GERON CORP
Form 10-Q
August 05, 2015
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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 June 30, 2015

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 July 31, 2015:**
Common Stock, $0.001 par value	158,142,170 shares

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GERON CORPORATION

QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTER ENDED JUNE 30, 2015

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PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED FINANCIAL STATEMENTS (UNAUDITED)

GERON CORPORATION

CONDENSED BALANCE SHEETS

(IN THOUSANDS)

	JUNE 30, 2015 (UNAUDITED)	DECEMBER 31, 2014 (NOTE 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 15,798	$ 42,796
Restricted cash	266	266
Marketable securities	122,214	108,645
Interest and other receivables	1,505	963
Prepaid assets	415	736
Total current assets	140,198	153,406
Noncurrent marketable securities	18,734	18,932
Property and equipment, net	151	173
	$ 159,083	$ 172,511
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 957	$ 1,033
Accrued compensation and benefits	1,731	4,213
Accrued collaboration charges	1,901	
Accrued restructuring charges	205	
Accrued liabilities	933	1,537
Deferred revenue	35,000	35,000
Fair value of derivatives		16
Total current liabilities	40,727	41,799
Commitments and contingencies		
Stockholders equity:		
Common stock	158	157
Additional paid-in capital	1,065,352	1,059,072
Accumulated deficit	(947,104)	(928,433)
Accumulated other comprehensive loss	(50)	(84)
Total stockholders equity	118,356	130,712
	$ 159,083	$ 172,511

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 JUNE 30,		SIX MONTHS ENDED JUNE 30,	
	2015	2014	2015	2014
Revenues:				
License fees and royalties	$ 251	$ 341	$ 788	$ 815
Operating expenses:				
Research and development	4,812	5,151	9,799	10,362
Restructuring charges	941		1,347	
General and administrative	3,977	3,853	8,577	7,847
Total operating expenses	9,730	9,004	19,723	18,209
Loss from operations	(9,479)	(8,663)	(18,935)	(17,394)
Unrealized gain (loss) on derivatives		(147)	16	77
Interest and other income	145	99	294	182
Interest and other expense	(22)	(23)	(46)	(39)
Net loss	$ (9,356)	$ (8,734)	$ (18,671)	$ (17,174)
Basic and diluted net loss per share	$ (0.06)	$ (0.06)	$ (0.12)	$ (0.11)
Shares used in computing basic and diluted net loss per share	158,066,910	156,706,196	157,807,239	150,086,007

See accompanying notes.

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GERON CORPORATION

CONDENSED STATEMENTS OF COMPREHENSIVE LOSS

(IN THOUSANDS)

(UNAUDITED)

	THREE MONTHS ENDED JUNE 30,		SIX MONTHS ENDED JUNE 30,	
	2015	2014	2015	2014
Net loss	$ (9,356)	$ (8,734)	$ (18,671)	$ (17,174)
Net unrealized gain (loss) on marketable securities	(33)	70	34	(6)
Comprehensive loss	$ (9,389)	$ (8,664)	$ (18,637)	$ (17,180)

See accompanying notes.

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GERON CORPORATION

CONDENSED STATEMENTS OF CASH FLOWS

CHANGE IN CASH AND CASH EQUIVALENTS

(IN THOUSANDS)

(UNAUDITED)

	SIX MONTHS ENDED JUNE 30,	
	2015	**2014**
Cash flows from operating activities:		
Net loss	$ (18,671)	$ (17,174)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	22	29
Accretion and amortization on investments, net	1,176	1,456
Loss on retirement of property and equipment		3
Stock-based compensation for services by non-employees	179	149
Stock-based compensation for employees and directors	4,389	3,743
Amortization related to 401(k) contributions	158	76
Unrealized gain on derivatives	(16)	(77)
Changes in assets and liabilities:		
Other current and noncurrent assets	(221)	(419)
Other current liabilities	(1,056)	(2,441)
Net cash used in operating activities	(14,040)	(14,655)
Cash flows from investing activities:		
Purchases of marketable securities	(109,090)	(128,203)
Proceeds from sales and maturities of marketable securities	94,577	41,663
Net cash used in investing activities	(14,513)	(86,540)
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of issuance costs	1,555	97,725
Net cash provided by financing activities	1,555	97,725
Net decrease in cash and cash equivalents	(26,998)	(3,470)
Cash and cash equivalents at the beginning of the period	42,796	12,990
Cash and cash equivalents at the end of the period	$ 15,798	$ 9,520

See accompanying notes.

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GERON CORPORATION

NOTES TO CONDENSED FINANCIAL STATEMENTS

JUNE 30, 2015

(UNAUDITED)

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The terms Geron , the Company , we and us as used in this report refer to Geron Corporation. The accompanying unaudited condensed financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. generally accepted accounting principles for complete financial statements. In the opinion of management of Geron, all adjustments (consisting only of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three and six months ended June 30, 2015 are not necessarily indicative of the results that may be expected for the year ending December 31, 2015 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, 2014, included in the Company s Annual Report on Form 10-K. The accompanying condensed balance sheet as of December 31, 2014 has been derived from audited financial statements at that date.

Net Loss Per Share

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

Because we are in a net loss position, diluted net loss per share excludes the effects of potential dilutive securities. Had we been in a net income position, diluted earnings per share would have included the shares used in the computation of basic net loss per share as well as an additional 4,876,361 and 786,999 shares for the three months ended June 30, 2015 and 2014, respectively, and 4,543,831 and 3,723,521 shares for the six months ended June 30, 2015 and 2014, respectively, related to outstanding stock options, restricted stock awards and warrants (as determined using the treasury stock method at the estimated average market value).

Use of Estimates

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

Fair Value of Financial Instruments

Cash Equivalents and Marketable Securities

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

We classify our marketable securities as available-for-sale. We record available-for-sale securities at fair value with unrealized gains and losses reported in accumulated other comprehensive income (loss) in stockholders equity. Realized gains and losses are included in interest and other income and are derived using the specific identification method for determining the cost of securities sold and have been insignificant to date. Dividend and interest income are recognized when earned and included in interest and other income in our condensed statements of operations. We recognize a charge when the declines in the fair values below the amortized cost basis of our available-for-sale securities are judged to be other-than-temporary. We consider various factors in determining whether to recognize an other-than-temporary charge, including whether we intend to sell the security or whether it is more likely than not that we would be required to sell the security before recovery of the amortized cost basis. Declines in market value associated with credit losses judged as other-than-temporary result in a charge to interest and other income. Other-than-temporary charges not related to credit losses are included in accumulated other comprehensive income (loss) in stockholders equity. We have not recorded any other-than-temporary impairment charges on our available-for-sale securities for the three and six months ended June 30, 2015 and 2014. See Note 2 on Fair Value Measurements.

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GERON CORPORATION

NOTES TO CONDENSED FINANCIAL STATEMENTS

JUNE 30, 2015

(UNAUDITED)

Fair Value of Derivatives

For non-employee options classified as liabilities, the fair value of these instruments is recorded on the condensed balance sheet at inception and adjusted to fair value at each financial reporting date. The change in fair value of the non-employee options is recorded in the condensed statements of operations as unrealized gain (loss) on derivatives. Fair value of non-employee options is estimated using the Black Scholes option-pricing model. The non-employee options continue to be reported as a liability until such time as the instruments are exercised or expire or are otherwise modified to remove the provisions which require this treatment, at which time these instruments are marked to fair value and reclassified from liabilities to stockholders equity. As of March 31, 2015, all non-employee options classified as liabilities expired unexercised. For non-employee options classified as permanent equity, the fair value of the non-employee options is recorded in stockholders equity as of their respective vesting dates and no further adjustments are made. See Note 2 on Fair Value Measurements.

Revenue Recognition

In general, 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 and the availability of the associated expertise in the general marketplace. In addition, we consider whether the collaboration partner 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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NOTES TO CONDENSED FINANCIAL STATEMENTS

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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, related to a license that has standalone value from the other deliverables to be provided under the agreement, have been delivered 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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NOTES TO CONDENSED FINANCIAL STATEMENTS

JUNE 30, 2015

(UNAUDITED)

Clinical Trial Costs

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

Depreciation and Amortization

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

Stock-Based Compensation

We recognize stock-based compensation expense on a straight-line basis over the requisite service period, which is generally the vesting period. The following table summarizes the stock-based compensation expense included in operating expenses on our condensed statements of operations related to stock options, restricted stock awards and employee stock purchases for the three and six months ended June 30, 2015 and 2014 which was allocated as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(In thousands)	**2015**	**2014**	**2015**	**2014**
Research and development	$ 612	$ 690	$ 1,234	$ 1,279

Restructuring charges	212		302	
General and administrative	1,552	1,412	2,853	2,464
Stock-based compensation expense included in operating expenses	$ 2,376	$ 2,102	$ 4,389	$ 3,743

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 is being 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 and six months ended June 30, 2015 and 2014 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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GERON CORPORATION

NOTES TO CONDENSED FINANCIAL STATEMENTS

JUNE 30, 2015

(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 six months ended June 30, 2015 and 2014 has been estimated at the date of grant using the Black Scholes option-pricing model with the following assumptions:

	Six Months Ended June 30,	
	2015	**2014**
Dividend yield	0%	0%
Expected volatility range	0.874 to 0.884	0.898 to 0.922
Risk-free interest rate range	1.68% to 1.70%	1.64% to 1.92%
Expected term	5.5 yrs	5.5 yrs

Employee Stock Purchase Plan

The fair value of employees purchase rights during the six months ended June 30, 2015 and 2014 has been estimated using the Black Scholes option-pricing model with the following assumptions:

	Six Months Ended June 30,	
	2015	**2014**
Dividend yield	0%	0%
Expected volatility range	0.721 to 1.392	0.835 to 1.062
Risk-free interest rate range	0.11% to 0.25%	0.09% to 0.15%
Expected term range	6 12 mos	6 12 mos

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

Restricted Stock Awards

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

Non-Employee Stock-Based Awards

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

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GERON CORPORATION

NOTES TO CONDENSED FINANCIAL STATEMENTS

JUNE 30, 2015

(UNAUDITED)

Recent Accounting Pronouncements

In April 2015, the Financial Accounting Standards Board, or FASB, issued Accounting Standard Update No. 2015-04, *Customer s Accounting for Fees Paid in a Cloud Computing Arrangement*, which identifies and determines whether a cloud computing arrangement contains a software license that should be accounted for as internal-use software. If a cloud computing arrangement does not contain a software license, it should be accounted for as a service contract. This guidance is effective for fiscal years beginning after December 15, 2015 and for interim periods within those fiscal years, with early adoption permitted. We are currently evaluating the impact of the adoption of this guidance on our financial statements and related notes.

