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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
WASHINGTON D.C. 20549

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**FORM 10-Q**

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(Mark One)

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

For the quarterly period ended March 31, 2017

OR

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

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

Commission File Number: 0-20859

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**GERON CORPORATION**

(Exact name of registrant as specified in its charter)

**DELAWARE**  
(State or other jurisdiction of  
incorporation or organization)

75-2287752  
(I.R.S. Employer  
Identification No.)

**149 COMMONWEALTH DRIVE, SUITE 2070, MENLO PARK, CA**  
(Address of principal executive offices)

**94025**  
(Zip Code)

**(650) 473-7700**  
(Registrant's telephone number, including area code)

**N/A**  
(Former name, former address and former fiscal year, if changed since last report)

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

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

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

Large accelerated filer

Accelerated filer

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

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

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

Class:	Outstanding at May 1, 2017:
Common Stock, \$0.001 par value	159,176,119 shares

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GERON CORPORATION

QUARTERLY REPORT ON FORM 10-Q  
FOR THE QUARTER ENDED MARCH 31, 2017

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PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED FINANCIAL STATEMENTS (UNAUDITED)

GERON CORPORATION  
CONDENSED BALANCE SHEETS  
(IN THOUSANDS)

	MARCH 31, 2017 (UNAUDITED)	DECEMBER 31, 2016 (NOTE 1)
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 14,861	\$ 12,810
Restricted cash	268	268
Marketable securities	84,432	102,035
Interest and other receivables	597	475
Litigation settlement insurance recovery	6,000	—
Prepaid assets	405	524
Total current assets	<u>106,563</u>	<u>116,112</u>
Noncurrent marketable securities	22,126	13,954
Property and equipment, net	158	183
	<u>\$ 128,847</u>	<u>\$ 130,249</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 308	\$ 225
Accrued compensation and benefits	1,489	2,843
Accrued collaboration charges	2,495	3,367
Litigation settlement payable	6,250	—
Accrued liabilities	1,054	1,434
Total current liabilities	<u>11,596</u>	<u>7,869</u>
Commitments and contingencies		
Stockholders' equity:		
Common stock	159	159
Additional paid-in capital	1,082,270	1,080,198
Accumulated deficit	(965,107)	(957,924)
Accumulated other comprehensive loss	(71)	(53)
Total stockholders' equity	<u>117,251</u>	<u>122,380</u>
	<u>\$ 128,847</u>	<u>\$ 130,249</u>

See accompanying notes.

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

	THREE MONTHS ENDED MARCH 31,	
	2017	2016
<b>Revenues:</b>		
License fees and royalties	\$ 537	\$ 749
<b>Operating expenses:</b>		
Research and development	3,374	5,033
General and administrative	4,657	4,793
Total operating expenses	8,031	9,826
Loss from operations	(7,494)	(9,077)
Interest and other income	332	256
Interest and other expense	(21)	(21)
Net loss	<u>\$ (7,183)</u>	<u>\$ (8,842)</u>
Basic and diluted net loss per share	<u>\$ (0.05)</u>	<u>\$ (0.06)</u>
Shares used in computing basic and diluted net loss per share	<u>159,161,550</u>	<u>158,896,038</u>

See accompanying notes.

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

	THREE MONTHS ENDED MARCH 31,	
	2017	2016
Net loss	\$ (7,183)	\$ (8,842)
Net unrealized (loss) gain on marketable securities	(18)	253
Comprehensive loss	<u>\$ (7,201)</u>	<u>\$ (8,589)</u>

See accompanying notes.

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

	THREE MONTHS ENDED MARCH 31,	
	2017	2016
<b>Cash flows from operating activities:</b>		
Net loss	\$ (7,183)	\$ (8,842)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	20	21
Loss on retirement of property and equipment	5	—
Accretion and amortization on investments, net	55	284
Stock-based compensation for services by non-employees	57	50
Stock-based compensation for employees and directors	1,983	2,019
Amortization related to 401(k) contributions	32	53
Changes in assets and liabilities:		

Other current assets	(6,003)	813
Other current liabilities	3,727	24
Net cash used in operating activities	(7,307)	(5,578)
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	—	(26)
Purchases of marketable securities	(28,282)	(46,751)
Proceeds from maturities of marketable securities	37,640	43,083
Net cash provided by (used in) investing activities	9,358	(3,694)
<b>Cash flows from financing activities:</b>		
Proceeds from issuances of common stock	—	826
Net cash provided by financing activities	—	826
Net increase (decrease) in cash and cash equivalents	2,051	(8,446)
Cash and cash equivalents at the beginning of the period	12,810	21,248
Cash and cash equivalents at the end of the period	\$ 14,861	\$ 12,802
<b>Supplemental Disclosure of Non-Cash Investing Activities:</b>		
Net unrealized (loss) gain on marketable securities	\$ (18)	\$ 253

See accompanying notes.

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**GERON CORPORATION**  
**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
**MARCH 31, 2017**  
**(UNAUDITED)**

**1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Basis of Presentation**

The terms “Geron”, the “Company”, “we” and “us” as used in this report refer to Geron Corporation. The accompanying unaudited condensed financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. generally accepted accounting principles for complete financial statements. In the opinion of management of Geron, all adjustments (consisting only of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three months ended March 31, 2017 are not necessarily indicative of the results that may be expected for the year ending December 31, 2017 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, 2016, included in the Company’s Annual Report on Form 10-K. The accompanying condensed balance sheet as of December 31, 2016 has been derived from audited financial statements at that date.

**Net Income (Loss) Per Share**

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

Since we incurred a net loss for the three months ended March 31, 2017 and 2016, 1,977,091 and 3,593,074 common stock equivalents, respectively, related to outstanding stock options and restricted stock awards (as determined using the treasury-stock method at the estimated average market value) were excluded from the diluted net loss per share calculation as their effect would have been anti-dilutive. In addition, for the three months ended March 31, 2017 and 2016, 14,776,920 and 10,617,930 potentially dilutive securities, respectively, were excluded from the treasury-stock method and calculation of diluted net loss per share as their effect would have been anti-dilutive.

**Use of Estimates**

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

**Fair Value of Financial Instruments**

**Cash Equivalents and Marketable Securities**

We consider all highly liquid investments with an original maturity of three months or less to be cash equivalents. We are subject to credit risk related to our cash equivalents and marketable securities. We place our cash and cash equivalents in money market funds, corporate notes and cash operating accounts.

We classify our marketable securities as available-for-sale. We record available-for-sale securities at fair value with unrealized gains and losses reported in accumulated other comprehensive income (loss) in stockholders' equity. Realized gains and losses are included in interest and other income and are derived using the specific identification method for determining the cost of securities sold and have been insignificant to date. Dividend and interest income are recognized when earned and included in interest and other income in our condensed statements of operations. We recognize a charge when the declines in the fair values below the amortized cost basis of our available-for-sale securities are judged to be other-than-temporary. We consider various factors in determining whether to recognize an other-than-temporary charge, including whether we intend to sell the security or whether it is more likely than not that we would be required to sell the security before recovery of the amortized cost basis. Declines in market value associated with credit losses judged as other-than-temporary result in a charge to interest and other income. Other-than-temporary charges not related to credit losses are included in accumulated other comprehensive income (loss) in stockholders' equity. We have not recorded any other-than-temporary impairment charges on our available-for-sale securities for the three months ended March 31, 2017 and 2016. See Note 2 on Fair Value Measurements.

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**GERON CORPORATION**  
**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
**MARCH 31, 2017**  
**(UNAUDITED)**

**Revenue Recognition**

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

**License and/or Collaboration Agreements**

In addition to the exclusive collaboration and license agreement, or Collaboration Agreement, that we entered into with Janssen Biotech, Inc., or Janssen, in November 2014 (which is more fully described in Note 3 on Collaboration Agreement), we have entered into several license or collaboration agreements with various oncology, diagnostics, research tools and biologics production companies. Economic terms in these agreements may include non-refundable license payments in cash or equity securities, option payments in cash or equity securities, cost reimbursements, cost-sharing arrangements, milestone payments, royalties on future sales of products, or any combination of these items. In applying the appropriate revenue recognition guidance related to these agreements, we first assess whether the arrangement contains multiple elements. In this evaluation, we consider: (i) the deliverables included in the arrangement and (ii) whether the individual deliverables represent separate units of accounting or whether they must be accounted for as a combined unit of accounting. This evaluation involves subjective determinations and requires us to make judgments about the individual deliverables and whether such deliverables are separable from the other aspects of the contractual relationship. Deliverables are considered separate units of accounting provided that: (i) the delivered item(s) has value to the customer on a standalone basis, and (ii) if the arrangement includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in our control. In assessing whether an item has standalone value, we consider factors such as the research, manufacturing and commercialization capabilities of the collaboration partner or licensee and the availability of the associated expertise in the general marketplace. In addition, we consider whether the collaboration partner or licensee can use the other deliverable(s) for their intended purpose without the receipt of the remaining element(s), whether the value of the deliverable is dependent on the undelivered item(s) and whether there are other vendors that can provide the undelivered element(s).

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

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

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**GERON CORPORATION**  
**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
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**(UNAUDITED)**

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 that depend 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 that depend 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 costs incurred under our collaboration and/or license agreements.

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

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**GERON CORPORATION**  
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**(UNAUDITED)**

### Depreciation and Amortization

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

### Stock-Based Compensation

We recognize stock-based compensation expense on a straight-line basis over the requisite service period, which is generally the vesting period. The following table summarizes the stock-based compensation expense included in operating expenses on our condensed statements of operations related to stock options, restricted stock awards and employee stock purchases for the three months ended March 31, 2017 and 2016 which was allocated as follows:

(In thousands)	Three Months Ended March 31,	
	2017	2016
Research and development	\$ 291	\$ 332
General and administrative	1,692	1,687
Stock-based compensation expense included in operating expenses	\$ 1,983	\$ 2,019

As stock-based compensation expense recognized in our condensed statements of operations for the three months ended March 31, 2017 and 2016 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. With the adoption of Accounting Standards Update No. 2016-09, *Improvements to Employee Share Based Payment Accounting*, or ASU 2016-09, in the first quarter of 2017, we elected to continue to estimate forfeitures expected to occur to determine the amount of stock-based compensation expense to be recognized in each period. In addition, the adoption of ASU 2016-09 did not impact our accounting for or presentation of excess tax benefits recognized on stock-based compensation expense on our financial statements since our net deferred tax assets are fully offset by a valuation allowance due to our history of operating losses. Presentation requirements for cash flows related to employee taxes paid for withheld shares had no impact to all periods presented.

### Stock Options

We grant options with service-based vesting under our equity plans to employees, non-employee directors and consultants. The vesting period for employee options is generally four years. The fair value of options granted during the three months ended March 31, 2017 and 2016 has been estimated at the date of grant using the Black Scholes option-pricing model with the following assumptions:

	Three Months Ended March 31,	
	2017	2016
Dividend yield	0%	0%
Expected volatility	0.892	0.890
Risk-free interest rate	1.98%	1.21%
Expected term	5.5 yrs	5.5 yrs

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**GERON CORPORATION**  
**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
**MARCH 31, 2017**  
**(UNAUDITED)**

**Employee Stock Purchase Plan**

The fair value of employees' purchase rights during the three months ended March 31, 2017 and 2016 has been estimated using the Black Scholes option-pricing model with the following assumptions:

	Three Months Ended March 31,	
	2017	2016
Dividend yield	0%	0%
Expected volatility range	0.577 to 0.641	0.684
Risk-free interest rate range	0.45% to 0.89%	0.28%
Expected term range	6 - 12 mos	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.

**Non-Employee Stock-Based Awards**

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

**Segment Information**

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

**Recent Accounting Pronouncements Not Yet Effective**

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update No. 2014-09, or ASU 2014-09, which creates Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers*, or Topic 606, and supersedes the revenue recognition requirements in Accounting Standards Codification Topic 605, *Revenue Recognition*, including most industry-specific revenue recognition guidance throughout the Industry Topics of the Codification. In summary, the core principle of Topic 606 is to recognize revenue when promised goods or services are transferred to customers in an amount that reflects the consideration that is expected to be received for those goods or services. Companies are allowed to select between two transition methods: (1) a full retrospective transition method with the application of the new guidance to each prior reporting period presented, or (2) a retrospective transition method that recognizes the cumulative effect on prior periods at the date of adoption together with additional footnote disclosures. The amendments in ASU 2014-09 are effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period. Earlier application is permitted only as of annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. In March, April, May and December 2016, the FASB issued Accounting Standards Update No. 2016-08 (Topic 606), *Revenue From Contracts With Customers: Principal vs. Agent Considerations*, or ASU 2016-08, Accounting Standards Update No. 2016-10 (Topic 606), *Revenue From Contracts with Customers: Identifying Performance Obligations and Licensing*, or ASU 2016-10, Accounting Standards Update No. 2016-12 (Topic 606), *Revenue From Contracts with Customers: Narrow-Scope Improvements and Practical Expedients*, or ASU 2016-12, and Accounting Standards Update No. 2016-20 (Topic 606), *Revenue from Contracts with Customers: Technical Corrections and Improvements to Topic 606*, or ASU 2016-20, respectively, to provide supplemental adoption guidance and clarification to ASU 2014-09. We do not plan to early adopt these standards.

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**GERON CORPORATION**  
**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
**MARCH 31, 2017**  
**(UNAUDITED)**

We currently anticipate adopting ASU 2014-09 and its related supplemental guidance using the full retrospective transition method to restate each prior reporting period presented in our financial statements. While we are continuing to assess the effect of this new standard, we have not identified any material differences in the accounting treatment under ASU 2014-09 compared to the current accounting treatment for the Collaboration Agreement with Janssen, which is currently the most material agreement to our financial statements. However, such assessment is preliminary and subject to change. Our analysis of other agreements could identify material changes from the current accounting treatment. ASU 2014-09 differs from the current accounting standard in many respects, such as in the accounting for variable consideration, including milestone payments. Under our current accounting policy, we recognize milestone revenue using the milestone method specified in ASC 605-28, *Milestone Method of Revenue Recognition*, which generally results in the recognition of milestone payments as revenue in the period that the milestone is achieved. However, under the new accounting standard, it is possible to start to recognize milestone revenue before the milestone is achieved, subject to management's assessment of whether it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

The new revenue standard is principles-based and the interpretation of those principles may vary from company to company based on their unique circumstances. It is possible that interpretation, industry practice, and guidance may evolve as companies and the accounting profession work to implement this new standard. We are still in the process of evaluating the effect of the new standard on our historical financial statements. While we have not completed our evaluation, we currently believe the impact to revenue and expense recognized will not be material to any of the years presented. As we complete our evaluation of this new standard, new information may arise that could change our current understanding of the impact to revenue and expense recognized historically, and we may decide to change the method in which we adopt the new standard. Additionally, we will continue to monitor industry activities and any additional guidance provided by regulators, standards setters, or the accounting profession and adjust our assessment and implementation plans accordingly.

