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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, 2018

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)

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

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

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

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:

Common Stock, \$0.001 par value

Outstanding at May 3, 2018:

173,080,653 shares

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GERON CORPORATION  
QUARTERLY REPORT ON FORM 10-Q  
FOR THE QUARTER ENDED MARCH 31, 2018

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**PART I. FINANCIAL INFORMATION**

**ITEM 1. CONDENSED FINANCIAL STATEMENTS (UNAUDITED)**

**GERON CORPORATION  
CONDENSED BALANCE SHEETS  
(IN THOUSANDS)**

	<u>MARCH 31, 2018</u>	<u>DECEMBER 31, 2017</u>
	(UNAUDITED)	(NOTE 1)
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 7,912	\$ 16,335
Restricted cash	268	268
Marketable securities	81,868	78,351
Interest and other receivables	569	436
Prepaid assets	512	580
Total current assets	91,129	95,970
Noncurrent marketable securities	13,184	14,241
Property and equipment, net	86	102
Other assets	1,114	-
	<u>\$ 105,513</u>	<u>\$ 110,313</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 502	\$ 503
Accrued compensation and benefits	1,100	3,385
Accrued collaboration charges	1,841	1,702
Other accrued liabilities	942	926
Total current liabilities	4,385	6,516
Commitments and contingencies		
Stockholders' equity:		
Common stock	161	160
Additional paid-in capital	1,092,931	1,089,684
Accumulated deficit	(991,633)	(985,840)
Accumulated other comprehensive loss	(331)	(207)
Total stockholders' equity	101,128	103,797
	<u>\$ 105,513</u>	<u>\$ 110,313</u>

See accompanying notes.

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

	THREE MONTHS ENDED MARCH 31,	
	2018	2017
<b>Revenues:</b>		
License fees and royalties	\$ 318	\$ 537
<b>Operating expenses:</b>		
Research and development	2,440	3,374
General and administrative	5,315	4,657
Total operating expenses	7,755	8,031
Loss from operations	(7,437)	(7,494)
Interest and other income	394	332
Change in fair value of equity investment	(125)	-
Interest and other expense	(18)	(21)
Net loss	\$ (7,186)	\$ (7,183)
Basic and diluted net loss per share	\$ (0.04)	\$ (0.05)
Shares used in computing basic and diluted net loss per share	160,525,947	159,161,550

See accompanying notes.

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

	<b>THREE MONTHS ENDED</b>	
	<b>MARCH 31,</b>	
	<b>2018</b>	<b>2017</b>
Net loss	\$ (7,186)	\$ (7,183)
Net unrealized loss on marketable securities	(124)	(18)
Comprehensive loss	<u>\$ (7,310)</u>	<u>\$ (7,201)</u>

See accompanying notes.

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

	THREE MONTHS ENDED MARCH 31,	
	2018	2017
<b>Cash flows from operating activities:</b>		
Net loss	\$ (7,186)	\$ (7,183)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	16	20
Loss on retirement of property and equipment	-	5
Accretion and amortization on investments, net	24	55
Change in fair value of equity investment	125	-
Stock-based compensation for services by non-employees	71	57
Stock-based compensation for employees and directors	1,614	1,983
Amortization related to 401(k) contributions	10	32
Changes in assets and liabilities:		
Other current and noncurrent assets	89	(6,003)
Other current liabilities	(2,131)	3,727
Net cash used in operating activities	(7,368)	(7,307)
<b>Cash flows from investing activities:</b>		
Purchases of marketable securities	(19,768)	(28,282)
Proceeds from maturities of marketable securities	17,160	37,640
Net cash (used in) provided by investing activities	(2,608)	9,358
<b>Cash flows from financing activities:</b>		
Proceeds from issuances of common stock, net of issuance costs	1,553	-
Net cash provided by financing activities	1,553	-
Net (decrease) increase in cash, cash equivalents and restricted cash	(8,423)	2,051
Cash, cash equivalents and restricted cash at the beginning of the period	16,603	13,078
Cash, cash equivalents and restricted cash at the end of the period	\$ 8,180	\$ 15,129

See accompanying notes.

**GERON CORPORATION**  
**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
**MARCH 31, 2018**  
**(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, 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, 2018 are not necessarily indicative of the results that may be expected for the year ending December 31, 2018 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, 2017, included in the Company’s Annual Report on Form 10-K. The accompanying condensed balance sheet as of December 31, 2017 has been derived from audited financial statements at that date.

**Prior Period Reclassification**

With the adoption of Accounting Standards Update, or ASU, No. 2016-18, *Statement of Cash Flows (Topic 230) Restricted Cash*, or ASU No. 2016-18, the prior period presentation of cash and cash equivalents in the condensed statements of cash flows has been updated to conform with current period presentation. See “New Accounting Pronouncements – Recently Adopted” in this Note 1 on Summary of Significant Accounting Policies for further discussion of the adoption of ASU No. 2016-18.

**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 potential common shares. Diluted net income per share would be calculated by adjusting the weighted-average number of shares of common stock outstanding for the dilutive effect of potential common shares outstanding for the periods presented, as determined using the treasury-stock method. Potential dilutive securities consist of outstanding stock options and warrants to purchase our common stock. Diluted net loss per share excludes potential common shares outstanding for all periods presented as their effect would be anti-dilutive. Accordingly, basic and diluted net loss per share is the same for all periods presented in the accompanying condensed statements of operations. Since we incurred a net loss for the three months ended March 31, 2018 and 2017, the diluted net loss per share calculation excludes potential common shares of 26,245,422 and 22,844,180, respectively, related to outstanding stock options and warrants as their effect would have been anti-dilutive.

**Use of Estimates**

The accompanying financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of financial statements in conformity with GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, we evaluate our estimates, including those related to accrued liabilities, revenue recognition, fair value of marketable securities and equity investments, income taxes, and stock-based compensation. We base our estimates on historical experience and on various other market specific and relevant assumptions that we believe to be reasonable under the circumstances. Actual results could differ from those estimates.

**Fair Value of Financial Instruments**

***Cash Equivalents and Marketable Securities***

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

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

**GERON CORPORATION**  
**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
**MARCH 31, 2018**  
**(UNAUDITED)**

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 judged as other-than-temporary result in a charge to interest and other income. We have not recorded any other-than-temporary impairment charges on our available-for-sale securities for the three months ended March 31, 2018 and 2017. See Note 2 on Fair Value Measurements.

***Equity Investments***

With the adoption of ASU No. 2016-01, *Financial Instruments - Overall: Recognition and Measurement of Financial Assets and Financial Liabilities*, or ASU 2016-01, beginning January 1, 2018, we measure our equity securities at fair value at each reporting period and changes in fair value are included in change in fair value of equity investment in our condensed statements of operations. See “New Accounting Pronouncements – Recently Adopted” in this Note 1 on Summary of Significant Accounting Policies for additional information on the adoption of ASU 2016-01.

**Revenue Recognition**

Beginning January 1, 2018, we recognize revenue in accordance with the provisions of Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers*, or Topic 606. In determining the appropriate amount and timing of revenue to be recognized under this guidance, we perform the following five steps: (i) identify the contract(s) with our customer; (ii) identify the promised goods or services in the agreement and determine whether they are performance obligations, including whether they are distinct in the context of the agreement; (iii) measure the transaction price, including the constraint on variable consideration; (iv) allocate the transaction price to the performance obligations based on stand-alone selling prices; and (v) recognize revenue when (or as) we satisfy each performance obligation. See “New Accounting Pronouncements – Recently Adopted” in this Note 1 on Summary of Significant Accounting Policies for further discussion of the adoption of Topic 606.

A performance obligation is a promise in an agreement to transfer a distinct good or service to the customer and is the unit of account in Topic 606. Significant management judgment is required to determine the level of effort required under an agreement and the period over which completion of the performance obligations is expected. If reasonable estimates regarding when performance obligations are either complete or substantially complete cannot be made, then revenue recognition is deferred until a reasonable estimate can be made. Revenue is then recognized over the remaining estimated period of performance using the cumulative catch-up method.

We allocate the total transaction price to each performance obligation based on the estimated relative stand-alone selling prices of the promised goods or service underlying each performance obligation. Estimated selling prices for license rights are calculated using an income approach model and include the following key assumptions, judgments and estimates: the development timeline, revenue forecast, commercialization expenses, discount rate and probabilities of technical and regulatory success.

Following is a description of the principal activities from which we generate revenue. Collaboration revenue primarily represents amounts earned under the collaboration and license agreement, or Collaboration Agreement, with Janssen Biotech, Inc., or Janssen, for the imetelstat program. License fees and royalty revenue primarily represents amounts earned under agreements that out-license our technology to various companies.

***License and/or Collaboration Agreements***

In addition to the Collaboration Agreement (which is more fully described in Note 3 on Collaboration Agreement), we have entered into several license agreements with various oncology, diagnostics, research tools and biologics production companies. Economic terms in these agreements may include non-refundable upfront license payments in cash or equity securities, annual license maintenance fees, cost sharing arrangements, milestone payments, royalties on future sales of products, or any combination of these items. Non-refundable upfront fees, annual license maintenance fees and funding of research and development activities are considered fixed, while milestone payments and royalties are identified as variable consideration.



**GERON CORPORATION**  
**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
**MARCH 31, 2018**  
**(UNAUDITED)**

*Licenses of Intellectual Property.* If we determine the license to intellectual property is distinct from the other performance obligations identified in the agreement and the customer can use and benefit from the license, we recognize revenue from non-refundable upfront fees allocated to the license upon the completion of the transfer of the license to the customer. For such licenses, we recognize revenue from annual license maintenance fees upon the start of the new license period. For licenses that are bundled with other performance obligations, we assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable upfront fees or annual license maintenance fees. At each reporting period, we reassess the progress and, if necessary, adjust the measure of performance and related revenue recognition.

*Milestone Payments.* At the inception of each agreement that includes milestone payments, we evaluate whether the milestones are considered probable of being achieved and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the value of the associated milestone is included in the transaction price. For milestones that we do not deem to be probable of being achieved, the associated milestone payments are fully constrained and the value of the milestone is excluded from the transaction price with no revenue being recognized. Milestone payments that are not within our control, such as regulatory-related accomplishments, are not considered probable of being achieved until those accomplishments have been communicated by the relevant regulatory authority. Once the assessment of probability of achievement becomes probable, we recognize revenue for the milestone payment under collaboration revenue. At each reporting period, we assess the probability of achievement of each milestone under our current agreements.

*Royalties.* For agreements with sales-based royalties, including milestone payments based on the level of sales, where the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (a) when the related sales occur, or (b) when the performance obligation, to which some or all of the royalty has been allocated, has been satisfied (or partially satisfied). At each reporting period, we estimate the sales incurred by each licensee based on historical experience and accrue the associated royalty amount.

*Cost Sharing Arrangements.* Research and development and other expenses being shared by both parties under an agreement are recorded as earned or owed based on the performance obligations by both parties under the respective agreement. 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 over time in a manner proportionate to the costs we incurred to perform the services using the input method.

