GERON CORP
Form 10-Q
November 01, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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

GERON CORPORATION

(Exact name of registrant as specified in its charter)

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

(650) 473-7700

(Registrant's telephone number, including area code)

N/A

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). Yes No

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

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company
Emerging growth company	

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

Exchange Act.

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

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

Class:	Outstanding at October 25, 2018:
Common Stock, $0.001 par value	186,348,066 shares

GERON CORPORATION

QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTER ENDED SEPTEMBER 30, 2018

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PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED FINANCIAL STATEMENTS (UNAUDITED)
GERON CORPORATION

CONDENSED BALANCE SHEETS

(IN THOUSANDS)

	SEPTEMBER 30, 2018 (UNAUDITED)	DECEMBER 31, 2017 (NOTE 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 12,729	$ 16,335
Restricted cash	269	268
Marketable securities	153,622	78,351
Interest and other receivables	778	436
Prepaid assets	1,476	580
Total current assets	168,874	95,970
Noncurrent marketable securities	18,143	14,241
Property and equipment, net	66	102
Other assets	851	-
	$ 187,934	$ 110,313
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 190	$ 503
Accrued compensation and benefits	1,833	3,385
Accrued collaboration charges	1,560	1,702
Other accrued liabilities	884	926
Total current liabilities	4,467	6,516
Commitments and contingencies		
Stockholders' equity:		
Common stock	186	160
Additional paid-in capital	1,187,557	1,089,684
Accumulated deficit	(1,004,164)	(985,840)
Accumulated other comprehensive loss	(112)	(207)
Total stockholders' equity	183,467	103,797
	$ 187,934	$ 110,313

See accompanying notes.

GERON CORPORATION

CONDENSED STATEMENTS OF OPERATIONS

(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)

(UNAUDITED)

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2018	2017	2018	2017
Revenues:				
License fees and royalties	$165	$163	$691	$874
Operating expenses:				
Research and development	2,707	2,637	8,351	8,510
General and administrative	4,263	4,770	13,824	13,833
Total operating expenses	6,970	7,407	22,175	22,343
Loss from operations	(6,805)	(7,244)	(21,484)	(21,469)
Interest and other income	1,060	363	2,171	1,041
Change in fair value of equity investment	205	-	(270)	-
Other expense	(57)	(18)	(134)	(59)
Net loss	$(5,597)	$(6,899)	$(19,717)	$(20,487)
Basic and diluted net loss per share	$(0.03)	$(0.04)	$(0.11)	$(0.13)
Shares used in computing basic and diluted net loss per share	184,301,986	159,216,642	173,187,753	159,186,853

See accompanying notes.

GERON CORPORATION

CONDENSED STATEMENTS OF COMPREHENSIVE LOSS

(IN THOUSANDS)

(UNAUDITED)

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2018	2017	2018	2017
Net loss	$(5,597)	$(6,899)	$(19,717)	$(20,487)
Net unrealized (loss) gain on marketable securities	(35)	27	95	1
Comprehensive loss	$(5,632)	$(6,872)	$(19,622)	$(20,486)

See accompanying notes.

GERON CORPORATION

CONDENSED STATEMENTS OF CASH FLOWS

(IN THOUSANDS)

(UNAUDITED)

	NINE MONTHS ENDED SEPTEMBER 30,	
	2018	2017
Cash flows from operating activities:		
Net loss	$(19,717)	$(20,487)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	45	57
Loss on retirement of property and equipment	-	5
Accretion and amortization on investments, net	(521)	213
Change in fair value of equity investment, including foreign currency translation	338	-
Stock-based compensation for services by non-employees	155	159
Stock-based compensation for employees and directors	4,774	6,152
Amortization related to 401(k) contributions	10	32
Changes in assets and liabilities:		
Current assets	(1,034)	(401)
Current liabilities	(2,049)	(1,899)
Net cash used in operating activities	(17,999)	(16,169)
Cash flows from investing activities:		
Purchases of property and equipment	(9)	-
Purchases of marketable securities	(149,720)	(81,260)
Proceeds from maturities of marketable securities	71,163	94,486
Net cash (used in) provided by investing activities	(78,566)	13,226
Cash flows from financing activities:		
Proceeds from issuances of common stock, net of issuance costs	92,960	37
Net cash provided by financing activities	92,960	37
Net decrease in cash, cash equivalents and restricted cash	(3,605)	(2,906)
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	$12,998	$10,172

See accompanying notes.

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GERON CORPORATION

NOTES TO CONDENSED FINANCIAL STATEMENTS

SEPTEMBER 30, 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 nine months ended September 30, 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 and nine months ended September 30, 2018 and 2017, the diluted net loss per share calculation excludes potential common shares of 23,075,718 and 22,996,422, 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 debt 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

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(UNAUDITED)

losses are included in interest and other income and are derived using the specific identification method for determining the cost of securities sold and have been insignificant to date. Dividend and interest income are recognized when earned and included in interest and other income in our condensed statements of operations. We recognize a charge when the declines in the fair values below the amortized cost bases 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 and nine months ended September 30, 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 investment in equity securities at fair value at each reporting period. Changes in fair value resulting from observable price changes are included in change in fair value of equity investment and changes in fair value resulting from foreign currency translation are included in other expense 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 and the period over which completion of the performance obligations is expected under an agreement. 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 services 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. License fees and royalty revenue primarily represent amounts earned under agreements that out-license our technology to various companies.

License and/or Collaboration Agreements

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.

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 licensee can use and benefit from the license, we recognize revenue from non-

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(UNAUDITED)

refundable upfront fees allocated to the license upon the completion of the transfer of the license to the licensee. 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, non-clinical 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 Biotech, Inc., or Janssen, under the recently-terminated collaboration and license agreement, or Collaboration Agreement, we monitor patient enrollment levels and related activities to the extent possible through discussions with Janssen personnel and base our estimates of clinical trial costs on the best information available at the time. However, additional information may become available to us which would allow us to make a more accurate estimate in future periods. In this event, we may be required to record adjustments to research and development expenses in future periods when the actual level of activity becomes more certain.

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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 and nine months ended September 30, 2018 and 2017 which was allocated as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	2018	2017	2018	2017
Research and development	$269	$235	$690	$776
General and administrative	1,346	1,859	4,084	5,376
Stock-based compensation expense included in operating expenses	$1,615	$2,094	$4,774	$6,152

As stock-based compensation expense recognized in our condensed statements of operations for the three and nine months ended September 30, 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 nine months ended September 30, 2018 and 2017 has been estimated at the date of grant using the Black Scholes option-pricing model with the following assumptions:

	Nine Months Ended September 30,

	2018	2017
Dividend yield	0%	0%
Expected volatility range	0.821 to 0.832	0.884 to 0.892
Risk-free interest rate range	2.55% to 2.94%	1.98% to 1.99%
Expected term	5.25 yrs	5.5 yrs

Employee Stock Purchase Plan

The fair value of employees' purchase rights during the nine months ended September 30, 2018 and 2017 has been estimated using the Black Scholes option-pricing model with the following assumptions:

	Nine Months Ended September 30,	
	2018	2017
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.

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The expected term of options is derived from actual historical exercise and post-vesting cancellation data and represents the period of time that options granted are expected to be outstanding. The expected term of employees' purchase rights is equal to the purchase period.

Non-Employee Stock-Based Awards

For our non-employee stock-based awards, the measurement date on which the fair value of the stock-based award is calculated is equal to the earlier of: (i) the date at which a commitment for performance by the counterparty to earn the equity instrument is reached or (ii) the date at which the counterparty's performance is complete. We recognize stock-based compensation expense for the fair value of the vested portion of non-employee 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 Sienna Cancer Diagnostics Limited, or Sienna. In accordance with ASU 2016-01, we remeasured the fair value of our equity investment in Sienna at each reporting date in 2018 and included the change in fair value resulting from observable price changes in change in fair value of equity investment and the change in fair value resulting from foreign currency translation in other expense in our condensed statements of operations. See Note 2 on Fair Value Measurements for additional information on our equity investment in Sienna.

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(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):

Condensed Balance Sheet	Balance at December 31, 2017	Adjustments Due to Topic 606	Adjustments Due to ASU 2016-01 and ASU 2018-03	Balance at January 1, 2018
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. In July 2018, the FASB issued ASU No. 2018-11, Leases (Topic 842): Targeted Improvements, or ASU 2018-11. In issuing ASU 2018-11, the FASB decided to provide another transition method in addition to the existing transition method by allowing entities to initially apply the new leases standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. We plan to adopt ASU 2016-02 on January 1, 2019 using a modified retrospective approach as allowed under ASU 2018-11. In addition, we plan to apply the practical expedients provided by the FASB. In evaluating the impact of adopting the new lease guidance, we have determined that our current operating lease for our office space will require us to record an asset and an obligation for the arrangement upon adoption of ASU 2016-02. We have also evaluated other facilities and equipment service contracts and believe such agreements do not contain any embedded lease arrangements.

In June 2018, the FASB issued ASU 2018-07, Improvements to Nonemployee Share-Based Payment Accounting, or ASU 2018-07, to simplify the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. The new guidance applies to nonemployee awards issued in exchange for goods or services used or consumed in an entity's own operations. There are no new disclosure requirements. The new guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted, including in an interim period for which financial statements have not been issued. We plan to adopt ASU 2018-07 on January 1, 2019. Since we currently project that all of our share-based payments to nonemployees will be fully vested as of the adoption date, we do not anticipate that the adoption of ASU 2018-07 will have a material impact on our financial statements.

In August 2018, the FASB issued ASU 2018-13, Disclosure Framework — Changes to the Disclosure Requirements for Fair Value Measurement, which modifies the disclosure requirements on fair value measurements. The new standard is effective for fiscal years beginning after December 15, 2019, and early adoption is permitted. While we continue to assess the potential impact of this standard, we do not expect the adoption of this standard to have a material impact on our condensed financial statements.