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

In June 2016, the FASB issued Accounting Standard Update No. 2016-13, *Measurement of Credit Losses on Financial Instruments*, or ASU 2016-13. ASU 2016-13 amends the guidance for measuring and recording credit losses on financial assets measured at amortized cost by replacing the "incurred loss" model with an "expected loss" model. Accordingly, these financial assets will be presented at the net amount expected to be collected. ASU 2016-13 also requires that credit losses related to available-for-sale debt securities be recorded through an allowance for such losses rather than reducing the carrying amount under the current other-than-temporary-impairment model. ASU 2016-13 is effective for interim and annual periods beginning after December 15, 2019. Early adoption is permitted for interim and annual periods beginning after December 15, 2018. We are currently evaluating the impact of the adoption of ASU 2016-13 on our financial statements and related disclosures and have not made any decision regarding the timing of adoption.

In August 2016, the FASB issued Accounting Standards Update No. 2016-15, *Classification of Certain Cash Receipts and Cash Payments*, or ASU 2016-15, to clarify how certain cash receipts and cash payments are presented and classified in the statement of cash flows. ASU 2016-15 is effective for annual periods beginning after December 15, 2017, and interim periods within those annual periods and early adoption is permitted. ASU 2016-15 must be applied retrospectively to each period presented. We do not plan to early adopt ASU 2016-15. We are currently evaluating the impact of the adoption of ASU 2016-15 on our financial statements and related disclosures.

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In November 2016, the FASB issued Accounting Standards Update No. 2016-18, *Statement of Cash Flows (Topic 230) Restricted Cash*, or ASU 2016-18, to address the diversity in practice in the classification and presentation of changes in restricted cash on the statement of cash flows. ASU 2016-18 is effective for annual periods beginning after December 15, 2017, and interim periods within those annual periods. Early adoption is permitted, including adoption in an interim period which would require any adjustments to be reflected as of the beginning of the annual period that includes that interim period. ASU 2016-18 must be applied using a retrospective transition method to each period presented. We do not plan to early adopt ASU 2016-18. We are currently evaluating the impact of the adoption of ASU 2016-18 on our financial statements and related disclosures.

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

**2. FAIR VALUE MEASUREMENTS**

**Cash Equivalents and Marketable Securities**

Cash equivalents, restricted cash and marketable securities by security type at March 31, 2017 were as follows:

<b>(In thousands)</b>	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Estimated Fair Value</b>
<b>Included in cash and cash equivalents:</b>				
Money market funds	\$ 9,946	\$ —	\$ —	\$ 9,946
Corporate notes	2,862	—	—	2,862
	<u>\$ 12,808</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 12,808</u>
<b>Restricted cash:</b>				
Certificate of deposit	\$ 268	\$ —	\$ —	\$ 268
<b>Marketable securities:</b>				

Government-sponsored enterprise securities (due in less than one year)	\$ 7,500	\$ —	\$ (9)	\$ 7,491
Government-sponsored enterprise securities (due in one to two years)	10,000	—	(29)	9,971
Commercial paper (due in less than one year)	20,577	21	(3)	20,595
Corporate notes (due in less than one year)	56,382	1	(37)	56,346
Corporate notes (due in one to two years)	12,170	—	(15)	12,155
	<u>\$ 106,629</u>	<u>\$ 22</u>	<u>\$ (93)</u>	<u>\$ 106,558</u>

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

(In thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Included in cash and cash equivalents:				
Money market funds	\$ 11,193	\$ —	\$ —	\$ 11,193
Restricted cash:				
Certificate of deposit	\$ 268	\$ —	\$ —	\$ 268
Marketable securities:				
Government-sponsored enterprise securities (due in less than one year)	\$ 5,000	\$ —	\$ (3)	\$ 4,997
Government-sponsored enterprise securities (due in one to two years)	12,500	—	(42)	12,458
Commercial paper (due in less than one year)	31,024	50	(5)	31,069
Corporate notes (due in less than one year)	66,012	4	(47)	65,969
Corporate notes (due in one to two years)	1,506	—	(10)	1,496
	<u>\$ 116,042</u>	<u>\$ 54</u>	<u>\$ (107)</u>	<u>\$ 115,989</u>

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Marketable securities with unrealized losses at March 31, 2017 and December 31, 2016 were as follows:

(In thousands)	Less Than 12 Months		12 Months or Greater		Total	
	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses
<b>As of March 31, 2017:</b>						
Government-sponsored enterprise securities (due in less than one year)	\$ 7,491	\$ (9)	\$ —	\$ —	\$ 7,491	\$ (9)
Government-sponsored enterprise securities (due in one to two years)	9,971	(29)	—	—	9,971	(29)
Commercial paper (due in less than one year)	5,885	(3)	—	—	5,885	(3)
Corporate notes (due in less than one year)	46,236	(34)	5,916	(3)	52,152	(37)
Corporate notes (due in one to two years)	12,155	(15)	—	—	12,155	(15)
	<u>\$ 81,738</u>	<u>\$ (90)</u>	<u>\$ 5,916</u>	<u>\$ (3)</u>	<u>\$ 87,654</u>	<u>\$ (93)</u>
<b>As of December 31, 2016:</b>						
Government-sponsored enterprise securities (due in less than one year)	\$ 4,997	\$ (3)	\$ —	\$ —	\$ 4,997	\$ (3)
Government-sponsored enterprise securities (due in one to two years)	12,458	(42)	—	—	12,458	(42)
Commercial paper (due in less than one year)	8,365	(5)	—	—	8,365	(5)
Corporate notes (due in less than one year)	39,218	(37)	6,944	(10)	46,162	(47)
Corporate notes (due in one to two years)	1,496	(10)	—	—	1,496	(10)
	<u>\$ 66,534</u>	<u>\$ (97)</u>	<u>\$ 6,944</u>	<u>\$ (10)</u>	<u>\$ 73,478</u>	<u>\$ (107)</u>

The gross unrealized losses related to government-sponsored enterprise securities, commercial paper and corporate notes as of March 31, 2017 and December 31, 2016 were due to changes in interest rates. We determined that the gross unrealized losses on our marketable securities as of March 31, 2017 and December 31, 2016 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 bases.

**Fair Value on a Recurring Basis**

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.

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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.

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.

The following table presents information about our financial instruments that are measured at fair value on a recurring basis as of March 31, 2017 and indicates the fair value category assigned.

(In thousands)	Fair Value Measurements at Reporting Date Using			Total
	Quoted Prices in Active Markets for Identical Assets	Significant Other Observable Inputs	Significant Unobservable Inputs	
	Level 1	Level 2	Level 3	
<b>Assets</b>				
Money market funds <sup>(1)</sup>	\$ 9,946	\$ —	\$ —	\$ 9,946
Government-sponsored enterprise securities <sup>(2)(3)</sup>	—	17,462	—	17,462
Commercial paper <sup>(2)</sup>	—	20,595	—	20,595
Corporate notes <sup>(1)(2)(3)</sup>	—	71,363	—	71,363
Total	\$ 9,946	\$ 109,420	\$ —	\$ 119,366

The following table presents information about our financial instruments that are measured at fair value on a recurring basis as of December 31, 2016 and indicates the fair value category assigned.

(In thousands)	Fair Value Measurements at Reporting Date Using			Total
	Quoted Prices in Active Markets for Identical Assets	Significant Other Observable Inputs	Significant Unobservable Inputs	
	Level 1	Level 2	Level 3	
<b>Assets</b>				
Money market funds <sup>(1)</sup>	\$ 11,193	\$ —	\$ —	\$ 11,193
Government-sponsored enterprise securities <sup>(2)(3)</sup>	—	17,455	—	17,455
Commercial paper <sup>(2)</sup>	—	31,069	—	31,069
Corporate notes <sup>(2)(3)</sup>	—	67,465	—	67,465
Total	\$ 11,193	\$ 115,989	\$ —	\$ 127,182

(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.

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**3. COLLABORATION AGREEMENT**

On November 13, 2014, we and Janssen entered into the Collaboration Agreement under which we granted to Janssen exclusive worldwide rights to develop and commercialize imetelstat for all human therapeutic uses, including hematologic myeloid malignancies. Upon the effectiveness of the Collaboration Agreement, we received \$35,000,000 from Janssen as an upfront payment.

Under the Collaboration Agreement, Janssen is wholly responsible for the development, manufacturing, seeking regulatory approval for and commercialization of, imetelstat worldwide. To that end, Janssen is currently proceeding with the development of imetelstat with two clinical trials: a Phase 2 trial in myelofibrosis, referred to as IMbark, and a Phase 2/3 trial in myelodysplastic syndromes, referred to as IMerge. Development costs for IMbark and IMerge are being shared between us and Janssen on a 50/50 basis. Additionally, under the terms of the Collaboration Agreement, we remain responsible for prosecuting, at Janssen's direction, the patents licensed to Janssen at the time we entered into the Collaboration Agreement, with costs shared between us and Janssen on a 50/50 basis. The cost-sharing arrangement with Janssen began in January 2015. As of March 31, 2017, accrued collaboration charges of \$2,495,000 on our condensed balance sheet represent the net amount owed to Janssen for our proportionate share of development costs incurred by Janssen under the Collaboration Agreement for the three months ended March 31, 2017.

If the protocol-specified primary analysis of IMbark is completed by Janssen, then Janssen must notify us of their decision, or a Continuation Decision, as to whether they elect to maintain the license rights granted to them under the Collaboration Agreement and continue to advance the development of imetelstat in any indication. In the event that IMbark is terminated early, or placed on clinical hold or suspended by a regulatory authority for an extended period of time, then Janssen must instead notify us of their Continuation Decision by the date that is approximately 24 months after the initiation of IMerge.

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

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

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

#### **4. COMMITMENTS AND CONTINGENCIES**

We and certain of our officers have been named as defendants in two purported class action securities lawsuits filed in the United States District Court for the Northern District of California, or the California District Court, as well as a third securities lawsuit, not styled as a class action, which was originally filed in the United States District Court for the Southern District of Mississippi, and subsequently transferred to the California District Court. These three cases, or the Class Action Lawsuits, which are based on the same factual background, have been consolidated for all purposes, and are currently stayed to enable the parties to seek to resolve them. On November 23, 2016, the parties signed a Memorandum of Understanding that set forth material deal points of resolving the Class Action Lawsuits. On December 13, 2016, the parties filed a notice of settlement, which the California District Court signed on December 16, 2016, staying the Class Action Lawsuits pending final approval of a settlement.

On March 2, 2017, the parties to the Class Action Lawsuits, through their respective counsel, executed a Stipulation and Agreement of Settlement, or the Stipulation, and related documents formalizing an agreement to settle the Class Action Lawsuits. Under the Stipulation, in exchange for the dismissal with prejudice of all claims against all defendants in connection with the Class Action Lawsuits, we agreed to settle the Class Action Lawsuits for \$6,250,000 in cash. We and our insurance providers agreed that \$6,000,000 of the settlement amount will be paid by our insurance providers and the remaining \$250,000 will be paid by us. The settlement does not constitute any admission of fault or wrongdoing by us or any of the individual defendants.

On March 2, 2017, plaintiff's counsel filed a motion for preliminary approval of the settlement, and on April 7, 2017, the California District Court issued an order preliminarily approving the settlement proposed in the Stipulation and directed that notice of the settlement, or the Notice, be given to certain

purchasers of our common stock during the period from December 10, 2012 through and including March 11, 2014. The Notice includes, among other things, the general terms of the settlement, the proposed plan of allocation of the settlement amount, and the terms of the plaintiff's counsel fee application.

The California District Court scheduled a settlement fairness hearing on July 21, 2017 to, among other things, make a final determination whether the settlement is fair, reasonable and adequate and should be approved by the California District Court. The settlement and the Stipulation remain subject to final approval by the California District Court and certain other conditions.

We accrue a liability for litigation matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. As a result of the fully executed Stipulation by the parties and subsequent receipt of preliminary approval from the California District Court of the settlement proposed in the Stipulation, we accrued a loss contingency and recorded an undiscounted liability of \$6,250,000, which is included in litigation settlement payable on our condensed balance sheet as of March 31, 2017. We also recorded an undiscounted receivable of \$6,000,000, the amount we expect to recover from our insurance providers, which is included in litigation settlement insurance recovery on our condensed balance sheet as of March 31, 2017. In April 2017, following the preliminary approval by the California District Court of the settlement and in accordance with the Stipulation, we paid \$250,000 and our insurance providers paid \$6,000,000 to a settlement escrow account. These amounts will be held in escrow until finalization of the settlement. In accordance with the Stipulation, upon full payment of the settlement amount to the escrow account, we have no further liability or obligation to make any further payments related to the Stipulation or the Class Action Lawsuits.

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The Class Action Lawsuits, including the settlement proposed in the Stipulation, remain subject to inherent uncertainties, and the actual defense and disposition costs may depend upon many unknown factors. Therefore, there can be no assurance that the Class Action Lawsuits will not have a material adverse effect on our business, cash flow, results of operations or financial position. It is possible that additional lawsuits will be filed, or allegations will be made by stockholders, with respect to these same or other matters and also naming us and/or our officers and directors as defendants. Monitoring, initiating and defending against legal actions is 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. In addition, despite the availability of insurance, we may incur substantial legal fees and costs in connection with litigation and such amounts could be material to our financial statements. We may expend significant resources in the settlement or defense of any additional lawsuits, and we may not prevail in such lawsuits. We have not established any reserve for any potential liability relating to any additional lawsuits.

For a more complete discussion of the Class Action Lawsuits, see the section entitled "Legal Proceedings" under Part II, Item 1 of this Form 10-Q.

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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," "expects," "plans," "intends," "will," "should," "projects," "believes," "predicts," "anticipates," "estimates," "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 the sections entitled "Business" and "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, 2016, as filed with the Securities and Exchange Commission, or SEC, on March 1, 2017.

**Business Overview**

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

In November 2014, we entered into a collaboration and license agreement, or the Collaboration Agreement, pursuant to which we granted Janssen the exclusive rights to develop and commercialize imetelstat worldwide for all indications in oncology, including hematologic myeloid malignancies, and all other human therapeutic uses. The Collaboration Agreement became effective in December 2014 and we received \$35 million from Janssen as an upfront payment. Additional consideration under the Collaboration Agreement includes potential payments of up to an aggregate maximum total of \$900 million for

the achievement of development, regulatory and sales milestones, as well as royalties on worldwide net sales of imetelstat. Janssen may terminate the Collaboration Agreement at any time for convenience or due to a safety-related concern. Under the Collaboration Agreement, Janssen is wholly responsible for development, manufacturing, seeking regulatory approval for, and commercialization of imetelstat worldwide. All worldwide regulatory, development, manufacturing and promotional activities related to imetelstat are being managed through a joint governance structure. The joint governance structure includes a Joint Steering Committee, or JSC, with equal membership from both companies.

Janssen is currently conducting two clinical trials of imetelstat: IMbark, a Phase 2 trial in MF, in which the first patient was dosed in September 2015; and IMerge, a Phase 2/3 trial in myelodysplastic syndromes, or MDS, in which the first patient was dosed in January 2016. We are contributing 50% of the development costs for these studies, which Janssen is solely conducting. For a further discussion of the Collaboration Agreement, see Note 3 on Collaboration Agreement in Notes to Condensed Financial Statements of this Form 10-Q.