In April 2015, the FASB issued Accounting Standard Update 2015-07, *Fair Value Measurement (Topic 820): Disclosures for Investments in Certain Entities That Calculate Net Asset Value per Share (or Its Equivalent)*. This amendment removes the requirement to categorize within the fair value hierarchy all investments for which fair value is measured using the net asset value per share. This guidance is effective for fiscal years beginning after December 15, 2015 and for interim periods within those fiscal years, with early adoption permitted. We are currently evaluating the impact of the adoption of this guidance on our financial statements and related notes.

In January 2015, the FASB issued Accounting Standard Update No. 2015-01, *Income Statement - Extraordinary and Unusual Items (Subtopic 225-20): Simplifying Income Statement Presentation by Eliminating the Concept of Extraordinary Items*, or ASU 2015-01. ASU 2015-01 eliminates the concept of an extraordinary item from generally accepted accounting principles. As a result, an entity will no longer be required to segregate extraordinary items from the results of ordinary operations to separately present an extraordinary item on its income statement, net of tax, after income from continuing operations or to disclose income taxes and earnings-per-share data applicable to an extraordinary item. However, ASU 2015-01 will still retain the presentation and disclosure guidance for items that are unusual in nature and occur infrequently. ASU 2015-01 becomes effective for annual periods, and interim periods within those annual periods, beginning on or after December 15, 2015. Early adoption is permitted. The adoption of ASU 2015-01 is not expected to have a material impact on our financial statements and related notes.

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.

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GERON CORPORATION

NOTES TO CONDENSED FINANCIAL STATEMENTS

JUNE 30, 2015

(UNAUDITED)

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 June 30, 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	$ 13,133	$	$	$ 13,133
Restricted cash:				
Certificate of deposit	$ 266	$	$	$ 266
Marketable securities:				
Government-sponsored enterprise securities (due in less than 1 year)	$ 400	$	$	$ 400
Government-sponsored enterprise securities (due in 1 to 2 years)	6,924	1	(3)	6,922
Commercial paper (due in less than 1 year)	21,728	20		21,748
Corporate notes (due in less than 1 year)	100,110	12	(56)	100,066
Corporate notes (due in 1 to 2 years)	11,836	1	(25)	11,812
	$ 140,998	$ 34	$ (84)	$ 140,948

Cash equivalents, restricted cash and marketable securities by security type at December 31, 2014 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	$ 40,342	$	$	$ 40,342
Restricted cash:				
Certificate of deposit	$ 266	$	$	$ 266

Marketable securities:				
Government-sponsored enterprise securities (due in less than 1 year)	$ 401	$	$ (1)	$ 400
Government-sponsored enterprise securities (due in 1 to 2 years)	6,556		(7)	6,549
Commercial paper (due in less than 1 year)	10,985	14		10,999
Corporate notes (due in less than 1 year)	97,307	2	(63)	97,246
Corporate notes (due in l to 2 years)	12,412		(29)	12,383
	$ 127,661	$ 16	$ (100)	$ 127,577

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GERON CORPORATION

NOTES TO CONDENSED FINANCIAL STATEMENTS

JUNE 30, 2015

(UNAUDITED)

Marketable securities with unrealized losses at June 30, 2015 and December 31, 2014 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 June 30, 2015:						
Government-sponsored enterprise securities (due in 1 to 2 years)	$ 4,218	$ (3)	$	$	$ 4,218	$ (3)
Corporate notes (due in less than 1 year)	76,377	(56)			76,377	(56)
Corporate notes (due in 1 to 2 years)	10,253	(25)			10,253	(25)
	$ 90,848	$ (84)	$	$	$ 90,848	$ (84)
As of December 31, 2014:						
Government-sponsored enterprise securities (due in less than 1 year)	$ 400	$ (1)	$	$	$ 400	$ (1)
Government-sponsored enterprise securities (due in 1 to 2 years)	5,549	(7)			5,549	(7)
Corporate notes (due in less than 1 year)	92,989	(63)			92,989	(63)
Corporate notes (due in 1 to 2 years)	12,383	(29)			12,383	(29)
	$ 111,321	$ (100)	$	$	$ 111,321	$ (100)

The gross unrealized losses related to government-sponsored enterprise securities and corporate notes as of June 30, 2015 and December 31, 2014 were due to changes in interest rates. We determined that the gross unrealized losses on our marketable securities as of June 30, 2015 and December 31, 2014 were temporary in nature. We review our investments quarterly to identify and evaluate whether any investments have indications of possible impairment. Factors considered in determining whether a loss is temporary include the length of time and extent to which the fair value has been less than the amortized cost basis and whether we intend to sell the security or whether it is more likely than not that we would be required to sell the security before recovery of the amortized cost basis. We currently do not intend to sell these securities before recovery of their amortized cost basis.

Derivatives

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

Options held by non-employees whose performance obligations are complete are classified as derivative liabilities on our condensed balance sheets. These options are marked to fair value at each reporting period, and upon the exercise of these options, the instruments are marked to fair value and reclassified from derivative liabilities to stockholders equity. As of December 31, 2014, non-employee options to purchase 284,600 shares of our common stock at an exercise price of $6.39 per share with a fair value of $16,000 were outstanding and classified as derivative liabilities. On March 31, 2015, these non-employee options expired unexercised. Accordingly, we have not reclassified any derivative liabilities to stockholders equity for any non-employee option exercises during 2015.

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Fair Value on a Recurring Basis

The following table presents information about our financial instruments that are measured at fair value on a recurring basis as of June 30, 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**
Assets:				
Money market funds(1)	$ 13,133	$	$	$ 13,133
Government-sponsored enterprise securities(2)(3)		7,322		7,322
Commercial paper(2)		21,748		21,748
Corporate notes(2)(3)		111,878		111,878
Total	$ 13,133	$ 140,948	$	$ 154,081

The following table presents information about our financial instruments that are measured at fair value on a recurring basis as of December 31, 2014 and indicates the fair value category assigned.

	Fair Value Measurements at Reporting Date Using			
(In thousands)	**Quoted Prices in Active Markets for Identical Assets / Liabilities Level 1**	**Significant Other Observable Inputs Level 2**	**Significant Unobservable Inputs Level 3**	**Total**
Assets:				
Money market funds(1)	$ 40,342	$	$	$ 40,342
Government-sponsored enterprise securities(2)(3)		6,949		6,949
Commercial paper(2)		10,999		10,999
Corporate notes(2)(3)		109,629		109,629
Total	$ 40,342	$ 127,577	$	$ 167,919
Liabilities:				
Derivatives(4)	$	$	$ 16	$ 16

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

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

(3) Included in noncurrent portion of marketable securities on our condensed balance sheets.

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

Changes in Level 3 Recurring Fair Value Measurements

The table below includes a rollforward of the balance sheet amounts for the six months ended June 30, 2015, including the change in fair value, for financial instruments in the Level 3 category. When a determination is made to classify a financial instrument within Level 3, the determination is based upon the significance of the unobservable parameters to the overall fair value measurement. However, Level 3 financial instruments typically include, in addition to the unobservable components, observable components (that is, components that are actively quoted and can be validated to external sources). Accordingly, the gain in the table below includes changes in fair value due in part to observable factors that are part of the methodology. As of March 31, 2015, all non-employee options classified as derivative liabilities within the Level 3 fair value category expired unexercised.

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	Fair Value Measurements Using Significant Unobservable Inputs (Level 3) Six Months Ended June 30, 2015						
(In thousands)	Fair Value at December 31, 2014	Total Unrealized Gain Included in Earnings(1)	Purchases and Issuances	Sales and Settlements	Transfers In and/or Out of Level 3	Fair Value at June 30, 2015	Change in Unrealized Gain Related to Financial Instruments Held at June 30, 2015
Derivative liabilities	$ 16	$ (16)	$	$	$	$	$

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

3. COLLABORATION AND LICENSE AGREEMENT

In November 2014, we and Janssen entered into the Collaboration Agreement to develop and commercialize imetelstat worldwide for oncology, including hematologic myeloid malignancies, and all other human therapeutic uses. Under the Collaboration Agreement, we granted to Janssen exclusive worldwide rights to develop and commercialize imetelstat for all indications, and Janssen is responsible for the development, manufacturing and commercialization of, and seeking regulatory approval for, imetelstat worldwide. Upon the early termination of the waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, the Collaboration Agreement became effective on December 15, 2014. Upon the effectiveness of the Collaboration Agreement, we received $35,000,000 from Janssen as an upfront payment, which has been classified as deferred revenue on our condensed balance sheets as of June 30, 2015 and December 31, 2014.

