstat fail to perform as needed, then the clinical and commercial supply of imetelstat will be limited.

Currently, third-party contractors perform certain process development or other technical and scientific work with respect to imetelstat, as well as supplying starting materials and manufacturing drug substance and drug product. Janssen, which is responsible for the manufacture and management of the supply of imetelstat on a global basis for clinical trials and, after any regulatory approval, all commercial activities, currently relies on these third-party contractors to produce and deliver sufficient quantities of imetelstat and other clinical trial materials to support clinical trials on a timely basis and to comply with applicable regulatory requirements. Janssen does not have direct control over these third-party personnel or operations. Reliance on these third-party manufacturers is subject to several risks, including:

- being unable to identify suitable third-party manufacturers, because the number of potential manufacturers is limited and regulatory authorities may require significant activities to validate and qualify any replacement manufacturer, which could involve new testing and compliance inspections;

- being unable to contract with third-party manufacturers on acceptable terms, or at all;

- the inability of third-party manufacturers to timely formulate and manufacture imetelstat or to produce imetelstat in the quantities or of the quality required to meet clinical and commercial needs;

- decisions by third-party manufacturers to exit the contract manufacturing business during the time required to supply clinical trials or to successfully produce, store and distribute products;

- compliance by third-party manufacturers with current Good Manufacturing Practice, or cGMP, standards mandated by the FDA and state agencies and other government regulations corresponding to foreign regulatory authorities;

- breach or termination of manufacturing contracts;

- capacity limitation and scheduling imetelstat as a priority in contracted facilities; and

- natural disasters that affect contracted facilities.

Each of these risks could lead to delays in drug supply, or the inability to manufacture drug supply necessary for preclinical and clinical activities, and commercialization. In addition, any decision by Janssen to self-manufacture imetelstat, change third-party contractor manufacturers or make changes to manufacturing processes, product vial size or packaging, or formulations for imetelstat, could result in manufacturing delays. Manufacturing delays could adversely impact the completion of current clinical trials, such as IMbark and IMerge , or the initiation of potential future clinical trials, which may cause Janssen to terminate the Collaboration Agreement or delay the timing of any Continuation Decision that Janssen could provide to us, either of which would severely and adversely affect our business prospects and might cause us to cease operations.

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In addition, current third-party contractors and/or any other contractors utilized by Janssen 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 of imetelstat. These third-party contractors 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 commercially reasonable costs. Janssen currently does not have any long-term commitments or commercial supply agreements with any of the third-party contractors for imetelstat, 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 Janssen to find a replacement manufacturer on acceptable terms, or at all.

It may not be possible to manufacture imetelstat at costs or scales necessary to conduct clinical trials or potential future commercialization activities.

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. Therefore, imetelstat for clinical use is more expensive to manufacture than most other treatments currently available today or that may be available in the future. Similarly, the cost of manufacturing imetelstat for commercial use will need to be significantly lower than current costs in order for imetelstat to become a commercially successful product. Janssen may not be able to achieve sufficient scale increases or cost reductions necessary for successful commercial production of imetelstat, which could result in decreased sales and reduced royalties for us.

We have not yet negotiated our agreement with Janssen specifying all of the terms for our co-promotion of imetelstat should we exercise our U.S. Co-Promotion Option. In addition, we do not have a sales force and may not develop an effective one, if at all.

Pursuant to the Collaboration Agreement with Janssen, we have a U.S. Co-Promotion Option if we exercise our U.S. Opt-In Rights. Assuming we exercise the U.S. Co-Promotion Option, we can elect to provide 20% of the U.S. imetelstat selling effort with Geron sales force personnel, in lieu of funding 20% of U.S. promotion costs upon regulatory approval and commercial launch of imetelstat in the United States. While the Collaboration Agreement includes the material terms of our U.S. Co-Promotion Option, we and Janssen mutually agreed to negotiate a separate agreement specifying detailed activities and responsibilities with respect to the marketing and co-promotion of imetelstat following our election to exercise our U.S. Co-Promotion Option. We will need to negotiate this separate agreement with Janssen and, as a result, Janssen may impose restrictions or additional obligations on us, including financial obligations. Any restrictions or additional obligations may restrict our co-promotion activities or involve more significant financial or other obligations than we currently anticipate. In addition, we have no sales experience as a company, and there are risks involved with establishing our own sales force capabilities, including:

- incurring substantial expenditures to develop a sales force and function;
- exposure to unforeseen costs and expenses; and
- being unable to effectively recruit, train or retain sales personnel.