IMerge is a two-part clinical trial evaluating imetelstat in transfusion dependent patients with Low or Intermediate-1 risk MDS who have relapsed after or are refractory to prior treatment with an erythropoiesis stimulating agent, or ESA. Part 1 of the trial is designed as a Phase 2, open-label, single-arm trial to assess the efficacy and safety of imetelstat. Efficacy assessments include hematologic improvement and reduction in transfusion requirements. Part 1 of IMerge is fully enrolled with approximately 30 patients. Before proceeding to Part 2, the data from Part 1 must support a positive assessment of the benefit-risk profile of imetelstat in these patients. Part 2 of the trial is planned as a Phase 3 double-blind, randomized, controlled trial in approximately 170 patients. The primary efficacy endpoint is the rate of red blood cell transfusion independence lasting at least 8 weeks. Key secondary endpoints include the rates of red blood cell transfusion independence lasting at least 24 weeks and hematologic improvement.

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In September 2016, an internal data review of IMerge was conducted, and the JSC determined to continue IMerge unmodified. In April 2017, a second internal review of IMerge was completed, which included data from the approximately 30 patients enrolled in Part 1. Based on this second internal data review, the JSC determined the following:

- The safety profile was consistent with prior clinical trials of imetelstat in hematologic malignancies, and no new safety signals were identified.
- The benefit-risk profile of imetelstat, including assessments of 8-week and 24-week transfusion independence and hematologic improvement by erythroid, or HI-E, response, across multiple MDS sub-types, supports continued development in lower risk MDS.
- Part 1 of the trial will continue unmodified, and patients remaining in the treatment phase may continue to receive imetelstat.
- A data package, as well as proposed refinements to the trial design for Part 2 of IMerge, is planned to be provided to the United States Food and Drug Administration, or FDA.
- Data from Part 1 are expected to be submitted for consideration for presentation at a medical conference in the future.

We expect that Janssen's decision whether to initiate Part 2 of IMerge will be informed by FDA feedback on the data package planned to be provided and the totality of imetelstat program information, including an assessment of the evolving treatment landscape in MDS and the potential application of imetelstat in multiple hematologic malignancies. Janssen has not committed to begin Part 2 of IMerge. It is possible that as a result of FDA feedback on IMerge or other factors, Janssen could decide not to proceed with Part 2 of IMerge and/or discontinue the imetelstat program and terminate the Collaboration Agreement. If Part 2 of IMerge is initiated by Janssen, we expect Part 2 to be opened for patient enrollment in the fourth quarter of 2017.

IMbark was originally designed as a Phase 2 clinical trial to evaluate two dose levels of imetelstat (either 4.7 mg/kg or 9.4 mg/kg administered every three weeks) in approximately 200 patients with Intermediate-2 or High risk MF who have relapsed after or are refractory to prior treatment with a janus kinase, or JAK, inhibitor. The co-primary efficacy endpoints for the trial are spleen response rate, defined as the proportion of patients who achieve a  $\geq 35\%$  reduction in spleen volume assessed by imaging, and symptom response rate, defined as the proportion of patients who achieve a  $\geq 50\%$  reduction in Total Symptom Score, at 24 weeks.

In September 2016, a planned internal review of data from IMbark was completed. From this first internal data review, the JSC determined that activity in the 4.7 mg/kg dosing arm did not warrant further investigation of that dose, and accordingly the 4.7 mg/kg dosing arm was closed to new patient enrollment. The JSC also determined that the 9.4 mg/kg dosing arm in IMbark warranted further investigation because encouraging trends in the efficacy data were observed, but new patient enrollment to this arm was suspended because an insufficient number of patients met the protocol defined interim efficacy criteria at 12 weeks. Following this first internal data review, the JSC determined to continue the trial to obtain additional and more mature data, and patients remaining in the treatment phase of IMbark were permitted to receive imetelstat.

In April 2017, a second internal review of IMbark was completed, which included data from the approximately 100 patients who were enrolled in the trial, with each dosing arm analyzed separately. Based on this second internal data review, the JSC determined the following:

- The safety profile was consistent with prior clinical trials of imetelstat in hematologic malignancies, and no new safety signals were identified.
- The data support 9.4 mg/kg as an appropriate starting dose for the relapsed or refractory MF patient population.

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- In these relapsed or refractory MF patients treated in the 9.4 mg/kg dosing arm, the spleen volume response rate observed to date was less than that reported in front-line MF patients treated in trials with other drugs. However, activity within multiple outcome measures was observed with imetelstat treatment, which suggests potential clinical benefit in this relapsed or refractory MF patient population. These outcome measures included a range of spleen volume reductions, reductions in Total Symptoms Score, and improvements in hematologic parameters, such as anemia and

peripheral blood counts. In addition, the data suggest there may be a potential overall survival benefit associated with imetelstat treatment in these patients.

- The trial will continue without any modifications, including the conduct of all safety and efficacy assessments as planned in the protocol, including overall survival. Patients remaining in the treatment phase may continue to receive imetelstat.
- Enrollment of new patients to the trial will remain suspended because the total number of patients enrolled to date is adequate to assess longer-term outcome measures when the data are fully matured.

During the next year, we expect Janssen to evaluate maturing efficacy and safety data from the IMbark trial, including an assessment of overall survival. We expect the longer-term data from the trial, potential regulatory feedback, the totality of imetelstat program information, including an assessment of the evolving treatment landscape in MF and the potential application of imetelstat in multiple hematologic malignancies, including MDS, will inform Janssen's decision whether to continue development of imetelstat in relapsed or refractory MF.

The protocol-specified primary analysis of the co-primary efficacy endpoints in IMbark is planned to occur after all patients (i.e., planned to be approximately 100 enrolled and treated patients on the 9.4 mg/kg dosing arm) have been followed for at least 24 weeks. Due to the current suspension of new patient enrollment in IMbark, the timing of the protocol-specified primary analysis for the trial remains uncertain and may be substantially delayed due to numerous factors, including whether Janssen resumes patient enrollment in the trial or the trial is extended to enable longer-term data collection to assess the potential overall survival benefit in IMbark, or the protocol-specified primary analysis may not occur at all if IMbark is terminated early based on preliminary or ongoing data assessments, safety concerns or for any other reason. Delay in the timing of the Continuation Decision, or a negative Continuation Decision which would result in termination of the Collaboration Agreement by Janssen, could increase our development costs, and impair our ability to earn revenues from milestone payments or royalties under the Collaboration Agreement, any of which would severely and adversely affect our business and business prospects and the future of imetelstat.

## Financial Overview

We had approximately \$121.7 million in cash and investments as of March 31, 2017. To grow and diversify our business, we plan to continue our business development efforts to identify, and seek to acquire and/or in-license other oncology products, product candidates, programs or companies. Acquisition or in-licensing opportunities that we may pursue could materially affect our liquidity and capital resources and may require us to incur indebtedness or seek equity capital, or both. While we reported a small profit for the year ended December 31, 2015 due to our recognition of revenue in connection with the upfront payment from Janssen under the Collaboration Agreement, until 2015 we had never been profitable. We have incurred significant net losses since our inception in 1990, resulting principally from costs incurred in connection with our research and development activities and from general and administrative costs associated with our operations. As of March 31, 2017, we had an accumulated deficit of \$965.1 million. Since our inception, we primarily have financed our operations through the sale of equity securities, interest income on our marketable securities and payments we received under our collaborative and licensing arrangements.

Substantially all of our revenues to date have been payments under collaborative agreements, and milestones, royalties and other revenues from our licensing arrangements. We currently have no source of product revenue. The significance of future losses, future revenues and any potential future profitability will depend primarily 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, and whether we in-license or acquire other oncology products, product candidates, programs or companies in order to grow and diversify our business. There can be no assurance that we will receive any milestone payments or royalties from Janssen in the future, or at all. In addition, if Janssen does not perform in the manner we expect or fulfill its responsibilities in a timely manner, or at all, including with respect to deciding whether to initiate Part 2 of IMerge and/or obtaining longer-term efficacy and safety data from IMbark to enable an assessment of overall survival, the clinical development, manufacturing, regulatory approval and/or commercialization of imetelstat could be delayed or terminated, and it could become necessary for us to assume responsibility for the clinical development, manufacturing, regulatory approval and/or commercialization of imetelstat at our own expense. In any event, imetelstat will require significant additional clinical testing prior to possible regulatory approval in the United States and other countries, and we do not expect imetelstat to be commercially available for many years, if at all.

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## CRITICAL ACCOUNTING POLICIES AND ESTIMATES

There have been no significant changes in our critical accounting policies and estimates during the three months ended March 31, 2017 as compared to the critical accounting policies and estimates disclosed in our Annual Report on Form 10-K for the year ended December 31, 2016 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 primarily upon the progress of research and development efforts in collaboration with Janssen and whether we are able to acquire and/or in-license other oncology products, product candidates,

programs or companies in order to grow and diversify our business. Results of operations for any period may be unrelated to results of operations for any other period. Thus, historical results should not be viewed as indicative of future operating results. For example, in 2015 we reported net income for the first time due to recognition of revenue in connection with the upfront payment from Janssen under the Collaboration Agreement. However, we expect to incur operating losses in the future as clinical development activities for imetelstat continue under our Collaboration Agreement with Janssen, and our operating losses may increase in size. We are subject to risks common to companies in our industry and at our stage of development, including, but not limited to, risks inherent in research and development efforts, our dependence on Janssen for the development, manufacture, regulatory approval for and commercialization of, imetelstat, uncertainty of preclinical and clinical trial results or regulatory approvals or clearances, the future development of imetelstat, including any future efficacy or safety results that may cause the benefit-risk profile of imetelstat to become unacceptable, need for future capital, enforcement of our patent and proprietary rights, reliance upon our collaborators, licensees, investigators and other third parties, and potential competition. In order for imetelstat to be commercialized, we are wholly dependent on Janssen to conduct preclinical tests and clinical trials to demonstrate the safety and efficacy of imetelstat, obtain regulatory approvals or clearances and enter into manufacturing, distribution and marketing arrangements, as well as obtain market acceptance. We do not expect to receive royalties based on sales of imetelstat for many years, if at all.

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**Revenues**

In addition to the Collaboration Agreement with Janssen for imetelstat, we have entered into several license or collaboration agreements with companies involved with oncology, diagnostics, research tools and biologics production, whereby we have granted certain rights to our non-imetelstat related technologies. In connection with these agreements, we are eligible to receive license fees, option fees, milestone payments and royalties on future sales of products, or any combination thereof.

We recognized license fee revenues of \$409,000 for the three months ended March 31, 2017, compared to \$463,000 for the same period in 2016 related to our various agreements. The decrease in license fee revenues for the three months ended March 31, 2017 compared to the same period in 2016 primarily reflects the recognition of lower license fees in the first quarter of 2017 for research licenses related to our human telomerase reverse transcriptase, or hTERT, technology. We recognized royalty revenues of \$128,000 for the three months ended March 31, 2017, compared to \$286,000 for the same period in 2016. The decrease in royalty revenues for the three months ended March 31, 2017 compared to the same period in 2016 primarily reflects lower product sales by our licensees.

Future license fee and royalty revenues are dependent on additional agreements being signed, if any, current agreements being maintained and the underlying patent rights for the licenses remaining active. We expect revenues under our license agreements related to our hTERT technology to decline significantly in the coming years, and to be eliminated by the end of 2019, due to upcoming patent expirations on such technology. Current revenues may not be predictive of future revenues.

**Research and Development Expenses**

During the three months ended March 31, 2017 and 2016, imetelstat was the sole research and development program we supported. For the imetelstat research and development program, we incur direct external, personnel related and other research and development costs. For the three months ended March 31, 2017 and 2016, direct external expenses primarily consisted of our proportionate share of clinical development costs incurred by Janssen under the Collaboration Agreement. Personnel related expenses primarily consist of salaries and wages, stock-based compensation, payroll taxes and benefits for Geron employees involved with ongoing research and development efforts. Other research and development expenses primarily consist of research related overhead associated with allocated expenses for rent and maintenance of facilities and other supplies.

Research and development expenses were \$3.4 million for the three months ended March 31, 2017, compared to \$5.0 million for the same period in 2016. Higher research and development expenses in 2016 were primarily due to clinical trial start-up costs for the initiation of IMerge, in which the first patient was dosed in January 2016.

Research and development expenses for the three months ended March 31, 2017 and 2016 were as follows:

(In thousands)	Three Months Ended March 31,	
	2017	2016
	(Unaudited)	
Direct external expenses	\$ 2,586	\$ 3,969
Personnel related expenses	608	856
All other expenses	180	208
Total research and development expenses	\$ 3,374	\$ 5,033

At this time, we cannot provide reliable estimates of how much time or investment will be necessary to enable imetelstat to be commercialized. For a more complete discussion of the risks and uncertainties associated with the development of imetelstat in collaboration with Janssen, 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.

**General and Administrative Expenses**

General and administrative expenses were \$4.7 million for the three months ended March 31, 2017, compared to \$4.8 million for the same period in 2016. The decrease in general and administrative expenses for the three months ended March 31, 2017 compared to the same period in 2016 primarily reflects lower consulting costs. We expect general and administrative expenses to remain consistent during the remainder of 2017.

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## Interest and Other Income

Interest income was \$332,000 for the three months ended March 31, 2017, compared to \$256,000 for the same period in 2016. The increase in interest income for the three months ended March 31, 2017 compared to the same period in 2016 primarily reflects higher yields on our marketable securities portfolio. Interest earned in future periods will depend on the size of our marketable securities portfolio and prevailing interest rates.

## Interest and Other Expense

Interest and other expense was \$21,000 for each of the three months ended March 31, 2017 and 2016. Interest and other expense primarily reflects bank charges related to our cash operating accounts and marketable securities portfolio.

## LIQUIDITY AND CAPITAL RESOURCES

As of March 31, 2017, we had cash, restricted cash, cash equivalents and marketable securities of \$121.7 million, compared to \$129.1 million at December 31, 2016. The decrease in cash, restricted cash, cash equivalents and marketable securities in 2017 was the result of cash being used for operations. We expect to experience negative cash flow for the foreseeable future as the development of imetelstat continues in collaboration with Janssen. We estimate that our existing capital resources and future interest income will be sufficient to fund our current level of operations through at least the next 12 months. However, we may use our available capital resources sooner than we anticipate. For example, in order to grow and diversify our business, we plan to continue our business development efforts to identify and seek to acquire and/or in-license other oncology products, product candidates, programs or companies. Acquisition or in-licensing opportunities that we may pursue could materially affect our liquidity and capital resources and may require us to incur indebtedness, seek equity capital or both. In addition, there can be no assurance that sufficient additional capital would be available to us in order to pursue any of these opportunities.

We have an investment policy to invest our cash in liquid, investment grade securities, such as interest-bearing money market funds, certificates of deposit, municipal securities, U.S. government and agency securities, corporate notes and commercial paper. Our investment portfolio does not contain securities with exposure to sub-prime mortgages, collateralized debt obligations, asset-backed securities or auction rate securities and, to date, we have not recognized any other-than-temporary impairment charges on our marketable securities or any significant changes in aggregate fair value that would impact our cash resources or liquidity. To date, we have not experienced lack of access to our invested cash and cash equivalents; however, access to our invested cash and cash equivalents may be impacted by adverse conditions in the financial and credit markets.