Under the Collaboration Agreement, development of imetelstat will initially proceed under a mutually agreed joint clinical development plan, or CDP, which includes two agreed upon Phase 2 studies to be pursued initially and conducted by Janssen, one in myelofibrosis, or the IMbark™ Study, and one in myelodysplastic syndrome, or the Initial Phase 2 MDS Study. Development costs for the IMbark™ Study and the Initial Phase 2 MDS Study will be 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 2015. As of June 30, 2015, accrued collaboration charges of $1,901,000 on our condensed balance sheet represent the net amount owed to Janssen for our proportionate share of research and development costs incurred under the imetelstat collaboration during the six months ended June 30, 2015.

Following the protocol-specified primary analysis of the IMbarkTM Study or after a certain time period after the initiation of the first Phase 3 MF study, 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 the IMbarkTM Study has been terminated early or suspended, Janssen must instead notify us of its election by the date that is the later of 24 months from the initiation of the planned Initial Phase 2 MDS Study or 24 months from the termination of the IMbarkTM Study 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 election, the Continuation Election), 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 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 the Continuation Election, 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 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 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 the IMbarkTM Study or Initial Phase 2 MDS Study would be borne by Janssen, we would receive the $65,000,000 Continuation Fee at the time of the Continuation Election 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.

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Under the terms of the Collaboration Agreement, we and Janssen created a joint governance structure, including joint committees and working groups, to oversee and manage worldwide regulatory, development and manufacturing work under the joint CDP and promotional activities (assuming we exercises the U.S. Opt-In Rights) for imetelstat, with Janssen responsible for the operational implementation of those activities. In addition, either of the parties may propose to the joint committees imetelstat development for any new indications not then provided for in the joint CDP and if the parties agree such development should be conducted outside of the joint CDP, each of Geron and Janssen would be entitled to independently undertake such development at its own cost, subject to the other party s obligation to provide reimbursement for its specified portion of the costs plus a premium for such independent development following marketing approval of imetelstat in such newly proposed indication as a result of such independent development. In the event that we do not exercise the U.S. Opt-In Rights following Janssen s Continuation Election, the joint governance structure under the Collaboration Agreement would be dissolved, a joint oversight committee would monitor the progress of the collaboration, and we would have no further rights to conduct any independent imetelstat development.

After a Continuation Election 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 a Continuation Election, 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.

The terms of the Collaboration Agreement contain multiple deliverables, which include at inception: (i) exclusive worldwide rights to develop and commercialize imetelstat for all indications, (ii) transfer of know-how and intellectual property, including our obligation to procure supply for manufacturing imetelstat for up to nine months after the effective date of the Collaboration Agreement and transfer existing supplies of imetelstat drug product to Janssen, (iii) participation on the joint committees and working groups and (iv) potential participation in selling imetelstat in the United States, if approved for commercial sale. We concluded the license for exclusive worldwide rights to develop and commercialize imetelstat has standalone value to Janssen based on the technical and financial resources of Janssen, including Janssen s drug development experience, sizeable employee base with specific experience in hematologic malignancies, and sufficient capital to independently develop imetelstat on a global basis. Since Janssen has final decision-making authority in the event a unanimous decision cannot be reached by the joint committees, we determined our participation on the joint committees does not represent a non-contingent deliverable under the Collaboration Agreement. In addition, we determined our potential participation in selling imetelstat in the United States does not represent a non-contingent deliverable because such participation is uncertain and dependent on the drug being approved for commercial sale, which is not within our control. Accordingly, we have determined delivery of the license rights granted by us to Janssen, together with our performance of the technology transfer-related activities, represents the sole non-contingent deliverable under the Collaboration Agreement associated with the upfront payment. Therefore, we have accounted for our delivery of the license rights and our performance of the technology transfer-related activities as a single unit of accounting. We currently expect completion of the technology transfer-related activities to occur by September 30, 2015 at which point we expect to fully recognize the $35,000,000 upfront payment from Janssen as collaboration revenue on our condensed statements of operations. As a result, we have not recognized any revenue related to the Collaboration Agreement for the three and six months ended June 30, 2015.

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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 the Continuation Election, (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 commercial 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. The reduction in our workforce was substantially complete as of June 30, 2015. In connection with this restructuring, we expect to record aggregate restructuring charges of approximately $1,395,000 related to one-time termination benefits which are being recognized on a pro-rata basis commencing from the date of announcement over the specified remaining service periods for the employees affected by the restructuring. For the three and six months ended June 30, 2015 we recognized $941,000 and $1,347,000 in restructuring charges, respectively, for the pro-rata portion of the one-time termination benefits. These charges include $212,000 and $302,000 of non-cash stock-based compensation expense for the three and six months ended June 30, 2015, respectively, 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. The remaining projected restructuring charges are expected to be recorded during the third quarter of 2015. We may incur other charges associated with this restructuring. Such charges, if any, will be recorded as they are determined. We expect this restructuring to be completed in 2015 and result in aggregate cash expenditures of approximately $1,088,000, of which $840,000 has been paid as of June 30, 2015.

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 June 30, 2015, are summarized in the following table:

(In thousands)		Employee Severance and Other Benefits
Beginning accrual balance as of December 31, 2014	$	
Restructuring charges		1,347
Cash payments		(840)
Non-cash stock-based compensation expense		(302)
Ending accrual balance as of June 30, 2015	$	205

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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, 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 in the Class Action Lawsuits to file its consolidated amended complaint, 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. On November 18, 2014, we filed a motion to dismiss the consolidated amended complaint in the Class Action Lawsuits. 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 20, 2015, we filed our answer to the consolidated amended complaint in the Class Action Lawsuits.

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. 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 lawsuit filed in the San Mateo County Court have been stayed pending further developments in the Class Action Lawsuits. 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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6. STOCKHOLDERS EQUITY

On March 31, 2015, warrants to purchase 235,000 shares of our common stock were exercised at an exercise price of $3.75 per share. We received cash proceeds of approximately $881,000 from the exercise of these warrants.

7. SEGMENT INFORMATION

Our executive management team represents our chief decision maker. We view our operations as one 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.

8. CONDENSED STATEMENTS OF CASH FLOWS DATA

Supplemental schedule of non-cash operating and investing activities:

	Six Months Ended June 30,	
(In thousands)	**2015**	**2014**
Supplemental Operating Activities:		
Issuance of common stock for 401(k) matching contributions	$	$ 313
Supplemental Investing Activities:		
Net unrealized gain (loss) on marketable securities	34	(6)

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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, 2014, as filed with the Securities and Exchange Commission, or SEC, on March 11, 2015.

We are a clinical stage biopharmaceutical company focused on the collaborative development of a telomerase inhibitor, imetelstat, in hematologic myeloid malignancies. The discovery and early development of imetelstat, our sole product candidate, was based on our core expertise in telomerase and telomere biology. Telomerase is an enzyme that enables cancer cells, including malignant progenitor cells, to maintain telomere length, which provides them with the capacity for limitless, uncontrolled proliferation. 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. Molecular responses in essential thrombocythemia, or ET, and remission responses, including reversal of bone marrow fibrosis, in myelofibrosis, or MF, suggest imetelstat has disease-modifying activity by inhibiting the progenitor cells of the malignant clone for the underlying disease in a relatively selective manner.

In November 2014, we entered into an exclusive collaboration and license agreement, or the Collaboration Agreement, with Janssen Biotech, Inc., or Janssen, 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 has been classified as deferred revenue on our condensed balance sheets as of June 30, 2015 and December 31, 2014. 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 responsible for developing, manufacturing, commercializing, and seeking regulatory approval for imetelstat worldwide. In March 2015, we transferred our investigational new drug application, or IND, for imetelstat to Janssen, as well as the IND that we received in September 2014 from Dr. Ayalew Tefferi at Mayo Clinic for the clinical trial evaluating imetelstat in patients with MF, or the MF Pilot Study. Upon transfer of the IND for the MF Pilot Study to Janssen, Janssen assumed responsibility as trial sponsor for the MF Pilot Study.

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Development of imetelstat will proceed under a mutually agreed clinical development plan, which includes two Phase 2 studies to be pursued initially and conducted by Janssen, one in MF, referred to as the IMbarkTM Study, and one in myelodysplastic syndrome, referred to as the Initial Phase 2 MDS Study. Study design information for the IMbarkTM Study, including patient eligibility criteria, is posted on www.clinicaltrials.gov, and the list of participating clinical trial sites for the study, including multiple sites in North America, Asia and Europe, will be updated on an ongoing basis. In July 2015, the IMbarkTM Study opened to patient enrollment. We expect Janssen to initiate the Initial Phase 2 MDS Study by the end of 2015. In addition, the clinical development plan may also include additional, possible registration studies in MF and myelodysplastic syndrome, or MDS, and possible exploratory Phase 2 and potential follow on Phase 3 studies in acute myelogenous leukemia, or AML. 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.

On June 11, 2015, the United States Food and Drug Administration, or FDA, granted orphan drug designation to imetelstat for the treatment of MF. For a drug to qualify for orphan drug designation, both the drug and the disease or condition must meet certain criteria specified in the Orphan Drug Act, or ODA, and FDA s implementing regulations at 21 CFR Part 316. Orphan drug designation is granted by the FDA s Office of Orphan Drug Products in order to support development of medicines for underserved or rare diseases and patient populations that affect fewer than 200,000 people in the United States or, if the disease or condition affects more than 200,000 individuals annually in the United States, if there is no reasonable expectation that the cost of developing and making the drug would be recovered from sales in the United States. Orphan drug designation qualifies the sponsor of the drug for various development incentives of the ODA, including, if regulatory approval is received, seven years of market exclusivity with certain limited exceptions, exemption from FDA application fees, and certain tax credits for qualified clinical testing. A marketing application for a prescription drug product that has received orphan drug designation is not subject to a prescription drug user fee unless the application includes an indication for a disease or condition other than the rare disease or condition for which the drug was granted orphan drug designation. The granting of orphan drug designation does not alter the standard regulatory requirements and process for obtaining marketing approval. The safety and effectiveness of a drug must be established through adequate and well-controlled studies. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition.