Accordingly, we may be unable to establish our own sales force, which would delay or preclude us from participating in co-promoting imetelstat in the United States. In addition, because of our current lack of expertise in sales operations, any sales force we establish may not be effective, or may be less effective than any sales force that Janssen utilizes to promote imetelstat. In such event, the commercialization of imetelstat may be adversely affected, since we would be wholly reliant on Janssen s sales efforts, and this could materially and adversely affect any sales milestone or royalties we may receive under the Collaboration Agreement.

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The Collaboration Agreement limits our ability to transfer our U.S. Co-Promotion Option to a potential acquirer.

Although the Collaboration Agreement permits us to be acquired by any company, our right to transfer our U.S. Co-Promotion Option in the case of an acquisition, merger, consolidation, share exchange, business combination, recapitalization, sale of a majority of assets or similar transaction is limited, and subject to Janssen s sole discretion under certain circumstances. If we are acquired outside of such limited circumstances, then we may not be able to transfer the U.S. Co-Promotion Option to such acquirer as part of the acquisition. This limiting provision may discourage potential acquisition bids for us or lower our value, thus preventing holders of our common stock from benefiting from what they may believe are the positive aspects of an acquisition, including the potential realization of a higher rate of return on their investment from this type of transaction.

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 clinical trials, including clinical trials that we may conduct under a Geron IDP or in collaboration with Janssen under the Collaboration Agreement. In addition, product liability insurance is becoming increasingly expensive. Being unable to obtain or maintain product liability insurance in the future on acceptable terms or with adequate coverage against potential liabilities could have a material adverse effect on our business.

RISKS RELATED TO PROTECTING OUR INTELLECTUAL PROPERTY

We remain responsible for prosecuting, at Janssen s direction, the patents we have exclusively licensed to Janssen. The success of our collaboration with Janssen will depend on our ability to protect our technologies and imetelstat through patents and other intellectual property rights.

Protection of our proprietary technology is critically important to our business, especially with respect to our collaboration with Janssen. 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 any of these regards, the value of our technologies and imetelstat will be adversely affected, and we and/or Janssen may be unable to continue development of imetelstat. Further, our patents may be challenged, invalidated or circumvented, and our patent rights may not provide proprietary protection or competitive advantages to us or Janssen. In the event that we are unsuccessful in obtaining and enforcing our patents and other intellectual property rights, we or Janssen may not be able to further develop or commercialize imetelstat, any of which might delay or halt ongoing or potential future clinical trials of imetelstat and any applications for regulatory approval and therefore delay or halt the payment of potential milestone payments to us, or, if imetelstat is approved for commercial sale, could impair Janssen s ability to sell imetelstat and therefore result in decreased sales and reduced royalties for us. Occurrence of any of these events could negatively impact our collaboration with Janssen or cause Janssen to terminate the Collaboration Agreement, which would materially and adversely affect our business, and might cause us to cease operations.

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 or Janssen infringe the patents of others, we or Janssen may be blocked from continuing development work with respect to imetelstat or be required to obtain licenses on terms that may impact the value of imetelstat or cause it to be commercially impracticable.

A number of significant changes to U.S. patent law occurred when the Leahy-Smith America Invents Act, or the AIA, was signed into law on September 16, 2011. These include provisions that affect the way patent applications are prosecuted and may affect patent litigation. Many of the substantive changes to patent law associated with the AIA, and in particular, the first to file provisions, became effective on March 16, 2013. For example, under the AIA, patent rights are awarded to the first inventor to file a patent application with respect to a particular invention. Since the publication of discoveries in scientific or patent literature tends to lag behind actual discoveries by at least several months and sometimes several years, the persons or entities that we 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. 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 or any joint inventions that we may develop with Janssen. 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. Significant impairment of our imetelstat patent rights would have a material adverse effect on our business and could cause Janssen to terminate the Collaboration Agreement, which might cause us to cease operations.

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Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and changes providing opportunities for third parties to challenge any issued patent in the Patent Office. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard necessary to invalidate a patent claim in Patent Office proceedings compared to the evidentiary standard in U.S. federal court, a third party could potentially provide evidence in a Patent Office proceeding sufficient for the Patent Office to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party could attempt to use the Patent Office procedures to invalidate patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

Recent court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. For example, on June 13, 2013, the U.S. Supreme Court, or the Court, issued a decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.* holding that claims to isolated genomic DNA were not patentable subject matter, but claims to complementary DNA, or cDNA, molecules were patentable subject matter. 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. In addition, recent court rulings in cases such as *BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig*. and *Promega Corp. v. Life Technologies Corp.* have also narrowed the scope of patent protection available in certain circumstances. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events may have created uncertainty with respect to the value of certain patents we have previously obtained or in-licensed.