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

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, or IDP, under the Collaboration Agreement, and to otherwise support the future growth of our business through the potential acquisition and/or in-licensing of other oncology products, product candidates, programs or companies. We cannot assure you that our existing capital resources, future interest income, potential milestone payments and royalties under the Collaboration Agreement with Janssen, and potential future sales of our common stock, including pursuant to our 2015 Sales Agreement with MLV, will be sufficient to fund future planned activities. The timing and degree of any future capital requirements will depend on many factors, including:

- the accuracy of the assumptions underlying our estimates for our capital needs;
- whether Janssen discontinues development of imetelstat and/or terminates the Collaboration Agreement and we choose to develop imetelstat ourselves;
- in the event that Janssen provides an affirmative Continuation Decision to us, whether we then elect our option, or the U.S. Opt-In Rights, to share further U.S. development and promotion costs for imetelstat beyond IMbark or IMerge under the Collaboration Agreement, including 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;
- to the extent permitted under the Collaboration Agreement, whether we independently pursue imetelstat development under our own IDP;

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- our potential reimbursement obligations to Janssen if any data from a Janssen IDP support approval by regulatory authorities in the United States or other countries;
- the achievement of development, regulatory and sales milestones resulting in the payment to us from Janssen under the Collaboration Agreement and the timing of receipt of such payments, if any;
- changes or delays in Janssen's development plans for imetelstat, including changes to ongoing current clinical trials of imetelstat, including IMbark and IMerge, which may result from any internal data reviews or any future clinical holds on any Investigational New Drug, or IND, applications for imetelstat;
- Janssen's ability to meaningfully reduce manufacturing costs of imetelstat;
- the progress, timing, magnitude, scope and costs of clinical development, manufacturing and commercialization of imetelstat, including the number of indications being pursued, subject to clearances and approvals by 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 sales price and availability of adequate third-party reimbursement for imetelstat;
- the timing, receipt and amount of any milestone payments or royalties under the Collaboration Agreement, if any;
- the cost of acquiring and/or in-licensing other oncology products, product candidates, programs or companies, if any;
- expenses associated with pending or potential future litigation; and
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims.

In addition, changes in our business may occur that would consume available capital resources sooner than we expect. If our existing capital resources, future interest income, and potential milestone payments and royalties under the Collaboration Agreement with Janssen are insufficient to meet future capital requirements, we will need to raise additional capital to fund our operations. Further, if the Collaboration Agreement is terminated, including as a result of Janssen’s failure to provide an affirmative Continuation Decision to us, or for any other reason, we would not receive any milestone payments or royalties under the Collaboration Agreement, and then, depending on the timing of such event, we would be required to fund all clinical development, manufacturing and commercial activities for imetelstat should we elect to continue the development of imetelstat ourselves, which would require us to raise additional capital or establish alternative collaborations with third-party collaboration partners, which may not be possible. If the Collaboration Agreement is terminated and we are unable to raise additional capital or establish alternative collaborations with third-party collaboration partners for imetelstat, the development of imetelstat would be discontinued, which might cause us to cease operations. Additional financing through public or private equity financings, including pursuant to our 2015 Sales Agreement with MLV, capital lease transactions or other financing sources may not be available on acceptable terms, or at all. We may raise equity capital at a stock price or on other terms that could result in substantial dilution of ownership for our stockholders. The receptivity of the public and private equity markets to proposed financings is substantially affected by the general economic, market and political climate and by other factors which are unpredictable and over which we have no control. In this regard, continued volatility and instability in the global financial markets and political climate could adversely affect our ability to raise additional funds through financings and the terms upon which we may raise those funds.

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

- changes or delays in Janssen’s development plans for imetelstat, including as a result of any future clinical holds on any IND for imetelstat or internal data reviews;
- a failure to show adequate safety or efficacy of imetelstat in current or potential future clinical trials, which may result in a decision by Janssen to delay or discontinue further development of imetelstat; or
- a termination of the Collaboration Agreement or if our collaboration with Janssen is otherwise unsuccessful.

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

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

*Cash Flows from Operating Activities.* Net cash used in operations for the three months ended March 31, 2017 and 2016 was \$7.3 million and \$5.6 million, respectively. The increase in net cash used in operations in 2017 compared to 2016 primarily reflects higher payments to Janssen in 2017 under the cost-sharing arrangement for imetelstat clinical development as outlined under the Collaboration Agreement.

*Cash Flows from Investing Activities.* Net cash provided by investing activities for the three months ended March 31, 2017 was \$9.4 million. Net cash used in investing activities for the three months ended March 31, 2016 was \$3.7 million. The increase in net cash provided by investing activities in 2017 compared to 2016 primarily reflects a higher rate of maturities than purchases of marketable securities in 2017.

*Cash Flows from Financing Activities.* Net cash provided by financing activities for the three months ended March 31, 2016 was \$826,000 which reflected the receipt of cash proceeds from the exercise of outstanding stock options under our equity plans. No comparable amounts were recognized for the three months ended March 31, 2017.

## **Contractual Obligations**

During the three months ended March 31, 2017, there have been no material changes to the contractual obligations previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2016.

## **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.

[Table of Contents](#)**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

During the three months ended March 31, 2017, 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, 2016.

**ITEM 4. CONTROLS AND PROCEDURES****Evaluation of Disclosure Controls and Procedures**

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

**Changes in Internal Control Over Financial Reporting**

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

**Limitations on Effectiveness of Controls and Procedures**

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

**PART II. OTHER INFORMATION****ITEM 1. LEGAL PROCEEDINGS**

On March 14, 2014, the first of two substantially similar purported class action securities lawsuits, or the Class Action Lawsuits, was filed 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 second such lawsuit was filed on March 28, 2014. On June 6, 2014, a securities lawsuit, not styled as a class action, was filed 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 was based on the same factual background as the Class Action Lawsuits.

On June 30, 2014, the Class Action Lawsuits were consolidated for all purposes into a single case, and on November 4, 2014, the securities lawsuit filed in the Mississippi District Court was transferred and also consolidated into the Class Action Lawsuits. The California District Court appointed a lead plaintiff and lead counsel for the Class Action Lawsuits on June 30, 2014. On September 19, 2014, the lead plaintiff filed his consolidated amended complaint which alleges violations of the Securities Exchange Act of 1934 in connection with allegedly false and misleading statements made by us, including that we allegedly failed to disclose facts related to the occurrence of persistent low-grade liver function test, or LFT, abnormalities observed in the Phase 2 clinical trial of imetelstat in essential thrombocythemia, or the ET Trial, and the potential risk of chronic liver injury following long-term exposure to imetelstat. The consolidated amended complaint seeks unspecified damages and an award of reasonable costs and expenses, including attorneys’ fees. We filed our motion to dismiss the consolidated amended complaint on November 18, 2014. On April 10, 2015, the California District Court granted our motion to dismiss with respect to some of the allegedly false and misleading statements made by us and denied our motion to dismiss with respect to other allegedly false and misleading statements made by us. On May 22, 2015, we filed our answer to the consolidated amended complaint.

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On September 9, 2016, the California District Court signed an order temporarily staying the Class Action Lawsuits to enable the parties to seek to resolve the Class Action Lawsuits. On November 23, 2016, the parties signed a Memorandum of Understanding that set forth material deal points of resolving the Class Action Lawsuits. On December 13, 2016, the parties filed a notice of settlement, which the California District Court signed on December 16, 2016, staying the Class Action Lawsuits pending final approval of a settlement.

On March 2, 2017, the parties to the Class Action Lawsuits, through their respective counsel, executed a Stipulation and Agreement of Settlement, or the Stipulation, and related documents formalizing an agreement to settle the Class Action Lawsuits. Under the Stipulation, in exchange for the dismissal with prejudice of all claims against all defendants in connection with the Class Action Lawsuits, we agreed to settle the Class Action Lawsuits for \$6.25 million in cash. We and our insurance providers have agreed that \$6.0 million of the settlement amount will be paid by our insurance providers and the remaining \$250,000 will be paid by us. The settlement does not constitute any admission of fault or wrongdoing by us or any of the individual defendants.

On March 2, 2017, plaintiff’s counsel filed a motion for preliminary approval of the settlement, and on April 7, 2017, the California District Court issued an order preliminarily approving the settlement proposed in the Stipulation and directed that notice of the Settlement, or the Notice, be given to certain purchasers of our common stock during the period from December 10, 2012 through and including March 11, 2014, or the Class Members. The Notice includes, among other things, the general terms of the settlement, the proposed plan of allocation of the settlement amount, and the terms of the plaintiff’s

counsel fee application. In April 2017, following the preliminary approval by the California District Court of the settlement and in accordance with the Stipulation, we paid \$250,000 and our insurance providers paid \$6,000,000 to a settlement escrow account. These amounts will be held in escrow until finalization of the settlement. In accordance with the Stipulation, upon full payment of the settlement amount to the escrow account, we have no further liability or obligation to make any further payments related to the Stipulation or the Class Action Lawsuits.

The California District Court scheduled a settlement fairness hearing on July 21, 2017 to, among other things, make a final determination whether the settlement is fair, reasonable and adequate and should be approved by the California District Court. Class Members may opt out of the settlement and they may object to the settlement in advance of and/or at the settlement fairness hearing. The settlement and the Stipulation remain subject to final approval by the California District Court and certain other conditions.

The Class Action Lawsuits, including the settlement proposed in the Stipulation, remain subject to inherent uncertainties, and the actual defense and disposition costs may depend upon many unknown factors. Therefore, there can be no assurance that the Class Action Lawsuits will not have a material adverse effect on our business, cash flow, results of operations or financial position. It is possible that additional lawsuits will be filed, or allegations will be made by stockholders, with respect to these same or other matters and also naming us and/or our officers and directors as defendants. Monitoring, initiating and defending against legal actions is 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. In addition, despite the availability of insurance, we may incur substantial legal fees and costs in connection with litigation and such amounts could be material to our financial statements. We may expend significant resources in the settlement or defense of any additional lawsuits, and we may not prevail in such lawsuits. We have not established any reserve for any potential liability relating to any additional lawsuits. Lawsuits could result in 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 could lead to increased volatility in our stock price and a decrease in the value of our stockholders' investment in our common stock.

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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 in our most recent Annual Report on Form 10-K for the year ended December 31, 2016, 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

***If Janssen discontinues the imetelstat program and/or terminates the Collaboration Agreement, the development and/or commercialization of imetelstat could be terminated or substantially delayed, and our business would be severely harmed. \****

Janssen may terminate the Collaboration Agreement at any time at their discretion. For example, Janssen has not committed to begin Part 2 of IMerge, and as a result of FDA or other regulatory authority feedback on IMerge, or other factors, Janssen could decide not to proceed with Part 2 of IMerge and/or discontinue the imetelstat program and terminate the Collaboration Agreement. Even if Janssen decides to initiate Part 2 of IMerge, the development of imetelstat could still be substantially delayed, for example, as a result of feedback from the FDA or other regulatory authorities. For IMbark, because the spleen volume response rate observed to date was less than that reported in front-line MF patients treated in trials with other drugs, it is uncertain whether such lower rates would support continued development and potential regulatory approval in relapsed or refractory MF; and for that reason or others, Janssen may discontinue the imetelstat program and terminate the Collaboration Agreement. Even if Janssen obtains longer-term efficacy and safety data for IMbark, Janssen may determine that such data do not show sufficient clinical benefit to support further development and potential regulatory approval for imetelstat in relapsed or refractory MF patients, based on spleen volume response, overall survival rates and/or other outcome measures, resulting in a decision by Janssen to discontinue IMbark and the imetelstat program and/or terminate the Collaboration Agreement. In addition, the time needed to obtain longer-term efficacy and safety data for IMbark, including sufficient data to conduct an assessment of overall survival, could significantly delay the development of imetelstat in MF and the timing of a Continuation Decision, if any. Any termination of the Collaboration Agreement by Janssen at any time would severely and adversely affect our financial results, business and business prospects, and the future of imetelstat, and might cause us to cease operations.

If Janssen discontinues the imetelstat program and/or terminates the Collaboration Agreement, it could become necessary for us to assume responsibility for the clinical development, manufacturing, regulatory approval and/or commercialization of imetelstat at our own expense. Should we elect to pursue the development of imetelstat ourselves, we would be required to fund all clinical development, manufacturing, and/or commercialization activities ourselves, which would require us to raise additional capital or establish alternative collaborations with third-party collaboration partners, which may not be possible on favorable terms, or at all. If such additional funds or alternative collaborations were unavailable, the development and/or commercialization of imetelstat would be discontinued or substantially delayed, which might cause us to cease operations.

***If our collaboration with Janssen is not successful, our business would be severely harmed. \****

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

- even if Janssen decides to continue IMerge and/or IMbark, the development of imetelstat could be substantially delayed depending on the feedback from the FDA on IMerge and the time needed to obtain longer-term efficacy and safety data for IMbark, including sufficient data to conduct an assessment of overall survival in IMbark;
- Janssen may choose to terminate the Collaboration Agreement for any reason;

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- Janssen may provide a negative Continuation Decision and halt its development of imetelstat, in which case we would receive no further payments from Janssen under the Collaboration Agreement;
- Janssen may believe that any preliminary or final results of IMbark and/or IMerge, including any future internal data reviews of these trials, are negative under the criteria set forth in the respective protocols or otherwise, are inconclusive, or do not otherwise demonstrate adequate efficacy or clinical benefit to warrant further development or commercialization of imetelstat by Janssen, which would likely result in a termination of the Collaboration Agreement by Janssen at any time, or a negative Continuation Decision;
- Janssen may observe safety issues in either IMbark and/or IMerge, or any potential future clinical trials of imetelstat, which may result in a termination of the Collaboration Agreement by Janssen at any time, or a negative Continuation Decision;
- Janssen may choose not to develop and commercialize imetelstat in certain, or any, markets or for one or more indications, if at all;
- in the event of a dispute between us and Janssen regarding Janssen's performance under the Collaboration Agreement, it may be difficult or impossible for us to prove that Janssen breached its obligations under the Collaboration Agreement, including the obligation to use "commercially reasonable efforts" with regard to the development, regulatory approval, manufacture and commercialization of imetelstat under the Collaboration Agreement;
- Janssen may not dedicate the resources necessary to carry imetelstat through clinical development, and this would delay or preclude the achievement of development, regulatory or sales milestones under the Collaboration Agreement;
- Janssen may be unable to obtain regulatory clearances or approvals to continue clinical development or commercialize imetelstat for sale in the United States and other countries, in a timely manner, or at all, or such regulatory clearances or approvals may be revoked or put on hold by governmental or regulatory authorities in any jurisdiction;
- Janssen's ability to develop, manufacture and commercialize imetelstat may be delayed or substantially impacted if we are unable to provide to Janssen in a timely manner, or at all, data or results from studies of imetelstat conducted by us and others prior to the Collaboration Agreement, or other information, related to imetelstat that may be requested by Janssen;
- subject to our election of the U.S. Co-Promotion Option, Janssen will be responsible for all aspects of the commercialization of imetelstat worldwide, including pricing decisions which would affect the royalties on worldwide net sales we could receive;
- Janssen may conclude that the commercial potential of imetelstat is not attractive enough to warrant continued development of imetelstat by Janssen, which would likely result in a termination of the Collaboration Agreement by Janssen;
- Janssen may change the focus of its commercialization efforts or prioritize other programs more highly and, accordingly, reduce the efforts and resources allocated to imetelstat, which might delay or halt the commercialization of imetelstat, and would have the direct effect of reducing our royalties or share of potential co-promotion activities since the extent of our U.S. Co-Promotion Option is limited to a percentage of overall promotion activities under the Collaboration Agreement;
- Janssen may fail to manufacture or supply sufficient quantities of imetelstat or other clinical trial materials for use in current and/or 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;

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- the loss or impairment of our intellectual property rights related to imetelstat might delay or halt ongoing or potential future clinical trials of imetelstat by Janssen and any applications for regulatory approval by Janssen, and therefore delay or halt the payment of any potential milestone payments to us;
- Janssen may not comply with all applicable regulatory requirements or may fail to report safety data from clinical trials of imetelstat in accordance with all applicable regulatory requirements, which could delay, suspend or stop clinical activities of imetelstat being performed by Janssen or by us; and
- if Janssen is acquired by a third party during the term of our collaboration with Janssen, the acquirer may have different strategic priorities that could cause it to terminate the Collaboration Agreement or reduce its commitment to our collaboration.