In August 2018, the Securities and Exchange Commission issued Release No. 33-10532 that amends and clarifies certain financial reporting requirements. The principal change to our financial reporting will be the inclusion of the annual disclosure requirement of changes in stockholders' equity in Rule 3-04 of Regulation S-X to interim periods. We will adopt this new rule beginning with our financial reporting for the quarter ended March 31, 2019. Upon adoption, we will include a Statement of Stockholders' Equity with each quarterly filing on Form 10-Q.

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2. FAIR VALUE MEASUREMENTS

Cash Equivalents and Marketable Securities

Cash equivalents, restricted cash and marketable securities by security type at September 30, 2018 were as follows:

(In thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Included in cash and cash equivalents:				
Money market funds	$ 10,065	$ -	$ -	$ 10,065
Restricted cash:				
Certificate of deposit	$ 269	$ -	$ -	$ 269
Marketable securities:				
Commercial paper (due in less than one year)	$ 63,019	$ 62	$ (22)	$ 63,059
Corporate notes (due in less than one year)	90,682	2	(121)	90,563
Corporate notes (due in one to two years)	18,176	-	(33)	18,143
	$ 171,877	$ 64	$ (176)	$ 171,765

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
Included in cash and cash equivalents:				
Money market funds	$ 11,030	$ -	$ -	$ 11,030
Commercial paper	2,242	-	-	2,242
Corporate notes	1,750	-	(1)	1,749
	$ 15,022	$ -	$ (1)	$ 15,021
Restricted cash:				
Certificate of deposit	$ 268	$ -	$ -	$ 268
Marketable securities:				
Government-sponsored enterprise securities (due in less	$ 12,500	$ -	$ (40)	$ 12,460

than one year)				
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
	$ 92,798	$ 4	$ (210)	$ 92,592

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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 September 30, 2018 and December 31, 2017 were as follows:

	Less Than 12 Months		12 Months or Longer		Total	
(In thousands)	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses
As of September 30, 2018:						
Commercial paper (due in less than one year)	$14,773	$ (22)	$-	$ -	$14,773	$ (22)
Corporate notes (due in less than one year)	59,876	(82)	15,482	(39)	75,358	(121)
Corporate notes (due in one to two years)	18,143	(33)	-	-	18,143	(33)
	$92,792	$ (137)	$15,482	$ (39)	$108,274	$ (176)
As of December 31, 2017:						
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)
	$77,168	$ (169)	$13,959	$ (42)	$91,127	$ (211)

The gross unrealized losses related to government-sponsored enterprise securities, commercial paper and corporate notes as of September 30, 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 September 30, 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.

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.

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The following table presents information about our financial instruments that are measured at fair value on a recurring basis as of September 30, 2018 and December 31, 2017 and indicates the fair value category assigned.

	Fair Value Measurements at Reporting Date Using			
(In thousands)	Quoted Prices in Active Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3	Total
As of September 30, 2018:				
Money market funds[1]	$10,065	$ -	$ -	$10,065
Commercial paper[2]	-	63,059	-	63,059
Corporate notes[2][3]	-	108,706	-	108,706
Equity investment[4]	-	851	-	851
Total	$10,065	$ 172,616	$ -	$182,681
As of December 31, 2017:				
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
Total	$11,030	$ 96,583	$ -	$107,613

(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.

Equity Investment

In December 2007, we received 13,842,625 ordinary shares in 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. As of September 30, 2018, the fair value of our shares in Sienna was $851,000. In accordance with ASU 2016-01, we remeasured the fair value of our shares in Sienna as of September 30, 2018 and recognized the resulting increase in fair value of $175,000 for the three months ended September 30, 2018 and overall decrease in fair value of $338,000 for the nine months ended September 30, 2018. The changes in fair value for the three and nine months ended September 30, 2018 include a loss of $30,000 and $68,000, respectively, related to foreign currency translation.

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 has been 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

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for IMbark and IMerge were shared between us and Janssen on a 50/50 basis. Additionally, under the terms of the Collaboration Agreement, we remained 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 September 30, 2018, accrued collaboration charges of $1,560,000 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 September 30, 2018.

Janssen terminated the Collaboration Agreement effective September 28, 2018. Upon the effective date of termination, we regained the global rights to the imetelstat program and plan to continue development of imetelstat on our own. As a result of the termination of the Collaboration Agreement, we will not receive any further milestone payments or royalties from Janssen for the development or commercialization of imetelstat, including any clinical development or sales milestones, and Janssen has no further obligations to us or any third parties, such as clinical sites or vendors, to fund any potential future imetelstat clinical trials. In addition, cost sharing for IMbark and IMerge clinical development expenses and patent prosecution expenses ceased upon the effective date of termination. Under the terms of the Collaboration Agreement, we expect Janssen to provide operational support for the imetelstat program during transition of the program to us, which is expected to take approximately 12 months, including the orderly transfer of all ongoing clinical, regulatory, medical affairs, manufacturing and non-clinical activities to us. Costs related to transition activities will be borne by each company unless otherwise specified in the Collaboration Agreement. In addition, Janssen is expected to supply imetelstat to us for up to 24 months during a transition period for clinical manufacturing and such supply will be charged to us at Janssen's cost plus a premium.

4. STOCKHOLDERS' EQUITY

At Market Issuance Sales Agreements

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. From January 2018 through April 2018, we completed the sale of the remaining common stock subject to the 2015 Sales Agreement and issued an aggregate of 13,195,106 shares of our common stock, resulting in net cash proceeds to us of approximately $47,651,000 after deducting sales commissions and offering expenses payable by us. No further shares of common stock may be sold under the 2015 Sales Agreement.

On May 18, 2018, we entered into an At Market Issuance Sales Agreement, or the 2018 Sales Agreement, with B. Riley FBR, Inc., or B. Riley FBR, pursuant to which we may elect to issue and sell shares of our common stock having an aggregate offering price of up to $100,000,000 in such quantities and on such minimum price terms as we set from time to time through B. Riley FBR as our sales agent. We pay B. Riley FBR 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 B. Riley FBR

under the 2018 Sales Agreement. From May 2018 through July 2018, we sold an aggregate of 10,083,079 shares of our common stock pursuant to the 2018 Sales Agreement, resulting in net cash proceeds to us of approximately $38,366,000 after deducting sales commissions and offering expenses payable by us. The 2018 Sales Agreement will expire upon the earlier of: (a) the sale of all common stock subject to the 2018 Sales Agreement and (b) May 18, 2021.

2018 Equity Incentive Plan

On May 15, 2018, our stockholders approved the adoption of the 2018 Equity Incentive Plan, or 2018 Plan, as the successor to our 2011 Incentive Award Plan, or 2011 Plan. The 2018 Plan provides for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, other stock awards, and performance awards that may be settled in cash, stock, or other property. Eligible participants under the 2018 Plan include our employees, consultants and directors. The number of shares reserved for issuance under the 2018 Plan (subject to adjustment for certain changes in capitalization) is equal to the sum of (i) the unallocated shares of common stock remaining available for grant under the 2011 Plan as of May 15, 2018, (ii) 10,000,000 newly reserved shares of common stock and (iii) the number of shares subject to awards granted under the Amended and Restated 2002 Equity Incentive Plan, or 2002 Plan, and the 2011 Plan as such shares become available from time to time, referred to as the Prior Plans' Returning Shares. Such Prior Plans' Returning Shares become available for issuance under the 2018 Plan if outstanding stock awards granted under the 2002 Plan and the 2011 Plan, after May 15, 2018, expire or terminate for any reason prior to exercise or settlement or are forfeited, cancelled or otherwise returned to us because of the failure to meet a

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contingency or condition required for the vesting of such shares, or, subject to certain exceptions, are reacquired or withheld (or not issued) by us to satisfy a tax withholding obligation in connection with a stock award. As a result of the approval of the 2018 Plan, no additional awards may be granted from the 2011 Plan.

Stock Option Exercises

For the three months ended September 30, 2018, outstanding stock options to purchase 3,144,878 shares of our common stock with a weighted average exercise price of $2.20 per share were exercised resulting in cash proceeds to us of approximately $6,929,000.

5. SUBSEQUENT EVENT

Effective October 1, 2018, our Board of Directors, or the Board, adopted a Directors' Market Value Stock Purchase Plan, or the Directors Market Plan. Under the Directors Market Plan, non-employee members of the Board may purchase shares of Geron common stock at the prevailing market price on the purchase date with cash compensation payable to them for their services as a Board member. As stated in Geron's Non-Employee Director Compensation Policy, each non-employee member of the Board receives annual cash compensation, payable quarterly in arrears, for their services on the Board and various committees of the Board. As provided in the Non-Employee Director Compensation Policy, a board member may elect to receive fully vested shares of common stock in lieu of cash and such shares shall be issuable from the Directors Market Plan. A total of 1,000,000 shares of common stock has been reserved for the Directors Market Plan. The Directors Market Plan is intended to qualify for the limited exemption from stockholder approval pursuant to Nasdaq Listing 5635(c)(2), as a plan that merely provides a convenient way to purchase shares from the Company at market value.

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," "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 is focused on the clinical development and potential commercialization of imetelstat, a first-in-class telomerase inhibitor, in hematologic myeloid malignancies. We believe clinical data from two clinical trials of imetelstat (IMbark and Part 1 of IMerge, discussed below) conducted by Janssen Biotech, Inc., or Janssen, support further development of imetelstat in hematologic myeloid malignancies. As such, we expect to initiate patient screening and enrollment for Part 2, or the Phase 3 portion, of IMerge, a trial evaluating imetelstat in transfusion dependent patients with Low or Intermediate-1 risk myelodysplastic syndromes, or MDS, who have relapsed after or are refractory to prior treatment with an erythropoiesis stimulating agent, or ESA, have not received prior treatment with either a hypomethylating agent or lenalidomide and do not have a deletion 5q chromosomal abnormality, by mid-year of 2019, after the sponsorship of ongoing imetelstat clinical trials has been transferred from Janssen to us. We also intend to discuss the results of the primary analysis from IMbark with experts in myelofibrosis and regulatory authorities, in order to guide our planning of any potential future clinical trials of imetelstat in patients with Intermediate-2 or High risk myelofibrosis who have relapsed after, or are refractory to, prior treatment with a janus kinase inhibitor.