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. Occurrence of these events could significantly impair our imetelstat patent rights which would have a material adverse effect on our business and could cause Janssen to terminate the Collaboration Agreement, which might cause us to cease operations.

Challenges to our patent rights would result in costly and time-consuming legal proceedings that could 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 could delay or prevent the issuance of patents, or result in the loss of issued patent rights.

Under the AIA, interference proceedings between patent applications filed on or after March 16, 2013 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, such as inter partes review, or IPR, covered business method post-grant reviews and other post-grant reviews. 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. In addition, the IPR process under the AIA permits any person, whether they are accused of infringing the patent at issue or not, to challenge the validity of certain patents. As a result, entities associated with hedge funds have challenged valuable pharmaceutical patents through the IPR process. A decision in such proceedings adverse to our interests could result in the loss of valuable patent rights which would have a material adverse effect on our business and could cause Janssen to terminate the Collaboration Agreement, which might cause

us to cease operations.

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Certain jurisdictions, such as Europe, New Zealand and Australia, permit oppositions to be filed against granted patents or patents proposed to be granted. Under the Collaboration Agreement, Janssen could commercialize imetelstat internationally if approved by regulatory authorities for commercial sale. Therefore, securing both proprietary protection and freedom to operate outside of the United States is important to the Collaboration Agreement with Janssen and our business. Opposition proceedings require significant time and costs, and if we are unable to commit these types of resources to protect our imetelstat patent rights, we and/or Janssen could be prevented or limited in the development and commercialization of imetelstat. Occurrence of any of these events would severely and adversely affect our business prospects and could negatively impact our collaboration with Janssen or cause Janssen to terminate the Collaboration Agreement, which might cause us to cease operations.

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, post-grant proceedings, oppositions, re-examinations, litigation or other means will likely increase. Challenges to our patents through these procedures would be extremely expensive and time-consuming, even if the outcome was favorable to us. An adverse outcome in a patent dispute could severely harm our collaboration with Janssen or cause Janssen to terminate the Collaboration Agreement, or could otherwise have a material adverse effect on our business, and might cause us to cease operations, by:

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

- subjecting us to litigation, or otherwise preventing Janssen or us from commercializing imetelstat in the relevant jurisdiction(s);

- requiring Janssen or us to obtain licenses to the disputed patents;

- forcing Janssen or us to cease using the disputed technology; or

- requiring Janssen or us to develop or obtain alternative technologies.

We or Janssen may be subject to infringement claims that are costly to defend, and as to which we may be obligated to indemnify Janssen or obtain unblocking licenses, and such claims may limit our or Janssen s ability to use disputed technologies and prevent us or Janssen from pursuing research and development or commercialization of imetelstat.

The commercial success of imetelstat will depend upon our and Janssen s 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. In the event our technologies infringe the rights of others or require the use of discoveries and technologies controlled by third parties, we or Janssen 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. For example, we are aware that certain third parties have or may be prosecuting patents and patent estates that may relate to imetelstat, 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 and/or Janssen in the future. Under the Collaboration Agreement, we are obligated under certain circumstances to indemnify Janssen from any claim of infringement of the patent rights of third parties in Janssen s development, manufacture or commercialization of imetelstat, or to obtain unblocking licenses from such third parties, at our cost.

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Since we cannot be aware of all intellectual property rights potentially relating to imetelstat and its uses, we do not know with certainty that imetelstat, or the intended commercialization thereof, does not and will not infringe or otherwise violate any third party s intellectual property. Any infringement claims against us or Janssen would likely be expensive to resolve, and the cost of any indemnification of Janssen or unblocking license that we could be required to obtain under the Collaboration Agreement is unpredictable and could be significant. If we or Janssen are unable to resolve an infringement claim successfully, we or Janssen could be subject to an injunction which would prevent us or Janssen from commercializing imetelstat, and could also require us or Janssen to pay substantial damages. In addition to infringement claims, in the future we or Janssen may also be subject to other claims relating to intellectual property, such as claims that we or Janssen have misappropriated the trade secrets of third parties. Provided that Janssen continues to progress the development of imetelstat, we expect to see more efforts by others to obtain patents that are positioned to cover imetelstat. Our success therefore depends significantly on our and Janssen s ability to operate without infringing patents and the proprietary rights of others.