If our collaboration with Janssen is unsuccessful as a result of any of the above factors, or any other factors, then Janssen may terminate the Collaboration Agreement or cease its efforts to develop, manufacture or commercialize imetelstat, and we would not be eligible for any further payments from Janssen under the Collaboration Agreement, which would adversely impact our financial results, business and business prospects, and the future of imetelstat, and could cause us to cease operations.

***If Janssen does not perform in the manner we expect or fulfill its responsibilities under the Collaboration Agreement in a timely manner, the clinical development, manufacturing, regulatory approval and/or commercialization of imetelstat could be delayed or terminated. \****

The timely and successful completion by Janssen of the development, manufacturing, regulatory and commercialization activities for imetelstat 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. Accordingly, there can

be no assurance that any of the development, regulatory or sales milestones under the Collaboration Agreement will be achieved or that we will receive any future milestone or royalty payments under the Collaboration Agreement.

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

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

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

The clinical development of imetelstat will be influenced by results from current clinical trials being conducted by Janssen, including IMbark, IMerge and the Pilot Study, and potential future clinical trials of imetelstat.

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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:

- demonstrating sufficient safety and efficacy of imetelstat in IMbark, IMerge and potential future clinical trials without safety issues, side effects or dose-limiting toxicities, including any additional or more severe safety issues in addition to those that have been observed to date in previous or ongoing clinical trials related to imetelstat, whether or not in the same indications or therapeutic areas;
- obtaining or maintaining regulatory clearances to continue to conduct current clinical trials being conducted by Janssen, such as obtaining FDA feedback on the data package planned to be provided by Janssen for IMerge or obtaining or maintaining regulatory clearances to commence, conduct or continue to conduct potential future clinical trials of imetelstat, in a timely manner, or at all, in the United States or other countries;
- maintaining the INDs for imetelstat without such INDs being placed on full or partial clinical hold by the FDA;
- properly designing, enrolling, conducting or completing IMbark, IMerge and potential future clinical trials of imetelstat, and promptly or adequately reporting data from such trials;
- properly conducting and/or completing the Pilot Study and promptly or adequately reporting data from such trial;
- obtaining or accessing necessary clinical data in accordance with appropriate clinical or quality practices to ensure complete data sets;
- responding to safety or futility findings by the data review committees of current clinical trials, including IMbark, IMerge and the Pilot Study, and potential future clinical trials of imetelstat, based on emerging data occurring during such clinical trials, such as significant systemic or organ toxicities, including hepatotoxicity, fatal bleeding, or other safety issues, including patient injury or death, resulting in an unacceptable benefit-risk profile;
- manufacturing sufficient quantities of imetelstat or other clinical trial materials in a manner that meets the quality standards of the FDA and other regulatory authorities, and responding to any disruptions to drug supply, clinical trial materials or quality issues that may arise;
- ensuring the ability to manufacture imetelstat at acceptable costs for potential Phase 3 clinical trials and commercialization;
- obtaining sufficient quantities of any study-related treatments, materials (including comparator products, placebo or combination therapies) or ancillary supplies;
- obtaining acceptance by regulatory authorities of manufacturing changes, as well as subsequently implementing such manufacturing changes successfully;
- complying with current and future regulatory requirements, policies or guidelines, including domestic and international laws and regulations pertaining to fraud and abuse, transparency, and the privacy and security of health information;
- reaching agreement on acceptable terms and on a timely basis, if at all, with collaborators and vendors located in the United States or foreign jurisdictions, including contract research organizations, laboratory service providers and clinical trial sites, on all aspects of clinical development;
- obtaining timely review and clearances by regulatory authorities of protocol amendments which may be sought for IMbark, IMerge and potential future clinical trials of imetelstat, including any refinements to the trial design sought for Part 2 of IMerge; and
- obtaining institutional review board or ethics committee approval of clinical trial protocols or protocol amendments, including any refinements to the trial design sought for Part 2 of IMerge, to conduct clinical trials at existing or prospective clinical trial sites.

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

Due to the current suspension of enrollment in IMbark, the timing of the protocol-specified primary analysis for the trial remains uncertain and may be substantially delayed due to numerous factors, including whether patient enrollment resumes in the trial, or the protocol-specified primary analysis may not occur at all if IMbark is terminated early based on preliminary or ongoing data assessments, safety concerns or for any other reason. Delay in the timing of the Continuation Decision or a negative Continuation Decision from Janssen, which would result in the termination of the Collaboration Agreement by Janssen, could increase our development costs and impair our ability to earn revenues from milestone payments or royalties under the Collaboration Agreement, any of which would severely and adversely affect our financial results, business and business prospects, and the future of imetelstat, and might cause us to cease operations.

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

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

- the patient eligibility criteria in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoint;
- the proximity of patients to study sites;
- the design of the trial;
- Janssen's ability to recruit and retain clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of imetelstat, both in relation to other available therapies, including any new drugs that may be approved for the indications being investigated, and as a result of any preliminary data from current clinical trials;
- the ability to obtain and maintain patient consents; and
- the risk that patients enrolled in the clinical trial will drop out of the trial before completion due to lack of efficacy, adverse side effects, enrollment suspension, investigator decision, slow progress to later stage clinical trials or personal issues.

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

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Delays in patient enrollment or the inability to retain or treat patients could result in increased costs, lead to incomplete data sets or adversely affect the timing or outcome of IMbark and IMerge, or potential future clinical trials of imetelstat, which could prevent completion of these trials and adversely affect the clinical development and commercialization of imetelstat, either of which would delay the timing of the Continuation Decision from Janssen or could cause Janssen to terminate the Collaboration Agreement. Such occurrences would severely and adversely affect our financial results, business and business prospects, and the future of imetelstat, and might cause us to cease operations. For example, during the next year, we expect Janssen to evaluate maturing efficacy and safety data from IMbark, including an assessment of overall survival. If such data are not available as a result of patient withdrawals from the trial, insufficient follow-up time, and/or inability to collect follow-up data on such patients, then Janssen will be unable to assess the potential overall survival benefit in IMbark, which could lead to the extension of IMbark to enable further data collection and significantly delay the Continuation Decision, or could cause Janssen to terminate the trial and potentially any further development of imetelstat in relapsed or refractory MF. These events could result in a termination of the Collaboration Agreement or could cause Janssen to limit its commercialization of imetelstat to certain indications. Such occurrences would severely and adversely affect our financial results, business and business prospects, and the future of imetelstat, and might cause us to cease operations.

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

Imetelstat may cause, or have attributed to it, undesirable or unintended side effects or other characteristics adversely affecting its safety or efficacy that could delay or prevent the commencement and/or completion of current or potential future clinical trials for imetelstat. In our Phase 1 clinical trials of imetelstat, we observed dose-limiting toxicities, including thrombocytopenia, when imetelstat was used as a single agent, and neutropenia when imetelstat was used in combination with paclitaxel, as well as a low incidence of severe infusion reactions. In our Phase 2 clinical trials of imetelstat in ET, multiple myeloma, and solid tumors, we observed hematologic toxicities as well as gastrointestinal events, infections, muscular and joint pain, fatigue and infusion reactions. In addition, in our Phase 2 clinical trials of imetelstat, we observed liver function test, or 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 initially could not be excluded as a causative agent but which was later determined by the investigator to be unrelated to imetelstat. In the Pilot Study, cytopenias have been the primary dose-limiting toxicity reported to date, consistent with our observations in previous Geron-sponsored imetelstat trials. However, during the Pilot Study, more persistent and profound cytopenias, particularly thrombocytopenia, were observed with imetelstat administered on a weekly basis. This included one case of febrile neutropenia after prolonged myelosuppression with intracranial hemorrhage resulting in patient death, which was assessed as possibly related to imetelstat by the investigator. In addition, adverse events previously observed in the ET Trial and the Pilot Study, such as LFT abnormalities, profound and prolonged thrombocytopenia and neutropenia, bleeding events, and other safety issues, including deaths, have also been observed by Janssen in IMbark and IMerge. If patients in current or potential future clinical trials of imetelstat experience similar or more severe adverse events, including LFT abnormalities, or severe hepatic, hemorrhagic, or new or unusual adverse events, the INDs for imetelstat may again be placed on clinical hold, as it was in March 2014, and Janssen may be delayed or precluded from further developing imetelstat.

Serious adverse events observed in current or future clinical trials could delay or prevent any regulatory clearances to continue clinical development, obstruct or preclude any regulatory approvals to commercialize imetelstat or hinder or prevent market acceptance of imetelstat. For example, patients experiencing serious adverse events may discontinue or withdraw from current or future clinical trials of imetelstat, resulting in incomplete data sets and the inability to adequately assess the benefit-risk profile of imetelstat in a specific patient population, including, for example, any overall survival benefit in IMbark. This could cause Janssen to delay the timing of the Continuation Decision, terminate the Collaboration Agreement or cause Janssen to limit its commercialization of imetelstat to certain indications. Such occurrences would severely and adversely affect our financial results, business and business prospects, and the future of imetelstat, and might cause us to cease operations.

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***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, and we might cease operations.***

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 protocol-specified primary analysis of IMbark, or, if IMbark is terminated early, or placed on clinical hold or suspended by a regulatory authority for an extended period of time, within approximately 24 months after the initiation of IMerge. Due to the current suspension of new patient enrollment in IMbark, the timing of the protocol-specified primary analysis remains uncertain. The timing of Janssen's Continuation Decision also affects the timing and our opportunity to make our decision regarding our U.S. Opt-In Rights, as well as our election, if we exercise our U.S. Opt-In Rights, of our U.S. Co-Promotion Option. If IMbark is terminated early, placed on clinical hold or suspended by a regulatory authority for an extended period of time, or extended by Janssen to enable longer-term data collection to assess the potential overall survival benefit in IMbark, or is otherwise unsuccessful, Janssen may delay the timing of the Continuation Decision or 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 financial results, business and business prospects, and the future of imetelstat, 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 be significantly delayed or terminated;
- we would bear all risks and costs related to any further clinical development, manufacturing, regulatory approval and commercialization of imetelstat, if we determine the commercial potential of imetelstat warrants further development by us;
- we might determine that the commercial potential of imetelstat does not warrant further development of imetelstat by Geron, in which case the development of imetelstat would likely cease;
- 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 qualified employees and secure multiple third-party vendors and service providers to support the development and commercialization of imetelstat, which may take significant amounts of time, may not be feasible, and which would increase our need for additional funding.

Any termination of the Collaboration Agreement by Janssen at any time would severely and adversely affect our financial results, business and business prospects, and the future of imetelstat, and might cause us to cease operations.

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

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

- the ability to scale-up and attain sufficient production yields with appropriate quality control and quality assurance;
- reliance on third-party manufacturers and suppliers;
- supply chain issues, including the timely availability and shelf life requirements of raw materials and other supplies;
- shortage of qualified personnel; and
- compliance with regulatory requirements, which are less well-defined for oligonucleotide products than for small molecule drugs and vary in each country where imetelstat might be sold or used.

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

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

If Janssen makes an affirmative Continuation Decision under the Collaboration Agreement, we must decide whether to elect to exercise our U.S. Opt-In Rights within a short timeframe following such a decision, and although we expect to receive information from Janssen regarding data from IMbark and IMerge, proposed future clinical development plans and costs for imetelstat, estimates in timing for commercializing imetelstat and related promotional activities, and a 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 we exercise our U.S. Opt-In Rights and imetelstat were to become unsuccessful in any Phase 3 registration-enabling clinical trial or were to fail to receive regulatory approval, we would not receive any financial return on this substantial capital investment. Such an occurrence would negatively impact our financial condition and results of operations, and might cause us to cease operations.

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

We have exclusively outlicensed imetelstat, which was our sole product candidate, to Janssen. Accordingly, we are relying exclusively upon our collaborative relationship with Janssen to further develop, manufacture and commercialize imetelstat. To grow and diversify our business, we plan to continue our business development efforts to identify and seek to acquire and/or in-license other oncology products, product candidates, programs or companies. Such efforts have not yet resulted in any transaction, and may never result in a transaction. Future growth through acquisition or in-licensing will depend upon the availability of suitable products, product candidates, programs or companies for acquisition or in-licensing on acceptable prices, terms and conditions. Even if appropriate opportunities are available, we may not be able to acquire rights to them on acceptable terms, or at all. 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, personnel, 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. In addition, even if we succeed in identifying promising products, product candidates, programs or companies, we may not have the ability to develop, obtain regulatory approval for and commercialize such opportunities, or the financial resources necessary to pursue them.

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Even if we are able to successfully identify and acquire or in-license new products, product candidates, programs or companies, we may not be able to successfully manage the risks associated with integrating any products, product candidates, programs or companies into our business or the risks arising from anticipated and unanticipated problems in connection with an acquisition or in-licensing. Further, while we seek to mitigate risks and liabilities of potential acquisitions through, among other things, due diligence, there may be risks and liabilities that such due diligence efforts fail to discover, that are not disclosed to us, or that we inadequately assess. Any failure in identifying and managing these risks and uncertainties effectively would have a material adverse effect on our business. In any event, we may not be able to realize the anticipated benefits of any acquisition or in-licensing for a variety of reasons, including the possibility that a product candidate fails to advance to clinical development, proves not to be safe or effective in clinical trials, or that a product fails to reach its forecasted commercial potential or that 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 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;
- the strain on, and need to expand, our existing operational, technical, financial and administrative infrastructure;
- our lack of experience in late-stage product development and commercialization;
- the difficulties in assimilating employees and corporate cultures;
- the difficulties in hiring qualified personnel and establishing necessary development and/or commercialization capabilities;
- the failure to retain key management and other personnel;
- the challenges in controlling additional costs and expenses in connection with and as a result of the acquisition;
- the need to write down assets or recognize impairment charges;
- the diversion of our management's attention to integration of operations and corporate and administrative infrastructures; and
- any unanticipated liabilities for activities of or related to the acquired business or its operations, products or product candidates.

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

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

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***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 have ongoing responsibilities to oversee and participate in the collaboration with Janssen. In addition, we remain responsible for prosecuting, at Janssen's direction, the patents we exclusively licensed to Janssen, and have sole responsibility for those patents that were non-exclusively licensed to Janssen. If we are unable to successfully retain, motivate and incentivize our personnel, our ability to support the Collaboration Agreement with Janssen could be impaired, and our business and the price of our common stock would be adversely impacted.