Status of Collaboration Agreement with Janssen

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. Under the Collaboration Agreement, we and Janssen established a joint governance structure which

included a Joint Steering Committee, or JSC, with equal membership from both companies, to oversee and manage worldwide regulatory, development, manufacturing and commercialization activities for imetelstat during the term of the Collaboration Agreement.

Janssen terminated the Collaboration Agreement effective September 28, 2018. Upon the effective date of termination, we regained the global rights to the imetelstat program. As a result of the termination of the Collaboration Agreement, we will not receive any further milestone payments or royalties from Janssen for the development or commercialization of imetelstat, including any clinical development or sales milestones, and Janssen has no further obligations to us or any third parties, such as clinical sites or vendors, to fund any of the ongoing or any potential future imetelstat clinical trials.

Under the terms of the Collaboration Agreement, Janssen is required to provide operational support for the imetelstat program during transition of the program to us, which is expected to take approximately 12 months, including the orderly transfer of all ongoing clinical, regulatory, medical affairs, manufacturing and non-clinical activities to us. Costs related to transition activities will

be borne by each company unless otherwise specified in the Collaboration Agreement. Under the Collaboration Agreement, Janssen is required, among other things, to:

- assign all regulatory files and regulatory clearances specific to imetelstat to us, including sponsorship of the ongoing clinical trials, Part 1 of IMerge, a Phase 2/3 trial in myelodysplastic syndromes, and IMbark, a Phase 2 trial in myelofibrosis currently in a one-year extension phase;
- transfer all safety data to us;
- facilitate negotiations between us and any subcontractors of Janssen performing development or manufacturing activities related to imetelstat;
- transfer any remaining inventory of imetelstat to us at Janssen's cost plus a premium, and use commercially reasonable efforts to facilitate an orderly and prompt transition of manufacturing activities to us; and
- supply imetelstat to us at Janssen's cost plus a premium for up to 24 months following the termination of the Collaboration Agreement for clinical manufacturing of imetelstat.

Until the sponsorship responsibilities for the Investigational New Drug, or IND, application for imetelstat transfers from Janssen to us, Janssen will continue conducting IMbark and Part 1 of IMerge. Patients currently enrolled in IMbark and Part 1 of IMerge will continue to receive treatment and follow-up under the respective trial protocols. After September 28, 2018, the effective termination date of the Collaboration Agreement, we no longer share development costs with Janssen for IMbark, including the extension phase, and Part 1 of IMerge. In addition, we no longer share costs for the prosecution of patents licensed to Janssen after the termination date of the Collaboration Agreement. In the second quarter of 2018, Janssen informed us that no patients remain on study or in follow-up in the pilot study of imetelstat in patients with myelofibrosis conducted at Mayo Clinic, or the Pilot Study. Therefore, we expect the Pilot Study to be closed, and the related IND under which the Pilot Study has been conducted to be withdrawn by Janssen.

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. Information about the transition of the imetelstat program from Janssen to us should be reviewed in the context of the section entitled "Risks Related to Transition of the Imetelstat Program from Janssen to Geron" included in Part II, Item 1A, "Risk Factors" of this Form 10-Q.

IMbark

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 myelofibrosis, or 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 were spleen response rate, defined as the proportion of patients who achieved a >35% reduction in spleen volume assessed by imaging, and symptom response rate, defined as the proportion of patients who achieved a >50% reduction in Total Symptom Score, or TSS, at 24 weeks. Key secondary endpoints included safety and overall survival.

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 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 the March 2018 internal data review of IMbark, which had a January 2018 data cut-off date, the JSC determined to officially close the trial to new patient enrollment, as the over 100 patients enrolled in IMbark to date were expected to be adequate for Janssen to assess overall survival. The JSC also concluded that as of the January 2018 data cut-off date, with a median follow up of approximately 19 months, median overall survival had not been reached in either dosing arm.

In March 2018, Janssen amended the IMbark protocol to establish a one-year extension phase of the trial to enable patients remaining in the treatment phase to continue to receive imetelstat treatment, per investigator discretion. Standard data collection for

patients in the extension phase, whether they continue to receive imetelstat or are in follow-up, consists primarily of serious adverse event information, as defined by the protocol, and such patients will continue to be followed for survival status.

IMbark Protocol-Specified Primary Analysis Highlights

In the second quarter of 2018, Janssen initiated a protocol-specified primary analysis of IMbark, which included an assessment of overall survival. The IMbark protocol-specified primary analysis coincided with the protocol-specified final analysis for the trial due to an overlap in the dates triggering each analysis, which resulted in a joint primary/final analysis, which we refer to herein as the primary analysis. An abstract containing detailed results from the IMbark primary analysis has been accepted for an oral presentation at the 60th American Society of Hematology (ASH) Annual Meeting and Exposition in December 2018. The abstract for the presentation can be found at www.hematology.org. More mature data from the extension phase of IMbark will be presented at ASH.

As reported in the ASH abstract, a total of 107 patients were enrolled in IMbark (48 in the 4.7 mg/kg dosing arm and 59 in the 9.4 mg/kg dosing arm). At the time of the clinical cut-off for the primary analysis, patients in IMbark were followed for a median of 22.6 months (range: 0.2 – 27.4), including median treatment duration of 6.2 months (range: 0.0 – 27.2.). Six patients (10.2%) in the 9.4 mg/kg dosing arm had a spleen response per MRI, with no responses in the 4.7 mg/kg dosing arm. Nineteen patients (32%) in the 9.4 mg/kg dosing arm and three patients (6%) in the 4.7 mg/kg dosing arm had a symptom response (TSS reduction ≥ 50%).

At the time of the clinical cut-off, as reported in the ASH abstract, median overall survival, or OS, in the 9.4 mg/kg dosing arm had not been reached, while median OS was 19.9 months for the 4.7 mg/kg dosing arm. The 18-month survival rates were 76.7% and 62.9% for the 9.4 mg/kg and 4.7 mg/kg dosing arms, respectively. These data are presented in the table below:

	Dosing Arm	
	4.7 mg/kg	9.4 mg/kg
Number of enrolled patients	48	59
Spleen response rate	0%	10.2%
Symptom response rate	6%	32%
Complete remission rate	0%	0%
Partial remission rate	0%	2%
Median overall survival	19.9 mos	not reached
Median follow-up	22.6 mos	22.6 mos
18-month survival rates	62.9%	76.7%

The safety profile was consistent with prior clinical trials of imetelstat in hematologic malignancies, and no new safety signals were identified. For the 4.7 mg/kg dosing arm, the most common adverse events on treatment (all grades) were diarrhea, nausea, anemia and thrombocytopenia. For the 9.4 mg/kg dosing arm, the most common adverse events on treatment (all grades) were thrombocytopenia, anemia, neutropenia and nausea. Grade 3/4 neutropenia and thrombocytopenia were more frequent in the 9.4 mg/kg dosing arm than the 4.7 mg/kg dosing arm and most cytopenias resolved within four weeks. An independent Hepatic Review Committee deemed that the observed liver function test elevations were not imetelstat-related hepatic toxicities.

IMerge

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 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

currently 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 rate, lasting at least 8 weeks. Key secondary endpoints include the RBC-TI rate lasting at least 24 weeks, amount and relative change in red blood cell transfusions and hematologic improvement.

In the original Part 1 of IMerge, 32 patients were enrolled, of which a subset of 13 patients had not received prior treatment with either a hypomethylating agent, or HMA, or lenalidomide and did not have a deletion 5q chromosomal abnormality, also known as non-del(5q). Janssen completed internal data reviews of Part 1 of IMerge in September 2016 and April 2017. In addition, preliminary data from Part 1 of IMerge were presented at the European Hematology Association, or EHA, Annual Congress, in June 2018. These data showed that the 13-patient initial cohort exhibited an increased rate and durability of transfusion independence compared to the overall trial population (≥8-week RBC-TI rate: 54% vs. 34%). 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 initial cohort.

Based on the preliminary data from the 13-patient initial cohort, Janssen expanded new patient enrollment in Part 1 of IMerge and enrolled 25 additional patients, or an expansion cohort, who are non-del(5q) and naïve to HMA and lenalidomide treatment, to increase the clinical experience and confirm the benefit-risk profile of imetelstat in this 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.

IMerge Data Snapshot Highlights

To align with the completion of the IMbark primary analysis and their decision about whether to continue the Collaboration Agreement, Janssen conducted an initial data review of the expansion cohort, which they called a “data snapshot”. The data snapshot was an early look at the expansion cohort since the median follow-up was less than half the length of time the 13-patient initial cohort had been followed when their data were first reported. The median baseline RBC transfusion burden for the expansion cohort (n=25) was 8.0 units/8 weeks, compared to 6.0 units for the 13-patient initial cohort, indicating that as a group, patients enrolled in the expansion cohort had a higher overall transfusion burden than patients in the 13-patient initial cohort.

An abstract containing detailed results from the combined 13-patient initial cohort and the expansion cohort for the target patient population (n=38) has been accepted for an oral presentation at the ASH Annual Meeting and Exposition in December 2018. The abstract for the presentation can be found at www.hematology.org. More mature data from this target patient population will be presented at ASH.

In the data snapshot for the expansion cohort (n=25), the ≥8-week RBC-TI rate was 28%. Combining the expansion cohort with the 13-patient initial cohort (n=38), the ≥8-week RBC-TI rate was 37%. As of the time of the data snapshot by Janssen, sufficient time had not elapsed in the expansion cohort to assess the ≥24-week RBC-TI rate. Among the combined patients in the 13-patient initial cohort and the expansion cohort, RBC-TI response rates were similar between ring sideroblast positive (33%) and other patients (27%), and between those with baseline erythropoietin levels >500 mU/mL (33%) and ≤500 mU/mL (32%). The safety profile from the additional enrolled patients was consistent with the safety profile from the original 32 patients, as well as with other clinical trials of imetelstat in hematologic malignancies. No new safety signals were identified. Reversible Grade ≥3 neutropenia and thrombocytopenia were each reported in 58% of patients in the target patient population. An independent Hepatic Review Committee deemed that the observed liver function test elevations were not imetelstat-related hepatic toxicities.