We or Janssen may become aware of discoveries and technologies controlled by third parties that are advantageous to developing or manufacturing imetelstat. Under such circumstances, we or Janssen may initiate negotiations for licenses to other technologies as the need or opportunity arises. We or Janssen may not be able to obtain a license to a technology required for the research, development, manufacture or commercialization of imetelstat on commercially favorable terms, or at all, or such licenses may be terminated on certain grounds, including as a result of our or Janssen s failure to comply with the obligations under such licenses. If we or Janssen do not obtain a necessary license or if such a license is terminated, we or Janssen may need to redesign such technologies or obtain rights to alternative technologies, which may not be possible, and even if possible, could cause delays in the development efforts for imetelstat. In cases where we or Janssen are unable to license necessary technologies, we and/or Janssen could be subject to litigation and prevented from researching, developing, manufacturing or commercializing imetelstat, and in certain circumstances we may be required to indemnify Janssen for infringement claims arising from Janssen s research, development, manufacture or commercialization of imetelstat, which could materially and adversely impact our business. Failure by us or Janssen to obtain rights to alternative technologies or a license to any technology that may be required to research, develop, manufacture or commercialize imetelstat would delay potential future clinical trials of imetelstat and any applications for regulatory approval and therefore delay the payment of potential milestone payments to us, or, if imetelstat is approved for commercial sale, could impair Janssen s ability to sell imetelstat and therefore result in decreased sales and reduced royalties for us. Occurrence of any of these events could negatively impact our collaboration with Janssen or cause Janssen to terminate the Collaboration Agreement, which would materially and adversely affect our business, and might cause us to cease operations.

We may become involved in disputes with Janssen or any past or future collaborator(s) over intellectual property inventorship or ownership, and publications by us or Janssen, or by 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, including our Collaboration Agreement with Janssen, 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 invents and owns a particular invention, or whether it is jointly owned, and disputes can arise regarding inventorship and 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, clinical trial investigators, scientific consultants and research collaborators generally have contractual rights to publish data and other proprietary information, subject to review by us and/or Janssen. Publications by us or Janssen, or by investigators, scientific consultants and research collaborators containing such information, either with permission or in contravention of the terms of their agreements, may impair the ability to obtain patent protection or protect proprietary information which would have a material adverse effect on our business and could cause Janssen to terminate the Collaboration Agreement, which might cause us to cease operations.

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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.

Significant disruptions of information technology systems, including cloud-based 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 cloud-based systems, to support business processes as well as internal and external communications. Our computer systems are potentially vulnerable to breakdown, malicious intrusion and computer viruses that may result in the impairment of key business processes. Such disruptions and breaches of security could have a material adverse effect on our business, financial condition and results of operations.

In addition, our data security and information technology 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 disclosure of sensitive clinical or commercial data, and the exposure of personally identifiable information (including sensitive personal information) of our employees, collaborators, clinical trial patients and others. A data security breach or privacy violation that leads to disclosure or modification of or prevents access to patient information, including personally identifiable information or protected health information, could harm our reputation, compel us to comply with federal and/or state breach notification laws, subject us to mandatory corrective action, require us to verify the correctness of database contents and otherwise subject us to liability under laws and regulations that protect personal data, resulting in increased costs or loss of revenue. If we are unable to prevent such data security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information, including sensitive patient data. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. Moreover, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information, trade secrets or other intellectual property. While we have implemented security measures to protect our data security and information technology systems, such measures may not prevent such events.

RISKS RELATED TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL FINANCING

Although we reported a small profit for the year ending December 31, 2015, we have a history of losses and anticipate continued future losses, and our continued losses could impair our ability to sustain operations.

Until 2015, we had never been profitable and we had incurred operating losses every year since our operations began in 1990. While we were profitable in 2015 due to the recognition of revenue in connection with an upfront payment from Janssen under the Collaboration Agreement, we

expect to incur additional operating losses and, as clinical development activities for imetelstat continue under our Collaboration Agreement with Janssen, our operating losses may increase in size. As of March 31, 2016, our accumulated deficit was approximately $937.2 million. Losses have resulted principally from costs incurred in connection with our research and development activities and from general and administrative costs associated with our operations.