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, representing a reduction of approximately 46% of our workforce at that time. This reduction in our workforce was substantially complete as of June 30, 2015, and we expect it will be fully completed by the end of September 2015. For a further discussion regarding the organizational resizing, see Note 4 on Restructuring in Notes to Condensed Financial Statements of this Form 10-Q.

We have incurred operating losses every year since our operations began in 1990. Losses have resulted principally from costs incurred in connection with our research and development activities and from general and administrative costs associated with our operations. Substantially all of our revenues to date have been research support payments under collaborative agreements, and milestones, royalties and other revenues from our licensing arrangements. We currently have no source of product revenue. Our revenues for 2015 are expected to primarily consist of revenue from the $35 million upfront payment from Janssen upon the completion of imetelstat technology transfer-related activities in 2015, and future revenues, including potential milestones and royalties, are substantially dependent on Janssen s successful development and commercialization of imetelstat in accordance with the Collaboration Agreement. 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.

As of June 30, 2015, we had an accumulated deficit of $947.1 million. The significance of future losses 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, programs or companies to diversify our business. 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. There can be no assurance that we will receive any milestone payments or royalties from Janssen in the future, or at all. Imetelstat, which is our sole product candidate, will require significant additional clinical testing prior to possible regulatory approval in the United States and other countries, and we do not expect imetelstat to be commercially available for many years, if at all.

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As of June 30, 2015, we had cash, restricted cash, cash equivalents and marketable securities of $157.0 million compared to $170.6 million at December 31, 2014. 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, to grow our business over the longer term and to diversify our sole product candidate development risk, we plan to continue our business development efforts to identify and seek to acquire and/or in-license other oncology products, 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.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

There have been no significant changes in our critical accounting policies and estimates during the six months ended June 30, 2015 as compared to the critical accounting policies and estimates disclosed in our Annual Report on Form 10-K for the year ended December 31, 2014 that materially impact our condensed financial statements.

Our condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported assets, liabilities, revenues and expenses. Note 1 of Notes to Condensed Financial Statements of this Form 10-Q describes the significant accounting policies used in the preparation of the condensed financial statements.

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

RESULTS OF OPERATIONS

Our results of operations have fluctuated from period to period and may continue to fluctuate in the future, based upon the progress of research and development efforts in collaboration with Janssen and whether we are able to acquire and/or in-license other oncology products, programs or companies to grow and diversify our business. Results of operations for any period may be unrelated to results of operations for any other period. In addition, historical results should not be viewed as indicative of future operating results. We are subject to risks common to companies in our industry and at our stage of development, including, but not limited to, risks inherent in research and development efforts, our dependence on Janssen for the development, regulatory approval, manufacture and commercialization of our sole product candidate, imetelstat, uncertainty of preclinical and clinical trial results or regulatory approvals or clearances, need for future capital, enforcement of our patent and proprietary rights, reliance upon our collaborators, investigators and other third parties, and potential competition. In order for imetelstat to be commercialized, we rely 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.

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Revenues

In addition to the Collaboration Agreement with Janssen, we have entered into several license or collaboration agreements with companies involved with oncology, diagnostics, research tools and biologics production. In each of these agreements, we have granted certain rights to our technologies. In connection with 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 $110,000 and $485,000 for the three and six months ended June 30, 2015, respectively, compared to $185,000 and $535,000 for the same periods in 2014 related to our various agreements. The decrease in license fee revenues for the three and six months ended June 30, 2015 compared to the same periods in 2014 primarily reflects the receipt of higher license payments in 2014 for research licenses related to our human telomerase reverse transcriptase, or hTERT, technology. We recognized royalty revenues of $141,000 and $303,000 for the three and six months ended June 30, 2015, respectively, compared to $156,000 and $280,000 for the same periods in 2014. The decrease in royalty revenues for the three months ended June 30, 2015 primarily reflects the receipt of a milestone fee in the second quarter of 2014 in connection with the achievement of a net sales milestone by a licensee of our hTERT technology. The increase in royalty revenues for the six months ended June 30, 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.

As of June 30, 2015, we have not recognized any revenue related to the Collaboration Agreement since we have determined that the sole non-contingent deliverable under the Collaboration Agreement is our delivery of the license rights to Janssen and our complete performance of imetelstat technology transfer-related activities. We currently expect completion of the technology transfer-related activities to occur by September 30, 2015, at which point we expect to fully recognize the $35 million upfront payment from Janssen as collaboration revenue. We expect our revenues for 2015 to primarily consist of collaboration revenue from the upfront payment from Janssen under the Collaboration Agreement upon our completion of the technology transfer-related activities. Any future collaboration revenues are substantially dependent on Janssen successfully developing and commercializing imetelstat in accordance with the Collaboration Agreement. See further discussion of revenue recognition for the Collaboration Agreement in Note 3 on Collaboration and License Agreement in Notes to Condensed Financial Statements of this Form 10-Q.

Research and Development Expenses

For our imetelstat research and development program, we incur direct external, personnel related and other research and development costs. During the three and six months ended June 30, 2015 and 2014, imetelstat was our sole research and development program. Direct external expenses primarily consist of costs paid 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. For the three and six months ended June 30, 2015, direct external expenses also included our proportionate share of research and development costs incurred by Janssen under the imetelstat collaboration. 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 laboratory supplies, research related overhead associated with leasing, operating and maintaining our facilities and equipment depreciation and maintenance.

Research and development expenses were $4.8 million and $9.8 million for the three and six months ended June 30, 2015, respectively, compared to $5.2 million and $10.4 million for the same periods in 2014. The decrease in research and development expenses for the three and six months ended June 30, 2015 compared to the same periods in 2014 primarily reflects lower personnel related expenses as a result of the organizational resizing announced in March 2015. During the remainder of 2015, 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 organizational resizing which was substantially complete as of

June 30, 2015.

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Imetelstat research and development expenses for the three and six months ended June 30, 2015 and 2014 were as follows:

(In thousands)	Three Months Ended June 30, 2015	2014	Six Months Ended June 30, 2015	2014
	(Unaudited)			
Direct external	$ 2,458	$ 2,266	$ 4,259	$ 4,190
Personnel related	1,855	2,370	4,457	5,055
Other	499	515	1,083	1,117
Imetelstat research and development expenses	$ 4,812	$ 5,151	$ 9,799	$ 10,362

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 expect to record aggregate restructuring charges of approximately $1.4 million related to one-time termination benefits which are being recognized on a pro-rata basis commencing from the date of announcement over the specified remaining service periods for the employees affected by the restructuring. For the three and six months ended June 30, 2015, we recognized $941,000 and $1.3 million in restructuring charges, respectively, for the pro-rata portion of the one-time termination benefits. These charges include $212,000 and $302,000 of non-cash stock-based compensation expense for the three and six months ended June 30, 2015, respectively, 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. The organizational resizing was substantially complete as of June 30, 2015, and we expect will be completed fully by the end of September 2015. We expect the resizing will reduce our personnel related costs by approximately $5.0 million on an annualized basis. 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 $4.0 million and $8.6 million for the three and six months ended June 30, 2015, respectively, compared to $3.9 million and $7.8 million for the same periods in 2014. The increase in general and administrative expenses for the three and six months ended June 30, 2015 compared to the same periods in 2014 is primarily the result of higher non-cash stock-based compensation expense and increased consulting costs associated with our business development efforts to diversify our sole product candidate development risk by identifying and seeking to acquire and/or in-license other oncology products, programs or companies. We expect general and administrative expenses to increase during the remainder of 2015 as we proceed with our business development efforts.

Unrealized Gain (Loss) on Derivatives

Unrealized gain (loss) on derivatives reflects a non-cash adjustment for changes in fair value of options held by non-employees that are classified as current liabilities. Derivatives classified as 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 loss on derivatives of $147,000 for the three months ended June 30, 2014. No comparable amount was incurred for the three months ended June 30, 2015 as all non-employee options classified as derivative liabilities expired unexercised during the first quarter of 2015. We incurred unrealized gains on derivatives of $16,000 and $77,000 for the six months ended June 30, 2015 and 2014, respectively. The unrealized gain on derivatives for the six months ended June 30, 2015 reflected a decline in the fair values of options held by non-employees that expired unexercised during the first quarter of 2015. The unrealized gains and losses on derivatives for the three and six months ended June 30, 2014 primarily reflected the change in fair values of derivative liabilities as a result of fluctuations in the market value of our stock and changes in other inputs factored into the estimate of their fair value, such as the volatility of our stock.

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Interest and Other Income

Interest income was $145,000 and $294,000 for the three and six months ended June 30, 2015, respectively, compared to $99,000 and $182,000 for the same periods in 2014. The increase in interest income for the three and six months ended June 30, 2015 compared to the same periods in 2014 is primarily due to an increase in our marketable securities portfolio as a result of the receipt of $35 million from Janssen as an upfront payment in December 2014 upon the effectiveness of the Collaboration Agreement. 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 $22,000 and $46,000 for the three and six months ended June 30, 2015, respectively, compared to $23,000 and $39,000 for the same periods in 2014. Interest and other expense primarily reflects bank charges related to our cash operating accounts and investment portfolios.