We expect final data from the Phase 2 portion of IMerge to be available in 2019 and anticipate submitting such final data for presentation at a future medical conference in 2019.

Continued Development of Imetelstat by Geron

We intend to continue the development of imetelstat in hematologic myeloid malignancies. For MDS, we expect to initiate Part 2, or the Phase 3 portion, of IMerge after sponsorship of the ongoing imetelstat clinical trials has been transferred from Janssen to us and expect patient screening and enrollment for the Phase 3 portion of IMerge to begin by mid-year of 2019. We have engaged a global contract research organization, or CRO, to support imetelstat clinical development activities. In addition, we plan to hire a number of senior personnel to re-staff our internal drug development group, as well as contract with subject matter experts in clinical science, biostatistics, clinical operations, pharmacovigilance, quality, manufacturing and regulatory affairs. For MF, we plan to discuss the results of the IMbark primary analysis, including the assessment of OS, with experts in MF, as well as regulatory authorities, to consider how these results compare with other therapies currently available to MF patients, and to gain a better understanding of the potential significance of these results to patients and physicians. We believe feedback from these discussions will provide important information on the feasibility, scope and design, including possible outcome

measures, of any potential future clinical trials for imetelstat in Intermediate-2 or High-risk MF patients who have relapsed after or are refractory to prior treatment with a JAK inhibitor.

Financial Overview

We had approximately $184.8 million in cash, cash equivalents, restricted cash and current and noncurrent marketable securities as of September 30, 2018. As a result of the termination of the Collaboration Agreement with Janssen effective September 28, 2018, we regained the global rights to imetelstat. Consequently, we expect our net losses to increase in the future as we assume responsibility for IMbark and IMerge and continue development of the imetelstat program on our own. 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 September 30, 2018, we had an accumulated deficit of $1,004.2 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 the clinical and commercial success of imetelstat, which will require significant additional clinical testing prior to possible regulatory approval in the United States and other countries. In addition, as a result of the termination of the Collaboration Agreement, we expect research and development expenses and losses to substantially increase in the future as we assume sole responsibility for the imetelstat development program. 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 nine months ended September 30, 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 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. 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 and the period over which completion of the performance obligations is expected under an agreement. 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 services 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 historically have consisted of collaboration revenue and license fees and royalties. Collaboration revenue primarily represented amounts earned under the Collaboration Agreement with Janssen for the imetelstat program. Effective September 28, 2018, the Collaboration Agreement with Janssen was terminated. As a result, we will not receive any further milestone payments or royalties from Janssen for the development or commercialization of imetelstat. 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 licensee 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 licensee. 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 2016-01, investments in equity securities are measured at fair value at each reporting period. Changes in fair value resulting from observable price changes are included in change in fair value of equity investment and changes in fair value resulting from foreign currency translation are included in other expense 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. In accordance with ASU 2016-01, we remeasured the fair value of our shares in Sienna as of September 30, 2018 and recognized the resulting change in fair value in our condensed statements of operations for the three and nine months ended September 30, 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, especially in light of the termination of the Collaboration Agreement with Janssen effective September 28, 2018. 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. Effective September 28, 2018, the Collaboration Agreement with Janssen was terminated. As a result, we will not receive any further milestone payments or royalties from Janssen for the development or commercialization of imetelstat. In addition, we expect to incur increasing operating losses in the future as we assume clinical development activities for imetelstat on our own to enable potential commercialization of imetelstat in the United States and other countries. 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, including the transition of the imetelstat program from Janssen to us, the development, manufacture, regulatory approval for and commercialization of, imetelstat, uncertainty of non-clinical and clinical trial results or regulatory approvals or clearances, the future development of imetelstat by us, including any future efficacy or safety results that may cause the benefit-risk profile of imetelstat to become unacceptable, our need for future capital, enforcement of our patent and proprietary rights, reliance upon our consultants, licensees, investigators and other third parties, and potential competition. In order for imetelstat to be commercialized, we must conduct non-clinical 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 revenue based on sales of imetelstat for many years, if at all.

Revenues

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 $95,000 and $435,000 for the three and nine months ended September 30, 2018, respectively, compared to $115,000 and $582,000 for the same periods in 2017 related to our various agreements. The decrease in license fee revenues for the three and nine months ended September 30, 2018 compared to the same periods in 2017 primarily reflects a reduction in the number of active license agreements in 2018 for research licenses related to our human telomerase reverse transcriptase, of hTERT, technology. We recognized royalty revenues of $70,000 and $256,000 for the three and nine months ended September 30, 2018, respectively, compared to $48,000 and $292,000 for the same periods in 2017. The changes in royalty revenues for the three and nine months ended September 30, 2018 compared to the same periods in 2017 primarily reflect 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. In addition, due to the termination of the Collaboration Agreement effective September 28, 2018, we will not receive any further milestone payments or royalties from Janssen for the development or commercialization of imetelstat. Current revenues may not be predictive of future revenues.

Research and Development Expenses

During the three and nine months ended September 30, 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 and nine months ended September 30, 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 $2.7 million and $8.4 million for the three and nine months ended September 30, 2018, respectively, compared to $2.6 million and $8.5 million for the same periods in 2017. The increase in research and development expenses for the three months ended September 30, 2018 compared to the same period in 2017 primarily reflects higher personnel related expenses and increased consulting expenses, partially offset by lower direct external costs for our proportionate share of clinical development expenses under the collaboration with Janssen. The decrease in research and development expenses for the nine months ended September 30, 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.

Research and development expenses for the three and nine months ended September 30, 2018 and 2017 were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	2018	2017	2018	2017
	(Unaudited)			
Direct external expenses	$1,953	$2,046	$6,284	$6,467
Personnel related expenses	588	473	1,625	1,616
All other expenses	166	118	442	427
Total research and development expenses	$2,707	$2,637	$8,351	$8,510

Since cost sharing between Janssen and us for IMbark and IMerge clinical development ceased on the effective date of termination of the Collaboration Agreement, or September 28, 2018, we expect research and development expenses to substantially increase in the future as we assume sole responsibility for the imetelstat development program, including any ongoing or potential future clinical trials, and hiring of senior personnel to oversee the program. Transition of the program to us from Janssen is expected to take approximately 12 months from the effective date of termination of the Collaboration Agreement and under the terms of the Collaboration Agreement, Janssen is required to provide operational support for the imetelstat program during this time. Costs related to transition activities shall be borne by each company unless otherwise specified in the Collaboration Agreement. In addition, following the effective date of termination of the Collaboration Agreement, we expect Janssen to supply imetelstat to us for up to 24 months during a transition period for clinical manufacturing and such supply will be charged to us at Janssen’s cost plus a premium. 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, see the sub-sections entitled, “Risks Related to Development of Imetelstat”, “Risks Related to Regulatory Approval and Commercialization of Imetelstat”, and “Risks Related to Transition of the Imetelstat Program from Janssen to Geron” in Part II, Item 1A entitled “Risk Factors” and elsewhere in this Form 10-Q.

General and Administrative Expenses

General and administrative expenses were $4.3 million and $13.8 million for the three and nine months ended September 30, 2018, respectively, compared to $4.8 million and $13.8 million for the same periods in 2017. The decrease in general and administrative expenses for the three months ended September 30, 2018 compared to the same period in 2017 primarily reflects the net result of reduced personnel related expenses, including lower stock-based compensation expense, partially offset by higher consulting expenses. We expect general and administrative expenses to substantially increase in the future since the cost sharing between Janssen and us for patent prosecution expenses

related to the imetelstat program ceased upon termination of the Collaboration Agreement and we expect to hire additional personnel to support our research and development activities for imetelstat.

Interest and Other Income

Interest and other income was $1.1 million and $2.2 million for the three and nine months ended September 30, 2018, respectively, compared to $363,000 and $1.0 million for the same periods in 2017. The increase in interest and other income for the three and nine months ended September 30, 2018 compared to the same periods in 2017 primarily reflects higher yields on our marketable securities portfolio and the increase in the size of our marketable securities portfolio in 2018 resulting from the receipt of net cash proceeds from issuances of common stock pursuant to our At Market Issuance Sales Agreement, or the 2015 Sales Agreement, with MLV & Co. LLC, or MLV, and our At Market Issuance Sales Agreement, or the 2018 Sales Agreement, with B. Riley FBR, Inc., or B. Riley FBR. 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, we remeasure the fair value of our equity investment in Sienna at each reporting date and any resulting change in fair value based on observable price changes is included in our condensed statements of operations. For the three months ended September 30, 2018, the increase in the fair value of our equity investment in Sienna resulting from observable price changes in Sienna's stock was $205,000 and for the nine months ended September 30, 2018, the overall decrease in the fair value of our equity investment in Sienna resulting from observable price changes in Sienna's stock was $270,000. No comparable amounts were incurred for the same periods in 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.

Other Expense

Other expense was $57,000 and $134,000 for the three and nine months ended September 30, 2018, respectively, compared to $18,000 and $59,000 for the same periods in 2017. Other expense reflects changes in the fair value of our equity investment in Sienna resulting from foreign currency translation and bank charges related to our cash operating accounts and marketable securities portfolio. Other expense for the three and nine months ended September 30, 2018 included losses of $30,000 and $68,000, respectively, related to foreign currency translation for our equity investment in Sienna. No comparable amounts were incurred for the same periods in 2017. The fair value of our equity investment in Sienna fluctuates based on changes in the exchange rate between the U.S. dollar and Australian dollar and is therefore subject to volatility that could adversely affect our future operating results.

LIQUIDITY AND CAPITAL RESOURCES

As of September 30, 2018, we had cash, restricted cash, cash equivalents, and current and noncurrent marketable securities of $184.8 million, compared to $109.2 million at December 31, 2017. The net increase in cash, restricted cash, cash equivalents, and current and noncurrent marketable securities during the nine months ended September 30, 2018 was the net result of the receipt of net cash proceeds of approximately $86.0 million from sales of our common stock under the 2015 Sales Agreement and the 2018 Sales Agreement and cash proceeds of $6.9 million from the exercise of outstanding stock options to purchase shares of our common stock, partially offset by cash being used for operations. 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 expect to experience negative cash flow for the foreseeable future as a result of the termination of the Collaboration Agreement with Janssen and as we assume responsibility for the development of the imetelstat program on our own.