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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. Any revenues generated from our licensing arrangements or ongoing collaborative agreements, including the Collaboration Agreement with Janssen, may not be sufficient alone to sustain our operations. In addition, there can be no assurance that we will receive any milestone payments or royalties from Janssen in the future. 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, such as the Collaboration Agreement with Janssen, may be terminated or expire.

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

We may require additional capital to support development and commercialization of imetelstat in collaboration with Janssen and to otherwise grow our business, and our ability to obtain the necessary funding is uncertain.

We may need additional capital to support development and commercialization of imetelstat, especially if we elect to exercise our U.S. Opt-In Rights and U.S. Co-Promotion Option under the Collaboration Agreement and potentially independently pursue imetelstat development under our own IDP, and to otherwise support the future growth of our business through the potential acquisition and/or in-licensing of other oncology products, product candidates, programs or companies. We cannot assure you that our existing capital resources, future interest income, potential milestone payments and royalties under the Collaboration Agreement with Janssen and potential future sales of our common stock, including pursuant to our At Market Issuance Sales Agreement, or 2015 Sales Agreement, with MLV & Co. LLC, or 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;

- in the event that Janssen provides an affirmative Continuation Decision to us, whether we then elect our U.S. Opt-In Rights to share further U.S. development and promotion costs for imetelstat beyond IMbark™ or IMerge™ under the Collaboration Agreement;

- to the extent permitted under the Collaboration Agreement, whether we independently pursue imetelstat development under our own IDP;

- our potential reimbursement obligations to Janssen if any data from a Janssen IDP support approval by a regulatory agency in the United States or other countries;

- the achievement of development, regulatory and commercial milestones resulting in the payment to us from Janssen under the Collaboration Agreement and the timing of receipt of such payments, if any;

- changes or delays in Janssen s development plans for imetelstat, including changes which may result from any future clinical holds on any INDs for imetelstat;

- Janssen s ability to meaningfully reduce manufacturing costs of imetelstat;

- the progress, timing, magnitude, scope and costs of clinical development, manufacturing and commercialization of imetelstat, including the number of indications being pursued, subject to permission from the FDA and other regulatory authorities;

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

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- Janssen s ability to successfully market and sell imetelstat, upon regulatory approval or clearance, in the United States and other countries;

- if we exercise our U.S. Opt-In Rights, our decision to also exercise our U.S. Co-Promotion Option, including the costs and timing of building a U.S. sales force;

- the timing, receipt and amount of royalties under the Collaboration Agreement on worldwide net sales of imetelstat, upon regulatory approval or clearance, if any;

- the cost of acquiring and/or in-licensing other oncology products, product candidates, programs or companies, if any;

- the timing, receipt and amount of royalties on sales of any stem cell products by Asterias, upon development, regulatory approval or clearance, if any;

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

- expenses associated with the pending and potential additional related purported class action 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. If our existing capital resources, future interest income, and potential milestone payments and royalties under the Collaboration Agreement with Janssen are insufficient to meet future capital requirements, we will need to raise additional capital to fund our operations. Further, if the Collaboration Agreement is terminated, including as a result of Janssen s failure to provide an affirmative Continuation Decision to us, we would not receive any milestone payments or royalties under the Collaboration Agreement, and we would be required to fund all clinical development, manufacturing and commercial activities for imetelstat ourselves, which would require us to raise additional capital or establish alternative collaborations with third-party collaboration partners, which may not be possible. If the Collaboration Agreement was terminated and we were unable to raise additional capital or establish alternative collaborations with third-party collaboration partners, the development of imetelstat would be discontinued. Additional financing through public or private equity financings, including pursuant to our 2015 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 any IND for imetelstat;
- a failure to show adequate safety or efficacy of imetelstat in current or potential future clinical trials; or
- a termination of the Collaboration Agreement or if our collaboration with Janssen is otherwise unsuccessful.

If sufficient capital is not available, we may be unable to fulfill our funding obligations under the Collaboration Agreement with Janssen, resulting in our breach of the Collaboration Agreement, which could lead to Janssen paying lower milestone payments and lower royalties to us under a reduced royalty tier. This would have a material adverse effect on our results of operations and financial condition.

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Moreover, to grow and diversify our business, we plan to continue our business development efforts to identify and seek to acquire and/or in-license other oncology products, product candidates, programs or companies. Acquisition or in-licensing opportunities that we may pursue could materially affect our liquidity and capital resources and may require us to incur indebtedness, seek equity capital or both. In addition, there can be no assurance that sufficient additional capital would be available to us in order to pursue any of these opportunities.