LIQUIDITY AND CAPITAL RESOURCES

Cash, restricted cash, cash equivalents and marketable securities at June 30, 2015 were $157.0 million, compared to $170.6 million at December 31, 2014. 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. We have an investment policy to invest these funds in liquid, investment grade securities, such as interest-bearing money market funds, certificates of deposit, municipal securities, U.S. government and agency securities, corporate notes and commercial paper. Our investment portfolio does not contain securities with exposure to sub-prime mortgages, collateralized debt obligations, asset-backed securities or auction rate securities and, to date, we have not recognized any other-than-temporary impairment charges on our marketable securities or any significant changes in aggregate fair value that would impact our cash resources or liquidity. To date, we have not experienced lack of access to our invested cash and cash equivalents; however, access to our invested cash and cash equivalents may be impacted by adverse conditions in the financial and credit markets. The decrease in cash, restricted cash, cash equivalents and marketable securities in 2015 was the result of cash being used for operations.

In October 2012, we entered into an At-The-Market Issuance Sales Agreement, or sales agreement, with MLV & Co. LLC, or MLV, which provides that, upon the terms and subject to the conditions and limitations set forth in the sales agreement, we may elect to issue and sell shares of our common stock having an aggregate offering price of up to $50 million from time to time through MLV as our sales agent. We are not obligated to make any sales of common stock under the sales agreement. To date, we have not sold any common stock pursuant to the sales agreement. The sales agreement will expire in October 2015 unless extended by the parties.

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 acquisition and/or in-licensing of other oncology products, 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 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 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, whether we then elect our option, or the U.S. Opt-In Rights, to share further U.S. development and promotion costs for imetelstat under the Collaboration Agreement;

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

- our potential reimbursement obligations to Janssen if any data from a Janssen independent development plan 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 our and Janssen s development plans for imetelstat, including changes which may result from any future clinical holds on the INDs for imetelstat, including the IND for the MF Pilot Study, both of which we transferred to Janssen in March 2015;

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

- the progress, timing, magnitude, scope and costs of clinical development, manufacturing and commercialization for 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;

- 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 co-promotion option under the Collaboration Agreement with Janssen, or the 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, 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.

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.

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Under the Collaboration Agreement, following the protocol specified primary analysis of the IMbarkTM Study, or a certain time period after the initiation of the first Phase 3 MF study, Janssen must notify us of their decision, or a Continuation Decision, as to whether they elect to maintain the license rights granted to Janssen under the Collaboration Agreement and continue to advance the development of imetelstat in any indication. 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. Additional financing through public or private equity financings, including pursuant to our sales agreement with MLV, capital lease transactions or other financing sources may not be available on acceptable terms, or at all. We may raise equity capital at a stock price or on other terms that could result in substantial dilution of ownership for our stockholders. The receptivity of the public and private equity markets to proposed financings is substantially affected by the general economic, market and political climate and by other factors which are unpredictable and over which we have no control.

Our ability to raise additional funds will be severely impaired in the event of:

- any future clinical holds on any IND for imetelstat;
- a failure to show adequate safety or efficacy of imetelstat in existing 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, to grow our business over the longer term and to diversify our sole product candidate development risk, we plan to continue our business development efforts to identify and seek to acquire and/or in-license other oncology products, 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 six months ended June 30, 2015 and 2014 was $14.0 million and $14.7 million, respectively. The decrease in net cash used in operations in 2015 compared to 2014

primarily reflects the net result of reduced costs for the manufacturing of imetelstat drug product, partially offset by cash payments for one-time termination benefits under the organizational resizing we announced in March 2015.

Cash Flows from Investing Activities. Net cash used in investing activities for the six months ended June 30, 2015 and 2014 was $14.5 million and $86.5 million, respectively. The decrease in net cash used in investing activities in 2015 compared to 2014 primarily reflects reduced purchases of marketable securities and increased proceeds from maturities of marketable securities.

Cash Flows from Financing Activities. Net cash provided by financing activities for the six months ended June 30, 2015 and 2014 was $1.6 million and $97.7 million, respectively. Net cash provided by financing activities in 2015 primarily reflects the receipt of cash proceeds from the exercise of outstanding stock options under our equity plans and warrants. Net cash provided by financing activities in 2014 primarily reflects the receipt of net cash proceeds of approximately $96.8 million, after deducting the underwriting discount and offering expenses payable by us, from an underwritten public offering of 25,875,000 shares of our common stock at a public offering price of $4.00 per share that we completed in February 2014.

Contractual Obligations

Our future minimum contractual obligations were reported in our Annual Report on Form 10-K for the year ended December 31, 2014, as filed with the SEC. There have been no material changes from the contractual obligations previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2014.

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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 six months ended June 30, 2015, 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, 2014.

ITEM 4. CONTROLS AND PROCEDURES

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

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

(b) *Changes in Internal Control Over Financial Reporting*. There was no change in our internal control over financial reporting for the three months ended June 30, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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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 20, 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. 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 lawsuit filed in the San Mateo County Court have been stayed pending further developments in the Class Action Lawsuits. 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 such amounts could be material to our financial statements even if we prevail in the defense against these lawsuits. 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.

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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, 2014, or the Form 10-K. Our business faces significant risks and uncertainties, and those described below may not be the only risks and uncertainties we face. Additional risks and uncertainties not presently known to us or that we currently believe are immaterial may also significantly impair our business, financial condition or results of operations. If any of these risks or uncertainties occur, our business, financial condition or results of operations could suffer, the market price of our common stock could decline and you could lose all or part of your investment in our common stock. We have marked with an asterisk (*) those risks described below that reflect substantive changes from, or additions to, the risks described under Part I, Item 1A, Risk Factors included in the Form 10-K.

RISKS RELATED TO OUR BUSINESS

We are dependent upon our collaborative relationship with Janssen to further develop, manufacture and commercialize imetelstat, our sole product candidate. If Janssen fails to perform as required by the Collaboration Agreement, 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 efforts related to 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. 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;

- the results of the IMbark™ Study and/or the planned Initial Phase 2 MDS Study 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, in which case we would receive no further payments from Janssen under the Collaboration Agreement;

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- Janssen may choose not to develop and commercialize imetelstat in certain 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 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 achieve development and manufacturing objectives or milestones 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 has been or 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 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;

- after assuming manufacturing responsibilities for imetelstat, Janssen may fail to manufacture or supply sufficient quantities of imetelstat 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 factor, 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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Delays in current clinical trials of imetelstat being conducted by Janssen, including the IMbark™ Study and the MF Pilot Study, and Janssen s initiation of, or the inability to initiate, subsequent clinical trials of imetelstat, such as the planned Initial Phase 2 MDS Study, could result in increased development costs and would delay our ability to earn revenues from milestone payments or royalties from the Collaboration Agreement with Janssen. *

The clinical development of imetelstat will be influenced by results from current clinical trials, including the IMbark™ Study and the MF Pilot Study being conducted by Janssen, and potential future clinical trials of imetelstat in hematologic myeloid malignancies, such as the Initial Phase 2 MDS Study planned to be conducted by Janssen. 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:

- properly designing, enrolling, conducting or completing the IMbark™ Study and commencing potential future clinical trials, including the Initial Phase 2 MDS Study planned to be conducted by Janssen under the Collaboration Agreement, and promptly or adequately reporting data from such trials;

- obtaining regulatory clearance to commence subsequent clinical trials of imetelstat, including the Initial Phase 2 MDS Study planned to be conducted by Janssen under the Collaboration Agreement, in a timely manner, or at all, in the United States or other countries;

- demonstrating sufficient safety and efficacy in the IMbark™ Study and future Phase 2 clinical trials, including the Initial Phase 2 MDS Study planned to be conducted by Janssen under the Collaboration Agreement;

- properly conducting and/or completing the MF Pilot Study;

- manufacturing sufficient quantities of imetelstat in a manner that meets the quality standards of the FDA and other regulatory authorities;

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

- obtaining clearance or approval of proposed imetelstat trial designs and/or manufacturing specifications from the FDA and other regulatory authorities;

- reaching agreement on acceptable terms and on a timely basis, if at all, with collaborators and vendors located in the United States or foreign jurisdictions, including contract research organizations, laboratory service providers and clinical trial sites, on all aspects of clinical trials;

- obtaining institutional review board or ethics committee approval to conduct clinical trials at prospective clinical trial sites; and

- identifying and successfully screening and enrolling appropriate subjects for participation in clinical trials and retaining those subjects in the clinical trials.

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 future clinical trials of imetelstat, which could increase development costs, impair our ability to earn revenues from milestone payments or royalties from the Collaboration Agreement with Janssen 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 may cause us to cease operations.

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If there are any safety or efficacy results that cause the benefit-risk profile of imetelstat to become unacceptable, the clinical development of imetelstat would be delayed or halted, and Janssen may terminate the Collaboration Agreement, which would severely and adversely affect our business prospects, and may cause us to cease operations. *

Imetelstat may prove to have 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. For example, although the FDA removed the full clinical hold on our IND for imetelstat on October 31, 2014 and in the first quarter of 2015 we ceased follow-up of patients enrolled in our Phase 2 clinical trial of imetelstat in ET, or the ET trial, if patients in current or future clinical trials of imetelstat experience similar or more severe hepatotoxicity, including elevated liver function tests, or LFTs, or severe hepatic adverse events, the IND for imetelstat may again be placed on clinical hold, and we, in collaboration with Janssen, may be precluded from further developing imetelstat.