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. From January 2018 through April 2018, we sold an aggregate of 13,195,106 shares of our common stock under the 2015 Sales Agreement, resulting in net cash proceeds to us of approximately $47.7 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.

In May 2018, we entered into the 2018 Sales Agreement with B. Riley FBR, pursuant to which we may elect to issue and sell shares of our common stock having an aggregate offering price of up to $100 million in such quantities and on such minimum price terms as we set from time to time through B. Riley FBR as our sales agent. Pursuant to the 2018 Sales Agreement, B. Riley FBR sells our common stock at market prices prevailing at the time of sale for which B. Riley FBR receives an aggregate commission rate equal to up to 3.0% of the gross proceeds. From May 2018 through July 2018, we sold an aggregate of 10,083,079 shares of our common stock under the 2018 Sales Agreement, resulting in net cash proceeds to us of approximately $38.4 million after deducting sales commissions and offering expenses payable by us. As of September 30, 2018, approximately $60.5 million of our common stock

remained available for issuance under the 2018 Sales Agreement. The 2018 Sales Agreement will expire upon the earlier of the remaining common stock being sold or May 2021.

We will require substantial additional capital in order to continue to conduct the research and development and clinical and regulatory activities necessary to bring imetelstat to market, and to establish sales and marketing capabilities. Because the outcome of any clinical activities and/or regulatory approval process is highly uncertain, we cannot reasonably estimate whether any development activities we may undertake will succeed, and we may never recoup our investment in any imetelstat development, which would adversely affect our financial condition and our business and business prospects, and might cause us to cease operations. Our future capital requirements are difficult to forecast and will depend on many factors, including:

- the accuracy of the assumptions underlying our estimates for our capital needs;
- 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 scope, progress, duration, results and costs of clinical trials, as well as non-clinical studies and assessments, of imetelstat;
- the costs, timing and outcomes of regulatory reviews or other regulatory actions related to imetelstat, including obtaining regulatory clearances and approvals in the United States and in other countries;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims;
- the costs of manufacturing imetelstat, including our ability to meaningfully reduce those manufacturing costs;
- the costs of multiple third-party vendors and service providers, including our CRO, to support the development, manufacturing and commercialization of imetelstat;
- our ability to establish, enforce and maintain collaborative or other strategic arrangements for research, development, clinical testing, manufacturing, commercialization and marketing of imetelstat;
- our ability to successfully market and sell imetelstat, if imetelstat receives future regulatory approval or clearance, in the United States and other countries;
- our need to hire additional qualified employees and consultants to support the development and commercialization of imetelstat;
- the costs and timing of building a U.S. sales force to market and sell imetelstat, should it receive regulatory clearance;
- the sales price for imetelstat;
- the availability of coverage and adequate third-party reimbursement for imetelstat; and
- the extent and scope of our general and administrative expenses, including expenses associated with potential future litigation.

As a result of the termination of the Collaboration Agreement effective September 28, 2018, we are responsible for funding all clinical development, manufacturing, intellectual property maintenance and commercial activities for imetelstat, which will require us to raise substantial additional capital or establish additional collaborative arrangements with third-party collaborative partners, which may not be possible. In addition, as a result of the termination of the Collaboration Agreement, we will not receive any further milestone payments or royalties from Janssen for the development or sale of imetelstat, including any clinical development milestones. If we are unable to raise additional capital or establish alternative collaborative arrangements with third-party collaborative partners for imetelstat, the development of imetelstat may be further delayed, altered or abandoned, which might cause us to cease operations. Additional financing through public or private equity financings, including pursuant to our 2018 Sales Agreement with B. Riley FBR, 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.

In addition, we may seek additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of equity or

convertible debt securities, the ownership interests of our stockholders may be diluted, and the terms may include liquidation or other preferences that materially and adversely affect the rights of our stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through alliance, collaborative or licensing arrangements with third parties, we may have to relinquish valuable rights to imetelstat or our technologies or grant licenses on terms that are not favorable to us.

We cannot assure you that our existing capital resources, future interest income, and potential future sales of our common stock, including under our 2018 Sales Agreement with B. Riley FBR, will be sufficient to fund our operating plans. We may need additional funds sooner than planned to meet operational needs and capital requirements for clinical development and commercialization. Our ability to raise funds if and when needed may be materially and adversely affected by challenging U.S. and global financial markets and additional funds may not be available on terms that are acceptable to us, or at all. If adequate funds are not available on a timely basis, if at all, we may be unable to pursue further development of imetelstat, which could adversely affect our business.

Cash Flows from Operating Activities. Net cash used in operations for the nine months ended September 30, 2018 and 2017 was $18.0 million and $16.2 million, respectively. The increase in net cash used in operations for the nine months ended September 30, 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 nine months ended September 30, 2018 was $78.6 million. Net cash provided by investing activities for the nine months ended September 30, 2017 was $13.2 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 resulting from the investment of net cash proceeds from the sales of our common stock pursuant to the 2015 Sales Agreement with MLV and the 2018 Sales Agreement with B. Riley FBR.

Cash Flows from Financing Activities. Net cash provided by financing activities for the nine months ended September 30, 2018 and 2017 was $93.0 million and $37,000, respectively. The increase in net cash provided by financing activities in 2018 compared to 2017 primarily reflects the receipt of net cash proceeds from the sales of our common stock under the 2015 Sales Agreement with MLV and the 2018 Sales Agreement with B. Riley FBR and cash proceeds from the issuance of common stock under our employee equity plans. See Note 4 on Stockholders' Equity for additional information about the 2015 Sales Agreement with MLV and the 2018 Sales Agreement with B. Riley FBR.

Contractual Obligations

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

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. In addition, as a result of the termination of the Collaboration Agreement by Janssen, the risk factors included under the caption reading, “Risks Related to our Collaboration with Janssen” that appeared in Part I, Item 1A, “Risk Factors” included in the Form 10-K have been removed.

RISKS RELATED TO THE DEVELOPMENT OF IMETELSTAT

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

Imetelstat is our sole product candidate, upon whose success we are wholly dependent. We do not have any other products or product candidates. Our ability to develop imetelstat to and through regulatory approval and commercial launch is subject to significant risks and uncertainties, including, among other things, our ability to:

- cause the IND for imetelstat to be maintained without such IND being placed on full or partial clinical hold by the FDA;
- generate additional safety and efficacy data from existing and potential future clinical trials of imetelstat, providing a positive benefit-risk profile that supports the continued and future development of imetelstat in hematologic myeloid malignancies;
- ascertain that the use of imetelstat does not result in significant systemic or organ toxicities, including hepatotoxicity, or other safety issues resulting in an unacceptable benefit-risk profile;
- develop clinical plans for, and successfully enroll and complete, potential future Geron-sponsored clinical trials of imetelstat in hematologic myeloid malignancies, including Part 2 of IMerge;

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

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

Commencement of potential future clinical trials of imetelstat, including Part 2 of IMerge, and completion of the extension phase of IMbark and Part 1 of IMerge, could be interrupted, further delayed or abandoned for a variety of reasons.*

Currently, there are two active clinical trials of imetelstat, the extension phase of IMbark and Part 1 of IMerge. Completion of these clinical trials, and the commencement of any potential future clinical trials of imetelstat, including Part 2 of IMerge, could be interrupted, delayed or abandoned for a variety of reasons, including as a result of failures or delays in:

- the comprehensive transition of the imetelstat program from Janssen to us, as discussed in more detail under the heading, “Risks Related to Transition of the Imetelstat Program from Janssen to Geron”;
- demonstrating sufficient safety and efficacy of imetelstat in IMerge and any 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, which could, for example, cause the commencement of Part 2 of IMerge to be delayed beyond mid-year 2019 or prevent us from commencing or completing Part 2 of IMerge;
- maintaining the IND for imetelstat without such IND being placed on full or partial clinical hold, suspended or subject to other requirements by the FDA or other regulatory authorities;
- properly (i) completing the extension phase of IMbark, including collecting data about serious adverse events and overall survival from the extension phase of IMbark; (ii) completing Part 1 of IMerge, including assessing the

≥24-week RBC-TI rate, and obtaining more mature data for the ≥8-week RBC-TI rate, in the expansion cohort; and (iii) designing, enrolling, conducting and completing Part 2 of IMerge, and promptly or adequately reporting data from such trials;

- determining, after consultations with experts in MF and discussions with regulatory authorities, whether the results from the IMbark primary analysis provide a feasible registration path, if any, for imetelstat in Intermediate-2 or High risk MF patients who have relapsed after or are refractory to prior treatment with a JAK inhibitor;
- obtaining or accessing necessary clinical data in accordance with appropriate clinical or quality practices to ensure complete data sets;
- responding to safety findings by the data review committees of current clinical trials, including the extension phase of IMbark and Part 1 of IMerge, and safety or futility findings by the data review committees of potential future clinical trials of imetelstat, such as Part 2 of IMerge, 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;
- obtaining funding necessary to advance the development of imetelstat;
- 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 Part 2 of IMerge and potential future clinical trials of imetelstat, including responding to questions or comments from these authorities in a timely and adequate manner, which could, for example, cause the commencement of Part 2 of IMerge to be delayed beyond mid-year 2019; and
- obtaining institutional review board or ethics committee approval of clinical trial protocols or protocol amendments, including any future refinements to the trial design we may seek for Part 2 of IMerge, which could, for example, cause the commencement of Part 2 of IMerge to be delayed beyond mid-year 2019.

Failures or delays with respect to any of these events could adversely affect our ability to continue or successfully complete the extension phase of IMbark or Part 1 of IMerge or to initiate potential future clinical trials of imetelstat, including Part 2 of IMerge, which could increase development costs, or interrupt, further delay or halt our development or commercialization of imetelstat, 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.