**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.

**GERON CORPORATION**  
**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
**MARCH 31, 2018**  
**(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 and employee stock purchases for the three months ended March 31, 2018 and 2017 which was allocated as follows:

<u>(In thousands)</u>	<u>Three Months Ended March 31,</u>	
	<u>2018</u>	<u>2017</u>
Research and development	\$ 155	\$ 291
General and administrative	1,459	1,692
Stock-based compensation expense included in operating expenses	<u>\$ 1,614</u>	<u>\$ 1,983</u>

As stock-based compensation expense recognized in our condensed statements of operations for the three months ended March 31, 2018 and 2017 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures, but at a minimum, reflects the grant-date fair value of those awards that actually vested in the period. Forfeitures have been estimated at the time of grant based on historical data and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

**Stock Options**

We grant options with service-based vesting under our equity plans to employees, non-employee directors and consultants. The vesting period for employee options is generally four years. The fair value of options granted during the three months ended March 31, 2018 and 2017 has been estimated at the date of grant using the Black Scholes option-pricing model with the following assumptions:

	<u>Three Months Ended March 31,</u>	
	<u>2018</u>	<u>2017</u>
Dividend yield	0%	0%
Expected volatility	0.821	0.892
Risk-free interest rate	2.55%	1.98%
Expected term	5.25 yrs	5.5 yrs

**Employee Stock Purchase Plan**

The fair value of employees' purchase rights during the three months ended March 31, 2018 and 2017 has been estimated using the Black Scholes option-pricing model with the following assumptions:

	<u>Three Months Ended March 31,</u>	
	<u>2018</u>	<u>2017</u>
Dividend yield	0%	0%
Expected volatility range	0.437 to 0.475	0.577 to 0.641
Risk-free interest rate range	1.53% to 1.76%	0.45% to 0.89%
Expected term range	6 - 12 mos	6 - 12 mos

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

**GERON CORPORATION**  
**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
**MARCH 31, 2018**  
**(UNAUDITED)**

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

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

***New Accounting Pronouncements – Recently Adopted***

In May 2014, the Financial Accounting Standards Board, or FASB, issued ASU No. 2014-09, which amends the guidance for accounting for revenue from contracts with customers. This ASU superseded the revenue recognition requirements in Accounting Standards Codification Topic 605, *Revenue Recognition*, or Topic 605, and created Topic 606.

We adopted Topic 606 on January 1, 2018 using the modified retrospective transition method for those agreements which were not completed as of January 1, 2018. Financial results for the reporting periods beginning after January 1, 2018 are presented under Topic 606, while prior period amounts have not been adjusted and continue to be reported in accordance with our historical accounting under Topic 605.

In connection with the adoption of Topic 606, we recognized a cumulative-effect adjustment to our opening balance of accumulated deficit and an increase to interest and other receivables of \$204,000 as of January 1, 2018 for projected sales-based royalties on product sales occurring in 2017 for which payments had not yet been received as of December 31, 2017. Such royalties were recognized as revenue in prior periods when payments were received from our licensees. In accordance with Topic 606-10-50-14a, we have elected to exclude providing further information about our sales-based royalties.

The adoption of Topic 606 did not result in any changes to the estimated transaction price or the performance obligations for current agreements or the amounts allocated to satisfied performance obligations. We do not have any deferred revenue associated with unsatisfied performance obligations. Since we view our operations as a single segment and all of our revenues are recognized at a point in time from similar license agreements, disaggregated revenue disclosures would not materially provide additional information. We do not expect the application of Topic 606 to have a material impact on our financial results on an ongoing basis in comparison to results that would have been realized if we had continued to apply Topic 605.

In January 2016, the FASB issued ASU 2016-01 which requires equity investments to be measured at fair value with changes in fair value recognized in the statements of operations. To further clarify ASU 2016-01, the FASB issued ASU No. 2018-03, *Technical Corrections and Improvements to Financial Instruments - Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*, or ASU 2018-03, in February 2018. ASU 2018-03 requires application of a prospective transition approach only for those equity investments for which the new measurement alternative is being applied. We adopted ASU 2016-01 and ASU 2018-03 on January 1, 2018 using the modified retrospective transition method and recognized a cumulative-effect adjustment to our opening balance of accumulated deficit and other assets for the fair value of our equity investment. In accordance with ASU 2016-01, at the end of first quarter of 2018, we remeasured the fair value of our equity investment and included the change in fair value in change in fair value of equity investment in our condensed statements of operations. See Note 2 on Fair Value Measurements for additional information on our equity investment.

**GERON CORPORATION**  
**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
**MARCH 31, 2018**  
**(UNAUDITED)**

The cumulative-effect adjustments to our January 1, 2018 condensed balance sheet for the adoption of Topic 606 and ASU 2016-01 and ASU 2018-03 were as follows (in thousands):

<u>Condensed Balance Sheet</u>	<u>Balance at December 31, 2017</u>	<u>Adjustments Due to Topic 606</u>	<u>Adjustments Due to ASU 2016-01 and ASU 2018-03</u>	<u>Balance at January 1, 2018</u>
Assets:				
Interest and other receivables	\$ 436	\$ 204	\$ -	\$ 640
Other assets	\$ -	\$ -	\$ 1,189	\$ 1,189
Stockholders' Equity:				
Accumulated deficit	\$ (985,840)	\$ 204	\$ 1,189	\$ (984,447)

As of January 1, 2018, we also adopted ASU No. 2016-15, *Classification of Certain Cash Receipts and Cash Payments*, ASU No. 2016-18, *Statement of Cash Flows (Topic 230) Restricted Cash*, and ASU No. 2017-09, *Compensation — Stock Compensation: Scope of Modification Accounting*. With the adoption of ASU No. 2016-18, changes in the total of cash, cash equivalents and restricted cash are presented in our condensed statements of cash flows. The adoption of these new standards did not have a material impact on our financial statements and related disclosures.

***New Accounting Pronouncements – Issued But Not Yet Adopted***

In February 2016, the FASB issued ASU 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 lease arrangements 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 plan to adopt ASU 2016-02 on January 1, 2019.

**2. FAIR VALUE MEASUREMENTS**

**Cash Equivalents and Marketable Securities**

Cash equivalents, restricted cash and marketable securities by security type at March 31, 2018 were as follows:

<u>(In thousands)</u>	<u>Amortized Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Estimated Fair Value</u>
Included in cash and cash equivalents:				
Money market funds	\$ 5,383	\$ -	\$ -	\$ 5,383
Restricted cash:				
Certificate of deposit	\$ 268	\$ -	\$ -	\$ 268
Marketable securities:				
Government-sponsored enterprise securities (due in less than one year)	\$ 10,000	\$ -	\$ (30)	\$ 9,970
Commercial paper (due in less than one year)	11,923	7	(5)	11,925
Corporate notes (due in less than one year)	60,201	-	(228)	59,973
Corporate notes (due in one to two years)	13,259	-	(75)	13,184
	<u>\$ 95,383</u>	<u>\$ 7</u>	<u>\$ (338)</u>	<u>\$ 95,052</u>

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

(In thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
<b>Included in cash and cash equivalents:</b>				
Money market funds	\$ 11,030	\$ -	\$ -	\$ 11,030
Commercial paper	2,242	-	-	2,242
Corporate notes	1,750	-	(1)	1,749
	<u>\$ 15,022</u>	<u>\$ -</u>	<u>\$ (1)</u>	<u>\$ 15,021</u>
<b>Restricted cash:</b>				
Certificate of deposit	\$ 268	\$ -	\$ -	\$ 268
<b>Marketable securities:</b>				
Government-sponsored enterprise securities (due in less than one year)	\$ 12,500	\$ -	\$ (40)	\$ 12,460
Commercial paper (due in less than one year)	10,928	4	(1)	10,931
Corporate notes (due in less than one year)	55,067	-	(107)	54,960
Corporate notes (due in one to two years)	14,303	-	(62)	14,241
	<u>\$ 92,798</u>	<u>\$ 4</u>	<u>\$ (210)</u>	<u>\$ 92,592</u>

Cash equivalents and marketable securities with unrealized losses that have been in a continuous unrealized loss position for less than 12 months and 12 months or longer at March 31, 2018 and December 31, 2017 were as follows:

(In thousands)	Less Than 12 Months		12 Months or Longer		Total	
	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses
<b>As of March 31, 2018:</b>						
Government-sponsored enterprise securities (due in less than one year)	\$ -	\$ -	\$ 9,970	\$ (30)	\$ 9,970	\$ (30)
Commercial paper (due in less than one year)	8,958	(5)	-	-	8,958	(5)
Corporate notes (due in less than one year)	52,947	(210)	6,527	(18)	59,474	(228)
Corporate notes (due in one to two years)	13,184	(75)	-	-	13,184	(75)
	<u>\$ 75,089</u>	<u>\$ (290)</u>	<u>\$ 16,497</u>	<u>\$ (48)</u>	<u>\$ 91,586</u>	<u>\$ (338)</u>
<b>As of December 31, 2017:</b>						
Government-sponsored enterprise securities (due in less than one year)	\$ -	\$ -	\$ 12,460	\$ (40)	\$ 12,460	\$ (40)
Commercial paper (due in less than one year)	7,717	(1)	-	-	7,717	(1)
Corporate notes (due in less than one year)	55,210	(106)	1,499	(2)	56,709	(108)
Corporate notes (due in one to two years)	14,241	(62)	-	-	14,241	(62)
	<u>\$ 77,168</u>	<u>\$ (169)</u>	<u>\$ 13,959</u>	<u>\$ (42)</u>	<u>\$ 91,127</u>	<u>\$ (211)</u>

The gross unrealized losses related to government-sponsored enterprise securities, commercial paper and corporate notes as of March 31, 2018 and December 31, 2017 were due to changes in interest rates and not credit risk. We determined that the gross unrealized losses on our marketable securities as of March 31, 2018 and December 31, 2017 were temporary in nature. We review our investments quarterly to identify and evaluate whether any investments have indications of possible other-than-temporary 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.

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**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.

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, corporate notes and equity investments 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, 2018 and December 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>As of March 31, 2018:</b>					
Money market funds(1)	\$ 5,383	\$ -	\$ -	\$ -	\$ 5,383
Government-sponsored enterprise securities(2)	-	9,970	-	-	9,970
Commercial paper(2)	-	11,925	-	-	11,925
Corporate notes(2)(3)	-	73,157	-	-	73,157
Equity investment(4)	-	1,064	-	-	1,064
<b>Total</b>	<b>\$ 5,383</b>	<b>\$ 96,116</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ 101,499</b>
<b>As of December 31, 2017:</b>					
Money market funds(1)	\$ 11,030	\$ -	\$ -	\$ -	\$ 11,030
Government-sponsored enterprise securities(2)	-	12,460	-	-	12,460
Commercial paper(1)(2)	-	13,173	-	-	13,173
Corporate notes(1)(2)(3)	-	70,950	-	-	70,950
<b>Total</b>	<b>\$ 11,030</b>	<b>\$ 96,583</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ 107,613</b>

- (1) Included in cash and cash equivalents on our condensed balance sheets.
- (2) Included in current portion of marketable securities on our condensed balance sheets.
- (3) Included in noncurrent portion of marketable securities on our condensed balance sheets.
- (4) Included in other assets on our condensed balance sheets. See "Equity Investment" in this Note 2 on Fair Value Measurements for further discussion of this equity investment.