In addition, our future growth and success depend to a significant extent on the skills, experience and efforts of our executive officers and key members of our staff. We face intense competition for qualified individuals from numerous pharmaceutical, biopharmaceutical and biotechnology companies, as well as academic and other research institutions. The previous restructurings we implemented, as well as the fact that we exclusively outlicensed imetelstat, which was our sole product candidate, to Janssen, and the uncertainties regarding our ability to diversify our business or related to the continued development of imetelstat by Janssen could have an adverse impact on our ability to retain and recruit qualified personnel or we may incur unanticipated inefficiencies caused by our reduced personnel resources. We may be unable to retain our current personnel or attract or assimilate other highly qualified management and development personnel in the future on acceptable terms. The loss of any or all of these individuals could harm our business and could impair our ability to support our collaboration with Janssen or to support future growth.

***We are involved in securities-related legal actions that are expensive and time consuming, and, if resolved adversely, could harm our business, financial condition, or results of operations. \****

Securities-related class action lawsuits and/or derivative lawsuits have often been brought against companies which experience volatility in the market price of their securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies often experience significant stock price volatility in connection with their product development programs.

We and certain of our officers have been named as defendants in two purported class action securities lawsuits filed in the United States District Court for the Northern District of California, or the California District Court, as well as a third securities lawsuit, not styled as a class action, which was originally filed in the United States District Court for the Southern District of Mississippi, but subsequently transferred to the California District Court. These three cases, or the Class Action Lawsuits, which are based on the same factual background, have been consolidated for all purposes, and are currently stayed to enable the parties to seek to resolve them. On November 23, 2016, the parties signed a Memorandum of Understanding that set forth material deal points of resolving the Class Action Lawsuits. On December 13, 2016, the parties filed a notice of settlement, which the California District Court signed on December 16, 2016, staying the Class Action Lawsuits pending final approval of a settlement.

On March 2, 2017, the parties to the Class Action Lawsuits, through their respective counsel, executed a Stipulation and Agreement of Settlement, or the Stipulation, and related documents formalizing an agreement to settle the Class Action Lawsuits. Under the Stipulation, in exchange for the dismissal with prejudice of all claims against all defendants in connection with the Class Action Lawsuits, we agreed to settle the Class Action Lawsuits for \$6.25 million in cash. We and our insurance providers agreed that \$6.0 million of the settlement amount will be paid by our insurance providers and the remaining \$250,000 will be paid by us. The settlement does not constitute any admission of fault or wrongdoing by us or any of the individual defendants.

On March 2, 2017, plaintiff's counsel filed a motion for preliminary approval of the settlement terms, and on April 7, 2017, the California District Court issued an order preliminarily approving the settlement terms proposed in the Stipulation and directing that notice of the Settlement, or the Notice, be given to certain purchasers of our common stock during the period from December 10, 2012 through and including March 11, 2014. The Notice includes, among other things, the general terms of the settlement, the proposed plan of allocation of the settlement amount, and the terms of the plaintiff's counsel fee application.

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The California District Court scheduled a final settlement fairness hearing on July 21, 2017 to, among other things, make a final determination whether the settlement is fair, reasonable and adequate and should be approved by the California District Court. The proposed settlement and the Stipulation remain subject to final approval by the California District Court. It is possible that:

- final approval of the proposed settlement and the Stipulation may not be obtained from the California District Court;
- we may be unable to overcome any objections or appeals regarding the proposed settlement;
- individual claimants may opt out of the class and pursue individual claims against us;
- the settlement may require more activity and/or defense and disposition costs than currently expected; and
- the settlement may not have the expected impact intended by the parties, including resolving the Class Action Lawsuits.

The occurrence of any of the above could have a material adverse effect on our business, cash flow, results of operations and financial condition. For a more complete discussion of the Class Action Lawsuits, see the section entitled "Legal Proceedings" under Item 3.

It is possible that additional suits will be filed, or allegations received from stockholders naming us and/or our officers and directors as defendants with respect to these same or other matters, including, for example, allegations related to the duration and nature of follow-up conducted by Janssen or us of patients enrolled in current and potential future clinical trials of imetelstat, the nature and timing of our disclosures related to efficacy or safety data observed in current and potential future clinical trials of imetelstat, or serious adverse events encountered in current and potential future clinical trials of imetelstat. We could be forced to expend significant resources in the settlement or defense of any additional lawsuits, and we may not prevail in such lawsuits. We have not established any reserve for any potential liability relating to any additional 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 in any such lawsuit, or in similar or related litigation, could result in the payment of substantial damages, or possibly fines, and could have a material adverse effect on our business, cash flow, results of operations and financial condition.

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

Our business may bring us into conflict with our licensees, licensors, or others with whom we have contractual or other business relationships, or with our competitors or others whose interests differ from ours. If we are unable to resolve those conflicts on terms that are satisfactory to all parties, we may become involved in litigation brought by or against us.

For example, as a result of possible disagreements with Janssen, we may become involved in litigation or arbitration, which would be time-consuming and expensive. Possible disagreements with Janssen could include disagreements 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 Janssen makes a Continuation Decision and 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 Janssen 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.

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Monitoring, initiating and defending against legal actions is 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. In addition, despite the availability of insurance, we may incur substantial legal fees and costs in connection with litigation. Lawsuits are subject to inherent uncertainties, and defense and disposition costs depend upon many unknown factors. Lawsuits could result in 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 could lead to increased volatility in our stock price and a decrease in the value of our stockholders' investment in our common stock.

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

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

The Collaboration Agreement could result in litigation arising out of any claims that our stockholders suffered financial losses due to the transaction, the approval of our stockholders was required under applicable law or otherwise should have been obtained prior to the completion of the transaction, or that our officers and directors breached their fiduciary duties in connection with the approval and completion of the transaction. Although we believe that stockholder approval was not required under applicable law in order to complete our transaction with Janssen, 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, or result in the termination of, the Collaboration Agreement.

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 the Collaboration Agreement could also result in claims against us by Janssen, and the Collaboration Agreement provides for indemnification by us of Janssen against all losses and expenses relating to breaches of our representations, warranties and covenants in the Collaboration 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 our Collaboration Agreement with Janssen is terminated or is otherwise unsuccessful, then our stock price would decline significantly, 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 condition or could otherwise severely harm our business.

## RISKS RELATED TO CLINICAL AND COMMERCIALIZATION ACTIVITIES

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

The science and technology of telomere biology, telomerase and our proprietary oligonucleotide chemistry are relatively new. There is no precedent for the successful commercialization of a therapeutic product candidate based on these technologies. Significant research and development activities will be necessary to further develop imetelstat, which was our sole product candidate that we have exclusively outlicensed to Janssen, which may take years to accomplish, if at all.

Because of the significant scientific, regulatory and commercial challenges that must be overcome to successfully research, develop and commercialize imetelstat, the development of imetelstat in hematologic myeloid malignancies, including MF and MDS, or any other indications, may be delayed or abandoned, even after significant resources have been expended on it. Examples of such decisions include the discontinuation of our Phase 2 clinical trial of imetelstat in metastatic breast cancer in September 2012, the discontinuation of our development of imetelstat in solid tumors with short telomeres in April 2013, and Janssen's determinations in the third quarter of 2016 to close the 4.7 mg/kg dosing arm in IMbark to new patient enrollment and to suspend enrollment in the 9.4 mg/kg dosing arm in IMbark because an insufficient number of patients in the 9.4 mg/kg dosing arm met the protocol defined interim efficacy criteria at 12 weeks. Any further delay, suspension 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 the future of imetelstat and our business prospects and likely result in the failure of our business.

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***Success in early clinical trials may not be predictive or indicative of results in current ongoing clinical trials or potential future clinical trials. Likewise, preliminary data from clinical trials should be considered carefully and with caution since the final data may be materially different from the preliminary data, particularly as more patient data become available. \****

A number of new drugs and biologics have shown promising results in preclinical studies and initial clinical trials, but subsequently have failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals to initiate commercial sale. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. Product candidates in later stages of clinical trials may fail to show the desired benefit-risk profile despite having progressed through preclinical studies and initial clinical trials.

Data from our preclinical studies and Phase 1 and Phase 2 clinical trials of imetelstat, including the Pilot Study, as well as the results of the internal interim data reviews conducted by Janssen for IMbark and IMerge, should not be relied upon as predictive or indicative of future clinical results, including any final results in the Pilot Study, IMbark or IMerge or the results in potential subsequent or larger-scale clinical trials of imetelstat. The results we obtained from the ET Trial and the Pilot Study and the results obtained by Janssen in the internal data reviews conducted for IMbark and IMerge, as well as any future results that may be obtained by Janssen from IMbark and IMerge, may not predict the future therapeutic benefit of imetelstat, if any, in hematologic myeloid malignancies, including MF and MDS. In addition, the known LFT abnormalities and dose-limiting toxicities associated with imetelstat, such as profound and prolonged thrombocytopenia and neutropenia and other safety issues, including deaths, that have been observed in both previous Geron-sponsored clinical trials and investigator-sponsored clinical trials, including in the Pilot Study, have also been observed in the internal data reviews conducted by Janssen of IMbark and IMerge. Since remaining patients in the treatment phase for the Pilot Study, IMbark and IMerge continue to receive imetelstat, efficacy and safety data continue to be generated, and additional and updated data may materially change the overall conclusions from the preliminary data reported for the Pilot Study, as well as determinations made by Janssen and the Joint Steering Committee based on the internal data reviews for IMbark and IMerge. If additional, new or more severe adverse events occur in current imetelstat clinical trials, including the Pilot Study, IMbark and IMerge, such trials could be discontinued by Janssen or the IND for imetelstat may again be placed on clinical hold, as it was in March 2014. Also, the criteria used to assess efficacy in the 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.

In addition, from time-to-time, preliminary or interim data from current clinical trials, such as the Pilot Study, IMbark and IMerge, or potential future clinical trials, may be reported or announced by Janssen, its investigators, or us. For example, preliminary results of the Pilot Study were presented by the investigator at the American Society of Hematology, or ASH, annual meeting in December 2013, and updated by the investigator at ASH in December 2014, and preliminary data were reported by the investigator from a cohort of MDS patients in the Pilot Study in December 2015. Since such data are preliminary, the final data from any protocol-specified primary analysis which may be conducted, or any future analyses of the Pilot Study, IMbark or IMerge, or potential future clinical trials of imetelstat, may be materially different. Material adverse differences in the final data, compared to preliminary or interim data, from the

Pilot Study, IMbark or IMerge, or potential future clinical trials of imetelstat, could result in a decision by Janssen to discontinue the imetelstat program, delay its Continuation Decision, or terminate the Collaboration Agreement, which would severely and adversely affect our financial results, business and business prospects, and the future of imetelstat, and might cause us to cease operations. Even if final safety and/or efficacy data from the Pilot Study, IMbark or IMerge or potential future clinical trials of imetelstat, are positive, significant additional clinical testing will be necessary to advance the future development of imetelstat in hematologic myeloid malignancies, including MF or MDS. Preliminary or interim results from the Pilot Study, IMbark or IMerge reported by us, Janssen or by the investigator in the Pilot Study may not be reproduced in any potential future clinical trials of imetelstat, and thus should not be relied upon as indicative of future clinical results of imetelstat in MF, MDS or in any other hematologic myeloid malignancy. Preliminary or interim data should be considered carefully and with caution.

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

Clinical trials by their nature examine the effect of a potential therapy in a sample of the potential future patient population. As such, clinical trials conducted with imetelstat, to date and in the future, may not uncover all possible adverse events that patients treated with imetelstat may experience. Because remaining patients in the treatment phase continue to receive imetelstat in the Pilot Study, IMbark and IMerge, additional or more severe toxicities or safety issues, including additional serious adverse events and clinically significant LFT abnormalities, may be observed as patient treatment continues and more data become available. In addition, since IMbark, IMerge and the Pilot Study are ongoing studies in which additional data are being generated, the benefit-risk profile of imetelstat will continue to be assessed, including the risk of hepatotoxicity, severe cytopenias, fatal bleeding and any other severe adverse effects that may be associated with life-threatening clinical outcomes. If such toxicities or other safety issues in any clinical trial of imetelstat result in an unacceptable benefit-risk profile, then:

- the commencement, continuation and/or completion of any current ongoing clinical trials, including IMbark, IMerge and the Pilot Study, or potential future clinical trials would likely be delayed, for example by being placed on a clinical hold, halted or prohibited;
- patients in current ongoing clinical trials, including IMbark, IMerge and the Pilot Study, might discontinue or withdraw from the trials, resulting in incomplete data sets; or
- additional, unexpected clinical trials or preclinical studies may be required to be conducted.

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

***Obtaining regulatory clearances and approvals to continue clinical development and in the future, potentially 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. For example in June 2016, the electorate in the United Kingdom voted in favor of exiting the European Union, and in March 2017, the Government of the United Kingdom initiated the formal procedure of withdrawal from the European Union. Although the impact of the withdrawal of the United Kingdom from the European Union will not be known for some time, this could lead to a period of considerable uncertainty in relation to the regulatory process in Europe, which could result in a delay in the review of regulatory submissions made in Europe by biotechnology and pharmaceutical companies, and could also lead to less efficient, more expensive, and potentially lengthier regulatory review processes for companies, including us and Janssen, who may seek to obtain regulatory approval for drug products in the European Union or the United Kingdom. Likewise, the new Trump Administration has and will appoint and employ many new secretaries, directors and the like into positions of authority in the U.S. federal government dealing with the pharmaceutical and healthcare industries that may potentially have a negative impact on the prices and the regulatory pathways for pharmaceuticals. Such changes could adversely affect and/or delay the ability of Janssen to obtain approval of, and market and sell, imetelstat in the United States. In addition, 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. We do not expect imetelstat to be approved for commercial sale for many years, if at all.

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Prior to initiating potential future clinical trials of imetelstat, clinical trial protocols must be submitted to the FDA or regulatory authorities in other countries. Questions or comments from these agencies regarding any protocol amendments of current clinical trials of imetelstat, including IMbark or IMerge, or protocols for potential future clinical trials of imetelstat must be addressed in a timely manner. Otherwise, further clinical development of imetelstat would likely be delayed, which could cause Janssen to delay its Continuation Decision or discontinue the imetelstat program entirely and terminate the Collaboration Agreement, which would severely and adversely affect our financial results, business and business prospects, and the future of imetelstat, and might cause us to cease operations.

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 if imetelstat is safe and effective for use in a diverse population. If imetelstat cannot be developed in potential future clinical trials, including Phase 3 clinical trials, our Collaboration Agreement with Janssen will be negatively impacted and likely be terminated altogether, which would have severe adverse effects on our business and business prospects, and might result in the failure of our business.

If the interpretation by us or Janssen of safety and efficacy data obtained from preclinical and clinical studies varies from interpretations by the FDA or regulatory authorities in other countries, this would likely delay, limit or prevent further development and approval of imetelstat which may cause Janssen to terminate the Collaboration Agreement. For example, the FDA and regulatory authorities in other countries may require more or different data than what has been generated from our preclinical studies and previous or ongoing clinical trials, such as IMbark, IMerge or the Pilot Study. 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 policy during the period of product development and/or the period of review of any application for regulatory approval for imetelstat.