Imetelstat may cause, or have attributed to it, undesirable or unintended side effects or other adverse events that further delay or prevent the commencement and/or completion of clinical trials for imetelstat, further 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 interrupt, further 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:

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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, were also observed in IMbark and Part 1 of IMerge. If patients in any potential future clinical trials of imetelstat, including Part 2 of IMerge, 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 IND 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 the extension phase of IMbark and in Part 1 of IMerge, 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 additional data are being generated from the extension phase of IMbark and Part 1 of IMerge, 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 us, 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, or by us following the transition of the imetelstat program to us 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;
- 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; or
- additional, unexpected clinical trials or non-clinical studies may be required to be conducted.

The occurrence of any of these events could interrupt, further delay, or halt, any development and commercialization of imetelstat by us, which 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.

Results obtained in prior non-clinical studies and clinical trials do not predict success in later clinical trials. Likewise, preliminary data from clinical trials should be considered carefully and with caution since final data may be materially different from preliminary data, particularly as more patient data become available. *

Success in non-clinical testing and early clinical trials does not ensure that later clinical trials will be successful. We cannot be certain that any of the prior, current or potential future clinical trials of imetelstat will generate sufficient, consistent or adequate efficacy and safety data demonstrating a positive benefit-risk profile, which would be necessary to obtain regulatory approval to market imetelstat in any indication. Product candidates in later stages of clinical trials may fail to show the desired benefit-risk profile despite having progressed through non-clinical studies and initial clinical trials. Other companies in the biopharmaceutical industry have frequently suffered significant setbacks in later

clinical trials, even after achieving promising results in earlier non-clinical studies or clinical trials.

Safety and efficacy data from previous or current imetelstat clinical trials in hematologic myeloid malignancies should not be relied upon as predictive or indicative of future clinical trial results. For example, complete and partial remissions observed in the Pilot Study suggested potential disease-modifying activity of imetelstat in the MF patient population enrolled in the Pilot Study. However, similar activity was not observed in the MF patients enrolled in IMbark, as shown by the one partial remission observed in the IMbark primary analysis. We believe that differences in the IMbark study design when compared to the Pilot Study design, such as more restrictive patient enrollment criteria requiring either documented objective lack of response to a JAK inhibitor or evidence of

progressive disease while on treatment with a JAK inhibitor, may have contributed to the data observed in IMbark differing significantly from data reported from the Pilot Study, but we cannot assure you that any future clinical trials of imetelstat in MF will yield results comparable to IMbark or the Pilot Study. In addition, the potential improvement in survival observed in IMbark will need to be further assessed in a Phase 3 clinical trial comparing imetelstat to a control therapy, and similar results, including potential improvement in survival, if any, with respect to any patient population or patient population subgroup, may not be observed.

Similarly, in Part 1 of IMerge, the data snapshot for the expansion cohort exhibited ≥8-week RBC-TI rate of 28%, while the 13-patient initial cohort exhibited ≥8-week RBC-TI rate of 54% resulting in an overall ≥8-week RBC-TI rate of 37% for the combined cohorts. We believe the observed difference in ≥8-week RBC-TI rate between the 13-patient initial cohort and the 25-patient expansion cohort may be attributable to factors such as the maturity of the data at the time of the data snapshot or the higher overall baseline transfusion burden of the expansion cohort, but we cannot assure you that the combined ≥8-week RBC-TI rate observed in Part 1 of IMerge will improve with longer follow-up, or at all.

Additional or updated safety and efficacy data from current or potential future imetelstat clinical trials may result in a benefit-risk profile that does not justify continued development of imetelstat in a particular patient population, or at all. For example, because patients remaining in the extension phase of IMbark and the treatment phase for Part 1 of IMerge continue to receive imetelstat, efficacy and safety data continue to be generated. Such additional data could result in a lower benefit-risk profile than initially expected, which could hinder the commencement, completion and potential success in Part 2 of IMerge, or could cause us to abandon further development of imetelstat entirely. Data from Part 2, or the Phase 3 portion, of IMerge could materially differ from the overall conclusions reported for Part 1 of IMerge. In general, Phase 3 clinical trials with larger numbers of patients or longer durations of therapy may fail to replicate efficacy results observed in earlier clinical trials, or may reveal safety concerns that were not identified in smaller or shorter trials, any of which could adversely affect future development prospects of imetelstat.

From time-to-time, safety and efficacy data from previous and current imetelstat clinical trials have been reported or announced by us, clinical investigators or Janssen. For example, preliminary data from Part 1 of IMerge was presented at the ASH annual meeting in December 2017 and at the EHA annual congress in June 2018. We expect similar reports or announcements of safety and efficacy data from us or clinical investigators as data matures in current imetelstat clinical trials and from potential future clinical trials. Preliminary or interim results may not be reproduced in any potential future clinical trials of imetelstat, and thus should be considered carefully and with caution, and not relied upon as indicative of future clinical results. Material adverse differences in final data, compared to preliminary or interim data, could severely and adversely affect our financial results, business and business prospects, and the future of imetelstat, and might cause us to cease operations.

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, 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 situations 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;
- Janssen's decision in the third quarter of 2017 to expand Part 1 of IMerge to enroll additional lower risk MDS patients in a target patient population; and
- Janssen's decision in September 2018 to terminate the Collaboration Agreement.

Further delay, suspension or abandonment of the development of imetelstat in hematologic myeloid malignancies, including further delays resulting from the termination of the Collaboration Agreement, transition of the imetelstat program from Janssen to us, and our ability to successfully plan for and initiate future clinical trials of imetelstat, including Part 2 of IMerge, could have a material adverse effect on the future of imetelstat and our business prospects, and we might cease operations.

If we encounter difficulties enrolling or retaining patients in current or potential future clinical trials of imetelstat, including in Part 2 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, and we might cease operations. *

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. For example, if we experience difficulties in retaining patients in IMbark, our ability to continue to assess OS would be adversely affected. In addition, we may encounter challenges in enrolling and retaining patients in potential future clinical trials of imetelstat, including Part 2 of IMerge, for a variety of reasons. The enrollment and retention of patients depends on many factors, including:

- the patient eligibility criteria specified 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;
- our 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 data reported from previous or current clinical trials of imetelstat;
- 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, potential future clinical trials of imetelstat, including Part 2 of IMerge, 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, potential future clinical trials of imetelstat, including Part 2 of IMerge, are expected to be conducted, at the same clinical trial sites used to develop competing drugs, 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, or may decide not to enroll, or may not recommend enrollment, in future clinical trials of imetelstat, based on efficacy and safety results reported to date and that may be reported in the future.

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 potential commercialization of imetelstat. 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.

We do not have experience as a company in conducting large-scale, late-stage clinical trials, such as Part 2 of IMerge or potential future similar trials, or in those functional areas that would be required for the successful commercialization of our sole product candidate, imetelstat.

We have no experience in conducting large-scale, late-stage clinical trials, such as Part 2 of IMerge, nor do we have experience with activities that would be required for the commercialization of imetelstat, should we receive future regulatory approval to do so. We cannot be certain that we will be able to design, enroll, conduct or complete Part 2 of IMerge, or any other future large-scale, late-stage clinical trial of imetelstat, in a timely fashion, or at all. Large-scale, late-stage clinical trials require additional financial resources and certain internal development experience that we do

not currently possess, as well as increased reliance on third-party clinical investigators, CROs, service providers, vendors, suppliers and consultants. Relying on these third parties and establishing effective and collaborative relationships with them to conduct large-scale, late-stage clinical trials may cause further delays that are outside of our control. Any such further delays could have a material adverse effect on our business.

We also do not have commercialization capabilities. Developing an internal sales, marketing and distribution capability would be an expensive and time-consuming process, and will require additional management expertise. We may not be able to negotiate and enter into third-party marketing and distribution agreements on terms that are economically attractive, or at all. Even if we do enter

into such agreements, third party marketers and distributors may not successfully market or distribute our sole product candidate, imetelstat.

Our inability to successfully conduct large-scale, late-stage clinical trials, such as Part 2 of IMerge or future similar trials, or to successfully establish commercialization capabilities for imetelstat if we receive future regulatory approval to do so, would severely and adversely affect our financial results, business and business prospects, and the future of imetelstat, and might cause us to cease operations.

We will rely on third parties to conduct our current and potential future clinical trials of imetelstat. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to continue the development of, obtain regulatory approval for, or commercialize imetelstat.

We do not have the ability to independently conduct clinical trials. Therefore, we will rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, service providers, vendors, suppliers and consultants, to conduct clinical trials of imetelstat. The third parties with whom we contract for execution of our clinical trials will play a critical role in the conduct of these trials and the subsequent collection and analysis of data. However, these third parties are not our employees, and except for contractual duties and obligations, we have limited ability to control their performance, or the amount or timing of resources that they devote to imetelstat. For example, the CRO we have retained to support clinical development activities will be critical to our development of imetelstat, and any failure by the CRO to perform its contractual obligations, or disputes with the CRO about the quality of its performance or other matters, could further delay or halt our imetelstat development activities. These third parties may also have relationships with other commercial entities, some of which may compete with us. Under certain circumstances, these third parties may terminate their agreements with us without cause and upon immediate written notice.

Although we will rely on third parties to conduct our imetelstat clinical trials, we remain responsible for ensuring that each clinical trial is conducted in accordance with its investigational plan and protocol. Moreover, the FDA and foreign regulatory authorities require us to comply with regulations and standards, including some regulations commonly referred to as good clinical practices, or GCPs, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that patients are adequately informed of the potential risks of participating in clinical trials. Our ability to comply with these regulations and standards is contingent upon activities conducted by third parties, and if they fail to perform in accordance with contractual obligations and legal requirements, our development of imetelstat may be interrupted, further delayed or halted, which 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.

In addition, the execution of clinical trials and the subsequent compilation and analysis of the data produced, requires coordination among various parties. In order for these functions to be carried out effectively and efficiently, it is imperative that these parties communicate and coordinate with one another. If the quality or accuracy of the clinical data obtained, compiled or analyzed by third parties is compromised due to their failure to adhere to our clinical trial protocols or GCPs, or for any other reason, we may need to enter into new arrangements with alternative third parties, which could be difficult, costly or impossible. If third parties conducting our clinical trials do not perform their contractual duties or obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, our clinical trials may be extended, delayed or terminated, or may be unsuccessful or need to be repeated, which could have a material adverse effect on our business and might cause us to cease operations.