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**Equity Investment**

In December 2007, we received 13,842,625 ordinary shares in Sienna Cancer Diagnostics Limited, or Sienna, in connection with a license we granted to them for our human telomerase reverse transcriptase, or hTERT, technology for use in human diagnostics. The shares were recorded at a zero cost basis upon receipt under the cost method of accounting. On August 3, 2017, Sienna became a publicly traded company on the Australian Securities Exchange Limited, or ASX, under the ticker symbol SDX. In connection with Sienna's initial public offering under Australian securities regulations, we signed a restriction agreement with Sienna which subjects our shares in Sienna to a 24-month trading restriction from the effective date of Sienna's listing on the ASX. Due to this trading restriction, under the cost method of accounting, we maintained a zero cost basis for our shares in Sienna as of December 31, 2017. With the adoption of ASU 2016-01 and ASU 2018-03, as described in Note 1 on Summary of Significant Accounting Policies, our equity investment in Sienna must be reported at fair value and therefore, we recorded a cumulative-effect adjustment of \$1,189,000 on our condensed balance sheet for the fair value of our shares in Sienna, as measured using the closing stock price reported on the ASX and converted to U.S. dollars as of January 1, 2018. Applying the same fair value measurement methodology in accordance with ASU 2016-01, we remeasured our shares in Sienna at a fair value of \$1,064,000 as of March 31, 2018 and recognized the resulting change in fair value of \$125,000 in change in fair value of equity investment in our condensed statements of operations.

**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 in December 2014, 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. Janssen is currently conducting two clinical trials of imetelstat: 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, 2018, accrued collaboration charges of \$1,841,000 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, 2018.

Following completion of the protocol-specified primary analysis of IMbark by Janssen, if completed, we expect Janssen to 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 March 2018, based on the rate of deaths occurring in the trial, the Joint Steering Committee of the collaboration determined that the protocol-specified primary analysis of IMbark, which includes an assessment of overall survival, will begin by the end of the second quarter of 2018. We expect Janssen to inform us of its decision by the end of the third quarter of 2018.

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 and 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.

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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.

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, if any, (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 or regulatory milestones, represent fully constrained variable consideration under Topic 606 as achievement of these milestones has not been deemed probable as of March 31, 2018. Royalties on future product sales of imetelstat, if successfully commercialized under the Collaboration Agreement, and any sales-based milestone payments will be recognized as revenue at the later of (a) when the related sales occur, or (b) when the performance obligation, to which some or all of the royalty has been allocated, has been satisfied (or partially satisfied) in accordance with Topic 606.

#### **4. STOCKHOLDERS' EQUITY**

On August 28, 2015, we entered into an At Market Issuance Sales Agreement, or the 2015 Sales Agreement, with MLV & Co. LLC, or MLV, under which we could elect to issue and sell shares of our common stock having an aggregate offering price of up to \$50,000,000. Pursuant to the 2015 Sales Agreement, common stock was sold at market prices prevailing at the time of sale through MLV as our sales agent. We paid MLV an aggregate commission rate equal to up to 3.0% of the gross proceeds of the sales price per share for common stock sold through MLV under the 2015 Sales Agreement.

In the first quarter of 2018, we sold an aggregate of 776,788 shares of our common stock pursuant to the 2015 Sales Agreement, resulting in net cash proceeds to us of approximately \$1,553,000 after deducting sales commissions and offering expenses payable by us. For further discussion of our use of the 2015 Sales Agreement, see Note 5 on Subsequent Event.

#### **5. SUBSEQUENT EVENT**

In April 2018, we completed the sale of the remaining common stock subject to the 2015 Sales Agreement and issued an aggregate of 12,418,318 shares of our common stock, resulting in net cash proceeds to us of approximately \$46,098,000 after deducting sales commissions and offering expenses payable by us. In connection with the sale of our common stock under the 2015 Sales Agreement, deferred issuance costs of \$50,000 have been included in other assets on our condensed balance sheet as of March 31, 2018. No further shares of common stock may be sold under the 2015 Sales Agreement. For further discussion of the 2015 Sales Agreement, see Note 4 on Stockholders' Equity.



## 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, 2017, as filed with the Securities and Exchange Commission, or SEC, on March 16, 2018.

#### 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 in essential thrombocythemia, or ET, myelofibrosis, or MF, and myelodysplastic syndromes, or MDS, suggest imetelstat may have disease-modifying activity by inhibiting the progenitor cells of the malignant clones for the underlying diseases.

On November 13, 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 on December 15, 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 developing, manufacturing, seeking regulatory approval for, and commercialization of, imetelstat worldwide. The Collaboration Agreement provides for a joint governance structure which includes a Joint Steering Committee, or JSC, with equal membership from both companies. Information about the Collaboration Agreement should be reviewed in the context of the sections entitled "Risks Related to Our Collaboration with Janssen" and "Risks Related to Clinical Development, Regulatory Approval and Commercialization of Imetelstat" included in Part II, Item 1A, "Risk Factors" of this Form 10-Q.

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 the last patient was enrolled in October 2016; and IMerge, a Phase 2/3 trial in MDS, in which the first patient was dosed in January 2016. We contribute 50% of the development costs for these trials, 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.

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. Key secondary endpoints include safety and overall survival. We expect an assessment of overall survival of this specifically defined relapsed and refractory MF patient population to provide important information for the imetelstat program, including for any potential

future clinical trials, and that without an adequate improvement in survival, with the determination of adequacy to be assessed by Janssen in its sole discretion, Janssen would decide to discontinue the imetelstat program and terminate the Collaboration Agreement.

For IMbark, Janssen completed internal data reviews in September 2016, April 2017 and March 2018. In these data reviews, the JSC determined that the safety profile was consistent with prior clinical trials of imetelstat in hematologic malignancies, and no new safety signals were identified. In addition, the JSC determined that data from the 4.7 mg/kg dosing arm did not warrant further investigation of that starting dose and the 4.7 mg/kg arm was closed to new patient enrollment following the September 2016 data review. The JSC also determined that data supported 9.4 mg/kg as an appropriate starting dose in the trial. In addition, the JSC observed activity within multiple outcome measures with imetelstat treatment at the 9.4 mg/kg starting dose, suggesting potential clinical benefit in patients with MF who are relapsed after or refractory to prior treatment with a JAK inhibitor. However, the JSC observed that the spleen volume response rate in the 9.4 mg/kg dosing arm was less than that reported in clinical trials with JAK inhibitors in front-line MF patients, and that an insufficient number of patients met the protocol defined interim efficacy criteria to continue enrollment in the 9.4 mg/kg dosing arm. Thus, new patient enrollment in the 9.4 mg/kg dosing arm was suspended in October 2016. In March 2018, Janssen officially closed the trial to new patient enrollment. The JSC expects that the over 100 patients enrolled in IMbark to date will be adequate to assess overall survival. Patients who remain in the treatment phase of IMbark may continue to receive imetelstat, and until the protocol-specified primary analysis, all safety and efficacy assessments are being conducted as planned in the protocol, including following patients, to the extent possible, until death, to enable an assessment of overall survival. The JSC concluded that as of January 2018, median follow up was approximately 19 months, and median overall survival had not been reached in either dosing arm.

In March 2018, based on the rate of deaths occurring in the trial, the JSC determined that the protocol-specified primary analysis of IMbark, which includes an assessment of overall survival, will begin by the end of the second quarter of 2018, using a clinical cut-off date of April 26, 2018. Upon the protocol-specified primary analysis, the main trial will be completed. The IMbark protocol is being amended to establish an extension phase of the trial to enable patients remaining in the treatment phase to continue to receive imetelstat treatment, per investigator discretion. Following completion of the primary analysis, Janssen must notify us of its decision, or the Continuation Decision, whether to: (i) maintain the license rights granted under the Collaboration Agreement and continue the development of imetelstat or (ii) discontinue the development of imetelstat and terminate the Collaboration Agreement. We expect Janssen to inform us of its decision by the end of the third quarter of 2018.

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 was originally designed as a Phase 2, open-label, single-arm trial to assess the efficacy and safety of imetelstat. 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, or RBC-TI, lasting at least 8 weeks. Key secondary endpoints include the rates of RBC-TI lasting at least 24 weeks, amount and relative change in red blood cell transfusions and hematologic improvement.

For IMerge, Janssen completed internal data reviews in September 2016 and April 2017. In addition, preliminary data from Part 1 of IMerge were presented at the American Society of Hematology Annual Meeting, or ASH, in December 2017. These data showed that among the 32 red blood cell transfusion-dependent MDS patients enrolled in Part 1 of the trial, a subset of 13 patients who had not received prior treatment with either a hypomethylating agent or lenalidomide and did not have a deletion 5q chromosomal abnormality, who are frequently identified as “non-del(5q)” patients, exhibited an increased rate and durability of transfusion independence compared to the overall trial population. Approximately half of the 13-patient subset population achieved  $\geq 8$ -week RBC-TI after treatment with imetelstat, and almost one-third of the subset population achieved  $\geq 24$ -week RBC-TI. The safety profile in Part 1 was consistent with prior clinical trials of imetelstat in hematologic malignancies, and no new safety signals were identified. The most frequently reported adverse events were cytopenias, which were predictable, manageable and reversible, in most cases, including Grade 3 and 4, or severe, neutropenia and thrombocytopenia. In addition, reported adverse events did not differ significantly between the overall trial population and the 13-patient subset. Based on the preliminary data from this 13-patient subset, Janssen has expanded new patient enrollment in Part 1 of IMerge to enroll approximately 20 additional patients to increase the experience and confirm the benefit-risk profile of imetelstat in this refined target patient population. In November 2017, the first patient was dosed in the expanded Part 1 of IMerge and enrollment was completed in February 2018.

Janssen has not committed to begin Part 2 of IMerge. We believe Janssen will initiate Part 2 only following an affirmative Continuation Decision, if any.

Janssen could discontinue the imetelstat program and terminate the Collaboration Agreement at any time, such as, before the start of the IMbark primary analysis, and for any reason, irrespective of whether there is data from IMbark suggesting an adequate improvement in survival in relapsed or refractory MF or whether there is sufficient data from the additional patients enrolled in the expanded Part 1 of IMerge to support the benefit-risk profile of imetelstat in lower risk MDS in the refined target patient population.

In this regard, we believe that without an adequate improvement in survival in relapsed or refractory MF, with the determination of adequacy to be assessed by Janssen in its sole discretion, Janssen would decide to discontinue the imetelstat program and terminate the Collaboration Agreement.