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.

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 April 1, 2006 and March 31, 2016, our stock has traded as high as $10.00 per share and as low as $0.91 per share. Between April 1, 2013 and March 31, 2016, the price has ranged between a high of $7.79 per share and a low of $0.98 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:

- not receiving timely regulatory clearances or approvals in any jurisdiction, whether within or outside of the United States, including, if we, Janssen or future investigators do not obtain regulatory clearance to commence or conduct studies of imetelstat in MF, MDS or any additional hematologic myeloid malignancies in a timely manner or at all, including IMbark™ and IMerge™;

- developments in our collaboration with Janssen, including the termination or modification of the Collaboration Agreement or disputes regarding the collaboration;

- announcements regarding the research and development of imetelstat, including results of or delays in any 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 plans to discontinue imetelstat clinical trials;

- perception by our stockholders about the adequacy of the consideration received for the divestiture of our stem cell assets to Asterias or the adequacy of potential payments we may receive under the Collaboration Agreement;

- 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;

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- 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 imetelstat 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 investors to raise additional capital or to acquire other oncology products, product candidates, programs or companies; and

- the occurrence of any other risks and uncertainties discussed under the heading Risk Factors.

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

If we fail to continue to meet the 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. In addition, we may be unable to meet other applicable NASDAQ listing requirements, including maintaining minimum levels of stockholders equity or market values of our common stock, in which case our common stock could be delisted. 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.

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 March 31, 2016, we had 300,000,000 shares of common stock authorized for issuance and 158,929,270 shares of common stock outstanding. In addition, we had reserved 30,592,946 shares of our common stock for future issuance pursuant to our option and equity incentive plans and outstanding warrants as of March 31, 2016. Issuing additional shares could negatively affect the market price of our common stock and the return on your investment.

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Future sales of our common stock, including pursuant to our 2015 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 August 2015 and declared effective by the SEC in September 2015, 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 $250 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 in the future, we issue preferred stock that has preference over our common stock with respect to the payment of dividends or upon our liquidation, dissolution or winding up, or if we issue preferred stock with voting rights that dilute the voting power of our common stock, the rights of holders of our common stock or the market price of our common stock could be adversely affected.

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

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

- prevent stockholders from taking actions by written consent;

- divide the board of directors into separate classes with terms of office that are structured to prevent all of the directors from being elected in any one year; and

- set forth procedures for nominating directors and submitting proposals for consideration at stockholders meetings.

Provisions of Delaware law may also inhibit potential acquisition bids for us or prevent us from engaging in business combinations. In addition, we have severance agreements with several employees and a company-wide severance plan, either of which could require a potential acquirer 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.

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

Section 404 of the Sarbanes-Oxley Act of 2002, 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 annual 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.

RISKS RELATED TO COMPETITIVE FACTORS

Competitors may develop technologies that are superior to or more cost-effective than ours, which may significantly impact the commercial viability of imetelstat, which could cause Janssen to terminate the Collaboration Agreement 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 related to imetelstat, the study of telomeres, telomerase, or 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. 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 an 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 cell counts; 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 for MF further along in development than imetelstat, such as pacritinib by CTI Biopharma Corporation in collaboration with Baxalta

Incorporated, and momelotinib by Gilead Sciences, Inc., which is currently in a Phase 3 clinical trial, 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, anti-fibrosis antibodies, hedgehog inhibitors, anti-LOX2 inhibitors, recombinant pentraxin 2 protein, KIP-1 activators, TGF-beta inhibitors, FLT inhibitors, and other tyrosine kinase inhibitors.

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If approved for commercial sale for the treatment of MDS, imetelstat would compete against a number of treatment options, including erythropoiesis stimulating agents and other hematopoietic growth factors; immunomodulators such as lenalidomide by Celgene Corporation, or Celgene; hypomethylating agents, such as azacitidine by Celgene and decitabine by Janssen; in addition to investigational treatments that may be further along in development than imetelstat, such as oral versions of azacitidine; histone deacetylase inhibitors; activin type IIA receptor inhibitors, such as sotatercept by Acceleron Pharma, Inc.; TGF-beta superfamily inhibitors, such as luspatercept by Acceleron in collaboration with Celgene; thrombopoietin receptor agonists, such as eltrombopag by Novartis, PI3 Kinase inhibitors, such as rigosertib by Onconova Therapeutics, Inc.; Flt-3 inhibitors, such as quizartinib by Ambit Biosciences Corporation; and JAK-STAT pathway inhibitors.