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

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

- impede or halt clinical development activities and plans;
- significantly harm the commercial potential of imetelstat;
- impose additional development costs;
- 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 Janssen, the required regulatory clearances and approvals may not be obtained for imetelstat. Further, if regulatory clearances and approvals are obtained to commence commercial sales of imetelstat, they may impose significant limitations on the indicated uses or other aspects of the product label for which imetelstat can be marketed. An approval might also be contingent on the performance of costly additional post-marketing clinical trials. The occurrence of any of these events could limit the potential commercial use of imetelstat, and therefore delay the payment of potential milestone payments to us, or, if approved for commercial sale, could reduce the market demand for imetelstat and therefore result in decreased sales and reduced royalties for us under the Collaboration Agreement. Occurrence of any of these events could negatively impact our collaboration with Janssen or cause Janssen to terminate the Collaboration Agreement, which would severely and adversely affect our financial results, business and business prospects, and the future of imetelstat, and might cause us to cease operations.

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

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

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

Approved products and their manufacturers are subject to continual review, and discovery of previously unknown problems with a product or its manufacturer may result in restrictions on the product or manufacturer, including import restrictions, seizure and withdrawal of the product from the market. If approved for commercial sale, future sales of imetelstat will be subject to government regulation related to numerous matters, including the processes of:

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

If, and to the extent that, we 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 financial results, business and business prospects, and the future of imetelstat, and might cause us to cease operations.

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***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 authority in the United States or other countries, then we would be required to reimburse Janssen for our share of the costs of that Janssen IDP plus a premium pursuant to the terms of the Collaboration Agreement. This cost reimbursement is payable as a lump sum up to a certain threshold upon receipt of regulatory approval for the Janssen IDP. Any remaining amounts in excess of the threshold are payable in installments by offsetting milestone payments or royalties received by us over a certain period of time, at which time any remaining reimbursement amount would be payable in a lump sum. This payment mechanism could result in reduced cash inflow from future milestone payments and royalties, which would adversely affect our results of operations and financial condition.

***Under the Collaboration Agreement, if we develop imetelstat independently under our own IDP, the success of that IDP depends on our ability to provide adequate financial and technical resources.***

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 authority 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 refused to contribute to projects on which we needed their help, our ability to conduct activities under a Geron IDP could be significantly harmed. Also, if the performance of these services is not of the highest quality, does not achieve necessary regulatory compliance standards, or if such organization or vendor stops or delays its performance for any reason, it would impair and delay our ability to report data from clinical activities under a Geron IDP which would, in turn, hinder our ability to make the necessary representations or provide the necessary information to regulatory authorities, if at all. As a result, we may not obtain regulatory approval and receive any reimbursement from Janssen for their share of the costs for the Geron IDP, which could adversely affect our business and financial condition.

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

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

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

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- the inability of third-party manufacturers to timely formulate and manufacture imetelstat or to produce imetelstat in the quantities or of the quality required to meet clinical and commercial needs;
- decisions by third-party manufacturers to exit the contract manufacturing business during the time required to supply clinical trials or to successfully produce, store and distribute products;
- compliance by third-party manufacturers with current Good Manufacturing Practice, or cGMP, standards mandated by the FDA and state agencies and other government regulations corresponding to foreign regulatory authorities;
- breach or termination of manufacturing contracts;
- capacity limitation and scheduling imetelstat as a priority in contracted facilities; and
- natural disasters that affect contracted facilities.

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

In addition, current third-party contractors and/or any other contractors utilized by Janssen may need to make substantial investments to enable sufficient capacity increases and cost reductions, and to implement those regulatory and compliance standards necessary for successful Phase 3 clinical trials and commercial production of imetelstat. These third-party contractors may not be able to achieve such capacity increases, cost reductions, or regulatory and compliance standards, and even if they do, such achievements may not be at commercially reasonable costs. Janssen currently does not have any long-term commitments or commercial supply agreements with any of the third-party contractors for imetelstat, and changing manufacturers may be prolonged and difficult due to inherent technical complexities and because the number of potential manufacturers is limited. It may be difficult or impossible for Janssen to find a replacement manufacturer on acceptable terms, or at all.

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

Oligonucleotides are relatively large molecules produced using complex chemistry, and the cost of manufacturing an oligonucleotide like imetelstat is greater than the cost of making typical small-molecule drugs. Therefore, imetelstat for clinical use is more expensive to manufacture than most other treatments currently available today or that may be available in the future. Similarly, the cost of manufacturing imetelstat for commercial use will need to be significantly lower than current costs in order for imetelstat to become a commercially successful product. Janssen may not be able to achieve sufficient scale increases or cost reductions necessary for successful commercial production of imetelstat. Failure to achieve necessary cost reductions could result in decreased sales and reduced royalties for us, could negatively impact our collaboration with Janssen or could cause Janssen to terminate the Collaboration Agreement, any of which would materially and adversely affect our financial results, business and business prospects, and the future of imetelstat, and might cause us to cease operations.

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

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

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

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

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

Although the Collaboration Agreement permits us to be acquired by any company, our right to transfer our U.S. Co-Promotion Option in the case of an acquisition, merger, consolidation, share exchange, business combination, recapitalization, sale of a majority of assets or similar transaction is limited, and

subject to Janssen's sole discretion under certain circumstances. If we are acquired outside of such limited circumstances, then we may not be able to transfer the U.S. Co-Promotion Option to such acquirer as part of the acquisition. This limiting provision may discourage potential acquisition bids for us or lower our value, thus preventing holders of our common stock from benefiting from what they may believe are the positive aspects of an acquisition, including the potential realization of a higher rate of return on their investment from this type of transaction.

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

Our business exposes us to potential product liability risks that are inherent in the testing, manufacturing and marketing of human therapeutic and diagnostic products. We may become subject to product liability claims if the use of imetelstat is alleged to have injured patients, including any injuries alleged to arise from any hepatotoxicity or hemorrhagic event associated with the use of 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.

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## **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, maintain, enforce and extend our patents and maintain trade secrets, both in the United States and in other countries. 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, maintaining, and enforcing our patents and other intellectual property rights, the value of our technologies and imetelstat will be adversely affected, and we or Janssen may not be able or willing to further develop or commercialize imetelstat. Loss or impairment of our intellectual property related to imetelstat might delay or halt ongoing or potential future clinical trials of imetelstat and any applications for regulatory approval, and therefore delay or halt the payment of potential milestone payments to us under the Collaboration Agreement. Further, if imetelstat is approved for commercial sale, such events 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 financial results, business and business prospects, and the future of imetelstat, and might cause us to cease operations.

The patent positions of pharmaceutical and biopharmaceutical companies, including ours, are highly uncertain and involve complex legal and technical questions. In particular, legal principles for biotechnology and pharmaceutical patents in the United States and in other countries are evolving, and the extent to which we will be able to obtain patent coverage to protect our technologies and imetelstat, or enforce or defend issued patents, is uncertain.

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.

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 U.S. Patent and Trademark Office, or the Patent Office. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard necessary to invalidate a patent claim in Patent Office proceedings compared to the evidentiary standard in U.S. federal court, a third party could potentially provide evidence in a Patent Office proceeding sufficient for the Patent Office to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party could attempt to use the Patent Office procedures to invalidate patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Significant impairment of our imetelstat patent rights would severely and adversely affect our financial results, business and business prospects, and the future of imetelstat, and could cause Janssen to terminate the Collaboration Agreement, which might cause us to cease operations.

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U.S. court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. For example, on June 13, 2013, the U.S. Supreme Court, or the Court, issued a decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.* holding that claims to isolated genomic DNA were not patentable subject matter, but claims to complementary DNA, or cDNA, molecules were patentable subject matter. On March 20, 2012, in *Mayo Collaborative Services, DBA Mayo Medical Laboratories, et al. v. Prometheus Laboratories, Inc.*, the Court held that several claims drawn to measuring drug metabolite levels from patient samples and correlating them to drug doses were not patentable subject matter. In addition, court rulings in cases such as *BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig.* and *Promega Corp. v. Life Technologies*

Corp. have also narrowed the scope of patent protection available in certain circumstances. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events may have created uncertainty with respect to the value of certain patents we have previously obtained or in-licensed.

Depending on decisions by the U.S. federal courts and the Patent Office, the interpretation of laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents. Occurrence of these events could significantly impair our imetelstat patent rights which would have a material adverse effect on our business and could cause Janssen to terminate the Collaboration Agreement, which might cause us to cease operations.

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

Our patents may be challenged through administrative or judicial proceedings, which could 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 or litigation, any of which could delay or prevent the issuance of patents, or result in the loss of issued patent rights.

Under the AIA, interference proceedings between patent applications filed on or after March 16, 2013 have been replaced with other types of proceedings, including derivation proceedings. The AIA also includes post-grant review procedures subjecting U.S. patents to post-grant review procedures similar to European oppositions, such as inter partes review, or IPR, covered business method post-grant reviews and other post-grant reviews. U.S. patents owned or licensed by us may therefore be subject to post-grant review procedures, as well as other forms of review and re-examination. In addition, the IPR process under the AIA permits any person, whether they are accused of infringing the patent at issue or not, to challenge the validity of certain patents. As a result, entities associated with hedge funds have challenged valuable pharmaceutical patents through the IPR process.

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.

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

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

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***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, development, manufacturing or commercialization of imetelstat.***

The commercial success of imetelstat will depend upon our and Janssen's ability to research, 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.

Since we cannot be aware of all intellectual property rights potentially relating to imetelstat and its uses, we do not know with certainty that imetelstat, or the intended commercialization thereof, does not and will not infringe or otherwise violate any third party's intellectual property. Any infringement claims against us or Janssen would likely be expensive to resolve, and the cost of any indemnification of Janssen or unblocking license that we could be required to obtain under the Collaboration Agreement is unpredictable and could be significant. If we or Janssen are unable to resolve an infringement claim successfully, we or Janssen could be subject to an injunction which would prevent us or Janssen from commercializing imetelstat, and could also require us or Janssen to pay substantial damages. In addition to infringement claims, in the future we or Janssen may also be subject to other claims relating to intellectual property, such as claims that we or Janssen have misappropriated the trade secrets of third parties. Provided that Janssen continues to progress the development of

imeteostat, we expect to see more efforts by others to obtain patents that are positioned to cover imeteostat. 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 imeteostat. 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 imeteostat on commercially favorable terms, or at all, or such licenses may be terminated on certain grounds, including as a result of our or Janssen's failure to comply with the obligations under such licenses. If we or Janssen do not obtain a necessary license or if such a license is terminated, we or Janssen may need to redesign such technologies or obtain rights to alternative technologies, which may not be possible, and even if possible, could cause delays in the development efforts for imeteostat and could increase the development and/or production costs of imeteostat. 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 imeteostat, and in certain circumstances we may be required to indemnify Janssen for infringement claims arising from Janssen's research, development, manufacture or commercialization of imeteostat, 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 imeteostat would delay potential future clinical trials of imeteostat and any applications for regulatory approval and therefore delay the payment of potential milestone payments to us, or, if imeteostat is approved for commercial sale, could impair Janssen's ability to sell imeteostat and therefore result in decreased sales and reduced royalties for us. Occurrence of any of these events could negatively impact our collaboration with Janssen or cause Janssen to terminate the Collaboration Agreement, which would materially and adversely affect our business, and might cause us to cease operations.

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***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, research collaborators or others 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, previous employees, research collaborators or others, either with permission or in contravention of the terms of their agreements or otherwise, may impair the ability to obtain patent protection or protect proprietary information which would have a material adverse effect on our business and could cause Janssen to terminate the Collaboration Agreement, which might cause us to cease operations.

***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.

In May 2016, the Defend Trade Secrets Act of 2016, or the DTSA, was enacted, providing a federal cause of action for misappropriation of trade secrets. Under the DTSA, an employer may not collect enhanced damages or attorney fees from an employee or contractor in a trade secret dispute brought under the DTSA, unless certain advanced provisions are observed. We cannot provide assurance that our existing agreements with employees and contractors contain notice provisions that would enable us to seek enhanced damages or attorneys' fees in the event of any dispute for misappropriation of trade secrets brought under the DTSA.

***Significant disruptions of information technology systems, including cloud-based systems, or breaches of data security could adversely affect our business.***

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

In addition, our data security and information technology systems are potentially vulnerable to data security breaches—whether by employees or others—that may expose sensitive data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public disclosure of sensitive clinical or commercial data, and the exposure of personally identifiable information (including sensitive personal information) of our employees, collaborators, clinical trial patients and others. A data security breach or privacy violation that leads to disclosure or modification of or prevents access to patient information, including personally identifiable information or protected health information, could result in increased costs or loss of revenue as a result of:

- harm to our reputation;
- additional compliance obligations under federal and/or state breach notification laws;
- requirements for mandatory corrective action to be taken by us; and
- requirements to verify the correctness of database contents and otherwise subject us to liability under laws and regulations that protect personal data.

If we are unable to prevent such data security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information, including sensitive patient data. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. Moreover, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information, trade secrets or other intellectual property. While we have implemented security measures to protect our data security and information technology systems, such measures may not prevent such events.

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

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

Until 2015, we had never been profitable and we had incurred operating losses every year since our operations began in 1990. While we were profitable in 2015 due to the recognition of revenue in connection with the upfront payment from Janssen under the Collaboration Agreement, we expect to incur additional operating losses and, as clinical development activities for imetelstat continue under our Collaboration Agreement with Janssen, our operating losses may increase in size. As of March 31, 2017, our accumulated deficit was approximately \$965.1 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.

Substantially all of our revenues to date have been payments under collaborative agreements and milestones, royalties and other revenues from our licensing arrangements. Any revenues generated from our licensing arrangements or ongoing collaborative agreements, including the Collaboration Agreement with Janssen, may not be sufficient alone to sustain our operations. For example, we expect revenues under our license agreements related to our telomerase technology to decline significantly in the coming years, and to be eliminated by the end of 2019, due to upcoming patent expirations on such technology. In addition, there can be no assurance that we will receive any milestone payments or royalties from Janssen in the future. We may be unsuccessful in entering into any new corporate collaboration, partnership or license agreements that result in revenues, or existing collaborative agreements or license arrangements, such as the Collaboration Agreement with Janssen, may be terminated or expire.