## **Financial Overview**

We had approximately \$103.2 million in cash, cash equivalents, restricted cash and current and noncurrent marketable securities as of March 31, 2018. 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, 2018, we had an accumulated deficit of \$991.6 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 obtaining sufficient efficacy and safety data from the additional patients enrolled in Part 1 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 on our own and 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.

## **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, 2018 as compared to the critical accounting policies and estimates disclosed in our Annual Report on Form 10-K for the year ended December 31, 2017, other than the adoption of the new accounting pronouncements on January 1, 2018 as described below.

Our condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles 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.

## **New Accounting Pronouncements – Recently Adopted**

### ***Revenue Recognition***

On January 1, 2018, we adopted the provisions of Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers*, or Topic 606, using the modified retrospective transition method as discussed in the subsection entitled, “New Accounting

Pronouncements – Recently Adopted”, in Note 1 of Notes to Condensed Financial Statements of this Form 10-Q. Financial results for the reporting periods beginning after January 1, 2018 are presented under Topic 606, while prior period amounts have not been adjusted and continue to be reported in accordance with our historical accounting under Accounting Standards Codification Topic 605, *Revenue Recognition*, or Topic 605, and therefore, there is a lack of comparability to the prior periods presented. In connection with the adoption of Topic 606, we recognized a cumulative-effect adjustment to our opening balance of accumulated deficit and an increase to interest and other receivables as of January 1, 2018 for projected sales-based royalties on product sales occurring in 2017 for which payments had not yet been received as of December 31, 2017. Such royalties were recognized as revenue in prior periods when payments were received from our licensees.

In determining the appropriate amount and timing of revenue to be recognized under Topic 606, we perform the following five steps: (i) identify the contract(s) with our customer; (ii) identify the promised goods or services in the agreement and determine whether they are performance obligations, including whether they are distinct in the context of the agreement; (iii) measure the transaction price, including the constraint on variable consideration; (iv) allocate the transaction price to the performance obligations based on stand-alone selling prices; and (v) recognize revenue when (or as) we satisfy each performance obligation. Significant management judgment is required to determine the level of effort required under an agreement and the period over which completion of the performance obligations is expected. If reasonable estimates regarding when performance obligations are either complete or substantially complete cannot be made, then revenue recognition is deferred until a reasonable estimate can be made. Revenue is then recognized over the remaining estimated period of performance using the cumulative catch-up method.

We allocate the total transaction price to each performance obligation based on the estimated relative stand-alone selling prices of the promised goods or service underlying each performance obligation. Estimated selling prices for license rights are calculated using an income approach model and include the following key assumptions, judgments and estimates: the development timeline, revenue forecast, commercialization expenses, discount rate and probabilities of technical and regulatory success.

Our revenues primary consist of collaboration revenue and license fees and royalties. Collaboration revenue primarily represents amounts earned under the Collaboration Agreement with Janssen for the imetelstat program. License fees and royalty revenue primarily represents amounts earned under agreements that out-license our technology to various oncology, diagnostics, research tools and biologics production companies. Economic terms in these agreements may include non-refundable upfront license payments in cash or equity securities, annual license maintenance fees, cost sharing arrangements, milestone payments, royalties on future sales of products, or any combination of these items. Non-refundable upfront fees, annual license maintenance fees and funding of research and development activities are considered fixed, while milestone payments and royalties are identified as variable consideration.

*Licenses of Intellectual Property.* If we determine the license to intellectual property is distinct from the other performance obligations identified in the agreement and the customer can use and benefit from the license, we recognize revenue from non-refundable upfront fees allocated to the license upon the completion of the transfer of the license to the customer. For such licenses, we recognize revenue from annual license maintenance fees upon the start of the new license period. For licenses that are bundled with other performance obligations, we assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable upfront fees or annual license maintenance fees. At each reporting period, we reassess the progress and, if necessary, adjust the measure of performance and related revenue recognition.

*Milestone Payments.* At the inception of each agreement that includes milestone payments, we evaluate whether the milestones are considered probable of being achieved and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the value of the associated milestone is included in the transaction price. For milestones that we do not deem to be probable of being achieved, the associated milestone payments are fully constrained and the value of the milestone is excluded from the transaction price with no revenue being recognized. Milestone payments that are not within our control, such as regulatory-related accomplishments, are not considered probable of being achieved until those accomplishments have been communicated by the relevant regulatory authority. Once the assessment of probability of achievement becomes probable, we recognize revenue for the milestone payment under collaboration revenue. At each reporting period, we assess the probability of achievement of each milestone under our current agreements.

*Royalties.* For agreements with sales-based royalties, including milestone payments based on the level of sales, where the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of: (a) when the related sales occur, or (b) when the performance obligation, to which some or all of the royalty has been allocated, has been satisfied (or partially satisfied). At each reporting period, we estimate the sales incurred by each licensee based on historical experience and accrue the associated royalty amount.

*Cost Sharing Arrangements.* Research and development and other expenses being shared by both parties under an agreement are recorded as earned or owed based on the performance obligations by both parties under the respective agreement. 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 over time in a manner proportionate to the costs we incurred to perform the services using the input method.

#### **Equity Investment**

We adopted Accounting Standards Update No. 2016-01, *Financial Instruments - Overall: Recognition and Measurement of Financial Assets and Financial Liabilities*, or ASU 2016-01, on January 1, 2018. Under ASU 2016-1, equity securities are measured at fair value at each reporting period and any changes in fair value are included in change in fair value of equity investment in our condensed statements of operations. Upon the adoption of ASU 2016-01, we recognized a cumulative-effect adjustment to our opening balance of accumulated deficit and other assets for the fair value of our equity investment in Sienna Cancer Diagnostics Limited, or Sienna. As of March 31, 2018, we remeasured the fair value of our equity investment in Sienna in accordance with ASU 2016-01 and included the change in fair value in change in fair value of equity investment in our condensed statements of operations for the three months ended March 31, 2018. The fair value of our equity investment in Sienna is subject to volatility and could adversely affect our future operating results. See Note 2 on Fair Value Measurements for additional information on our equity investment in Sienna.

#### **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 continuation of the collaboration with Janssen and the related progress, if any, of the development and commercialization of the imetelstat program 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, the possibility that Janssen could discontinue the imetelstat program and terminate the Collaboration Agreement at any time and for any reason, irrespective of whether there is data from IMbark suggesting an adequate improvement in survival in relapsed or refractory MF, with the determination of adequacy to be assessed by Janssen in its sole discretion, or whether there is sufficient data from the additional patients enrolled in the expanded Part 1 of IMerge to support the benefit-risk profile of imetelstat in lower risk MDS in the refined target patient population, our 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.

#### **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. As discussed above, we adopted Topic 606 using the modified retrospective transition method on January 1, 2018. As a result, prior period amounts have not been adjusted and continue to be reported in accordance with our historical accounting under Topic 605 and therefore, there is a lack of comparability to the prior periods presented. However, we do not expect the application of Topic 606 to have a material impact on our financial results on an ongoing basis in comparison to the results that would have been realized if we had continued to apply Topic 605.

We recognized license fee revenues of \$248,000 for the three months ended March 31, 2018, compared to \$409,000 for the same period in 2017 related to our various agreements. The decrease in license fee revenues for the three months ended March 31, 2018 compared to the same period in 2017 primarily reflects a reduction in the number of active license agreements in the first quarter of 2018 for research licenses related to our human telomerase reverse transcriptase, of hTERT, technology compared to the first quarter of 2017. We recognized royalty revenues of \$70,000 for the three months ended March 31, 2018, compared to \$128,000 for the same period in 2017. The decrease in royalty revenues for the three months ended March 31, 2018 compared to the same period in 2017 reflects overall lower product sales by our licensees and a change in the method that revenue is being recognized for royalties upon the adoption of Topic 606 as of January 1, 2018. Under Topic 606, we estimate sales-based royalties earned on product sales by our licensees in each reporting period and accrue the associated royalty amount. In prior periods, revenue from royalties was being recognized when payments were received from 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 license fee and royalty revenues under our license agreements related to our hTERT technology to be lower in 2018 than in previous 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, 2018 and 2017, 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, 2018 and 2017, 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 \$2.4 million for the three months ended March 31, 2018, compared to \$3.4 million for the same period in 2017. The decrease in research and development expenses for the three months ended March 31, 2018 compared to the same period in 2017 primarily reflects lower direct external costs for our proportionate share of clinical development expenses under the collaboration with Janssen and reduced personnel related expenses due to reduced stock-based compensation expense.

Research and development expenses for the three months ended March 31, 2018 and 2017 were as follows:

(In thousands)	Three Months Ended March 31,	
	2018	2017
	(Unaudited)	
Direct external expenses	\$ 1,887	\$ 2,586
Personnel related expenses	414	608
All other expenses	139	180
Total research and development expenses	<u>\$ 2,440</u>	<u>\$ 3,374</u>

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 Collaboration with Janssen" and "Risks Related to Clinical Development, Regulatory Approval and Commercialization of Imetelstat", in Part II, Item 1A entitled "Risk Factors" and elsewhere in this Form 10-Q.

### General and Administrative Expenses

General and administrative expenses were \$5.3 million for the three months ended March 31, 2018, compared to \$4.7 million for the same period in 2017. The increase in general and administrative expenses for the three months ended March 31, 2018 compared to the same period in 2017 primarily reflects higher legal and consulting expenses in connection with our business development activities. We expect general and administrative expenses to remain consistent during the remainder of 2018.

### **Interest and Other Income**

Interest and other income was \$394,000 for the three months ended March 31, 2018, compared to \$332,000 for the same period in 2017. The increase in interest and other income for the three months ended March 31, 2018 compared to the same period in 2017 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.

### **Change in Fair Value of Equity Investment**

With the adoption of ASU 2016-01 on January 1, 2018, as noted above, the change in the fair value of our equity investment in Sienna of approximately \$125,000 has been included in our condensed statements of operations for the three months ended March 31, 2018. No comparable amounts were incurred for the three months ended March 31, 2017. The fair value of our equity investment in Sienna fluctuates based on changes in Sienna's stock price and is therefore subject to volatility that could adversely affect our future operating results.