RISKS RELATED TO TRANSITION OF THE IMETELSTAT PROGRAM FROM JANSSEN TO GERON

Encountering delays or difficulties in transitioning the imetelstat program from Janssen to us would prevent us from timely developing imetelstat, or preclude us from developing imetelstat at all, which could severely and adversely affect our financial results, business and business prospects, and might cause us to cease operations.*

Under the terms of the Collaboration Agreement, Janssen is required to provide operational support for the imetelstat program during transition of the program to us, which is expected to take approximately 12 months from the effective termination date, including the orderly transfer of all ongoing clinical, regulatory, medical affairs, manufacturing and non-clinical activities to us. Our future clinical development plans for imetelstat substantially depend on the timely and comprehensive transition of the imetelstat program from Janssen to us. Delays in completing the transition activities or unwillingness by Janssen to fully perform all of the transition activities will further delay or preclude the clinical development of imetelstat, increase our operating costs and thereby negatively impact our financial results, as well as harm imetelstat's future prospects, any of which could severely and adversely affect our business and business prospects, and might cause us to cease operations.

During the transition period, we remain dependent on Janssen for several key operational development areas. Poor or incomplete performance by Janssen in these areas could severely and adversely affect imetelstat's future value and our business and business prospects, and might cause us to cease operations.*

During the transition period, we will remain dependent on Janssen to perform certain activities related to imetelstat, which subjects us to a number of risks, including:

- Janssen may not perform as expected or required by the Collaboration Agreement, and we are not able to control the amount or timing of the resources that Janssen may devote to the transition;
- there may be disputes between us and Janssen that result in the delay of the transition, or the achievement of development, regulatory and commercial objectives, or affect our license to the proprietary rights arising under the Collaboration Agreement, which may result in costly litigation or arbitration that diverts our management's attention and resources;
- the manner and timing in which Janssen effects the transition could adversely impact the development of imetelstat;
- failure by Janssen to comply with applicable regulatory guidelines could result in our inability to assume sponsorship responsibility for the IND application for imetelstat or to plan for and initiate future clinical trials of imetelstat, including Part 2 of IMerge, or could result in administrative or judicially imposed sanctions on us, including warning letters, civil and criminal penalties, injunctions, product seizures or detention, product recalls, total or partial suspension of manufacturing activities, and the potential refusal to approve any new drug applications;
- our ability to transfer and subsequently maintain the IND for imetelstat and to submit required regulatory reports within required timelines may be compromised if Janssen is not fully cooperative in transferring all data and information from the imetelstat program, including IMbark and IMerge, to us;
- business combinations or significant changes in Janssen's business strategy or failure to apply financial and other resources to the transition may also adversely affect Janssen's ability to perform its obligations related to transition of the imetelstat program to us; and
- Janssen may not properly maintain or defend intellectual property rights arising from the Collaboration Agreement, may use our proprietary information in such a way as to cause disputes that could jeopardize or invalidate our proprietary information or expose us to potential litigation, or may disclose our proprietary information in a manner that could put our intellectual property rights at risk.

The occurrence any of these events could severely and adversely affect imetelstat's future value and our business and business prospects, and might cause us to cease operations.

RISKS RELATED TO REGULATORY APPROVAL AND COMMERCIALIZATION OF

IMETELSTAT

Maintaining regulatory clearances and approvals to continue the clinical development of imetelstat, and obtaining future regulatory clearances to potentially market imetelstat, in the United States and other countries, is a costly and lengthy process, and we cannot predict when or if regulatory authorities will permit additional imetelstat development or when or if regulatory authorities will approve imetelstat for commercial sale.*

Federal, state and local governments in the United States and governments in other countries have significant regulations in place that govern drug research and development and may prevent us from successfully conducting development efforts or from commercializing imetelstat. Delays in obtaining regulatory clearances and approvals or limitations in the scope of such clearances or approvals could:

- impede or halt our 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 to us; or
- further delay or preclude any revenue we may receive from the future commercialization of imetelstat, if any.

Before we 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. Significant additional research, non-clinical testing and clinical testing is required before we can file any application with the FDA or other regulatory authorities for regulatory approval of imetelstat. As such, we do not expect imetelstat to be commercially available for many years, if at all. Our clinical development program for imetelstat may not lead to regulatory approval from the FDA and similar foreign regulatory authorities if we fail to demonstrate that imetelstat is safe and effective. If imetelstat cannot be developed in potential future clinical trials, including in Phase 3 clinical trials, our business and business prospects would be severely and adversely affected, and we might cease operations. Even if we do successfully complete one or more future clinical trials of imetelstat in hematologic myeloid malignancies, including Part 2 of IMerge, those results are not necessarily predictive of results of future pivotal trials that may be needed before we may submit an NDA to the FDA for the initial or other future indications. We may therefore fail to further develop or commercialize imetelstat.

If our interpretation of safety and efficacy data obtained from non-clinical studies and clinical trials varies from interpretations by the FDA or regulatory authorities in other countries, this would likely further delay, limit or prevent further development and approval of imetelstat. For example, the FDA and regulatory authorities in other countries may require more or different data than what has been generated from our non-clinical studies and previous or ongoing clinical trials, even though protocols for these trials may have been reviewed by FDA and any resulting feedback incorporated. 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 us to halt future development and commercialization of imetelstat, if any, 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 like 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 our ability 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 us, 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. Any failure to advance imetelstat to subsequent clinical trials, failure to obtain regulatory approval of imetelstat, or limitations on any regulatory approval that we might receive, could reduce the potential commercial use of imetelstat, and potential market demand for imetelstat and therefore result in decreased revenue for us from any commercialization of imetelstat, 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.

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 decreased sales revenue from commercialization of imetelstat, if any, and would likely harm our business and business prospects.*

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. The designation of imetelstat as an orphan drug does not guarantee that any regulatory authority will accelerate regulatory review of, or ultimately approve, imetelstat, nor does it limit the ability of any regulatory authority to grant orphan drug designation to product candidates of other companies that treat the same indications as imetelstat prior to imetelstat receiving any exclusive marketing approval.

We may lose orphan drug exclusivity if the FDA or EMA determines that the request for orphan drug designation was materially defective or if we cannot ensure sufficient quantities of imetelstat to meet the needs of patients with MF or MDS.

Even if we maintain orphan drug exclusivity for imetelstat, the 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 of imetelstat, should it ever receive marketing approval, 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 erythropoiesis stimulating agent, 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.*

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 unable to comply with these regulations, our ability to earn potential revenue from the commercialization of imetelstat, if any, 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 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 quantities of imetelstat on a timely basis, or at all, for the period set forth in the Collaboration Agreement, or our failure thereafter to establish a manufacturing supply chain to appropriately and adequately supply imetelstat for future clinical and commercial uses, would result in a further delay in or cessation of clinical trials and a further delay in or our inability to obtain regulatory approvals of imetelstat, and our business and business prospects could be severely harmed, and we could cease operations.*

Pursuant to the Collaboration Agreement, Janssen is required to supply imetelstat to us until September 28, 2020. Consequently, we will remain dependent on Janssen to appropriately supply imetelstat and other clinical trial materials until such date. Thereafter, we will be responsible for the manufacture and supply of imetelstat for future clinical and commercial uses. 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 and other risks, Janssen may not perform as agreed or may default in its obligations to supply clinical quantities of imetelstat for the period of time called for by the Collaboration Agreement, or may fail to deliver the required quantities of imetelstat on a timely basis, or at required or applicable quality standards, which would result in a further delay or cessation of current and potential future clinical trials and otherwise significantly further delay our ability to develop imetelstat, which would severely and adversely affect our business and business prospects, and might cause us to cease operations. In addition, our inability to establish a manufacturing supply chain capable of providing imetelstat for clinical trials and potential future commercial uses following the termination of Janssen's obligation to supply us with imetelstat would further delay or result in a cessation of potential future clinical trials and would further delay or preclude any applications for regulatory approval and therefore further delay or preclude our ability to earn revenue from the commercialization, if any, of imetelstat, 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, and we may be unable to conduct future clinical trials of imetelstat, including Part 2 of IMerge, or to commercialize imetelstat in the future.*

Following the termination of Janssen's obligation to supply us with imetelstat, we expect to rely solely upon third-party contractors to perform certain process development or other technical and scientific work with respect to imetelstat, as well as to supply starting materials and manufacture drug substance and drug product. We currently have no arrangements with third parties for the manufacture of imetelstat, and the establishment of such arrangements could further delay, perhaps substantially, or preclude our ability to pursue imetelstat development on our own, increase our costs and otherwise negatively affect our financial results, business and business prospects. We cannot assure that we will be able to obtain third party manufacturers for imetelstat on acceptable terms, or at all. We expect to rely on

third-party contractors to produce and deliver sufficient quantities of imetelstat and other materials to support clinical trials on a timely basis and to comply with applicable regulatory requirements. We will 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;
- 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;
- inadequate storage at contracted facilities resulting in theft or spoilage;
- 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 non-clinical and clinical activities, and commercialization. In addition, manufacturing delays could adversely impact the completion of current clinical trials, such as the extension phase of IMbark and Part 1 of IMerge, or the initiation of potential future clinical trials, including Part 2 of IMerge, 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.

In addition, third-party contractors and/or any other contractors 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. Changing manufacturers may be prolonged and difficult due to inherent technical complexities and because the number of potential manufacturers is limited. It may be difficult or impossible for us to find a replacement manufacturer on acceptable terms, or at all.

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. We 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, if any, for us, 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 be unable to successfully retain or recruit key personnel to support the development and potential future commercialization of imetelstat or to otherwise successfully manage our growth.*

The termination of the Collaboration Agreement by Janssen became effective on September 28, 2018. As a result of this termination, we regained worldwide rights to imetelstat and are now wholly responsible for all costs associated with IMbark and IMerge, any additional clinical or non-clinical development of imetelstat, and any potential regulatory approvals for and the potential commercialization of imetelstat. Our ability to successfully develop imetelstat in the future and to potentially commercialize imetelstat depends to a significant extent on the skills, experience and efforts of our executive officers and key members of our staff. In addition, we will need to hire a

number of senior personnel to re-staff our internal drug development group, as well as to contract with subject matter experts in clinical science, biostatistics, clinical operations, pharmacovigilance, quality systems, manufacturing and regulatory affairs, to enable us to further develop and potentially commercialize imetelstat.