Independently, Janssen is developing therapies for hematologic malignancies, including AML, MDS, multiple myeloma and ABC-subtype diffuse large B-cell lymphoma. Molecular and cellular pathways of interest include:

- cell surface targets for immune-directed therapy;
- immune checkpoint inhibition;
- leukemia stem cells;
- pathway addiction (genetic alterations, cell-type specific pathways);
- conditional sensitivity (stress, protein-producing tumors);
- targeting of T-cells and natural killer NK cells to tumors;
- identification of novel tumor-specific antigens; and
- progression from early MDS to AML and cancer interception.

Success by Janssen in any of these approaches may compete with imetelstat or render imetelstat obsolete or noncompetitive, which could lead to a decision by Janssen to discontinue the imetelstat program and terminate the Collaboration Agreement, which would materially and adversely affect our business and business prospects and might cause us to cease operations.

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 imetelstat. These companies and institutions compete with us in recruiting and retaining qualified development and management personnel as well as in acquiring technologies complementary to the imetelstat program.

In addition to the above factors, imetelstat will face competition based on:

- product efficacy and safety;
- convenience of product administration;
- cost of manufacturing;
- the timing and scope of regulatory consents;
- status of reimbursement coverage;
- price; and
- patent position, including potentially dominant patent positions of others.

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As a result of the foregoing, competitors may develop more commercially desirable or affordable products than imetelstat, or achieve earlier patent protection or product commercialization than us or Janssen. 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 or superior to those that may be demonstrated by imetelstat. 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, competitors may price their products below what Janssen 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 competitors may render imetelstat obsolete, which may cause Janssen to terminate the Collaboration Agreement, which would severely and adversely affect our business prospects and might cause us to cease operations.

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

If approved for marketing, imetelstat may not achieve market acceptance since hospitals, physicians, patients or the medical community in general may decide not to accept and utilize 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:

- the clinical indications for which imetelstat is approved;
- the establishment and demonstration to the medical community of the clinical efficacy and safety of imetelstat;
- the ability to demonstrate that imetelstat is superior to alternatives currently on the market;
- the ability to establish in the medical community the potential advantage of imetelstat over alternative treatment methods, including with respect to cost and route of administration;
- the label and promotional claims allowed by the FDA or other regulatory authorities for imetelstat, if any;
- the timing of market introduction of imetelstat as well as competitive products;

- the effectiveness of sales, marketing and distribution support for imetelstat;

- the availability of adequate coverage, reimbursement and pricing by government and third-party payors; and

- the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors, including governmental authorities.

The established use of conventional products competitive with imetelstat may limit or preclude the potential for imetelstat to receive market acceptance upon any commercialization. Janssen 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 ability to earn potential milestone payments and royalties under the Collaboration Agreement with Janssen would be negatively impacted and our business prospects would be severely and adversely affected.

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

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute any product of ours for which marketing approval is obtained. Such laws include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;

- the federal false claims and civil monetary penalties laws, including the civil False Claims Act, which impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, which imposes obligations, including mandatory contractual terms, on certain types of individuals and entities with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children s Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other transfers of value made to physicians and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by the physicians and their immediate family members; and

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

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable healthcare laws. If our operations are found to be in violation of any of these or any other health regulatory laws that may apply to us, we may be subject to significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

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If acceptable prices or adequate reimbursement for imetelstat is not obtained, the use of imetelstat could be severely limited.

The ability to successfully commercialize imetelstat will depend significantly on obtaining acceptable prices and the availability of coverage and adequate reimbursement to the patient from third-party payors. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. Assuming Janssen obtains coverage for imetelstat by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. If approved for commercial sale, patients are unlikely to use imetelstat unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of imetelstat. Therefore, coverage and adequate reimbursement is critical to new product acceptance.

Government authorities and other third-party payors are developing increasingly sophisticated methods of controlling healthcare costs, such as by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices as a condition of coverage, are using restrictive formularies and preferred drug lists to leverage greater discounts in competitive classes, and are challenging the prices charged for medical products. Further, no uniform policy requirement for coverage and reimbursement for drug products exists among third-party payors in the United States. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require Janssen to provide scientific and clinical support for the use of imetelstat to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

We cannot be sure that coverage and reimbursement will be available for imetelstat, if approved for commercial sale, and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which marketing approval is obtained. If coverage and reimbursement are not available or reimbursement is available only to limited levels, Janssen may not successfully commercialize imetelstat, even if marketing approval is obtained.