### **Interest and Other Expense**

Interest and other expense was \$18,000 for the three months ended March 31, 2018, compared to \$21,000 for the same period in 2017. 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, 2018, we had cash, restricted cash, cash equivalents, and current and noncurrent marketable securities of \$103.2 million, compared to \$109.2 million at December 31, 2017. The overall decrease in cash, restricted cash, cash equivalents, and current and noncurrent marketable securities during the three months ended March 31, 2018 was the net result of cash being used for operations, partially offset by proceeds from the sales of common stock under our At Market Issuance Sales Agreement, or the 2015 Sales Agreement, with MLV & Co. LLC, or MLV. 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 the 2015 Sales Agreement with MLV, under which we could elect to issue and sell shares of our common stock having an aggregate offering price of up to \$50 million. Pursuant to the 2015 Sales Agreement, common stock was sold at market prices prevailing at the time of sale through MLV as our sales agent. We paid MLV an aggregate commission rate equal to up to 3.0% of the gross proceeds of the sales price per share for common stock sold through MLV under the 2015 Sales Agreement. In the first quarter of 2018, we sold an aggregate of 776,788 shares of our common stock under the 2015 Sales Agreement, resulting in net cash proceeds to us of approximately \$1.6 million after deducting sales commissions and offering expenses payable by us. In April 2018, we completed the sale of the remaining common stock subject to the 2015 Sales Agreement and issued an aggregate of 12,418,318 shares of our common stock, resulting in net cash proceeds to us of approximately \$46.1 million after deducting sales commissions and offering expenses payable by us. Under the 2015 Sales Agreement, we sold a cumulative total of 13,809,336 shares of our common stock resulting in net cash proceeds to us of approximately \$48.7 million after deducting sales commissions and offering expenses payable by us. No further shares of common stock may be sold under the 2015 Sales Agreement. We expect the net cash proceeds to provide additional capital structure flexibility to potentially support: (i) the future development of imetelstat in collaboration with Janssen, if Janssen elects to continue the collaboration, including potentially conducting one or more independent development plans, or IDPs, under the Collaboration Agreement; (ii) the further development of imetelstat by Geron in the event the collaboration with Janssen does not continue and we elect to continue development of imetelstat; or (iii) prospective in-licenses or

acquisitions of other oncology products, programs or companies to diversify our business. The amounts and timing of our use of the net cash proceeds will depend on a number of factors, such as the timing and progress of the imetelstat development program under the Collaboration Agreement with Janssen or on our own, the timing and progress of any potential acquisition or in-licensing efforts and the availability and cost of other capital.

We may need additional capital resources in order to support the development and commercialization of imetelstat, especially if Janssen makes a negative Continuation Decision and we choose to develop imetelstat on our own, or if Janssen makes an affirmative Continuation Decision and we elect to exercise our U.S. Opt-In Rights under the Collaboration Agreement and potentially independently pursue imetelstat development under our own 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 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 on our own;
- further changes or delays in Janssen's development plans for imetelstat, including changes to or further expansion of or delays in ongoing clinical trials decided upon by Janssen or required by regulatory authorities, such as clinical holds or other requirements, or any other factors;
- the achievement of development, regulatory and sales milestones resulting in payments to us from Janssen under the Collaboration Agreement and the timing of receipt of such payments, if any;
- 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;
- in the event that Janssen provides an affirmative Continuation Decision to us, whether we then exercise 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;
- 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 United States Food and Drug Administration, or 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 for imetelstat;
- the availability of coverage and 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;
- the progress, timing, magnitude, scope and costs of clinical development, manufacturing and commercialization of any acquired or in-licensed oncology products, product candidates, programs, or companies, including the number of indications being pursued, subject to clearances and approvals by the FDA and other regulatory authorities;
- expenses associated with 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 choose to continue the development of imetelstat on our own, which would require us to raise substantial 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, 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:

- further changes or delays in Janssen's development plans for imetelstat;
- imetelstat failing to meet the criteria determined by Janssen to support an affirmative Continuation Decision;
- assuming an affirmative Continuation Decision, a failure or inability 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, 2018 and 2017 was \$7.4 million and \$7.3 million, respectively. The increase in net cash used in operations for the three months ended March 31, 2018 compared to the same period in 2017 primarily reflects the net result of higher payments for business development expenses, partially offset by lower payments to Janssen in 2018 under the cost-sharing arrangement for imetelstat clinical development.

*Cash Flows from Investing Activities.* Net cash used in investing activities for the three months ended March 31, 2018 was \$2.6 million. Net cash provided by investing activities for the three months ended March 31, 2017 was \$9.4 million. The increase in net cash used in investing activities in 2018 compared to 2017 primarily reflects a higher rate of purchases than maturities of marketable securities in 2018.

*Cash Flows from Financing Activities.* Net cash provided by financing activities for the three months ended March 31, 2018 was \$1.6 million and reflects net cash proceeds from the issuances of common stock under the 2015 Sales Agreement with MLV. See Note 4 on Stockholders' Equity for additional information about the 2015 Sales Agreement with MLV. No comparable amounts were recognized for the three months ended March 31, 2017.

### **Contractual Obligations**

During the three months ended March 31, 2018, 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, 2017.

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

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

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

During the three months ended March 31, 2018, 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, 2017.

### **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.

Beginning January 1, 2018, we implemented Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers*. Although the new revenue standard is not expected to have a material impact on our ongoing revenues, we implemented changes to our processes related to revenue recognition and the control activities within them. These included the development of new policies based on the five-step model provided in the new revenue standard, estimates for sales-based royalties and ongoing review requirements for current agreements related to the probability assessment of achievement of milestones as well as new training.

#### **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

None.

### 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, 2017, 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 COLLABORATION WITH JANSSEN

***We have outlicensed our sole product candidate, imetelstat, to Janssen. If Janssen discontinues the imetelstat program and/or terminates the Collaboration Agreement, our business and business prospects would be severely harmed, and we might cease operations, the development and/or commercialization of imetelstat would be terminated or substantially delayed, and the market price of our common stock would be adversely affected.***

Janssen may terminate the Collaboration Agreement at any time at its sole discretion. If imetelstat fails to meet criteria determined by Janssen to support an affirmative Continuation Decision, or for any other reason, Janssen may discontinue the imetelstat program and terminate the Collaboration Agreement. In this regard, we believe that without an adequate improvement in survival in relapsed or refractory MF in IMbark, with the determination of adequacy to be assessed by Janssen in its sole discretion, Janssen would decide to discontinue the imetelstat program and terminate the Collaboration Agreement.

In addition, Janssen could discontinue the imetelstat program and terminate the Collaboration Agreement at any time and for any reason, irrespective of whether there is data from IMbark suggesting an adequate improvement in survival in relapsed or refractory MF or whether there is sufficient data from the additional patients enrolled in the expanded Part I of IMerge to support the benefit-risk profile of imetelstat in lower risk MDS in the refined target patient population. Any discontinuation of the imetelstat program or 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, and the market price of our common stock would be adversely affected.

If Janssen terminates the Collaboration Agreement:

- we would no longer have the right to receive any milestone payments or royalties under the Collaboration Agreement;
- further development of imetelstat, if any, 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 any;
- we might determine that the commercial potential of imetelstat does not warrant further development of imetelstat by us, in which case the development of imetelstat would cease, which might cause us to cease operations;
- we would need to raise substantial 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;
- if we were to choose to pursue imetelstat development on our own, 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; and

- if we were to choose to pursue imetelstat development on our own, we would need to work collaboratively with Janssen to transfer the imetelstat program back to us, and such a transfer might take significant amounts of time, would be resource intensive and costly, and might not be feasible, in which case the development of imetelstat would likely be significantly delayed or terminated.

***If Janssen does not provide an affirmative Continuation Decision in a timely manner, or at all, our business and business prospects would be severely harmed, the market price of our common stock would be adversely affected 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. In March 2018, the JSC agreed that the protocol-specified primary analysis for IMbark will begin by the end of the second quarter of 2018. As such, we expect the Continuation Decision to occur by the end of the third quarter of 2018. If Janssen terminates IMbark early based on preliminary or ongoing data assessments, safety concerns or for any other reason, or the trial is placed on clinical hold or suspended by a regulatory authority, the protocol-specified primary analysis for IMbark may not take place at all, which would further delay the timing of any Continuation Decision or result in a negative Continuation Decision. Delays in the timing of the Continuation Decision or a negative Continuation Decision from Janssen could increase our development costs and would 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 there are further delays in IMerge or IMbark, Janssen may decide to cease the development of imetelstat and terminate the Collaboration Agreement, and our business and business prospects would be severely harmed.***

The expansion of enrollment in Part 1 of IMerge has prolonged the development of imetelstat in lower risk MDS, and Janssen could decide not to proceed with Part 2 of IMerge. Janssen has made no commitment to commence Part 2 of IMerge. Even if Janssen obtains additional data from the refined target patient population in Part 1 of IMerge, such data may not support the development of imetelstat in the refined target patient population for Part 2. In any event, we believe Janssen will initiate Part 2 only following an affirmative Continuation Decision, if any. Janssen could discontinue the imetelstat program and terminate the Collaboration Agreement at any time, such as, before the start of the IMbark primary analysis, and for any reason, irrespective of whether there is data from IMbark suggesting an adequate improvement in survival in relapsed or refractory MF or whether there is sufficient data from the additional patients enrolled in the expanded Part 1 of IMerge to support the benefit-risk profile of imetelstat in lower risk MDS in the refined target patient population. In this regard, we believe that without an adequate improvement in survival in relapsed or refractory MF, with the determination of adequacy to be assessed by Janssen in its sole discretion, Janssen would decide to discontinue the imetelstat program and terminate the Collaboration Agreement. In addition, delays, including in the commencement of Part 2 of IMerge, could cause Janssen to discontinue the imetelstat development program and terminate the Collaboration Agreement.

For IMbark, although the JSC agreed that the protocol-specified primary analysis will begin by the end of the second quarter of 2018, the primary analysis may not occur on the timing that we expect, or at all, if any of the following occurs:

- Janssen terminates IMbark based on preliminary or ongoing data assessments, safety concerns, feedback or requirements from the FDA or other regulatory authorities, or terminates the Collaboration Agreement;
- the FDA or any other regulatory authority places a clinical hold on or suspends IMbark for any reason;
- Janssen decides that further changes to the trial are necessary;
- additional time is needed to obtain longer-term efficacy and safety data; or
- sufficient efficacy and safety data are not available to assess overall survival.

Even if Janssen obtains longer-term efficacy and safety data for IMbark, Janssen or the FDA or any other regulatory authorities may determine that such data do not show an adequate improvement in survival to support further development and potential regulatory approval of imetelstat in relapsed or refractory MF patients, which we expect would result in a decision by Janssen to discontinue IMbark and the imetelstat program and terminate the Collaboration Agreement. Such termination would severely harm our business and business prospects, adversely affect the market price of our common stock and could cause us to cease operations. In addition, the time needed to obtain longer-term efficacy and safety data for IMbark, including sufficient data to assess overall survival, could significantly further delay the development of imetelstat in MF and in lower risk MDS, and the timing of a Continuation Decision, if any.