Further, 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 have observed hematologic toxicities as well as gastrointestinal events, infections, muscular and joint pain, fatigue and infusion reactions. In addition, in our Phase 2 clinical trials of imetelstat, we have observed LFT abnormalities, the clinical significance and long-term consequences of which are currently undetermined. In the ET trial, one patient died of bleeding esophageal varices, a complication of chronic liver disease, for which imetelstat could not be excluded as a causative agent. In the MF Pilot Study, myelosuppression has been the primary dose-limiting toxicity reported to date, consistent with our observations in previous Geron-sponsored imetelstat studies. However, during the MF Pilot Study, more persistent and profound myelosuppression, particularly thrombocytopenia, was observed with imetelstat administered on a weekly basis. This included one case of febrile neutropenia after prolonged myelosuppression with intracranial hemorrhage resulting in patient death, which was assessed as possibly related to imetelstat by the investigator.

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. In collaboration with Janssen, we may observe or report dose-limiting toxicities or other safety issues in the IMbark™ Study and in potential future clinical trials of imetelstat, including the Initial Phase 2 MDS Study planned to be conducted by Janssen under the Collaboration Agreement. Because previously enrolled patients continue to receive imetelstat in the MF Pilot Study, additional or more severe toxicities or safety issues in the MF Pilot Study, including additional serious adverse events and clinically significant LFT abnormalities, may be observed or reported as patient treatment continues and more data become available. Since the IMbark™ Study and the MF Pilot Study are ongoing studies in which additional data is being generated, the benefit-risk profile of imetelstat in MF will continue to be assessed, including the risk of hepatotoxicity and severe cytopenias 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 future clinical trials, including the MF Pilot Study and the IMbark™ Study being conducted by Janssen and the Initial Phase 2 MDS Study planned to be conducted by Janssen under the Collaboration Agreement, would likely be delayed or prevented;

- the MF Pilot Study and the IMbark™ Study being conducted by Janssen or any potential future clinical trials, including the Initial Phase 2 MDS Study planned to be conducted by Janssen under the Collaboration Agreement, may be placed on clinical hold or halted by regulatory authorities similar to the manner in which the FDA previously halted clinical trials of imetelstat by placing clinical holds on our IND for imetelstat and the IND for the MF Pilot Study; or

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

The occurrence of any of these events would likely cause Janssen to abandon their development of imetelstat entirely and terminate the Collaboration Agreement. Any termination of the Collaboration Agreement by Janssen

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would have a severe adverse effect on our results of operations, financial condition, business prospects and the future of imetelstat, any of which may cause us to cease operations.

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, after reviewing the data in such submissions, the FDA and regulatory authorities in other countries may conclude that the overall benefit-risk profile of imetelstat treatment, including hepatotoxicity or severe hepatic adverse events, may preclude approval of imetelstat for marketing or further development for any indications, including hematologic malignancies. Any of these events could cause Janssen to terminate the Collaboration Agreement, which would severely harm our business and prospects, and would likely 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 the IMbarkTM Study, or, if the IMbarkTM Study 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 the IMbarkTM Study 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.

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.

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Our decision to exercise our U.S. Opt-In Rights under the Collaboration Agreement with Janssen for imetelstat 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 Continuation Decision. Although we expect to receive information from Janssen regarding data from the IMbarkTM Study and the planned Initial Phase 2 MDS Study, 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, 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, programs or companies into our business or we may otherwise fail to realize the anticipated benefits of these acquisitions. **

To grow our business over the longer term and to diversify our sole product candidate development risk, we plan to continue our business development efforts to identify and seek to acquire and/or in-license other oncology products, programs or companies. 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. Any growth through development will depend upon our identifying and obtaining product candidates, our ability to develop those product candidates and the availability of funding to complete the development of, obtain regulatory approval for and commercialize these product candidates. Even if appropriate opportunities are available, we may not be able to successfully identify them, or we may not have 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 cannot assure you that we will 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 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;
- the potential disruption of our historical business and our activities under the Collaboration Agreement;

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

- our lack of experience in commercializing any products;

- the difficulties in assimilating employees and corporate cultures;

- the failure to retain key managers 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 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 U.S. 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 will 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.

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 and our March 2015 organizational resizing, as well as our collaboration with Janssen and uncertainties regarding our ability to diversify our sole product candidate development risk, 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.

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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 three 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, including many biotechnology companies, which experience volatility in the market price of their securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies often experience significant stock price volatility in connection with their product development programs.

On March 14, 2014, a purported 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 20, 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. 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 lawsuit filed in the San Mateo County Court have been stayed pending further developments in the Class Action Lawsuits.

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

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 October 1, 2013, we closed the transaction to divest our human embryonic stem cell assets and our autologous cellular immunotherapy program pursuant to the terms of an asset contribution agreement, or the Contribution Agreement, that we entered into in January 2013 with BioTime, Inc., or BioTime, and Asterias. 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 value received by our stockholders, if any, from our distribution of the Asterias Series A common stock and/or the warrants to purchase BioTime common stock, or the BioTime Warrants, distributed by Asterias under the Contribution Agreement, or our role as a named underwriter with respect to our distribution of the Asterias Series A common stock, including the delays we experienced with respect to completing our distribution of the Asterias Series A common stock, or we may face litigation based on other matters related to the Contribution Agreement and 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.

As a result of these and other factors, we may be exposed to litigation risks related to the transactions contemplated by the Contribution Agreement and the Collaboration Agreement, including declines or fluctuations in our stock price, additional advisor and legal fees, distractions to our management caused by activities undertaken in connection with resolving any disputes related to the transactions, or the loss of important contractual rights. As another example, some of our investors purchased shares of our common stock because they were interested in the opportunities presented by our human embryonic stem cell programs. Thus, certain stockholders may have attributed substantial financial value to our stem cell assets and may believe that the Asterias Series A common stock, BioTime Warrants and/or cash received in the distributions pursuant to the Contribution Agreement were inadequate consideration for such assets.

Similarly, the announcement and/or completion of these strategic transactions 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 either or both 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 either or both of these transactions 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:

- we or Janssen are otherwise 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 that we transferred to Janssen in March 2015;

- we, 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 the IMbark™ Study and the MF Pilot Study being conducted by Janssen, and future clinical trials, such as the Initial Phase 2 MDS Study planned to be conducted by Janssen under the Collaboration Agreement, results in patient injury or death, or any failure to meet regulatory and/or compliance requirements;

- the final or any preliminary results from the IMbark™ Study or the MF Pilot Study, or any subsequent clinical trial of imetelstat, including the Initial Phase 2 MDS Study planned to be conducted by Janssen under the Collaboration Agreement, are not deemed to be successful;

- we or Janssen are 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,

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. In collaboration with Janssen, we must undertake significant research and development activities to develop imetelstat, our sole product candidate, based on these technologies, 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 further 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 subsequent clinical trials. Likewise, preliminary data reported by investigators from time-to-time are subject to review or verification procedures that could result in material differences to final data and may change as more patient data become available.

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

Data from our preclinical studies and Phase 1 and Phase 2 clinical trials of imetelstat, as well as preliminary, additional or updated data from the MF Pilot Study, should not be relied upon as evidence that subsequent or larger-scale clinical trials of imetelstat will succeed. The positive efficacy results we have obtained from the Phase 2 clinical trial of imetelstat in ET may not predict the future therapeutic benefit of imetelstat, if any, in other hematologic myeloid malignancies, including MF. 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, could cause complexities in treating patients with MF and could result in the discontinuation of the MF Pilot Study, the IMbark™ Study and any future clinical trials of imetelstat, including the Initial Phase 2 MDS Study planned to be conducted by Janssen under the Collaboration Agreement. 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 the updated preliminary results presented 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 may not be reproduced in the IMbark™ Study or any imetelstat trials conducted in the future, including the Initial Phase 2 MDS Study planned to be conducted by Janssen under the Collaboration Agreement, or by any other investigator or group of investigators, or in any trial enrolling a larger number of patients or conducted at multiple treating centers, and thus should not be relied upon as indicative of future clinical results of imetelstat in MF or any other hematologic myeloid malignancy.

In addition, from time-to-time, we or Janssen may report or announce preliminary data from current or potential future clinical trials, such as the ongoing IMbark™ Study and the planned Initial Phase 2 MDS Study to be conducted by Janssen under the Collaboration Agreement. For example, the investigator for the MF Pilot Study reported preliminary data from the trial in December 2013 and updated preliminary data in December 2014. Since those data were preliminary, the final data from the MF Pilot Study may be materially different than the data reported by the investigator in December 2013 or December 2014. Since patients previously enrolled in the MF Pilot Study continue to receive imetelstat, safety and efficacy data continue to be generated, and additional and updated data from the MF Pilot Study may materially change the overall conclusions from the preliminary data reported in December 2013 or December 2014. Therefore, such preliminary data should be considered carefully and with caution. Additional and updated data from the MF Pilot Study are also subject to any review or verification procedures that Janssen may conduct as the trial sponsor for the MF Pilot Study, and since this could result in material differences from the data reported by the investigator or us, additional or updated data that may be reported from the MF Pilot Study should be considered carefully and with caution. Analyses performed by Janssen may result in conclusions that are materially different from the investigator s analyses or ours, and therefore such preliminary data should be considered carefully and with caution.

Material adverse changes in the final data from the MF Pilot Study 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 and efficacy data from the MF Pilot Study are positive, significant additional clinical testing will be necessary for the future development of imetelstat in MF. Any such final safety and efficacy data from the MF Pilot Study may not be reproducible in the IMbark™ Study or future clinical trials, including the Initial Phase 2 MDS Study planned to be conducted by Janssen under the Collaboration Agreement.

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. There is typically an extremely high rate of attrition from the failure of drug candidates proceeding through clinical trials. If imetelstat cannot be developed in 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.

The timely conduct and completion of the IMbark™ Study and potential future clinical trials of imetelstat, including the Initial Phase 2 MDS Study planned to be conducted by Janssen under the Collaboration Agreement, is subject to risks and uncertainties.