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

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

We may need additional capital resources in order to support development and commercialization of imetelstat, especially if we elect to exercise our U.S. Opt-In Rights and U.S. Co-Promotion Option under the Collaboration Agreement and potentially independently pursue imetelstat development under our own IDP, and to otherwise support the future growth of our business through the potential acquisition and/or in-licensing of other oncology products, product candidates, programs or companies. We cannot assure you that our existing capital resources, future interest income, potential milestone payments and royalties under the Collaboration Agreement with Janssen and potential future sales of our common stock, including pursuant to our 2015 Sales Agreement with MLV, will be sufficient to fund future planned activities. The timing and degree of any future capital requirements will depend on many factors, including:

- the accuracy of the assumptions underlying our estimates for our capital needs;
- whether Janssen discontinues development of imetelstat and/or terminates the Collaboration Agreement and we choose to develop imetelstat ourselves;

- in the event that Janssen provides an affirmative Continuation Decision to us, whether we then elect our U.S. Opt-In Rights to share further U.S. development and promotion costs for imetelstat beyond IMbark or IMerge under the Collaboration Agreement, including 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;
- 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 regulatory authorities in the United States or other countries;
- the achievement of development, regulatory and commercial milestones resulting in the payment to us from Janssen under the Collaboration Agreement and the timing of receipt of such payments, if any;
- changes or delays in Janssen's development plans for imetelstat, including changes to ongoing current clinical trials of imetelstat, including IMbark and IMerge, which may result from any internal data reviews or any future clinical holds on any INDs for imetelstat;
- Janssen's ability to meaningfully reduce manufacturing costs of imetelstat;

- the progress, timing, magnitude, scope and costs of clinical development, manufacturing and commercialization of imetelstat, including the number of indications being pursued, subject to clearances and approvals by 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 sales price and availability of adequate third-party reimbursement for imetelstat;
- the timing, receipt and amount of royalties under the Collaboration Agreement on worldwide net sales of imetelstat, upon regulatory approval or clearance, if any;
- the cost of acquiring and/or in-licensing other oncology products, product candidates, programs or companies, if any;
- expenses associated with pending or potential future 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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Further, if the Collaboration Agreement is terminated, including as a result of Janssen's failure to provide an affirmative Continuation Decision to us, or for any other reason, we would not receive any milestone payments or royalties under the Collaboration Agreement, and then, depending on the timing of such event, we would be required to fund all clinical development, manufacturing and commercial activities for imetelstat should we elect to continue the development of imetelstat ourselves, which would require us to raise additional capital or establish alternative collaborations with third-party collaboration partners, which may not be possible. If the Collaboration Agreement is terminated and we are unable to raise additional capital or establish alternative collaborations with third-party collaboration partners for imetelstat, the development of imetelstat would be discontinued, which might cause us to cease operations. Additional financing through public or private equity financings, including pursuant to our 2015 Sales Agreement with MLV, capital lease transactions or other financing sources may not be available on acceptable terms, or at all. We may raise equity capital at a stock price or on other terms that could result in substantial dilution of ownership for our stockholders. The receptivity of the public and private equity markets to proposed financings is substantially affected by the general economic, market and political climate and by other factors which are unpredictable and over which we have no control. In this regard, continued volatility and instability in the global financial markets and political climate could adversely affect our ability to raise additional funds through financings and the terms upon which we may raise those funds.

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

- changes or delays in Janssen's development plans for imetelstat, including as a result of any future clinical holds on any IND for imetelstat or internal data reviews;
- a failure to show adequate safety or efficacy of imetelstat in current or potential future clinical trials, which may result in a decision by Janssen to delay or discontinue further development of imetelstat; or
- a termination of the Collaboration Agreement or if our collaboration with Janssen is otherwise unsuccessful.

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

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

***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 which could adversely impact our financial position.

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

Historically, our stock price has been extremely volatile. Between April 1, 2007 and March 31, 2017, our stock has traded as high as \$9.85 per share and as low as \$0.91 per share. Between April 1, 2014 and March 31, 2017, the price has ranged between a high of \$5.30 per share and a low of \$1.69 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, conduct or continue clinical trials of imetelstat in MF, MDS or any additional hematologic myeloid malignancies in a timely manner or at all, or to amend any clinical trial protocol with respect to the conduct of a current clinical trial;
- developments in our collaboration with Janssen, including the termination, modification or amendment of the Collaboration Agreement, or disputes regarding the collaboration;
- announcements regarding the research and development of imetelstat, including results of, delays in, discontinuation of, or modifications to any clinical trials of imetelstat as a result of any internal data reviews, and investor perceptions thereof;
- announcements regarding the safety of imetelstat;
- announcements regarding plans to discontinue any imetelstat clinical trials, including IMbark or IMerge;
- announcements regarding regulatory developments concerning imetelstat, including announcements similar to our March 2014 announcement that the FDA had placed a full clinical hold on our IND for imetelstat;
- the experimental nature of imetelstat;
- perception by our stockholders about the adequacy of potential payments we may receive under the Collaboration Agreement;
- the demand in the market for our common stock;
- announcements of technological innovations, new commercial products, or clinical progress or lack thereof by us, our collaborators, licensees, partners or our competitors;
- 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 concerning imetelstat proprietary rights;
- comments by securities analysts;
- large stockholders exiting their position in our common stock;
- announcements of or developments concerning pending and/or potential future litigation;
- the issuance of common stock to partners, vendors or investors to raise additional capital or to acquire other oncology products, product candidates, programs or companies; and
- the occurrence of any other risks and uncertainties discussed under the heading “Risk Factors.”

Stock prices and trading volumes for many biopharmaceutical companies fluctuate widely for a number of reasons, including factors which may be unrelated to their businesses or results of operations, such as media coverage, statements made on message boards and social media forums, legislative and regulatory measures and the activities of various interest groups or organizations. In addition to the 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 March 31, 2017, we had 300,000,000 shares of common stock authorized for issuance and 159,176,119 shares of common stock outstanding. In addition, we had reserved 30,131,347 shares of our common stock for future issuance pursuant to our option and equity incentive plans and outstanding warrants as of March 31, 2017. 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 2015 Sales Agreement with MLV, or the issuance of common stock to satisfy our current or future cash payment obligations or to acquire technology, property, or other businesses, could cause immediate dilution and adversely affect the market price of our common stock. In addition, under the universal shelf registration statement filed by us in August 2015 and declared effective by the SEC in September 2015, we may sell any combination of common stock, preferred stock, debt securities and warrants in one or more offerings, up to a cumulative value of \$250 million. The sale or issuance of our securities, as well as the existence of outstanding options and shares of common stock reserved for issuance under our option and equity incentive plans and outstanding warrants, also may adversely affect the terms upon which we are able to obtain additional capital through the sale of equity securities, which could negatively affect the market price of our common stock and the return on your investment.

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

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

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

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

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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 provide an opinion annually 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 material weaknesses or significant deficiencies will not exist or otherwise be discovered in the future. If material weaknesses or other significant deficiencies occur, such 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.

**Competitors may develop technologies that are superior to or more cost-effective than ours, which may significantly impact the commercial viability of imetelstat, which could cause Janssen to terminate the Collaboration Agreement and damage our ability to sustain operations. \***

The pharmaceutical and biotechnology industries are intensely competitive. Other pharmaceutical and biotechnology companies and research organizations currently engage in or have in the past engaged in efforts related to the biological mechanisms related to imetelstat, the study of telomeres, telomerase, or our proprietary oligonucleotide chemistry, and the research and development of therapies for the treatment of hematologic myeloid malignancies. In addition, other products and therapies that could directly compete with imetelstat currently exist or are being developed by pharmaceutical and biopharmaceutical companies and by academic institutions, government agencies and other public and private research organizations. We expect Janssen's decisions regarding proceeding with Part 2 of IMerge and/or advancing the development of imetelstat in relapsed or refractory MF will be informed in part by what Janssen believes is the estimated commercial potential of imetelstat for the treatment of multiple hematologic malignancies.

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Many companies are developing alternative therapies to treat hematologic myeloid malignancies. For example, if approved for commercial sale for the treatment of MF, imetelstat would compete against Incyte Corporation's ruxolitinib, or Jakafi<sup>®</sup>, which is orally administered. In clinical trials, Jakafi<sup>®</sup> 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<sup>®</sup> treatment. Other treatment modalities for MF include hydroxyurea for the management of splenomegaly, leukocytosis, thrombocytosis and constitutional symptoms; splenectomy and splenic irradiation for the management of splenomegaly and co-existing cytopenias, or low blood cell counts; chemotherapy and pegylated interferon. Drugs for the treatment of MF-associated anemia include erythropoiesis-stimulating agents, androgens, danazol, corticosteroids, thalidomide and lenalidomide. There are other investigational treatments for MF further along in development than imetelstat, such as pacritinib by CTI Biopharma Corporation, or CTI Biopharma, some which have reported results from Phase 3 clinical trials. Other investigational treatments for MF include inhibitors of the JAK-STAT pathway, such as NS-018 by NS Pharma, Inc.; histone deacetylase inhibitors; interleukin-3 receptor targeted agents; inhibitors of heat shock protein 90; hypomethylating agents; PI3 Kinase and mTOR inhibitors; anti-fibrosis antibodies, such as PRM-151 from Promedior, Inc.; hedgehog and SMO inhibitors; PIM kinase inhibitors; IAP inhibitors; anti-LOX2 inhibitors; recombinant pentraxin 2 protein; KIP-1 activators TGF-beta superfamily inhibitors, such as sotatercept and luspatercept by Acceleron Pharma, Inc., or Acceleron, in collaboration with Celgene Corporation, or Celgene; FLT inhibitors; and other tyrosine kinase inhibitors.

If approved for commercial sale for the treatment of lower risk MDS, imetelstat would compete against a number of treatment options, including erythropoiesis stimulating agents and other hematopoietic growth factors; immunomodulators, such as lenalidomide by Celgene ; hypomethylating agents, such as azacitidine by Celgene and decitabine by Janssen; in addition to investigational treatments that may be further along in development than imetelstat, such as oral versions of azacitidine; histone deacetylase inhibitors; TGF-beta superfamily inhibitors, such as luspatercept by Acceleron, in collaboration with Celgene; PI3 Kinase inhibitors; aminopeptidase inhibitor, such as tosedostat by CTI Biopharma; TLR2-specific antibodies; anti-CD33 antibodies; Fas ligand inhibitors; and JAK-STAT pathway inhibitors.

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

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

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

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

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

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

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

As a result of the foregoing, competitors may develop more commercially desirable or affordable products than imetelstat, or achieve earlier patent protection or product commercialization than us or Janssen. Competitors have developed, or are in the process of developing, technologies that are, or in the future may be, competitive to imetelstat. Some of these products may have an entirely different approach or means of accomplishing therapeutic effects similar or superior to those that may be demonstrated by imetelstat. Competitors may develop products that are safer, more effective, or less costly than imetelstat, or more convenient to administer to patients and, therefore, present a serious competitive threat to imetelstat. In addition, competitors may price their products below what Janssen may determine to be an acceptable price for imetelstat, may receive better third-party payor coverage and/or reimbursement, or may be more cost-effective than imetelstat. Such competitive products or activities by competitors may render imetelstat obsolete, which may cause Janssen to terminate the Collaboration Agreement, which would severely and adversely affect our financial results, business and business prospects, and the future of imetelstat, and might cause us to cease operations.

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

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

- the clinical indications for which imetelstat is approved;
- the establishment and demonstration to the medical community of the clinical efficacy and safety of imetelstat;
- the ability to demonstrate that imetelstat is superior to alternatives on the market at the time;
- the ability to establish in the medical community the potential advantages of imetelstat over alternative treatment methods, including with respect to efficacy, safety, cost or route of administration;
- the label and promotional claims allowed by the FDA or other regulatory authorities for imetelstat, if any;
- the timing of market introduction of imetelstat as well as competitive products;
- the effectiveness of sales, marketing and distribution support for imetelstat;
- the availability of adequate coverage, reimbursement and pricing by government and third-party payors; and
- the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors, including governmental authorities.

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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. 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 and business prospects would be severely and adversely affected.

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal false claims and civil monetary penalties laws, including the civil False Claims Act and its *qui tam* or whistleblower provisions, which impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, which imposes obligations, including mandatory contractual terms, on certain types of individuals and entities with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other transfers of value made to physicians and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by the physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians, other healthcare providers, and healthcare entities, or marketing expenditures; and state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

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

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

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

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

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

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively known as the Affordable Care Act, or ACA, became law and substantially changed the way healthcare will be financed by both governmental and private insurers, and significantly impacted the pharmaceutical industry. The ACA contains a number of provisions that may have a significant impact on our business.

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While the Court upheld the constitutionality of most elements of the ACA in June 2012 and upheld the ACA against challenges to nationwide tax subsidies in July 2015, other judicial and Congressional challenges against the ACA have been brought, and are likely to be brought in the future. In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the ACA. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Congress also could consider subsequent legislation to replace elements of the ACA that are repealed. In March 2017, members of Congress sought unsuccessfully to repeal the ACA. We cannot assure that the ACA, as currently enacted or as amended in the future, or any legislation that may replace the ACA, will not adversely affect our business and financial results and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

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

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

Cost control initiatives also 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 would have a material adverse effect on our ability to earn potential milestone payments and royalties under the Collaboration Agreement, or could cause Janssen to terminate the Collaboration Agreement. Any of these events would severely and adversely affect our financial results, business and business prospects, and might cause us to cease operations.

[Table of Contents](#)**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

None.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**ITEM 5. OTHER INFORMATION**

None.

**ITEM 6. EXHIBITS**

See Exhibit Index.

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

GERON CORPORATION

Date: May 9, 2017

By: /s/ OLIVIA K. BLOOM

OLIVIA K. BLOOM

*Executive Vice President, Finance, Chief Financial Officer and Treasurer*

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#### EXHIBIT INDEX

<b>Exhibit Number</b>	<b>Description</b>
31.1	Certification of Chief Executive Officer pursuant to Form of Rule 13a-14(a), as Adopted Pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002, dated May 9, 2017
31.2	Certification of Chief Financial Officer pursuant to Form of Rule 13a-14(a), as Adopted Pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002, dated May 9, 2017
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated May 9, 2017 *
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated May 9, 2017 *
101	The following materials from the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2017 formatted in Extensible Business Reporting Language (XBRL) include: (i) Condensed Balance Sheets as of March 31, 2017 and December 31, 2016, (ii) Condensed Statements of Operations, Comprehensive Loss and Cash Flows for the three months ended March 31, 2017 and 2016 and (iii) 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.

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**CERTIFICATION PURSUANT TO  
FORM OF RULE 13A-14(A)  
AS ADOPTED PURSUANT TO  
SECTION 302(A) OF THE SARBANES-OXLEY ACT OF 2002**

I, John A. Scarlett, M.D., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Geron Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 9, 2017

/s/ JOHN A. SCARLETT

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JOHN A. SCARLETT, M.D.

*President and Chief Executive Officer*

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**CERTIFICATION PURSUANT TO  
FORM OF RULE 13A-14(A)  
AS ADOPTED PURSUANT TO  
SECTION 302(A) OF THE SARBANES-OXLEY ACT OF 2002**

I, Olivia K. Bloom, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Geron Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 9, 2017

/s/ OLIVIA K. BLOOM

OLIVIA K. BLOOM

*Executive Vice President, Finance, Chief Financial Officer and Treasurer*

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**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to 18 U.S.C. Section 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Geron Corporation (the "Company") hereby certifies, to such officer's knowledge, that:

- (i) the accompanying quarterly report on Form 10-Q of the Company for the quarter ended March 31, 2017 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
- (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 9, 2017

/s/ JOHN A. SCARLETT

JOHN A. SCARLETT, M.D.

*President and Chief Executive Officer*

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is 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 the Form 10-Q), irrespective of any general incorporation language contained in such filing.

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**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to 18 U.S.C. Section 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Geron Corporation (the “Company”) hereby certifies, to such officer’s knowledge, that:

- (i) the accompanying quarterly report on Form 10-Q of the Company for the quarter ended March 31, 2017 (the “Report”) fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
- (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 9, 2017

/s/ OLIVIA K. BLOOM

OLIVIA K. BLOOM

*Executive Vice President, Finance, Chief Financial Officer and Treasurer*

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is 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 the Form 10-Q), irrespective of any general incorporation language contained in such filing.

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