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

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

- the development of imetelstat could be further delayed, perhaps substantially, depending on: the time needed to collect sufficient efficacy and safety data from the expanded Part 1 of IMerge to assess the clinical benefit, if any, of imetelstat in the refined target patient population of Part 1; the time needed to obtain longer-term efficacy and safety data for IMbark, including sufficient data to conduct the protocol-specified primary analysis, which would include an assessment of overall survival in IMbark; and any feedback or other actions relating to past and potential future information requests from the FDA or other regulatory authorities;
- 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, including if Janssen believes that there is not an adequate improvement in survival in relapsed or refractory MF in IMbark, which would likely result in a termination of the Collaboration Agreement by Janssen at any time, or a negative Continuation Decision;
- Janssen may choose to terminate the Collaboration Agreement for any reason;
- 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 observe additional or new 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 conclude that the commercial potential of imetelstat does not meet Janssen's internal thresholds or yield a timely return on its investment in imetelstat, either of which would cause Janssen to reconsider continued development of imetelstat, and could result in a renegotiation or a termination of the Collaboration Agreement by Janssen, and if we were to agree to renegotiated terms and Janssen were to continue development of imetelstat, the potential milestone payments and royalties we may receive under such renegotiated agreement would likely be less than the potential milestone payments and royalties under the current Collaboration Agreement;
- Janssen may choose not to develop and commercialize imetelstat in certain, or any, markets or for one or more indications, if at all;
- Janssen may 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 change the focus of its development or commercialization efforts or prioritize other programs more highly and, accordingly, reduce the efforts and resources allocated to imetelstat, which might delay or halt the development or commercialization of imetelstat, and would have the direct effect of delaying milestone payments or 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 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 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;
- 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 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 for Janssen and reduced royalties for us;

- 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;
- 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’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; 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, the future of imetelstat, and the market price of our common stock 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, or at all, the clinical development, manufacturing, regulatory approval and/or commercialization of imetelstat could be further 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, and commercialization assumptions or criteria set by Janssen for the continued development and commercialization 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.

***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 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.

## **RISKS RELATED TO CLINICAL DEVELOPMENT, REGULATORY APPROVAL AND COMMERCIALIZATION OF IMETELSTAT**

***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 is 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 further 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;
- Janssen's decisions 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; and
- Janssen's decision in the third quarter of 2017 to expand enrollment in Part 1 of IMerge to include approximately 20 additional lower risk MDS patients in a refined target population.

Any further delay, suspension or abandonment of the development of imetelstat in hematologic myeloid malignancies, including delays resulting from potential future protocol amendments for IMerge, IMbark or potential future clinical trials of imetelstat, 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.

***Imetelstat may cause, or have attributed to it, undesirable or unintended side effects or other adverse events 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.***

Imetelstat may cause, or have attributed to it, undesirable or unintended side effects or other adverse events affecting its safety or efficacy that could cause Janssen to interrupt, delay or halt current or potential future clinical trials of imetelstat. For example, adverse events and dose limiting toxicities observed in previous clinical trials of imetelstat include:

- hematologic toxicities, such as profound and/or prolonged thrombocytopenia or neutropenia, including one case of febrile neutropenia after prolonged myelosuppression with intracranial hemorrhage resulting in patient death, which the investigator assessed as possibly related to imetelstat;
- bleeding events, with or without thrombocytopenia;
- liver function test, or LFT, abnormalities, the clinical significance and long-term consequences of which are currently undetermined;
- gastrointestinal events;
- infections;
- muscular and joint pain;
- fatigue; and
- infusion reactions.

Such adverse 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, or new or unusual adverse events, or if the FDA or other regulatory authorities determine that efficacy and safety data in current or potential future clinical trials of imetelstat, do not support an adequate benefit-risk profile to justify continued treatment of patients, then the FDA or other regulatory authorities may again place the investigational new drug applications, or INDs, for imetelstat on clinical hold, as occurred in March 2014.

Further, 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 IMbark and IMerge, including the expanded Part 1, additional or more severe toxicities or safety issues, including additional serious adverse events and dose limiting toxicities, may be observed as patient treatment continues and more data become available. In addition, since IMbark and IMerge 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 with or without any associated thrombocytopenia, patient injury or death, 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 are determined by Janssen, the FDA or any other regulatory authority to result in an unacceptable benefit-risk profile, then:

- additional information supporting the benefit-risk profile of imetelstat may be requested by the FDA or other regulatory authorities and if any such information supplied by Janssen is not deemed acceptable, current clinical trials of imetelstat could be suspended, terminated, or placed on clinical hold by the FDA or other regulatory authorities;



- patient recruitment and the ability to retain enrolled patients in current clinical trials may be negatively affected, resulting in incomplete data sets and the inability to adequately assess the benefit-risk profile of imetelstat in a specific patient population, such as the inability to assess overall survival in IMbark or the benefit-risk profile of imetelstat in the refined target patient population in Part 1 of IMerge; 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 further 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.

***Success in early clinical trials may not be predictive or indicative of results in current 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 a pilot study of imetelstat in patients with MF conducted at Mayo Clinic, or the Pilot Study, as well as the results of the past or future internal 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 IMbark or IMerge or the Pilot Study, or the results in potential subsequent or larger-scale clinical trials of imetelstat. The results we obtained from a Geron-sponsored Phase 2 trial of imetelstat in patients with ET, or the ET Trial, and the Pilot Study, and the results that have been obtained by Janssen in the internal data reviews conducted for IMbark and IMerge to date, as well as any future results that may be obtained by Janssen from IMbark and IMerge, may not predict the future therapeutic effect of imetelstat, if any, in hematologic myeloid malignancies, including MF and MDS. For example, the potential disease-modifying activity observed through molecular responses in the ET trial and partial or complete remissions observed in the Pilot Study may not be seen in current or future clinical trials of imetelstat. Since remaining patients in the treatment phase for IMbark, IMerge, including the expanded Part 1 of IMerge, continue to receive imetelstat, efficacy and safety data continue to be generated. Such additional and updated data may materially change the overall conclusions from the preliminary data reviewed or reported for IMbark or IMerge. In addition, such additional and updated efficacy and safety data may not support an adequate benefit-risk profile to justify continued treatment of patients enrolled in current clinical trials of imetelstat. Moreover, we have not presented specific data from IMbark or IMerge, apart from preliminary data from Part 1 of IMerge that was announced in November 2017 and presented at the American Society of Hematology, or ASH, annual meeting in December 2017, and have no plans to do so prior to a Continuation Decision from Janssen, at the earliest, particularly in light of the current focus on the assessment of overall survival in relapsed or refractory MF in IMbark. In this regard, we believe that without an adequate improvement in survival in relapsed or refractory MF in IMbark, with the determination of adequacy to be assessed by Janssen in its sole discretion, Janssen would decide to discontinue the imetelstat program and terminate the Collaboration Agreement. 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.

From time-to-time, preliminary or interim data from current or prior clinical trials, such as IMbark, IMerge or the Pilot Study, 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 ASH annual meeting in December 2013, and updated by the investigator at the ASH annual meeting in December 2014, and preliminary data were reported by the investigator from a cohort of MDS patients in the Pilot Study in December 2015. In addition, preliminary data from Part 1 of IMerge was announced in November 2017 and presented at the ASH annual meeting in December 2017. Since such data are preliminary, the final data from any final analysis which may be conducted, or any future analyses of IMbark, IMerge or the Pilot Study, or potential future clinical trials of imetelstat, may be materially different. In addition, changes in study design, including changes in patient enrollment criteria and target patient population, such as the decision to expand enrollment in Part 1 of IMerge for patients in a refined target population, may cause data from later stage clinical trials to differ significantly from data obtained in earlier clinical trials. Preliminary or interim results from IMbark, IMerge or the Pilot Study reported by us, Janssen or by investigators in those trials 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.

Material adverse differences in final data, compared to preliminary or interim data, from IMbark, IMerge or the Pilot Study, or potential future clinical trials of imetelstat, could result in a decision by Janssen to discontinue the imetelstat program, further delay its Continuation Decision, or terminate 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. Even if final safety and/or efficacy data from IMbark, IMerge or the Pilot Study 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.

***Clinical development involves a lengthy and expensive process with uncertain outcomes. Current clinical trials of imetelstat being conducted by Janssen and potential future clinical trials of imetelstat may fail to demonstrate sufficient safety and efficacy of imetelstat to warrant further development of the drug, which could prevent or further delay regulatory approval and commercialization of imetelstat.***

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 and potential future clinical trials of imetelstat. The advancement of current clinical trials of imetelstat and commencement of potential future clinical trials of imetelstat could be further delayed or abandoned for a variety of reasons, including as a result of failures or delays by Janssen in:

- demonstrating an adequate improvement in survival in relapsed or refractory MF in IMbark;
- otherwise 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 in the United States or other countries to conduct clinical trials, such as obtaining or maintaining regulatory clearances to commence, conduct or modify current or potential future clinical trials of imetelstat, in a timely manner, or at all;
- maintaining the INDs for imetelstat without such INDs being placed on full or partial clinical hold, suspended or subject to other requirements by the FDA or other regulatory authorities;
- properly designing, enrolling, conducting or completing: (i) IMerge, including collecting sufficient efficacy and safety data from the expanded Part 1 to assess the benefit-risk profile of imetelstat in the refined target patient population; and (ii) IMbark, by collecting longer-term efficacy and safety data to enable an assessment of overall survival, 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 severe cytopenias, hepatotoxicity, fatal bleeding with or without any associated thrombocytopenia, patient injury or death, or other safety issues, 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 successfully implementing any such manufacturing changes;
- 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 future protocol amendments which may be sought for IMbark, IMerge and potential future clinical trials of imetelstat; and
- obtaining institutional review board or ethics committee approval of clinical trial protocols or protocol amendments, including any future refinements to the trial design sought for Part 1 and Part 2, if any, of IMerge, or any potential protocol amendments for IMbark.

Failures or delays with respect to any of these events could adversely affect Janssen's ability to continue or successfully complete any current clinical trials of imetelstat or to initiate potential future clinical trials of imetelstat, which could increase development costs, further 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.

***If Janssen encounters difficulties enrolling or retaining patients in current or potential future clinical trials of imetelstat, including the expanded Part 1 of IMerge, clinical development and commercialization activities could be further delayed or otherwise adversely affected, which would cause our business and business prospects to 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 trial until its conclusion. Janssen may experience difficulties in patient enrollment or retention in IMbark and IMerge, including the expanded Part 1 of 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 trial 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 of 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 any imetelstat clinical trial will drop out of the trial before completion due to lack of efficacy, adverse side effects, 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 imetelstat clinical trials.

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 current or potential future clinical trials of imetelstat, which could prevent

completion of these trials and adversely affect the clinical development and commercialization of imetelstat. For example, delays in or the inability to collect sufficient safety and efficacy data from the expanded Part 1 of IMerge will delay or potentially preclude an assessment of clinical benefit, if any, in the refined target patient population in Part 1. For IMbark, if the data necessary for the protocol-specified primary analysis 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 overall survival in IMbark. If Janssen is unable to assess overall survival in IMbark or believes there is not an adequate improvement in survival, we believe Janssen would decide to discontinue the imetelstat program and terminate the Collaboration Agreement. However, Janssen could discontinue the imetelstat program and terminate the Collaboration Agreement at any time and for any reason, irrespective of whether there is data from IMbark suggesting an adequate improvement in survival in relapsed or refractory MF or whether there is sufficient data from the additional patients enrolled in the expanded Part 1 of IMerge to support the benefit-risk profile of imetelstat in lower risk MDS in the refined target patient population. 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.