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Delays or terminations of current and potential future clinical trials, including the ongoing IMbarkTM Study and the Initial Phase 2 MDS Study planned to be conducted by Janssen under the Collaboration Agreement, could be caused by matters such as:

- not receiving timely regulatory clearances or approvals in any jurisdiction, whether within or outside of the United States, including, if Janssen or future investigators do not obtain and maintain regulatory clearances to commence studies of imetelstat in MF, MDS or any additional hematologic myeloid malignancies in a timely manner or at all, including the IMbarkTM Study and the Initial Phase 2 MDS Study planned to be conducted by Janssen under the Collaboration Agreement;

- the inability of Janssen to maintain the INDs for imetelstat that we have transferred to Janssen, including the IND for the MF Pilot Study, without such INDs being placed on full or partial clinical hold by the FDA;

- the inability to properly design, conduct and/or complete current and potential future clinical trials of imetelstat, including the MF Pilot Study, the IMbarkTM Study and the Initial Phase 2 MDS Study planned to be conducted by Janssen under the Collaboration Agreement;

- data showing lack of effectiveness of imetelstat during clinical trials, or results that do not demonstrate statistically significant efficacy;

- safety issues, side effects or dose-limiting toxicities, including any additional or more severe safety issues related to imetelstat in addition to those that have been observed to date in previous or ongoing clinical trials, whether or not in the same indications or therapeutic areas;

- disruptions due to drug supply or quality issues;

- the inability of Janssen to obtain acceptance of manufacturing changes or clinical trial protocol amendments by regulatory authorities, as well as its inability to subsequently implement such manufacturing changes and/or clinical trial protocol amendments successfully;

- failure by investigators conducting current and future clinical trials of imetelstat, including the ongoing IMbarkTM Study and the Initial Phase 2 MDS Study planned to be conducted by Janssen under the Collaboration Agreement, to timely commence, enroll, complete or report data from such clinical trials;

- not receiving timely institutional review board or ethics committee approval of clinical trial protocols or protocol amendments;

- delays in patient enrollment due to size or nature of patient population, nature of protocols, proximity of patients to clinical sites, availability of effective treatments for the relevant disease and eligibility criteria for the trial;

- inability to retain patients to complete clinical trials or to return for post-treatment follow-up;

- difficulty in obtaining or accessing necessary clinical data, including additional and future data from the MF Pilot Study, which may result in incomplete data sets;

- unavailability of any study-related treatment (including comparator therapy);

- issues or disputes with key vendors of clinical services, such as contract research organizations, clinical trial sites and laboratory service providers; or

- governmental or regulatory delays in any jurisdiction, whether within or outside of the United States, information requests, clinical holds, such as the previous clinical holds placed by the FDA on the IND for imetelstat and the IND for the MF Pilot Study, both of which were transferred to Janssen in March 2015, and changes in regulatory requirements, policies and guidelines.

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Advancing clinical development of imetelstat in the United States is dependent on obtaining positive results from current and potential future clinical trials of imetelstat in hematologic myeloid malignancies, including the MF Pilot Study, the IMbarkTM Study and the Initial Phase 2 MDS Study planned to be conducted by Janssen under the Collaboration Agreement. Obtaining additional and future data from the MF Pilot Study may provide additional insights into the further development of imetelstat for MF, MDS or AML, including with respect to Janssen s ability to advance the ongoing IMbarkTM Study or initiate the Initial Phase 2 MDS Study planned to be conducted by Janssen under the Collaboration Agreement. Accordingly, a delay in the timely completion of the MF Pilot Study, including any delay caused by any future clinical hold placed by the FDA on the INDs for imetelstat, including the IND for the MF Pilot Study that we transferred to Janssen in March 2015, could have a material adverse effect on advancing the development of imetelstat in current and potential future clinical trials, including the ongoing IMbarkTM Study and the Initial Phase 2 MDS Study planned to be conducted by Janssen under the Collaboration Agreement. Also, adverse safety results from clinical trials of imetelstat, including those results that have been reported and those that may in the future be reported from the MF Pilot Study, the IMbarkTM Study or the Initial Phase 2 MDS Study planned to be conducted by Janssen under the Collaboration Agreement, could delay or prevent the initiation or continuation of further clinical development of imetelstat, whether under the Collaboration Agreement or otherwise. Occurrence of any of these events would delay the timing of any Continuation Decision Janssen could provide to us or could cause Janssen to terminate the Collaboration Agreement, which would severely and adversely affect the future of imetelstat and our business prospects and may cause us to cease operations.

In addition, enrollment goals for current and potential future clinical trials of imetelstat, including the ongoing IMbarkTM Study and the Initial Phase 2 MDS Study planned to be conducted by Janssen under the Collaboration Agreement, may not be met. The inability to retain or treat patients who have enrolled in a clinical trial but may be prone to withdraw due to side effects from imetelstat, lack of efficacy or personal issues, or who are lost to further follow-up, could result in clinical trial delays, the inability to complete clinical trials, or incomplete data sets. Further, any ongoing and future clinical trials of imetelstat may be overseen by safety monitoring committees, which may determine to significantly modify, delay or suspend one or more of these trials due to safety or futility findings based on emerging data occurring during a clinical trial. Data that we have received or that we or Janssen may in the future receive from investigators may be flawed or incomplete if the investigators fail to follow appropriate clinical or quality practices. Delays in timely initiation or completion of clinical testing of imetelstat could increase research and development costs and could prevent or would delay obtaining regulatory approval for imetelstat, either of which would delay the timing of any Continuation Decision Janssen could provide to us or could cause Janssen to terminate the Collaboration Agreement, which would severely and adversely affect the future of imetelstat and our business prospects and could cause us to cease operations.

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 future clinical trials of imetelstat, including the Initial Phase 2 MDS Study planned to be conducted by Janssen under the Collaboration Agreement, the 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.

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Prior to submission of any regulatory application seeking approval to commence commercial sales of imetelstat, extensive preclinical and clinical testing will be required. If the interpretation by us or Janssen of safety and efficacy data obtained from these 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 the MF Pilot Study and the IMbarkTM Study or potential future clinical trials, including the Initial Phase 2 MDS Study planned to be conducted by Janssen under the Collaboration Agreement. 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.

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.

Even if the necessary time and resources are committed by us and Janssen, the required regulatory agency clearances and approvals may not be obtained for imetelstat. Even if regulatory agency clearances and approvals are obtained to commence commercial sales of imetelstat, they may entail limitations on the indicated uses or other aspects of the product label for which imetelstat can be marketed, which could limit the potential commercial use of imetelstat, or an approval might be contingent on the performance of costly additional clinical trials that would be required after approval. The occurrence of any of these events could delay any applications for regulatory approval 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.

Even though the FDA has granted orphan drug designation to imetelstat for the treatment of MF, this designation may not be maintained, which would eliminate the benefits associated with orphan drug designation, including the potential for market exclusivity, which may cause potential sales revenue for imetelstat, if any, to be reduced, and harm our business and business prospects. *

Although the FDA granted orphan drug designation to imetelstat in June 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 may be limited if Janssen seeks approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for orphan drug designation was materially defective or if Janssen is unable to assure 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 can subsequently approve a different drug with the same active moiety for the same condition if the FDA 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.

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

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.

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 may 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.

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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.

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 refuse 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.

We will be dependent on Janssen and third parties to manufacture clinical and commercial quantities of imetelstat, which could result in a delay of clinical trials or regulatory approval or lost sales.

Under the Collaboration Agreement, after a transition period, Janssen will be responsible for the manufacture and/or manage the supply of imetelstat on a global basis for clinical trials and all commercial activities. Consequently, we will be, and expect to remain, dependent on Janssen to appropriately supply imetelstat. Janssen may encounter difficulties in production scale-up, including problems involving production yields, quality control and quality assurance, and shortage of qualified personnel. Janssen may not perform as agreed or may default in its obligations to supply imetelstat for clinical trials and/or commercial activities. Janssen also may fail to deliver the required quantities of imetelstat on a timely basis. Any such failure by Janssen could delay current and/or 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.

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. Neither we nor Janssen have direct control over their personnel or operations. We and Janssen rely on these third-party contractors to produce and deliver sufficient quantities of imetelstat to support clinical trials on a timely basis and to comply with applicable regulatory requirements. If requested by Janssen, we may transfer certain of our agreements with these third parties to Janssen, if permitted by the terms and conditions of the respective agreements or otherwise allowed by the

third parties. If these companies do not perform the work which they are contracted to perform, fail to comply with applicable cGMP regulations, do not complete the work within the expected timelines, fail to produce materials which are suitable for use in clinical trials or choose to exit the business, the ability to develop or manufacture imetelstat could be significantly harmed. For example, changes to one or more suppliers due to these or other reasons could lead to delays in drug supply. Manufacturing delays could adversely impact the completion of current clinical trials, such as the ongoing IMbarkTM Study, or the initiation of future clinical trials, such as the Initial Phase 2 MDS Study planned to be conducted by Janssen under the Collaboration Agreement, 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 may 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. Neither we nor Janssen 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.

There are other risks and uncertainties with respect to manufacturing that could adversely impact the initiation or completion of future clinical trials. For example, market shortages may occur with respect to certain commonly used reagents and solvents and, if these shortages occur, such shortages may adversely impact the ability to manufacture imetelstat. If a significant issue arises regarding manufacturing, this 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 may cause us to cease operations.

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.

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

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

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.