We face intense competition for qualified individuals from numerous pharmaceutical, biopharmaceutical and biotechnology companies, as well as academic and other research institutions, and competition in our geographic region is particularly intense. Termination of the Collaboration Agreement by Janssen, as well as the previous restructurings we implemented, and the uncertainties

regarding our future business viability could have an adverse impact on our ability to retain and recruit qualified personnel or we may incur unanticipated inefficiencies caused by our reduced personnel resources. We may also face higher than expected personnel costs in order to attract new management or development personnel, or to maintain our current executive officers and staff. If we are unable to successfully retain, motivate and incentivize our existing personnel, or to attract, assimilate and retain other highly qualified management and senior development personnel in the future on acceptable terms, our ability to further develop imetelstat will be impaired, and our business and the price of our common stock would be adversely impacted.

As our operations potentially expand, we expect that we will need to manage new and additional relationships with various service providers, vendors, suppliers and other third parties. Such potential growth and expansion will require members of our management to assume significant added responsibilities. Our performance in managing any such future growth, if ineffective, could negatively impact our business prospects. We may not successfully manage our anticipated imetelstat development efforts and potential future imetelstat clinical trials, including Part 2 of IMerge, effectively. If we fail to achieve key development goals, our abilities to grow as a company, and to further develop and commercialize imetelstat, could be prevented or hindered, and our business and business prospects would be severely harmed, which might cause us to cease operations.

We expect imetelstat to remain our sole product candidate for the foreseeable future. If we are unable to successfully develop or commercialize imetelstat, our business and business prospects would be severely harmed, which might cause us to cease operations.*

We plan to focus our efforts on the further development of imetelstat in hematologic myeloid malignancies. Accordingly, we do not currently have any plans to engage in any efforts to discover new product candidates or to seek to acquire and/or in-license other oncology products, product candidates, programs or companies in order to diversify our business. Since we do not currently have a discovery function or capabilities, and do not plan to establish such capabilities or to seek to diversify our product candidate portfolio through acquisition and/or in-licensing activity, we will be wholly reliant upon the development of imetelstat, our sole product candidate, for the foreseeable future. If we are unable to successfully develop and commercialize imetelstat, our business and business prospects would be severely harmed, which might cause us to cease operations.

If we are unable to establish potential future collaborative arrangements for imetelstat, we may have to delay, alter or abandon our imetelstat development and commercialization plans.*

We intend to develop imetelstat broadly for hematologic malignancies, and to potentially commercialize, market and sell imetelstat by ourselves in the United States. We plan to seek another collaborative partner or partners, at an appropriate time, to assist us in the potential development and commercialization of imetelstat outside the United States, and to provide funding for such activities. We face significant competition in seeking appropriate collaborative partners, and these collaborative arrangements are complex and time consuming to negotiate, document and implement. We may not be able to negotiate collaborative arrangements on acceptable terms, or at all. In this regard, collaborative arrangements with third parties may require us to relinquish material rights, including revenue from potential commercialization, on terms that are less attractive than under the Collaboration Agreement we had with Janssen, or to assume material ongoing development obligations that we would have to fund or otherwise support. In any event, we are unable to predict when, if ever, we will enter into any collaborative arrangements because of the numerous risks and uncertainties associated with establishing collaborative arrangements. Moreover, as a result of the termination of the Collaboration Agreement and the significant uncertainty regarding the future imetelstat development program, potential collaborative partners may be less willing to enter into new collaborative arrangements with us, or may only be willing to do so on terms that are not favorable to us. As a result, we may not be successful in finding a new collaborative partner or partners on favorable terms, if at all. If we are unable to negotiate collaborative arrangements, we may have to curtail the development of imetelstat, further delay, alter or abandon the

imetelstat development program, further delay or abandon its potential commercialization, reduce the scope of potential future sales or marketing activities or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund imetelstat development or commercialization activities outside the United States on our own, we will be required to substantially increase our personnel resources and we will need to obtain substantial additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring imetelstat to market and generate product revenues. Establishing the infrastructure necessary to further develop, commercialize, market and sell imetelstat worldwide will require substantial resources and may divert the attention of our management and key personnel and negatively impact our imetelstat development efforts in the United States.

We currently have no products approved for commercial sale and we have not yet demonstrated an ability to obtain marketing approvals for any product candidates, which makes it difficult to assess our future viability.*

As of September 30, 2018, we have not derived any revenue from the sales of any products. Our operations to date have been limited to organizing and staffing our company, acquiring, developing and securing our technology, undertaking non-clinical studies

and early stage clinical trials of imetelstat and past product candidates that we have subsequently discontinued, and engaging in research and development under collaboration agreements. We have not yet demonstrated an ability to obtain regulatory approval, formulate and manufacture commercial-scale products, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, for these and other reasons discussed elsewhere in these risk factors, it is difficult to predict our future success and the viability of our business and the imetelstat program.

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 and other 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, or this type of insurance may become too expensive for us to afford because of the highly risky and uncertain nature of clinical trials generally and the high cost of insurance for our business activities. In addition, business liability and product liability insurance are becoming increasingly expensive, particularly for biotechnology and pharmaceutical companies, and the pool of insurers offering insurance coverage to biotechnology and pharmaceutical companies generally is becoming smaller, making it more difficult to obtain insurance for our business activities at a reasonable price, or at all. Being unable to obtain or maintain product liability, clinical trial liability, or other insurance for our business activities 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.

The termination of the Collaboration Agreement could also result in litigation arising out of any claims that our stockholders suffered financial losses. The market price of our common stock declined significantly after the announcement on September 27, 2018 of the termination of the Collaboration Agreement, and certain stockholders experienced financial losses. Therefore, it is possible that lawsuits will be filed naming us and/or our officers and directors as defendants with respect to the termination of the Collaboration Agreement by Janssen or other matters related to the Collaboration Agreement. 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. Additionally, we may not be successful in having any

such lawsuit dismissed or settled within the limits of our insurance coverage.

We have not established any reserve for any potential liability relating to any 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, our stock price, cash flow, results of operations and financial condition.

We may be subject to third-party litigation, 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.

We may face litigation with Janssen arising from or related to the Collaboration Agreement and Janssen’s termination of it. Possible disagreements with Janssen could include disagreements regarding the transition of the imetelstat program from Janssen back

to us, or the ownership of proprietary rights arising from the work performed by Janssen under the Collaboration Agreement. We may become involved in performance or other disputes with the CRO we have retained to support our imetelstat clinical development activities, or with other third parties such as service providers, vendors, suppliers or consultants, which could result in a further delay or cessation of current and potential future clinical trials and otherwise significantly further delay our ability to develop imetelstat.

Lawsuits are subject to inherent uncertainties, and defense and disposition costs depend upon many unknown factors. Despite the availability of insurance, we may incur substantial legal fees and costs in connection with litigation. 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

Our success and the success of our planned future development of imetelstat 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. 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. In the event that we are unsuccessful in obtaining, maintaining, and enforcing our patents and other intellectual property rights or having our licensors maintain the intellectual property rights we have licensed, the value of our technologies and imetelstat will be adversely affected, and we may not be able to further develop or potentially commercialize imetelstat. Loss or impairment of our intellectual property related to imetelstat might further delay or halt ongoing or potential future clinical trials of imetelstat and any applications for regulatory approval, and therefore further delay or preclude any future development or commercialization of imetelstat by us. Further, if imetelstat is approved for commercial sale, such events could impair our ability to sell imetelstat and therefore result in decreased sales for us. Occurrence of any of these events 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 inventions that were developed by Janssen under the Collaboration Agreement and to which we have an exclusive license for the further development, commercialization and manufacture of imetelstat. 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 BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig. and Promega Corp. v. Life Technologies Corp. have also narrowed the scope of patent protection available in certain circumstances. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events may have created uncertainty with respect to the value of certain patents we have previously obtained or in-licensed.

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 of our products based on our United Kingdom patents and our ability to establish and maintain European trademarks in the United Kingdom.

In 2012, the European Union Patent Package, or EU Patent Package, regulations were passed with the goal of providing for a single pan-European Unity Patent, or UP, and a new European Unified Patent Court, or UPC, for litigation of European patents. Once established, the UPC would have jurisdiction over traditional European patents and new UPs in the United Kingdom and all Contracting Member States of the European Union. However, political activity in the United Kingdom and a legal challenge in Germany has delayed ratification of the EU Patent Package in these countries. There have been many delays in the implementation of the EU Patent Package, and further delays may occur. When the EU Patent Package is ratified and in effect, all European patents, including those issued prior to ratification, would by default automatically fall under the jurisdiction of the UPC and allow for the possibility of obtaining pan-European injunctions. Under the EU Patent Package as currently proposed, once the UPC is established, patent holders are permitted to “opt out” of the UPC on a patent-by-patent basis, although the time permitted for this opt-out is not yet known. Owners of traditional European Patent applications who receive notice of grant after the EU Patent Package is ratified could validate the patent nationally, and file an opt-out demand. The EU Patent Package may increase the uncertainties and costs surrounding the enforcement or defense of our issued European patents. The full impact on future European patent filing strategy and the enforcement or defense of our issued European patents in member states and/or the UPC is not known.

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, which might cause us to cease operations.

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

Our patents or those patent rights we have licensed, including patent rights that we may seek with respect to inventions made by Janssen under the Collaboration Agreement 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, or those we have licensed and may license from others, including Janssen, 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 and those we have licensed and may license from others, including Janssen, 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, 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. Because we may in the future seek to commercialize imetelstat internationally, securing both proprietary protection and freedom to operate outside of the United States is important to 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 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 ability to further develop or commercialize imetelstat, or could otherwise have a material adverse effect on our business, and might cause us to cease operations, by:

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