***Obtaining regulatory clearances and approvals to continue clinical development of, and in the future, to 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 Janssen or us, in collaboration with Janssen, from successfully conducting development efforts or from commercializing imetelstat. Delays in obtaining regulatory clearances and approvals or limitations in the scope of such clearances or approvals could:

- cause Janssen to terminate the Collaboration Agreement;
- 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.

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 and adequate manner. The inability to timely or adequately address any questions, comments or requests for information from regulatory authorities could impede further clinical development of imetelstat, which could cause Janssen to further 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 Janssen or us 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.

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 Janssen and us, who may seek to obtain regulatory approval for drug products in the European Union or the United Kingdom. Likewise, the Trump Administration has appointed and employed 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.

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 for Janssen 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.

***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 imetelstat sales revenue for Janssen, 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 December 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. The occurrence of any of these events could result in decreased sales for Janssen 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.

***A fast track designation by the FDA, such as the Fast Track designation received for imetelstat, does not guarantee approval and may not lead to a faster development, regulatory review or approval process.***

In October 2017, following submission by Janssen of an application to the FDA requesting fast track designation for the imetelstat clinical development program for the treatment of adult patients with transfusion-dependent anemia due to Low or Intermediate-1 risk MDS who are non-del(5q) and who are refractory or resistant to treatment with an ESA, the FDA notified Janssen

that imetelstat has been granted such fast track designation. Fast track designation provides opportunities for frequent interactions with FDA review staff, as well as eligibility for priority review, if relevant criteria are met, and rolling review. Fast track designation is intended to facilitate and expedite development and review of a New Drug Application to address unmet medical needs in the treatment of serious or life-threatening conditions. However, fast track designation does not accelerate conduct of clinical trials or mean that the regulatory requirements are less stringent, nor does it ensure that imetelstat will receive marketing approval or that approval will be granted within any particular timeframe. In addition, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data emerging from the imetelstat clinical development program.

***Failure to achieve continued compliance with government regulations 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 are or Janssen is unable to comply with these regulations, our ability to earn potential milestone payments and royalties from worldwide net sales of imetelstat would be materially and adversely impacted.

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

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

The imposition of any of these penalties or other commercial limitations could negatively impact our collaboration with Janssen or cause Janssen to terminate the Collaboration Agreement, either of which would severely and adversely affect our financial results, business and business prospects, and the future of imetelstat, and might cause us to cease operations.

#### **RISKS RELATED TO MANUFACTURING IMETELSTAT**

***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.

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. If Janssen were to terminate the Collaboration Agreement, and we chose to pursue imetelstat development on our own, we would be reliant upon Janssen for the manufacture and supply of adequate clinical quantities of imetelstat or other clinical trial materials, until such time as we could establish our own independent third-party manufacturers or suppliers, which might not be feasible for a significant period of time, and could significantly delay our ability to further develop imetelstat on our own. Any such failure by Janssen to supply imetelstat or other clinical trial materials for clinical trials and/or commercial activities, including to us in the event that the Collaboration Agreement was terminated, 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 for Janssen 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 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 numerous risks, including:

- being unable to identify suitable third-party manufacturers, because the number of potential manufacturers is limited and regulatory authorities may require significant activities to validate and qualify any replacement manufacturer, which could involve new testing and compliance inspections;
- being unable to contract with third-party manufacturers on acceptable terms, or at all;
- the inability of third-party manufacturers to timely formulate and manufacture imetelstat or to produce imetelstat in the quantities or of the quality required to meet clinical and commercial needs;
- decisions by third-party manufacturers to exit the contract manufacturing business during the time required to supply clinical trials or to successfully produce, store and distribute products;
- compliance by third-party manufacturers with current Good Manufacturing Practice, or cGMP, standards mandated by the FDA and state agencies and other government regulations corresponding to foreign regulatory authorities;
- breach or termination of manufacturing contracts;
- capacity limitation and scheduling imetelstat as a priority in contracted facilities; and
- natural disasters that affect contracted facilities.

Each of these risks could lead to delays 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 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 further 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. To our knowledge, Janssen currently does not have any long-term commitments or commercial supply agreements with any of the third-party contractors for imetelstat. Changing manufacturers by Janssen 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.

If Janssen were to make a negative Continuation Decision and if we were to choose to pursue imetelstat development on our own, we would need to rely on third-party contractors for the manufacture of imetelstat. Since Janssen is currently responsible for the manufacture and management of the supply of imetelstat, we currently have no arrangements with other third parties for the manufacture of imetelstat, which could substantially delay our ability to pursue imetelstat development on our own, increase our costs and otherwise negatively affect our financial results, business and business prospects. In any event, we cannot assure that we would be able to obtain third party manufacturers for imetelstat on acceptable terms, or at all, if Janssen were to make a negative Continuation Decision and we were to choose to pursue imetelstat development on our own.

***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 for Janssen 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.

## **RISKS RELATED TO MANAGING OUR GROWTH AND OTHER BUSINESS 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.

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 such 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, including risks related to intellectual property, research, manufacturing, regulatory approval and/or commercialization. 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 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, or employing personnel and managing facilities in multiple locations, including potentially outside of the U.S.;
- 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.

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

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. In addition, if we acquire or in-license new products, product candidates, programs or companies as a result of our business development efforts, we may not be able to successfully retain or recruit any executive officers or key staff members knowledgeable about such new products, product candidates, programs or companies. 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 or attract or assimilate

other highly qualified management and development personnel in the future on acceptable terms, our ability to support the Collaboration Agreement with Janssen and any future growth could be impaired, and our business and the price of our common stock would be adversely impacted.

***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 Janssen makes an affirmative Continuation Decision and 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 U.S. Co-Promotion Option, we will need to negotiate this separate agreement with Janssen and, as a result, Janssen may impose restrictions or additional obligations on us, including financial obligations. Any restrictions or additional obligations may restrict our co-promotion activities or involve more significant financial or other obligations than we currently anticipate. In addition, we have no sales experience as a company, and there are risks involved with establishing our own sales force capabilities, including:

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

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

***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 on our own, 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.

***We have been, and may in the future be, involved in securities-related legal actions that are expensive and time consuming. Any securities-related legal actions, 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 were 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 transferred to the California District Court. These three cases, or the Class Action Lawsuits, were consolidated for all purposes and settled in July 2017. In connection with the settlement, in April 2017, we paid \$250,000 and our insurance providers paid \$6.0 million to a settlement escrow account to be paid to members of the settlement class, less payment of attorneys' fees and costs to plaintiff's counsel.

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 alleged matters. Monitoring, initiating and defending against legal actions is time-consuming for our management, is likely to be expensive and may detract from our ability to fully focus our internal resources on our business activities. 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, including securities-related litigation, if the results of our business and collaboration activities are not successful, and such litigation would 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.

On November 13, 2014, we announced that we had entered into the Collaboration Agreement with Janssen. We may face litigation arising from or related to the Collaboration Agreement or the transactions contemplated thereby, including the outcome of Janssen's Continuation Decision or if we are unable to generate substantial value under the Collaboration Agreement with Janssen or such collaboration is otherwise unsuccessful. 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 an affirmative 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.

The Collaboration Agreement could also 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 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, for example, if:

- we receive a negative Continuation Decision from Janssen or Janssen otherwise terminates the Collaboration Agreement;
- 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, including if Janssen is unable to assess overall survival in IMbark or believes there is not an adequate improvement in survival in IMbark;
- serious adverse events are encountered in current and potential future clinical trials of imetelstat; or
- in the event that we acquire and/or in-license other oncology products, product candidates, programs or companies, we do not achieve the perceived benefits of any such transaction as rapidly or to the extent anticipated by financial analysts or investors, or any such transaction is otherwise unsuccessful;

our stock price would decline significantly, and future litigation may result. In addition, allegations and statements have been made, and may again in the future be made, in lawsuits, blogs, articles, advertisements by law firms seeking plaintiffs, and other media related to the scope, nature and timing of our disclosures related to efficacy or safety data observed in current and potential future clinical trials of imetelstat, the duration and nature of follow-up of patients, or any other activities conducted by Janssen or us in current and potential future clinical trials of imetelstat, any of which could cause our stock price to decline significantly and subject us to litigation.

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.

#### **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 for Janssen 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.

***Changes in U.S. or foreign patent law or interpretations of such patent laws could diminish the value of our patents in general, thereby impairing our ability to protect our technologies and imetelstat.***

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.

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.

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 examined 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, the AIA limits where a patentee may file a patent infringement suit. 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.

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 *BRCAl- & 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.

In addition, in June 2016, the electorate of the United Kingdom voted to exit the European Union, and in March 2017 the Government of the United Kingdom initiated the formal procedure of withdrawal from the European Union. While the exit of the United Kingdom from the European Union is planned to be completed in 2020, the exact timing of the withdrawal and the resulting effect of withdrawal will not be known for some time, which could lead to a period of considerable uncertainty relating to our ability to obtain and maintain Supplementary Protection Certificates (SPCs) of our products based on our United Kingdom patents and our ability to establish and maintain European trademarks in the United Kingdom.

Depending on decisions by the U.S. federal courts, the U.S. Patent and Trademark Office, or the Patent Office, and similar authorities in foreign jurisdictions, 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 and/or 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.

***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. 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. 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. 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.

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 unsuccessful or are unable to commit these types of resources to protect our imetelstat patent rights, we could lose our patent rights and 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.

***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 the development of imetelstat continues to progress, we expect to see more efforts by others to obtain patents that are positioned to cover imetelstat. Our success therefore depends significantly on our and Janssen's ability to operate without infringing patents and the proprietary rights of others.

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

***We may become involved in disputes with Janssen or any past or future collaborator(s) over intellectual property inventorship or ownership, and publications by us or Janssen, or by investigators, scientific consultants, 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 our 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, and those of our collaborators and contractors, 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, as well as those of our collaborators and contractors, are potentially vulnerable to data security breaches, whether by employees or others, that may expose sensitive data or personal information to unauthorized persons. Effective May 25, 2018, the European Union, or EU, will implement the General Data Protection Regulation, or GDPR, a broad data protection framework that expands the scope of current EU data protection law to non-European Union entities that process, or control the processing of, the personal information of EU subjects, including clinical trial data. The GDPR allows for the imposition of fines and/or corrective action on entities that improperly use or disclose the personal information of EU subjects, including through a data security breach. Accordingly, data security breaches experienced by us, our collaborators or contractors could lead to significant fines, required corrective action, the loss of trade secrets or other intellectual property, 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 fines, increased costs or loss of revenue as a result of:

- harm to our reputation;
- fines imposed on us by regulatory authorities;
- additional compliance obligations under federal, state or foreign 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, 2018, our accumulated deficit was approximately \$991.6 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 potential 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 potential 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 the development and commercialization of imetelstat, especially if Janssen makes a negative Continuation Decision and we choose to develop imetelstat on our own, or if Janssen makes a positive Continuation Decision and 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 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 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 on our own;
- further changes or delays in Janssen's development plans for imetelstat, including changes to or further expansion of or delays in ongoing clinical trials decided upon by Janssen or required by regulatory authorities, such as clinical holds or other requirements, or any other factors;
- the achievement of development, regulatory and sales milestones resulting in payments to us from Janssen under the Collaboration Agreement and the timing of receipt of such payments, if any;
- 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;
- 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;
- 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 for imetelstat;
- the availability of coverage and 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;
- the progress, timing, magnitude, scope and costs of clinical development, manufacturing and commercialization of any acquired or in-licensed oncology products, product candidates, programs, or companies, including the number of indications being pursued, subject to clearances and approvals by the FDA and other regulatory authorities;
- expenses associated with 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 on our own, which would require us to raise substantial 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, 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:

- further changes or delays in Janssen's development plans for imetelstat;
- imetelstat failing to meet the criteria determined by Janssen to support an affirmative Continuation Decision;
- assuming an affirmative Continuation Decision, a failure or inability to show adequate safety or efficacy of imetelstat in 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.