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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 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. Developing an internal sales force and function will require substantial expenditures and will be time-consuming, may expose us to unforeseen costs and expenses, and we may not be able to effectively recruit, train or retain sales personnel. Accordingly, we may be unable to establish our own sales force which could effectively preclude us from participating in co-promoting imetelstat in the United States. In addition, 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, which could materially and adversely affect any sales milestone or royalties we may receive under the Collaboration Agreement.

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 to a potential acquirer is limited, and subject to Janssen s sole discretion under certain circumstances. If we are acquired under 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.

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. By way of example, we do not yet have issued compound patent coverage for imetelstat in Europe after 2020. Further, our patents may be challenged, invalidated or circumvented, and our patent rights may not provide proprietary protection or competitive advantages to us 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 could delay ongoing or 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 could cause us to be unable to continue our 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.

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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 could cause us to cease operations.

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 United States 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. The effect of the decision on patents for other isolated natural products is uncertain. On March 20, 2012, in *Mayo Collaborative Services, DBA Mayo Medical Laboratories, et al. v. Prometheus Laboratories, Inc.*, the Court held that several claims drawn to measuring drug metabolite levels from patient samples and correlating them to drug doses were not patentable subject matter. The decision has created uncertainty around the ability to patent certain biomarker-related method patents. 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 would severely and adversely affect our business prospects and could 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.

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Under the AIA, interference proceedings have been eliminated for patent applications filed on or after March 16, 2013, and have been replaced with other types of proceedings, including derivation proceedings. The AIA also includes post-grant review procedures subjecting U.S. patents to post-grant review procedures similar to European oppositions, 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 recently begun challenging 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 would severely and adversely affect our business prospects.

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 could negatively impact our collaboration with Janssen or cause Janssen to terminate the Collaboration Agreement, which would severely and adversely affect our business prospects and may 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 may 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. We expect that as imetelstat continues to progress in development, we will see more efforts by others to obtain patents that are positioned to cover imetelstat. Our success therefore depends significantly on our 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 our technologies or obtain rights to alternate technologies, which may not be possible, and even if possible, could cause delays in the development efforts for imetelstat. In cases where we 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 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 may 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 may 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.

RISKS RELATED TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL FINANCING

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

We have incurred operating losses every year since our operations began in 1990. As of June 30, 2015, our accumulated deficit was approximately $947.1 million. Losses have resulted principally from costs incurred in connection with our research and development activities and from general and administrative costs associated with our operations. We expect to incur additional operating losses and, as clinical development activities for imetelstat continue under our Collaboration Agreement with Janssen, our operating losses may increase in size.

Substantially all of our revenues to date have been research support payments under collaborative agreements and milestones, royalties and other revenues from our licensing arrangements. Any revenues generated from our licensing arrangements and revenues generated from 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 profitability. We may not be able to generate these revenues from the Collaboration Agreement with Janssen through milestone payments or royalties, and we may never achieve profitability. Our failure to achieve profitability could negatively impact the market price of our common stock and our ability to sustain operations. Even if we do become profitable, we may not be able to sustain or increase profitability on a quarterly or annual basis.

We 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.

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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 acquisition and/or in-licensing of other oncology products, programs or companies. We cannot assure you that our existing capital, 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-The-Market Issuance Sales Agreement, or 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 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 our and Janssen s development plans for imetelstat, including changes which may result from any future clinical holds on the INDs for imetelstat, including the IND for the MF Pilot Study, both of which we transferred to Janssen in March 2015;

- 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;

- 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, 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.

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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. Additional financing through public or private equity financings, including pursuant to our sales agreement with MLV prior to its expiration in October 2015, 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, to grow our business over the longer term and to diversify our sole product candidate development risk, we plan to continue our business development efforts to identify and seek to acquire and/or in-license other oncology products, 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 July 1, 2005 and June 30, 2015, our stock has traded as high as $12.18 per share and as low as $0.91 per share. Between July 1, 2012 and June 30, 2015, the price has ranged between a high of $7.79 per share and a low of $0.91 per share. The significant market price fluctuations of our common stock have been due to and may in the future be influenced by a variety of factors, including:

- 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 the ongoing IMbark™ Study and the Initial Phase 2 MDS Study planned to be conducted by Janssen under the Collaboration Agreement;

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

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- 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 our plans to discontinue certain programs or clinical trials, such as our prior announcements regarding the discontinuation of our stem cell programs and certain clinical trials;

- perception by our stockholders about the adequacy of the consideration received for the divestiture of our stem cell assets to Asterias 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;

- general market conditions or market conditions relating to the biopharmaceutical and pharmaceutical industries;

- announcements of technological innovations, new commercial products, or clinical progress or lack thereof by us, our collaborators, licensees, partners or our competitors;

- announcements concerning regulatory developments, such as grant of the orphan drug designation to imetelstat for the treatment of MF, 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; 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.

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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 June 30, 2015, we had 300,000,000 shares of common stock authorized for issuance and 158,122,877 shares of common stock outstanding. In addition, we had reserved 31,399,339 shares of our common stock for future issuance pursuant to our option and equity incentive plans and outstanding warrants as of June 30, 2015. Issuing additional shares could negatively affect the market price of our common stock and the return on your investment.

Future sales of our common stock, including pursuant to our sales agreement with MLV prior to its expiration in October 2015, or the issuance of common stock to satisfy our current or future cash payment obligations or to acquire technology, property, or other businesses, could cause immediate dilution and adversely affect the market price of our common stock. In addition, under the universal shelf registration statement filed by us in July 2012 and declared effective by the SEC in October 2012, we may sell any combination of common stock, preferred stock, debt securities and warrants in one or more offerings, up to a cumulative value of $96.5 million. The sale or issuance of our securities, as well as the existence of outstanding options and shares of common stock reserved for issuance under our option and equity incentive plans and outstanding warrants, also may adversely affect the terms upon which we are able to obtain additional capital through the sale of equity securities, which could negatively affect the market price of our common stock and the return on your investment.

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

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

In addition, if 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.

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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.

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.

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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, including the study of telomeres, telomerase and our proprietary oligonucleotide chemistry, and the research and development of therapies for the treatment of hematologic myeloid malignancies. In addition, other products and therapies that could directly compete with imetelstat currently exist or are being developed by pharmaceutical and biopharmaceutical companies and by academic institutions, government agencies and other public and private research organizations.

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

Independently, Janssen is developing therapies for hematologic malignancies, including AML, MDS, MM 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 ours. 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.

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

- 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.

As a result of the foregoing, competitors may develop more commercially desirable or affordable products, 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 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 may 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 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;

- the label and promotional claims allowed by the FDA or other regulatory authorities for imetelstat, if any;

- sales, marketing and distribution support for imetelstat; and

- reimbursement policies of government and third-party payors.

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The established use of conventional products competitive with imetelstat may limit or preclude the potential for imetelstat to receive market acceptance upon any commercialization. We or 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.

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

- mandates a further shift in the burden of Medicaid payments to the states;

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

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

- requires manufacturers to participate in a coverage gap discount program, under which they must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer s outpatient drugs to be covered under Medicare Part D, beginning January 2011; and

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

While the U.S. Supreme Court upheld the constitutionality of most elements of the Affordable Care Act in June 2012 and upheld the Affordable Care Act against challenges to nationwide tax subsidies in July 2015, other legal challenges against the Affordable Care Act may be brought in the future. In addition, the United States Congress has also proposed a number of legislative initiatives, including possible repeal of the Affordable Care Act. At this time, it remains unclear whether there will be any changes made to the Affordable Care Act, whether to certain provisions or its entirety. We cannot assure that the Affordable Care Act, 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 Affordable Care Act was enacted. The American Taxpayer Relief Act of 2012, signed into law in January 2013, among other things, also reduced Medicare payments to 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. On March 1, 2013, the President signed an executive order implementing sequestration, and on April 1, 2013, Medicare payment reductions of 2% went into effect and will remain in effect through 2024 unless additional Congressional action is taken.

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In the future, there may continue to be additional proposals relating to the reform of the United States healthcare system, some of which could further limit the prices, or the amounts of reimbursement available for imetelstat. 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 from the Collaboration Agreement with Janssen on sales of imetelstat, if approved.

While the Affordable Care Act 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.

RISKS RELATED TO ENVIRONMENTAL AND PRODUCT LIABILITY

Activities conducted by us or Janssen involve hazardous materials, and improper handling of these materials by employees, contractors, or agents could expose us or Janssen to significant legal and financial penalties.

We, Janssen, or contractors or agents may be required to incur significant costs to comply with current or future environmental laws and regulations and may be adversely affected by the cost of compliance with these laws and regulations. Additionally, an accident could damage the manufacturing facilities and operations of any third-party contracted by us or Janssen to perform services with respect to imetelstat. If we, Janssen or contractors or agents are unable to comply with federal, state and county environmental and safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of biohazardous materials, chemicals and various radioactive compounds, or an accident occurs, considerable additional costs, fines, penalties or liabilities could be assessed which 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 prospects.

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.

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. The size and complexity of our computer systems make them potentially vulnerable to breakdown, malicious intrusion and computer viruses that may result in the impairment of key business processes.

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In addition, our systems are potentially vulnerable to data security breaches whether by employees or others that may expose sensitive data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of 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.

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

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

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

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: August 5, 2015	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
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 August 5, 2015
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 August 5, 2015
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated August 5, 2015*
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated August 5, 2015*
101	The following materials from the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2015 formatted in Extensible Business Reporting Language (XBRL) include: (i) Condensed Balance Sheets as of June 30, 2015 and December 31, 2014, (ii) Condensed Statements of Operations and Comprehensive Loss for the three and six months ended June 30, 2015 and 2014, (iii) Condensed Statements of Cash Flows for the six months ended June 30, 2015 and 2014 and (iv) Notes to Condensed Financial Statements

* 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.