There may also be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities.

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, or ACA, became law and substantially changed the way healthcare will be financed by both governmental and private insurers, and significantly impacted the pharmaceutical industry. The ACA contains a number of provisions that may have a significant impact on our business, including provisions that:

- expand eligibility criteria for Medicaid programs;

- increase the minimum level of Medicaid rebates payable by manufacturers of brand-name drugs from 15.1% to 23.1%;

- require collection of rebates for drugs paid by Medicaid managed care organizations;

- impose a new methodology by which rebates owed under the Medicaid Drug Rebate Program are calculated for certain drugs;

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- create a new Patient-Centered Outcomes Research Institute to oversee clinical effectiveness research;

- require 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

- impose a non-deductible annual fee on pharmaceutical manufacturers or importers who sell branded prescription drugs to specified federal government programs.

While the Court upheld the constitutionality of most elements of the ACA in June 2012 and upheld the ACA against challenges to nationwide tax subsidies in July 2015, other judicial and Congressional challenges against the ACA are likely to be brought in the future. In addition, the U.S. Congress has also proposed a number of legislative initiatives, including possible repeal of the ACA, and recently enacted the Consolidated Appropriations Act, 2016, which among other things suspended or delayed the implementation of several taxes that were intended to be used to fund ACA programs. At this time, it remains unclear whether there will be any additional changes made to the ACA, whether to certain provisions or its entirety. We cannot assure that the ACA, as currently enacted or as amended in the future, will not adversely affect our business and financial results and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, in August 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least $1.2 trillion for fiscal years 2012 through 2021, triggering the legislation s automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect beginning on April 1, 2013 and, following passage of the Bipartisan Budget Act of 2015, will stay in effect through 2025 unless additional Congressional action is taken. Further, the American Taxpayer Relief Act of 2012, signed into law in January 2013, among other things, also reduced Medicare payments to certain providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

In the future, there may continue to be additional proposals relating to the reform of the U.S. healthcare system, some of which could further limit the prices, or the amounts of reimbursement available for imetelstat. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. If future legislation were to impose direct governmental price controls and access restrictions, it could have a significant adverse impact on our business and financial results. Managed care organizations, as well as Medicaid and other government agencies, continue to seek price discounts. Some states have implemented, and other states are considering, price controls or patient access constraints under the Medicaid program, and some states are considering price-control regimes that would apply to broader segments of their populations that are not Medicaid-eligible. Due to the volatility in the current economic and market dynamics, we are unable to predict the impact of any unforeseen or unknown legislative, regulatory, payor or policy actions, which may include cost containment and healthcare reform measures. Such policy actions could have a material adverse impact on the potential royalties under the Collaboration Agreement with Janssen on net sales of imetelstat, if approved.

While the ACA has likely increased the number of patients who have insurance coverage for imetelstat, it is uncertain whether its cost containment measures will adversely affect reimbursement for imetelstat. Cost control initiatives could decrease the price that Janssen may receive for imetelstat in the future. If imetelstat is not considered cost-effective or adequate third-party reimbursement for the users of imetelstat cannot be obtained, then Janssen may be unable to maintain price levels sufficient to realize an appropriate return on the investment in imetelstat, which could impair our ability to earn potential milestone payments and royalties under the Collaboration Agreement with Janssen and our financial condition, operating results and business prospects would be severely and adversely affected.

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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.

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SIGNATURE

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

GERON CORPORATION

Date: May 5, 2016

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

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EXHIBIT INDEX

Exhibit Number	Description	Incorporation by Reference			
		Exhibit Number	Filing	Filing Date	File No.
10.1	Non-Employee Director Compensation Policy, as amended +	10.30	10-K	March 10, 2016	000-20859
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 May 5, 2016				
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 May 5, 2016				
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated May 5, 2016 *				
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated May 5, 2016 *				
101	The following materials from the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 formatted in Extensible Business Reporting Language (XBRL) include: (i) Condensed Balance Sheets as of March 31, 2016 and December 31, 2015, (ii) Condensed Statements of Operations, Comprehensive Loss and Cash Flows for the three months ended March 31, 2016 and 2015 and (iii) Notes to Condensed Financial Statements				

+ Management contract or compensation plan or arrangement.

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