***The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.***

On December 22, 2017, President Trump signed into law new legislation that significantly revises the Internal Revenue Code of 1986, as amended, or the Code. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%; limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses); limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks; one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated; immediate deductions for certain new investments instead of deductions for depreciation expense over time; and modifying or repealing many business deductions and credits (including reducing

the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions). Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

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

Our net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the newly enacted federal income tax law, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. It is uncertain if and to what extent various states will conform to the newly enacted federal tax law. In addition, under Section 382 of the Code, and corresponding provisions of state law, 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.

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

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

Historically, our stock price has been extremely volatile. Between April 1, 2008 and March 31, 2018, our stock has traded as high as \$9.24 per share and as low as \$0.91 per share. Between April 1, 2015 and March 31, 2018, the price has ranged between a high of \$6.68 per share and a low of \$1.74 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:

- announcements regarding the research and development of imetelstat, including results of, further delays in, discontinuation of, or further modifications or refinements to any clinical trials of imetelstat as a result of any internal data reviews or decisions by joint governance committees, and investor perceptions thereof;
- 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 IMerge, IMark or any future clinical trial of imetelstat;
- developments in our collaboration with Janssen, including the termination, modification or amendment of the Collaboration Agreement, or disputes regarding the collaboration;
- announcements regarding the safety of imetelstat;
- 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 or other third parties, including blogs, articles and other media;
- large stockholders exiting their position in our common stock or an increase in the short interest in our common stock;
- announcements of or developments concerning 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.

***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.\****

As of April 30, 2018, we had 300,000,000 shares of common stock authorized for issuance and 173,080,653 shares of common stock outstanding. In addition, we had reserved 30,036,149 shares of our common stock for future issuance pursuant to our option and equity incentive plans and outstanding warrants as of April 30, 2018. 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, of which \$200 million remains as a result of the full use of the 2015 Sales Agreement with MLV in 2018.

Future sales of our common stock or the perception that such sales could occur 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. The sale or issuance of our securities, as well as the existence of outstanding options and shares of common stock reserved for issuance under our option and equity incentive plans and outstanding warrants, also may adversely affect the terms upon which we are able to obtain additional capital through the sale of equity securities, which could negatively affect the market price of our common stock and the return on your investment.

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

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

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

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

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

- prevent stockholders from taking actions by written consent;
- divide the board of directors into separate classes with terms of office that are structured to prevent all of the directors from being elected in any one year; and
- set forth procedures for nominating directors and submitting proposals for consideration at stockholders' meetings.

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

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

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

***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.

## **RISKS RELATED TO COMPETITIVE FACTORS**

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

The pharmaceutical and biotechnology industries are intensely competitive. Other pharmaceutical and biotechnology companies and research organizations currently engage in or have in the past engaged in efforts related to the biological mechanisms related to imetelstat, the study of telomeres, telomerase, or our proprietary oligonucleotide chemistry, and the research and development of therapies for the treatment of hematologic myeloid malignancies. In addition, other products and therapies that could directly compete

with imetelstat currently exist or are being developed by pharmaceutical and biopharmaceutical companies and by academic institutions, government agencies and other public and private research organizations. We expect Janssen's decisions regarding continued development and/or commercialization, if any, of imetelstat, including completing IMerge and/or IMbark, its Continuation Decision or the termination of the Collaboration Agreement, to be informed in part by what Janssen believes is the estimated commercial potential of imetelstat for the treatment of hematologic malignancies, such as MF or MDS.

Many companies are developing alternative therapies to treat hematologic myeloid malignancies. For example, if approved for commercial sale for the treatment of MF, imetelstat would compete against Incyte Corporation's ruxolitinib, or Jakafi®, which is orally administered. In clinical trials, Jakafi® reduced spleen size, abdominal discomfort, early satiety, bone pain, night sweats and itching in MF patients. Recently, there have also been reports of overall survival benefit as well as improvement in bone marrow fibrosis from Jakafi® treatment. Other treatment modalities for MF include hydroxyurea for the management of splenomegaly, leukocytosis, thrombocytosis and constitutional symptoms; splenectomy and splenic irradiation for the management of splenomegaly and co-existing cytopenias, or low blood cell counts; chemotherapy and pegylated interferon. Drugs for the treatment of MF-associated anemia include erythropoiesis stimulating agents, androgens, danazol, corticosteroids, thalidomide and lenalidomide. There are other investigational treatments for MF further along in development than imetelstat, such as pacritinib by CTI Biopharma Corporation, or CTI Biopharma, and fedratinib by Impact Biomedicines, Inc., acquired by Celgene Corporation, or Celgene, 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; 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 inhibitors, such as tosedostat by CTI Biopharma; TLR2-specific antibodies; anti-CD33 antibodies; anti-CD38 antibodies, such as daratumumab by Genmab A/S in collaboration with Janssen; anti-CD123 antibodies, such as talacotuzumab by Janssen; retinoic acid receptor alpha agonists, such as SY-1425 by Syros Pharmaceuticals; hypoxia-inducible factor prolyl hydroxylase inhibitors, such as roxadustat by FibroGen, Inc.; 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 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 coverage and level of reimbursement;
- 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 country and/or regions within 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 coverage, adequate reimbursement and pricing by government and third-party payors; and
- the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors, including governmental authorities.

The established use of conventional products competitive with imetelstat may limit or preclude the potential for imetelstat to receive market acceptance upon any commercialization. Janssen may be unable to demonstrate any pharmacoeconomic advantage for imetelstat compared to established or standard-of-care therapies, or newly developed therapies, for hematologic myeloid malignancies. Third-party payors may decide that any potential improvement that imetelstat may provide to clinical outcomes in hematologic myeloid malignancies is not adequate to justify the costs of treatment with imetelstat. If 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 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 payors, such as the Medicare and Medicaid programs, 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. 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. 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, which would negatively impact our business and business prospects.

***The adoption of health policy changes and health care reform in the United States may adversely affect our business and financial results.***

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 is funded 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.

While the Supreme 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. Since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed repeal legislation, the Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate”. Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees. Congress may consider additional legislation to repeal or repeal and replace other elements of the ACA. Therefore, we cannot assume that the ACA, as currently enacted or as amended in the future, or any legislation that may replace, or repeal other elements of 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, due to subsequent legislative amendments to the statute, including the Bipartisan Budget Act of 2018, will stay in effect through 2027 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 in light of the rising cost of prescription drugs and biologics. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted legislation 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, some of which are included in the Trump administration's budget proposal for fiscal year 2019. At the federal level, Congress and the Trump Administration have each indicated that they will continue to seek new legislative and/or administrative measures to control drug costs. 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. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biologic product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, to encourage importation from other countries and bulk purchasing. 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.

***If we fail to comply with federal, state and foreign 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, including prescription drug manufactures (or a party acting on its behalf), from knowingly and willfully, directly or indirectly, 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, lease or recommendation of, any good, facility, item or service for which payment may be made under a federal healthcare program such as Medicare and Medicaid. The term "remuneration" has been broadly interpreted to include anything of value. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the federal Anti-Kickback Statute has been violated. The ACA, among other things, amended the intent requirement of the federal Anti-Kickback Statute such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate, in order to commit a violation;
- the federal civil and criminal false claims and civil monetary penalties laws, including the federal 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. Entities can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers, promoting a product

off-label, or for providing medically unnecessary services or items. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false or fraudulent statements in connection with the delivery of or payment for healthcare benefits, items or services;
- 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, with respect to safeguarding the privacy, security, transmission and breach reporting of individually identifiable health information, upon entities subject to the law, such as health plans, healthcare clearinghouses and certain healthcare providers and their respective business associates that perform services for them that involve individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- 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 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; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information, including the GDPR, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our current and future business arrangements will comply with applicable healthcare, privacy and data security laws and regulations will involve substantial costs. For example, the GDPR, which will be effective on May 25, 2018, will impose several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third party processors in connection with the processing of personal data. The GDPR will also impose strict rules on the transfer of personal data out of the EU to the United States, will provide an enforcement authority and will impose large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. The GDPR will increase our responsibility and liability in relation to personal data that we process or control, including in clinical trials, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, which could divert management's attention and increase our cost of doing business. In any event, 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 or privacy laws, in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. If our operations are found to be in violation of any of these or any other healthcare and privacy-related 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, 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.

**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**

Exhibit Number	Description	Incorporation by Reference			
		Exhibit Number	Filing	Filing Date	File No.
10.1	<a href="#">Second Amendment to Employment Agreement between the Registrant and John A. Scarlett, M.D., effective as of January 31, 2018 *</a>	10.1	8-K	February 2, 2018	000-20859
10.2	<a href="#">Non-Employee Director Compensation Policy, as amended January 31, 2018 *</a>	10.31	10-K	March 16, 2018	000-20859
31.1	<a href="#">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 10, 2018</a>				
31.2	<a href="#">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 10, 2018</a>				
32.1	<a href="#">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 10, 2018 **</a>				
32.2	<a href="#">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 10, 2018 **</a>				
101	The following materials from the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2018 formatted in Extensible Business Reporting Language (XBRL) include: (i) Condensed Balance Sheets as of March 31, 2018 and December 31, 2017, (ii) Condensed Statements of Operations, Comprehensive Loss and Cash Flows for the three months ended March 31, 2018 and 2017 and (iii) Notes to Condensed Financial Statements				

\* Management contract or compensation plan or arrangement.

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

**SIGNATURE**

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

GERON CORPORATION

Date: May 10, 2018

By: /s/ OLIVIA K. BLOOM

OLIVIA K. BLOOM

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

**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 10, 2018

/s/ JOHN A. SCARLETT

JOHN A. SCARLETT, M.D.

*President and Chief Executive Officer*

**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 10, 2018

/s/ OLIVIA K. BLOOM

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OLIVIA K. BLOOM

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

**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, 2018 (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 10, 2018

/s/ JOHN A. SCARLETT

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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.

**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, 2018 (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 10, 2018

/s/ OLIVIA K. BLOOM

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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.



